Bundesministerium
Klimaschutz, Umwelt,
Energie, Mobilität,
Innovation und Technologie

CSS and the role of Green Chemistry in the EU

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Vienna, 16th July 2024

Contents

- Green Deal and the Chemical Strategy for Sustainability (CSS)
- Key thematic issues of the CSS
  - „Safe and sustainable by design“ (SSbD)
  - Revision of legislation (REACH, CLP, …)
  - Comprehensive data base
  - Progressing a global sound management of chemicals
- The new EcoDesign Regulation for chemicals
- Reflection on the interlinks of ESPR and REACH
- Mora about the SSbD comncept of the Commission and JRC
- Preliminary conclusions

EU environment policy starting point – The Green Deal

Brussels, 11.12.2019
COM(2019) 640 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

The European Green Deal

Mobilising industry for a clean and circular economy (2.1.3)

*In March 2020, the Commission will adopt an **EU industrial strategy to address the twin challenge of the green and the digital transformation**. Europe must leverage the potential of the digital transformation, which is a key enabler for reaching the Green Deal objectives. Together with the industrial strategy, a new circular economy action plan will help modernise the EU's economy and draw benefit from the opportunities of the circular economy domestically and globally. A key aim of the new policy framework will be to **stimulate the development of lead markets for climate neutral and circular products**, in the EU and beyond.*

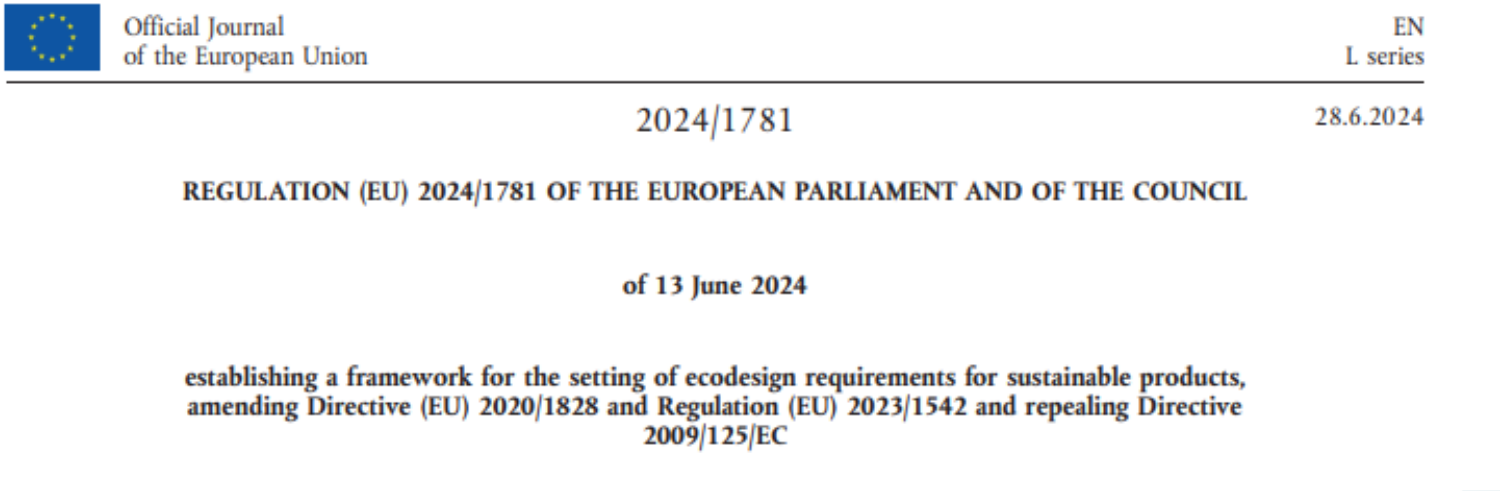
Mobilising industry for a clean and circular economy, ctd.

***Energy-intensive industries**, such as **steel, chemicals and cement**, are indispensable to Europe's economy, as they supply several key value chains. The **decarbonisation and modernisation of this sector is essential**. The recommendations published by the High Level Group of energy-intensive industries show the industry's commitment to these objectives.*

European Commission, 2023

Sustainable Product Policy

The circular economy action plan will include a 'sustainable products' policy *to support the circular design of all products based on a common methodology and principles. It will prioritise reducing and reusing materials before recycling them. It will foster new business models and set minimum requirements to prevent environmentally harmful products from being placed on the EU market. Extended producer responsibility will also be strengthened.*



Official Journal
of the European Union

EN
L series

2024/1781

28.6.2024

REGULATION (EU) 2024/1781 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 13 June 2024

establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC

A zero pollution ambition for a toxic-free environment (2.1.8)

To ensure a toxic-free environment, the Commission will present a chemicals strategy for sustainability. *This will both help to protect citizens and the environment better against hazardous chemicals and encourage innovation for the development of safe and sustainable alternatives. All parties including industry should work together to combine better health and environmental protection and increased global competitiveness. This can be achieved by* ***simplifying and strengthening the legal framework*** *…*

EUROPEAN
COMMISSION

Brussels, 14.10.2020
COM(2020) 667 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Chemicals Strategy for Sustainability
Towards a Toxic-Free Environment

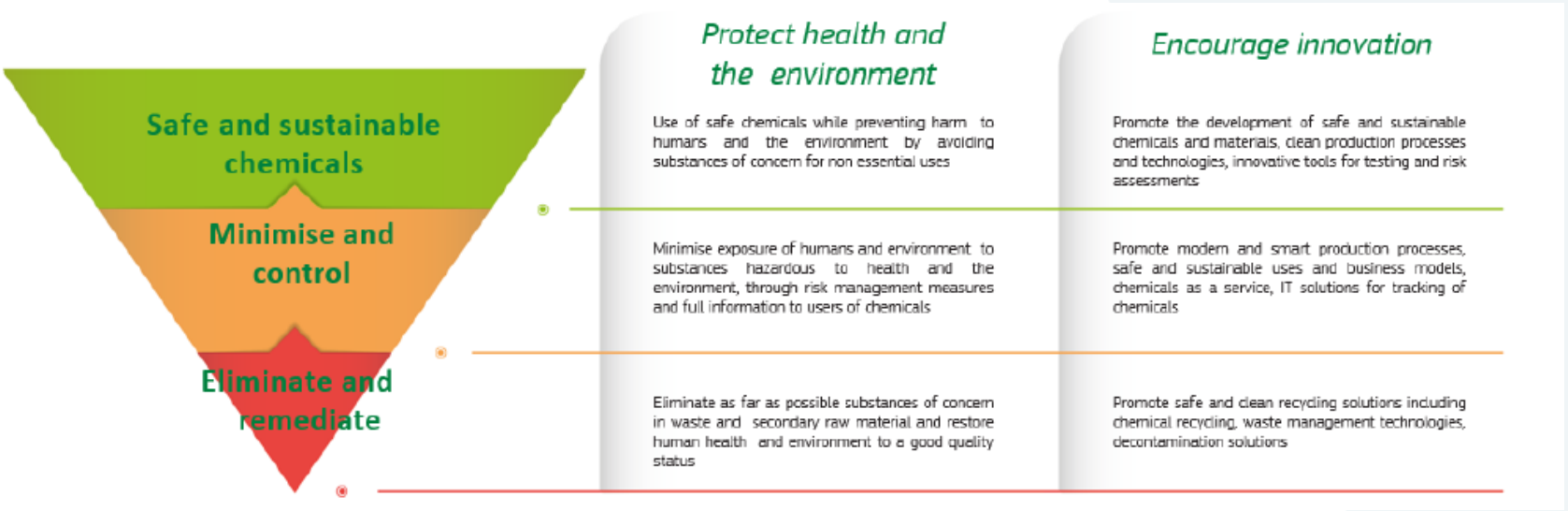
{SWD(2020) 225 final} - {SWD(2020) 247 final} - {SWD(2020) 248 final} -
{SWD(2020) 249 final} - {SWD(2020) 250 final} - {SWD(2020) 251 final}

CSS – Chemicals Strategy for Sustainability - - Towards a Toxic-Free Environment

Why it matters …

- Europe is the 2nd largest chemicals producer (world sales in 2019 3669 Mrd. EUR, Europe 711 Mrd. EUR)
- The EU share will decrease until 2030, Europe becoming 3rd largest
- Chemical production ist 4th biggest industry sector in the EU (30 000 companies of which 95 % SME)
- 84 % of Europeans are concerned about health impacts of chemicals in products, 90 % about the environment impacts

CSS – the toxic-free hierarchy (figure pg. 4)



CSS – Five key thematic chapters (chapt. 2)

	Key follow-up actions
1. Innovating for safe and sustainable EU chemicals	SSbD framework by R&D
2. Stronger EU legal framework to address pressing environmental and health concerns	REACH revision (open) and CLP revision (done)
3. Simplifying and consolidating the legal framework	
4. A comprehensive knowledge base on chemicals	Common data platform and „OSOA" in progress
5. Setting the example for a global sound management of chemicals	Higher engagement of COM in UN chemicals policy

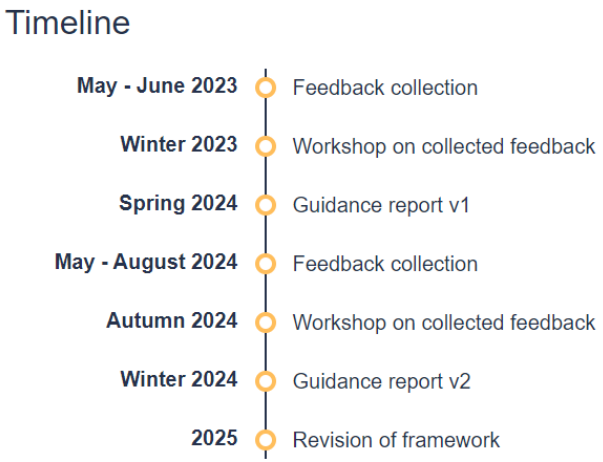
Promoting SSbD chemicals (ch. 2.1.1.)

*The transition to chemicals that are **safe and sustainable by design** is not only a societal urgency but also a great economic opportunity, as well as a key component of EU's recovery from the COVID-19 crisis. Considering the trends in global chemical production, this is an opportunity for the EU chemical industry to regain competitiveness by further developing safe and sustainable chemicals and to bring sustainable solutions across sectors*

*Footnote: 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 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.*

SSbD - Framework

The Recommendation proposes a European framework for 'safe and sustainable by design' chemicals and materials be established for R&I activities. The SSbD framework combines the disciplines of "Risk Assessment" (RA) and "Sustainability Assessment" (SA), which have different methodologies, framing and terminology.



20.12.2022 EN Official Journal of the European Union L 325/179

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2022/2510

of 8 December 2022

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

Annex – list of contents

SSbD – technical support by the Joint Research Centre

https://publications.jrc.ec.europa.eu/repository/handle/JRC128591

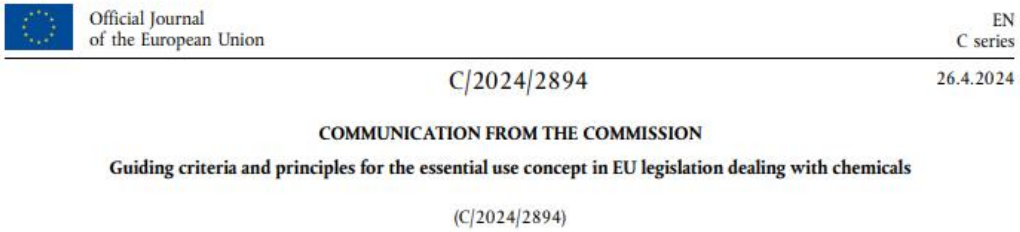
https://publications.jrc.ec.europa.eu/repository/handle/JRC138035

Priorities for legal protection goals (chapt. 2.2)

1. Protection against most harmful substances
2. Endocrine Disrupters
3. Protecting people and the environment from the combination effects of chemicals
4. Towards zero chemical pollution in the environment – Chemical pollution in natural environment
5. Towards zero chemical pollution in the environment – PFAS

What happened since ?

- CLP revision agreed: most importantly new hazard classes for endocrine disruption, PMT/vPvM and PBT/vPvB; acceleratiion of classification process; betterenforcement for oinline trade of chemicals, more practical classification rules
- Communication on essential use (EU):



Official Journal of the European Union — EN, C series

C/2024/2894 — 26.4.2024

COMMUNICATION FROM THE COMMISSION

Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals

(C/2024/2894)

Criterion principle:

The use of a most harmful substance is essential for society if

1) that use is **necessary for health or safety** or is critical for the **functioning of society**

AND

1) there are **no acceptable alternatives**

What happened since ? Ctd.

- What are most harmful substances (acc. To EU communication)

A most harmful substance has one or more of the following hazard properties ([17]) ([18]) ([19]):

— Carcinogenicity Cat. 1A and 1B

— Germ cell mutagenicity Cat. 1A and 1B

— Reproductive/developmental toxicity Cat. 1A and 1B

— Endocrine disruption Cat. 1 (human health)

— Endocrine disruption Cat. 1 (environment)

— Respiratory sensitisation Cat. 1

— 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)

— Persistent, mobile and toxic/very persistent and mobile (PMT/vPvM) ([20])

— Hazardous to the ozone layer Cat. 1 ([21])

What happened since ? Ctd.

- After extended consultations on the REACH revision, the process was interrupted
- In the revision discussions the Commission announced that they plan to implement a number of revision elements by comitology (modification of annexes):
  - increased information requirements for low tonnage substances
  - Mixture allocation factor (MAF) to account for combination effects in the risk assessment factors
  - Clear rules for the derivation of Derived Minimal Effect Levels (DMELs)
  - Update on nanoforms
- As a major innovation in the REACH revision, COM is planning to extend the scope of the so-called **generic restrictions under REACH**, which is currently defined as:

Article 68 (2). For a substance on its own, in a mixture or in an article which meets the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1A or 1B, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4). Articles 69 to 73 shall not apply.

What happened since ? Ctd.

- This extension will probably include all **most harmful substances** and, in addition to consumers also **professional users**.
- Restrictions will be exempted or derrogated for essential uses. Comanies will have the right to apply for such exemptions/derrogations
- In 2023 the Member States Germany, the Netherlands, Denmark, Norway, and Sweden submitted a comprehensive restriction dossier for per- and polyfluoroalkyl substances (PFAS) to ECHA:
  - PFAS is any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (with certain specific exemptions)
  - The proposal is currently analysed by the expert for a of ECHA, the process being assumed to take time until 2025/2026
  - Information: https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term

What happened since ? Ctd.

- The goal to establish a Common Data Platform and introduce the principle of "one substance – one assessment" (OSOA) has significantly advanced. The Commission has tabled three proposals:
  - Proposal for a Regulation establishing a **common data platform on chemicals**
  - Proposal for a Regulation on the **re-attribution of scientific and technical tasks** and improving cooperation among Union agencies **in the area of chemicals**
  - Proposal for a Directive on the **re-attribution of scientific and technical tasks to the European Chemicals Agency**
  - **For more details see:**
    https://ec.europa.eu/commission/presscorner/detail/en/ip_23_6413

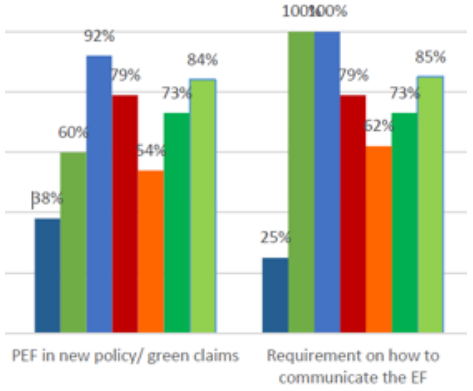
- ECHA will get a number of other assessment and data storage tasks regulated by legislation other than REACH and CLP. The proposal for re-establishing ECHA to achieve these additional performance has not yet been published.

Sustainable product initiative evolution

- There are more than 200 environmental labels active in the EU
- Communication on the Single Market Act: *"Before 2012, the Commission will look into the feasibility of an initiative on the Ecological Footprint of Products to address the issue of the environmental impact of products, including carbon emissions. The initiative will explore possibilities for establishing a common European methodology."*
- The European Commission proposed the Product Environmental Footprint (PEF) method as a common way of measuring environmental performance
- This approach was tested between 2013-2018 together with more than 280 volunteering companies and organisations

Sustainable product initiative evolution, ctd.

- In 2018/2019 the European Commission launched a series of consultations on the PEF



Source: https://ec.europa.eu/environment/eussd/smgp/EFconference_2018.htm

- The 2020 Circular Economy Action Plan (as part of the Green Deal) foresees that *"The Commission will also propose that companies substantiate their environmental claims using Product and Organisation Environmental Footprint methods."*
- In June 2024, the Regulation "establishing a framework for setting ecodesign requirements for sustainable products" (ESPR) was published

EcoDesign Regulation - Article 1 (objective)

"… framework to improve the environmental sustainability of products … by setting ecodesign requirements that products shall fulfil to be placed on the market … Those ecodesign requirements, …, relate to:

(a) product durability and reliability; (b) product reusability; (c) product upgradability, reparability, maintenance and refurbishment; (d) the presence of substances of concern in products; (e) product energy and resource efficiency; (f) recycled content in products; (g) product remanufacturing and recycling; (h) products' carbon and environmental footprints; (i) products' expected generation of waste materials.

… also establishes a digital product passport ('product passport'), … "

EcoDesign Regulation – Article 2 (relevant definitions)

'product' means any physical good that is placed on the market or put into service (1)

'environmental footprint' means a quantification of a product's environmental impacts, whether in relation to a single environmental impact category or an aggregated set of impact categories based on the Product Environmental Footprint method (23)

'Product Environmental Footprint method' means the life cycle assessment method to quantify the environmental impacts of products established by Recommendation (EU) 2021/2279 (24)

'product passport' means a set of data specific to a product that includes the information specified in the applicable delegated act adopted pursuant to Article 4 and that is accessible via electronic means… (29)

EcoDesign Regulation – Article 2 (relevant definitions)

'substance of concern' means a substance that:

(a) meets the criteria and is identified as "substance of very high concern" (SVHC) under REACH

(b) is classified under CLP as carcinogenic (cat 1 and 2, mutagenic (cat 1 and 2), reprotoxic (cat 1 and 2), persistent, bio-accumulative, toxic (PBTs), very persistent and very bioaccumulative (vPvBs), persistent, mobile and toxic (PMT), very persistent and very mobile (vPvM), endocrine disrupting, respiratory or skin sensitising cat 1, chronic hazardous to the aquatic environment categories 1 to 4, hazardous to the ozone layer, – specific target organ toxic – repeated exposure cat 1 and 2, specific target organ toxic single exposure cat 1 and 2, or

(c) negatively affects the re-use and recycling of materials in the product in which it is present;

EcoDesign Regulation – Article 5 (ecodesign requirements)

The Commission shall, … , establish ecodesign requirements to improve the following product aspects: (a) durability; (b) reliability; … ; (g) presence of substances of concern; (h) energy use or energy efficiency; (i) resource use or resource efficiency; (j) recycled content; … ; (m) environmental impacts, including carbon and environmental footprint; (n) expected generation of waste materials.

Ecodesign requirements shall, as appropriate, include:

(a) performance requirements as set out in Article 6;

(b) information requirements as set out in Article 7.

EcoDesign Regulation – Article 7 (information requirements)

Products shall comply with information requirements related to the product aspects listed in Article 5(1), …

The information requirements … shall:

(a) include, as a minimum, requirements related to the product passport referred to in Chapter III and requirements related to substances of concern referred to in paragraph 5; and

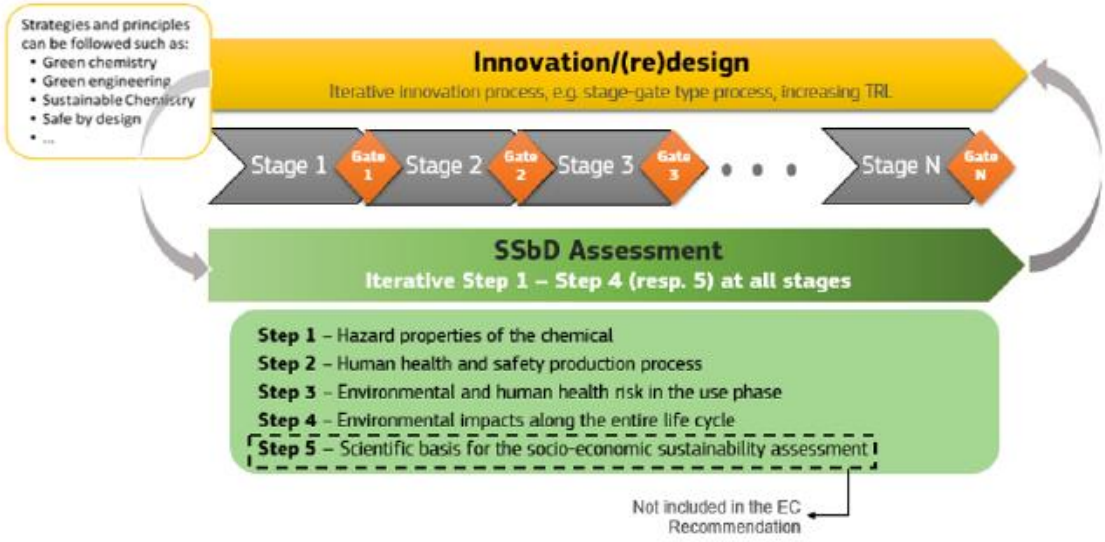
(b) as appropriate, require products to be accompanied by: … [other information requirements related to the information elements under (a)]

Reflection on the interlinks of ESPR and REACH

- Chemicals and mixtures are products, thus within the scope;
- Article 5 empowers COM to restrict substances of concern in (certain categories of) products; note that the scope of substances of concern is wider than the scope of SVHC under REACH
- If information on the PEF is required for a certain product (article in the terminology of REACH), the producer will need to know, inter alia, the PEF of the chemicals from which the product is made (similar for a formulator of a mixture)
- Potentially for substances, more likely for certain (categories of) mixtures, ecodesign requirements will be established by COM; certain formulators will need to establish a digital product pass
- More specific requirements can be expected in the Green Claims Regulation (currently progressing)

A little more on SSbD

- Current technical basis can be found in the following papers:
  - JRC Technical Report on Safe and Sustainable by Design (2022)
  - Safe and Sustainable by Design chemicals and materials - Methodological Guidance chemicals and materials (by COM)
- Overview of the SSbD framework:

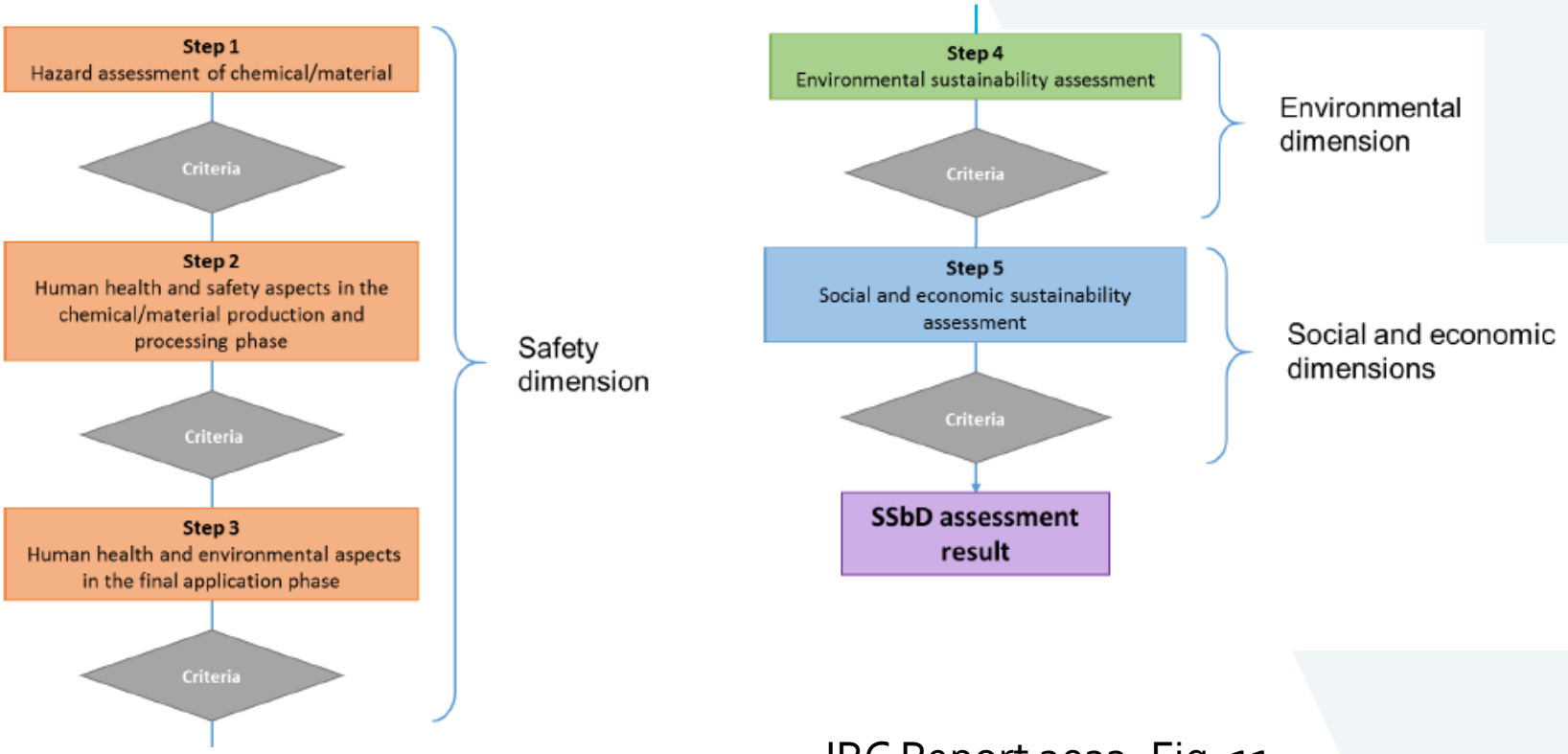


SSBD – Framework: dimensions considered

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 **risks** 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: Stepwise approach



JRC Report 2022, Fig. 11

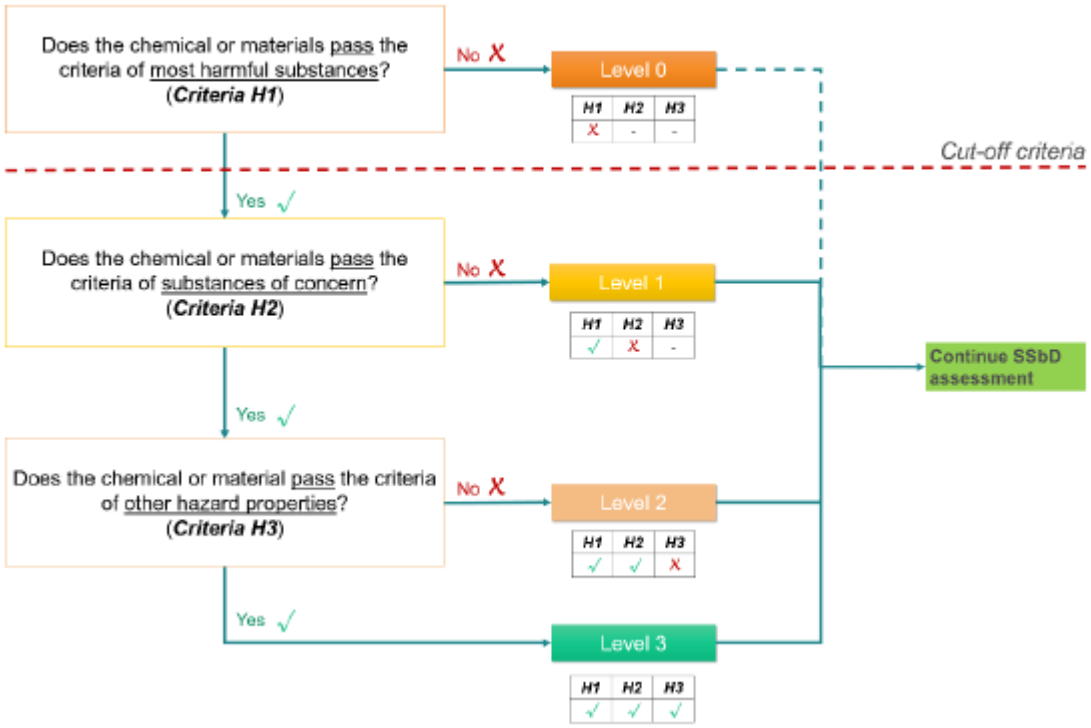
SSBD – Framework: Criteria for hazard assessment (step 1)

Step	Assessment Dimension	Assessment aspects	System Scope	Aspect/Indicator	Criteria
1	**Hazard assessment**	The assessment focuses on the hazard properties (human health, environmental and physical hazards) of the manufactured chemicals and materials	Chemical/Material intrinsic properties	See Table 3	See Section 4.4.1 and Table 4
2	**Human health and safety aspects in the production and processing phase**	Assessment of the human health and safety aspects during the production phase of the chemical/material from the used raw materials (production) and the manufactured chemical/material (processing, waste stage).	Chemical/material production and processing	See Section 4.2.2	See Section 4.2.2
3	**Human health and environmental aspects in the final application phase**	This step evaluates the human health and environmental impacts during the chemical/material final application phase.	Chemical/material application	See section 4.2.3	The indicator values should be below the safe levels. For details see section 4.2.3.
4	**Environmental sustainability (Life Cycle Assessment)**	Assess life cycle environmental impact categories for: Toxicity and Eco-toxicity Climate Change Ozone Depletion, Particulate Matter, Ionising radiation, Photochemical Ozone Formation, Acidification, Eutrophication Resources, Land Use, Water Use	Chemical/Material entire life cycle	See Table 7	Reduction by X% compared to the current state of the art for intended use. The 'X' might differ depending on the impact category. For details see section 4.2.4.
5	**Social Sustainability, Economic Sustainability**	This step is at an exploratory phase. It present an overview of social aspects that could be considered in the future. For the economic pillar, the step focuses on non-financial aspects, i.e. the identification and monetization of externalities arising during the life cycle of a chemical or a material.	Chemical/Material entire life cycle (for the economic part) Chemical/Material production and relevant suppliers (for the social part)	See Table 10 for examples	To de defined.

JRC Report 2022, Table 2

SSBD – Franmework: Example of the evaluation in step 1

Figure 12. Workflow relevant to Step 1 of the SSbD framework



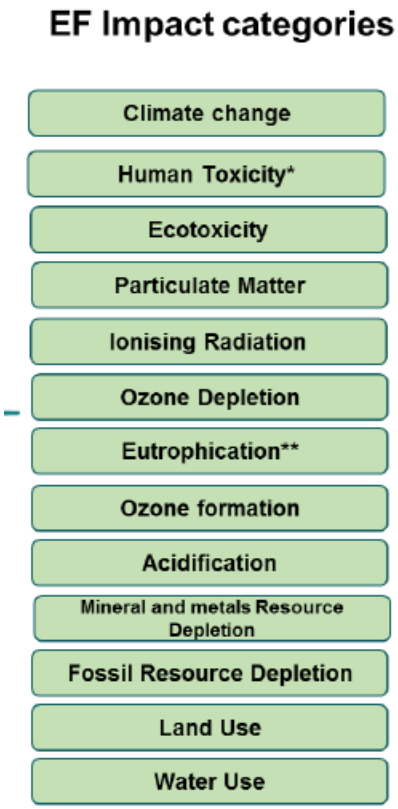
A similar is followed for step 2 (process) and step 3 (use) phase

E.g. criterion H1 reads:

*The criterion refers to the **most harmful substances**, according to CSS, including the substances of very high concern (SVHC) according to REACH Art. 57(a-f) and additional hazard properties, as defined in Table 3.*
This is a cut-off criterion, establishing a minimum set of hazard requirements that need to be fulfilled by a chemical or material in order to be considered eventually SSbD after the other assessments are performed.
Therefore, the assessment of the other aspects can be performed in order to understand the overall SSbD performance (e.g. safety during the use assessed in Step 3, other environmental sustainability aspects assessed in Step 4) if this helps the innovation process.

JRC Report 2022, Fig. 12, Table 4

SSBD – Framework: Step 4 – Environmental sustainability



The proposed impact categories are based on the PEF concept recommended by the European Commission to measure the life cycle environmental performance of products

- In total, 16 impact categories are related to policy objectives (e.g. protection of human health, biodiversity).
- Human toxicity (cancer and non-cancer) and eco-toxicity relate to the SSBD goal towards a "toxic-free environment'. They differ from the assessments in Step 1 and Step 2 as they refer to impacts through the life cycle emissions to the environment (e.g. soil, water, air) and not via direct exposure.
- The 16 impact categories result from modelling of the life cycle of the chemical, from raw material extraction up to the end of life. The impacts result from the multiplication of the emissions and resources used along the life cycle as well as of the chemicals in the given material/product application.
- The 16 individual indicators are retained (rather than aggregated) to better illustrate the trade-offs among them and the main hotspots.

JRC Report 2022, Fig. 16

***) cancer + non-cancer, **) terrestrial + freshwater + marine**

SSBD – Framework: Scoring on the basis of targets

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.

Setting a science-based target requires a concept of planetary boundaries:

- a global assessment of the current magnitude of a problem and its future trajectories;
- a consensus on the acceptable level of impact that society can tolerate.

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		

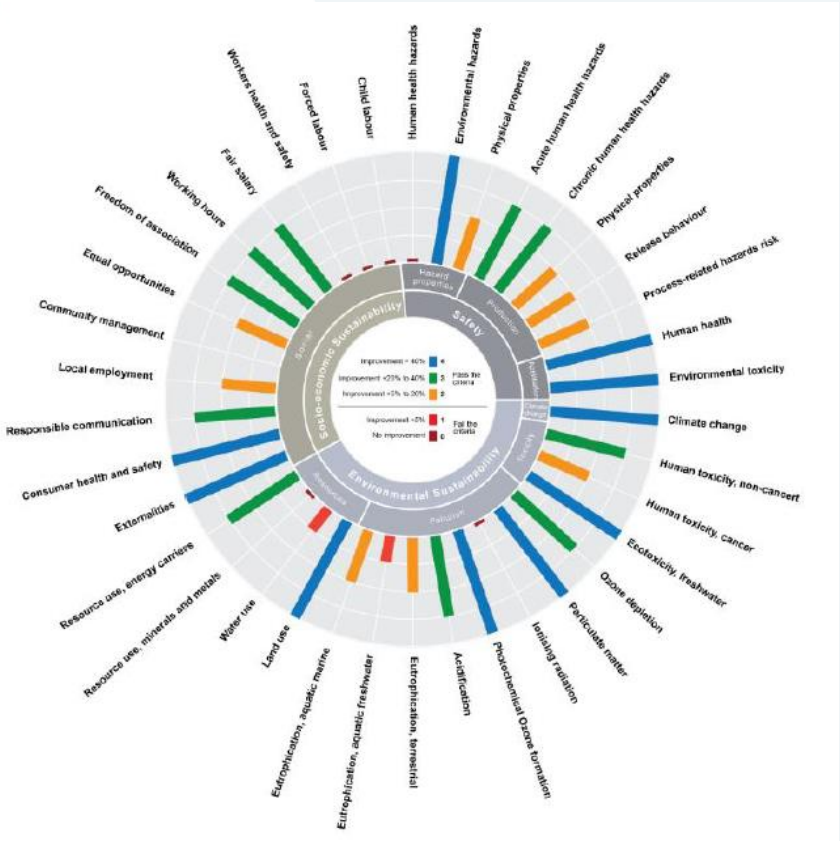
Illustration example

LCA Assessment level (max score)	Aspect	Score
Toxicity ES1 (max 12)	Human Toxicity, cancer	3
	Human Toxicity non cancer	2
	Ecotoxicity	1
Climate Change ES2 (max 4)	Climate Change	3
Pollution ES3 (max 32)	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 ES4 (max 16)	Land Use	4
	Water use	2
	Resource use, minerals and metals	2
	Resource use, energy carriers	2

JRC Report 2022, Table 8, 9

SSBD – Example for a final score

Dimension	Aspect	Score
Hazard properties	H1	3
	H2	2
	H3	3
Human health and safety aspects (production & processing phase)	OSH1	4
	OSH2	4
	OSH3	4
	OSH4	4
	OSH5	4
Human health and environmental aspects (application phase)	SD1	4
	SD2	1
Environment Sustainability	E1	1
	E2	3
	E3	1
	E4	3
Social & Economical Sustainability		1



JRC Report 2022, Fig. 18, 20

Preliminary conclusions

- The EU does not promote Green Chemistry as such, but there is a clear commitment to implement the principle of SSbD in the (chemical) industry, which requires a change to green chemicals management
- SSbD provides an option for developing a harmonized metrics for measuring “green” chemicals, so it is important to follow the process
- The PEF for chemicals is very complex, probably too complex for a mandatory roll-out, but certain key elements may be implemented in a more pragmatic approach
- Better alignment of EU chemicals legislation between ESPR, SSbD and REACH is needed
- Chemical manufacturers should get involved in the testing period of SSbD to be well-prepared for future enforcement (participation in the EU case studies is advisable)

Thank you for your attention!

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