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Environmental Research Plan of the German Federal Environment Ministry

R+D Project 297 28 521

# **Requirements with regard to Substances Released to Water Bodies Guidance for Users of Chemicals**

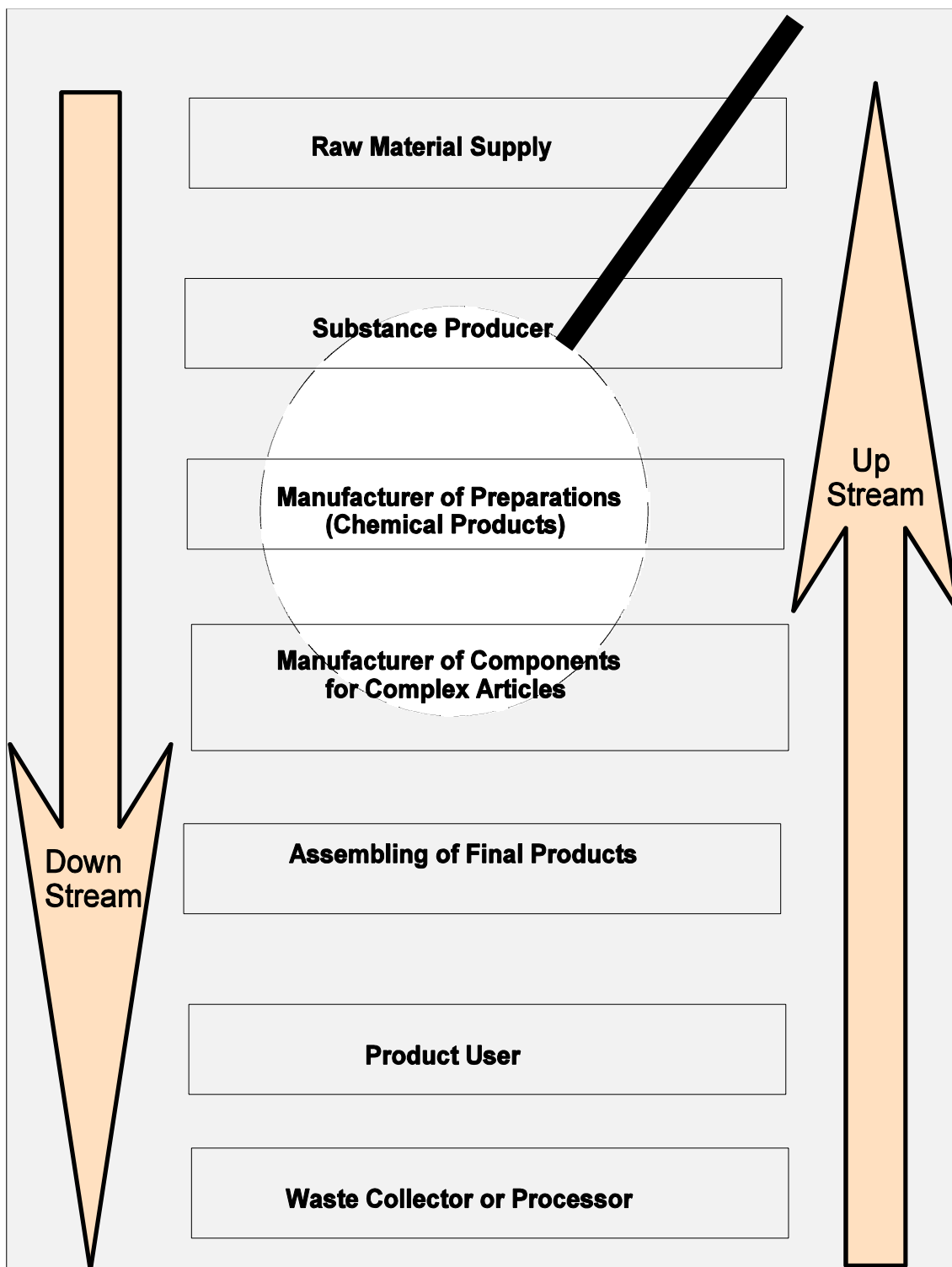
## EXECUTIVE SUMMARY

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**Figure 1: Focus on Manufacturers of Chemical Products (Preparations)**

## 1. Background

In 1998 the Ministers of Environment of the North-East-Atlantic States and the Baltic Sea Region agreed on a new „Strategy with regard to hazardous substances" under the existing conventions for the protection of the marine environment (OSPARCOM and HELCOM). This was the first step in the implementation of the 1995 Esbjerg Declaration, where the Ministers of Environment of the North Sea States had agreed on the „**generation goal**": *This (the precautionary principle) implies the prevention of the pollution of the North Sea by continuously reducing discharges, emissions and losses of hazardous substances, thereby moving towards the target of their cessation within one generation (25 years) with the ultimate aim*

- *of concentrations in the environment near background concentration for naturally occurring substances and*
- *close to zero concentrations for man-made synthetic substances.*

The OSPAR and HELCOM strategy is mainly targeting **diffuse emissions from land based sources**.

The strategies include a list of 15 (OSPAR) and 44 (HELCOM) hazardous substances or groups of substances for **priority action**.

Also in mid 1998 the „United Nation Economical Commission For Europe" (UNECE) adopted a POP-Protocol as a basis for an international program for phasing out 15 persistent, bioaccumulative and toxic substances.

An OSPAR expert group (OSPAR DYNAMEC) is currently developing a method for the **selection and prioritisation** of further hazardous substances.

The contracting parties under the marine conventions are expected to develop instruments for the practical implementation of the political agreements. National or international programs on risk reduction will usually target only a few priority substances and preparations. The broad implementation for the bulk of relevant substances should be the task of the producers and the professional users of substances. In this, the **professional users of chemicals** play a key role. It depends on their demands to which extent the producers provide hazard information on the chemical products, and less hazardous alternatives if necessary. The task of **the producer** is to meet these demands and to promote further search for information.

In the framework of the study „**Requirements for Substances Released to Water Bodies - Guidance for Users of Chemicals (FKZ 297 28 521)**", criteria and indicators have been worked out for the assessment of possible releases of chemicals to water systems. These criteria may enable the users of substances and preparations to better characterise the chemicals with a view on the long term objectives for the protection of inland and marine waters.

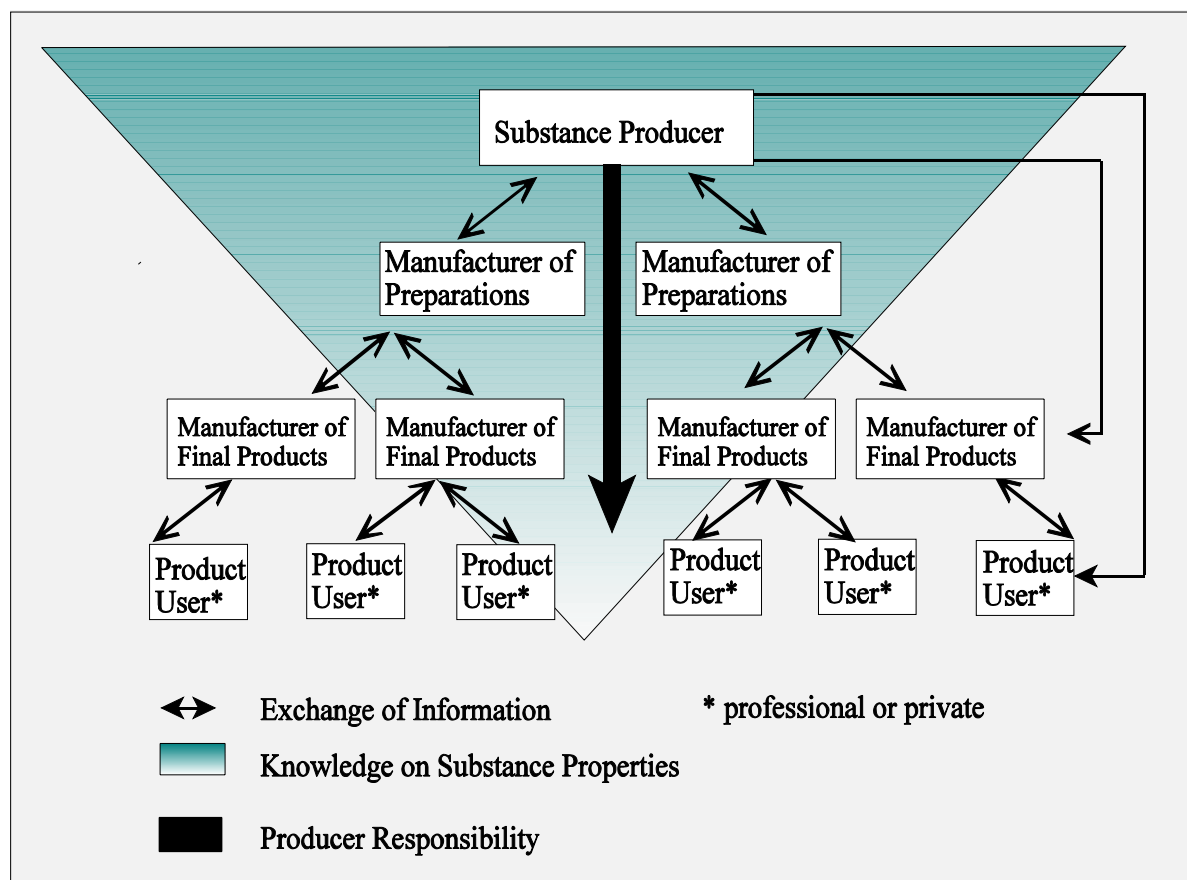
The report provides a systematic overview on the different approaches for the assessment of potential releases of substances with regard to: use patterns, substance properties, availability

and validity of information, procedures and outcome of the assessment process. **The assessment techniques** were evaluated with respect to their applicability under the long term objective regarding hazardous substances in the aquatic environment.

The report links the **existing legal requirements and management standards** systematically to each other: Chemicals legislation, transport of dangerous goods, legislation on water protection and air pollution control, HSE (health, safety, environment) management on company level, product safety and product labelling. The report identifies approaches for better harmonisation and integration of requirements related to chemicals on the one hand and environment on the other hand. The focus is on **characterisation and comparative assessment** of industrial chemicals with regard to their environmental properties. This is considered to be the basis for the substitution of hazardous substances by less hazardous substances or non hazardous alternatives.

Based on the study results, a **guide for the industrial users of chemicals** and their associations has been worked out. This manual may support the development of specific instruments for the assessment of chemical products addressing the particularities of certain product groups or sectors. The guide is aiming at creating awareness among the professional users of chemicals, and giving advice for the practical implementation of the new requirements. The main target group are the manufacturers of preparations and their clients in industry, for example: textile industry, metal processing industry, manufacturers of plastic articles.

Figure 2: Communication on the Supply Chain



The assessment of chemical products is overcharging many small companies. Consultancy services provided by the associations and/or the substance producers may in particular be important in cases

- where chemicals do not undergo an authorisation process and the responsibility for substitution therefore lies fully with the user;
- where the size of a company and the qualification of staff does not allow risk characterisation and systematical search for environmentally sound substances;
- where the composition of a preparation shall not be disclosed towards the user of the preparation.

The guide aims at challenging the industry associations to develop and offer consultations services to their members, in particular to the small companies.

## 2. Results

### 2.1 Criteria for Hazardous Substances in the Marine Environment

Substances classified as dangerous to the aquatic environment in connection with the risk phrase R 53 (not readily biodegradable or liable to bioaccumulate) are in general considered relevant with regard to the long term objectives for the aquatic environment. In case they are used in more or less open systems, risk reduction measures by the users are necessary. These may focus on **reduction of releases** to the environment or **substitution** by less hazardous substances. Priority substances are:

- substances not readily biodegradable and highly liable to bioaccumulate and
- toxic (including endocrine effects) to water organisms and/or animals high in the food chain and
- used and released to the environment in high volumes.

The release to the environment may occur due to i) the application of a chemical directly in the environment (for example car screen cleaner), emissions from waste water treatment plants, or diffuse losses from articles (for example abrasion of tyres).

Possible releases of hazardous substances cannot exclusively be identified by **screening of the chemicals input** to a process, since conversion of chemicals may occur during processing or waste water treatment. Organic substances in waste water discharges are monitored by the sum parameter **Total Organic Carbon** (TOC). Depending on the sector or process, the TOC may include a relatively high share of persistent substances. To which extent these may have toxic effects on water organisms or tend to bioaccumulate can be evaluated by **biological testing of the whole effluent**. The enhanced use of these types of tests is necessary in order to meet the long term objective for the protection of marine ecosystems. This applies in particular to bioaccumulation and chronic toxic effects.

## 2.2 Availability of Data

For about 50% of the existing high production volume chemicals the accessible data do not allow to judge whether or not a substance should be classified *dangerous to the environment*. Consequently, the information on the **Safety Data Sheets** is insufficient, despite the fact that the Safety Data Sheet is regarded as the important communication tool between producers and professional users of chemicals. Apart from that, the **classification of preparations** concerning the environment was not legally requested up to now.

This situation will fundamentally change within the next five years: The revised EU Preparation Directive requires environmental classification of preparations. In addition, the International Council of Chemical Industry Associations (ICCA), CEFIC and the CMA have committed themselves to provide **base set data for about 1000 high volume chemicals** which are not sufficiently characterised by now.

In 1997, the German chemical industry association VCI gave a public commitment that, latest by 2002, industry would provide a minimum set of data on the environmental properties of all substances, which are used in amounts of more than 1 t per year latest by 2002.

Due to implementation of these measures, the users of substances and preparations will find it easier to substitute hazardous substances by less hazardous alternatives in a targeted way. Their customers may develop corresponding demands.

As a matter of principle, any **substitution** of substances needs a comparative assessment of substances based on a comparable set of data. This is the only way to ensure that a substance classified as dangerous is not substituted by a substance lacking the relevant data to judge whether or not a classification would be appropriate.

Even though the availability of *base set* data on existing chemicals will be improved, the knowledge on **possible effects in the marine environment** remains very limited: Chronic ecotoxicity of substances is neither covered by the base set data nor by classification and labelling. The same applies for potential endocrine effects. Often, the aquatic toxicity of substances is characterised by one acute test on one species only. Effects on sediment organisms are not tested at all. In addition, the liability to bioaccumulate may be underestimated in bioconcentration tests in case the substance has a low water solubility. Also, the biodegradability in the environment may be overestimated based on laboratory testing. In the light of these uncertainties, the **precautionary principle** must play an important role in the assessment of chemicals.

**Measured concentrations of substances in the marine environment** or evident adverse effects in the environment may indicate the need for action in particular cases. In the context of the ranking of substances for the selection of priority substances under the draft Water Framework Directive and OSPAR's strategy with regard to hazardous substances, the availability of existing European monitoring data may be improved in future. Users of chemicals may systematically take into account the occurrence of certain substances in the environment as relevant for decisions on enterprise level. However, the number of substances for which representative

measurements are available will remain very limited also in the future.

In cases where data from concentration measurements in the environment and from laboratory testing of effects are lacking, hazardous properties of chemicals and potential accumulation in the environment can be predicted from **modelling**. Modelling based prediction of slow degradation and tendency to bioaccumulate can provide information in sufficient quality for the characterisation of environment related properties of substances.

### 2.3 Information Instruments and Environmental Management

The key instruments for the transfer of chemicals information from the supplier to the user is the **Safety Data Sheet**. Since there was no legal obligation to classify preparations with respect to the environment, up to now most of the current Safety Data Sheets are lacking these informations. The users of preparations, for example in the car manufacturing industry, the textile industry or the furniture industry, may motivate the manufacturers of preparations to improve the supply with hazard information by clearly expressing the demand for these informations.

The **guide** developed in the framework of the present project provides advise and suggestions which specific information the user of a chemical should ask his supplier for. Furthermore, an assessment method is proposed allowing to draw up **environmental risk profiles** of the used chemicals. Figure 4 gives an overview on the criteria and the scaling. Figure 3 shows the result of the procedure with regard to two substances used as cleaning agents in industry and private households.

**Figure 3: Risk Profile of a Dangerous Substance (A) and its Substitute (B)**

Case 1: Substance A Properties and Use Patterns	Increasing Risk				
	I	II	III	IV	IVa
1. Biodegradability in 28 days					
2. Abiotic degradability	not relevant				
3. Liability to bioaccumulate					
4. Lowest toxic (no) effect concentration on water organisms					
5. Mutagenous, carcinogeneus, toxic to reproduction					
6. Priority substance for reduction measures	malus				
7. Use pattern at the customer's, perhaps elevated level of emission					
8. Use pattern in the own enterprise					
9. Substance volume					
10. Pattern of disposal					

Case 1: Substance B Properties and Use Patterns	Increasing Risk				
	I	II	III	IV	IVa
1. Biodegradability in 28 days					
2. Abiotic degradability	not relevant				
3. Liability to bioaccumulate					
4. Lowest toxic (no) effect concentration on water organisms					
5. Mutagenous, carcinogeneuous, toxic to reproduction					
6. Priority substance for reduction measures	not relevant				
7. Use pattern at the customer's, perhaps elevated level of emission					
8. Use pattern in the own enterprise					
9. Substance volume					
10. Pattern of disposal					

Industry associations may consult and support their members to develop practicable procedures for communication with suppliers and customers. The users of chemicals and their clients should be enabled to make the best choice with regard to environmentally sound products, based on transparent criteria and information. However, at the same time confidentiality of the composition needs to be ensured. A way out of these conflicting goals are product specific classification systems or sector specific lists of undesired substances. The German association of manufacturers of textile processing chemicals (TEGEWA) and the European Thermal Paper Association (EPTA) have committed themselves to introduce such systems.

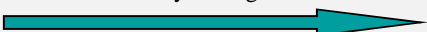
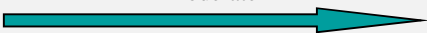
## 2.4 Regulations and other Measures to be taken by State Institutions

Legal **marketing and use restrictions** on substances will remain to be an exemption as it has been up to now. Also **authorization** is only applicable for certain types of dangerous substances. In both cases the administrative efforts are extremely high. Therefore, broad implementation needs „softer" instruments.

Comparable to existing internal „black lists" of undesired substances in certain sectors of industry, the Swedish Chemical Inspectorate (KEMI) regularly publishes the „**Observation List**". KEMI recommends to evaluate and avoid the use of these substances in certain areas. It is KEMI's understanding that this list is seen as an expert recommendation and that the responsibility for potential substitution measures lies with the user of the substance.

In co-operation with sectors intensively using chemicals, like for example manufacturing of textiles, plastics and rubber products, **inventories** of substances and preparations may be drawn up. Based on such inventories, priority substances for a phase out have been determined, for example in Sweden. The national authorities and the industry associations may sign an agreement on the implementation of such an objective in a certain time frame.

Figure 4: Environmental Risk Profile of Industrial Chemicals

Properties and Use Patterns of the Substance	Increasing Risk				IVa
	I	II	III	IV	
Ready or inherent biodegradability in OECD -Test	ready biodegradable	not ready biodegradable 		not inherent biodegradable	unknown
No rapid atmospheric degradation <u>and</u> low to moderate volatility	Malus				
Liability to bioaccumulate (BCF or log Pow)	low	moderate 		high	unknown
Lowest (no) effect concentration on water organisms from three trophic levels	not toxic	harmful	toxic	very toxic	unknown
Mutagenous, carcinogenous or toxic to reproduction	no indication		suspected	evident	unknown
Priority substance for reduction measures based on national or international agreement (⇒ annex 1)	Malus				
Use pattern at customer's (⇒ table 6.4) Elevated emission level despite water-free process	closed system	industrial use	wide disperse use	used in environment	unknown
Use pattern in own enterprise (⇒ table 6.5)	closed system	no direct relevance for discharge	direct relevant for discharge	used in the environment	unknown
Substance volume on enterprise level, tons per year High Production Volume Substance (HPV) in EU	very low	low	high**	very high HPV	unknown
Type of disposal operations after end of service life (⇒ table 6.6)	take back system in place	no take back system in place	no take back system in place <u>and</u> critical components regarding disposal operation		unknown

\*\* Value triggering the reporting obligation under the EU existing substance program phase III (> 10 t/y).

In order to obtain data on the use patterns and amounts of potentially dangerous substances on the national markets, the Nordic countries introduced **Product Registers** based on legal acts. Importers and producers of substances and preparations under certain trading codes are obliged to register their product. The information in the register is in general publicly accessible unless it contains business secrets.

Regular updating of the register is very resource consuming. Nevertheless it may be necessary to introduce instruments for better information on use patterns and market volumes also in other countries.

Up to now, discharge permits or supervision of discharges into the sewage system are based up to now on concentration limits of sum parameters in the waste water but not on characterisation of the chemicals input to the company. It is recommended to broaden the **regular screening** of the chemicals used for processing with regard to degradability, toxicity and liability to bioaccumulate. This would also strengthen the integration of requirements based on water legislation on the one hand and chemicals legislation on the other hand.

Under the EU Existing Substance Regulation, all companies importing or producing an **existing substance in amounts larger than 10 tons a year** were obliged to report these substances, the amount, the area of use and the classification to the European Commission. To which extent this reporting obligation was fulfilled should be evaluated by the Member States.

Companies where dangerous chemicals are used at the working place are obliged to **search for less or non hazardous alternatives** with regard to human health. In order to create incentives for a broad substitution process, it would be useful to extend this obligation also to the environmental properties of chemicals.

**Regular identification, characterisation and assessment** of chemical products by the users may contribute to the reduction of emissions, discharges and losses of hazardous substances. Appropriate instruments should be integrated into the existing HSE management systems on enterprise level. A concept for such instruments has been developed under the title „**Guide for Users of Chemicals**“ in the framework of the present study.

Similar to the company level, better **integration and harmonisation** of environmental requirements would be desirable as well in **public administration**: The assessment of existing and new substances as „products on the market“, as „pollutants in waste water and waste“, as „components in articles“, as „pollutants in the natural environment“, as „dangerous chemicals in the working environment“, as „contaminants in food“ and as „indoor pollutants“ requires close co-operation and co-ordination among the different authorities and agencies.