The Integrated
Water Management
Committee

Assessment of substances and preparations within the context of the implementation of the water discharge policy

May 2000

Preface

The assessment of the extent to which substances and preparations are harmful to the aquatic environment is an important element in the implementation of the Dutch discharge policy. This report describes a general assessment methodology, which categorises substances on the basis of their properties. The Dutch discharge policy links these categories to a set level of effort to limit pollution at source. The methodology complies with (inter-) national regulations in the field of classification and labelling of substances and preparations. In other words, the methodology harmonises and operationalises the categorising of substances and preparations in implementation of the discharge policy. This is important to both the authorities dealing with the Pollution of Surface Waters Act and the Environmental Protection Act and to the corporate sector. In fact, this methodology will provide the corporate sector with a better insight into the environmental harmfulness of the substances and preparations they produce and use. This insight is necessary if they wish to meet the requirements set by their Corporate environmental care system or environmental certifications.

This report also describes how producers may provide the eventual users and authorities with information about the harmfulness of substances and preparations through the commercial chain. Applicants for permits are responsible for providing the authorities with information about the harmfulness of their substances and preparations. This is nothing new. But in many cases, applicants do not have this information. Producers do, or ought to have this information. As a result, they are best qualified to carry out the assessment. This approach is efficient, has proved to be practical and links up with the initiatives put forward by the corporate sector, such as 'responsible care' and 'product stewardship'. Meanwhile, the cabinet has agreed that a system will be set up in consultation with the corporate sector, which will make all standard information about raw and auxiliary materials relating to permit-application procedures accessible to all parties involved.

Both government authorities and the corporate sector value the proper verification of information provided by the corporate sector. At present, it is not clear how and by which authorities this information will be verified. In 1999, the Dutch Ministry of Housing, Spatial Planning and the Environment launched a programme entitled SOMS, Strategy on Management of Substances. This programme is to be followed up by a strategy memorandum, which will be submitted to the Dutch Lower House at the end of 2000. The verification of information about the properties of substances and preparations provided by the corporate sector is one of the aspects that will be dealt with in this programme. The Integrated Water Management Committee (CIW) will make sure the verification will be properly organised in due time.

The methodology will have to be integrated into the permit-application procedure and become part of everyday practice. This is not expected to require extra manpower, although the intensified attention for substances and preparations will demand a greater effort, especially during the

introductory period. In due time, however, it is expected that time can be gained, because sufficient information about substances and preparations will be submitted together with the application. To give both authorities and the corporate sector the opportunity to prepare themselves for the use of this methodology, a transitional period will apply. In principle, the authorities will assume that from 1 August 2002 the methodology is included in the permit-application procedure. This date links up with the deadline for incorporation of the European Preparations Directive into Dutch legislation.

I hope and expect that this methodology will help reinforce the implementation of the discharge policy.

His Royal Highness de Prins van Oranje
Chairman of CIW, the Integrated Water Management Committee

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Summary

The lead-up to the grant of a permit under the Dutch Pollution of Surface Waters Act comprises three phases: information provision, establishing measures to be taken to control emissions, and assessing any residual emissions. The assessment of substances and preparations relates mainly to the 'information provision' phase. However, the data required to assess a substance or preparation are equally relevant to the assessment of residual emissions (immission assessment). The implementation of the Pollution of Surface Waters Act demands an understanding of the toxicity of individual substances and preparations to the aquatic environment.

This report describes both the general method of assessment and the procedure for informing the competent authority (via the user) of the water toxicity of individual substances and preparations. The general method of assessment is designed to apply to direct and indirect discharges under the Pollution of Surface Waters Act, but can also be used to assess substances and preparations involved in indirect discharges falling under the Environmental Protection Act. The method employs parameters and criteria which comply with European regulations regarding the classification and characteristics of substances and preparations, but couples to the properties of substances a set level of effort to limit pollution at source. The method can be used wherever it is necessary to determine the water toxicity of substances and preparations. This means that companies can use it if they need to supply information on substances and preparations to competent authorities in relation to permit or licence applications under the two aforementioned Acts or, for example, to demonstrate that a decision to use a particular substance or preparation will contribute to the on-going reduction of pressure on the environment.

It should be remembered that the general assessment method is a means of using various properties of substances to categorise them with regard to their toxicity to the aquatic environment. It will not indicate what measures should be taken in a specific case to prevent or reduce emissions. Nor can it be used to assess residual emissions.

With regard to the procedure, it should be stressed that responsibility for supplying information to the competent authority still lies with the applicant for a permit or licence under the relevant Acts. This is a blanket rule and therefore also applies to information about any basic or auxiliary substance, and any intermediate or final product which may find its way into waste-water. However, producers wishing to preserve confidentiality regarding the composition of their preparations do not always provide complete information to users. This means that users are in turn unable to pass it on to the competent authority.

For this reason, and for the sake of efficiency, producers are expected to use the general method of assessment to assess substances and preparations and to supply wholesalers and users with the results of the assessment, together with information about the relevant substances and preparations. The procedure is in line with the widely supported

programmes of ’responsible care’ and ’product stewardship’ within the chemical industry. The private sector is launching international programmes to identify the missing data necessary for the assessment of the toxicity of a large number of substances.

The procedure described in this report can be used to resolve the dilemma between the need of applicants for permits under the Pollution of Surface Waters Act to supply information on the toxicity of preparations and the desire of producers to protect information on the composition of their preparations. The description of the procedure is accompanied by a discussion of possible means of monitoring and enforcement.

In addition to describing the general method of assessment and the procedure, the report focuses on points relevant to their application. It ends with conclusions and recommendations.

1 Introduction

Why has a GAM been developed for the assessment of substances and preparations within the scope of the (aquatic) discharge policy? And how can we use this methodology?

1.1 Cause

How harmful to the surface water are certain substances or preparations? The answer to this question is essential when deciding whether or not to grant a discharge permit under the Pollution of Surface Waters Act (Wvo [lit. 1]) and whether decontamination measures are required.
In the past, various methodologies have been used to assess substances and preparations for various branches of industry or producers, such as in the textile and paper industries and for cooling and boiler water additives. In 1994, these methods were reviewed. It was decided to develop a methodology for assessing substances and preparations, regardless of the branch of industry in which they are used [lit. 4]. Basic principle: the discharge policy formulated in the Indicative Multi-year Water Programmes [IMP-water, lit. 5, 6] and the National Policy Documents on Water Management [lit.7,8].

The assessment of substances and preparations has to overcome two important bottlenecks:
- the lack of (eco-) toxicological details,
- the confidentiality of the composition of preparations.

In practice, a situation had been created in which RIZA, the Dutch Institute for Inland Water Management and Waste Water Treatment, was provided with the required information confidentially and then passed on the results of its assessment ('is possible discharge resulting from the use of this product acceptable in this specific situation') to the competent authorities.
However, the Dutch Council of State pronounced on several occasions that this procedure is contrary to the Enforcement Decree on Pollution of Government Waters [UVR, lit. 9] and to the regulations issued by regional water authorities. According to these regulations, all the relevant information must be included in the application for a permit. The water authority reviews the application and decides whether or not discharge is permitted on certain conditions. The information must be provided in such a manner that third parties, such as neighbours, are also able to review the discharge permits applied for.

1.2 Object

The need for one general methodology for assessing substances and preparations within the scope of the discharge policy (and also the jurisprudence referred to above) has instigated the methodology described in this report as well as a proposed procedure for providing information.
This report describes the methodology, its relations with other relevant

laws and regulations, as well as the procedure for providing authorities with the required information.
The object is to ensure that both companies and water authorities know what is expected of them and that substances and preparations are assessed in a uniform manner.

1.3 Approach

The GAM uses the ecotoxicological parameters and criteria of the European regulations concerning the classification of substances and preparations (Substances Directive (67/548/EEC), [lit.10]; Preparations Directive (1999/45/EC), [lit. 11]). The procedure also complies with these European regulations. These European directives have been (and/or will be shortly) incorporated into the Dutch Act on Environmentally Hazardous Substances (Wms, [lit.12]). Developments in Dutch environmental policies have also been taken into account. This is expected to create a situation in which companies and authorities receive information about substances and preparations, in addition to other information required by permit-application procedures under the Pollution of Surface Waters Act, to assess the aquatic harmfulness and consequently the efforts required to prevent or reduce discharge.

At its meeting of 17 January 1997, the working group VI of the Integrated Water Management Committee (CIW) discussed the methodology and the procedure. It was agreed to set up a sub-working group (GAM implementation), with the task to develop the implementation process and supervise the implementation. Areas for special attention were e.g. the reliability of information provided about substances and preparations and the enforceability of the system. CIW has consented to the proposed process. The definition of its task is included in Appendix 1 to this report.

While in office, it became evident to the sub-working group that a number of matters had to be specified as regards both the GAM and the procedure. It was not enough to simply implement the GAM and the procedure. For this reason, it was decided to split the tasks into, on the one hand, the further specification of the GAM and the procedure and, on the other hand, the development of an implementation process. The introduction plan for the implementation is described in a separate report [lit. 13].

Apart from defining the measures to prevent or reduce discharge of substances or preparations, the authorities must decide whether or not possible residual discharge is permitted by means of the so-called water quality test. Residual discharge is the discharge that remains after the measures resulting from the efforts required in accordance with policy have been carried out (bat, alara). A method for assessing a residual discharge has been developed by the CIW. [lit. 14]

In the past period, the sub-working group has not only developed an introduction plan, but has also worked hard on obtaining wider support for the GAM. Presentations have been given and meetings have been held with representatives of the corporate sector and of the relevant authorities. At these meetings, and also on other occasions, any issues important to the implementation of the methodology were brought to the attention of the sub-working group. This report describes the manner in which these areas for special attention may be dealt with. But apart from

these areas for special attention, situations may of course arise in practice that have not been specified in this report. It must be borne in mind that this report describes the main outlines. Situations may arise in which consultation or additional information is called for. The procedure for providing information about substances and preparations has also been specified. A solution has been sought for the bottleneck of providing information about the harmfulness of preparations, the availability of information and, especially, the confidentiality of the composition of preparations.
Besides, the possibilities of using the GAM in permit-application procedures under the Environmental Protection Act have been explored.

1.4 Bookmarker

After this introduction, chapter 3 will deal with the GAM. Chapter 4 will pay attention to the relations with laws and regulations concerning the assessment of substances and preparations. The procedure for providing information about substances and preparations is described in chapter 5, while chapter 6 contains the areas for special attention to be dealt with during the implementation. Chapter 7, finally, comprises the conclusions and recommendations.
The methodology and the backgrounds to its relations with current regulations are described in several appendices.

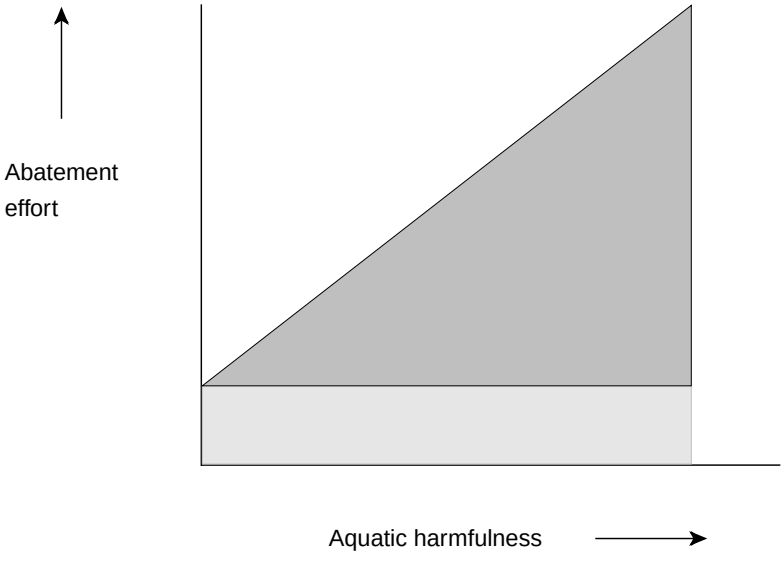
2 Methodology

This chapter deals with the basic criteria and results of the GAM for substances and preparations within the scope of the water discharge policy. With this methodology, both companies and authorities will be able to assess the aquatic harmfulness of substances and preparations based on their properties in a uniform manner.
For the GAM for substances and preparations and relevant explanatory notes, reference is made to Appendices 4 and 5.

2.1 Introduction

For the proper implementation of the water quality policy in the Netherlands, and the discharge policy in particular, it is necessary to gain an insight into the aquatic harmfulness of substances and preparations (products). By aquatic harmfulness is meant the degree to which substances may have hazardous effects on the aquatic environment. The notion that the efforts to reduce or prevent discharge of substances or preparations must increase as they are increasingly harmful to the environment is generally recognised and accepted. The degree to which substances and preparations are harmful may vary, and so may, therefore, the effort that is required. This is represented in diagram form in figure 1. This general notion must be converted into an approach that is feasible in practice.

Figure 1
General relation between abatement efforts and aquatic harmfulness of substances.



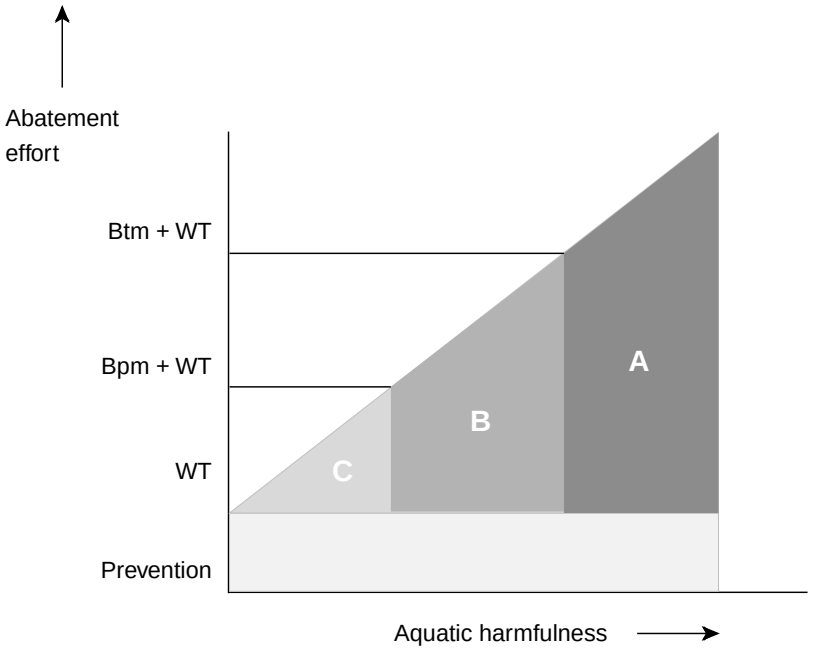
2.2 Background

The aquatic harmfulness of a substance is assessed by a combination of this substance's properties. Properties that are often used to assess aquatic harmfulness are, for example, carcinogenicity, mutagenicity,

toxicity, persistence and bioaccumulating capacity. This leaves the question open of what properties are and are not used to assess aquatic harmfulness and the manner in which these properties are included. It has been decided, for instance, not to include reprotoxicity and hormone-disrupting effects in the GAM for the time being. The background to this decision is given in section 2.4. Theoretically, a large number of categories of aquatic harmfulness can be distinguished on the basis of the combination of ecotoxicological properties of substances. Taken to extremes, each combination of properties might form a separate category. On the basis of the general notion, all these different categories of aquatic harmfulness ought to be linked to specific decontamination measures, to be taken to prevent or reduce discharge of substances or preparations. This is hardly feasible, if at all, in practice. Clustering into a limited number of categories is advisable, if not necessary. In compliance with the present water discharge policy, substances have been divided into three categories. Each of these three categories is linked to a abatement effort required in accordance with policy. This is represented in diagram form in Figure 2.

Figure 2
Discharge policy represented in diagram form.

Btm = Best technical means
Bpm = Best practical means
WT = Water quality test

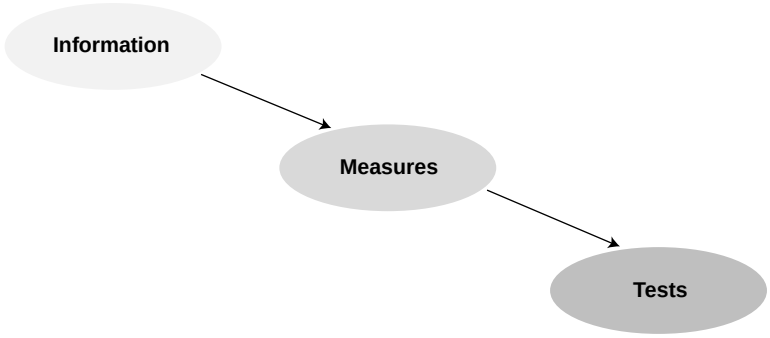


The GAM has been developed within the scope of the implementation of the discharge policy, to assess the aquatic harmfulness of substances and preparations, or, in other words, to assign every single substance and preparation to one of the three defined categories.

2.3 Use of the GAM in the implementation of the Pollution of Surface Waters Act

The permit-application procedure can be divided into three phases, i.e.:
- provision of information,
- definition of measures to prevent or reduce discharge,
- assessment of possible residual discharge.

Figure 3
Steps in the permit-application procedure under the Pollution of Surface Waters Act.



The GAM plays an important part in the process of providing information. With the GAM substances and preparations are categorised on the basis of their (eco-) toxicological properties[1].

Example:
Benzothiazole-2-thiol
CAS no.: 149-30-4
Ecotoxicological properties based on Environmentally Hazardous Substances Act: R51, R53

Log P_{ow}:	2.34
Water-solubility:	18 mg/l
Biodegradability according to OECD 301 C:	less than 2.5%
Bioaccumulation according to OECD 305 C:	< 8
LC_{50},96 hours Pimephales promelas according to OECD 203:	11 mg/l
LC_{50},48 hours Daphnia magna according to OECD 202:	4.1 mg/l
EC_{50},96 hours Alg according to OECD 201:	25 mg/l

Lowest level of acute toxicity is between 1 and 10 mg/l.
Substance is persistent

According to the GAM (see appendix 4), this substance is ranged under the following category of aquatic harmfulness:
{6} Toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.

The corresponding abatement effort is: Approach A
For more examples, please see appendix 8.

In this classification, the discharge situation of the substance or the preparation is not taken into account. The GAM categorises the aquatic harmfulness of substances and preparations in a simple and uniform way. The category of aquatic harmfulness is then linked to a degree of effort (best practical or best technical means; bpm/btm) with which the discharge of a substance or preparation must be decontaminated in principle. The information about the aquatic harmfulness of substances and preparations does not only play a part in the application for permits under the Pollution of Surface Waters Act, but also when substances and preparations used and/or produced by companies are changed after the permit has been granted.

[1] The General Assessment Methodology categorises substances on the basis of their substance-intrinsic properties. The properties of a substance used in the assessment of substances are not necessarily all substance-intrinsic. For example, the environment in which the organism is exposed to this substance affects the ecotoxicity of a substance. Since the ecotoxicological details used for the assessment are determined in accordance with standard test methods and under standard conditions, these details are considered substance-intrinsic properties in this report.

Following on the developments in environmental policies, certain companies have included the assessment of substances and preparations in their own corporate environmental care system. This is based on the idea that a company with a certified care system is obliged to provide insight into the effects on the environment of the substances and preparations used by this company. The GAM allows for mutual comparison between substances and/or preparations where their harmfulness to the aquatic environment is concerned. When the eventual choice is made between alternative substances and/or preparations, more aspects play a part, such as quantities and to what extent they can be removed from waste water. In this way, companies are able to show that by making conscious decisions regarding the use of substances or preparations they support the effort to continuously improve the environment.

The methodology provides a quick insight into the substance's potential harmfulness to the aquatic environment. This insight may lead, on the one hand, to the search for alternatives by the user, while, on the other hand, additional information may prove that the substance is potentially harmful, but is not found in waste water due to certain properties. The information about the properties of a substance, in combination with details about the use and behaviour of a substance in the process, is helpful in the selection of substances that are specifically targeted by decontamination measures.

GAM limits

The GAM assesses, in a simple and uniform way, based on a number of properties of a substance, the abatement effort required for that substance in accordance with policy. The limits of the GAM are generally set by the scope of the discharge policy. The methodology is not suitable for deciding whether or not a substance may be used in a process. In an extreme case, the authorities may refuse a permit to discharge substances or preparations after due consideration of all aspects involved. The GAM is not meant to be used for an overall assessment of waste water. This is being developed within the scope of the Whole Effluent Assessment Methodology.

The GAM does not provide a practical interpretation of the abatement effort that is required in accordance with policy. In other words, the methodology does not dictate what concrete measures are to be taken to restrict discharge of certain substances or preparations. When converting the abatement effort into concrete measures, other aspects play a part in addition to the harmfulness of a substance or preparation, such as the costs of measures, the (production) process, available water purification facilities and the concentration or load of pollutants in the waste water. Suggestions within this context are given in the various branch studies of the Integrated Water Management Committee.

Example:
A company uses a certain preparation of which it is known that its active substance clings to fibre material and is largely left behind in the process. Due to these bonding properties, the substance will attach itself to sludge when discharged through biological industrial purification. The same preparation contains additives that are easily soluble in water. Based on its properties, one of the additives is ranged under category {4} of aquatic harmfulness. On the basis of this information, it may be decided to research the additive rather than focus all attention on the active substance.

Definition in relation to the water quality test

After the abatement effort has been determined on the basis of the properties of a substance or preparation and it has been converted into concrete decontamination measures, the permissibility of the residual discharge must be assessed. The permissibility of the residual discharge is assessed by means of the water quality test.

Three basic criteria have been formulated for the purpose of developing the water quality test. Each of these basic criteria must be met (if not, additional measures may be required):

1. Discharge may not contribute significantly to exceeding the quality objectives for the water system (water and water bed) into which the discharge takes place;
2. Discharge may not result in acute toxic effects on water organisms in the mixing zone.
3. Discharge may not result in acute toxic effects on organisms living the sediments in the mixing zone.

The details of this water quality test are laid down in the CIW report entitled Emissie-Immissie Prioritering van bronnen en de immissietoets - [lit. 14]. To carry out the water quality test, the properties of the substance included in the assessment of substances and preparations are used together with information about the concentration or load of a substance in the waste water.

2.4 Basic assumptions of the GAM

The development of the GAM for substances and preparations is based on a number of assumptions.

(Inter-) national compliance

The structure of the GAM for substances and preparations complies as much as possible with the national policy criteria and (inter-) national regulations. For example, the link-up of the category of aquatic harmfulness of substances and preparations with the abatement effort required in accordance with policy is based on the national discharge policy, which distinguishes three categories of substances.

The GAM also complies with the regulations laid down by the European Union concerning the assessment of substances and preparations. The Substances Directive [67/548/EEC, lit. 10] and the Preparations Directive [1999/45/EC, lit.11] comprise international agreements regarding the classification, packaging and labelling of substances and preparations. The Substances Directive has been incorporated into the Dutch Act on Environmentally Hazardous Substances [Wms, lit. 12]. The Preparations Directive must be implemented before 31 July 2002. Consequently, the criteria of the GAM for mutagenicity, carcinogenicity, acute toxicity of organisms living in water, biodegradability, log Pow and bioconcentration are the same as the criteria for classification of substances agreed on a European level. These criteria may be changed on the basis of new scientific findings or when international classification systems are harmonised. At that time, it will be evaluated whether the GAM needs to be adjusted.

Human-oriented effects

The GAM focuses primarily on the harmfulness of substances and preparations to the aquatic environment. But the substances and preparations are also tested for carcinogenicity and mutagenicity. Although these criteria are human-oriented, they are included in the assessment, because these are the usual criteria for indicating extremely harmful substances in environmental policies.
Apart from carcinogenicity and mutagenicity, reprotoxicity is also sometimes included in the assessment of the harmfulness of substances to or through the water. Contrary to carcinogenicity and mutagenicity, however, the GAM for substances and preparations does not include reprotoxicity. Why it is not included is explained in the following section. Appendix 3 contains a more detailed description.

Substances with reprotoxic effects are substances that harm human fertility or cause developmental disorders in humans and their descendants. Reprotoxicity appears in many different forms, including the hormone-disrupting effect of substances (e.g. estrogenic effect). Both the research methods and the degree of harmfulness to humans and the environment are currently topics of a wide debate. What is certain is that reprotoxic effects are often subject to threshold concentrations. This means that a certain concentration must be exceeded before the effect can be demonstrated. Many effects that are defined as reprotoxic are included in chronic toxicity experiments. To categorise a substance with these properties (reprotoxicity) simply as a substance, which, when discharged, must be abated with the best technical means, is not the obvious solution.

In view of the many forms in which reprotoxicity is found (estrogenic effect, reduced egg or sperm cells, etc.) and the fact that these are also ranged under chronic effects, it has been decided not to include reprotoxicity in the GAM for substances and preparations within the scope of the discharge policy. As soon as it becomes more certain whether and, if so, how, estrogenic or hormone-disrupting effects must be included in the assessment of aquatic harmfulness of substances and preparations, the GAM will be adjusted.

Assessment of preparations

The GAM of preparations is based on the properties of the components (substances) of which the preparations are made up. This means that the GAM has to be carried out separately for each of the components that together make up a preparation. The preparation is assessed on the basis of the assessment of the various components of the preparation and the quantities of these components in the preparation. The system for this is based on the conventional method described in the Preparations Directive [lit. 11], which uses concentration limits.

Based on the assumptions described above, the GAM has been developed. For more details about the contents of this methodology for substances and preparations reference is made to appendices 4 and 5. The next section deals with the results of assessments.

2.5 Explanation of GAM results

The result of assessments of substances or preparations in accordance with GAM is the so-called 'category of aquatic harmfulness'. In compliance with the present discharge policy, this 'category of aquatic harmfulness' is linked to a degree of abatement effort that is required in accordance with policy. (see figure 2 on page 14)

2.5.1 Category of aquatic harmfulness

The 'category of aquatic harmfulness' gives a short description of the properties of a substance that are most harmful to the aquatic environment. As mentioned in the introduction to this chapter, aspects involved are the degree of toxicity, biodegradability and bioaccumulation of the substance. But also properties such as 'black-list substances[2]', carcinogenicity and mutagenicity, determine the category of aquatic harmfulness.

2.5.2 Abatement effort

The abatement effort indicates the level of the effort to be made to reduce the discharge of a substance. In compliance with the national water quality policy, three levels of abatement efforts have been defined (see figure 2): A, B or C.
The section below gives a brief description of the abatement efforts for substances or preparations related to each category. These efforts comply as much as possible with the national discharge policy.

Abatement effort A:

Substances in a category of aquatic harmfulness linked to abatement effort A are subject to the principle that pollution by these substances must be terminated. Companies must endeavour to reach the target of cessation of emissions. They will have to bring their processing decisions and internal operating procedures into line with this. On the other hand, these substances can also be replaced by alternative substances that are less harmful to the environment. If an essential abatement effort must be made, then the best technical means must be used. Whether the residual discharge after introduction of the best technical means still result in unacceptable concentrations in the surface water is checked by means of the water quality test. If so, additional measures may be required.

Abatement effort B:

In the case of substances in a category of aquatic harmfulness linked to abatement effort B, the discharge of these substances must be prevented as much as possible. Companies must bring their processing decisions and internal operating procedures (good-housekeeping and process-integrated measures) into line with this. An essential abatement effort must be made by using the best practical means.

.....

[2] After a transitional period of 13 years from the moment the Water Framework Directive [lit. 15] will come into effect, the European Directive 76/464/EEG [lit. 16] will be withdrawn. The withdrawal of this directive will eliminate the distinction between black-list substances and other substances.

After the introduction of these measurements, the water quality test is carried out to determine whether residual discharge may be permitted. If not, additional measures may be required.

Abatement effort C:

In the case of a limited number of other substances that are relatively harmless, such as sulphate, carbonate and chloride, the utmost must be done to prevent these substances from being discharged into the waste water (good housekeeping). To what extent measures must be taken to restrict the discharge of these substances, however, depends on the water quality objectives. If the water quality objective is exceeded, abatement measures must be carried out in order to meet the required water quality objectives.

3 GAM in relation to current laws and regulations

This chapter deals with the (inter-) national laws and regulations for assessing substances and preparations, as well as their relation to the GAM.

Various discussion forums have suggested that substances and preparations are already being assessed on the basis of the Environmentally Hazardous Substances Act and that the GAM doubles this approach. This chapter deals with the relation between assessments within the scope of the Pollution of Surface Waters Act and those within the scope of the Environmentally Hazardous Substances Act. Appendix 7 contains a more detailed description of European laws and regulations on the assessment of substances and preparations and those in the field of the environment.

3.1 Laws and regulations

As mentioned in the introduction, the GAM for substances and preparations focuses on the implementation of the discharge policy. Any knowledge of the aquatic harmfulness of substances and preparations is crucial to the implementation of the discharge policy. But there are more (Dutch and European) laws that require such an assessment. For example, where the consequences for humans and the environment in general are concerned, e.g. the Substances Directive (79/831/EC, 6th revision of Directive 67/548/EEC [lit. 17], the Preparations Directive (1999/45/EC) [lit.11], the Environmentally Hazardous Substances Act [lit. 12] and the Environmental Management Act (lit. 2]). Or when the consequences for humans and the environment are evaluated in the assessment of a substance or preparation for a specific application, such as in the Pesticides Directive (91/414/EEC) [lit.18], Biocides Directive (98/8/EC) [lit. 19] and the Pesticides Act [lit. 20]). The latter assessment is not dealt with in this report. In fact, in the development of the GAM, the Substances Directive (which is incorporated in the Dutch Environmentally Hazardous Substances Act) is taken into account, because this contains an assessment of the consequences for the environment.

3.2 Relation between assessments of substances and preparations under the Pollution of Surface Waters Act (Wvo) and the Environmentally Hazardous Substances Act (Wms)

As mentioned earlier, substances and preparations are assessed within various scopes and for various purposes. These assessments are not always based on the same parameters and criteria. In its pursuance of harmonisation and reducing the burden for the corporate sector, the GAM within the scope of the Wvo is linked up with the assessment of substances and preparations within the scope of the Wms. Nevertheless, there are a few differences. This section deals with the similarities and differences.

Type of details required for assessment

To assess the effects on the aquatic environment, the GAM is based on the same ecotoxicological parameters (LC_{50}, Log Pow, biodegradability, etc.) and criteria as those used to assess Risk phrases under the Environmentally Hazardous Substances Act. These risk phrases indicate the special hazard of a substance based on its intrinsic properties. For example, substances with an acute toxicity to water organisms below 1 mg/l are given the risk phrase: R-50 (Very toxic to aquatic organisms). The assessment of the Risk phrases and therefore the aquatic harmfulness of substances under the Environmentally Hazardous Substances Act makes it possible for the GAM to assess the abatement effort required by the emission policy. As a result, producers and suppliers do not need to carry out any extra ecotoxicological research for substances categorised on the basis of the Substances Directive.

Example:
A company wishes to market a new substance in the Netherlands and has provided the Ministry of Housing, Spatial Planning and the Environment with information about the new substance within the framework of the Notification Decree [lit. 21] based on the Environmentally Hazardous Substances Act. In view of its properties, the following R-phrases have been defined for the substance as regards its ecotoxicity: R50-R53.

This means that the substance has an acute toxicity to water organisms of less than 1 mg/l and that the substance is persistent and/or has a bioaccumulating capacity. According to the R-phrase system and according to the GAM for substances and preparations within the scope of the discharge policy, the aquatic harmfulness of this substance is categorised as:
{4} Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.

The corresponding abatement effort is A.

Amount of details required for assessment

The full risk assessment for humans and the environment, carried out for new and specially selected existing substances under the Act on Environmentally Hazardous Substances, is much more comprehensive than the assessment according to the GAM. This is also valid for the assessment of the category of aquatic harmfulness. Only the details relating to the aquatic environment are required for the GAM; details about human effects (carcinogenicity, mutagenicity) are used insofar as they are available.

Hazard versus risk approach

Under the Environmentally Hazardous Substances Act, a risk assessment is carried out to verify whether risk-reducing measures are required. The intrinsic properties of a substance (the potential danger) are considered, as well as the quantity of the substance that may be discharged into the environment. The latter aspect is estimated by means of the computer model named Uniform System for the Evaluation of Substances (USES 3.0, [lit. 22]). The resulting estimated risk to a 'standard environment', expressed in the ratio between the 'Predicted Environmental Concentration' and the 'Predicted No Effect Concentration' (PEC/PNEC-ration), determines whether or not risk-reducing measures are required.

Availability of data

The assessment of the harmfulness of discharge into surface water requires data that are not always available. The Environmentally Hazardous Substances Act prescribes that the Ministry of Housing, Spatial Planning and the Environment must be notified of new substances before they are marketed, and a file with data about the substance must be submitted. The producer of a new substance will therefore have the data required for the GAM. A programme has been launched to also retrieve information about existing substances. Depending on the quantities produced or marketed, certain data must be provided. These data are then collected and stored by the European Commission at a central place, i.e. the International Uniform Chemical Information Database (IUCLID, [lit. 23]). There are also various other databases, whether or not commercially operated, with data about substances. The quality of all this information is not always certain. It is recommended that government authorities and the corporate sector together promote that validated data are entered into databases.

For small companies, branch associations may play an important part in retrieving information about substances and preparations that are frequently used in certain branches of industry.

Examples
Initiative of the Association of Dutch Paper and Cardboard Manufacturers
The Association is negotiating with the STFI (Swedish Pulp and Paper Research Institute) about the option of acquiring the STFI database [lit. 24], which contains information about substances and preparations used by the paper industry.

Textile and carpet industry
Textile and carpet manufacturers have founded associations that manage databases with information about the substances and products they use.

The rate at which substances are being assessed is low, due to the large amount of substances. The Ministry of Housing, Spatial Planning and the Environment as well as the European Commission are looking for a way to deal with substances that have not been assessed yet, the so-called 'non-assessed chemicals'. The Netherlands started a programme entitled "Strategy on Management of Substances" (SOMS, [lit.25]) in 1999. By the end of 2000, the SOMS programme must have resulted in a cabinet decision/memorandum to the Lower Chamber concerning the 'new substances policy'.
That relatively few substances have been assessed on a European level does not automatically imply that there are data about only a limited number of substances. These data are partly incorporated in non-public literature in the possession of companies and/or research institutes. Besides, not all substances are used in large quantities or discharged through waste water. About 1,500 substances together constitute about 95% of world production. It is unlikely that the ecotoxicological data of all substances will become available in the near future. Internationally, however, the corporate sector and government authorities are trying to complete the necessary information at least for chemicals that are used in large quantities (OECD, UN-ECE).

Since the publication of the Preparations Directive in May 1999, the environmental assessment of preparations has been regulated on a

European level. Because of this, more data about the effects on the environment of preparations will also become available in due time.

The Pollution of Surface Waters Act prescribes the provision of information about substances and preparations, regardless of whether or not they have priority for the EU based on risk calculations. Under the Pollution of Surface Waters Act, priorities are set on the basis of actual use and discharge of substances into the aquatic environment.
The next chapter deals with the procedure for obtaining the required information and/or how to ensure that the risks of discharges are limited as much as possible.

4 Procedure

This chapter deals with the procedure for providing the authorities with information about substances and preparations by means of the user. Key issues are the information that must be provided, the verifiability of this information and the enforceability of the procedure.

4.1 Introduction

The Pollution of Surface Waters Act prescribes that anyone applying for a permit under this act is obliged to provide information to enable the competent authorities to review the application. This obligation also applies to information about raw and auxiliary materials and partly processed and finished products that are used by companies and may be discharged into the surface water. Due to the confidentiality of information about the composition of preparations, producers and suppliers are not always willing to provide this information. In this situation, the customer does not have the exact information. A request to observe secrecy with regard to part of the permit applications by the user does not solve this problem, because in the confidential section of the application the water quality manager cannot be provided with any information about the preparation.
To solve this bottleneck, a procedure has been designed to help users, authorities and third parties to gain sufficient insight into the aquatic harmfulness of a substance or preparation, while guaranteeing the confidentiality of the information vis-à-vis the producer or supplier.

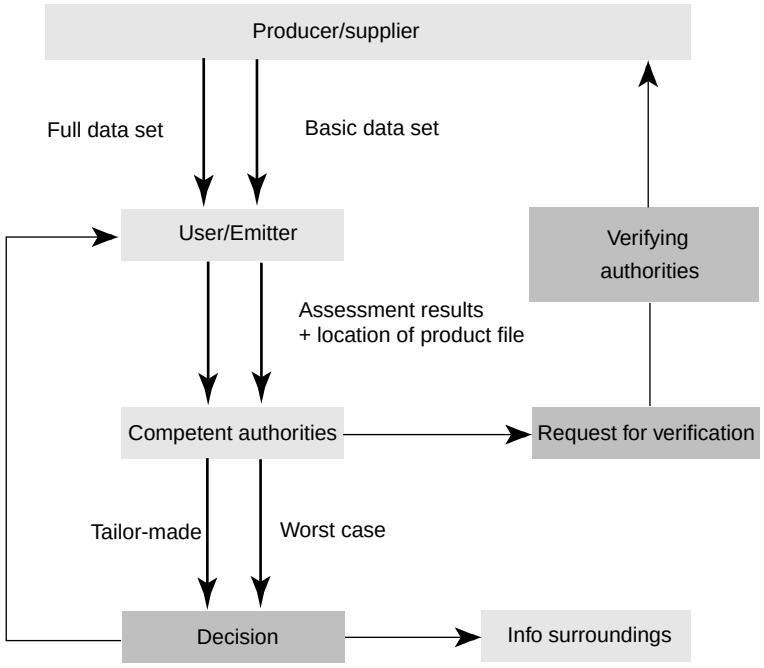
Producers and suppliers of substances and preparations play an important part in the provision of information and the assessment of substances and preparations in accordance with the GAM. The working group dealing with the effects on the market of the deregulation of legislation concerning permits granted under the Pollution of Surface Waters Act [lit. 3] has recommended to encourage that in consultation with the corporate sector a system is set up within certain branches, which will make all standard information about raw and auxiliary materials relating to the permit-application procedure accessible to all parties involved. This working group has proposed to link up with the initiatives taken by the Integrated Water Management Committee. The Dutch cabinet has adopted this recommendation.

4.2 Procedure

Producers of substances and preparations play an important part in the procedure. In fact, if there are any details available about substances and preparations, it is most likely the producers who have this information. Besides, it is not efficient to have numerous users collect the data of properties of the same substances and preparations. The most obvious approach is to have the producer/supplier collect the data and assess the substances. This is in line with Directive 86/609/EEC [lit. 26], which deals with the protection of animals used for experimental and

other scientific purposes. The procedure distinguishes between the submission of a basic set[3] and a full set of information about substances and preparations.
The following figure represents the proposed procedure in diagram form.

Figure 4
Diagram of procedure.



4.2.1 Full data set

The full data set for assessing substances and preparations contains the answers to the questions below, plus the results of the assessment. This information must be made available through the commercial chain to the user, who can pass this on to the authorities dealing with the permits.

Substances

The details of each substance required to carry out the GAM are:
- Is the substance carcinogenic (R-45), insofar as is known?
- Is the substance mutagenic (R-46), insofar as is known?
- What is the acute toxicity to water organisms (LC_{50}), preferably for four trophic levels, but in any case for crustaceans or fish.
- What is the degree of biodegradability?
- What is the Log P_{ow}?
- What is the BCF? (optional)
- What is the water solubility if the acute toxicity to water organisms cannot be determined.

Preparations

For preparations, the results of the GAM must be given, as well as the exact composition of the preparation and information about the

[3] Basic set should not be confused with Base-set according to Annex 7 of the Substances Directive.

substances of each component.

4.2.2 Basic data set

Producers may provide only a basic set of information about substances or the composition of a preparation, if the substance or preparation is assessed in accordance with the GAM.

Substances

If the producer/supplier assesses the substance and provides only a basic set of information, then it is in principle enough to indicate its aquatic harmfulness and the place at which the substance file is available for inspection by the (verifying) authorities. In this case, the authorities will apply a worst-case approach to the water quality test (i.e. assessment of residual discharge after introduction of btm/bpm), based on the most harmful properties that have resulted to this category. In other words: if a substance falls into category {6} of aquatic harmfulness according to the GAM, it is assumed that the substance has an acute toxicity to water organisms of 1 mg/l and is persistent. If this results in additional decontamination measures, then a more accurate water quality test may be carried out if the producer provides more exact data about the properties of the substance.

Preparations

In principle, users must be provided with the following basic data set for preparations:

- Results of assessment of the preparation in accordance with the GAM.
- Components in the category of aquatic harmfulness of 'black-list substance, may cause hereditary damage and/or cancer', as well as the rough quantities of the components that make up the preparation.
- Components with abatement effort A and the rough quantities of these components in the preparation.
- The place at which the product file is available for inspection by the (verifying) authorities.

The exact composition of the preparation is only known to the producer or supplier.

In the case of preparations, too, the authorities will base the water quality test on the most harmful properties, which have led to the category of aquatic harmfulness, if the producer fails to state the exact composition. If this results in additional measures, then the producer may ensure that a more accurate water quality test is carried out by providing more exact data about the composition of the preparation.

4.3 Verifiability[4]

To assess substances and preparations, information is necessary. But it is impossible to verify whether all the information provided is correct. Users and authorities must be able to trust that the assessment is based on the correct information and that the assessment itself has been

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[4] The manner in which details are to be verified will be further specified in the elaboration of the Netherlands new chemicals policy (SOMS).

carried out correctly. Those who carry out the assessment, the producers of substances and preparations, are responsible for this. The details of properties of substances may be determined by or under the authority of the producer.

For many existing substances, the information stored in databases may be used. In both cases, the details are preferably verified by certified laboratories (Good Laboratory Practice) in accordance with standardised methods. Any information about properties or substances that may have been assessed before standard test methods and the GLP came into force, may be used if valid conclusions can be drawn on the basis of this information. This is dealt with by the technical guidelines in Directive 93/67/EEC [lit. 27] and Regulation 1488/94 for risk assessment of new and existing substances [lit. 28].

To reduce the risk of errors in the assessment, a software application has been made of the GAM. However, both the corporate sector and the government value a form of verification, which may be carried out in various ways.

4.3.1 Verification by authorities

In case of doubt (but also simply as a random test), the authorities must be able to verify whether the information provided is correct and whether the assessment is carried out correctly. It is proposed to use the same procedure as that used in the verification of information for the assessment of effects on humans and the environment. In other words, the authorities (for example, in the shape of the Inspectorate for the Environment) will be permitted to inspect the product file, at their request. Of course, the user and the authorities must know by whom and where the product file is kept. This file must also contain the information that has been used for the assessment of preparations.[5]

4.3.2 Verification by the corporate sector

Apart from the authorities, the corporate sector may organise the verification themselves. For example, an independent, certified body may be designated to carry out or verify the assessment. The assessment may also form part of a section of the business operations that may be certified. This means that in environmental audits within the scope of the certification, the auditor will then verify whether the assessment has been carried out correctly. But the protocols for this will have to be set up first.

4.3.3 Product liability

Apart from this, the producer is at all times responsible for the correctness of information provided. On the other hand, the customer must also verify whether the information is correct, for example, by comparing the properties to those of other products. In this way, the user of a hazardous product that has been incorrectly categorised by the producer may prevent the incorrect use of the product.

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[5] Requests for verification by the Dutch water authorities may be sent to the Steunpunt Emissies of RIZA, tel. +31.320.29 84 28; fax: +31.320.29 84 80; email: steunpunt@riza.rws.minvenw.nl.

However, if the user of a product has been misled by its supplier and the user could not reasonably have known this, then the producer can be held liable. According to criminal law, the user will always be liable. But based on product liability, the user is able to recover any damage from the producer in civil proceedings.
In the Netherlands, the Environment Inspectorate verifies whether the information provided is correct. If misleading information has been provided, steps can be taken. The EU member countries have entered into agreements in the event that companies from EU countries are involved.

4.4 Enforceability

In the permit-application procedure, the information provided must be verified; usually, the body that grants the permits (competent authorities) verifies the information itself. After that, the manner in which the permit is formulated determines its enforceability. For example, the wording of the conditions must provide clear legal grounds to allow for measures to be taken if other substances are discharged than those mentioned in the permit. In enforcing the permit conditions, special attention may be paid, for instance, to the availability of information about raw and auxiliary materials, as well as partly processed and finished products that are used by a company and may be discharged into the waste water. Enforcers also ought to be alert if the permit allows the holder, for example, to change any raw or auxiliary materials, provided that the authorities are notified, whether in advance or afterwards.

5 Application of the GAM

This chapter deals with the areas for special attention relating to the use of the GAM for substances and preparations within the scope of the discharge policy.

In the past period, remarks have been made on various parts, which are important to the use of the GAM. A number of these remarks is based on the experience of those who grant permits and companies that use the GAM in practice or are otherwise involved in it.

5.1 Areas for special attention

Results of assessment on the basis of intrinsic properties

The GAM links the intrinsic properties of a substance or preparation to an abatement effort that is required to reduce its discharge. But it would be wrong to assume that a defined abatement effort A for a substance is automatically a ban on the use or discharge of this substance. The assessment is a first step in the permit-application process within the scope of the discharge policy. The results of the assessment, the corresponding measures, the quantities of the substance in the waste water and the results of the water quality test must be regarded as a coherent complex.
Substances that fall into the "approach A" category in accordance with the GAM may be replaced by alternative substances. Apart from intrinsic properties, aspects such as quantities used and the results of the water quality test must also be reviewed.

How to deal with data that are lacking

Not all substances come with all the data required for assessment. The pace at which these data are made available on the basis of other legal frameworks is low. The protection of the aquatic environment therefore requires a creative approach in order to solve this problem.
As a result, it has been decided to use a worst-case approach for substances of which the data (including data based on QSAR calculations) are lacking. This means that the 'environmentally safest' route of the GAM is followed, in compliance with the precautionary principle [lit.29; see also section 4.2.2]. If the data of, for example, the acute toxicity to fish or waterfleas are lacking, then the GAM will assume that the LC_{50} is below 1 mg/l. If no data are supplied at all, the substance is ranged under category of aquatic harmfulness: {4} very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment; with corresponding abatement effort A. It is then up to the applicant to provide more data about the substance or preparation, preferably based on information from the producer or supplier.

In Germany, the procedure is the same. The *Verwaltungsvorschrift wassergefährdende Stoffe* [lit. 30]' prescribes that a "*Wassergefährdungsklasse*" (WGK) is specified for substances and preparations. Depending on the

category under which a substance or preparation is ranged, more or less stringent measures must be taken during the storage and transport of the substance. If there is no information to categorise the substances and preparations, the substance is ranged under the highest category, i.e. most harmful to the environment. The methodology for determining the WGK has been harmonised with the European rules for the identification and categorisation of substances and preparations [lit. 31].

Data of preparations

Even though the assessment of preparations as to their effects on the environment only became regulated on a European level in May 1999, the environmental aspects of preparations have been researched in the past few years. In many cases, the entire preparation has been researched and not the components of which the preparation is made up. Waste water, however, will often contain not the entire preparation, but its individual components. That is why the GAM for preparations is based on the assessment of the preparation's individual components. On the other hand, the toxicity of the entire preparation may be used, in addition to other details, to consider alternative products.

In practice, it becomes evident that producers market their preparations in a diluted version, for the very reason that the preparation is assessed as a whole. Due to this dilution, the result of the assessment of the preparation is 'more favourable'. This method is contrary to the notion that the corporate sector has accepted its responsibility for the environment, but it is, at the same time, difficult to prevent. An alternative method is to only accept the assessment of preparations in their most concentrated form. Users and authorities ought to consider not only the degree of aquatic harmfulness of a preparation, but expressly also the quantity in which it is used. Although it may seem paradoxical, the quantity of the substance in the residual discharge may actually be higher in the 'diluted' product than in its concentrated version. There are two reasons for this:

- diluted products often require a higher quantity;
- as a result of the dilution, the preparation is assessed as "less" harmful to the environment and consequently a less drastic abatement effort is required. Resulting in a higher residual emission.

Based on this, the authorities are otherwise certainly entitled to demand additional measures by means of an water quality test.

Specific substance groups or situations

The GAM indicates roughly how the harmfulness to the aquatic environment of substances and preparations may be assessed on the basis of their intrinsic properties and what decontamination measures are then advisable. In practice, situations will undoubtedly sometimes require consultation and tailor-made solutions, for example, when standard tests are less appropriate for assessing the effects of substances. There must always be an opportunity for consultation on the basis of additional information.

5.2 Indirect discharge

Direct discharge into surface waters and indirect discharge (through sewage systems) of designated categories of companies are subject to

the Pollution of Surface Waters Act. All other indirect discharge fall under the Environmental Protection Act. In the case of direct discharge, the permit under the Pollution of Surface Waters Act contains regulations to prevent pollution of the surface waters as much as possible. Permits for indirect discharge (within the context of both acts), on the other hand, must include regulations to protect the effective operation of the waste water treatment plan and the relating pressure pipelines and pumping stations.

Companies subject to applying for permits under the Environmental Protection Act

Companies that have to apply for permits under the Environmental Protection Act, in common with those that fall under the Pollution of Surface Waters Act, are verified as to what substances are used and possibly discharged. The permit contains target and/or resource regulations to limit the consequences of the discharge. The permit regulations are verified during inspections. The GAM is a valuable tool for determining the abatement effort. With indirect discharge, not only the assessment of aquatic harmfulness of substances is important, but also the consequences for sewage systems, waste water treatment plants and sludge.

Discharge may especially have effects on the sewage system when volatile, flammable and explosive substances are used, as well as substances that may cause blockages (quickly settling substances, grease) and substances that damage the sewage systems (acids, sulphate). Discharge of these substances into the sewage system are therefore prohibited. The effects on sludge mainly concern the processing of sewer and sewer sludge. It is difficult to include these waste water treatment plant-specific aspects in a GAM. They demand a more location-specific approach. For this reason, it has been decided not to include the effects on sewer systems and sludge in the GAM, but to deal with these separately.
This also applies to the assessment of the effects of discharge on the proper operation of the waste water treatment plant. If a source-oriented approach has been selected on the basis of the properties of substances and preparations, then the possible effect of discharge on the operation of the waste water treatment plant may be assessed on the basis of inhibition of respiration or nitrification. These tests can be seen as part of the Whole Effluent Methodology for assessing harmfulness to the environment.

In view of the foregoing, it is logical that the authorities enforcing the Environmental Protection Act use the GAM to assess the aquatic harmfulness of substances and preparations also in indirect discharge.

5.3 Companies liable to Decrees.

By far the majority of indirect discharge is covered by Decrees under the Environmental Protection Act. Companies that are subject to these Decrees are obliged to report to the authorities, which will decide whether or not the Decrees apply. The test criteria described in the Decrees do not comprise any discharge criteria. As a result, no attention is paid to discharge when the report is reviewed, nor to substances that are found in the waste water. The companies involved are inspected on the basis of

the Decrees, which indicate which discharge can be expected within the facilities and what measures are to be taken or which requirements must be met by the discharge.

In view of the practice described above, an assessment methodology for substances and preparations does not seem useful in the individual assessment of facilities that are subject to the Decrees under section 8.40 of the Environmental Protection Act or the Discharge Decree under the Pollution of Surface Waters Act. On the other hand, the GAM ought to play a part in the design and revision of the Decrees.

5.4 Task per target group

Producers

Producers are expected to collect the details required for the assessment of substances and preparations. Based on these details, the degree of aquatic harmfulness of a substance or preparation can be determined by means of the GAM. The buyer/end user must be provided with at least a basic set of information by disclosing the information in, for example, the Material Safety Data Sheet (MSDS) or another document.

> *Example:*
> Producers of cooling water chemicals and poly-electrolytes have taken initiatives to collect the properties of 'their' substances and products and to incorporate these into a background document. The behaviour of substances in the operating process and the possible effects of residual discharge on the environment are also included.

Users

Users are expected to collect the details of substances and preparations that are available at their company and may be discharged into waste water, or at least their degree of aquatic harmfulness and the corresponding abatement effort. This method may be included in their Corporate environmental care system. A few companies have already done this.

> *Example:*
> A paper company uses the GAM when purchasing substances and preparations. The effects of substances on the company's waste water treatment plant are researched by means of a test strategy.
> Many paper companies have decided to switch to other auxiliary materials. Some companies use the GAM as a selection method to notify the water quality manager of the use of substances and preparations, whether in advance or afterwards.

This links up with the amended UVR, the Enforcement Decree on Pollution of Government Waters. According to this Decree, applicants for permits under the Pollution of Surface Waters Act must provide information about substances and preparations and about the effects of their discharge on the surface water. To be permitted to do so, applicants for these permits must have this information at their disposal.

Competent authorities

The competent authorities are obliged to mention at their (preliminary) consultation with companies that information about substances and

preparations must be submitted with their application for a permit. According to the explanatory notes to the UVR, it is at the preliminary consultation that the authorities are obliged to explain into what detail the information must be provided. Subsequently, applications are to be verified as to the availability of information about the aquatic harmfulness of and abatement efforts required for the substances and preparations. This verification is an essential part of the decision as to whether or not an application will be dealt with. If the required information is not available, the application may be refused. For that matter, the competent authorities may enter into consultation with companies as a result of inspections, for example, with regard to the substances and preparations they have found.

The authorities are recommended to encourage companies to include the GAM in their In-house Environmental Procedures. The preliminary consultations about permit procedures are an excellent opportunity to do so. As from 1 August 2002 (implementation deadline for Preparations Directive), the competent authorities will assume in their decision-making processes that substances and preparations have been assessed in accordance with the GAM.

5.5 Current agreements and transition

In 1997, the contents of the GAM were approved by the CIW, the Integrated Water Management Committee. Since then, experience has been gained with the methodology at a number of companies. The branches of industry with which agreements have been reached in the past with regard to the assessment of substances and preparations, such as the textile, paper, graphics and cooling water chemicals industries, have been notified of the developments. They have also anticipated these. That is why it is proposed to implement the GAM for all branches of industry at the same time.

5.6 Manner of implementation

The GAM will be introduced primarily through the permit-application procedures.
This means that attention must be paid to the assessment of aquatic harmfulness of and abatement efforts required for substances and preparations according to the GAM at the (preliminary) consultations between the competent authorities and companies.
When applying for a permit under the Pollution of Surface Waters Act, the company must provide the water quality manager or the authorities responsible for the Environmental Pollution Act with information about raw and auxiliary materials, partly processed and finished products that are used by the company and may be discharged into the waste water in compliance with the UVR [lit. 9] or the relevant regulations. The verification of whether or not the information has been provided forms part of the decision of whether or not the application will be dealt with. A notification system may be required for changes in the raw and auxiliary materials, partly processed and finished products. Depending on the result of the assessment, authorities must be notified, either in advance or afterwards. This approach may be required by the permit, but may also be incorporated by companies in their Corporate environmental care system.

If companies use substances and preparations in compliance with their 'care system conditions' (which have been approved by the authorities), then it will be sufficient if the authorities are notified afterwards. If the properties or the quantities discharged of a substance or preparation are such that the conditions are not met, then the authorities must be asked for permission before the substances or preparations are used and discharged.

6 Conclusions and recommendations

Conclusions

1. To achieve a uniform approach in the categorising of substances and preparations for the purpose of permits being granted within the context of the water discharge policy, a methodology is required. The General Assessment Methodology (GAM) has proved to be feasible in practice and provides companies themselves with insight into the aquatic harmfulness of substances and preparations.

2. The GAM complies with European regulations in the field of the classification, packaging and labelling of substances and preparations.

3. The GAM provides all branches of industry with a transparent and unambiguous method of categorising substances and preparations on the basis of their properties.

4. The GAM indicates to what extent discharge-reducing measures are advisable with certain substances or preparations, in view of their properties. The GAM does not deal with the question of whether or not a substance or preparation must be used or the assessment of residual discharge.

5. Those who wish to discharge substances or preparations are responsible for providing information about both the properties of the substances and the results of the assessment according to the GAM (category of aquatic harmfulness and abatement effort).

   Data required for a full data set for the assessment of substances are:
   - Properties of the substance, such as toxicity, biodegradability, bioaccumulating capacity, and assessment results.

   Data required for a full data set for the assessment of preparations are:
   - Properties of substances of each component, the results of the GAM, plus the exact composition of the preparation.

   Data required for the basic data set for the assessment of substances are:
   - Results of the assessment.
   - The place at which the product file is available for inspection by the (verifying) authorities.

   Data required for the basic data set for the assessment of preparations are:
   - The component with category of aquatic harmfulness of black-list substance, heritable genetic damage or carcinogenic and the rough quantity of the component(s) in the preparation.

- Component(s) with abatement effort A and the rough quantities of these components in the preparation.
- The place at which the product file is available for inspection by the (verifying) authorities.

6. For preparations, the GAM uses the conventional calculation method of the Preparations Directive, i.e. the aquatic harmfulness of preparations is deduced from the properties of the individual substances in the preparation and the quantities of these substances in the preparation. The reason for this approach is that the implementation of the discharge policy requires an insight into the properties of individual substances, since the individual substances will often be found in the waste water instead of the preparation in its original composition.

7. Because of their specific knowledge, producers of substances and preparations are in an excellent position to apply the GAM to these substances and preparations and they can do this in the most efficient way. The end user must be provided (by means of the chain) with information and/or the results of assessments.

8. Substances and preparations can still be assessed even if not all the relevant information about them is available. Based on the precautionary principle, a 'worst-case' approach is then followed.

9. Based on new scientific or other findings, including revisions of the European Substances Directive and Preparations Directive, the method of classification and labelling substances and preparations may be changed. If necessary and useful, the GAM for substances and preparations will be adjusted in accordance with these changes.

10. The procedure mentioned under 7 links up with developments in environmental policies, in which the responsibility for its implementation is shifted increasingly towards the corporate sector. This also gives the corporate sector the opportunity to put their principles of responsible care and product stewardship into practice.

11. This procedure also solves the bottleneck of the fact that applicants for permits under the Pollution of Surface Waters Act are obliged to provide an insight into the aquatic harmfulness of their preparations, whereas producers wish to preserve confidentiality as regards the composition of their preparations.

12. The procedure provides companies, authorities and third parties with insight into the aquatic harmfulness of substances and preparations. Companies need this insight within the framework of, for example, their Corporate environmental care system and for permit applications.

13. Verification of the assessment of substances and preparations is necessary to obtain support from authorities and the corporate sector.

14. To achieve optimum effects with the GAM, its careful introduction is essential. Object: no later than on 1 August 2002, producers will be assessing the aquatic harmfulness of 'their' substances and preparations in a uniform and transparent way and authorities will assume in their decision-making processes that substances and preparations have been assessed in accordance with the GAM.

15. When the GAM is implemented in practice, the competent authorities must expressly take a unanimous stand. This is a prerequisite for its success and will contribute to the equality before the law of companies. Within this context, a sounding board group with representatives of the competent authorities and the corporate sector may play a useful part.

Recommendations

1. It is recommended that companies start applying the GAM as from now in order to use all knowledge available about raw and auxiliary materials, partly processed and finished products, to gain insight themselves and provide insight to others about the aquatic harmfulness of substances and preparations. Information about the aquatic harmfulness of substances and preparations may be submitted to the authorities by means of the Material Safety Data Sheet or as an appendix to it.

2. It is recommended that water quality managers adjust their regulations well in advance of 1 August 2002, to the extent that they are in line with the revised UVR and pay explicit attention to the information about properties of substances to be submitted with the applications. The permit application forms will also have to include this information.

3. It is recommended that the CIW adjusts the GAM if this is necessary and useful on the basis of new findings, including revisions of the European Substances and Preparations Directives.

4. It is recommended that incidental verifications at the request of the authorities of whether or not the correct data are provided and whether or not the GAM is applied by the corporate sector are organised properly and in a uniform manner.

5. It is recommended that the working methods of producers are verified as to their suitability for use in a uniform process, for example, by means of a protocol. When companies are certified on the basis of ISO 14001, inspections can be carried out more efficiently.

6. It is recommended to evaluate the methodology and procedure in two or three years' time.

7. It is recommended that companies only purchase, use and/or produce substances and preparations of which the aquatic harmfulness is known, or of which enough details are known to assess their aquatic harmfulness. This is to prevent that companies themselves are obliged to (cause other parties to)

assess the properties of the substances and preparations for the benefit of the competent authorities.

8. It is recommended to verify, within the scope of the evaluation of Decrees under the Pollution of Surface Waters Act and the Environmental Protection Act, to what extent the GAM may be included to enable companies that are subject to these Decrees to use the information about the aquatic harmfulness of substances and preparations.

9. It is recommended that as from 1 August 2002 the competent authorities assume in their decision-making processes that substances and preparations have been assessed in accordance with the GAM.

Recommendations addressed to:
National government: 3, 4, 5, 6, 8
Authorities enforcing the Pollution of Surface Waters Act: 2, 4, 9
Authorities enforcing the Environmental Protection Act: 4, 9
The corporate sector: 1, 7

7 Bibliography

[1] Wet verontreiniging oppervlaktewateren. Wet van 13 november 1969, Stb. 1992, 628, houdende regelen omtrent de verontreiniging van oppervlaktewateren, zoals laatstelijk gewijzigd en aangevuld bij de wet van 28 januari 1999.

[2] Wet milieubeheer. Wet van13 juni 1979, zoals herplaatst in Stb. 1992, 551 en Stb. 1994, 80.

[3] Rapport van de MDW-werkgroep Wvo-vergunningverlening, 1997 Rapportage in het kader van de operatie Marktwerking, Deregulering en Wetgevingskwaliteit.

[4] Hoezo hulpstof? Procedures bij het beoordelen van hulpstoffen in het kader van de Wvo, RIZA-Werkdocument nr 96.014X , R. Edelijn c.s., RIZA.

[5] Ministerie van Verkeer en Waterstaat, 1981, Indicatief meerjaren-programma water 1980-1984.
Ministerie van Verkeer en Waterstaat.

[6] Ministerie van Verkeer en Waterstaat, 1985, Indicatief meerjaren-programma water 1985-1989.
Ministerie van Verkeer en Waterstaat, Tweede Kamer, vergaderjaar 1984-1985, 19 153 nrs. 1-2.

[7] Ministerie van Verkeer en Waterstaat, 1989, Derde Nota Water-huishouding. Ministerie van Verkeer en Waterstaat, Tweede Kamer, vergaderjaar 1988-1989, 21 250 nrs. 1-2.

[8] Ministerie van Verkeer en Waterstaat, Vierde Nota Water-huishouding Regeringsbeslissing. 1999, Ministerie van Verkeer en Waterstaat, Tweede Kamer, vergaderjaar 1998-1990, 26 401 nr. 1.

[9] Uitvoeringsbesluit verontreiniging rijkswateren, 1999,
Wet verontreiniging oppervlaktewateren. Staatscourant, 1999, nr. 27, p. 12.

[10] Europese Commissie,1967, Richtlijn 67/548/EEG van 27 juni 1967 betreffende de onderlinge aanpassing van de wettelijke en bestuursrechtelijke bepalingen van de lidstaten inzake de indeling, de verpakking en het kenmerken van gevaarlijke stoffen. Official Journal of the European Communities No. 196, 16 augustus 1967.

[11] Europese Commisie, 1999, Richtlijn 1999/45/EG van het Europees Parlement en de Raad van 31 mei 1999 betreffende de onderlinge aanpassing van de wettelijke en bestuursrechtelijke bepalingen van de lidstaten inzake de indeling, de verpakking en het kenmerken van gevaarlijke preparaten. Official Journal of the European Communities L200/1, 30 juli 1999.

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[13] Commissie Integraal Waterbeheer, 2000, Introductieplan Algemene Beoordelingmethodiek voor stoffen en preparaten.

[14] Commissie Integraal waterbeheer, 2000. Emissie-immissie; prioritering van bronnen en de immissietoets. (In voorbereiding).

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[17] Europese Commissie, 1979, Richtlijn van 18 september 1979 met 6e wijziging van Richtlijn 67/548/EEG betreffende de onderlinge aanpassing van de wettelijke en bestuursrechtelijke bepalingen van de lidstaten inzake de indeling, de verpakking en het kenmerken van gevaarlijke stoffen. (79/831/EEG) Official Journal of the European Communities, L259.

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[26] Europese Commissie 1986, Richtlijn 86/609/EEG van de Raad van 24 november 1986 inzake de onderlinge aanpassing van de wettelijke en bestuursrechtelijke bepalingen van de lidstaten betreffende de bescherming van dieren die voor experimenten en andere wetenschappelijke doeleinden worden gebruikt.

[27] Europese Commissie,1993, Richtlijn 93/67/EEG van de Commissie van de Europese Gemeenschappen van 20 juli 1993 tot vaststelling van de beginselen die gelden bij de beoordeling van risico's voor mens en milieu van stoffen die zijn aangegeven krachtens richtlijn 67/548/EEG van de Raad.

[28] Europese Commissie, 1994, Verordening (EG) nr. 1488/94 van de Commissie van 28 juni 1994 tot vaststelling van de beginselen voor de beoordeling van de risico's voor mens en milieu van bestaande stoffen krachtens Verordening nr. 793/93 van de Raad.

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Appendices

Appendix 1 Task of the sub-working group dealing with the Implementation of the General Assessment Methodology

1. Introduction

In the permit-application procedure under the Pollution of Surface Waters Act, the details of substances and preparations play an important part. The harmfulness of a substance or preparation to the aquatic environment determines the effort that has to be made to prevent or restrict the discharge of these substances or preparations. In order to establish a relation between the intrinsic properties of a substance and the policy effort required to prevent or restrict discharge, a General Assessment Methodology and a procedure for the assessment of substances and preparations within the scope of the Pollution of Surface Waters Act have been developed. This has resulted in two documents:

- The assessment of substances and preparations within the scope of the Pollution of Surface Waters Act;
- The procedure for the assessment of substances and preparations within the scope of the Pollution of Surface Waters Act.

These documents focus on the information about the properties of substances and preparations required for the assessment of their aquatic harmfulness and a procedure for providing this information to the water quality manager through the applicant. The General Assessment Methodology and the procedure comply with the European regulations in the field of assessing substances and preparations and developments in environmental policies.

At its meeting of 17 January 1997, the VI working group of CIW, the Integrated Water Management Committee, discussed both documents. It was agreed that the two documents would serve as basic information for the process that will have to result in implementation. The contents of the documents were approved, but not adopted. It was also agreed that a sub-working group of the VI working group was to be set up with the task to develop the details of this process and to carry out/supervise its implementation. Areas for special attention included the reliability of information provided about substances and preparations and the enforceability of the system. CIW has consented to the process proposed by the VI working group.

Apart from the information that is needed to determine the measures to prevent or reduce discharge of substances or preparations, the water quality test is used by the water authority to determine to what extent possible residual discharge is permitted. Residual discharge is the discharge that remains after the policy efforts required have been implemented (bpm/btm). The policy tool for assessing residual discharge has not been developed yet. This is currently being done by a sub-working group of CIW VI. Although the tasks of the two sub-working groups have a clearly different character, exchange of information between the IGAM sub-working group and the Emission-immission sub-working group is advisable. For this purpose, the documents produced by the Emission-immission sub-working group about the water quality test will be submitted to the IGAM sub-working group.

2. Object

The object of the study is to implement the General Assessment Methodology and the procedure for assessing substances and preparations within the scope of the Pollution of Surface Waters Act.
This is expected to create a situation in which companies and authorities receive information about substances and preparations, in addition to any other information required for the assessment of an application under the Pollution of Surface Waters Act, to assess their aquatic harmfulness and consequently the efforts required to prevent or reduce discharge.

3. Description

The two documents mentioned in the introduction contain a description of the General Assessment

Methodology and the procedure. Producers and distributors of substances and preparations may play an important part in the provision of information and the assessment of substances and preparations according to the General Assessment Methodology. Both the General Assessment Methodology and the procedure must be implemented in the near future. This means, amongst other things, that corporate sector and authorities must be notified. Before implementing the methodology and procedure, the parties involved must have reached agreement about the General Assessment Methodology. Although the contents of the General Assessment Methodology have been approved by CIW and CIW has consented to its implementation, it has become evident that there are still questions, especially on the part of corporate sector. To prevent that the implementation of the General Assessment Methodology is delayed due to recurrent discussions about the General Assessment Methodology, the parties represented in the sub-working group will be given one more opportunity to respond to this methodology.

It is proposed that the sub-working group carries out its tasks in stages. The following stages can be distinguished:
1. Reaching agreement about the General Assessment Methodology and proposed procedure.
2. Identification of any bottlenecks in the implementation and providing solutions.
3. The implementation process.

After agreement has been reached about the General Assessment Methodology and the proposed procedure, any bottlenecks that may obstruct its implementation must be identified, after which solutions will be suggested for these bottlenecks. Attention will have to be paid to aspects such as the reliability of information provided about substances and preparations and the enforceability of the system. Its relation with national and international (European) regulations will have to be taken into account. At the completion of each stage, the sub-working group will report back to the VI working-group.

Finally, the General Assessment Methodology and proposed procedure will be implemented. The study must eventually result in the implementation of the General Assessment Methodology and the procedure.

4. Organisation

It is proposed to set up a sub-working group under the VI working group of the CIW, whose members are persons involved in the implementation, as well as persons with know-how about the assessment of substances and preparations on a national and international (European) level, representing both government authorities and corporate sector.
An important task of the sub-working group is to identify bottlenecks in the implementation. Attention will be paid to the reliability of information and enforceability of the system, solutions for these bottlenecks and the implementation of the General Assessment Methodology and the procedure.

Members of the sub-working group (IGAM):

Ir. J. Jelsma (chairman)	Dept. of Public Works, South Holland Directorate
G. Niebeek (secr.)	Dept. of Public Works / RIZA
J. Loois, B.Eng.	District Water Authority of Amstel, Gooi and Vecht
Ms M. Bergman, B.Eng.	Regge and Dinkel Water Authority
C. Schut, B.Eng.	Dept. of Public Works, East Netherlands Directorate (until 1 January 1999)
K. Meijer, M.A.	Ministry of Housing, Spatial Planning and the Environment (DGM/DIA)
A.P.M. Meulenberg	DSM (on behalf of VNCI)
J.C. de Boer, M.A.	Dutch Association of Soap Manufacturers (on behalf of VNO/NCW)
J. van Hensbergen	KRL (on behalf of VNO/NCW)
Ms E. Gouman, M.Sc.	Environmental Department of Amsterdam (on behalf of VNG)

5. Schedule

The study started in October 1997 and was scheduled for completion by the middle of 1998 when a final report was submitted. Meeting frequency was approx. once every two months. Members were expected to contribute 2-3 man weeks, depending on the division of tasks.

Appendix 2 Glossary

Acute toxicity	The harmful effect that occurs within an exposure time that is short in relation to the life span of an organism.
Bioaccumulation	The net result of absorption, distribution and elimination of a substance as a result of all exposure routes, such as exposure through air, water, soil/sediment or food.
Carcinogenicity	The capacity of a substance, physical or biological agents, to cause cancer.
Direct discharge	Discharge of waste water directly onto the surface water.
Hormone-disrupting substances	Substances that, when exposed, may affect the hormonal system to the extent that they may cause harmful effects on the person exposed or his/her descendants.
Indirect discharge	Discharge of waste water through the sewage system onto the surface water.
$L(E)C_{50}$	The concentration or dose estimated to be lethal to (or have an effect on) 50% of the tested organisms.
Maximum Acceptable Risk	Concentration of a substance, which is not expected to have any harmful effects on humans or the ecosystem
Mutagenicity	Introduction of hereditary changes (mutations) in the genotype of a cell.
Persistence	Parameter of a substance, describing the time during which a substance remains in an environmental compartment before being physically removed or chemically or biologically converted.
P_{ow}	Partition coefficient of a substance among the n-octanol and water phases.
Preparation	Mixtures or solutions consisting of two or more substances.
Product file	File kept by the producer, containing the composition of a product/preparation and the data sets of the components that make up the product/preparation.
Product stewardship	The control of risks and improvement of the Safety, Health and Environmental performance of a product throughout its life cycle in a responsible way from a management point of view by means of continuous improvement processes.
Responsible care	An international programme in which companies may participate on a voluntary basis to continuously improve their performance in the fields of safety, health, environmental protection and communication.
Reprotoxic substances	Substances with reprotoxic effects, or substances that are toxic to reproduction, are substances that harm human fertility or cause developmental disorders in humans and their descendants.
Residual discharge	Discharge that remains after measures in compliance with btm/bpm/alara have been carried out to reduce discharge.
Serious risk	Limit set for each substance on the basis of scientific details, which indicates at which concentration in an environmental compartment harmful effects can be expected among 50% of the types or processes in the ecosystem.
Substances	Chemical elements and their compounds, whether existing naturally or as a result of production, including all additives required to maintain product stability and all impurities as a result of the production process, but excluding solvents that can be separated without affecting the stability of the substance or changing its composition.

Appendix 3 Reprotoxicity

Within the context of environmental policies, including water quality policies, carcinogenicity has been used for some time as one of the parameters indicating the harmfulness of a certain substance to humans and the environment. Directive 72/464/EC reads as follows at point 4 of list I: those substances of which it has been proved that they may be carcinogenic, *whether in or through the water*.
Before substances were designated on a European level as substances included in list 1, the Dutch Working Group for Water Pollution Assessment Criteria set up an assessment system (BCW diagram) to select substances for its 'black list' and 'grey list' in the Netherlands. The Working Group stated that the first, extremely important indication of the possible carcinogenic effect of a substance may be shown by mutagenicity research. This applies in particular when genotoxicity is the common operating mechanism. However, mutagenicity is not a separate selection criterion in the working group's assessment system, in common with other human-oriented effects of substances.

The risk assessment of new and existing substances based on the Substances Directive (67/548/EC) focuses on the risks for humans and the environment. Human risk evaluation includes aspects such as carcinogenicity, mutagenicity and reprotoxicity. Substances with reprotoxic effects are harmful to human fertility or may cause developmental disorders in humans and their descendants.

The European Water Framework Directive stipulates that the European Council must take specific measures to deal with pollutants or groups of substances that constitute an unacceptable environmental risk. These substances will be prioritised on the basis of their risks to or through the aquatic environment. Aspects such as carcinogenicity, mutagenicity and reprotoxicity are included. Appendix III to the IPPC Directive also mentions substances that have a harmful effect on reproduction.

The question is now whether reprotoxicity must be included as a criterion in the General Assessment Methodology for substances and preparations (GAM) within the scope of the Pollution of Surface Waters Act and, if so, what decontamination efforts ought to be required in policy terms. Reprotoxicity appears in many different forms, including hormone-disrupting effects of substances (e.g. estrogenic effects). These effects are found both directly in the water phase and through the water. The research methods used, as well as the degree of harmfulness to humans and the environment, are currently topics of a wide debate. What is certain is that reprotoxic effects are often subject to threshold concentrations. This means that effects are only found when a certain concentration is exceeded. Many of the effects that are defined as reprotoxic are included in chronic toxicity experiments. To categorise a substance with these properties (reprotoxicity) simply as a substance, which, when discharged, must be decontaminated with the best technical means, is not the obvious solution.

In view of the many forms in which reprotoxicity appears (estrogenic effect, reduced egg or sperm cells, etc.) and the fact that these are also ranged under chronic effects, it has been decided not to include reprotoxicity in the GAM within the scope of the Pollution of Surface Waters Act. As soon as it becomes clearer whether (and, if so, how) estrogenic or hormone-disrupting effects must be included, the programme will be adjusted, if required.

Appendix 4[6] Assessment of substances

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Explanation of GAM-diagram for substances

Table B-4-1 shows the GAM in diagram form. However, the following notes must be made first:

Degradation products
If it becomes evident from research and/or literature that degradation of a substance produces harmful degradation products, these products will also have to be assessed by the GAM. An example of this is the decomposition of nonylphenolethoxylate into the more harmful nonylphenol.

Inorganic substances
The GAM applies to both organic and inorganic substances and preparations. For inorganic substances, such as salts and metals, the following assumptions can be made:

easily biodegradable $\rightarrow$ yes
log $P_{ow} \geq 3.0 \rightarrow$ no

It is known that a number of inorganic substances (metals in particular) accumulate easily while they do not degrade easily. Since the most harmful inorganic substances, such as mercury and cadmium, have been designated as black-list substances, the assumptions mentioned above are justifiable from an ecological point of view.

EU-classifications
Appendix I to the Substances Directive (67/548/EEC) contains a list of more than 1,400 substances that are identified as harmful within the scope of this Directive. For each substance, risk sentences are defined, amongst other things, which are attached to a substance. The risk sentences in Appendix I to the Substances Directive can be translated directly into the categories of aquatic harmfulness used by the GAM.

The absence of risk sentences R50, R51, R52 and/or R53 does not imply that the substance is not harmful to water organisms and/or does not cause any harmful effects on the aquatic environment in the long term. In fact, if insufficient information has been submitted for a substance (including a technical file in accordance with Appendix VIIA of the Substances Directive), then there cannot be any certainty as to its aquatic toxicity, biodegradability and bioaccumulating capacity.

Category of harmfulness (EU)	Category of aquatic harmfulness	
R 45	{3.}	May cause cancer.
R 46	{2.}	May cause heritable genetic damage.
R 50	{5.}	Very toxic to aquatic organisms.
R 50/53	{4.}	Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.
R 51/53	{6.}	Toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.
R 52/53	{8.}	Harmful to aquatic organisms; may cause long-term adverse effects in the aquatic environment.
R 52	{9.}	Harmful to aquatic organisms.
R 53	{10.}	Slightly harmful to aquatic organisms; may cause long-term adverse effects in the aquatic environment.

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[6] This appendix has been taken over from RIZA report 97.024.

Lower limits for substances
Substances (additives, impurities) whose percentage in weight is below the limits given in the following table do not need to be taken into account, unless a lower limit has been set by Appendix I of Directive 67/548/EEC.

Black-list substances	0.1%
Substances that may cause heritable genetic damage (R 46)	0.1%
Substances that may cause cancer (R 45)	0.1%
Substances with an acute toxicity of below 1 mg/l (R 50)	0.1%
Substances with an acute toxicity of between 1 and 10 mg/l (R 51)	0.1%
Other substances	1%

Black-list substances[7]
"Black-list substances" are substances that are included in the appendix to the Notification of the Commission to the Council (of 22 June 1982) concerning hazardous substances that must be included in list I of Directive 76/464/EEC. This appendix currently contains 132 substances.

May cause heritable genetic damage and May cause cancer
Substances are considered mutagenic (may cause heritable genetic damage) and carcinogenic (may cause cancer) when this has been proved. Appendix I to the Substances Directive (most recently amended by Directive 94/69/EC) contains a list of hazardous substances and includes specifications about the categorising, packing and marking of each of these substances. It also states whether or not a substance is carcinogenic (R 45) or mutagenic (R 46).
The GAM does not make allowance for the possible degradation of a carcinogenic and mutagenic substance. Indeed, this substance will never - certainly not within a limited period of time - degrade completely, whereas any residual discharge is extremely harmful.

Acute toxicity
Acute toxicity is understood to mean the direct toxicity of a certain substance to water organisms, which occurs after short exposure. To obtain a proper insight into the acute toxicity of a certain substance, this acute toxicity must be assessed for test organisms on four trophic levels (fish, crustaceans, algae and bacteria). These organisms are selected on the basis of criteria such as ecological relevance, availability of the organisms and availability of operational protocols. In order to carry out the GAM, the acute toxicity must be introduced to the most sensitive organism, i.e. the trophic level with the lowest $LC_{50}/EC_{50}/E(I)C_{20}$.

Especially in the case of existing substances, the toxicity data of the organisms on the four trophic levels are not always available. In fact, when authorities are notified of new substances, the toxicity details for test organisms on at least three trophic levels must be submitted, but this obligation does not apply to existing substances (Substances Directive).
To prevent that a great deal of additional research is to be carried out at short notice, the assessment of acute toxicity to either fish (LC_{50}, 96 h) or crustaceans (EC_{50}, 48 h) is considered sufficient for the time being. If a substance is known to have a specific effect on an organism on a trophic level other than fish or crustaceans, the acute toxicity for an organisms of this trophic level must be assessed. Examples of this are bactericides and algicides.
If the toxicity details of organisms on several trophic levels are available from experimental research and/or literature, then the acute toxicity to the most sensitive organism is a criterion.
If it is impossible to assess the acute toxicity, the reasons for this must be submitted with the test results.

Biodegradability
Substances are considered easily degradable if the following criteria apply:
A If the following degradation levels are reached in biodegradation studies of 28 days:
- in tests based on dissolved organic carbon: 70%,
- in tests based on oxygen depletion or carbon dioxide development: 60% of the theoretical

.....

[7] After a transitional period of 13 years from the moment the Water Framework Directive comes into effect, it is expected that Directive 76/464/EEC will be withdrawn. The withdrawal of this directive will eliminate the distinction between black-list substances and other substances.

maximum levels.
These biodegradation levels must be reached within ten days from the start of the degradation (= the moment at which 10% of the substance has been degraded).
Or:

B In those cases, in which only the details of CZV and BZV_5 are available, if the BZV_5/CZV quotient is higher than or equal to 0.5;
Or:

C If other convincing scientific evidence shows that the substance will degrade in the aquati environment
(biotic and/or abiotic) by more than 70% within a period of 28 days.

The biodegradability criterion does not apply to inorganic substances.

Log P_{ow}
The log Pow is the logarithm of the partition coefficient of a substance among the n-octanol and water phases. It is a criterion for the bioaccumulating capacity of a substance, and it does not apply to inorganic substances.

BCF
The bioaccumulating capacity of a substance is generally indicated by means of the bioconcentration factor (BCF) or the ratio between the concentration of a substance in an organism and the concentration of this substance in the water (in a balanced situation). The bioconcentration factor must always be assessed experimentally. The BCF assessment is otherwise optional.

Additional scientific evidence
Additional scientific evidence is evidence relating to degradation and/or toxicity to provide sufficient certainty that neither the substance nor its degradation products constitute a potential long-term and/or delayed risk to the aquatic environment.
The producer or supplier is given the opportunity to prove by means of additional scientific evidence that the expected long-term effects will not occur.

Solubility
By solubility is meant the solubility of a substance in water. Substances that do not dissolve in water, but can be mixed or emulsified in water, are regarded as non-soluble.

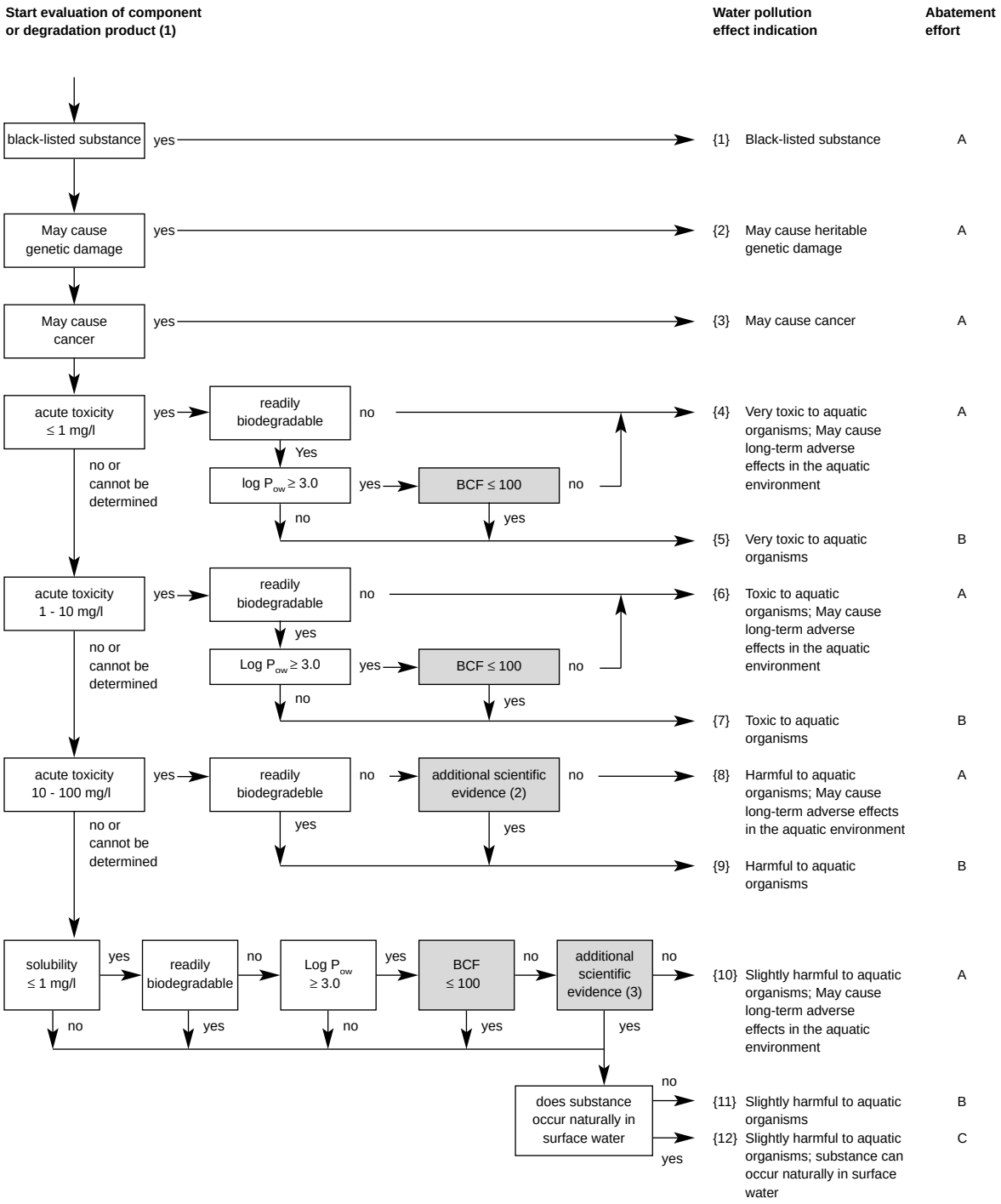
Are there natural occurrences of the substance in surface water?
These are relatively harmless pollutants that are found naturally in the surface water and have only a slight degree of toxicity. At present, only sulphate and chloride are considered to be substances with natural occurrence in the surface water.

Test methods
In principle, the properties of substances must be assessed in accordance with methods that are described in Appendix V to the Substances Directive (67/548/EEC). Other methods, which are comparable and standardised (OECD, NEN, CEN, DIN, ISO), are permitted. Appendix 6 to this report lists a number of accepted test methods.
Under certain circumstances, it is also permitted to estimate the properties of substances. Several estimating methods have been developed for this, the so-called QSARs (quantitative structure-activity relation). The Technical Guidance Document of the European Union for the risk assessment of new and existing substances states a number of QSARs for estimating the physico-chemical parameters (such as log P_{ow}) and ecotoxicological effects (such as acute toxicity) of substances with a non-specific operating mechanism. These recommended QSARs may be used to carry out the GAM. The use of QSARs to estimate BCF is not permitted.

Absence of information
In the absence of information, the following assumptions must be made:
- in the absence of information about degradability, the substance is considered not easily degradable;
- in the absence of information about the log Pow, it is assumed to be higher than 3.0;
- in the absence of information about BCF, it is assumed to be higher than 100 (if log $P_{ow} \geq 3.0$);
- If information about acute toxicity is lacking or not known (taking into account that which has been

Table B-4.1

Hazard identification test for substances



(1) If research and/or the literature indicates that the degradation products of a substance are harmful, these products must also be subjected to a hazard identification test.

(2) If a substance/degradation product does not present a potential long-term and/or delayed danger to the aquatic environment, classification abatement effort A can decay. The additional scientific evidence can compromise the following studies:
I) proof of rapid biodegradation in an aquatic environment;
II) no chronic toxicity effects at a concentration of 1 mg/l.
(See also notes to additional scientific evidence)

(3) See 2, on the understanding that there must be no chronic toxicity effects at the solubility limit instead of 1 mg/l.
(See also notes to additional scienific evidence)

Facultative test, if data lacking follow 'no' route

Abatement effort A: approach as for black-listed substances or substances with comparable characteristics.

Abatement effort B: approach as for relatively hazardous substances.

Abatement effort C: approach as for relatively harmless substances.

Appendix 5[8] Assessment of preparations

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Explanation of GAM diagram for preparations

Table B-5.1 shows the diagram for preparations.

The category of aquatic harmfulness of preparations is assessed on the basis of concentration limits (expressed in percentages of weight) in relation to the category of aquatic harmfulness of the individual substance(s) that make(s) up the preparation. The following section describes how the categories of aquatic harmfulness and decontamination efforts for preparations are assessed. A summary is given in table B-5.1.

General notes
- The numbers between {} refer to the categories of aquatic harmfulness shown in table B-5.1 on page 59;
- P_x = the weight percentage of each substance used to make the preparation, ranged under category of aquatic harmfulness {x}.

The following preparations are assigned the category of aquatic harmfulness indicated by "*Contains black-list substance*" and "*Abatement effort A*":
a) Preparations that contain at least one substance ranged under category of aquatic harmfulness {1}, in a concentration that is individually equal to or higher than 0.1%.

The following preparations are assigned the category of aquatic harmfulness indicated by "*Mutagenic*" and "*Abatement effort A*":
a) Preparations that contain at least one substance ranged under category of aquatic harmfulness {2}, in a concentration that is individually equal to or higher than 0.1%.

The following preparations are assigned the category of aquatic harmfulness indicated by "*Carcinogenic*" and "*Abatement effort A*":
a) Preparations that contain at least one substance ranged under category of aquatic harmfulness {3}, in a concentration that is individually equal to or higher than 0.1%.

The following preparations are assigned the category of aquatic harmfulness indicated by "*Very toxic to aquatic organisms; contains substances that are harmful to the aquatic environment*" and "*Abatement effort A*":
a) Preparations that contain one or several substances ranged under category of aquatic harmfulness {4}, in concentrations that are individually equal to or higher than 25%;
b) Preparations that contain two or more substances ranged under category of aquatic harmfulness {4}, in concentrations that are individually not higher than 25%, but for which:

$$\sum \left(\frac{P_4}{25} \right) \geq 1$$

The following preparations are assigned the category of aquatic harmfulness indicated by "*Very toxic to aquatic organisms*" and "*Abatement effort B*":
a) Preparations that contain one or several substances ranged under category of aquatic harmfulness {5}, in concentrations that are individually equal to or higher than 25%;

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[8] This appendix has been copied from RIZA report 97.024.

b) Preparations that contain two or more substances ranged under categories of aquatic harmfulness {4} or {5}, in concentrations that are individually not higher than 25%, but for which:

$$\sum \left(\frac{P_4 + P_5}{25} \right) \geq 1$$

The following preparations are assigned the category of aquatic harmfulness indicated by "*Very toxic to aquatic organisms; contains substances that are harmful to the aquatic environment*" and "*Abatement effort A*":

a) Preparations that contain one or several substances, ranged under category of aquatic harmfulness {4}, in a concentration that is individually equal to or higher than 2.5%, but lower than 25%;
b) Preparations that contain one or several substances, ranged under category of aquatic harmfulness {6}, in a concentration that is individually equal to or higher than 25%;
c) Preparations that contain more than one substance, ranged under categories of aquatic harmfulness {4} or {6}, in concentrations that are individually not higher than the limits stated under a) and b), but for which:

I) $\sum \left(\frac{P_4}{2,5} \right) \geq 1$ of

II) $\sum \left(\frac{P_4 + P_6}{25} \right) \geq 1$

The following preparations are assigned the category of aquatic harmfulness indicated by "*Toxic to aquatic organisms*" and "*Abatement effort B*":

a) Preparations that contain one or several substances, ranged under category of aquatic harmfulness {5}, in a concentration that is individually equal to or higher than 2.5%, but lower than 25%;
b) Preparations that contain one or several substances, ranged under category of aquatic harmfulness {7}, in a concentration that is individually equal to or higher than 25%;
c) Preparations that contain more than one substance, ranged under categories of aquatic harmfulness {4}, {5}, {6} or {7}, in concentrations that are individually not higher than the limits stated under a) and b), but for which:

I) $\sum \left(\frac{P_4 + P_5}{2,5} \right) \geq 1$ of

I I) $\sum \left(\frac{P_4 + P_5 + P_6 + P_7}{25} \right) \geq 1$

The following preparations are assigned the category of aquatic harmfulness indicated by "*Harmful to aquatic organisms; contains substances that are harmful to the aquatic environment*" and "*Abatement effort A*":

a) Preparations that contain one or several substances, ranged under category of aquatic harmfulness {4}, in a concentration that is individually equal to or higher than 0.25%, but lower than 2.5%;
b) Preparations that contain one or several substances, ranged under category of aquatic harmfulness {6}, in a concentration that is individually equal to or higher than 2.5%, but lower than 25%;
c) Preparations that contain one or several substances, ranged under category of aquatic harmfulness {8}, in a concentration that is individually equal to or higher than 25%;
d) Preparations that contain more than one substance, ranged under categories of aquatic harmfulness {4}, {6} or {8}, in concentrations that are individually not higher than the limits stated under a), b) and c), but for which:

I) $\sum \left(\frac{P_4}{0,25} \right) \geq 1$ of

II) $\sum \left(\frac{P_4 + P_6}{2,5} \right) \geq 1$ of

III) $\sum \left(\frac{P_4 + P_5 + P_8}{25} \right) \geq 1$

The following preparations are assigned the category of aquatic harmfulness indicated by "*Harmful to aquatic organisms*" and "*Abatement effort B*":

a) Preparations that contain one or several substances, ranged under category of aquatic harmfulness {5}, in a concentration that is individually equal to or higher than 0.25%, but lower than 2.5%;
b) Preparations that contain one or several substances, ranged under category of aquatic harmfulness {7}, in a concentration that is individually equal to or higher than 2.5%, but lower than 25%;
c) Preparations that contain one or several substances, ranged under category of aquatic harmfulness {9}, in a concentration that is individually equal to or higher than 25%;
d) Preparations that contain more than one substance, ranged under categories of aquatic harmfulness {4}, {5}, {6}, {7}, {8} or {9}, in concentrations that are individually not higher than the limits stated under a), b) and c), but for which:

I) $\sum \left(\frac{P_4 + P_5}{0,25} \right) \geq 1$ of

II) $\sum \left(\frac{P_4 + P_5 + P_6 + P_7}{2,5} \right) \geq 1$ of

III) $\sum \left(\frac{P_4 + P_5 + P_6 + P_7 + P_8 + P_9}{25} \right) \geq 1$

The following preparations are assigned the category of aquatic harmfulness indicated by "*Slightly harmful to aquatic organisms; contains substances that are harmful to the aquatic environment*" and "*Abatement effort A*":

a) Preparations that contain one or several substances, ranged under category of aquatic harmfulness {10}, in a concentration that is individually equal to or higher than 25%;
b) Preparations that contain more than one substance, ranged under categories of aquatic harmfulness {4}, {6}, {8} or {10}, in concentrations that are individually not higher than 25%, but for which:

$\sum \left(\frac{P_4 + P_6 + P_8 + P_{10}}{25} \right) \geq 1$

The following preparations are assigned the category of aquatic harmfulness indicated by "*Slightly harmful to aquatic organisms; contains substances that are harmful to the aquatic environment*" and "*Abatement effort C*":

a) Preparations that *exclusively* contain substances ranged under category of aquatic harmfulness {12}.

The following preparations are assigned the category of aquatic harmfulness indicated by "*Slightly harmful to aquatic organisms*" and "*Abatement effort B*":

a) Preparations that are not covered by the criteria mentioned in this chapter.

Table B-5.1 represents the methodology described above in diagram form.

On the basis of the foregoing, it becomes evident that a preparation may be ranged under various categories of aquatic harmfulness. The list below indicates what information about categories of aquatic harmfulness must be provided with the preparation.

The categories of aquatic harmfulness mentioned below must always be stated with the preparation.

- Contains a black-list substance.
- Mutagenic.
- Carcinogenic.

Apart from the categories of aquatic harmfulness mentioned above (insofar as applicable), in the case of the following categories of aquatic harmfulness only the category mentioned first needs to be stated:

- Very toxic to aquatic organisms; contains substances that are harmful to the aquatic environment.
- Toxic to aquatic organisms; contains substances that are harmful to the aquatic environment.
- Harmful to aquatic organisms; contains substances that are harmful to the aquatic environment.
- Slightly harmful to aquatic organisms; contains substances that are harmful to the aquatic environment.
- Very toxic to aquatic organisms;
- Toxic to aquatic organisms;
- Harmful to aquatic organisms;
- Slightly harmful to aquatic organisms;
- Slightly harmful to aquatic organisms; natural occurrence of substance in surface water.

Abatement effort

After the categories of aquatic harmfulness of the preparations have been assessed, the abatement effort for the preparations may be determined. Each category of aquatic harmfulness is linked to a abatement effort, such as ''abatement effort A', which is linked to the '"Mutagenic" category.

The abatement effort that applies to the preparation is equal to that of the category(-ies) with the most stringent abatement effort. The order in which the abatement efforts are mentioned below is also the order in which the degree of effort diminishes.

- Abatement effort A;
- Abatgement effort B;
- Abatement effort C.

Table B-5.1

General Assessment Methodology for preparations

Category of substance	**Classification of preparation (category of aquatic harmfulness and decontamination effort)**											
	Contains black-list substance	Mutagenic	Carcinogenic	Very toxic to aquatic organisms; contains substances that are harmful to the aquatic environment	Very toxic to aquatic organisms	Toxic to aquatic organisms; contains substances that are harmful to the aquatic environment	Toxic to aquatic organisms	Harmful to aquatic organisms; contains substances that are harmful to the aquatic environment	Harmful to aquatic organisms	Slightly harmful to aquatic organisms; contains substances that are harmful to the aquatic environment	Slightly harmful to aquatic organisms	Slightly harmful to aquatic organisms; contains substances occurring naturally in surface waters
	A	A	A	A	B	A	B	A	B	A	B	C
{1} Black-list substance	≥ 0,1%										< 0,1	
{2} May cause heritable genetic damage		≥ 0,1%									< 0,1	
{3} May cause cancer			≥ 0,1%								< 0,1	
{4} Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment				≥ 25%		2,5 ≤ conc < 25%		0,25 ≤ conc < 2,5%			< 0,25%	
{5} Very toxic to aquatic organisms (in combination with {4})					≥ 25%		2,5 ≤ conc < 25%		0,25 ≤ conc < 2,5%		< 0,25%	
{6} Toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment (in combination with {4})						≥ 25%		2,5 ≤ conc < 25%			< 2,5%	
{7} Toxic to aquatic organisms (in combination with {4}, {5} and {6})							≥ 25%		2,5 ≤ conc < 25%		< 2,5%	
{8} Harmful to aquatic organisms; may cause long-term adverse effects in the aquatic environment (in combination with {4} and {6})								≥ 25%			< 25%	
{9} Harmful to aquatic organisms (in combination with {4}, {5}, {6}, {7} en {8})									≥ 25%		< 25%	
{10} Slightly harmful to aquatic organisms; may cause long-term adverse effects in the aquatic environment (in combination with {4}, {6} and {8})										≥ 25%	< 25%	
{11} Slightly harmful to aquatic organisms											≥ 1%	
{12} Slightly harmful to aquatic organisms; natural occurrence in surface water												100%

Appendix 6[9] Summary of test methods

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This appendix describes the test methods used to determine the criteria of the substance-intrinsic test. These criteria are: acute toxicity, biodegradability, log P_{ow}, BCF and solubility. In principle, the properties of substances must be assessed in accordance with methods that are described in Appendix V to the Substances Directive (67/548/EEC). Other methods that are similar and standardised (OECD, NEN, CEN, DIN, ISO) are permitted.
If one of the methods in this appendix is not suitable for researching a certain property, an explanation must be given of the alternative method used. The methods listed below are permitted in any case.

Assessment of acute toxicity to fish
- Annex V, C.1 (Directive 67/548/EEC)
- OECD 203
- NEN 6504
- ISO 7346

Assessment of acute toxicity to crustaceans
- Annex V, C.2 (Directive 67/548/EEC)
- OECD 202
- NEN 6501
- ISO 6341

Assessment of acute toxicity to algae
- Annex V, C.3 (Directive 67/548/EEC)
- OECD 201
- ISO 8692

Assessment of acute toxicity to bacteria
- OECD 209
- NVN 6516
- NEN and ISO 9509
- ISO 10712
- NEN and ISO 8192

Assessment of biodegradability
- Annex V, C.4-A: DOC (dissolved organic carbon) levelling test
- Annex V, C.4-B: Revised OECD screening test - DOC levelling
- Annex V, C.4-C: Carbon dioxide development test (amended Sturm test)
- Annex V, C.4-D: Manometric respirometrics
- Annex V, C.4-E: Closed bottle test
- Annex V, C.4-F: MITI (Ministry of International Trade and Industry, Japan)
- OECD 301 A-E

For more information about these methods, reference is made to Appendix V to Directive 67/548/EEC.

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[9] This appendix has copied from RIZA report 97.024.

Assessment of partition coefficient (log P_{ow})

- Annex V, A.8 (Directive 67/548/EEC)
- OECD 107

These methods are not suitable for assessing the log P_{ow} of surface-active substances, for which the calculation methods based on fragment-constants are recommended.

Assessment of bioconcentration factor (BCF)

- OECD 305 A-E

Assessment of solubility in water

- Annex V, A.6 (Directive 67/548/EEC)
- OECD 105

Appendix 7 European and national laws and regulations

. . . . . .

1. European regulations

This appendix deals with European regulations in the field of the assessment of substances and preparations. The legal principles of the internal market and the environment are important in this context. When rules are issued on the basis of the internal market, it is important to prevent unfair competition between companies in the various member countries. The member countries are entitled to issue their more stringent rules only if they can account for them. When incorporating European regulations in the field of the environment into national legislation, the member countries must offer the same minimum level of protection. The regulations for (the release of) substances and preparations have been developed giving appropriate consideration to the environment and the internal market. The regulations involved are, on the one hand, the Framework Directive (76/464/EEC), the IPPC Directive (96/61/EC) and the Water Framework Directive (2000/60/EC) and, on the other, the Substances Directive (79/831/EEC, 6th revision of Directive 67/548/EEC) and the Preparations Directive (1999/45/EC).

Framework Directive (76/464/EEC)

The European Directive of 4 May 1976 (76/464/EEC) is important to water quality management. Under this Directive, all EU member countries are obliged to take all the appropriate measures:
- to end the pollution of water by list I substances, and
- to reduce the pollution of water by list II substances.

At present, a total of 132 substances qualify for inclusion in list I.
Of these 132 substances, 18 have meanwhile been classified as list I. The EU has drawn up emission limit values for these substances. The work is progressing slowly. At the moment, EU water regulations are being revised thoroughly. A Water Framework Directive has been developed. Directive 76/464/EEC will be withdrawn 13 years after the Water Framework Directive comes into effect. Apart from these substance-oriented regulations, the IPPC Directive, which rather concentrates on the process, has recently come into force.

IPPC Directive (96/61/EC)

On 24 September 1996, Directive 96/61/EC was adopted, which deals with Integrated Pollution Prevention and Control (IPPC Directive). The Directive focuses on the integrated pollution prevention and control for a number of specified operations. For example, measures are included to prevent or reduce release by operations in the air, water and soil, including measures regarding waste material. The Directive contains an indicative list of substances, for which release limits must be included in the permit, if there is a risk of these substances being released in significant quantities by the equipment involved.

Water Framework Directive (2000/60/EC)

October 2000, the Water Framework Directive (2000/60/EC) was adopted. This framework directive has consequences for water management in Europe.
Under the framework directive, member countries are obliged to draw up river basin management plans. These plans must contain a programme of measures to prevent, for example, the deterioration of the ecological and chemical condition of surface and groundwaters and to improve the condition of polluted surface and groundwaters. The plan must include measures to end the contamination of water by certain pollutants. The basic measures with regard to the release of pollutants must be based on a combined approach at the source, by setting emission limits and environmental quality standards.
The framework directive prescribes that the prior permission is required for all process releases of significant quantities of pollutants and certainly the substances of Annex VIII.

The basic measures must include the release limits or comparable measures and quality standards laid down by current directives, as well as the specific measures required by the European Commission to prevent the contamination of surface waters by individual pollutants or groups of pollutants, which cause an unacceptable risk to or through the water. The Commission's proposal for a priority list of 33 (groups of) substances will be adopted. Additional measures are still possible.

Insofar as not mentioned in Annex VIII to the Water Framework Directive, substances on the priority list will be added. This is also valid for Annex III to the IPPC Directive (96/61/EC).
For substances on the priority list, the Commission will propose measures to be taken at the source (processes and products). Where possible, steps will be taken on an EU level to lay down process measures for each branch of industry. Moreover, measures at product level are being specified. The Commission will also make quality target proposals for these substances, with regard to water, sediment and organisms. If these are not defined at community level, the member countries must include quality targets for these substances in their river basin management plans for all the waters that are affected by discharge of these substances.

From the list of priority substances so called hazardous priority substances will be selected by the European Commission. For these pollutants measures shall be aimed at ceasing or phasing out discharges, emissions and losses within 20 years after the adoption of the measurements.

The Commission is also entitled to issue measures for all other substances in order to prevent water pollution, including pollution due to accidents. In other words, the Commission may define measures for substances that constitute a risk to water at community level in order to protect the water against pollution. These measures may be either process-oriented or product-oriented. Process-oriented measures focus on the application of the latest techniques or compliance with emission limits and water quality objectives.

OSPAR Hazardous substances strategy

OSPAR is developing a strategy for dealing with hazardous substances. Its purpose is to put into practice a statement that was drawn up during the NSMC at Esbjerg: "The ministers agree that the objective is to ensure a sustainable, sound and healthy North Sea ecosystem. The guiding principle for achieving this objective is the precautionary principle. This implies the prevention op 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 values for naturally occurring substances and close to zero concentrations for man-made synthetic substances."
A working-group has been set up that is to develop a dynamic tool for selecting and prioritising hazardous substances (DYNAMEC). In anticipation of this tool, a preliminary list of fifteen substances has been drawn up whose release must be reduced to 'zero' within one generation. During OSPAR 2000 twelve (groups of) substances have been added to this list.

Substances Directive (79/831/EEC, 6th revision of Directive 67/548/EEC)

Apart from regulations based on the principle of protection of the environment, regulations have also been drawn up that are based on the principle of the internal market. Substances and preparations must be assessed by virtue of these European regulations, i.e. Substances Directive 79/831/EEC, 6th revision of Directive 67/548/EEC; Preparations Directive 1999/45/EC and various amendments and additional regulations and directives. A distinction is made between new and existing substances. Existing substances are those that are included in the EINECS list (European Inventory of Existing Chemical Substances) of 1981 (approx. 100,000 substances).
An phased approach has been developed for substances of the EINECS list. Substances with the highest production volume (> 1,000 tons/year; approx. 2,000 substances) have first been dealt with. By now, phase 3 has started. Primarily, the submission of available information by the producers of the various substances is sufficient. No research is necessary. Only when a substance is placed on the priority list by the European Commission, the companies involved will have to provide any missing information. Up till now, four priority lists have been published with approx. 150 substances. So far, nine

of the substances of these lists have been fully assessed. The object is to assess approx. 20-50 substances in Europe every year.

For new substances, i.e. substances introduced onto the European market after 18 September 1981, research into their properties is compulsory. Depending on the relevant quantity, a general or specific set of research details must be submitted with the notification. In the Netherlands, this notification must be addressed to the Ministry of Housing, Spatial Planning and the Environment, not to the user or competent authorities. Ecotoxicity details must be provided if more than 1,000 kg/year/supplier are supplied or 10 tons/year/manufacturer are produced for export outside the European Economic Space (EU plus Norway, Iceland and Liechtenstein). By now, about 2,400 new substances have been notified. The new substances are included in the European List of Notified Chemical Substances (ELINCS list). This list is published annually by the EU.

Preparations Directive (1999/45/EC)

The Preparations Directive gives rules for assessing preparations as to their effects on the health of humans and the environment. The classification is based on the properties of substances of which a preparation is made up. Preparations are categorised by means of calculating rules that convert the properties of a substance and the quantity of a substance in the preparation. The assessment of preparations developed in the GAM complies with this system.
Notification is not necessary for preparations as a whole, contrary to the substances used in the preparation, which are subject to notification. For this reason, the composition must be disclosed. Details that have been used for categorising preparations must be kept available for inspection by the competent authorities, such as the Public Health or Environmental Inspectorate. In the Netherlands, the Substances Directive has been incorporated into the Act on Environmentally Hazardous Substances (Wms). The Preparations Directive (1999/45/EC) must be incorporated into the Wms before July 2002.

The producer or supplier is entitled to make the assessment and may request the Public Health Inspector to treat the details of the composition of the preparation confidentially. The Public Health Inspector is authorised to verify the assessment of preparations on the basis of the product file that is kept by the producer or supplier. For the assessment of preparations within the scope of the Pollution of Surface Waters Act, an additional procedure has been developed to ensure, on the one hand, that users of preparations and the competent authorities have sufficient insight into the environmental harmfulness of a preparation and, on the other hand, that it is treated confidentially.

2. National laws and regulations

The level of national laws and regulations is based partly on European regulations.

Pollution of Surface Waters Act (Wvo)

The Wvo came into force on 1 December 1970. The object of the law is to prevent or control the pollution of surface waters with a view to the various purposes for which these waters are used in our society.

Obligation to apply for permits

The Wvo includes a system of permits. Section 1 of the Wvo reads that it is prohibited to discharge waste material, pollutants or hazardous substances in whatever form into the surface water without a permit. A permit under the Pollution of Surface Waters Act must be applied for with the water quality manager of the surface waters onto which effluents are discharged. For state waters, these are the Regional Directorates of the Department of Public Works. For regional waters, these are the water district boards, polder boards, etc. These compulsory permits provide the water quality manager with a tool to achieve the objects of the Wvo.

Implementation Decree on the pollution of state waters (UVR)

The UVR states the information to be provided by the applicant. For example, the application must include:

- the nature, composition, properties, quantity and location on the company premises of the raw materials, auxiliary materials, partly processed and finished products, which may be expected to be present on the premises, insofar as they may be discharged, whether or not directly, onto the surface waters.

This information and the other information that must be provided must enable competent authorities as well as third parties to assess the requested discharge. However, the details of the nature of raw and auxiliary materials, partly processed and finished products are not always available.

Parties

A number of parties is involved in the Wvo permit application procedure. The applicant/user is obliged to provide the information required to assess discharges. The water quality manager must assess the requested discharge on the basis of the information submitted with the application. RIZA is the legal advisor and may give advice, for example, about the decontamination measures to be taken. Third parties (neighbours, environmental movements, etc) will protect their own interests. Producers and suppliers of substances and preparations, except if they are subject to the Pollution of Surface Waters Act, are not considered to be parties that are directly involved.

Environmental Protection Act (Wm)

On 13 July 1979, the Environmental Protection Act came into force.
The object of this law is to protect the environment. In common with the Wvo, the Wm also applies the tools of compulsory permits and General rules. Parts of sectoral environmental laws (Nuisance Act, Act on Chemical Waste Material, etc.) are integrated into the Wm. The Act of 2 November 1994 pertaining to the revision of the Wm and Wvo ensured the regulation of all harmful effects on the environment caused by most discharges onto the sewage system on the basis of the Wm Act. This revision came into effect on 1 March 1996 (Waste Water Act). The consequences for the surface waters of any discharge onto the sewage system not covered by the Wvo must be included in the Wm permit application procedure.

Environmentally Hazardous Substances Act (Wms).

In the Netherlands, the European regulations in the field of categorisation, packing and identification of substances and preparations are incorporated into the Wms. The object of this law is to protect the health of humans and the environment against hazardous substances. Important decrees within the context of the Wms are the Notification Decree and the Material Safety Data Sheet Decree. Based on this law, rules have been issued for the notification, identification and packing of substances and preparations. It must be noted that the criteria for assessing the environmental effects of preparations are still being drawn up. A number of categories of substances is excluded if they are marketed in the shape of finished products. These are not subject to the Wms. In addition, a number of substances are exempt from the obligation to notify authorities. For a complete summary, reference is made to the Wms Notification Decree.

Notification Decree

Under the Notification Decree, producers or suppliers/importers of substances and preparations are obliged to submit details about the properties of substances and the overall composition of preparations to the competent authorities (Ministry of Housing, Spatial Planning and the Environment). The notification is company-specific.
Substances are categorised on the basis of these details. In this classification, certain risk sphrases (R 50, R 51-R 53, etc.) are attached to the substance, depending on its properties.
Within the scope of the Wms, the risk to the environment is assessed on the basis of the same data. This risk assessment is carried out by means of the European Uniform System for the Evaluation of Substances (EUSES). A generic assessment for a standard environment is carried out by means of this system. Depending on the ratio between the Predicted Environmental Concentration (PEC) and the

Predicted No-Effect Concentration (PNEC), this may result in the industry involved being asked for more information or the issuance of generic measures by virtue of the Wms at a PEC/PNEC of > 1,000. This may entail a ban on the production or use in a certain product, such as the Cadmium Decree. Preparations are not subject to the obligation to notify authorities. Details that have been used for categorising preparations must be kept available for inspection by the competent authorities.

Material Safety Data Sheets Decree

Apart from the obligation to notify the national government, there is also an obligation to inform the users of substances. Based on the Wms Safety Material Safety Data Sheets Decree, producers and suppliers of hazardous substances or preparations are obliged to provide professional users with a Material Safety Data Sheet (MSDS). The MSDS is a tool for providing the user of the substance or preparation with important information about safety, health, the environment and transport. A MSDS contains sixteen categories; each category specifying the information to be provided. Moreover, on the basis of the Wms rules for identification and packing, a number of the properties of substances and preparations must be disclosed to the user by means of a label on the packing.
A MSDS that is fully completed contains practical information for the user and competent authorities. Experience shows that ecotoxicological information is only scarcely available and is often not even included. This may be due to the fact that users sometimes prefer products of which no details are given ('then it is probably not toxic') to products for which it is stated explicitly that they contain a component that is, for example, highly toxic to water organisms.

Appendix 8 Example of how the General Assessment Methodology works

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Assess the category of aquatic harmfulness and the related decontamination effort required by policy for these substances, which do not naturally appear in the surface water on the basis of the details in the table and the General Assessment Methodology for substances (Substance-intrinsic test for substances).

. . . . . .
Table 1

Name	Black-list substance	May cause heritable genetic damage	May cause cancer	LC_{50} (mg/l)	Biodegradability	Log P_{ow}	BCF	Solubility in water (mg/l)	Category of aquatic harmfulness
Substance A	yes	no	no	0,4	30 %	5,6	6500	>10.000	
Substance B	no	no	no	170	55 %	3,2	1000	2	
Substance C	no	no	no	3,2	80 %	3,1	90	560	
Substance D	no	no	no	38	40 %	4,0	–	>100	
Substance E	no	no	no	0,8	80 %	–	–	>100	
Substance F	no	no	yes	13	95 %	2,1	130	>100	
Substance G	no	no	no	0,1	85 %	4,2	12,6	3	
Substance H	no	no	no	n.m.*	– %	5,8	–	< 0,2	
Substance I	no	no	no	67	80 %	–	–	>100	
Substance J	no	no	no	4,5	85 %	–	160	> 1000	

* not measurable

Answers

Assess the category of aquatic harmfulness and the related decontamination effort required by policy for these substances, which do not naturally appear in the surface water on the basis of the details in the table and the GAM for substances (Substance-intrinsic test for substances).

Name	Black-list substance	May cause heritable genetic damage	May cause cancer	LC_{50} (mg/l)	Biodegradability	Log P_{ow}	BCF	Solubility in water (mg/l)	Category of aquatic harmfulness
Substance A	Yes	no	no	0,4	30 %	5,6	6500	>10.000	1
Substance B	no	no	no	170	55 %	3,2	1000	2	11
Substance C	no	no	no	3,2	80 %	3,1	90	560	7
Substance D	no	no	no	38	40 %	4,0	–	>100	8
Substance E	no	no	no	0,8	80 %	–	–	>100	4
Substance F	no	no	Yes	13	95 %	2,1	130	>100	3
Substance G	no	no	no	0,1	85 %	4,2	12,6	3	5
Substance H	no	no	no	n.m.*	– %	5,8	–	< 0,2	10
Substance I	no	no	no	67	80 %	–	–	>100	9
Substance J	no	no	no	4,5	85 %	–	160	> 1000	6

* not measurable

Preparations

Assess the category of aquatic harmfulness of the preparations with the following compositions on the basis of the details in the table and the substance details of table 1.

Preparation	Composition (percentage of weight)	Category of aquatic harmfulness
I	1% A; 80% B; 19% H	...
II	2,3% J; 20 %I; 0,2 %E; 77,5% B	...
III	0,1% G; 2,1 % J; 0,2% C; 23% I; 74,6% B	...
IV	23% C; 0,2% G; 2,4% J; 74,4 B	...
V	23% J; 2,4% E 12% I; 62,6% H	...

Preparations (Answers)
Assess the category of aquatic harmfulness of the preparations with the following compositions on the basis of the details in the table and the substance details of table 1.

Preparation	Composition (percentage of weight)	Category of aquatic harmfulness
I	1% A; 80% B; 19% H	Contains black-list substance (A)
II	2,3% J; 20 %I; 0,2 %E; 77,5% B	Harmful to aquatic organisms; contains substances that are harmful to the aquatic environment (A)
III	0,1% G; 2,1 % J; 0,2% C; 23% I; 74,6% B	Harmful to aquatic organisms (B)
IV	23% C; 0,2% G; 2,4% J; 74,4 B	Toxic to aquatic organisms (B)
V	23% J; 2,4% E 12% I; 62,6% H	Toxic to aquatic organisms; contains substances that are harmful to the aquatic environment (A)

Details: Example of substances

Results follow from Table B-4.1, appendix 4. Please note that in those cases in which no details have been provided, the 'worst-case' route must be followed.

Details substance E:

acute tox. 0.8 mg/l	LC_{50} < 1 mg/l;
biodegradability 80%	easily biodegradable,
Log P_{ow} unknown	select >3.0
BCF unknown	select BCF > 100

Result: Category of aquatic harmfulness {4} Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Abatement effort (A)

Details: Examples of preparations

The numbers between {} denominate the category of aquatic harmfulness of the substance.

Preparation I: *1% substance A {1}; 80% substance B {11}, 19% substance H {10}.*

Details:
(note: Start with the substance with the lowest category of aquatic harmfulness.)
80% of substance B and 19% of substance H: Slightly harmful to aquatic organisms.
Contains more than 0.1% of black-list substance.

Result: Category of aquatic harmfulness: 'Contains black-list substance' and 'Slightly harmful to aquatic organisms'. (note: both categories must be stated) Abatement effort: (A)

Preparation II: *2.3% substance J {6}, 20% substance I {9}, 0.2% substance E {4}, 77.5% substance B {11}.*

Details:

77.5% of substance B {11}	Slightly harmful to aquatic organisms.
20% of substance I {9}	Slightly harmful to aquatic organisms (Also in combination with substances with categories {4}, {5}, {6}, {7} and {8}: 20% + 2.3% + 0.2% = 22.5% does not exceed concentration limit of 25%)
2.3% of substance J {6}	Slightly harmful to aquatic organisms (In combination with substances with category {4} 2.3% + 0.2% = 2.5% exceeds concentration limit) : Harmful to aquatic organisms; contains substances that are harmful to the aquatic environment.
0.2% of substance {4}	Slightly harmful to aquatic organisms

Result: Category of aquatic harmfulness: Harmful to aquatic organisms; contains substances that are harmful to the aquatic environment.
Abatement effort: (A)

Preparation III: *0.1% substance G {5}, 2.1% substance J {6}, 0.2% substance C {7}, 23% substance I {9}, 74.6% substance B {11}*

Details:

74.6% of substance B {11}	Slightly harmful to aquatic organisms
23% of substance I {9	Slightly harmful to aquatic organisms (In combination with substances with categories {4}, {5}, {6}, {7} and {8}: 23% + 0.1% + 2.1% + 0.2% = 25.4% exceeds concentration limit) → Harmful to aquatic organisms
0.2% of substance C {7}	Slightly harmful to aquatic organisms (In combination with substances with categories {4}, {5}, {6}: 0.2% +0.1% 2,1% = 2.4% does not exceed concentration limit of 2.5%)
2.1% of substance J {6}	Slightly harmful to aquatic organisms
0.1% of substance {5}	Slightly harmful to aquatic organisms

Result: Category of aquatic harmfulness: Harmful to aquatic organisms
Abatement effort: (B)

Preparation IV: *23% substance C {7}, 0.2% substance G {5}, 2.4% substance J {6}, 74.4% substance B {11}.*

Details:

74.4% of substance B {11}	Slightly harmful to aquatic organisms
23% of substance C {7}	Harmful to aquatic organisms (In combination with substances with categories {4}, {5}, {6}: 23% + 0.2 % + 2.4% = 25.6% exceeds concentration limit of 25%) → Toxic to aquatic organisms
2.4 % of substance J {6}	Slightly harmful to aquatic organisms
0.2 % of substance G {5}	Slightly harmful to aquatic organisms

Result: Category of aquatic harmfulness: Toxic to aquatic organisms
Abatement effort: (B)

Preparation V: *23% substance J {6}, 2.4% substance E {4}, 12% substance I {9}, 62.6% substance H {10}.*

Details:

62.6% of substance H {10}	column: Slightly harmful to aquatic organisms; contains substances that are harmful to the aquatic environment. (In combination with {4}, {6} and {8}: 62.6% + 2.4% + 23% = 88% does not exceed the concentration limit)
12% of substance I {9}	Slightly harmful to aquatic organisms (In combination with {4}, {5}, {6}, {7} and {8}: 12 % + 2.4% + 23% = 37.4% exceeds concentration limit of 25%) → Harmful to aquatic organisms
23% of substance J {6}	Harmful to aquatic organisms; contains substances that are harmful to the aquatic environment. (In combination with {4}: 23% + 2.4% = 25.4% exceeds concentration limit of 25%) → Toxic to aquatic organisms; contains substances that are harmful to the aquatic environment.
2.4% of substance E {4}	Harmful to aquatic organisms; contains substances that are harmful to the aquatic environment.

Result: Category of aquatic harmfulness: Toxic to aquatic organisms; contains substances that are harmful to the aquatic environment.
Abatement effort: (A)