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Subject:	ANNEX to the COMMISSION RECOMMENDATION establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials

Delegations will find attached document C(2022) 8854 final - ANNEX.

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ANNEX

ANNEX

to the

COMMISSION RECOMMENDATION

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

ANNEX

Framework for the future definition of safe and sustainable by design criteria and the procedure for assessing chemicals and materials

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1. PRINCIPLES UNDERPINNING THE SAFE AND SUSTAINABILE BY DESIGN FRAMEWORK

A set of principles has been defined for the development of the new ‘safe and sustainable by design’ (SSbD) framework.

- Define a hierarchy that puts safety first, to avoid regrettable substitutions.
- Define cut-off criteria for the design of chemicals and materials to stimulate sustainable research and innovation (R&I), based not only on data referred to in the requirements of EU legislation on chemicals, but also on data that are outside the scope of those requirements.
- Focus on iteratively minimising environmental pressures, using dynamic boundaries and cut-offs, so that the framework becomes a tool for managing improvements along the innovation process.
- Ensure optimal use of available data on adverse effects. Every (new) chemical or material should be compared to the full spectrum of structurally or functionally similar substances to assess the expected potential to cause negative impact on human health or the environment.
- Communicate SSbD actions taken throughout the supply chain; make all relevant and non-confidential data available in a findable, accessible, interoperable and reusable (FAIR) format, for greater transparency and accountability and to better discharge the duty of care.
- Promote the use of a coherent framework by the various stakeholders, including industry and policy makers.

2. FRAMEWORK FEATURES AND STRUCTURE

The SSbD framework proposed is a general approach to assessing and defining safety and sustainability criteria for chemicals and materials, throughout the innovation process. It can be applied to the development of new chemicals and materials or to the re-assessment of existing ones. In the case of existing chemicals and materials, the framework can be used: i) to support the redesign of their production processes to make them safer and more sustainable by evaluating alternative processes, or ii) to compare them using the SSbD criteria (e.g., for innovation by substitution with better performing chemicals or materials or for selection in downstream applications).

The framework consists of a (re)design stage and a safety and sustainability assessment across the different steps in the life cycle of a chemical or material, considering functionality and end-use(s). Although the framework does not assess the safety and sustainability of products, it does address how the chemicals or materials are used in products.

The SSbD framework comprises the following two components:

1. a **(re)design stage** at which guiding design principles are proposed to support the safe and sustainable design of chemicals and materials;
2. a **safety and sustainability assessment stage** at which the safety and sustainability of the chemical or material in question are assessed.

The SSbD framework can help with the various stages of the innovation process (design, planning, experimental testing and prototyping) where decisions are taken to proceed with, abandon or tweak the innovation approach. The safety and sustainability assessment should start as early as possible in the innovation process to ensure that SSbD principles are being applied to a chemical's or material's design. After that, the assessment should be done iteratively, at the subsequent stages of development, as more information gradually becomes available. The framework should allow for flexibility in its implementation, to ensure alignment with horizontal or product specific legislations or with regulatory exemptions.

The proposed safety and sustainability assessment follows a hierarchical approach in which safety aspects are considered first, before moving on to sustainability aspects.

The first step is to ensure safety by considering chemicals or materials with certain (human health as well as environmental) hazardous properties as non-sustainable by design, even if their design follows recommended design principles or they have a relatively low environmental impact. If the chemical or material in question fulfils the minimum safety criteria, the assessment can proceed to environmental sustainability aspects. In future applications of the framework, socio-economic sustainability aspects can also be evaluated as a complementary assessment.

This stage-based approach is intended to reduce the burden of the assessment as the initial steps propose to identify 'prohibitive' issues. For example, if the assessment of a chemical or material identifies safety concerns, an LCA would only be done after these had been addressed, e.g., by determining if risk management measures can address the safety concerns. Nevertheless, depending on each organisation's working methods, the different steps could be conducted simultaneously.

3. Stage 1: Guiding (re)design principles

The SSbD framework covers three levels of the term 'by design':

(1) molecular design, to design new chemicals and materials based on their chemical structure;

(2) process design, to make the production process safer and more sustainable, both for chemicals and materials being developed and for existing chemicals and materials;

(3) product design, where the results of the SSbD assessment support the selection of the chemicals or materials to meet the functional demands of the final product in which they are used.

The purpose of this stage is to provide guidance on the principles to be considered at the (re)design stage to maximise the possibilities of a successful safety and sustainability assessment outcome. At this stage, the goal, scope and system boundaries, which will determine the parameters of the assessment of the chemical or material in question, should be defined. This includes choices such as assessing a mixture as a single element or as components of mixtures. Adhering to those principles does not necessarily make it possible to draw conclusions about the safety and sustainability performance of the chemicals and materials in question. This requires an assessment of safety and sustainability in the next stage.

The design principles are summarised in Table 1 (a non-exhaustive list). They are derived from existing best practices, e.g. Green Chemistry Principles[1], Green Engineering Principles[2], Sustainability Chemistry Criteria[3], German Environment Agency (UBA) Golden Rules[4], Circularity Chemistry Principles[5]. Other principles from those best practices can also be considered.

Table 1: Non-exhaustive list of guiding design principles, associated definitions, and examples of actions at the (re)design stage

Design principle	Definition	Examples of actions
Material efficiency	Incorporating all the chemicals or materials used in a process into the final product or fully recovering them inside the process, thereby using fewer raw materials and generating less waste.	Maximise yield during reaction to reduce chemical or material consumption. Recover more unreacted chemicals or materials. Select materials and processes that

1 Anastas, P., and Warner, J. (1998), Green Chemistry: Theory and Practice, Oxford University Press, New York, p. 30.

2 Anastas, P. T. and Zimmerman, J. B. (2003), 'Peer Reviewed: Design Through the 12 Principles of Green Engineering', Environmental Science & Technology 37(5), 94A–101A: https://doi.org/10.1021/es032373g

3 UBA (2009), 'Sustainable Chemistry: Positions and Criteria of the Federal Environment Agency', p. 6; https://www.umweltbundesamt.de/en/publikationen/sustainable-chemistry

4 UBA (2016), 'Guide on sustainable chemicals – A decision tool for substance manufacturers, formulators and end users of chemicals': https://www.umweltbundesamt.de/en/publikationen/guide-on-sustainable-chemicals

5 Keijer, T., Bakker, V., Slootweg, J. C. (2019), 'Circular chemistry to enable a circular economy', Nature chemistry 11(3), pp. 190-195: https://doi.org/10.1038/s41557-019-0226-9

Design principle	Definition	Examples of actions
		minimise the generation of waste. Identify the occurrence of the use of critical raw materials[6], in order to minimise or substitute them.
Minimise the use of hazardous chemicals or materials	Preserving the functionality of products while reducing or completely avoiding the use of hazardous chemicals or materials where possible. Using the best technology to avoid exposure at all stages of the life cycle of a chemical or material.	Reduce and/or eliminate hazardous chemicals or materials in production processes. Redesign production processes to minimise the use of hazardous chemicals/materials. Eliminate hazardous chemicals or materials in final products.
Design for energy efficiency	Minimising the energy used to produce and use a chemical or material in the production process and/or in the supply chain.	Select or develop (production) processes that: a. involve alternative and less energy-intensive production/separation techniques b. maximise energy re-use (e.g. integration of heat networks and cogeneration) c. have fewer production steps d. use catalysts, including enzymes e. reduce inefficiencies and exploit available residual energy in the process or select lower temperature reaction pathways
Use renewable sources	Conserving resources, by means of resource-closed loops or by using renewable material and energy sources.	Promote the use of feedstocks that: a. are renewable b. are circular c. do not create land competition d. do not negatively affect biodiversity or processes that: a. use renewable energy resources with low-carbon emissions and without adverse effects on biodiversity
Prevent and avoid hazardous emissions	Applying technologies to minimise or avoid hazardous emissions or the release of pollutants into the environment.	Select materials or processes that: a. minimise the generation of hazardous waste and hazardous by-products b. minimise the generation of

6 https://ec.europa.eu/growth/sectors/raw-materials/areas-specific-interest/critical-raw-materials_en

Design principle	Definition	Examples of actions
		emissions (e.g. volatile organic compounds, total organic carbon, acidifying and eutrophication pollutants, and heavy metals)
Design for end of life	Design chemicals and materials so that, once they have served their purpose, they break down into chemicals that do not pose any risk to the environment or to humans. Design chemicals and materials in a way that makes them fit for re-use, waste collection, sorting and recycling/upcycling.	Avoid using chemicals or materials that impede end-of-life processes such as recycling. Select materials that are: a. more durable (longer life and less maintenance) b. easy to separate and sort c. valuable even after being used (commercial afterlife) d. fully biodegradable for uses that unavoidably lead to release into the environment or wastewater
Consider the whole life cycle	Applying the design principles to the entire life cycle, from the raw materials supply chain to the final product's end of life.	Consider: a. using reusable packaging for the chemical or material being assessed and for chemicals or materials in its supply chain b. energy-efficient logistics (e.g., reducing transported quantities, changing the means of transport) c. reducing transport distances in the supply chain

4. STAGE 2: SAFETY AND SUSTAINABILITY ASSESSMENT

Once the design principles have been listed, the next stage is the safety and sustainability assessment composed of four steps. The first three steps mainly cover different aspects of the safety of chemicals or materials. These three steps build on knowledge generated with existing EU chemicals legislation like Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006, Classification, Labelling and Packaging (CLP) Regulation (EC) No 1272/2008 or occupational safety and health (OSH) Directive 89/391/EEC, which is adapted to the R&I application of SSbD. The fourth step covers the environmental aspect of sustainability. Depending on how the SSbD framework is applied, it may also be worthwhile assessing socio-economic aspects of sustainability – for instance, as an additional element to complement the main safety and sustainability assessment in the framework's future application.

The four steps, although presented sequentially, can be performed in parallel, as information becomes available at various points of the life cycle of the chemical or material in question and depending on whether a new or existing chemical or material is being assessed.

Each step consists of aspects that can be measured using indicators. The indicators are assessed with the methods proposed in the framework. For the purposes of the framework a criterion can be formed by an aspect with an assessment method and a minimum threshold or target values (on which a decision about the safety or sustainability of a chemical or material may be based). At this stage thresholds for Step 1 are available as they have been set in EU legislations on chemicals (CLP and REACH).

At this stage the SSbD framework has applicability only in the innovation stage of chemicals and materials development, as explained in stage 1; it does not interfere with Union legal obligations for chemicals and materials.

Step 1 – Hazard assessment (intrinsic properties)

This step looks at the intrinsic properties of the chemical or material in order to understand its hazard[7] profile (human health, environment and physical hazards), before assessing the safety during its production, processing and use.

Step 2 – Human health and safety aspects of production and processing

This step assesses the human health and safety aspects of the production and processing of the chemical or material in question. Production means the production process from raw material extraction to production of the chemical or material including recycling or waste management.

The goal is to assess whether the production and processing of the chemical or material in question poses any risk to workers, in line with, or beyond, EU Occupational Health and Safety directives.

Step 3 – Human health and environmental aspects in the final application phase

This step assesses the hazards and risks of the final application of the material or chemical in question. It covers use-specific exposure to the chemical or material and the associated risks.

The goal is to assess whether the use of a chemical or material in its final application poses any risk to human health or the environment.

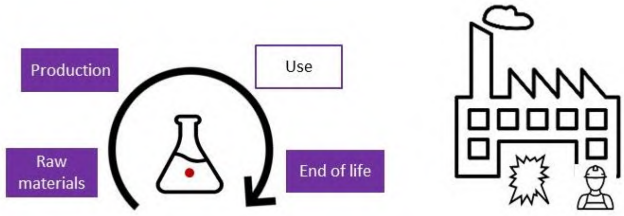
Step 4 – Environmental sustainability assessment

In the fourth step environmental sustainability impacts along the entire chemical/material life cycle are considered by means of an LCA, assessing several impact categories such as climate change and resource use. Toxicity and ecotoxicity are also considered in this step, referring to impacts due to life cycle emissions to humans and the environment via environmental compartments (e.g., soil, water, air), including mobility between compartments and not via direct exposure (covered in Step 3).

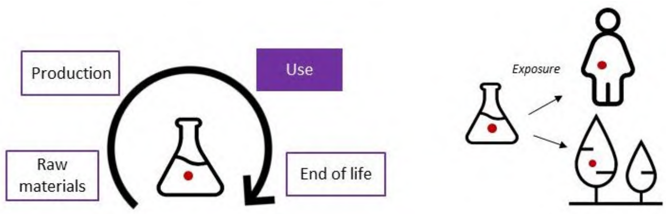
(1) Hazardous properties of the chemical or material in question


7 Hazard is defined as a property or set of properties that make a substance dangerous (definition provided by the terminology portal of ECHA https://echa-term.echa.europa.eu/).

(2) Human health and safety aspects of production and processing



(3) Hazards and risks of the final application of the chemical or material in question



(4) Environmental impacts throughout the life cycle of the chemical or material in question

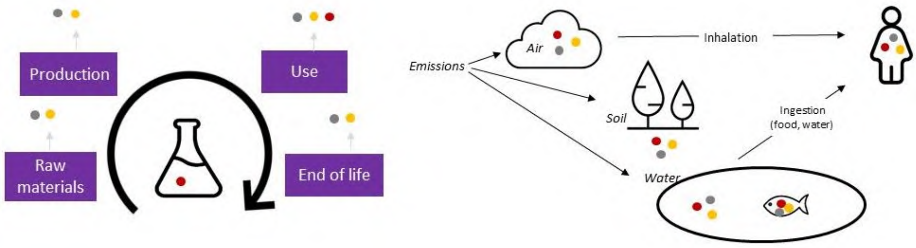


Figure 2: Illustration of the safety and sustainability aspects of the chemical or material covered by the safety and sustainability assessment. Coloured boxes indicate which life cycle stage is covered. The red dot refers to the chemical or material being assessed, while the yellow and grey dots refer to all the other substances emitted during its life cycle (e.g., other toxic chemicals emitted during the extraction of raw material or as a result of the energy used in the production process).

4.1. Hazard assessment (Step 1)

In EU legislation on chemicals (REACH and CLP), chemical hazards are divided in human health hazards, environmental hazards and physical hazards. These hazards are further divided into hazard classes and categories, which are included in the assessment. The aim is to establish a set of SSbD criteria for the intrinsic properties of chemicals and materials that can have adverse effects on humans or the environment. It is based on the hazard classes and categories established in the CLP Regulation. The SSbD assessment is voluntary and linked to R&I activities. Its scope may therefore be broader than the data these Regulations cover. The three main hazard categories are:

1. intrinsic hazardous properties relevant to human health (human health hazards)
2. intrinsic hazardous properties relevant to the environment (environmental hazards)
3. hazard physical properties (physical hazards).

The SSbD classification of the hazardous properties is closely linked to relevant EC initiatives, such as the Chemicals Strategy for Sustainability[8], the proposal for a regulation regarding sustainable products[9] or the EU sustainable finance[10]. The classification criteria for substances and mixtures established by the CLP Regulation need to be consulted for any detailed information on the assessment methods.

The test methods Regulation[11] lays down the test methods to use for generating data for hazard assessment, and the methods are to a large extent based on the OECD Guidelines for the Testing of Chemicals[12], which are one of the main tools for globally assessing the potential adverse effects of chemicals on human health and the environment. Additionally, methods recommended for assessing the hazardous properties are included in the ECHA's Guidance on the Application of the CLP Criteria[13], which supports the CLP criteria for hazard properties. Further support on assessment methods is available in the European Chemical Agency's (ECHA's) Guidance on Information Requirements and Chemical Safety Assessment[14], that describes the information requirements and how to fulfil them in accordance with the REACH Regulation. Classification for SSbD assessment can already consider further hazard classes like: persistent, bioaccumulative and toxic (PBT), very persistent very bioaccumulative (vPvB), persistent, mobile and toxic (PMT), very persistent very mobile (vPvM), endocrine disruption. Even if those hazard classes are not yet in place under CLP, draft criteria under development could already be applied.

For the assessment of aspects in Table 2[15], a tiered approach is proposed depending on the data availability. As the information available for new developed chemicals or materials could be limited at the beginning of the process, a tiered approach is beneficial to be able to characterise hazards as early as possible at the innovation stage (i.e. during the design of the chemical or material) by using, for example, new approach methodologies (NAMs) to generate data and knowledge. A tiered approach makes it possible to identify suspected hazardous chemicals or materials early on the innovation process, and take informed decisions (e.g., further assess the hazard, screen out the substance, request more data through the life cycle of the chemical or material in question). High-throughput screening, computer-based models, read-across and other alternative approaches should initially be used so that only the most promising candidates (less hazardous chemicals or materials) are tested at higher tiers in accordance with the regulatory requirements for chemicals to be placed on the market. If the assessment is performed on an existing chemical (e.g., already on the market), NAMs could be used to fill-in any data gaps needed to fulfil the information requirements for the aspects mentioned in Table 2. A screening of available academic data should also be done before deciding on the need for additional studies, in particular those involving laboratory animals.

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8 COM(2020) 667 final

9 COM(2022) 142 final

10 Technical Working Group, Part B-Annex: Technical Screening Criteria, March 2022. https://wwfeu.awsassets.panda.org/downloads/220330_sustainable_finance_platform_finance_report_remaining_environmental_objectives.pdf

11 Council Regulation (EC) No 440/2008

12 https://www.oecd.org/chemicalsafety/testing/

13 https://echa.europa.eu/guidance-documents/guidance-on-clp

14 https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

15 Table 2 will be revised after the testing period.

Table 2: List of aspects (hazardous properties) relevant for Step 1

Group definition	Human health hazards	Environmental hazards	Physical hazards
Group A: Includes the most harmful substances (according to the Chemicals Strategy for Sustainability), including substances of very high concern (SVHC) (i.e., substances meeting the criteria laid down in REACH Art. 57(a-f) and identified in accordance with REACH Art. 59(1)[16],[17]	• 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)[18] • Endocrine disruption Cat. 1 (environment)	
Group B: Includes substances of concern, as described in the Chemicals Strategy for Sustainability and defined in Article 2(28) of the ecodesign proposal for sustainable products[19], but not included in Group A	• 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)	• Hazardous for the ozone layer • Chronic environmental toxicity (chronic aquatic toxicity) • Endocrine disruption Cat. 2 (environment)	

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16 Article 57(a) of the REACH Regulation – carcinogenic category 1A or 1B; Article 57(b) of the REACH Regulation – mutagenic category 1A or 1B; Article 57(c) of the REACH Regulation – toxic for reproduction category 1A or 1B; Article 57(d) of the REACH Regulation – persistent, bioaccumulative and toxic (PBT); Article 57(e) of the REACH Regulation – very persistent and very bioaccumulative (vPvB); Article 57(f) of the REACH Regulation – equivalent level of concern with probable serious effects on human health (and/or) the environment.

17 Some substances with other hazardous properties (e.g. STOT RE) may be classified as substances of very high concern because of their ‘equivalent level of concern’ (see Article 57 (f) of the REACH Regulation).

18 The inclusion of all PMT and vPvM in the subgroup of most harmful substances will be subject to further assessment.

19 Proposal for a Regulation establishing a framework for setting ecodesign requirements for sustainable products (COM(2022 142 final)) Article 2(28) - ‘Substance of concern’ means a substance that:
(a) meets the criteria in Article 57, and is identified in accordance with Article 59(1), of the REACH Regulation; or
(b) is classified in Part 3 of Annex VI to the CLP Regulation in one of the following hazard types or hazard categories:

	Cat. 2 • Specific target organ toxicity - single exposure (STOT-SE) Cat. 1 and 2 • Endocrine disruption Cat. 2 (human health)		
Group C: Includes the other hazard classes not in Groups A or B	• 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 • Oxidising gases, liquids, solids • Gases under pressure • Self-reactive • Pyrophoric liquids, solids • Self-heating • In contact with water emits flammable gas • Organic peroxides • Corrosivity • Desensitised explosives

– carcinogenicity categories 1 and 2,
– germ cell mutagenicity categories 1 and 2,
– reproductive toxicity categories 1 and 2,
– respiratory sensitisation category 1,
– skin sensitisation category 1,
– chronic hazard for the aquatic environment categories 1 to 4,
– hazardous for the ozone layer,
– specific target organ toxicity – repeated exposure categories 1 and 2,
– specific target organ toxicity – single exposure categories 1 and 2; or
(c) negatively affects the reuse and recycling of materials in the product in which it is present.

4.2. Human health and safety aspects of production and processing (Step 2)

The aspects included in this step are related to occupational health and safety during the production and processing of a chemical or material. The risk should be estimated as a combination of the chemical or material hazards, exposure during the different processes and the risk management measures in place.

For this part of the assessment, it is important to identify all the production and processing steps, the substances used in each of them (e.g., raw chemicals or materials, processing aids), the substances that may be produced during the processes (volatile organic compounds, by-products, etc.), and identify their hazards and risks for workers. The operational conditions (how the substance is used in the process, whether its processing is closed/open, its concentration in a preparation) together with the release potential (volatility, dustiness, fugacity, temperature, pressure), and the risk management measures in place (e.g., local exhaust ventilation) will determine the likelihood of workers' exposure and the potential exposure route (inhalation, dermal, oral ingestion).

As in Step 1, a tiered approach can be applied, depending on data availability.

There are various qualitative/simplified models available (also known as control-banding models) for assessing safety and managing risks at the workplace. These models are designed to characterise risk at the workplace using a tier 1 approach, when the whole set of data required to perform a quantitative assessment is not available. The models are based on assigning scores or levels to some of the following variables to be considered during the characterisation of risk:

- hazards of chemicals
- frequency and duration of exposure
- amount of the chemical or material in question that is used or present
- physical properties of the chemical or material in question, such as volatility or dustiness
- operational conditions
- type of risk management measures in place

There are two types of models: models that estimate the potential risk of exposure (they do not include the preventive measures taken as an input variable) and models that estimate the expected risk of exposure (they estimate the final risk, considering the preventive measures implemented, if any).

The result is a categorisation into different risk levels, to determine if the risk is acceptable and, if needed, the types of preventive measures to be applied.

Among the recommended assessment tools for Step 2 is the tiered targeted risk assessment (TRA) tool developed by the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC). ECETOC TRA[20], developed to facilitate the registration of chemicals in accordance with the REACH Regulation, and widely used by industry and known by small and medium-sized enterprises. To use this tool, it is recommended to apply ECHA guidance (Chapter R12 Use description[21]) to define the use of the chemical or material in question at the different stages, since the tool uses this guidance as a reference. Other models and tools

20 ECETOC's TRA tool: https://www.ecetoc.org/tools/tra-main/

21 https://echa.europa.eu/documents/10162/17224/information_requirements_r12_en.pdf

are also available, e.g., Chesar[22] (also relevant for Step 3 where more details are provided), the International Labour Organization (ILO) model[23], the German Hazardous Substances Column Model, supported by the 'Easy-to-use Workplace Control Scheme for Hazardous Substances' (EMKG) tool[24], the INRS model[25]; the Dutch Stoffenmanager model[26], or the Belgian REGETOX model[27].

Examples of relevant aspects and indicators to be assessed in Step 2 are listed in Table 3. They are adapted from the German Hazardous Substances Column Model developed by the Institute for Occupational Safety and Health of the German Social Accident Insurance Body[28]. For the case of chronic human health hazards, they are linked to the grouping of hazard classes in Step 1. The Column Model has been developed primarily to support the substitution assessment of hazardous substances, but the approach could be adapted for other purposes and by using the same information.

22 Chemical safety assessment and reporting tool, https://chesar.echa.europa.eu/home

23 ILO – International Chemical Control Toolkit, https://www.ilo.org/legacy/english/protection/safework/ctrl_banding/toolkit/icct/

24 Easy-to-use Workplace Control Scheme for Hazardous Substances (EMKG), https://www.baua.de/EN/Topics/Work-design/Hazardous-substances/EMKG/Easy-to-use-workplace-control-scheme-EMKG_node.html

25 INRS model, https://www.inrs.fr/media.html?refINRS=ND%202233

26 Stoffenmanager, https://stoffenmanager.com/en/

27 *Réseau* de *Gestion* des *Risques Toxicologiques* (REGETOX 2000), http://www.regetox.med.ulg.ac.be/accueil_fr.htm

28 The GHS Column Model 2020 — An aid to substitute assessment, edited by Smola T., Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (IFA), https://www.dguv.de/ifa/praxishilfen/hazardous-substances/ghs-spaltenmodell-zur-substitutionspruefung/index.jsp

Table 3: Examples of aspects and indicators relevant for Step 2 adapted from the German Hazardous Substances Column Model.

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

Aspect	Sub-aspects and indicators				
	Acute human health hazards	Chronic human health hazards	Physical properties	Hazards from release behaviour	Processing-related risk contribution
High-risk process	• Acutely toxic substances or mixtures, Cat. 3 (H301, H311, H331) • Substances or mixtures that are toxic in contact with the eyes (EUH070) • Substances or mixtures that, in contact with water or acids, liberate toxic gases (EUH029, EUH031) • Substances or mixtures with specific target organ toxicity (single exposure), Cat. 1: Organ damage (H370) • Skin-sensitising substances or mixtures (H317, Sh) • Substances or mixtures that sensitise the respiratory organs (H334, Sa) • Substances or mixtures corrosive to the skin, Cat. 1, 1A (H314)	• Human hazards similar to Group B of Step 1	• Aerosols, Cat. 1 (H222 and H229) • Flammable liquids, Cat. 2 (H225) • Flammable solids, Cat. 1 (H228) • Self-reactive substances or mixtures, Types C and D (H242) • Organic peroxides, Types C and D (H242) • Self-heating substances or mixtures Cat. 1 (H251) • Substances or mixtures that, in contact with water, emit flammable gases, Cat. 2 (H261) • Oxidising gases, Cat. 1 (H270) • Oxidising liquids or solids, Cat. 2 (H272) • Desensitised explosives, Cat. 1 (H206) and Cat. 2 (H207) • Substances or mixtures with certain properties (EUH001, EUH014, EUH018, EUH019, EUH044)	• Liquids with a vapour pressure of 50-250 hPa (mbar)	• Partially open design, processing-related opening with simple extraction, open with simple extraction

Aspect	Sub-aspects and indicators				
	Acute human health hazards	**Chronic human health hazards**	**Physical properties**	**Hazards from release behaviour**	**Processing-related risk contribution**
Medium-risk process	• Acutely toxic substances or mixtures, Cat. 4 (H302, H312, H332) • Substances or mixtures with specific target organ toxicity (single exposure), Cat. 2: Possible organ damage (H371) • Substances or mixtures corrosive to the skin, Cat. 1B, 1C (H314) • Eye-damaging substances or mixtures (H318) • Substances or mixtures that have a corrosive effect on respiratory organs (EUH071) • Non-toxic gases that can cause suffocation by displacing air (e.g. nitrogen)	• Human hazards similar to Group C of Step 1, except those listed under 'acute human health hazards' (left column).	• Aerosols, Cat. 2 (H223 and H229) • Flammable liquids, Cat. 3 (H226) • Flammable solids, Cat. 2 (H228) • Self-reactive substances or mixtures, Types E and F (H242) • Organic peroxides, Types E and F (H242) • Self-heating substances or mixtures, Cat. 2 (H252) • Substances or mixtures that, in contact with water, emit flammable gases, Cat. 3 (H261) • Oxidising liquids or solids, Cat. 3 (H272) • Gases under pressure (H280, H281) • Corrosive to metals (H290) • Desensitised explosives, Cat. 3 (H207) and Cat. 4 (H208)	• Liquids with a vapour pressure of 10-50 hPa (mbar), with the exception of water	• Closed processing with possibilities of exposure, e.g. during filling, sampling or cleaning • Closed design, tightness not ensured, partially open design with effective extraction
Low-risk process	• Skin-irritant substances or mixtures (H315) • Eye-irritant substances or	• Substances chronically harmful in other ways (no H-phrase)*	• Aerosols, Cat. 3 (H229 without H222, H223) • Not readily flammable substances or mixtures (flash point > 60 ... 100 °C, no H-	• Liquids with a vapour pressure 2 - 10 hPa (mbar)	• Closed design, tightness ensured, partially closed design with integrated

Aspect	Sub-aspects and indicators				
	Acute human health hazards	**Chronic human health hazards**	**Physical properties**	**Hazards from release behaviour**	**Processing-related risk contribution**
	mixtures (H319) • Skin damage when working in moisture • Substances or mixtures with a risk of aspiration (H304) • Skin-damaging substances or mixtures (EUH066) • Substances or mixtures with specific target organ toxicity (single exposure), Cat. 3: irritation of the respiratory organs (H335) • Substances or mixtures with specific target organ toxicity (single exposure), Cat. 3: drowsiness, dizziness (H336)		phrase) • Self-reactive substances/mixtures, Type G (no H-phrase) • Organic peroxides, Type G (no H-phrase)		extraction, partially open design with highly effective extraction
Negligible risk	Substances of no concern regarding intrinsic hazardous properties, according to Step 1 (i.e., not classified in groups A, B or C)			• Liquids with a vapour pressure < 2 hPa (mbar) • Non-dust-generating solids	

4.3. Human health and environmental aspects of the final application (Step 3)

This step assesses the human health and environmental impacts of the application of the chemical or material in question. As in Step 2, the conditions of use will determine the likelihood of exposure to the chemical or material as well as the potential exposure routes (all relevant pathways) and the related toxicity impacts on human health, including service-life exposure, and the environment (e.g., from wash-off uses, such as shampoo ending up in wastewater treatment plant effluents).

The risk is characterised as a combination of the chemical or material hazards and the assessment of the estimated exposure of human health and the environment to the hazards during the application of the chemical or material in question.

Information on the chemical's or the material's intrinsic properties are necessary for the safety assessment, and mainly covers the same hazard properties as considered in Step 1: physical hazards, environmental hazards and human health hazards.

Information about other physico-chemical properties is also needed to identify the fate of the chemical or material in question, estimate the exposure and identify the exposure pathway(s) and characterise risk (e.g., properties such as the chemical's or material's physical form and vapour pressure relevant for human health, or water solubility and the octanol water partition coefficient (Log K_{ow}) relevant for the environment).

To estimate exposure, it is particularly important to identify/describe the application of the chemical or material in question and define the use conditions by providing information on frequency and duration of exposure, the amount of the chemical or material used or present in the application, the conditions of use of the chemical or material and the instructions for its use. If the chemical or material has several possible uses, ideally the different exposure routes should be considered.

As in previous steps, the approach might be optimised depending on whether a new or existing chemical or material is being assessed, and on what data are available.

As in Step 2, it is recommended to apply ECHA guidance (Chapter R12 Use description[21]) as a starting point to define the use of the chemical or material in question in this step. R12 guidance provides lists of product categories and article categories and many available exposure estimation tools, such as ECETOC TRA[20], use these description categories as input for assessing exposure and safety.

The chemical safety assessment and reporting tool (Chesar)[22] is another tool recommended for the safety assessment of the chemical/material. The tool was developed by ECHA for assisting companies in producing chemical safety reports (CSR) and exposure scenarios (ES) in a structured, harmonised, transparent and efficient way. This includes reporting the substance-related data (relevant phys-chem, fate and hazard data), describing the uses of the substance, carrying out exposure assessment including identifying conditions of safe use, related exposure estimates and demonstrating control of risks. For carrying out the exposure assessment, a number of exposure estimation tools are included in Chesar: the ECETOC TRA tool for workers' and for consumers' exposure estimation, as well as EUSES for environmental exposure estimation. Those tools require as input the expected conditions of use. Use maps, developed by industry sectors, collect information on the uses and the conditions of use of chemicals in their sector in a harmonised and structured way. They contain the input parameters for workers' exposure assessment (SWEDs), for consumers' exposure assessment (SCEDs) and for environmental exposure assessment (SPERCs). The existing use maps are available in Chesar format at https://www.echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library. It is also possible to document in Chesar the exposure estimates obtained from other tools or measured exposure data. Some tools, such as ConsExpo[29], can directly export their outputs to Chesar.

As in Step 2, tools from higher tiers (e.g., ConsExpo[29]) or sector specific tools developed by industry for assessing specific product types and articles, can also be used if the data are available to do so.

4.4. Environmental sustainability assessment (Step 4)

This step covers the assessment of the environmental sustainability aspects of the chemical or material in question, focusing on its environmental impacts throughout the value chain.

To assess the environmental sustainability of the chemical or material in question, a function-based LCA, covering the entire life cycle, must be done. If the new chemical or material has several possible uses, or if it can be produced by means of several production routes, different LCAs must be done considering each production, use and its end of life. Ideally, the LCA studies of the different uses of the chemical or material should be conducted following the same modelling principles to ensure harmonisation and allow comparison of results. It is therefore recommended, whenever possible, to use the product environmental footprint method[30] as a guiding document for doing the LCA.

The environmental footprint impact assessment method is recommended to be used to assess the life cycle environmental performance of products[30]. It consists of a minimum set of impacts to assess. Other aspects, not yet fully covered by current LCA practices, might need to be assessed on a case-by-case basis using possible indicators that could be developed for the purpose.

Given that existing environmental impacts go beyond those the environmental footprint method covers, there could be the possibility of adding other impacts in the future.

The underlying models and characterisation factors for the environmental footprint method, available at https://eplca.jrc.ec.europa.eu/LCDN/developerEF.xhtml, should be applied in accordance with the latest environmental footprint package available. The aspects taken into consideration, the indicators and methods in place at the date of the publication of this recommendation are listed in Table 5, which should be regarded solely as an example, given that recommended methods are constantly evolving.

29 https://www.rivm.nl/en/consexpo
30 C (2021) 9332 final

Table 5: Aspects, indicators and methods for the environmental footprint method for Step 4

LCA assessment level/aspects	**Sub-aspect**	**Indicator and unit**	**Recommended default LCIA method**
Toxicity	Human toxicity, cancer effects	Comparative Toxic Unit for humans (CTU_h)	based on USEtox2.1 model (Fantke et al., 2017[31]) adapted as in (Saouter et al., 2018[32])
	Human toxicity, non-cancer effects	Comparative Toxic Unit for humans (CTU_h)	Based on USEtox2.1 model (Fantke et al., 2017[31]), adapted as in Saouter et al., 2018[32]
	Ecotoxicity freshwater	Comparative Toxic Unit for ecosystems (CTU_e)	Based on USEtox2.1 model (Fantke et al., 2017[31]), adapted as in Saouter et al., 2018[32]
Climate change	Climate change	Global warming potential (GWP100, kg CO_2 eq)	Bern model – Global warming potential (GWP) over a 100-year time horizon (based on IPCC, 2013[33])
Pollution	Ozone depletion	Ozone depletion potential (ODP) (kg CFC-11eq)	EDIP model based on the ODPs of the World Meteorological Organization (WMO) over an infinite time horizon (WMO, 2014[34]+ integrations)
	Particulate matter/respiratory inorganics	Human health effects associated with exposure to $PM_{2.5}$ (Disease incidences[35])	PM model (Fantke et al., 2016[36]) in UNEP, 2016[37]
	Ionising radiation, human health	Human exposure to U^{235} (kBq U^{235})	Human health effect model as developed by Dreicer et al., 1995 (Frischknecht et al, 2000[38])

31 USEtox®2.0 Documentation (Version 1), http://usetox.org. https://doi.org/10.11581/DTU:00000011

32 Using REACH and *the* EFSA database to derive input data for the USEtox model, EUR 29495 EN, Publications Office of the European Union, Luxemburg, 2018, ISBN 978-92-79-98183-8, Joint Research Centre (JRC) 114227, https://doi.org/10.2760/611799

33 Anthropogenic and Natural Radiative Forcing. In: Climate change 2013: The Physical Science Basis. Contribution of Working Group I to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change. T.F. Stocker, D. Qin, G.-K. Plattner, M. Tignor, S.K. Allen, J. Doschung, A. Nauels, Y. Xia, V. Bex, and P.M. Midgley, Eds. Cambridge University Press, pp. 659-740, doi:10.1017/CBO9781107415324.018

34 Scientific Assessment of Ozone Depletion: 2014, Global Ozone Research and Monitoring Project Report No. 55, Geneva, Switzerland. Retrieved from https://csl.noaa.gov/assessments/ozone/2014/preface.html

35 The name of the unit has been changed from ‘Deaths’ in the original source (UNEP, 2016) to ‘Disease incidences’.

36 Health impacts of fine particulate matter. In: Frischknecht, R., Jolliet, O. (Eds.), Global Guidance for Life Cycle Impact Assessment Indicators: Volume 1. UNEP/SETAC Life Cycle Initiative, Paris, 76–99. Retrieved from www.lifecycleinitiative.org/applying-lca/lcia-cf/

37 Global guidance for life cycle impact assessment indicators*:* Volume 1, ISBN: 978-92-807-3630-4. Retrieved from https://www.ecocostsvalue.com/EVR/img/references%20others/global-guidance-lcia-v.1-1.pdf

LCA assessment level/aspects	Sub-aspect	Indicator and unit	Recommended default LCIA method
	Photochemical ozone formation	Tropospheric ozone concentration increase (kg NMVOC eq)	LOTOS-EUROS (Van Zelm et al., 2008[39]) as applied in ReCiPe 2008
	Acidification	Accumulated exceedance (mol H^+ eq)	Accumulated exceedance (Posch et al., 2008[40]; Seppälä et al., 2006[41])
	Eutrophication, terrestrial	Accumulated exceedance (mol N eq)	Accumulated exceedance (Seppälä et al., 2006[41], Posch et al., 2008[40])
	Eutrophication, aquatic freshwater	Fraction of nutrients reaching freshwater end compartment (P, kg P eq)	EUTREND model (Struijs, et al. 2009[42]) as implemented in ReCiPe 2008
	Eutrophication, aquatic marine	Fraction of nutrients reaching marine end compartment (N, kg N eq)	EUTREND model (Struijs et al., 2009[42]) as implemented in ReCiPe 2008
Resources	Land use	Soil quality index[43] (Biotic production, erosion resistance, mechanical filtration and groundwater replenishment), dimensionless	Soil quality index based on the LANCA model (De Laurentiis et al., 2019[44]) and on the LANCA CF version 2.5 (Horn & Maier, 2018[45])

38 Human health damages due to ionising radiation in life cycle impact assessment. Environmental Impact Assessment Review. https://doi.org/10.1016/S0195-9255(99)00042-6

39 'European characterisation factors for damage to human health caused by PM10 and ozone in life cycle impact assessment', Atmospheric Environment 42, pp. 441-453. https://doi.org/10.1016/j.atmosenv.2007.09.072

40 'The role of atmospheric dispersion models and ecosystem sensitivity in the determination of characterisation factors for acidifying and eutrophying emissions in LCIA', The International Journal of Life Cycle Assessment, 13, pp. 477-486, https://doi.org/10.1007/s11367-008-0025-9

41 'Country-dependent Characterisation Factors for Acidification and Terrestrial Eutrophication Based on Accumulated Exceedance as an Impact Category Indicator', The International Journal of Life Cycle Assessment 11(6), pp. 403-416, https://doi.org/10.1065/lca2005.06.215

42 Aquatic Eutrophication. Chapter 6 in: Goedkoop, M., Heijungs, R., Huijbregts, M.A.J., De Schryver, A., Struijs, J., Van Zelm, R. (2009). ReCiPe 2008.A Life Cycle Impact Assessment Method Which Comprises Harmonised Category Indicators at the Midpoint and the Endpoint Level. Report I: Characterisation Factors, First Edition

43 This index is the result of the aggregation by the JRC of the 4 indicators provided by the LANCA model for assessing impacts due to land use as reported in De Laurentiis et al., (2019)

44 'Soil quality index: Exploring options for a comprehensive assessment of land use impacts in LCA', Journal of Cleaner Production, 215, pp. 63-74, https://doi.org/10.1016/j.jclepro.2018.12.238

45 LANCA®- Characterization Factors for Life Cycle Impact Assessment, Version 2.5 November 2018. Retrieved from http://publica.fraunhofer.de/documents/N-379310.html

LCA assessment level/aspects	Sub-aspect	Indicator and unit	Recommended default LCIA method
	Water use	User deprivation potential (deprivation-weighted water consumption, m3 water eq. of deprived water)	Available WAter REmaining (AWARE) model (Boulay et al., 2018[46]; UNEP, 2016[37])
	Resource use, minerals and metals	Abiotic resource depletion (ADP ultimate reserves, kg Sb eq)	CML (Guinée et al., 2002[47]) and (Van Oers et al. 2002[48])
	Resource use, energy carriers	Abiotic resource depletion – fossil fuels (ADP-fossil, MJ)[49]	CML (Guinée et al., 2002[47]) and (Van Oers et al., 2002[48])

46 'The WULCA consensus characterization model for water scarcity footprints: assessing impacts of water consumption based on available water remaining (AWARE)', The International Journal of Life Cycle Assessment 23(2), pp. 368-378, https://doi.org/10.1007/s11367-017-1333-8

47 'Handbook on Life Cycle Assessment: Operational Guide to the ISO Standards', Series: Eco-efficiency in industry and science, Kluwer Academic Publishers, Dordrecht: https://doi.org/10.1007/BF02978897

48 Abiotic Resource Depletion in LCA. Road and Hydraulic Engineering Institute, Ministry of Transport and Water, Amsterdam

49 In the ILCD flow list, and for this recommendation, uranium is included in the list of energy carriers. It is measured in MJ.

5. ASSESSMENT PROCEDURE AND REPORTING

The application of the SSbD framework to a chemical or material will provide three outputs:

1. adherence to SSbD principles during the (re)design stage;
2. a safety and sustainability assessment;
3. the dashboard summarising the results.

Not all current aspects and indicators have thresholds associated (these are mainly in place for regulatory safety aspects). This means that, for aspects and indicators without thresholds, the criteria are not complete. In such cases, a pragmatic approach in the testing is to compare the chemical/material under assessment with the chemical(s) or material(s) that might be replaced, in line with what is currently done using alternative assessment methods. In case of new chemicals or materials the comparison should be based on functionality. This approach will lead to relative improvements, based on the performance of the chemical(s) or material(s) compared.

Templates for presenting the results will be made available online by the Commission, including a proposal for their graphic visualisation.

For **Step 1** of the safety and sustainability assessment, four assessment levels are envisaged.

- Level 0 – chemicals or materials in criteria group A (e.g., considered most harmful substances, including SVHC).
- Level 1 – chemicals or materials in criteria group B (e.g., having chronic human health or environmental effects, substances of concern not included in group A).
- Level 2 – chemicals or materials in criteria group C (e.g., having other hazardous properties).
- Level 3 – chemicals or materials not in any of the hazard categories listed in the previous criteria groups. For these, it should be borne in mind that the chemical or material in question could still be harmful in certain applications from a risk perspective that goes beyond generic hazard criteria and involves the consideration of application-specific exposure settings.

The aspects listed in groups A, B and C (Table 2) are hierarchical, meaning that they need to be assessed one after the other, and the next aspect-related criterion will only be assessed if the previous one has been fulfilled.

If there is evidence that the chemical or material in question possesses one of the hazardous properties included in the group of hazardous properties being assessed, there is, for the SSbD assessment, no need to gather information on the other properties in the same group. This aims to simplify the assessment and make it easier to gather data and to eliminate problematic chemicals or materials faster, early in the research and development process. However, to proceed to assessing the next criterion, evidence on all aspects of the same set of criteria needs to be provided.

For **Steps 2, 3 and 4** of the safety and sustainability assessment it is recommended to report the complete assessment for the case analysed, indicating what methods have been used. It is also recommended to benchmark the results of the steps with the chemical or material that is being replaced, to see if there is an improvement (comparative assessment). The final SSbD report should include an analysis of the results obtained in Steps 2, 3 and 4 and identify the aspects and indicators with the highest impact on safety and sustainability. Criteria for Steps

2, 3 and 4 are to be defined case-by-case on the basis of the results obtained, as not all chemicals and materials will require the same safety and sustainability measures.

6. OVERVIEW OF DATA SOURCES TO SUPPORT THE SAFETY AND SUSTAINABILITY ASSESSMENT

As a starting point and in addition to the tools mentioned in the description of Steps 1-4, sources such as the ECHA's Information on Chemicals[50] (including C&L Inventory[51] and EUCLEF[52]), the European Food Safety Authority's (EFSA's) Chemical Hazards Database (OpenFoodTox)[53], the Organisation for Economic Cooperation and Development's (OECD's) eChemPortal[54], the United States of America Environmental Protection Agency's (EPA's) CompTox[55], can be screened first, especially for information on the hazardous properties of existing chemicals.

For the environmental footprint, Life Cycle Inventory (LCI) datasets are available on the European Platform for Life Cycle Assessment[56], created and managed by the Commission. If available, environmental footprint-compliant datasets should be used. A large platform for searching for data across different databases is the Global LCA Data Access Network[57]. It also provides tools for harmonising datasets from different sources.

For modelling the end-of-life scenario, the variety of data needed depending on the chemical or material being assessed makes it difficult to pinpoint specific data sources. A recommended source for general end-of-life statistics is the EUROSTAT database[58], which provides data on waste management in Europe. Additional useful information is published by trade associations of producers that often release studies and statistics on their own sector's sustainability.

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50 ECHA Information on Chemicals: https://echa.europa.eu/information-on-chemicals
51 https://echa.europa.eu/information-on-chemicals/cl-inventory-database
52 https://echa.europa.eu/legislation-finder
53 EFSA Chemical Hazards Database (OpenFoodTox): https://www.efsa.europa.eu/en/microstrategy/openfoodtox
54 OECD eChemPortal: https://www.echemportal.org/echemportal/
55 US EPA CompTox Chemicals Dashboard: https://comptox.epa.gov/dashboard/
56 European Platform on Life Cycle Assessment. https://eplca.jrc.ec.europa.eu/LCDN/contactListEF.xhtml
57 Global LCA Data Access Network: https://www.globallcadataaccess.org/
58 https://ec.europa.eu/eurostat/web/main/data/database