Deliverable Report D1.2

Needs Assessment Report of Regulatory & Policy Frameworks

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[1]R= Document, report (excluding the periodic and final reports); DEM = Demonstrator, pilot, prototype, plan designs; DEC = Websites, patents filing, press & media actions, videos, etc.; DATA =Data sets, microdata, etc.; DMP = Data management plan; ETHICS = Deliverables related to ethics issues; SECURITY = Deliverables related to security issues; OTHER = Software, technical diagram, algorithms, models, etc.

[2]PU = Public, fully open, e.g. web (Deliverables flagged as public will be automatically published in CORDIS project's page); SEN = Sensitive, limited under the conditions of the Grant Agreement; Classified R-UE/EU-R = EU RESTRICTED under the Commission Decision No2015/444; Classified C-UE/EU-C = EU CONFIDENTIAL under the Commission Decision No2015/444; Classified S-UE/EU-S = EU SECRET under the Commission Decision No2015/444

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Acronyms Listed in this Document	
Cefic	European Chemical Industry Council
CNTs	Carbon nanotubes
EU	European Union
FAIR	Findable, Accessible, Interoperable, and Reusable
GD	Guidance Document
GPSR	General Product Safety Regulation
HR-TEM	High Resolution Transmission Electron Microscopy
ICT	Information and communications technology
ISO	International Organisation for Standardisation
JRC	Joint Research Centre
LCA	Life Cycle Assessment
LCIA	Life cycle impact assessment
NAMs	New Approach Methodologies
OECD	Organisation for Economic Cooperation and Development
OECD WPMN	OECD Working Party on Manufactured Nanomaterials
REACH	European Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SSbD	Safe and Sustainable by Design
TG	Test Guideline
TOF-SIMS	Time-of-Flight Secondary Ion Mass Spectrometry

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Executive Summary

Advanced materials are pivotal for Europe's industrial innovation and the ambitious goals of the European Green Deal. Their novel or enhanced properties are essential for achieving a sustainable and resilient future for Europe. However, the rapid pace of innovation presents significant challenges for risk governance, particularly in terms of safety and sustainability.

The European Green Deal sets a roadmap for a sustainable future by 2050, aiming for a toxic-free environment and a circular economy. Key strategies include the Zero Pollution Ambition, the Circular Economy Action Plan, and the Chemicals Strategy for Sustainability. Central to these efforts is the Safe and Sustainable by Design (SSbD) approach, balancing safety, sustainability, and socio-economic factors throughout a material's life cycle.

While regulations like REACH have been adapted for nanomaterials, they may not fully cover advanced materials. Recent legislative actions such as the Corporate Sustainability Reporting Directive and the Ecodesign for Sustainable Products Regulation are steps towards comprehensive sustainability reporting and product design. However, specific guidelines for advanced materials, particularly in waste management, remain underdeveloped.

Ensuring the safety and sustainability of advanced materials requires harmonised test methods, comprehensive life cycle assessments, and robust data management. Challenges include the multitude of shapes and behaviours of (nano)materials and material transformations during their life cycle. Furthermore, assessing the whole life cycle for emerging technologies prospectively raises challenges.

To address these challenges, several recommendations are proposed. First, it is crucial to define and categorise advanced materials to identify specific regulatory needs and amend existing legislation accordingly. Facilitating life cycle thinking in material design and developing sector-specific methodologies and tools for SSbD, along with incentives to encourage their use, is essential towards innovative safe and sustainable materials. Additionally, combined imaging and analytical approaches should be developed to quantify transformed advanced materials. Enhancing data management practices to ensure the availability and reuse of data, including harmonised ontologies, is also vital to support SSbD. Finally, adjusting harmonised test methods to be applicable for advanced (nano)materials, incorporating New Approach Methodologies (NAMs), and ensuring harmonised test methods for sustainability assessments are necessary steps forward.

1 Introduction

Materials innovation, put under the label of advanced materials, is perceived as a key enabling technology for Europe's industry. Advanced materials are crucial building blocks for the EU's resilience and open strategic autonomy and in achieving the goals of the European Green Deal [1]. The challenge for European risk governance is to keep pace with these developments and application of advanced (nano)materials (*e.g.* [2, 3]), while it is not always clear which specific advanced materials will be used to achieve these goals [4, 5]. For successful application of advanced materials, proper governance in terms of safety and sustainability is essential. However, the roadmaps and strategies underlying European research efforts do not specifically cover governance of advanced materials beyond nanomaterials. The three risk governance projects Gov4Nano, NANORIGO and RiskGONE[3] have addressed the challenges and issues in risk governance of nanomaterials. Three insights from these projects are transferrable to efficient and effective risk governance of advanced (nano)materials: (i) harmonisation and standardisation of test methods and tools, (ii) FAIR data management, and (iii) implementation of a governance organisational structure. Nevertheless, further refinement is needed for advanced (nano)materials, especially when their implementation needs to incorporate the full material life cycle and value chain.

These life cycle aspects become important towards the more sustainable future that the European Commission aims for in its European Green Deal [1]. This Green Deal includes policies towards zero-pollution [6] and re-use of (critical) raw materials [7], including the safe-and-sustainable-by-design concepts (*e.g.* [8]).

In this deliverable we describe the different regulations and policy frameworks (chapters 2 and 3) most relevant for safe and sustainable advanced materials. In chapter 3.3 we discuss several aspects that may challenge these frameworks, in particular for advanced materials. Chapter 5 summarises the needs and provides recommendations to address these needs.

1.1 Advanced Materials encompass a diverse Group of Materials

Despite their crucial role in policy, an unambiguous definition of advanced materials does not exist. To allow a common understanding, the OECD's working description [9] is commonly used as an alternative. It states that *'advanced materials are understood as materials that are rationally designed to have new or enhanced properties, and/or targeted or enhanced structural features with the objective to achieve specific or improved functional performance. […] It is acknowledged that what are currently considered as advanced materials will change with time.'*

In the area of research and development and the corresponding funding systems of the European Commission, advanced materials generally mean materials that have novel or enhanced properties that improve performance over conventional products and processes [10]. Preferably, the improved performance includes increased safety and sustainability.

These very general descriptions demonstrate that advanced materials are not a homogeneous group of materials that can be easily defined but instead encompass diverse materials. A comprehensive report by the German Environmental Agency [11], that aims to identify relevant advanced materials in regard to chemical safety, describes the following (partly overlapping) clusters of advanced materials, including the following:

- Biopolymers (*e.g.* DNA- and protein-based biopolymers)

[3] More information on these projects is available on their respective websites: www.gov4nano.eu, nanorigo.eu/ and riskgone.eu (website accessed: 30.11.2024).

- Composites (*e.g.* hybrid materials and fibre-reinforced composites)
- Porous materials (*e.g.* micro-, meso- and macro-porous materials)
- Metamaterials (*e.g.* electromagnetic and acoustic metamaterials)
- Particle systems (*e.g.* quantum dots, supraparticles, graphene)
- Advanced fibres (*e.g.* organic fibres, carbon-based fibres (incl. CNTs), inorganic fibres)
- Advanced polymers (*e.g.* electro-active polymers, self-repairing polymers, co-polymers)
- Advanced alloys (*e.g.* alloys which comprise more than two components of which at least two components have a large share in the final material)

Advanced materials challenge regulation and safety and sustainability testing in various ways. The new properties that give advanced materials their enhanced functionalities, can also introduce unknown hazards. For some types of advanced materials, preliminary indications on safety issues have already been identified. For example, it has been demonstrated that inhalation of various graphene-related materials can lead to DNA damage and lung inflammation [12], which suggests that these materials may be carcinogenic or mutagenic [13]. Sustainability challenges include a lack of life cycle inventory data for the production of advanced materials and insufficient information on the status of transformed materials. This hinders the characterisation of the environmental impact of their released forms [14]. From a regulatory perspective, some advanced materials are covered in the European chemicals regulation REACH [15] as they fall under the REACH definition of a nanoform [16]. For other advanced materials it is unclear whether they are a substance, a mixture or an article[4] and thus how to regulate them under REACH. Depending on their use they may fall under sectoral regulations, but also these should be assessed to see if they are sufficiently equipped to deal with advanced materials.

2 Policy Frameworks

The European Green Deal [1] presents a roadmap to transform the economy of the EU in support of a more sustainable future by 2050. One of the goals is to achieve a toxic-free environment [6], where chemicals are produced and used in a way that maximises their contribution to society, while avoiding harm to the planet and to current and future generations. Major investments are required to achieve this and advanced materials are regarded pivotal to find solutions for the challenges ahead. The Green Deal has been further developed through various strategies and action plans (Figure 1).

The Zero Pollution Ambition includes pollution prevention by advanced materials or advanced materials-enabled products [6]. The zero pollution vision for 2050 is a *'healthy planet for all'*. *'Air, water and soil pollution is reduced to levels no longer considered harmful to health and natural ecosystems and that respect the boundaries our planet can cope with, thus creating a toxic-free environment.'* The Zero Pollution Action Plan [6] implements this vision by providing a roadmap to mainstream pollution prevention in all relevant EU policies. Closely related is the Circular Economy Action Plan [17], which covers the full life cycle of products. It has been adopted with a view to boosting global competitiveness, fostering sustainable economic growth

[4] These terms are defined in Article 3 of the REACH Regulation *[15]: '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'*, *'article: means 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'*.

and generating new jobs. The plan addresses key product value chains: electronics and ICT, batteries and vehicles, packaging, plastics, textiles and food.

The Chemicals Strategy for Sustainability [18] envisions the European industry as a global leader in safe and sustainable chemical production and usage by simplifying and strengthening the legal framework on chemicals. A specific action of the Chemicals Strategy for Sustainability is the promotion of the Safe and Sustainable by Design (SSbD) approach to chemicals and materials.

Figure 1: Policy frameworks and their interconnections. The Zero Pollution Ambition includes pollution prevention by advanced materials or advanced materials-enabled products. The desired outcome is to have a circular economy, zero pollution and climate neutrality.

SSbD *'can be described as an approach that focuses on providing a function (or service), while avoiding onerous environmental footprints and chemical properties that may be harmful to human health or the environment'* [19]. The approach addresses the safety and sustainability and associated processes along the entire life cycle. In 2022 the European Commission adopted the recommendation to establish a European assessment framework for SSbD chemicals and materials developed by the Joint Research Centre (JRC) [8]. The JRC SSbD framework [20] is a voluntary approach that aims to steer the design, development, production and use of new safe and sustainable chemicals and materials. It can also be applied for the re-assessment of existing chemicals and materials to steer substitution of hazardous and less sustainable chemicals and materials. JRC developed an iterative framework combining risk and sustainability assessment in a hierarchical manner in which occupational health and safety is considered first, followed by environmental and socio-economic aspects [20]. The SSbD framework and the accompanying guidance [21] aims to help with assessing trade-offs between sustainability, safety and socio-economical assessments along the life cycle of a chemical and material. The European Chemical Industry Council (Cefic) recently released its own SSbD guidance with a focus on early innovation [22]. In its guidance Cefic emphasises the need to increase the speed and likelihood to bring solutions to the market (fail fast, fail cheap concept).

Various tools exist to operationalise (parts of) SSbD, mainly in the scientific domain. In the OECD WPMN a report that provides an overview of such tools is close to publication (ENV/CBC/NANO(2024)3). Examples include the SSbD Toolbox in PARC[5] and the HARMLESS Decision Support System[6], and the SUNSHINE tools[7]. In addition, regulatory tools like Ecodesign [23, 24] may provide tools to address sustainability and circularity in SSbD.

5 PARC: Partnership for the Assessment of Risks from Chemicals: www.parc-ssbd.eu (website accessed: 30.11.2024)

6 HARMLESS webinar on SSbD: DSS demo with AdMa case study (zenodo.org/records/11459527) (website accessed: 30.11.2024)

7 SUNSHINE Safe and Sustainable Innovation Approach Digital E-infrastructure (www.dev.sunshine.greendecision.eu) (website accessed: 30.11.2024)

3 Regulatory Frameworks

European countries can have their own regulations, some of which are harmonised at EU level. Within the EU, different types of legislation can be used[8]. A regulation is a binding legislative act, which is applied in its entirety across the EU. A directive, on the other hand, sets out a goal that EU countries must achieve. However, it is up to the individual member states to devise their own laws to reach these goals. Where a decision is binding to those it addresses, a recommendation is not binding but suggests a preferred line of action.

Here we summarise the most relevant legislation for safety and sustainability related issues. More elaborate descriptions are available in ANNEX I.

3.1 Chemical and Product Regulations adapted for Nanomaterials

For nanomaterials European legislation has been adapted to allow risk assessment of such small particulate materials. In this context regulatory areas of industrial chemicals [15, 16], cosmetics [25], food/feed [26, 27], biocides/pesticides [28, 29], and medical/veterinary [30, 31] have been adapted. This included incorporation of nanomaterial definitions as well as specific requirements to characterise the (physical) identity of the material and (additional) toxicological endpoints.

REACH is European regulation that applies to all chemical substances and which places the burden of proof on companies [15]. According to Schwirn *et al.* [5], and as mentioned previously, it is unclear how different categories of advanced materials – other than nanoforms – will be considered under REACH.

3.2 Product Regulations

The Corporate Sustainability Reporting Directive [32] entered into force in January 2023. This Directive extended the rules to report sustainability to a broader range of companies (large, small and medium-sized enterprises, and some non-EU companies). Companies now must report according to European Sustainability Reporting Standards. In this sense, talking about materiality assessment, companies should follow Environmental Footprint methods, *i.e.* the Product Environmental Footprint, and the Organisation Environmental Footprint [33], which are LCA-based methods. However, there is not a clear statement on how advanced materials should be evaluated.

The Ecodesign for Sustainable Products Regulation is the European Commission's approach to more environmentally sustainable and circular products [24]. This Regulation entered into force on 18 July 2024 and applies to a broad range of products. It sets 'ecodesign requirements' for physical goods (except those that are dealt with in other legislation already, *e.g.* food/feed, medicinal products, etc.). Requirements include improving lifecycle span, reusability, upgradability and reparability, aimed at making more energy and resource-efficient products (including recycling of resources). In the list of product parameters, one can find release of particles, and emissions to environmental compartments in one or more life cycle stages of the product. In its Chapter III [24], this regulatory framework sets requirements for the 'Digital Product Passport' which will facilitate the traceability of materials and substances within products.

The General Product Safety Regulation (GPSR) [34] will apply from 13 December 2024 and repeals the General Product Safety Directive from 2001 [35]. The GPSR provides a new framework to keep up with the challenges of digitalisation, particularly due to the number of

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8 european-union.europa.eu/institutions-law-budget/law/types-legislation_en (website accessed: 30.11.2024)

products in online marketplaces. However, there are some exceptions which have their own or are subjected to another legal framework. In general, the GPSR mentions that the safety of the product during its entire lifespan should be assessed prior to market availability. It mentions the responsibilities of each economic operator, *i.e.* manufacturer, importer, authorised representative or service provider, and distributor. Moreover, the GPSR states that if new technologies are introduced, the economic operator should assess the product for a new risk assessment if that modification were to have a substantial impact on the safety of the product. Thus, advanced materials are implicitly covered in the GPSR.

Various specific product regulations have been adapted to accommodate nanomaterials, but there are still methodological challenges (see [36, 37]). These regulations include cosmetics, food packaging, biocides, pesticides, medicines, food and feed, medical devices and veterinary medicine [36]. Where advanced materials can be defined as nanomaterials, these adaptations should be sufficient to address safety assessment of advanced materials as well, but it is unclear whether other categories of advanced materials can be sufficiently assessed as well.

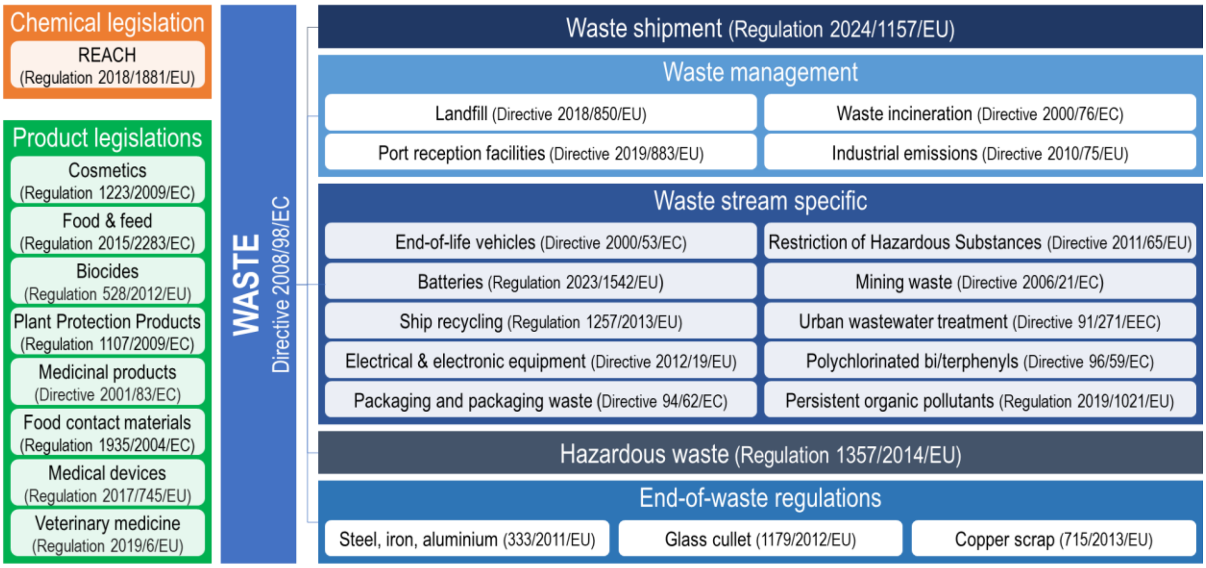

Figure 2: European legal frameworks related to chemicals, products and waste (source: [38-56]).

3.3 Waste Regulations

Waste does not fall under REACH [57], but is covered by the Waste Directive [58] (Figure 2). This Directive describes how waste and waste streams should be classified, treated and managed in the EU. According to this framework, waste is *'any substance or object which the holder discards or intends or is required to discard'* [58]. It is important to consider the type of waste (*e.g.* industrial, commercial or hazardous) as some types of waste are excluded (radioactive waste and wastewater among others). The Waste Directive targets specific sector and product waste due to their crucial role in developing a circular economy. Figure 2 shows an overview of the European waste legislation with specific post-consumer product-waste streams. Advanced materials are not explicitly mentioned in any of these streams. The Waste Directive does mention that non-targeted waste materials should be removed prior to recycling to facilitate high-quality recycling (Article 11a (c)), which could have implications for advanced materials. As soon as a material 'ceases to be waste' (becoming a product or a secondary material, *i.e.* starting a new life cycle), REACH requirements do apply once more (with some exceptions) ([58]; Article 6(1) and (2)). However, it has proven difficult to reach an agreement on end-of-waste criteria [59].

4 Discussion

4.1 Challenges in Safety Assessment and Regulation of Advanced Materials

To ensure the safety and sustainability of advanced materials along their entire life cycle, their innovation and design must be accompanied by safety research. This also requires awareness by material developers that apart from desired properties for a specific purpose, safety and sustainability should be considered in material developments. Assessment of safety and sustainability requires a profound risk and life cycle assessment. This may, therefore, require specific training and knowledge transfer to material developers about these aspects.

There is also a significant need for harmonised test methods that cover the specific requirements of advanced materials and have a high predictivity towards regulatory testing (see also section 4.5). Although additional work is required [37], substantial efforts have been made to adapt and develop validated test methods that account for the particle character and the increased importance of the physical properties of nanomaterials in their fate and behaviour [60]. These test methods for nanomaterials, however, often assume particles to be spherical and dispersible, which does not adequately reflect the diverse shapes (*e.g.* fibres, 2D-materials) and dispersion behaviours of all nanomaterials. As a result, such methods may have large uncertainties, or they may not be applicable at all for other shapes. Also, mechanisms of toxicity may be different (*e.g.* physical damaging of cells versus chemical toxicity), questioning whether such toxicity mechanisms can be captured by current test methods. Furthermore, for some types of particles (quantitative) detection in test media and/or inside of cells and tissues is quite challenging and validated and/or standardised protocols may still be missing. Especially distinguishing organic and carbon-based materials from biological tissues is a huge challenge.

One of the lessons learned from regulating nanomaterials is that keeping pace with technological developments is very challenging. With the current political focus on advanced materials [10] a high speed of innovation and uptake of advanced materials can be expected, making it even more challenging for safety research and regulation to keep up. Failing to cover safety and sustainability aspects of advanced materials and having regulation lagging behind innovation can have severe consequences. Producers of advanced materials might struggle to bring materials to the market as regulation might be unclear, and/or having difficulties in providing the regulatory information requirements as test methods are not adapted to advanced materials. Uncertainties of risks and applicability of legislation and tools might result in a delay of innovation, and form a major barrier for their market exploitation, as identified for nanomaterials [61].

Advanced materials with unknown risks might enter the markets with severe consequences for human health and the environment as happened in the past with *e.g.* chlorofluorocarbons [62], asbestos [63], or more recently per- and polyfluoroalkyl substances [64]. These examples show, that so-called 'wonder materials' may also need attention towards possible risks.

4.2 Life Cycle Assessment and Sustainability

According to the United Nations Brundtland Commission, sustainability may be defined as 'meeting the needs of the present without compromising the ability of future generations to meet their own needs' [65]. How to assess this, however, is a challenge.

With the SSbD Framework [8] the European Commission aims to facilitate assessment of sustainability. Furthermore, in research programmes the Commission encourages the development of tools, methods for easily implementable strategies to facilitate SSbD. General life cycle-based methods may provide a starting point as tools (Figure 3).

Sustainability in the form of life cycle thinking was found in 60% of EU policies [66]. In certain sectors (products, vehicles, and waste for example) life cycle concepts and approaches have been adopted with greater rigor, whereas implementation in other sectors (*e.g.* food and agriculture) is still at preliminary stages [66].

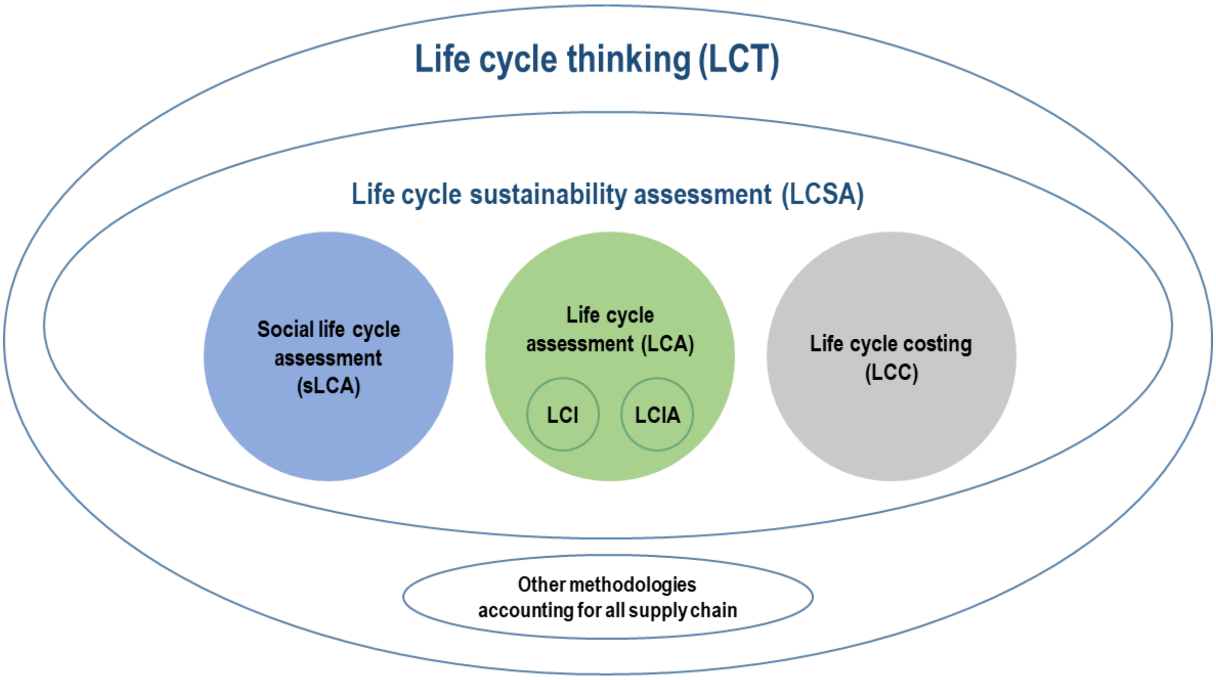

Figure 3: Life cycle-based methodologies. Life Cycle Inventory (LCI) and Life Cycle Impact Assessment (LCIA) are phases within the broader LCA framework (figure adapted from [67]).

Life cycle assessment (LCA) is a method to estimate a set of environmental impacts of a product or a service through the application of life cycle thinking perspective, based on a particular function, and considering different life cycle stages [68]. These usually comprise consecutive and interlinked stages of a product system, from raw material acquisition or generation from natural resources to final disposal [69]. This means that an LCA quantifies all relevant emissions and resources consumed and the related environmental and health impacts and resource depletion issues that are associated with the corresponding goods or services [70]. Thus, LCA may help to evaluate the environmental dimension of sustainability and be adapted to evaluate the socio-economic dimensions as well [67].

Currently some EU legislation include LCA (*e.g.* the Ecodesign Directive [23] or the EU Packaging and Packaging Waste Directive [38]. The current emphasises on sustainability may, however, not be fully covered in such legislation, partly due to limitations of LCA itself.

LCA by itself will only provide a partial answer on the sustainability of a product [71]. Economic and social criteria are (often) not taken into account. Another limitation of LCA as a sustainability measurement tool is that it is often regarded as too generic, which hinders its effective implementation by third parties [72]. Furthermore, the lack of technical knowledge about LCAs and limited trust in the process and its results, create barriers to incorporating sustainability into policies. Additionally, there is no standardised method for verifying compliance with sustainability practices, which remains an unresolved issue [72, 73].

With the multidisciplinary development of the SSbD framework [20], a common understanding of the term ‘life cycle’ becomes necessary. For a LCA, additional clarity is needed on whether chemicals, materials and products are considered and in which applications (Figure 4) [74]. The life cycle of a chemical including all its material and product applications is a completely different life cycle that comprises multiple product life cycles, rapidly branching out from the simplified 'one product, one application' life cycle in Figure 4.

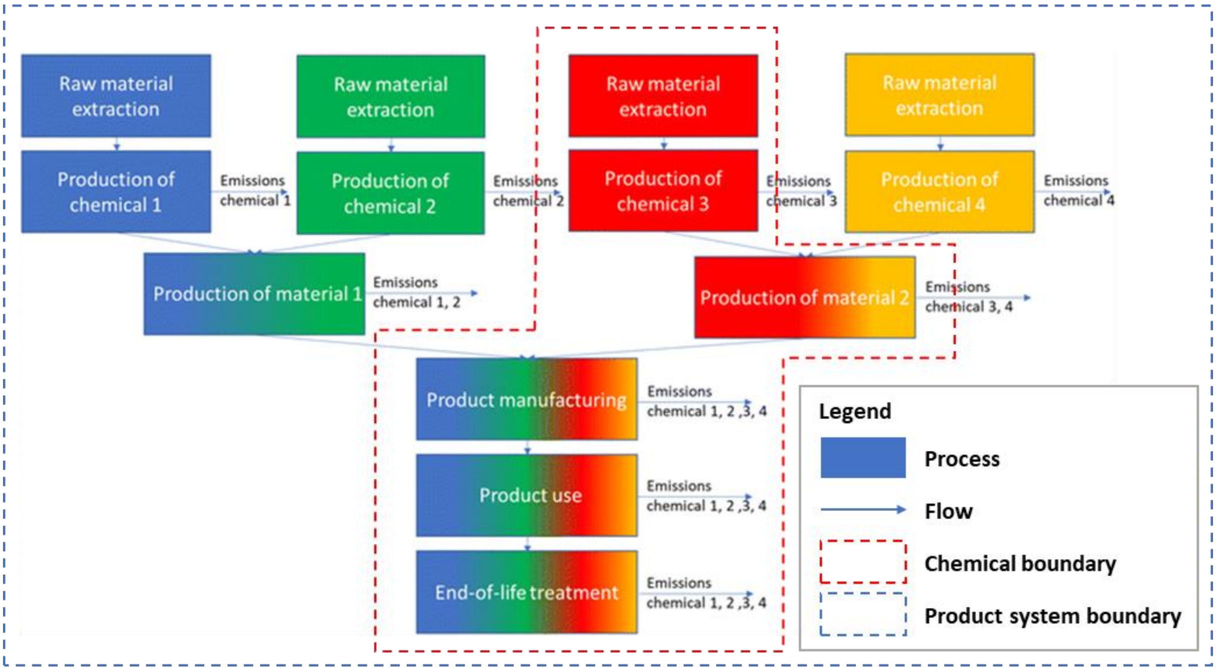

Figure 4: The life cycle of a hypothetical product existing of four chemicals and two materials (material 1 manufactured of chemical 1 and 2, and material 2 manufactured of chemical 3 and 4). The life cycle of a product system captures all 13 processes (blue dotted line). The life cycle of a chemical (i.e. 'any basic substance that is used in or produced by a reaction involving changes to atoms or molecules') in one specific product application captures only 6 out of the 13 processes (red dotted line as an example). Figure adapted from. [74].

In the SSbD context, one could assess the risk in specific life cycle stages (or the entire life cycle) of a chemical, material, or product, using risk assessment methodologies and tools. Both SSbD and LCA use the life cycle thinking perspective and have similarities, particularly by using the same (toxicological) data [75-77]. Assessing safety along the life cycle, however, does not necessarily mean performing an LCA. Some researchers have therefore suggested integrating SSbD and LCA (*e.g.* [78-80]), mainly to facilitate implementation of the SSbD framework.

LCA is standardised in guidelines and good practices developed in the ISO 14000 series on environmental management, particularly in the 14040 series [69]. It is important to highlight the general limitations of LCA, regardless of the specific product or service a LCA is evaluating. An important limitation lies in the process of data collection and insufficient data may necessitate making assumptions. The interpretation and communication of the results should therefore be transparent and clear on any limitations [68]. Finally, it is relevant to highlight that LCA is a 'relative approach' in which all inputs and outputs of the system are collected in relation to a (specific) function [69].

For LCA in a product life cycle, the choice of lifecycle stage(s) considered can add another factor of variability. This brings some categorisation of product life cycle models, depending on the number of stages included (Figure 5):

- Gate-to-gate focuses on what happens to a product at a manufacturing site.
- Cradle-to-gate includes the stages between material extraction (cradle) from the environment and the purchase of a product (before it is distributed to the consumer).

- Cradle-to-grave looks at what happens from material extraction (cradle) until the product is disposed of by the final owner (grave).
- Cradle-to-cradle examines what happens to the product after its end-of-life stage, and how it is used for further manufacturing processes (*e.g.* whether it was recycled, and how). This approach considers 'closed loop' recycling and circularity. Here, a recycling process replaces the waste stage. It considers the feasibility of the disposed material to be reprocessed into the life cycle of the product.

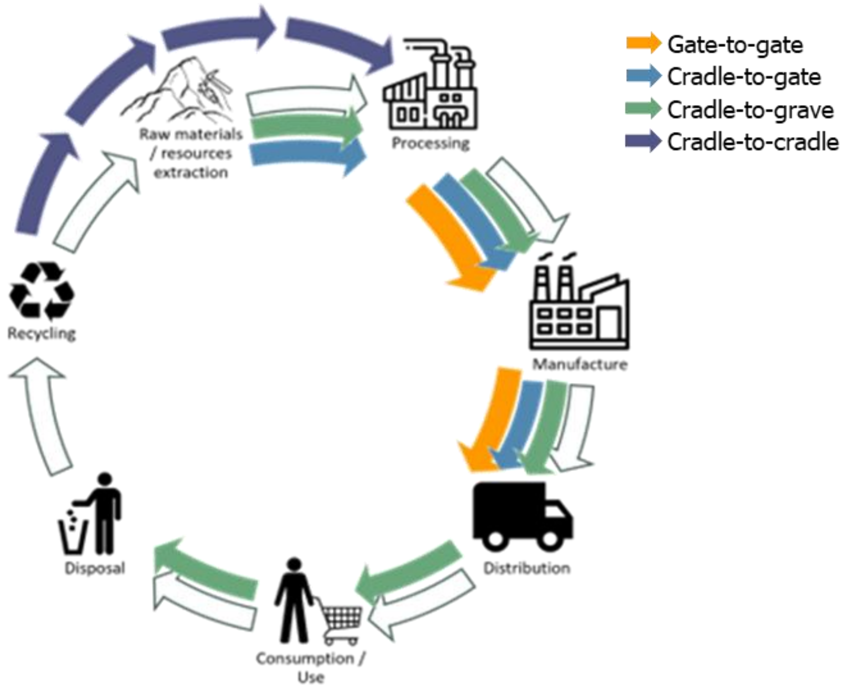

Figure 5: Categorisation of product life cycle models, based on the life cycle stages included.

Despite extensive experience with LCA, it remains challenging to apply LCA to emerging technologies. Experiences in nanosafety research, for instance, have shown the need for specific characterisation factors in life cycle impact assessment (LCIA) [81]. LCIA is the phase in LCA where results from a life cycle inventory are associated to environmental impacts (*e.g.* climate change, ecotoxicity, human toxicity) [82]. Prospective LCA is an approach that may facilitate LCA for emerging technologies by modelling them at a future point in time when the technologies are mature and produced at a large scale [83]. This approach addresses three levels of change, *i.e.* changes in (emerging) technologies themselves, in production processes and in surrounding production systems. The scientific community is currently in the early stages of developing prospective LCA. To fully realise its potential, a standardised methodology that is easily interpretable by policy makers, is needed. This involves constructing future storylines that can be described in a reasonable number of scenarios and time horizons [83]. To come to a common methodology requires a concerted effort by software and database developers, LCA practitioners, the scientific community and guideline and harmonization initiatives [83]. These issues also apply to the advanced materials that have emerged and will emerge in the (near) future.

4.3 Identifying specific Steps in the Life Cycle for further Safety Assessment

The life cycle assessment outlined in Section 4.2 may identify specific steps that require further safety assessment. What these steps are, is usually highly dependent on the specific material used and its specific application. Spray application for instance is more likely to result in inhalation, while advanced materials strongly embedded in a composite matrix may not be released before the end-of-life phase. The general lifecycle of a material can be captured in four steps: the processing of chemicals into the pristine/original materials, manufacturing of products with the material, consumption/use of the products, and disposal (Figure 5). Each of these steps can have sub-steps that further complicate finding the critical steps for assessment throughout the life cycle, in particular where such sub-steps may lead to transformation of material. Depending on the (complexity of the) product and how a material is embedded within it, certain sub-steps (*e.g.* bagging) may be more important, whereas others may not be relevant at all.

4.3.1 Transformations of Material during the Life Cycle of Products

Chemicals and materials used in products can undergo transformations during their life cycle. For certain chemicals and nanomaterials, it is known that the transformed products could behave differently during usage or end-of-life [84]. It is important to be aware of the transformation products of advanced materials and potential safety and sustainability issues as highlighted by the OECD [85] and discussed by Wohlleben *et al.* [86].

From a life cycle perspective, the transformation of advanced materials could differ depending on the product's physical form, intended use, storage conditions, end-of-life processing (abrasion or combustion) and eventual release into different environmental compartments (air, water or soil). Advanced materials generally comprise only a small part (1-5%) of a market-relevant product. The product matrix comprises the largest part of a product, and therefore could have a significant impact on the transformation of advanced materials. Examples are graphene-related materials added in market products to improve composite properties [87]. It is also important to note that advanced materials in colloidal dispersions could behave differently from those embedded in a solid product. Furthermore, there is a lack of methodologies to assess how advanced materials transform in real-time during the life cycle and difficulties in distinguishing pristine versus transformed advanced materials.

The MACRAMÉ Project elaborates on life cycle issues in 5 use cases, *i.e.* (1) the use of graphene oxide flakes in drinking-water filters, (2) the use of few-layer graphene batteries, (3) graphene-related materials in bicycles/car lubricant consumer sprays, (4) carbon nanotubes in car-seats, and (5) poly lactic-co-glycolic acid for inhalable antibiotics. For each of these use cases samples were collected in different parts of the life cycle, including where the initial material is embedded in a matrix, and including use and end-of-life phases as well [88].

The MACRAMÉ case studies differentiate between advanced materials in solid consumer products and in biomedically relevant therapeutic materials. Advanced materials embedded in solid consumer products can undergo multiple transformations during their life cycle, which can be physical (aggregation/agglomeration) or chemical (reactions) [86, 89]. Furthermore, structural and chemical transformations can be induced by environmental ageing or washing (in case of reusable textiles). Advanced materials used in therapeutic or food-based products will intentionally end up in the human body and can undergo extensive biotransformation and even biodegradation (due to enzymatic reactions).

In use phases, the process of leaching may play a role in releasing advanced materials or its components from a matrix. In food packaging for instance, this process is the main process assessed to determine safety of components in the packaging. As long as the amount of chemical/material released is below a threshold, the use of the chemical/material in a food packing is considered safe [90].

Combustion or mechanical abrasion are the two commonly used methods to mimic the degradation of advanced materials embedded in a polymer matrix at the end-of-life. In practice, however, waste management companies often have no clear view on what type of materials are incorporated in a product/waste that they encounter [91]. This makes it difficult to target a specific material in waste to assess its potential hazards.

Abrasion of advanced material products could release an increased number of transformed particles into the environment, thereby increasing human exposure. It could also produce fragmented composites where advanced materials protrude from the polymer matrix and cause mechanical damage to cells upon inhalation. The release of pristine advanced materials from the product matrix is currently considered negligible [86, 92, 93]. Nevertheless, safety concerns of transformed advanced materials should still be addressed since these fragmented composites or chemically transformed materials could behave differently in biological environments than the corresponding pristine counterparts [94]. On the other hand, the transformation of advanced materials in the product matrix may also reduce toxicities when compared to pristine counterparts (*e.g.* [92, 95]). Recent publications from the EU Graphene Flagship project demonstrated that inhalation exposure to abrasion particles from graphene-related materials and other 2D-material-reinforced nanocomposites did not trigger acute toxicity in the lung, immune system or skin cells [95-99].

4.3.2 Critical Steps in the Life Cycle

A very critical step in hazard assessment is the possibility to characterise/identify the pristine materials, to ensure methods are available to do so. Without such methods it is not possible to link a specific response to the specific material. As long as no transformation of the material occurs, in principle, the same or similar methods can be used to identify the materials in later steps of the life cycle of the products. The biggest challenge, however, is then to be able to distinguish the pristine material from the matrix it is in. Most likely this requires sample preparation that differs from sample preparation needed to characterise/identify the pristine material just after its production.

Another dilemma may arise when releases from abrasion/sanding are complex particles. Should these complex particles be tested as such, or can we rely on existing data for their components? This also raises questions on what the exposure will be and who will be exposed. Similar questions can be asked for any chemical/material in a product/use, and answers generally depend on the specific product/use. For advanced materials, however, it further complicates the already difficult questions on how to ensure (relevant) exposure in test systems/dispersions.

Recent papers [100, 101] stated that the presence of nanomaterials in certain waste streams may be an obstacle to high recycling rates and multiple material cycles. The recovery of nanomaterials is complex, high energy demanding, and with potential low quality to be re-used [100, 101]. Nonetheless, the authors of these papers proposed a set of questions to use life cycle thinking when one would like to add a nanomaterial into a product in a circular economy context. This approach could also be applicable and extended to other advanced materials. To fully exploit this further research is needed on some critical questions. What is the impact on recycling processes? What is the impact on stability and releases during the entire procedure (and such conditions)? What are potential risks when treating waste containing any advanced materials? What are potential benefits of using advanced materials as secondary raw material in linear and circular life cycles?

They MACRAMÉ Project aims to answer some of the questions. The characterisation methodologies developed in MACRAMÉ may be used to characterise advanced materials at the end of life and hence support sorting and recycling in waste streams. MACRAMÉ is currently testing such methodologies in specific use cases (see section 4.3.1) to see if they can be used in incinerated, abraded or grinded composites that can simulate end-of-life. Results on the lessons learnt and limitations of such methodologies will be reported in *MACRAMÉ Deliverable 4.6 - Science-based Recommendations to develop new TGs & Standards*.

4.4 FAIR Data

For risk assessment to keep up with the rapid innovations in advanced materials and in support of SSbD, reuse of data is essential, not in the least to allow for understanding of toxicity mechanisms and computer modelling of such processes. FAIR (Findable, Accessible, Interoperable, and Reusable data are thus an important prerequisite.

The need for FAIR data has been clearly outlined in general. Especially for nanomaterial (and other advanced materials) FAIR data are crucial for safety assessment due to the inherent multidisciplinary and multitude of data types (physicochemical, hazard, exposure, life cycle assessment) required [102, 103]. Requirements and approaches for the generation and evaluation of FAIR data have been published previously (*e.g.* [104-106]) and will not be extensively replicated here. In short, standardised formats and ontologies should be established to ensure consistent and interoperable data across various platforms. This will facilitate easier sharing and reuse of data throughout the life cycle (of advanced materials)

Openness or the idea of making data freely available is a common request, but FAIR principles do not necessarily require that all data be fully open to the public. However, even if data cannot be completely open, it is important to know they exist and clearly define access routes. This means specifying who can access the data, under what conditions or licences, and how they can do so. Nevertheless, challenges will remain to share data across the whole value chain, *e.g.* where data are considered as confidential business information.

Another important aspect is data trustworthiness. A (re-)user of data should be able to get insight how data were generated, *i.e.* data should be accompanied by a detailed description of the metadata (*i.e.* the used methods, measurement protocols, and data analysis tools) to allow evaluation of the results, including relevance and reliability of methods used [107]. Examples of approaches that can accommodate this include the instance-map-based documentation of the material fate in NanoFASE [108] and MACRAMÉ.

The holistic nature of SSbD adds additional requirements to the data management and FAIRification process. SSbD takes the entire life cycle and value chain of a material into account to include sustainability aspects. This requires distribution of data both up and down through the value chain in an unambiguous way. Two EU key initiatives are aimed at facilitating this: (1) the EU's goal of building a European digital materials infrastructure and materials data ecosystem, known as the Materials Commons [7], to boost innovative potential by encouraging data sharing, and (2) the development of digital material/product passports [24], which will enable the sharing of essential material and product-related information for sustainability and circularity. It remains to be seen whether this approach is sufficient to ensure the transfer of all required information along the value chain for a comprehensive safety and sustainability evaluation of the final product. Otherwise, the implementation of a specific SSbD digital passport may be considered.

4.5 Applicability of Test Methods

For nanomaterials the OECD examined applicability of test methods already in 2009 [109]. Issues were identified in (lack of) characterisation methods, both for the pristine material and for methods that distinguish them from a surrounding matrix (including biological tissues). Another remaining challenge for nanomaterials is the sample preparation necessary for determination of physicochemical properties, hazard, toxicokinetics, fate or exposure assessment. Work on adapting test guidelines or developing new ones only gained momentum in recent years, mainly as a result of inclusion of nanospecific requirements in legislation [36]. While several OECD Test Guidelines (TGs) and Guidance Documents (GDs) are now available that are applicable or specific for nanomaterials [110], this work is not finished yet. Just recently the Malta Initiative published its priority list for further needs for (adaptations of) OECD documents [37]. In addition, ISO has produced a range of documents to clarify vocabulary and provide methodologies for nanomaterials[9]. Despite advanced materials representing a wide group of materials and generalisation is difficult, some lessons can be learned from this progress described for nanomaterials.

For non-soluble advanced materials adequate dispersion protocols need to be available. To assure this, assessing the applicability of those developed for nanomaterials (*e.g.* [111, 112]) appears a logical first step. Related to this, concentration metrics and maximum concentrations achievable need assessment as well. Current practices may represent high overexposures to cells and animals, although it may be challenging to find a balance between realistic exposures and identification of potential (potency for) effects.

Molecular and cellular events used to develop in vitro approaches may be different for advanced materials (*e.g.* like for nanomaterials, uptake of advanced materials is likely to be an active process rather than driven by passive diffusion of solutes). Certain tests should therefore be identified and regarded as non-applicable (*e.g.* Ames test [113], covalent interactions with skin proteins [114]).

With the increase of importance of sustainability (next to safety) the life cycle assessment becomes more important (see Section 4.3.2). Additional testing on life cycle aspects (also for conventional chemicals/materials) may be required for which methods may not (yet) exist. Methodologies (*e.g.* LCA-based) that do exist may be a starting point to test/validate their applicability and explore how these could be harmonised and standardised (further) for specific sustainability issues. In particular, for safety aspects in the life cycle, method development should include NAMs (*e.g.* [114]), in particular where these can assist in early research and innovation phases for innovative advanced materials. The focus on testing may also need to be diverted to the release fraction of advanced materials along the life cycle, rather than the advanced materials itself. As a result, also testing what is being released may become more important. Here the ongoing work in the OECD WPMN towards guidance on release testing of nanomaterials [115] may form a valuable starting point, but also the characterisation methodologies developed in MACRAMÉ may be used to characterise advanced materials at the end of life (see section 4.3.2).

Test method development and adjustment can be laborious and time consuming. To allow adequate and timely development of test methods, it is crucial to have knowledge on the necessary steps in the development process [116]. This is independent of the specific purpose of test method development. To facilitate this for method developers the 'NanoHarmony OECD TG/GD Process Mentor' [117] has been developed. This also include training material. The

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9 On 22 October 2024 a total of 216 different standards were found (www.iso.org/search.html, keyword 'nano').

knowledge of the key aspects of test method development identified are also applicable for advanced materials and continuous training of test method developers is needed.

5 Conclusions and Recommendations

5.1 Challenges of Advanced Materials in Regulation

The potential multitude of compositions, properties and application domains, advanced materials may have, as well as the continuous advancements in their development challenge their risk governance. It is therefore important to raise awareness among regulators and risk assessors about their existence and challenges. For nanomaterials, it was shown that awareness raising can be achieved by a close exchange among the different stakeholders. Additionally, providing training on the challenges of advanced materials and their unique properties can help preparing regulators for upcoming challenges and to understand the specific challenges advanced materials pose.

The current document provides an overview of frameworks and legislation that exist in Europe to measure, assess, and mitigate (potential) risks of chemicals and products that should potentially address advanced materials throughout their lifecycle as well. To identify any gaps and needs for the regulatory and policy frameworks a very basic question is clearly on defining what advanced materials are. Experiences with nanomaterials have shown that a uniform definition is an important building block [118] to amend regulatory frameworks and improve hazard and risk assessment of new materials. For advanced materials however, a uniform definition may not be feasible. As shown in the OECD Working description [9], what we see as advanced today may over time become conventional and not advanced at all. This temporal aspect challenges legal clarity over time. A way forward may be found in definitions of relatively uniform classes of advanced materials. This is already a very challenging task, but establishing a definition and setting the scope of advanced materials appears to be a prerequisite for any (enforceable) regulatory action. The MACRAMÉ Use-Cases may provide a starting point here.

A lot of the legislation for chemicals (including REACH and specific sectorial legislation) has now been adapted for nanomaterials [36]. It is likely that the amendments to legislation to cover nanomaterials are insufficient to identify potential hazards and risks for advanced materials as well. Not all advanced materials fulfil the size criteria of the nanomaterial definition, making the nanospecific requirements (including those on form characterisation) not applicable. This raises questions on whether additional amendments to legislation are needed for advanced materials. Further requirements may be needed, *e.g.* on characterisation or otherwise addressing the physical and morphological properties of a substance in hazard and risk assessment. Towards sustainability of such materials, also legislation on handling their waste streams may become (more) important and may require adaptations. In line with the situation for nanomaterials (*e.g.* [36, 37]), this may also result in further needs for validated test methods and guidelines.

Recommendation - Advanced Materials in Regulation
Identify which groups of advanced materials may need specific requirements for their regulatory risk assessment and need a clear regulatory definition.
Identify whether there is a need for regulatory amendments to allow for a regulatory risk assessment of (groups of) advanced materials.
Identify whether there is a need for regulatory amendments for certain waste streams to ensure sustainability and circularity of resources. This may need broader identification, not only for (groups of) advanced materials.

5.2 Life Cycle Assessment and Sustainability

Currently the SSbD Framework is a voluntary approach. Further incentives may be needed to encourage its use, not in the least because its implementation will be at a cost of companies. Research on alternative, safer chemicals, implementation of adapted processes and regulatory compliance of the new materials/products may delay progress of innovations. Quality stamps to appeal customers or financial triggers may be examples of such incentives.

To avoid unnecessary waste of resources it will be desirable that projects that develop methodologies and tools work together and build on the legacy of (nearly) finished initiatives (*e.g.* SSbD Toolbox in PARC[5], HARMLESS Decision Support System[10], SUNSHINE tools[11], etc.). It is also encouraged that, rather than continuing developing general frameworks, the EU supports research on the special needs of different sectors, such as biocides, or pharmaceuticals. Different sectors have different needs regarding safety and performance which cannot be addressed by current general strategies.

In the SSbD context, one could assess the risk in specific life cycle stages (or the entire life cycle) of a chemical, material, or product, using risk assessment methodologies and tools. Sustainability, however, comprises more than risk assessment alone.

Life cycle assessment may help as a tool in gaining insight in the sustainability of a chemical/material/product. Yet, it remains challenging to perform LCA for emerging technologies, although prospective LCA shows potential in this area.

Further (agreements on) methodologies, however, are still needed. To come to a common methodology requires a concerted effort by software and database developers, LCA practitioners, the scientific community and guideline and harmonisation initiatives, including regulators that set the requirements.

To prepare regulators for new developments and potential associated regulatory needs, while at the same time preparing developers for (changes in) regulatory requirements.

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10 HARMLESS webinar on SSbD: DSS demo with AdMa case study (zenodo.org/records/11459527).

11 SUNSHINE Safe and Sustainable Innovation Approach Digital E-infrastructure (www.dev.sunshine.greendecision.eu)

Recommendation - Life Cycle Assessment and Sustainability
Develop methodologies and tools for an easy implementation of SSbD, where needed specific for different sectors to accommodate their special needs.
Develop incentives to encourage the use of the SSbD Framework and SSbD thinking in material innovations.
A multi-disciplinary approach, including a common language, is needed to fully exploit the potential of the use of LCA in SSbD.
Identify the role that Prospective LCA may have in life cycle assessment for emerging technologies, although further development and harmonisation of methodologies is still needed.

5.3 Identifying specific Steps in the Life Cycle of Products

Studying advanced materials transformation is critical in identifying critical steps in the life cycle where (potential) release may trigger the need for (additional) safety assessment.

Challenges in advanced materials transformation lie in the lack of methodologies to assess real-time transformations (including physical changes in shape, size, etc.) and the difficulties in detecting pristine vs transformed advanced materials from products during the life cycle. Combined imaging and analytical approaches need to be developed that allow the quantification of transformed advanced materials in chemical and biological matrices. MACRAMÉ is filling the gaps by developing high-resolution imaging approaches based on high-Resolution Transmission Electron Microscopy (HR-TEM), Raman microscopy, and Time-of-Flight Secondary Ion Mass Spectrometry (ToF-SIMS) to detect advanced materials in complex chemical (in products) and biological (when transformed materials reach the cells) matrices.

The use life cycle thinking is crucial when one would like to add a specific advanced material into a product in a circular economy context. Such thinking should include answering questions on impacts that transformations or recycling of the material may have on the safety aspects. To facilitate such life cycle thinking in advanced material innovations, existing approaches may need to be adapted for advanced materials.

Recommendations – Identifying specific steps in the life cycle of products
Combined imaging and analytical approaches need to be developed that allow the quantification of transformed advanced materials in chemical and biological matrices.
Develop methodologies to facilitate life cycle thinking in design processes of advanced materials.

5.4 FAIR Data

Properties of nanomaterials and advanced materials are highly dependent on the product matrix they are embedded in and their chemical or biological environment. Thus, governance of such materials needs to consider the current life cycle stage of the material, the environment from which the sample was taken, and the history of the material leading up to this lifecycle stage. This challenges data collection and highlights the need for (re)use of data that are available. To optimise such reuse, Findable, Accessible, Interoperable, and Reusable (FAIR) data are crucial, including harmonised ontologies to improve combining information from different sources.

Recommendation – FAIR data
To increase FAIRness (and thus availability of data) data management approaches should be provided. These should allow for the documentation of material, sample and data provenance trails.

5.5 Method Development

For nanomaterials, progress has been made on characterisation methods for pristine nanomaterials [60], although separating them from complex matrices remains challenging. Also some sample preparation issues remain, together with applicability of methods for certain endpoints [37]. Most of these issues originate in the particulate nature of nanomaterials and related physico-chemical properties. This includes the physical transformations of particles that may play a role in their fate and kinetics [86]. It can be anticipated that for (many) advanced materials similar challenges exist. By acknowledging this, adjustments of test methods for nanomaterials may also consider applicability of a method for (groups of) advanced materials.

With the increase of importance of sustainability (next to safety) the life cycle assessment becomes more important. Additional testing on life cycle aspects and sustainability (also for conventional chemicals/materials) may be required (*e.g.* for transformation and recycling processes) for which methods may not (yet) exist.

Test method development and adjustment can be laborious and time consuming. Test method developers should have knowledge on the necessary steps in the development process to allow effective development of harmonised/standardised test methods [116]. This may require specific training on this process.

Recommendation - Method development
When adjusting test methods (*e.g.* for nanomaterials) consider the applicability of a method for (groups of) advanced materials, in particular where the physical form of a material may play a role in their behaviour in a test system and subsequent test outcomes.
Method development should include New Approach Methodologies (NAMs), in particular where these are applicable to assist in early research and innovation phases for innovative advanced materials.
With the increasing importance of sustainability testing of innovative advanced materials, harmonised/standardised test method should be made available to address life cycle aspects and sustainability.
Training on the development process is crucial for effective development of harmonised/standardised test methods.

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ANNEX I – European Legislation

A-I-1. Chemical and Product Regulations adapted for Nanomaterials

Recently an overview was made of the EU legislation that was adapted for nanomaterials [1]. The authors summarised the requirements included in each of these regulations to address the specific challenges of nanomaterials. Regulatory areas that were assessed include industrial chemicals [2, 3], cosmetics [4], food and feed [5, 6], plant protection products [7], biocidal products [8], medicinal products for human [9] and for veterinary [10, 11] use, and medical devices [12]. To further clarify the regulatory requirements a range of guidance documents from the European Chemicals Agency (ECHA), the Scientific Committee on Consumer Safety (SCCS), the European Food Safety Authority (EFSA), the European Medical Agency (EMA), and the International Organisation for Standardisation (ISO) were referenced (see [13] for details). The authors showed that there is considerable overlap in regulatory requirements for the safety assessment of chemicals/nanomaterials/products that are regulated within these different regulatory frameworks. In general, most additional requirements for nanomaterials were related to their (physical) characterisation and their behaviour in biological and environmental media.

Apart from the nanospecific adaptations, none of these regulations are focussing on advanced materials. Based on the nanospecific assessment of requirements, however, it appears likely that any adaptations for advanced materials (if deemed necessary) will also focus on identification, characterisation and behaviour in different media.

A-I-2. Ecodesign for Sustainable Products Regulation

The Ecodesign for Sustainable Products Regulation (ESPR) is a new Regulation [14] that builds on the 2009 Ecodesign Directive [15], which only covers energy-related products. The new Regulation adds some other criteria, *i.e.* durability and repairability, to a broader range of products The ESPR entered into force on 18 July 2024.

It sets 'ecodesign requirements'for physical goods. These include improving lifecycle span, reusability, upgradability and reparability, making more energy and resource-efficient products, addressing the presence of substances that inhibit circularity, increasing recycled content, and/or making them easier to remanufacture and recycle in accordance with a life cycle approach. Furthermore, it points out rules on environmental footprints (*e.g.* carbon footprints), and the improvement of data availability on product sustainability.

The ESPR considers performance requirements, which could be either quantitative or non-quantitative, for or in relation to a product to achieve a certain performance level in relation to a product parameter (Annex I [14]). In the list of product parameters, one can find the releases of particles (micro- and nanoplastics), and the emissions to environmental compartments in one or more life cycle stages of the product. Nevertheless, there are exemptions for setting these requirements. For example, when ecodesign requirements are not necessary to contribute to the environmental sustainability of specific products. This may be products with a particular purpose that could not be fulfilled when complying with the requirements or products produced in very small quantities are other exemptions [14]. Additionally, it should not apply to products for which it is already clear that ecodesign requirements would not be suitable or where other frameworks provide for the setting of such requirements, *e.g.* in food and feed [16], or human [12, 17] or veterinary medicinal products [10].

This regulation aims to avoid creating a regulatory burden. Consistency should be ensured between the ESPR and requirements set in or pursuant to other EU law, especially concerning products, chemicals, packaging and waste. In this sense, the ESPR should not impose restrictions on substances or mixtures based on chemical safety, as this task is performed under REACH [2]. However, setting performance requirements should, where appropriate, reduce significant risks to human health or the environment. Therefore, it is intrinsically connected to advanced materials. The concern would be that 'new materials', such as advanced materials, are not clearly or sufficiently considered under the corresponding EU chemical legal framework.

Finally, the ESPR allows the development of the 'Digital Product Passport' [14]. This will facilitate the traceability of materials and substances within products and will provide information about products' environmental sustainability.

A-I-3. Corporate Sustainability Reporting Directive

The Corporate Sustainability Reporting Directive [18] entered into force in January 2023. This Directive extended the rules to report sustainability to a broader range of companies (large, small and medium-sized enterprises, and some non-EU companies). Companies now must report according to European Sustainability Reporting Standards [19]. In this sense, talking about materiality assessment, companies should follow Environmental Footprint methods, *i.e.* the Product Environmental Footprint, and the Organisation Environmental Footprint [19], which are LCA-based methods. However, there is no clear statement on how advanced materials should be evaluated.

A-I-4. Environmental Product Declaration and Product Environmental Footprint

In 2001, the European Commission published the Integrated Product Policy (IPP) [20]. This policy establishes a framework for the consideration of a product dimension within the European environmental policy landscape. Since then, several other policy-related tools have been introduced. For instance, the Environmental Product Declaration (EPD) and the Product Environmental Footprint (PEF) [19]. LCA can contribute to both by assessing the environmental impact of a product and supporting organisations to communicate results as a sustainability indicator. There are clear differences, however, between the EPD and PEF.

An EPD is a standardised document describing LCA results for a specific product without revealing sensitive information [21]. Additionally, businesses should follow specific Product Category Rules (PCR) (Annex II of [19]). The choice of PCR to use depends on the scope and system boundaries (product, and country or region), and/or the database where the EPD will be registered.

A PEF is an LCA calculation method developed on behalf of the European Commission. It aims to establish a harmonised method for quantifying and evaluating the environmental impact of products. PEF intends to help businesses comply with EU regulations and to enable consumers to make informed choices. Similar to EPD, PEF include category rules. An LCA practitioner should follow the dedicated Product Environmental Footprint Category Rules (PEFCRS) (Annex II of [19]). Therefore, companies can choose whichever method is more appropriate depending on their needs. Needs may include *e.g.* satisfying customer requests or completing their sustainable corporate report.

A-I-5. General Product Safety Regulation

The General Product Safety Regulation (GPSR) will apply from 13 December 2024 on [22]. It repeals the GPS Directive from 2001 [23]. The GPSR provides a new framework to keep up with the challenges of digitalisation, particularly due to the number of products in online marketplaces. However, there are a range of exemptions, such as medicinal products for human or veterinary use, food and feed, living plants and animals (also genetically modified organisms and microorganisms in contained use), animal-derived and by-products, plant protection products, transport equipment operated by a service provider, aircraft (from the low safety risk category as defined in [24]), antiques, and products clearly marked to be repaired or reconditioned prior to use.

In general, the GPSR mentions that the safety of the product (safe over its entire lifespan) should be assessed prior to it being available on the market. It mentions the responsibilities of each economic operator, *i.e.* manufacturer, importer, authorised representative or service provider, and distributor. Their responsibilities include, *e.g.* evaluating the characteristics of the product (design, technical features, composition, packaging, and instructions), the effect on other products, and labelling. The GPSR integrates product safety for a certain category of consumers, as well as unintentionally affected people (children, older persons, or persons with disabilities). This includes for instance that a product could look 'child appealing', while it is not intended to be (*e.g.* it should be avoided that dish washer pods may look like candy for kids).

Moreover, the GPSR also mentions the option that substantial new technologies are introduced. In that case the economic operator should assess the product for a new risk assessment if that substantial modification were to have an impact on the safety of the product. Implicitly the GPSR thus covers the use of advanced materials as *'new technologies (modification of a product) that have consequences on the nature and characteristics of the product'*.

A-I-6. Waste Directive

The Waste Directive is the legal framework (Figure 2) for treating and managing waste in the EU [25]. This Directive covers a general description on waste classification and specific waste streams, how waste operations should proceed, and the baseline for obtaining secondary raw materials after reprocessing.

According to this framework, waste *is 'any substance or object which the holder discards, or intends or is required to discard'* [25]. Some types are excluded, including *e.g.* radioactive waste, gaseous effluents emitted into the atmosphere, and waste water. On the other hand, the European Waste Catalogue (EWC) [26] categorises wastes using a six-digit code based on a combination of what they are, and the process or activity that produces them [27]. It is important to consider that waste could be industrial or commercial waste or health care waste or post-consumer waste or hazardous waste [28] or another type of waste.

Annex III [28] of the Waste Directive [25] lists properties of waste which render it hazardous. These include explosive and flammable properties, but also specific toxic properties towards humans (*e.g.* irritating, or toxic for reproduction). As advanced materials may also have such properties, they have potential to be considered as hazardous waste. Identification and classification of chemicals as hazardous is regulated under the CLP Regulation [29].

The Waste Directive targets waste from specific sectors and products (Figure 2) due to their key role in developing a circular economy. Therefore, the EU incorporated these sectors in the waste-policy targets to improve waste management, stimulate innovation in recycling, and limit landfilling. These sectors and products include the following:

- Batteries and accumulators: the new Batteries Regulation [30] applies to all categories of batteries, regardless of their shape, volume, weight, design, material composition, chemistry, use or purpose. These include portable batteries, starting, lighting and ignition batteries (SLI batteries), light means of transport batteries (LMT batteries), electric vehicle batteries and industrial batteries. The Commission targeted some critical raw materials in batteries to increase recycling and recovery of those substances, *e.g.* cobalt, lead, lithium and nickel.
- Advanced materials are not explicitly mentioned. Nevertheless, Article 86(1) of the regulation indicates that the Commission shall request a restriction dossier under REACH (Annex XV) [2] if the use of a substance poses a risk to human health or the environment that is not adequately controlled. This suggest that if any advanced materials could pose a (uncontrolled) risk along the life cycle of the battery, their use could be restricted.
- Waste electrical and electronic equipment (WEEE or e-waste): the WEEE Directive [31] and the Restriction of Hazardous Substances (RoHS) Directive [32] tackle the issue of the growing amount of disposed electronics in the EU. The WEEE Directive requires the separate collection and proper treatment of WEEE and sets targets for their collection, recovery and recycling for the following years. Furthermore, it mentions the substances, mixtures and components that should be removed from any separately collected WEEE (Annex VII), such as mercury containing components (from switches or backlighting lamps for example). In the RoHS, there are some substances that are tolerated in certain applications but limited to a maximum concentration value, such as mercury (Annex II - IV). Advanced materials are not specifically mentioned in either of these Directives.
- Construction and demolition waste (CDW): this is the largest waste stream in Europe [33]. To manage this waste stream, the European Commission launched a protocol that explains some guidelines to increase confidence in the CDW management process and the trust in the quality of the corresponding CD recycled materials [34]. Advanced materials could enter the waste value chain in different forms. The advanced material may be embedded in any of the targeted (economic valuable) recycled materials. They may also be incorporated in separated material that is usually used for energy recovery as a substitute fuel. Lastly, they may be incorporated in, or by itself be a material that falls under one of the 15 hazardous properties (Annex C [34]).
- End-of-life vehicles: the end-of-life vehicles directive [35] focuses on preventing waste from vehicles and sets out measures for the reuse, recycling and other forms of recovery of end-of-life vehicles and their components. Under the prevention strategies, the Commission has established maximum concentration values for substances.
- Advanced materials are not specifically mentioned, but might be used in different parts of new vehicles, such as in composites for car seats, batteries, etc. These advanced materials will follow the same pathway as the treatment operations for depolluting or recycling streams of those parts where they are embedded or used.
- Packaging waste: the Packaging Directive [36] aims to harmonise national measures concerning the management of packaging and packaging waste. In Article 11 of this Directive, there are some accepted (total) concentration levels of heavy metals in the packaging.
- A relevant aspect of this Directive is the use of information systems (databases) where manufacturers should provide information on the toxicity or danger of packaging materials and components used for their products. Another point is that packaging must be manufactured in a way that minimises the presence of noxious and other hazardous substances and materials as constituents of the packaging material or of any of the

packaging components. Minimisation includes reducing their presence in emissions, ash or leachate when packaging or residues from management operations or packaging waste are incinerated or landfilled [36].

- Therefore, all materials should be tested and evaluated during the design phase, in order to consider their potential emissions and minimise them during the end-of-life management operations. Finally, the Directive [36] mentions that the management of packaging and packaging waste should be harmonised in order to reduce its environmental impact. For instance, the inclusion of recycled material in packaging should not contradict relevant provisions on hygiene, health or consumer safety.
- Textile waste: under the Waste Directive [25], textiles are targeted to improve separation and collection. In 2022, this initiated the EC to present an EU strategy for sustainable and circular textiles [37]. Such textiles should be *'long-lived and recyclable, to a great extent made of recycled fibres, free of hazardous substances and produced in respect of social rights and the environment'* by 2030 [37]. In addition, the European Commission proposed the Extended Producer Responsibility [38] in this sector to support the sustainable management of textile waste across the EU. Even though the new strategy implicitly mentions the intention to reduce microplastic pollution, there are no explicit comments related to advanced materials.
- Biodegradable waste: includes biodegradable garden and park waste, food and kitchen waste from households, restaurants, caterers and retail premises, and comparable waste from food processing plants. It does not include forestry or agricultural residues, manure, sewage sludge, or other biodegradable waste. The main objective is to reduce the production of methane from biodegradable waste decomposing in landfills. Nowadays, the incineration of bio-waste as a part of mixed municipal solid waste may be used to recover energy (heat and/or electricity), depending on the available technology, in waste incineration plants, regulated in [39]. However, since waste incineration plants should potentially be reduced, bio-waste could be treated using other waste management options, *e.g.* for composting in agricultural purposes [40]. Nevertheless, according to the Green Paper on the management of bio-waste in the European Union [41], bio-waste easily gets contaminated during mixed waste collection. Consequently, its use on soil can lead to accumulation of hazardous substances in soil and plants. This could happen if advanced materials are found in products that are not separated and collected in mixed municipal solid waste, as suggested from material flow analysis studies related to nanomaterials (*e.g.* [42]).

A-I-7. Waste management operation procedures and circular economy

Other waste management operation procedures or treatments, rather than for solid waste, are also relevant. These can potentially release materials to the environment from multiple products flowing through those treatment facilities or end-of-life management operation procedures (*e.g.* using sludge in soils), such as the case for engineered nanomaterials estimated *via* material flow analysis studies [43]. For instance, there are EU Directives highlighting the importance of sustainability management, such as the Landfill Directive [44], Water Framework Directive [45], the Groundwater Directive [46], Sewage sludge [47], and Urban wastewater treatment [48]. For the latter a new proposal for a revised Urban Waste Water Treatment Directive [49] recently reached a provisional agreement and mentions microplastics. However, there are no explicit comments regarding advanced materials.

Residues (residual waste) could be part of a production or manufacturing process when a substance that is not the end product(s) that the industrial process directly seeks to produce. This same meaning can be applied to recycling processes. These are recovery operations by which waste materials are reprocessed into products, materials or substances whether for the original or other purposes. As a result, recycling residues may become part of a production or manufacturing process.

The Industrial Emissions directive [39], related to the permits for waste incineration plants mentions that the residues should be minimised in their amount and harmfulness and recycled where appropriate. When the disposal of the residues cannot be prevented, reduced or recycled, it will be carried out in conformity with national and European law. In the context of a circular economy, secondary materials ('waste-based raw materials') are not considered as 'waste' anymore, if they are obtained from recycling streams or by-products and fulfil the conditions of (Article 5.1) of the Waste Directive [25]. The Waste Directive defines by-products as *'a substance or object, resulting from a production process, the primary aim of which is not the production of that item'* [25]. Nonetheless, it is relevant to mention that the Waste Directive, Article 11a [50], mentions that non-targeted waste materials should be removed prior to the used recycling technique to facilitate high-quality recycling. This raises questions on how and where advanced materials end up in the recycling and waste processes.

According to the definition of waste, REACH requirements do not apply as they do for substances, mixtures and articles [51] However, it does not mean that substances in waste are fully exempted from REACH. It is relevant to mention that, according to the Waste Directive (Article 6(1) and (2) [25, 52]), as soon as a material 'ceases to be waste' (becoming a product or a secondary material), REACH requirements apply in the same way as to other substances (with some exceptions). The topic has been under discussion for several years and the JRC has been working on developing the corresponding 'end-of-waste criteria' proposals (using techno-economic-environmental assessments)[12]. However, according to Johansson and Forsgren [53], many proposals for end-of-waste criteria have been halted since it has proven difficult for member states to reach an agreement.

There are some key points to take into account, which make it difficult for recycle companies:

- Recovery processes often take place in several steps, and sometimes only the last step will result in a material that will no longer be classified as waste under the Waste Directive [25].
- There may be cases where only a fraction of the material resulting from the recovery process will be non-waste.
- For REACH, recovered substances are understood as substances that, after having been part of waste materials, have ceased to be waste according to the Waste Directive [25]. As such they should then be registered under REACH. This raises additional challenges:
  - The life cycle and supply chain of the original substance ends with the waste stage. If waste ceases to be waste, a new life cycle of the substances starts. This means that the uses of a recovered substance does not have to be covered in the exposure scenario of the 'original' substance.
  - The recovery process may generate one or several or more substances, either individually or in a mixture. Thus, the recovery operator has to decide how to classify these substance(s)/mixture(s). Furthermore, the recovery operator has to check if the constituents and/or substances have been already registered previously (with exemptions or not).

This section shows the interlinkages among waste management operations (end-of-life compartments), the complexity of considering the use of recovered materials from recycling

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processes (related to circular economy strategies), and their potential regulatory compliance under a circular economy context.

A-I-8. General problems for waste management related to advanced materials

The concept of 'nanowaste' emerged to refer to waste containing engineered nanomaterials and some authors have even suggested destroying it *via* specialised waste treatment facilities [54]. Some studies mentioned that nanomaterials (and potentially advanced materials) could end up in waste management operation facilities at any point in time (depending on the life cycle span of the product/application). Moreover, recycling operators should understand whether they should discard any materials to obtain potential secondary raw materials. Materials to remove may be of non-economic interest or those that could negatively affect reprocessing methods. Therefore, it is important to evaluate which advanced materials could enter their facilities and streams, especially in a circular economy context where advanced materials can (intentionally or unintentionally) re-enter life cycles.

For instance, translating from nanotechnology to advanced materials, recent papers [55, 56] stated that the presence of nanomaterials in certain waste streams may be an obstacle to high recycling rates and multiple material cycles. The recovery of nanomaterials is complex, high energy-demanding, and may result in low quality materials for re-use [55, 56]. Nonetheless, they proposed a set of questions to use life cycle thinking when considering adding a nanomaterial into a product in a circular economy context. This approach could also be applicable and extended to other advanced materials. It is important to further research the impact on recycling processes, the stability and releases during the entire procedure (and under such conditions). Furthermore, the potential risks when treating waste containing any advanced materials should be weighed against the potential benefits of using advanced materials as secondary raw material in linear and circular life cycles.

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