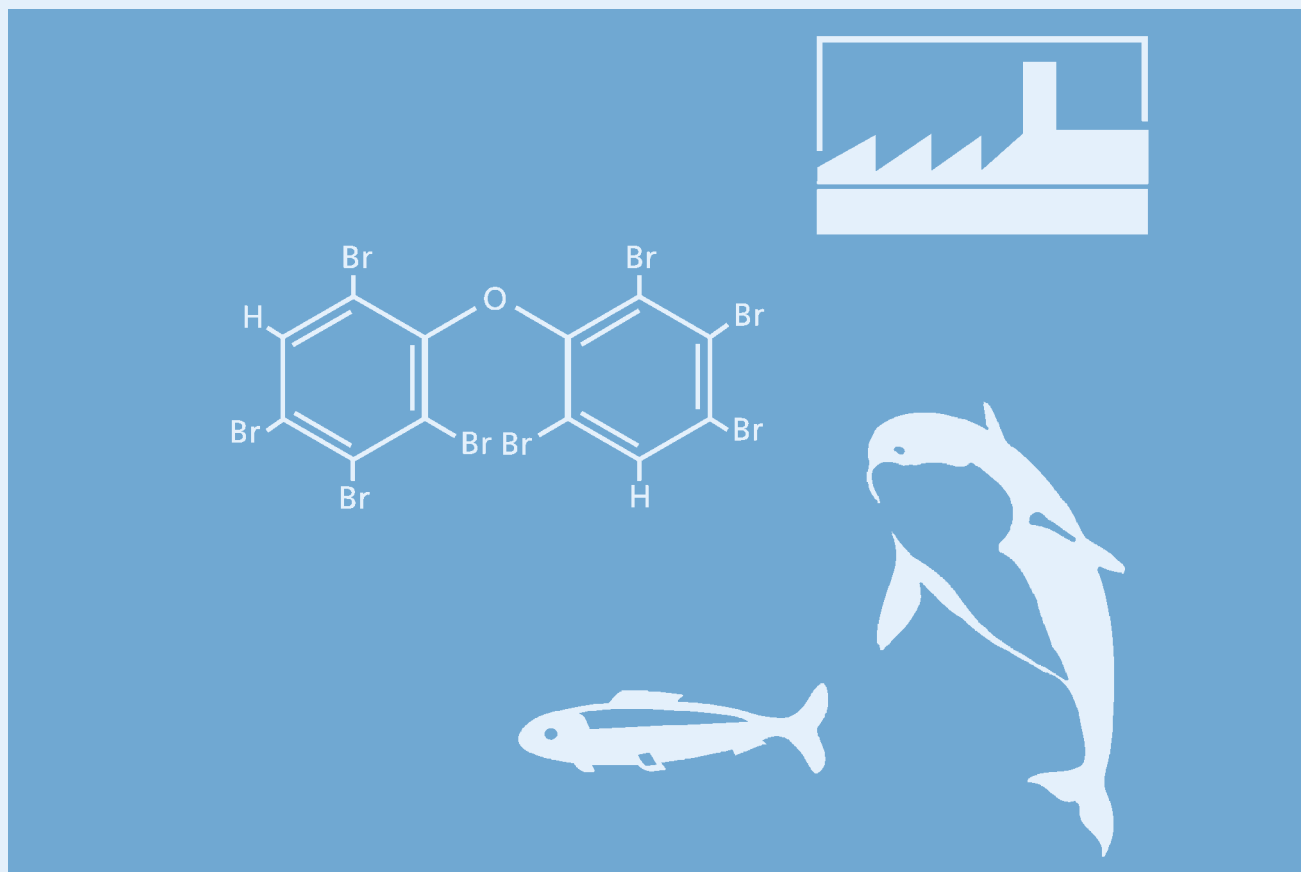

Guidance for the use of environmentally sound substances

*For producers and professional
users of chemical products relevant
to the aquatic environment*

PART ONE

*Five steps for the evaluation
of environmental risks*



February 2003

**Substitution of PBT*- substances
in products and processes**

* persistent, bioaccumulative, toxic

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Five steps for the evaluation of environmental risks

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Imprint

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Single modules of the guidance

Further parts of the guidance are of a more specific nature. They can be downloaded from the internet: www.umweltbundesamt.de/umweltvertraegliche-stoffe/leitfaden.htm

- Part 1: Five steps for the evaluation of environmental risks
- Part 2: Guidance for taking inventory and comparative assessment of substances
- Part 3: Product specific strategy – additives in plastics
- Part 4: Product specific strategy – cooling lubricants
- Part 5: Considerations on the substitution of certain hazardous substances
 - 5.1 Use category: Plasticisers
 - 5.2 Use category: Flame retardants
 - 5.3 Use category: Pigments and stabilisers
 - 5.4 Use category: High pressure additives in metal processing fluids
 - 5.5 Use category: Surfactants and emulsifiers
- Part 6: Example for practical implementation

Foreword

Chemical substances usually serve a specific technical purpose in a product or production process. At the same time, the technical qualities of a substance may be connected with risks to the environment and human health. A particular risk results from the release of long-lived (persistent) and harmful chemicals, which may accumulate in the long run in living organisms or water eco-systems. Such chemicals play an important role in the current European Chemicals Policy and the European Water Policy.

This guide is written for enterprises and industry associations. Its focus is on products and production processes which may contribute to the contamination of water eco-systems caused by persistent chemical substances. The focus is set on the many small emission sources which, when looking at their total contribution, pose however a risk to the environment and human health. Examples are textile finishing and metal processes and also plastic articles, textile products, electronic components or products for the construction sector (materials and chemicals).

The guide shall support the replacement of substances in products and processes, that are hazardous for the environment by less harmful solutions with sufficient technical performance (substitution). It can be regarded as a complement to the already existing instruments of corporate environmental protection and the evaluation of product safety. The guide may also be used in audits of company environmental management systems.

However, the guide is not a simple “recipe”, which can be used by all enterprises in the same way and without external assistance. Working with this guide requires certain expertise in chemicals and environmental legislation.

The guide mainly refers to organic industrial chemicals which are intentionally applied in products and processes and which, with a few exemptions, are not subject to authorisations. Neither pharmaceuticals, cosmetics, plant protection products and biocides nor accident related pollution of surface waters and emissions from combustion processes are elaborated on.

The first part of this guide explains which challenges manufacturers and users of chemical products will have to meet in the future. The guide introduces measures to be taken on the company level or in co-operation with other companies which may help to solve the problems in a systematic manner. It also contains a list of prioritised substances, which should be avoided in products and processes.

Further modules of the guide are more specific and can be downloaded from the internet: www.umweltbundesamt.de/umweltvertraegliche-stoffe/leitfaden.htm.

Naturally, the available information is not complete. Amendments and additions will be taken into account in the updating of this document.

The guide intentionally focuses on the risks chemicals pose to the environment. It is desirable that links to risk assessments related to chemical agents at the workplace are established on enterprise level.

1. New challenges

1.1 Technical performance of products and market trends

Almost all production processes, services and consumer products require the use of chemicals. Many times the technical performance of products and processes depends on the composition of the chemicals applied. Frequently the technical characteristics a client expects from a product are constituted by the combination of various chemicals.

In the past decades, aiming at producing high technical qualities at low prices has distracted attention from the fact that certain chemical substances may severely and permanently harm human health or influence the state of water eco-systems. Hence, the environmental quality of products and services should in future be considered more systematically in company practice. This would also contribute to avoiding serious conflicts with clients and the undesirable effects of bad reputation.

Moreover, placing more environmentally sound and high-performance products on the market may improve the overall competitiveness. Integrating ecological considerations into production may contribute to an improved transparency towards the business partner and hence gaining trust. At the same time such products may provide an added value to the final consumers (e.g. safe products).

The chances of an environmentally sound product thriving on the market depend on whether attractive groups of clients can be won for it and whether these clients can clearly see why a certain technology or a certain product is especially valuable from an environmental perspective. For purchasing products clients define selection criteria. Chemicals produced from renewable resources, for example, are regarded as especially “ecological” or product information disclosing the full composition would be regarded as “highly credible”.

1.2 Changing roles and responsibilities

In Spring 2001 the EU commission published the White Paper on a New European Chemicals Policy. According to the White Paper there are plans to request industrial users of chemicals, much more than in the past, actively to select the least risky solution for their respective technical needs (substitution). This means that the assessment of risks posed by chemicals at different levels in the supply chain, including the disposal, of a given product will be a basic duty that each individual enterprise will have to take care of. Taking over this responsibility will only be possible if close communication with chemicals producers and clients is established and maintained because the risk depends on the properties of the respective substance (classification, labelling) as well as the conditions under which it is applied. It is most likely that the forthcoming European chemicals legislation in 2004/5 will introduce a new system that obliges substance producers and importers to unambiguously define the dangerous properties as well as the intended uses of each chemical. Moreover, a risk assessment for the whole life-cycle and the operating conditions allowing a “safe use” will have to be specified in detail. In case the conditions described for a “safe” application are not met, the respective user takes over the full risk and responsibility for all possible consequences in the further supply chain. The user has to verify

that the varying conditions during usage still provide for a sufficiently safe handling of the chemical. Such verification can also be worked out in co-operation with the producer of the respective chemical.

The aim of the new regulation will be to close and prevent gaps in information flow and responsibilities in the life-cycle of a substance.

Flows of chemicals and flows of information

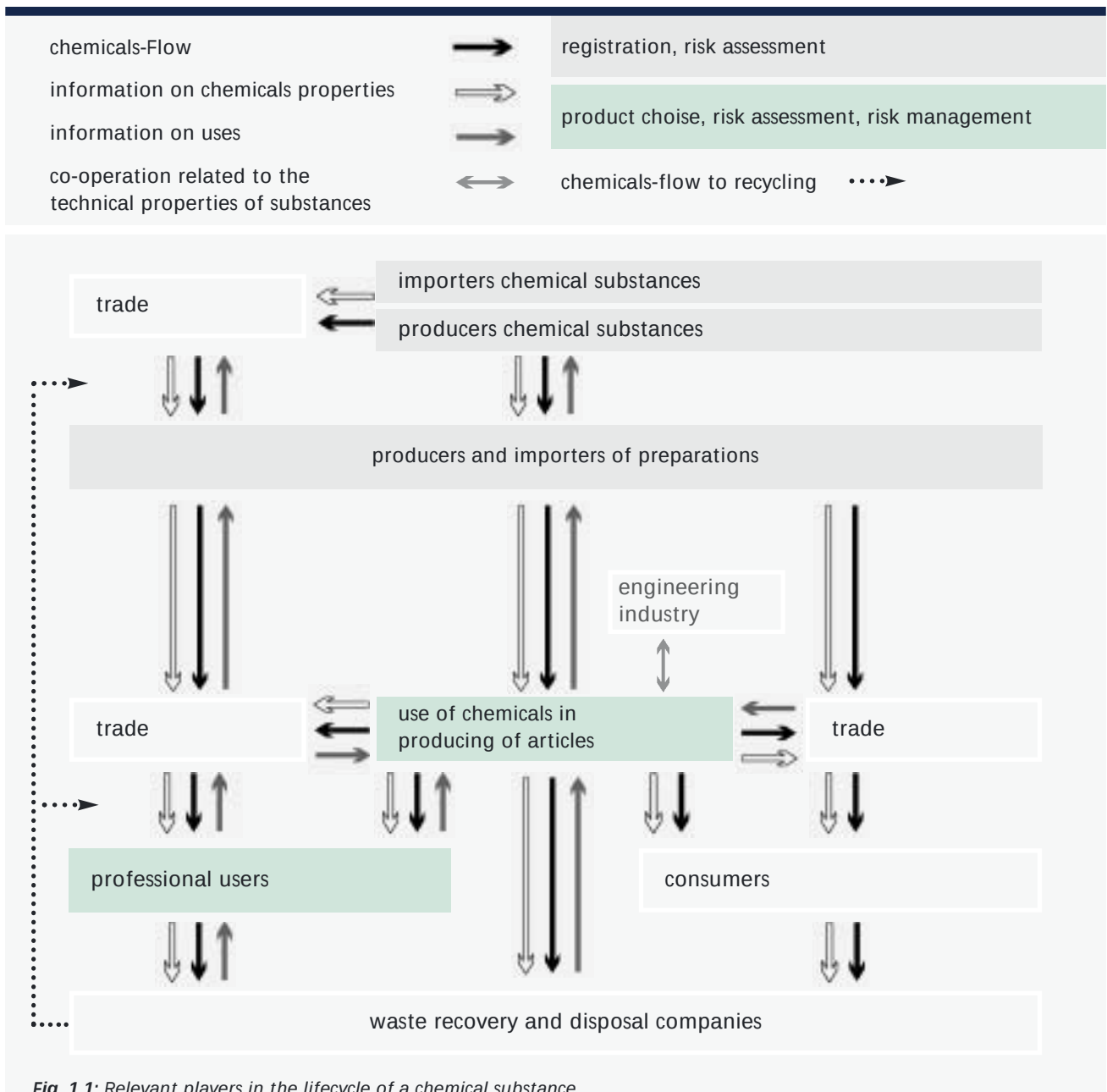


Fig. 1.1: Relevant players in the lifecycle of a chemical substance

1.3 Duties for evaluation and documentation

Until now, for the production and use of most chemicals, the principle “Everything that is not forbidden is allowed” was valid, and the burdens to proof adverse effects of a chemical lay with the authorities. This principle will be changed in the future by the new chemicals legislation. Producers and users of chemicals will have to be ready to demonstrate that adverse effects will most certainly not occur. Therefore, each enterprise handling chemicals in the supply chain will have to be able to provide adequate documentation of the effects a certain product may have, how it is used and should be disposed of, which releases may occur and how risks can be prevented in practice. Otherwise, companies will not be able to dispel the reasons for concern their clients, creditors or insurance companies as well as authorities may have.

1.4 Substitution of dangerous substances

According to the EU Commission, the substitution of dangerous substances by less dangerous alternatives in products and processes shall be implemented in enterprises and given high priority for continuous improvement. In the future, special emphasis will be placed on the avoidance of those substances which are especially long-lived (persistent = P) which accumulate in the environment (bioaccumulative = B) and which are toxic (toxic = T). In case such substances are released to the environment from products and processes,

- they may accumulate from waters (bioaccumulation) and harm organisms or may indirectly contaminate food for human consumption (especially fish and mussels),
- they may additionally accumulate in the food chain in a multi-step process (biomagnification) which especially affects animals and humans at the end of the food chain,
- long term-adverse effects on humans and the environment will be hardly predictable and
- it will not be possible to stop or reverse such damages once they do become visible, even if the chemical is immediately phased out from all uses.

Therefore, precaution should be taken and any release should be prevented.

The classification of substances (symbols of danger and respective R-phrases as e.g. R50/53) or material safety data sheets usually don't suffice for deciding if a substance is a PBT or not. Frequently additional information is necessary. The following picture (fig. 1.2) demonstrates the characteristics which indicate that a substance has or may have PBT properties. Risk prevention measures are to be taken in case all three critical properties (P+B+T) are found in one substance. Also for substances exhibiting only two of the three characteristics (P+B or P+T) the necessity for taking measures should be looked into.

Preparations not classified and labelled as dangerous may nevertheless contain persistent and bioaccumulative substances in relevant amounts¹. Therefore, respective additional information should be requested from the suppliers on a routine basis.

¹ In case such substances are not classified toxic for the aquatic environment ($LC_{50} \leq 10 \text{ mg/l}$) at the same time, classification in preparation is only needed when their concentration exceeds 25%.

What are PBT substances?

criteria	definition
<i>persistence</i>	Chemical substances, for which a 50% biodegradation under relevant environmental conditions takes more than 1 to 2 months (fresh water) or 4 to 6 months (sediments). ²
<i>bioaccumulation</i>	Substances which dissolve much more readily in body fats than in water and thus may accumulate in living tissue and body fluids. The critical threshold for the accumulation in tissue of aquatic organisms (fish) compared to the concentration in surrounding water is set at a bioconcentration factor (BCF) of 2000. ³
<i>persistence and high tendency to bioaccumulate</i>	Substances that are very persistent and very bioaccumulative (BCF > 5000) are considered very hazardous regardless if toxicity has been demonstrated or not.
<i>high aquatic toxicity</i>	Substances which are acutely toxic to algae, daphnia or fish at a concentration of $\leq 0,1$ mg/l in laboratory testing (50% of the test organisms die => LC ₅₀).
<i>toxicity to mammals</i>	Substances for which carcinogenic, mutagenic, reprotoxic or other chronic toxic effects have been demonstrated in humans or laboratory testing (category 1 or 2). Substances which are suspected of having carcinogenic, mutagenic, reprotoxic or other chronic toxic effects on animals (category 3).
<i>measured concentrations in the environment</i>	The analytical evidence of synthetic substances at sampling points far distant from the source of pollution or the evidence of occurrence in animal or human tissue may indicate that a substance is persistent or bioaccumulative.

Fig. 1.2: Criteria for the identification of substances especially harmful to the environment (PBT substances)

In future it will be necessary to replace dangerous substance with a more environmentally sound alternative. This may be another chemical substance or another material or a non-chemical solution (substitution). In some cases the solution can also be found in the prevention of releases of the dangerous substance by means of closed production processes, closed production cycles or changes in process management. The use of special coatings in products physically preventing the release of dangerous substances from the product may present an opportunity to reduce product-related risks.

Which of these strategies is best or most suitable depends on various factors, each of which must be evaluated by the individual enterprises. This guide introduces a systematic procedure supporting the consideration of the relevant issues and indicating who and for what external advice should be taken. The guide may also serve as a basis for communication between actors in the supply chain.

² For the protection of the marine environment and the assessment of substances on the EU-level, the preliminary values of 40 to 60 days in water and 120 to 180 days in sediments (depending on testing conditions) are applied. In case such data are not available, results of OECD screening tests may also be used (see fig. 1.9)

³ Preliminarily fixed value in the revised EU-Technical Guidance Document for the risk assessment of chemical substances. The critical value for a possible concern is set to a more protective value in the scope of the convention on the protection of the marine environment (OSPAR): BCF ≥ 500 and LC₅₀ ≤ 1 mg/l.

1.5 Measures for priority substances

In autumn 2001, the EU Commission published a list of 33 substances dangerous to water eco-systems, for which emission sources in processes and products shall be reduced with high priority. For half of these substances, the necessity for risk reduction has also been determined in the framework of the EU risk assessment program for “existing substances”. These substances include various additives and “active substances” which constitute the technical function and the durability of plastics, chemical construction materials (including paints), textile chemicals, metal processing fluids and industrial cleaners. A list of substances which have been classified as priority for the protection of waters is attached in Annex 1. The list contains:

- priority substances according to the EU Water Framework Directive,
- priority substances identified in the European Risk Assessment Programme on Existing Substances and identified in the evaluation programme regarding the protection of the marine environment in the scope of the Oslo and Paris Convention (OSPAR) and
- substances for which risks regarding the environment have been identified under the European Existing Substances Regulation (ESR) and thus for which risk reduction measures are needed.⁴

It is likely that these substances will be of high importance in permits for water discharges, European waste regulations, supply contracts with clients or as a topic in environmental reporting.

Moreover, it can be assumed that state authorities will determine the necessity to take action for other chemicals in the future. This will regard especially substances which

- are slowly degraded in the environment,
- are marketed in large amounts and enter the environment in considerable amounts during their service-life,
- have a tendency for bioaccumulation or
- dissolve well in water that efforts to supply drinking water from river bank filtrate must be considerably increased,
- may cause (eco)toxic effects,
- show hormone-like modes of action.

Therefore, it is wise to concentrate on identifying which substances or application types may require alternative solutions (securing of market!) in the future. Measures preventing the release of these substances into the environment as well as the use of less hazardous substances should be considered. In this context it is important that the alternatives can also be sufficiently evaluated so that a substitution does not result in a simple shift of risks. It is crucial that the overall risks are reduced.

⁴ Further substances are added continuously depending on the progress in the risk assessment work.

1.6 Decision making despite limited information

For many technically feasible alternative substances, producers can only give limited information on their physical-chemical and (eco)toxicological properties. Each enterprise seriously concerned with the substitution of hazardous chemicals will discover that there are considerable information gaps for alternative solutions and their risks. This means that it is necessary to discuss with the supplier which data are reviewed and available and where uncertainties about substitutes exist. Simple management rules should be applied in order to then take a decision.

1.7 The clients need to be informed

Starting in Summer 2002, all chemical products (preparations) containing substances hazardous for the environment must be labelled with the respective danger symbols and R-phrases. The amended EU directive 2001/58/EC on safety data sheets requires an extensive environment-related characterisation of chemical products. In the future, clients and authorities will expect from the users of chemical products that this information will be available at the company and that it will be evaluated with regard to the necessary risk reduction measures. This concerns for example the composition of wastes and waste waters as well as potentially hazardous substances in textiles, construction materials or furniture.

1.8 Market opportunities and innovation

The implementation of the new requirements at the enterprise level requires more working time, the coverage of costs for the collection of information, changes in communication with suppliers and business clients and, if necessary, investments for the modification of production process technologies or product designs. This has to be seen in the light of competition with national and foreign producers which invest less in the search for and use of healthy and environmentally sound substances.

Substitution takes time. Potential alternatives should be thoroughly assessed and adapted to the practical needs in order to prevent risks being shifted or technical quality being lost. It is also important to know how additional benefits gained by the substitution of hazardous substances can be communicated to the clients. What are then the advantages of actively promoting a systematic elimination of hazardous substance in products and processes and doing it earlier than the competitors?

- Manufacturers of consumer products and/or especially waste-relevant articles such as cars, electric and electronic devices, textiles or furniture will pose stronger demands for components free from hazardous substances to their suppliers. The situation will be similar for handicrafts and services for consumers.
- The general public and financial markets react sensitively to scandals. This also applies to scandals about hazardous substances. It will be possible to trace back chemical substances which are found for example in breast milk, food, drinking water or dolphins, revealing the identity of its producers and industrial or professional users. Pressure from the public, loss of a positive company image and decreasing turnovers are possible consequences.

- Globalisation leads to more intense competition. Germany-based producing companies will have advantages in that competition, whenever they can apply their technical know-how to fulfill special client's demands or to set quality standards. Consulting on the use of less dangerous chemical products and auxiliary processing chemicals can be one of these.

2. How the guide works

2.1 Existing legal requirements

Paragraph 16 of the Gefahrstoffverordnung (GefStoffV = German decree on dangerous substances) already obliges employers to carry out risk assessments at workplaces and to find alternative substances when the health of their employees is at risk. Environmental risks are to be taken into account in the search for alternative solutions (substitution). The requirements are explained in the TRGS 440*. The proposed "column model" also contains a column on environmental risks. In order to adapt the company management system for the protection of workers with an environment-related column in a straightforward way, this guide relates closely to the procedure of the TRGS 440.

A comparable dynamic duty to search for substitutes related to environmental risks does not exist so far. However, the responsibility for an environmentally sound product design and the application of "environmentally friendly" processes by producers of chemicals and operators of installations is mentioned in the Kreislaufwirtschafts- und Abfallgesetz (§ 22 ff)* as well as the Wasserhaushaltsgesetz (§ 21 b)* and the Bundesimmissionsschutzgesetz (§ 54)*. In the European Directive on Integrated Pollution Prevention and Control (96/61/EC) the assessment of possibilities for using less dangerous substances is required as an indirect basic duty of each operator of an installation (article 3a in connection with Annex III and Annex IV). It is therefore necessary not only to systematically assess chemical products regarding the protection of workers but also to take environmental risks and potential health risks for the clients into account. Chemical substances and preparations (mixtures of different substances) which are used in a manufacturing company must comply with the requirements of the chemicals legislation, labour safety and the protection of the environment. Besides the requirements of general product safety, the authorisation of certain ingredients for certain products (food packaging, toys) may play an important role if chemicals are manufactured into articles.

2.2 Risk factors and evaluation concepts

Whether a chemical substance has adverse effects on the environment in its practical application depends on four parameters:

Hazardousness of the substance:

- (1) Type of toxic effects (e.g. damage to liver function, developmental defects of mammal embryos, reduced ability of fish to swim), which may be caused after exposure to a certain amount of the substance for a certain time (in laboratory testing).

* Explanation in English see page 31

- (2) Environmental fate of the substance regarding the partitioning in environmental media (air, soil, water), its degradability and the tendency to accumulate in biota (bioaccumulation).

Exposure:

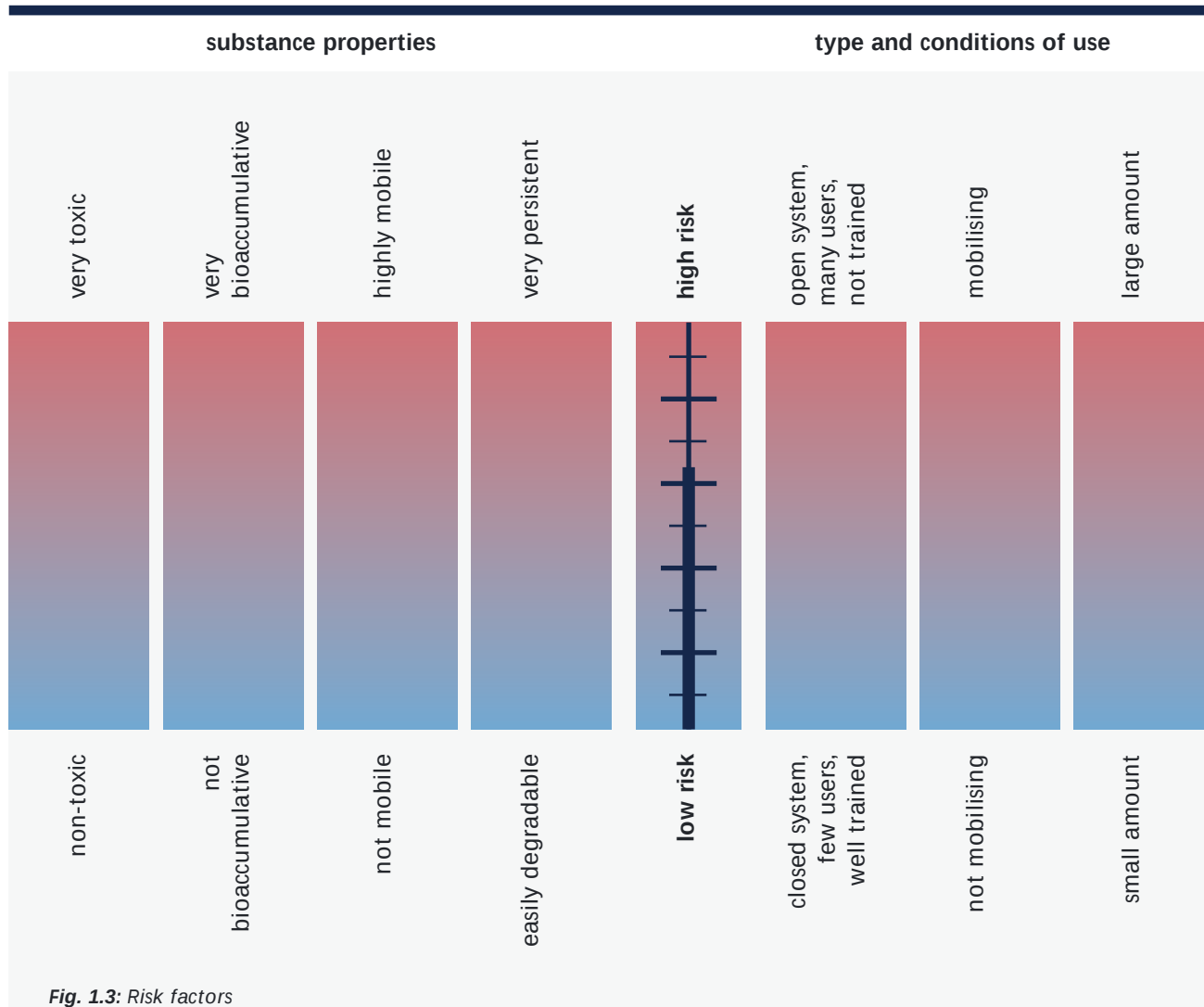
- (3) Amount of the substance which is released to water, air or soil during its application. This depends on the amount used, the conditions during application (e.g. temperature, abrasion) and the mobility of the substance (volatility, dustiness, water solubility, open or closed system). Frequently, the knowledge of these three factors alone allows for a qualitative estimation of where risks are to be expected.
- (4) Effective concentration, determined by transport and dilution as well as the environmental behaviour of the substance. The released amount of substances is diluted, adsorbed to sediments and dust particles or (partly) degraded, before humans, animals or plants are exposed to it. Measurements or models can predict the environmental concentrations, however, usually high measuring efforts or high safety margins are necessary.

Figure 1.3 illustrates the above mentioned dependency of the risk (probability of adverse environmental effects) on these two factors. A reduction or prevention of the risk is principally possible on both sides. Depending on the specific case, one strategy may be more efficient than another.

If a substance has especially hazardous properties (**red area**) it should be substituted by less hazardous alternatives. An exceptional use of the substance is possible, when it is ensured by the type of application that the substance cannot escape the “closed system” when being normally handled and used under normal conditions (blue area in “conditions of use”). In the extent of releases various factors play a role:

- Technical-organisational avoidance of losses of hazardous substances from products and processes: e.g. closed systems of operating facilities in metal processing, emission reducing process technology in processing plastics, minimised migration rates of additives from plastics or recollecting used cadmium-containing accumulators.
- The education (expertise) and the number of users of the products determine the rate of releases due to wrong applications that has to be anticipated. The number of users also determines the efforts necessary for collecting end-of-service-life products for their disposal.
- Mobilising conditions in the production, such as the temperature during application, contact with water or mechanical removal of material (dust) may lead to the release of substances.
- During the service-life of articles contained, substances may be mobilised by being heated up, weather conditions (e.g. wind and rain), mechanical abrasion (e.g. car tires) or intense contact with water (e.g. textile washing).
- In principle the following general rule applies: the larger the surface of a hazardous substances-containing article in relation to its volume, the higher are the diffuse losses. Diffuse losses from paints and plastic foils are therefore significantly higher than losses from solid plastic products.
- The percentage of diffuse losses rises with the life span of the article. Therefore, long-lasting articles (construction products, cars) play a special role.

$$\text{Risk} = \text{hazard of the substance} \times \text{exposure}$$

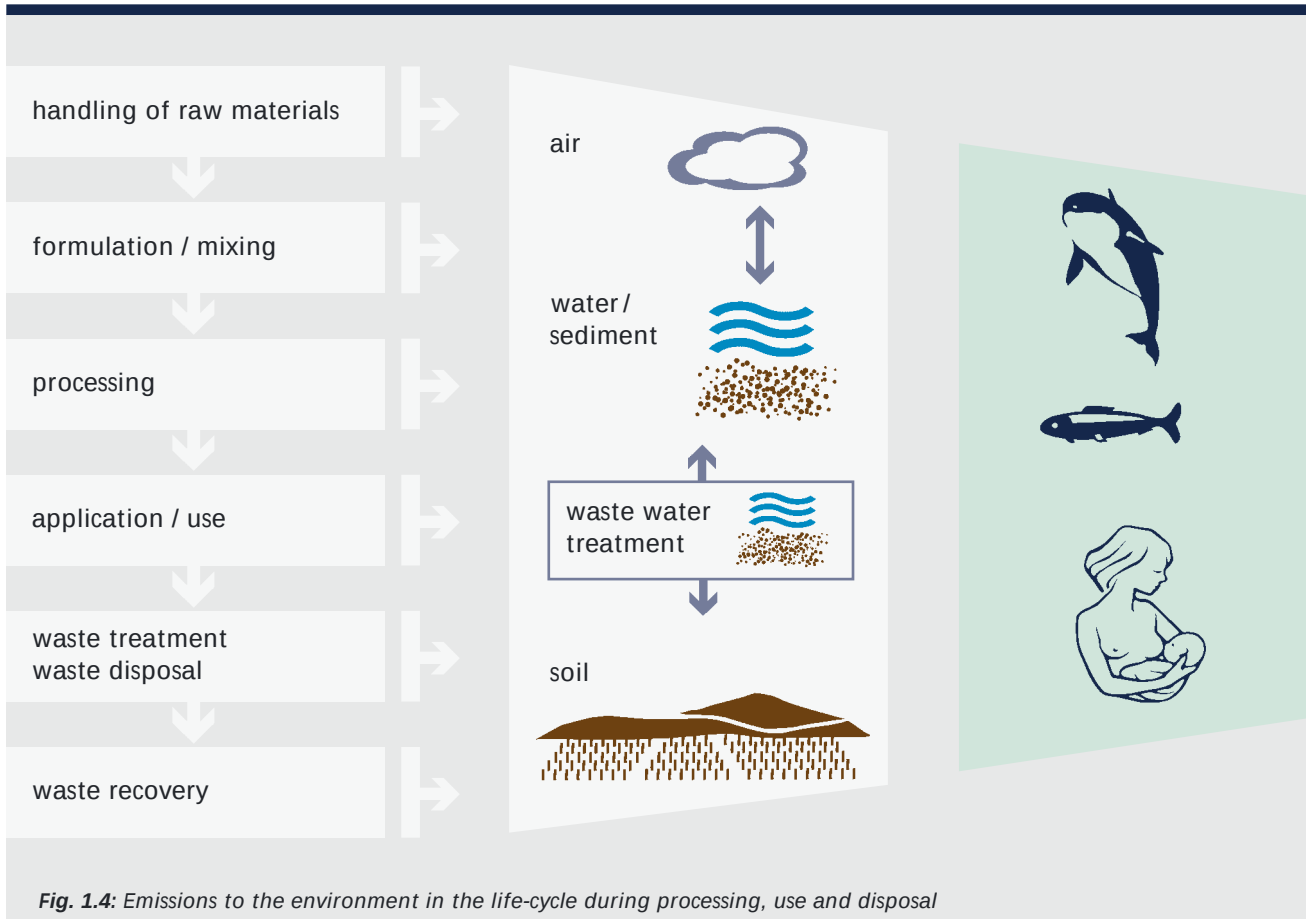


- Finally the market volume determines the extent of the potential risk of adverse effects. Substances in mass-produced products with market volumes above e.g. 100 000 tons per year may, just because of the amount, result in considerable concentrations in the environment, even if the rate of losses is very low.

If the substance properties are in the **blue area**, the substance can be used in a broad spectrum of applications by many users. If the substance properties are in the **purple area**, a less hazardous alternative solution should be found or conditions of use should be changed in a way that the released amounts are so small that they can be neglected.

Figure 1.4 shows in an abstract manner the emissions of a chemical to the environment at different life cycle stages.

Emissions to the environment in the life-cycle during processing, use and disposal



2.3 Five steps to assess environmental risks

The evaluation of input materials and possible alternatives requires an iterative information search. A step-wise procedure ensures that information needs are precisely identified and that only those data are investigated which are really essential. It is advised to apply an evaluation matrix similar to that used in labour protection work (TRGS 440) to support the transparent and qualitative estimation and consideration of risks.

The evaluation process consists of five main steps guiding the decision taking for a reasonable risk management strategy (see chapter 4 and 5, www.umweltbundesamt.de/umweltvertraegliche-stoffe/leitfaden.htm):

1. Taking inventory of chemicals with regard to use patterns and substance properties based on information at hand (e.g. classification, labelling, safety data sheets);
2. Stepwise elaboration of risk profiles, seek for additional information where needed;
3. Systematic estimation of potential releases based on further information;
4. Characterisation of hazardous properties based on further information;
5. Selection of an adequate management strategy and elaboration of measures.

3. Method for risk assessment

The risk factors shown in figure 1.3 may be used for the systematic comparison of different substitutes and for determining the alternative with the lowest risks. The risk factors relevant for the environment can be ranked on a five-step scale in the table in Figure 1.5. This evaluation matrix closely relates to the so called “column-model” that is proposed by the TRGS 440 for the evaluation of substitutes according to the § 16 of the GefStoffV on health hazards in the workplace.

Evaluation matrix

type of contribution of risk	substance properties					use pattern			risk-index ³
	persistence	bioaccumulation	aquatic toxicity	chronic toxicity for vertebrates	mobility (intrinsic) ¹	amount	mobilising conditions of use ²	indirect releases	
extent of risk contribution									
very high									
high									
medium									
low									
very low									
weighting									

¹ The intrinsic mobility is determined by the substance properties such as vapour pressure, dustiness, waterwater solubility or interferences with the product matrix.

² Mobilising conditions during use relate e.g. to the temperature during application, water contact, abrasion or atmospheric influences.

³ A weighting can be assigned to various contributions to the risk (e.g. persistence = very important = 0.3 = 30% of the total risk). The extent of the risk can be scaled by number from 1-5. Summing up the weighted numbers results in the risk index of a certain substance in a specific application.

Fig. 1.5: Evaluation matrix for the elaboration of risk profiles

Part 2 of the guide (www.umweltbundesamt.de/umweltvertraegliche-stoffe/leit-faden.htm) contains a system of indicators which support the ranking of substances in the evaluation matrix. Additionally, examples are given of how the different risk factors can be weighted against each other for comparing the assessment results of different substances (see part 2 of the guide, chapter 2).

4. Provision of information

4.1 Inventory of the chemicals used

Creating a good overview of chemical substances and preparations in use as well as the technical requirements they have to meet is the starting point for each assessment. The purchasing department, process technologists and production department should cooperate on this. Figure 1.6 shows which basic information is necessary for this. A systematic identification of all dangerous chemicals ⁵ is obligatory according to § 16.1 of the GefStoffV.

Inventory of chemicals used (minimum information)

- Substance identity or brand name of preparation, identity of dangerous components
- Name of producer or supplier
- Specific technical purpose and location of use within the enterprise
- Determination of company output path-ways for the respective chemicals
- Partitioning into waste waters and waste or air emission
- Specific technical purpose of use at the clients' in cases where the chemical is introduced into a finished product
- Fate in waste disposal and/or recovery (product waste)
- Amount used per year
- Classification and labelling
- EU Safety Data Sheet
- Technical data sheet.

Fig. 1.6: Necessary minimum information for carrying out a risk assessment

4.2 Step-by-step elaboration of risk profiles

Data collection should be done step-by-step and based on information which can be easily obtained, in order to help determine the selection of an effective management strategy. Information on substance properties and the conditions of use should be regarded as equally important. Further information should be sought on those items where the smallest efforts lead to improved decision making.

It may make sense, for example, to first clarify the conditions of use in detail and only then to decide which additional information on substance properties are necessary. For multi-purpose chemicals which are used under many different conditions, it may make sense to gather more information for the documentation of substance properties as a first step.

⁵ According to § 19 of the Chemikaliengesetz, dangerous chemicals are: Dangerous substances and preparations in the sense of the EU Directive 67/548; substances and preparations which have other chronically damaging properties; substances, preparations and finished products during the production and use of which dangerous substances or preparations may be formed or released. This means, for example, that a plasticizer-containing plastic article itself can be legally classified dangerous when dangerous plasticizers are released.

Steps for the elaboration of risk profiles

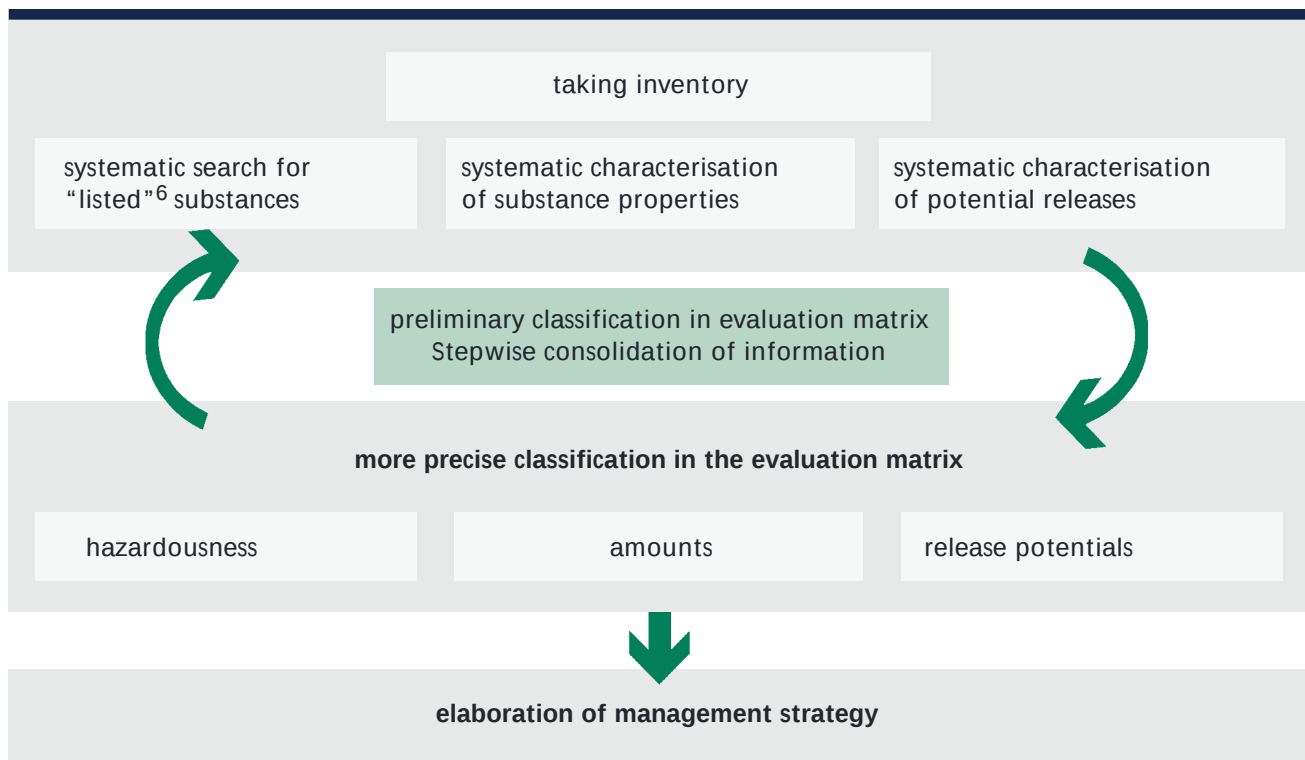


Fig. 1.7: Evaluation steps

It may be administrable to first fill out the evaluation table (fig. 1.5) with the information at hand and then decide where additional data are needed. If it appears that only relatively small contributions to a risk can be expected, further data collection can be foregone.

4.3 Estimation of potential releases

In order to concentrate the available resources at first on those substances, processes and products which are actually released into the environment in relevant amounts, the potential release pathways should be systematically estimated. For that, a minimum amount of information is needed, to allow for a rough determination of the probability with which critical releases of a substance may occur (criteria see fig. 1.8).

⁶ Substance lists in figure 1.10 of chapter 4.5

Factors influencing the exposure

1. application within the individual company or at the clients' [as far as it concerns process auxiliaries which do not remain in the article (see point 6 in this table)]
2. relevance of application for the water pathway
3. degree of containment of the installation
4. temperature during processing
5. state of abatement equipment for wastewater and waste air
6. final use of the substance as part of an article
7. destination of elements critical to disposal such as cadmium, lead, mercury, arsenic, antimony, chlorine and bromine
8. annual amount used in the enterprise

Examples in part 3 and 4 of the guidance

(www.umweltbundesamt.de/umweltvertraegliche-stoffe/leitfaden.htm)

Fig. 1.8: Minimum asset of information for the estimation of exposure potential

4.4 Completion of substance-related data

A judgement from the environmental perspective on substances in use requires an evaluation of the information in the safety data sheet (especially sections 9 and 12) as well as additional information which has to be obtained from the suppliers. Figure 1.9 shows the minimum information necessary from the perspective of water protection.

The evaluation according to the criteria of the GefStoffV leads to the classification (with respective R-phrases) and labelling as “dangerous for environment N” when a substance remains under or exceeds certain thresholds:

- A very toxic substance ($\leq 1\text{ mg/l}$) is classified “dangerous for environment N” with R50.
- A substance which is not readily degradable or is bioaccumulative with an acute toxicity of $\leq 1\text{ mg/l}$ is classified “dangerous for environment N” with R50/53. If the acute toxicity lies between 1 mg/l and 10 mg/l it is to be classified “dangerous for environment N” with R51/53. In case acute effects occur between 10 mg/l and 100 mg/l , R52/53 needs to be assigned, no label with “dangerous for environment N” is necessary
- Substances which are hardly soluble in water and for which neither ready degradation nor the absence of chronic effects in long-term testing have been proven, are to be classified R53.

If information in the safety data sheet (section 12) is either missing, contradictory or insufficient for judging the necessity of classification, further data should be obtained from the supplier.

The standard information in safety data sheets usually does not suffice for determining whether a PBT-risk exists. In figure 1.9 thresholds and testing methods are listed, which can be used to check the PBT properties of a substance in case the available information indicates a possible PBT profile:

- If ready degradation is not proven in the screening test and the octanol-water coefficient is high, further tests on inherent degradability and/or bioconcentration are necessary.

Information needs for substance evaluation (waters)

	Property	Criteria for classification according to GefStoffV	Critical threshold for PBT properties
P	1. biological degradability	not readily degradable ⁷ : OECD Screening 301 A-F	half-life > 60 days (marine) or > 40 days (freshwater), OECD simulation test 308 or ISO/DIN 14592-1/2; not inherently degradable ⁷ , OECD Screening 302 B-C
	2. potential persistence	no criteria	
B	3. partitioning coefficient octanol–water ⁸	$\log K_{OW} \geq 3$ OECD 107, 117	$\log K_{OW} > 4,5$
	4. test for bioaccumulation ⁹	$BCF \geq 100$ OECD 305 A-E	$BCF > 2000$
T	5.1 acute aquatic toxicity	$LC_{50} \leq 100$ mg/l $LC_{50} \leq 10$ mg/l $LC_{50} \leq 1$ mg/l OECD 201-203	$LC_{50} < 0,1$ mg/l not relevant if $BCF > 5000$
	5.2 chronic aquatic toxicity	If water solubility < 1 mg/l a NOEC may be needed.	$NOEC^{10} < 0,01$ mg/l
	6. water solubility ¹¹	see 5.2	Especially at vapour pressures between 10^{-6} Pa and 10^4 Pa releases and dispersion of PBTs are probable.
	7. vapour pressure	no criteria	

Fig. 1.9: Information needs for the further evaluation of environmental risks

⁷ In the test, less than 70% of the dissolved carbon (DOC) is degraded (or accordingly less than 60% of the theoretically possible carbon dioxide (CO₂) is produced).

⁸ $\log K_{OW}$ is the partitioning ratio between water and octanol on a logarithmic scale.

⁹ BCF = bioconcentration factor = concentration of a substance in living tissue compared to the concentration in surrounding water.

¹⁰ NOEC = No Observed Effect Concentration = highest concentration applied in long term testing, at which no effect could be observed.

¹¹ If the given concentration value for an observed acute toxic effect to fish or daphnia (LC_{50}) is higher than the water solubility, the results of the respective testing are hardly useful. They don't reflect the true concentration (dissolved and measured in water) which the test organism is exposed to, but only the nominal concentration. The true effect level may be much lower than the nominal test concentration. Therefore, a classification as dangerous (R53) is required for those substances which have a low water solubility, and ready biodegradability is not proven and the $\log K_{OW} \geq 3$. However, if long-term testing has revealed that no adverse effects on water organisms can be observed at true water solubility (e.g. OECD 202 or 203 test) the classification is not necessary.

4.5 “Listed” substances and other information sources

The term “negatively listed” refers to substances for which a need to avoid their use was expressed at the EU-level, national level or in certain industry sectors. The list of substances in this guide is a selection of those substances which are regarded as being a problem for waters in the European Union. Further substance lists of importance are shown in figure 1.10.

Figure 1.10 also contains links to other recommended data bases with the help of which first and general information on potentially critical properties of a certain substance may be obtained. In addition, the list contains a link to Emission Scenario Documents, which provide guidance on realistic emission factors for certain sectors of industry and production processes, based on which a deeper exposure analysis can be carried out.

In case chemical preparations rather than single substances are used, it is not always possible to find data in the product information on the content of “listed” substances. On his own behalf the producer must only indicate those dangerous ingredients which lead to the overall classification of the preparation as “dangerous for the environment N”. Therefore it is necessary to approach the supplier or producer of a respective preparation and ask for further information on substances dangerous for the environment that are contained in the preparation in a percentage exceeding 1% ¹². This procedure is common also for substances dangerous to human health (e.g. sensitizers).

¹² Threshold according to the Preparations Directive (99/45/EC) for the obligatory indication of dangerous components in preparations not classified dangerous themselves. In force since Summer 2002.

“Listed” substances and other information sources

content	status of information	institution	access
OSPAR List of Substances of Possible Concern: substances suspected of having PBT properties	suspect	OSPAR	www.ospar.org
Priority substances for the marine environment	definitive concern	OSPAR	www.ospar.org
Priority substance in European waters	definitive concern	EU Commission	http://europa.eu.int/comm/environment/water/water-dangersub/index_en.html
Priority substances under the EU existing substances regulations	partly regulatory measures expected	EU	http://ecb.jrc.it
List of substances hazardous to waters	definitive classification	UBA	www.umweltbundesamt.de/wgk.htm
SEARCH CLASSLAB: EU Database on classified dangerous substances (annex 1 to 67/548) and proposals on new classifications	definite classification	ECB	http://ecb.jrc.it/classification-labelling/
Observation List: Dangerous substances, the use of which shall be thoroughly checked	definitive concern	KEMI	www.kemi.se
List of Undesirable Substances: Dangerous substances, the use of which shall be thoroughly checked	definitive concern	Danish EPA	http://mst.dk/homepage/
List of priority substances suspected of having hormone-like properties	suspect	EU Commission	http://europa.eu.int/comm/environment
PBT Profiler: Online-instrument for checking substances regarding potential PBT-properties (no substance list!)	indication on the basis of modelled substance properties	US EPA	www.epa.gov/oppt/pbtprofiler
Syracuse EPIWIN: Software for checking environmental properties based on their molecular structure (about 100.000 substances)	indication based on modelled substance properties	Syracuse	http://esc.syrres.com/
N-Class Data Base of the Swedish chemicals inspectorate: Environment related data of about 7900 substances	indication based on measured substance properties	KEMI	http://www.kemi.se/aktuellt/nclass_eng.htm
EnviChem: Data Base of the Finnish Environmental Institutes on environment related properties of substances	indication based on measured substance properties	FEI	www.environment.fi/syke (CD ROM)
Ecotox Database (including AQUIRE): Database on environment related properties of substances	indication based on measured substance properties	US EPA	http://www.epa.gov/ecotox/
Environmental Residue-Effects Database (ERED): Literature data base	indication of measured occurrence of substances in tissue and measured adverse effects	US EPA	http://www.wes.army.mil/el/ered/
Risk Line: Database on health and environment related properties of substances	monographs (peer reviewed)	Kemi	http://www.kemi.se/riskline/index.htm
SPIN: Database of the Nordic Countries on uses of substances in preparations	indication of use patterns of substances	Nordic Chemicals Group	http://www.spin2000.net/spin.html
TGD: Emission Scenarios in the EU Technical Guidance Document (chapter 4) on Risk Assessment of chemical substances	indication of specific emission factors related to certain applications, and exposure estimates.	ECB	http://ecb.jrc.it/existing-chemicals/

Fig. 1.10: Substance lists, screening instruments and data base

5. Selecting the best management strategy

This guide recommends different management strategies, each consisting of a group of typical measures. Process-related strategies are distinguished from product-related strategies.

- (a) The process-related measures aim at reducing or preventing as far as possible all releases of dangerous substances into the work environment, waste, water and air.
- (b) For product-related strategies the whole life-cycle of substances contained in a product is considered. This concerns chemical products (preparations) as well as non-chemical products (articles). When assessing paints for example it needs to be taken into account that cleaning water for paint-brushes and bins is usually discharged into the sewage system. Also, the behaviour in waste disposal for example plays an important role in the evaluation of flame retardants in construction materials.

It is the explicit goal to reduce the entry of dangerous substances into the environment during the manufacture of a product, its processing and the service-life as well as during its disposal. To achieve this, four approaches are possible, depending on the hazardousness of the respective substance as well as the technical and organisational resources of the users to establish a sophisticated risk management strategy. Different management strategies can be assigned to each approach (compare figure 1.11).

Management strategies

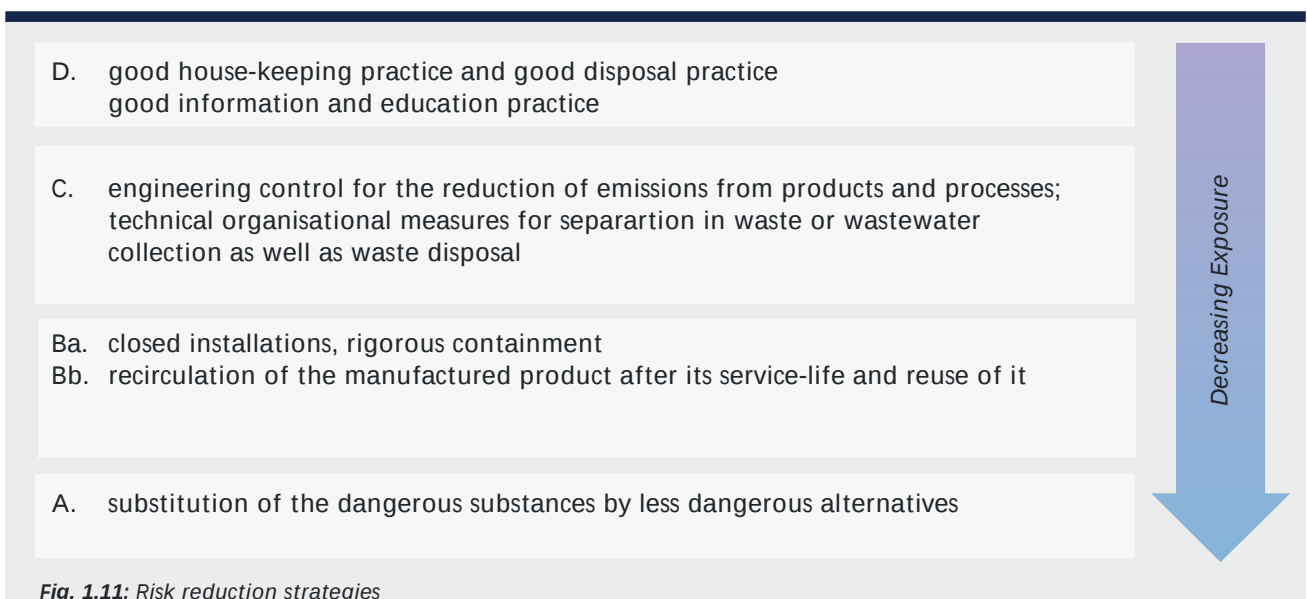


Fig. 1.11: Risk reduction strategies

Figure 1.12 gives an overview of standard risk reduction measures. Depending on the risk profiles the most reasonable combination of measures should be selected.

Risk reduction measures

product design (preparations and articles)	process design and process handling	Decreasing Exposure Potential
D. labelling of dangerous components, information of clients	D. good plant management (housekeeping, tidiness, maintenance, care for processing fluids) ¹³	
D. consultation and training of users of products	D. information and training of employees	
	C. efficient retention or destruction of substances on the waste gas or wastewater pathway	
C. decrease of the substance's mobility by altering the product design	C. external waste and waste water treatment with best available techniques	
C. decrease of amounts used per service unit	C. reduction of the amounts of process auxiliaries through changed design of machines or installation, optimisation of process management	
B. closing of the substance's circulation through economy by recollection of products after the end of their service	B. use of closed installation ¹⁴ , if necessary with external conditioning of process chemicals (no releases there as well)	
A2. substitution by a demonstrably less dangerous chemical	A2. substitution by a demonstrably less dangerous chemical	
A1. substitution by a non-chemical solution ¹⁵	A1. substitution by a non-chemical solution	

Fig. 1.12: Risk reduction measures

¹³ Caring for circulating processing chemicals, such as cooling lubricants, also belongs to a responsible labour protection approach (prevention of formation of dangerous substances and germs, TRGS 611, BGR 143, BioStoffVO). Taking care with auxiliary processes increases the lifetime of circulating media and reduces the amount of waste as well as releases into the environment.

¹⁴ Chemical substances can be released from a „closed installation“ during opening and closing, cleaning, together with wastes (or as process auxiliary material which needs to be conditioned) or as contamination on the product surface. An installation should be regarded as closed only when compared to the volume of the system the losses remain under 0.001-1% per year. The specific target to be achieved needs to be defined for each branch, substance or process separately.

¹⁵ The choice of a mechanical or physical solution or the selection of a base material which needs fewer auxiliaries is the most efficient form of reducing releases. A potential shift of risks to non-chemical effects (e.g. increase in energy consumption) should however always be examined.

The selection of a management strategy can be deduced from the substances' risk profiles. The risk profiles can also be used to compare alternative products (substitutes), which shall be applied under the same conditions. With the help of the evaluation matrix a rough overview can be created. The indicators for the evaluation and guidance for carrying out the evaluation (part 2 of the guidance) can be downloaded from the internet: www.umweltbundesamt.de/umweltvertraegliche-stoffe/leitfaden.htm.

When taking a decision, some principles should be followed:

- For all cases where the hazardousness of a substance is very high, management strategies of the type A (substitution) or type B (closed systems) are required.
- A prerequisite for a "closed" system at the product level is that the release behaviour of the product and the operating conditions during its use only lead to very small losses during the lifetime (e.g. dishware). This is hardly possible for products subject to high attrition such as car tires, brakes, soles of shoes or construction materials intended for out-door use.
- "Closed" systems, including waste collection, require that the articles are not dispersed in high amounts or over a wide area. If articles are dispersed it is almost impossible to install waste collection systems with high coverage. A good example of this are nickel-cadmium batteries for private use, for which return rates of less than 50% are realised.
- In substitution, only those alternative substances are desirable which are significantly less hazardous to human health and the environment. At the same time, the results of the other evaluation criteria should at least be equal to those of the substance to be substituted. A comparison between substances can only be performed if the minimum information on substance properties and the intended conditions of use are available.
- For substances with low or medium hazardousness, management strategies of the type C and D are usually sufficient.

After selecting a suitable strategy for risk management, the recommendations in more specific guidance on risk management can be applied, if available. These recommendations are specific to particular fields, products and processes and provide information on the reduction and prevention of environmentally relevant risks caused by dangerous substances. **Beginning in April 2003, guidance on risk management for additives in plastics and cooling lubricants (metal cutting fluids) are available on the website of the Umweltbundesamt (see part 3 and 4 of the guidance¹⁶).**

¹⁶ Depending on needs, the guidance could be extended to other product groups in future.

**Annex 1 – List of priority substances
(without active substances in plant protection products or pharmaceuticals)**

substance group	examples	CAS-Nr.	reference
metal compounds (org. and inorg.)	As and compounds	7440-38-2	[5]
	Cd and compounds *	7440-43-9	[1],[2],[4],[5]
	Hg and compounds *	7439-97-6	[1],[2],[4],[5]
	Pb and compounds °	7439-92-1	[1],[2],[5]
	Ni and compounds		[1]
chlorinated paraffins	Short chain chlorinated paraffins (C10-C13) *	85535-84-8	[1],[2]
	Medium chain chlorinated paraffins (C14-C17)	85535-85-9	[3]
chlorinated hydrocarbons	Trichloroethene (TRI)	79-01-6	[4]
	Tetrachloroethene (PER)	127-18-4	[4]
	1,2-Dichloroethane	107-06-2	[1],[4]
	Dichloromethane	75-09-2	[1]
	Trichloromethane (chloroform)	67-66-3	[1],[4]
	Tetrachloromethane	56-23-5	[4]
	Trichlorobenzene *	12002-48-1	[4]
	1,2,4 Trichlorobenzene	120-82-1	[1]
	1,3,5 Trichlorobenzene	108-70-3	[1]
	1,2,3 Trichlorobenzol	87-61-6	[1]
	Pentachlorobenzene *	608-93-5	[1]
	Hexachlorobenzene (HCB) *	118-74-1	[1],[4]
	Hexachlorobutadien (HCBd) *	87-68-3	[1],[4]
	Hexachlorocyclopentadiene	77-47-4	[2]
organic tin compounds	Tributyl tin (cation) *	36643-28-4	[1],[2],[5]
	Tetrabutyl tin	1461-25-2	[5]
	Triphenyl tin (cation)	668-34-8	[2],[5]
alkylphenol ethoxylates and degradation products	Nonylphenol *	25154-52-3	[1],[2]
	4-Nonylphenol *	104-40-5	[1]
	Octylphenol	1806-26-4	[1]
	(para-tert-octylphenole)	140-66-9	[1]
	2,4,6-tri-tert-butylphenole	732-26-3	[2]
musk compounds	Musk xylene	81-15-2	[2]
esters of phthalic acid	Di(ethylhexyl)phthalate (DEHP)°	117-81-7	[1],[2]
	Dibutylphthalate (DBP)	84-74-2	[2]
brominated flame retardants	Polybrominated Biphenyls	36355-01-8	[2]
	Polybrominated Diphenylethers *		[1],[2]
	Tetrabromobisphenol A	79-94-7	[2]
	Hexabromocyclododecane	25637-94-4	[2]
complexing agents	Ethylendiamintetraacetate (EDTA)	60-00-4	[3],[5]
	Diethylentriaminpentaacetate (DTPA)	67-43-6	[5]
other organic substances	Naphthalene	91-20-3	[1]
	Benzene	71-43-2	[1]
	4-tert-butyltoluene	98-51-1	[2]
	Neodecane acid, ethenylester	51000-52-3	[2]
	4-(dimethylbutylamino)diphenylamine (6 PPD)	793-24-8	[2]
	Hexamethyldisiloxane (HMDS)	107-46-0	[2]

substance group	examples	CAS-Nr.	reference
biocides	Hexachlorcyclohexane (HCH,all isomers.) *	608-73-1	[1],[2],[4]
	Pentachlorophenole (PCP)	87-86-5	[1],[2],[4]
	Diuron	330-54-1	[1],[3]
other organic pollutants	Polychlorinated dibenzodioxines (PCDD)	1746-01-6	[2],[5]
	Polychlorinated dibenzofuranes (PCDF)	1746-01-6	[2]
	Polychlorinated naphthalines (PCN)		[2]
	Polychlorinated biphenyls (PCB)	1336-36-3	[2]
	Polyaromatic hydrocarbons *		[1],[2],[5]
	Benzo-a-pyrene	50-32-8	
	Benzo-b-fluoranthene	205-99-2	
	Benzo-g,h,i-perylene	191-24-2	
	Benzo-k-fluoranthene	207-08-9	
	Indeno(1,2,3-cd)pyrene	193-39-5	
	Fluoranthene	206-44-0	
	Naphthaline		
	Anthracene *	120-12-7	

type of substance list	formal legitimation
[1] <i>priority substances according to the EU Water Framework Directive 2000/60/EC</i> * <i>priority hazardous substances according to EU Water Framework Directive (priority substances with PBT or similar properties)</i> ° <i>borderline "Priority hazardous" substance</i>	<i>decision 24/2001/EC of Council and Parliament</i> <i>evaluation by Expert Advisory Forum (EAF) [in scope of 24/2001/EC] and evaluation by EU Technical Meeting on Existing Substances [in scope of regulation 793/93/EC] till end of 2002</i>
[2] <i>OSPAR-List of substances for priority action</i>	<i>OSPAR List of Chemicals for Priority Action (Update 2002) [OSPAR 02/21/1-E, Annex 5]</i>
[3] <i>substances for which a need for risk reduction measures has been stated according to the EU "existing substances" regulation (state 2002, further substances may be added as the work progresses)</i>	<i>harmonized evaluations by EU Technical Meeting on Existing Substances [in scope of regulation 793/93/EC]</i>
[4] <i>annex 48 (use of certain dangerous substances) of the waste water decree (AbwV) in the version of 20.9.2001 (BGBl. I p.2440)</i>	<i>german waste water decree</i>
[5] <i>attachment on footnote 1 on the "self-commitment for the classification of textile processing chemicals according to their relevance for waters" of the association of textile, leather, tanning and detergents industry (TEGEWA).</i>	<i>commitment of a German industrial association</i>

Literature and legislation

Abwasserverordnung (Decree on waste water)

Verordnung über Anforderungen an das Einleiten von Abwasser in Gewässer. Publication of the new version of 15. October 2002. On the internet: <http://217.160.60.235/BGBL/bgbl1f/bgbl102s4047.pdf>

Bundesimmissionsschutzgesetz (Law on the protection from adverse effects on the environment)

Gesetz zum Schutz vor schädlichen Umwelteinwirkungen durch Luftverunreinigungen, Geräusche, Erschütterungen und ähnliche Vorgänge. New version of 26.09.2002. On the internet: <http://bundesrecht.juris.de/bundesrecht/bimschg/gesamt.pdf>

Chemikaliengesetz (Law on dangerous chemicals)

Gesetz zum Schutz vor gefährlichen Stoffen. Last version of 06.08.2002.
On the internet: <http://bundesrecht.juris.de/bundesrecht/chemg/gesamt.pdf>

EU Commission: Priority substances in European waters

Decision No 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 establishing the list of priority substances in the field of water policy and amending Directive 2000/60/EC
On the internet: http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_331/l_33120011215en00010005.pdf

EU Commission: Safety Data Sheet Directive

Commission Directive 2001/58/EC of 27 July 2001 amending for the second time Directive 91/155/EEC defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 14 of European Parliament and Council Directive 1999/45/EC and relating to dangerous substances in implementation of Article 27 of Council Directive 67/548/EEC (safety data sheets).
On the internet: http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_212/l_21220010807en00240033.pdf

European standard emission scenarios

are contained in part 4 (chapter 7) of the "Technical Guidance document in support of the commission directive 93/67/EEC on risk assessment for new notified substances and commission regulation (EC) no 1488/94 on risk assessment for existing substances".
On the internet http://ecb.jrc.it/Documents/Existing-Chemicals/TECHNICAL_GUIDANCE_DOCUMENT/

GefStoffV (Decree on dangerous chemicals)

Verordnung zum Schutz vor Gefahrstoffen (Gefahrstoffverordnung – GefStoffV). Version of 01.01.2003.
On the internet <http://www.baua.de/prax/ags/gefahrstoffv.pdf>

Kreislaufwirtschafts- und Abfallgesetz (Law on cycle economy and waste management)

Gesetz zur Förderung der Kreislaufwirtschaft und Sicherung der umweltverträglichen Beseitigung von Abfällen. Last version of 21st of August 2002. On the internet: http://bundesrecht.juris.de/bundesrecht/krw-_abfg/gesamt.pdf

OSPAR List of substances of possible concern (Reference Number 2002-17).

On the internet: <http://www.ospar.org/eng/html/substances/content.htm>

TRGS 200 (Technical Rules on dangerous chemicals)

Technische Regeln für Gefahrstoffe: Einstufung und Kennzeichnung von Substanzen, Zubereitungen und Erzeugnissen.
Published version of January 2003. On the internet http://www.baua.de/prax/ags/trgs_200.pdf

TRGS 220 (Technical Rules on dangerous chemicals)

Technische Regeln für Gefahrstoffe: Sicherheitsdatenblatt. Published version of January 2003.
On the internet: http://www.baua.de/prax/ags/trgs_220.pdf

TRGS 440 (Technical Rules on dangerous chemicals)

Technische Regeln für Gefahrstoffe: Ermitteln und Beurteilen der Gefährdungen durch Gefahrstoffe am Arbeitsplatz: Ermitteln von Gefahrstoffen und Methoden zur Gefahrstoffprüfung. Last version of 3/2002. (Identification and evaluating of risks at working place, methods to assess substitutes). On the internet <http://www.baua.de/prax/ags/trgs440.pdf>

Wassergefährdungsklassen (Water Hazard Classes)

Information on the classification into water hazard classes and downloads of formulars can be found on the web site of the Umweltbundesamt. (<http://www.umweltbundesamt.de/wgs/wgs-index.htm>)

Wasserhaushaltsgesetz (Law on water management)

Gesetz zur Ordnung des Wasserhaushalts last version of 19. August 2002.
On the internet: <http://217.160.60.235/BGBL/bgbl1f/bgbl102s3245.pdf>

White Paper on a Strategy for a future Chemicals Policy

Commission of the European Communities: White Paper– Strategy for a New Chemicals Policy. Comm(2001) 88 final.
On the internet http://europa.eu.int/comm/environment/chemicals/0188_en.pdf

EU Preparations Directive

Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations. On the internet: http://europa.eu.int/eur-lex/pri/de/oj/dat/1999/l_200/l_20019990730en00010068.pdf

**Substitution of PBT*- substances
in products and processes**

* persistent, bioaccumulative, toxic

**Guidance for the use of
environmentally sound substances**

*For producers and professional users
of chemical products relevant to the aquatic environment*

PART TWO

**Guidance for taking inventory and
comparative assessment of substances**

February 2003

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2. Foreword

Chemical substances usually serve a specific technical purpose in a product or production process. At the same time, the technical qualities of a substance may be connected with risks for the environment and human health. A relevant risk results from the release of long-lived (persistent) and harmful chemicals, which may accumulate in the long run in living organisms or water eco-systems. Such chemicals play an important role in the current European Chemicals Policy and the European Water Policy.

This guide is written for enterprises and industry associations. Its focus is on products and production processes which may contribute to the contamination of water eco-systems caused by persistent chemical substances. The focus is on the many small emission sources which, when looking at their total contribution, pose however a risk to the environment and human health. Examples are textile finishing and metal processing but also plastic articles, textile products, electronic components or products for the construction sector (materials and chemicals).

The guide shall support the replacement of substances in products and processes, that are hazardous for the environment by less harmful solutions with sufficient technical performance (substitution). It can be regarded as a complement to the already existing instruments of corporate environmental protection and the evaluation of product safety. The guide may also be used in audits of company environmental management systems.

The first part of this guide explains which challenges users of chemical products will have to meet in the future and how they can cope with them in a systematic manner, including internal measures in the company or co-operation between companies. Additionally, the guide contains a list of prioritised substances which should be avoided in products and processes.

The **second part of the guide** contains recommendations for taking inventory of substances used in a company, as well as for comparing risks in a qualitative way. Additionally, an overview of the most important applications and emission pathways for a selection of substances which are considered a priority in protection of European water eco-systems is given in table form. A Glossary with explanations of terms important for the assessment of substances can be found in the annex. A list of databases helpful for searching information is also included.

2.1 Issues in evaluation

At the company or association level, different strategies can be chosen for preventing or reducing the entry of hazardous substances into the environment.

Which of these strategies is most suitable depends on many factors which need to be assessed by each single company separately. The second part of the guide outlines a systematic procedure for determining the constitutive aspects of water-related risk reduction. The guide can also be regarded as a basis for communication between actors in the supply chain.

2.2 Evaluation model

The proposed evaluation model is closely related to the so-called "column model" of the TRGS 440 (Technical Rules on Dangerous Chemicals Number 440), which stipulate the basic principles and procedures of the health-related search for substitutes according to § 16 (2) of the GefStoffV (German Decree on Dangerous Chemicals). In Table 2.1, environmentally relevant risk factors (like persistence, bioaccumulation, amount, conditions of use) can be ranked on a 5-step scale. The estimation of the respective risk contribution of the single factors is explained in the following paragraphs. The evaluation matrix in Table 2.1 may be used for two kinds of assessments:

- Determination of a substance's risk profile in order to detect information gaps or room for improvement by comparing the single risk factors with one another.
- Comparison of dangerous substances with potential substitutes (chemical substances) regarding their environmental risks. In addition, it is always necessary to simultaneously assess health-related criteria. Depending on the company policy and the type of product, different weights can be assigned to the single risk factors. An overall risk-index can then be calculated which allows comparison of the different technical solutions.

The weighting of risk factors against one another highly depends for example on the question whether the technical function of the substance or protection of human health requires the biological stability of product components. Due to reasons of resource efficiency, waste prevention and labour protection it may for example be reasonable that metal cutting fluids are not easily biodegradable. In this case the risk reduction measures should focus on the prevention of releases within the company and during disposal. The contributions of the respective risk factors should be weighted accordingly in the overall evaluation. In other cases (e.g. detergents and cleaners) a high biodegradability is required, because the disposal regularly takes place in biological wastewater treatment plants. In this case, the risk factor *persistence* should be given special weight when products are compared.

Type of contribution to risk Extent of risk contribution	Persistence	Bioaccumulation	Aquatic toxicity	Chronic toxicity for vertebrates	Mobility (intrinsic) ¹	Amount	Mobilising conditions of use ²	Indirect releases	Risk-index ³
Very high									
High									
Medium									
Low									
Very low									
Weighting									

1. The intrinsic mobility is determined by the substance properties such as vapour pressure, dustiness, water solubility or interferences with the product matrix.
2. Mobilising conditions during use relate e.g. to the temperature during application, water contact, abrasion or atmospheric influences.
3. A weighting can be assigned to various contributions to the risk (e.g. persistence = very important = 0.3 = 30% of the total risk). The extent of the risk can be scaled by number from 1-5. Summing up the weighted numbers results in the risk index of a certain substance in a specific application.

2.3 Systematic search for substances to be substituted

An inventory of all handled substances is a prerequisite when systematically assessing which substances should be substituted in products and processes. According to GefStoffV, inventories containing information on at least all dangerous substances and preparations should be available in each company (compare § 16.1 GefStoffV). The following information is essential and should be made accessible by the inventory.

- Which substances or products are assigned the health-related risk phrases R45, R46, R48, R60, R61 (carcinogenic, mutagenic or reprotoxic, category I and II; other serious damage to health after prolonged exposure)?
- Which substances or products are assigned the environment-related risk phrases R50, R50/53, R51/53, R52/53, R53?
- Which substances or products are assigned the R-phrase for risks due to contamination of breast milk (R64)?

- Which substances or products are assigned the health-related risk phrases R40, R62, R63, R68 (Limited evidence of carcinogenic, mutagenic or reprotoxic effects shown in animal testing)?
- Are safety data sheets available for all of these products, including sufficient¹ *Ecological Information*? In section 12 of the safety data sheet respective information should be given. Otherwise, the producer should be requested to provide additional data on the ecotoxicological properties of his product.
- Are unambiguous recommendations given by the producers for all dangerous chemicals concerning the intended technical purposes of the products and how potential environmental risks can be avoided?
- Did the producer state for those products not classified regarding the environment, whether the non-classification is based on available test results or on “lack of data”. Producers are obliged to communicate the respective information.

The plausibility of information from suppliers should be checked. In case of doubts or in case different producers have provided conflicting information, advice can be obtained from associations, local authorities or another supplier who is trustworthy and competent. Data bases on the internet can also provide further information (see annex 3).

Table 2.2 gives an overview of the information necessary for carrying out assessment of substances related to the environment. The test results quoted in the safety data sheet should be the main data source. Only when this does not work in practice the evaluation should be based on R-phrases or on *Water Hazard Classes*.

¹ The necessary coverage of data can be seen in section 6.12 of the TRGS 220 (April 2002).

Information needs for the PBT evaluation			
Test results Property		Screening information => indication on potential PBT properties	Critical threshold for PBT properties in further testing
P	Biological degradability	Degradation rate in OECD test on ready degradation (OECD 301 A-F or equivalent); critical: $\leq 60\%$ of the theoretical amount of CO ₂ in 28 days ²	Half-life (DT ₅₀) ³ in OECD simulation test 308 or ISO/DIN 14592-1/2; critical: > 40 (60) days ⁴
		Degradation rate in screening test on inherent degradability (202 B-C); critical: $\leq 60\%$ CO ₂ ⁵	
B	Partitioning Octanol –water	Partitioning in octanol-water (log K _{OW}) ⁶ OECD 107/117 Critical: log K _{OW} > 4.5	
	Bioconcentration		Bioconcentration in fish tests (OECD 305 A-E or equivalent); Critical: BCF > 2000 [500] ⁷
T	Acute aquatic Toxicity ⁸		Critical: LC ₅₀ ⁹ < 0.1 [1] ¹⁰ mg/l If BCF > 5000 and the degradation half life exceeds 60 days, the measured toxicity is not relevant anymore.
	Chronic aquatic toxi- city		Critical: NOEC ¹¹ < 0.01 [0.1] ¹² mg/l If BCF > 5000 and the degradation half life exceeds 60 days, the measured toxicity is not relevant anymore.

Table 2.2: Information needs for the identification of substances with PBT properties

2.4 Qualitative risk evaluation

2.4.1 Systematic search for critical releases

In order to make sure that the available resources are concentrated first on those substances, processes and products which are actually released into the environment in relevant amounts, a minimum of emission-related information is necessary.

² Or equivalent test, e.g. disappearance of dissolved carbon (DOC) $\leq 70\%$ in 28 days; the degradation rate must be reached within 10 days after the beginning of degradation processes (10-day-window), except for surface active substances (surfactants, emulsifiers).

³ DT₅₀ is the time necessary for a 50% degradation of a substance (half life).

⁴ 60 days refers to the conditions for degradation in the marine environment, 40 days refers to conditions in freshwater.

⁵ Or equivalent test; if a degradation rate of more than 20% but less than 60% is reached within 28 days, the substance is regarded as degradable, but persistent degradation products can be formed.

⁶ Log K_{OW} is the relation with which a substance partitions between water and octanol, expressed on a logarithmic scale.

⁷ In the framework of marine protection strategies, the critical threshold is set at a BCF ≥ 500 (=> compare www.ospar.org)

⁸ When evaluating test results, it should be considered that only those effect concentrations are meaningful which are in the same range as the water solubility of the substance.

⁹ LC₅₀ is the concentration applied in a test at which 50% of the test organisms die. Other adverse effects is given as effect concentrations (EC₅₀) or inhibition concentration (IC₅₀)

¹⁰ In the framework of marine protection strategies the critical threshold is set at LC₅₀ ≤ 1 mg/l.

¹¹ NOEC = No Observed Effect Concentration = Highest tested concentration at which no effect was observed.

¹² In the framework of marine protection strategies the critical threshold is set at LC₅₀ ≤ 1 mg/l.

Recommended minimum information for the estimation of the environmentally relevant exposure potential		
Factor influencing the exposure	Less critical applications	Critical applications
1. Application within the own company or at the clients' site (as far as not part of articles)	Chemical synthesis Application in industrial installations	Application directly in the environment Application in private households Application in handicraft Application in small industries
2. Water relevance of the application	Substance or preparation does not come into contact with water	Substance or preparation is used in water based systems or in direct contact to environmental media.
3. Degree of containment	Substance or preparation is used in a closed installation ¹³ . Waste disposal by destruction or recycling.	Open or semi-open installation, occurrence of air emission or discharge
4. Temperature during application	Depending on the single case	
5. State of abatement equipment for wastewater and air emission	Waste gases and wastewaters are usually treated by high performance retention systems or biological wastewater treatment plants.	Emission control according to best available technique (BAT) is not ensured.
6. Final application of substance as component in articles	Products with small surface/volume relation Indoor uses No abrasion Normal temperature during application	Products with large surfaces, coatings Outdoor uses Abrasion to be expected Elevated temperature during use Durable article ¹⁴
7. Fate of elements problematic for disposal such as cadmium, lead, mercury, arsenic, antimony, chlorine and bromine	Small number of users Re-collection is ensured	Wide spread final use No specific re-collection or disposal system exists
8. Used amount per year at company level	The critical amount depends on the substance properties and the release potential. Stating a critical limit is not possible as a first step.	
9. Chemical-physical properties: log K _{OW} , vapour pressure, water solubility, dustiness	Release and partitioning behaviour can be estimated from the chemical-physical properties.	

Table 2.3: Minimum information needs for estimating exposure potential

The exposure potential is also an important issue for discussions with suppliers and may help in making plausible the need for additional information on substance properties. Only when the supplier of a substance or preparation understands the reasons why a user requests further information he will be willing to provide it. Occasionally, producers simply state that emissions to the environment cannot occur in certain applications and therefore don't provide ecotoxicological information. Here, it can help to make clear where exactly the risk of a release is seen. For certain industry branches and processes, European standard emission scenarios have been developed that can be used as an instrument for the estimation of ex-

¹³ As preliminary guidance, an installation should be regarded as closed when, compared to the volume of the system, the losses remain under 0.001 to 1% per year. The target to be achieved needs to be defined for each branch, substance or process separately.

¹⁴ In case of long-lived articles it is much more difficult to take risk management measures. If problems only become evident retrospectively, these products may remain in use for decades.

posure (information source see annex 3).

2.4.2 Substance properties as risk factor

The TRGS 440 contains a model for including the evaluation of environmental dangers into the assessment of substitutes according to §16 GefStoffV. This model is based on the classification established by the European chemicals legislation (R-phrases) and the classification according to *Water Hazard Classes*¹⁵. The long term hazards to the health of mammals (and birds) are of special importance from the environmental perspective when substances are persistent and/or bioaccumulative. In this case, the substances can be accumulated in the food chain and may cause the respective harm.

In this guide, the first ranking is based on the health-related risk phrases as given in sections 2 and 15 and the ecotoxicological information in sections 9 and 12 of the safety data sheets:

- Health-related risk phrases can be directly marked in the right column of Table 2.4
- In the columns on bioaccumulation or persistence, the hazard is to be classified as medium to high, where any of the following criteria are met:
 - The octanol-water partitioning coefficient of a substance ($\log P_{OW}$ or K_{OW}) > 4 (section 9) and the bioconcentration factor (BCF) determined in fish tests > 500 or no data is available (section 12).
 - The substance is not (readily) biodegradable or not inherently degradable [OECD 301 or 302 B-C] (section 12).
 - No comprehensible statements on the biological degradability of a substance and/or on the partitioning behaviour between octanol and water are given at all. The information “90% elimination in biological wastewater treatment plants” is for example insufficient to determine, whether the elimination is attributed to real biological degradation or to adsorption to sewage sludge. The indication “biologically degradable” alone (without reference to a test) is not satisfactory either because it remains unclear under which conditions the test has been carried out and how the degradation was measured.
- In the column *aquatic toxicity*, the results of tests with fish, daphnia or algae can be marked.
- In case the water hazard class of a substance is given in the safety data sheet it can also be noted down.

¹⁵ When ranking according to *water hazard classes* it needs to be kept in mind that in this system the criterion “acute toxicity” takes precedence over the criterion “environmental behaviour”. Consequently, the danger of toxic but non-persistent substances may be overestimated and that of persistent substances with no high acute toxicity may be underestimated.

Hazard-ousness	Water hazard class	Persistence and bioaccumulation		Aquatic toxicity [mg/l]	Chronic toxicity for humans or animals
		Persistence OECD Biodegradation Test 301 or 302	Bioaccumulation log K _{OW} or BCF		
E very high	3	Not readily degradable or not inherently degradable in OECD screening test	log K _{OW} > 4 and BCF not < 500	LC ₅₀ ≤ 1mg/l	R45, R46, R60, R61
D high	3				R40, R68, R62, R63, R64, R48
C medium	2			LC ₅₀ ≤ 10 mg/l	
B low	1			LC ₅₀ ≤ 100 mg/l	
A very low					

Table 2.4: Evaluation scheme for the first ranking according to aquatic toxicity

The results from OECD tests on ready degradability and the log K_{OW} usually do not allow for definitely determining whether or not a substance is persistent or accumulates in organisms or the food chain. Therefore the hazard classification with R-phrases R50/53, R51/53, R52/53 or R53 can only give indication about possible persistence or bioaccumulation.

If the safety data sheet does not contain sufficient information, or indicates slow degradation or a tendency to bioaccumulate, further data should be collected in a second step. Such data collection should begin with those substances which are actually released into the environment (see results according to Table 2.3).

With the help of the ranking scheme in Table 2.5. the degree of hazard of can be determined more precisely:

- Substances which are extremely toxic (LC₅₀ < 0.1 mg/l) to aquatic organisms can be determined using the data on acute toxicity (compare Section 12 of the safety data sheet)
- Bioconcentration factors determined in fish tests allow for an estimation of the probability with which a substance could accumulate in the food chain.
- Based on the results of the OECD tests on inherent degradability (OECD 202 B-C) it can be estimated whether degradation in biological wastewater treatment plants can be expected. If there are doubts as to the degradability of a substance, a simulation test can give further information on how long degradation under environmental conditions may take and which hazardous degradation products may be formed. The results are expressed in half-lives (DT₅₀) and refer to the number of days which are necessary for a 50% degradation.

Property	Persistence and bioaccumulation		Toxicity	
Level of hazard	Persistence ¹⁶	Bioaccumulation	Aquatic Toxicity [mg/l]	Chronic toxicity for humans or animals
E very high	and		and or	
	not readily or inherently degradable, unless DT ₅₀ < 60 days	log K _{OW} > 4.5 If BCF ¹⁷ not < 5000	not relevant for very persistent and very bioaccumulative substances	
	not readily or inherently degradable, unless DT ₅₀ < 40 [60] ¹⁸ days	log K _{OW} > 4.5 If BCF not < 2000	LC ₅₀ ≤ 0.1 (R50)	R45, R46, R60, R61
D high	and/or		and/or or	
	not readily or inherently degradable, unless DT ₅₀ < 40 [60] days	log K _{OW} > 4 If BCF not < 2000	LC ₅₀ ≤ 0.1 (R50)	R45, R46, R60, R61
	not readily or inherently degradable, unless DT ₅₀ < 40 [60] days	log K _{OW} > 4 If BCF not < 500	LC ₅₀ ≤ 1 (R50)	R40, R68, R62, R63, R64, R48
C medium	not readily but inherently degradable	log K _{OW} ≥ 3 If BCF not < 100	LC ₅₀ ≤ 10	
B low	readily degradable	log K _{OW} < 3	LC ₅₀ ≤ 100	
A very low			LC ₅₀ > 100	

Table 2.5: Evaluation scheme for a more in-depth evaluation of aquatic hazards

The substances need to be ranked separately for each criterion in the table. It is possible that not all substance properties are on the same level of hazard for all risk factors, because the table does not illustrate all conceivable cases. The highest level of hazard is only assigned in cases where the risk factors persistence and bioaccumulation occur together. The other levels of hazard result from an overall evaluation in which the risk factors are ranked independently of each other.

In case ecotoxicological data are missing (e.g. no log K_{OW} or no aquatic toxicity are given) the highest level of hazard is to be assumed until the supplier or producer has delivered the respective information.

Test methods on bio-degradability

With the OECD tests **on ready biodegradability** (OECD 301) it can be determined whether or not a substance is largely degraded to CO₂ and water within 4 weeks under laboratory conditions which are unfavourable for biodegradation (few nutrients, low concentration of bacteria).

With the OECD tests **on inherent biodegradability** (OECD 302) it is tested, whether a substance can be largely degraded within 4 weeks under optimal degradation conditions (e.g. biological wastewater treatment plant).

In the **simulation test** certain environmental conditions are simulated (water temperature, sediment fraction, bacteria from the potentially affected types of water). The changes in concentration of the original substances are measured during several weeks. Additionally to the determination of the half-life (number of days after which the starting concentration has decreased by 50%) degradation products are chemically analysed.

¹⁶ If the OECD standard test reveals that a substance is not readily degradable, its degradation behaviour requires further assessment. To this end, the half-life can be determined in a simulation test (e.g. OECD 308) or alternatively the test on inherent degradability

¹⁷ BCF-study on mussels or fish

¹⁸ degradation under marine conditions

When it is determined in the OECD screening tests that a substance is neither readily nor inherently degradable and it is also considered hazardous due to its bioaccumulation and toxicity, there are three alternatives:

- Substitution based on the precautionary approach where a readily degradable alternative is available, technically sensible and will not cause other risks
- Carrying out a simulation test for obtaining further data on persistence
- Strict prevention of any release during the whole life-cycle of the substance (only possible in case of very limited application and high technical and organisational efforts).

Many safety data sheets contain information on *Water Hazard Classes* (WHC). Which water hazard class a substance belongs to is determined by a relatively complicated scoring system which also uses results of ecotoxicological tests and R-phrases defined in the chemicals legislation (compare www.umweltbundesamt.de/wgs/). Nevertheless, the water hazard classes show accident-related substance properties rather than the properties important when considering daily emissions under normal conditions. Moreover health-related R-phrases are assigned a high importance because dangers from the handling of leaking substances in accidents during transportation and storage shall be reflected also. A high acute toxicity expressed with the R-phrases R26 and R28 in combination with a high aquatic toxicity (R50) already leads to a classification in WHC 3 and hence to a significant overestimation of the danger regarding the long-term risk for accumulation.

The WHC 2 can over- or underestimate the environmental risks depending on the specific case. In Table 2.6 examples are given which show,

- how long-term dangers may be overestimated by assigning too much weight to acute effects, or
- how the classification as “dangerous for the environment N” with R50/53 in connection with demonstrated toxicity to reproduction (R60 or R61) may lead to an underestimation of the PBT-risk when using the WHC-system.

An exclusive orientation by water hazard classes may lead to wrong priority setting in the company. Substances and preparations belonging to the WHC 2 and 3 should therefore be primarily regarded as **PBT-candidates** in the same manner as products classified R53 (alone or in combination with other R-phrases) if no further information is provided in sections 9 and 12 of the safety data sheet. If no environmental substance information is given at all, the same precautionary approach should be taken.

R-phrases	Resulting WHC	Reflection of PBT-Risks
Health-related R-phrases R23 to 28 or R39 or R48 Plus R50 ($LC_{50} \leq 1\text{mg/l}$) without R53 (readily degradable and not bioaccumulative)	WHC 2	Overestimation
Health-related R-phrases: R60 or 61 Plus R50 ($LC_{50} \leq 1\text{mg/l}$) with R53 (not readily degradable and/or bioaccumulative)	WHC 2	Underestimation

Table 2.6: Possible ambiguity in reflecting long-term risks of substances by WHCs

The method of assigning water hazard classes to substances is defined in the Verwaltungsvorschrift für wassergefährdende Stoffe (*administrative regulation of substances dangerous to waters* (VwVwS)). If it is unclear due to which properties a substance has been classified in the WHC system, Umweltbundesamt can be approached to obtain the relevant data set (FG IV 2.6, Documentation and Information point for substances dangerous to waters, Tel: 030-8903-4169).

2.4.3 Amounts as risk factor

When evaluating environmental risks, the continuously released¹⁹ amounts of substances play a central role. As it is difficult to determine the exact amount of a substance released during the life-cycle of a chemical, usually the worst case is assumed as long as no better data is available. The amounts which can be potentially released at the company level can be calculated taking the amount used in the company and a rough estimation factor for the total release: for example 20% emission for applications in industrial processes and 100% release for applications in preparations intended for general commercial or private use.

Potential exposure	Annual amount ²⁰ of substance in preparations intended for general commercial use outside installations or use in private households.	Annual amount ²¹ of substance for applications in well controlled industrial processes or installations
E very high	> 10 t	> 50 t
D high	> 1,0 t	> 5 t
C medium	> 0,1 t	> 0,5 t
B low	> 0,01 t	> 0,05 t
A very low	< 0,01 t	< 0,05 t

Table 2.7: Evaluation scheme for the ranking of amounts handled in the company

The scale takes into account that chemicals legislation applies to substances when placed on the market in volumes of > 0.01 t/a per company.

¹⁹ Continuous releases means the permanent emissions or losses occurring during normal operating conditions in installations or during the normal use of a product in its intended applications. This excludes all types of accidents and incidents occurring during processing.

²⁰ Amount released from a company (process auxiliaries or product components), if a substance is intended for general commercial use or for private households.

²¹ Amounts applied in a company (process auxiliaries or product components) if the substance is exclusively intended for application in industrial installations. It is assumed that the potentially released amounts are five times lower than in a wide disperse application in households and general commercial activities.

2.4.4 Risk factor „mobility under conditions of use“

The potential release of chemical substances from production processes and finished products depends on the substance properties as well as the conditions under which it is used. Analogous to the column model of the TRGS, the following table assigns different levels of exposure to the release potential. The substance properties are characterised by water solubility, vapour pressure and, for solid substances, particle size. For substances which are used as additives in different materials such as polymers, leather, glass, paper, wood, metal bodies or alloys, the strength with which the substance binds to the matrix is important. Flame retardants, for example, which are chemically fixed to the carbon chains, show a lower mobility than additive flame retardants, which can migrate through the polymer matrix. To estimate the tendency to migrate or diffuse only a few standardised methods exist to date. Respective references can be found in the third part of the guide.

Potential Exposure	Potential release due to Water solubility ²²	Potential release due to Vapour pressure ²³ or dustiness	Binding to matrix, Migration in standard test ²⁴
E very high	> 100 mg/l	Dusty substances or aerosols $10^0 - 10^4$ Pa	Not bound to matrix
D high	10 – 100 mg/l	$10^{-3} - 10^0$ Pa	High mobility in the matrix
C medium	0,1 – 10 mg/l	$10^{-3} - 10^{-6}$ Pa	Medium mobility in the matrix
B low	1 – 100 µg/l	$< 10^{-6}$ Pa	Hardly mobile in the matrix
A very low	< 1 µg/l	Not dusty, no aerosols $< 10^{-8}$ Pa	Real chemical bond with the matrix

Table 2.8: Evaluation scheme on the mobility of substances

The ranges of vapour pressures shown in the table relate to possible risks for water ecosystems via the emission pathway “air.” That means, substances are addressed which, after their release to air adsorb to particles or rain and deposit into waters. The critical range of vapour pressures for water ecosystems is therefore rather low: It is just high enough that substances evaporate in relevant amounts but at the same time low enough that they do not remain as gas in the atmosphere but return to the ground.

Actual release potential depends on the conditions of use which can be assigned to certain classes of applications shown in the following scheme.

²² Water solubility at 20 degrees. The scaling of water solubility has been developed using EU risk assessments for various plastic additives. Compared to detergents and cleansers, the water solubility of additives is relatively low. Nevertheless under certain conditions of use and when high amounts are used, relevant releases to the environment occur.

²³ Vapour pressure (measured in Pascal [Pa] at 20/25 °C); the vapour pressure rises by several orders of magnitude at higher temperatures during processing. The scaling of vapour pressures has been developed using EU risk assessments for different plastic additives. Compared to solvents, the vapour pressures are all relatively low. Nevertheless under respective conditions of use and when high amounts are used, relevant releases to the environment occur.

²⁴ For example: tests for food packaging, a saliva migration test, and a migration test for water pipes.

Potential Release	Conditions of use of substances and preparations in installations	Conditions of use of substances and preparations outside installations	Conditions of use of finished articles
E very high	application of preparations in water based processes, discharge without wastewater treatment plant	intended use open in the environment (e.g. lubricants for chain saws)	wide-spread and open use of consumer articles with outdoor applications, long service lives (e.g. roof coverings)
D high	application of preparations in water based processes, discharge via a biological wastewater treatment plant	intended use open in the environment; substances are more or less firmly bound to a matrix (e.g. wall paint); preparation in outdoor uses; application in water-based processes and discharge via a biological wastewater treatment plant	articles which are regularly cleaned with water (e.g. textiles)
C medium	application of preparations in water-free processes with elevated temperatures, open or semi-open process technology; application of preparations in water-based processes, discharge via special pre-treatment according to best available technique;	Intended use open to the environment, substances are more or less firmly bound to the matrix (e.g. wall paint), preparation is used indoor; mobile, contained machinery, controlled disposal of wastes according to best available technique;	application in compact open to the environment in consumer products for outdoor uses (e.g. window frames); widespread application open to the environment in consumer products with large surfaces for indoor uses (e.g. wallpapers)
B low	application of preparations in water-free processes at normal temperatures	mobile, contained machinery, no disposal of residues via municipal wastewater treatment plants or general waste disposal systems	applications with no or low environmental losses during use, articles with a wide disperse use (e.g. batteries)
A very low	rigorous containment, no disposal of residues via municipal wastewater treatment plants or general waste disposal systems ²⁵		application with no or low environmental losses during use, low dispersal (e.g. accumulators for industry)

Table 2.9: Evaluation scheme for release potentials according to types of applications

2.4.5 Risk factor indirect release

All possible pathways for releases should be known in order to choose a suitable management strategy and take targeted measures for the prevention of emissions. Eventually these measures should go beyond the borders of the company itself or the immediate use of the manufactured product. This is especially important for the following pathways:

- Disposal pathway for water-containing production residues (e.g. washing water and water for rinsing, emulsions from metal processing, metal concentrates from galvanisation, solvents) and possible emissions into the environment due to insufficient treatment of waste or agricultural use of biological sewage sludge.

²⁵ Such closed installations usually are only operated within the scope of chemical services where the suppliers take back the used process auxiliaries for recycling. Releases that can occur under these conditions are explained in chapter 2.4.5.

- Process auxiliaries unintentionally remaining in or on the product (e.g. remnant biocides in paper, residues of wetting agents in textiles, concrete release agents on construction products, residues of catalysts in plastics), which may be released during the service-life of the product.
- Recovery of articles after the end of their service-life, which may result in releases to the environment (e.g. additives in waste paper in paper recycling, metals-containing biocides in heat recovery from wooden construction material, flame retardants in recycling of electronic scrap, utilisation of slag from waste incineration open in the environment).

Examples for indirect releases		
Disposal of production residues	Carrying off of processing aids to products	Recovery of end-of-service-life products
treatment of emulsions and discharge of resulting wastewater via the sewage system separation of water from spray painting sludge Losses of metal cutting fluids due to leakage in storage, transport and recovery	process auxiliaries in textile finishing and paper manufacture catalysts in plastic articles	arsenic and halo-organic biocides in the thermal use of impregnated woods plastic additives during mechanical crushing, reprocessing of thermoplasts or thermal recovery of articles printing inks and paper additives in the recycling of waste paper metal-containing components of articles in the use of waste incineration slag

Table 2.10: Examples for indirect releases

Indicators for the importance of a risk factor's contribution to the overall risk cannot be given here, as this depends on the technical design of the respective production processes. As long as no specific information on the emission potential exists, the highest risk contribution should be taken from the evaluation matrix. In cases where the information is sufficient, the contribution to the risk may eventually be re-ranked as "low" if appropriate.

2.5 Examples for the evaluation

The evaluation Tables 2.11 and 2.12 have been filled out for two brominated flame retardants as examples: Decabromodiphenylether in textile products (additive flame retardant) and TBBA used in materials for circuit boards (polymer chain-integrated flame retardant). In both cases, the annual amount used by the company is 10 t per year.

Five-step evaluation matrix

Contribution to risk	Persistence	Bioaccumulation	Aquatic Toxicity	Chronic toxicity to vertebrates	Inherent mobility	Amount	Mobilising conditions of use	Indirect releases	Risk-index
Very high									
High									
Medium									
Low									
Very low									
Weighting									

Table 2.11: Risk profile DECA in textiles

Table 2.12: Risk profile TBBA in circuit boards

Five-step evaluation matrix									
Contribution to risk	Persistence	Bioaccumulation	Aquatic toxicity	Chronic toxicity for vertebrates	Inherent mobility	Amount	Mobilising conditions of use	Indirect releases	Risk-index
very high									
high									
medium									
low									
very low									
weighting									

For both substances, the predominating contributions to the overall risk result from their persistence and the potential releases of dangerous substances in recovery and disposal operations. For TBBA the high aquatic toxicity and the tendency to bioaccumulate also play an important role. For DECA it is still unclear, whether less brominated degradation products are slowly formed in the environment, which would have a high potential to bioaccumulate.

For both substances the intrinsic mobility is relatively low due to low vapour pressures or firm binding to the matrix. However, for DECA the conditions of use (textiles with possible contact with water when being washed) result in a higher contribution to the risk for releases than for TBBA (widespread use in plastic articles, partly at elevated operating temperatures).

When comparing the two risk profiles, no evident advantage can be seen for either of the two substances which would justify a substitution of one by the other. It does however become evident which the key risk factors are and with which strategies the risks could be reduced.

Annex 1 – List of priority substances

The following table can be used for the identification of products and production processes which contribute to the emission of *priority substances* under the Water Framework Directive into European waters. At the same time those substances are noted for which substitution alternatives have been compiled within the scope of this guide and for which product-related strategies are proposed to reduce risks. Several substance groups are not taken into account because they are not relevant for industrial and commercial users with regard to searching for alternatives:

- Mercury: Only of minor importance in the application of chemical substances.
- PAH: Main sources of (air) emissions are combustion processes; no emission reduction can be achieved by the substitution of chemical products.
- Plant protection products: A separate substitution strategy with separate criteria and a user-specific concept is necessary.

Chlorinated benzenes: in Germany chlorinated benzenes are not relevant in chemical products anymore. Emissions may occur from contaminated sites or due to the formation of by-products in chemical synthesis. Both sources cannot be influenced by substitution measures.

- Biocides: In Europe, the biocides TBT and PCP are rarely used in chemical products with the exception of antifouling paints (TBT). Releases may occur from long-lived articles or imported articles. Both sources cannot be influenced by substitution measures.

The guidance also does not cover chlorinated solvents. From the three substances on the list, only dichloromethane occurs in wide disperse use. In particular in paint strippers dichloromethane should be replaced by less hazardous alternatives, however this relates to health concerns rather than to a risk for the aquatic environment.

Overview on prioritised substances under the WFD – Application, important emission pathways and relevance in the frame of the current guide (Böhm et al., 2002, modified)

Substance name	Application	Emissions in Germany – Emission pathways	Relevance in current Guide
Lead	Most important application: accumulators Besides: semi-finished products, alloys (construction, apparatus engineering, radiation protection, noise protection, storage metals, weights, shot for hunting) cable sheath, pigments, crystal glass, picture tubes, ceramics	Only relatively low emissions from production and processing; Abrasion from lead-containing material (construction, apparatus, water pipes, wheel balancing weight); Air emissions (accompanying element) from combustion, non-ferrous metals, iron + steel, waste incineration, metal casting, stones + earths (high volumes of waste gases); Frequently lead-containing articles have a long lifetime (e.g. stabilised and pigmented plastics).	+ stabilisers, pigments
Cadmium	Nowadays, batteries account for the far most important use; pigments only to little extent used in technical plastics, glazes, enamels, stabilisers, galvanic technology, alloys are only rarely used	Only relatively low emissions from production and processing ; Abrasion from zinc, zinc alloys or zinc-coated materials in construction (decreasing); Entry into agriculture through cadmium contained in phosphate fertilisers but also in sewage sludge and manure; Air emissions (Cd as accompanying element) from iron + steel production, non ferrous metals, combustion, waste incineration, stones + earths (high volumes of waste gases) Stock of long-lived products from past production (especially construction materials from PVC)	(+) stabilisers, pigments
Nickel	Most important application: corrosion resistant and stainless steels and nickel alloys, thereafter batteries, nickel coatings, catalysts and pigments.	relatively low emissions to water and air from processing (regulated). Abrasion from nickel-containing materials in contact with high amounts of water (energy technology, chemical industry, food sector, construction sector, kitchen techniques) Air emissions from steel production and combustion (accompanying element with mineral oils and coal)	+ pigments
Mercury	Most important application: Chlorine alkali electrolysis (Amalgam-process), dental medicine, button cells (only < 2 % Hg), fluorescent lamps; minor applications : measuring techniques, apparatus engineering, chemicals, reagents.	Emissions to air and water from amalgam installations for production of chlorine (decreasing); relatively low emissions from processing Emissions from uncontrolled disposal of articles Air emissions (accompanying element) from combustion, iron + steel, waste incineration, stones + earths (high amounts of waste gases) High amounts are stored in products from past production (measuring technique, apparatus, amalgam installations)	-

Substance name	Application	Emissions in Germany – Emission pathways	Relevance in current Guide
PAKH (Polycyclic aromatic hydrocarbons)	Use of creosote (contains up to 85 % PAH) as wood preservative (placing on the market of tar oils is prohibited since 1991, but exception for e.g. railway sleepers, telephone poles)	Emissions to water mainly indirectly via air emissions (combustion processes like furnaces and traffic, production of aluminium, coking plants, production of iron and steel); Partly via creosote in the open use as wood preservative	-
Anthracene	Wood preservation (creosote), furthermore colourings, specialities such as membranes	s. PAH Water emissions from the production of anthracene is very low (ca. 75 g/a)	-
Fluoranthene	Research purposes, fluorescent colouring	s. PAH (Air emissions are in equilibrium with other PAH)	-
Naphthaline	Azo-dye, phthalic acid anhydride, naphthaline sulfonic acid, formaldehyde condensation products, alkyl derivatives and component of solvents	s. PAH Emissions of naphthaline production to water is low, ca. 3,75 kg/a; according to „worst case“ 297 kg as intermediate 15 kg through wood impregnation	-
1,2-Dichloroethane	More than 95% as intermediate of vinyl chloride production; further use as additive in fuels and oils, intermediate, technical process auxiliary, solvent	Emissions during production (68,3 t - air, 3,33 t - water) Emissions during application: low compared to production	-
Dichloromethane	Application as blowing agent (spray cans) decreased considerably in the last years; diverse uses as important industrial solvent; intermediate; Further application: glues/lacquers, metal cleaner, paint stripper, noise protection, technical aerosols	Emissions during production (77,4 t – air; 4,55 t water) Total emissions during use: from 1994 till 1996 from 3.340 t to 3.650 t slightly increased	-
Trichloromethane (Chloroform)	Intermediate, laboratory chemical, solvent, other (agent for extractions, paint remover, thinner for lacquers)	Emissions during production: 1,95 t - air; 0,433 t - water	-
Hexachlorobenzene	No production (since 1993); no consumption; (earlier widely used as fungicide in agriculture)	Emissions as intermediate in the chlorine chemical industry: (in 1995 < 10 kg – air ; < 48 kg water) Furthermore emissions as by-product in the refinery of aluminium and from contaminated sites and combustion processes etc.	-
Hexachlorobutadiene	No production, no application (earlier biocide, intermediate etc.)	Emissions as intermediate in the chlorine chemical industry (in 1995 <10 kg air; < 14 kg water)	-
Pentachlorobenzene	Base material for the production of the fungicide pentachloronitrobenzene (Quintozone)	Emissions may occur during the production of Quintozone; emissions from past use of HCB and Quintozen, which were contaminated with Pentachlorobenzene.	-

Substance name	Application	Emissions in Germany – Emission pathways	Relevance in current Guide
1,2,4 Tri-chlorobenzene	80 % intermediate, 14 % process solvent; furthermore: paints/lacquers, technical auxiliaries solvents fuels/oils, plant protection, disinfectants	EU-wide emissions to the environment: 15 t (estimated according to TGD for the sum of all scenarios „intermediate“, „process solvent“, „other“ and „carrier of colouring“)	-
1,2,3 Tri-chlorobenzene	Intermediate in the synthesis of pesticides via 2,3,4-Trichloro-nitrobenzene; furthermore like the 1,2,4-isomere as solvent (paints, lacquers)		-
Alachlor	PPP (selective herbicide) In Germany no production, no consumption	Low	-
Atrazin	PPP (herbicide for soil and leaves) no production, no consumption;	Emissions from residues in soils related to historical usage and illegal applications	-
Chlorfenvinphos	PPP(insecticide and acaricide)	Occurrence in surface waters cannot be determined	-
Chlorpyrifos	PPP (insecticide)	Occurrence in surface waters cannot be determined	-
Diuron	PPP (herbicide) Low consumption as biocide in paints/lacquers	High concentrations in surface waters measured; emissions probably mainly via point sources	-
Endosulfane	PPP (insecticide, acaricide), in Germany not authorised	No indication of occurrence in surface water	-
Isoproturon	PPP (herbicide)	High concentration in surface waters measured	-
γ-HCH (Lindane)	PPP (insecticide), medicine against head lice; Not authorised in Germany	Industrial direct emissions (Rhine 2000: < 1 kg; Elbe 2000: ca. 10 kg); Estimations on diffuse emissions: ca. 500 kg	-
Simazin	PPP (herbicide); not authorised in Germany	Relatively high emissions to surface waters (decreasing trends) demonstrated; reason are historical and/or illegal applications	-
Trifluraline	PPP (herbicide)	No diffuse emissions are expected, no industrial direct emissions known	-
Benzene	Intermediate in aromatic chemistry, component of carburettor fuel (~1%)	Emissions to waters in Germany according to „realistic worst case“ estimate: 4.540 t; air emissions: 30.000 t	-
Brominated Diphenylethers (pentaBDE)	Additive flame retardant in soft polyurethane foams (e.g. neck support in cars, soft chairs, packaging) in Germany only little amounts	„Worst case“ estimate for EU water emissions of 5,26 t; Products have long lifetimes (Depot);	+ flame retardants
Short chain chlorinated paraffins (SCCP)	Cooling lubricant (metal processing), paints, flame retardants (rubber, textiles), sealing material, leather; in Germany only small amounts	low (applications with high emission factors are of minor market relevance)	+ flame retardants, metal cutting fluids

Substance name	Application	Emissions in Germany – Emission pathways	Relevance in current Guide
Di(2-ethyl-hexyl) phthalate (DEHP)	Very dominating use as plasticiser for PVC (e.g. floor coverings, cables, hoses, plastic films, underbody coating, soles of shoes); furthermore in paints, lacquers, dispersions etc.	predominantly via DEHP-containing products/particles remaining in the environment (ca. 574 t/a) and outdoor applications (177 t/a); during production and processing only low emissions Long lived products (depot);	++ plasticiser
Nonylphenols (NP)	Nonylphenol: production of NPEO, glues, lacquers; NPEO: Tensides, emulsifiers	Production and processing: only few emissions; Municipal wastewater treatment plants ca. 21 t/a (partly via indirect dischargers) Agro chemistry: ca. 10 t	++ emulsifier
Octylphenols (OP)	In Germany only little use (earlier similar to NP)	Emissions predominantly via OPEO-contamination in NPEO-products (s. Nonylphenol)	(+) emulsifier
Pentachlorophenol (PCP)	Wood preservative, textiles, leather, preservative; in Germany application is prohibited	Treated materials have long service life-times (depot) Emissions only via depots or imports (e.g. in textiles)	-
Tributyl tin compounds (TBT)	Antifouling paints for ships; non-biocidal uses: auxiliary in organic synthesis (< 200 t/a TBTCI); Past applications: wood protection, leather, paper, textiles, polyisobutylene roof coverings, silicone sealings, pot preservatives	Predominantly via antifouling paints Some products have long life-times (depot); from former applications, contamination in mono-/dibutyl tin compounds etc. via municipal wastewater treatment plants	-

Annex 2 - R-phrases

R-phrase	Criteria	
Classification due to certain effects on waters		
Very toxic to aquatic organisms/ May cause long-term adverse effects in the aquatic environment	The substance is very toxic to fish, daphnia or algae <u>as well as</u> not readily degradable or bioaccumulative	R50/53
Very toxic to aquatic organisms	The substance is very toxic to fish, daphnia or algae.	R50
Toxic to aquatic organisms/ May cause long-term adverse effects in the aquatic environment	The substance is toxic to fish, daphnia or algae <u>as well as</u> not readily degradable or bioaccumulative	R51/53
Harmful to aquatic organisms/ May cause long-term adverse effects in the aquatic environment	The substance is harmful to fish, daphnia or algae, not readily degradable. <u>And</u> no additional scientific evidence exists which would demonstrate with sufficient certainty that neither the substance nor its degradation products pose a potential danger or a delayed danger for waters.*	R52/53
Harmful to aquatic organisms	Substances not covered by the above mentioned R-phrases, but which have been proven to pose a danger to the structure/functioning of aquatic eco-systems.	R52
May cause long-term adverse effects in the aquatic environment	Substances not covered by the above mentioned R-phrases, but for which it has been shown that they pose a long-term danger to the structure/functioning of aquatic eco-systems due to their persistency and tendency to accumulate as well as the predicted or observed behaviour. <u>And</u> no additional scientific evidence exists which would demonstrate with sufficient certainty that neither the substance nor its degradation products pose a potential danger or a delayed danger for waters*.	R53
Dangers for human health		
Limited evidence of a carcinogenic effect	Substances which give rise to concern because of a possible carcinogenic effect on humans, but for which the available information does not suffice for a satisfactory assessment. Animal tests give some clues which are not sufficient for a classification with R45.	R40
May cause cancer	Substances which are known carcinogens or which are regarded carcinogens or give rise to concern because of animal tests.	R45
May cause heritable genetic damage	Substances which are known mutagens or which are regarded as mutagens or give rise to concern because of animal tests	R46
Danger of serious damage to health by prolonged exposure	Repeated or prolonged exposure to the substance may cause serious damage to health (functional or morphological disorders).	R48
May impair fertility	Substances which impair fertility in humans	R60
May cause harm to the unborn child	Substances which damage the normal development of human embryos.	R61

R-phrase	Criteria	
Possible risk of impaired fertility	Substances which give rise to concern that fertility of humans is damaged	R62
Possible risk of harm to the unborn child	Substances which give rise to concern that the normal development of humans embryos is damaged	R63
May cause harm to breastfed babies	Substances which give rise to concern because they may be released into breast milk during lactation and may cause toxic effects on the breastfed baby.	R64
Possible risk of irreversible effects	Substances which give rise to concern due to possible mutagenic effects in humans. Tests on mutagenicity have provided some evidence which do however not suffice for a classification as R46	R68

* Evidence exists when a rapid degradation in waters is demonstrated or a chronic toxicity of > 1mg/l (NOEC) in prolonged toxicity testing in daphnia or fish is shown.

Annex 3 – Databases

The substance list in part 1 of the guide is a selection of substances which are regarded as especially problematic for European water eco-systems. Further important substance lists are shown in the following table.

Additionally the table contains links to recommendable database with the help of which initial general information on potentially critical properties of a substance can be found. The table also makes reference to the so called Emission Scenario Documents which contain realistic worst case emission factors for specific branches and processes to be applied in quantitative exposure analysis.

Content	Status of information	Institution	Access
OSPAR List of <i>Substances of Possible Concern</i> : substances suspected of having PBT properties	Suspicion	OSPAR	www.ospar.org
Priority substances for the marine environment	Definitive concern	OSPAR	www.orspar.org
Priority substance in European waters	Definitive concern	EU Commission	http://europa.eu.int/comm/environment/water/water-dangersub/index_en.html
Priority substances under the EU existing substances regulation	Partly regulatory measures expected	EU	http://ecb.jrc.it
List of substances dangerous to waters	Definitive classification	UBA	www.umweltbundesamt.de/wgk.htm
Observation List: Dangerous substances, the use of which shall be thoroughly checked	Definitive concern	KEMI	http://www.kemi.se/publikationer/obs_eng/default.htm
List of Undesirable Substances: Dangerous substances, the use of which shall be thoroughly checked.	Definitive concern	Danish EPA	http://mst.dk/homepage/default.asp?Sub=http://mst.dk/chemi/01040000.htm
List of priority substances suspected of having hormone-like properties	Suspicion	EU Commission	http://europa.eu.int/comm/environment/docum/01262_en.htm#bkh
PBT Profiler: Online-instrument for checking substances regarding potential PBT-properties (no substance list!)	Indication on the basis of modelled substance properties	US EPA	http://www.pbtprofiler.net/
Syracuse EPIWIN: Software for checking environmental properties based on their molecular structure (about 100.000 substances)	Indicators based on modelled substance properties	Syracuse	http://esc.syrres.com/
N-Class Data Base of the Swedish chemicals inspectorate: Environment related data of about 7900 substances	Indicators based on measured substance properties	KEMI	http://www.kemi.se/nclass/
EnviChem: Databank of the Finish Environmental Institute (CD ROM)	Indicators based on measured substance properties	FEI	www.environment.fi/syke
Environmental Residue-Effects Database (ERED)	Literature databank on residue concentrations in body tissue and measured biological effects	US EPA	http://www.wes.army.mil/ered/

Content	Status of information	Institution	Access
Risk Line: Databank on health and environment related substance properties	Monographic information (peer review)	Kemi	http://www.kemi.se/riskline/index.htm
SEARCH CLASSLAB: EU Database on classified dangerous substances (annex 1 to 67/548) and proposals on new classifications	Definite classification	ECB	http://ecb.jrc.it/classification-labelling/
SPIN: Database of the Nordic Countries on uses of substances in preparations	Indication of use patterns of substances	Nordic Chemicals Group	http://www.spin2000.net/spin.html
TGD: Emission Scenarios in the EU Technical Guidance Document (chapter 4) on Risk Assessment of chemical substances	Indication of specific emission factors related to certain applications, and exposure estimates.	ECB	http://ecb.jrc.it/existing-chemicals/

Annex 4 - Glossary

Acute toxicity: Damage (fatal or not fatal), resulting from (continuous or interrupted) exposure to a substance or a mixture of different substances over a time period which is shorter than a generation of the affected organisms (from minutes to several days). Normally the duration of environment-related acute test systems remains under 96h.

Anaerobic degradability: Degradation of a substance taking place with very low oxygen concentrations (lack). Anaerobic degradability provides for conclusions on the behaviour of substances in sewage plants (sludge) or sediments.

Base Set: Substance information necessary for the registration/notification of a substance, e.g., production volume, chemical-physical properties, as well as toxicological and ecotoxicological test data.

BAT (Best Available Technique): BAT describes the environment related „State of the Art,, on European level. Those techniques which are already realised in industry are described.

BCF (Bio-concentration factor): The relation between the substance concentration in an organism and surrounding waters which is determined via experiments (OECD 305 A-E).

Best environmental practice: Most suitable combination of measures, which guarantee an environmentally benign handling of hazardous substances. The focus is set on measures of communication with substance users, standards for the organisation of work procedures, maintenance and monitoring and the economic use of substances.

Bioaccumulation: Accumulation of a substance in an organism resulting in concentrations in the organisms exceeding those in the medium in which it lives. Bioaccumulation covers the taking up of the substance from the surrounding medium (bioconcentration) and via food (biomagnification).

Biocides: Substances and preparations which are designed to fight damaging organisms with chemical or biological methods, but which are not used in agriculture (plant protection products).

BOD (Biological oxygen demand): Amount of oxygen consumed during microbiological degradation processes.

Calendering: Special process in the continual plastic processing. Primarily the plastic is melted within a fissure between two counter-rotating heated metal rollers. Further downstream rollers additionally harmonise the mass and regulate the thickness of the flat final product. Mainly platters and plastic foils but also floor coverings and artificial leathers are manufactured in this manner.

Carcinogenity: Carcinogenic effect of substances and preparations via inhalation, swallowing or skin contact, as well as the increase of cancer cases.

Classification of substances: Assessment of a substance according to the dangerous proper-

ties on the basis of Europe-wide harmonised criteria and standardised test methods. Depending on the dangerous properties the substance is assigned, one or more risk phrases (R-phrases). The classification must not automatically lead to a corresponding labelling as "dangerous substance".

Chronic toxicity: Non-fatal damage, resulting from a continuous exposure to a substance or a mixture of different substances over a time period which is not shorter than a generation cycle of the affected organisms.

Combined effects: additive (sum of single effects), synergies (enhancement of single effects) and antagonistic effects (single effects either cancel out or attenuate each other).

Compounds: Polymer granulate containing additives which are used in plastic processing. The content of additives is in accordance with the use concentration.

Dangerous chemicals: According to § 19 of the ChemG (*German Law on Dangerous Chemicals*), dangerous chemicals are: dangerous chemicals and preparations in the sense of the EU directive 67/548; substances and preparations with other chronic toxic properties; substances, preparations and articles from which dangerous substances and preparations may be formed or released during production and use.

Diffuse losses: Emission of mobile substances from finished products and preparations outside installations and other closed uses or disposal systems. The entry of the substance into the environment is not determined by point sources, meaning that production or processing is not the predominant source of emissions.

Dry deposition: Deposition of gaseous substances or particles which carry adsorbed substances. Opposite process to volatility.

EC₅₀ (Effective concentration): Concentration of a substance at which 50% of the test organisms exhibit the examined effect.

EINECS (European Inventory of Existing Chemical Substances): List of substances which were available on the European market before 18th September 1981 (approx. 100 000 entries).

ELINCS (European List of Notified Chemical Substances): EU register of substances registered after 18th September 1981 (approx. 3000 entries).

Endocrine disrupting substances: Substances foreign to the body which cause changes in the body's hormone system and thereby adverse effects for the organisms or their offspring. There is a general definition for marine systems: substances which directly or indirectly interfere with the hormone system of organisms, by showing hormone-like effects, or enzyme systems which steer the hormonal balance.

Environmental hazardousness: Substances and preparations are environmentally hazardous when on introduction into the environment they pose an immediate or delayed threat to one or more environmental compartments.

Existing substances: Substances which have been produced and/or marketed in the European Union before September 1981.

Finished product: Product manufactured from one or more different materials (fibres, polymer matrix, metal grids, glass), whose properties are mainly determined by the material construction and surface structure. Chemical substances and preparations can be contained in the form of additives or contamination.

EU Eco-Label: Eco-label of the European Union (Regulation 880/92/EEC) given to products which have fewer environmental effects throughout their life-cycle than similar conventional products (e.g. paints and varnishes, wash-up liquids, washing detergents).

Exposure: Exposure of an organism to substances or to the chemical composition of environmental media.

Formulator: Industrial or commercial company which manufactures preparations by mixing individual substances.

Half-life: Time period in which half of a quantity of a substance is biologically degraded or physically or chemically destroyed.

HELCOM: Helsinki Commission on Marine Protection in the Baltic Sea, foundation of the co-operation between the nine countries bordering on the Baltic Sea.

IC₅₀ (Inhibiting concentration): Concentration of a substance which causes an inhibition of the examined parameter in 50% of the test organisms.

Inherent degradability (= potential (bio)degradability): Classification of a substance meeting the pass level in standardised degradation tests (OECD 302 A-C). It is assumed that these substances may be primarily or totally degraded under aerobic conditions in the aquatic environment.

ISO 14000: International standard which regulates the introduction, contents and implementation of an environmental management system.

IUCLID: Database of the European Chemicals Bureau with records on production volumes, chemical-physical properties, toxicology and eco-toxicology of the substances produced in volumes of more than 1000 t/a in the EU.

Labelling of substances: Labelling of substances or preparations as dangerous with respective symbols and R-phrases and S-phrases. Not all dangerous properties of a substance automatically lead to labelling.

LC₅₀ (Lethal concentration): Concentration of a substance which is lethal for 50% of the test organisms.

Leaching: Slow release of chemical substances from a matrix when coming into contact with water.

Lifetime of a product: Covers the generation of raw materials, manufacture, marketing, use and disposal of a product.

log P_{ow}: Logarithm of the octanol-water partitioning coefficients; substances which have a log P_{ow} ≥ 3 have a tendency to accumulate in organisms.

Masterbatch: Colourings and/or additive concentrates in solid plastics or plastic-like matrices with a concentration of colourings/additives which is higher than that in the final application.

Mineralization: Total degradation of an organic substance to carbon dioxide, water and inorganic salts.

Mutagenicity: Effect of a substance causing heritable genetic damage resulting in phenotypic characteristics of an organism. This means any permanent change in the amount or the structure of genetic material in an organism which has an observable influence on the function or appearance of the organism.

Natural background values: Natural concentrations level of non-synthetic substances in the environment

NOEC (No observed effect concentration): Highest concentration of a substance which does not cause an observable effect in log-term tests.

Notified new substances: Substances which have been placed onto the European market after September 1981. These chemicals must be registered in accordance with the Chemical legislation.

OSPARCOM: Oslo and Paris Commission which co-ordinates the co-operation of the contracting parties in the frame of the OSPAR Convention for the "Protection of the north-east Atlantic from pollution" (by ships, aeroplanes and from land). Until 1996 the Paris-Commission (PARCOM) and the Oslo Commission (OSCOM) were the precedent organisations.

PEC (Predicted Environmental Concentration): Environmental concentrations for certain areas of the environment are calculated on the basis of production and market volumes, use patterns and physical-chemical properties of substances. This is done with the aid of mathematical models which simulate the substance transport and emissions.

Persistence: Durability of a substance in the environment. For a specific environmental medium, persistence is the property of a substance which determines the length of its stay in this medium before it is physically removed, chemically altered or biologically degraded.

PNEC (Predicted No-Effect Concentration): On the basis of acute or chronic effect concentrations established in laboratory tests, concentrations are calculated using safety margins, for which no effects are expected to occur in the environment.

Preparation: Mixtures, combinations and solutions consisting of two or more substances. Including polymer-containing preparations such as "masterbatches" or "compounds"

Primary degradation: Changes in the chemical structure of a substance which can be traced back to biodegradation. Occasionally the primary degradation simply leads to the formation of biologically stable metabolites. The percentage of total degradation achieved would be

correspondingly small.

Product: Substances, preparations, semi-finished or finished products, complexly constituted consumer products or other goods, which are industrially manufactured with the purpose of being marketed.

POP (Persistent Organic Pollutant): Organic substances which are persistent in the environment, which can accumulate, have toxic properties and which can be transported over long distances.

PTBs: Substances which are persistent, toxic and bioaccumulative at the same time.

Ready degradability: Classification of substances which meet the pass level (70% degradation of organic hydrocarbon DOC, 60% formation of CO₂/O₂) in standard degradation tests (OECD 301 A-D, OECD 306). It is assumed that these substances are subject to a quick total degradation (mineralization) in an aquatic environment with sufficient oxygen supply.

Reproductive toxicity: Harmful effects on reproductive functions or capacity as well as non-inheritable effects on progeny caused by substances. The effects are categorised under the two main headings "effects on male or female fertility" and "developmental toxicity".

R-Phrase (Risk Phrase): Characterisation of dangerous properties (e.g. "toxic for aquatic organisms" = R51) of substances according to EU Directive 67/548/EEC or the Gefahrstoffverordnung (GefStoffV)

Simulation test on degradability: Test method with which degradation under environmental conditions is simulated (water-sediment system, temperature, bacterial society and concentrations typical for a specific habitat)

Sub-acute toxicity: A not immediately fatal damage, resulting from a continuous or interrupted exposure to a substance or mixture of different substances over a time period which is shorter than a generation of the affected organisms.

Substance: Chemical elements and their compounds in natural form or manufactured in a production process, including the necessary additives for guaranteeing product stability and contamination which cannot be avoided during manufacture, with the exception of solvents, which can be extracted from the substance without impairing its stability or changing its composition.

TEGEWA: Association of industries producing textile finishing and leather processing products, tanning agents and raw materials for washing agents.

Ten-day window: The time period of 10 days in a biological degradation of a substance starting directly at the end of the lag-phase (delay phase until the bacterial culture reaches the full degradation capacity).

Teratogenity: substance property causing structural defects to unborn life. Apart from the dose of a teratogenic substance the time when the embryo is exposed to it plays a role (see also reproductive toxicity).

TGD (Technical Guidance Document): Technical rules for the implementation of the EU Directive on the risk assessment for New Substances (notified after September 1981), the Regulation 1488/94 on the risk assessment of Existing Substances and for risk assessments for biocides under the EU Directive 98/8.

Total degradation: Elimination rate of a substance which results from a mineralization to carbon dioxide, oxygen and inorganic salts, as well as the build-up of new biomass of degrading micro-organisms.

Toxicity: The potential of a substance to cause harmful effects on an organism and its offspring. Toxic effects are e.g.: decrease of survival rates, growth or reproduction as well as carcinogenicity, mutagenicity, teratogenicity or other adverse effects modulated through the endocrine system.

Vapour pressure: Inherent pressure under which a substance evaporates from a solid or a liquid phase. The vapour pressure increases with increasing temperature and characterises the volatility of a substance.

VCI: Association of the Chemicals Industry

Volatility: Transition of a substance from a solid or liquid state into the atmosphere via evaporation.

vPvBs: Very persistent and very bioaccumulative substances.

Wet deposition: Deposition of substances dissolved in fog or rain.

WGK (WHC): Water Hazard Class

Annex 5 – List of abbreviations

BCF	Bioconcentration Factor
DeBDPE	Decabromodiphenylether
DEHP	Di(2-ethylhexyl)phthalate
DOC	Dissolved organic carbon
DT ₅₀	Time necessary for a 50% degradation of a substance (half-life).
EC ₅₀	Concentration of a substance in testing at which 50% of the test organisms show the adverse effects
ECB	European Chemicals Bureau
GefStoffV	Gefahrstoffverordnung (German decree on dangerous substances)
HCB	Hexachlorobenze
HCH	Hexachlorocyclohexan
IC ₅₀	Concentration of a substance in testing at which 50% of the test organisms show inhibition of growth.
LC ₅₀	Concentration of a substance in testing at which 50% of the test organisms die (lethal concentration)
log K _{OW}	Logarithm of the octanol-water partitioning coefficient of a substance
NE-Metalle	Non-ferrous metals
NOEC	No Observed Effect Concentration = highest concentration in testing at which no effect could be observed
NP	Nonylphenol
NPEO	Nonylphenolethoxylate
OP	Octylphenole
OPEO	Octylphenolethoxylate
PAH	Polyaromatic hydrocarbons
PBT	Substances, which are persistent, bioaccumulative and toxic
PCP	Pentachlorophenol
PentaBDE	Pentabromodiphenylether
PPP	Plant protection product
PVC	Polyvinylchloride
SCCP	Short chain chlorinated paraffins
TBBA	Tetrabromobisphenol A
TBT	Tributyl tin
TGD	Technical Guidance Document
TRGS	Technische Regeln Gefahrstoffe (German technical rules on dangerous substances)
VwVwS	Administrative order on substances hazardous to water ecosystems
WGK	Water hazard class

Annex 6 – Literature and legislation

Böhm et al: Ermittlung der Quellen für die prioritären Stoffe nach Artikel 16 der Wasserrahmenrichtlinie und Abschätzung ihrer Eintragsmengen in die Gewässer in Deutschland. Forschungsvorhaben des Umweltbundesamt (UBA-Texte 68/02), September 2002.

Chemikaliengesetz (Law on dangerous chemicals)

Gesetz zum Schutz vor gefährlichen Stoffen. Last version of 06.08.2002. On the internet: <http://bundesrecht.juris.de/bundesrecht/chemg/gesamt.pdf>

EU Commission: Priority substances in European waters

Decision No 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 establishing the list of priority substances in the field of water policy and amending Directive 2000/60/EC On the internet: http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_331/l_33120011215en00010005.pdf

European standard emission scenarios

are contained in part 4 (chapter 7) of the “Technical Guidance document in support of the commission directive 93/67/EEC on risk assessment for new notified substances and commission regulation (EC) no 1488/94 on risk assessment for existing substances”. On the internet http://ecb.jrc.it/Documents/Existing-Chemicals/TECHNICAL_GUIDANCE_DOCUMENT/

GefStoffV (Decree on dangerous chemicals)

Verordnung zum Schutz vor Gefahrstoffen (Gefahrstoffverordnung – GefStoffV). Version of 01.01.2003. On the internet <http://www.baua.de/prax/ags/gefahrstoffvo.pdf>

OECD testing methods

CO2 Evolution test (OECD 301B), MITI Biodegradation Test (OECD 301C), Closed Bottle TEST (OECD 301D), Modified OECD Screening Test (OECD 301E), Manometric Respirometry Test (OECD 301F), Tests on inherent biodegradability OECD 302 – the test methods are described in the Annex V of the directive 67/548/EEC. On the internet: <http://ecb.jrc.it/testing-methods/>

OSPAR List of substances of possible concern (Reference Number 2002-17). On the internet: <http://www.ospar.org/eng/html/substances/content.htm>

TRGS 440 (Technical Rules on dangerous chemicals)

Technische Regeln für Gefahrstoffe: Ermitteln und Beurteilen der Gefährdungen durch Gefahrstoffe am Arbeitsplatz: Ermitteln von Gefahrstoffen und Methoden zur Gefahrstoffprüfung. Last version of 3/2002. On the internet <http://www.baua.de/prax/ags/trgs440.pdf>

VwVwS (Administrative instructions on the classification of substances hazardous to water eco-systems into water hazard classes)

Allgemeine Verwaltungsvorschrift zum Wasserhaushaltsgesetz über die Einstufung wassergefährdender Stoffe in Wassergefährdungsklassen (Verwaltungsvorschrift wassergefährdende Stoffe – VwVwS) Vom 17. Mai 1999. Im Internet:

<http://www.umweltdaten.de/down-d/vwvws.pdf>

Wassergefährdungsklassen (water hazard classes)

Information on the classification into water hazard classes and downloads of formulars can be found on the web site of the Umweltbundesamt.

(<http://www.umweltbundesamt.de/wgs/wgs-index.htm#>)

White Paper on a Strategy for a Future Chemicals Policy

Commission of the European Communities: White Paper– Strategy for a New Chemicals Policy. Comm(2001) 88 final. On the internet

http://europa.eu.int/comm/environment/chemicals/0188_en.pdf