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Background on Safe-and-sustainable-by-design (SSbD)

The SSbD concept may be considered as the identification of sustainability (safety (risks concerning humans and the environment), environmental, social and/or economic impacts) hotspots at an early phase of the innovation and product development process in order to minimize potential hazard(s) and/or exposure [1], and to maximize sustainability. A first description of the SSbD concept can be found in the EU- Chemical Strategy for Sustainability (EU-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 minimizing the environmental footprint of chemicals in particular on climate change, resource use, ecosystems and biodiversity from a life cycle perspective"[2]*.

For the human and environmental safety dimensions, the EC Joint Research Center (JRC) has developed a report for the framework for SSbD criteria where a two-phase approach is recommended: a (re)-design phase in which guiding principles are proposed to support the design of chemicals and materials and a step-wise hierarchical approach to address chemical safety, direct toxicological/ecotoxicological impact, and aspects of environmental sustainability [3].

In the (re)design phase, SSbD principles have been identified by the EC JRC including: *1) Material efficiency (Pursuing the incorporation of all the chemicals/materials used in a process into the final product or full recovery inside the process, thereby reducing the use of raw materials and the generation of waste), 2) Minimize the use of hazardous chemicals, 3) Design for energy efficiency 4) Use renewable sources, 5) Prevent and avoid hazardous emissions, 6) Reduce exposure to hazardous substances, 7) Design for end of life (Design chemicals/materials in a way that, once they have fulfilled their function, they break down into products that do not pose any risk to the environment/humans. Design for preventing the hindrance of reuse, waste collection, sorting and recycling/upcycling). 8) Consider the whole life cycle*

In the sustainability assessment phase, five steps were provided for defining criteria for SSbD chemicals and materials. The first step is based on the intrinsic hazards (based on the hazard classes in the CLP Regulation). The second and third steps are based on risk considerations (occupational safety and health aspects and health and environmental impacts from the use phase (direct exposure)) based on CLP Regulation and USEtoxModel. The fourth step is environmental sustainability and is based on the impact categories that are constituting the Product Environmental Footprint (PEF) and it is supported by the Ecodesign for Sustainable Products Regulation (SPI) [4][5][6]. The fifth step covers socio-economic aspects but these due to the limited level of implementation, this step in in an exploratory phase *(Figure 1, Figure 2;Table 1*).

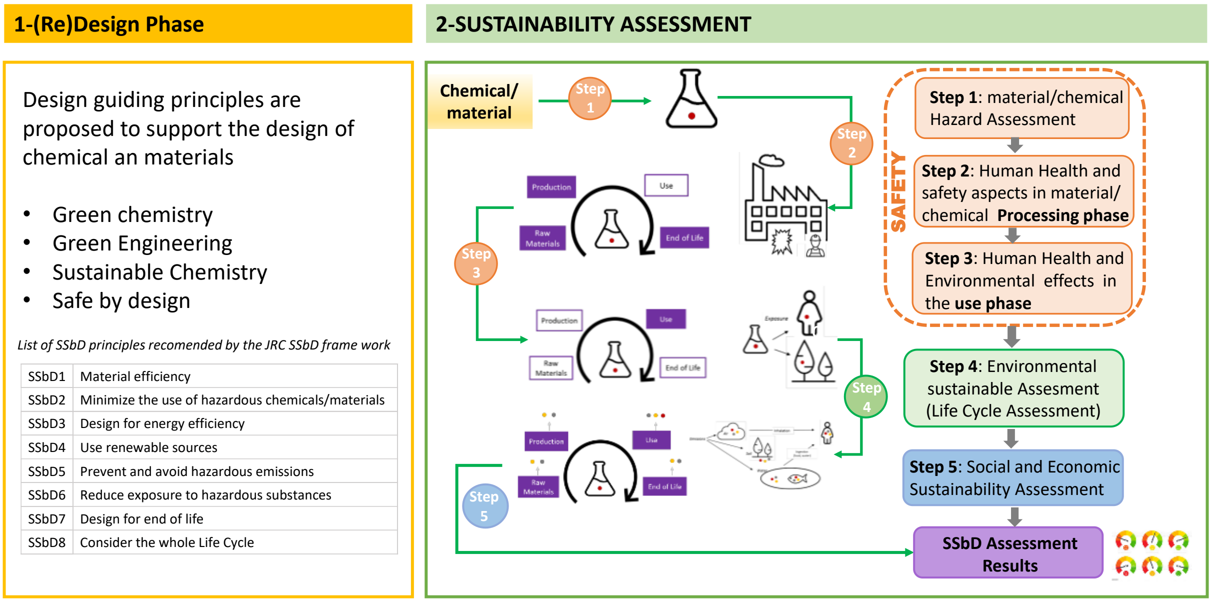

Figure 1. Two-phase process in the JRC framework for the definition of criteria and evaluation procedure for chemicals and materials (adapted from [3]*)*

Sustainability

Sustainability covers and integrates safety, economic, environmental, and social aspects to avoid harm to humans and the environment [7]. Sustainability also supports the EU Green Deal [8] whose ambitions include becoming climate neutral; protecting human life, animals and plants by cutting pollution; helping companies become world leaders in clean products and technologies; and being inclusive helping ensure a just and inclusive transition [9]. '*In the context of chemicals, sustainability can be seen as the ability of a chemical, material, product or service to deliver its function without exceeding environmental and ecological boundaries along its entire life cycle, while providing welfare and socio-economic benefits [3][7]*'.

A new understanding of safety

The safety concept is related to the absence of unacceptable risk for humans and the environment by avoiding the use of hazardous chemicals [3]. In the EU-CSS, the ambitions towards a toxic-free environment and protection against the most harmful chemicals are evident. An important development is the extension of the generic approach to risk management to ensure that chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative are not present in consumer products. This generic approach will be extended to other harmful chemicals including those affecting the immune, neurological or respiratory systems and chemicals toxic to specific organs[2]. The scope of this EU-CSS is also to protect vulnerable groups which typically include pregnant and nursing women, the unborn, infants and children, the elderly people as well as workers and residents subject to high and/or long term chemical exposure.

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Group definition	Human health hazards	Environmental hazards	Physical hazards
Includes the most harmful substances (according to CSS (EC, 2020a)), including the substances of very high concern (SVHC) according to REACH Art. 57(a-f)[13],[14] (EU, 2006). These hazard properties will form Criterion S1.	• 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) • 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) • Endocrine disruption Cat. 1 (environment)	
Includes hazardous substances with chronic effect, which are part of the substances of concern, described in CSS (EC, 2020a) and are not included already in Criterion S1. These hazard properties will form Criterion S2.	• Skin sensitisation Cat 1 • Carcinogenicity Cat. 2 • Germ cell mutagenicity Cat. 2 • Reproductive / developmental toxicity Cat. 2 • Specific target organ toxicity - repeated exposure (STOT-RE) Cat. 2 • Specific target organ toxicity - single exposure (STOT-SE) Cat. 1 and 2 • Endocrine disruption Cat. 2 (human health)	• Hazardous for the ozone layer • Chronic environmental toxicity (chronic aquatic toxicity) • Endocrine disruption Cat. 2 (environment)	
Includes the other hazard classes not part already in Criteria S1 and S2. These hazard properties will form Criterion S3.	• Acute toxicity • Skin corrosion • Skin irritation • Serious eye damage/eye irritation • Aspiration hazard (Cat. 1) • Specific target organ toxicity - single exposure (STOT-SE) Cat. 3	• Acute environmental toxicity (acute aquatic toxicity)	• Explosives • Flammable gases, liquids and solids • Aerosols • Oxidising gases, liquids, solids • Gases under pressure • Self-reactive • Pyrophoric liquids, solid • Self-heating • In contact with water emits flammable gas • Organic peroxides • Corrosivity • Desensitised explosives

Figure 2 List of aspects and indicators (hazard properties) relevant for Step 1 ***¡Error! No se encuentra el origen de la referencia.***

Table 1. Overview of dimensions and aspects covered in the assessment phase from the EC JRC draft report for defining criteria for SSbD chemicals and materials (adapted from ***¡Error! No se encuentra el origen de la referencia.****)*

Dimension	*Aspect*
Safety of chemical and material – hazard-based approach	Human health hazards
	Environmental hazards
	Physical hazards
Chemical or material processing safety – occupational safety and health aspects	Acute human hazards
	Chronic human hazards
	Physical properties
	Hazards from release behavior
	Process-related hazards
Safety – direct exposure	Human health
	Ecotoxicity
Environmental sustainability – Life cycle assessment	Climate change
	Human toxicity - cancer
	Human toxicity – non-cancer
	Ecotoxicity
	Particulate matter
	Ionizing radiation
	Ozone depletion
	Eutrophication terrestrial
	Eutrophication fresh water
	Eutrophication marine
	Ozone formation
	Acidification
	Fossil resources
	Mineral and metal resources
	Soil quality index
	User deprivation potential (deprivation weighted water consumption)

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