NanoDialogue
of the German Government

Which aspects could be considered in prioritising advanced materials?

A compilation of criteria that could be used to assess the relevance of advanced materials based on the discussions at the ExpertDialogue on advanced materials organised by the BMU in May 2019

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Ökopol
Institut für Ökologie und Politik GmbH

Authors: Antonia Reihlen & Dirk Jepsen

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ÖKOPOL GmbH
Institut für Ökologie und Politik

Nernstweg 32–34
D – 22765 Hamburg

www.oekopol.de
info@oekopol.de

Tel.: + 49-40-39 100 2 0
Fax: + 49-40-39 100 2 33

Content

1 Introduction

The German Ministry of the Environment, Nature Protection and Nuclear Safety (BMU) organised a national ExpertDialogue on May 22nd and 23rd 2019 titled "Opportunities and risks of advanced materials". The topic was introduced and several speakers presented specific fields of application. In addition, the relevant German authorities presented the aspects on advanced materials they are currently working on.

The stakeholder discussions at the ExpertDialogue showed that at present:

- the high number of (combinations of) advanced materials and their applications makes it hardly possible to assess them in a comprehensive and harmonised manner;
- some advanced materials and their applications suggest a necessity of evaluating the suitability and applicability of existing risk assessment instruments;
- very little /(little) information is available to decide if and how advanced materials could be grouped regarding research funding, potential risks and a possible need for regulation;
- it is unclear if and which (combinations of) materials and applications might require additional regulation at all;
- the developmental aims and potential benefits of the use of advanced materials are very diverse and manifold and therefore difficult to monitor.

Any work on the safe use of advanced materials, including on the above aspects, would be supported if advanced materials and their applications could be differentiated into high or low human/environmental risk or economic/technical impact. Thereby, trend monitoring could be focused on advanced materials with high potential risks or increasing market amounts or on advanced materials for which risk assessment instruments are not applicable (and hence, the development or at least adaptation of instruments is necessary). This leads to the question of which criteria could guide a prioritisation of advanced materials and their uses.

The prioritisation criteria which could support a targeted monitoring, assessment and potentially regulation of advanced materials named and partly discussed at the ExpertDialogue are compiled and described in this report. In addition, possible indicators are listed how the relevance criteria could be measured.

The relevance criteria are based on different concerns and are summarised in this report under the following headings:

- Relevance based on assumed risks: from this perspective, advanced materials could be prioritised if they have (particularly) critical properties (toxicity, environmental toxicity, mobility and persistence) or if they are used in products or services, which are associated with high release rates (cf. Chapter 3).
- Relevance due to missing assessment instruments: from this perspective, an advanced material could be prioritised if the instruments currently available to determine the hazardousness, release, exposure and/or possible risks of chemicals are not applicable or are totally missing (cf. Chapter 4).
- Relevance due to regulatory gaps: from this perspective, an advanced material could be prioritised if the existing legal framework does not ensure the identification of possible risks for human health and the environment. This could be the case if advanced materials are covered by legislation that does not require (a sufficiently thorough) risk assessment or that does not include provisions to generate information (cf. Chapter 5).
- Relevance due to significant environmental impacts: from this perspective, advanced materials could be prioritised if its production is very resource intensive (cf. Chapter 6).
- Relevance based on ethical considerations: from this perspective, advanced materials could be prioritised if their application would violate ethical principles, e.g. in terms of access to innovation (cf. Chapter 7)

This report should initiate further thinking on how advanced materials can be prioritised. It is addressed to the interested public as well as stakeholders, which are involved in the evaluation of advanced materials from a societal perspective. The report does not target the scientific discourse.

This compilation of possible relevance criteria should be understood as “open list”, which does not aim to be complete. Most individual criteria used alone do not indicate a regulatory need or general priority. However, a set of different relevance criteria may give an initial indication of priority advanced materials. Hence, the report is a tool-box invitation to select and combine criteria to identify relevant materials.

The predominance of relevance criteria based on risk concerns as compared to benefit-driven relevance criteria results from the discussion focus at the Expert-Dialogue as well as the fact that the report is written to support the protection of environmental and human health.

2 Classes of advanced materials

At the ExpertDialogue, it was presented[1] that currently, no legal definition exists but that advanced materials are generally described, in particular in scientific literature. These descriptions are based, among others, on the "novel properties" or on the fact that these materials are still "under development".

The stakeholders at the Expert Dialogue found a definition of (specific) advanced materials necessary for regulatory purposes. Such a definition should be unambiguous regarding the (groups of) advanced materials to be regulated, understandable and controllable. Developing a universal regulatory definition was assumed hardly possible and not useful by many participants mainly because of the large number of (combinations of) advanced materials.

The stakeholders also evaluated the terms currently used as inappropriate for regulation, because of their "relative" elements: advanced are described in comparison to "existing", "older" or "less performing" materials. Therefore, it was stated unclear when a property or functionality could be regarded as "novel", "innovative" or "different than before". In addition, it would be problematic that the understanding of "old/new" or "innovative" changes over time.

Grouping advanced materials into different classes was found necessary in order to:

- unambiguously clarify and specify the subject of communication and thereby simplify the information exchange between all actors on the topic;
- structure information collection and generation;
- prioritise funding of innovative research projects on material safety;
- systematically scrutinize the suitability of existing regulation.

However, it was also critically questioned whether it is possible to develop an unambiguous system to differentiate advanced materials, as their allocation to (only) one category was considered partly impossible. In addition, depending on the degree of differentiation, very complicated classes could be developed.

Some categorisation systems were introduced, which differ in the classification criteria[2] and the number of the resulting classes. Nanomaterials are one class of

[1] Cf. presentation by Steffen Foss Hansen at the ExpertDialogue at: https://www.oekopol.de/wp-content/uploads/02-Categorisation-of-advanced-materials_Hansen.pdf.

[2] For example, advanced materials are differentiated according to the types of products and processes they are developed for or based on their unique properties or material composition.

advanced materials in all systems. A common feature of all systems is that they characterise advanced materials as products with a high added value, which are superior to conventional materials due to their novel, unique or improved functionalities or properties.

3 Relevance based on assumed risks

This section discusses assumptions of risks because information on possible risks from advanced materials is currently missing. Risk assumptions could be based on an advanced material's hazardous properties or on the possibility of high exposure levels from its use. The latter depends on the application type and related conditions of use as well as on the persistence of advanced materials or their degradation to "critical" products.

Apart from the "classical" indicators of risk used in chemicals legislation, this section also discusses criteria on additional aspects.

3.1 Criteria on environmental and health hazards

The following criteria address possible hazardous properties of advanced materials that could justify a risk assumption and hence be an indicator of relevance.

3.1.1 "Classical" hazardous properties

This criterion relates to an advanced material's health or environmental hazards.

Chemicals legislation defines several classes of adverse effects on humans and the environment. The applicability of a class is determined based on information from testing or other sources. The legally defined process of and criteria for allocating a particular hazard class to a chemical is called classification.

The functionality of an advanced material may already indicate whether adverse effects could be expected, e. g. if a material has an increased reactivity or biological activity. However, hazardous properties could also exist independently from the desired functionality and obviously would not be intended.

Information on the (eco-)toxicity of advance materials that fulfil the substance definetion may be obtained from testing, from data on the bulk materials (e. g. in the case

of nanomaterials) or, if they have structural similarities[3] with other substances, from data on these substances. If advanced materials fulfil the mixture definition, this information may be deduced from the ingredients' properties or testing of the mixture. However, due to the targeted combination of substances/materials effects may exist that cannot be predicted using the logics of mixture classification.

Advanced materials could be considered relevant if they have the following hazards: carcinogenicity, mutagenicity, reprotoxicity (CMR), persistence, bioaccumulation (and toxicity) (PBT/vPvB) or endocrine disruption and sensitisation. If adverse effects cannot be assessed with the existing methods of chemicals legislation, the relevance would be based on "lack of assessment instruments" (cf. chapter 4) or because of the ignorance of hazards.

3.1.2 Effects from particles and fibres

This criterion concerns particulate and/or fibrous advanced materials. These forms may be problematic for human health or the environment, as has been shown in related safety research on dusts and nanomaterials.

According to current knowledge, nanoparticles do not cause any adverse effects which have not yet been defined in chemicals legislation. However, they cause these effects partly via different modes of action. These may be due to their morphology (fibres in the lung) or reactivity at the particle surface.

Research on nanomaterials has identified two groups of dusts as particularly harmful for human health because they may e.g. cause inflammations of the lung and/or could cause cancers. These are specific fibres, so-called WHO[4]-fibres, and granular, biopersistent dusts (GBD). WHO-fibres are more than 5 µm long and have a diameter of less than 3 µm. The size of GBD may be in the nano or the microscale. Hence, both nanomaterials and advanced materials which do not fulfil the nano definition could fall into these groups.

In addition to morphological aspects, particle surfaces that are catalytic or chemically or biologically reactive may be indicators of relevance, because interactions with biological systems are likely. If the various types of advanced materials have further particle properties, which could cause adverse effects they could be subject to further

[3] According to REACH Annex XI, grouping may be used to fulfil the data requirements for the registration and evaluation of substances. This also applies to nanomaterials (Regulation (EU) 2018/1881), which defines a category of similar nanoforms as a group of nanoforms within the limits of specific parameters listed in the Annexes. It must be ensured that for all individual nanoforms in a category the assessment of hazards, exposures and risks can be performed together. Any deviations must be within the limits, justified and may not affect the assessment results in the category. A nanoform may only pertain to one category of similar nanoforms.

[4] World Health Organisation

research. A high relevance would hence result for advanced materials, which are particles and either fulfil the definition of WHO-fibres or of GBD or which have a reactive surface.

3.1.3 Behaviour of advanced materials

This criterion combines different aspects, which may affect the exposure duration or exposure level to advanced materials, such as persistence, bioaccumulation, degradation to critical metabolites and translocation in the body.

The exposure level to a substance depends, among others, on its stability (persistence) and if and to what extent it accumulates in certain environmental compartments and organisms ((bio-)accumulation).

In technical applications, high persistence is frequently a desired property and may therefore be a development target. Stable advanced materials may, for example, increase the lifetime of materials, substitute materials with lower durability or be used under “extreme” conditions (heat, friction, contact with acids etc.). Hence, persistence is a criterion of increased technical relevance.

In regards to environmental risks, persistence is problematic, as a continuous release of persistent advanced materials may cause high environmental exposures. Depending on the physical-chemical properties, advanced materials could also accumulate in organisms and/or the food chain, which could indicate relevance. Furthermore, an accumulation in the human body and/or a possible translocation from the point of intake to other areas or organs in the body is evaluated as critical.

As advanced materials are frequently a combination of single substances, mixtures and/or materials, the assessment methods of (single) substances may not be applicable. Persistence and bioaccumulation may not be assessable for mixtures. For example, the degradability of detergents (mixtures) is determined based on the degradability of the contained substances. In a detergent and different from the case of many advanced materials, the ingredients are not firmly bound to each other but coexist in a solution. Therefore, the single substance-based approach is not applicable for advanced materials (relevance consists in the lack of assessment methods; cf. Chapter 4).

Degradation and aging may generate metabolites with other properties than the original advanced material, which may either cause higher or lower risks to humans and the environment. Analyses by the German Federal Agency for Occupational Health and Safety (BAuA)[5] showed that pitch-based carbon fibres may degrade to

[5] Cf. presentation by Rolf Packroff https://www.oekopol.de/wp-content/uploads/05-Perspektive-BAuA_advanced-materials_Packroff.pdf.

WHO-fibres (cf. chapter 3.1.2). Hazardous metabolites can only be (well) predicted if the structure of an advanced material already suggests a possibility (e.g. like carbon fibres).

High relevance of advanced materials in this group of criteria could be indicated by:

- persistence and/or
- bioaccumulation potential and/or
- degradation products, which fulfil a relevance criterion and/or
- translocation in the human body.

3.1.4 Carrier effects and conditioned (re-)activity

This criterion describes relevance as a function of an advanced material‘s interactivity with other chemicals and/or materials.

Some advanced materials can change the mobility of other substances or “carry” them. This functionality is used e. g. in medicinal applications to surpass biological barriers or to deliver drugs within the body. It may also (inadvertently) cause an uptake of hazardous substance into organisms/humans, which would not have been bioavailable if the advanced material had not been present.

Active advanced materials change properties or structures depending on specific outside conditions, such as after input of energy, light or adjustment of pH. They may cause or stop specific functionalities as such or in other materials or products. Such activities cannot be properly addressed with existing risk assessment instruments (cf. chapter 4).

Carrier effects and the “switchability” indicate a high relevance both with regards to potential risks and potential benefits.

3.1.5 Sequential effects and degradation

Many advanced materials are characterised by a specific structure and they may consist of several different layers. If an outer layer separates an inner layer from the “outside environment”, the hazard potential of the advanced material is determined by the properties of the outer layer, e.g. a functionalised surface.

If under the conditions of use and/or after release of such an advanced material, the outer layer is degraded, any possible adverse effects and properties of the inner layer would predominate. If and which effects could occur due to degradation of advanced materials is currently not known. Therefore, a relevance criterion could prioritise core-shell structures, where inner parts of the materials are shielded during (eco-)toxicity testing.

3.1.6 Hazards from combinations with biological materials

This criterion relates high relevance to the presence of biological materials.

The term “biological advanced materials” concerns advanced materials which are either made from biological raw materials or which should interact with biological systems.

Advanced materials containing biologically active entities (e. g. bacteria or viruses), hence combining biological and synthetic components, could be considered relevant. This is because the behaviour of the biological component is not predictable by existing risk assessment instruments and/or difficult to steer and control.

Advanced materials that should have an effect on biological systems are expected mainly in the medicinal area and will hence be covered by the respective legislation. The tests and assessments required under legislation on pharmaceuticals and medicinal products should ensure that possible adverse effects of advanced materials are identified and controlled, even if they contain a biologically active entity.

Consequently, a high relevance may exist if a) biologically active structures are contained in advanced materials and/or b) the final product is used in biological systems which are not covered by medicinal legislation.

3.2 Criteria on exposure

Besides the hazardousness of substances, the types of exposures, their levels and their durations determine the risk according to chemicals legislation. Hence, indications of relevance may be a high, a long-enduring and/or a frequent exposure.

3.2.1 Production and use amounts

This criterion is based on the assumption that high production and use amounts of advanced materials correlate with high potential exposures.

Relevance with a view to potential exposures

The assumed relation between production and use amounts and possible exposures is one of the reasons, why a tonnage threshold triggering information requirements for registration was included under REACH. However, it is possible that substances are used in very large amounts but their uses give rise to very low releases. An example is the use as an intermediate or in articles, where substances may be firmly bound to the article matrix. Hence, compared to the production and use amount, a

low exposure level can be expected.[6] Data on the production and use amounts are at least theoretically available from the manufacturers and importers of advanced materials.

Relevance with a view to the market occurrence

The relevance of an advanced material may also be based on the extent of (expected) benefits, as well making production and use amounts a “positive relevance criterion”. However, this type of relevance has a reversed relation to the risk and is difficult to interpret. Generally, high production and use amounts would be associated with high and small amounts with a low economic relevance. However, the economic and technical importance of an advanced material could also be high if the use amounts are low, e.g. if advanced materials are used as a catalyst or enable other technologies. Therefore, any decision on relevance should consider in which form and with which functionality an advanced material is used.

As market trends over time may show the success of an advanced material on the market, they may also be a relevance criterion.

3.2.2 Uses with high exposure levels

This criterion includes several possible indicators of high release rates from products and processes.

Critical exposure potentials in risk assessments are typically those, with either a short contact with humans/the environment to high amounts of a substance, or a long enduring or frequent contact (to lower amounts). Examples of conditions or products with high exposure potentials are:

- consumer mixtures;
- chemicals’ use over a longer time and/or without technical protection;
- direct use of chemicals in and/or intended release to the environment and/or use in (semi-)open processes and installations;
- individual particles or chemicals at nanoscale are released to the environment and/or exposure of humans is evident (e.g. nano carriers in medicine enter the environment through urine and faeces; composite materials are exposed to weather);

[6] Note that at a product’s waste stage formerly bound advanced materials may be released and may cause environmental and health risks. This should be considered in the relevance assessment.

- large surfaces release chemicals indoors, i.e. chemicals are not firmly bound to the surface or matrix below;
- chemicals are included in articles that remain in the environment for a long time;
- the use of chemicals generates dusts or aerosols leading to release;
- wide dispersive use of chemicals;
- chemicals are released during disposal or recycling.

Whether a specific advanced material is used under the above-described conditions and whether this actually results in exposures would be assessed on a case-by-case basis.

The use of advanced materials in many different products and processes may also be an indication that they can be flexibly used and hence, could create benefits in many different areas. In addition, innovations from advanced materials may spill over to other technical areas and thus creating synergies and accelerating the development of better materials, products and processes. Consequently, this (sub-)criterion could indicate relevance also based on possible benefits.

3.3 Use of advanced materials

3.3.1 Uses in and on the body

This criterion addresses a specific case of a high exposure potential, because the use implies an intense direct human contact with the advanced materials. Interaction with the body or its prevention is intended (medicinal uses).

Medicinal uses are covered by either pharmaceuticals or medicinal products legislation, both require comprehensive assessments including data generation and evaluation. Advanced materials evaluated for medicinal uses[7] may cause high risks but these are assumed to be either sufficiently controlled or justified by the expected benefits, hence resulting in low relevance. However, it is possible that advanced

[7] It would have to be assessed if advanced materials are already authorised for use in their "conventional form" (if existing) and if an authorisation based on that can be used also for the advanced material. If no new assessment is done, the new properties of the advanced material would not necessarily be identified and potential (additional) risks may not be assessed.

materials for use in medical applications are also used in other areas, such as cosmetics or clothing[8], which are not regulated in a similar way.

Similarly, legislation covering the food sector includes procedures for chemical safety assessment and authorisation, ensuring that advanced materials in food and food-related products are evaluated by authorities. Evaluations have to be conducted for all "novel foods" and substances used therein[9] or substances applied as food additives or complements. In the food sector, further analyses may be necessary to clarify if existing legislation is sufficient to assign a low relevance[10].

The cosmetics regulation does not require a safety assessment of the used ingredients by their producer or placers on the market of cosmetic products but substances with some specific functionalities may only be used after prior assessment by the authorities (e.g. preservatives). However, the requirements are less strict and are only randomly controlled.

Articles, which are worn on the body and for which no specific assessments are required include jewelry (earrings, piercing etc.) and non-medical sensors and devices. Also, these products come in close contact with the human body with a respective possible exposure and uptake.

A high relevance would hence result from uses of advanced materials in cosmetics as well as in articles, which are worn in or on the body and for which no risk assessment is currently required.

3.3.2 Potential of "non-intended uses"

The criterion describes relevance based on the potential that an advanced material can be used in another way other than as intended. This may result in risks not being identified but also additional benefits of an advanced material.

Relevance due to missing risk assessments

Research and development of advanced materials normally target a particular application. Hence, material solutions are explored and developed for defined products or their components (e.g. batteries, lighting) and, if they reach the market, are assessed for these uses. If an advanced material is used in non-intended uses, it is possible that assessment gaps arise (cf. chapter 4). An example would be materials, which are developed as protective car undercoating but are also applied (non-intentionally)

[8] Sports clothing appears to be an important application area.

[9] In the case of food legislation, novelty is determined by having not been on the market before 1997 in the EU.

[10] At the time of writing this report, food legislation was under review with no possibility to predict if and how the regulations might change.

in polymer for 3D printing by consumers. This use would not be assessed by the producer of the advanced material but would be the responsibility of the downstream user making the mixture for printing. However, there are several conditions that limit the (quality of the) actual implementation of the requirement.

Relevance due to a high innovation potential

On the other hand, the potential for "unintended" uses could also be seen as a benefit and/or indicate a high future technological and economic importance, because of possible uses in (many) areas other than the intended one. Unintended uses are likely, if an advanced material has functionalities which are of "general technical interest", i.e. that enable uses under similar conditions or for similar purposes as intended. Unintended uses tend to be innovative which prevents broad communication in the market and/or to the advanced material's manufacturers. A second option why non-intended uses could occur is that advanced materials are enabling technologies which improve the performance of other products. An example could be advanced materials improving battery performance, where different uses (including by consumers) may occur.

According to the above, relevance might be indicated if advanced materials have many "non-intended" uses. Relevance would result from potential benefits and risks[11].

4 Relevance as assessment tools are not applicable

This criterion would indicate a relevance if possible risks from advanced materials could not or not sufficiently be assessed using existing risk assessment instruments.

REACH and the CLP Regulation require that certain toxicological and ecotoxicological properties of chemicals are determined and that at least some information on the uses and potential exposures and risks are described. The instruments for hazard and risk identification include, among others:

- lists of information to be collected and/or how to generate it;
- descriptions of adverse effects and methods how they are to be identified (test guidelines, rules on the interpretation of test results, read-across, grouping, QSARs or waiving). Rules for translating hazard information into standardised

[11] Substance registrants may restrict uses if they cannot or do not want to assess the risks or if they consider them not controllable. This is called a "use advised against" and would better ensure the implementation of risk assessments by the downstream users.

language is described by classification and labelling rules, REACH Annex XIII (PBT/vPvB) as well as the (newly implemented) criteria on endocrine disrupters (plant protection products and biocidal products);

- procedures to determine exposure levels, including standardised models for releases, degradation and partitioning in the environments, models to simulated kinetics in the human body etc.

Research shows that due to the particulate nature of nanomaterials, both toxicity and the parameters driving exposure levels, such as release rate, degradation, adsorption or accumulation, could differ as compared to the bulk substances. Therefore, the identity of nanomaterials must be described using additional parameters and the instruments for risk assessment have to be adapted.

A high relevance of advanced materials regarding the applicability of risk assessment instruments could be indicated among others by the following:

- advanced materials cannot be applied in toxicity tests (in vivo or in vitro) or in tests on degradation and distribution due to their physical-chemical properties, e.g. they are not stable, not soluble in water or cannot be analytically detected;
- data on similar substances or mixtures cannot be transferred to advanced materials;
- degradation and behaviour of advanced materials (in the environment and/or the body) cannot be predicted by exposure models because they depend on further parameters and/or their structure;
- parameters which influence the effects on biological systems are not considered in traditional risk assessments (e.g. morphology).

5 Relevance due to “regulatory gaps”

Generally, relevance in the regulatory context should target those advanced materials, which are currently not covered/regulated or which are covered but the potential risks for humans and the environment are not sufficiently well determined and can therefore not be addressed. Regulatory relevance is rather an indicator of uncertainty and does not necessarily mean that there is an inacceptable risk.

To identify possible risks from advanced materials sufficient information has to be available and there must be actors that are responsible for it. Whether these conditions are fulfilled depends on whether or not advanced materials are covered by the scope of respective legislation, i.e. if the respective definitions are fulfilled. For industrial chemicals, REACH is relevant and defines substances, polymers, mixtures

and articles as well as nanoforms of substances. In addition, risk assessments may be foreseen in legislation, which regulates individual application areas (of advanced materials), such as the regulation on pharmaceuticals, the EU legislation on food contact materials or the regulation on Waste of Electrical and Electronic Equipment.

All advanced materials for which existing legislation does not require a risk assessment, i.e. assessment and implementation of safe use is not ensured, may be regarded as “relevant”.

REACH requires the registration of industrially used substances in amounts exceeding 1 t/a per manufacturer or importer. Only if the registered amount exceeds 10 t/a, a safety assessment is obligatory. This may include the assessment of risks from different uses under certain conditions. REACH does therefore not ensure that risks of all advanced materials are identified.[12]

Another aspect aggravating the evaluation of advanced materials is the fact that many materials are not substances in the meaning of chemicals legislation but consist of several components; i.e. they are mixtures or articles. Particularly this combination of materials creates the desired properties of many advanced materials. However, it is not always known if these combinations also generate further/new (eco-)toxicologically critical properties[13].

If product legislation exists and covers an advanced material, the assessment gaps of REACH would be closed in those cases, where it includes self-standing requirements on information generation and assessment of the product (e.g. pharmaceuticals). If only a risk assessment of the ingredients is required or if no information needs to be collected and generated on the hazardous properties of the advanced materials as such, it is likely that the information is insufficient and a risk assessment is impossible or highly uncertain. This could be a reason to prioritise an advanced material as “relevant”.

If an advanced material fulfils the mixture definition, it has to be classified and labelled according to the CLP regulation[14], using the available information. It is not

[12] Reasons for missing or insufficient assessments under REACH are, among others: advanced materials below 1 t/a are not registered, advanced materials below 10 t/a are not subject to a detailed safety assessment, the hazardousness of an advanced material is underestimated and therefore risks are not assessed, uses are unknown and/or insufficiently determined, advanced materials are polymers and do not have to be registered.

[13] Assuming that the combination of substances in an advanced material creates new properties which are potentially not predictable based on information on the properties of the individual substances, an assessment of an advanced material as “use of a substance” under REACH might not be sufficient.

[14] Classification and labelling use information from (eco-)toxicological tests or other methods to classify and label a substance’s or mixture’s hazards and determine the types of effects and severities. As a result, substances or mixtures may be classified as carcinogenic, toxic or hazardous to the environment etc.

required to generate new data. Hence, the CLP regulation does not ensure that the specific (new) properties potentially arising from the combination of substances and materials are identified and communicated. However, it is possible, as described above, that an advanced material falls under further legislation with respective requirements that closes the assessment gap on hazards.

If an advanced material is an article[15] there is no systematic requirement to identify the hazardous properties (of its components) and assess the related risks. If the structure of active materials is decisive for their function, they might be considered articles from a legal perspective. In addition, products from additive manufacturing (which may use advanced materials as input material) are normally articles.

The following table lists core definitions of chemicals legislation and proposes indicators which could justify a prioritisation of relevance.

Table 1: Overview of selected criteria on regulatory definitions[16]

Relevance criterion	Possible reasons why a criterion could be fulfilled	Possible consequences which could justify prioritisation of advanced materials
Substance definition does not apply[17]	Advanced material is a mixture or article.	Advanced materials which are not substances do not have to be registered; other legislation with assessment requirements may exist (e.g. pharmaceuticals). Ingredients of advanced material are to be registered if > 1 t/a but their uses (in an advanced material) may not be sufficiently assessed (cf. above).
Substance definition applies but is not differentiated enough[18]	Advanced material is substance and particle > 100 nm	Advanced materials are covered but not specifically addressed as the same requirements apply for advanced and non-advanced materials
Definition of nanoform	Advanced material is particle with size > 100 nm	The nano-specific (information) requirements under REACH do not apply.

[15] REACH defines articles as objects, where physical properties are more important for the function than the chemical composition. In simple words, generally all goods with a fixed form are articles, while liquids and gases are chemicals. The transition from chemical to article is fluent. Cf. the guidelines by ECHA for further information.

[16] This table only includes definitions of REACH. Further legislation, such as the regulations on biocidal products and plant protection products, pharmaceuticals or cosmetics also contain definitions, which trigger requirements for safety or risk assessment and which would have to be checked. This is not included in this report and would be subject to further analyses.

[17] REACH Article 3(1): "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;"

[18] It could be further analysed if there are advanced materials that have different properties because of physical-chemical parameters and that cannot be differentiated with the current substance definition or if their properties only change under certain conditions of use, such as in certain milieus or in connection with certain (other) substances/materials (e.g. carrier systems).

Relevance criterion	Possible reasons why a criterion could be fulfilled	Possible consequences which could justify prioritisation of advanced materials
does not apply[19]	in all dimensions.	
Definition of polymer does not apply[20]	Advanced material is considered a polymer; REACH definitions of polymers and substances are not fulfilled	Advanced materials, which are considered polymers are legally either substances (higher requirements) or mixtures (lower requirements).

A high relevance would be assigned if an advanced material does not fulfil the definition of a substance or a substance in nanoform, because in those cases, neither information would be gathered, generated and provided to the authorities, nor would a risk assessment be performed by the industry or the authorities.

6 Relevance due to lifecycle impacts

6.1 Lifecycle assessment and/or resource consumption

The following criteria describe possible lifecycle impacts of the use of advanced materials. These impacts could be higher or lower than if other methods or products were used to achieve the same result.

From an ecological perspective, an advanced material can be beneficial if fewer resources are consumed to achieve a particular functionality or function or if less hazardous emissions occur as if “conventional” methods or materials are used.

The resource consumption is normalised to a “functional unit”, i.e. the result that should be obtained by a product or process. This enables comparing technologies, products or services which are very different in nature. For example, to compare

[19] REACH Annex VI: “a nanoform is a form of a natural or manufactured substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm, including also by derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm.“

[20] REACH Article. 3.5: “polymer: means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:
(a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
(b) less than a simple weight majority of molecules of the same molecular weight.
In the context of this definition a ‘monomer unit’ means the reacted form of a monomer substance in a polymer;“.
Literature on advanced materials describes polymers differently, e.g. “polymers, which are enhanced by biological fibres or nanomaterials and have strongly improved properties for innovative uses” (cf. presentation by Mr. Hansen at the ExpertDialogue on “advanced materials” on May 22/23 2019 in Berlin).

different constructions of cars, a functional unit of 1,000 person kilometres could be defined. All resources needed for this transportation target, including for car production, the use phase and potentially the waste phase would be included in the lifecycle assessment of e.g. a lightweight construction (advanced material) and a conventional car (steel), including the necessary amount of fuels. For the defined amount of person kilometres, one could also compare hazardous emissions, which might affect e.g. eutrophication of surface waters or acidification of ecosystems.

Different approaches to compare resource consumption and related impacts exist. The most extensive variant is the so-called (standardised) lifecycle assessment, where the total resource consumption is balanced. The environmental impacts from the resource consumption are calculated and described in form of standardised impact categories, such as toxicity, biodiversity or greenhouse gas emission. The method of “cumulative energy consumption” is a less cumbersome assessment method. Software tools and databases are available to support such assessments with data on resource use.

All of the above mentioned assessments require that the specific use of an advanced material is known because it is necessary to define the functional unit and compare it with another (conventional) process or product. The comparison with “conventional” or “other” approaches to achieve a function is necessary because an “absolute” value of a resource use is not meaningful.

From an environmental perspective, a high resource consumption (compared to other methods/products) to achieve a specific function or functionality may be a justification of relevance because a particular use should also be environmentally friendly. But also from a society or economic perspective such use should be challenged, as an increase in resource consumption is generally not reasonable.

6.2 Recyclability

This criterion addresses the possibility that advanced materials are recovered from waste products or materials. A high recyclability of a material exists if:

- it is used in products which are collected and sorted when becoming waste;
- it can be easily and quickly separated from products or the different parts of a material are easily and quickly separable from each other;
- an infrastructure exists for collection and sorting of products, for separating recyclable parts and for conducting the specific recycling processes;
- parts of the advanced material (in products) can be reused if sufficient information is available;

- the material does not contain substances of very high concern, which could cause risks in a second lifecycle, reduce the quality of secondary raw materials or disturb recycling processes.

Recyclability is significant from an ecological and economic perspective. A high relevance in this area could be assigned to a non-recyclable advanced material.

6.3 Use of critical resources

This criterion describes if the production of an advanced material causes either ecological or social impacts because it contains or requires the use of critical resources.

Critical resources are either generally rare or difficult to obtain because of their low concentration (rare earths and some metals). Resources may also be critical because they are obtained under ecologically and socially undesirable conditions (e.g. gold). Both from an ecological and a social perspective, the use of critical resources should be avoided. Even more, their substitution should be promoted to prevent or at least reduce economic dependencies and to avoid supporting countries that do not ensure environmental protection and safe workplaces.

In this sense, advanced materials could be prioritised as relevant if they contain either critical resources or if their production requires the use of critical resources. They could also be considered relevant if they contribute to the reduced use of critical resources.

7 Ethical aspects

An ethical relevance assessment of advanced materials needs to consider the specific use. Ethical aspects of technology assessment in general regard, for example:

- Justice: people should have equal access to product innovations and services, in particular in health care; disadvantages for coming generations should be prevented (sustainability);
- Keeping natural limits: for example in relation to “human enhancement”, the biological divide between living organisms and the utilisation of life by people should be respected;
- Sense and direction of societal development in general.

These aspects are of different relevance for advanced materials. An ethical assessment appears more important for advanced materials which are used in the medical area or for weapons than e.g. for advanced polymers used in light-weight construction.

8 Summary

The relevance of an advanced material can be prioritised using different criteria and depends on why prioritisation is undertaken. Various aspects why an advanced material could be relevant are compiled in this report. These (aspects) were discussed at an ExpertDialogue organised by the BMU on “advanced materials”. The meaning of each criterion is described and illustrated with possible indicators. From the BMU’s perspective, criteria indicating potential risks are of high importance, because they may also indicate a possible regulation need.

This report aims to raise awareness on the different perspectives that could be taken on the use of advanced materials and their assessment. It aims to provide possible assessment criteria to be used in an extended and more in-depth discussion on possible priorities. The ethical criteria for relevance assessment are only generically described.

The following table gives an overview of the relevance criteria and possible indicators. These (and further) criteria may indicate priorities for monitoring and further assessment of advanced material due to possible risks, lack of regulatory coverage or potentially high benefits for humans and the environment.

Table 2: Summary of described relevance criteria and possible indicators

Perspective	Criterion of relevance	Examples of indicators showing that a criterion could be fulfilled
Regulatory	Substance definition does not apply	Advanced material is a mixture or an article.
Regulatory	Substance definition is not differentiated enough	Advanced material is a substance but cannot be unambiguously described by the "classical" substance identity; the advanced material is a particle > 100 nm.
Regulatory	The definition of a nanoform does not apply	Advanced material is a particle with a size > 100 nm in all dimensions.
Regulatory	Polymer definition does not apply	Advanced material is considered a polymer despite not fulfilling the REACH polymer definition; the substance definition is also not fulfilled.
Regulatory	Instruments to assess critical properties (hazard, behaviour) are not applicable	Advanced material cannot be used in (eco-)toxicity tests. The advanced materials' properties cannot be deduced, as (data of) similar materials are missing. The hazardousness results from the combination of materials. Active materials change their properties.
Regulatory	Exposure assessment tools cannot be used	The behaviour of advanced materials in the body and the environment cannot be determined using existing models. Metabolisation and degradability of advanced materials are unknown.
Potential hazards	(Indications of) severe adverse effects (CMR, PBT/vPvB; EDC, sensitisation)	Tests or other sources assess advanced materials as of concern. Structural similarity to SVHC. Functionality indicates adverse effects. Classification of advanced materials is not possible due to lack of data.
Potential hazards	Particle properties	Advanced material falls under the definition of WHO-fibres or GBD. Advanced material is a catalyst or chemically or biologically reactive.
Potential hazards	Sequential effects	Advanced material has a core-shell structure which masks the inner parts, which, however, may determine the (further) adverse effects after degradation, which were not identifiable of the outer layer.
Potential hazards	Combinations with biological materials	Advanced material contains biologically active structures. Advanced material is used in products for medicinal purposes or with intimate body contact.
Exposure potential	Production and use amounts	Advanced material is manufactured/used in large amounts.[21] Production and use amounts increase over time.
Exposure potential	Applications with high use potential	Advanced material is used in different applications Synergies are possible through spill-over effects
Exposure potential	Uses with high exposure potential	Advanced material is used: in mixtures for consumer use; at unprotected workplaces; open in the environment or with intended environmental release; in (semi-)open installations; in/on large surfaces indoors;

[21] To evaluate if an amount is "large" or "small", further information is necessary.

Perspective	Criterion of relevance	Examples of indicators showing that a criterion could be fulfilled
		in products (intentionally) remaining in the environment for a long time; with generation of dusts and aerosols; in many processes, installations and products (dispersive use); in products from which release is likely during the waste stage.
Exposure potential	Uses in/on the body, which are not (sufficiently) regulated	Use of advanced materials in cosmetics. Use of advanced materials in articles to be worn on/in the body.
Exposure potential	Risks of unintended uses not identified	Advanced materials could be used in many unintended (and hence not or insufficiently assessed) uses.
Exposure potential	High benefit potential and unintended uses	Advanced material/its functionality is technically “interesting”. Advanced material supports/enhances other technologies or functions.
Exposure potential	Persistence	Advanced material increases product lifetime.
Exposure potential	Persistence	Advanced material is biologically or abiotically not degradable, stable, or not dissolvable in water. Advanced materials is applied for uses under “extreme conditions“ or used to increase the lifetime of products.
Exposure potential	Bioaccumulation	Advanced material bioaccumulates.
Exposure potential	Translocation in the body	Advanced material is distributed in the body and/or not metabolised and excreted.
Exposure potential	Critical degradation products	Advanced material maybe degraded to substances/materials with adverse effects. Advanced material consists of “problematic components“ that might be released after degradation or aging.
Exposure potential	Specific benefit potential due to functionality	Carrier effects Ability to “switch”
Exposure potential	Risks from carrier effects and activity	Advanced material changes the mobility of other substances (carrier effects). Advanced material can be switched by environmental conditions.
Life cycle	Resource consumption	To achieve the functional unit, the advanced material requires more resources than other processes/products or leads to higher amounts of hazardous emissions.
Life cycle	Resource consumption	Advanced material requires less resources to achieve a functional unit than other processes/products.
Life cycle	Suitability for recycling	Advanced material is applied in products/applications, which are not recycled (not collected, not sorted). Components of advanced materials cannot be separated from the product and/or are not easily separable. Advanced material cannot be recovered. Advanced material contains substances of high concern.
Life cycle	Consumption of critical resources	Advanced material can substitute the use of critical raw materials in products and processes.
Life cycle	Consumption of critical resources	Advanced material contain/the production of advanced materials requires the use of critical raw materials.

Which of these criteria are used for relevance assessment and how the indicators are defined to identify a “high” relevance depends on the aim of prioritisation as well as the interests of those doing it.

Abbreviations

3D	3-dimensional
BMU	German Federal Ministry of the Environment, Nature Protection and Nuclear Safety
CLP	Regulation on the classification, labelling and packaging of substances and mixtures
CMR	carcinogenic, mutagenic, reprotoxic substances
EU	European Union
GBD	granular, biopersistent dusts
PBT	Persistent, bioaccumulative and toxic substances
vPvB	Very persistent, very bioaccumulative substances
QSAR	Qualitative structure activity relationship
REACH	Regulation on the registration, evaluation and authorisation of chemicals
WHO	World Health Organisation –