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Substances classified as carcinogenic, mutagenic and toxic for reproduction (CMR) and other substances of concern in consumer products

Identification of relevant substances and articles, analytical control and consequences for the regulation of chemicals

Summary

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Substances classified as carcinogenic, mutagenic and toxic for reproduction (CMR) and other substances of concern in consumer products

**Identification of relevant substances and articles,
analytical control and consequences for the
regulation of chemicals**

Summary

by

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Introduction

This project deals with chemical substances in consumer-relevant articles that may be of concern for health or the environment. The present state is investigated (What substances of concern are currently found in what articles), and the changes expected under the new European chemicals legislation REACH are analysed.

In this approach, there must first be a definition of what a “substance of concern” is understood to mean. On the basis of such a definition, a comprehensive list of substances that are characterised as being of concern is presented as an overall “Master List”.

The examination of what substances of concern occur in what articles can only be carried out for selected industries, article groups or materials. This research project focuses on:

- Toys,
- Electrical and electronic equipment, and
- Floor and wall coverings.

Therefore, apart from the comprehensive Master List, specific lists of substances containing substances of concern that are important for these three industries as examples related to the specific industry or article group are generated for each of the three areas:

a) *List 1 with regulated substances of concern*, taken from existing regulations, industry recommendations, quality seals or company check lists and thus classified as relevant,

and

b) *List 2 with substances of concern found*, collated from laboratory analytical evidence, if a certain substance has been found in a toy, electrical equipment, a floor covering, etc.

Many substances of concern occur in more than one industry or article group if the same materials are used. For example, “polycyclic aromatic hydrocarbons” (PAH) are found in elastic plastics as contaminants both in toys and in electrical equipment as well as in floor coverings.

The current project links the information on substances of concern, the current legal position and the expected changes under REACH with a weak-point analysis in which possibilities for improvement are addressed (e.g. by changes in REACH, by supporting single-state measures and by activities at the level of trading companies and consumers). In this connection, the generated substance lists provide assistance for checking whether there are improvements in regulation and whether in the execution (implementation of the specifications of old and new regulations), fewer exposures are in fact identifiable.

The summary of the project report is arranged according to sections that follow the structure of the report:

1. Effects of REACH on substances of concern in articles
2. List of substances of concern: the Master List
3. Substances of concern in toys

4. Substances of concern in electrical/electronic equipment
5. Substances of concern in floor and wall coverings
6. Substances of concern in several industries; focus on “polycyclic aromatic hydrocarbons”

Effects of REACH on substances of concern in articles

Protection from substances of concern in consumer articles is currently frequently inadequate. The aim of this project was to investigate whether this situation will probably substantially improve with REACH (Regulation (EC) No. 1907/2006).

Substance registration

If a substance is registered appropriately under REACH, all identified uses supported by the manufacturer including the use of a substance in articles (manufacture, use and disposal) should be covered and have been subjected to a chemical safety assessment. Accordingly, if REACH is fully implemented, a significant improvement of consumer protection from dangerous substances in articles can be expected. It should be pointed out that the focus is on quantitative considerations in the chemical safety assessment. Therefore, dangerous substances would not completely disappear from articles, but would be below limit values. Moreover, thorough chemical safety assessments can only be expected in connection with a chemical safety report, which is not required until the production volume (import volume) of a substance is more than 10 tonnes per year.

As a rule, manufacturers or importers of an article do not have to register the constituents of this article themselves. However, if substances are deliberately released from an article (best known example: the filled toner cartridge), the specific manufacturer or importer may have an obligation to register if the use of the released substance has not yet been registered.

Protection of the environment and health from substances that may be released from articles unintentionally is fundamentally provided for under REACH by means of the above-mentioned registration by the manufacturer of the substance. However, there may be a possible difference between articles that are manufactured in the EU (scope of REACH) and articles that are manufactured outside the EU and are then imported into Europe. In the latter case, there is no assurance that all relevant constituents have been registered and subjected to a chemical safety assessment if the supplier of the constituents of the article is also located outside Europe. In this way, for example, an allergenic substance could be released from an imported article (unintentionally), without this constituting a violation of the regulations under REACH. In the case of an article that contains substances registered in Europe, this allergy risk ought to have already been examined and taken into consideration with the registration.

Furthermore, nor are substances that are marketed in amounts of less than one tonne per year and manufacturer or importer covered by the registration obligations under REACH. Therefore, no changes are expected for articles containing these substances.

Substances of very high concern (SVHCs)

Further-reaching requirements under REACH regarding environmental and health protection from substances in articles that are not deliberately released mainly relate to only a narrow selection of substances of very high concern (SVHCs). These are for example carcinogenic and mutagenic substances and substances toxic for reproduction or very persistent and very bioaccumulative substances. REACH has the following instruments for SVHCs:

- Notification,
- Authorisation requirement,
- Restriction, and
- Duty to communicate information to purchasers of the articles (including consumers).

Notification

Notification means that each manufacturer or importer of articles shall notify the European Chemicals Agency ECHA (REACH, Article 7.2) of the presence of SVHCs in its articles. However, this notification requirement is bound by a concentration limit (0.1 percent weight by weight) and a tonnage threshold (1 tonne per manufacturer and article). The purpose of the notification is to provide ECHA with an information base possibly to take further measures regarding the registration, restriction or authorisation requirement in respect of SVHCs. Since registration of constituents in the case of imported articles is not guaranteed, this notification requirement appears to be of importance particularly for imports of goods from outside Europe. It is still not clear at present how this instrument will be used by ECHA under REACH or whether this reporting obligation by importers will be fulfilled.

Authorisation requirement

The authorisation requirement for SVHCs under REACH (inclusion of a substance in Annex XIV) is a very far-reaching measure in health and environmental protection. Here, the manufacturer or user of SVHCs must apply for and document a (fixed-term) authorisation in order to be allowed to use the substance, for example in an article. The disadvantage: The authorisation procedure does not immediately apply to all SVHCs, but comes into force according to a graduated method, which means that it will frequently not be effective for many substances for a long time. A second serious disadvantage: The authorisation requirement applies to the use of SVHCs in Europe, but not to SVHCs in (imported) articles. Thus the objective of the authorisation requirement, namely that SVHCs should disappear from the market (substitution objective), unless they are really irreplaceable, is possibly undermined.

Restriction

The position is different with the instrument of restriction under REACH (inclusion of a substance in Annex XVII). For example, the placing of a substance in an article on the market can be addressed here, which also includes the importer of an article. Concentration or release levels documented specifically to the substance can be specified as maximum tolerated limit values (instead of the general 0.1 percent weight by weight limit). Furthermore, specific bans on the use of substances with

differentiated scopes and exceptions can be established. Therefore, the restrictions that are laid down in Annex XVII of REACH offer a comprehensive opportunity for improvements in environmental and health protection.

Most of such restrictions relate to SVHCs, but do not have to be linked to the narrow SVHC term: It is possible to ban other highly toxic substances as well, if they are considered to be “of concern”. This research project of the German Federal Environmental Agency suggests an extended term of a “substance of concern”.

Duty to communicate information

The fourth instrument of REACH mentioned above, which in its turn is linked to the SVHC term, is the duty of a supplier of an article to communicate information according to Article 33. This article is of central importance: The manufacturer or importer of an article (but also a distributor or a firm placing the article on the market) must inform downstream commercial customers of the article about SVHCs that it contains and how the article can be used safely. There is an opportunity here for general stores, for example, not to use articles that contain such SVHCs.

Consumers are not automatically informed. However, they have a right to be informed about SVHCs if they become active and request such data. In this case, too, the 0.1 percent weight by weight of a substance generally applies as the limit below which the information does not have to be disclosed openly.

REACH and chemical analysis

The above limit of 0.1 percent weight by weight for SVHCs is thus of central importance under REACH, but is only a very inaccurate benchmark in practice if an analytical determination or monitoring of this specified concentration becomes necessary. The regulation itself and guidelines on REACH do not give any further help as to

- What formal requirements are to be placed on the laboratory,
- What test methods have to be used,
- How sampling is to be carried out (preparation of a representative mixed sample, homogenisation or individual sample), and
- What sample preparation has to be carried out (incomplete extractions).

It is still in dispute whether a complete article or the individual parts of the article are to be analysed. The questions regarding standard reference substances and matrix-dependent effects are not taken into consideration in the analysis of the SVHC compounds. Furthermore, the analysis is frequently carried out by initially detecting certain chemical elements (e.g. heavy metals and halogens). However, in order to be able to draw conclusions about the identified SVHC compounds, further analytical steps and corresponding interpretations and calculations are generally necessary. Since the methods used as a basis are currently neither standardised nor validated, the data that are obtained when SVHC substances are being analysed are not valid particularly regarding their comparability.

Conclusions

Finally, it should be pointed out that manufacturers frequently follow existing legal regulations for substances of concern in articles. Infringements constantly occur particularly in the case of imports, and it is not expected that this will change under REACH.

Apart from these deficits that undoubtedly exist, our considerations on environmental and health protection in the case of consumer articles show areas under REACH

- In which REACH should very probably lead to improvements in the course of the next few years (particularly via the consequences of a qualified substance registration),
- In which loopholes must be taken into account (particularly in the case of imported articles from outside the EU, the constituents of which do not have to be registered, and because SVHCs in such imported articles are not subject to authorisation),
- In which the use of loopholes can be avoided by appropriate action to be taken by the authorities and in which the authorities can initiate further important improvements, and
- In which other actors, through their activities, can also help to achieve improvements in connection with REACH.

List of substances of concern: the Master List

What is known as the “Master List” presented here contains a list of those substances and groups of substances that are considered to be “of concern” in this research project. The list provides a guide as to which substances or groups of substances should not be present in mixtures and articles, if possible, from the point of view of the German Environmental Agency.

The term of the substance of concern

The list was composed independently of the definition of the term “substances of very high concern” according to REACH (cf. Article 57, REACH) and is broader. In this way, it will be possible to carry out a critical assessment of the health and environmental relevance of constituents in mixtures and articles that are unaffected by the compromise solutions of the REACH Regulation.

Examples of substances of concern in this sense are:

- Substances that are classified as carcinogenic, mutagenic or toxic for reproduction of Category 1 or Category 2 (CMR substances Categories 1 and 2)
- Substances that are classified as carcinogenic, mutagenic or toxic for reproduction Category 3 (CMR substances of Category 3)
- Substances that are classified as very toxic (T+)
- Respiratory sensitisers
- Skin sensitisers

- Endocrine disruptors
- Persistent, bioaccumulative and toxic (PBT) substances and very persistent and very bioaccumulative (vPvB) substances
- Persistent substances
- Bioaccumulative substances
- Substances classified as dangerous for the environment (with R50/53) and further substances of concern for the environment.

As a rule, substances and groups of substances were selected for the Master List on the basis of their classification according to Directive 67/548/EEC (at the time at which the project was being performed, it was not possible to carry out the classifications consistently according to the CLP Regulation). In individual areas, such as substances classified as skin sensitisers and substances dangerous for the environment, it was not possible to consider all classified substances because of the very high number of substances; instead there was (documented) prioritisation. In individual cases, substances were also included for which substance-specific data (e.g. from toxicological studies) supported inclusion in the list analogously to the particular classification criteria, even though there was no corresponding official classification according to Directive 67/548/EEC at the time. Finally, evaluations by groups of experts were also taken into account for some properties of concern, such as endocrine disruption, persistence and tendency to bioaccumulate, for which no classifications were provided under Directive 67/548/EEC.

Similar lists

Lists of substances of concern have already been drawn up by various institutions in the past. The project refers to the lists used in individual industries (e.g. electrical and electronic equipment) in the description of the particular industries. The Master List drawn up in the project is deliberately independent of industries.

A large number of industry-independent lists are available. What is new about the Master List drawn up here is that it provides a compilation of substances classified according to the individual properties of concern. No substances are excluded on account of production volumes or data on the usage pattern (e.g. evidence in product registers). This is the case with many other lists.

The number of substances

The various groups of substances of concern and the number of substances or groups of substances assigned to them are specified in the following Table 0-1. A total of approximately 800 substances of concern were found. Double entries were avoided when classifying the substances or groups of substances. If multiple classifications are possible, the substance or the substance group is assigned to the first table in which it is listed. In addition, all the substances classified as “dangerous for the environment” and “skin sensitisers” at the time of the evaluation are listed in the Annexes.

Table 0-1: Overview of the groups of substances of concern and the number of pertinent substances or groups of substances.

No.	Problematic property	Number of substances or groups of substances in the Master List	Remarks, Extensions of the Master List
1	CMR substances Categories 1 and 2	275	
2	CMR substances Category 3	153	without substances listed under No. 1
3	Very toxic substances (T+)	145	without substances listed under No. 1+2
4	Respiratory sensitisers	83	without substances listed under No. 1-3
5	Skin sensitisers	14 (selection)	737 substances or groups of substances (extension of the Master List)
6	Endocrine disruptors	67	without substances listed under No. 1-5
7	PBT/vPvB substances according to REACH criteria Annex XIII	9	without substances listed under No. 1-6
8	Persistent substances according to REACH criteria Annex XIII	28	without substances listed under No. 1-7
9	Bioaccumulative substances according to REACH criteria Annex XIII	20	without substances listed under No. 1-8
10	Further substances dangerous for the environment that have not been covered by the above named properties	no selection	449 substances or groups of substances (extension of the Master List)
	Total number of substances or groups of substances	794 substances in the Master List	1286 additional substances in the extended Master List

Topicality and limits of the Master List

Annex I of Directive 67/548/EEC including the 29th Adaptation to Technical Progress was evaluated in drawing up the lists. The 30th Adaptation to Technical Progress was used for substances that are carcinogenic, mutagenic and toxic for reproduction Categories 1 and 2 and for respiratory sensitisers and skin sensitisers.

The Master List is not designed to be a generally valid reference of substances of concern that can be used generally in this form beyond this project. Such a reference list would require constant updating of the substances. Moreover, such a generally valid reference list requires broader legitimization than the list drawn up here for the specific research project has.

Substances of concern in toys

The safety of toys to health is at the centre of public interest since children are a sensitive group of people and since – in comparison with adults – there may be an increased uptake of constituents of concern by the child's body (e.g. by mouth contact when playing).

Furthermore, toys are a group of articles for which a relatively large number of analytical results on exposures to chemicals exist, from which conclusions can be drawn for other product groups as well. With the European Toy Safety Directive, the toy industry has its own legislation that applies in addition to the specifications relating to the legislation on substances.

Lists of regulated substances and substances found

At the beginning, a list was compiled of the known substances of concern in toys in which the statutory regulations were evaluated with reference to toys:

- The currently valid European Toy Safety Directive (88/378/EEC)
- The new Toy Safety Directive (2009/48/EC)
- The REACH Regulation (Regulation (EC) No. 2006/1907, restrictions in Annex XVII¹)
- The German Consumer Goods Ordinance (BedGgstV)
- From the series of standards DIN EN 71 – Safety of Toys, standards DIN EN 71-3 (Migration of certain elements) and DIN EN 71-9 (Organic chemical compounds – requirements)

Further substances of concern relevant to toys are specified in voluntary product requirements (e.g. criteria for the “play well” or “Blue Angel” seals). The check lists from regulations, quality seals or related to toys include a total of approximately 68 substances or groups of substances, which we call “List of regulated substances”. For these substances, the reference to toys is documented and there appears to be a relevance (with regard to health or the environment) in the toy sector. This is only an approximate number, because groups of substances may contain several individual substances that may also feature as individual substances in such a list, and because – e.g. in the case of fragrances – there is no sharp demarcation as to which of them should in fact be included in the case of toys.

Subsequently, data on the actual occurrence of substances of concern in children’s toys were collated from numerous sources (“List of substances of concern found”). These sources include national statistics, test reports, international reports, personal communications of qualified people from laboratories and our own studies. The result was a list that covered approximately 70 different substances of concern or groups of substances that were found in toys. Particularly recent reports (generally from 2005 and only individual sources from 2001) were taken into consideration. However, the impression must not be conveyed that all substances of concern were tested in all studies. As a rule, the studies focus rather on only a small selection of substances. Therefore, the “List of substances of concern found” makes no claims to be complete – it must be assumed that there are a substantial number of further substances of concern that have not been discovered.

Among the 70 substances of concern found, 33 substances have already been covered by statutory regulations, but these were not observed, with the result that existing limit values for the concentration or release have been exceeded. In this group, excessive levels of plasticisers (phthalates), regulated dyes and heavy metals

¹ The REACH Candidate List was not yet available at the time of this analysis in 2008; however, most of the substances specified there are probably covered by other regulations.

as well as of solvents were mainly found – however, the number of 33 substances shows that the stipulations are frequently not implemented in the case of numerous further substances.

Most of the other substances that were found are covered by the new version of the Toy Directive; there are stricter provisions there particularly for CMR substances of Category 3. There is therefore uncertainty about a future binding regulation particularly in the case of some endocrine disruptors and some chemicals classified as PBT substances or dangerous for the environment.

Our own studies

The following toys were examined in this project:

- 35 plastic toys (e.g. plastic ducks, teething rings, rubber balls and dive snorkel masks),
 - a) for the material of which they consist,
 - b) with reference to defined individual compounds of concern (“target components”),
 - c) with reference to further substances of concern not previously restricted (“screening”),
- Two individual toys or toylike articles that were conspicuous on account of their odour (a bath toy and a hand exercise ball).

First, the main material component of the 35 toys was identified (differentiation of the plastics). Then a search was carried out for defined individual compounds (4-nonylphenol, 4-tert-octylphenol, isophorone, cyclododecane, 2-ethylhexanoic acid and benzophenone), after these substances of concern had been found more frequently in a different test in certain plastics used for toys. Only some of the results from the literature have been substantiated in the toys examined here: Elevated levels of 4-nonylphenol (up to 4500 mg/kg) were found in various PVC derivatives and isophorone was also observed in modified PVC and, small amounts of it, in ethylene vinyl acetate (EVA). 2-Ethylhexanoic acid was also detected in PVC derivatives (up to 4100 mg/kg). Only small levels of the other target components were found in the samples examined or none at all.

In the screening studies on the 35 toys, various phthalates (plasticisers) were particularly conspicuous, some of which are restricted in the toys field (Annex XVII, REACH) and the limit was substantially exceeded (up to 20 times) in individual articles. It also became apparent that there is a general trend to a switch to other phthalates that have not been classified under chemical legislation as substitutes for the banned phthalates. Other constituents or contaminants of concern were also discovered (bisphenol A, cyclohexanone, styrene, highly volatile chlorinated hydrocarbons, toluene and dimethyltin chloride), the levels of which were below 0.1% weight by weight, although it cannot safely be assumed that they are not relevant to health. The release would also have to be examined to obtain more accurate evidence, but there are currently no clear and valid rules for such a migration test.

Furthermore, dramatic hydrocarbon concentrations were determined in the hand exercise ball and one of the 35 toys mentioned above, a yellow koosh ball, which presumably contradicts the provisions of the Toy Safety Directive regarding ready flammability. If an article is not formally covered by the Toy Safety Directive, there is

no appropriate mandatory restriction. The emissions of volatile hydrocarbons are currently also posing a non-regulated problem with regard to health. This was also apparent in the case of bath toys (inflatable “bath beaver”). A total of approximately 3500 µg/m³ of volatile organic compounds were found in the bath beaver in the testing model. There are currently no (sum) limit values for such complex mixtures of volatile organic compounds (total volatile organic compounds; TVOC). Thus there is a difference between the situation here and that regarding construction materials.

Further development of legal regulations

As the result of the new version of the Toy Safety Directive (2009/48/EC), which will not be binding until July 2013 regarding the requirements in respect of chemical safety, some substances for which there have not previously been any specific restrictions, as for example substances of Category 3 suspected of being carcinogens, will also be regulated and restricted in toys. The measured values found show that such additional regulations are urgently needed. At present, such substances of concern are being found or released in material at concentrations that do not comply with the new limit values in the regulations that have been notified. However, a more exact analysis shows that the new provisions sometimes drop behind the previously valid limit values of the current Toy Safety Directive and now permit even higher limit values (e.g. for the migration of lead from scrap materials). Even the maximum concentrations of carcinogenic and mutagenic substances and substances toxic for reproduction (CMR substances) permitted under the new Toy Safety Directive are too high to ensure adequate protection for children.

Nor does the new version of the Toy Safety Directive provide any improvement for a number of substances of concern since for example endocrine disruptors (without simultaneous classification as toxic for reproduction) or the very environmentally dangerous PBT or vPvB substances are not covered. In future, however, some of these substances will be subject to authorisation according to REACH, which may result in relevant conditions for articles manufactured in Europe and would thus protect children at play. However, the consequences of authorisation according to REACH do not affect the importer that imports ready-made (toy) articles from outside the EU. This problem is of particular importance since the majority of toys imported into Europe come from China. Imported goods can only be appropriately regulated under REACH if corresponding restrictions are additionally laid down in Annex XVII of REACH.

Similarly, only consideration in the chemical safety assessment in connection with the substance registration is provided for environmentally damaging substances in articles such as toys outside the group of PBT or vPvB substances under REACH.

Finally, toys that are excluded from the scope of the Toy Safety Directive (e.g. swimming aids) are not subject to the important provisions of this directive. At a national level, the German Food, Consumer Goods and Feed Code (Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch; LFGB) steps in; however, specific examples are missing there as to when hazards to health must actually be assumed. Thus the LFGB does not provide any binding or clear regulations either.

Substances of concern in electrical/electronic equipment

Electrical and electronic articles (EE articles) are playing an ever greater role in private households. The lifespan of electronic equipment is becoming ever shorter, the import rate is high and the variety of materials used is large.

The sector-specific legislation at EU level for EE articles regarding chemical safety is still relatively young. In this connection, there is the Directive on the “Restriction of the use of hazardous substances in electrical and electronic equipment” (RoHS Directive; in force since 2006). Little information is available publicly to date about its implementation. Thus, on the one hand, the object of the project was to gain insight into the present degree of implementation of the RoHS Directive by manufacturers. On the other hand, it was to be investigated whether further substances of concern in EE articles require binding regulation.

The constantly shortening lifespan of electrical and electronic articles is also causing a disposal problem. The question arises whether aspects of environmental toxicology (effects on humans via substances in the environment) and ecotoxicology (effects on ecosystems) have sufficiently been taken into account in legislation and its current implementation.

Lists of regulated substances and substances found

Initially, the substance-related legal regulations with reference to the electrical/electronic industry (EE area) were evaluated for drawing up the List of regulated substances of concern:

- RoHS Directive (Directive 2002/95/EC)
- REACH Regulation (Regulation (EC) No. 2006/1907, particularly restrictions in Annex XVII and Candidate List for Annex XIV)
- POPs Regulation (Regulation (EC) No. 850/2004)
- German Chemicals Ban Ordinance (national law).

The Directive on “Waste Electrical and Electronic Equipment” (WEEE Directive, 2002/96/EC) is relevant to the collection and reuse of EE articles, although it does not contain the names of any substances.

There is also an analysis by the Institute for Applied Ecology (Öko-Institut), Freiburg, which, in a project of the EU Commission, was commissioned to determine substances of concern in EE articles. Finally there are “negative lists” for the EE area in industry, *i.e.* substances that, from the angle of manufacturers, should be used in articles only to a limited extent or avoided altogether. For orientation, an aggregated list of substances of concern in the EE area was drawn up from all these sources and including information from industry and material aspects (List of regulated substances). It covers some 53 substances or groups of substances. However, this number is only an approximate quantification since, on account of the different sources, the list contains some groups of substances like “lead and compounds” or individual substances that may also be found in a substance group.

Subsequently to the listing of potential substances of concern in EE articles, an attempt was made to determine substances that (at possible concentrations of concern) are in fact found in EE articles and/or are released from these. The result

was the “List of the substances of concern found”. The usual test journals, relevant publications and sources searched on the internet were evaluated, including communications by the chemical investigation offices of the German Federal States or the German Technical Inspection Association TÜV and foreign regulatory bodies. However, very few recent analytical results on substances of concern in EE articles were found. Statements about their hazard impact can thus only be made to a limited extent. Altogether, 25 substances of concern, some of them at an increased level, were found in EE articles. Since only a small number of the potential substances of concern were analysed in all studies that were evaluated, the list is neither complete nor representative. Apart from various heavy metals, flame retardants of concern were detected in EE articles, as well as various phthalates as plasticisers and PAH as contaminants. Furthermore, six of the 25 substances or groups of substances found were not included in the List of regulated substances of concern in the EE articles. They are 1,2-dibromomethane, formaldehyde, tetrachlormethane, N,N-dimethyl formamide, phenol and siloxanes. It should be investigated whether the list of known potential substances of concern should be extended accordingly.

Our own studies

One of our studies carried out and evaluated in the project was a series of measurements on ten cordless telephones from various manufacturers, comprising the following parameters:

- The substances lead, cadmium, chromium VI, mercury, polybrominated diphenyl ethers (PBDEs) and polybrominated biphenyls (PBBs) restricted under the RoHS Directive
- The material of the wire of the power supply unit and the presence of polycyclic aromatic hydrocarbons (PAH), phthalates or nonylphenol in it
- The material of the housing of the power supply unit and the presence of further brominated flame retardants (tetrabromobisphenol A (TBBPA), hexabromocyclododecane (HBCD) and brominated polymers) or other flame retardants in it

The studies were carried out by the Testing and Certification Institute of the German Association for Electrical, Electronic & Information Technologies (Verband der Elektrotechnik, Elektronik, Informationstechnik e.V.; VDE). First, an element screening was carried out and the six substances banned in the RoHS Directive were evaluated in more detail (lead, cadmium, chromium VI, mercury, polybrominated diphenyl ethers (PBDEs) and polybrominated biphenyls (PBBs)). Five out of the ten telephones examined proved to be non-RoHS compliant. One device even infringed the RoHS provisions in several respects. Most of the RoHS infringements found related to small components (e.g. increased chromium VI levels in hidden screws or loudspeaker components). In view of the small scope of the series of measurements, the substantial infringement of the RoHS stipulations in a cheap article can nevertheless be regarded as relevant evidence that serious infringements of the RoHS Directive occur in the European market.

Moreover, the housings and wires of the power supply units were tested for further substances of concern that are not listed in the RoHS; there was no evaluation of the gas phase (ambient air emissions). Among the housings of the power supply units, five consisted of ABS (acrylonitrile butadiene styrene) plastic, all of which were finished with brominated flame retardants, and five were made of PC (polycarbonate)

plastic, which contained only traces of bromine or none at all. The analysis of individual brominated flame retardants carried out showed that non-extractable (covalently bonded or macromolecular) brominated flame retardants are being increasingly used. Furthermore, tetrabromobisphenol A (TBBPA) used additively was found several times as brominated individual compound. Attention is drawn to the environmental problems of this substance and its avoidance at least in additive use. The synergistic flame retardant antimony trioxide was also always detected at higher concentrations of brominated flame retardants. However, extractable phosphorous compounds were not found in the housings of the power supply units; no nitrogen-containing flame retardants were investigated. High concentrations of aluminium in some samples indicate the use of hydroxide as a flame retardant, frequently in combination with brominated flame retardants.

The jackets of the wires of the power supply units of all ten telephones consisted of PVC and were tested for the use of phthalates as plasticisers and for contamination with nonylphenol and polycyclic aromatic hydrocarbons (PAH). Phthalates were used in nine out of ten cases; in three cases the plasticiser di(2-ethylhexyl) phthalate (DEHP) was used, which is on the Candidate List for authorisation under REACH as a substance of very high concern (SVHC). Nonylphenol was found only once at a very low concentration, and PAH, too, were only detected in very small amounts.

Our analysis of telephones and the evaluation of the few available control studies on RoHS compliance indicate that the RoHS provisions for computers tend to be adhered to more than for other electronic articles, and that electrical articles still do not comply with RoHS relatively frequently. However in-depth and more comprehensive studies are required for a representative assessment.

Further development of legal regulations

The consequences of REACH particularly refer to a possible restriction of further substances (extension of Annex XVII) or a possible authorisation requirement (Candidate List; inclusion in Annex XIV). It should be pointed out that the Candidate List under REACH is regularly extended. It already contains some substances that are also relevant for EE articles as for example certain flame retardants and plasticisers. For example, the persistent, bio-accumulative and toxic (PBT) flame retardant hexabromocyclododecane has been listed as a candidate for authorisation required under REACH, just as are some reproductive toxicant plasticisers from the group of phthalates.

A discussion on the future of the RoHS Directive as a further regulation in addition to REACH cannot currently be concluded since the demarcation between the two regulations is being reconsidered at present. However, the tendency is for the RoHS Directive to be developed further complementarily to REACH with criteria that make a more differentiated assessment of the waste phase possible. Moreover, the regulatory loophole for articles imported from outside the EU could be closed by including substances subject to authorisation under REACH in the RoHS Directive.

Effects of substances of concern on the environment under poor disposal or recycling technology

Particular attention focused on the effects of substances of concern in EE articles on the environment including the indirect effects on health resulting from contamination of the environment by these chemicals. The waste phase is of importance here,

although export to countries with poorer disposal and recycling technology should be borne in mind. Four relevant substances or groups of substances were considered:

- Mercury emissions from energy-saving light bulbs: This problem is particularly relevant since they are increasingly being used because of the restriction on electric light bulbs in Europe. In view of the neurotoxicity and reproduction toxicity and the accumulative effect of mercury (Hg), improved protection against the escape of Hg if a bulb breaks and a substantial increase of the share separated for the recycling of used bulbs that have been collected are essential demands that are put forward for avoiding negative effects on humans and the environment.
- Gallium arsenide as a semiconductor component: Its sharply increasing use in the electronic sector and particularly in the form of powerful LED illuminants call for the development of sustainable disposal channels in order to counter the carcinogenic potential of the substance itself and the possible release of arsenic (particularly during disposal and incineration).
- Brominated flame retardants as the cause of the formation of polybrominated dibenzodioxines and dibenzofuranes in plastic recyclates and in the unregulated disposal or uncontrolled, simple recycling processes outside the EU: Where technically feasible, the substantial abandonment of these flame retardants is advocated in order to make the mechanical recycling of the plastics in Germany possible without any problems and to be able to be fair to countries where there is no controlled disposal.
- Antimony trioxide as a synergistic flame retardant: The possible environmentally toxic and hitherto little heeded ecotoxic relevance is shown.

Substances of concern in floor and wall coverings

On account of their large surface, articles laid on extensive areas, such as wallpapers, floor carpets and flexible floor coverings, may release substantial amounts of hazardous substances into the ambient air either directly or adsorbed to dust particles. When children are playing, there may be skin contact with contaminated material or dust, and dust may be swallowed.

The regulations for consumer goods do not apply to floor and wall coverings. Instead, under a national regulation, extensive, fitted floor coverings are subject to technical authorisation by the German Institute for Construction Technology (Deutsches Institut für Bautechnik; DIBt)², which investigates indoor suitability. Movable rugs and carpets are currently only subject to the general restrictions for chemicals as they apply under REACH (Annex XVII) or the German Chemicals Ban Ordinance. Here, quality is monitored – if at all – by voluntary guidelines for granting various quality seals.

For these reasons, it seemed to be necessary to examine the consumer articles floor and wall coverings for substances of concern within the meaning of this project as well.

² Deutsches Institut für Bautechnik: <http://www.dibt.de>

Priorities were set on:

- Elastic floor coverings on the basis of polyvinylchloride (PVC)
- Elastic floor coverings on the basis of rubber
- Textile floor coverings (synthetic fibres; wall-to-wall carpeting, tiles, carpets and rugs)
- Textured wallpaper (fleece, generally based on PVC).

Lists of regulated substances and substances found

First, the question of regulations that are available for floor and wall coverings was examined. The following regulations were evaluated:

- REACH Regulation (Regulation (EC) No. 2006/1907, particularly restrictions in Annex XVII and Candidate List for Annex XIV)
- POPs Regulation (Regulation (EC) No. 850/2004)
- Principles of health assessment of construction products used in interiors ("Grundsätze zur gesundheitlichen Bewertung von Bauprodukten in Innenräumen") of Deutsches Institut für Bautechnik (DIBt)
- Standards DIN EN 14041 for floor coverings and DIN EN 15102 for decorative wall coverings

As far as substances are linked to content restrictions or release limits in these regulations, they were included in the consideration. An aggregated list of substances of concern for coverings was established for orientation on the basis of these sources and taking into account important quality seals and environmental seals (GUT, Oeko-Tex, RAL quality mark and Blue Angel) as well as information from the specific industry and about the materials. It includes 94 substances or groups of substances (List of regulated substances of concern). However, this number only permits a rough quantification since, because of the different sources, some groups of substances are listed, such as "lead and compounds", as well as individual substances that simultaneously belong to a group of substances (e.g. lead chromate). Categories of substances (e.g. "biocides", "carcinogenic substances Category 1" and "volatile organic substances") were excluded, although individual representatives of these categories have explicitly been included in the number and list (e.g. individual biocides or carcinogenic substances). Among these 94 substances there are five substances that are currently not listed in the Master List or that have only been included in the extended list (the extended Master List also comprises all substances classified as "dangerous for the environment" labelled with R50/53 and all substances classified as "sensitising"). These are the substances triclosan, 2,3,4,6-tetrachlorophenol, thiram, permethrin and zinc bis(diethyldithiocarbamate). They must also be classified as possibly relevant and of concern for the area of floor and wall coverings.

In addition to listing potential substances of concern, the attempt was made to determine substances that actually occur (possibly at concentrations of concern) in floor and wall coverings and/or are released from them (List of substances of concern found). Usual test journals, relevant publications and sources searched on the internet were evaluated including communications by the chemical investigations offices of the German Federal States and by foreign regulatory authorities or

laboratory reports (e.g. of the German Technical Inspection Association TÜV). Evaluation of the substances actually found in the articles (floor or wall coverings) revealed 36 substances or groups of substances in various coverings. Almost all substances found had already been mentioned in the list of the (above-mentioned) expected 94 substances of concern. However, this does not apply to five substances, namely 1,3-dichloro-2-propanol, aniline, 4-aminoazobenzene, chlorocresol and nonylphenol. These substances should possibly be added to the above-mentioned 94 substances or groups of substances for the area of floor and wall coverings.

Our own studies

Our own studies included the following floor and wall coverings:

- 11 wall coverings (foamed wallpaper and fleece wallpaper)
- 7 textile coverings (artificial fibres)
- 2 PVC floor coverings
- 8 rubber floorings

The following parameters were examined:

- Plasticisers in PVC wallpapers
- Polycyclic aromatic hydrocarbons in rubber coverings
- Styrene, naphthalene and 1,3-dichloropropanol in rubber coverings; evidence from a known case for the latter substance
- Azo dyes in textile coverings
- Flame retardants on the basis of bromine, phosphorus, boron, antimony or aluminium (mainly in PVC wallpapers)
- Organotin compounds (statistically distributed)
- Heavy metals (statistically distributed)
- Chlorinated paraffins (C₁₄-C₁₇; statistically distributed)
- Volatile organic substances (VOC) – determination by means of a screening approach (statistically distributed);
- Determination of fluorine in a carpet since the advertising message on the article suggested the use of fluorine as a dirt- and water-repellent fibre finish

The results provided evidence of organotin compounds (monobutyltin and mono-octyltin) in one elastic floor covering (PVC), but at a level of below 1 mg/kg. The antimony content was 29 mg/kg. High emission of volatile organic substances (VOC) at a sum value of almost 50 mg/m³ ("alkane accumulation") in one of the PVC coverings investigated here was also abnormal. Although the term of a "substance of concern" within the meaning of this project does not apply to volatile organic substances, they are to be limited according to the principles of approval by the DIBt and may be of concern to health as a mixture.

As expected, naphthalene was found in the rubber coverings, but at low levels (maximally 0.53 mg/kg). Likewise, only small amounts of styrene were detected (maximally 0.87 mg/kg). The carcinogenic 1,3-dichloro-2-propanol was not detected in any of the samples examined (< 0.1 mg/kg). Besides naphthalene, other polycyclic

aromatic hydrocarbons were found in rubber coverings (maximum value: pyrene at 13 mg/kg), but without the potent carcinogenic representatives such as benzo(a)pyrene. An increased lead content of 170 mg/kg observed in one rubber covering was too low for lead having been used as a stabiliser here. Although VOC emissions were increased (2470 µg/m³), no individual substances were identified that might be classified as being of concern within the meaning of this project.

As expected, a fluorine content of 232 mg/kg was determined in the carpet that has a fluorine-carbon finish (dirt-repellent). It is assumed that a persistent perfluorinated compound was used here; it is to be regarded as a substance of concern according to the Master List. A rug, which had been purchased commercially without a quality seal, revealed a 4-aminoazobenzene level of 19 mg/kg. The level of this azo dye is thus still below 30 mg/kg permitted under REACH, Annex XVII. However, the use of carcinogenic azo dyes should generally be avoided.

Flame retardants were considered in more detail in the case of PVC wallpapers. No brominated compounds were detected, nor was antimony used in the wall coverings examined. Lack of evidence of brominated compounds is not in line with data found in the literature. High aluminium levels were observed in three wallpapers examined (3100–5500 mg/kg), aluminium hydroxide being used as flame retardants. This is not a substance of concern. Medium-chain chlorinated paraffin levels of 9.68 mg/kg were found in one wallpaper. Again, unlike in literature data, no retardants on a phosphoric acid ester basis were determined in the wallpapers examined here, nor was zinc borate found.

All samples of the PVC wallpapers contained the plasticisers diisononyl phthalate (DINP) or diisodecyl phthalate (DIDP) at high concentrations (up to 121 g/kg DINP and up to 9.3 g/kg DIDP). Moreover, in individual cases, phthalates, which are on the Candidate List, were found: up to 2.1 g/kg diisobutyl phthalate (DIBP), up to 528 mg/kg bis(2-ethylhexyl) phthalate (DEHP; in one imported article) and up to 8 mg/kg dibutyl phthalate (DBP), only traces of the latter thus being found, probably as a contaminant. Diethyl hexyl adipate was observed in some wallpapers at a level of up to 3.8 g/kg. Food is allowed to contain up to 18 mg/kg of this non-classified substance, which is assessed as very toxic in the aquatic environment.

Three wallpapers were examined for organotin compounds. Contrary to reports in the literature, there was no evidence of a relevant organotin exposure here either.

In summary, the field of floor and wall coverings seems to be either regulated (DIBt approval) or addressed by voluntary labels. Therefore, violations of the existing standards were only observed in isolated cases. Attention should be paid to plasticisers that occur in wallpapers and are mentioned on the Candidate List and to the high emissions of volatile substances from PVC floor coverings and rubber.

Further development of legal regulations

There were no binding restrictions in the regulations for eight substances among the 36 substances of concern found in coverings, namely for nonylphenol, tetrabutyltin, permethrin, chlorocresol, antimony trioxide, tris(2-chloro-1-methylethyl) phosphite (TCPP), tris(2-chloroethyl) phosphate (TCEP) and triclosan. It is expected that in future all these eight substances will be regulated for the manufacture of floor and wall coverings in the EU via risk assessments of the substance registration under REACH or according to the authorisation of biocidal products and – in the case of TCEP – via the requirements of an authorisation under REACH. Nevertheless, a

regulation loophole not covered by REACH is expected to continue for imports unless additional restrictions are imposed.

The analysis also shows the substances for which the regulatory restrictions that exist seem to be imprecise or insufficient. Five substances or groups of substances were established: diethylhexyl phthalate (DEHP), lead compounds, perfluorooctanoate, dibutyltin and tributyltin.

In the case of DEHP, it is expected that REACH will lead to a clear improvement of the situation for floor and wall coverings, but the authorisation procedure will have no direct effect on imported articles. There are restrictions according to Annex XVII (REACH) for perfluorooctanoate and the two organotin compounds that also address imports. However, in our opinion, they are not far-reaching enough in view of the possibility of avoiding the use of the substances of concern mentioned. For a definite and effective EU-wide regulation of metals, such as lead, no generally applicable restrictions or bans related to the metal as an element exist, although individual substances are covered by the procedure of authorisation and restrictions under REACH. National authorisation according to DIBt that requires “toxic” or “very toxic” substances to be avoided should be examined with regard to the binding character of this requirement. If definite standards are applied to the “technical avoidability” as a criterion of authorisation/non-authorisation, authorisation according to DIBt might mean a regulation similarly comprehensive as authorisation according to REACH.

The evaluation finally provides information about violations of national or EU-wide regulatory provisions since levels or releases of substances of concern from floor and wall coverings were found that are not permitted even today. Such infringements were established for cadmium (PVC floor coverings), ethylhexanoic acid (PVC floor coverings), diisobutyl phthalate (PVC floor coverings), decabromodiphenyl ether (textile floor coverings), phenol (cork coverings; rubber coverings), naphthalene (rubber coverings) and 1,3-dichloro-2-propanol (rubber coverings). For example, in a test chamber study, a naphthalene emission of 136 µg/m³ was reported from a rubber floor covering, whereas the LCI (lowest concentration of interest) is 50 µg/m³.

Substances of concern in several industries: Focus on polycyclic aromatic hydrocarbons

The aim of the subproject “Substances of concern in typical materials” was to establish an association between the use of certain materials and the occurrence of individual substances of concern. Verification of such an association would improve the possibilities of taking monitoring measures and enable specific considerations of substitution to be initiated. The main focus was on the occurrence of polycyclic aromatic hydrocarbons (PAH) in various materials. This example was also used to analyse migration (and thus exposure), the toxicological data and the legal situation (REACH and other regulations).

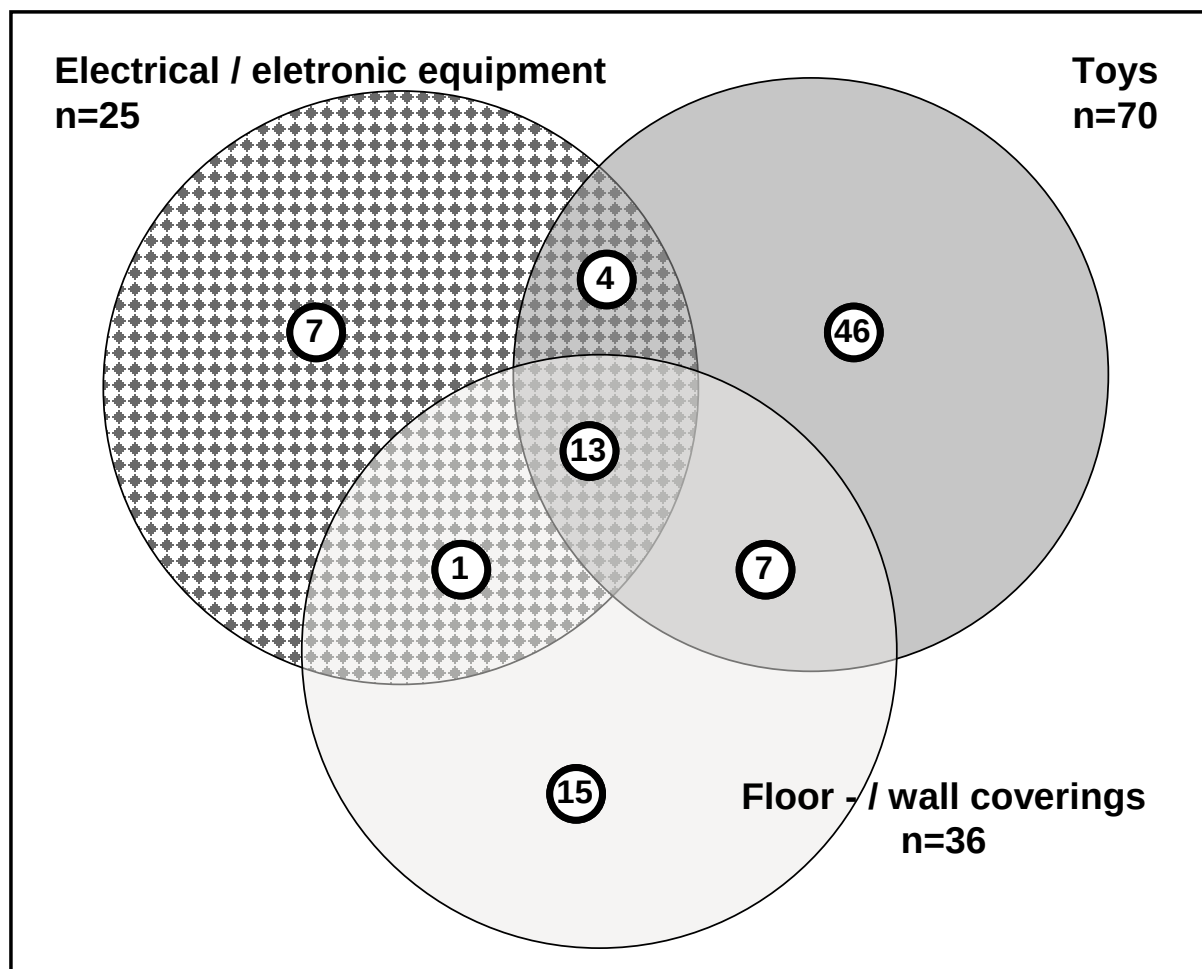
Assignment of substances to specific materials

Assignments between materials and additives they presumably contain can be made to a limited extent. This applies in particular to the consideration of functions that ought to be or must be guaranteed in materials. For example, these may be the functions of stabilisation, UV resistance, flame retardants, plasticisers, pigments and dyes, fragrances, etc., which can be related to certain basic materials (e.g. plastic polymers).

There are many such data related to specific industries. They are reported in the documented substance lists of this project. However, in most cases, reference to the material and the functions of substances (e.g. additives) are not limited to the group of articles and the specific industry. This means that additives contained in plastic material in toys may substantially be the same substances of concern as those contained in the same plastic material if it is used in the electrical or electronic industry or in the area of floor and wall coverings. A particularly well-known example of this is plasticised PVC, which is generally treated with plasticisers (phthalates) and often with certain flame retardants and stabilisers. However, the allocation of certain hazardous substances to certain materials is more difficult than expected since a large number of plastics exist (also as copolymers). In addition to the few known and regularly examined constituents, these may contain different additives that cannot be differentiated from each other in simple categories. Therefore, this approach is not very practicable for the laboratory. For plasticised PVC, however, the associations are relatively clear.

Substances of concern in the considered industries

In this project, a purely statistical evaluation was carried out by comparing the lists of substances found in the three industries (toys, electrical/electronic equipment and floor/wall coverings) that have been considered in detail here. The evaluations of Annexes 3.B, 4.B and 5.B ("Substances found") were used as a basis to investigate the substances that are of relevance for all industries. The evaluation is not complete since it cannot be ruled out for any of the groups of industries/articles that a specific consideration would have revealed even more identical substances of concern. Furthermore, no direct reference to the material was made. However, the relationships shown below (see Figure 0-1 and the following explanations) for example demonstrate the relevance of PVC plastics and the plasticisers and flame retardants they contain in all areas and the widespread occurrence of heavy metals as stabilisers or pigments. Formaldehyde that is detected in wood, for example, is also found in all industries. Furthermore, as expected, the PAH issue documented in detail here is reflected in all areas.



(Key: e.g. n=13 substances of concern or groups of substances that were found in electrical/electronic equipment, toys and floor and wall coverings; n=1 was found in both electrical/electronic equipment and floor/wall coverings.)

Figure 0-1: Substances of concern that were found in various industries

The 13 substances of concern found in all three industries are:

- Antimony
- Phthalates
 - o Diethylhexyl phthalate (DEHP)
 - o Dibutyl phthalate (DBP)
 - o Diisononyl phthalate (DINP)
 - o Diisodecyl phthalate (DIDP)
- Lead compounds
- Cadmium compounds
- Chromium compounds
- Formaldehyde
- Nonylphenol
- Phenol
- Toluene

- PAH

The following 7 substances/groups of substances were found both in the floor/wall covering industries and in the toy industry (no evidence in the electrical/electronic industries in this project):

- 2-Ethylhexanoic acid
- Aniline
- Azo dyes
- Medium-chain or short-chain chlorinated paraffins
- Diisobutyl phthalate (DIBP)
- Organotin compounds
- Tris(2-chlorethyl) phosphate (TCEP)

The following substance was found both in the electrical/electronic industries and in the floor/wall covering industries (no evidence in the toy industry in this project):

- Decabromodiphenyl ether

The following 4 substances/groups of substances were found both in the electrical/electronic industries and in the toy industry (no evidence in the floor/wall covering industries in this project):

- Benzene
- Cobalt
- Nickel
- Siloxane compounds

Polycyclic aromatic hydrocarbons in consumer articles

Polycyclic aromatic hydrocarbons (PAH), which are found in numerous materials and are regarded as being of concern because of their carcinogenicity, were considered in detail. They enter articles either via contaminated plasticiser oils, which are used in elastic plastics (rubber and plasticised PVC), or via carbon blacks for blackening. For example, PAH are found in:

- Parts of electrical equipment (switches, cable sheathing, power supplies, hoses, etc.)
- Handles (e.g. for tools, bicycles and hairbrushes)
- Contact areas of sports equipment (e.g. mats and dumbbells)
- Toys
- Other contact material close to the skin such as shoes and gloves
- Diverse consumer articles with skin contact such as headphones, mouse pads, bangles, steering wheel covers, etc.
- Tyres and rollers
- Floor coverings or artificial turf for which scrap tyre granules are used

- Other articles such as doormats, doorstops, hook coverings, elastic bands, etc.

In this project, PAH were found in one mouse pad and in bathing shoes, for example.

A thorough analysis revealed that the most important carcinogenic PAH are currently not included in the REACH Candidate List and have therefore not been envisaged for the authorisation procedure. The restrictions under REACH, Annex XVII, also include regulations for only a few individual uses of PAH in articles (in tyres or wood preservatives). The use of harmful constituents for consumer goods is basically banned, but in the absence of clear-cut definitions of the concentrations from which PAH in articles are to be regarded as harmful, there are no suitable limit values as a basis for action to be taken.

Moreover, linking concentration data with harmful effects is difficult since contact with an article does not necessarily release the total content (and thus becomes relevant to exposure). In the case of the migration analyses that must be envisaged here, there is still need for discussion about standardisation and a competent and adequately precautionary reflection of usual substance transitions when using articles contaminated with PAH (e.g. skin contact via handles and shoes and mouth contact in toys).

Although not all details of the methods are validated yet migration tests for the bathing shoes – which showed a very high content of PAH – were conducted. As migration liquid Ethanol and Isooctane were used, which are very common in the field of food testing. Based on the migration results an exposure assessment and a toxicological risk assessment were done. The risk assessment showed that consumer articles containing PAK can have a significant contribution to the risk of humans of getting skin cancer. In this respect the content of PAH in consumer articles should be minimized as far as possible.

In June 2010, in connection with this project and on the basis of parallel and further studies of the German supreme authorities, the Federal Government submitted an application to the EU Commission to envisage restrictions for PAH in consumer articles according to Annex XVII (REACH). The aim is to extend the regulation that currently applies to tyres (see No. 50 under Annex XVII). The tolerated level of PAH is to be limited to 0.2 mg/kg material according to the ALARA principle (“as low as reasonably achievable”).