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**Nanomaterials in the environment –
Current state of knowledge and
regulations on chemical safety
Recommendations of the
German Environment Agency**

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1. Introduction

Nanotechnology is one of the key technologies of the Hightech Strategy 2020 of the German Federal Government¹. Nanotechnology involves research and development, production and processing of structures and materials on a nanometre scale. Such nanomaterials² can have different or completely new properties and functions in comparison with conventional chemicals and materials. The most important fields of application for nanomaterials include electrical engineering, energy technology, chemistry and materials development, but also pharmaceuticals, coatings, construction materials, and textiles. By using the specific properties of nanomaterials, improved efficiencies or new functionalities can be achieved for a wide range of products and applications.

Nanotechnology can offer various environmental opportunities, e.g. in the field of energy and resource efficiency, decontamination of wasteland sites, or water purification. But the dynamic development of nanomaterials and their applications means that the amounts produced are increasing. This can also result in increased burdens for humans and the environment when nanomaterials are released from products and applications.

In 2009, the German Environment Agency (UBA) published a background paper on the opportunities and risks of nanotechnology³. At that time, the potential benefits and impact of nanomaterials for humans and the environment still represented a relatively new

field of research and some questions remain concerning the potential environmental benefits and the possible risks posed by nanomaterials. As a result of the findings from a range of scientific projects, research is no longer focused solely on the properties, behaviour and effects, but also addresses the adaptation of assessment tools for an appropriate regulation of nanomaterials.

Until now, with few exceptions, there are no specific provisions for nanomaterials within the substance legislations. As a result, specific environmental risks cannot be described and assessed adequately and appropriate measures to minimize the risks cannot be taken. Therefore, the main aim of this paper is to outline the necessary further development of chemicals regulations for nanomaterials with regard to the environment from UBA's perspective. It is addressed particularly to players and decision-makers involved in discussions related to the adaptation of the various regulations on chemical safety. Firstly, the current state of knowledge about the environmental behaviour and the effects of nanomaterials is presented. The paper then considers general aspects of regulatory needs such as the definition of nanomaterials, their characterisation, and the assessment of related risks. It also describes the current consideration of nanomaterials in the existing active substance regulations and the specific requirements for adaptations. Finally, the activities of UBA are presented and the Agency's recommendations with regard to this topic.

2. Effects and behaviour in the environment – State of knowledge

In order to be able to make risk assessments, it is necessary not only to know the hazard potential of nanomaterials but also how about they are released and their fate and behaviour in the environment and the resulting exposure.

In recent years, intensive research has provided new insights about the behaviour and effects of nanomaterials. Processes and mechanisms could also be identified that are important for the description of the behaviour and the impact of nanomaterials in the environment. These findings are summarised in the following subsection.

2.1. Effects in the environment

The fact that a substance is present as nanomaterial alone does not necessarily indicate a hazard potential. In addition to the chemical composition of a nanomaterial, its potentially harmful effect is also determined by properties such as its size, geometry, crystal structure, and surface properties (e.g. charge, surface chemistry)⁴. Furthermore, the ambient environmental parameters (e.g. pH-value, salinity, and content of natural organic substances) influence the properties of nanomaterials and can therefore affect their mobility, bioavailability, and the toxic effects in the environment⁵. Current investigations to determine the eco-toxic effects of nanomaterials focus primarily on nanomaterials with simple structures, some of which have already been on the market for many years but have not yet been considered specifically as nanomaterials in hazard investigations.

Most of the findings relate to the effects on aquatic organisms. In recent years, increasing amounts of data have been generated also on the effects on soil organisms or sediment-dwelling organisms. Many of the nanomaterials investigated show only a moderate to low toxicity or no toxicity for environmental organisms after short-term exposure. A high acute toxicity for aquatic organisms can be observed for those nanomaterials that release ions with aquatic toxic effects (e.g. silver (Ag), zinc oxide (ZnO))⁶. Thereby, additional effects caused by the particles cannot be excluded⁷. Certain photo-catalytically active forms of titanium dioxide (TiO₂) show increased toxicity

in laboratory tests under the influence of simulated sunlight⁸. In extended tests, some nanomaterials have been observed to lead to sub-lethal effects in fish, such as malformations in tissues and organs, damage to the gills, and developmental effects.⁹ In addition, it has been found that aquatic organisms show changes in behaviour after short-term exposure to certain nanomaterials, e.g. changed feeding habits, increased flight behaviour, or their energy budget is influenced¹⁰.

Since a large majority of nanomaterials on the market are inorganic, and are therefore not biologically degraded, it can be assumed that they will persist in the environment. In order to take the specialities of nanomaterials and their complex behaviour in the environment into account when determining ecotoxicological effects, it is not sufficient to investigate toxicity only after short-term exposure. Long-term effects on various invertebrate organisms have been investigated for a limited number of nanomaterials (mainly TiO₂, ZnO, Ag). It was found that exposing nematodes (“roundworms”) and daphnids (“water fleas”) to various nanomaterials (TiO₂, Ag, and gold (Au)) can lead to losses in the progeny, and over several generations to markedly increased mortality and limited reproduction¹¹. There have as yet been no comprehensive and sufficient studies of the chronic effects on vertebrates such as fish that go beyond the larval stage.

Little information is available about the ecotoxic effects of nanomaterials on soil- and sediment-dwelling organisms, partly because of the methodological difficulties faced in such investigations. Some studies find no effects on soil- und sediment-dwelling invertebrate organisms, whereas other studies show that test organisms avoid soil contaminated with nanomaterials¹². Further studies report changes in the reproduction rate (stimulation or suppression) after nanomaterials are introduced into the test soil¹³. However, these findings are not always clearly dose-dependent. Investigations with various plants show that they can take up and translocate nanomaterials. In some cases, an influence on germination and growth was found¹⁴. Evidence has also been found for negative

effects of TiO₂ nanomaterials on the biodiversity of soil microorganism communities.¹⁵

Transformations and ageing of nanomaterials in the environment (e.g. sulphidation of metallic nanomaterials) can alter their ecotoxicological effects. Studies with various environmental organisms show that effects can be increased or decreased¹⁶. However, since these studies were not carried out using the same test systems and organisms, it is difficult to compare the results.

In addition to the direct toxic effects, indirectly harmful effects on environmental organisms are also described for a number of nanomaterials. For example, it is known from laboratory tests that many nanomaterials can adhere to organisms and at sufficiently high concentrations they can block respiratory organs or the feeding apparatus¹⁷. On photosynthetically active organisms, e.g. algae, they can block out light, affecting metabolic processes. In addition, nanomaterials adsorb many of the available organic substances in the environment on their surface. This can also promote the uptake of harmful substances by organisms in the environment¹⁸.

Despite the knowledge that has been gained about potentially harmful effects of nanomaterials on environmental organisms, assessing the environmental hazards of nanomaterials remains a challenge (see also section 3.1.3).

A comparison of the many studies on hazard assessment is made more difficult because the development of uniform specifications on application into the test systems and test performance is still under development.

On a case-by-case basis, it is necessary to check whether existing studies provide a suitable basis for an assessment of the environmental hazard. In many studies, the physical and chemical properties of the investigated nanomaterials are not described adequately. In other cases there is no accompanying analysis and reference is only made to the nominal exposure concentration. This is questionable, because interactions of the particles between one another and with the test system can significantly change the effective exposure concentration.

2.2. Release into the environment

Nanomaterials find a very wide range of applications and with regards to their specific properties without limitation. Some nanomaterials, for example TiO₂, silicon dioxide (SiO₂) or carbon black, are produced in large tonnages and have already been used for decades, and indeed some nanomaterials were already used in ancient times¹⁹. These nanomaterials have found new applications as technology has developed. Other nanomaterials such as quantum dots or carbon nano tubes (CNTs) are relatively recent developments that have yet to establish themselves on the markets²⁰.

In order to be able to assess the environmental exposure to nanomaterials, it is important to know about the presence of nanomaterials in the various products and applications, and about their release over the life cycle (production, use, transport, recycling, and waste disposal). In many cases, insufficient qualitative and quantitative data about the uses and releases are available to derive the potential environmental exposure.

The release of nanomaterials into the environment has been investigated exemplarily for the weathering and mechanical wear of various coatings, and for the washing of textiles²¹. Conceivable are also releases from sunscreen into recreational surface waters, or releases during the decontamination of wasteland sites, wastewater treatment, or the spray applications of pesticides.²²

Depending on the product and process in question, the released nanomaterials may be included in fragments of the product²³. It has not yet been determined whether these fragments are further degraded in the environment to the extent that the included nanomaterials are finally released.

Experiments with model water treatment plants show that some 90 % of the nanomaterials investigated so far is retained in the sewage sludge, while less than 10 % finds its way into bodies of surface water.²⁴ The agricultural use of sewage sludge would therefore make the exposure of farmland likely. The fate of nanomaterials in soil has not yet been analysed sufficiently. But also irrespectively of the release of nanomaterials into the environment, the UBA is opposed to the agricultural use of sewage sludge in view of the other associated risks.

Initial investigations of the behaviour of nanomaterials (cerium dioxide (CeO₂), TiO₂) in waste incineration plants show that these are primarily included in solid residues such as slag and flue dust, while only negligible quantities are released with the cleaned flue gas.²⁵ The release of nanomaterials from landfill sites has hardly been investigated. The results of one study show the release of pigment TiO₂ in the leachate from building waste disposal sites. The possible release of nanomaterials into the environment by this route must therefore be taken into consideration²⁶.

In general there are still insufficient qualitative and quantitative data on the release of nanomaterials into the environment for conclusions to be drawn about the entire life cycle. This is due in part to the manifold and high dispersive use of nanomaterials, but also to the methodological challenges involved and the lack of standardised methods.

2.3. Behaviour and persistence in the environment

The majority of the known nanomaterials on the market are inorganic, so that biological degradation usually plays only a subordinate role. Other processes such as (hetero-)agglomeration, sedimentation, adsorption of substances, adhesion to surfaces and transformation or dissolution determine the behaviour in the environment. These processes are affected by both the properties of the particles (e.g. size, geometry, surface properties) and the properties of the surrounding environmental medium (e.g. pH-value, salinity, concentrations of naturally occurring organic substances)²⁷.

Agglomerations lead to an attachment of individual particles by electrostatic and steric interactions. In the case of heteroagglomeration, nanomaterials agglomerate with particles occurring naturally in the environment. Depending on their density and state of agglomeration, nanomaterials settle out over time from the atmosphere or from aquatic systems to the ground or to the sediment.

Nanomaterials transform under environmental conditions by reduction or oxidation. They can adsorb other substances or may lose a synthetic coating due to mechanical, chemical or biological processes. These processes can reduce or enhance the mobility of nanomaterials and influence their bioavailability²⁸.

Investigations of the uptake, accumulation and persistence in environmental organisms have already been conducted for a limited number of nanomaterials. Most of these studies have been carried out with invertebrates such as water fleas and earthworms, but in some cases also with fish. The current findings indicate the potential of nanomaterials to accumulate in organisms, although generally at low levels²⁹. In most studies, not only an uptake of nanomaterials but also good but often incomplete excretion could be demonstrated³⁰.

In experiments with fish and earthworms, despite good clearance of metal and metal-oxide nanomaterials an increase in the levels of the corresponding metallic elements in the peripheral organs was demonstrated³¹. Low accumulation with rapid uptake and release from the gut of fish was also demonstrated for multi-walled carbon nanotubes (MWCNTs). However, a few fragments of these nanomaterials reached the blood and muscle tissue³². Studies with earthworms show the possibility for the accumulation of metals and metal oxides after taking in corresponding nanomaterials³³.

Other studies have confirmed an uptake and accumulation of nanomaterials, for example in plants³⁴. In various studies with mussels, the ingestion of nanomaterials by filter-feeding organisms could be demonstrated³⁵. In reports on cell tests, possible uptake mechanisms in the cells of organisms have been described³⁶. In particular, the incomplete clearance of nanomaterials by organisms at the beginning of the food chain is of critical importance. Several studies have shown that nanomaterials can be transported along simple food chains³⁷.

The data situation on the behaviour and persistence of nanomaterials in the environment and in environmental organisms has improved considerably in recent years. However, the usefulness of the data for an environmental assessment is limited because most of the studies are not based on consistent methodologies, so that comparisons are difficult. There is a need for standardised methods that take into account the specific processes for the description of the environmental behaviour.

3. Further development of legislation on chemical safety

Nanomaterials are in principle covered by the legislation and regulations on chemical substances. However, very few specific requirements, if any, take into account the special features of nanomaterials for data collection and risk assessment. These deficits and possible options for adapting the relevant regulations have been under discussion in various German and European bodies for a considerable time.

When adapting regulations to cover nanomaterials, findings about their behaviour and effects must be taken into account, as well as newly acquired knowledge about exposure and applications. This is important in order to ensure an appropriate assessment, to maintain the trust of civil society in nanotechnology, and to provide legal certainty.

In this section, general requirements for the appropriate regulation of nanomaterials under the various laws and regulations on substances are first presented. The individual regulations on substances that are relevant for nanomaterials are then considered, in particular the EU Regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)³⁸, the EU Regulation on classification, labelling, and packaging of substances and mixtures³⁹ (CLP Regulation), the EU Regulation concerning the making available on the market and use of biocidal products⁴⁰ (Biocidal Products Regulation), the EU Regulation concerning the placing of plant protection products on the market⁴¹, and the EU directives relating to medicinal products for human use and to veterinary medicinal products⁴². In Germany, the German Environment Agency is responsible for assessing the relevant environmental risks under these regulations. Furthermore, the needs for amending the criteria for awarding of the eco-label and the need for a European register of products containing nanomaterials are discussed.

3.1. Requirements for general regulatory amendments

3.1.1 Applying the definition for nanomaterials

A regulatory definition of nanomaterials is very important in order to ensure clarity about which materials are covered by a specific regulation. On 18.10.2011, the European Commission issued a recommendation for a definition of nanomaterials⁴³

(see text box). The intention of the Commission was to review this recommendation until 2014 and if necessary to make amendments.

Concise EU Recommendation on the definition of a nanomaterial (2011/696/EU)

‘Nanomaterial’ means a natural, incidental or manufactured material 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 dimension is in the size range 1 nm-100 nm.

In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.

By derogation, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.

For the application, ‘particle’, ‘agglomerate’ and ‘aggregate’ are defined as follows:

- (a) ‘particle’ means a minute piece of matter with defined physical boundaries;
- (b) ‘agglomerate’ means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;
- (c) ‘aggregate’ means a particle comprising of strongly bound or fused particles.

Where technically feasible and requested in specific legislation, compliance with the definition may be determined on the basis of the specific surface area by volume. A material should be considered as falling under the definition where the specific surface area by volume of the material is greater than 60 m²/cm³. However, a material which, based on its number size distribution, is a nanomaterial should be considered as complying with the definition even if the material has a specific surface area lower than 60 m²/cm³.

The German Environment Agency considers the proposed definition suitable, and welcomes the inclusion of natural and incidental nanomaterials. Any specification of the definition, e.g. to cover only manufactured nanomaterials, should be provided where necessary in the relevant regulations.

The applicability of the proposed definition was reviewed in 2014 and 2015 on behalf of the European Commission by the Joint Research Centre (JRC).⁴⁴ Experience with the definition was collated and evaluated. In its final report, the JRC recommends retaining the scope of the definition to cover natural, incidental and manufactured nanomaterials with a size of 1-100 nm. In addition, eleven options are considered for making the definition clearer and thus simplifying its application.

An important point in the opinion of UBA is the introduction of criteria to clarify the conditions under which a material is no longer covered by the definition, e.g. materials which contain only a negligible proportion of nanoscale impurities. The European Commission announced a further consultation on the proposed definition in 2015, with a final version to be approved in mid 2016. The delays are regrettable, because they further prolong the legal uncertainty for all parties (manufacturers, users and authorities).

The application of the definition is currently limited because there are not yet any guidance or standardised methods for determining and characterising nanomaterials. This is particularly problematic for marginal cases under the definition. Efforts are being made at national and European levels to develop appropriate specifications.⁴⁵ Meanwhile, existing methods should be used as far as possible in accordance with available scientific knowledge.

In addition to the definition recommended by the European Commission, which has already been adopted for manufactured nanomaterials in the Biocidal Products Regulation (EU (No.) 528/2012), other definitions are used in a number of specific regulations which differ from the recommendation⁴⁶. In order to achieve coherency and equality of treatment, the UBA declares oneself in favour for the use of a harmonised definition. This should follow the recommendation of the European Commission from October 2011.

To achieve a coherent regulation and subsequently equal treatment, UBA declares oneself in favour for a harmonised definition in the various legislations. This should follow the recommendation made by European Commission in October 2011. The development and standardisation of methods to identify nanomaterials should be expedited.

3.1.2 Sufficient physical and chemical characterisation

The characteristics of a nanomaterial are influenced by its chemical composition and also by its size, geometry, crystal structure and surface properties (e.g. charges, surface chemistry, organic and inorganic coatings). Parameters can differ from the corresponding parameters for the non-nanoscale substance, or between various nanomaterials of the same chemical substance. In addition, some properties of nanomaterials (e.g. surface charge, solubility and agglomeration behaviour) depend on the properties of the surrounding environmental medium.

It is therefore necessary to fully characterise nanomaterials. This is an important pre-condition in order to be able to identify nanomaterials, to interpret and compare test results, but also in future to be able to predict possible behaviour and effects. This must be taken into account when formulating the requirements in the various regulations.

Nanomaterials have to be fully characterised regarding their physical-chemical properties in order to be able to identify them as nanomaterials, and to be able to interpret and compare test results. This must be taken into account when formulating the requirements in the various regulations. Methods and guidance for physical-chemical characterisation need to be developed further.

3.1.3. Adaptation of risk assessment for nanomaterials

In order to be able to assess the potential environmental risks posed by nanomaterials, it is necessary to have appropriate estimates of the hazards and the environmental exposure.

Basically, the principles of environmental risk assessment for chemicals also apply for nanomaterials. These involve comparing the predicted environmental concentration with the concentration limit below which it is not expected to have any eco-toxicological effect. However, if the environmental risk of nanomaterials is to be assessed appropriately, there is a need for adaptations both with regard to the assessment of the concentrations in the environmental compartments (exposure assessment), as well as with regard to determining the concentrations that describe the ecotoxicological effects on environmental organisms (hazard assessment).

Challenges for hazard assessment

The commonly used endpoints in ecotoxicology⁴⁷ such as the growth, mortality, and reproduction of various test organisms are in principle suitable for determining the ecotoxicity of nanomaterials. But adaptations are needed in order to take the special features of nanomaterials into account.

The ecotoxicological effects of nanomaterials are influenced by their physical and chemical properties (chemical composition, shape, surface properties) and by the properties of the test medium (e.g. pH-value, salinity, concentrations of naturally occurring organic substances). For the correct interpretation and for the comparability of the test results it is therefore essential to have full details about the properties of both the nanomaterial in question and the test medium. However, many current available studies characterise nanomaterials and test media inadequately, severely limiting the usability of the results for hazard assessment. Ecotoxicological tests should also be accompanied by comprehensive analysis, demonstrating the concentration and the behaviour of the nanomaterial in the course of the test. The latter is particularly important in order to be able to determine the actual exposure concentration in the test system, which can differ considerably from the nominal concentration at the beginning of the test.

Currently there are no standardised procedures for introducing nanomaterials into the test systems, which means that the availability of the nanomaterials for the test organisms in the test systems can differ while the ecotoxicological effects depend to a considerable extent on the procedure of the application used in the test. In order to increase the comparability and repro-

ducibility of ecotoxicological studies it is therefore important to develop consistent methods for applying nanomaterials in the test (see section 3.1.4).

Assessments of the possible environmental hazard posed by nanomaterials are at present based mainly on studies involving short-term exposure. However, such studies are often inadequate for an assessment in view of the changed behaviour in comparison with the non-nanoscale form of a substance (including also different kinetic behaviour caused by low solubility in water or delayed dissolution), the higher persistence and longer bioavailability. Findings are needed about long-term effects in the environment and effects after ageing of the nanomaterials. In order to be able to make reliable statements about the environmental hazard that can be presented by nanomaterials, valid long-term studies are preferable to acute studies.

On the basis of the behaviour of nanomaterials, it can be assumed that soil and sediments are key target compartments in which nanomaterials accumulate in the longer term. Therefore it is important to consider the ecotoxicological effects on soil organisms and sediment-dwelling organisms at an early stage. However, depending on the legislation in question, these organisms are only considered in the hazard assessment under specific conditions. In the opinion of the UBA, more attention should be paid to the effects on soil and sediment-dwelling organisms in hazard assessments for nanomaterials.

The evaluation of the effects on selected test organisms is normally based on the principle that a higher exposure concentration will have greater effects (dose-effect relationship). However, nanomaterials may show increased agglomeration and sedimentation at high concentrations caused by higher particle interaction. In contrast, an improved distribution at lower concentrations can mean that the nanomaterial is more available to the test organisms, so that low-dose effects seem possible in the test.

If no effects are observed in the hazard assessment at high exposure concentrations, this does not exclude the possibility of effects on the test organism at lower exposure concentrations. This must be taken into account in hazard assessments, e.g. by conducting more tests over a wider range of exposure concentrations,

or by more detailed analysis of the available concentration of the nanomaterials in the test system.

In the frame of a standardised test, only the outcome of ecotoxicological effects is taken into account (e.g. mortality), but not the underlying molecular mechanism. If nanomaterials release ions that are known to have ecotoxicological effects, it is an open question whether the toxicity is due solely to the release of toxic ions or whether the nanoscale character of the metal also contributes to the ecotoxicity. In order to be able to evaluate in particular the long-term behaviour and effects of ion-releasing nanomaterials, it is necessary in the course of the environmental hazard assessment to determine the intensity of the ion release over time, and where appropriate in which period the nanomaterial dissolves, respectively. In this context, it is essential to develop criteria for determining when a nanomaterial can be considered to be fully dissolved. In turn, it may then be possible to determine if and under which conditions one could abstain from a nanomaterial specific assessment.

For photo-catalytically active forms of nanomaterials, it is important to consider natural light conditions rather than artificial lighting when determining ecotoxicological effects (in particular with aquatic organisms)⁴⁸. Furthermore, by attachment on the surface of the test organisms, or blocking respiratory organs or the feeding apparatus, nanomaterials can affect the feeding habits and mobility of the organisms, or processes such as moulting, which in turn may impair their vitality and influence the outcome of the ecotoxicological test. The instruments to derive the environmental hazards focus on direct toxic effects of substances. In the opinion of the UBA, the hazard assessment of nanomaterials should also take into consideration the potentially increased toxicity under sunlight as well as the above-mentioned indirectly harmful effects.

The effect concentration of conventional chemicals is described in terms of mass to volume or weight of the test medium (water, soil, sediment). However, for nanomaterials the toxicity is also determined with reference to the particle size or the total external surface area. To describe the environmental hazard posed by nanomaterials it is necessary to determine whether the reference to particle surface area and numbers is more relevant than the reference to the mass.

In the view of UBA, the obligations for information within the various provisions should prefer long term studies rather than acute studies. Also effects on soil and sediment organisms need greater considerations. For the hazard assessment, beside the chemical toxicity also effects caused e.g. by mechanical influences, photo-activity or additional particle toxicity need to be included. For the ecotoxicological investigation of nanomaterials both the investigated nanomaterial and the used test medium are to be characterized sufficiently and accompanied with appropriate analytics.

Challenges of exposure assessment

Whereas considerable amounts of data have been generated in recent years for assessing the effects of nanomaterials on environmental organisms, the data situation is much more limited with regard to production quantities, fields of application and sources of release, all of which are important for assessing potential environmental exposure. It is also necessary to standardise the methods and techniques used to determine the release of nanomaterials from products and applications and also to determine the presence of nanomaterials in the various environmental compartments, both qualitatively and quantitatively.

The established models usually used to assess environmental exposure focus on production and use data and release data in combination with information about the behaviour and fate of substances in order to derive concentrations in the various environmental compartments. However, many of the principles and methods on which these models are based are not appropriate for nanomaterials. Existing models on exposure assessment assume thermodynamic processes in which the distribution between the various environmental compartments reaches a concentration equilibrium. But this is not the case for nanomaterials⁴⁹. The behaviour and persistence of nanomaterials in the environment is subject mainly to kinetic processes such as agglomeration and sedimentation. Besides, the dissolution rate is of importance. A significant proportion of nanomaterials may also adhere to the surfaces of solids present in the environmental compartments. Biodegradation, an important parameter for determining the environmental exposure of many substances, is not really relevant for many nanomaterials, which are mainly inorganic. More

important factors for reliable exposure assessment are abiotic changes, e.g. by chemical transformation, by loss of surface coating, or by adhesion to other substances. These factors influence the behaviour and the effect of nanomaterials in the environment. However, such processes, which are characteristic for the behaviour and persistence of nanomaterials in

the environment, find little or no consideration in the existing exposure models and regulatory information requirements. These must therefore be adapted in order to improve the description and assessment of the qualitative and quantitative distribution and the fate of nanomaterials in the environment.

In the opinion of UBA, for the exposure assessment of nanomaterials, specific obligations on adapted information requirements need to be made within the various regulations. Beside agglomeration behaviour and dissolution rate, important parameters are abiotic changes, e.g. due to chemical transformation, loss of surface coating or binding of other substances. These parameters have to be incorporated in exposure models.

3.1.4 Nano-specific procedures for standardised testing

For the reproducible and comparable testing of chemicals, there are a series of standardised, internationally harmonised, and accepted models, test guidelines and guidance documents⁵⁰. These were developed primarily for more or less water soluble organic chemicals.

In 2007, in the framework of the OECD chemicals programme activity “OECD Working Party on Manufactured Nanomaterials”, OECD launched the so called Sponsorship Programme (2009-2014) in which 14 representative nanomaterials were to be tested⁵¹. The remit was to examine whether the existing OECD test guidelines for chemicals could also be applied for nanomaterials or whether amendment is required. One conclusion was that the existing test guidelines are generally applicable, but that there are requirements for adaptations and additions. At an OECD meeting of experts on the environmental behaviour and ecotoxicology of nanomaterials, the suitability of selected OECD test guidelines for the testing of nanomaterials was discussed and recommendations were made⁵². The identified need for adapting the OECD test guidelines arises primarily from the difference between the behaviour of soluble organic chemicals and of nanomaterials in the environment and in the corresponding test systems. This means it is not possible to obtain reliable data for nanomaterials with these test guidelines in their present form.

For a series of test guidelines, additional guidance documents are needed for the testing of nanomaterials. This applies in particular for the application of

nanomaterials into the test systems, for accompanying analysis and the interpretation and documentation of results for the investigation of effects on and bioaccumulation in aquatic organisms and sediment-dwelling organisms. The existing instructions allow leeway in carrying out the tests that are justified for conventional chemicals. However, when they are applied for nanomaterials, this makes it difficult to obtain reliable, comparable results⁵³. On the basis of these recommendations, two OECD guidance documents are currently being developed. One will provide instructions for the use of existing OECD test guidelines for the environmental effect of nanomaterials on aquatic organisms and sediment-dwelling organisms. The second guidance document is intended to address the bioaccumulation in fish of nanomaterials from feed, as an addition to the existing OECD test guideline.

New test guidelines are needed above all to determine the environmental behaviour of nanomaterials. These include endpoints such as dissolution rate and agglomeration behaviour as well as abiotic degradation and transformation in the environment. There are as yet no OECD test guidelines for these properties. The development of guidance for determining mobility in soil was also proposed at the above mentioned OECD expert meeting. A draft test guideline for testing the agglomeration behaviour of nanomaterials dependent on environmental parameters has been developed in Germany under the leadership of UBA and submitted for the OECD test guidelines programme at the end of 2015. In addition, a test guideline is being developed on determining the dissolution rate of nanomaterials in dependence on environmental parameters, as well

as guidance on bringing together and interpreting the results of investigations on the basis of the test guidelines for agglomeration behaviour and for the dissolution rate. The aim is also to use data from both test guidelines for planning suitable test conditions for the investigation of the behaviour of the examined nanomaterials in further tests.

The OECD test guidance for determining the water solubility, and generally all methods that use distribution coefficients to derive behaviour and distribution in the environment, are not suitable for nanomaterials because they are based on thermodynamic principles. However, kinetic processes are more important for the behaviour and distribution of nanomaterials in the environment. The OECD test guideline for estimating the adsorption/desorption of chemicals is also not applicable for nanomaterials. Under the instructions for testing it is not possible to reliably distinguish between nanomaterials that are indeed adsorbed on soil and those that are only agglomerated.

Essential for the appropriate risk assessment of nanomaterials, is also the specific characterisation of the properties of the investigated nanomaterial, e.g. particle size and distribution, surface chemistry and surface charge. Therefore the development of specific OECD test guidelines to characterise the physical and chemical properties of nanomaterials are of central importance. In addition to the development of the OECD guidance documents and test guidelines for determining the environmental behaviour and environmental effects, urgent steps must be taken to develop OECD test guidelines on determining the physical and chemical properties.

In the view of UBA, amendment and development of nanomaterial specific OECD test guidelines and guidance documents are important components for the appropriate assessment of the environmental risks of nanomaterials. These activities should be further strengthened.

3.1.5 Developing nano-specific substance group and analogue approaches

Approaches to meet data requirements in deviation from performing standard test requirements are already established for chemical substances. One of these is the grouping and read-across/analogue approach. The aim is firstly to predict the physical-

chemical, toxicological, and behavioural properties of chemical substances based on structural similarities. If sufficient evidence is available it should then be possible to transfer available data on the hazards of one chemical substance to another one.

This approach is intended to reduce the amount of testing necessary to determine the behaviour and effects of all individual members of a group. In addition, the number of experiments with animals should be reduced. The current guidelines of ECHA⁵⁴ and OECD⁵⁵ on the use of substance group and read-across/analogue approaches do not include any specific approach for nanomaterials. Criteria must first be developed for the identification of groups on the basis of similar properties and for transferring data. Thus, parameters or combinations of parameters need to be identified which are important for distinguishing or comparing nanomaterials, e.g. chemical identity, intrinsic particle properties such as size and morphology, or extrinsic particle properties such as dissolution or agglomeration behaviour⁵⁶. The reactivity of the nanomaterial can also be an important parameter for grouping nanomaterials. Both the ECHA and the OECD have identified the development of grouping concepts as a key field for the assessment and regulation of nanomaterials. Aspects for grouping of nanomaterials should be taken into consideration when revising the relevant guidelines for grouping of chemicals. In ongoing national and international research projects, scientists are working on the identification of key parameters and the development of approaches for grouping.

Given the numerous manufactured nanomaterials already on the market and expected in future, the effort for the individual investigation and assessment would be enormous. Therefore, it is necessary to develop approaches that allow an adequate hazard assessment of nanomaterials while avoiding individual testing of a large number of the different forms.

3.2. Regulatory deficits and the need for adaptations

3.2.1. Chemicals

The manufacture, import and use of chemical substances are regulated in the European Chemicals Regulation REACH (EC (No.) 1907/2006). According to that a registrant is obliged to assess the hazards

of the substance and the risks associated with it, in order to be able to provide sufficient protection for humans and the environment. Among other things, data must be presented to ECHA on (eco)-toxicity and the uses, with an estimate of the extent to which humans and the environment could be exposed to these substances over the entire life cycle. The information requirements for the substance are specific to the tonnage bands, depending on the quantity manufactured or imported annually (1, 10, 100, or 1000 tonnes per annum and manufacturer). There is a broad consensus that REACH, with its approaches, tools, and methods (tests for hazard assessment, risk assessment and risk management measures) also provides a suitable framework for the secure handling of nanomaterials. However, adaptations are needed to take the special features of nanomaterials into account. Discussions on amending REACH have been going on for many years.

Clear specifications are required for nanomaterials regarding the information requirements, and transparent presentation in the registration dossier. REACH does not provide details concerning information requirements and the chemical safety report for nanoscale forms of substances. In the interests of legal clarity, equality of treatment and compliance with the precautionary principle, it is necessary for the demands on nanomaterials to be stated clearly in REACH. This would considerably reduce the challenges presented by applying REACH instruments for nanomaterials, such as dossier evaluation, substance evaluation or the preparation of safety data sheets.

Proposals for regulating nanomaterials were already published by the environmental groups Client Earth, CIEL and BUND in November 2012⁵⁷ and by the Swedish Chemicals Agency (KemI) in April 2013⁵⁸. An approach for the special regulation of nanomaterials under REACH was developed by UBA in cooperation with the German Federal Institute for Occupational Safety and Health (BAuA) and the Federal Institute for Risk Assessment (BfR). This was presented to the European Commission and other EU bodies in May 2012 and published in January 2013⁵⁹. In principle, the European Commission and Member States reached an agreement that REACH should be adapted to the specialities of nanomaterials. In early 2013, the European Commission and the Member States agreed not to change the articles of REACH before the final

registration deadline, but only to adapt the annexes to the Regulation. UBA considered this as an important first step in order to ensure an entry into force of the proposed amendments before the end of the third registration phase (31 May 2018). For this purpose a text proposal was presented as an interim solution by BAuA, BfR and UBA at CASG Nano (Competent Authority Sub-Group on Nanomaterials)⁶⁰ that has also found favour with the representatives of the EU Member States.

This only makes it all the more disappointing that for many years the European Commission, which has the exclusive right to propose legislation, has not made any official proposal. Also the process for the regulatory impact assessment for the adaptation of the REACH Annexes has been ongoing since 2013 without reaching a conclusion. It took the European Commission until May 2014 to present to CASG Nano an unofficial proposal (a so-called “non-paper”) for discussion.⁶¹ Again only in March 2016 the Commission presented a revised version based on the comments received.⁶² UBA welcomes that the new version contains many of the amendments proposed by the German authorities and addresses some of the identified weaknesses. Nevertheless the proposal is not sufficient for an adequate regulation of nanomaterials.

It is worrying that it took the Commission almost 2 years to present the slightly altered version. The objectives of the REACH regulation will not be achieved without an adequate adaptation to nanomaterials.

Thus, the opportunity has been wasted to provide registrants at least for the third registration phase, which ends on 31 May 2018, with nano-related instructions. This is particularly regrettable because it is in this final registration phase that substances marketed in quantities between 1 and 100 tonnes per annum will have to be registered. It is to be expected that this will apply to many market-relevant nanomaterials. In view of UBA, the European Commission should promptly submit a proposal ready for approval to the REACH regulatory committee.

Already now some nanomaterials are registered as such under REACH. For other substances there are indications or evidence that they are nanomaterials or that the substance is also marketed as a nanoma-

terial. A substance evaluation of nanomaterials under REACH has been carried out by the Netherlands for SiO₂ and silver. France has registered the evaluation of TiO₂, but is awaiting the results of the dossier evaluation by ECHA. In view of the legal uncertainty created by the delays in the adaptation of REACH and the definition proposal, the registrants of SiO₂ and TiO₂ have

objected to the ECHA decision to demand further data for the dossier and substance evaluations.

In the coming years, BfR, BAuA and UBA plan three substance evaluations for nanomaterials under REACH: ZnO, multi-walled carbon nanotubes (MW-CNTs), and CeO₂.

For nanomaterials, clear obligations regarding information requirements and transparency within the registration dossiers are required. In the sense of legal clarity, equal treatment and for the fulfillment of the precautionary principle it is needed that these obligations are clearly specified. In view of UBA, the European Commission should promptly submit a proposal ready for approval to the REACH regulatory committee.

3.2.2. The classification, labelling and packaging of chemical substances and mixtures

The classification, labelling, and packaging of substances and mixtures are not subject of REACH but to the CLP Regulation which came into force on 20 January 2009 ((EC) No. 1272/2008). The CLP Regulation aligns the European Union system of classification, labelling and packaging of chemical substances and mixtures to the UN's Globally Harmonised System (GHS). The goals of the GHS are the simplification of world trade and at the same time the protection of human health and the environment by the introduction of a consistent global system for hazard identification and hazard communication. With only a few exceptions, all substances and mixtures are covered by the CLP Regulation.

The classification is hazard-related and is made on the basis of specified criteria and limit values in various hazard classes and hazard categories. On this basis, appropriate labelling is derived with hazard and safety precautionary statements. The classification criteria of the GHS or CLP Regulation are intended to be applied for all chemicals and are to be applied to the actual form in which a substance is brought onto the market. This means that manufacturers, importers and subsequent users must take into account whether the chemical substance in question is a nanomaterial and base their decision for the classification on form-specific data.

It is necessary to check whether the existing GHS classification criteria are applicable for nanomaterials. To this end, a working group has been set up at the UN level. Pilot projects are currently being carried

out to test the classification criteria for nanoscale TiO₂ and CNTs. Recommendations are expected to be made on the basis of the findings of these projects about any necessary adaptations to the classification system.

A distinction is made between self-classification by the person who is responsible for placing the chemical substance on the market and the legally-binding harmonised classification by the competent authorities. Since the form of a substance has to be taken into account according to CLP, data should be used that have taken into consideration the specific requirements for the investigation of nanomaterials.

For the classification according to CLP the form of the substance has to be considered. In the view of UBA, the classification of a nanoform of a substance should base on data which was collected taking into account the specific demands for the testing of nanomaterials.

3.2.3. Biocidal products and plant protection products

Plant protection products and biocidal products represent a probably environmentally relevant open application for nanomaterials. Indications for the use of nanomaterials in biocidal products and plant protection products provides for instance the French register of nanomaterials. Here, three substances and twelve substances, respectively, are listed⁶³. In its nano-inventory, produced on the basis of a literature search, the European Food Safety Authority (EFSA) assumes the use of up to 39 substances in nanoscale

form in plant protection products and 12 in biocidal products in the areas of agriculture, food, and feed⁶⁴. It is to be expected that the use of nanomaterials in biocidal products and plant protection products will become increasingly important⁶⁵.

Nanomaterials are used with the aim of reducing the amounts of active substances required and increasing the overall efficiency of the application. Used as co-formulants or directly as active substances, the greater specific surface area or increased adsorption potential of nanomaterials could help to reduce the loss of active substances by processes such as run off, evaporation or leaching into groundwater. Specifically formed external surfaces of nanomaterials could protect active substances against unwanted degradation by microorganisms or by light. The efficiency of a product can also be increased by the controlled release of the active substances in capsule or targeted delivery systems made up of nanoscale components. Formulations are conceivable including nanomaterials that ensure better solubility and distribution of active substances, replacing or supplementing conventional co-formulants. The increased reactivity of nanoscale active substances could lead to a reduction in the necessary quantities of active substances, co-formulants, or overall formulations.

Because of the expected increase of nanomaterial's application in plant protection products and biocidal products a future increase in the release of nanomaterials or nano-formulated active substances into the environment must be expected. To identify a potential risk as a result of the application of nanomaterials and to protect the environment against negative consequences, it is necessary in the course of approval of active substances and authorisations of biocidal products and plant protection products to take the properties of nanomaterials into account.

Biocidal products

Under the Regulation of the European Parliament and of the Council concerning the making available on the market and use of biocidal products ((EU) 528/2012)⁶⁶ in the European Union, manufacturers or importers must successfully go through a 2-stage authorisation process. In a first step, the biocidal active substance is evaluated in an EU procedure. After an active substance has been given EU-wide approval, in a second step, the product authorisation

procedure, a decision is taken about the authorisation of a specific biocidal product, mostly at the national levels. In the Biocidal Products Regulation, nanomaterials in accordance with the definition proposed by the European Commission are expressly mentioned. They must be noted in the product's labelling and their health and environmental risks must be considered separately. This means, that the notification, assessment and approval of the nanoscale form of an active substance must be carried out separately from any potentially existing non-nanoscale form. Under the Biocidal Products Regulation, nanoscale active substances had to be registered as such by the end of October 2015. Currently, one nanoscale active substance is approved under the EU Review Programme (synthetic amorphous SiO₂ for insecticides), but no application has yet been made for product authorisation in Germany. Active substances are currently being evaluated for two other nanomaterials (another form of SiO₂, also for insecticide products, and Ag adsorbed on SiO₂ as material preservative). Furthermore, notification was submitted for nanoscale Ag as active substance for three types of product in the field of disinfectants. The application documents for approval of an active substance must be submitted to ECHA by December 2017. The Review Programme for active substances ends in 2024, i.e. all active substances for which applications have been submitted, including nanoscale active substances, must have been evaluated by then. In the interim, transitional rules apply for all registered active substances under which the nanoform of these active substances may still be used.

Although nanomaterials are regulated under the Biocidal Products Regulation in principle, at present it does not include specific data requirements regarding physical and chemical properties or specifications for risk assessment.

For these reasons, a specific further development of the basis of assessment is urgently needed in the opinion of the UBA. In particular, binding requirements are needed concerning physical and chemical characterisation and specific information about the behaviour and effects of the nanoscale active substances. Guidance must be prepared by ECHA with expert support from the Member States in order to provide assistance for applicants. If the authorities

are to be able to properly examine the application documentation it is essential that all evaluating bodies have access to the data on the characterisation of the nanoscale active substances. Only then is it possible to identify the nanoscale active substance as such and to determine whether an appropriate investigation of the behaviour and effects is carried out taking the specific properties of the nanomaterial into account, in order to provide a sound basis for an assessment.

The use of nanomaterials as co-formulant in biocidal products is possible and represents a further potential route of entry of nanomaterials into the environment. The process of product authorisation includes checking whether the product contains critical co-formulants. These co-formulants also need to be assessed. It is also checked if the product contains nanoscale co-formulants. However, the discussion about the identification of nanoscale co-formulants and its consideration in the risk assessment procedure has not been concluded at the EU level.

There is a demand for binding specifications for the physical-chemical characterisation and specific information requirements regarding behaviour and effects of nanoscale active substances in the frame of the assessment of biocidal products. Also related guidance needs to be developed. It needs to be clarified how to deal with nanoscale co-formulants in the environmental risk assessment.

Plant protection products

The approval and authorisation of plant protection products and their active substances, respectively, is carried out in Germany on the basis of the Regulation of the European Parliament and Council concerning the placing of plant protection products on the market (Regulation (EC) No. 1107/2009) and the German Act on plant protection (PflSchG).

The Europe-wide approval of an active substance is valid for ten years for the first approval, and 15 years for renewed approval. After that a new application must be made. This provides an occasion to examine whether approval is still justified in the light of advances in science and technology. The evaluation and authorisation of the actual plant protection pro-

duct is carried out in a second step in the relevant Member States.

There are currently no specific provisions concerning nanoscale active substances in plant protection products. It is possible that preparations containing nanomaterials are evaluated in the course of EU active substance approval or product authorisation but are not recognised as such, because disclosure is at present not obligatory.

As is the case for biocidal products, it is very likely that nanomaterials are already used in plant protection product formulations as synergists, safeners, and other co-formulants. The Nano-Inventory commissioned by the EFSA includes a number of products using nano-emulsions or encapsulation techniques with nanomaterials that are already on the market or will soon be marketable.

In the opinion of the UBA it is therefore necessary to establish technical and legal bases which ensure that plant protection products containing nanomaterials can be adequately assessed concerning their environmental risk. As discussed with respect to REACH and the Biocidal Products Regulation, the regulation of nanomaterials or nanoscale active substances in plant protection products also requires the introduction of a definition, as well as provisions for the physical and chemical characterisation and specific information requirements for risk assessment.

In view of the potentially different kinetics and bioavailability in comparison with conventional active substances or formulations, nanoscale active substances or formulations with nanoscale components should be subjected to a separate assessment of hazards and exposure in the course of the approval and authorisation procedures. Corresponding guidance must be developed and harmonised which explain what has to be taken into consideration for the environmental risk assessment of a nanoscale active substance or a plant protection products with nanoscale components in the formulation.

The guidance provided by EFSA on risk assessment for nanomaterials and nanotechnology in food and feed does mention plant protection products, but its recommendations concern primarily the risk assess-

ment for human health and do not target environmental exposure and ecotoxicology⁶⁷. The need to develop adequate test methods is also mentioned.

In the opinion of UBA, it is necessary to establish technical and legal bases which ensure that plant protection products containing nanomaterials can be adequately assessed concerning their environmental risk.

In addition, related guidance needs to be developed which demonstrates elements that need to be considered during the environmental risk assessment.

3.2.4. Medicinal products

The authorisation of medicinal products for human use and for veterinary medicinal products in the EU is regulated by the revised versions of the Directives 2001/83/EC and 2001/82/EC and their national transpositions. Under the former, the potential environmental risk posed by a medicinal product is to be assessed and inspected for harmful environmental impacts. For veterinary medicinal products, an EU Regulation is currently being prepared to replace the above-mentioned directive and its national transpositions.

For medicinal products for human use, the result of the environmental assessment is not relevant for the authorisation, but measures to reduce the risk can be included in the summary product information and the package leaflet. For veterinary medicinal products, the outcome of the environmental risk assessment is included in the final evaluation of the benefits and risks for the product authorisation.

It is the duty of the manufacturer to supply information about the environmental risk assessment when applying for marketing authorisation. The first step is to estimate the environmental exposure for a preparation. If this exceeds a defined threshold it becomes necessary to submit information about the behaviour and effects in the environment (second phase of assessment). An environmental risk assessment is provided for the active substance. Other components, such as co-formulants, are not included. There are currently no binding requirements with regard to nanoscale active substances in a medicinal product.

Under the working definition of the European Medicines Agency (EMA), nanomaterials include a wide spectrum of nanoscale active substances. In addition to active substances that have been reduced to nanoscale size by physical activity (grinding), there are also (modified) proteins, peptides and oligonucleotides, and liposomes, (co)polymer particles, dendrimers, carbon- or silicon-based nanoparticles, and metal- or metal oxide- nanoparticles⁶⁸. In contrast, the definition proposed by the European Commission explicitly excludes medicinal products.

Nanoscale substances can be used to transport an active substance in patients. The use of nanoscale formulations in this area is expected to offer improved availability, better targeted and controlled release at the desired location, and reduced side-effects. For example, nanomaterials could be used in cancer therapy to increase the effectiveness of radiotherapy and chemotherapy. In diagnostics and medical imaging procedures, nanomaterials are used in contrast agents and in Lab-on-a-chip technology⁶⁹.

In case of a second phase assessment an in-depth environmental risk assessment is performed, which involves the collection of physical and chemical data and data on environmental behaviour and effects. This approach was developed for low-molecular medicinal products, but in some respects it proves to be inadequate for the evaluation of nanoscale active substances⁷⁰. It is therefore necessary to consider whether the current approach using a threshold based on mass concentration is adequate for nanoscale active substances in view of their potentially increased activity. Adaptations may be necessary.

Nanoscale active substances are currently not assessed separately from non-nanoscale active substances. As with nanomaterials in biocidal products, nanoscale active substances in medicinal products should also be subjected to a separate environmental evaluation. This should be conducted on the basis of appropriate data about the physical and chemical characterisation and environmental behaviour and effects.

For the evaluation it should be taken into account that nanomaterials can be metabolised or transformed either in the body of the patient or in the environment after being excreted. Information about this is available in the environmental assessment, but is not consi-

dered further. If an active substance leaves the body nanoscaled this should be taken into account in the environmental risk assessment. On the other hand, it would be possible to dispense with a separate assessment of a nanoscale active substance if the possibility of excretion as a nanomaterial can be excluded.

The current guidance documents do not include an assessment of co-formulants, so that there is also no specific identification and assessment of nanosca-

le co-formulants. However, it can be assumed that nanomaterials are already being used⁷¹. UBA appraises that the use of nanomaterials as co-formulants, e.g. in medicinal products, contributes to the entry of nanomaterials into the environment. In order to obtain a better quantitative and qualitative overview of this entry, UBA sees the need to require specific details of nanoscale co-formulants when applying for authorisation of medicinal products.

In the opinion of UBA, nanoscale active substances in medicinal products should undergo a separate environmental risk assessment. This should be carried out on basis of suitable data on physical-chemical characterisation as well as environmental behavior and effects. In order to obtain a better quantitative and qualitative overview of the environmental entry, UBA sees the need to require specific information on nanoscale co-formulants when applying for authorisation of medicinal products.

3.3. Register for products containing nanomaterials

There is no consistent picture of nanomaterials in products. Only a few of the products containing nanomaterials are covered by specific legal requirements (e.g. biocidal substances, cosmetics, plastics as food contact materials, food additives).

Because requirements for declaration and notification for nanomaterials are largely missing, the lack of knowledge about their use in products affects not only consumers but also the regulatory authorities. The REACH regulation cannot remedy that situation because it applies primarily for substances and mixtures. In addition, the regulation does not in general include obligations to report on the composition of individual products. Without adaptation, the provisions in REACH would also not ensure sufficient information about nanomaterials.

There are already a number of databases and platforms on nanomaterials and their products, e.g. JRC NanoHub, the so-called Woodrow Wilson Database (“Project on emerging nanotechnologies”), ANEC/BEUC List, Online Database of BUND, DaNa 2.0⁷². These databases serve a wide range of purposes and draw on information of varying quality from different sources, so that they provide an inconsistent and incomplete picture.

Due to the lack of transparency about the types, amounts and applications of nanomaterials, an

estimate of the exposure and thus an assessment of the potential risks posed for humans and the environment is only possible to a very limited extent. For some years, discussions have been going on at the European level about setting up a product register for nanomaterials and products containing nanomaterials.

The aim of such a register and the associated reporting obligations is to provide the authorities with an overview of the products containing nanomaterials that are produced in Europe or are available on the EU Single Market. It should also increase the transparency for consumers.

France, Denmark and Belgium, but also Norway, have introduced national reporting obligations for nanomaterials and products containing nanomaterials, respectively⁷³. These have differing orientations, regulatory objectives and intentions. Italy is preparing to introduce a register, and the Swedish Chemicals Agency (KemI) has proposed reporting requirements to the Swedish government⁷⁴. The first registrations obligation for nanomaterials in mixtures is envisaged in Sweden for 2018. All of the aforementioned Member States would prefer a European approach but have decided on a national register because a European instrument is not yet in sight.

In 2013, the German *Bundesrat* urged the Federal Government to actively promote the creation of a nano-product database at the European level⁷⁵. Howe-

ver, the Federal Government, represented by the German Federal Ministry of Food and Agriculture, does not regard independent national activities towards a European nano-product register as appropriate at the present time. It gives as reasons the current lack of analytical procedures and the revision activities of the European Commission on the definition of nanomaterials⁷⁶.

Already in June 2012, the UBA published a proposal for a trans-sectoral European register of products containing nanomaterials, which is based on existing regulations, complemented by further provisions, and brings together the information obtained from these regulations⁷⁷. In addition to substances and mixtures, products for which release of nanomaterials over their life cycle cannot be excluded should also be included. Such a register would be used first of all by regulatory authorities. For reasons of transparency, the UBA also proposes making parts of the data available to the general public. A European register would lead to less distortion of competition than various national registers⁷⁸.

In 2009, the European Parliament called on the Commission to draw up a public register of the types of nanomaterials on the European market and their applications by June 2011. The European Commission announced in October 2012 that an impact assessment would be carried out in order to develop a suitable instrument to increase the transparency and regulatory clarity with regard to nanomaterials. The results of the impact assessment are not yet available. Nevertheless, the European Commission does not plan to propose the establishment of a register but of a so-called "NanoObservatory"⁷⁹.

It shall compile the data from existing databases (e.g. REACH), registers and studies but shall also generate new information from market studies and business surveys. The information is supposed to be presented user friendly to businesses, users, consumers and authorities. In view of the European Commission the NanoObservatory should focus on hazard assessment of the nanomaterials looked at and a comprehensible communication of the information collected, and less on the risk assessment of these nanomaterials. In view of the Commission, for that purpose a European register would not provide an additional value to existing instruments. Furthermore, due to the wide

dispersive use of nanomaterials the costs for such a register would be too severe.

The UBA favours a European register for products containing nanomaterials. However, a register could be potentially dispensable if the aforementioned adaptations of chemical regulations would take place.

In view of UBA, the proposed NanoObservatory is not suitable to reach the goal of transparency concerning the types, amounts and applications of nanomaterials on the European market. Even the limited aim of the European Commission by introducing a NanoObservatory can only be achieved based on an appropriate adaptation of chemicals regulation.

3.4 Eco-labelling

Eco-labelling should offer consumers guidance for identifying and choosing more environmentally-friendly products and services over a broad range of products, in order to promote environmentally beneficial product innovations and to reduce environmental pollution. Eco-labelling is backed up by a number of instruments and methods which are deployed in order to check whether a product meets the environmental quality requirements.

In 2009, the UBA argued against awarding the 'Blue Angel' label to products containing new manufactured nanomaterials, drawing attention to unresolved issues relating to the health risk and environmental risks.⁸⁰

With the presentation of the broad EU definition recommendation in October 2011, it quickly became clear that many products contain nanomaterials and some of these materials have been in use for decades (see section 3.1.1). On the basis of the knowledge gained in recent years, there are no scientific grounds to generally disqualify products with nanomaterials from receiving environmental quality labels. At the same time it is not possible to assume that all nanomaterials are without risks; for many nanomaterials gaps remain in the knowledge about their hazard potentials. These uncertainties cannot be ignored when awarding eco-labelling, and nanomaterials must be dealt with in a way which pays due attention to environmental and health protection.

In principle, the German and EU eco-labelling exclude substances with certain toxicological and ecotoxicological properties – to a greater or lesser extent depending on the product group in question. This applies in the same way for nanomaterials. Under the CLP Regulation, substances must be classified and labelled according to the form in which they are used, i.e. corresponding to the nanoform used⁸¹. Therefore, all information needs to be gathered which is appropriate for the particular form. If the nanoform of a substance has critical properties (e.g. it is carcinogenic or highly toxic for aquatic organisms), then, like other substances with these properties, it will be excluded from eco-labelling. In order to ensure that the test data relate to the nanoform of the substance, in the case of relevant product groups when presenting the safety data sheets for substances which are

solid under normal conditions, it should in addition be specified whether these are nanomaterials in accordance with the EU definition. Safety data sheets should in future provide a precise description of the form of a substance to which the details apply, and whether this is a nanomaterial.

In addition, there is the possibility of explicitly disqualifying products containing specific nanomaterials from the eco-labelling if the benefits of the nanomaterial are questionable or other negative effects on humans and the environment cannot be excluded. For example, this is the case for nanoscale silver in products such as refrigerators and telephones. The decision is taken for specific product groups and discussed with all affected interest groups at the expert meetings on the award principle.

In the view of UBA, it should be indicated together with the submission of the safety data sheet for a substance in a relevant product categories whether or not this substance falls under the definition of the EU definition. Safety data sheets should be organized in such a way that it is described precisely for which form of the substance the information relates and if it involves a nanomaterial.

4. Activities of the German Environment Agency

The German Environment Agency provides information on environmentally-relevant aspects of nanotechnology, aims to fill gaps in knowledge and to determine needs for action. It supports the responsible use of nanomaterials by actively participating in the discussions on taking account of the special characteristics of nanomaterials in the legislations on chemical safety at national, European and international levels.

One of the focal points of the work of the German Environment Agency is the assessment of the risks posed by nanomaterials for the environment. The Agency has been active since 2006 in the OECD Working Party on Manufactured Nanomaterials (WPMN). The current focus of the UBA relates to the development of OECD test guidelines and guidance documents for the appropriate investigation of the behaviour and effects of nanomaterials in the environment as well as the assessment of the potentials of relief and burden of applications with nanomaterials for the environment. In the Working Party on Resource Productivity

and Waste (WPRPW), the UBA is involved in tackling environmentally relevant questions concerning the disposal of waste containing nanomaterials.

A further field of activity of the UBA is the adaption of legislation to meet the requirements concerning nanomaterials. In various working groups, e.g. the Nanomaterial Working Group of ECHA, UBA participates in discussions on adapting the regulations and risk assessment for nanomaterials. The involvement of UBA in national and international committees on the topic is presented in the Annex in Table 1. Together with other higher federal authorities in Germany (BAuA, BfR, Federal Institute for Materials Research and Testing (BAM), National Metrology Institute (PtB)), UBA has formulated a research strategy on the risks to health and the environment posed by nanomaterials; this is revised periodically in accordance with the latest research requirements⁸². To implement this strategy, UBA initiates and supervises various research projects (Table 2 in the Annex). The Agency also participates in various national and Eu-

European third-party funded projects on the topic, and among other things provides connections to regulatory and political bodies (Table 3 in the Annex).

Information about the work of UBA and its research activities, together with further information and links to nanotechnology topics can be found on the UBA website⁸³.

5. Summary and recommendations

The nanoscale form of a substance does not necessarily constitute a hazard or risk. However, nanomaterials have specific properties that distinguish them from other chemicals. The knowledge about characteristics, behaviour, and effects of nanomaterials gained during the last years allows it already now to identify which aspects are needed for the testing and assessment of their environmental risks and have to be reflected in the regulatory requirements.

In the opinion of UBA, key measures in the framework of chemical safety to adequately depict and assess the nanomaterial specific environmental risks as well as to take appropriate measures for risk minimisation are:

- ▶ Implementation of a harmonised definition of nanomaterials in the various regulations on the safety of chemicals
- ▶ Implementing nano-specific requirements in the regulations on chemicals safety, in particular in the REACH Regulation but also in the Regulations on biocidal products and plant protection products, and the Directives on human and veterinary medicinal products
- ▶ Continuing the adaption of the guidelines and models for hazard and risk assessment in the framework of chemicals regulations to provide appropriate risk assessment for nanomaterials
- ▶ Continuing the adaption of the instruments for environmental risk assessment, above all the development of nanomaterial specific test guidelines and guidance documents for testing of environmental behaviour and effects, and the physical and chemical properties
- ▶ Continuing the standardisation of methods for characterisation and qualitative and quantitative analytics for nanomaterials in the environment
- ▶ Development of substance group and analogy concepts for nanomaterials to reduce the test demands while ensuring appropriate assessment

- ▶ Using the information relating to the relevant nanoform for classification in hazard classes and categories
- ▶ Setting up a register of products containing nanomaterials at the European level, in particular as long as the regulations for chemicals safety are not sufficiently adapted to nanomaterials.

These measures follow also the SAICM⁸⁴ resolution of the 4th international conference on chemical management (ICCM4) in Geneva in regards to the encouragement to adequately consider manufactured nanomaterials in national and international regulatory instruments.⁸⁵

In the view of UBA, the European Commission should expedite the implementation of the definition proposal of nanomaterials in the various regulations as well as the implementation of nanomaterial specific requirements into REACH in a constructive manner.

With regard to the implementation and further development of the regulations of concern and the required risk assessment instruments, UBA will continue to cooperate closely with the other assessment and authorisation bodies in Germany (BAuA, BfR), the Federal Office for Chemicals, the Federal Ministry of the Environment as well as the representatives of the other European Member states, the European Chemical Agency ECHA, the European Food Safety Agency EFSA, the European Medicine Agency EMA, the European Commission and the OECD. The nanomaterials research strategy developed in cooperation with other higher federal authorities (BAuA, BfR, BAM, PtB) is still being pursued. The steady progress of advancement of nanomaterials has to be observed carefully in order to ensure that the adaptations of individual instruments for risk assessment currently being called for and discussed will still be adequate in the future.

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- 84 The Strategic Approach to International Chemical Management (SAICM) is an under international law, non-binding, overarching, political framework within the environmental programme of the United Nations (UNEP) for the international chemicals management.
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8. Annex

Table 1

National and international cooperation and participation in panels/boards since 2009

Internat. and nat. cooperation and participation in panels	Brief description
Joint Research Strategy of German Governmental Research Institutions (together with BAuA , BfR, BAM and PTB): "Nanotechnology – Risks related to Nanomaterials for Humans and the Environment" (since 2007)	Review regarding the research of German higher federal authorities on nano-safety and alignment of future research within the focus of the joint research strategy. Emphasis is given on scientific issues supporting regulation and risk assessment of nanomaterials to protect humans and environment.
The Nano Dialogue of the Federal Government: Participation in issue groups to support the work of the NanoKommission (until 2011) and in expert dialogues (since 2011) (with representatives from NGOs, industry, science and authorities)	Active participation in different issue groups of the NanoKommission, as well as in expert dialogues on different topics (assessment, regulation, traceability, sustainability, research, nanomedicine, aquatic environment, waste and disposal)
OECD Working Party on Manufactured Nanomaterials (WPMN) (since 2006)	„Sponsorship Programme“with main responsibility for the dossier on TiO ₂ („lead sponsor“), partial responsibility for the dossier on Ag („co sponsor“) and support of dossiers for four additional nanomaterials. Steering Group „Testing and Assessment“: Assessment of data regarding environment, development of OECD test guidelines and guidance documents specific for nanomaterials. Steering Group “Environmentally Sustainable Use of Manufactured Nanomaterials”: knowledge building about life cycle aspects, development of instruments and guidance manual towards integration of risk assessment into life cycle assessment of nano-enabled applications.
OECD Working Party on Resource Productivity and Waste (WPRPW)	Currently, the WPRPW deals with four projects on nanomaterial-containing waste. UBA is leading a report regarding waste incineration. In this report, information on the incineration of waste containing nanoscale TiO ₂ are processed which were deduced from a project dealing with the disposal of nanomaterial-containing waste in waste incineration plants.
Nanomaterial Working Group (NMWG) of the ECHA (since 2012)	The NMWG consists of representatives of EU MS, ECHA and observers from industry and NGO. Task of the NMWG is the discussion of topics relevant for the regulation of nanomaterials in order to support ECHA in their tasks (e.g. development of specific guidance) by giving expert advice. Important aspects are the physical-chemical characterization of nanomaterials and the development of analogy concepts for grouping and read across specifically for nanomaterials.
Competence Authority Sub Group on Nanomaterials (CASG Nano)	In the CASG Nano, experts discuss the adaptation of the European chemical regulation REACH to nanomaterials, as well as additional aspects of regulation of nanomaterials, i.e. the EU definition and transparency measures for products containing nanomaterials. On behalf of the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety, UBA supports the German representative by giving expert advice.
Strategic Approach to International Chemicals Management (SAICM)	At the 4th International Conference on Chemicals Management of SAICM (autumn 2015), it was decided to continue activities regarding the emerging policy issue “nanotechnology and manufactured nanomaterials”. UBA supports by commenting related documents of SAICM.
Group assessing already registered Nanomaterials (GAARN) (January 2012-October 2013)	GAARN was constituted by the European Commission (GD ENV) as informal advisory group with the task to find consensus regarding an adequate assessment of nanomaterials in the framework of the REACH regulation and thus, improve trust and mutual understanding between concerned parties.
REACH Implementation Project on Nanomaterials (RIPoN) 1 (October 2009-March 2011)	Technical as well as scientific advice regarding substance identity of nanomaterials under the REACH regulation

Quelle: Umweltbundesamt 2016

Table 2

Research projects and reports regarding nanotechnology on behalf of the Umweltbundesamt (2009- today)

Research Project/Report	Duration	Short description
Analysis and Strategic Management of Nano-products with Regard to their Sustainability Potential - Nano-Sustainability Check	2009-2011	<p>Aim of this study was the development of a "Nano-Sustainability Check" to examine the sustainability of products and applications involving nanomaterials with respect to their potential environmental benefits but also potential threats to the environment. The most important feature in this context is an evaluation grid which can be used to compare benefits and risks of a nano-enabled product to an existing reference product that has been manufactured without the use of nanomaterials. The results of this study allow to develop recommendations for a strategic optimization of the investigated applications to maximize the potential strengths and opportunities with regard to sustainability while minimizing the potential negative effects. The methodical approach was described by two case studies (surface coating of glass, concrete catalyst).</p> <p>http://www.umweltbundesamt.de/publikationen/analysis-strategic-management-of-nanoproducts</p>
Investigation of widely used nanomaterials (TiO ₂ , Ag) and gold nanoparticles in standardized ecotoxicological tests	2009-2012	<p>Aim of this study was to collect basic data on ecotoxicology of selected nanomaterials. For this aim, standardized OECD test guidelines were used which were also checked for their applicability to determine the ecotoxic effect of nanomaterials.</p> <p>http://www.umweltbundesamt.de/publikationen/investigation-of-widely-used-nanomaterials-tio2-ag</p>
Fate and behaviour of TiO ₂ nanomaterials in the environment, influenced by their shape, size and surface area	2009-2011	<p>This study investigated the behavior and fate of different nanoscale TiO₂ in different environmental matrices. Amongst other tests, a simulation of the passage through a sewage treatment plant was performed. In addition, OECD test guidelines applied in this study were checked for their applicability for investigating nanomaterials.</p> <p>http://www.umweltbundesamt.de/publikationen/fate-behaviour-of-tio2-nanomaterials-in-environment</p>
Investigation of two widely used nanomaterials (TiO ₂ , Ag) for ecotoxicological long-term effects Adaption of testguidelines	2009-2012	<p>In this study standardized OECD test methods were used to investigate potential ecotoxicological long-term effects of nanomaterials. Amongst other tests, an Early Life Stage Test with fish was performed with nanosilver. In addition, OECD test guidelines applied in this study were checked for their applicability for investigating nanomaterials.</p> <p>http://www.umweltbundesamt.de/publikationen/investigation-of-two-widely-used-nanomaterials-tio2</p>
Environmental hazard of selected TiO ₂ nanomaterials under consideration of relevant exposure scenarios	2010-2013	<p>In this study specific ecotoxicological scenarios with selected TiO₂ nanomaterials were investigated. Using different standardized OECD test methods, mixture experiments with nano-TiO₂ and an organic contaminant as well as toxicity tests under solar radiation were performed.</p> <p>http://www.umweltbundesamt.de/publikationen/environmental-hazard-of-selected-tio2-nanomaterials</p>

Quelle: Umweltbundesamt 2016

Research Project/Report	Duration	Short description
Mobility, fate and behavior of TiO ₂ nanomaterials in different environmental media	2010-2012	<p>This study dealt with the environmental fate of TiO₂ nanomaterials. Different aspects were investigated, i.e. the stability of different coatings as well as the mutual influence of nanomaterials and pollutants on fate and behavior in the environment.</p> <p>http://www.umweltbundesamt.de/publikationen/mobility-fate-behavior-of-tio2-nanomaterials-in</p>
Carcinogenicity and Mutagenicity of Nanoparticles – Assessment of Current Knowledge as Basis for Regulation	2010-2012	<p>In this research project, long-term studies with rodents and different nanomaterials were surveyed to identify relevant indicators of toxicity including possible precursors of carcinogenicity. Due to the heterogeneous characteristics of the materials and the different study types, a structured and systematic data analysis was performed by means of a relational database. More than 100 studies on inhalation and instillation with nanomaterials like Carbon Black, SiO₂, metals, metal oxides, and carbon nanotubes were analysed. Effects like neutrophil number, total protein and LDH content in the bronchioalveolar lavage fluid (BALF) proved to be frequently measured and to be sensitive indicators of toxicity of all particles/fibers investigated. In addition, infiltration of inflammatory cells in the lung and increased lung weights were often observed.</p> <p>http://www.umweltbundesamt.de/publikationen/carcinogenicity-mutagenicity-of-nanoparticles</p>
Toxicology of nanomaterials, modes of action and carcinogenicity – kinetics of CNT after short-term inhalation	2010-2012	<p>Rats were exposed to carbon nanotubes (MWCNTs) in a short-term inhalation study. The objective of the study was to investigate the uptake, distribution, and excretion of MWCNTs. In lung lavage inflammatory reactions were observed 1 day after exposure but not 28 days after exposure. Individual MWCNTs were detected in liver, kidneys and in the agarose cast of the pleural cavity using a high resolution light microscope.</p> <p>Final report (available in German with English abstract): http://www.umweltbundesamt.de/publikationen/toxikologie-von-nanomaterialien-wirkmechanismen</p>
Assessment of the chronic toxicity/carcinogenicity of selected nanomaterials	2012-2018	<p>To fully reveal relevant health hazards of selected nanoparticles BASF Experimental Toxicology has performed a long-term inhalation study under the auspices of the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB) and in collaboration with the higher federal authorities BAuA, BfR und UBA. This whole-body inhalation study was performed according to OECD test guideline no. 453 with several protocol extensions.</p>
Investigation of the influence of selected nanoenabled products on the raw material and energy demands	2011-2013	<p>The applications described in the study show that, in general, nanotechnological innovations can save significant amounts of resources and energy. However, these potentials depend at least partially on boundary conditions that still have to become reality in future. With regard to the effects of nano-enabled products on the consumption rate of raw materials and energy, as well as for the determination of relevant rebound effects, the results of the study show that the analysis of the entire life cycle of an application is an absolute prerequisite for obtaining reliable results.</p> <p>Final report (available in German with English abstract): http://www.umweltbundesamt.de/publikationen/untersuchung-der-auswirkungen-ausgewaehlder</p>

Quelle: Umweltbundesamt 2016

Research Project/Report	Duration	Short description
Legal questions regarding the application of the substance definition to nanomaterials within the framework of the REACH Regulation	2011-2012	<p>Aim of this study was to investigate how current regulations like REACH and CLP need to be adapted in order to cover nanomaterials appropriately. It was examined if it is therefore necessary to amend the definition of the term substance in Art. 3 REACH.</p> <p>Final report (available in German with English abstract): http://www.bmub.bund.de/fileadmin/Daten_BMU/Pools/Forschungsdatenbank/fkz_3711_65_434_nanomaterialien_reach_bf.pdf</p>
Assessment of Impacts of a European Register of Products Containing Nanomaterials	2012-2013	<p>Aim of this study was to identify and analyze the impacts of a „Concept of a European Register of Products Containing Nanomaterials” which was proposed by UBA. Therefore, sectors and companies affected by such a registers were identified and number of products were estimated. Based on these data, the administrative costs of concerned companies and competent authorities were quantified. Finally, the impact of such a register on innovation and competition, as well as the benefits for public authorities, consumers and notifiers were described.</p> <p>http://www.umweltbundesamt.de/publikationen/assessment-of-impacts-of-a-european-register-of</p>
Integrative Test Strategy for the Environmental Assessment of Nanomaterials	2012-2014	<p>Objective of this study was to develop a tiered strategy for the investigation of ecotoxicity and environmental fate, that allows both the considerations of conventional test requirements and alternative aspects, specific for nanomaterials.</p> <p>http://www.umweltbundesamt.de/publikationen/integrative-test-strategy-for-the-environmental</p>
Survey on possible Environmental Exposure of Disposal of Waste Containing Nanomaterials	2012-2015	<p>Aim of the study was the investigation of the behaviour of nanomaterials during the incineration using nanoscale TiO₂. In order to optimize the application technique into the waste as well as the measurement technique, nanomaterials were incinerated in a small scale incineration plant. In addition, experiments were performed in a real existing waste incineration plant and a sewage sludge incineration plant.</p> <p>Final report (available in German with English abstract): https://www.umweltbundesamt.de/publikationen/untersuchung-moeglicher-umweltauswirkungen-bei-der</p>
Review of Methodological Problematic Issues regarding the Examination of Nanomaterials in the Environment – Development of a Decision Support Tool for the Investigation of Environmental Behavior of Nanomaterials on the Basis of their Dispersion Stability and Solubility as a Function of Environmental Conditions	2013-2016	<p>In this study, a draft for a new OECD test guideline dealing with the examination of agglomeration behavior of nanomaterials in the aquatic environment is developed. In addition, a proposal for an OECD guidance document is compiled, dealing with a tiered approach for the investigation of dissolution and agglomeration of nanomaterials, which can be used for decision-making on further tests on environmental behavior of nanomaterials.</p>
Grouping of Nanomaterials for a Joint Assessment of Environmental Fate and Effects for Regulatory Purposes	2014-2017	<p>The study aims to correlate physical-chemical properties with ecotoxicological effects. For this objective, selected nanomaterials with defined properties are investigated for their short-term aquatic toxicity using standardized OECD methods.</p>

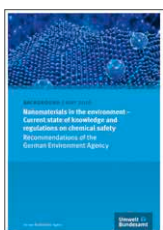
Quelle: Umweltbundesamt 2016

Table 3



Participation and partnership in national and international externally funded research projects

Title of project	Duration	Funding source	Topic
UMSICHT	2010-2013	BMBF (Federal Ministry of Education and Research)	Assessment of the environmental hazards of silver nanomaterials
DENANA	2014-2017	BMBF	Design criteria for sustainable nanomaterials
NanoGRAVUR	2015-2018	BMBF	Nanostructured materials – Grouping regarding worker, consumer, and environment safety and risk mitigation
NanoMobil (UBA acts as associated partner)	2014-2017	BMBF	Synthetic Silver Nanoparticles in the system Soil-Groundwater - mobility, effects on cohabitation and interaction between hydro, pedo- and biosphere
NanoUmwelt (UBA acts as associated partner)	2014-2017	BMBF	Risk analysis of engineered nanomaterials in the environment: identification, quantification and analysis of the human- and ecotoxicological effects
SOILMOBILE (INTERNANO)	2015-2018	DFG (German Research Association)	Masking and catching mechanisms control mobility, aging and functioning of engineered inorganic nanoparticles at the aquatic-terrestrial interface
ProSafe	2015-2017	EU Horizon 2020	Promoting the safe implementation of nanomaterials
NanoFase (UBA participates in the advisory board)	2015-2019	EU Horizon 2020	Nanomaterial fate and specification in the environment

Quelle: Umweltbundesamt 2016



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