

**NanoDialogue of
the German government**

**Regulation of construction products and
possibilities to address (new) risks from
nanomaterials**

Report complementing the ExpertDialogue 'Opportunities and
risk from the use of nanomaterials in the construction area'

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1 Introduction

Since 2006, the Ministry for the Environment, Nature Protection, Building and Nuclear Safety has organised the German NanoDialogue for the German Government. The aim of the NanoDialogue is to support experience and information exchange of national stakeholders from industry and trade, academia, ministries and authorities as well as civil society groups on the opportunities and risks from the use of nanomaterials. Besides horizontal topics, such as ‘nano databases’, ‘regulation’ or ‘nanomaterials in waste’, different application areas of nanomaterials were subject to discussion in the NanoDialogue.

At the ExpertDialogue ‘Opportunities and risks from the use of nanomaterials in the construction area’ that took place in November 2016, the regulatory framework for construction products was discussed and proved to be complex and difficult to understand for many stakeholders. As nanomaterials are chemicals, they are covered by existing legislation. However, due to the lack of a legal definition and agreed testing and evaluation procedures, they are not specifically addressed.

At the end of the ExpertDialogue it remained unclear, if and to what extent potential risks from nanomaterials are or could be identified and regulated in practice. Therefore, this report aims to illustrate how construction products are currently evaluated at EU and national level (June 2017). It outlines possibilities how new risks, for example from the use of nanomaterials, could be introduced in the product assessment under the current legal framework. This includes a discussion of the interaction between the EU chemicals legislation and the regulation of construction products. The report focuses on the health and environmental assessment; technical aspects, such as fire protection or the stability of buildings are not discussed.

The German legislation on construction products was under discussion at the time of writing this report. As the future legislation cannot be foreseen, the report refers to the current situation. While the assessment principles and the legal references may change in the new legal provisions, fundamental differences in the principles and procedures for product assessment are unlikely.

The report is directed at persons working in the construction sector, but which are not familiar with the legal requirements in detail as well as informed non-professionals and the interested public.

2 Requirements on the use of construction products

2.1 General requirements and regulatory principles

Placing construction products on the market is regulated at EU and at national level. Two sets of requirements, which relate to different processes, can be distinguished:

- requirements that are a precondition for placing construction products on the market and which have to be fulfilled by the producers¹ and which could be set at EU or at national level;
- requirements, which limit the possibilities to use a construction product in a building and which are to be ensured by the product users and which, are defined at national level.

2.1.1 Provisions on placing construction products on the market

Before placing a construction product on the market, its manufacturer has to assess and describe its performance using defined methods. The scope of the assessment and the methods to be used may be defined at EU level in the so-called European technical specifications, which can be either a harmonised European standard (hEN) or a European Assessment Document (EAD). If no EU technical specifications exist, the requirements are defined nationally. In Germany these may be national standards developed by the national standardisation institute (DIN e.V.²), or in the national provisions on the applicability of construction products, such as in the product approval.

2.1.2 Requirements on the use of construction products

Before using a construction product, the responsible persons, such as architects, planners or builders must check if it fulfils the national requirements for the intended use. In Germany, these requirements are defined in the building laws of the Federal States. For health protection, they relate to the content or the release of hazardous substances from construction products to the indoor air. Environmental requirements concern the content and the leaching of hazardous substances into water. The requirements may differ depending on the intended use, e.g. for an indoor application or a use on the outside of a façade with water and soil contact. The information necessary to check if a construction product fulfils the national provisions, should be contained in the producers' declarations of performance that are prepared for placing the product on the market.

¹ The actor who attaches the CE-label to a product takes the responsibility for product safety and develops the declaration of performance. It is not relevant who actually manufactured the construction product.

² Deutsches Institut für Normung

2.2 Requirements in Germany (Model Building Ordinance)

The building legislation of the Federal states are derived from the Model Building Ordinance (Musterbauordnung (MBO)) and are therefore similar. Among others, the MBO includes the requirements for marketing and using construction products in Germany.

In Germany, construction products may only be used if during their use and when contained in a building, this building fulfils all legal requirements under the condition that they are appropriately maintained and for a duration adequate for the purpose of the product³ (MBO §16b). This general requirement is defined more specifically for certain product types in technical building rules. While they primarily address the products' stability and fire safety additional aspects, like environmental and health protection may also be addressed.

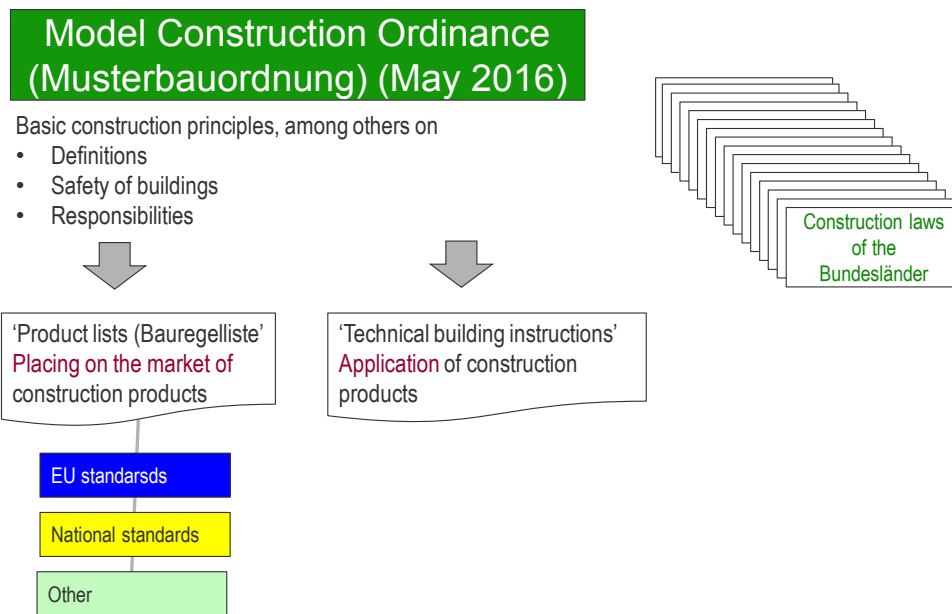


Figure 1: Contents of the German Model Building Ordinance

While the applicability of a construction product for a particular use is regulated nationally – in Germany in the technical building rules – the requirements for its

³ The original German legal text is: „bei ihrer Verwendung die baulichen Anlagen bei ordnungsgemäßer Instandhaltung während einer dem Zweck entsprechenden angemessenen Zeitdauer die Anforderungen dieses Gesetzes oder aufgrund dieses Gesetzes erfüllen und gebrauchstauglich sind“ (MBO §16b)

assessment, i.e. the identification of product performance, are defined at EU or national level (c.f. Figure 1). Therefore, the construction product manufacturers have to identify, which requirements apply. For some construction products the national responsible authorities decided that no assessment is necessary for construction products with a low safety relevance (e.g. door handles).

Products that have to be assessed according to EU technical specifications (hEN or EAD) and for which a declaration of performance must be prepared have to be marked with a CE label. This label is a precondition for marketing construction products in the EU. If the assessment follows German provisions, the product should be labelled with an Ü label. The Ü label indicates the usability of the product in Germany.

The national requirements on the applicability of construction products should correlate with the EU norms and assessments. This means that the information needed to decide if and for which purposes a construction product may be used should be included in the declaration of performance. However, this is currently seldom the case for health and environmental criteria, because the EU product standards do not sufficiently include the respective assessments.

There are no general criteria or rules regulating whether the requirements for a particular product type are defined at EU level or nationally, however the current set of specifications has developed over time. Usually the development of (EU or national) standards is triggered by a request from product manufacturers, associations or standardisation organisations. Similarly, EADs are only developed, if a manufacturer has requested that his product be assessed at EU level (EU technical assessment (ETA)) and if no applicable norm exists.

For all product types without EU standards, the German responsible authorities have defined which national rules should apply to their assessment in the Construction Products List, i.e. if they should be evaluated according to an existing national standard or if they should follow the rules for a national technical approval. They decided that for some products no assessment is needed at all. The list is updated if new EU or national standards are published.

3 Development of European technical specifications

In Section 3.2 the procedures to develop harmonised EU standards (hEN) and EU assessment documents (EAD) are described. For a better understanding, the roles and responsibilities of the most important actors are described first.

3.1 Involved actors

The EU Commission:

- assigns standardisation mandates to the EU standardisation organisations. A mandate is the basis for the development of a standard and defines the essential characteristics that should be addressed in the declaration of performance. Before a harmonised EU standard is finally agreed on, the Commission checks if it covers all aspects of the mandate;
- may adopt legislation to define material requirements for construction products or may agree that such requirements are developed by other organisations;
- plans, coordinates and directs all standardisation activities in the implementation of the Construction Products Regulation (CPR). The Directorate General Grow is responsible for that.

The Standing Committee for Construction advises the EU Commission, among others, on the content of standardisation mandates and various other issues related to the CPR. Its members represent the member states and the EU Commission.

The standardisation organisations, i.e. the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) develop EU standards in different technical committees, including for construction products. The members of the CEN are the national standardisation organisations, e.g. the German DIN e.V. The member states are not directly represented in the CEN but may participate as delegates of the national standardisation organisations. Associations and other stakeholders may be involved as observers in the work of CEN as so called ‘partner organisations’⁴.

In Germany, the DIN organises the cooperation of the interested parties, such as manufacturers, consumers, trade, academia, research institutes, authorities or laboratories, in the development of standards. If an EU standard is developed, it establishes a ‘mirror group’ that discusses the EU draft standards, proposes changes and feeds the ‘German position’ into the EU discussions.

The member states have different roles in the implementation of the CPR, such as:

- notifying national legislation and rules to the EU Commission so they can be considered at EU level;
- enforcing the implementation of the CPR;

⁴ According to its website, there are eight partner organisations to the CEN, of which four are civil society groups (<https://standards.cen.eu/dyn/www/f?p=CENWEB:47:::NO::>).

- designating national technical assessment bodies (c.f. next paragraph), which, among others, contribute to the development of EADs and make European technical assessments (ETA) of specific products.

The national Technical Assessment Bodies (TAB) are designated by the member states. Their core responsibility is the assessment of specific construction products either in the national context or at EU level if an ETA is requested. In Germany, the Deutsche Institut für Bautechnik (DIBt) is the designated TAB.

The European Organisation for Technical Assessment (EOTA) coordinates the work of the national technical assessment bodies including, the development of, the decision-making on and the publication of EADs. It communicates on these issues with the EU Commission and the Standing Committee for Construction.

3.2 Environmental and health aspects in EU technical specifications

Environmental and health aspects in harmonised EU standards and EAD are derived from the basic requirements of a building (c.f. Annex I of the EU CPR):

Hygiene, health and the environment

The construction works must be designed and built in such a way that they will, throughout their life cycle, not be a threat to the hygiene or health and safety of workers, occupants or neighbours, nor have an exceedingly high impact, over their entire life cycle, on the environmental quality or on the climate during their construction, use and demolition, in particular as a result of any of the following:

- (a) the giving-off of toxic gas;*
 - (b) the emissions of dangerous substances, volatile organic compounds (VOC), greenhouse gases or dangerous particles into indoor or outdoor air;*
 - (c) the emission of dangerous radiation;*
 - (d) the release of dangerous substances into ground water, marine waters, surface waters or soil;*
 - (e) the release of dangerous substances into drinking water or substances which have an otherwise negative impact on drinking water;*
- [...]

EU standards and EADs have a defined structure and include a description of:

- the scope, i.e. to which product types they apply and if any products are exempted;
- the essential characteristics of the construction product, which are relevant to fulfil the requirements of buildings and the performance of which is to be assessed, including those impacting human health and the environment;
- the assessment criteria, i.e. the parameters that determine the performance and the respective measurement method;

- the classes of performance to be used in the declaration of performance and, in some cases also the threshold values⁵.

| | |
|---|---------------------------------------|
| Example | |
| Scope: | PE-pipes for drinking water supply |
| Essential characteristic (for environment and health): | Substance emissions to drinking water |
| Assessment criterion: | Leaching of substances |
| Measurement method: | CEN TS 16637-3 |

According to the EU Commission⁶, there are 457 EU standards and more than 2000 accompanying standards, which cover 75-80% of all construction products (state of 2016). Most of them were mandated before the CPR entered into force. Although this was already foreseen in the mid-1990s, i.e. under the 'old' Construction Products Directive, they do not yet require assessments for environmental or health characteristics. Only after 2010 did the EU Commission decide to update ten mandates of product standards with regard to these environmental and health aspects.

It is hardly possible to identify if the standardisation mandates underlying an EU standard includes requirements of environmental and health assessments. In most cases, this cannot be deduced from the text of the published standards and is not obvious from the list of standards that are under development on the website of CEN⁷.

In addition to the product standards, horizontal norms exist that specify how a particular assessment criterion should be tested and quantified. For the protection of the environment and health, three types of horizontal standards exist. They define how to evaluate the:

- content of hazardous substances,
- release of hazardous substances into soil and/or water,
- emission of hazardous substances to indoor air.

3.2.1 Consideration of hazardous substances

For the implementation of the CPR, the EU Commission developed an [indicative list of hazardous substances](#), which may be relevant for construction products. The

⁵ Classes of performance group construction products into specific ranges, e.g. regarding concentration limits, for the related essential characteristics. Threshold levels are minimum or maximum values for a parameter above or below which the construction product may be placed on the market or not. At EU level, only few threshold levels exist. These are usually derived from substance bans (e.g. PCBs).

⁶ European Commission (2016): REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the implementation of Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, Brussels.

⁷ <https://standards.cen.eu/dyn/www/f?p=CENWEB:84:::NO::>

substances on this list should be considered in EU product standards, horizontal standards and EADs.

The list includes substances (from an EU database⁸) that are regulated at EU level and where that legislation is relevant for construction products or the construction sector, such as legislation on chemicals, workers protection and environmental protection⁹. In addition, substances for which national requirements on construction products exist¹⁰ and that were notified to the EU Commission are included. DG Grow maintains the database, from which the indicative list is an extract. The list is separated into the section of 'Soil and Water' and 'Indoor Air' and was last updated in 2012.

3.2.2 EU harmonised standards

The development of new and updating of existing (product) standards follows a multi-step procedure. After the publication of agreed standards, the national standardisation organisations publish corresponding German versions.

With regard to hazardous substances, the following questions are considered in the standardisation process in order to ensure a pragmatic implementation:

- Can/should the content of certain hazardous substances in a construction product be excluded?
- Which release scenarios are relevant for humans and the environment and can these be predefined for a particular intended use?
- What exactly needs to be assessed in order to prevent the occurrence of potential risks to humans and the environment along the product life cycle?
- Which assessment results should be included in the performance declaration?

Figure 2 illustrates the standardisation process.

⁸ https://ec.europa.eu/growth/tools-databases/cp-ds_de (only The Netherlands and Germany)

⁹ Among others: REACH Annex XVII (use restrictions), POP regulation (bans and use restrictions of persistent organic pollutants), the Biocidal Products Regulation (placing on the market and use of active substances and biocidal products), Water Framework Directive (substances relevant for surface waters), the Groundwater Directive (substances relevant for drinking water).

¹⁰ This includes substances regulated in an administrative rule or other non-legislative rules.

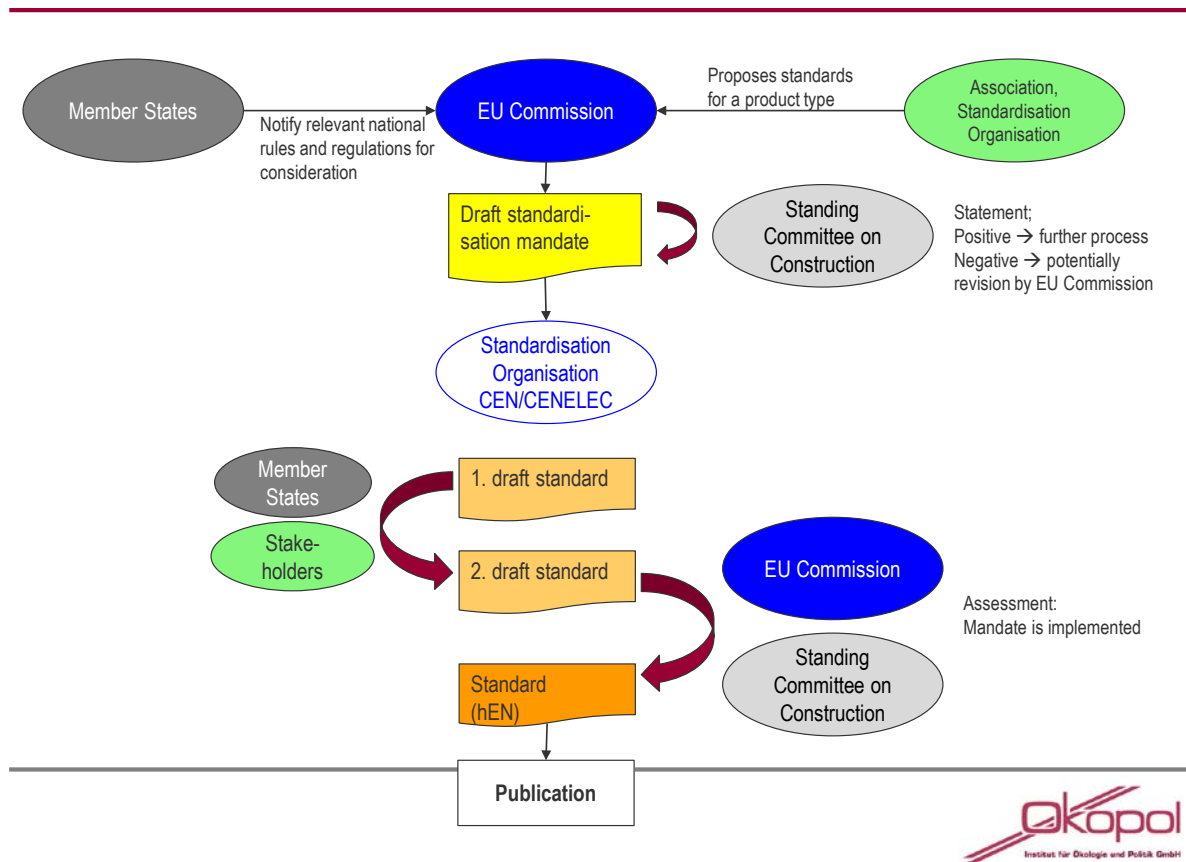


Figure 2: Steps in the European standardisation process

3.2.3 European Assessment Documents

EU Assessment Documents (EADs) describe how to conduct a European Technical Assessment (ETA). ETAs are conducted by the national assessment bodies, in Germany the DIBt.

If a construction product manufacturer requests an ETA, the DIBT checks if:

- an applicable EU standard exists. In this case the application is declined and the manufacturer is informed of the standard;
- an EAD already exists. In this case, it informs the EU Commission and the EOTA and carries out the ETA according to the EAD.

In all other cases, the EOTA forms a working group that develops a new EAD according to the procedure outlined in Annex II of the CPR. The working group considers potential opinions by the EU Commission. If an EAD needs updating, the EOTA initiates a respective work process by a working group. No stakeholders are involved in the process, except the product manufacturer.

An EAD resembles an EU standard in its structure (c.f. above). The result of an ETA is the product manufacturer's declaration of performance, which is the basis for the CE label Figure 3 illustrates the process.

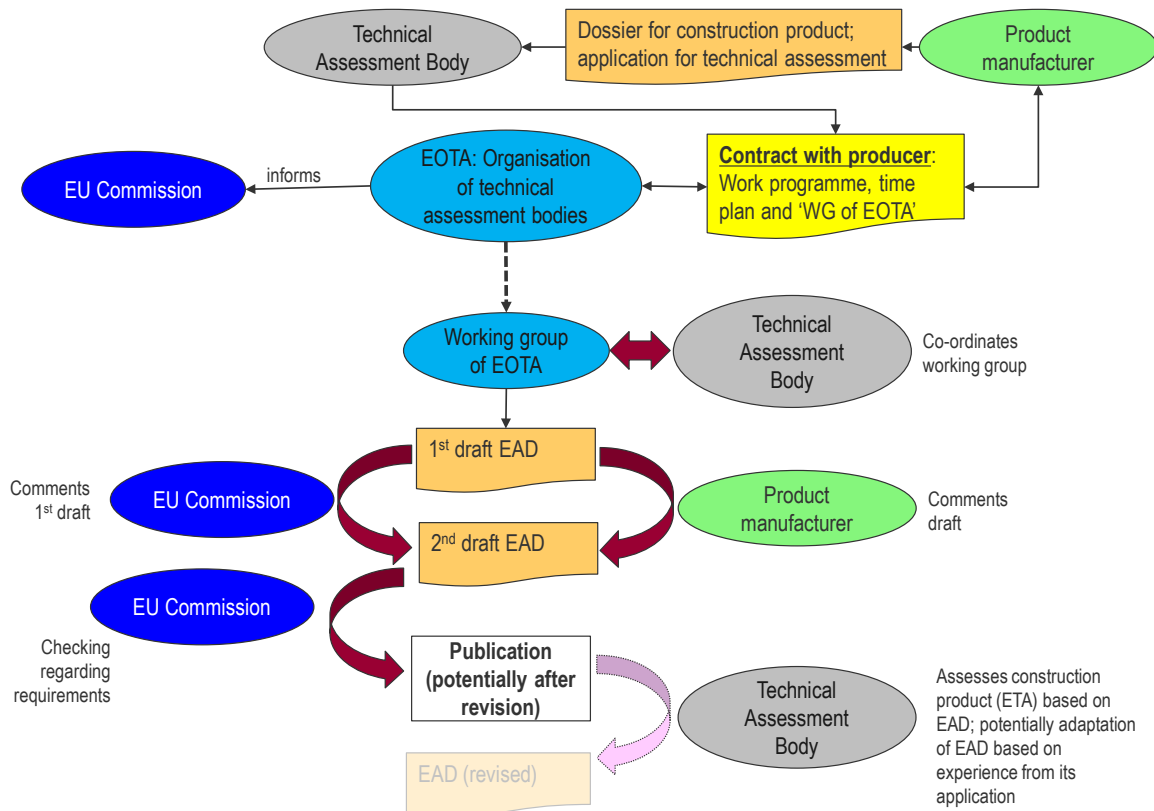


Figure 3: Development of European Assessment Document

3.2.4 Threshold values and classes of performance

It is generally possible that minimum requirements, so called threshold values, are defined in EU standards and EADs in relation to the essential characteristics of a construction product. Regarding environmental and health effects of construction products, these could be maximum concentrations or release rates for substances. For example, maximum release rates could be defined for volatile substances or limit values for the leaching of substances from construction products into water. Currently, there are only few EU threshold values for hazardous substances.

In addition, classes of performance may be defined - i.e. ranges of values – for example for the release of volatile substances. Classes of performance support the categorisation of products and are to be provided in the declaration of performance and potentially also with the CE label.

If classes of performance or threshold values exist, they apply to any EU procedure or documentation¹¹. They may be specific for a construction product or may cover several groups of construction products. They can be implemented by the EU Commission in form of legislation or be defined by the standardisation organisations. If no classes of performance or threshold values exist for a characteristic, they may also be defined by the EOTA in agreement with the EU Commission and the Standing Committee for Construction, in the development process of an EAD.

Only few stakeholder groups are involved in the development of EU standards or EADs. Interested parties are involved only through their concrete contributions¹². The standardisation organisations publish a work programme every year, which should increase transparency on the procedures.

4 Placing on the market of construction products in Germany

Construction products with a CE label, i.e. the performance of which is declared according to an EU harmonized standard or an ETA, may be placed on the market in all EU member states. Products without a CE label are covered by national legislation (c.f. Chapter 2). In Germany, two categories of products can be distinguished:

- Products that conform to a national standard or technical rule and which are labelled with an Ü label after assessment. These products may be assessed by different actors, depending on the applicable procedure:
 - conformity to a German standard and declaration of conformity by the construction product manufacturer (construction product list, part A);
 - assessment and national approval by the DIBT or consent for individual cases by responsible authority;
 - assessment and development of testing certificate by a notified assessment body and according to criteria defined by DIBT.
- Products which are not labelled with a Ü label because:
 - they conform to requirements in other member states and the German ones are thereby ensured;
 - they do not need an assessment because they are of low relevance regarding the construction legislation (product list C).

¹¹ Construction Products Regulation Art. 27.

¹² Differing from that, the German standardisation process of the DIN e.V. include public consultations of the norms.

The Construction Products List¹³ defines the categories a construction product falls into and the procedure to demonstrate and declare the performance / conformity of it. In the following, the national approval procedure for construction products is explained, which is required for all product types which are not included in the construction products list¹⁴.

National approval procedure

The technical rules for construction and the products lists¹⁵ specify for all construction products requiring national approval the general requirement that a construction product should not endanger the users of a building or the environment. For the approval procedure, the general requirements are 'translated' into specific assessment methods and criteria. If these exist, this happens in accordance with the DIBt's general principles for national approval.

An expert group of the DIBt developed the 'Principles for the Health Assessment of Construction Products for Indoor Use'. They are based on an assessment method developed by the Committee for Health-related Evaluation of Building Products (AgBB)¹⁶ and that is called AgBB – Scheme. A dedicated project group developed the 'Principles for the Assessment of Impacts of Construction Products on Soils and Groundwater'. The principles were notified to the EU Commission.

The product manufacturers disclose the composition of construction products in the application for national approval to the DIBt. The DIBt first assesses, if the product fulfils an exclusion criterion of the above-mentioned principles. The criteria require construction products not to contain:

- substances, which are banned at EU level or the use of which is restricted in construction products;
- substances, which are included in Annex 2 of the DIBt's approval principles;

¹³ Deutsches Institut für Bautechnik: „Mitteilungen - Bauregelliste A, Bauregelliste B und Liste C“ Ausgabe 2015/2, Berlin, Oktober 2015; <https://www.dibt.de/de/Service/Dokumente-Listen-BRL.html>. The legal situation at the time of writing the report was not fully clear, because the 'Musterverwaltungsvorschrift Technische Baubestimmungen(MVV TB)' was foreseen to enter into force as new legal instrument but this was not yet the case.

¹⁴ In addition, it is possible that the simplified procedure of developing a national approval certificate (bauaufsichtliches Prüfzeugnis) is needed, for which the assessment is not done by the DIBt, but by an external certified organisation. This procedure is not presented here, as it is analogous to the national technical approval.

¹⁵ In the future, the technical building rules and the construction products lists (Bauregellisten) will be replaced by the administrative rule on technical building rules, which was still being developed at the time of writing the report. (https://www.dibt.de/de/dibt/data/Notification_draft_2016_376_D_DE.pdf). Annex 3 of the administrative rule describes the general requirements on hygiene, environmental protection and health protection, which relate to construction products as well as to buildings.

¹⁶ German: Ausschuss für die gesundheitliche Bewertung von Bauprodukten

- very toxic and toxic substances as well as substances which are very toxic or toxic for aquatic organisms¹⁷;
- carcinogenic or mutagenic substances (category 1A or 1B), except if they have been shown not to cause a risk to humans or the environment;
- persistent organic pollutants (POPs);
- wastes, which do not fulfil the requirements of the circular economy (values for solids and leachates).

If the DIBt has formerly assessed similar construction products as those, for which a national approval is sought, and if this assessment proved that such products do not endanger the safety of building users and the environment, it is possible that an approval is given without further assessment. If no assessments from similar products exist or if these revealed a potential danger to the environment or human health, the applicable second assessment step is conducted.

For the health assessment (AgBB-scheme), the applicant for approval conducts standardised chamber tests to determine the emissions of hazardous substances from the construction product. The results from testing are translated into indoor air concentrations using specific exposure models that consider the substances' dissemination and dilution in indoor environments. Finally, the estimated indoor air concentrations are compared to substance specific limit values for the indoor air (NIK-values). The AgBB toxicologically derives the NIK-values. The values for health assessment do not include exposures from dermal contact and oral intake.

In order to assess the environmental impacts (soil and water), a leachate is made from construction products to determine which constituents are mobilised from it and could reach water and soils. The leaching methods consider the purpose of the product and are partly standardised at EU level. Using so called 'transfer functions' the expected substance concentrations in the environment are calculated from the testing results. The expected environmental concentrations are compared to so-called thresholds of negligibility, which were derived by a working group. If the estimated environmental concentrations remain under those thresholds, the construction product is considered safe. If no thresholds of negligibility exist, biological tests need to be performed, which are used to determine a construction product's safety.

If a construction product fulfils all national requirements applicable to its use, it gets a national approval and the manufacturer can apply the Ü label. If a national standard that the building authorities consider as sufficient exists and which is hence included

¹⁷ These substances should be avoided but are not prohibited; if their content cannot be avoided, a separate assessment is necessary.

in the product list A, the manufacturer assesses conformity according to that standard himself.

5 Influence of REACH on the safety of construction products with a particular view to nanomaterials

New information generated under the European chemicals regulation REACH may influence the assessment of a construction product's environmental and health effects in different ways: via the identification of hazardous properties, via the chemical safety assessment and via the communication on hazardous substances in the supply chain.

5.1 Identification of hazardous properties

Due to substance registration, more information on the hazardous properties of chemicals is available. This may reveal a need for national regulation of substances in construction products. Regarding the specific case of nanomaterials, it is to be noted that nanomaterials are only insufficiently addressed by REACH. There are ambiguities regarding the (requirements for) physical-chemical characterisation and identification of nanomaterials. In addition, the testing requirements specified in the regulation's annexes are not adapted to nanomaterials. If they were appropriately assessed, the properties of a substance's nanoform would be described independent of its bulk form.

The identification of a substance's hazardous properties under REACH may have different consequences for the regulation of construction products containing them. For example, the following cases are possible:

- A member state develops national rules for the use of hazardous substances in construction products and notifies them to the EU, with the aim of having:
 - them included in the indicative list of hazardous substances (c.f. Section 3.2.1) and considered in standardization work;
 - the national rule considered in a standardisation mandate.
- The manufacturer of a construction product containing hazardous nanomaterials that form a specific product claim applies for an ETA. This creates the necessity to develop assessment criteria and methods for the nanomaterial.
- Due to (new) information on the hazards of a (nano) substance, the threshold for its content in or emission from a construction product is reduced in the

national requirements. This may lead to the prohibition of (a particular) use of a construction product containing this (nano) substance.¹⁸

- Classification-based exclusion criteria may apply, such as those defined in the principles for national approval (c.f. Chapter 4) in Germany. If a (nano) substance is newly classified in a respective hazard category, construction products containing it should not be nationally approved.

5.2 Identification of life cycle risks

A chemical safety assessment is required under REACH for all substances that are registered in amounts exceeding 10 t/a. For hazardous substances, in addition, the registrants must estimate exposures and characterise risks. The chemical safety assessment aims at identifying if risks to human health or the environment could occur from the use of a substance along its entire life cycle¹⁹. Based on the chemical safety assessment, the registrants decide which uses they consider safe and, therefore, want (further) to enable by registering it. They must explicitly exclude uses from registration for which they identify a risk and indicate them in the safety data sheet ('use advised against'). For construction products, the consequences of a chemical safety assessment may be that²⁰:

- the use of a substance in construction products is not registered and therefore, they may not be included in respective products them anymore;
- the registrant defines risk management measures that have to be implemented by the downstream users. Examples are:
 - Uses with potential consumer exposures are excluded. In this case, the construction product could not be used indoors anymore.
 - Uses with potential water contact are excluded, which would prevent any uses on the outside of buildings and for building parts that are cleaned with water (e.g. flooring).
 - Uses are possible only if personal protective equipment is applied. This would exclude any use in consumer mixtures.²¹

¹⁸ Due to the lack of EU threshold values, this is applicable mostly at the national level.

¹⁹ Consequently, the possible exposures at each life cycle stage are identified and compared with the effect thresholds of the substance. This includes substance manufacture, inclusion of substances into mixtures and articles, use of mixtures and articles that contain the substance and disposal of products containing the substance.

²⁰ If another actor in the supply chain demonstrates that the use of the substance is safe, these uses are possible despite not being registered. This process is called downstream user chemical safety assessment (DU CSR).

²¹ This is due to the assumption that consumers do not use and cannot be expected to use any personal protective equipment.

5.3 Communication on hazardous substances in the supply chain

Information on hazardous properties of substances and on the safe conditions of uses have to be provided with the safety data sheets of substances and mixtures under REACH. This should increase transparency on chemical products and ensure all actors have sufficient knowledge to implement their safe use.

REACH requires that information on substances of very high concern (SVHC)²² in articles²³ be communicated along the supply chain if they are included in these articles in concentrations above 0.1 %. This obligation also applies to construction products, such as flooring, door handles, insulation panels or window frames. At least the identity of the contained SVHC must be provided along the supply chain and, upon request, also to the consumers.

Safety data sheets and/or information on SVHC in articles are available to the actors producing or placing construction products on the market. This information is to be included in the performance declaration. SVHC may also be included in the indicative list of hazardous substances if they are relevant for construction products.

6 Considering new risks (from nanomaterials) in the assessment of construction products

The environmental and health requirements for construction products at EU and national level are specified with regard to substance risks. However, they are limited to substance intake via inhalation and emissions to water and soil.²⁴

Nanomaterials may be classified as hazardous under chemicals legislation and/or identified as SVHC²⁵. Therefore, (new risks from the use of) nanomaterials are generally covered in the assessment of construction products. However, this is counteracted by the fact that:

- There is no legally binding definition for nanomaterials (under REACH),
- A nanomaterial's hazardous properties are not sufficiently identified under REACH (c.f. Chapter 5.1). In addition, the EU standards and EADs only

²² These are substances that have at least one of the dangerous properties defined in REACH Article 57 and which have therefore been included in the 'candidate list' for authorisation.

²³ An article is defined as an object the physical properties (structure and form) of which are more important for its function than its chemical composition. The difference between chemicals (substances and mixtures) and articles is not always obvious. An ECHA guidance document is available that explains the requirements and the definition applicable to articles.

²⁴ The lack of further exposure routes for humans and the environment is a general aspect that does not only apply to (new risks from the use of) nanomaterials.

²⁵ When drafting this report, no nanomaterial was identified as an SVHC.

include substances on the indicative list of hazardous substances. Furthermore, the established methods are not adapted to the specific characteristics of nanomaterials, e.g. that they behave differently than the related bulk material.

6.1 Assessment of new risks in construction products

Several conditions need to be fulfilled to ensure that new risks, e.g. from nanomaterials, are considered in the assessment methods as a precondition for placement on the market and in the national requirements for applying construction products. In the application of standards, EADs and national approval principles:

1. Nanomaterials would have to be identifiable and quantifiable in the recipe of a product. This requires identification and communication under REACH;
2. Nanomaterials need to be distinguishable from their bulk forms in content measurements. This requires specific measurement methods;
3. The methods to determine the release (chamber tests and leaching tests) and to model the behaviour of nanomaterials in the environment and in indoor air need to be applicable. This requires an evaluation of the adequacy of available methods and a potential adaptation or development of new methods if the existing ones are not adequate for nanomaterials;
4. Applicable threshold values, classes of performance, NIK-values and thresholds of negligibility for nanomaterials should exist. This requires that information on the toxicity and ecotoxicity of nanomaterials are available from REACH.

Explanation for bullet point 1: Nanomaterials in mixtures can only be identified if the product manufacturers provide that information in the safety data sheet. For articles, this information is only legally required if nanomaterials are identified as SVHC on the candidate list and if their concentration exceeds 0.1% w/w in the construction product. It is not legally required that the exact concentration of a substance in a mixture or article is provided; however, this information could be obtained through communication in the supply chain.

Explanation for bullet points 2 and 3: The available harmonised EU methods for the content of substances in products, their release to air and water as well as their distribution in indoor air and the environment were not developed with a view to nanomaterials. Due to their small size and increased surface area, nanomaterials frequently behave differently than the respective bulk forms. Therefore, existing measurement and modelling methods may have to be adapted to nanomaterials. It is therefore questionable if results from existing standards are valid and meaningful for the assessment of risks from nanomaterials.

Explanation for bullet point 4: Currently, nanomaterials are not registered as separate substances under REACH (c.f. Chapter 5.1). A well-founded database to derive threshold values for the assessment of environmental and health risks is therefore missing, including for construction products. While classes of performance could be defined in principle, it is not possible to relate them to a certain risk level.

Another consequence of the incomplete data on hazardous properties of nanomaterials is that the exclusion criteria, which are based on the classification of substances, such as available in the national approval principles, cannot be fully applied with sufficient certainty.²⁶

6.2 Assessment of risks from nanomaterials under REACH

It may be questioned if the chemical safety assessment under REACH is sufficient to identify risks from the use of nanomaterials in construction products, due to the following gaps in legislation and its implementation. Some of these aspects may be solved in the future, whereas others may continue to exist.

- As nanomaterials are mostly not characterised and registered as individual substances, information on their hazardousness may be missing²⁷.
- The nanomaterials' hazards and behaviours may largely differ depending on the coating/functionalisation. If this is sufficiently considered in the chemical safety assessments is not fully clear.
- No chemical safety assessment is required for nanomaterials registered in amounts below 10 t/a; i.e. the safety of a use in construction products is not assessed.
- The methods to determine the release of substances from articles are criticised by several actors as being too "rough" and therefore insufficient for risk assessment;
- The regulatory risks assessment does not fully represent the total exposure of humans and the environment. Neither cumulated exposures (same substance from different sources), nor combination effects (simultaneous exposure to different substances) are considered sufficiently in the exposure and risk assessment methodologies.²⁸

²⁶ This problem exists for all substances with incomplete hazard data and is therefore not specific for nanomaterials.

²⁷ It is normally not possible to deduce the nanomaterial's properties from those of the bulk material.

²⁸ This applies to any substance, regardless of its size.

6.3 Summary of possibilities to integrate new risk in the assessment of construction products

Nanomaterials can be considered in the EU standardisation processes in two ways. They can be either:

- 1) directly included in the standardisation mandates for products or methods or
- 2) indirectly included via the indicative list of hazardous substances.

An EU member state could initiate consideration of (certain) nanomaterials in product standards or their inclusion in the indicative list by developing national legislation or subordinated rules and notifying them to the EU Commission. However, they cannot force their consideration in a standardisation mandate or their inclusion on the list.

Consideration in EU assessment documents (EAD) could also be triggered by the inclusion of (certain) nanomaterials on the indicative list (see above). In addition, considering nanomaterials would be necessary if a construction product manufacturer applies for an EU technical assessment (ETA). This could be the case, if a nanomaterial fulfils an essential function in the construction product and the manufacturer intends an EU-wide placing on the market. Any consideration of nanomaterials at EU level requires prior development or adaptation of respective standards for assessment methods.

Similarly, consideration of nanomaterials in the national approval process necessitates the development of respective methods and their integration into the approval principles. This could be initiated if requirements for nanomaterials were included in the technical rules. A related trigger could be that authorities regard a risk likely based on the assessment of a product composition and would make a more detailed assessment. This could only occur, if nanomaterials are identified in the recipes and if their release is likely.

7 Conclusions

Only a few construction products considered as 'high priority' are assessed regarding the environmental and health impacts at EU level. Placing on the market requires the application of EU or national standards or assessment procedures. For the actual use of a construction product, the member states define, frequently quantified requirements, which may relate to the environmental and health performance. For their evaluation, the results from the tests are needed.

The EU procedures for mandating and developing standards are published on the internet pages of CEN in form of work programmes and reports. However, for outsiders it is frequently not transparent, which requirements apply to which construction products and which requirements or standards are still under

development. The list of construction products includes all regulated construction products for which norms exist or for which conformity needs to be demonstrated. However, also here it is not fully clear, which requirements a construction product must fulfil regarding its environmental and human health impacts.

The European standards and assessment documents as well as the national approval principles are not yet adjusted to support the assessment of environmental and health effects of nanomaterials. There are neither provisions that the substances' sizes are to be specified nor are the testing and measurement methods regarding the content and the emissions of nanomaterials adjusted. In addition, the exposure scenarios for the identification of substance concentrations in indoor air and in the environment do not consider that nanomaterials behave differently than their bulk forms, due to their reduced size. As nanomaterials are not specifically assessed in the registration under REACH, a solid database on their hazardous properties, including their classification are not available. Therefore, the classification-based exclusion criteria cannot be applied and the derivation of reference values for risk assessments include a number of uncertainties.

While in the mid-term data on the properties of nanomaterials are expected to improve, also for low volume substances, the adjustment of the assessment methods for construction products would need a longer time. Here, the member states would have to pass national requirements in order to initiate respective EU-wide adjustments.

Unfortunately, it is not possible to make a statement on the extent of potential risks from nanomaterials in construction products for human health or the environment, as the necessary information for risks assessment are missing. It is neither known if and which nanomaterials with a relevant hazard classification are actually used in construction products, nor can the extent of their release be estimated.