



European  
Commission

Mapping study for  
the development of

# Sustainable-by-Design criteria



Research and  
Innovation

## Mapping study for the development of Sustainable-by-Design criteria

European Commission  
Directorate-General for Research and Innovation  
Directorate E – Prosperity  
Unit E3 – Industrial Transformation

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# Mapping study for the development of Sustainable-by-Design criteria

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## LIST OF ABBREVIATIONS

BOM	Bill of Materials
BPR	Biocidal products Regulation
CalEPA	California Environmental Protection Agency
CAS	Chemical Abstracts Service
CEAP	Circular economy action plan
CLP	Classification, labelling and packaging (Regulation EC No 1272/2008)
DfE	Design for the Environment
DG ENV	Directorate-General for Environment
DG GROW	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
DG RTD	Directorate-General for Research and Innovation
EC	European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EMAS	Environmental Management Accounting System
EoL	End-of-life
ErP	Energy-related products
EU	European Union
FSC	Forest Stewardship Council
GCI	Green claims initiative
GDS	Guideline documents
GPP	Green public procurement
ICT	Information and communications technology
ILO	International Labour Organisation
ISC	Inter-service consultation
ISC3	International Sustainable Chemistry Collaborative Centre
JRC	European Commission's Joint Research Centre
LCA	Life cycle assessment
MEErP	Methodology for ecodesign of energy-related products
MNMs	Multi-component nanomaterials
NEP	Nano-engineered product
NGO	Non-governmental organisation
NM	Nanomaterial
NMEG	ECHA's Nanomaterials Expert Group
NOP	National Organic Programme
OECD	Organisation for Economic Cooperation and Development
OITBs	Open Innovation Test Beds
PEFC	Programme for the Endorsement of Forest Certification Schemes
PEF	Product Environmental Footprint
PEFCR	Product Environmental Footprint Category Rules
PVC	Polyvinyl chloride

QSARs	Quantitative structure–activity relationship model
R&I	Research and innovation
RA	Risk assessments
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RIA	Research and innovation action
RM	Risk management
RoHS	Restriction of hazardous substances
SEA	Socioeconomic assessment
SIA	Safe(r) innovation approach
SMEs	Small and medium enterprises
SVHC	Substance of very high concern
TGs	Test guidelines
UNEA	United Nations Environment Assembly
UVCB	Unknown, variable composition, complex products or biological materials
VOC	Volatile organic compounds
WTO	World Trade Organization

## 1. Introduction

With the European Green Deal<sup>1</sup>, the European Commission aims to transform the European Union's (EU) economy for a more sustainable future and to implement the United Nations 2030 Agenda and the sustainable development goals (SDGs). These include public health and environmental safety as an integral element of sustainable development, which was defined in 1987 as "meeting the needs of the present without compromising the ability of future generations to meet their own needs"<sup>2</sup>. At present, however, the concept of sustainability is not so well defined. New policy proposals seek to gradually bring clarity to the definition of sustainability.

To accomplish the Green Deal goals, the EU's new action plan for the circular economy (CEAP)<sup>3</sup> and the European industrial strategy<sup>4</sup> proposed a number of industrial, environmental, climate and energy priorities. The Commission has also set a goal to better protect public health and the environment as part of an ambitious approach to tackle pollution from all sources and move towards a toxic-free environment<sup>5</sup>. To achieve these objectives, the chemicals strategy for sustainability<sup>6</sup> calls for a new, safe and sustainable-by-design approach to chemicals. To align these policy goals, a holistic approach is needed, in which the aims to achieve a high protection of public health and the environment, industrial relevance, societal empowerment and regulatory preparedness translate into well-defined criteria for safe and sustainable products and services. The 'sustainable-by-design' concept takes a holistic approach by integrating safety, circularity, energy efficiency and functionality of chemicals, materials, products, and processes throughout their life cycle and minimising the environmental footprint. It aims to facilitate the transition to a safe, carbon-neutral and resource-efficient industrial ecosystem.

The purpose of this study is to provide input into the process to develop a framework for sustainable-by-design that will guide definition of a set of criteria to increase the safety and sustainability of chemicals, materials and products. The sustainable-by-design concept is seen as an overarching concept that encompasses safety as an integral component of sustainability. The long-term ambition of DG RTD is to apply this concept as a guiding principle along the entire development chains in key sectors of the economy (e.g. agriculture, manufacturing, transport).

One important area in which this approach can be applied is the chemicals sector. The main aim is to prevent negative impacts on public health and the environment by addressing safety and sustainability considerations very early in the product development process. To this end, the concept of safe and sustainable-by-design chemicals was included and mainstreamed in the chemicals strategy for sustainability. Thus, the transition to safe and sustainable-by-design chemicals, materials and products in the chemicals sector is a demonstration of systemic solutions to roll out the sustainable-by-design approach.

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<sup>1</sup> [https://ec.europa.eu/info/publications/communication-european-green-deal\\_en](https://ec.europa.eu/info/publications/communication-european-green-deal_en)

<sup>2</sup> United Nations General Assembly. (1987). Report of the world commission on environment and development: Our common future. Oslo, Norway: United Nations General Assembly, Development and International Cooperation: Environment.

<sup>3</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52015DC0614&locale=en>

<sup>4</sup> [https://ec.europa.eu/info/sites/info/files/communication-eu-industrial-strategy-march-2020\\_en.pdf](https://ec.europa.eu/info/sites/info/files/communication-eu-industrial-strategy-march-2020_en.pdf)

<sup>5</sup> [https://ec.europa.eu/environment/strategy-offline/zero-pollution-action-plan\\_en](https://ec.europa.eu/environment/strategy-offline/zero-pollution-action-plan_en)

<sup>6</sup> [https://ec.europa.eu/environment/strategy-offline/chemicals-strategy\\_en](https://ec.europa.eu/environment/strategy-offline/chemicals-strategy_en)



This study carried out by DG RTD aims to:

- map current policies and initiatives that implement sustainability criteria (Chapter 3);
- analyse a sample of criteria under these policies and initiatives with a focus on materials and chemicals (Chapter 4);
- analyse progress in R&I (Chapter 5).

The analysis and findings of this study will serve as input into the framework for sustainable-by-design criteria, which will be developed over the course of 2021. With the European Green Deal, the action points listed in this introduction have led to a series of new policy initiatives. This study identifies these new initiatives (e.g. sustainable finance, the sustainable products initiative and the new regulation on sustainable batteries) and looks into current policy tools to achieve their aims (Ecodesign, EU Ecolabel and green public procurement).

To draw on the knowledge compiled in the frameworks and the tools developed by projects focusing on safe-by-design in the field of nanomaterials, this study includes a specific chapter collating input from: (1) the lessons learned in policy support on safe-by-design nanomaterials; (2) assessment methodologies; and (3) tools and frameworks developed.

## 2. Definitions

Before developing sustainable-by-design criteria, the terms ‘chemicals’, ‘materials’ and ‘products’ need to be fully clear. These terms are in common use and their meaning can differ depending on the context.

Since an important focus is on the group of chemicals as published under the chemical strategy for sustainability, the study looked into the definitions used in related legislation and by international organisations. The applicable legislation includes REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) (EC 1907/2006)<sup>7</sup>, the CLP Regulation (on classification, labelling and packaging) (EC 1272/2008)<sup>8</sup>, and RoHS (Restriction of the use of certain hazardous substances in electrical and electronic equipment, EC 2002/95)<sup>9</sup>. The relevant organisations are CAS<sup>10</sup> (Chemical Abstracts Service) registry number) and the IUPAC (International Union of Pure and Applied Chemistry). The most important piece of legislation on chemicals does not define the term ‘chemicals’. The words ‘substance’ and ‘mixture’ are the main terms used. The secondary legislation linked to REACH uses, in general, the REACH terminology.

Both REACH (Article 3)<sup>7</sup> and CLP (Article 2)<sup>8</sup> define these terms as:

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<sup>7</sup> European Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20200824&from=en>

<sup>8</sup> European Regulation on classification, labelling and packaging of chemical substances and mixtures. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1272-20201114&from=EN>

<sup>9</sup> European Regulation on Restriction of Hazardous Substances on electrical and electronic equipment.

<sup>10</sup> [www.cas.org/](http://www.cas.org/) (accessed on 09/02/2021)

***'Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.'***

***'Mixture: means a mixture or solution composed of two or more substances'***

To identify chemicals, the Chemical Abstracts Service (CAS), a division of the American Chemicals Society<sup>11</sup>, defined a chemical substance as follows:

*'Chemical substance is a chemical element and its compounds with constant composition and properties. It is defined by the CAS number.'*

It is important to note that the CAS number does not acknowledge the form of the substance. This is particularly relevant to nanoforms of substances.

IUPAC has a similar definition of a chemical substance:<sup>12</sup>

*'Chemical substance: matter of constant composition best characterized by the entities (molecules, formula units, atoms) it is composed of. Physical properties such as density, refractive index, electric conductivity, melting point etc. characterize the chemical substance.'*

Based on these definitions, for this study the commonly used term 'chemicals' means these substances (elements and compounds) and mixtures (using the definitions of both given in the REACH Regulation).

In addition to the chemicals sector, this study also looks at sustainable-by-design materials. The term 'material' is not defined in the REACH Regulation. For materials, the focus is on their functional properties relevant to the application when designing or assembling products. Therefore, the term 'material' covers more than substances or mixtures, as they are characterised according to their chemical and physical properties. A material may be a substance or a mixture but it is a broader concept than substances or mixtures.

Another relevant term is 'article', which is defined under REACH as follows:

***'Article: is an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition'***<sup>13</sup>

This term encompasses more than substances or mixtures. An interesting definition of the term 'material' that connects with the already mentioned REACH terms was found in a public report by Ökopol, prepared for the European Chemicals Agency (ECHA):<sup>14</sup>

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<sup>11</sup> <https://www.acs.org/content/acs/en.html> (accessed on 09/02/2021).

<sup>12</sup> <https://doi.org/10.1351/goldbook.C01039> (accessed on 09/03/2021).

<sup>13</sup> European Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20200824&from=en>.

<sup>14</sup> Feasibility of a materials' information platform (ECHA SR22BIS), by Ökopol, September 2015. [https://echa.europa.eu/documents/10162/13563/mip\\_public+report\\_en.pdf/4f7208b9-a45e-41be-9c82-c6b1838f971e](https://echa.europa.eu/documents/10162/13563/mip_public+report_en.pdf/4f7208b9-a45e-41be-9c82-c6b1838f971e)

***"The term 'material' is not defined under REACH. As a working definition the term 'material' is used [...] to denote either substances or mixtures which may or may not yet fulfil the definition of an article under REACH and may be of natural or synthetic origin."***

This study uses this working definition to distinguish between 'chemicals' (lacking the connection with 'article') and materials (with a connection to the concept of 'article'). This definition explicitly includes both substances/mixtures and articles. Taking into account the above definitions, the function of each 'material' will determine whether the material is also considered a chemical. ECHA provides guidance explaining the distinction between substance, mixture and article.<sup>15,16</sup>

For the definition of the term 'product', the General Product Safety Directive<sup>17</sup> provides a starting point with the following definition:

*"product' shall mean any product — including in the context of providing a service — which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned."*

In the context of this study, the above definition might be too broad: the aspect of 'providing a service' is not particularly relevant, since the focus of this study is on the physical goods, linked with chemicals and materials.

However, the aspect "intended for consumers, or likely to be used by consumers" is an important characteristic. This is also recognised in the description of 'products' in Article 2 of the EU Ecolabel Regulation<sup>18</sup>:

*"any goods or services which are supplied for distribution, consumption or use on the Community market whether in return for payment or free of charge (hereinafter 'products')."*

Again, the aspect of service is not considered applicable for this study, but it encompasses the aspect of availability for consumption and use.

To summarise, when referring to sustainable-by-design products, this study covers only the products that can also be identified as chemicals or materials (as defined above). Thus, the term 'product' in the sustainable-by-design context is used as part of the term 'chemical product' or 'material product', meaning chemicals and materials that are intended for consumers, or likely to be used by consumers. An example of a 'chemical product' is paint, and an example of a material product is 'impregnated wood'.

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<sup>15</sup> Guidance on requirements for substances in articles (June 2017, ECHA-17-G-19-EN) [https://echa.europa.eu/documents/10162/23036412/articles\\_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c](https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c)

<sup>16</sup> An example is the forms meant by the term 'aluminium': aluminium as a chemical element (metal) is regarded as a substance, an aluminium alloy can be a mixture or an article, depending on the form: an aluminium alloy ingot is a mixture, an aluminium sheet (for further processing) is an article, (p.79 of ECHA-17-G-19-EN). Another example is the material polyethylene. Polyethylene pellets (containing additives) are considered a polymer mixture, while polyethylene foils are an article, (p.86 of ECHA-17-G-19-EN).

<sup>17</sup> Directive 2001/95/EC on general product safety <https://eur-lex.europa.eu/eli/dir/2001/95/2010-01-01>.

<sup>18</sup> Regulation (EC) No 66/2010 on the EU Ecolabel, <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31999L0045>

**Table 1: Proposed definitions**

Term	Definition
Chemical	A substance or a mixture as defined under REACH.
Material	An article, substance or mixture as defined under REACH that may be either of natural or synthetic origin.
A chemical product or a material product	A chemical or material intended for consumers or that is likely under reasonably foreseeable conditions to be used by consumers.

### 3. Existing sustainability criteria initiatives

This section analyses current initiatives related to the development of sustainability criteria. The objective is to collect insights on the frameworks used to develop criteria, on how they are implemented and how they apply to chemicals, materials and products. The analysis is categorised into three groups: European Commission initiatives, European initiatives and non-European initiatives. Table 2 lists the initiatives identified and their scope. It describes only the most relevant initiatives, with further information on all the initiatives provided in Annex I.

**Table 2: Summary of initiatives analysed**

Title	Scope	Criteria areas covered		
		Environmental	Social	Safety
Ecodesign Directive (Table 10)	Energy-related products	yes	no	yes
Sustainable Products Initiative (Table 14)	All type of products	yes	yes	yes
Energy Label (Table 11)	Energy-related products	yes	no	yes
Sustainable Batteries (Table 14)	All batteries	yes	yes	yes
EU Ecolabel (Table 12)	Consumer products and services	yes	no	yes

EU GPP criteria (Table 13)	Products and services in public procurement	yes	no	yes
Sustainable finance (Table 16)	Financial products	yes	yes	no
TCO certified (Table 18)	IT products	yes	yes	yes
Nordic Swan (Table 19)	Consumer products or products for professional use	yes	no	no
Blue Angel (Table 20)	Consumer products	yes	no	no
NaturePlus Ecolabel (Table 21)	Building and accommodation products	yes	no	yes
OEKO-TEX (Table 22)	Textiles and leather	yes	no	yes
Bluesign (Table 23)	Textiles	yes	no	yes
Green Seal (Table 24)	Consumer products and services	yes	yes	no
GreenScreen for safer chemicals (Table 25)	Consumer products	yes	no	yes

### 3.1 European Commission initiatives

The Commission has adopted some sector- or product-specific pieces of legislation that define and implement sustainability criteria. These apply mainly to consumer products, and in some cases to services, as shown in Table 2. Depending on the nature of the legislation, application of the criteria can be either mandatory or voluntary. The criteria set out in several Commission initiatives are explained below.

The Ecodesign Directive (Directive 2009/125/EC) sets minimum requirements on energy efficiency during the use stage for energy-related products (ErP criteria are based on a self-declaration by the manufacturer/distributor and supervised by market surveillance authorities in the Member States. The Commission is working on expanding the scope of the Ecodesign Directive to cover more environmental impacts, the whole product life

cycle and also products other than ErPs, such as electronics, ICT<sup>19</sup>. This work is being carried out in the Sustainable Products Initiative under the CEAP<sup>19</sup> and a legislative proposal is planned for the end of 2021<sup>20</sup>.

The Energy Label Regulation, (EU) No 2017/1369<sup>13</sup>, sets out a harmonised framework for the labelling and provision of information on the consumption of energy during the use stage. The consumption of other essential resources can also be reported, as can other supplementary information. The Energy Label complements the Ecodesign Directive by enabling end users to choose more efficient products. It has seven efficiency classes ranging from A to G, with A being the most efficient.

In December 2020, the Commission published a new legislative proposal on sustainable batteries<sup>21</sup>. The legislation proposes mandatory requirements for all batteries (i.e. industrial, automotive, electric vehicle and portable) placed on the EU market. The list of requirements includes the use of responsibly sourced materials, restricted use of hazardous substances, a minimum content of recycled materials, carbon footprint, performance, durability, labelling, and collection and recycling targets. The carbon footprint requirement is based on the product environmental footprint category rules (PEFCR) for batteries<sup>22</sup>. New PEFCRs will be developed to cover the types of batteries under the scope of the regulation. The Product Environmental Footprint (PEF)<sup>23</sup> is a method to provide harmonised LCA rules for quantifying the relevant environmental impacts of products throughout their life cycle (either as 'goods' or as 'services').

The voluntary tools adopted by the European Commission include the EU Ecolabel (Regulation (EC) No 66/2010), EU green public procurement criteria (COM(2008) 400), the Environmental Management Accounting System (EMAS) (Regulation (EU) 2018/2066) and the new Regulation on Sustainable Finance (EU 2020/852). The EU Ecolabel is classified as a Type I ecolabel, which means that it follows ISO 14024:2018 (Environmental labels and declarations – Type I environmental labelling – Principles and procedures). All these tools have specific criteria for the products and services that they cover. They differ in the level of flexibility on compliance; for example under the EU Ecolabel rules, all criteria must be met in order to be awarded with the label, while the EU GPP gives the public entities flexibility to select the criteria that are most relevant to their needs, and proposes two ambition levels: core and comprehensive criteria.

A public consultation on the proposed Sustainable Finance Regulation (EU 2020/852) was published at the end of 2020. One of its goals is to make available financial products that pursue environmentally sustainable objectives. The legislation covers a range of economic activities, including manufacturing some materials and chemicals that are of relevance to the sustainable-by-design concept (e.g. organic basic chemicals, chlorine, anhydrous ammonia, cement, aluminium, iron and steel). The first legislative proposal includes criteria for products that make a 'substantial contribution to climate change adaptation' and that do not significantly harm the other five environmental impacts covered (see Annex I for more details). The remaining criteria are expected to be published by the end of 2021.

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<sup>19</sup> <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12567-Sustainable-products-initiative>

<sup>20</sup> CEAP – Circular Economy Action Plan for a cleaner and more competitive Europe. [https://ec.europa.eu/environment/circular-economy/pdf/new\\_circular\\_economy\\_action\\_plan.pdf](https://ec.europa.eu/environment/circular-economy/pdf/new_circular_economy_action_plan.pdf)

<sup>21</sup> <https://ec.europa.eu/environment/waste/batteries/>

<sup>22</sup> [https://ec.europa.eu/environment/eussd/smgp/pdf/PEFCR\\_Batteries\\_Feb%202020-2.pdf](https://ec.europa.eu/environment/eussd/smgp/pdf/PEFCR_Batteries_Feb%202020-2.pdf)

<sup>23</sup> Commission Recommendation 2013/179/EU of 9 April 2013 on the use of common methods to measure and communicate the life cycle environmental performance of products and organisations

As described above, the Commission is currently working on the development of several policy initiatives that aim to develop sustainability criteria, among other objectives. These initiatives are highly relevant to the development of the sustainable-by-design concept and criteria.

All the criteria definitions set out in these Commission initiatives follow a similar approach. It starts with a technical, environmental and economic analysis of the product, covering a number of representative models of the product on the market. It then sets out different options (criteria) for improving the environmental performance of the product and for avoiding any significant loss of functionality. The trade-offs and consequences with different environmental impacts are taken into account to define the final criteria, which must be clear and verifiable.

No single policy is capable of addressing all product- and sector- specific challenges, and it is broadly accepted that a combination of voluntary and mandatory tools is needed. Depending on the nature of the policy tool (see Table 3), the criteria set out lower or higher ambition levels. Mandatory tools set a minimum entry level to place the products in the EU market, such as Ecodesign, with the objective to push the market towards more sustainable products. The EU Ecolabel or the EU GPP set voluntary criteria with a higher ambition level to award frontrunner products, and have a pull effect. The energy label covers both aspects, the minimum entry level and high-end level, as it is based on seven efficiency classes. This classification is a very good approach when only one parameter is assessed, e.g. energy efficiency. The classification becomes increasingly complex when it covers several parameters, as for the sustainable-by-design criteria.

**Table 3: Summary of the nature, scope, lifecycle stage and verification of the mapped Commission tools - initiatives**

Policy instrument	Nature	Scope	Lifecycle stage	Verification
Ecodesign	Mandatory	Energy-related products	Use stage and end-of-life	Market surveillance
Energy label	Mandatory	Energy-related products	Use stage	Market surveillance
Sustainable product initiative	Mandatory	Products	Entire life cycle	Market surveillance
Sustainable batteries	Mandatory	Batteries	Entire life cycle	Market surveillance and notified bodies (3 <sup>rd</sup> party)
EU Ecolabel	Voluntary	Goods and services	Entire life cycle	Competent bodies (Member State)
EU GPP	Voluntary	Goods and services	Entire life cycle	Procurer
Sustainable finance	Voluntary	Financial products	Entire life cycle	Entity requesting the

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		and corporate bonds related to economic activities		criteria
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### 3.2 European initiatives

There is a plethora of initiatives in the EU that define environmental and/or suitability criteria. This study carried out an initial screening on a sample of initiatives covering different product types. A short description of the initiatives is presented below, with more details provided in Annex 1. The authors expect to expand the list after consultation with stakeholders and to analyse other relevant initiatives.

TCO Certified<sup>24</sup> is a global sustainability certification label for IT products. It is based in Stockholm, and available in Europe, Asia and North America. Every certified product meets the requirements of ISO 14024:2018 Ecolabel Type 1 and has been approved by the Global Ecolabelling Network<sup>25</sup>. All verification is carried out by independent verification organisations in accordance with ISO/IEC 17025, the international standard for competence requirements applied to testing and calibration laboratories. Compliance is independently verified, both before and after certification. Certified products must meet comprehensive environmental and social criteria throughout the life cycle. For instance, the factories making certified products must follow the criteria on working hours, working environment and wages. Products must meet criteria covering energy efficiency, ergonomic design and limited hazardous substance content. Criteria and verification methods are science-based and developed in an open process with an international network of stakeholders that includes users, buyers, brands, manufacturers, researchers, NGOs and subject-matter experts. Once awarded, certification is valid for three years.

The Nordic Swan Ecolabel<sup>26</sup> creates sustainable solution-based sets of requirements and criteria for products and services. The criteria are produced from a lifecycle assessment of raw material to waste and with an overall goal to reduce the environmental impact from the production and consumption of goods. The Nordic Swan is awarded to products and services if the company applies and can show with documentation and tests that the product fulfils the requirements. Checks are carried out regularly and the criteria for the Nordic Swan Ecolabel are continuously revised so that products and services remain among the best on the market. According to Nordic Swan, 9 out of 10 Nordic consumers know the Nordic Swan Ecolabel – and half of these look for it when they shop, while 3 out of 4 Nordic consumers are concerned about what they can do themselves to take care of the environment. Nordic Swan supports the United Nations Sustainable Development Goals and covers 60 consumer product groups. A combination of experts, businesses and

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<sup>24</sup> <https://tcocertified.com/>

<sup>25</sup> The Global Ecolabelling Network is a non-profit association of leading ecolabelling organisations worldwide, which fosters cooperation, information exchange and standards harmonisation among ecolabelling programmes <https://globalecolabelling.net/>

<sup>26</sup> [www.nordic-ecolabel.org](http://www.nordic-ecolabel.org)



other stakeholders are involved in the process of developing criteria and once awarded, the label is valid for four years. One product group identified under the Nordic Swan label relevant to this study is chemical building products, which includes adhesives, fillers, primers, sealants, self-levelling products, industrial paints and exterior paints and varnishes. The criteria for this product group meet tough performance standards and describe the required low levels of substances that are harmful to health and the environment, together with low air and water emissions.

Blue Angel<sup>27</sup> is a German Type I ecolabel awarded to products and services. In general, it covers environmental impacts, occupational health, safety and fitness for use. Blue Angel is owned by the Federal Ministry for the Environment Nature Conservation and Nuclear Safety. The Federal Environment Agency develops the criteria for each product group, with an Environment Label Jury, while a third party (RAL gGmbH) manages the process to award the label.

Natureplus<sup>28</sup> ecolabel is a European label for building products, based on strict scientific criteria and on three key groups of criteria: climate protection, healthy accommodation and sustainability. It is also classified as a type I environmental label and is valid across Europe. Its main focus is on the protection of limited resources by minimising the use of petrochemical substances and sustainable raw material extraction/harvesting, using resource-efficient production methods and maximising product longevity. Natureplus has criteria for several products relevant to the sustainable-by-design concept, for example surface coatings, adhesives and insulation materials. This ecolabel includes a set of requirements with a minimum value for certain impact categories that must be calculated applying an LCA, and it also defines the impact methods used.

OEKO-TEX<sup>29</sup> is a certification system for human-ecological safety for textile and leather materials. It covers all lifecycle and supply chain phases for raw materials and fibres, yarns, fabrics and ready-to-use end products. Some categories also cover social and environmental conditions in production facilities. The criteria are tested by 18 independent research and test institutes, both scientific and open-based. The criteria are updated at least once a year and expanded with new scientific knowledge or statutory requirements.

Bluesign<sup>30</sup> is a label for textile products based in Switzerland. Their system analyses all input streams (raw materials, chemical components, and resources) before production, to avoid health risk health or ecotoxicological impact. The main criteria areas are consumer safety, environmental management and occupational health and safety. Additionally, specific subcriteria are defined on product-by-product basis.

### *3.3 Non-European initiatives*

This study identified several initiatives from the United States, and analysed two in more depth: the Green Seal (Annex I) and GreenScreen for safer chemicals. Other initiatives

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<sup>27</sup> [www.blauer-engel.de/en](http://www.blauer-engel.de/en)

<sup>28</sup> [www.natureplus.org/](http://www.natureplus.org/)

<sup>29</sup> [www.oeko-tex.com/en/](http://www.oeko-tex.com/en/)

<sup>30</sup> [www.bluesign.com/en](http://www.bluesign.com/en)

such as the Safer Choice Label and Green Chemistry philosophy are included in Annex I but are not discussed in detail at this stage.

The Green Seal<sup>31</sup> is a type I ecolabel, following the ISO 14020/14024 standards, and part of the Global Ecolabelling Network. It certifies products (construction materials, food packaging, paper, cleaning products, sanitary paper products) and services (cleaning, hotels, restaurants). The manufacturer pays a fee, and the certification review process takes between five and eight months. Criteria are developed after a feasibility assessment, based on the potential for significant impact and data availability, followed by stakeholder consultations. Each group of criteria is reviewed every three years, or earlier if significant market or regulatory developments so require. The criteria are designed to reflect the top 15-20% of environmental leadership products available on the market. The criteria (impact) should be measurable. Functional criteria are also covered, e.g. adhesion or abrasion resistance for paints and coatings. However, the focus is mainly on environmental impact: the environmental and toxicological impact. The Green Seal lays down minimal requirements for social criteria e.g. no child labour and the right to trade unions. Another notable requirement is the focus on 'second degree' resources, e.g. reusing external wastewater; restrictions on wastewater treatment methods; or the agricultural residue permitted in sustainable agriculture.

GreenScreen for safer chemicals<sup>32</sup> is a method developed specifically to assess chemical hazards. The aim is to guide decision making on the design and development of products and processes. It focuses on chemicals of high concern and their safer alternatives. The only criterion is chemical hazard assessment, excluding energy or resource extraction. Product manufacturers identify all the chemicals used in the production of the product, by chemical name and CASRN. Those chemicals are then crosschecked against the GreenScreen databases<sup>33</sup> that are based on global databases or lists (around 650), for example REACH and OECD. It assigns products bronze, silver or gold labels, corresponding to the environmental standards achieved. When data gaps are identified, missing data may be estimated by modelling. Note that if there are too many data gaps, a label cannot be assigned to that product. The criteria mainly focus on restricted substances (see Section 3), which are selected by assessing environmental impact and public health effects. Physical hazards are connected with form-specific hazards: powders/liquids. The criteria are assessed by taking into account the environmental endpoints, for example, 'hazardous waste is not created'. The resulting products of environmental transformation of the parent substances, for example as a result of biodegradation of the mother substance in the product, are explicitly assessed.

### *3.4 Other relevant initiatives*

In 1998, the Organisation for Economic Co-operation and Development (OECD) initiated work on environmentally benign chemicals or '**sustainable chemistry**'<sup>34</sup>. In October 1998, a first workshop on sustainable chemistry was organised where the participants agreed that sustainable chemistry provides a cost-effective means to reduce chemical threats to health and to the environment as it accelerates the pace of chemical innovation and thereby contributes to economic competitiveness and sustainable development. The interest in and work to achieve sustainable chemistry so far has

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<sup>31</sup> <https://greenseal.org/>

<sup>32</sup> <https://www.greenscreenchemicals.org/>

<sup>33</sup> <https://store.greenscreenchemicals.org/gs-assessments/chemicals>

<sup>34</sup> <http://www.oecd.org/env/ehs/risk-management/sustainablechemistry.htm>

resulted in other workshops, reports and guidance documents,<sup>35</sup> with the most relevant for this study being the recently published **Guide on safer chemicals alternatives**<sup>36</sup>. This guide aims to reduce the lack of uniformity in the criteria used to define 'safer' chemical alternatives, in terms of both hazard and exposure. It provides a set of minimum requirements necessary to determine whether a chemical alternative is safer, combined with a self-assessment checklist that helps put the minimum criteria into practice. Interestingly, the report closes with the acknowledgement that, currently, there is a growing demand for sustainable choices that go beyond the notion of 'safe' and encompass a broader spectrum of down- and upstream chemical or product impacts.

The OECD report on **sustainable materials management**<sup>37</sup> provides a series of policy principles in a practical guidance to improve the resource productivity of economies and put in place sustainable materials management policies. The principles identified aim to:

- 1) preserve natural capital;
- 2) design and manage materials, products and processes for safety and sustainability throughout the product's life cycle;
- 3) use the full range of policy instruments to stimulate and improve sustainable economic, environmental and social outcomes; and
- 4) engage all parts of society to take active, ethically-based responsibility for achieving sustainable outcomes.

In 2019, the United Nations Environment Assembly (UNEA) mandated the development of a **Framework Manual on Green and Sustainable Chemistry**<sup>38</sup>. Its aim is to address the questions of why, what and how regarding green and sustainable chemistry. A draft version (November 2020) is available for review, with a final version expected in the future. This work was preceded by an "analysis of stakeholder submissions on sustainable chemistry pursuant to UNEA Resolution 2/7<sup>39</sup>" where sustainable chemistry was recognised as a widely used term, though its exact definition was unclear. Nevertheless, the majority of stakeholders agree that sustainable chemistry will play a key role in achieving Sustainable Development Goal 12: Responsible consumption and production, especially in the sound management of chemicals and waste.

The International Sustainable Chemistry Collaborative Centre (ISC3)<sup>40</sup> is an international institution promoting and developing sustainable chemistry solutions, funded by the German Federal Ministry for the Environment and the German Federal Environment Agency. In November 2020, a **dialogue paper on sustainable chemistry** was presented at the ISC3 stakeholder forum, as a result of a 2019-2020 dialogue process

<sup>35</sup><http://www.oecd.org/chemicalsafety/risk-management/series-on-risk-management-publications-by-number.htm>

<sup>36</sup> [www.oecd.org/chemicalsafety/risk-management/guidance-on-key-considerations-for-the-identification-and-selection-of-safer-chemicals-alternatives.pdf](http://www.oecd.org/chemicalsafety/risk-management/guidance-on-key-considerations-for-the-identification-and-selection-of-safer-chemicals-alternatives.pdf)

<sup>37</sup> OECD (2012), *Sustainable Materials Management: Making Better Use of Resources*, OECD Publishing. <http://dx.doi.org/10.1787/9789264174269-en>

<sup>38</sup> <https://www.unenvironment.org/explore-topics/chemicals-waste/what-we-do/policy-and-governance/sustainable-chemistry>

<sup>39</sup> UNEP/EA.4/INF.20

[https://wedocs.unep.org/bitstream/handle/20.500.11822/31194/inf20\\_analysis\\_of\\_stakeholder\\_submissions\\_on\\_sustainable\\_chemistr.pdf?sequence=2&isAllowed=y](https://wedocs.unep.org/bitstream/handle/20.500.11822/31194/inf20_analysis_of_stakeholder_submissions_on_sustainable_chemistr.pdf?sequence=2&isAllowed=y)

<sup>40</sup> [https://www.isc3.org/fileadmin/user\\_upload/Documentations\\_Report\\_PDFs/ISC3\\_Sustainable\\_Chemistry\\_key\\_characteristics\\_20210113.pdf](https://www.isc3.org/fileadmin/user_upload/Documentations_Report_PDFs/ISC3_Sustainable_Chemistry_key_characteristics_20210113.pdf)

where stakeholders voiced their opinions and shared their expectations regarding the concept. The paper presents 10 key characteristics of sustainable chemistry: holistic, precautionary, systems thinking, ethical and social responsibility, collaboration and transparency, sustainable and responsible innovation, sound chemicals management, circularity, green chemistry, and life cycle.

The German Environmental Agency published a **Guide on Sustainable Chemicals**<sup>41</sup> in 2016, which mentions criteria for selecting chemicals. The guide distinguishes between substance-specific criteria and use-specific criteria.

- The evaluation of sustainability is based on eight substance-specific criteria: lists of 'problematic substances'; physiochemical properties; human toxicity; problematic properties related to the environment; mobility, greenhouse gas emissions; resource consumption; and responsibility in the supply chain. Colour coding indicates the evaluation result, ranging from green (no action needed), yellow (further analysis with use-specific criteria), red (substitution is high priority), to white (insufficient information).
- The next step in the evaluation of sustainability is based on seven use-specific criteria: emission potential, user groups, used amount, waste, substitution alternatives, the benefits of a chemical, and the innovation potential.

It also provides a tool named SubSelect<sup>42</sup> to evaluate the sustainability of substances and mixtures. It includes a database for use with the Guide on Sustainable Chemicals. The database gives the user information on hazard, mobility, resource and CO<sub>2</sub>-emission aspects, how to prioritise substitution needs or compare alternatives.

The **Chemical Footprint Project**<sup>43</sup> is a programme run by the initiative Clean Production Action<sup>44</sup> to develop and advance the concept and practice of chemical footprinting with the goal of reducing the use of chemicals of high concern. A chemical footprint is a metric measuring the chemicals of high concern in products, manufacturing processes, facilities, supply chains, and/or packaging. CLP measures corporate progress towards safer chemicals by providing a metric for benchmarking companies as they select safer alternatives and reduce their use of chemicals of high concern. In 2020, they published their 5th Annual Chemical Footprint Project Report<sup>45</sup> including best practice by frontrunners in proactive chemicals management.

The **Sustainable Chemistry R&D Act**<sup>46</sup> was enacted by the US Senate on 1 January 2021<sup>47</sup>. An interagency unit will create a roadmap for sustainable chemistry within two years. The first phase is to consult stakeholders to come to an agreed definition of 'sustainable chemistry'. Another important task is to create a framework of attributes to characterise and metrics to assess sustainable chemistry. Participating

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<sup>41</sup> Guide on Sustainable Chemicals by the German Environment Agency (November 2016) <https://www.umweltbundesamt.de/en/publikationen/guide-on-sustainable-chemicals>.

<sup>42</sup> <https://www.umweltbundesamt.de/en/document/subselect-guide-for-the-selection-of-sustainable>.

<sup>43</sup> <https://www.chemicalfootprint.org/>.

<sup>44</sup> <https://cleanproduction.org/>.

<sup>45</sup> <https://www.chemicalfootprint.org/assets/downloads/ChemicalFootprintProject-2020-Report.pdf>.

<sup>46</sup> HR.2051 Sustainable Chemistry Research and Development Act of 2019 text at: <https://www.congress.gov/bill/116th-congress/house-bill/2051/text>.

<sup>47</sup> The mentioned HR.2051 Sustainable Chemistry Research and Development Act was included in a modified version in the "William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021" and became public law No: 116-283 <https://www.congress.gov/bill/116th-congress/house-bill/6395/>.

agencies will be expected to incorporate sustainable chemistry into existing research, development, technology transfer, marketing, education and training programmes.

The California Environmental Protection Agency (CalEPA)<sup>48</sup>, formally established in 1991, has played a key role in implementing environmental policies in the US, such as the Global Warming Solutions Act (AB 32)<sup>49</sup> and launching the Green Chemistry Initiative<sup>50</sup>. In addition, CalEPA has contributed to the wider use and compliance of businesses with Proposition 65<sup>51</sup>, a law voted in 1986, which today contains approximately 900 chemicals that can cause cancer, birth defects or other reproductive harm. Businesses are required to place a warning in the form of a label, sign, or published information if a product exposes people to one or more of the listed chemicals. These warnings are legally required and must be given for the listed chemicals unless a business is able to prove that the exposure is low enough to pose no significant risk to human health.

#### 4. Criteria analysis

This section presents an analysis of the majority of the criteria used under the above initiatives. The objective is to understand how they cover materials and chemicals and to identify gaps to guide the process of developing sustainable-by-design criteria. For the purpose of this analysis, the authors made a selection of product groups, prioritising the groups where materials and chemicals play a relevant role (see Table 4). In total, the authors reviewed 466 criteria, covering around 40 different products. The analysis is presented per criteria group. It is worth highlighting that for some criteria, it is challenging to distinguish between two groups and select the correct criteria group. For example, there is often only a thin line separating restricted substances, emissions and waste. The purpose of this analysis is not to make the right distinction but to understand how materials and chemicals are covered in existing sustainability criteria schemes.

All the initiatives cover a fitness-for-use criteria to ensure that the products are of good quality and function properly, either generally or specifically to certain applications. The products then undergo a suitability test.

**Table 4: List of product groups analysed**

Tool name	Products analysed
EU Ecolabel	Absorbent hygiene products; hard surface cleaning; dishwasher detergents; hand dishwashing; laundry detergents; textiles; footwear; paints and varnishes; televisions; electronic displays; wood, cork and bamboo-based floor coverings; furniture; bed mattresses; growing media, soil improvements and mulch; lubricants; converted paper; printed paper, stationary paper, paper carrier bag products

<sup>48</sup> <https://calepa.ca.gov/about/>.

<sup>49</sup> <https://ww2.arb.ca.gov/resources/fact-sheets/ab-32-global-warming-solutions-act-2006>.

<sup>50</sup> <https://www.global-green-chemistry-initiative.com/>.

<sup>51</sup> <https://oehha.ca.gov/proposition-65/about-proposition-65>.

EU GPP criteria	Data centres, server rooms and cloud services; electrical and electronic equipment used in the healthcare sector; imaging equipment, consumables and print services
TCO certified	Headsets; all-in-one PCs; smartphones
Nordic Swan	Indoor paints and varnishes; chemical building products
Blue Angel	Nappies; dishwasher detergents; shampoo; toys; lamps; non-toxic pest control chemicals; coffee machines; stationary air conditioners; computers and keyboards; printers and multifunction devices; kitchen roll paper; finished products from recovered paper
Natureplus	Paints, varnishes, lacquers and glazes for wood
OEKO-TEX	Textiles and leather
Bluesign	Textile accessories
GreenScreen for safer chemicals	Furniture and fabrics; firefighting foam; textiles

## Restricted substances

The analysis identified some 250 criteria, showing that chemicals mostly come under the restricted substances criteria group. The most common approach is to prohibit or restrict the presence of substances from the candidate list of substances of very high concern from REACH (EC No 1907/2006)<sup>52</sup>. Another criterion common to almost all initiatives is to ban or limit the presence of substances classified as carcinogenic, mutagenic, toxic for reproduction, acute toxic or specific target organ toxicity, etc. under the CLP Regulation (EC No 1272/2008), though the impact indicator varies depending on the product. The presence of heavy metals is also limited and when the product contains plastic parts, certain substances are restricted; for example halogen polymers, solvents and certain flame retardants (especially halogenated ones). The ban of such substances from plastics reflects mainly recyclability concerns. Moreover, fragrances and dyes are usually restricted or banned from certain products (e.g. nappies, detergents or tissue paper). In general, the list of restricted substances varies by product and the restriction is often linked to the presence of the substance in different lifecycle stages of the product (e.g. manufacturing, use or end-of-life). Some initiatives allow derogations for substances that cannot be avoided in the product. All restricted substances criteria take into account the hazard of each substance to health and/or to the environment.

## Emissions

<sup>52</sup> <https://echa.europa.eu/candidate-list-table>.

Emissions are the second largest criteria group that cover chemicals and substances under the analysed initiatives. The criteria differ from product to product, although some common areas are covered, such as water emissions (addressed as sodium and chloride content in water extracts or waste water emissions of colourants and brighteners) or the biodegradability of surfactants (used in detergents, cleaning products or shampoos). Volatile organic compounds (VOCs) are limited during the use stage (e.g. when paints or varnishes are used), as is the level of dust during the manufacturing process. In general, all the emissions criteria take into account the harm caused by each substance to human health and/or to the environment.

### **Sourcing certification**

The criteria governing sourcing certification are used to verify that products are sourced in an ecological and socially responsible manner. This criterion is applied to primary or raw materials such as wood, cork, bamboo, rattan, oil plants, natural textile fibres, natural rubber, and paper fibres. Several certification schemes cover sourcing requirements: Forest Stewardship Council (FSC)<sup>53</sup> (both FSC Mix Credit or FSC 100%); Programme for the Endorsement of Forest Certification Schemes (PEFC)<sup>54</sup>; Council Regulation (EC No 834/2007)<sup>55</sup>, and the US National Organic Programme (NOP)<sup>56</sup>. In general, the criteria encourage the use of recycled materials instead of raw materials where certified sources are required to a certain degree. Some ecolabels include a ban on using biomass for primary products sourced from areas with both a high level of biodiversity and conservation value or restrict the use of genetically modified organisms.

### **Recycled content**

Recyclability criteria encourage the use of recyclable sources in raw materials in paper, cardboard and plastic. These criteria establish the obligation to use a certain percentage of recycled source material by weight of the total product, and distinguish between the content of the product itself and the packaging. For example, the rating set for recycled plastic varies from 50% to 20%, with higher rates expected for paper and cardboard used specifically for packaging (80% - 100%).

### **Recyclability**

The focus of this criteria group is on ensuring that the final product will be recyclable. In some cases, it means limiting the use of substances or products that would compromise recyclability, such as paints, adhesives, certain coatings, plastics and chemicals. Some ecolabels take into account the disassembly or removability of product parts for recycling purposes. The recyclability criteria mainly concern the packaging.

### **Waste**

To reduce and/or limit the environmental impact of product waste, several ecolabels include waste restriction in their criteria. The criteria sometimes cover the production stage, with some requesting waste management systems for example. Examples of the standards or regulations used are the European ISO 14000 series on environmental

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<sup>53</sup> <https://fsc.org/en>

<sup>54</sup> <https://www.pefc.org/>

<sup>55</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32007R0834>

<sup>56</sup> <https://www.ams.usda.gov/about-ams/programs-offices/national-organic-program>



management systems<sup>57</sup>, or the hazardous waste regulations from the California Department of Toxic Substances Control<sup>58</sup>, which is used under the GreenScreen for safer chemicals initiative. For ICT products, ecolabel schemes generally request appropriate e-waste collection and treatment. This is achieved by using, for example, an e-waste rate that ensures companies remove the waste from the market. Another approach is the direct obligation for distributors to take back modules, containers or parts that contain substances that could compromise future recycling or are especially dangerous to the environment (constituents with selenium, lead, mercury or cadmium in printers, or PVC).

### **Social responsibility**

The aim of this criteria group in the ecolabel schemes is to ensure products meet fundamental principles and labour rights, for example prevention of child labour, prevention of harassment, abuse or specifications applicable to work contracts and ergonomics. The criteria refer to compliance with specific standards or guidelines such as the International Labour Organisation Core Labour Standards<sup>59</sup>, the UN Global Compact<sup>60</sup> and the OECD Guidelines for Multi-National Enterprises<sup>61</sup>.

### **Information criteria**

The majority of the analysed schemes cover information aspects about consumer or safety requirements, but also information on social standards or sustainable sourcing. The GreenScreen for safer chemicals sets information requirements, for example producers must identify each homogeneous material in the product and provide a chemical inventory listing each intentionally added chemical compound (>0ppm) and impurities (>100ppm) identified by their CAS registry number.

### **Conclusions**

The criteria analysis has shown that the hazard of the substances used in products is the main driver for all the criteria reviewed. Hazard relates both to health and to the environment and is typically linked to substance identification in legislation such as REACH (with the candidate list of substances of very high concern (SVHC) and CLP. The way hazards are addressed in the criteria can vary from a ban on substances, limits to amounts, the obligation to provide information for consumers on the label, ensuring product recyclability; or by explicitly allowing substances with a 'good to use' list of safer alternatives. Because the purpose of the ecolabels is to distinguish frontrunner products in the market (in terms of environmental performance), there are criteria that go beyond regulatory requirements and set stricter requirements.

The schemes reviewed appear to cover chemicals well in terms of level of hazard. However very few criteria were found to cover other sustainability aspects, for example related to the production stage. Production is practically only covered in terms of the raw materials used in furniture, textiles and paper products, where a criterion on sustainable sourcing is often used. An interesting finding has been the Natureplus ecolabel, which sets criteria on sustainable sourcing for paints, varnishes and glazes (among other relevant products), which could be a source of inspiration for the sustainable-by-design

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<sup>57</sup> [https://ec.europa.eu/eip/ageing/standards/general/general-documents/iso-14000\\_en](https://ec.europa.eu/eip/ageing/standards/general/general-documents/iso-14000_en)

<sup>58</sup> <https://dtsc.ca.gov/>

<sup>59</sup> [www.ilo.org/global/standards/lang--en/index.htm](http://www.ilo.org/global/standards/lang--en/index.htm)

<sup>60</sup> [www.unglobalcompact.org/what-is-gc/mission/principles](http://www.unglobalcompact.org/what-is-gc/mission/principles)

<sup>61</sup> [www.oecd.org/corporate/mne/](http://www.oecd.org/corporate/mne/)



concept. Natureplus also sets minimum values on impact categories that must be calculated applying an LCA. The EU Ecolabel also has criteria for paints and varnishes, but it mainly covers restricted substances and efficiency during use (not production); the only emissions covered are VOCs during application/use.

Analysing the criteria used in different schemes has provided insights into how the sustainable-by-design criteria for chemicals, materials and products could be structured. Looking at the structures of the schemes analysed and drawing on the initiatives mapped, Table 5 presents an initial structure of the sustainable-by-design criteria. These criteria should be taken into account during the design stage of chemicals and materials where the research and development is implemented to achieve safe and sustainable-by-design.

**Table 5: Proposed structure of the sustainable-by-design criteria to be considered in the design stage – R&D**

	Environmental criteria	Safety criteria	Social criteria
<b>Production stage</b>	Emissions (to air, water and soil)  Resource consumption (energy, water, etc.)  Waste management  Restricted substances related to environmental hazards  Sustainable sourcing of raw materials / natural resources  Recycled material content	Restricted substances related to worker health and safety	Social responsibility
<b>Use stage</b>	Functionality (fitness for use)  Durability  Reparability	Restricted substances related to user health and safety  Information	
<b>End-of-life</b>	Recyclability	Restricted substances related	

	Waste	to health and safety for recyclers	
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## 5. Safe-by-design nanomaterials: R&I landscape

DG RTD has supported the development of the safe-by-design concept for nanomaterials and nano-enabled products since 2013, when it launched a series of specific projects. The aim of safe-by-design is to prevent negative impacts on public health and the environment by bringing safety requirements into research, development and innovation (R&D&I) throughout the entire development chain, and specifically at the design process of substances, materials and products. Safe-by-design concepts and solutions developed for nanotechnologies have the potential to provide essential input to the future sustainable-by-design approach.

### 5.1 Activities in Europe related to safety aspects of nanomaterials

This section briefly describes the main strands of work taking place in Europe on the safety aspects of nanomaterials, including policies, standards and labelling schemes.

Several regulations and standards cover the safety of nanomaterials:

- Regulation (EC) No 1907/2006 – REACH<sup>62</sup>
- Regulation (EC) No 1272/2008 – on classification, labelling and packaging of substances and mixtures (CLP) <sup>63</sup>
- Regulation (EC) No 1223/2009 on cosmetic products<sup>64</sup>
- Regulation (EU) No 2017/745 on medical devices<sup>65</sup>
- Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR)<sup>66</sup>
- Regulation (EU) 2016/425 on personal protective equipment<sup>67</sup> (PPE)EU standards on PPE certification: UNE-EN 149:2001+A1:2010 / UNE-EN 13274-7/ UNE-EN 143 / UNE-EN 13274-5 / UNE-EN 148-1 / UNE 0064-1 / UNE 0064-2 / UNE 0065 / UNE-EN 14683:2019+AC:2019
- Directive 2001/95/EC on general product safety<sup>68</sup>Directive 89/391 - OSH "Framework Directive"<sup>69</sup>CEN/TS 17276:2018 Nanotechnologies - Guidelines

<sup>62</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410>

<sup>63</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32008R1272>

<sup>64</sup> <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R1223>

<sup>65</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745>

<sup>66</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012R0528>

<sup>67</sup> <https://osha.europa.eu/en/legislation/directive/regulation-eu-2016425-personal-protective-equipment>

<sup>68</sup> <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32001L0095>

<sup>69</sup> <https://osha.europa.eu/en/legislation/directives/all>

for Life Cycle Assessment - Application of EN ISO 14044:2006 to Manufactured Nanomaterials<sup>70</sup>

- ISO/TS 13830:2013<sup>71</sup> Nanotechnologies - Guidance on voluntary labelling for consumer products containing manufactured nano-objects (ISO/TS 13830:2013)

The **Nanomaterials Expert Group** of the European Chemicals Agency (ECHA) aims to provide information and advice on scientific and technical issues regarding the implementation of REACH, CLP and BPR legislation governing nanomaterials. Participants of the expert group are nominated experts from: i) EU Member State authorities; ii) the European Commission: DG Environment (ENV), DG Internal Market, Industry, Entrepreneurship and SMEs (GROW), and the Joint Research Centre (JRC), iii) the European Food Safety Authority (EFSA); iv) accredited stakeholder organisations (e.g. industry associations; and non-governmental organisations). The group's work includes:

- preparing new and updated ECHA guidance documents;
- sharing experience with, and generating consensus among, Member State authorities and members of the risk assessment Member State and Biocidal Products committees on safety information for nanomaterials in REACH registration and biocide files;
- providing feedback and advice to companies that register nanomaterials;
- debriefing on ongoing international regulatory activities (such as the OECD Working Party on Manufactured Nanomaterials or the Malta Initiative for developing test guidelines).

The ECHA also organises webinars to inform about and discuss the latest developments regarding REACH and CLP processes related to nanomaterials, and to help registrants prepare and submit files that involve nanomaterials.

The ECHA hosts the European Union Observatory for Nanomaterials to increase the level of transparency of information on nanomaterials<sup>72</sup>.

The **Malta initiative towards safer nanomaterials** brings together a group of EU Member States, the European Commission (notably DG RTD, DG ENV, DG GROW and JRC), ECHA, industry and other institutions committed to adapting/developing test guidelines and guidance documents for testing nanomaterials.<sup>73</sup>

The **NanoSafetyCluster**<sup>74</sup> is a high profile platform for the coordination of nanosafety research in Europe. It provides strategic direction for the EU and Member States, improves synergies between ongoing and new projects, collects the outputs and data from completed projects and promotes FAIR data (findable, accessible, interoperable and

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<sup>70</sup> [https://standards.cen.eu/dyn/www/f?p=204:110:0:::FSP\\_PROJECT,FSP\\_ORG\\_ID:37704,508478&cs=13FE1438685CE24B8F3FBC6D6F0F062A1](https://standards.cen.eu/dyn/www/f?p=204:110:0:::FSP_PROJECT,FSP_ORG_ID:37704,508478&cs=13FE1438685CE24B8F3FBC6D6F0F062A1)

<sup>71</sup> <https://www.iso.org/standard/54315.html>

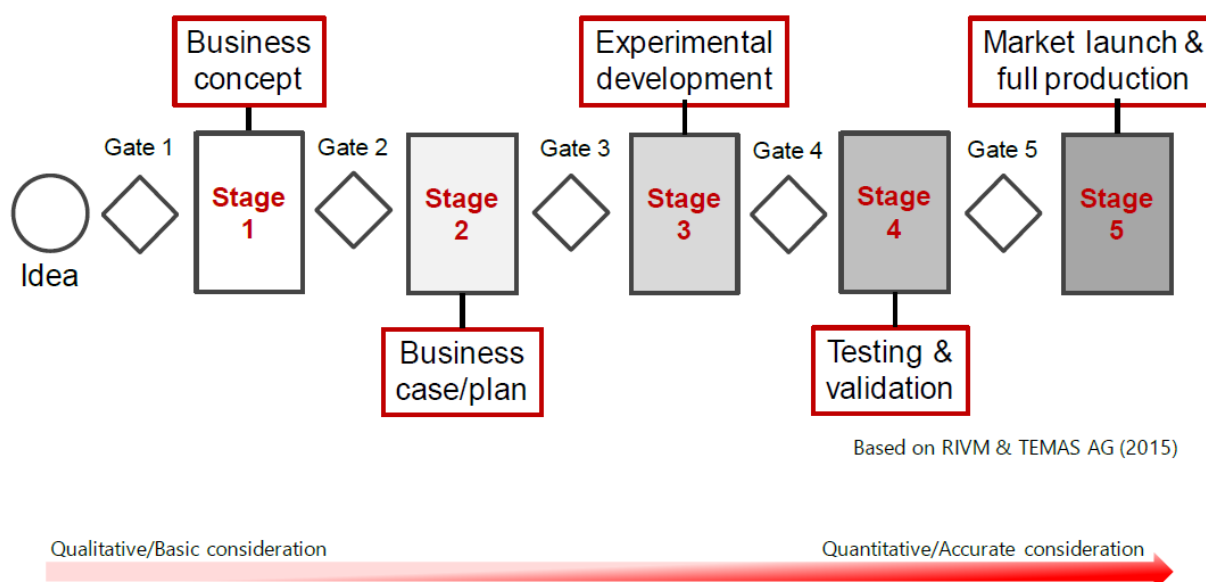
<sup>72</sup> <https://echa.europa.eu/regulations/nanomaterials>

<sup>73</sup> <https://www.nanosafetycluster.eu/international-cooperation/the-malta-initiative/>

<sup>74</sup> <https://www.nanosafetycluster.eu/>

reusable). The NanoSafetyCluster integrates and synthesises current and emerging nanosafety knowledge to provide a consistent message to stakeholders including academics, regulators, industry and civil society.

In addition, several research projects make use of the safe-by-design methods and tools, support implementation and help overcome regulatory challenges. Under Horizon 2020, several research projects made significant contributions to the development and testing of the safe-by-design concept. For example, **NanoReg2**<sup>75</sup> linked the safe-by-design concept (developed for nanomaterials in the flagship FP7 project **NanoReg**<sup>76</sup>, then refined and put into practice in Horizon 2020 **ProSafe**<sup>77</sup>) with regulatory preparedness as pillars of the safe innovation approach. NanoReg2 also developed grouping and testing strategies for nanomaterials categorised as safe-by-design and provided industrial-scale demonstration of implementation. Using Cooper's Stage-Gate<sup>78</sup> innovation methodology as the basis, the model guides the innovation process along a pathway with stage gates, which are decision points as to whether proceed, stop or adjust the innovation (Figure1).



**Figure 1. Standard 'stage-gate' model.** When starting the innovation process (Stage 1: setting up research ideas/business plans for a new nanomaterial/nano-engineered product or for new processes or usages), safety principles are applied. As knowledge increases gradually as the innovation progresses, more complex risk assessments, lifecycle analyses and socioeconomic assessments are carried out. Although the safe-by-design process can still be applied at later stages of the innovation process, it could require substantial and more expensive adjustments<sup>79</sup> to the product under development.

<sup>75</sup> <https://cordis.europa.eu/project/id/646221>

<sup>76</sup> <https://cordis.europa.eu/project/id/310584>

<sup>77</sup> <https://cordis.europa.eu/project/id/646325>

<sup>78</sup> Cooper, Robert. (1990). Stage-Gate Systems: A New Tool for Managing New Products. *Business Horizons*. 33, 44-54. 10.1016/0007-6813(90)90040-I.

<sup>79</sup> OECD: Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable Nanomaterials and Nano-enabled Products. (2020) [https://images.chemycal.com/Media/Files/env-jm-mono\(2020\)36-REV1.pdf](https://images.chemycal.com/Media/Files/env-jm-mono(2020)36-REV1.pdf)

The NanoReg2 safe-by-design concept covers three pillars of development: (1) safe products, (2) safe production and (3) safe use. It includes three risk elements: (1) prompt identification of uncertainties, (2) exposure assessment and (3) hazard characterisation. However, most risk assessment and risk management methods and tools used in safe-by-design processes focus mainly on pristine or simplified nanomaterials. The outcomes achieved in the NanoReg2 were leveraged at international level in a dedicated OECD project 'Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable Nanomaterials and Nano-enabled products' (see Section 5.2 for the outcomes).

Another project, **NanoFASE**<sup>80</sup> resulted in an integrated exposure assessment framework of models and characterisation protocols to address the need for regulatory development, to give industry a cost-effective product-to-market process and to substantially improve understanding of nanomaterials, thus increasing public and consumer confidence.

As part of the **caLIBRAte**<sup>81</sup> project, a framework for nano-risk governance was developed with tested tools for risk appraisal, public health and environmental risk assessment and risk management, accessible via the caLIBRAte nano-risk governance portal.

Another example is a catalogue of services for testing and measuring, certification, training, consultancy, models developed in the **EC4SafeNano**<sup>82</sup> with a comprehensive inventory of available tools, methods, approaches and best practice.

Under the **OpenRiskNet**<sup>83</sup> project, an integrated, service-driven infrastructure was developed for toxicology data management, data sharing, processing, analysis, information mining, modelling and simulations in the field.

In addition, the **NanoGenTools**<sup>84</sup> project developed some potentially useful tools including a manual of good practice, protocols and steps in the safe-by-design approach to the carbon-based production of nanomaterials. The table below lists the outputs of selected projects that have the potential for further use.

**Table 6: Horizon 2020 project outputs that enable progress to move beyond the current state-of-the-art**

H2020 project	Outputs of initiatives that enable further progress
NANoREG II	<p>A toolbox has been developed to support decision making in developing nano-enabled technology:<sup>85</sup> the SIA toolbox (see <a href="https://www.siatoolbox.com/tool">https://www.siatoolbox.com/tool</a>)</p> <p>TEMAS <a href="#">SbD Implementation Platform</a> - the project-specific safety file and safety profile</p> <p>NanoReg2 database integrated data from multiple EU projects such as:</p>

<sup>80</sup> <https://cordis.europa.eu/project/id/646002>.

<sup>81</sup> <https://cordis.europa.eu/project/id/686239>

<sup>82</sup> <https://cordis.europa.eu/project/id/723623>

<sup>83</sup> <https://cordis.europa.eu/project/id/731075>

<sup>84</sup> <https://cordis.europa.eu/project/id/691095>

<sup>85</sup> <https://www.rivm.nl/en/about-rivm/mission-and-strategy/international-affairs/international-projects/NanoReg2/introduction-sia-toolbox>

	FP7: NANoREG, MARINA, NanoTest, ENPRA, NanoGenotox, H2020: NanoReg II, GRACIOUS, BIORIMA, PATROLS, caLIBRAtE (using eNanoMapper database, the largest searchable compilation of nanosafety data: <a href="https://search.data.enanomapper.net">https://search.data.enanomapper.net</a> )
NanoFASE	Models and methods have been integrated into ECHA guidance.  An integrated <a href="#">NanoFASE Exposure Assessment Framework (CFW)</a> of models and characterisation protocols to address the need for regulatory development.  Outcomes of NanoFASE (CFW, databases, models etc.) were used in NanoCOMMONS.
NanoCommons	Provides <a href="#">a nanosafety knowledge infrastructure</a> , which organises and visualises data and data relationships, integrating computational tools for risk assessment and decision support <sup>86</sup>
caLIBRAtE	A framework for nano-risk governance with tested tools for risk appraisal, human health and environmental risk assessment and risk management, accessible via the <a href="#">caLIBRAtE Nano Risk Governance</a> portal. It provides information on nanomaterials and nano-enabled products, their safety and different stakeholders' perception of risk. It also provides tools for horizon scanning, identification of nanomaterials, risk assessment, risk management, decision support and workplace monitoring
EC4SafeNano	A catalogue of services for testing and measuring, certification, training, consultancy and models (e.g. LCA): <a href="https://ec4safenano.eu-vri.eu/Public/Guidance">https://ec4safenano.eu-vri.eu/Public/Guidance</a>
OpenRiskNet	Integrated, service-driven infrastructure for toxicology data management, data sharing, processing, analysis, information mining, modelling and simulations in the field, with a service catalogue: <a href="https://openrisknet.org/">https://openrisknet.org/</a>
NanoGenTools	The project developed multiscale and quantitative structure–activity relationship models (QSARs) to be integrated and further developed in the EU H2020 project NanosolveIT.  It provided a publicly-accessible database of nanomaterial descriptors for SmartNanoTox data within the NanoCommons (EU H2020 project): the full database can be accessed through the NanoCommons Knowledge Base at <a href="https://www.nanocommons.eu/">https://www.nanocommons.eu/</a>

The European Commission is committed to supporting the advancement of available safe-by-design tools and models and to making them future proof. Several H2020 projects (either on materials and models level<sup>87</sup>, as well as on complex systems<sup>88</sup>) strive to implement the Safe-by-Design approach in the standard development process, while

<sup>86</sup> <https://www.nanocommons.eu>

<sup>87</sup> [NMBP-15-projects](#): ASINA, SABYDOMA, SABYNA and SbD4Nano

<sup>88</sup> [NMBP-16-projects](#): DAIGONAL, HARMLESS, and SUNSHINE

others aim to prepare the ground for setting up a Nano-Risk Governance Council<sup>89</sup>. Since a key driver for innovation is making research results and data available in a timely and usable way, several European initiatives (e.g. EOSC<sup>90</sup>, EUON<sup>91</sup>) joined forces via an umbrella infrastructure (i.e. NanoCommons<sup>92</sup>) to include and share data from H2020 projects (e.g. **PROCETS**<sup>93</sup>, **caLIBRAtE**<sup>81</sup>, **ACEnano**<sup>94</sup>, **Purenano**<sup>95</sup>, **Hi-ccuracy**<sup>96</sup>, etc.) and future initiatives funded under the successor Horizon Europe programme. This will be in line with the 'FAIR'-principles<sup>97</sup> to secure data access and use over the long-term.

It is worth stressing that several EU-funded projects carried out under H2020 have already begun to integrate sustainability aspects into their work, opening new avenues for considering health and environmental impacts in addition to function very early in the innovation process. A good example is R2R Biofluidics<sup>98</sup> that has already incorporated sustainability considerations (in relation to the UN Sustainable Development Goals) in its work. In other EU-funded projects, industrial case studies<sup>99,100</sup> have been carried out and discussions held on Safe Innovation Approach<sup>101</sup> (which integrates the two complementary concepts: sustainable-by-design and regulatory preparedness). In a few 'closer-to-the-market' projects (e.g. Open Innovation Test Beds<sup>102</sup>), the Open Innovation Ecosystem has been included specifically.

## 5.2 Inventory of tools for safe-by-design implementation – OECD study

The OECD SIA project<sup>79</sup> carried out a review of the frameworks and tools for safe-by-design implementation. The main findings of this review process are reported below. The text and the tables have been adapted from the OECD project report. The tools are classified according to the different aspects required for full implementation of the safe-by-design concept. There are three pillars to the safe-by-design concept:

- safer materials and products;
- safer production processes; and
- safer use and end-of-life of products.

To fulfil the requirements under all three pillars, the following health and safety aspects along the material lifecycle must be covered (Table 7).

<sup>89</sup> [NMBP-13-projects](#) : Gov4Nano, RiskGone and NanoRigo

<sup>90</sup> EOSC portal <https://eosc-portal.eu/>

<sup>91</sup> European Observatory Nano <https://euon.echa.europa.eu/>

<sup>92</sup> <https://cordis.europa.eu/project/id/731032>

<sup>93</sup> <https://cordis.europa.eu/project/id/686135>

<sup>94</sup> <https://cordis.europa.eu/project/id/720952>

<sup>95</sup> <https://cordis.europa.eu/project/id/821431>

<sup>96</sup> <https://cordis.europa.eu/project/id/862410>

<sup>97</sup> Wilkinson, M., Dumontier, M., Aalbersberg, I. et al. The FAIR Guiding Principles for scientific data management and stewardship. Sci Data 3, 160018 (2016). <https://doi.org/10.1038/sdata.2016.18>

<sup>98</sup> <https://cordis.europa.eu/project/id/646260>

<sup>99</sup> [NanoReg2](#); [EC4SafeNano](#); [Hi-Response](#); [Smart-4-Fabry](#);

<sup>100</sup> [GRACIOUS](#); [PATROLS](#)

<sup>101</sup> Shandilya, Shandilaya et al. (2020). Perspective on a risk-based roadmap towards the implementation of the Safe Innovation Approach for Industry. NanoImpact. 20. 10.1016/j.impact.2020.100258.

<sup>102</sup> [NextGenMicrofluidics](#); [FlexFunction2Sustain](#)



**Table 7: Aspects to cover to achieve safer materials/products, processes, safer use and safer end-of-life.**

Safety aspect	Safer material /product	Safer production	Safer use and end-of life
Human hazard	X		
Environmental hazard	X		
Worker exposure (chemical hazards)		X	
Worker safety during production (physical hazards)		X	
Releases to the environment during production (outdoor air, liquid & solid waste)		X	
Releases to the environment during product use & end-of life processes			X
Consumer exposure (including professional & industrial use of the final product)			X

However, the safe-by-design concept goes beyond the classical risk assessment of combining hazard and exposure. To achieve safer materials, their structure and physico-chemical properties must be linked to their prospective hazard at the design stage. Following this approach, hazards can either be omitted or the least hazardous form with the desired functionality can be chosen for the next stage. At the same time, the implementation of safe-by-design must be economically viable for the industry, and therefore cost-benefit analysis tools are also required. Furthermore, to assess the overall social benefits of developing safe-by-design products as opposed to non-safe-by-design products, a social impact assessment must be carried out.

Other aspects considered when classifying the tools were the exposure route, the lifecycle stage, whether the tool performs a complete lifecycle assessment, and, for environmental assessment tools, which environmental compartments are covered. Table 8 overleaf provides an inventory of the models and tools reviewed<sup>103</sup>.

The table shows that there are a number of tools available for estimating human hazard and exposure for workers and consumers, with some tools combining both hazard and exposure assessment in a traditional risk assessment approach for chemicals. Some tools can be used to perform the risk assessment throughout the lifecycle of multi-component nanomaterials (MCMs). Environmental assessment tools include tools for hazard assessment, risk assessment, material flow analysis, transport and fate assessment of MNMs in different micro environments and, to a lesser extent, tools that estimate the

<sup>103</sup>[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2020\)36/REV1&docLanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2020)36/REV1&docLanguage=en)



uptake of MCNMs by different species. The table shows that several tools can be used to check different aspects but a combination is required to carry out a complete analysis.

**Table 8: Inventory of models and tools**

	Safer nanomaterials				Safer production			Safer use						LCA	SEA
	Human Hazard	Human RA	Environ. Hazard	Environ. RA	Workers Exposure	Workers Risk	Process Safety	Consumer Exposure	Consumer RA	Release from products	Flow analysis	Transport & fate	Uptake		
Licara NanoScan	✓	✓	✓	✓	✓	✓		✓	✓					✓	✓
SUNDS	✓	✓	✓	✓	✓	✓		✓	✓					✓	✓
Guidenano tool	✓	✓	✓	✓	✓	✓		✓	✓					✓	✓
Precautionary Matrix for NMs			✓			✓		✓							
ANSES CB Tool for NMs		✓	✓		✓	✓		✓							
Control Banding Tool	✓	✓			✓	✓									
Stoffenmanager Nano	✓	✓			✓	✓		✓ <sup>104</sup>	✓p						
Nanosafer CB	✓	✓			✓	✓		✓p	✓p						
SbD Implementation Platform	✓	✓						✓	✓						
NanoRiskCat	✓	✓						✓	✓						
ConsExpo Nano Tool								✓							
QSARs	✓														
NANOSOLUTIONS	✓	✓													
Future Nano Needs – Bayesian network (FNN-BNN)				✓											
CENARIOS @ Risk Management and monitoring system		✓		✓		✓									
Golden Egg Check															
US EPA SSD generator			✓												
SSWD			✓												
NanoQSAR model			✓												
NanoQSAR model			✓												
Nanoprofiler			✓												
FINE				✓											
pPERA				✓											
PFMA											✓				
DPMFA										✓	✓				
Lear nano											✓				
SimpleBox4Nano												✓			
NanoFASE: NanoFASE model System												✓			
NanoRelease										✓	✓				
NanoFate												✓			
NanoDuFlow												✓			
Rhone/Rhine Model												✓			
LearNano										✓					
MendNano												✓			

<sup>104</sup> p = professional use

RedNano												✓			
WSM/WASP7												✓			
Rhone/Rhine Model												✓			
GWAVA with water quality module												✓			
Kinetic model/BCF													✓		
Two component efflux/uptake model													✓		
Biodynamic model													✓		

### 5.3 Horizon 2020 ongoing projects

Several projects funded under the Horizon 2020 programme and related to safe-by-design activities in the nanomaterials domain are still ongoing.

A comprehensive but non-exhaustive list is presented in Table 9 below. Some projects are built on the outcomes of the EU-funded projects mentioned above. In particular:

- HARMLESS will be based on the framework of NanoReg2 and on the framework of Guidenano and SUN projects;
- SUNSHINE will transfer safe-by-design and safe innovation approaches from previous projects (NANoREG, NanoReg2, and NanoMILE) to form the basis for the SUNSHINE SIA e-infrastructure.

**Table 9: List of projects funded under Horizon 2020 relating to the safe-by-design concept in nanomaterials**

No	Project	End date	No	Project	End date	No	Project	End date
1	ACEnano	06-2021	10	Purenano	05-2022	18	Nanomet	12-2024
2	npSCOPE	06-2021	11	Gov4Nano	12-2022	19	ASINA	12-2024
3	GRACIOUS	09-2021	12	RiskGone	02-2023	20	SAbYNA	12-2024
4	PATROLS	09-2021	13	NanoRigo	02-2023	21	SABYDOMA	12-2024
5	Evo-Nano	09-2021	14	NanoSolveIT	02-2023	22	HARMLESS	01-2025
6	NanoCommons	12-2021	15	NanoinformaTIX	02-2023	23	SUNSHINE	01-2025
7	M3DLoC	12-2021	16	Hi-Accuracy	03-2023	24	SbD4Nano	03-2024
8	NanoFABNet	02-2022	16	Hi-Accuracy	03-2023	25	DIAGONAL	06-2025
9	NanoExplore	03-2022	17	Nanoharmony	12-2023			

Of these ongoing projects under Horizon 2020, two groups of projects are particularly relevant, those funded under topics NMBP-15-2019 and NMBP-16-2020. In particular:

- NMBP-15-2019: Safe-by-design, from science to regulation: metrics and main sectors (RIA).

Develop and validate low-cost techniques for delivering an integrated exposure-driven risk assessment and the associated design of the required post-use monitoring. Projects funded: ASINA, SABYDOMA, SABYNA and SbD4Nano.

Expected impact:

- safe-by-design approaches and tools for use at an early stage of the nanomaterial development process;
  - quality workplaces that ensure maximum technical and economic performance in line with acceptable risk levels;
  - control and mitigate exposure to acceptable risk levels in the event of the release of nanomaterials from products;
  - develop and validate low-cost techniques for producing an integrated exposure-driven risk assessment and the associated design of the required post-use monitoring.
- NMBP-16-2020: Safe-by-design, from science to regulation: multi-component nanomaterials (RIA)

Projects funded: DIAGONAL, HARMLESS, and SUNSHINE.

Expected impact:

- implementation of validated safe-by-design strategies including enabling their uptake by small and medium enterprises (SMEs);
- recommendations on adapting and improving current guidelines for exposure and hazard assessment of multi-component NMs as necessary;
- a categorisation scheme to cluster sector-specific multi-component nanomaterials by assessing nano-specific properties in real-life environments;
- integration of specific characteristics of multi-component nanomaterials, including the potential for mixture effects, in risk assessment and safe-by-design strategies.

It is important to highlight the links and cooperation among ongoing projects. For example, the SUNSHINE SIA e-infrastructure will be developed in close collaboration with ongoing **SbD4Nano** project, based on the NanoReg2 SIA Platform. There will be a connection with NMBP-15-2019-projects (SbD4Nano, ASINA, SAbYNA and SABYDOMA) to align SUNSHINE with work on safe-by-design of nanomaterials to be developed in these projects. The H2020 projects **SUN**, **GUIDEnano** and **SANOWORK** will provide data on specific surface modification and safe-by-design strategies for nanomaterials (e.g. doping, coating, functionalisation, passivation, and agglomeration) and safe process design strategies, while **NanoMicex** will provide information on the efficacy of risk

management measures for nanomaterials to use as starting points for the work under the **SUNSHINE** project.

### *5.4 Conclusions*

DG RTD has funded a series of research projects that aim to define and implement the safe-by-design concept for nanomaterials. This has generated a knowledge base that should serve as the foundation for the sustainable-by-design concept. It is important to stress that many of the funded projects have generated data, ready-to-use and publicly available tools that allow users to consider safety aspects early in the process of developing nanomaterials and nano-enabled products. Moreover, the general framework developed in the NanoReg2 project aims to accommodate not only safety aspects but also sustainability considerations (e.g. environmental impact) by using LCA and, at a later stage, socioeconomic assessments. Although this approach was developed and tested through few nano-related industrial case studies, in principle the model can be applied beyond nanomaterials and nano-enabled products. Still, several constraints in implementing safe-by-design were identified in the OECD SIA Study<sup>79</sup>, clustered around:

1. the availability of technical and human resources and related costs;
2. existing knowledge gaps (e.g. the lack of specific underlying knowledge at early stages of the innovation process);
3. inadequate or missing tools, guidance and standards (e.g. predictive tools in RA, LCA, and SEA);
4. regulatory barriers (e.g. lack of legal instruments and legal liabilities);
5. insufficient communication, collaboration and open-mindedness (ref. OECD study).

Some of these constraints will be analysed and addressed by ongoing H2020 projects (see Section 5.4). For this reason, it is key to keep monitoring the initiatives and to constantly encourage coordination and collaboration. The policy feedback mechanism will be important to achieve this aim.

Since sustainability is a far wider and less well-defined concept, additional barriers and constraints will emerge for the sustainable-by-design approach that need to be mapped out early in the process of concept definition and criteria development.

## 6. Conclusions / next steps

The aim of this study is to map current initiatives and R&I activities related to sustainability criteria that are relevant for the development of sustainable-by-design criteria. The analysis shows that there is a significant number of relevant activities, the Commission already has a number of actions under development that merit collaboration with the sustainable-by-design criteria, for example the Sustainable Product Initiative and the Sustainable Finance criteria. The study also maps some policy tools for implementing the sustainable-by-design criteria, ranging from mandatory (minimum entry level) to voluntary (for frontrunners) criteria. Further analysis of the policy options is required to identify the most appropriate tool to implement the sustainable-by-design criteria.

Other relevant initiatives identified outside the European Commission are the OECD's work on safer chemical alternatives, the UNEA framework manual on green and sustainable chemistry, the International Sustainable Chemistry Collaborative Centre and the recently launched sustainable chemistry R&D Act from the US government. Collaboration with these initiatives would be beneficial in developing the criteria.

As a result of the analysis of the current criteria used in several schemes (Chapter 4):

- chemicals and materials are in general addressed as part of the final product;
- chemicals are addressed in terms of the level of hazard to human health or to the environment, and very few criteria cover other sustainability aspects of chemicals, for instance the way they are produced or treated at the end-of-life stage;
- a first sketch is provided of how to structure the criteria for sustainable-by-design (Table 5), to be developed along with the upcoming activities and complemented with methods or tools to integrate specifications on all the listed subcriteria.

Next steps:

1. Develop the methodology for the criteria, identifying:
  - a. which aspects of safety and sustainability are to be covered;
  - b. the best methods to evaluate the criteria on safety and sustainability.
2. Apply the method and define criteria for specific sectors/applications of chemicals, materials and products.

Regarding the R&I agenda, the Commission has recently proposed new actions under the European Union's Horizon Europe Work Programme for 2021–2022. The aim is to promote research and development of innovative materials that are sustainable-by-design and to extend the timeframe for H2020 projects that focus on safe-by-design. Two priorities to test the concept and to validate and further develop a proposal for sustainable-by-design criteria will be launched in the first two years:

- HORIZON-CL4-2021-RESILIENCE-01-11: Safe and sustainable-by-design polymeric materials (RIA)

- HORIZON-CL4-2021-RESILIENCE-01-12: Safe and sustainable-by-design metallic coatings and engineered surfaces (RIA)

Moreover, a dedicated coordination and support action will be launched via the project HORIZON-CL4-2021-RESILIENCE-01-08: creating an EU-led international community on safe and sustainable-by-design materials to support embedding sustainability criteria over the life cycle of products and processes. This will be a stepping stone to implementing the chemical strategy for sustainability to support the transition to an overarching framework that makes the safety and sustainability of chemicals essential market entry conditions.

As knowledge and functions build up gradually, more challenging sectors and applications will be addressed over the coming years under Horizon Europe e.g. safe and sustainable-by-design organic and hybrid coatings. As knowledge grows, the scope of innovation will also grow. Thus, future research into safe and sustainable-by-design materials may open up new and unexpected avenues that will be then tested in dedicated Open Innovation Test Beds. In addition, the European Partnership for the Assessment of Risks from Chemicals will aim to put into practice the European Commission's goal to implement the safe and sustainable-by-design approach and engage national public authorities in this work.

## Annex I

Table 10: Ecodesign Directive

<b>Title</b>	Ecodesign Directive (Directive 2009/125/EC)
<b>Short description</b>	<p>The Directive sets out consistent EU-wide rules for improving the environmental performance of products, such as household appliances, information and communication technologies and engineering. The Directive sets minimum mandatory requirements for energy efficiency and water efficiency of these products. This helps prevent barriers to trade, improve product quality and environmental protection.</p> <p><a href="https://ec.europa.eu/growth/industry/sustainability/product-policy-and-ecodesign_en">https://ec.europa.eu/growth/industry/sustainability/product-policy-and-ecodesign_en</a></p>
<b>Scope</b>	<p>Energy-related products (ErP) – 28 products in total:</p> <p>(air conditioners, domestic ovens and range hoods, electrical lamps and luminaires, dishwashers, refrigerating appliances, tumble driers, washing machines, local space heaters, professional refrigerated storage cabinets, residential ventilation units, vacuum cleaners, space heaters, electronic displays and TVs, computers and computer servers, etc.)</p>
<b>Criteria groups covered under each sustainability pillar</b>	<p>The main focus is on energy and water consumption during the use stage.</p> <p>Material efficiency: reparability and recyclability criteria are included in the latest revision of Ecodesign (October 2019) which start to fully apply in 2021.</p>
<b>Certification/validation on scheme</b>	<p>Self-declaration</p> <p>National market surveillance authorities verify whether products sold in the EU meet the requirements laid out in the Ecodesign and energy labelling regulations.</p>
<b>Criteria development methodology</b>	<p>MEErP (Methodology for ecodesign of energy-related products) 2011 – currently under revision (3-3.5 year' process)</p> <ol style="list-style-type: none"> <li>1. Preparatory study following MEErP and consultation with stakeholders via the consultation forum</li> <li>2. Impact assessment</li> <li>3. Inter-service consultation</li> <li>4. Consultation with the World Trade Organisation</li> <li>5. Regulatory committee – adoption of the legal act</li> </ol>

**Table 11: Energy label**

<b>Title</b>	Energy Label Directive (2010/30/EU – revised EU 2017/1369)
<b>Short description</b>	<p>The energy labels provide a clear and simple indication of the energy efficiency and other key features of products at the time of purchase. This makes it easier for consumers to save money on their household energy bills and contribute to reducing greenhouse gas emissions across the EU.</p> <p><a href="https://ec.europa.eu/info/energy-climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/energy-label-and-ecodesign/about_en">https://ec.europa.eu/info/energy-climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/energy-label-and-ecodesign/about_en</a></p>
<b>Scope</b>	Energy-related products. Same scope as Ecodesign Directive.
<b>Criteria groups covered under each sustainability pillar</b>	The main focus is on energy and water consumption during the use stage.
<b>Certification/validation on scheme</b>	<p>Self-declaration</p> <p>National market surveillance authorities verify whether products sold in the EU follow the requirements laid out in the Ecodesign and energy labelling regulations. Suppliers must provide sufficient technical documentation to assess the accuracy of the information contained in the label and the technical specification.</p>
<b>Criteria development methodology</b>	Analysis of the energy/water consumption of a representative group of products and define the value ranges, from low to high efficiency values.



**Table 12: EU Ecolabel**

<b>Title</b>	EU Ecolabel (EU 2010/66)
<b>Short description</b>	<p>The EU Ecolabel is a voluntary label of environmental excellence awarded to products and services that meet high environmental standards throughout their lifecycle: from raw material extraction to production, distribution and disposal. The EU Ecolabel promotes the circular economy by encouraging producers to generate less waste and CO<sub>2</sub> during the manufacturing process. The EU Ecolabel criteria also encourages companies to develop products that are durable, easy to repair and recycle.</p> <p><a href="https://ec.europa.eu/environment/ecolabel/index_en.htm">https://ec.europa.eu/environment/ecolabel/index_en.htm</a></p>
<b>Scope</b>	<p>All types of products and services</p> <p>Personal care (cosmetics and diapers); cleaning (detergents for dishwasher, industrial dishwasher detergents, hand washing detergents, laundry detergents, indoor cleaning services); textile products; footwear; TVs; paints and varnishes; hard coverings; lubricants; printed paper; converted paper; tourist accommodation; financial products; office buildings.</p>
<b>Criteria groups covered under each sustainability pillar</b>	The Ecolabel covers the entire life cycle (material extraction, manufacturing, use stage and end-of-life) looking at environmental impacts and safety aspects in terms of SVHC (substances of very high concern – REACH) and worker safety.
<b>Certification/validation on scheme</b>	Applications to obtain the EU Ecolabel are sent via the competent bodies (in the Member States) who verify evidence of compliance and award the label.
<b>Criteria development methodology</b>	<p>2.5 to 3 year' process</p> <p>Preliminary report and technical report – 2 consultations with stakeholders via the ad hoc working groups</p> <p>Consultation with the EUEB (EU Ecolabelling Board) which meets at least twice a year</p> <p>ISC</p> <p>Regulatory committee – formal adoption legal act</p>

**Table 13: EU GPP**

<b>Title</b>	EU GPP criteria (COM 2008/400)
<b>Short description</b>	The EU GPP criteria are developed to help integrate green requirements into public tender specifications. While the EU GPP criteria aim to achieve a good balance between environmental performance, cost, market availability and ease of verification, procuring authorities may choose, according to their needs and ambition level, to include all or only certain requirements in their tender documents.
<b>Scope</b>	Similar to the EU Ecolabel but with a broader approach to public procurement product and services (e.g. office building design construction and management; public space maintenance, food catering services and vending machines).
<b>Criteria groups covered under each sustainability pillar</b>	<p>The entire life cycle is covered (material extraction, manufacturing, use stage and end-of-life) looking at environmental impacts and safety aspects in terms of the substances of very high concern (REACH) and safety for workers.</p> <p>The criteria also cover social aspects for absorbent hygienic products.</p>
<b>Certification/validation scheme</b>	Verification of the evidence from tenderers provided during the procurement process.
<b>Criteria development methodology</b>	<p>2.5-3 year' process</p> <p>Preliminary report and technical report – 2 consultation with stakeholders via ad hoc working groups.</p> <p>Consultation with GPP advisory group.</p> <p>ISC</p>

**Table 14: Sustainable products initiative**

<b>Title</b>	Sustainable products initiative (under development)
<b>Short description</b>	<p>This initiative will expand the scope of the Ecodesign Directive to non-energy-related products and covering the entire lifecycle. It will also address the presence of harmful chemicals in products such as electronics and ICT equipment, textiles, furniture and steel, cement and chemicals.</p> <p>As in the Ecodesign Directive, it will set mandatory requirements for products to enter the EU market.</p>
<b>Scope</b>	ErP + electronics and ICT equipment, textiles, furniture and steel, cement and chemicals.
<b>Criteria groups covered under each sustainability pillar</b>	Still under development, but it aims to cover circular economy aspects such as durability, reusability, repairability and recyclability, as well as other relevant sustainability criteria.
<b>Certification/validation scheme</b>	Under development.
<b>Criteria development methodology</b>	MEErP will be updated to accommodate the expanded scope of SPI

**Table 15: Green claims initiative**

<b>Title</b>	Green claims initiative (GCI) - (under development)
<b>Short description</b>	<p>The initiative will cover voluntary environmental (green) claims that may be substantiated by the Environmental Footprint methods.</p> <p>This initiative will be developed in close coordination with other initiatives:</p> <ul style="list-style-type: none"> <li>- the revision of EU consumer law to empower consumers to participate actively in the green transition (also announced in the CEAP);</li> <li>- a sustainable product policy initiative focusing on making products fit for a climate-neutral, resource-efficient and circular economy (also announced in the CEAP);</li> <li>- action to create a sustainable labelling framework, announced in the farm-to-fork strategy.</li> </ul> <p>These initiatives will seek to establish a coherent policy framework to help the EU make sustainable goods, services and business models the norm and to integrate environmental considerations into the decision-making process.</p> <p>The legislative proposal is expected to be adopted by 2022.</p> <p><a href="https://ec.europa.eu/environment/eussd/smgp/initiative_on_green_claims.htm">https://ec.europa.eu/environment/eussd/smgp/initiative_on_green_claims.htm</a></p>
<b>Scope</b>	Products (goods and services) and organisations
<b>Criteria groups covered under each sustainability pillar</b>	<p>The GCI focuses on environmental claims. The initiative proposes to set requirements on the use of standard environmental footprint methods to substantiate and quantify the environmental impact of products and organisations.</p> <p>The initiative aims to set minimum requirements on how to communicate this environmental information and the related green claims. The EF methods are included in Annex I to Recommendation No 179/2013/EC.</p>
<b>Certification/validation scheme</b>	-
<b>Criteria development methodology</b>	-

**Table 16: Sustainable finance**

<b>Title</b>	Sustainable finance (EU) 2020/852
<b>Short description</b>	Voluntary criteria to assess whether an economic activity qualifies as environmentally sustainable for the purposes of establishing the degree to which an investment is environmentally sustainable. The criteria apply to financial products and corporate bonds.
<b>Scope</b>	Financial products and corporate bonds related to the following economic sectors:  (Agriculture and forestry; environmental protection and restoration; manufacturing; energy; water supply, sewerage, waste management; transport; construction and real estate; ICT; education; Human health and social work)
<b>Criteria groups covered under each sustainability pillar</b>	1. Towards the achievement of one of the environmental objectives (listed below)  2. Do not cause significant harm to other areas  3. Application of governance frameworks integrating environmental, social and governance factors of responsible investment (UN)  The regulation focuses on six environmental objectives:  (a) climate change mitigation; (b) climate change adaptation; (c) the sustainable use and protection of water and marine resources; (d) the transition to a circular economy; (e) pollution prevention and control; (f) the protection and restoration of biodiversity and ecosystems.
<b>Certification/validation scheme</b>	Carried out by the bank/entity requesting the criteria
<b>Criteria development methodology</b>	Criteria (a) and (b) under consultation, the rest are under development. An external technical expert group has been created to provide support.  All criteria to be published by end of 2021.

**Table 17: New proposal on sustainable batteries**

<b>Title</b>	Batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020.
<b>Short description</b>	This Regulation aims to ensure that batteries placed on the EU market are sustainable and safe throughout their entire life cycle.
<b>Scope</b>	All batteries (i.e. industrial, automotive, electric vehicle and portable) placed on the EU market, and all lifecycle stages.
<b>Criteria groups covered under each sustainability pillar</b>	Responsibly sourced materials, restricted use of hazardous substances, minimum content of recycled materials, carbon footprint, performance, durability, labelling and collection and recycling targets.
<b>Certification/validation scheme</b>	<p>Self-declaration for all requirements, except for recycled content, carbon footprint and responsible sourcing (due diligence), which are third-party verified via notified bodies.</p> <p>National market surveillance authorities verify whether products sold in the EU meet the requirements laid out in the regulation.</p>
<b>Criteria development methodology</b>	<p>There are three main avenues:</p> <p>Secondary legislation:</p> <ul style="list-style-type: none"> <li>- harmonised rules for carbon footprint requirements (based on existing PEFCRs) (Article 7)</li> <li>- harmonised rules for recycled content (Article 8)</li> </ul> <p>Harmonised standards:</p> <ul style="list-style-type: none"> <li>- performance and durability for primary and secondary batteries (Articles 9 and 10)</li> <li>- safety of energy storage systems (Article 12)</li> <li>- state of health (Articles 14 and 59.5)</li> </ul> <p>Common specifications (as per Article 16, if harmonised standards fail)</p>

**Table 18: TCO certified**

<b>Title</b>	TCO certified
<b>Short description</b>	Sustainability certification for IT products in offices and data centres. ( <a href="https://tcocertified.com/tco-certified/">https://tcocertified.com/tco-certified/</a> )
<b>Scope</b>	TCO Certified is available for 11 product categories: displays, notebooks, tablets, smartphones, desktops, all-in-one PCs, projectors, headsets, network equipment, data storage products and servers.
<b>Criteria groups covered under each sustainability pillar</b>	<p><b>Socially responsible manufacturing</b></p> <ul style="list-style-type: none"> <li>• Code of conduct: compliance and corrective action independently verified</li> <li>• Responsible mineral sourcing, including conflict minerals and cobalt</li> <li>• Reduced worker exposure to hazardous chemicals used in manufacturing</li> <li>• Independently verified management system for anti-corruption and whistleblowing</li> <li>• Intensified monitoring of progress and corrective action at high-risk factories</li> <li>• The criteria cover labour laws, International Labour Organisation core conventions and the United Nations Convention on the Rights of the Child</li> </ul> <p><b>Environmentally responsible manufacturing</b></p> <ul style="list-style-type: none"> <li>• Reduced impact from manufacturing: management system, energy consumption</li> </ul> <p><b>User health and safety</b></p> <ul style="list-style-type: none"> <li>• Electrical safety, limited noise levels, electric and magnetic fields</li> </ul> <p><b>Product performance</b></p> <ul style="list-style-type: none"> <li>• Ergonomic design, image quality, adjustability</li> <li>• Product energy efficiency: Energy Star® or equivalent</li> </ul> <p><b>Product lifetime extension</b></p> <ul style="list-style-type: none"> <li>• Product durability: drop and temperature resistance</li> <li>• Battery life and replaceability</li> </ul>

	<ul style="list-style-type: none"> <li>• Availability of replacement parts and service manuals</li> <li>• Secure data removal</li> <li>• Standardised connectors</li> </ul> <p><b>Reduction of hazardous substances</b></p> <ul style="list-style-type: none"> <li>• Reduction or elimination of hazardous substances including heavy metals (beyond RoHS)</li> <li>• Only flame retardants and plasticisers that are independently verified as safer are accepted</li> </ul> <p><b>Material recovery</b></p> <ul style="list-style-type: none"> <li>• Take-back options for discarded products</li> <li>• All packaging must be recyclable</li> </ul> <p><b>Sustainability performance indicators*</b></p> <ul style="list-style-type: none"> <li>• Indicators provided on product energy consumption, weight and recycled plastic content help you measure progress toward set sustainability goals</li> </ul>
<b>Certification/ validation scheme</b>	<p>The criteria for TCO Certified are verified by independent and accredited verification organisations, in accordance with ISO/IEC 17025.</p> <p>3-5 weeks</p> <p>Phase 1: Review criteria/ meet with TCO/ sign agreement/ find a verifier</p> <p>Phase 2: Test &amp; verification</p> <p>Phase 3: Apply for TCO certification either personally or through the verifying organisation</p>
<b>Criteria development methodology</b>	<p>Criteria and verification methods are science-based and developed in an open process with an international network of stakeholders that includes users, buyers, brands, manufacturers, researchers, NGOs and subject matter experts. A new generation of TCO Certified is released every three years.</p>



**Table 19: Nordic Swan**

<b>Title</b>	Nordic Swan (Denmark, Finland, Iceland, Norway & Sweden)
<b>Short description</b>	<p>The Nordic Swan Ecolabel (<a href="https://www.nordic-ecolabel.org/">https://www.nordic-ecolabel.org/</a>):</p> <ul style="list-style-type: none"> <li>- sets strict environmental requirements in all relevant phases of a product's life cycle;</li> <li>- sets strict requirements for chemicals used in ecolabelled products;</li> <li>- tightens the requirements for goods and services continuously to create sustainable development;</li> <li>- certifies and verifies that all requirements are met before a product is approved.</li> </ul>
<b>Scope</b>	Nordic Swan covers several hundred product types. These include chemical building products, industrial cleaning and degreasing agents, indoor paints and varnishes, solid fuels and firelighting products and renovation (more info: <a href="#">here</a> ).
<b>Criteria groups covered under each sustainability pillar</b>	<p>Development of criteria for new areas is based on preliminary studies (6-9 months together with existing criteria)</p> <p>Revision of existing criteria is based on an evaluation of environmental concerns (6-9 months)</p> <p>Experts from all Nordic countries, in contact with businesses and other stakeholders contribute to new or revised criteria (9-12 months)</p> <p>Proposal to the Nordic Ecolabelling Boards</p> <p>The criteria carry an expiry date; typically after 4 years</p>
<b>Certification/validation on scheme</b>	Apply and submit documents / national ecolabelling organisation carries out an inspection / obtain certification
<b>Criteria development methodology</b>	<p>Complex criteria based on product group</p> <p>E.g. chemical building products: <a href="https://www.nordic-ecolabel.org/product-groups/group/?productGroupCode=097">https://www.nordic-ecolabel.org/product-groups/group/?productGroupCode=097</a></p>

**Table 20: Blue Angel**

<b>Title</b>	Blue Angel (DE)
<b>Short description</b>	<p><a href="https://www.blauer-engel.de/sites/default/files/sidebar/downloads/be-factsheet-prinzipien-en.pdf">https://www.blauer-engel.de/sites/default/files/sidebar/downloads/be-factsheet-prinzipien-en.pdf</a></p> <p>Services are awarded the label when they have a significant impact on reducing pressure on the environment, for example:</p> <ul style="list-style-type: none"> <li>• resource-conserving production (water, energy)</li> <li>• preference for recycled materials e.g. paper and plastic</li> <li>• sustainable products made out of raw materials</li> <li>• avoiding pollutants in products</li> <li>• reducing emissions of harmful substances into the soil, air, water and indoor spaces</li> <li>• reducing noise and electromagnetic radiation</li> <li>• efficient use and products that use a low level of energy or water</li> <li>• durability, repairability and recyclability</li> <li>• good fitness for use</li> <li>• return systems and services that enable the common use of products such as car sharing</li> </ul> <p>The Blue Angel label guarantees that a product or service meets high standards of environmental, health and performance. In the process of awarding the label, products and services are always evaluated across their entire life cycle. Criteria are developed for each individual product group. (<a href="https://www.blauer-engel.de/en/blue-angel/what-is-behind-it">https://www.blauer-engel.de/en/blue-angel/what-is-behind-it</a>)</p>
<b>Scope</b>	Five different product groups: home and living; paper and printing; electric devices; construction and heating; business and municipality
<b>Criteria groups covered under each sustainability pillar</b>	<p>The criteria used depends on the product group:</p> <p><b>Home and living:</b> protecting resources using recycled materials, protecting water with ecological washing and cleaning agents, a healthy indoor climate thanks to furniture and mattresses low in harmful substances, using products instead of owning, and mobility service.</p> <p><b>Paper and printing:</b> protecting resources using recycled paper, environmentally friendly printing and printing services.</p>

	<p><b>Electric devices:</b> energy-efficient devices, and options to upgrade the devices so they can be used for as long as possible.</p> <p><b>Construction and heating:</b> products release very low levels of solvents and other volatile substances into the room air, limit pollutants and preservatives to a minimum and use wood sourced from sustainably managed forests, good insulation.</p> <p><b>Business and municipality:</b> supports the transition to sustainable vehicle and mobility services, limits for the permissible sound pressure levels and exhaust emission levels, resource and eco-friendly data centres.</p>
<b>Certification/validation on scheme</b>	<p>For an existing basic award criteria:</p> <ol style="list-style-type: none"> <li>1- application submitted</li> <li>2- a third party (RAL GmbH) checks the requirements</li> <li>3- federal state submits a statement</li> <li>4- RAL authorises the contract on use.</li> </ol>
<b>Criteria development methodology</b>	<p>The validity for each basic award criteria is generally 3-5 years. The basic award criteria are always agreed for a limited period by the environmental label jury.</p> <p>For a new basic award criteria:</p> <ol style="list-style-type: none"> <li>1) application submitted,</li> <li>2) specialist evaluation by the Federal Environment Agency,</li> <li>3) the environmental label jury decides on the investigative order,</li> <li>4) Federal Environment Agency expert preparation and proposals for the basic award criteria,</li> <li>5) RAL GmbH organises the expert hearing that makes recommendations for the environmental label jury,</li> <li>6) environmental label jury ratification of the basic award criteria,</li> <li>7) announcement of the decisions</li> </ol>

**Table 21: Natureplus**

<b>Title</b>	Natureplus ecolabel (DE)
<b>Short description</b>	<p>Natureplus is an international label of quality for sustainable building and accommodation products, tested for health, environmental-friendliness and functionality.</p> <p>The label's primary aim is to provide consumers as well as architects, tradesmen, building companies and all those involved in construction, with a reliable guide to encourage the use of sustainable products i.e. environmentally friendly products that do not pose any health risk.</p>
<b>Scope</b>	The Natureplus ecolabel is the only European environmental label for building products that is founded on strict scientific criteria and it is based on three key pillars: <i>climate protection, healthy accommodation and sustainability</i> .
<b>Criteria groups covered under each sustainability pillar</b>	<p>1. <i>Clean and efficient production:</i></p> <p>The manufacture of the building products is environmentally friendly and energy efficient. It helps to protect the climate, avoid CO<sub>2</sub> emissions and meet social responsibility standards. The products must be functional and recyclable.</p> <p>2. <i>Protection of the environment and health:</i></p> <p>Building products with the Natureplus label do not adversely affect the environment or human health through harmful substances and ensure, in particular, healthy indoor living spaces.</p> <p>3. <i>Sustainability of resources:</i></p> <p>Only building products made from renewable resources or mineral raw materials that are available in abundance or secondary raw materials are permissible. The raw materials must stem from sustainable sources.</p>
<b>Certification/validation on scheme</b>	<p>Inspection of the production site</p> <p>Lifecycle assessment of the manufacturing process</p> <p>Product-specific laboratory tests</p> <p>Analysis of the product life cycle</p> <p>Award decision for the Natureplus label</p>
<b>Criteria development methodology</b>	The Natureplus®-Ecolabel is classified as a Type 1 environmental label as per ISO 14024, taking into consideration the EU Ecolabel Regulation 2 and the EMAS Regulation on environmental auditing, and is valid across the whole of Europe according to uniform criteria.

**Table 22: OEKO-TEX**

<b>Title</b>	OEKO-TEX
<b>Short description</b>	OEKO-TEX® consists of 18 independent research and test institutes in the field of textile and leather ecology in Europe and Japan with contact offices in over 60 countries. The partner institutes have joint responsibility for developing test methods and limit values, which form the basis for the standards.
<b>Scope</b>	Manufactures and brands for textiles and leather
<b>Criteria groups covered under each sustainability pillar</b>	<p>Different ecolabels depending on the scope:</p> <p>STANDARD 100 by OEKO-TEX® and LEATHER STANDARD by OEKO-TEX®: Testing for harmful substances</p> <p>MADE IN GREEN by OEKO-TEX®: Testing for harmful substances. Guarantees manufacturing using sustainable processes under socially responsible working conditions</p> <p>STeP by OEKO-TEX®: Chemical management, Environmental performance, Environmental management, Social responsibility, Quality management, Health protection and safety at work</p> <p>ECO PASSPORT by OEKO-TEX®: Independent certification system for chemicals, colourants and auxiliaries used in the textile and leather industry. Designed for manufacturers that process chemical compounds.</p>
<b>Certification/validation scheme</b>	<ol style="list-style-type: none"> <li>1- Application form completed</li> <li>2- Selected OEKO-TEX® institute gets in touch</li> <li>3- Definition of the scope of the audit and success parameters. A quality audit by an independent OEKO-TEX® institute test the materials against the criteria for the type of label. They also examine the documents</li> <li>4- If your product has successfully passed the laboratory test, you receive the certification</li> <li>5- An OEKO-TEX® expert visits your site in order to confirm all the details</li> </ol>
<b>Criteria development methodology</b>	<p>The criteria are scientific and open-based. They are updated at least once a year and expanded to integrate new scientific knowledge or statutory requirements. For each ecolabel criteria changes. Different criteria can be found on the <a href="#">website</a>.</p> <p>The certification process is fast and certificates are valid for a year.</p>

**Table 23: Bluesign**

<b>Title</b>	Bluesign
<b>Short description</b>	Independent verifier to build trust and transparency in tracing each textile along the manufacturing process, making improvements at every stage from factory floor to finished product.
<b>Scope</b>	From production sites, converters, brands and products (Chemical suppliers, textile and trim manufacturers)
<b>Criteria groups covered under each sustainability pillar</b>	<p>In general:</p> <ul style="list-style-type: none"> <li>• Highest degree of safety for the consumer</li> <li>• Manufacturing with lowest possible impact on people and the environment (water reduction, wastewater reduction, energy reduction, reduction of chemicals and hazardous substances...)</li> <li>• Responsible use of resources</li> </ul> <p>Specific criteria for production sites, converters, brands and products can be found here</p>
<b>Certification/validation scheme</b>	<p>For a product:</p> <ol style="list-style-type: none"> <li>1- have passed a Bluesign® company assessment;</li> <li>2- be a Bluesign® system partner and have the right to use a Bluesign® trademark;</li> <li>3- be authorised in writing by Bluesign technologies to self-declare articles as Bluesign® products;</li> <li>4- maintain a robust quality management system to manage the supply chain and verify supplier qualification based on traceability, a comprehensive/appropriate restricted substance list and a bill of materials.</li> </ol>
<b>Criteria development methodology</b>	<p>The Bluesign® criteria define the essential requirements within the Bluesign® system in the form of:</p> <ul style="list-style-type: none"> <li>- requirements for inputs, production sites and products;</li> <li>- selection of priority substances and substance limits.</li> </ul> <p>Bluesign revises and improves the system to reflect and meet the requirements of the strictest and most advanced regulations worldwide on sustainable textile production, to maintain a high level of product safety, to encourage use of the latest technology, and to meet stakeholder expectations.</p> <p>Selection and/or amendment of priority substances, updating related limits, and publishing related documents (BSBL, BSSL) takes place regularly, at least once a year.</p>

**Table 24: Green seal**

<b>Title</b>	Green Seal
<b>Short description (with reference)</b>	<p><a href="https://www.greenseal.org/about/faq">https://www.greenseal.org/about/faq</a></p> <p>Green Seal is a United States' premier ecolabel. They develop stringent, lifecycle-based, multi-attribute standards and certify products and services that meet them.</p> <p>Green Seal Certification is a process that ensures that a product or service meets rigorous performance, health, and environmental criteria. These criteria can be found in official standards, which are organised by product/service category. Earning Green Seal Certification allows manufacturers &amp; providers to substantiate their environmental claims and helps purchasers identify products that are proven to be safer for human health and the environment.</p>
<b>Scope (e.g. products, materials, processes, industrial sectors)</b>	<p>Products: paper, cleaning products, paints/coatings, food packaging, adhesives, soaps, laundry care products</p> <p>Services: hotels and lodging, cleaning services, restaurant &amp; food services</p> <p>Environmental innovation</p>
<b>Criteria groups covered under each sustainability pillar (environmental, safety, circular, governance, economic and social)</b>	<p>Green-Seals-Standard-Development-Process.pdf on sharedrive</p> <p>Environmental (including lifecycle considerations to avoid impact transfer)</p> <p>Human health: toxicity, carcinogens, mutagens, reproductive toxins, neurotoxins, endocrine disruptors, asthmagens, volatile organic compounds (VOCs); skin sensitisation, particulate matter, ionising radiation, combustibility and flammability</p> <p>Minimise waste: recovered materials, recyclability, product performance</p> <p>Clean water: acute aquatic toxicity, aquatic eutrophication, aquatic biodegradability, bioaccumulation, water use</p> <p>Preserve the climate: volatile organic compounds (VOCs), energy use, mineral extraction, concentrated products</p> <p>Social responsibility (found in a particular standard): freedom of association/collective bargaining, freedom of labour, freedom from discrimination, health and safety, employment conditions</p> <p>Circular: scope for optional claims on the use of recovered materials</p>

<b>Certification/validation scheme</b>	<p>To keep the certification, the product manufacturer, hotel, restaurant, or cleaning service needs to update and re-submit certain documents on a regular basis as part of compliance monitoring. In many cases, compliance monitoring requires another on-site audit. This process ensures that the product or service still meets the applicable Green Seal standard.</p> <p>To be completed</p>
<b>Criteria development methodology (only if considered relevant)</b>	<p>Green Seal operates under the international guidelines for environmental labelling programmes, ISO 14020 and 14024, set by the International Organization for Standardization.</p> <p>The requirements are the result of research by in-house environmental scientists, who identify the major impacts of a product category on health and environment and set requirements that represent leadership in that product category. They then consult stakeholders to ensure that criteria are both challenging and achievable, and accurately capture the environmental impacts and current market practice.</p>



**Table 25: GreenScreen for safer chemicals**

<b>Title</b>	GreenScreen for safer chemicals <a href="https://www.greenscreenchemicals.org/">https://www.greenscreenchemicals.org/</a>
<b>Short description (with reference)</b>	The Clean Production Action developed the GreenScreen for safer chemicals as a publicly available and transparent chemical hazard screening method to help move our society quickly and effectively toward the use of greener and safer chemicals. GreenScreen allows users to evaluate chemicals based on their inherent hazards — for example, to check whether they are linked to cancer, are toxic to fish, or are persistent in the environment — and to promote continuous improvement in safer chemicals.
<b>Scope (e.g. products, materials, processes, industrial sectors)</b>	Chemicals used in the following product categories:  Textile chemicals, firefighting foam, furniture & fabric chemicals
<b>Criteria groups covered under each sustainability pillar (environmental, safety, circular economy, governance, economic and social)</b>	Human toxicity  Environmental (toxicity, persistence, bioaccumulation)  Safety (physical reactivity, flammability)
<b>Certification/validation scheme</b>	Three levels: Bronze, Silver, Gold, depending on meeting the benchmarks:  1) Chemical of High Concern (by crosschecking existing databases of high hazard chemicals, including REACH);  2) search for safer substitutes;  3) room for improvement;  4) preferred, safe® chemical
<b>Criteria development methodology</b>	<a href="https://www.greenscreenchemicals.org/images/ee_images/uploads/resources/GS_TwoPager_July2018.pdf">https://www.greenscreenchemicals.org/images/ee_images/uploads/resources/GS_TwoPager_July2018.pdf</a>

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<b>gy (only if considered relevant)</b>	<p>Reference to both US as to EU standards or directives</p> <p>GreenScreen sets out four benchmarks to work towards the use of safer chemicals, with each benchmark defining progressively safer chemicals. It builds on the 12 principles of green chemistry and the US EPA's Design for the Environment (DfE) alternatives assessment method, which consolidates the available data on a chemical's inherent characteristics, including effects on public health, environment and toxicity, and safety, with a table of hazard endpoints each ranked as high, moderate or low.</p> <p>From there, the hazard evaluations are further consolidated into a single benchmark that provides an easy means to compare chemicals. GreenScreen also looks at the hazards posed by a chemical when it breaks down in the environment. By using GreenScreen, companies can rank chemicals and understand why some alternatives are more or less preferable. This helps them make more informed decisions, reduce their business risk, and promote innovation.</p>
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**Table 26: Green chemistry**

<b>Title</b>	Green chemistry  Anastas, P. T.; Warner, J. C. Green Chemistry: Theory and Practice, Oxford University Press: New York, 1998
<b>Short description (with reference)</b>	Green chemistry is the design of chemical products and processes that reduce or eliminate the use or generation of hazardous substances. Green chemistry applies across the lifecycle of a chemical product, including its design, manufacture, use, and ultimate disposal. Green chemistry is also known as sustainable chemistry.  The aim is to prevent pollution and source reduction, and the principles it espouses are a philosophy.
<b>Scope (e.g. products, materials, processes, industrial sectors)</b>	Chemicals
<b>Criteria groups covered under each sustainability pillar (environmental, safety, circular economy, governance, economic and social)</b>	Sustainability: human health and the environment  Safety: Eliminating hazard from products and processes for workers and consumers  Economic: higher efficiency, less waste, better performance, higher sales
<b>Certification/validation scheme</b>	Not a certification scheme as such but a philosophy summarised in the below principles  Link with <i>safer choice</i> labelling and many other initiatives
<b>Criteria development methodology (only if considered relevant)</b>	12 principles: <ul style="list-style-type: none"> <li>- Prevent waste</li> <li>- Maximise atom economy (less atoms wasted)</li> <li>- Design less hazardous chemical syntheses</li> <li>- Design safer chemicals and products</li> <li>- Use safer solvents and reaction conditions</li> <li>- Increase energy efficiency (at room temperature if possible)</li> <li>- Use renewable feedstock (agricultural, waste stocks)</li> <li>- Avoid chemical derivatives</li> <li>- Use catalysts, not stoichiometric reagents</li> <li>- Design chemicals and products to degrade after use</li> <li>- Analyse in real time to prevent pollution</li> <li>- Minimise the risk of accidents (incl. physical form)</li> </ul>

Table 27: Safer choice label

<b>Title</b>	Safer Choice label <a href="https://www.epa.gov/saferchoice/learn-about-safer-choice-label">https://www.epa.gov/saferchoice/learn-about-safer-choice-label</a>
<b>Short description (with reference)</b>	A label for safer chemical-based products. A product may only carry the Safer Choice label if each ingredient is among the safest in its category. Additionally, the product as a whole must meet safety criteria, qualify as high-performing and be packaged in an environmentally friendly manner. Some consumers want to know which chemicals are in the products they use so there is a labelling requirement to disclose all ingredients either on the product or the manufacturer's website.
<b>Scope (e.g. products, materials, processes, industrial sectors)</b>	Chemical ingredients: chelating/sequestering agents, colourants, polymers, preservatives, defoamers, enzyme (stabilisers), fragrances, oxidants (stabilisers), processing aids and additives, solvents, surfactants
<b>Criteria groups covered under each of the sustainability pillars (environmental, safety, circular economy, governance, economic and social)</b>	Human health Environmental health Renewable content Product performance
<b>Certification/validation scheme</b>	Ingredients are checked for safer alternatives against a safer chemical ingredients list. Only products with the safest possible ingredients can be awarded the label.  3-year renewal  <a href="https://www.epa.gov/saferchoice/safer-ingredients">https://www.epa.gov/saferchoice/safer-ingredients</a>
<b>Criteria development methodology (only if considered relevant)</b>	The master criteria enable users to distinguish products at the greener or 'low-concern' end of the chemical safety spectrum. To define low concern, Safer Choice uses toxicological thresholds set by highly respected health and environmental protection authorities.  For functional categories where there are currently no 'low-concern' ingredients, Safer Choice works with its stakeholders to carefully adjust the master criteria in a way that allows for ingredient choices while ensuring the safest possible ingredients in that functional category.

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The aim of this study is to map existing initiatives and R&I activities related to sustainability that are relevant for the development of sustainable-by-design criteria for chemicals, materials and products.

It includes three main parts, 1) Identification of existing policies and initiatives that implement sustainability criteria, 2) Analysis of a sample of criteria under the relevant policies and initiatives with a focus on materials and chemicals, and 3) Analysis of the progress in R&I.

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