

EFFECTS OF EUROPEAN REGULATIONS FOR HEALTH AND ENVIRONMENTAL PROTECTION ON BUILDINGS AND BUILDING PRODUCTS

EXECUTIVE SUMMARY

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1. Context and aim of the project

In context with the still unsatisfactory status of the effective implementation of essential requirement No 3 „Hygiene, Health and Environmental Protection“ in the harmonised European Legislation for Construction Products the question arises for the German authorities in how far the new European Legislation on Chemicals (REACH VO No 1907/2006) can provide perspectives in regard to the guarantee of an appropriate protection level of health and environmental protection and what kinds of problems can arise regarding the interaction with the existing Construction Products Directive (CPD) and their implementation.

With this background the building ministry contracted out a research project with the aim to provide a systematic analysis of both the common ground and the differences between CPD and REACH as well as providing concrete starting points for concepts leading to an effective regulation of health and environmental aspects.

This research project has been undertaken by Oekopol from September 2007 until December 2008. The processes have been accompanied by an advisory committee, consisting of representatives of different sectors of the building product industry and of the federal authorities.

From the point of view of the advisory committee it was particularly important to identify approaches ensuring an efficient interaction of REACH and CPD, to avoid duplication of work and to avoid the establishing of non-harmonized or contradictory requirements.

2. Results of the Analysis

2.1. REACH and CPD-ER 3

When the respective REACH requirements are implemented for „dangerous“ substances used in construction products, mechanisms and concepts apply which bear a distinct analogy to concepts and mechanisms discussed or applied for the implementation of essential requirement (ER) No 3 under CPD.

The following diagram graphically identifies some of the main elements:

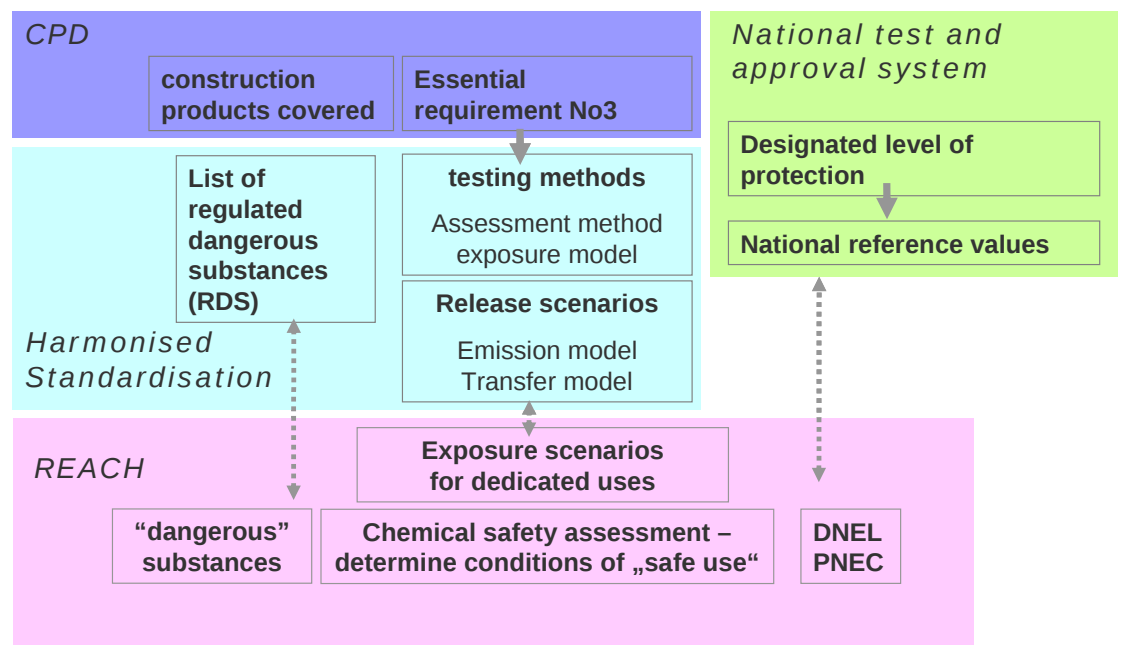


Figure 1: Schematic overview of corresponding regulatory elements of REACH and CPD ER3

Both regulatory systems cover among other aspects a projection of emissions resulting from installed construction products and an assessment of the exposure to be expected for certain end points (human health concerns indoor and environmental effects in soil and (ground-) water) using (eco-) toxicologically, based threshold values. This means that both systems are risk-based and thus, in regard to their scientific basis and their aims, basically compatible and can be harmonised.

2.2. Differences between REACH and CPD ER3

Apart from the common ground mentioned above, certain differences have been identified:

Different objectives

REACH focuses on single substances. The chemical safety assessment for dangerous substance according to REACH refers to the single substance covering its different life-cycle stages and uses. Possible emissions and resulting exposure from its use in an installed construction product are thus subject of assessment among many others.

The CPD focuses on the use phase of construction products ("articles" mainly in REACH terms). The testing of the defined characteristics of a construction product (i.e. ER 3) refers to the installed product as a whole. Sum parameters are taken into account for the assessment of emission measurements as well as distinct substances.

Different addressees

The addressees according to the CPD are the national approval systems, the manufacturers of construction products and the property developers.

The addressees according to REACH are the importers and manufacturers of chemical substances for, among many others, construction products. The recommendations for the safe use of substances as generated under REACH are not binding for downstream users (e.g. the manufacturers of construction products), but they may cause further own assessments.

Different substance concepts

The substance concept of REACH is not entirely congruent with the substance concept existing in the context of ER 3. REACH essentially refers to intentionally manufactured chemical substances

Not subject of REACH are

- natural substances without any dangerous characteristics as pertains to chemical legislation (e.g. wood, natural fibres, minerals);
- Substances from aging processes in products.

The term „substance“ in the framework of CPD is basically understood in a wider sense. Emissions from natural products like wood (content substances and substances resulting from aging processes), from impurities in resources and summary parameters are covered as well.

On the basis of the different aims of the regulations (substance assessment vs. article assessment) a complete harmonisation would make, according to the opinion of the consultant team, only limited sense.

Different „procedures“ for the determination of „relevant“ substances

The „dangerous substances concept“ of REACH differs in its procedural structures considerably from those under CPD.

Under REACH the classification as „dangerous substance“ is based on the criteria of the guideline 67/548 (or will in the future be based on the „Regulation on classification, labelling and packaging“ EC No 1272/2008 (CLP Regulation)).

The list of regulated dangerous substances (RDS) in the field of construction product regulation has in contrast been created with reference to existing regulation concerning substances and products in the different EU member states.

This is in principle not an elementary contradiction, as most substances labelled as dangerous according to chemical legislation are covered by the regulations for substances and products of the member states. But due to political value targets, different revision cycles and possibly differing aims, both derivational methods in “real life” regularly differ in their results.

This situation presents itself as unsatisfactory especially with regard to the possibly rapidly growing knowledge about PTB-characteristics of substances under REACH, which might well be relevant for the assessment of environmental characteristics of construction products. Pragmatic concepts for a better harmonisation would be desirable.

Different timelines

The implementation processes under REACH and the activities concerning CPD-ER 3 harmonisation follow different timelines.

The assessment and description of safe use conditions under REACH for substances which may occur in construction products has to be concluded by 2010, 2013 or 2018 respectively, dependent on the amounts brought on the internal market (phase-in-status).¹

An assessment of the existing RDS-lists identified

- o 146 substances as High Production Volume Chemicals (HPVs), which have a registration deadline until 2010 under REACH
- o 37 substances as Low Production Volume chemicals (LPVs) which have a registration deadline until 2013 or 2018.

The harmonising standardisation with regard to RE-3 intends to publish respective standards between 2012 and 2014.²

¹ The episode labelled „service life“ in the life cycle, which means the „installed state“ for building products, is explicitly dealt with in the substance safety evaluation in the framework of REACH. For dangerous substances > 1000 t/a and for substances > 100 t/a classified under R50/53, R45, R46, R49, R60, R61, a substance safety report including an exposition assessment is to be submitted by 01.12.2010.

² This is at least what can be taken from the time planning of CEN TC 351 and its working groups

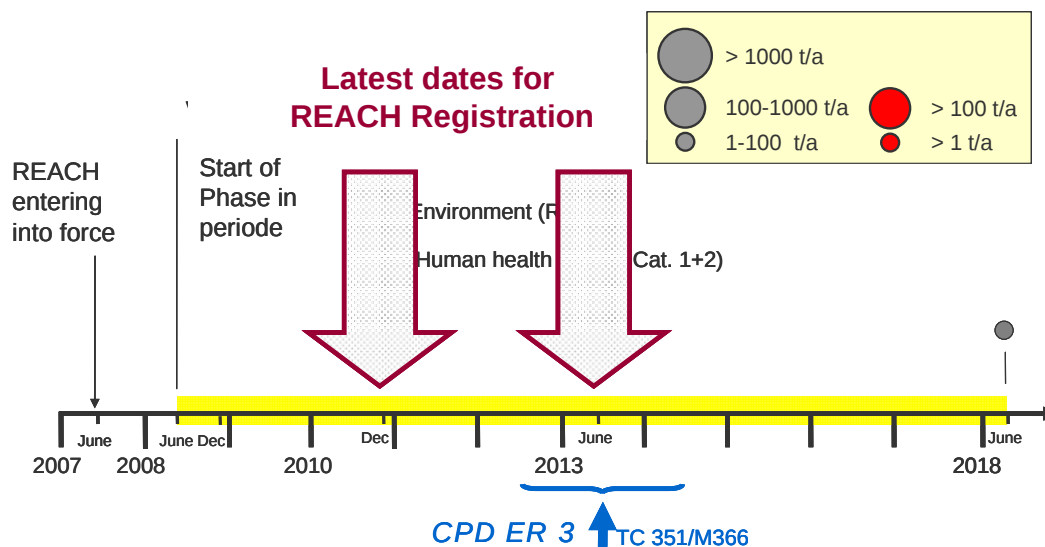


Figure 2: Timing gap between REACH registration and the availability ER 3 related standards

So a considerable part of the REACH-registrations of substances used in the field of construction products will presumably be concluded before harmonised standards for construction products tests or harmonised procedures for WT- or WFT-decisions will be available.

This means that actors according to REACH (manufacturers of substances and downstream users) will (have to) develop their own methods for the exposure assessment (the emission estimation) in the field of construction products.

Not interlinking these two processes might lead of factual double standards in the evaluation of emissions from construction products, resulting in higher costs and in cases possibly even contradictory results.

Different responsibilities for the derivation of reference values

Under REACH central (eco-)toxicological reference values will be generated (according to a harmonised EU-wide method) under the individual responsibility of the manufacturers.

In contrast, the (eco-) toxicological reference values for the CPD are being adopted from different legal regulations.

2.3. Common ground

Comparable level of ambition

No "new" human- or ecotox reference values (DNEL and PNEC values) from the implementation of REACH were available over the course of the project.

An exploratory comparison of the respective concepts and the level of ambition to be expected was nevertheless conducted, on the basis of the reference values currently used in Germany for the evaluation of construction products. It showed that the reference values have been composed by comparable scien-

tific methods and thus should lead to the same level of protection. A more detailed analysis over the next years will be necessary to decide if this proves to be true in all cases.

Furthermore REACH can be expected to yield a considerable amount of additional DNEL and PNEC values, for substances where up to now no reference values have been available.

A structured assessment of those upcoming de facto EU-wide harmonised REACH-reference values in relation to the existing national reference values of the approval of construction products is deemed advisable by the consultant team. Furthermore transparent routines for the adaptation of such values from the REACH context into the field of construction product regulation can lead to an increased harmonisation regarding required environmental performance. (see as well 3.1)

REACH exposure assessments and CPD release scenarios

There is, concerning basic methodological concepts, generally a significant congruence between the exposure assessments according to REACH and the release scenarios discussed in the context of CPD-ER 3.

A release scenario is to be regarded as a subset of an exposure scenario. It covers primarily the question of release (emission, diffusion, dissolution) of substances from the building product and thus is equivalent to the emission part of an exposure scenario.

The following diagram schematically illustrates these differences in „range“:

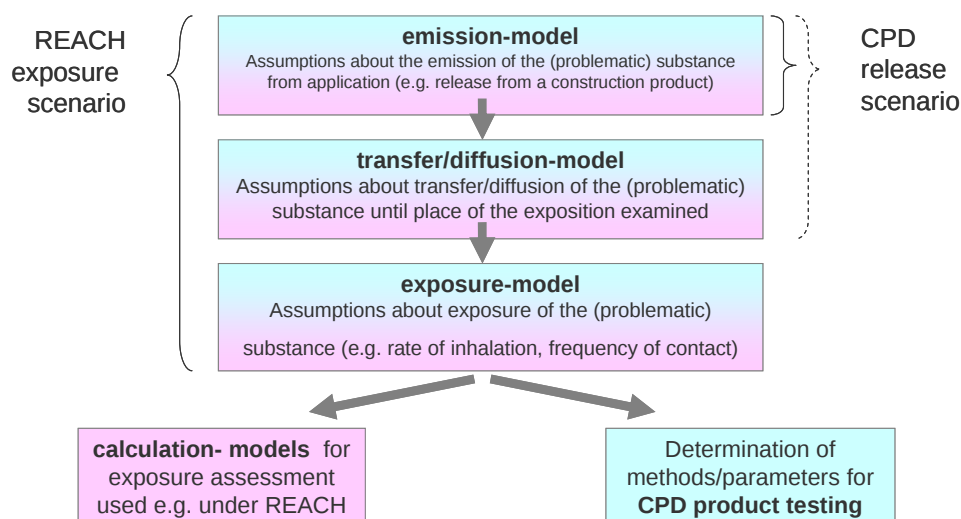


Figure 3: Comparison between exposure scenario and release scenario

Commonly agreed release scenarios from the field of construction products regulation could play an interesting role as part of the generic REACH exposure scenarios with regard to a harmonisation of the proceeding within the framework of both regulations.

2.4. Further aspects

Further „self-sustaining“ harmonisation processes

Considering other elements from areas where both regulations overlap, e.g. the possible use of information from the extended REACH safety data sheets for the composition of product information for construction products, the consultants assume that due to the self-interest of the market actors these processes will run autonomously. There will be no need for additional initiatives.

Lack of structured communication

Experience from several completed projects showed that there was no pronounced exchange of experiences between the CPD and REACH communities up to now.

Due to the background of different regulatory objectives and the respective competence structures the picture the “CPD community” has of the mechanisms induced by REACH is largely unclear.

On the other hand central actors of the ongoing implementation of REACH (manufacturers and importers of substances) often exhibit no or only very limited knowledge about the details of the established procedures for the evaluation of construction products and the ongoing efforts for harmonisation.

The necessity for the exchange of information and for coordination between CPD and REACH implementation has been recognised by now, especially on the level of the formulators of construction products but also on the different levels of state authorities. But there is still a noted lack of structured processes for this exchange and simple action-oriented displays of the existent and important interdependencies.

3. Starting points for efficient interaction

On the basis of the analysis of differences and common ground of CPD and REACH some starting points have been identified which are of special relevance to the efficient interaction of both regulatory systems, and particularly for the prevention of duplication of work.

The following diagram gives an overview of the starting points discussed during the project.

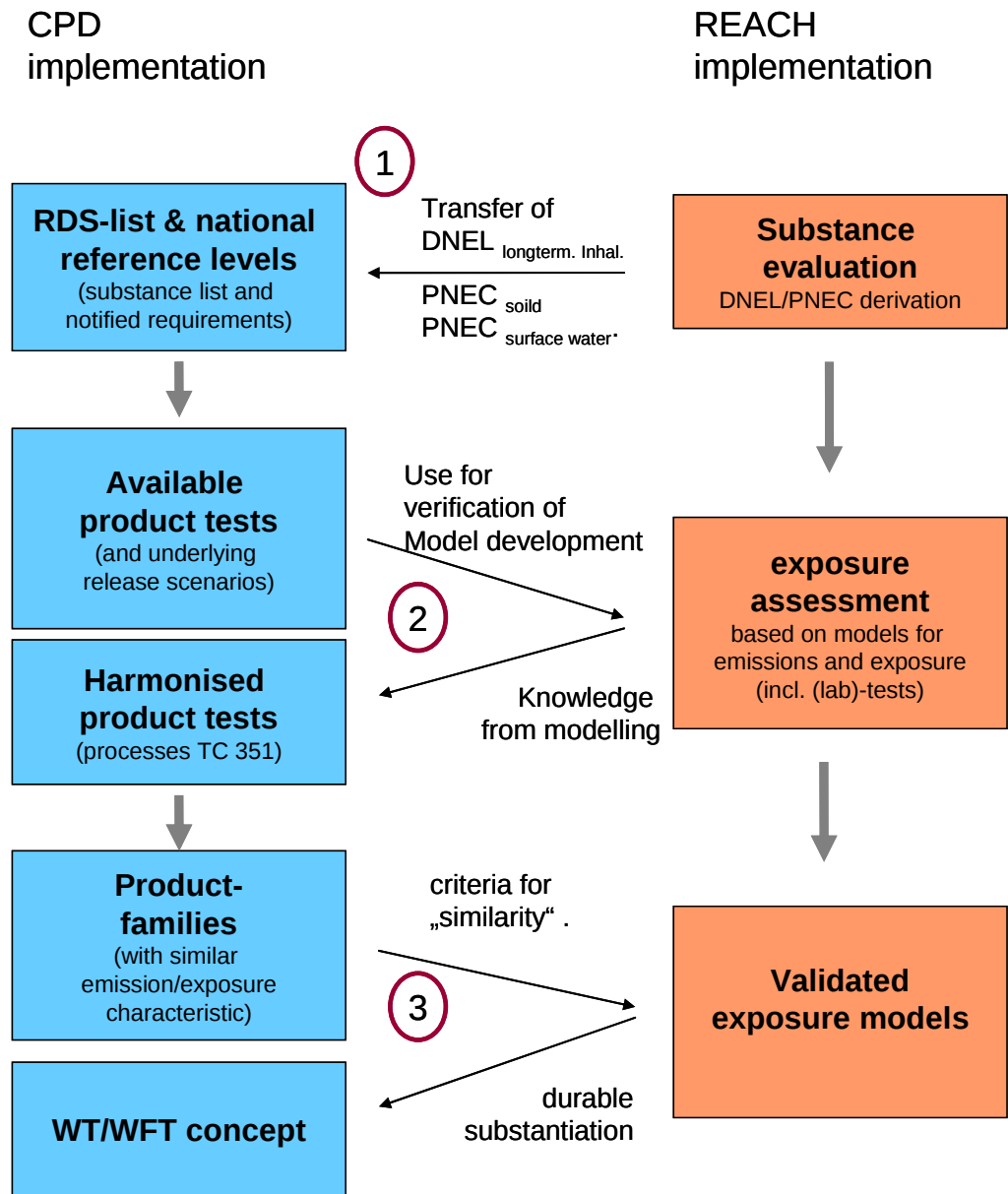


Figure 4: Starting points for increased efficiency of interaction

In the following the different starting points will each be described briefly and the results of a first study of their implement ability, undertaken within the scope of the project, will be displayed.

3.1. Integration of PNEC and DNEL values into the derivation of national reference values of construction product evaluation

Starting point

A systematic use of REACH DNEL and PNEC values during the derivation of reference values in the building product evaluation could support

- a) harmonisation of reference values within the EU
- b) a basically comparable level of protection with regard to the safe use of chemical substances in construction products in both regulatory systems.

The use of supplemental factors for the addressing of particular protection needs on a national level would remain unaffected by this.

Result

In principle an integration of the consideration of available REACH DNEL and PNEC values into the derivation routines and hierarchies of the national reference values for the construction product evaluation and approval could result in a higher consistency between both regulatory areas.

The DNEL and PNEC values derived by a harmonised methodology under REACH in individual responsibility of the manufacturers will in future be available on the internet site of the European Chemical Agency (ECHA). Referential experiences as to their quality and durability will not be available for some more years.

It is therefore deemed necessary, at least for an interim period, to conduct independent quality assessments of the derivations before transferring available data into the area of CPD. This presupposes access to the relevant sections of the REACH chemicals safety reports. Here it needs to be clarified in detail by whom and under which circumstances these information can be accessed.

No proposal could be developed to the question by what measure the EU member states could be stimulated to integrate consideration of REACH threshold values into the derivation routines of the national reference values.

Further systematic limitations arise from the different substance concepts of both regulations. This necessitates further research in order to e.g. make requirements more compatible on the level of single substances and sum parameters.

3.2. Harmonised tests for building products and exposure assessments under reach

Starting point

Results of construction product tests, which reliably represent the emission conditions (release scenarios) for the conditions of use of the respective con-

struction products could make a relevant contribution in order to adjust possibly „overly conservative“ exposure estimations under REACH.

On the other hand they can contribute to the derivation and validation of exposure assessment models which reliably predict the release of substances from a (complex) substance matrix.

Furthermore such models could then make a relevant contribution in the framework of tiered evaluation approaches for the efficient derivation of WT/WFT-decisions (see starting point 3).

Result

Over the duration of the project exposure scenarios, conducted systematically according to REACH were not (yet) available.

The consultants exploratory surveys showed:

- There are no appropriate scenarios to be found in the relevant exposure assessment models for emissions from installed construction products.
- The preset parameters for a orientating exposure assessment (tier 1) lead to conservative results under comparably „simple“ emission conditions (release of a volatile solvent from a homogeneous floor covering).
- By appropriate modification of the input parameters (tier 2) exposure predictions can be reached that show a good agreement with results of respective chamber measurements.

The developers of the appropriate exposure models showed a general interest in the development of exposure models for the release from a complex substance matrix using relevant test results (e.g. gained under CPD) as validation..

3.3. Tiered REACH exposure assessment and WT/WFT approach of CPD

Starting point

The exposure assessment for substances under REACH and the testing regime for construction products aim at

- quantitatively assessing the exposure of humans and the environment to substances emitting from the construction product
- doing this as efficient as possible in an EU-wide harmonised, product group spanning manner

For this both regulatory systems provide tiered assessment systems („tiering“ and „waiving“ in the framework of REACH and „WT/WFT“ in the framework of CPD), the „expert judgement“ aspect of which should be kept to a minimum.

With this background it has been discussed in the context of the project, in how far the REACH concepts of „tiering“ and „waiving“ could support WT/WFT decisions under CPD-ER 3.

Results

The examination of the „tiered REACH exposure assessment and WT/WFT approach of CPD yielded the two following results:

- The waiving-concept under REACH, i.e. the well founded waiving of certain tests concerns only distinct, single substances and is tied to usually quite detailed requirements. Thus it can not contribute directly to a simplification in the assessment of complex products as aimed at in the context of WT/WFT decisions.
- The tiered exposure assessment approach under REACH could contribute more directly to such WT/WFT decisions. If appropriate conservative emission and exposure models (tier-1 assumption) show that there is no reason to expect relevant exposure for a substance (or a substance group with certain, comparable properties (e.g. the same level of volatility)), further tests for the said exposure pathway (e.g. emission to compartment indoor air) may be dispensed with. This presupposes that appropriate models for the said emission and exposure situations are available. This is presently not the case with regard to the release of substances bound in a matrix (the “normal” situation regarding most construction products).

4. Conclusions

The limitation of substance-related health and environmental risks originating from construction products are touched upon by Essential Requirement No. 3 of the Construction Products Directive as well as by the implementation of REACH.

Both regulatory systems feature fundamental systematic differences e.g. with regard to the objects of regulation.

REACH focuses on chemical substances. The manufacturer has to derive the substance characteristics for every distinct substance, including human- and eco-toxicological threshold values and has to make specifications for a safe use of the substance throughout its whole life cycle. The derivation of these conditions for safe use is usually based on simplified model assumptions concerning the different possible uses.

The CPD addresses instead the environment related „performance“ of complex construction products under certain conditions of use. Standard instrument for the verification are tests of the respective products. The CPD thus can in its implementation conceptionally surpass the distinct substance and deal with the multilayer interdependencies of the use of complex products and also address the product specific conditions of use.

Despite these differences between the regulatory systems there are clear analogies on the level of their basic conceptual elements. These, given appro-

appropriate definition, provide starting points for an efficient combination of both regulatory areas.

On the one hand it seems reasonable to make available and to use the substance-related knowledge about human- and ecotox values, which will be generated under REACH in great numbers in a manageable time frame, in a structured manner for the derivation of reference values for the evaluation of construction products. If the consideration of available REACH DNEL- and PNEC-values would be integrated systematically in the routines for derivation national reference values a strong impulse for a more harmonised level of required ER 3 performance would be given to the European construction products market.

On the other hand there is a pool of knowledge about the actual emission behaviour of substances to be found in the area of construction product testing as well as an expert consensus about appropriate release scenarios. Both would be very helpful for the verification of the model-based emission and exposure assessments under REACH. It would furthermore be adequate for the further elaboration testing of the relevant prediction models.

Validated prediction models, for the release of substances from an article matrix, developed on this basis could make a medium-term contribution to the reduction of testing efforts beneath the level of the CPD (WT/WFT-decisions)

Central obstacles in the development of the said synergies are at present especially the differences in timelines and the comparably low intensity of the technical discussion between the actors of both regulatory areas.

5. Illustrative Example

5.1. Exemplification of corresponding concept elements

The different corresponding concept elements of REACH and CPD will be illustrated using the example of the construction product synthetic resin screeds and its ingredient „benzyl alcohol“:

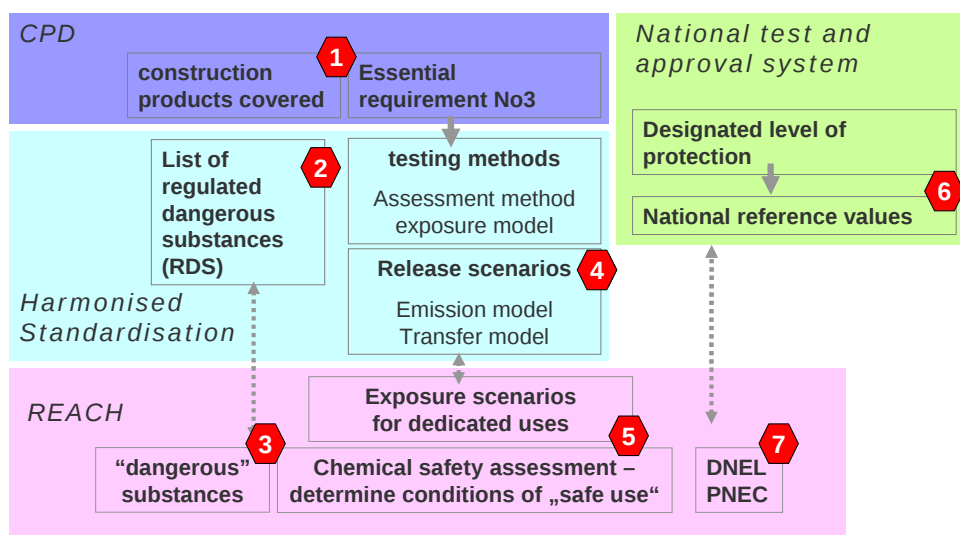


Illustration 1: Schematic overview on corresponding concept elements under REACH and CPD-ER 3

1. It is a harmonised construction product in the framework of the CPD, described in EN 13813 as „Screed material and floor screeds – Screed material – Properties and requirements“.
2. Benzyl alcohol is to be found in the appendix B-2 of the indicative list of regulated dangerous substances (RDS list).
3. Benzyl alcohol is, as a chemical substance, subject to REACH. Benzyl alcohol is, according to 67/548/EC, to be appropriately assessed and labelled as „Xn“ and „R20/22“. Thus it is also a “dangerous substance” under REACH.
4. If a market actor produces or imports into the EU more than 10 t/a of a dangerous substance³, like e.g. benzyl alcohol, generation of exposure scenarios is compulsory within the framework of the chemical safety assessment under REACH for all (identified and supported) uses of this

³ Substance with dangerous properties in the sense of guideline 67/548/EWG or substance fulfilling the criteria of a PBT (persistent, bioaccumulating and toxic) or vPvB (very persistent, very bioaccumulating) substance according to article 57 of REACH.

substance. In the exposure scenarios (ES) conditions of use are described which ensure a safe use of the substances. Such an ES for benzyl alcohol would have to cover the use of this substance in synthetic resin screeds materials consequently.

5. In the context of the generation of horizontal testing procedures relating ER 3, „release scenarios“ play a relevant role⁴. They describe how the dangerous substances contained in construction materials could be released under the intended conditions of use and how they might end up in the soil, ground or surface water or the indoor air. They are used for the development of realistic testing methods for construction products. The testing method for the release into indoor air will be based, according to current discussions⁵, on a release scenario that is represented in a relevant test chamber test.
6. Reference values for the evaluation of substance emissions from construction products are not defined by the CPD and the related processes of harmonised standardisation, but are derived on a national level from existing laws and other regulations. Examples would be the „NIK-values“⁶ derived mainly from threshold values for workplaces, which are consulted in Germany regarding the evaluation of test chamber tests in the framework of the AgBB-scheme.⁷
7. All registrants are obliged under REACH to derive threshold values (PNEC and DNEL values) within the framework of the chemical safety assessment. The relevant „Technical Guidance Documents“⁸ explain how these values are to be derived, taking into account adequate safety factors from the results of relevant (animal) tests or other relevant information. The same derivation procedures from practical scientific experience, are used that are found e.g. in the determination of threshold values for workplaces. There are yet no REACH threshold values for benzyl alcohol. Due to the amount of benzyl alcohol on the market they are to be derived by 2010 and to be submitted in the course of registration to ECHA, which will make them publicly available.

⁴ In the context of the relevant mandate M /366 EN „Development of horizontal standardized assessment methods for harmonized approaches relating to dangerous substances under the Construction Products Directive (CPD)“, March 2005

⁵ Within CEN/TC 351 WG 2

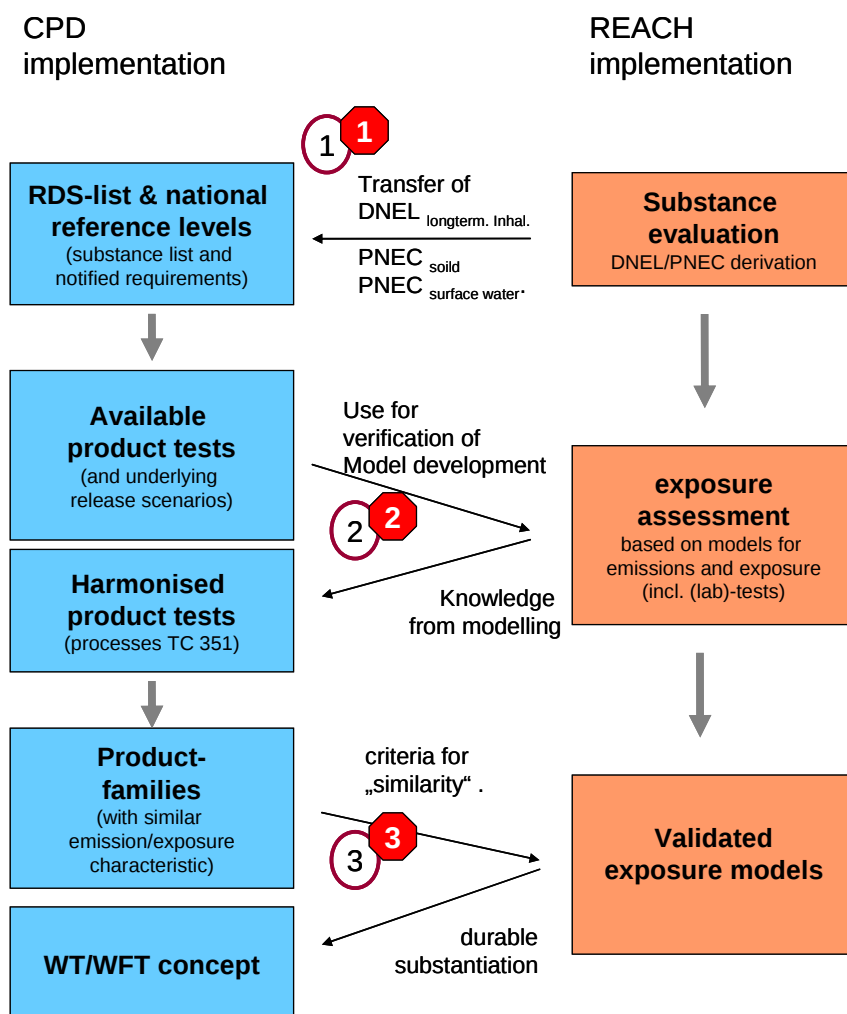
⁶ Lowest concentration of interest values

⁷ This NIK value is derived from a Workplace Environmental Exposure Limit (WEEL-value) of the American Industrial Hygiene Association (AIHA). It is 44 mg/m³.

⁸ These are the chapters (guideline fractions) R 8 and 10 of the ECHA guideline „Guidance on information requirements and chemical safety assessment“. Both can be downloaded from the ECHA homepage under http://reach.jrc.it/docs/guidance_document/information_requirements_en.htm?time=1225765085.

5.2. Exemplary illustration of starting points for efficient interaction

In the following the 3 approaches for a more efficient interaction of REACH and CPD identified in the concluded project will be illustrated using the aforementioned example:



1. With the REACH threshold values publicly available from 2010 on for benzyl alcohol and many other substances, EU-wide reference values derived by standardised methods will become available. The DNEL_{long term user} is especially relevant in the example mentioned. These threshold values can be consulted by member states for the derivation of reference values for the evaluation of the results of standardised test chamber tests. e.g. for the construction product „synthetic resin screeds“.
2. The results from test chamber tests already undertaken with construction products containing benzyl alcohol seem suitable for the improvement of the available models for the assessment of indoor exposition of users. Evaluations of the established exposition models Consexpo and ECETOC in the course of the project show that there are yet no models available, which directly represent the release of a solvent of low volatility like benzyl

alcohol from a complex substance matrix like „ synthetic resin screeds “. With the appropriate modification of the model parameters, a significant concurrence of measuring chamber results and model predictions can be observed.

3. An orientating tier-1 modelling for the product example under worst case assumptions, following the tiered evaluation approach under REACH, leads to very conservative results. If the safe use of benzyl alcohol in the construction product can be demonstrated even under the tier-1 assumptions in the context of the chemical safety assessment, a WT/WFT decision could be supported for benzyl alcohol and similar solvents contained in the construction product. This would, however, presuppose a further development and evaluation of the appropriate models (see “2”)