European Commission

# Safe and Sustainable by Design (SSbD) chemicals and materials

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

*Carla Caldeira, Lucian Farcal, Kirsten Rasmussen, Hubert Rauscher, Juan Riego Sintes, Serenella Sala*

2nd SSbD Stakeholder Workshop

22 March 2022

Joint Research Centre

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**Sections from the JRC report D3 'Safe and Sustainable by Design chemicals and materials - Framework for the definition of criteria and evaluation procedure for chemicals and materials'*

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# Underpinning concepts of the SSbD Framework

**Serenella Sala**

*Joint Research Centre*

Land Resources Unit

European Commission

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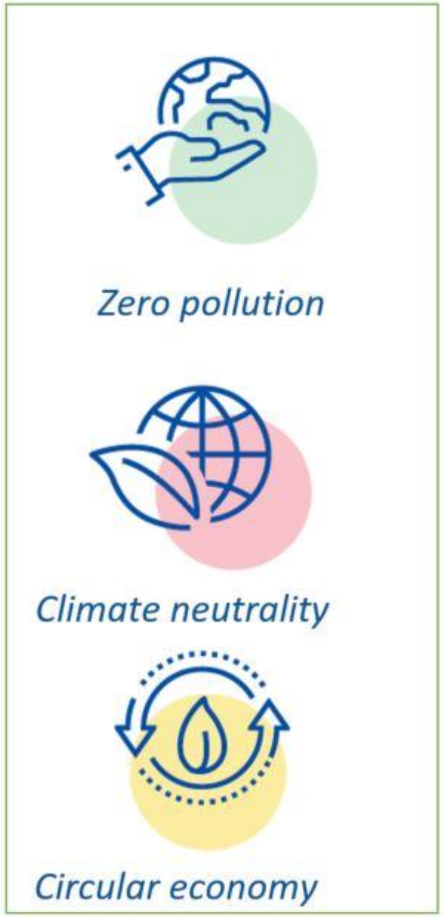
# Policy context for SSbD

The EU Green Deal




## Chemicals Strategy for Sustainability (CSS)

- 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

# SSbD in the CSS

**EU Chemicals Strategy for sustainability (CSS)**

*"**safe and sustainable-by-design** can be defined as **a pre-market approach to chemicals** that focuses on providing a function (or service), while **avoiding volumes and chemical 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 in particular on **climate change, resource use, ecosystems and biodiversity from a lifecycle perspective."*** (EC, 2020a)

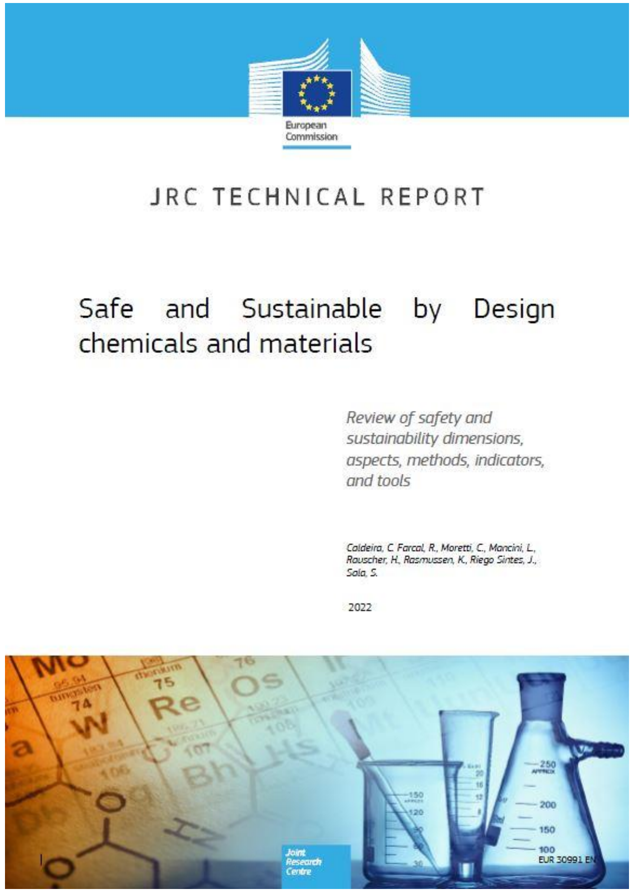
Framework to define safe and sustainable by design (SSbD) criteria for chemicals and materials that should **contribute to achieve the CSS ambitions**, **beyond current regulatory compliance**

# JRC support to the development of the SSbD Framework

| Existing frameworks | Sustainability dimensions | Methods, tools, and indicators | Procedure to developing and set criteria | Procedure to evaluate chemical, material, product |
|---|---|---|---|---|
| e.g. - OECD Safe and Sustainable Design of Plastics from a chemicals perspective<br>- EEA Designing safe and sustainable products requires a new approach for chemicals'<br>- Member States Initiatives | Sustainable Development Goals, Safety, Human Health, Ecosystems, Climate, Resources, Waste and Material Circularity, Social Impacts | Risk assessment<br>LCA-PEF, Prospective LCA and scenario analyses,<br>Material Circularity Indicators<br>Social LCA and other socio-economic indicators | Procedure to define the criteria, e.g.<br>Alignment with EU targets and existing criteria in other frameworks used in the EU system<br>Identification of benchmarks | Identification of pass/fail criteria<br>Multi-criteria decision problem<br>Scoring system |

# Scope of the review of frameworks

Existing frameworks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JRC TECHNICAL REPORT

Safe and Sustainable by Design chemicals and materials

*Review of safety and sustainability dimensions, aspects, methods, indicators, and tools*

Caldeira, C. Farcal, R., Moretti, C., Mancini, L., Rauscher, H., Rasmussen, K., Riego Sintes, J., Sala, S.

2022

Joint Research Centre

EUR 30991 EN

- Reviewing current approaches to alternative assessment of chemicals, addressing safety and sustainability
- The term **'framework'** is used to refer to approaches that are proposing how to consider different dimensions of sustainability when comparing alternatives (chemicals, products, or services)
- The review includes **for comprehensiveness all sustainability dimensions**, namely safety and environmental dimensions, as well the social and economic dimensions

Caldeira C., Farcal R., Moretti C., Mancini L., Rasmussen K., Rauscher H., Riego Sintes J., Sala S. (2022) **Safe and Sustainable by Design chemicals and materials - Review of safety and sustainability dimensions, aspects, methods, indicators, and tools**. EUR 30991 EN, Publications Office of the European Union, Luxembourg, ISBN 978-92-76-47560-6, doi:10.2760/879069

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# Objective of the review

Existing frameworks

- Reviewing **how sustainability aspects have been implemented in decision frameworks for safety** by identifying which **dimensions, aspects, methods and indicators** have been proposed as well as the approaches applied in the overall sustainability assessment

- Identifying guiding principles and best practices for the definition of criteria for SSbD chemicals and materials

# Reviewed frameworks

Existing frameworks

- Scientific literature
- Grey literature
- EC guidelines and legislation
- Certification schemes
- Documents from companies and NGOs

**Topic eligibility screening:**

- Safety & environmental dimensions & social dimensions & economic dimensions
- Safe by design
- Safe and sustainable
- Substances substitution
- Alternative assessment
- etc..

119 conceptual and operational frameworks

*Plus capitalising on 1st WS on SSbD and DG RTD mapping study*

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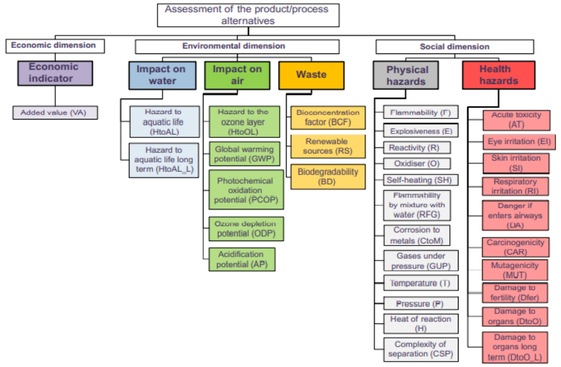
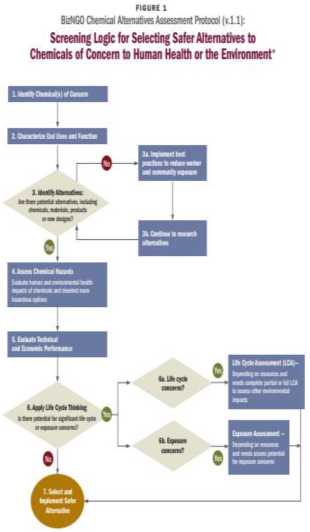
# Conceptual and operational frameworks

Existing frameworks

Conceptual → Operational → Including criteria and scoring systems




| SSG class | Solvent | Environ-mental - Waste | Environ-mental - Impact | Health | Safety | LCA ranking |
|---|---|---|---|---|---|---|
| Alcohols | Ethylene glycol | 4 | 9 | 8 | 9 | 9 |
| | 1-Butanol | 5 | 8 | 8 | 8 | 5 |
| | Diethylene glycol butyl ether | 5 | 7 | 10 | 9 | 7 |
| | Isoamyl alcohol | 7 | 7 | 7 | 8 | 6 |
| | 2-Ethylhexanol | 9 | 6 | 8 | 7 | 6 |
| | 2-Butanol | 4 | 7 | 7 | 7 | 6 |
| | 1-propanol | 3 | 7 | 5 | 8 | 7 |
| | Ethanol | 3 | 8 | 10 | 7 | 9 |
| | 2-propanol | 3 | 9 | 9 | 7 | 5 |
| | t-butanol | 3 | 10 | 7 | 7 | 8 |
| | Methanol | 3 | 10 | 5 | 8 | 9 |
| Esters | t-butyl acetate | 7 | 10 | 7 | 7 | 7 |
| | Butyl Acetate | 7 | 8 | 9 | 8 | 5 |
| | n-Propyl acetate | 6 | 7 | 8 | 7 | 5 |
| | Isopropyl acetate | 5 | 8 | 8 | 7 | 6 |
| | Ethyl Acetate | 4 | 8 | 8 | 4 | 6 |
| | Methyl acetate | 2 | 10 | 7 | 5 | 7 |
| | Dimethyl carbonate | 3 | 7 | 8 | 7 | 8 |
| Aromatics | p-Xylene | 8 | 2 | 7 | 5 | 7 |
| | Toluene | 7 | 3 | 6 | 4 | 7 |
| | Fluorobenzene | 4 | 2 | 4 | 5 | 1 |
| Ketones | Methyl isobutyl ketone | 7 | 6 | 6 | 7 | 2 |
| | Acetone | 2 | 9 | 8 | 5 | 3 |
| | Methyl ethyl ketone | 3 | 6 | 8 | 5 | 3 |
| Polar Aprotics | N-Methyl-2-pyrrolidone | 4 | 6 | 8 | 9 | 3 |
| | dimethyl acetamide | 4 | 7 | 2 | 10 | 3 |
| | Dimethyl formamide | 4 | 6 | 2 | 8 | 6 |
| | Dimethylpropylene urea | 4 | 7 | 5 | 9 | 4 |
| | Dimethylsulphoxide | 4 | 4 | 8 | 3 | 6 |
| | Formamide | 3 | 7 | 2 | 10 | 8 |
| | Acetonitrile | 2 | 6 | 6 | 8 | 4 |
| Acids | Propionic acid | 5 | 8 | 4 | 9 | 7 |
| | Acetic acid | 3 | 8 | 4 | 8 | 8 |
| Alkanes | Cyclohexane | 5 | 6 | 8 | 2 | 7 |
| | Methyl cyclohexane | 7 | 5 | 8 | 2 | 7 |
| | Heptane | 6 | 3 | 9 | 1 | 7 |
| | 2-Methylpentane | 5 | 3 | 5 | 1 | 7 |


Annex 4 of the review

# Areas of application of the frameworks

## by type of actor/stakeholder

Existing frameworks

| Area of application | Academia | Industry | NGOs | EU legislation (or proposal) | Governmental agencies (-related) | Certification organisations | International organisations | Total |
|---|---|---|---|---|---|---|---|---|
| **Chemicals** | | | | | | | | **71** |
| Generic | 23 | 3 | 4 | 3 | 8 | 2 | 4 | 47 |
| Solvents | 17 | 7 | - | - | - | - | - | 24 |
| Fluorinated GHG (F-gases) | - | - | - | 1 | - | - | - | 1 |
| **Products** | | | | | | | | **26** |
| Generic | 3 | 3 | - | 1 | 2 | 5 | - | 14 |
| Energy products | 1 | - | - | 3 | - | - | - | 4 |
| Financial products | - | - | - | 1 | - | - | - | 1 |
| Construction products | - | - | - | | - | 1 | - | 1 |
| Electronics | - | - | 1 | 1 | - | 1 | 1 | 4 |
| Bio-based products | 1 | | - | | - | - | - | 1 |
| Cosmetics | - | - | - | - | - | 1 | - | 1 |
| **Materials** | | | | | | | | **14** |
| Generic | 4 | - | - | - | - | - | - | 4 |
| Nanomaterials | 2 | - | - | - | 1 | - | 1 | 4 |
| Plastics | - | - | - | - | - | 1 | 1 | 2 |
| Textiles | - | - | - | - | - | 4 | | 4 |
| **Services** | | | | | | | | **6** |
| Suppliers' selection | 1 | - | - | 1 | - | - | - | 2 |
| Waste management | 2 | - | - | - | - | - | - | 2 |
| Transport systems | 1 | - | - | - | - | - | - | 1 |
| Soil remediation | 2 | - | - | - | - | - | - | 2 |
| **Total** | **57** | **13** | **5** | **11** | **11** | **15** | **7** | **119** |

# Sustainability dimensions covered by the frameworks

Existing frameworks

| Area of Application | Number of frameworks | Safety | Environmental | Social | Economic |
|---|---|---|---|---|---|
| Products, chemicals, energy, plastics | 34 | ■ | ■ | | ■ |
| Products, chemicals, energy, plastics. | 30 | ■ | ■ | | |
| Chemicals, electronics, textiles, cosmetics | 14 | ■ | ■ | ■ | |
| Products, chemicals | 11 | | ■ | | ■ |
| Chemicals, nanomaterials, electronics | 11 | ■ | | | |
| Products, chemicals | 9 | ■ | ■ | ■ | ■ |
| Products, chemicals, textiles | 4 | | ■ | ■ | |
| Energy, chemicals, transport systems | 3 | | ■ | ■ | ■ |
| Nanomaterials, chemicals | 2 | ■ | | | ■ |
| Products | 1 | ■ | | | |

# Key considerations in the development of a SSbD framework

Reviewed frameworks were (mainly):

- Devised for alternative assessment, and not for the actual ‘design’ of safe and sustainable chemicals.
  - An ideal **framework for SSbD should take into account safety and sustainability consideration from the design phase**;
- Including **safety dimension using the EU approach to regulatory safety assessment of chemicals**, hazard identification and characterisation, and hazard classification.
  - An SSbD framework should **go beyond regulatory requirements**
- Pointing out that SSbD criteria for selection of alternatives should be based on equal functional performance, while this is seldom applied
  - An SSbD framework should consider a **substitution factors for a specific function and/or structured methods to detect alternatives.**

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# Key considerations in the development of a SSbD framework

- A **comprehensive set of life cycle environmental impact categories** should be considered/developed to allow identifying any trade-offs adequately, avoiding regrettable substitution
- **Thresholds for the environmental sustainability** assessment of chemicals should ideally be defined based **on human health and ecological carrying capacity**;
- **Addressing lack of data and quantification of uncertainty should** also be considered in the assessment
- The evaluation procedure should **supports the decision-makers' analysis of trade-offs and guides their decision-making**

# Objectives of the proposed framework


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JRC TECHNICAL REPORT

Safe and Sustainable by Design chemicals and materials

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

*Draft Report for consultation*

*Caldeira, C Farcal, L., Tosches D., Amelio, A., Rasmussen, K., Rauscher, H., Riego Sintes, J., Sala, S.*

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- **Providing guidance on how to develop criteria for ‘safe’ and ‘sustainable’ chemicals/materials** and how to perform the assessment
- **Steering innovation towards the green industrial transition**, including for SMEs and becoming a global reference for safety and sustainability targets;
- **Substituting (as far as possible) or minimising the production and use of substances of concern**, in line with and beyond upcoming regulatory obligations;
- **Minimising the impact on climate and the environment** (air, water, soil) along the entire chemical’s and material’s **life cycle**;
- **Ranking chemicals and materials based on safety and sustainability performance** for a given function or application context.

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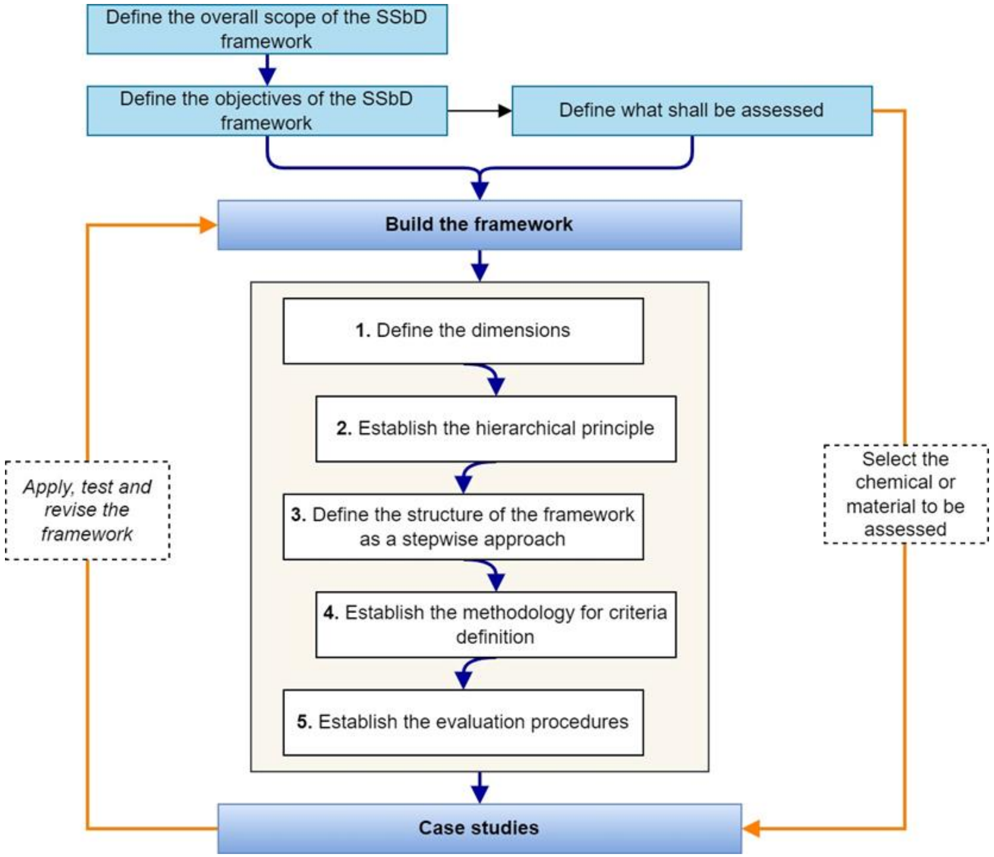
# Iterative process applied for the framework development

1. Definition of the assessment dimensions considered in the SSbD framework
2. Establishing the hierarchical principle underpinning the SSbD framework
3. Definition of the structure of the framework as a stepwise assessment approach and the aspects to be included in each assessment step
4. Establishing the methodology for criteria definition
5. Establishing the procedures for evaluating the criteria

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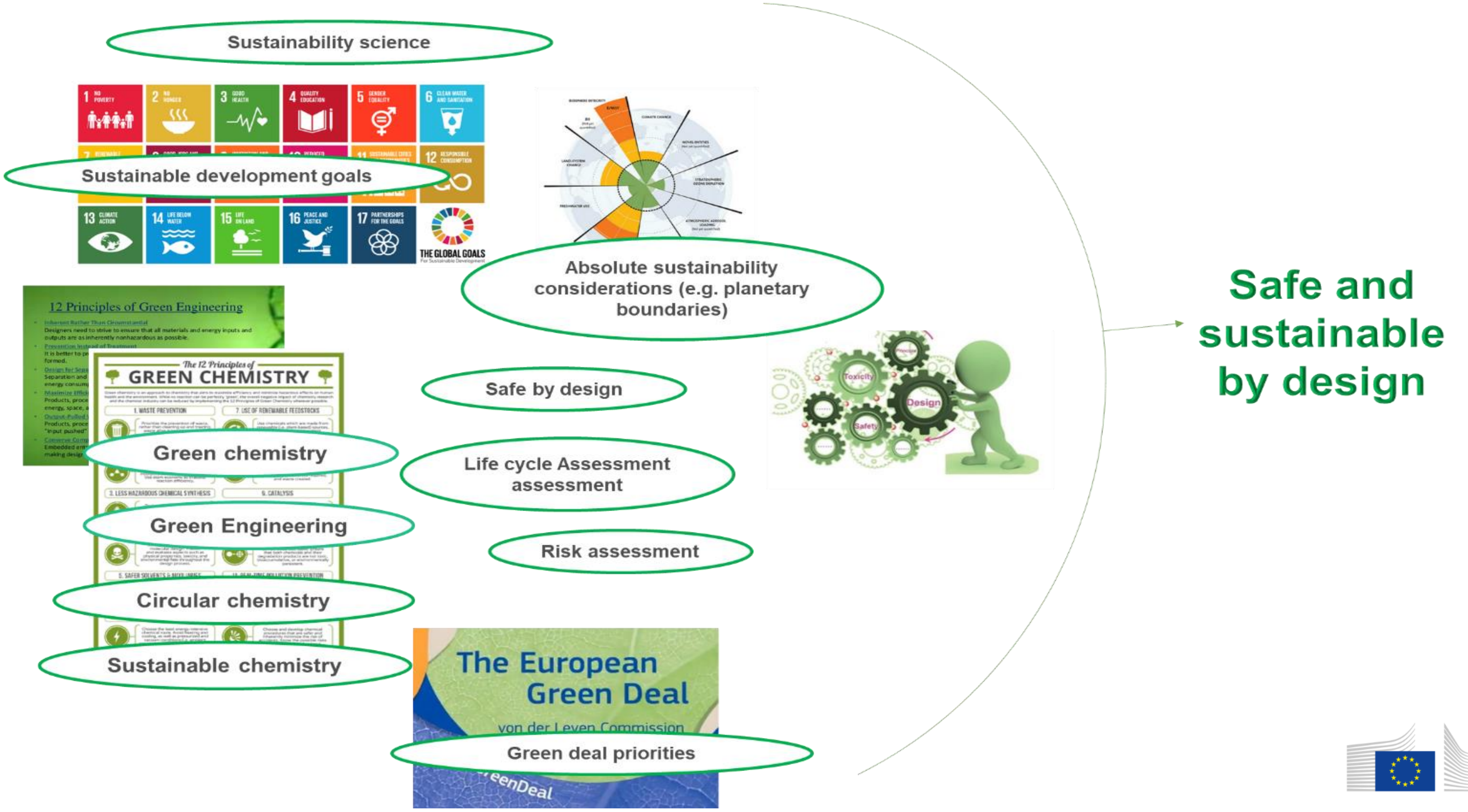
# Background concepts underpinning the SSBD framework

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# Sustainability, safety and Sustainable development goals

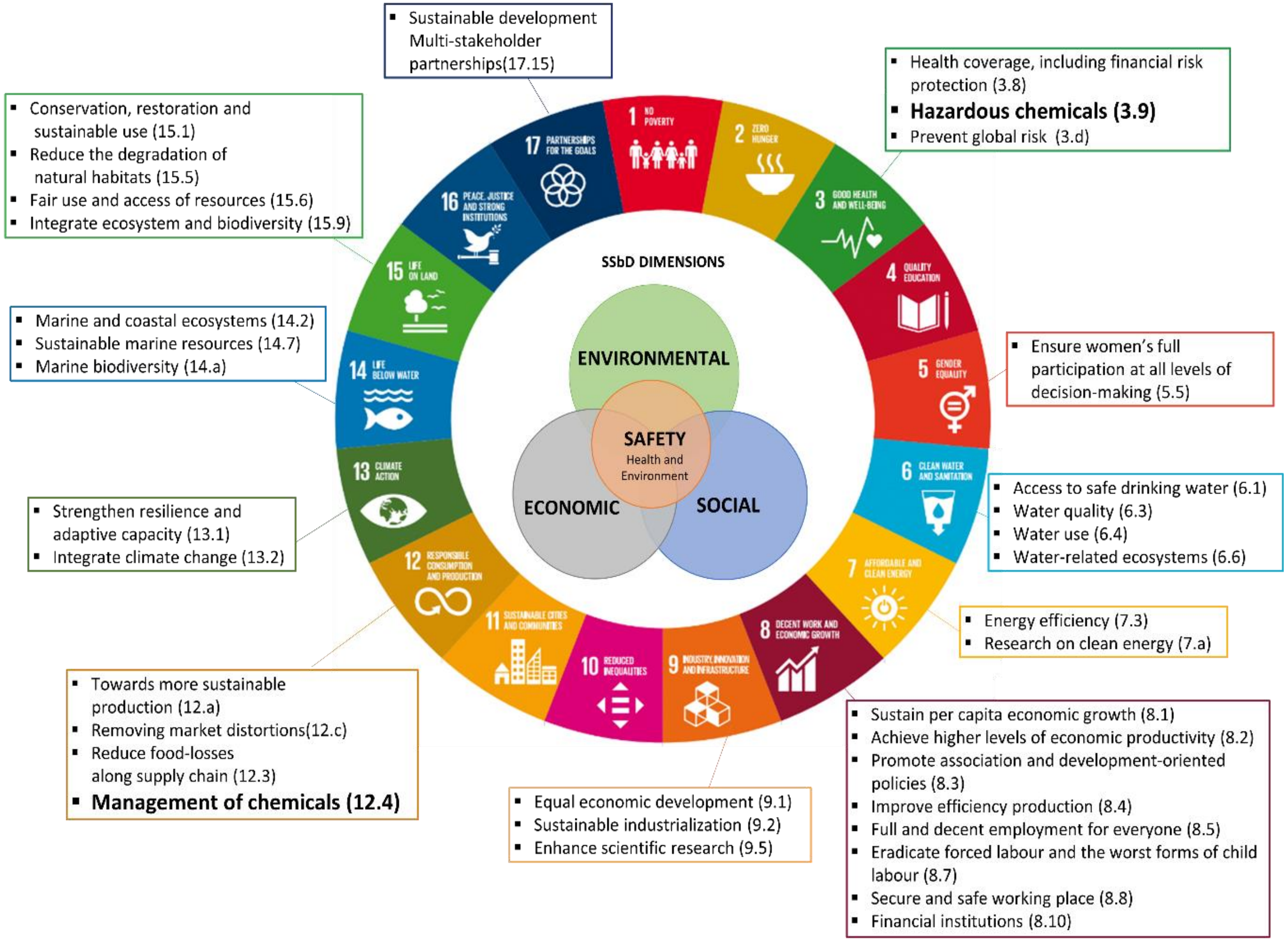
- The **SSbD concept literally emphasizes safety and sustainability**
- **Safety is an inherent element of both environmental** (pollution) and **social** (health) aspects of sustainability, and it has an **economic** component as well
- While recognising that **safety is integrated into the three sustainability pillars**, in the framework we specifically consider the safety dimension and therefore reflect these four dimensions as underpinning the SSbD

# Sustainability


- *"the needs of the present generations without compromising the ability of future generations to meet their own needs"*
- *"sustainability refers to a state of the global system, encompassing the environmental, social and economic subsystems, in which the needs of the present are met without compromising the ability of future generations to meet their needs."* (ISO, 2019)

SDGs as the overarching set of goals towards achieving sustainability

# Sustainable development goals and chemicals

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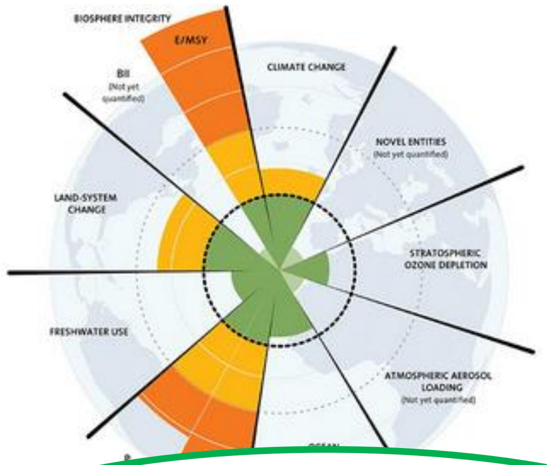
# Sustainability, safety and Sustainable development goals


Environment and ecosystems as building blocks for socio-economic development - ‘doughnut model’

In line with the ‘strong sustainability’ perspective, where the **conservation of the natural capital is the main objective** and where the increase in economic and social capital should not happen at the expenses of natural capital.

*Azote Images for Stockholm Resilience Centre*

# Planetary boundaries




**Absolute sustainability considerations (e.g. planetary boundaries)**

- **Planetary Boundaries** framework developed by Rockström et al. (2009) referring to the need for **humankind to operate within a safe space respecting Earth's ecological limit**
- Preconditions for **sustainable development** by **identifying and quantifying environmental planetary boundaries** that must not be transgressed by human activities
- Assessing a system in term of contribution to transgressing planetary boundaries, means to perform an **absolute sustainability assessment**

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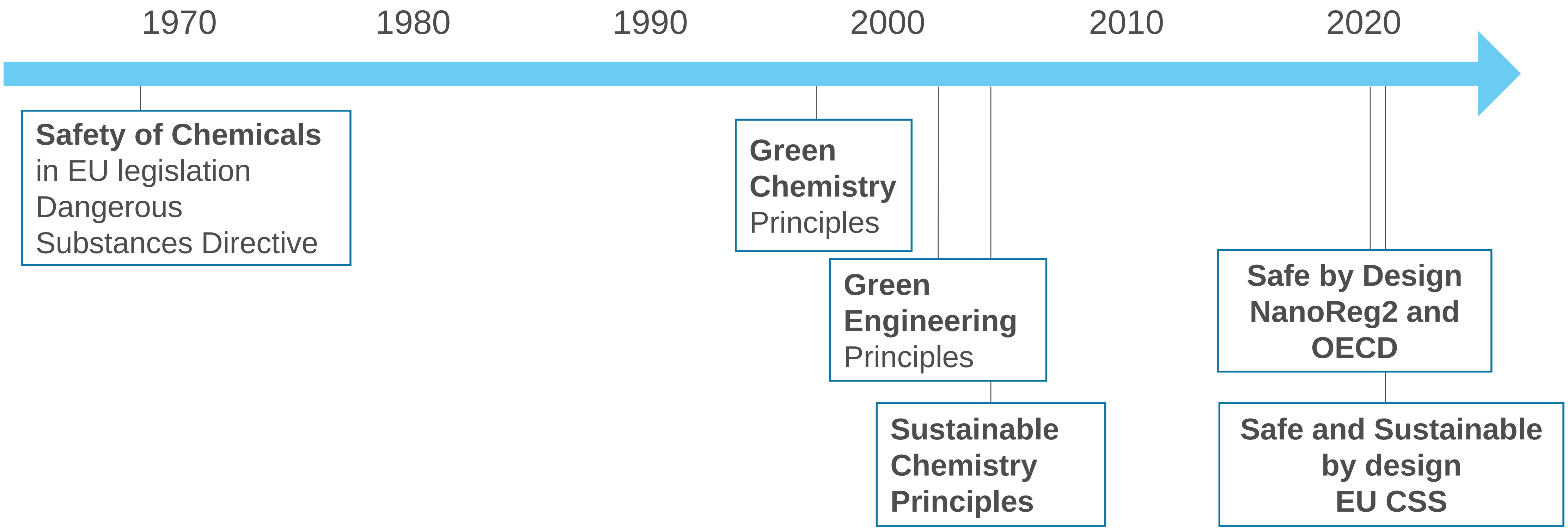
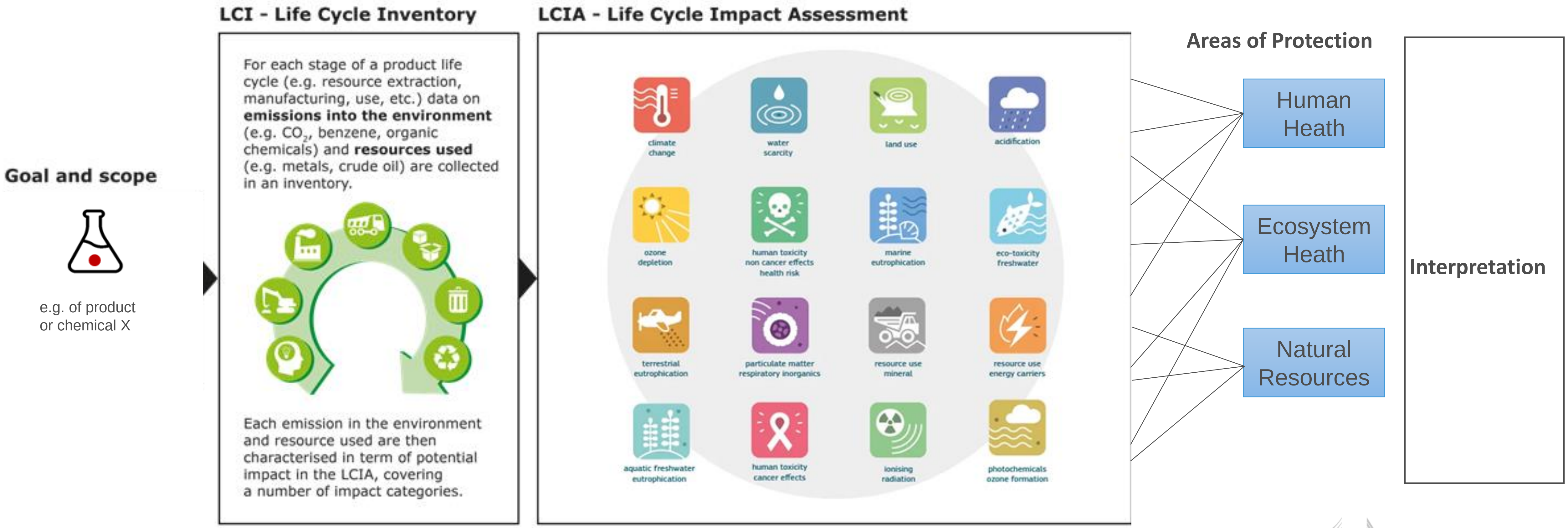
# Green chemistry, sustainable chemistry, circular chemistry, green engineering, safe by design




- Principles proposed on the design of chemicals to minimize their environmental impacts and hazardous properties.
- Traditionally very much focused on the properties of the chemicals and the production process

# Life Cycle Assessment

A systematic approach for the assessment of the environmental impacts of products along their entire life cycle, from design to end of life.




EC(2021) 9332 final Commission Recommendation of 16.12.2021 on the use of the Environmental Footprint methods to measure and communicate the life cycle environmental performance of products and organisations

# Life Cycle Assessment in EU policies


**"Farm to Fork" strategy**

***Adopting a system perspective to reduce the overall environmental footprint of the EU food system***
***Supporting sustainability labelling of food products***

**Biodiversity strategy**

***Measuring the environmental footprint of products and organisations on the environment**, including through **life-cycle approaches and natural capital accounting***


**Zero pollution and Chemical strategy**

- ***Overall sustainability of chemicals should be ensured by minimising the environmental footprint of chemicals in particular on climate change, resource use, ecosystems and biodiversity from a lifecycle perspective***
- ***How to best introduce information requirements under REACH on the overall environmental footprint of chemicals, including on emissions of greenhouse gases***
- ***Safe and sustainable by design chemicals along their life cycle***


**Circular economy action plan**

***The European Commission will also propose that companies substantiate their environmental claims using Product and Organisation Environmental Footprint methods***

Sala et al. (2021) The evolution of Life Cycle Assessment in European policies over three decades. The International Journal of Life Cycle Assessment https://doi.org/10.1007/s11367-021-01893-2

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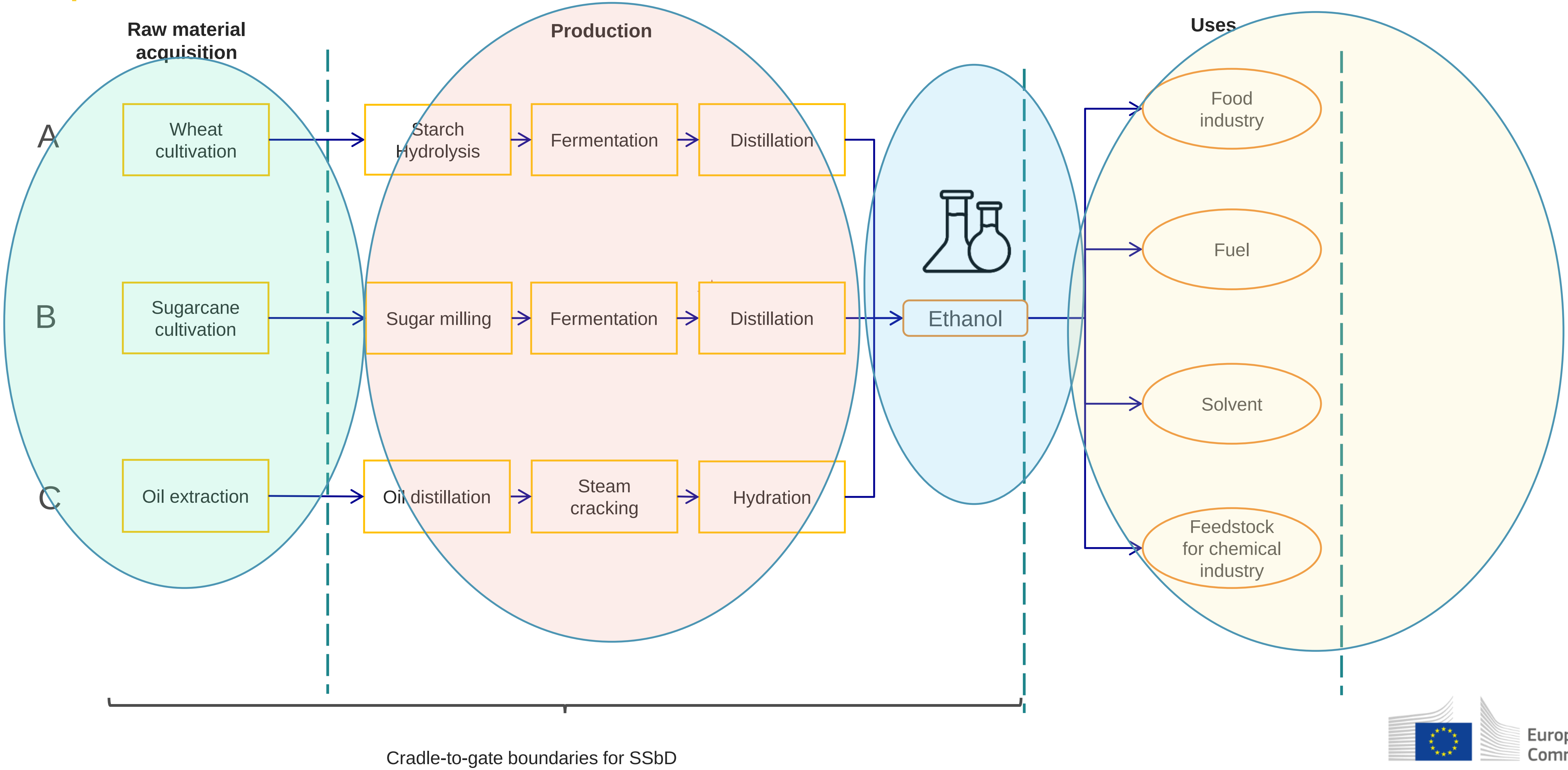
# Why to consider **both process and chemical related aspects**?

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# Key features of LCA

- Embracing the entire life cycle
- Multiple environmental impacts
- Trade-off among environmental impacts and life cycle stages
- Comparing different feedstocks or production scenarios
- Link to planetary boundaries


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# Q&A

# Building blocks of the SSbD framework

**Serenella Sala**
*Joint Research Centre*
Land Resources Unit

European Commission

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# Definition: safety and sustainability

- The **sustainability** concept is complex and multifaceted. The general definition is related to the original definition of sustainable development: the **development that meets the needs of the present without compromising the ability of future generations to meet their own needs.** Hence, ensuring that any human actions remains far from irreversibility (in terms of loss of resources of impacts to the environment) and consider present and future conditions.

- **When applied in the context of chemicals**, the concept of **sustainability** could be formulated as the **ability of a chemical (material/product/service) to deliver its function without exceeding environmental and ecological boundaries along its life cycle, while providing welfare and socio-economic benefits.**

- The **safety** concept is transversal to all sustainability dimensions (environmental, social and economic) and it is related to the **absence of unacceptable risk for humans and the environment, preferably ensured by the absence of intrinsic hazard properties of chemicals**.

# Definitions: chemicals and materials

- **Chemical** has different interpretations. REACH (EU, 2006) and CLP (EU, 2008), the basis for EU chemicals legislation, do not define ‘chemical’, but they do define and distinguish ‘**substances’ and ‘mixtures**’, which, **combined**, can be considered as constituting **‘chemicals’**. For REACH and CLP, **most ‘materials’ can be considered as ‘mixtures**’. The SSbD criteria developed in this report cover both chemicals and materials.

- **Substance:** ‘a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition’ *Please note that a ‘substance’ can have a very complicated chemical composition, for example creosote, which is produced by the distillation of tar from wood or coal, is a substance.*

- **Mixture**: ‘a mixture or solution composed of two or more substances’ denote either substances or mixtures which may or may not yet fulfil the definition of an article under REACH and may be of natural or synthetic origin (EC, 2021e)

# Definitions: 'By-design' (re-design)

In the context of SSbD criteria for chemicals and materials, the term 'by-design' can be interpreted at 3 levels:

- **Molecular design**: this is the design of new chemicals and materials based on the atomic level description of the molecular system. This type of design effectively delivers new substances, of which the properties may be tuned to be safe(r) and (more) sustainable.
- **Process design:** this is the design of new or improved processes to produce chemicals and materials. Process design does not change the intrinsic properties (e.g. hazard properties) of the chemical or material, but it can make the production of the substance safer and more sustainable (e.g. more energy or resource efficient, less reliant on the need for other hazardous substances in the process).
- **Product design**: this is the design of the end-product that will eventually be used or consumed by industrial workers, professionals or consumers.

**The SSbD framework proposed covers all three phases.** It can be used to **determine into which direction molecular or process design should go,** but it is also intended to be useful for guiding the **new production processes (re-design)** for already existing chemicals and materials, and for product designers, when they need **to select different chemicals and materials to meet the functional demands of the product** they are developing.

# Definitions: Criteria

- A criterion is defined as an **aspect** (e.g. climate change) with an assessment method and a **minimum or maximum threshold or target values**, on which a **decision may be based**.
- The **SSbD criteria for chemicals and materials** will be used to assess the **overall sustainability** of the use of a particular **chemical or material in a particular application**.
- The criteria can also be used to **compare different chemicals and materials**,
  - informed decision when choosing between chemicals and materials for a particular application.
  - taking into account the **specific functional needs of the end-user**. For example, it will have to take into account that to achieve a particular function, one may need a bigger amount of chemical A than of chemical B.

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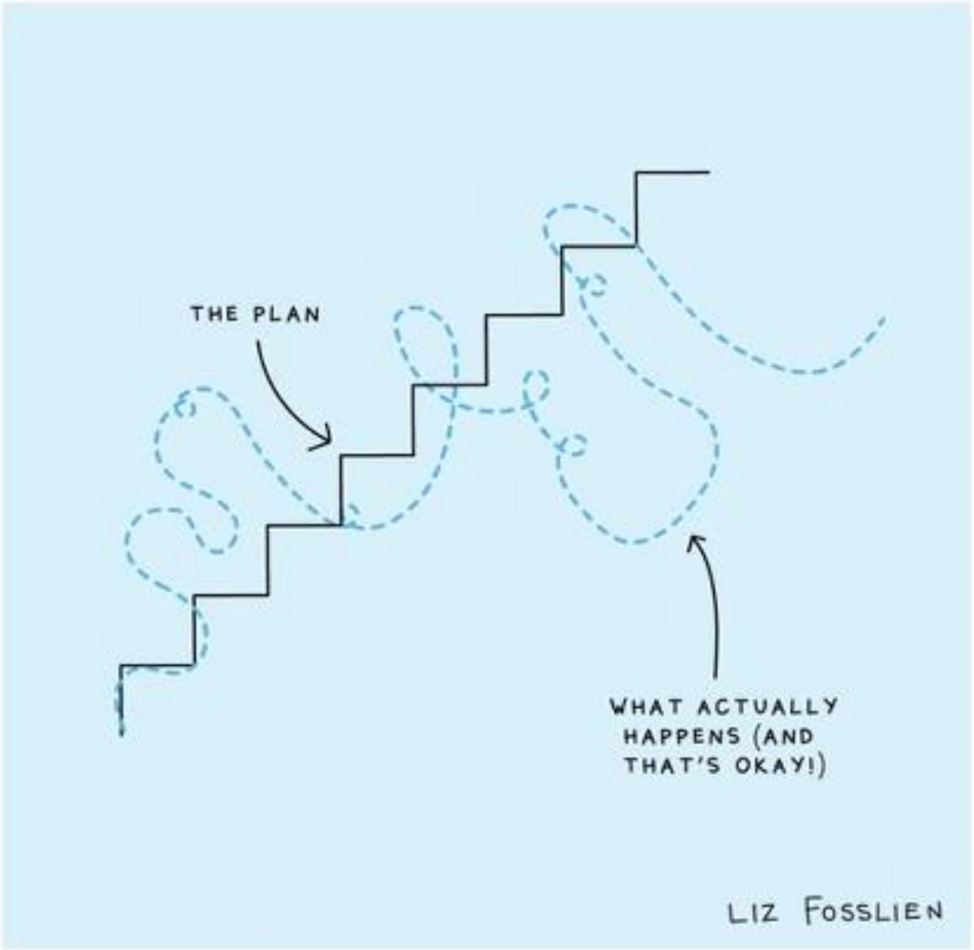
# Sustainability in the SSbD framework

- Safe and environmentally sustainable *chemicals/materials*
- Safe and environmentally sustainable *chemical production processes*
- Safe and environmentally sustainable *raw materials and inputs*
- Safe and environmentally sustainable *when recycled or reused, as well as when treated as waste*
- *Chemicals designed to contribute to sustainability*: that are generating benefits at system level where applied

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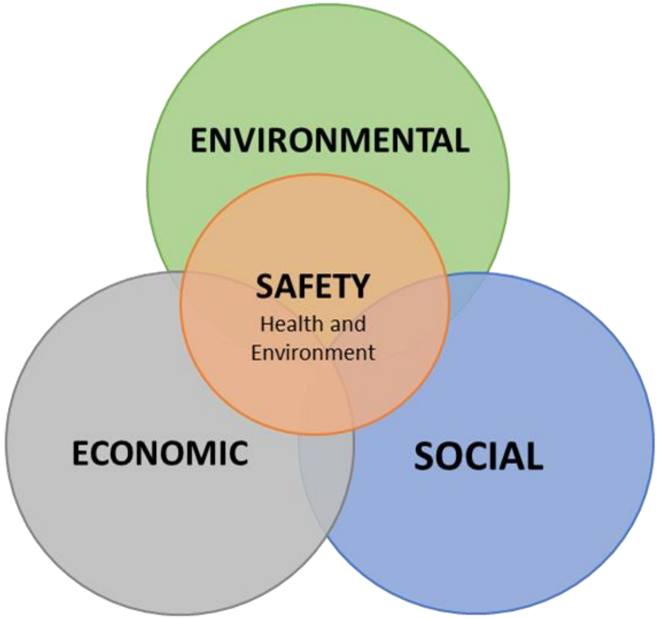
# Dimensions in the proposed framework

- Sustainability dimensions:
  - Safety
  - Environmental
  - Social
  - Economic

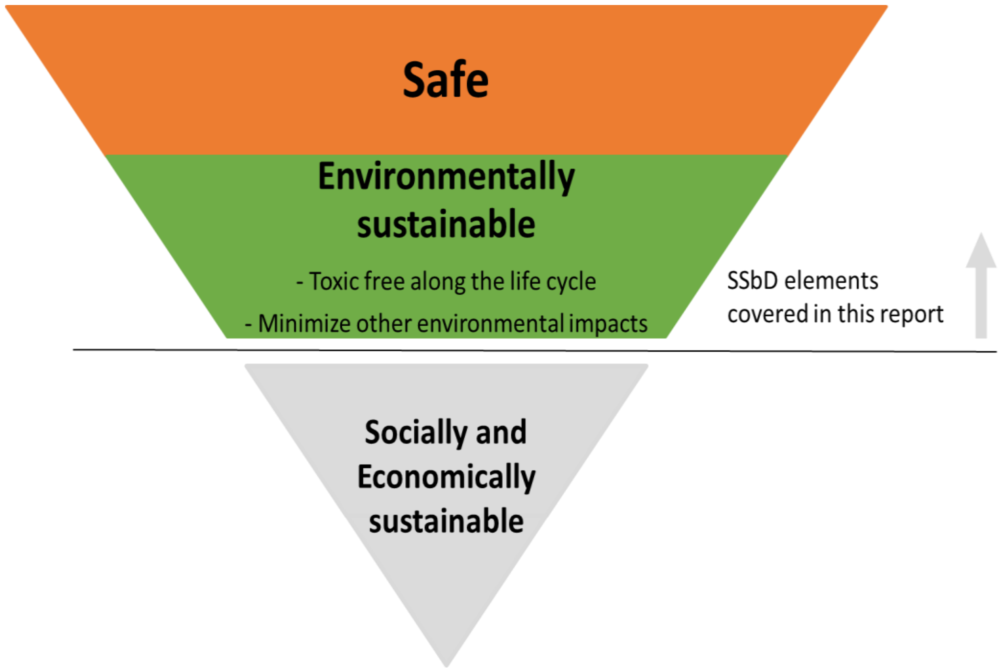
- The proposed SSbD framework addresses **safety and environmental dimensions**

- It is outside the scope of the report under consultation to provide suggestions for the definition of criteria to assess social and economic sustainability.



# Hierarchical principle underpinning the framework

- The framework has been built  to adhere to the following narrative, which implies a hierarchical role of the different sustainability dimensions.




A chemical could be considered SSbD when:

- Its inherent properties and features all along the value chain for its production and consumption are safe
- The risk associated to chemical exposure are minimal
- The chemical and its production process demonstrate to remain within ecological boundaries and to be significantly better than alternatives
- *The chemical and its production processes avoid generating threats to socio-economic systems*

# SSbD framework features

- SSbD framework proposed is a **general approach for the definition of criteria for SSbD for chemicals and materials**.
- It can be **broadly applicable** allowing the **definition of a set of operational criteria** that can be implemented and that **increase or ensure compliance with reference targets for safety and sustainability** of chemicals and materials.
- It can be applied to **new chemicals and materials**
- or to **existing ones**
  - to support the redesign of their production processes by evaluating alternative processes to improve their safety and sustainability performance, or
  - to rank them on the basis of SSbD criteria (e.g. for substitution purposes).

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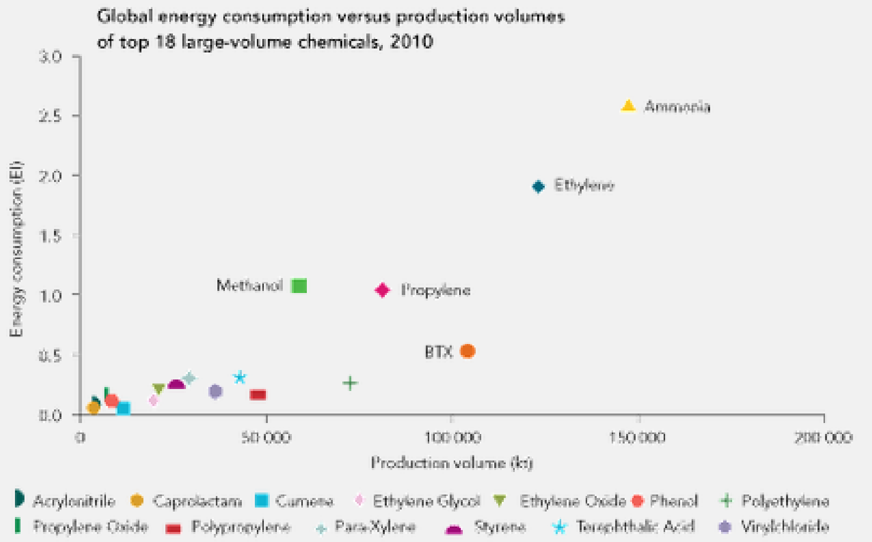
# Scope and objectives

- Important to consider also existing chemicals
- Process improvement of existing safe chemicals could be part of chemical redesign for sustainability
- Important to be able to help addressing priority chemicals from an environmental point of view

Chemicals being major consumers of energy

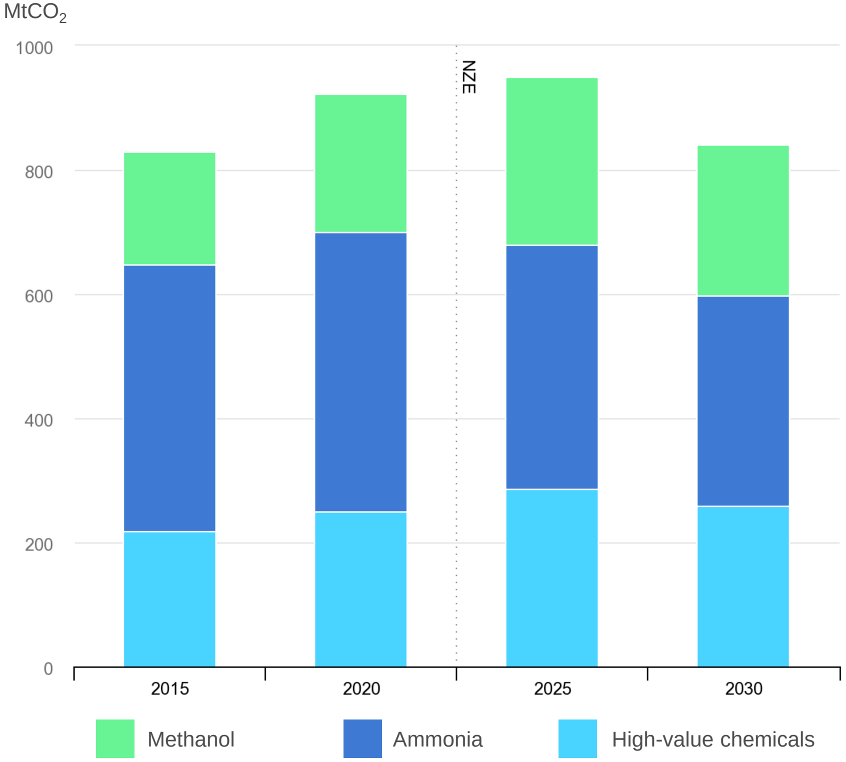



**KEY ENERGY CONSUMERS**

Figure 1. Five large-volume chemicals dominated chemical industry energy consumption in 2010. *Source: Dechema.*

Source: Dechema. “Energy and GHG Reductions in the Chemical Industry via Catalytic Processes” https://dechema.de/en/industrialcatalysis.html

Direct $CO_2$ emissions from primary chemical production




Source: IEA Chemicals report. https://www.iea.org/data-and-statistics/charts/direct-co2-emissions-from-primary-chemical-production-in-the-net-zero-scenario-2015-2030

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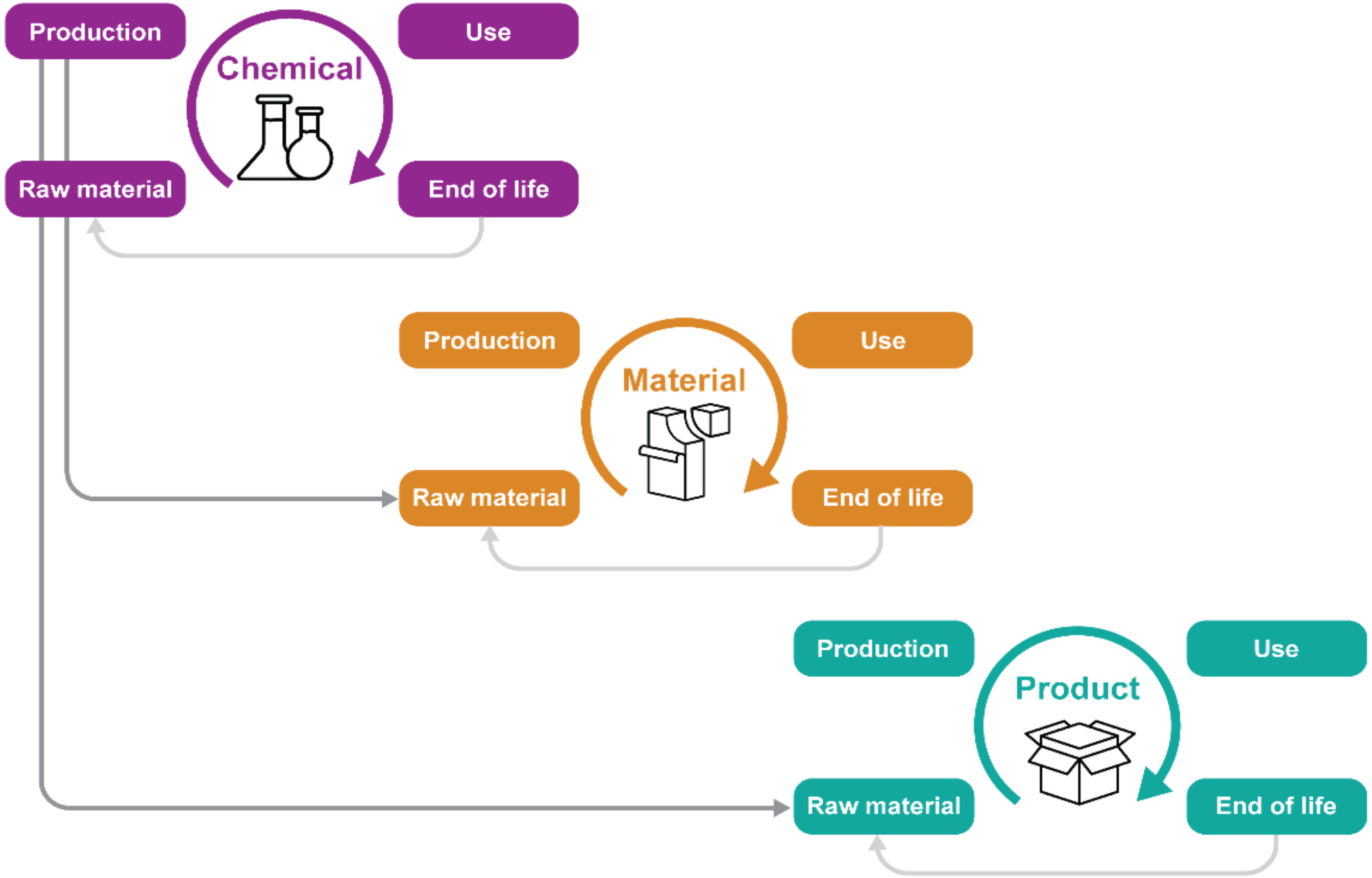
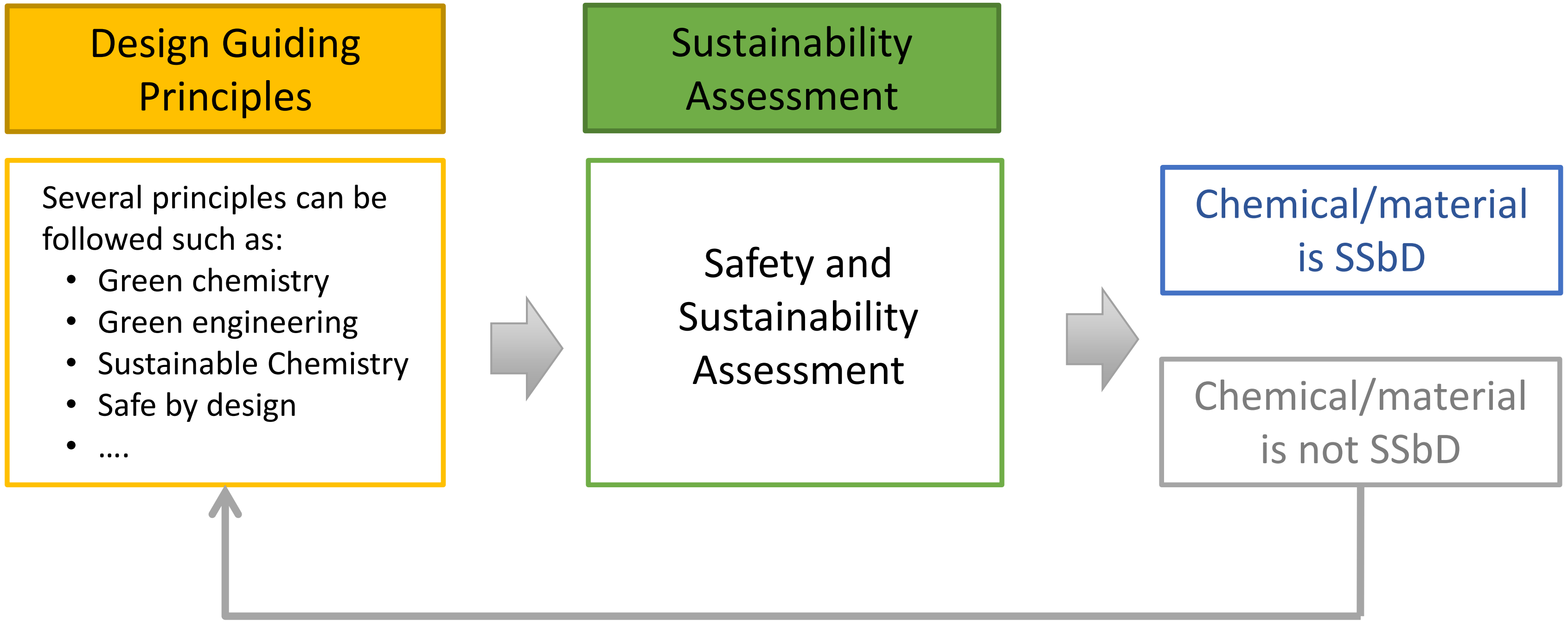
# SSbD framework features

Assessment of the entire life cycle of a chemical or material, including the design phase and considering the functionality, intermediate and final use



# SSbD framework components



# Design guiding principles

- Green chemistry principles
- Green engineering principles
- Sustainable chemistry
- Circularity principles
- Others

| | SSBD principles |
|---|---|
| SSBD1 | Atom economy |
| SSBD2 | Design with less hazardous chemicals |
| SSBD3 | Design efficiently to be more sustainable |
| SSBD4 | Use renewable sources |
| SSBD5 | Prevent and avoid hazardous emissions |
| SSBD6 | Reduce exposure to hazardous substances |
| SSBD7 | Design for commercial after life |
| SSBD8 | (The E Factor) Consume less Natural Resources by Reduction, Reuse, Recycle of waste |
| SSBD9 | Dematerialisation: sell service, not product |
| SSBD10 | Design and promote new process strategies |
| SSBD11 | Supportive policy framework |
| SSBD12 | Reduce production |
| SSBD13 | Consider the whole life-cycle |

# Q&A

# Structure of the framework: a stepwise approach (part I)

**Lucian Farcal**

*Joint Research Centre*

Consumer Products Safety Unit

# Contents

- 4.2 Sustainability assessment
  - 4.2.1 Safety of chemical and material - hazard-based approach (Step 1)
  - 4.2.2 Chemical or material processing safety - occupational safety and health aspects (Step 2)

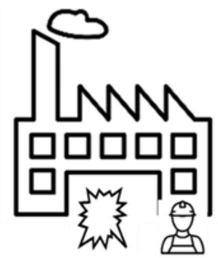
# Sustainability assessment

Safety and sustainability components captured in the framework with the illustration of the **life cycle stages covered** and the **subject of the assessment**

**Intrinsic chemical or material safety - hazard properties**

- The hazards are evaluated first in order to understand whether the chemical or material safety can be ensured independently of exposure levels or use
- The assessment addresses the following aspects: **human health hazards, environmental hazards and physical hazards**

**Chemical or material processing safety - occupational safety and health aspects**

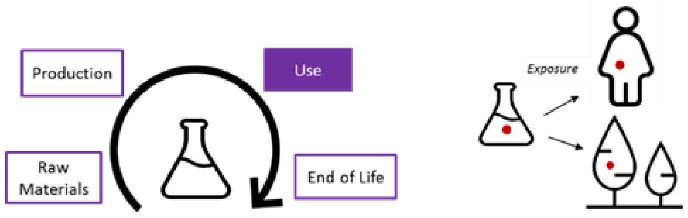



- The assessment addresses occupational safety and health (OSH) related aspects relevant to the processing (raw material extraction, production and end of life) of chemicals and materials: **human health hazards, physical hazards, hazards from release behavior and other specific process-related hazards**

# Sustainability assessment

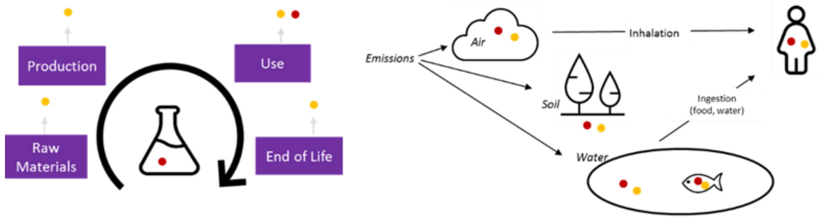
Safety and sustainability components captured in the framework with the illustration of the **life cycle stages covered** and the **subject of the assessment**

**Human health and environmental impacts from the use phase (direct exposure)**




- This step considers the application and use-specific exposure of humans and environment
- The assessment covers toxicity-related impacts associated with direct exposure and addresses the aspects: **human toxicity and ecotoxicity**

**Environmental sustainability (Life Cycle Assessment)**

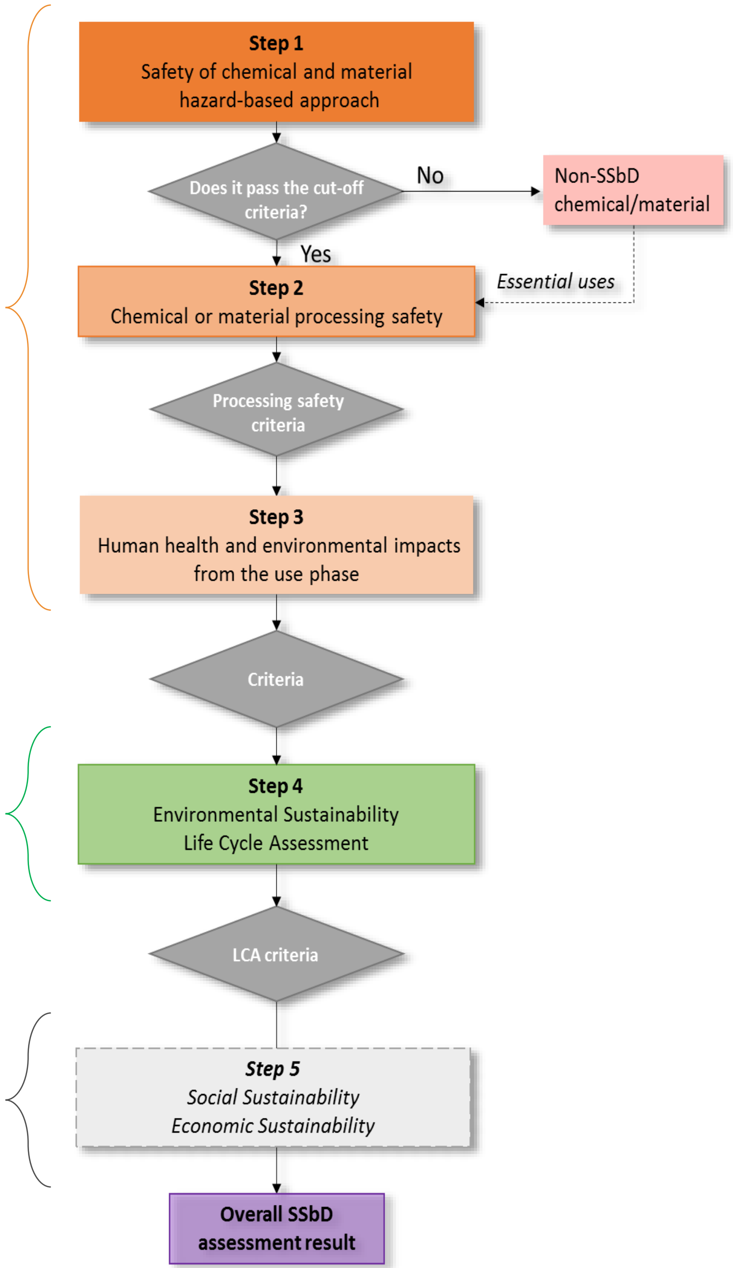



- This step covers other environmental sustainability aspects along the life cycle
- The assessment addresses the environmental footprint (EF) impact categories at the level of **toxicity, climate change, pollution and resources**

# Sustainability assessment

A stepwise approach was defined for the assessment:

- **Step 1** - Safety of chemical and material - hazard-based approach
- **Step 2** - Chemical or material processing safety - occupational safety and health aspects
- **Step 3** - Human health and environmental impacts from the use phase (direct exposure)
- **Step 4** - Environmental sustainability assessment
- **Step 5** - Social and Economic Sustainability assessment

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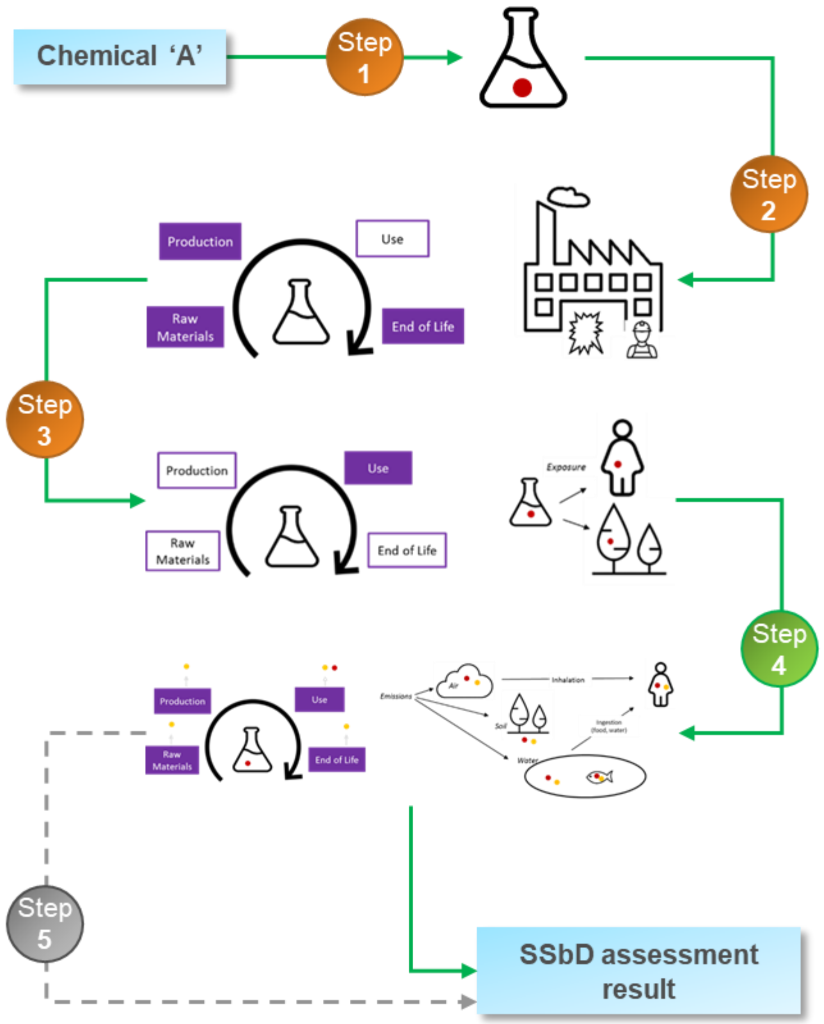
# Methodology for criteria definition

- For each step the methodology refers to the SSbD dimensions, aspects, system assessed, indicators and criteria, and includes the following:
  - Definition of the aspects and indicators
  - Definition of criteria
  - Evaluation system

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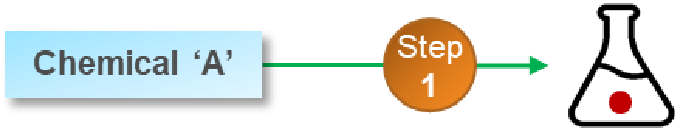
# **Step 1** - Safety of chemical and material - hazard-based approach

- This step looks at the **intrinsic hazard properties** of the chemical or material
- The hazard is evaluated first, independently of exposure levels or use
- The hazard-based criteria as a first step in the SSbD framework follows on the idea that a '*safe and sustainable by design*' chemical should be 'inherently' safe to use in all kinds of applications (including unforeseen uses) in future life cycles
- In this context the term 'by design' is interpreted and refers to intrinsic properties
- The goal here is to identify the most appropriate criteria that can be applied during the **molecular design** (or re-design) of chemicals and materials in order to ensure that those placed on the market are 'inherently' safe (as defined by the criteria).




**'Molecular design' phase**

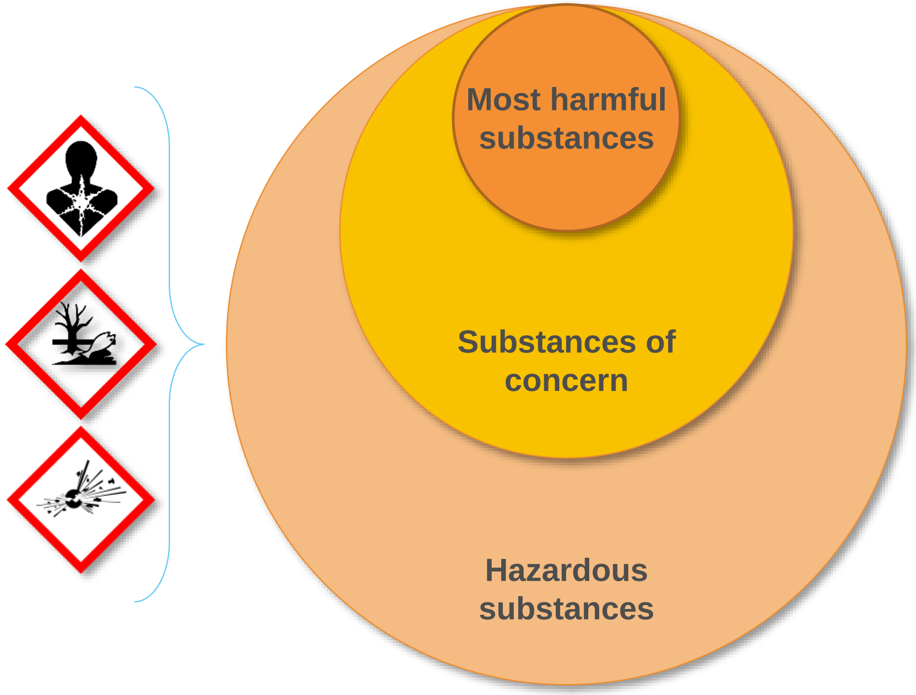
- This is the design of new chemicals and materials based on the atomic level description of the molecular system.
- This type of design effectively delivers new substances, of which the properties may be tuned to be safe(r) and (more) sustainable

Step 1

# Aspects and indicators

- The identification of relevant **aspects and their indicators** regarding the **intrinsic properties** of chemicals or materials in order to establish the **hazard-based safety criteria**
- Generally, the methodology for criteria definition follows the specifications and criteria established in CLP and REACH regulations and CSS

- In the EU chemicals legislation, three main categories of hazards are described and these categories are also considered in the SSbD framework:
  - **Human health hazards**
  - **Environmental hazards**
  - **Physical hazards**
- Based on the hazard properties, three main groups of substances are established (*in accordance also with CSS*):
  - **Most harmful substances**
  - **Substances of concern**
  - **Other hazardous substances**




*Regulation (EC) No 1272/2008; Regulation (EC) No 1907/2006; EU Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (COM (2020) 667)*

# Aspects and indicators check-list

| Group definition | Human health hazards | Environmental hazards | Physical hazards | |
|---|---|---|---|---|
| Includes the most harmful substances (according to CSS), including the substances of very high concern (SVHC) according to REACH Art. 57(a-f). | ❑ Carcinogenicity Cat. 1A and 1B<br>❑ Germ cell mutagenicity Cat. 1A and 1B<br>❑ Reproductive / developmental toxicity Cat. 1A and 1B<br>❑ Endocrine disruption Cat. 1 (human health)<br>❑ Respiratory sensitisation Cat 1<br>❑ Specific target organ toxicity - repeated exposure (STOT-RE) Cat. 1, including immunotoxicity and neurotoxicity | ❑ Persistent, bioaccumulative and toxic / very persistent and very bioaccumulative (PBT/vPvB)<br>❑ Persistent, mobile and toxic / very persistent and mobile (PMT/vPvM)<br>❑ Endocrine disruption Cat. 1 (environment) | | Criterion **S1** |
| Includes hazardous substances with chronic effect, which are part of the substances of concern, described in CSS and are not included already in Criterion S1. | ❑ Skin sensitisation Cat 1<br>❑ Carcinogenicity Cat. 2<br>❑ Germ cell mutagenicity Cat. 2<br>❑ Reproductive / developmental toxicity Cat. 2<br>❑ Specific target organ toxicity - repeated exposure (STOT-RE) Cat. 2<br>❑ Specific target organ toxicity - single exposure (STOT-SE) Cat. 1 and 2<br>❑ Endocrine disruption Cat. 2 (human health) | ❑ Hazardous for the ozone layer<br>❑ Chronic environmental toxicity (chronic aquatic toxicity)<br>❑ Endocrine disruption Cat. 2 (environment) | | Criterion **S2** |
| Includes the other hazard classes not part already in Criteria S1 and S2. | ❑ Acute toxicity<br>❑ Skin corrosion<br>❑ Skin irritation<br>❑ Serious eye damage/eye irritation<br>❑ Aspiration hazard (Cat. 1)<br>❑ Specific target organ toxicity - single exposure (STOT-SE) Cat. 3 | ❑ Acute environmental toxicity (acute aquatic toxicity) | ❑ Explosives<br>❑ Flammable gases, liquids and solids<br>❑ Aerosols<br>❑ Oxidising gases, liquids, solids<br>❑ Gases under pressure<br>❑ Self-reactive<br>❑ Pyrophoric liquids, solid<br>❑ Self-heating<br>❑ In contact with water emits flammable gas<br>❑ Organic peroxides<br>❑ Corrosivity<br>❑ Desensitised explosives | Criterion **S3** |

*See Table 3 in JRC Technical Report*

Step 1

# Criteria definition

- Based on the properties, **three main criteria (S1, S2 and S3)** were defined and a workflow was developed in order to integrate them
- The criteria are **hierarchic** - they need to be assessed one after the other and the upper criterion will only be assessed only if the previous has been passed
- These criteria include the aspects that need to be investigated in order to conclude on the hazard properties of the chemical or material evaluated, **before assessing the other sustainability dimensions**
- Sub-criteria that could be developed, e.g.:
  - Consider separately the hazard properties relevant for human health and environment
  - Score or weight individually the aspects
  - Consider the methodology type applied for the hazard assessment (e.g. use of New Approach Methodologies versus *in vivo* testing)

- With these criteria the aim is to align with the overall objectives of the **EU Chemicals Strategy for Sustainability**, e.g.:
  - Ensure that products do not contain the **most harmful substances** (only allowed in uses proven essential for society and if there are no alternatives available)
  - Ensure that **most harmful substances** are prioritised for substitution
  - Substitute, as far as possible, the **substances of concern**

**Criterion S1** (most harmful substances )

**Criterion S2** (substances of concern)

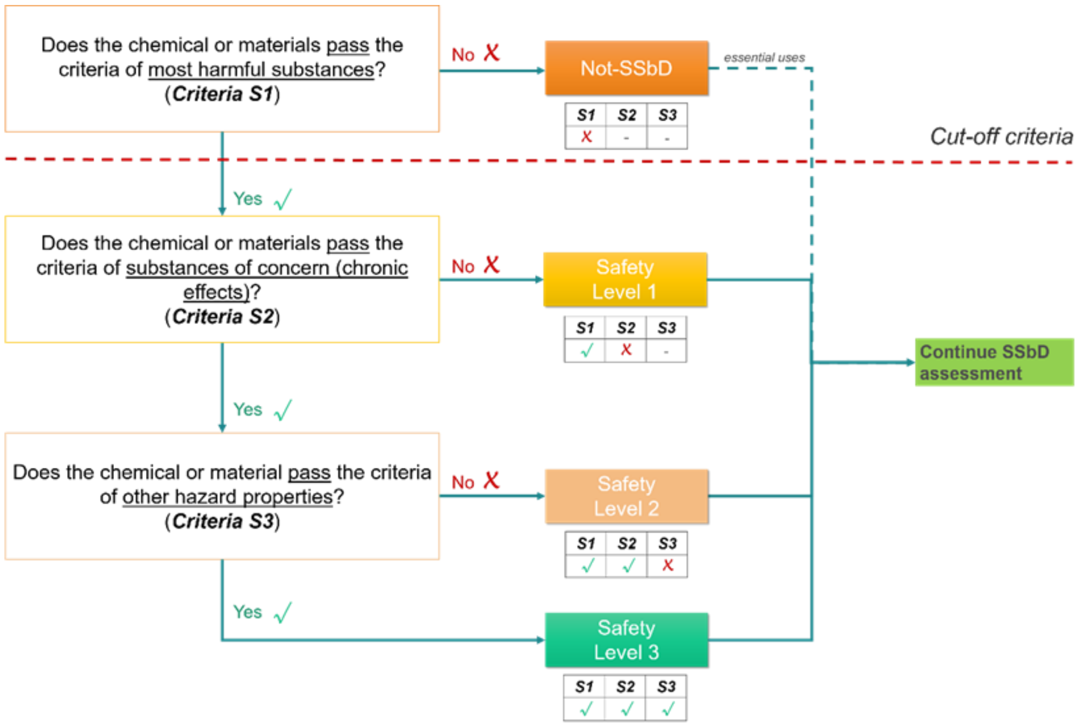
**Criterion S3** (other hazard classes)

*See Table 4 in JRC Technical Report*

Step 1

# Evaluation system

- Following the assessment, several **levels & scoring system of safety** are established based on the fulfilment of the **hazard-based criteria**, including ‘cut-off’ criteria
  - **Cut-off criteria** = chemicals or materials with such hazard properties will not be considered SSbD, regardless of the results of the other safety and sustainability assessments performed




**Not-SSbD** - chemicals or materials that do not pass Criterion S1 (e.g. considered most harmful substances)

**Level 1** - chemicals or materials that pass Criterion S1 but do not pass Criterion S2 (e.g. induce chronic effects, part of the substances of concern)

**Level 2** - chemicals or materials that pass Criteria S1 and S2 but do not pass Criterion S3 (e.g. with other hazard properties)

**Level 3** - chemicals or materials that pass all hazard properties criteria of Step 1.

*For Level 3 chemicals or materials that are considered to be of no concern regarding intrinsic hazard properties it should be recognised that the chemical/material could still pose harm in certain applications from a risk perspective that goes beyond generic hazard criteria and includes consideration of application-specific exposure settings.*

# Sustainability assessment

## Assessment steps

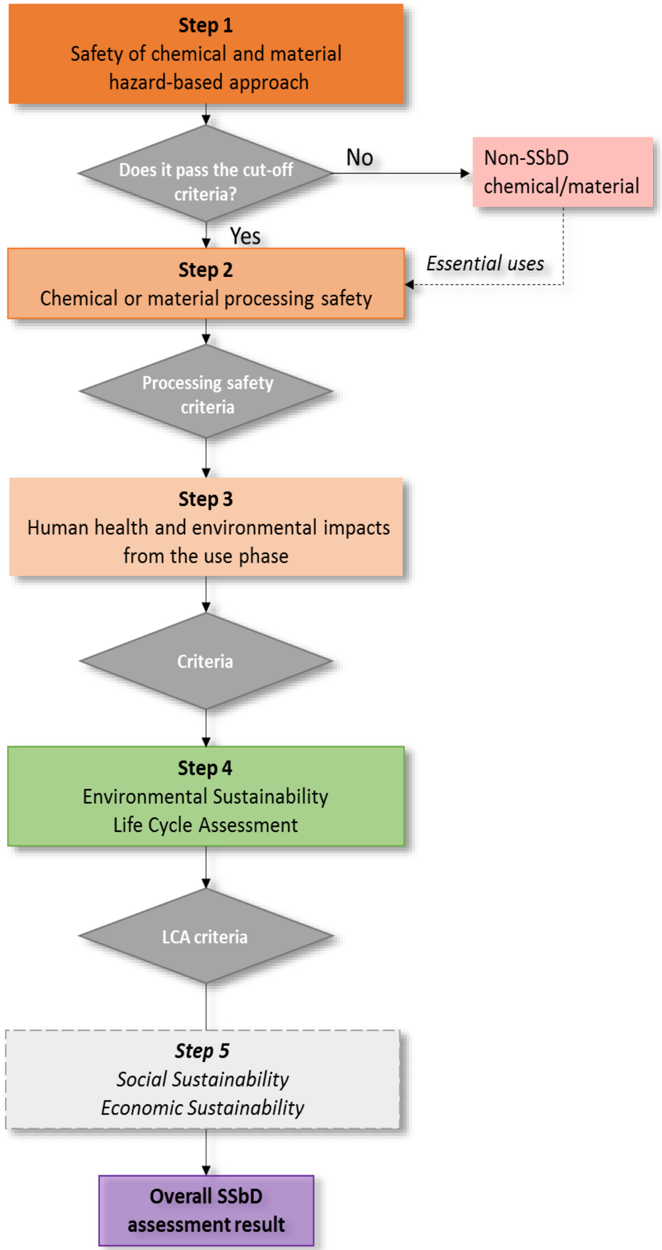
**Step 1** - Safety of chemical and material - hazard-based approach

**Step 2** - Chemical or material processing safety - occupational safety and health aspects

**Step 3** - Human health and environmental impacts from the use phase (direct exposure)

**Step 4** - Environmental sustainability assessment

**Step 5** - Social and Economic Sustainability assessment

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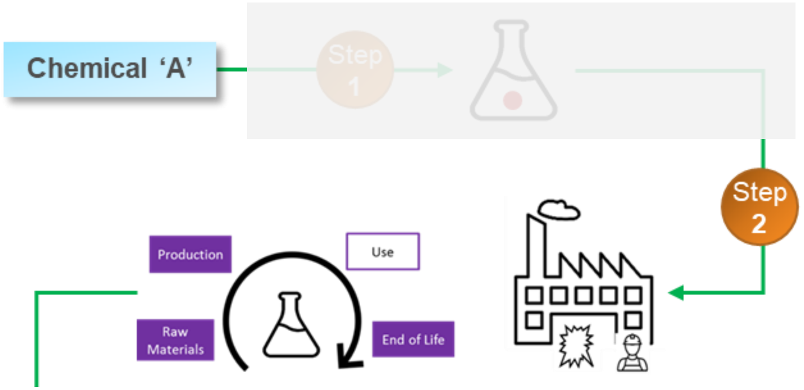
# **Step 2** - Chemical or material processing safety - occupational safety and health aspects




- In this step the hazards and risks related to **processing of chemical and materials** are assessed
- It refers to chemical processing e.g. from raw material extraction to production (substance manufacturing, mixing, etc.), recycling or waste management and covers **occupational safety and health (OSH) related aspects**
- The subject of the assessment are the **input substances** (*including any processing substances not entering the final product but being used in the processes*) or **other specific process-related hazards** applied during extracting/manufacturing/recycling etc. of the chemical under evaluation
- The goal is to assess whether these processing steps could result in **adverse effects** to workers

**'Process design' phase**

- This is the design of new or improved processes to produce chemicals and materials
- Process design does not change the intrinsic properties (e.g. hazard properties) of the chemical or material, but it can make the production of the substance safer and more sustainable (e.g. more energy or resource efficient, less reliant on the need for other hazardous substances in the process)

# Aspects and indicators

- In this step, the assessment addresses occupational safety and health aspects:
  - **Acute human health hazards**
  - **Chronic human health hazards**
  - **Physical hazards**
  - **Hazards from release behaviour**
  - **Process-related hazards**
- Based on the indicators for each aspect, several groups were defined and that correspond to different levels:
  - **Very high-risk process**
  - **High-risk process**
  - **Medium-risk process**
  - **Low-risk process**
  - **Negligible risk**

Step 2

# Aspects and indicators check-list

| Group definition | Acute human health hazards* | Chronic human health hazards | Physical hazards* | Hazards from release behaviour* | Specific process-related hazards* |
|---|---|---|---|---|---|
| **Aspects related to <u>very high-risk process</u>** | ❑ Acutely toxic substances/mixtures, Cat. 1 or 2 (H300, H310, H330)<br>❑ Substances/mixtures that in contact with acids liberate highly toxic gases (EUH032) | ❑ Human hazards similar to Step 1 / Criterion S1. | ❑ Unstable explosive substances/mixtures (H200)<br>❑ Explosive substances/mixtures/articles, divisions 1.1 (H201), 1.2 (H202), 1.3 (H203), 1.4 (H204), 1.5 (H205) and 1.6 (without H-phrase)<br>❑ Flammable gases, Cat. 1A (H220, H230, H231, H232) and Cat. 1B and 2 (H221)<br>❑ Pyrophoric gases (H232)<br>❑ Flammable liquids, Cat. 1 (H224)<br>❑ Self-reactive substances/mixtures, Types A (H240) and B (H241)<br>❑ Organic peroxides, Types A (H240) and B (H241)<br>❑ Pyrophoric liquids or solids, Cat. 1 (H250)<br>❑ Substances/mixtures which in contact with water emit flammable gases, Cat. 1 (H260)<br>❑ Oxidising liquids or solids, Cat. 1 (H271) | ❑ Gases<br>❑ Liquids with a vapour pressure > 250 hPa (mbar)<br>❑ Dust-generating solids<br>❑ Aerosols | ❑ Open processing<br>❑ Possibility of direct skin contact<br>❑ Large-area application<br>❑ Open design or partially open design, natural ventilation |

*See <u>Table 5</u> in JRC Technical Report for the other indicators of:*

- Aspects related to high-risk process
- Aspects related to medium-risk process
- Aspects related to low-risk process
- Aspects related to negligible risk

**Grouping adapted from GSH Column Model (version 2020) developed by the Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA)*

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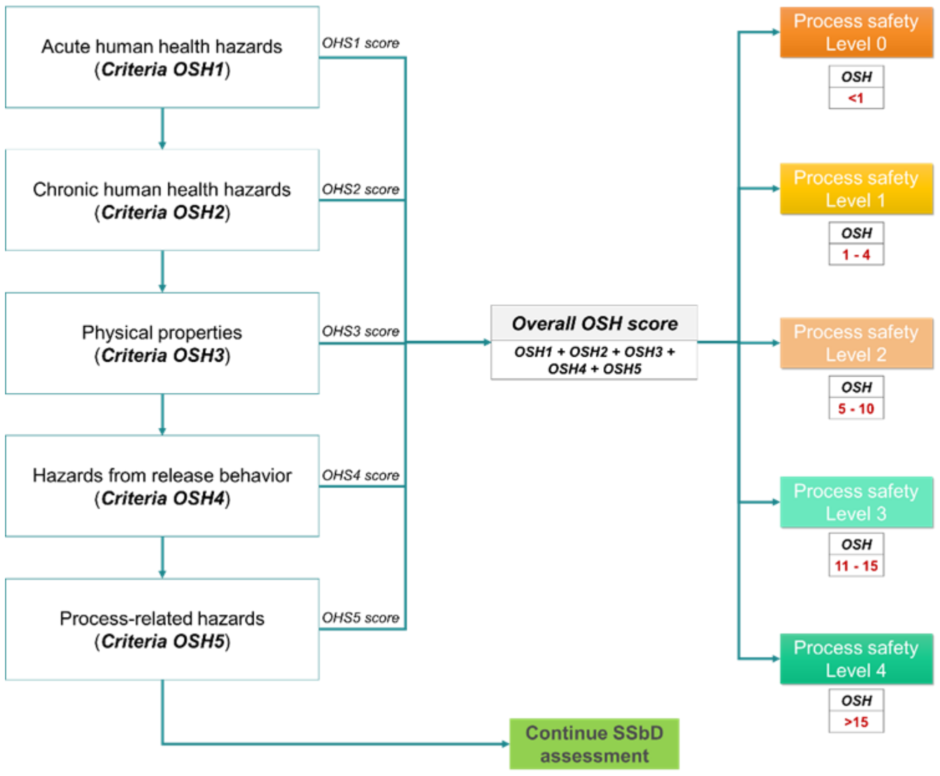
Step 2

# Criteria definition and evaluation system

- From these aspects and their indicators, a set of **occupational safety and health (OSH) criteria** are defined
- For the evaluation, each aspect will be assessed separately and will receive a **score** (*from 0 = very high-risk to 4 = negligible risk*) that will be included in the final score of this step so a **process safety level** could be finally assigned.

| Risk level | Acute human health hazards | Chronic human health hazards | Physical properties | Hazards from release behaviour | Process-related hazards |
|---|---|---|---|---|---|
| Very high-risk | 0 | 0 | 0 | 0 | 0 |
| High-risk | 1 | 1 | 1 | 1 | 1 |
| Medium-risk | 2 | 2 | 2 | 2 | 2 |
| Low-risk | 3 | 3 | 3 | 3 | 3 |
| Negligible risk | 4 | 4 | 4 | 4 | 4 |

- This assessment will give additional information on the safety of several processes (workers safety) during the chemical life cycle (e.g. extraction, production, recycling, waste treatment) that will **contribute to the overall sustainability assessment score.**



# Sustainability assessment

## Assessment steps

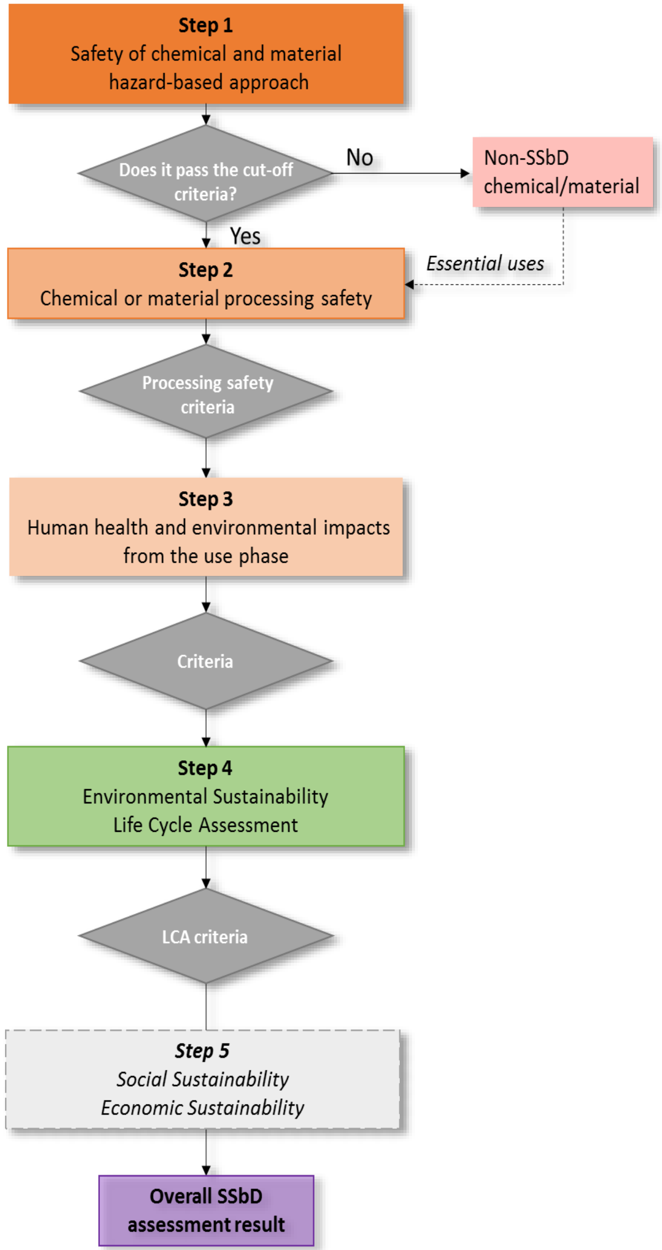
**Step 1** - Safety of chemical and material - hazard-based approach

**Step 2** - Chemical or material processing safety - occupational safety and health aspects

**Step 3** - Human health and environmental impacts from the use phase (direct exposure)

**Step 4** - Environmental sustainability assessment

**Step 5** - Social and Economic Sustainability assessment

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# Q&A

# Structure of the framework: a stepwise approach (part II)

**Carla Caldeira**

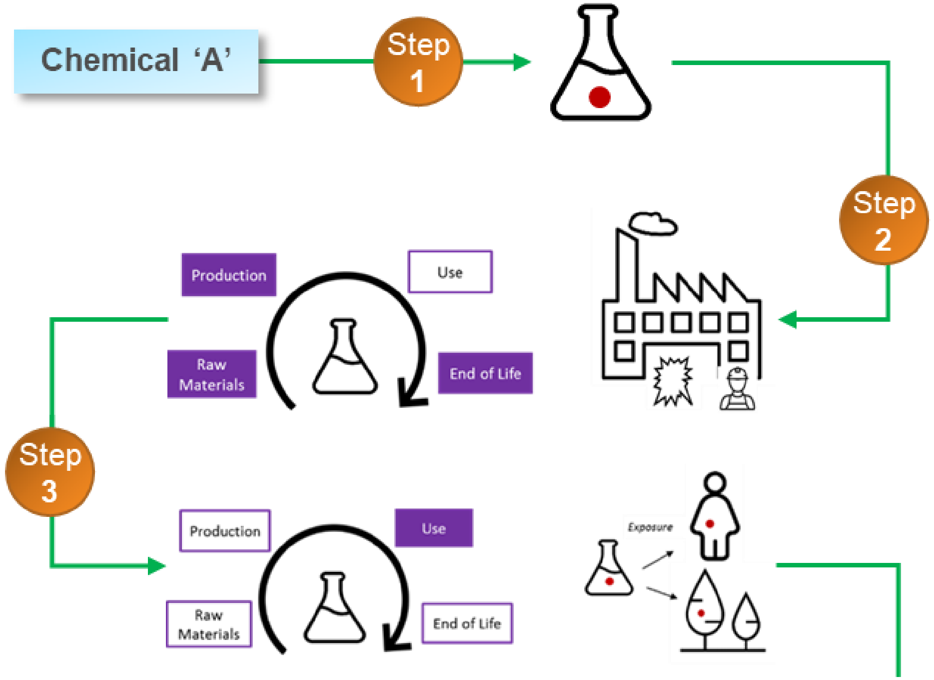
*Joint Research Centre*

Land Resources Unit

# Contents

- 4.2.3 Human health and environmental impacts from the use phase (direct exposure) (Step 3)
- 4.2.4 Environmental sustainability assessment (Step 4)

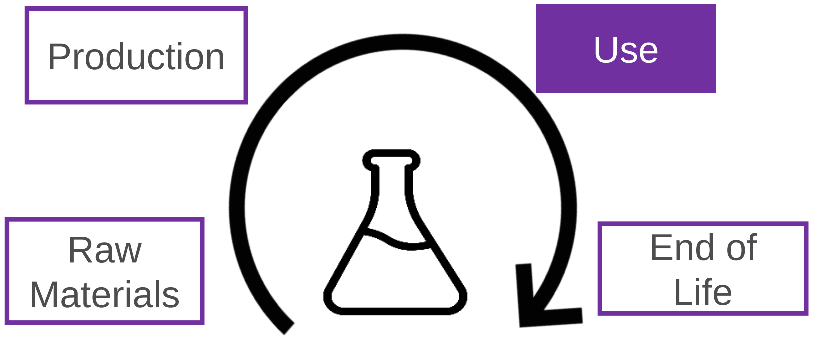
# Step 3 -Human health and environmental impacts from the use phase

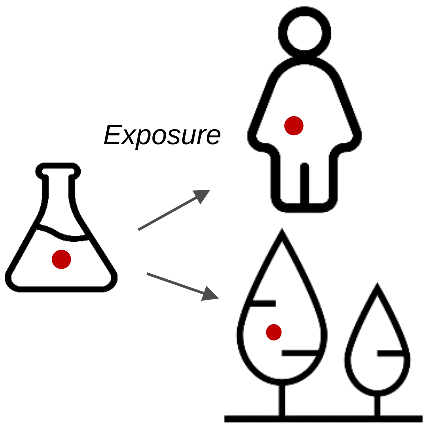


# Human health and environmental impacts from the use phase (direct exposure)

Step 3

- The impacts due to application/use-specific exposure are considered in this step
- Even for safer chemicals, the exposure of users/consumers in certain applications need to be evaluated
- SSbD assessment requires a risk perspective beyond generic hazard criteria, considering the contact (i.e. exposure) between stressors (e.g. chemical) and receptors (e.g. humans and other organisms)



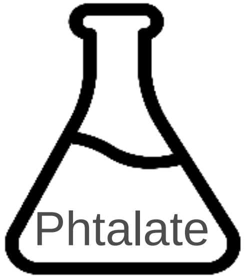



# Human health and environmental impacts from the use phase (direct exposure)

Step 3

The same chemical/material can be used for different functions depending on the actual application context, which implies differences in use-stage exposure settings and related risks for humans and the environment.

For example:




Plastic-material applications (function material flexibility)

Cosmetic applications (function material dissolution)

- Very different exposure
- Different implications for consumer and ecosystem exposure

Step 3

# Aspects and indicators

Based on **state of the art science** in human and ecosystem **exposure assessment** to account for the **potential risks** posed by the chemical/material under assessment

- **Human health**

**Intake fractions** (for emissions from e.g. processes) and **product intake fractions** (for chemicals in product applications) as **exposure metric** combined with **effect factors**

- **Ecotoxicity**

**Cumulative transfer fractions** (of chemical from processes or products) into the **environment** combined with **Species Sensitivity Distribution-based effect factors**

Step 3

# Definition of criteria and evaluation

### *Definition of criteria*

A benchmark dose-based approach can be used to derive **reference doses** that are widely accepted to define **“safe” levels that are compared with actual exposure/risk levels**.

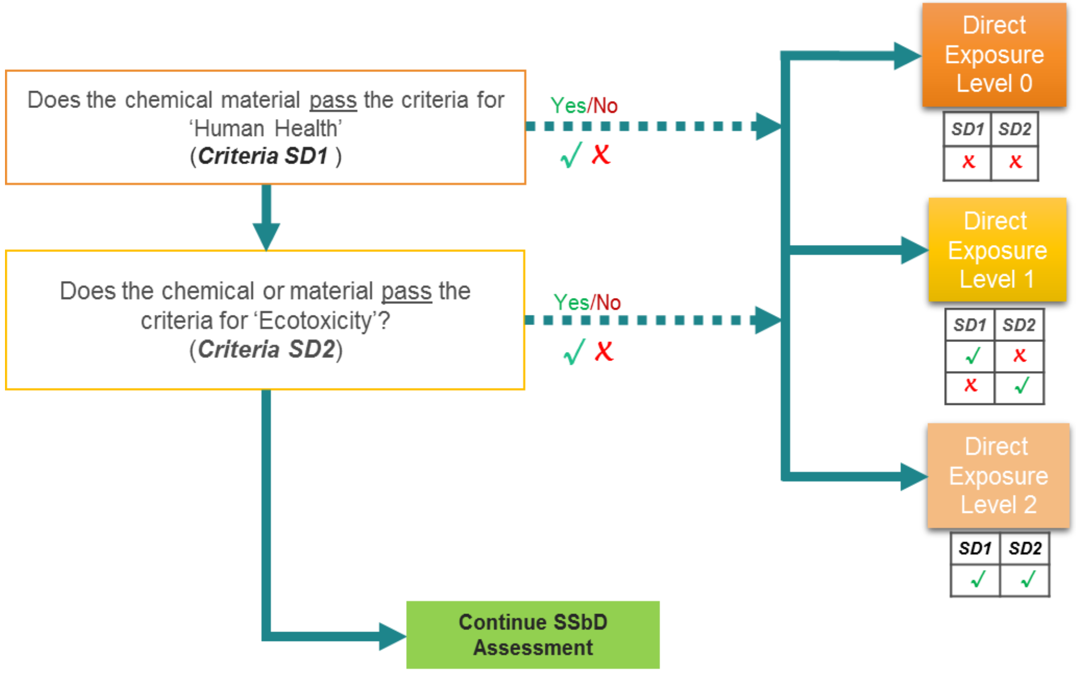
The values for the SSbD chemical/material should be below the safe levels.

### *Evaluation system*

| Position to safe level | Score | Color code | Criteria evaluation |
|---|---|---|---|
| > Safe level + 50% | 0 | | Fail the criteria |
| >Safe level; < safe level +50% | 1 | | |
| >Safe level - 25% ; **< Safe level** | **2** | | Pass the criteria |
| >safe level -50% ; <Safe level - 25% | 3 | | |
| < Safe level – 50% | 4 | | |

*Note: these ‘classes” are illustrative and should be defined considering the uncertainty of the assessment.*

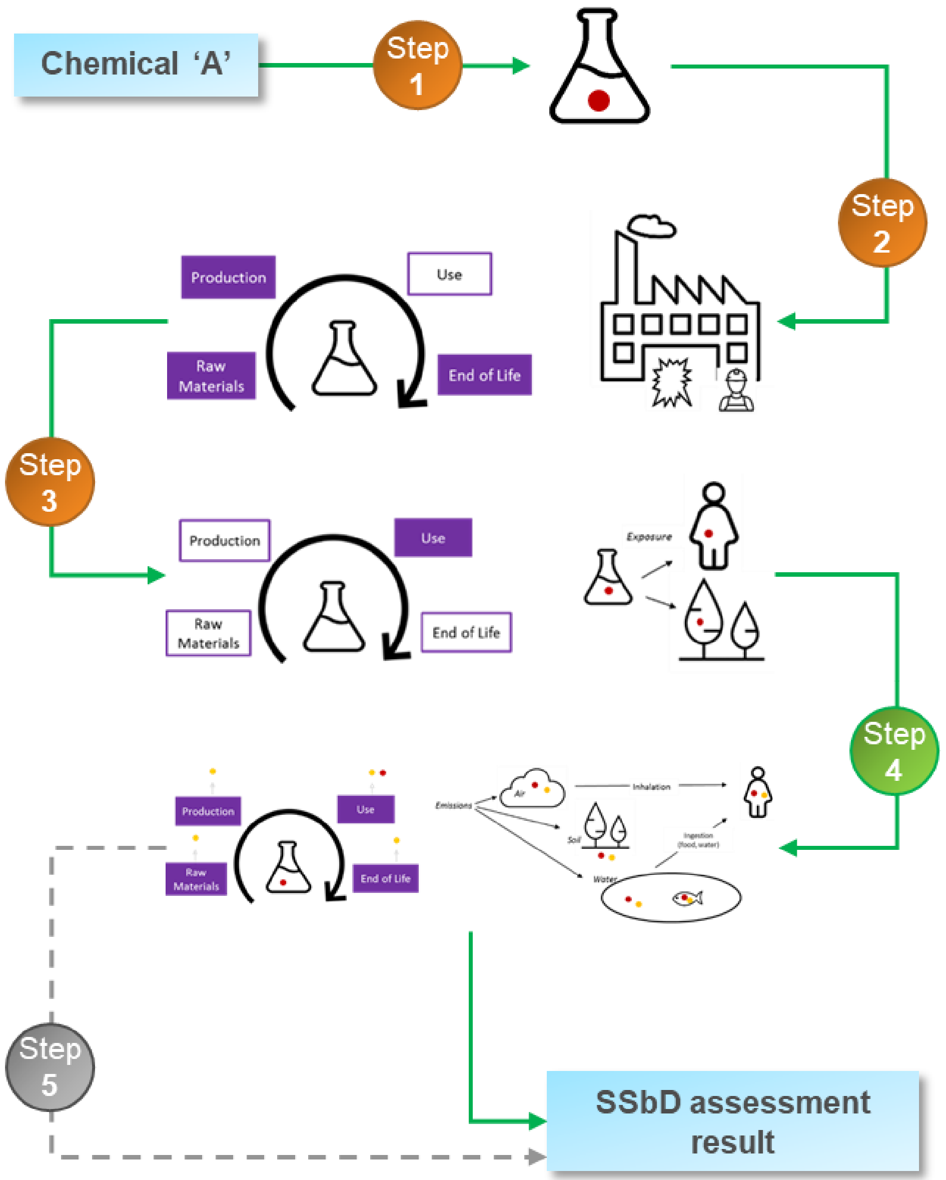
# Definition of criteria and evaluation




Three levels can be defined according to the number of criteria that the chemical/material complies with:

- **Level 0**: The chemical/material in not compliant with any of the criteria
- **Level 1**: The chemical/material complies with one of the criteria
- **Level 2**: The chemical/material complies with both criteria

# Step 4 - Environmental sustainability



# Environmental sustainability

**Environmental sustainability** refers to the ability to conserve natural resources and protect global ecosystems to support human health and wellbeing, within the limits of our Planet.

Assess the environmental impacts generated by chemicals/materials along the entire life cycle to ensure:

| "Toxic-free" environment | "Climate-neutral" economy | Resource efficient economy | Reduction of biodiversity loss |
|---|---|---|---|
| • Total toxicity footprint- ecotoxicity and human toxicity - at each stage of the production and consumption life cycle | • Greenhouse gases emissions along the life cycle | • Sustainable use of natural resources | • Conservation of ecosystem functioning, addressing the main drivers of biodiversity and functional diversity loss |

Step 4

# System benefits - Regenerative economy

“EU needs to accelerate the transition towards a **regenerative growth model** that gives back to the planet more than it takes” (CEAP, 2020)

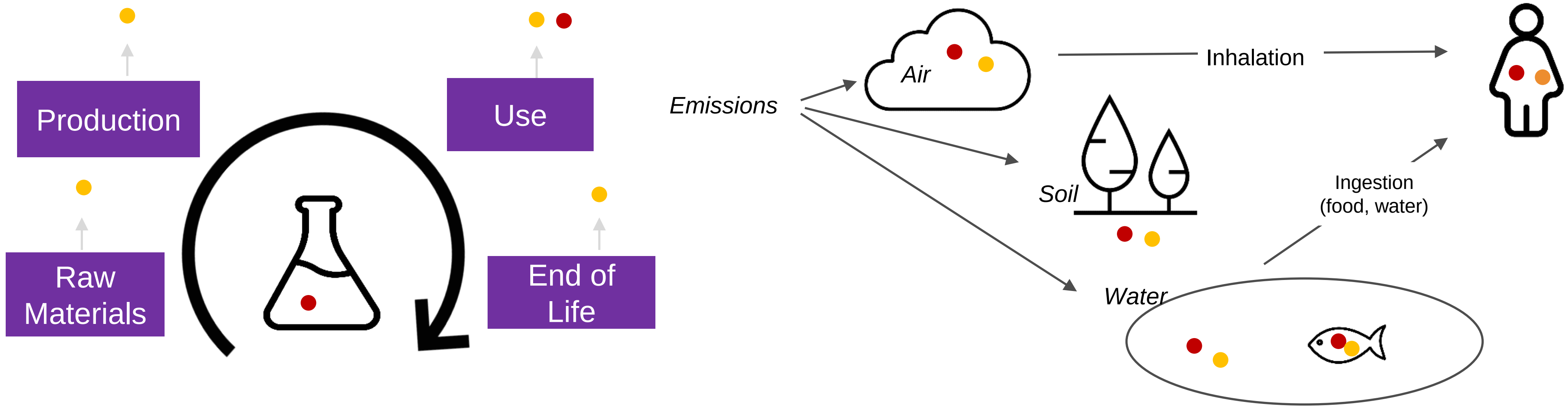
- Potential that a chemical or material has to generate **environmental benefits at system level** when applied in a specific context.
  - chemical/material designed for reducing environmental pressure/impacts
  - chemical/material that when applied is reducing the environmental burdens of the system where it is applied
  - a chemical/material which allow to reduce and substitute virgin resources to preserve and regenerate ecosystems

CEAP, 2020 A new Circular Economy Action Plan For a cleaner and more competitive Europe.COM(2020) 98.

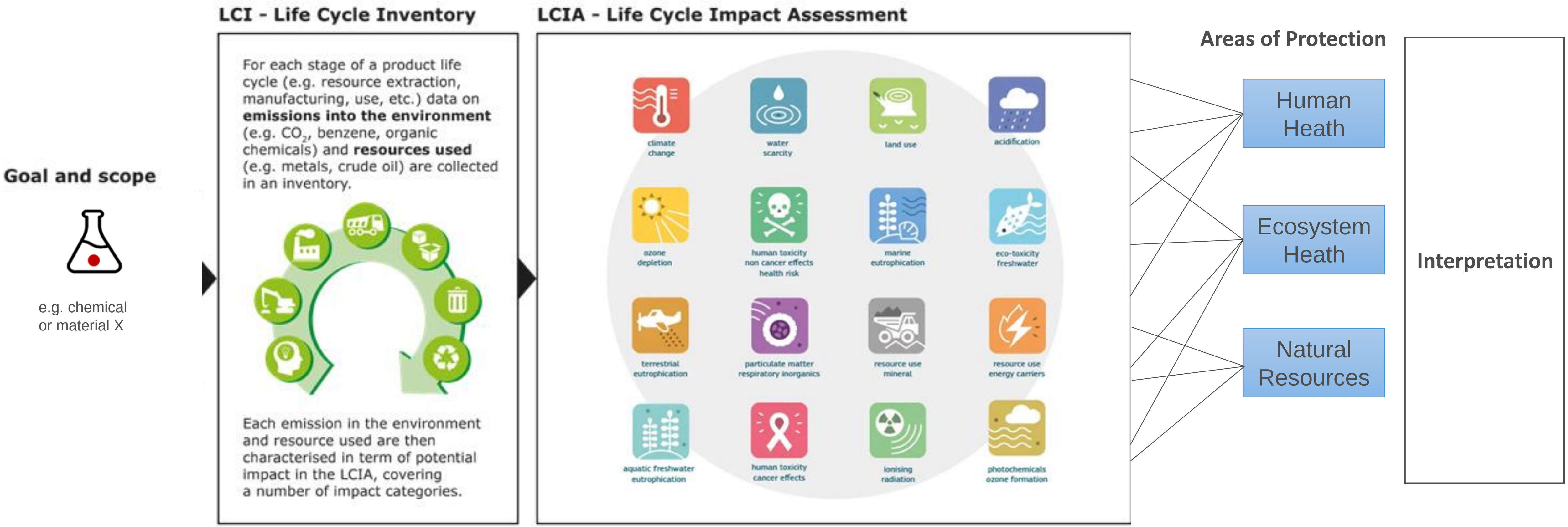
# Environmental sustainability

Step 4

## Life Cycle Assessment

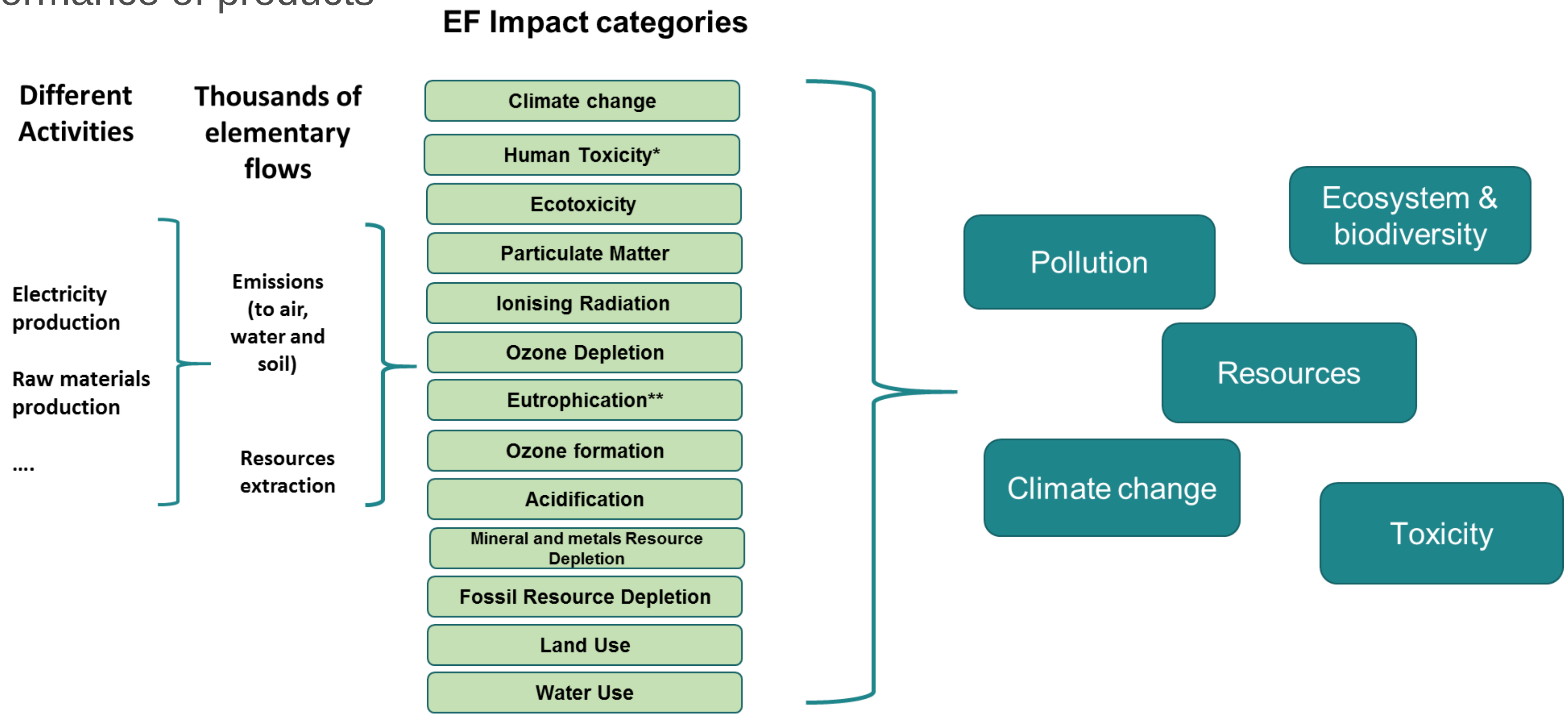


# Life Cycle Assessment



# Aspects and indicators

Impact categories considered in the **Environmental Footprint Impact Assessment method** recommended by the European Commission to be used to measure the life cycle environmental performance of products



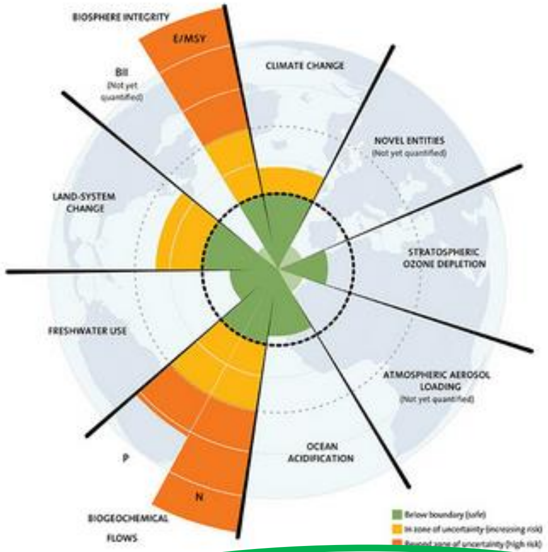

+ Other environmental impact categories and methods to assess impacts on biodiversity e.g. IMPACT world, LC-IMPACT, ReCipe2016

# Definition of criteria (Step 4)

For each impact category a criterion should be defined as **a reduction of the impact category value of X% (target)** relative to a **reference value**.

The **ambition of the SSbD** is to move from relative (safer and more sustainable) to **absolute (safe and sustainable)** improvements ensuring that chemicals and materials are produced and used **without exceeding acceptable boundaries**

The integration of ecosystems carrying capacities has been advocated since long in the sustainability science domain and as a mean to **move LCA from comparative to absolute assessment.**




**Absolute sustainability considerations (e.g. planetary boundaries)**

# Mapping PBs with LCIA impact categories



Connecting LCA impact categories with the 16 EF impact categories

Blue – link

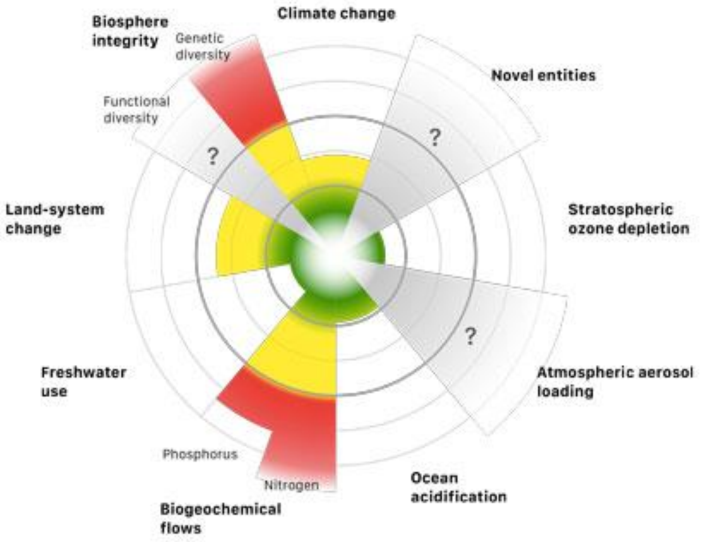
Black – mapped category

PLANETARY BOUNDARIES

| SDGs | LCA impact categories (EF 3.0) | Biodiversity integrity – Functional | Biodiversity integrity - Genetic | Climate change | Novel entities | Stratospheric ozone depletion | Atmospheric aerosol loading | Ocean acidification | Biogeothermal flows - Nitrogen | Biogeothermal flows - Phosphorus | Freshwater use | Land-system change | Resource use |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 3 | Human toxicity, cancer | | | | Blue | | | | | | | | |
| 3 | Human toxicity, non cancer | | | | Blue | | | | | | | | |
| 3 | Particulate matter | | | | | | Blue | | | | | | |
| 3 | Photochemical ozone formation | | Black | | Blue | | | | | | | | |
| 3 | Ionising radiation | | | | Blue | | | | | | | | |
| 6 | Water use | | Black | | | | | | | | Blue | | |
| 6 | Ecotoxicity, freshwater | | Black | | Black | | | | | | | | |
| 13 | Climate change | | Black | Blue | | | | Black | | | | | |
| 13 | Resource use, fossil | | | Black | | | | | | | | | Blue |
| 13 | Ozone depletion | | | | | Blue | | | | | | | |
| 14 | Euthrophication, marine | | Black | | | | | | | Blue | | | |
| 14 | Eutrophication, freshwater | | Black | | | | | | | Blue | | | |
| 15 | Land use | | Black | | | | | | | | | Blue | |
| 15 | Euthrophication, terrestrial | | Black | | | | | | | Blue | | | |
| 15 | Acidification | | Black | | | | | | | Blue | | | |
| 15 | Resource use, minerals and metals | | | Black | | | | | | | | | Blue |

Sala et al. (2020). Environmental sustainability of European production and consumption assessed against planetary boundaries. *Journal of environmental management*, *269*, 110686.

# Set of PB factors used in Environmental Footprint (3.0)



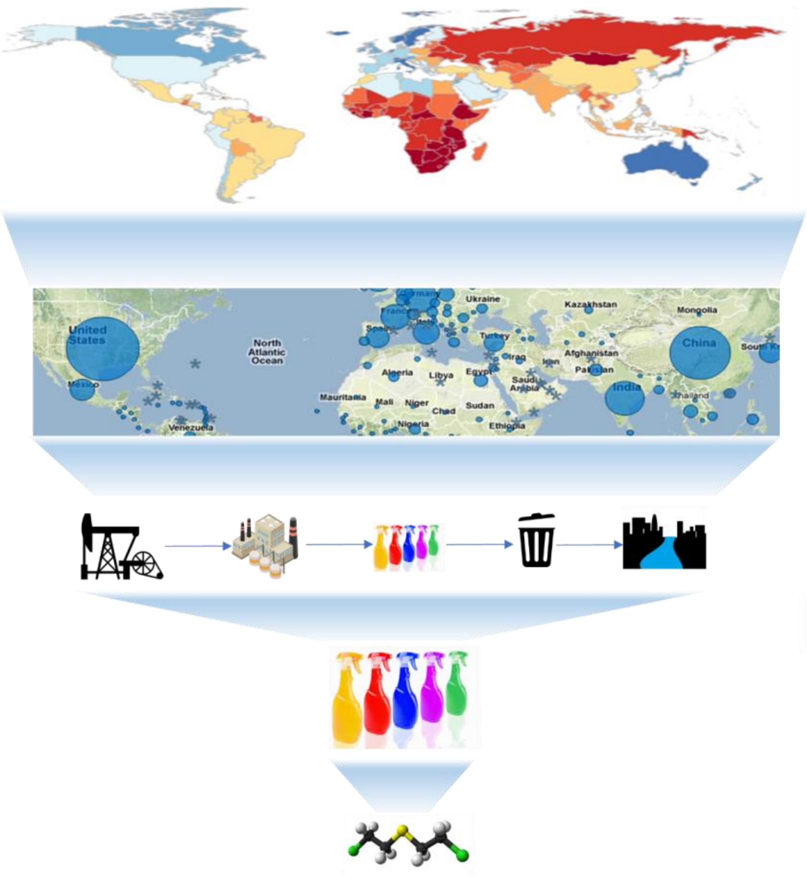

| Impact category | Planetary Boundary (PB) | PB per capita | Unit |
|---|---|---|---|
| Acidification | 1.00E+12 | 1.45E+02 | mol $H^+$ eq. |
| Climate change | 6.81E+12 | 9.85E+02 | kg $CO_2$ eq. |
| Ozone depletion | 5.39E+08 | 7.79E-02 | kg CFC-11 eq. |
| Human toxicity, non-cancer | 4.10E+06 | 5.93E-04 | CTUh |
| Human toxicity, cancer | 9.62E+05 | 1.39E-04 | CTUh |
| Particulate matter | 5.16E+05 | 7.46E-05 | disease incidence |
| Ionising radiation | 5.27E+14 | 7.62E+04 | kg U-235 eq. |
| Photochemical ozone formation | 4.07E+11 | 5.88E+01 | kg NMVOC eq. |
| Eutrophication, terrestrial | 6.13E+12 | 8.86E+02 | mol N eq. |
| Eutrophication, freshwater | 5.81E+09 | 8.40E-01 | kg P eq. |
| Eutrophication, marine | 2.01E+11 | 2.91E+01 | kg N eq. |
| Ecotoxicity, freshwater | 1.31E+14 | 1.89E+04 | CTUe |
| Land use | 3.98E+15 | 5.75E+05 | Pt |
| Water use | 1.82E+14 | 2.63E+04 | $m^3$ water eq. |
| Resource use, fossil | 2.24E+14 | 3.24E+04 | MJ |
| Resource use, mineral and metals | 2.19E+08 | 3.17E-02 | kg Sb eq. |

Sala et al. (2020). Environmental sustainability of European production and consumption assessed against planetary boundaries. *Journal of environmental management*, *269*, 110686.

Step 4

# Definition of criteria – how to set the target?

Many "layers" of a chemical's safety and sustainability, overlaying of which provides additional insights (and costs)




| Main focus | Analytical outcomes |
|---|---|
| Environmental concentration/ exposure | Global mortality and morbidity |
| Global Production Volume | Safe Operating Space/ Planetary boundaries |
| Life Cycle/ Multiple Impact Categories | LCA |
| Application context | Alternative Assessment |
| Chemical properties | Hazard characteristics |

- Spatial scale is of utmost importance as chemicals or materials are rarely as such planetary-scale problems

- Transgression of local-to-regional boundaries

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Step 4

# Definition of criteria – how to set the target?

Setting a **science-based target** requires:

A. a global (or regional, depending on the impact being considered) assessment of the **current magnitude of a problem** and its future trajectories;

B. building a consensus on the **acceptable level of impact** that society can tolerate.

**A - B** -> target for reduction that can then be scaled down to the chemical/material

**Adoption proposed targets in EU policies**

e.g. 50% reduction of $CO_{2eq}$ or even carbon neutral as criteria for climate change in the SSbD framework.

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Step 4

# Definition of criteria – how to set the target?

## Factor 10

- Studies on the environmental impacts of EU production and consumption have shown that **current level of impacts is 10 times higher than the acceptable limits**, e.g. for climate change (Sala et al. 2020)

- This factor 10 is also referenced since long time as a mean for society to achieve sustainability (Schmidt-Bleek, 2008; Srinivas, 2015).

- Factor 10 states that over the next 30 to 50 years (one or two generations) a **decrease in energy use and material flows by a factor of 10** and an **increase in resource productivity/efficiency by a factor of 10** is required to achieve **dematerialisation**.


Sala et al. (2020). Environmental sustainability of European production and consumption assessed against planetary boundaries. *Journal of environmental management*, *269*, 110686.
Schmidt-Bleek, F. (2008). Factor 10: The future of stuff,, 4:1, 1-4, DOI: 10.1080/15487733.2008.11908009. Sustainability: Science, Practice and Policy, 4(1), 1–4
Srinivas, H. (2015). SD Features- Sustainability Concepts https://www.gdrc.org/sustdev/concepts/11-f10.html

Step 4

# Definition of criteria – reference

**Reference:** the state of the art of the intended use

- **representative chemical/material** within a chemical/material class or group
  - challenging in terms of granularity of the chemical class to be addressed, and when alternatives are proposed pertaining to different classes. BUT some classes e.g. solvents rankings already exist so one should expand on these general lists and not fall below this standard by intentionally selecting worse reference chemicals/materials

- **chemical/material that will be replaced** or **among the possible alternatives** in the design stage

Criteria may result from collecting evidences of a significantly better environmental performance of the alternative compared to the base case

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Step 4

# Environmental sustainability

## Evaluation system

| Position to target | Score | Color code | |
|---|---|---|---|
| >Target + 50% | 0 | | Fail the criteria |
| >Target; <Target + 50% | 1 | | |
| >Target - 25%; **<Target** | 2 | | Pass the criteria |
| >Target - 50%; <Target -25% | 3 | | |
| <Target – 50% | 4 | | |

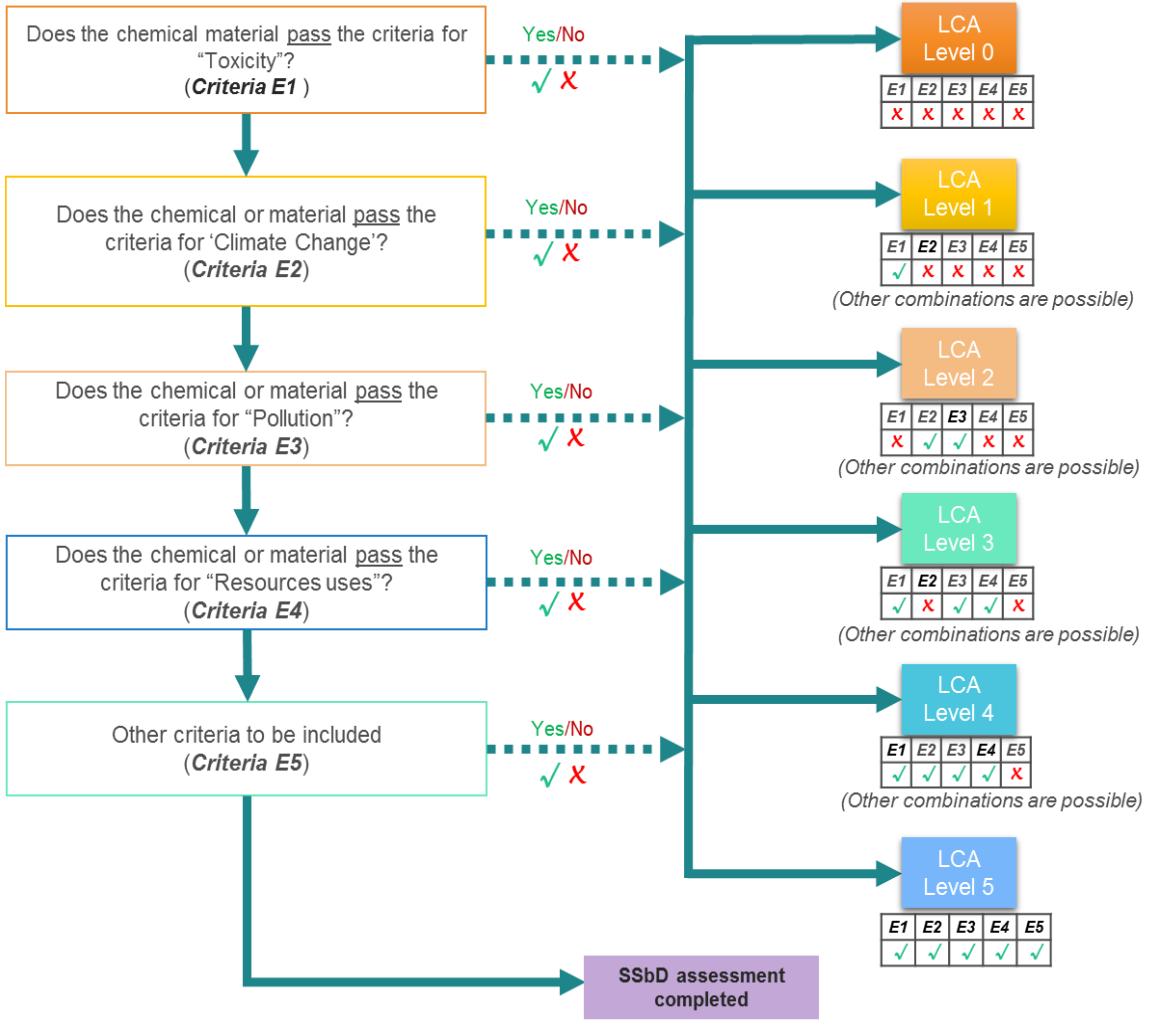
## Example of a summary table of the evaluation of step 4

| LCA Assessment level | Aspect | Score |
|---|---|---|
| **Toxicity** | Human Toxicity cancer | 3 |
| | Human Toxicity non cancer | 2 |
| | Ecotoxicity | 1 |
| **Climate Change** | Climate Change | 3 |
| **Pollution** | Ozone depletion | 4 |
| | Particulate matter/Respiratory inorganics | 2 |
| | Ionising radiation, human health | 2 |
| | Photochemical ozone formation | 1 |
| | Acidification | 0 |
| | Eutrophication, terrestrial | 4 |
| | Eutrophication, aquatic freshwater | 3 |
| | Eutrophication, aquatic marine | 2 |
| **Resources** | Land Use | 4 |
| | Water use | 2 |
| | Resource use, minerals and metals | 2 |
| | Resource use, energy carriers | 2 |

*Note: these 'classes" are illustrative and should be defined considering the uncertainty of the assessment.*

Step 4

# Environmental sustainability




**LCA level** can be derived counting the number of passed **assessment levels**

- **LCA level 0** means that all the chemical/material did **not comply with any** of the criteria
- **LCA Level 1** chemical/material comply with the criteria of **one** assessment level
- ….
- **LCA level 5** means that the chemical/material comply the criteria of **all assessment level**

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# Q&A

# Evaluation procedure

**Carla Caldeira**

*Joint Research Centre*

Land Resources Unit

# Content



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# Procedures in decision frameworks (review)

- Most of the **frameworks present a hierarchical procedure** underlying the decision process in which **safety aspects are mandatory and considered first, whilst environmental and social aspects are considered after**

- **Integrating all sustainability aspects is considered inappropriate** since the **trade-off between harmful chemicals** (e.g. due to a carcinogen) and **green chemicals** (e.g. low energy-intensity) is not directly equivalent

- A few reviewed frameworks also provide an **outcome aggregating safety, health and environmental impacts**

- To **facilitate the decision making**, the impact profiles of the alternatives can also be presented at an aggregated level with **single scores per dimension** i.e., safety, economic and environmental (and social)

# Trade-offs and support to decision making

- Sequential framework:
  - **hierarchy defined by the responsible organisation**; allows removal of aspects or indicators that do not differ among the alternatives.
- Simultaneous framework:
  - considers all aspects at once, allowing good performance on one attribute to offset less favourable performance to another. It usually requires **weighting and trade-off criteria**, **ranking aspects and indicators by level of importance**. As result, they can provide a ranking of alternatives.
- Hybrid framework: Consist in a combination of the sequential and simultaneous frameworks.

**Having more than one acceptable** alternative may be desirable under certain circumstances

IC2, 2017 Alternatives Assessment Guide Version 1.1
NRC, 2014. A framework to guide selection of chemical alternatives

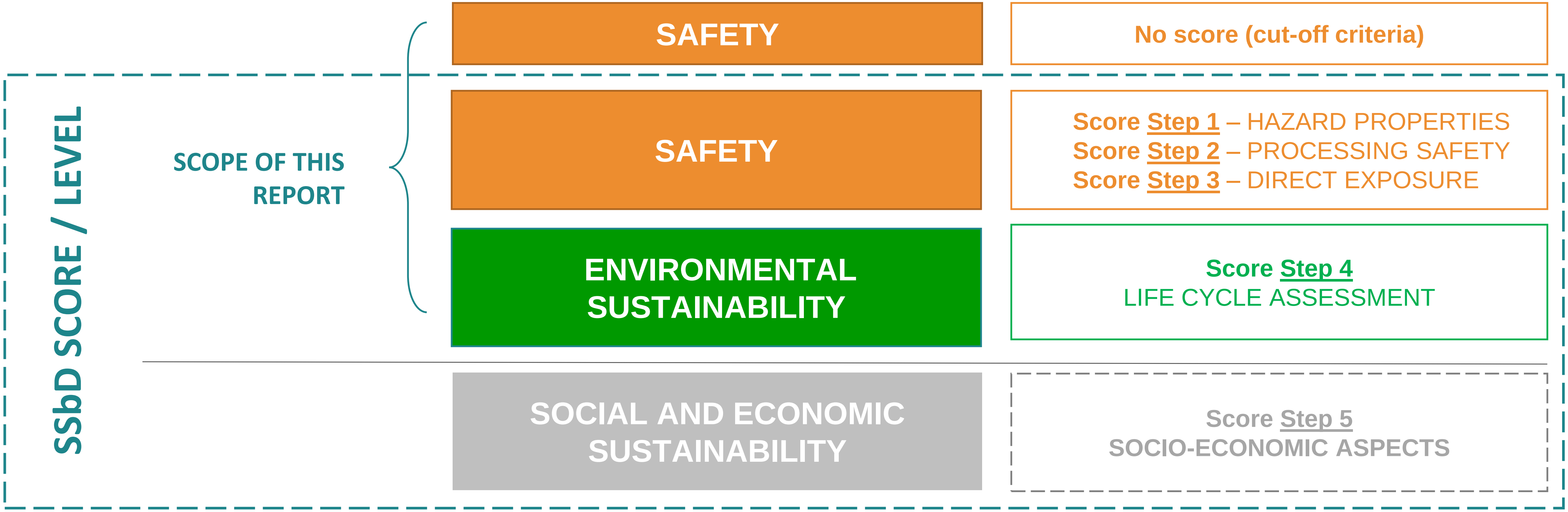
# Trade-offs and support to decision making

Strategies to deal with trade-offs:

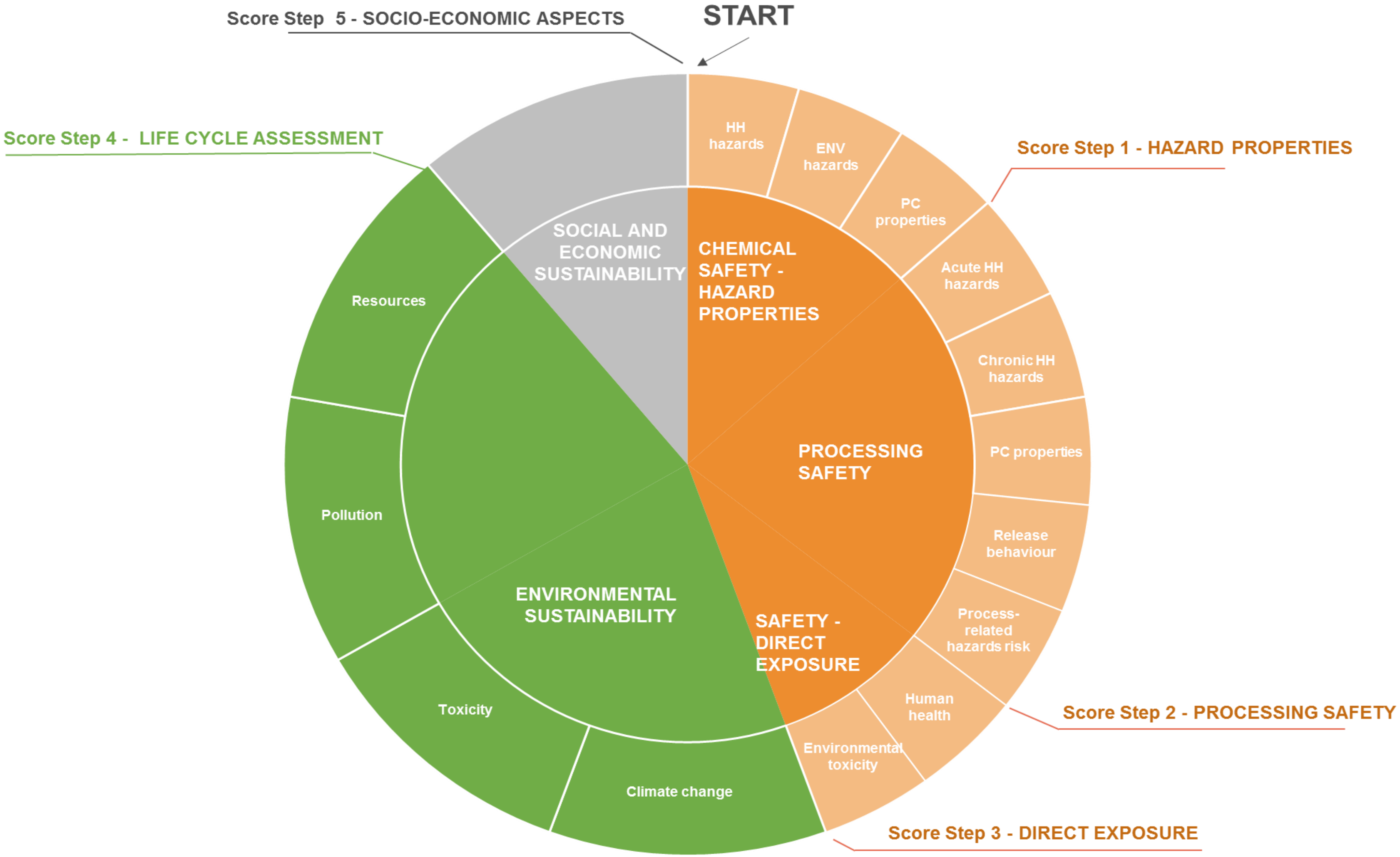
- ***Improvement on key aspects*****:** In some contexts, the alternatives assessment may be motivated by the need to improve the safety of the chemical/material with respect to a specific aspect.
- ***Equal weighting of aspects*****:** Each aspect is considered to have equivalent importance, and the trade-off is resolved by averaging the score.
- ***Weighted scoring of aspects*****:** Unequal weight are assigned to different aspects, reflecting their relative importance and the final score is determined by summing up the weighted scores.
- ***Rule-based ranking*****:** The preferences can be ordered by a series of logical statements, rather than using weights.
- ***Eliminate the "high" rating*****:** In this strategy, the alternative is eliminated if it scores higher than a specified threshold.
- ***Expert-manager judgment*****:** Fully relies on the application of expert judgment.
- ***List-based preference ordering***: There is a preference order of aspects to be addressed. It can be based on the organisation needs or on external ones (regulation, other companies). This strategy can also be applied at indicator level.

NRC, 2014. A framework to guide selection of chemical alternatives
OECD, 2021. Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives

# Evaluation procedure



# Evaluation procedure




SSbD SCORE

# Overview of the SSbD components of the framework

**Design Guiding Principles**

| SSbD Principles | |
|---|---|
| Indicator 1 | √ |
| Indicator 2 | √ |
| Indicator 3 | √ |
| ... | √ |

**Sustainability Assessment**

| Dimension | Aspect | Indicator/ unit | Chemical/Material under assessment value | Reference value | Criteria | Score |
|---|---|---|---|---|---|---|
| Safety of chemical and material - hazard-based approach | Human health hazards | | | | | |
| | Environmental hazards | | | | | |
| | Physical hazards | | | | | |
| Chemical or material processing safety | Acute human health hazards | | | | | |
| | Chronic human health hazards | | | | | |
| | Physical properties | | | | | |
| | Hazards from release behaviour | | | | | |
| | Process-related hazards | | | | | |
| Safety - Direct exposure | Human Health | | | | | |
| | Eco toxicity | | | | | |
| ENVIRONMENTAL SUSTAINABILITY Life Cycle Assessment | Climate Change | Radiative forcing as Global Warming Potential (GWP100) (kg CO2 Eq) | | | | |
| | Human toxicity cancer | Comparative Toxic Unit for humans (CTUh) | | | | |
| | Human toxicity - Non cancer | Comparative Toxic Unit for humans (CTUh) | | | | |
| | Eco-toxicity | Comparative Toxic Unit for ecosystems (CTUe) | | | | |
| | Particulate matter | Human health effects associated with exposure to PM2.5 disease incidence | | | | |
| | Ionising radiation | Human exposure efficiency relative to U235 kBq U235 equivalents | | | | |
| | Ozone Depletion | Ozone Depletion Potential | | | | |
| | Eutrophication terrestrial | Accumulated Exceedance | | | | |
| | Eutrophication Fresh water | Fraction of nutrients reaching freshwater and compartment (P) | | | | |
| | Eutrophication Marine | Fraction of nutrients reaching marine and compartment (N) | | | | |
| | Ozone formation | Tropospheric ozone concentration increase | | | | |
| | Acidification | Accumulated Exceedance (AE) | | | | |
| | Fossil resources | Abiotic resource depletion – fossil fuels (ADP-fossil) | | | | |
| | Mineral and metals resources | Abiotic resource depletion (ADP ultimate reserves) | | | | |
| | Land Use | Soil quality index | | | | |
| | Water Use | User deprivation potential (deprivation weighted water consumption) | | | | |
| | Other | | | | | |

| Safe and sustainable by design (SSbD) dashboard | | |
|---|---|---|
| **Dimension** | **Aspect** | **Score** |
| Safety - Hazard | S1 | √ |
| | S2 | √ |
| | S3 | √ |
| Safety - Occupational safety and health | OSH1 | √ |
| | OSH2 | √ |
| | OSH3 | √ |
| | OSH4 | √ |
| | OSH5 | √ |
| Safety - Direct exposure | SD1 | √ |
| | SD2 | x |
| Environment | E1 | x |
| | E2 | √ |
| | E3 | x |
| | E4 | √ |
| Social & Economical Sustainability | | x |

SSbD Level

Scoring system

Open questions:

- Weighting scheme?
- Visualization of results of specific criteria

# Data availability

One major challenge for sustainability assessment is data availability and accessibility.

Chemicals sector there is a lack of public information on the use of 200.000 chemicals or chemical mixtures (Wang and Hellweg, 2021)

To be explored:

- Use of **new approach methodologies** (NAMs) for safety assessment
- The role of **digital developments** building on works done by e.g. (Liao et al., 2021; Weber, et al., 2021, Fantke et al.,2021)

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Mochen Liao, Kai Lan, Yuan Yao

First published: 13 November 2021 | https://doi.org/10.1111/jiec.13214 | Cita

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Perspective

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Peter Fantke [1], Claudio Cinquemani [2], Polina Yaseneva [3], Jonathas De Mello [4], Henning Schwabe [5], Bjoern Ebeling [6], Alexei A. Lapkin [7]

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Jana M. Weber, [ab] Zhen Guo, [bc] Chonghuan Zhang, [a] Artur M. Schweidtmann [d] and Alexei A. Lapkin [*abc]

Wang, Z., Hellweg, S., 2021. First Steps Toward Sustainable Circular Uses of Chemicals: Advancing the Assessment and Management Paradigm. ACS Sustain. Chem. Eng.

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# Data Uncertainty

Quality of the data influences significantly the results

- **“Data quality Score’** based on the use of a pedigree matrix in which a **score is attributed to the data source** considering the following indicators: **reliability, completeness, temporal, geographical, further technological correlation and sample size**. Additionally, the indicator ‘basic uncertainty’ is considered to account for intrinsic variability and stochastic error of the data.
- **Other options to be explored**

# Acknowledgements

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# Q&A

# Case studies

**Lucian Farcal**

*Joint Research Centre*

Consumer Products Safety Unit

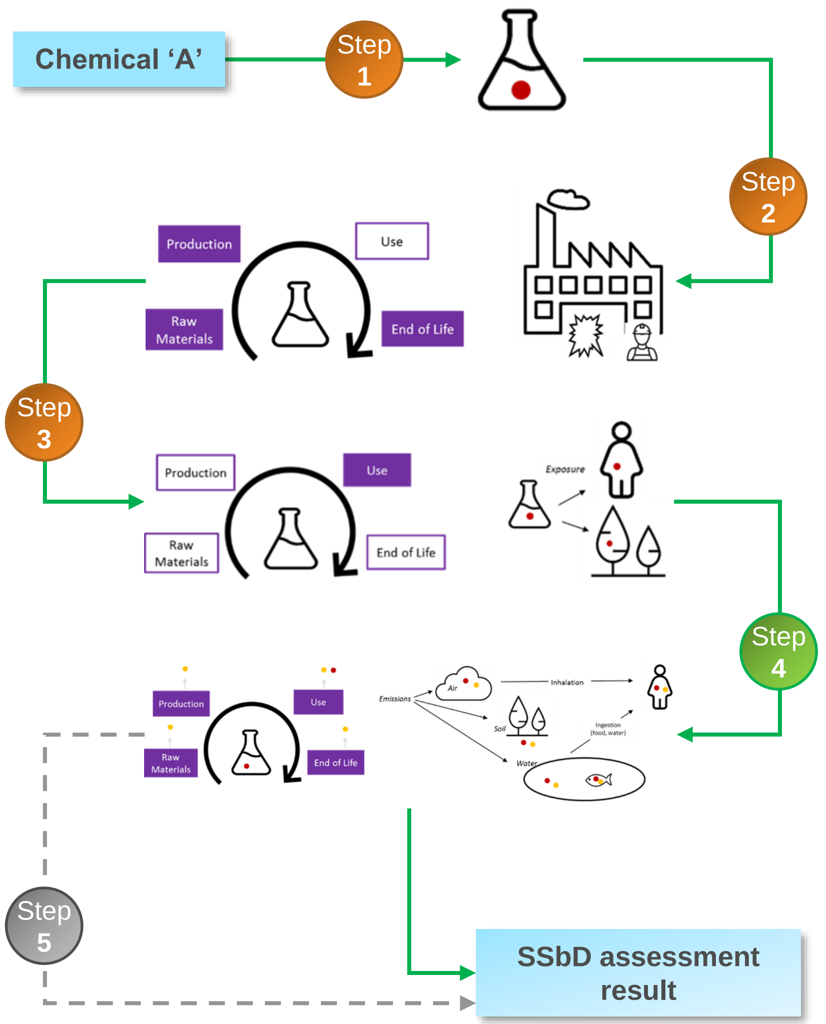
European Commission

# Objectives

- Three case studies will be considered in order to:
  - Assess the SSbD methodology and its feasibility
  - Identify the data needs and availability
  - Define specific criteria
  - Provide additional knowledge for the optimisation and refinement of the methodology

- 3rd JRC Technical Report on the elaboration of criteria with application to a case study (expected Q3 2022)
  - Consultation with stakeholders (3rd Stakeholder workshop to be organised in Q3 2022)

SSbD assessment workflow



# Selection of chemicals or materials

- Possible case studies

| Group | Application | Description |
|---|---|---|
| Plasticisers (*non-phthalate*) | Food contact materials (FCM) | Case study on phthalate-free plasticisers, as an example addressing consumer exposure |
| Surfactants | Textiles processing | Case study on surfactants used in the textile processing during the cleaning phase (scouring) |
| Flame retardants (*halogen-free*) | Information and communications technology (ICT) products | Case study on flame halogen-free flame retardants, addressing circularity and also consumer exposure |

- The selection was based on the input received in the stakeholder survey (June 2021) and alignment with relevant EC policies
- Analysis of information on these possible case studies and evaluate the relevancy in the context of the SSbD framework:
  - Identification and description of chemicals belonging to these groups
  - Alternatives available
  - Data availability

# Collaboration on the case study

- Call for data on existing/new chemicals relevant to the proposed cases and collaboration in developing the case study
- If you' like to contribute with data, please let us know by 5 April 2022 to

  RTD-SUSTAINABLE-BY-DESIGN@ec.europa.eu

| Group of chemicals | Application |
|---|---|
| Plasticisers (*non-phthalate*) | Food contact materials (FCM) |
| Surfactants | Textiles processing (e.g. scouring) |
| Flame retardants (*halogen-free*) | Information and communications technology (ICT) products |

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# Thank you



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