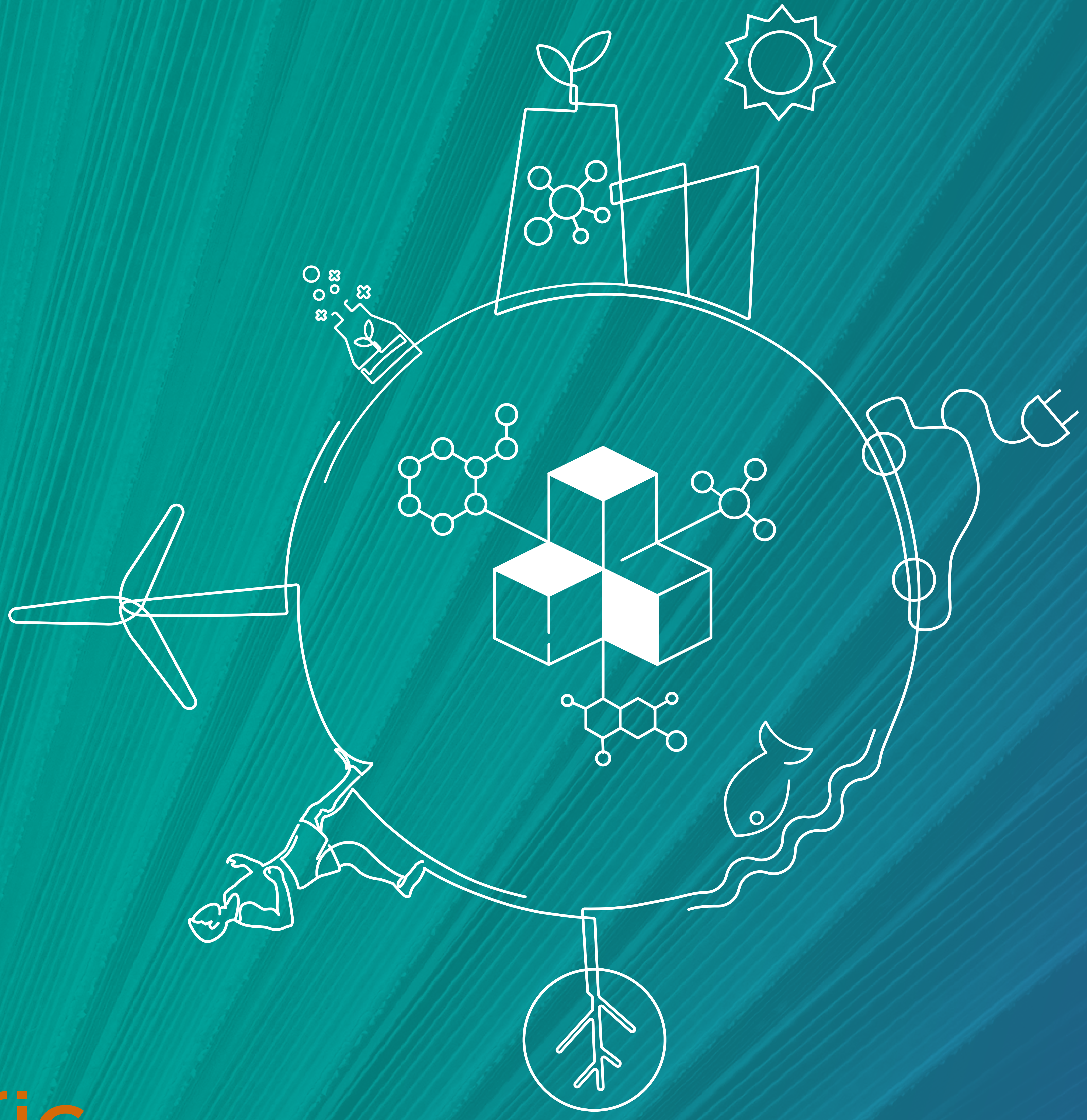
# SAFE AND SUSTAINABLE-BY-DESIGN: A TRANSFORMATIVE POWER

APRIL 2022



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# Preamble

## A guidance on Safe and Sustainable-by-Design

This guidance considers which safety and sustainability aspects are recommended to be part and parcel of the innovation process, to ensure chemicals, materials, products, processes, and services are Safe and Sustainable-by-Design.

The guidance focuses on dimensions and considerations for safety and sustainability, that need to be integrated into an innovation process, with the aim to reach the above ambition. This document was developed with the support of Cefic's experts active in the field of sustainability and innovation, and will be kept under review as the concept of Safe and Sustainable-by-Design develops.

## Scope

To identify the dimensions for safety and sustainability, we could rely on the experience of Cefic member companies implementing the framework for Portfolio Sustainability Assessment, developed by pioneering companies under the umbrella of the WBCSD[1]. In the chemical industry methodology, the following "signals"[2] need to be assessed e.g., the chemical hazards and exposure across the life cycle, anticipated regulatory trends, sustainability ambitions along the value chain, authoritative ecolabels, sustainability-related certification and standards, environmental and social performance across the life cycle compared to alternative solutions. Other "signals" are recommended to be assessed, the sustainable value creation, the Sustainable Development Goals and the company's internal guidelines & objectives.

The application scope the writers of this guidance have in mind is innovation for safe and sustainable chemicals as put forward in the Chemicals Strategy for Sustainability (CSS). The innovation goal of the CSS is said specifically to bring solutions across sector markets, notably for construction materials, textiles, low-carbon mobility, batteries, wind turbines and renewable energy sources. And for the European chemical industry this translates to innovation questions on how to design for safe and sustainable chemicals, materials, processes & services linked to these and other market segments. These innovations can be new or following an improvement process regarding the safety and sustainability assets.

## Target Audience

This guidance is intended to be used by innovators within chemical companies and is offered as another source of information for the ongoing work at the Commission regarding the developments of indicators for Safe and Sustainable-by-Design chemicals, materials and products and services.

Whilst this guidance adresses in the first place Cefic members, we'd consider it good practice to extend its use to international value chains as well.

## Requirements for Success

The European chemical sector supports the ambition to transition towards safe and sustainable chemicals, materials, products in their specific uses, and processes and is committed to contribute to the development and implementation of Safe and Sustainable-by-Design, by spreading this guidance, and reporting on how it is used.

The sector further aims to innovate in assessment methodologies, and transparently sharing the knowledge supporting the assessment methodologies. In doing so, we will in particular focus on the needs of the small and medium enterprises (SMEs) to enable them to get up to speed.

The so-called Green transition sets an unprecedented challenge for the chemical industry, Safe and Sustainable-by-Design presents a way forward. It will be important to flank this transition vision with enabling policy measures to ensure predictability of goals, within timelines that are ambitious yet realistic, and providing for the skills and resources – financial and non-financial – needed.

We believe that, a thorough development of the concept and its implementation will result in a powerful and effective approach towards Safe and Sustainable-by-Design solutions, strengthen the European industry's competitiveness and lead to increased supply and production security within the European Union.

With this guidance, we want to contribute to the exciting transition journey.

# Executive Summary

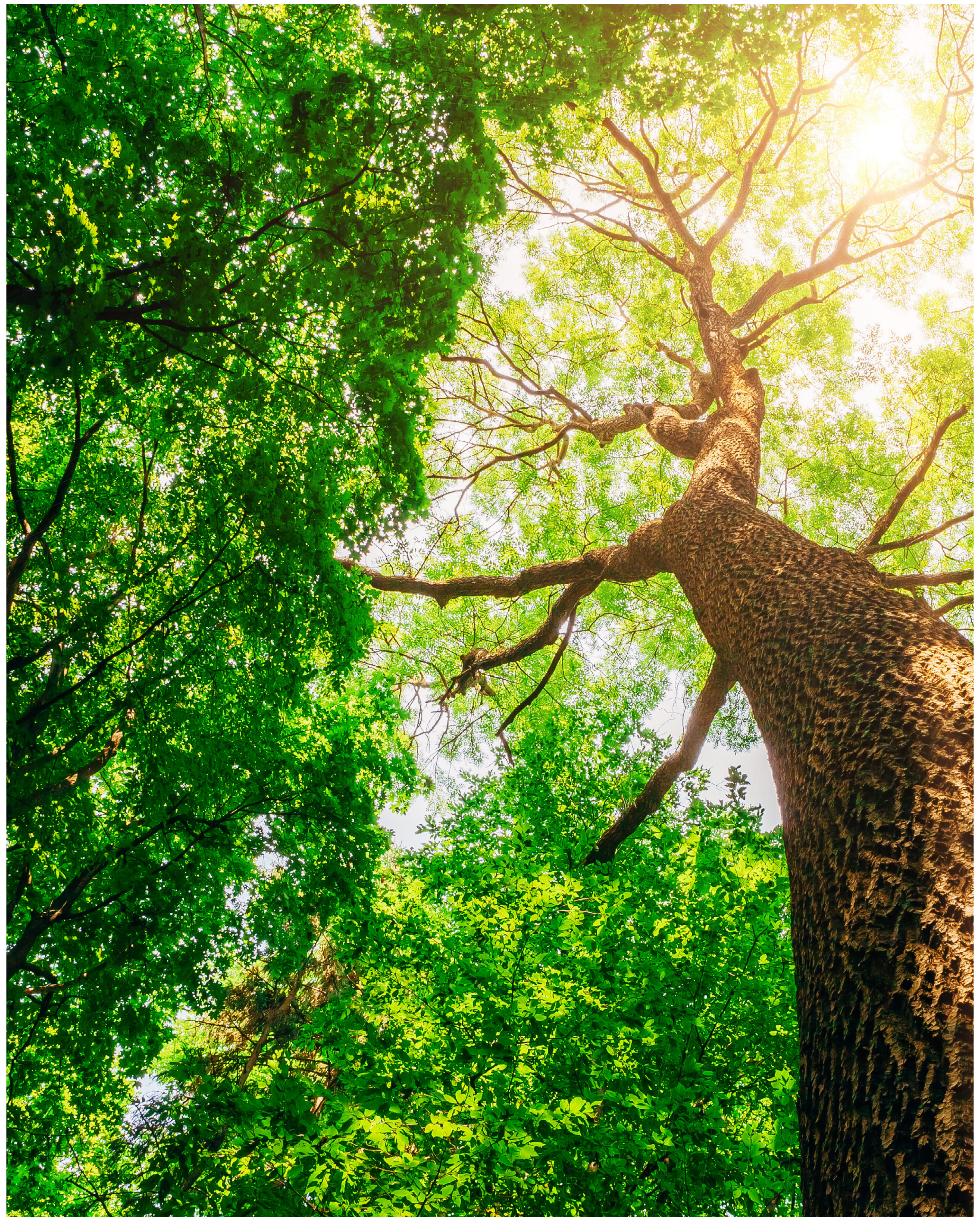
Cefic and its members have defined Safe and Sustainable-by-Design (SSbD) as an iterative process guiding innovation and the placement on the market of chemicals, materials, products, processes and services that are safe, and deliver environmental, societal, and/or economical value through their applications. In scope are new chemicals, materials, products, processes and services, as well as re-designing existing ones.

This report proposes **guiding design principles** for a selected set of safety and sustainability considerations, dimensions or **criteria** to be assessed at the level of product-application combination in a stage-gate process[3] during innovation.

The **basic principle** when innovating to improve the functionality and performance of chemicals, materials, products, processes or services, is the aim to **significantly improve** performance in at least one of the dimensions of safety and sustainability without significant negative impacts[4] in any of the other dimensions, compared to the incumbent solutions.

As a minimum, a sound implementation of **"Safety"** shall be applied by a risk-based assessment considering the hazard, use and exposure in line with REACH and anticipating future regulatory changes. But in applying SSbD, the chemical industry has the ambition to innovate beyond that legally fixed minimum requirement. This can be achieved by continuous reduction of toxicological risks for humans and the environment especially for consumer use and considering the end-of-life and circularity aspects.

The **"Sustainability"** assessment[5] as an integral part of the innovation process covers the life cycle of a product-application-combination. It is advised that all assessments cover focus dimensions deemed of high importance to reach the Green Deal objectives. Additional sustainability contributions may be considered.
A comprehensive, yet not exhaustive list of safety and sustainability dimensions will be discussed throughout the document.



# 1. The transformative power of Safe and Sustainable-by-Design

## 1.1 Background

In 14 October 2020, the European Commission published the Chemicals Strategy for Sustainability (CSS)[6] as part of the European Green Deal's pillar[7] "Zero Pollution Ambition"[8]. The EU Green Deal the main policy initiative of the Von der Leyen Commission, aims to achieve a climate-neutral, pollution-free, sustainable, circular and inclusive economy by 2050.

The goal of the CSS is to enable the green transition of the chemical sector and its connected value chains. Aligned herewith are the goals of the New Industrial Strategy for Europe promoting a green and digital transformation of the European industry in general.

The capacity of manufacturing new chemicals that are "inherently safe and more sustainable from production to end-of-life"[9] including circularity is said to play a crucial role in the green and digital transition. Chemicals and materials that are Safe and Sustainable-by-Design (SSbD)[10] are likely to be promoted and rewarded on the EU market in the future.

Through its up-stream positioning, the chemical industry has a significant impact on almost all value chains, resulting in a key pivotal and enabling position to contribute to the realisation of the European Green Deal ambitions. To foster this transition, the EU is taking a dual approach of restricting and banning existing hazardous substances in certain applications, and incentivising innovation for new safe and more sustainable chemical products by respectively:

1. a (targeted) reopening of REACH and CLP to, amongst others, include new hazard classes and stricter regulations and restrictions for the use of the most harmful chemicals, especially in consumer goods;
2. development and implementation of a pre-market Safe and Sustainable-by-Design approach for new, innovate solutions for the development of new chemical products.

On SSbD, the European Commission has conducted a first stakeholder workshop (March 2021), presenting the basic thoughts around scoping, process and timeline. A detailed mapping study (April 2021), compares existing initiatives to assess safety and sustainability at the product[11] level. From this document, the CSS and in alignment with the Green Deal objectives, three overarching goals for the development of SSbD products become evident: i) protection of humans and the environment from the "most harmful chemicals"[12] ii) enabling circularity, and iii) contribution to resource efficiency. These goals should be considered by all companies, from the innovation phase towards the development of products.

Cefic has presented its preliminary views on SSbD, and how to take it forward in a previous report. In this guidance, we are presenting additional views on how to integrate safety and sustainability design considerations into the innovation process.

## 1.2 Safe and Sustainable-by-Design: guiding the innovation process

Safe and Sustainable-by-Design is an iterative process guiding innovation and the placement on the market of chemicals, materials, products, processes and services that are:

- safe, and
- deliver environmental, societal, and/or economical value through their applications.

Hence, the SSbD process should enable the (re)design of the **next generation chemicals, products, processes and services** for a resilient economy, including transitioning to a climate neutral society, circular economy and avoiding harm to people and planet.

We propose the SSbD concept to be implemented as a **process** based on **guiding design principles** for the innovation phase using **criteria** to be assessed at the level of product-application combination in a stage-gate-like approach during innovation.

- The basic principle when innovating to improve the functionality and performance of chemicals, materials, products, processes or services, is the aim to significantly improve performance in at least one of the dimensions of safety and sustainability without significant negative impacts[13] in any of the other dimensions, compared to the incumbent solutions.

- As a minimum, a sound implementation of "Safety" shall be applied by a risk-based assessment considering the hazard, use and exposure in line with REACH and anticipating future regulatory changes. In applying SSbD, the chemical industry has the ambition to innovate beyond that legally fixed minimum requirement and go for continuous reduction of toxicological risks for humans and the environment especially for consumer use and considering the end-of-life and circularity aspects.
- The sustainability assessment[14] as an integral part of the innovation process shall cover the life cycle of a product-application-combination. It is advised that all assessments cover focus dimensions deemed of high importance to reach the Green Deal objectives. Additional sustainability contributions may be considered. A comprehensive, yet not exhaustive list of safety and sustainability dimensions is presented schematically below (Figure 1) and further detailed in paragraph 2.4.2.

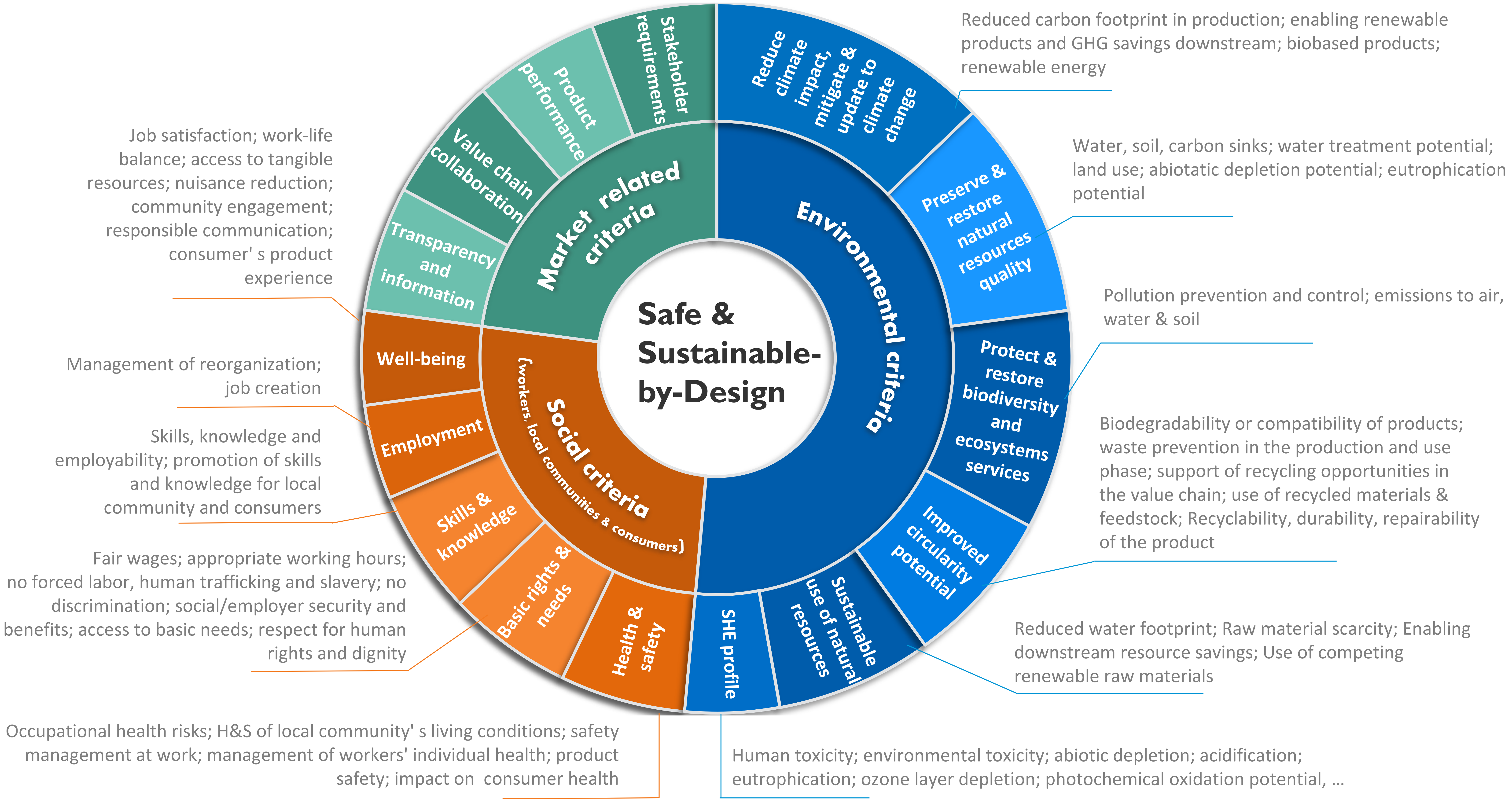



**Figure 1:** A comprehensive, yet not exhaustive list of safety and sustainability dimensions to assess and design sustainable chemicals, materials, products and processes.

## 1.3 Incorporating Safe and Sustainable-by-Design into the innovation process

Any process of innovation starts with the ideation, generating ideas to create options in the form of new possibilities or new problems that might be solved as well as by generating new opportunities that might be capitalised on. The next step is the conceptualisation, to create options in the form of alternative ways to understand and define a problem or opportunity as well as by offering good ideas that help solve it. After the business planning, the experimental work in the labouratory may follow, where the different concept candidates are tested and evaluated against the targeted innovation goals. With ongoing validation, the number of suitable candidates decreases. If one of the candidates fulfils all innovation goals (safety, sustainability, economy), a solution will go into the launch phase and be placed on the market. Before getting to this final stage, the innovation process often loops back-and-forth between earlier steps.

Any framework for the development of Safe and Sustainable-by-Design chemicals, materials, products and services, will require a structure accounting for the vast variety in chemical products going into several applications, resulting in multiple combinations of sustainability assessments including hazard and exposure along multiple life cycle paths. In addition to this structure, the framework also needs to consider the high level of uncertainty because of limited information, especially in early innovation stages. Information on product properties, performance and, therefore on safety and sustainability, is becoming increasingly available throughout the innovation stages. As a result, assessment tools, information and criteria need to evolve over time. A simplified depiction of the innovation process, e.g., stage-gate process, and potential shaping of the different assessment stages is given in Figure 2.

It is important to note that an economical evaluation is also being made, demonstrating the business case of the innovation at the different stages. These aspects fall outside the scope of this document.

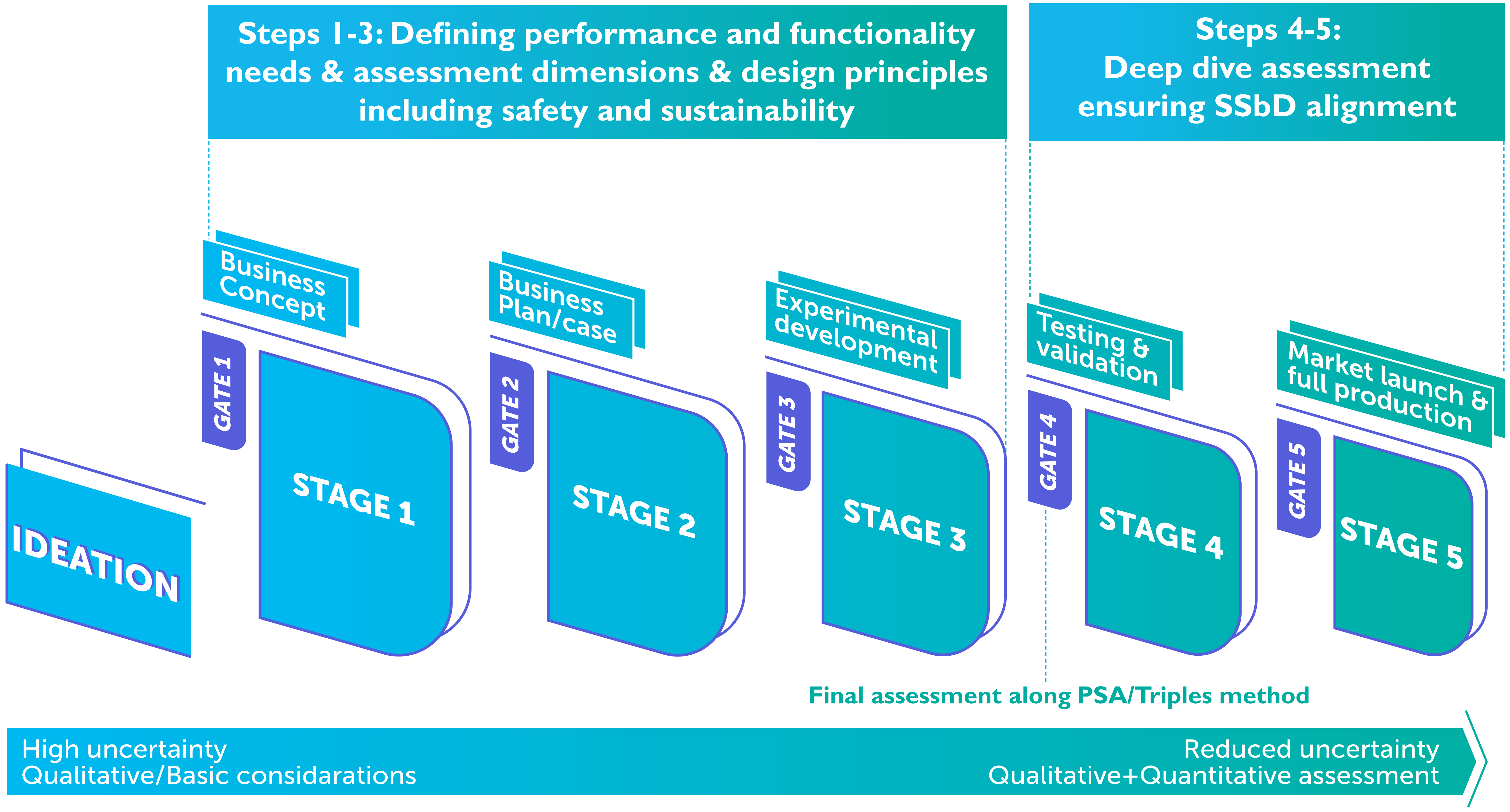



**Figure 2.** Simplified and idealised depiction of an iterative innovation process, e.g. stage-gate process, illustrating the increasing level of detail for the assessment of safety and sustainability

The evolution of the toolbox for evaluation and assessment throughout the innovation stages can take following forms:

- At the **ideation stage** the overarching design principle along with the more specific principles for selected design dimensions give guidance how to approach innovation towards SSbD and what to consider early on. With regards to safety, the hazard aspects of a chemical, material, product or process (e.g. human-toxicity, eco-toxicity) and the respective exposure scenario, including the environmental fate need to be considered. The use of predictive modelling tools could be helpful to support looking into e.g., structure property relations, as well as new approach methodologies (NAMs) to perform risk assessments. For the sustainability dimensions, very simplified methodologies to evaluate life cycle impacts are needed but are yet to be developed and verified.
- At later innovation stages and specifically prior to launching an innovation, all criteria must be assessed, which builds the basis of an enterprise portfolio sustainability assessment. The SSbD methodology should contain clear guidance on the application of additional qualitative assessments giving enough flexibility for opting-out depending on the impact of a product-application (like small scale products in a controlled lab setting). E.g., the cradle-to-gate Product Carbon Footprint[4] could be integrated into the assessment, once available. Further quantitative parameters should be added as soon as they become available and will require also **further development of tools** and supporting information.

## 1.4 Identifying innovation needs using the Product Sustainability Assessment approach

Given that chemicals are part and parcel of over 90% of manufactured goods, the chemical industry has a major impact on almost all value chains, and is therefore a key player in enabling the ambitions of the EU Green Deal. To innovate towards tangible improvements with regards to "safe" and "sustainable", it is of great importance to always consider the full life cycle of a chemical product in its respective application. The development stage, production, use phase and end-of-life should be considered with regards to their specific requirements.

For an efficient transformation towards Safe and Sustainable-by-Design, the framework should be applied to all chemicals, material, product, process and service innovations. Innovation should be interpreted broadly, also covering minor changes e.g., re-formulations. In the case of minor changes, a simplified check can be used for the assessment. In doing so, the approach, over time, will thus "influence" the composition of the full product portfolio.

Assessing regulatory and other signals covering chemicals safety, as promoted in the Portfolio Sustainability Assessment[5] (PSA) methodology, is an established practice already in more than 20 chemical companies[15] around the globe.

The assessment results of the existing portfolio, based on Product-Application-Region-Combination (PARC)[16], are clustered in so-called sustainability performance categories and then aggregated on portfolio level based on products' sales contribution:

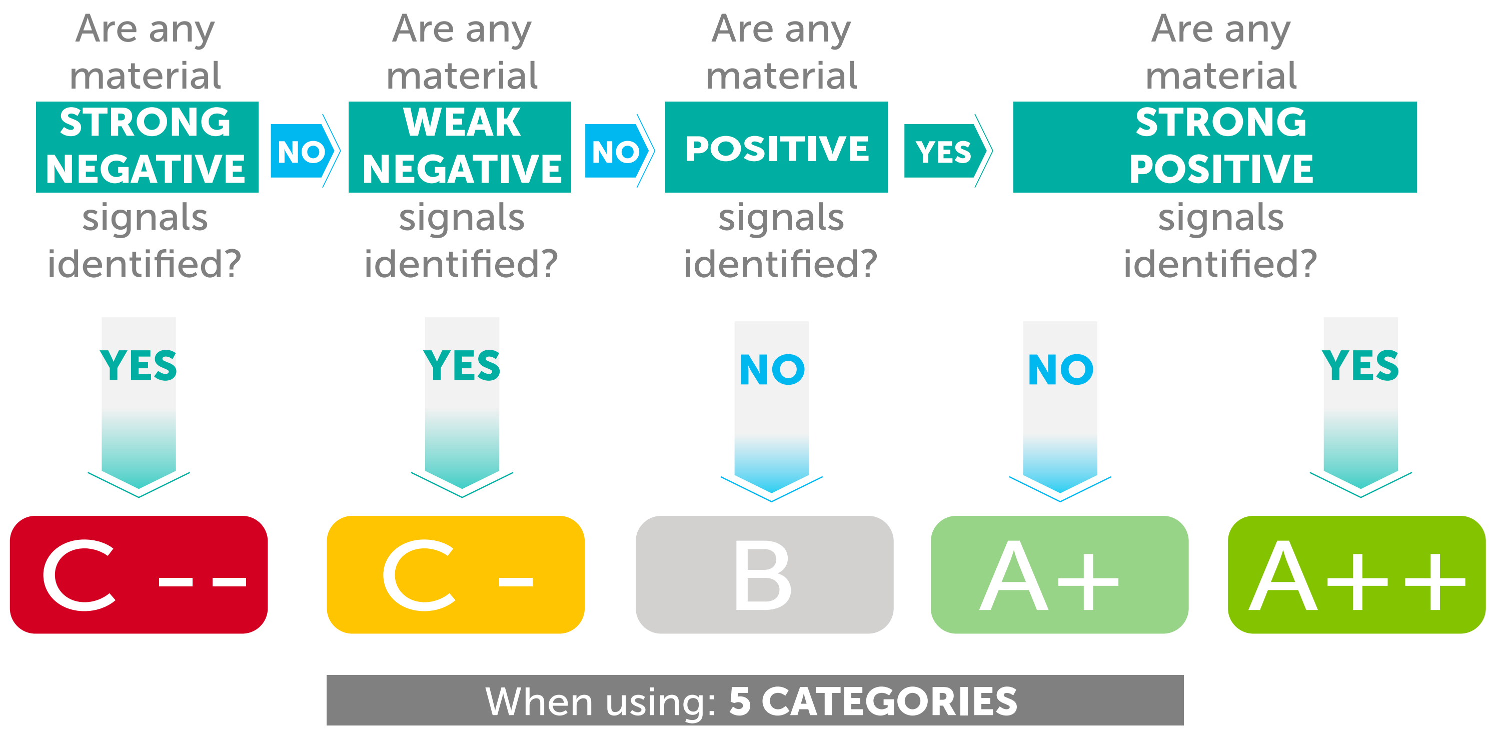



**Figure 3.** WBCSD: Decision tree towards sustainability performance categories on a "Product-Application-Region-Combination" (PARC)[16] basis (in this example 5 categories).

Consequent prioritisation of industry sectors, e.g., fast moving consumer goods, but also other signals, including regulatory follow-up, will help companies to leverage the biggest impacts first. Implementing the generic framework of the WBCSD's PSA methodology can thus help identify the company's innovation needs. Linking the Safe and Sustainable-by-Design concept as an innovation approach to the PSA framework will bring up safe and more sustainable products in the sense of a continual improvement process.

Coupling the assessment and ranking of the portfolio with the company's innovation process, will over time move the portfolio of products towards safe & sustainable chemicals, materials, products, processes and services.

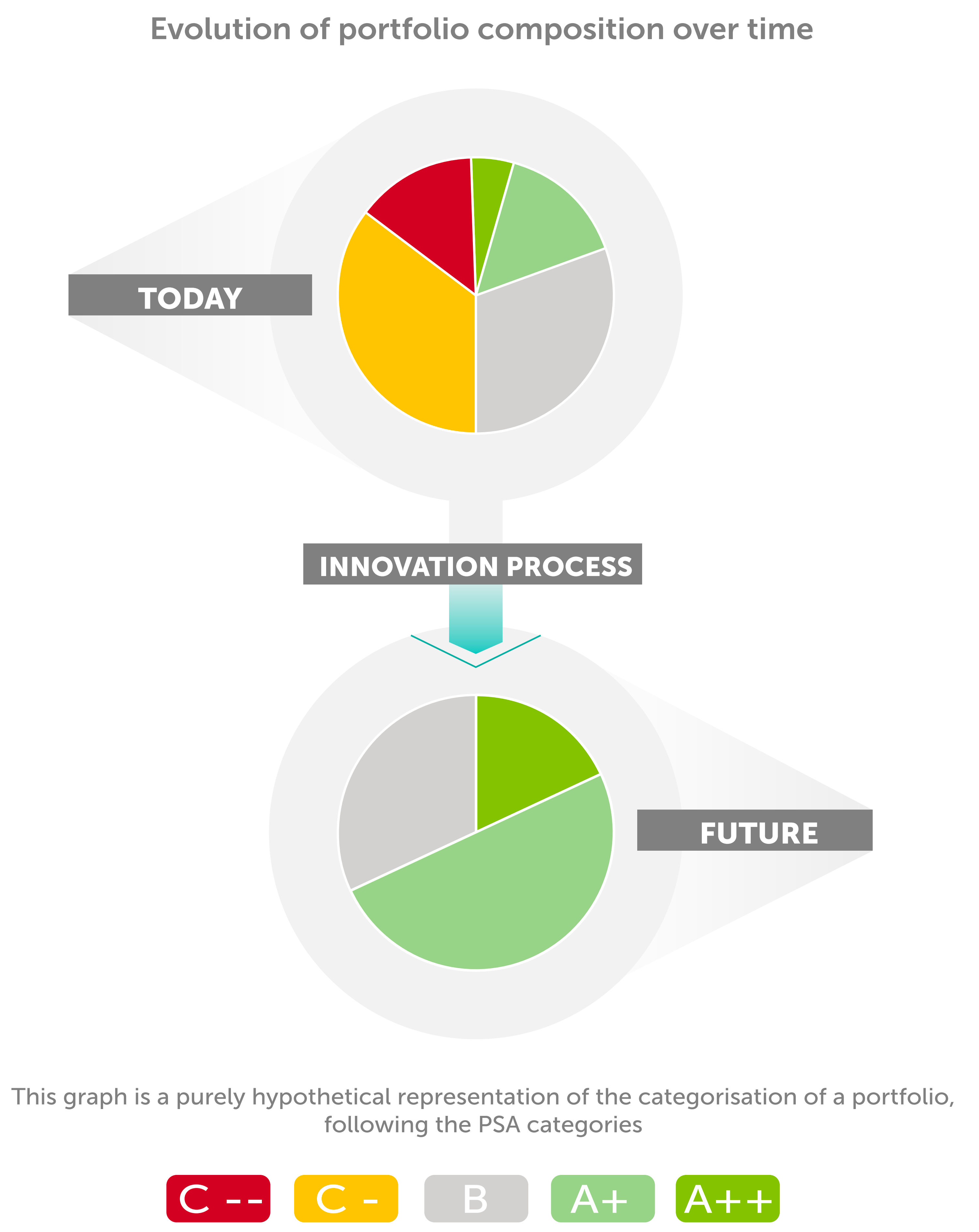



**Figure 4.** Schematic depiction, how applying the SSbD framework over time will move the portfolio of products towards safe & sustainable chemicals, products and processes.

## 1.5 Transparency and non-financial reporting

**Sustainability needs transparency and transparency should ensure comparability in assessment methodologies through harmonised terminology and standards.** At the same time, the assessment methodology needs to take into account the different stages of the design process, as well as the differences in innovations e.g., from improvement of existing products to the design of totally new ones.

Data requirements supporting the respective assessments need to be FAIR (findable, accessible, interoperable and reusable). Special attention for the needs to SMEs on tools and supporting data will be necessary.

Companies are advised to report on their journey towards Safe and Sustainable-by-Design chemicals, materials, products, processes & services. For instance, reporting on the companies' PSA improvements which contributes to ESG achievements is considered good practice.

# 2. Safe and Sustainable-by-Design in practice

The European Commission wants to introduce SSbD as a pre-market concept to ensure innovation towards future enhanced safety and increased product sustainability. Reflecting the huge variety of consumer products and services, it is recommended to conduct Safe and Sustainable-by-Design assessments on a product-application level with the intended use in mind.

## 2.1 Workflow integrating safety and sustainability dimensions in the innovation process

To arrive to Safe and Sustainable-by-Design chemicals, materials, products, processes and services, the SSbD approach requires the consideration of safety and sustainability aspects from the ideation stage onwards throughout the full life cycle. To achieve this, a five steps workflow is suggested. The steps are further detailed in paragraphs 2.3-2.6.

**Steps one to three** support the identification of performance and functionality needs of the envisaged innovation, including safety and sustainability considerations, along respective design dimensions and respective principles. A set of recommended design dimensions and principles can be adopted in a modular fashion defining the assessment scope relevant to a particular innovation (schematic see Figure 5).

The identification of the assessment scope and selection of design principles will thus require an assessment framework, further detailed in paragraph 2.2.

**Steps four and five** support the decision taking in a stage-gate assessment approach, between several options from the lab to launch phase, also guiding through potential trade-offs.

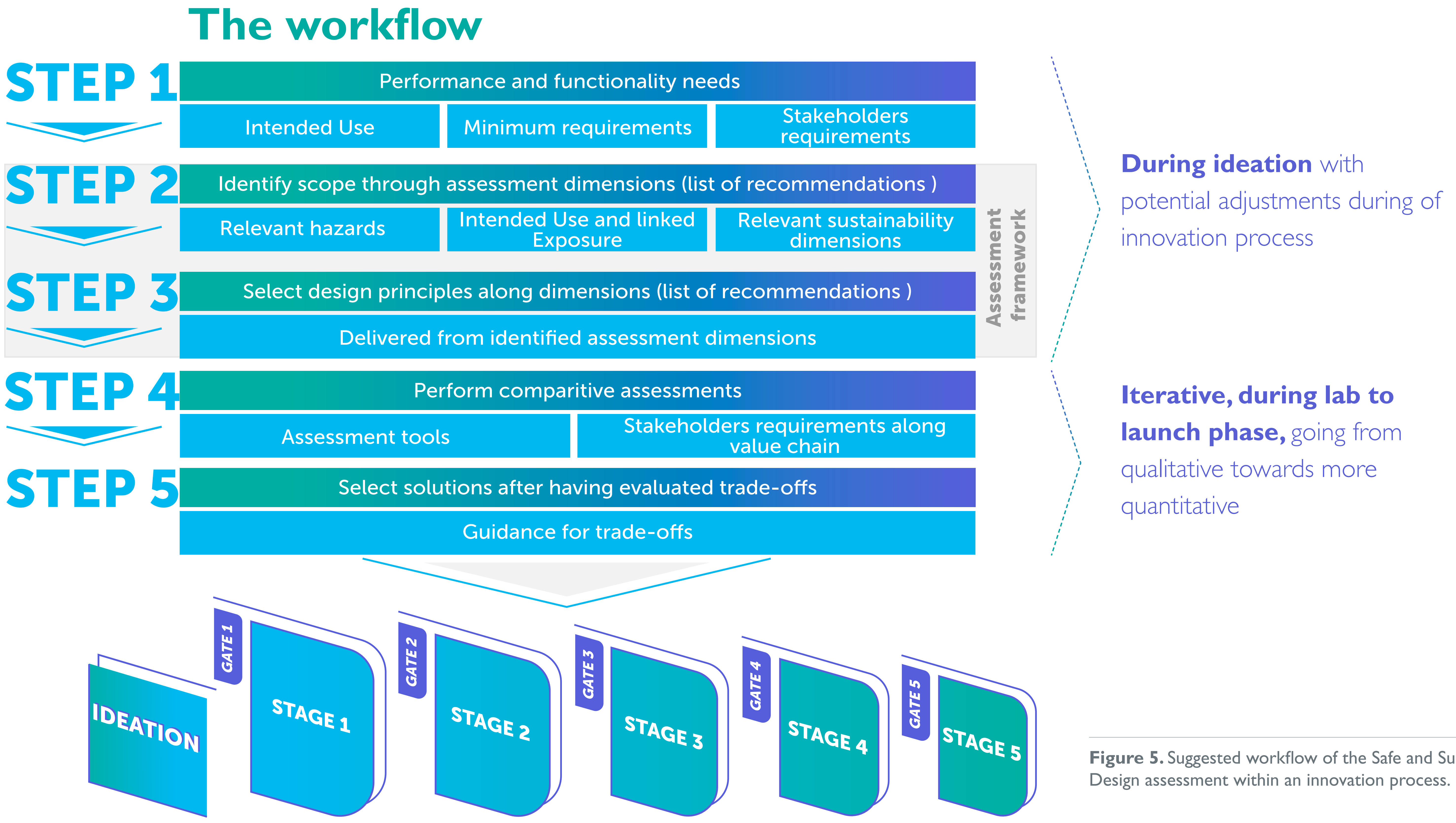



**Figure 5.** Suggested workflow of the Safe and Sustainable-by-Design assessment within an innovation process.

## 2.2 The "safe" and "sustainable" assessment framework

The assessment framework is proposed as a layered structure of dimensions for assessment under the key words "safe" and "sustainable", which are to be selected in process step two. The dimensions indicate which aspects to look into in the ideation phase of an innovation and to further assess, prior to launching a solution, covering the full life cycle.

Within the dimensions, we differentiate between focus dimensions and additional dimensions. **Focus dimensions** are said to be critical to meet the EU Green Deal goals and should always be assessed.

Next, we identify **minimum requirements** to be fulfilled at all times, e.g., regulatory requirements as enshrined in law and respecting human rights.

The focus dimensions are associated with **design principles** to be considered as guidance, which are to be selected in process step three. The principles give guidance on which aspects should be considered when designing a chemical, material, product, process, or service.

Finally, a **toolbox** provides a variety of assessment practices for the user to choose from, and available FAIR data (FAIR: findable, accessible, interoperable, and reusable) which allows a specific safety and sustainability assessment depending on the stage an innovation is currently in.

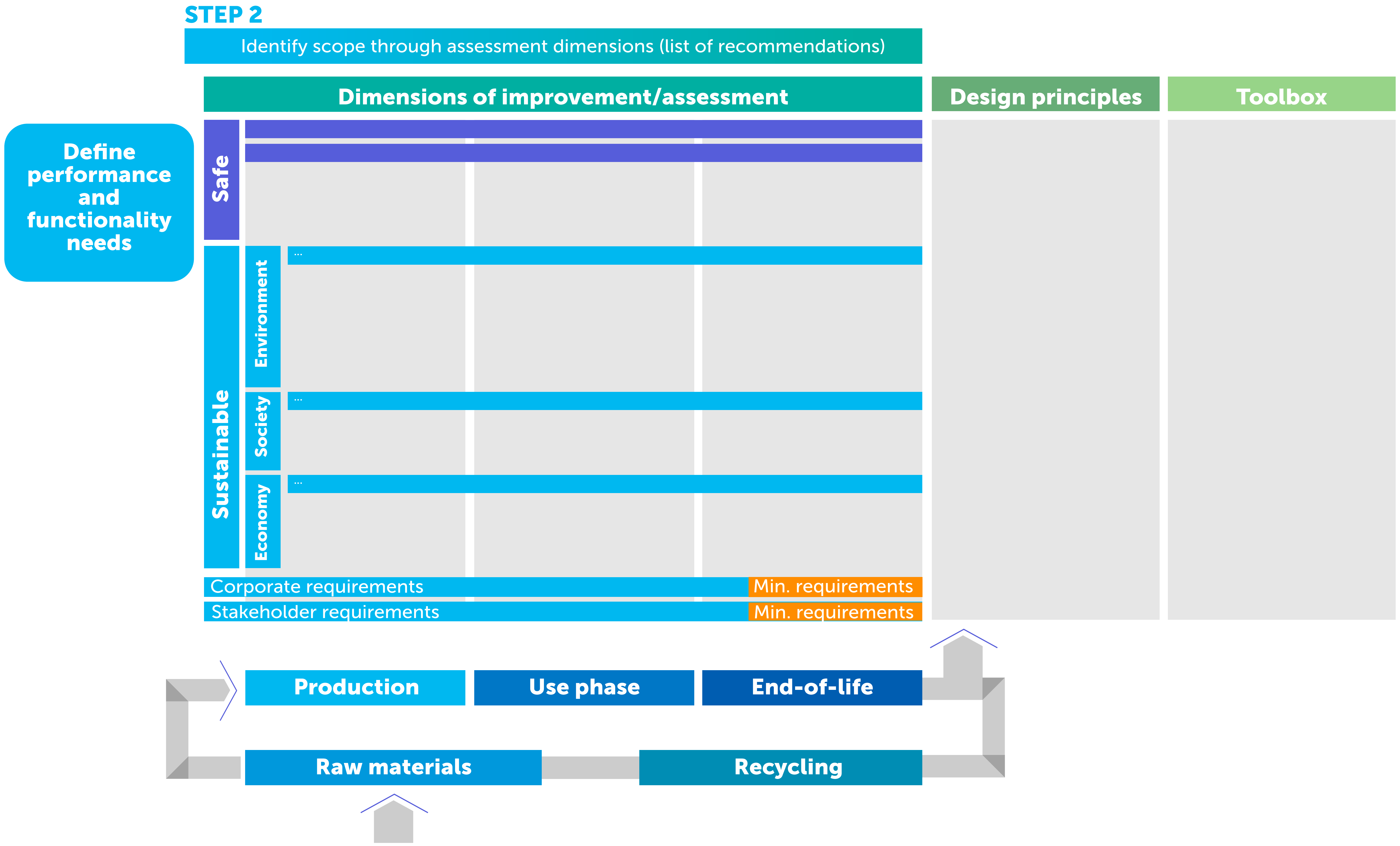



**Figure 6.** Suggested assessment framework for Safe and Sustainable-by-Design.

Midst all assessment dimensions suggested, seven dimensions are identified as focus dimensions. They cover all three dimensions under "safe" (see figure Figure 7 and paragraph 2.4.1) and four of the dimensions under "sustainable" (see paragraph 2.4.2), where all others can be assessed if considered relevant on a case-by-case basis.

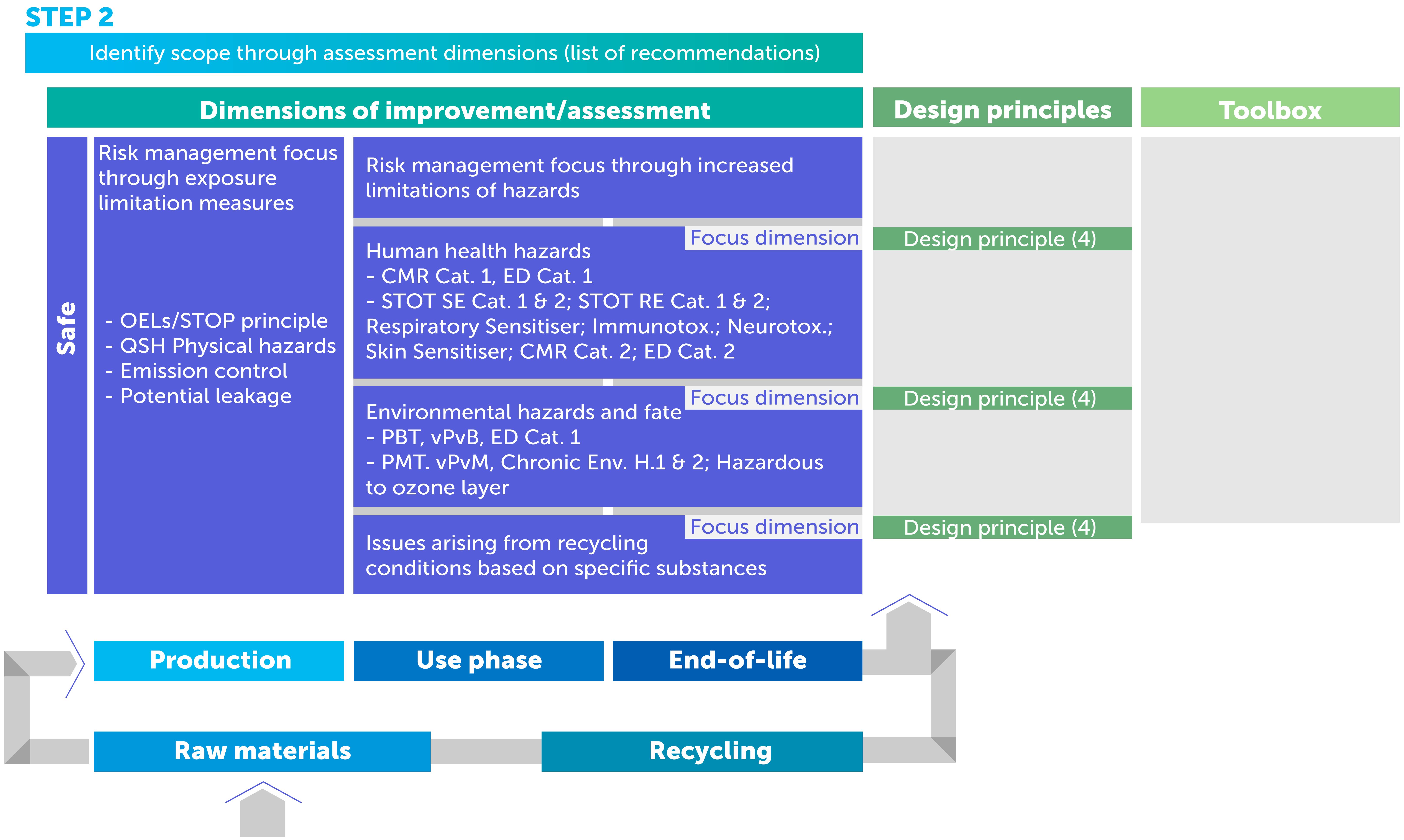



**Figure 7.** Full set of assessment dimensions to assess safety, all of them being focus dimensions.

Four dimensions are identified as minimum requirements, which always need to be fulfilled (see paragraph 2.4.1 and 2.4.2).

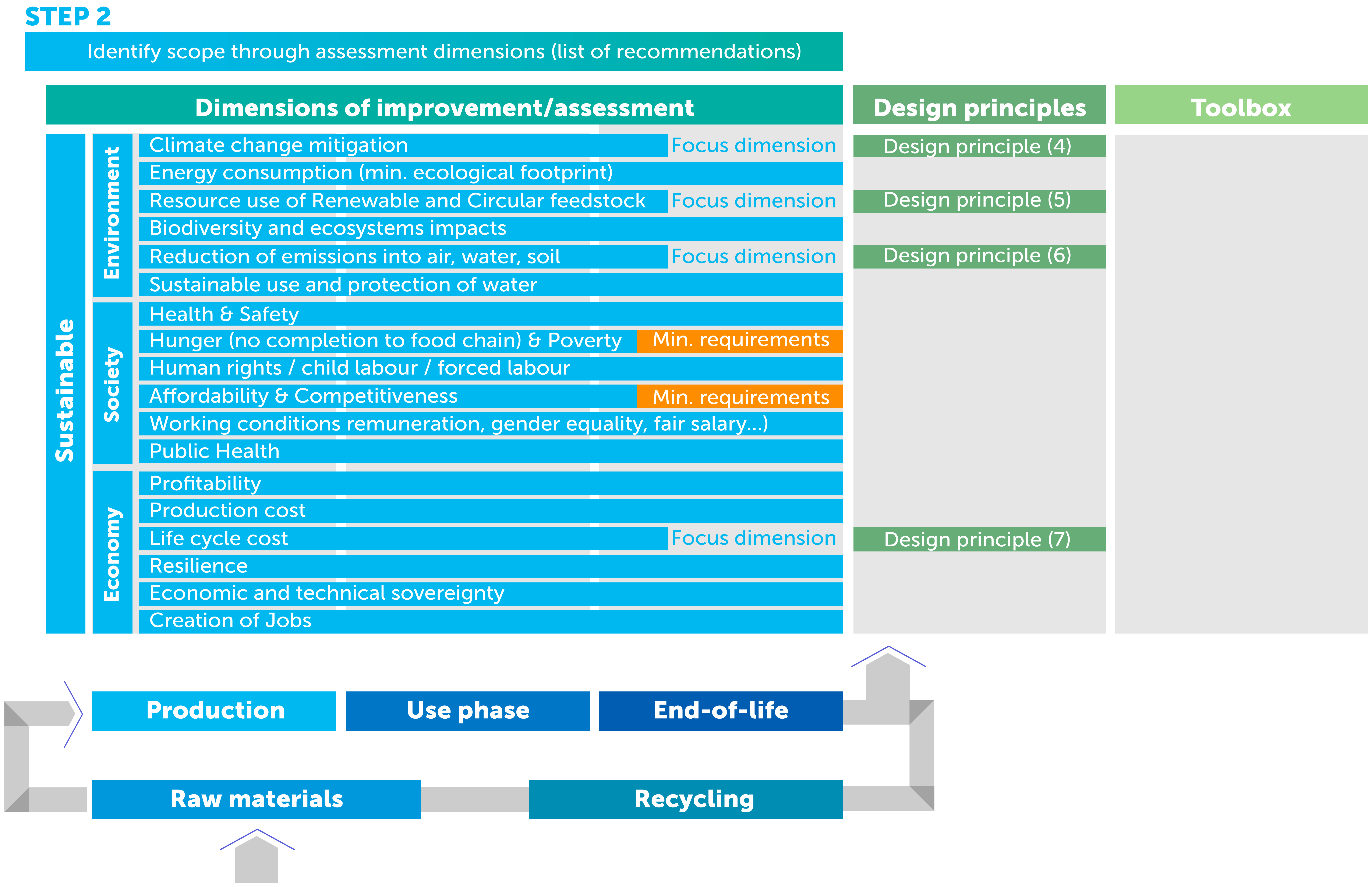



**Figure 8.** Full set of assessment dimensions to assess sustainability with focus dimensions and minimum requirements indicated.

## 2.3 Performance and functionality needs – Step 1

The starting point of many innovations is the identification of needs for improvement. These needs should address the most relevant or material safety and sustainability dimension. They can be found in the raw materials used, the production process applied or in the functionality and performance of a solution in its application or end-of-life. Adequately assessing the innovation needs, therefore calls for the involvement of several disciplines covering all stakeholder requirements along the value chain for a particular intended use. To ensure single improvement measures do not result in significant negatives in other areas, it is necessary to investigate all material dimensions along the life cycle of a given product-application-combination. In doing so, we suggest creating a list with all primary performance and functionality needs, which are directly linked to the solution in its application as well as all secondary needs resulting from stakeholders in the value chain, the legal framework and beyond, e.g., requirements from relevant eco-labels.

When looking into the performance and functionality needs, special care should be taken to identify those assisting as well as contradicting the desired transition of the EU Green Deal. Especially those contradicting the EU Green Deal targets should be a key focus for improvement of a solution.

Once the performance and functionality needs have been identified, the relevant dimensions for the SSbD assessment can be selected, according to step 2.

## 2.4 Assessment Dimensions – Step 2

For SSbD the key assessment areas of chemicals, materials, products, processes and services in their respective use are "safe" and "sustainable".

### 2.4.1 Key dimensions to assess safety

Under the key word "safe" we suggest to consider the dimensions listed below, looking into hazard properties covering substances of very high concern as well as other categories amongst those that the CSS identified "as the most harmful chemicals[10]," and other hazardous substances with a focus on consumer products.

The dimensions become relevant for the assessement if a substance under consideration for innovation displays the listed hazard. The assessment should include a careful evaluation of the improvement potentials during ideation and throughout the development phase:

**Human health hazards (focus dimension 1):**

- Substances of Very High Concern (CMR[17] Cat. 1A & 1B, ED[18] Cat. 1)
- Other hazardous substances including STOT SE[19] Cat. 1 & 2; STOT RE[20] Cat. 1 & 2; Respiratory Sensitiser; Immunotox.; Neurotox.; Skin Sensitiser; CMR Cat. 2; ED Cat. 2

**Environmental hazards (focus dimension 2):**

- Substances of Very High Concern (PBT[21], vPvB[22], ED Cat. 1)
- Other hazardous substances, including PMT[23], vPvM[24], the Chronic Environmental Hazards Cat. 1 & 2,; Hazardous to the ozone layer

**Recyclability and Circularity (focus dimension 3):**

- Relevant substances in material cycle

### 2.4.2 Key dimensions to assess sustainability

Under the key word "sustainable", we are suggesting the following dimensions from all three pillars of sustainability to be considered (non-exhaustive list). Hereby, we differentiate between focus dimensions, minimum requirements, and additional dimensions, as defined above.

For the dimension "Biodiversity and ecosystems impact" we see a need to make this a focus dimension in the near future, reflecting on the increasing use of renewable raw material. Validated methods to correctly assess the impacts will need to be developed.

**Environment:**

- Climate change mitigation (focus dimension 4)
- Energy consumption (min. ecological footprint)
- Resource use of renewable and circular feedstock (focus dimension 5)

- Biodiversity and ecosystems impacts
- Reduction of emissions into air, water, soil (focus dimension 6)
- Sustainable use and protection of water

These dimensions are overlapping with the six environmental objectives, as defined in the Taxonomy Regulation[25].

**Society:**

- Health & Safety (minimum requirement)
- Hunger (no competition to food production) & Poverty
- Human rights / child labour / forced labour (minimum requirement)
- Afordability & Competitiveness
- Working conditions (remuneration, gender equality, fair salary…)
- Public Health

**Economy:**

- Profitability
- Production cost
- Life cycle cost (focus dimension 7)
- Resilience
- Economic and technical sovereignty
- Creation of Jobs

### 2.4.3 Other key dimensions

Finally, in accordance with the PSA methodology, we suggest two additional dimensions to be considered as requirement:

- Corporate requirements (minimum requirement)
- Stakeholder expectations (minimum requirement)

## 2.5 Design Principles – Step 3

The overarching principle in innovating towards a pre-determined performance of functionality is to significantly improve in at least one of the dimensions, considered under i.e., safety or sustainability, without significant negative effects on any of the other dimensions, compared to incumbent solutions always in full respect of certain minimum requirements, e.g., regulation and international conventions. This will lead to an iterative improvement process progressively pushing the performances on "safe" and "sustainable" over time.

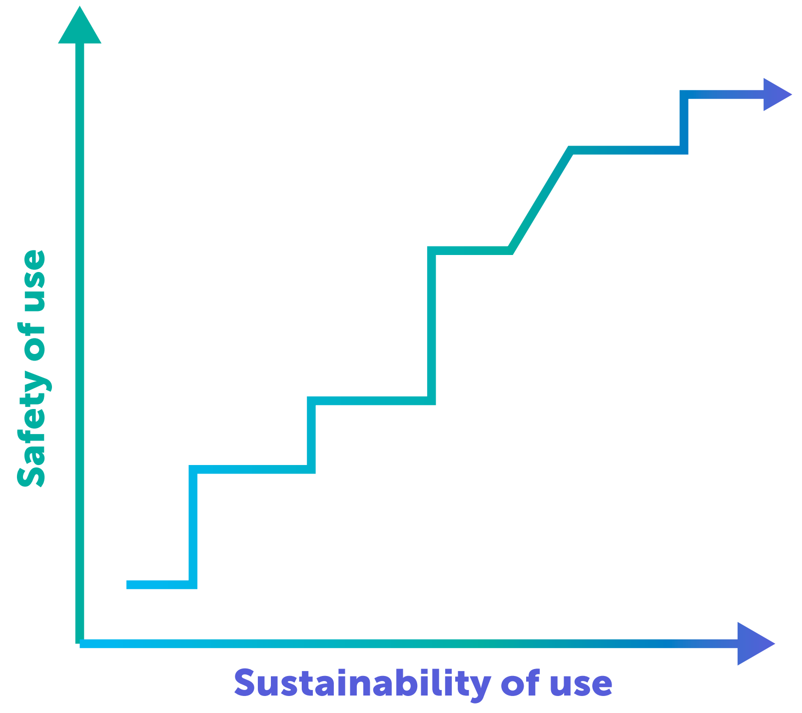



Figure 9. Schematic depiction of iterative steps of improvement in the dimensions "safety of use" and "sustainability of use".

For the three focus dimensions considering aspects of safety, the **design principles** listed below are to be considered in the innovation phase. Design principles for other aspects of safety, e.g., physical hazards have also to be formulated.

### Risks derived from Substances of Very High Concern

e.g. CMR Cat. 1A & 1B, ED Cat. 1, PBT, vPvB

- For the anticipated production process(es):
  - Eliminate or minimise risk through reduction of hazards and/or exposure
  - Analyse and avoid as much as possible the use of substances identified as Substances of Very High Concern
  - Consider value chain-specific regulations
- For the anticipated use phase and end-of-life:
  - For intended consumer use, do not develop solutions with characteristics qualifying or likely to be identified as Substance of Very High Concern according to article 57 of the REACH Regulation[6]
  - Consider value chain-specific regulations

### 2 Risks derived from other "hazardous chemicals" including PMT, vPvM, STOT SE Cat. 1 & 2, STOT RE Cat. 1 & 2, Respiratory Sensitisers, Immunotoxicitants, Neurotoxicitants, Skin Sensitisers, CMR Cat 2, ED Cat. 2, Chronic Environmental Hazards Cat. 1 & 2, Hazardous to the ozone layer or substances listed under "Annex 2 – Authoritative and other relevant substances lists"

- For the anticipated production process(es):
  - Reduce risk through reduction of hazards and/or exposure
  - Analyze and try to avoid the use of substances with the above hazard classifications
  - Consider value chain-specific regulations
- For the anticipated use phase and end-of-life:
  - Avoid the development of consumer solutions with characteristics qualifying or likely to qualify for a classification as the above hazard classifications
  - Consider value chain-specific regulations

### 3 Recyclability and Circularity

- Think of the planned EPR[26] schemes and recycling routes which can identify the substances hampering the recycling technology
- For the anticipated production process(es):
  - Analyse and try to avoid the use of substances considered to hamper recycling
  - Consider value chain-specific regulations
- For the anticipated use phase and end-of-life:
  - Avoid utilisation or development of solutions hampering recycling
  - Consider value chain-specific regulations
  - Consider waste-related aspects in order to avoid obstacles in waste transports and end-of-waste status

For the 4 focus dimensions, which are covering the aspects of sustainability, the following **design principles** are to be considered in the ideation phase:

### 4 Climate change mitigation

- Select raw materials and processes that minimise the generation of greenhouse gases
- Select and / or develop (production) processes with minimised generation of greenhouse gases, e.g. the possibility of green heat networks and electrification
- Develop products, which enable greenhouse gas emission savings down stream (use phase and end-of-life)

### 5 Resource use of renewable and circular feedstock

- Select materials and processes that minimise the generation of waste
- Select materials and processes that use/allow the use of sustainably[27] sourced biobased feedstock and/or sustainably[25] sourced circular feedstock.
- Select materials that have (where appropriate) an increased durability or enable product sharing, reduced maintenance or a commercial 'afterlife'
- Compose products in a way, which - as much as meaningful– strive for recyclability
- Compose products in a way, which - as much as meaningful – strive for biodegradability[28]
- Match the raw material selection to the capabilities of the waste management operations in the intended market
- Select materials and processes that reduces the abiotic depletion potential[29]

### 6 Reduction of emissions into air, water, soil

- Select raw materials and processes that minimise the generation of emissions, e.g. volatile organic compounds (VOCs), total organic compounds (TOCs), acidification, overfertilisation and heavy metals)
- Select and / or develop (production) processes with minimised generation of emissions (e.g. VOCs, TOCs, acidification, overfertilisation and heavy metals)
- Develop products, which enable emission savings down stream (use phase and end-of-life)

### 7 Life cycle cost

- Select raw materials and processes that allow for cost savings over the life-cycle of a product, process or service through:
  - Savings on e.g. use of energy, water and fuel
  - Savings on e.g. maintenance and replacement
  - Savings on e.g. recycling or disposal costs

## 2.6 Comparative assessment – Step 4

Out of the seven dimensions, identified as focus dimensions (Toxicological potential for humans, Toxicological potential for the environment, Risks resulting from recycling, Climate change mitigation, Resource use of renewable and circular feedstock, Reduction of emissions into air, water, soil, Life cycle cost), which should always be assessed looking for a significant improvement, three cover aspects of safety. Comparative assessments need to be done for the same functional and/or performance basis for the innovation relative to the incumbent solution.

An exhaustive toolbox of assessment methodologies and data will be needed in this step.

The method to do the safety assessment is according to the best available method being the risk assessments as laid out in REACH, e.g., consider both hazard and exposure.

Sustainability assessments will be needing different tools, for instance, carbon footprint of the product, energy and water consumption in production and use. It needs to be acknowledged that the toolbox for assessing the sustainability dimensions is at different levels of maturity and will need further development.

In doing so, we will in particular focus on the needs of the SMEs to enable them to get up to speed.

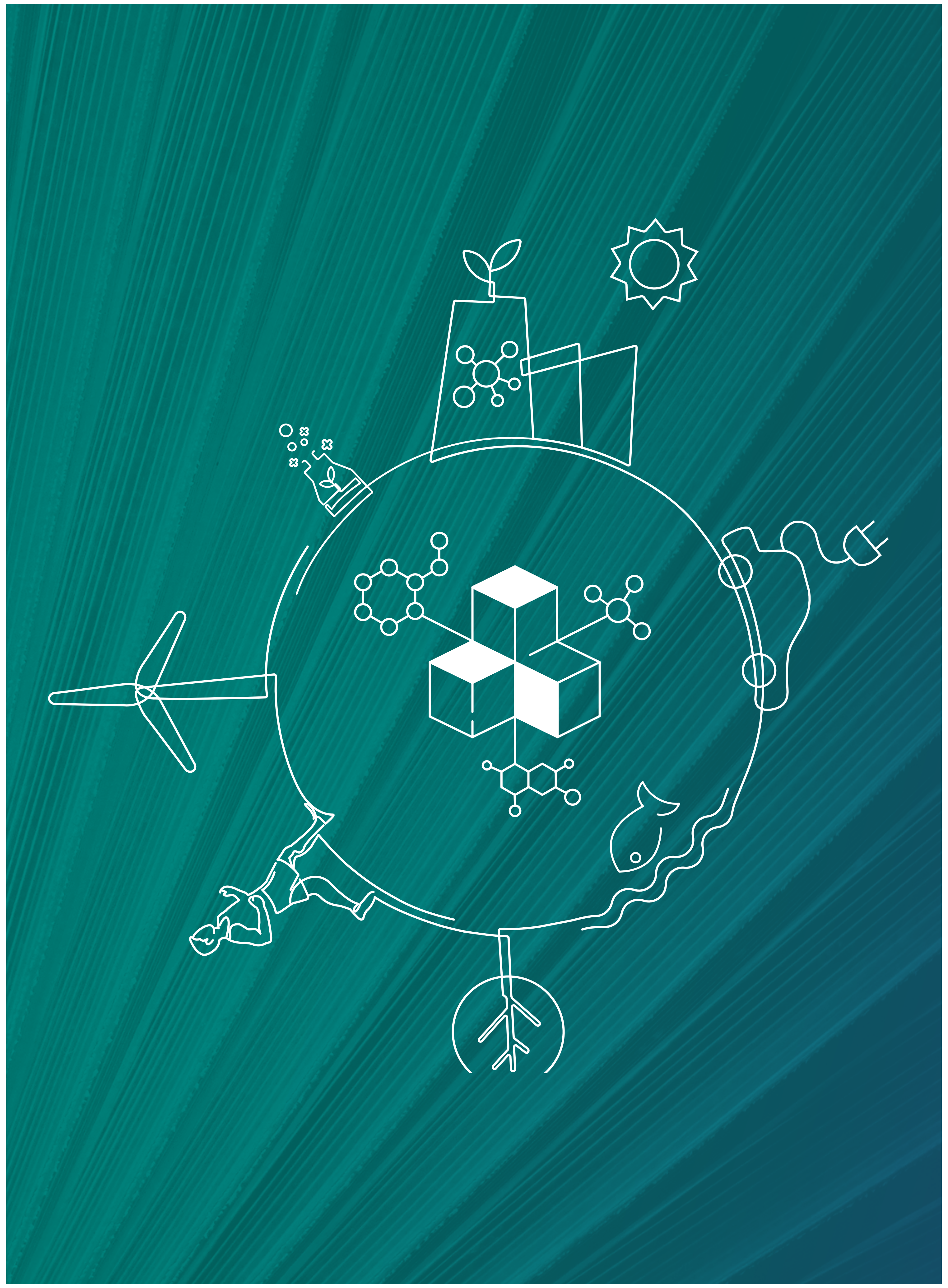
The combination of dimensions end up in a complete picture of the innovation with respect to SSbD. It should be noted that some key dimensions having a strong improvement can compensate a lower performance on the other dimensions. In any case, the comparative assessment also includes an assessment to avoid significant negatives into other relevant dimensions.

## 2.7 Trade-offs – Step 5

Clear guidance on how to deal with trade-offs will be required and can be supported by a prioritisation of the assessment dimensions, which is to be detailed further.

Suboptimal solutions can be accepted or taken forward in the innovation process, if accompanied by a reasoned justification.

Trade-off decisions need to be properly documented in a verifiable way.



# 3. Conclusion and recommended next steps

## 3.1 Assessment based on a full life cycle approach

To ensure a full assessment of chemical products, their contributions to applications during their use-phase need to be integrated – covering the full life cycle.

Our vision towards SSbD chemicals, materials, products, processes & services reflects the complexity that goes with transforming a complete industry sector within Europe while offering a practical and scalable solution.

The following cornerstones are critical from our perspective:

- A process based on guiding principles for the innovation phase of all new products and criteria to be assessed at the level of product-application combination.
- The basic principle when innovating to improve the functionality and performance of chemicals, materials, products, or processes, is the aim to significantly improve performance in at least one of the dimensions of safety and sustainability without significant negative impacts[30] in any of the other dimensions, compared to the incumbent solutions.
- As a minimum, a sound implementation of "safe" shall be applied using a risk-based assessment considering the hazard, use and exposure in line with REACH and anticipating future regulatory changes. In applying SSbD, the chemical industry has the ambition to innovate beyond that legally fixed minimum requirement and go for continuous reduction of toxicological risks for humans and the environment especially for consumer use and considering the end-of-life and circularity aspects.
- The sustainability assessment[31] as an integral part of the innovation process covers the life cycle of a product-application-combination. All assessments shall, as a minimum cover focus dimensions deemed of high importance to reach the EU Green Deal objectives. Additional sustainability contributions may be considered.

## 3.2 Connect the PSA framework with the assessment dimensions of an SSbD approach

PSA allows for sustainability portfolio classifications on a single product level, and is already validated and fully aligned with the SSbD assessment framework, as presented in this report. Hence, the PSA enables a comprehensive sustainability steering on a detailed level, and is already in use at many companies within the chemical sector.[5]

The categorisation of the portfolio is a powerful tool to inform the company's innovation process to eventually move the entire portfolio into ever more sustainable solutions, and address products shortcomings.

A cross-industry aligned extension of the assessment framework fitting the innovation design requirements would allow faster and effective steering towards improved products and processes with regards to "safe" and "sustainable" and is recommended to be taken forward.

# 4. Further research and innovation needs

The Research & Innovation needs for developing safe and sustainable chemicals, materials, products and services should be "CSS compliant" and address the Green Deal objectives, as previously demonstrated when developing the different dimensions of the methodology. Investments are needed for such innovations, and given the short time left until 2050, and the complexity of investment cycles, the chemical industry needs the right funding instruments and methods, including for its academic partners.

Applying the SSbD methodology, new solutions will be developed across the life cycle of chemicals and materials towards achieving the CSS and Green deal Goals.

Below is a non exhaustive list of R&I needs:

- Safe and sustainable production processes and technologies with a focus on:
  - Circularity of processes, industrial symbiosis and use of alternative raw materials ( bio waste, plastic waste, captured $CO_2$ and methane, secondary raw materials )
  - Enabling biotechnologies and biological decompositions/degradation
  - Digital strategy for the whole supply chain, modelling, simulation and advanced data monitoring and optimisation
  - Innovative business models
- New chemicals and materials as substitutes and alternatives with a focus on:
  - Direct substitution of hazardous substances
  - New molecules that can form an alternative for the application
  - Methodological development for addressing increased use of circular carbon
  - Digital tools for chemicals information along the value chain
  - SSbD toolbox development (including modelling, collabourative models, trade-offs decisions or iterative process)
  - Integration of SSbD in education (Innovation skills and curricula)
- Exposure of humans and environment & exposure models
  - Quantitative exposure assessments, air and human biomonitoring methods
  - Alternative methods to avoid animal testing
  - Analytical methods for monitoring ultra trace levels for robust monitoring
  - Machine learning models for future impacts estimations
- Hazard (human and environmental)
  - Develop hazard assessment techniques (including polymer, nanomaterials, mixtures)
  - Intensify research on quantitative methodologies
  - Predictive Toxicology Methods - New Approach Methodologies (NAMs)
  - Biodegradation methods & particulates assessment
- Risk assessment
  - Further development for identifying and quantifying interactions in mixtures
  - Develop analytical and toxicological methods for interactions
  - Harmonisation of risk-based approaches
  - Cost-benefit analysis & improvement in biodiversity considerations
- Decontamination and remediating pollution
  - Standardised toolbox of instruments for carrying out risk assessments including sustainability criteria, combined effects
  - Digitalisation for data processing
- FAIR data: innovation in data science and access to data platform on chemicals removing barriers to Research (preservation of IP and CBI)

# Annex I – Definitions

### Safe and Sustainable-by-Design:

At this stage, 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 put human health or the environment at risk. Overall sustainability should be ensured by minimising the environmental footprint of chemicals in particular on climate change, resource use, ecosystems and biodiversity from a life cycle perspective[32]. [Definition taken from page 4 EU COM, CSS from Oct. 2020].

### SSbD product:

Shall mean any product – including in the context of providing a service (considering the full life cycle) – which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers and whether new, used or reconditioned. When referring to Safe and Sustainable-by-Design products, this definition covers only the products that can also be identified as chemicals or materials (as defined above). Thus, the term 'product' in the Sustainable-by-Design context is used as part of the term "chemical product" or "material product", meaning chemicals and materials that are intended for consumers, or likely to be used by consumers. An example of a 'chemical product' is paint, and an example of a material product is "impregnated wood"[33].

### Substance[33]:

Means 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, as defined under REACH and CLP.

### Mixture[33]:

Means a mixture or solution composed of two or more substances, as defined under REACH and CLP.

### Chemical[33]:

Means these substances and mixtures, as defined under REACH.

### Material[33]:

A term that is used to 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.

# Annex 2 – Authoritative and other relevant substances lists

Potential and non-exhaustive lists to consider:

- The candidate list for authorisation under REACH
- The list of priority and priority hazardous substances of the Water Framework Directive
- Persistent organic compounds regulated under the POPs-Convention
- Substances on the priority lists of OSPAR and HELCOM
- Substances affecting the climate according to the Montreal- and Kyoto-Protocol
- Ozone-depleting substances according to the Montreal Protocol
- The SIN ("Substitute it now")-list

# Notes

1 https://www.wbcsd.org/d7hok.

2 Within the PSA methodology by the WBCSD, a "signal" is defined as a fact-based observation on material, sustainability-related actions or commitments of key stakeholders which indicate whether the PARC is perceived to be contributing to a transition towards a more sustainable world. These can include legislation, purchasing decisions, ecolabel requirements, among others.

3 A stage-gate process or waterfall process is a project management technique in which an initiative or project is divided into distinct stages or phases, separated by decision points (known as gates).

4 In full respect of minimum requirements, such as regulations and international conventions, which must be met.

5 It needs to be noted that work is still in progress to arrive at a mature level of sustainability assessment for many sustainability dimensions.

6 https://ec.europa.eu/environment/strategy/chemicals-strategy_nl

7 https://eur-lex.europa.eu/resource.html?uri=cellar:b828d165-1c22-11ea-8c1f-01aa75ed71a1.0002.02/DOC_1&format=PDF

8 https://ec.europa.eu/environment/strategy/zero-pollution-action-plan_nl

9 Taken from the introduction from the CSS

10 Safe and Sustainable-by-Design has been defined at this stage in the CSS 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.

11 Shall mean any product – including in the context of providing a service (considering the full life cycle) – which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers and whether new, used or reconditioned.

12 The "most harmful chemicals" is a terminology introduced in the Chemicals Strategy for Sustainability under the Action "Protection against the most harmful chemicals". The Commission will a.o. extend the generic approach to risk management to ensure that consumer products –including, among other things, food contact materials, toys, childcare articles, cosmetics, detergents, furniture and textiles - do not contain chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative. In addition, immediately launch a comprehensive impact assessment to define the modalities and timing for extending the same generic approach, with regard to consumer products, to further harmful chemicals, including those affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ;

13 In full respect of minimum requirements, such as regulations and international conventions, which must be met.

14 It needs to be noted that work is still in progress to arrive at a mature level of sustainability assessment for many sustainability dimensions.

15 Non-exhaustive list of chemical companies applying the PSA methodology as of July 2021: Arkema, Asml, BASF, Borealis, Clariant, Covestro, Dow, DSM, Evonik, Infineum, Lanxess, Lyondellbasell, SIKA, Solvay.

16 PARC: "Product-Application-Region-Combination" = defined unit of analysis within the PSA methodology.

17 CMR: carcinogenic; mutagenic or reprotoxic.

18 ED: Endocrine disruptor.

19 STOT SE: Specific target organ toxicity - single exposure

20 STOT RE: Specific target organ toxicity - repeated exposure

21 PBT: Persistent, bioaccumulative, toxic

22 vPvB: Very persistent, very bioaccumulative

23 PMT: Persistent, mobile, toxic

24 vPvM: Very persistent, very mobile

25 The Taxonomy Regulation establishes six environmental objectives: Climate change mitigation; Climate change adaptation; The sustainable use and protection of water and marine resources; The transition to a circular economy; Pollution prevention and control; The protection and restoration of biodiversity and ecosystems.

26 EPR: Extended Producer Responsibility - EPR schemes are set up at national level in Europe and enable public authorities and producers/importers to meet obligations relating to the recycling and recovery of packaging waste.

27 Avoiding competition with food production or social or ecological land use and outweighing externalities.

28 Taking in consideration the conditions in which the biodegradation of product-application-combination takes place.

29 Abiotic depletion refers to the depletion of non-living (abiotic) resources e.g. fossil fuels, minerals, clay, peat.

30 In full respect of minimum requirements, such as regulations and international conventions, which must be met.

31 It needs to be noted that work is still in progress to arrive at a mature level of sustainability assessment for many sustainability dimensions.

32 Footnote 21 in https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

33 Aligned with the definition section in European Commission, Directorate-General for Research and Innovation, Amodio, A., Malyska, A., Markouli, C., et al., Mapping study for the development of sustainable-by-design criteria, Publications Office, 2021, https://data.europa.eu/doi/10.2777/109081.

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