Ministerie van Infrastructuur en Milieu

General Assessment Methodology (GAM) 2016

Method to determine the required decontamination effort for discharges based on the properties of substances

16-3-2016

Publication Information

Published by	Ministry of Infrastructure and the Environment
Executed by	Rijkswaterstaat
Information	R.P.M. Berbee
Date	12 May 2016

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Summary

This document[1] comprises the General Assessment Methodology (GAM), the most recent version (2016) of the methodology adopted by what was then the Committee on Integrated Water Management (CIW). The CIW report was based on the ecotoxicological parameters and criteria under European legislation on the classification of substances and mixtures as laid down in the Dangerous Substances Directive and the Dangerous Preparations Directive. The new version of the GAM takes the most recent developments in European legislation into account (REACH Regulation as successor to the above directives and the CLP Regulation). In 2015, the Ministry of Infrastructure and the Environment also adopted policy on Substances of Very High Concern (SVHC) for water. This approach has also been incorporated into the GAM update. Moreover, the document was updated for use under the forthcoming Environment and Planning Act as part of the assessment framework for discharges.

Part of general water quality policy, the GAM is a methodology for classification of the aquatic hazard of substances and mixtures into categories (Z, A, B or C), based on intrinsic properties of substances, such as toxicity, carcinogenicity and mutagenicity. Aquatic hazard is understood to mean: 'the degree to which a substance is likely to have adverse effects on the aquatic environment'. Key differences from the old GAM are that biodegradability is used as a starting point for the assessment of substances and mixtures, that SVHC have been added as a separate class (Z) and that the rules for assessment of mixtures have been brought in line with European legislation.

Classification into aquatic hazard classes serves as an overall guideline for the decontamination effort that may be desired in the case of discharge of the substances and mixtures in question. The decontamination effort is indicative of the level of effort needed to reduce discharge of a substance. The more hazardous a substance or mixture is to the water environment, the larger the decontamination effort that may be desired. When determining the decontamination effort related to each of the four categories, possibilities of tackling pollution at the source (substitution and process modification) and minimisation (purification of the waste water flow) are considered. Application of the best available techniques (BAT) is paramount; the decontamination effort is used as a basis for the selection of technologies that can be qualified as BAT. The GAM does not discuss residual discharges; these are assessed using the discharge test.

The GAM is to be used by the initiator intending to discharge and by the competent authorities for issuing discharge permits, drafting customised discharge regulations and, where necessary, enforcement based on the duty of care. This concerns both direct and indirect discharges.

Companies are responsible for the data used as input for the GAM assessment.

A software tool has been developed to guarantee uniform implementation of the GAM. Based on specific substance data, this tool generates the classification of a substance or mixture into one of the GAM classes.

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[1] This GAM report is a translation of the Dutch ABM report (2016). Although this a thorough and careful translation, there might be discussion due to differences in language. In case of interpretation differences, the Dutch text takes precedence.

A task force comprising industry representatives from the Association for Energy, Environment and Water (VEMW), employees of the Ministry of Infrastructure and the Environment, and the Vechtstromen water board, the Stichtse Rijnlanden water board and the DCMR environmental protection agency in the Rijnmond Region has brought the GAM in line with the REACH and CLP Regulations. This document has furthermore been coordinated with VNO/NCW (Confederation of Netherlands Industry and Employers) in joint consultation with the heads of licensing of Rijkswaterstaat and the water boards.

1 Introduction

1.1 Content of the GAM

A General Assessment Methodology (GAM) was developed in 2000 for the implementation of emissions policy on discharges of substances into surface water. This document is a key component in the assessment of discharges by the competent authorities. The GAM was updated in 2016, integrating the approach to Substances of Very High Concern (SVHC).

This document first of all discusses how the aquatic hazard class of substances and mixtures is determined, based on intrinsic properties of substances such as toxicity, carcinogenicity and mutagenicity. Aquatic hazard is understood to mean: 'the degree to which a substance is likely to have adverse effects on the aquatic environment'. A higher/more severe aquatic hazard means a greater chance of adverse effects. These adverse effects may include toxic effects (acute or chronic), mutagenic or carcinogenic effects, reprotoxic effects, bioaccumulation, or the long-term presence of poorly biodegradable substances in the aquatic environment.

This document distinguishes between four categories of decreasing aquatic hazard:

- Z (Substances of Very High Concern: set of substances that are most hazardous to humans and the environment, such as PAHs, dioxins, mercury and mercury compounds);
- A (not readily biodegradable aquatic harmful substances);
- B (readily biodegradable aquatic harmful substances);
- C (substances that occur naturally in local surface water).

The way in which the aquatic hazard of a substance is determined is described in Chapter 2 of this document. Determination of the aquatic hazard of compounds of different substances, called 'mixtures', is discussed separately.[2] The aquatic hazard of a mixture is determined based on the properties of the substances in the mixture or, if data on the toxicity of the mixture is available, based on the mixture itself. To determine biodegradability, it is important to consider the individual components; this often means that the GAM must be carried out for each of the components of a mixture.

Each category of aquatic hazard of a substance or mixture comes with a decontamination effort. The decontamination effort is indicative of the level of effort needed to reduce the discharge of a substance.

The second key component of this document therefore is a description of how the required decontamination effort of a discharge is determined based on the aquatic hazard of the substances in the discharge. Chapter 3 discusses in more detail how the decontamination effort is to be determined for each of the categories of aquatic hazard.

The third key component of this document concerns the division of responsibilities between the initiator and the competent authority for information provision to be able to determine the first two components – aquatic hazard and decontamination effort. This is discussed in Chapter 4 of the GAM.

[2] These mixtures used to be called 'preparations'.

The essence of this chapter is the initiator's obligation to supply the required data and the competent authority's task to test that data.

1.2 Reason for the update

1.2.1 Origin of the GAM

In 2000, the then Committee on Integrated Water Management (CIW) published the first General Assessment Methodology[3]. This was based on emissions policy as formulated in the Multi-Annual Indicative Programme on Water[4, 5] and the Memorandum on water management[6, 7]. This introduced a uniform method for the assessment of discharge permit applications. Companies were made responsible for providing (eco)toxicological data for permit applications. The competent authority then assessed the application and determined whether discharge was allowed, possibly subject to certain terms and conditions. The data must be transparent enough for third parties (residents) to assess the discharge applied for.

The old CIW report had to be amended for a number of reasons. These reasons are explained below. The amendment also includes a terminology update and references to amended Dutch laws and regulations. The document is formulated in such a manner that it can also be used under the forthcoming Environment and Planning Act as part of the assessment framework for discharges. Where legislation used to prescribe the application of the CIW report, this document will have to be used from now on.

1.2.2 Amendment of European legislation

The CIW report was based on the ecotoxicological parameters and criteria from European legislation on the classification of substances and mixtures as laid down in the Dangerous Substances Directive[8] and the Dangerous Preparations Directive[9]. These directives were succeeded in the European Union in 2006 by the REACH Regulation[10]. Analogous to the approach in the CIW report, the REACH Regulation delegates responsibility for the provision and generation of data on substances and mixtures of substances to the producers. Important in addition to the REACH Regulation is the CLP Regulation[11], which guarantees that employees and consumers in the European Union are informed in detail about the hazards of chemical substances by means of the classification and labelling of products. Both regulations are implemented in Dutch law in Section 9 of the Environmental Management Act.

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[3] CIW report 'Assessing substances and preparations for the implementation of water emissions policy', May 2000.

[4] Report from the MDW working group on granting permits under the Pollution of Surface Waters Act, 1997. Report as part of the Market Mechanisms, Deregulation and Legislation Quality operation.

[5] *Hoezo hulpstof? (*Additive or not?) Procedures for the assessment of additives within the framework of the Pollution of Surface Waters Act, RIZA working document no. 96.014X, R. Edelijn et al. RIZA.

[6] Ministry of Transport, Public Works and Water Management, 1981, Multi-Annual Indicative Programme on Water 1980-1984.

[7] Ministry of Transport, Public Works and Water Management, 1985, Multi-Annual Indicative Programme on Water 1985-1989.

[8] Directive 67/548/EEC of the Council dated 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJEU 196, 1967, p. 1-98.

[9] Directive 1999/45/EEC concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, OJEU, L 200, 1999, p. 1-68.

[10] Commission Regulation (EC) no. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

[11] Commission Regulation (EC) no. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. The method for classification and labelling of chemical substances introduced with this Regulation is based on the globally harmonised system (GHS) of the United Nations.

Annex 1 to the CLP Regulation includes the criteria with which substances can be classified into what are known as H Sentences (H for Hazard) and P Sentences (P for Precaution). These succeed the R and S Sentences relevant under old European legislation. The CIW report referred to the R Sentences and also used the criteria from the Preparations Directive. The criteria in the Preparations Directive and the CLP Regulation are different. Moreover, from 1 June 2015 all companies must declare the hazard categories of substances on safety information sheets (MSDSs)[12] in accordance with the CLP Regulation. Use of R and S Sentences is no longer allowed. The GAM had to be amended for these reasons.

1.2.3 Substances of Very High Concern

In 2015, the Ministry of Infrastructure and the Environment also adopted policy on Substances of Very High Concern (SVHC) for water[13]. This approach has also been incorporated into the GAM update.

SVHC have been classified as the most hazardous substances for humans and the environment and must be given priority.[14] Government policy aims to keep these substances out of the living environment or at least reduced them to (or keep them at) a negligible level of risk.[15]

The approach to SVHC is based on the general approach to water quality as discussed below in paragraph 1.3, comprising tackling pollution at the source, minimisation and discharge test. The approach to SVHC differs from that to other substances on two scores:

1. SVHC must be given priority. To that end, SVHC must be identified as such in the testing diagram, and the source approach to these substances in particular must be emphasised.
2. The reduction of SVHC emissions into water is achieved by means of continuous improvement. The process of gradually working toward the lowest possible concentration of these substances in surface water must be viable and affordable[16]. Although the regular procedure for water permits is already cyclical in nature,[17] a separate track is followed for SVHC[18].

This specific approach to SVHC has resulted in a number of revisions in the GAM. First of all, it is important to identify SVHC as such. The GAM flowchart (see Chapter 2) includes a separate category for aquatic hazard (Z). This category is a subset of what was defined as category A in the previous

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[12] MSDS is short for 'material safety data sheet'.

[13] Policy Document Approach to Substances of Very High Concern in waste water (See Water Manual). This policy elaborates the previously formulated policy objective for SVHC as documented in a letter dated 29 June 2011 from the State Secretary for Infrastructure and the Environment to the House of Representatives, reference RB/2011048246, with enclosure. In this letter, the government adopts the RIVM National Institute for Public Health and the Environment criteria as referred to below.

[14] The National Institute for Public Health and the Environment (RIVM) has formulated criteria to determine whether a substance is an SVHC (see 'Criteria for Substances of Very High Concern', RIVM letter report 601357004/2011). The RIVM publishes a semi-annual list of substances that meet those criteria (see http://www.rivm.nl/rvs/Stoffenlijsten/Zeer_Zorgwekkende_Stoffen and click on 'ZZS Basislijst and Annexes' – in Dutch).

[15] Letter dated 29 June 2011 from the State Secretary for Infrastructure and the Environment to the House of Representatives, reference RB/2011048246, with enclosure. In this letter, the government adopts the RIVM National Institute for Public Health and the Environment criteria as referred to below.

[16] Costs are viable and affordable when the technology opted for is considered BAT and applicable to the industry where discharge takes place, or when drastic measures are needed from a water quality point of view and the costs of the measures are proportional to the environmental impact of the discharge. In 2016, government parties (Ministry of Infrastructure and the Environment, Rijkswaterstaat and water boards) together with the industry will start up a process for the development of a cost effectiveness tool for emission-reducing measures.

[17] Permits for some of the substances in list I of Annex I to Directive 2006/11/EC may only be granted for a maximum of 10 years (Art. 6.1 of the Water Regulation). In addition, these permits must be reviewed every four years by the competent authority (Art. 6.2 of the Water Regulation). Note: This does not apply to permits granted under the Environmental Licensing (General Provisions) Act (Wabo).

[18] This approach has been described in the policy document Approach to Substances of Very High Concern for water (2015).

version of this document. Accordingly, category Z and category A-new together comprise category A-old. This new category Z is linked to the highest decontamination effort category. Secondly, the description of this decontamination effort (Chapter 3) clearly indicates how continuous improvement can be achieved.

Using this approach, the GAM also implements the European obligation[19] to 'stop or gradually reduce discharges of priority substances by determining controls for the most important sources of those discharges, also based on an assessment of all technical reduction options'. The priority hazardous substances are SVHC, and discharges of these substances will be gradually terminated by taking a cyclical approach aimed at exploring options to prevent emissions. This will be discussed in more detail in Chapter 6.

1.2.4 Working method for the drafting of the GAM

A task force comprising industry representatives from the Association for Energy, Environment and Water (VEMW), employees of the Ministry of Infrastructure and the Environment, and the Vechtstromen water board has brought the GAM in line with the REACH and CLP Regulations. This document has furthermore been coordinated with VNO/NCW (Confederation of Netherlands Industry and Employers) in joint consultation with the heads of licensing of Rijkswaterstaat and the water boards and the DCMR environmental protection agency in the Rijnmond Region.

1.3 Position in the general approach to water quality

The relationship between decontamination effort and aquatic hazard described in this document is created as part of general water quality policy as applies to the assessment of discharges. This water quality policy comprises three elements as consecutive testing steps in the assessment of a discharge:[20]

- Test step 1 – **Source approach:** The emphasis in this step is on prevention, ensuring that certain substances do not enter the surface water through waste water discharges. This step of testing a discharge first of all assesses which substances are permitted from a water quality point of view in the (production) process to be assessed and whether any used substances can be replaced by other, less hazardous substances (substitution). Secondly, it assesses to what extent these substances are allowed to end up in the waste water to be discharged, considering whether adjusting processes may prevent contact of these substances with water and/or whether these substances can be reused. Both assessments take into account that at least the best available techniques (BAT) are used. After this step, the remaining waste water flow is as small as possible and has the lowest possible environmental impact.
- Test step 2 – **Minimisation:** This step of testing a discharge assesses to what extent the waste water flow must be purified before it is discharged into the surface water. This assessment also takes into account that at least the best available techniques (BAT) are used. Any emission limit values applicable under legislation are taken into account as well.

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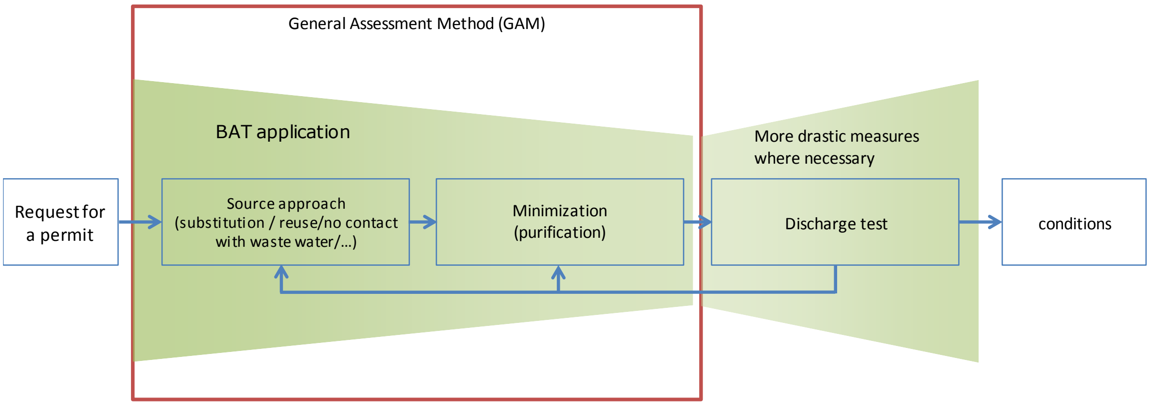
[19] Art. par. 1(a) under iv in conjunction with Art. 16 par. 8 of the Water Framework Directive.

[20] The first two steps are taken from national emissions policy as formulated at the time in the Fourth National Policy Memorandum on Water Management. In this memorandum it is called the 'chain approach': prevention, reuse and processing (purification). The elements of prevention and reuse originally occurred in what is known as the 'Lansink Ladder' (motion by Lansink et al., *Parliamentary Documents II* 1979/80, 15800, XVII, no. 21). The final step in the assessment of waste water discharges – the discharge test – was added to the testing diagram at a later point in time, prompted by the effect-oriented approach that became popular under the European Water Framework Directive. This discharge test was first developed in the CIW report 'Emission – discharge. Prioritisation of sources and the discharge test' (2000) and was then documented in the Discharge Test Manual (2000). An update of the Discharge Test Manual will be adopted in 2016.

- Test step 3 – **Discharge test:** This step of testing a discharge assesses whether, from a water quality point of view, more far-reaching source approach and/or purification is needed than follows from the first two steps. This is determined based on the quality of the surface water into which the waste water is discharged and the relevant applicable norms.

The GAM plays a role in test steps 1 and 2: source approach and minimisation. The required decontamination effort may have consequences for the permissibility of the use of substances, the permissibility of contact of substances with waste water, and the required purification effort of the waste water flows. This document gives an overall indication of which category of decontamination effort relates to which substance properties. See paragraph 3.3 for a more detailed explanation.

The third test step of a discharge, the discharge test, is beyond the scope of the GAM and is discussed in the Discharge Test Manual.



1.4 Relationship with permit issue and general rules

The GAM is used by the initiator intending to discharge and the competent authority[21] in 1) (the assessment of) permit applications for discharges for which permission is mandatory; 2) (the assessment of) a permit for extending customisation for discharges covered by general rules; and 3) the official assessment whether customisation must be tightened for discharges covered by general rules, or whether enforcement based on the duty of care is appropriate. This concerns both direct and indirect discharges.

[21] The competent authority for direct discharges is the water manager and for indirect discharges the competent authority under the Environmental Licensing (General Provisions) Act.

2 Determining aquatic hazard

2.1 Scope

The GAM is applied to substances in a discharge that are relevant to the chemical and ecological water quality and to the social functions of the water systems involved. These not only include substances used in the processes where the discharges originate; they also comprise degradation products known to originate from using purification techniques.

Because it is impossible to assess *all* substances in a discharge, application of the GAM is not necessary for:

- substances present in concentrations smaller than trace elements; and
- (in mixtures:) substances that are present in concentrations below the lower concentration limits (see paragraph 2.3.1.).

If, however, there are indications that substances present as trace elements are also relevant, the GAM will also be completed for these substances.

2.2 The aquatic hazard of substances

Aquatic hazard is understood to mean: the degree to which a substance is likely to have adverse effects on the aquatic environment. Theoretically, a large number of categories of aquatic hazard can be distinguished based on the combination of substance properties discussed below. Taken to extremes, every combination of properties could form a separate category. It would then be necessary to determine the decontamination effort required for all these different categories of aquatic hazard to limit or prevent emission of the substance or mixture. That would be impractical or even impossible. For that reason it was decided to cluster aquatic hazard in a limited number of categories. This document distinguishes between four categories of descending aquatic hazard:

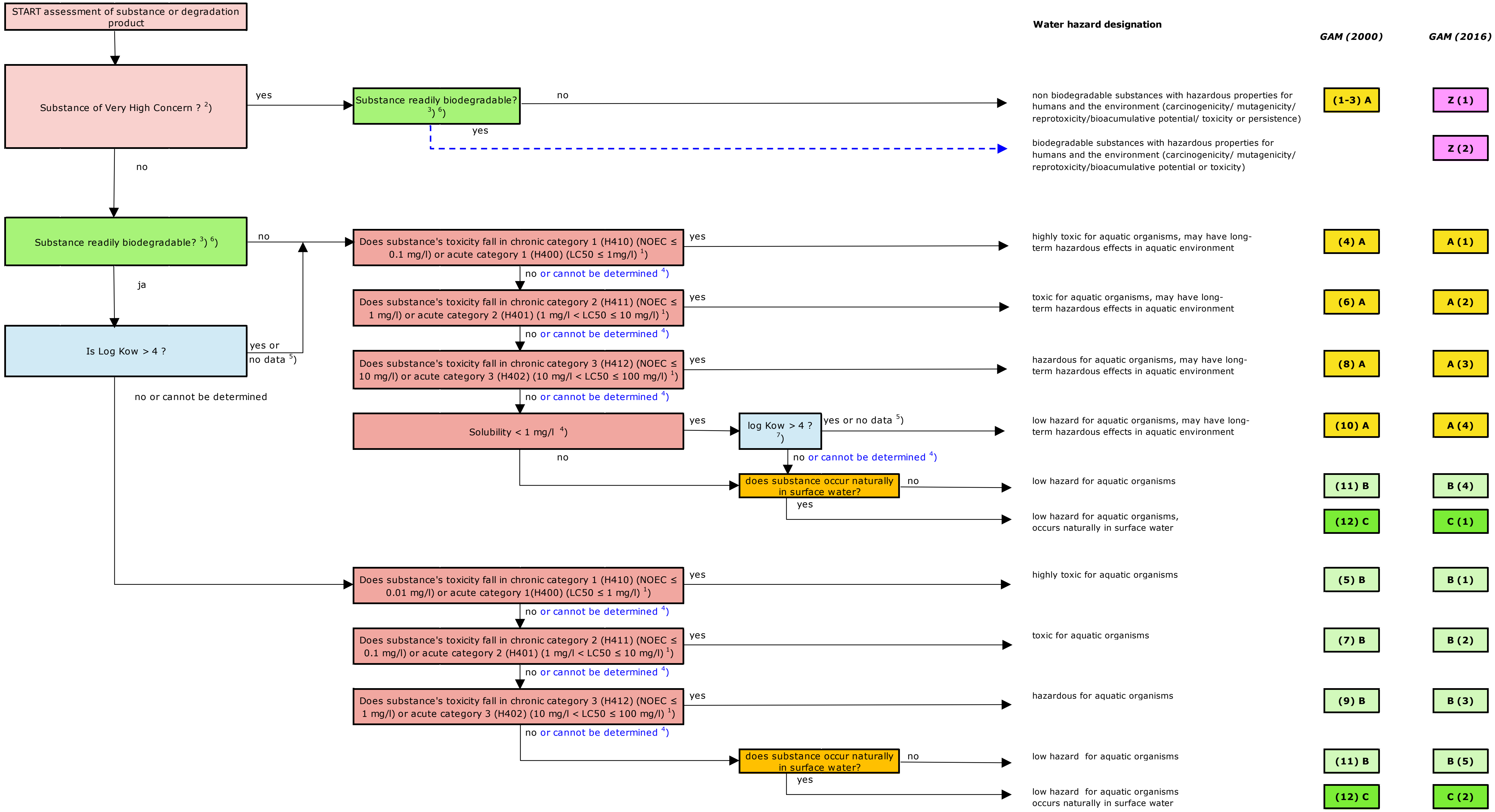
- Z (Substances of Very High Concern, SVHC: set of substances that are most hazardous for humans and the environment)[22];
- A (not readily biodegradable aquatic harmful substances);
- B (readily biodegradable aquatic harmful substances);
- C (substances that occur naturally in local surface water).

[22] A substance is considered an SVHC if it meets at least one of the following criteria:

1. The substance has been labelled as Carc. 1A or Carc. 1B (carcinogenic), as Muta. 1A or Muta. 1B (mutagenic), or as Repr. 1A or Repr. 1B (reprotoxic) in the most recent version of Annex VI to the European GHS Regulation, or the substance does not have a harmonised hazard class (and is therefore not included in Annex VI) but is available in the C&L inventory of the European Chemicals Agency (ECHA), where, in accordance with Art. 4 of the GHS Regulation, it is considered Carc. 1A, Carc. 1B, Muta. 1A, Muta. 1B, Repr. 1A, or Repr. 1B.
2. The substance is on the ECHA list of candidates for inclusion in Annex XIV to the REACH Regulation, where it is considered PBT (persistent, bioaccumulative and toxic) or as vPvB (very persistent and very bioaccumulative).
3. The substance is listed in one of the appendices to the UNEP Stockholm Convention[22] on persistent organic pollutants.
4. The substance is listed in one of the appendices to the Protocol on Persistent Organic Pollutants to the UN-ECE Convention on Long-Range Transboundary Air Pollution.
5. The substance is on the most recent chemicals list for priority action of the OSPAR Convention.
6. The substance is considered a priority hazardous substance in Annex X to the European Water Framework Directive.
7. There are scientific indications that the substance has a hormone disrupting effect.
8. While the substance does not meet the criteria for PBT or vPvB, there are scientific indications that, given its effects on humans and the environment, it can be considered PBT or vPvB.

The following diagram (figure 1) indicates how substances can be divided into the above categories based on certain properties.

Figure 1. General assessment methodology of substances[23]



1) most stringent value takes precedence (e.g.: H410 over H400)
2) Substances on the list Substances of Very High High Concern or substances that the producer has marked as SVHC
3) A substance is readily biodegradable when it meets the OECD criteria for "readily biodegradable" (70% of the substance degraded within 28 days (see OECD-301 tests). Substances that are degradable in the inherent biogradable tests (OECD-320-tests) are not necessarily biodegradable in screening tests.
4) If solubility is lower than the effect concentration at which toxic effects can occur, toxicity cannot be determined because the effect concentration is never reached
5) When log Kow cannot be determined and no data are available, it is recommended to check whether BCF data are available. When testing, the rule Kow ≈ 10*BCF is used, in line whith the old GAM (2000).
6) When a substance and/or degradation product does not conctitute a potential long-term hazard and/or delayed hazard to the aquatic environment, the classification into decontamination effort A may be abandoned. The additional scientific evidence may compromise the folowing studies: I) a proven potential for rapid degradation in the aquatic environment; II) the lack of chronic toxicity effects at a concentration of 1 mg/l.
7) see 6), albeit that chronic toxicity effects must be lacking at the solubility limit instead of at 1 mg/l.

[23] The GAM uses a worst-case approach. If no information on specific substance properties is available, a worst-case scenario is applied: either the most toxic class or NOT readily biodegradable or log Kow >4.

2.2.1 Explanation of substance assessment diagram

The environmental harmfulness of a substance depends on a large number of properties, such as toxicity (acute and/or chronic), biodegradability, bioaccumulative potential, reprotoxicity, hormone disrupting effect, carcinogenicity and mutagenicity. This document discusses the effects that a substance can have on water, so it only refers to the *aquatic hazard* of substances.

Carcinogenicity, mutagenicity and reprotoxicity are not distinguished as separate assessment criteria in the GAM, but are clustered in the Substances of Very High Concern (SVHC) category. The hormone disrupting effect of substances (e.g. oestrogenic effect) can manifest itself in reprotoxicity, harming fertility or causing developmental disorders in offspring.

The criteria included in the GAM link up with the criteria used in the CLP[24] for classification of substances into hazard categories. The substance properties used for classification of substances into certain hazard categories are in line with the criteria that were used in the GAM from 2000. Compared with the GAM from 2000, category Z has been added to include SVHC, while the layout of the diagram has also been modified. First of all, it is considered whether the substance to be assessed belongs in category Z. The next step in the assessment for both SVHC and other substances is assessing whether the substance is readily biodegradable or not[25]. Not readily biodegradable substances and substances with a bioaccumulative potential (log Kow > 4)[26] are then classified into category A, based on toxicity (chronic or acute). The criteria for toxicity are in line with the classification into toxicity categories in the CLP. In the current diagram, the bioaccumulative potential of a substance is only related to log Kow, because usually no experimental bioconcentration data is available in practice. For non-bioaccumulative substances with a low level of toxicity (NOEC > 1 mg/l or LC50 > 100 mg/l), it is then considered whether the substance occurs naturally in surface water. The substances that occur naturally[27] are classified into category C.

Example

The following data on a substance is available:

SVHC	Is substance easily degradable?	Is complete chronic data set available?	Lowest NOEC value [mg/l]	Lowest LC-50 [mg/l]	Log Kow
no	no	yes	0.01	1	4.1

It concerns a biodegradable, but bioaccumulative substance. This means it will be included in category A. Chronic toxicity data is available for all trophic levels, which means a complete chronic data set is available. As such, the chronic data set determines the classification into toxicity classes. A chronic toxicity of 0.01 mg/l results in a classification A(1) (highly toxic for aquatic organisms and may cause long-term harmful effects in the aquatic environment).

2.3 Assessment of mixtures

Determining the aquatic hazard of a mixture is, in principle, based on weighting the aquatic hazard of the substances in the mixture. This weighting is described below. If, however, the properties of a

[24] Annex I CLP regulations for classification and labelling of hazardous substances and mixtures, 2008R1272-NL-01.12.2013-003.001.
[25] A substance is readily biodegradable if 70% of the substance degrades within 28 days (see Annex I CLP, referred to in full in footnote 23). This is a substance that, in OECD screening tests, meets criteria on 'readily biodegradable' (OECD-301 tests). It should be noted that substances that are degradable in inherent biodegradability tests (OECD-3022 tests) need not be in screening tests.
[26] In the GAM assessment diagram from 2000, the criterion was log Kow > 3 or BCF > 100
[27] These include chlorides and sulphates.

mixture that are relevant to GAM other than biodegradability and bioaccumulation (low Kow)[28] are already known in the ECHA database as a result of a thorough analysis of the mixture itself, the method described below for other relevant GAM properties is not necessary and it will suffice to complete the flowchart in paragraph 2.2, with the properties of the mixture being used for classification of aquatic hazard. However, the composition of the mixture based on individual substances is needed to be able to assess the consequences of the use of such a mixture for the surface water into which it will be discharged.

To determine aquatic hazard of mixtures based on the component substances, it was decided to link the GAM to the system used by the European CLP Regulation (Classification, Labelling and Packaging). This regulation classifies substances into toxicity categories on the basis of their toxicity and includes calculation rules for classification of mixtures into these toxicity categories.

2.3.1 Concentration limits as lower limits for weighting

First of all, it is important to note that the lower concentration limits determine whether a substance is taken into account when ascertaining the aquatic hazard of a mixture. The CLP prescribes when a component present in a mixture must be stated on an MSDS. This must be done using weighting factors based on a substance's toxicity. The more toxic a substance, the higher its weighting factor (M) and as such it must be stated as a component of the mixture from lower concentrations upwards. The table below indicates how the weighting factor is applied to determine the concentration limit at which the substance is relevant under the CLP.

Table 1. Concentration limits under CLP per category [1])

Category of substances	**Concentration limit (% m/m) [2])**
Acute toxicity 1 (H400)	M
Chronic toxicity 1 (H410)	0.1/M
Other substances	1

[1]) See Article 10 of CLP Regulation, par. 4; Annex I to CLP table 1.1 chapter 4.1.3.1 (p. 529) of the 'Guidance on the application of the CLP' (June 2015)
[2]) percentage by weight (weight/weight)

The GAM conforms to this approach for inclusion on the MSDS or safety information sheet. Substances that are present in a mixture at concentrations greater than or equal to the concentration limits referred to in Table 1 are taken into account when determining the aquatic hazard of a mixture; at lower levels they are not.

As the category of Substances of Very High Concern includes highly toxic substances, a lower limit for this category of 0.1/M % is applied. This means that if an SVHC is present in a mixture and the total concentration of SVHC in the mixture is lower than 0.1/M%, the mixture will not be considered an SVHC. It will be when it is present in higher concentrations.

2.3.2 Determining aquatic hazard based on substances that are weighted

Substances that exceed the concentration limit in a mixture are then classified into their corresponding GAM categories (category 1 (A1;B1), 2 (A2;B2), 3 (A3;B3) and 4 (A4) and other (B4; B5; C1 and C2). Details on how this is done can be found in Appendix 6.4.3). Then, using the calculation rules given in Table 8 in Appendix 6.4.4., the aquatic hazard of the mixture as a whole is determined.

[28]CLP Annex 1, Art 4.1.3.3.2: Classification of mixtures based on their long-term harmfulness requires additional information on biodegradability and, in some cases, bioaccumulation. No biodegradability and bioaccumulation tests are used for mixtures, as these are usually difficult to interpret and may only be relevant for individual substances.

The decisive factor for this is the percentage by weight of the substances in the mixture, combined with their GAM classification. When the percentage by weight exceeds the limits given in Table 8, the mixture is classified into the corresponding aquatic hazard category. If this is the case for multiple categories, the highest category determines the classification of the mixture. Substances with the same GAM categorisation are clustered; in that case, the sum of their concentrations is used to test against the limits given in Table 8.

A more detailed explanation of how aquatic hazard is determined can be found in Appendix 6.4. A digital tool has been developed for this approach, which will enable a more rapid and transparent determination of the aquatic hazard of a mixture. Below is a screen shot of the input fields and results of the GAM tool. Appendix 6.4 has some examples of classification of a mixture by the tool.

Name of mixture:	**example**
Give the number of different components the mixture is consisting of?	**4**

Name of substance (insert CAS-nr.)	**Does it concern a substance that has been classified before?**	**Composition by weight-percentage (%)**	**Does it concern a designated SVHC or a substance that meets the SVHC-criteria? *****	**Is the substance readily biodegradable?***	**Is CLP H-classification for aquatic toxicity available?**	**Geef H-classification**	**Are chronic toxicity data available?**	**Is a complete chronic toxicity dataset available?**	**Give lowest chronic NOEC-value [mg/l]**	**Are acute toxicity data available?**	**Give lowest LC-50 value [mg/l]**	**M-factor**	**Solubility [mg/l]**	**Log Kow**	**Does substance naturally occur in aquatic environment **?**	**GAM-classification for individual substance ******
Substance U	no	0.090%	yes	yes	no		yes	yes	0.01			1		4		Z2
Substance V	no	10.000%	no	no	yes	H410	yes	yes	0.01			10				A1
Substance W	no	20.000%	no	no	no		yes	yes	5			1				A3
Substance Y	no	69.000%	no	yes	no		yes	yes	3			1		3	no	B5

GAM classification:	**A1**	**The GAM classification of the mixture is:**	**A1**

result based on calculation rules for mixtures:

classification	result calculation rule		criteria	
Z1	0.000%	≥	0.10%	
Z2	0.090%	≥	0.10%	
A1	100.000%	≥	25.00%	<<==
A2	1000.000%	≥	25.00%	
A3	10020.000%	≥	25.00%	
A4	10020.000%	≥	25.00%	
B4	0.000%	≥	1.00%	
C1	0.000%	=	100%	
B1	0.000%	≥	25.00%	
B2	0.000%	≥	25.00%	
B3	0.000%	≥	25.00%	
B5	69.000%	≥	1.00%	
C2	0.000%	=	100%	

degradable part of the mixture	69.72%
non degradable part:	30.28%

sum of Z2 < 0.001/M; Z2 ==> B4

LEGENDA:

- cells (to be filled) needed for GAM classification
- (filled-in) cells
- cells (te be filled) NOT needed for GAM category but desired for the environmental profile of the substance

3 Determining the required decontamination effort

3.1 General requirements to the decontamination effort: BAT

3.1.1 BAT in general and in relation to previous concepts

The decontamination effort is indicative of the level of effort needed to reduce the discharge of a substance. The required decontamination effort is determined on the basis of the possibilities of source approach (substitution and process modification) and minimisation (purification of the waste water flow) as described in paragraph 1.3.

As stated in the introduction, the competent authority must ensure that at least the best available techniques (BAT) are used for source approach and minimisation. The concept of 'best available techniques' has a specific definition in the European Industrial Emissions Directive (IED) and in the Environmental Licensing (General Provisions) Act (Wabo).[29] In it, the concept of 'best available techniques' is defined as: 'the most effective techniques in achieving a high general level of protection of the environment as a whole designed to prevent and, where that is not practicable, to reduce emissions and the impact on the environment as a whole that may be caused by an installation, that, taking into consideration the costs and advantages, can be implemented in the relevant industrial sector under economically and technically viable conditions, and that are reasonably accessible to the operator of the installation in or outside the Netherlands; "techniques" include both the technology used and the way in which the installation is designed, built, maintained, operated and decommissioned'[30]

Guidance as to which techniques are included under this term is given in the European BAT conclusions (BREFs), various CIW industry studies and Dutch BAT documents. Under Dutch legislation, the competent authority takes these documents into consideration when determining best available techniques. However, these documents may be outdated.[31] BAT is a dynamic concept, which means that new techniques that are not described in the guidance documents referred to above but that are economically and technically viable (similar cost range and feasibility as the techniques that are described), can be considered BATs. In such cases, the competent authority must also take these new techniques into consideration.[32]

When determining the best available techniques referred to in the BAT conclusions, the economic feasibility of these techniques was already taken into account. The competent authority must therefore assume that the techniques described are *a priori* acceptable from a cost perspective. If no BAT conclusions are available or where newer techniques are available, the competent authority

[29] This concept conforms to the English 'best available techniques' (BAT) but differs from meanings attributed to the Dutch term for BAT in the past and from related terms such as 'best practicable means' (BUT: those techniques with which, taking into consideration economic aspects, i.e. acceptable from a cost perspective for a going concern, the largest reduction in pollution is achieved), 'best existing techniques' (called BBT at the time: those techniques with which an even greater reduction of pollution is achieved than with BUT and that can be applied in practice,[29], 'state of the art' (this includes measures that offer the best possible protection of the environment. In Dutch legislation considered synonymous with 'alara' ('as low as reasonably achievable'; indicates the highest possible level of environmental protection that can reasonably be achieved. Synonym of 'state of the art'). It should be noted here that BAT in this GAM has a different meaning than the same term used in the previous version of this document.

[30] Article 3 par. 10 of the IED and Section 1.1. par. 1 of the Environmental Licensing (General Provisions) Act.

[31] The BREF Industrial Cooling Systems, for instance, dates back to 2000.

[32] See for example ABRvS Administrative Law Division 21 December 2007, ECLI:NL:RVS: 2007:BC1391, legal ground 2.3.4.

itself must determine which techniques may qualify as BAT; the competent authority may take cost considerations into account. It is important to note that *individual* economic aspects may not be taken into account. The techniques must be economically viable 'in the relevant industrial sector'.

3.1.2 BAT and an integrated assessment

In determining the 'best' techniques, it is important to also consider the effects that those techniques have on environmental impact in a broad sense. After all, BAT is defined as 'the most effective techniques to prevent emissions and impact on the environment as a whole'. Sometimes, measures that have favourable effects on one environmental aspect may cause or exacerbate other problems. This is the case when the (incorrect) use of a paint stripper results in volatile environmental pollutants being emitted into the air instead of being discharged into waste water, possibly in higher concentrations. Besides the fact that this may have undesirable consequences for air quality, these substances may end up in the surface water at a later point in time anyway – by way of atmospheric deposition – which means that there are no (optimal) benefits for water quality. Conversely, this effect comes into play when a scrubber is used to change undesirable substances from air emission to water emission. As such, 'the consequences for the environment, *also considered in their mutual relationship*'[33], must be taken into account. An integrated assessment of the environmental and other effects of activities can prevent a worse outcome for the environment as a whole as a result of such a shift.

In concrete terms this means that in some cases a technique cannot be classified as BAT if it merely shifts the emission of hazardous substances to another environmental sphere or if it causes the substances to still end up in the surface water to a significant degree. While it is not possible to indicate in which cases this leads to a specific technique being unacceptable, the competent authority must take this integrated assessment into account when determining BAT. Where possible, this assessment must take place in consultation with the competent authority for the other environmental spheres that may be compromised.

3.2 Specific requirements per aquatic hazard category

3.2.1 From aquatic hazard to acceptable costs

The notion that increasing aquatic hazard of a substance comes paired with an increased effort to reduce or prevent an emission is generally recognised and accepted. While the aquatic hazard of substances, and, with it, the required decontamination effort, increases gradually, a division into four categories of aquatic hazard level is nevertheless used for the purposes of review, as also explained in the previous chapter. Figure 2 is a schematic representation of the gradual increase in aquatic hazard level, the division into categories and the link to the decontamination effort.

[33] See Section 6.26 of the Water Act in conjunction with Section 2.14, first paragraph, under a, point 2, of the Wabo.

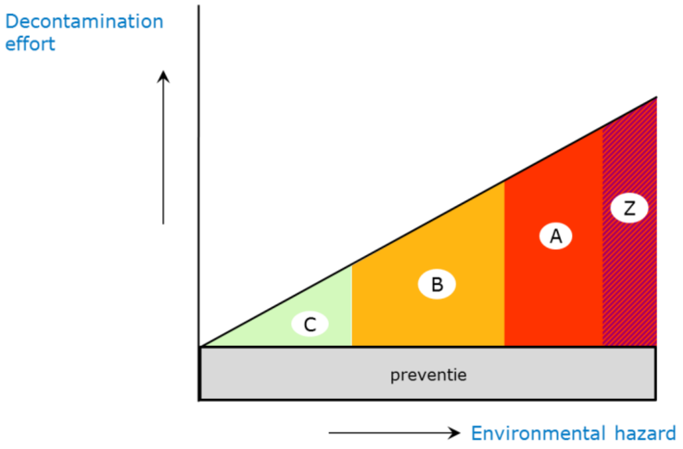


Figure 2 General relationship between decontamination effort and the aquatic hazard level of substances

The decontamination effort is indicative of the level of effort needed to reduce the discharge of a substance. The more hazardous to water a substance or mixture is, the larger the decontamination effort that may be required. When determining the decontamination effort related to each of the four categories, possibilities of tackling pollution at the source (substitution, reuse and process modification) and minimisation (purification of the waste water flow) are considered.

In addition to the decontamination effort to reduce emissions into water by taking purification and other technical measures, prevention of emissions into water is also paramount. This may include measures related to environmental management in general; the selection of additives or substances; proper monitoring of processes and flows, resulting in the right doses (no more than strictly necessary) of additives or substances.

As indicated in Chapter 1, use of the best available techniques is a prerequisite. The previous paragraph explained that BAT conclusions play a key role in determining which techniques may be classified as BAT. These BAT conclusions describe which techniques may be considered BAT and sometimes comprise different alternative techniques that may all be considered BAT for the same purpose. In addition, some of these BAT conclusions include a performance range that indicates what can be achieved by using the BAT in the relevant industrial sector.

As such, determining which techniques may be classified as BAT is a step preceding determination of the decontamination effort. In determining which technique is appropriate in a specific case, a selection is to be made from different techniques with different performance ranges that are all within the limits of what is acceptable. Even if there are no BAT conclusions, a set of techniques may be considered for qualification as BAT.

The previous paragraph explained that the concept of BAT also comprises a cost element: techniques can only be considered ‘available’ when, taking into consideration costs and advantages, it is economically viable to apply them.[34] As a rule, a technique that results in a more drastic emission reduction will cost more than a technique with a more limited effect.

As may be clear from the above, the competent authority has some options in determining exactly which techniques have to be applied, which has financial consequences for the decontamination effort that the initiator of the discharge has to make to prevent or reduce pollution. In this document, the aquatic hazard of the substances and mixtures present in the discharge is used to guide the competent authority in their choice. As a rule, a higher aquatic hazard level justifies higher costs. As the aquatic hazard of a substance increases, greater financial efforts are, in principle, acceptable. [35] What costs are reasonably acceptable depends on other factors than just aquatic hazard, such as the effect of the measures to be considered. It would not be logical to prescribe a very cost-intensive measure if it does not result in a quantifiable improvement in the quality of the surface water. To give guidance for determining which costs are acceptable in terms of effect, the costs of potential measures can be compared to the costs invested (in the past) in emission-reducing measures for substances similar in terms of aquatic hazard level. A proper understanding of the relationship between effect and acceptable costs of measures is essential for a proper assessment of 'measures that can reasonably be required'.

As indicated above, aquatic hazard is divided into gradually changing categories. For each hazard level on that scale, the competent authority may consider whether the costs are acceptable – within the techniques that can be qualified as BAT – to mitigate the related risk for humans and the environment. The four aquatic hazard categories that have been identified provide direction in this respect for the competent authorities. The next paragraphs explain which requirements can be set for the decontamination effort for each of the four categories. If, in a specific case, there is *no* freedom of choice because only one technique qualifies as BAT, the technique to be applied and the costs to be incurred cannot be influenced on the basis of the properties of substances; the technique in question will simply have to be applied.[36]

After the desired decontamination effort has been determined, the consequences of the residual discharge into the surface water must be mapped in test step 3 (see 1.3) of the discharge test. If the discharge test criteria cannot be met, more drastic decontamination measures with a greater decontamination effort may be required. This discharge test is not part of the GAM, but is described in the Discharge Test Manual.

3.2.2 Decontamination effort Z

General

Substances of Very High Concern (SVHC) are a set of substances that are most hazardous to humans and the environment.

In terms of pollution by substances with an aquatic hazard level linked to a decontamination effort Z, zero discharge will have to be aimed at. After all, the policy objective for these substances is, first of

[34] Note: this concerns economic viability *in the relevant industrial sector*. Economic considerations specific to the initiator of the discharge assessed cannot be included in this consideration.

[35] See also the Multi-Annual Indicative Programme on Water 1985-1989.

[36] This has no effect on the fact that more stringent requirements may ensue from the discharge test to be subsequently conducted.

all, to keep these substances out of the living environment. A cyclical approach comprising source approach, minimisation and continuous improvement[37] is used to try and achieve this objective.

Companies will have to adjust their choice of process and internal operations to this. This may first of all include substitution of substances with alternatives that form less of an aquatic hazard. Only when all possibilities have been exhausted (within the limits of what is viable and affordable) can they consider process optimisation or opt for different processes to prevent or reduce contact of these substances with water. Improved purification of the residual discharge is a last resort.

The following should be noted, however: Where it concerns additives, substitution would be a logical choice, but that may not be an option for substances in the raw materials that are an integral part of production processes,[38] as substances may still be released during the process. An example is the release of mercury (SVHC) in the production of petroleum. Substitution is also not an option for the generation of by-products, such as benzene (SVHC) in the production of petroleum. In this case potential measures must be found in in-process and purification measures.

When determining the extent of decontamination, techniques should be used that are the most effective within the set of techniques that can be classified as BAT.[39]

Obligation to report

In accordance with the approach to SVHC emissions into the air (see fourth section of the Activities Decree), a five-year cycle aiming at a greater reduction in emissions was also selected for emissions into water. The initiator of the discharge of SVHC must report to the competent authority every five years on any progress made in the emission reduction of SVHC and possibilities for further reducing emissions by applying newer techniques that may qualify as BAT. This should take the development of these techniques on a global scale into account. The competent authority then assesses whether a viable and affordable step can be taken in the reduction of the environmental impact on surface water.

This serves to achieve a continuous improvement in SVHC emissions. The reports reveal the innovation of the best available techniques over time and their practical application. This also offers the industry the possibility of further detailing their product stewardship policy.

In concrete terms this means that an aquatic hazard level linked to decontamination effort Z comes with a condition to the water permit instructing the permit holder to provide information to the competent authority every 5 years on:

a. the extent to which Substances of Very High Concern are discharged into surface water; and
b. the possibilities of preventing or, where this is not practicable, reducing emissions of these substances.

As indicated before, this should take into account the development of these techniques on a global scale. Moreover, this is a *continuous* process. The report is not a random indication of the state of

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[37] To this end, dischargers test and report to the competent authority every 5 years whether a viable and affordable step can be taken in the reduction of the environmental impact on surface water by SVHC discharges, working towards the lowest possible concentrations of SVHC in waste water by means of source approach and minimisation.

[38] This frequently occurs with chemical processes.

[39] This is the same approach as that for substances with an aquatic hazard level A. This can be explained from the fact that this category of substances is a sub-set of the substances that (in the previous version of this document) qualified as A substances. The main differences between Z substances and the current A substances is the emphasis on substitution.

affairs immediately prior to the deadline given in the permit, but should provide information on all action taken (including results) in the 5-year period.

This concerns an obligation to inform rather than just an obligation to measure all Substances of Very High Concern. Even if certain emissions are theoretically possible, the applicant may argue why such emissions are unlikely, for instance using a mass balance. There is an obligation to investigate whether and, if so, how a further emission reduction may be achieved. This obligation exists even if the best available techniques have been applied and the discharge of SVHC does not exceed environmental quality requirements. This minimisation can be achieved in a number of different ways: by means of substitution, new purification techniques or new production techniques, by means of optimisation or by means of sustainable business operations. The assessment should at least address the technical feasibility, the financial consequences and the ecological returns of the minimisation options.

It is important to note that this is not a condition extending the obligation to report over the term of the permit because substances discharged turned out to be SVHC while they did not appear to be so when the permit was applied for. The GAM is applied to applications for permits to discharge or for the (official) modification of such permits. The time of application or modification is the appropriate moment for completing the GAM to find out if the substances to be discharged are SVHC.

If an installation discharges multiple Substances of Very High Concern into water, it may be decided, with a view to limiting administrative charges, that information may be provided in various stages. This allows companies to integrate this process into their regular plan-do-check-act cycle. Moreover, this makes a link to the cycle for emissions into air a logical step. In these cases, the permit applicant must provide an appropriately substantiated proposal for this phasing. The provision of this information is preceded by an investigation, which also comes with costs. In this case, the information to be provided may initially be limited, as determined by the water quality manager, to those Substances of Very High Concern that are most relevant because they result in the highest overrun or because they are most relevant within a group of substances with the same emission pattern and emission behaviour.

The obligation to report on discharges subject to the general rules is usually laid down in those general rules.

3.2.3 Decontamination effort A

Pollution by substances with an aquatic hazard level linked to a decontamination effort A will have to be terminated. Zero discharge will have to be aimed at. Here, too, it is appropriate to opt for those techniques that achieve the most drastic decontamination within the set of techniques that can be qualified as BAT.

Companies will have to adjust their choice of process and internal operations to this. This may include substitution of substances with alternatives that form less of an aquatic hazard, or process optimisation. The same should be noted as for decontamination effort Z: Where it concerns additives, substitution would be a logical choice, but that may not be an option for substances in the raw materials that are an integral part of production processes and substances may still be released during the process. An example is the release of metals such as selenium and copper in the production of petroleum. In this case potential measures must be found in in-process and purification measures.

A difference with substances in category Z is that for A substances purification is a more explicit decontamination option. A key difference with substances linked to decontamination effort B is, however, the poor biodegradability of A substances. This must be given close consideration when determining the purification effort of A substances.

3.2.4 Decontamination effort B

Discharge of substances with an aquatic hazard level linked to a decontamination effort B will have to be prevented wherever possible. Businesses will have to adjust their choice of process and internal operations to this (good housekeeping and process-integrated measures).

In this category of aquatic hazard level, the competent authority has a free choice of techniques that are considered BAT. Depending on the specific aquatic hazard in a specific case, they may choose from different BAT techniques. This is subject only to the general principle that a higher level of aquatic hazard (within category B) justifies higher investments; there are no specific reasons to opt for the best or worst technique within the set of techniques that can be classified as BAT. An example of the discharge of a B substance is the discharge of toluene in the production of petroleum.

These substances are generally readily biodegradable. As such, it is not absolutely necessary to substitute them or avoid contact with waste water when these substances are removed from the waste water by means of purification, as long as the purification process used can be classified as BAT.

3.2.5 Decontamination effort C

Substances with an aquatic hazard level linked to a decontamination effort C occur naturally in surface water and have less of an environmental impact. This is taken into consideration when determining the need for taking (additional) emission-reducing measures.

Generally speaking, there is no immediate need in this category to prescribe a technique more drastic than the most limited decontamination effort within the set of BAT techniques.[40] An example of an exception is phosphate, as this is one of the nutrients.

3.3 Consequences of decontamination effort and concrete measures

Although the above information provides direction in determining appropriate techniques for specifying the required decontamination effort, this document does not give *specifics* as to when exactly substitution is needed, which substance may or may not be used in a process, which specific process modifications are needed to prevent contact with waste water, and which specific purification techniques are to be used. In that sense, the properties of substances do not directly result in concrete conditions.

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[40] However, based on the discharge test, a limited number of relatively harmless C substances (such as sulphates and chlorides) must be prevented wherever possible (for instance by means of good housekeeping) from being discharged in waste water.

4 Provision of information: roles and responsibilities

The GAM plays a key role in the process of information provision. The GAM is used to classify substances and mixtures based on their (eco)**toxicological properties**[41] and to determine the required decontamination effort. A prerequisite for application of the GAM, then, is that relevant information on the properties of substances is available.

Information on substances is stored in the ECHA database (http://echa.europa.eu/nl/). The business community is responsible for providing input to this database and for the quality and accuracy of the data included in it. In principle, only the data classified with reliability index 1 and 2 may be used to determine the aquatic hazard of substances based on the information in this database. Other data is not sufficiently reliable. Appendix 6.2 provides more detailed information on the use of data in GAM assessment.

Starting point for granting permits is that the applicant must first of all provide sufficient information to the competent authority. Under Section 4:2 par. 2 of the General Administrative Law Act (Awb), the applicant of a permit or customised regulation provides the information needed to decide on the application they can reasonably be awarded. Under Awb Section 3:2, the competent authority is obligated to collect the required information on the relevant facts and interests to be weighed. As such, the competent authority must obtain satisfactory information on the hazard properties of chemicals from the applicant before a decision can be taken. This includes at least the information needed to be able to apply the GAM. This is further detailed for permit applications in Article 6.21 of the Water Regulation, which stipulates that the nature, composition, properties and origin of the substances to be discharged are provided.

The GAM is applied to substances in a discharge that are relevant to the chemical and ecological water quality and to the social functions of the water systems involved (see paragraph 2.1). For discharges subject to a permit or notification, these substances must be included in the application or notification. The competent authority subsequently checks whether all relevant substances have been included and, where necessary, completes the GAM for other relevant substances.

It would be advisable for the competent authority to indicate in the pre-consultation phase which information on substances is required for the careful assessment of the application. The applicant is responsible for providing sufficient information. The competent authority must then assess whether the information is sufficient to be able to take a sensible decision and, as such, whether the permit application or the request for customisation can be allowed. It is important, therefore, that the competent authority can substantiate why the application comprises sufficient information and can be allowed. The competent authority must act as follows.

1) The worst-case approach: in this approach, the assessment flowchart is completed for substances and mixtures. If information is lacking to answer a certain question from the flowchart, the 'worst-case' track is opted for. This may result in a greater required decontamination effort. Then two possible outcomes remain:
    a) After implementing this approach, the discharger is carrying out or will carry out the required decontamination effort as determined in this manner. The decision can be taken based on

[41] Acute and/or chronic toxicity, mutagenicity, carcinogenicity, persistence and bioaccumulative potential.

this scenario, which means that the information in the application can be considered satisfactory.

b) After implementing this approach, the (intended) effort by the discharger turns out to be insufficient for the required decontamination effort as determined in this manner. This does not solve the problem of the missing data. Based on the GAM, the discharger would have to take additional measures to protect the environment. However, the competent authority is unable to substantiate which costs of the additional measures are justifiable in terms of environmental benefits. After all, the environmental hazard level of the discharge is not known because information is missing. The competent authority must therefore rule that the information provided with the application is not sufficient to reach a decision. The application cannot be handled. This conclusion may be avoided if the company agrees to taking additional measures, adds the missing information to the application, or withdraws the application in order to submit a new application with the missing information at a later point in time.

2) There is no additional knowledge or information that shows that there is no hazard for aquatic organisms in the long term. This may be the case for discharges of inorganic substances. In that case, the assessment criteria for biodegradability and bioaccumulative potential from Chapter 2 cannot be properly applied.

3) The residual discharge is so small that the costs of an additional measure are disproportional to the environmental gain (relevance). In that case, no additional information has to be provided and the application can be handled after all.

   a) This may be the case if a purification technique with a high purification yield has already been implemented.

   b) If the load of the non-purified waste water flow is not significant, possible decontamination measures will not be cost-effective. In that case, better protection of the environment cannot reasonably expected and the application can be handled.

5 Abbreviations

GAM	General Assessment Methodology
AMvB	*Algemene maatregel van bestuur* (Order in Council)
ATCN	Association of tank cleaning companies in the Netherlands
BAT	Best available techniques
BAT conclusion	Document that describes the (European) BAT for each industrial sector for installations in the sense of the IED (previously called 'BREF documents')
CIW	*Commissie Integraal Waterbeheer* (Committee on Integrated Water Management)
CLP	Classification, Labelling and Packaging
CTB	College toelating bestrijdingsmiddelen (Pesticides Authorisation Board)
ECHA	European Chemicals Agency
LC50	Concentration at which 50% of laboratory animals die
IPPC	Integrated Pollution and Prevention Control (European directive for application to certain industrial sectors, succeeded by the IED)
LC50	Concentration at which 50% of laboratory animals die
M-factor	Weighting factor, related to toxicity, to determine when a substance is to be considered a component in a mixture when determining the aquatic hazard level of the mixture.
MKE	*MilieuKwaliteitsEis* (environmental quality standard)
MSDS	Material safety data sheet .
PAH	Polycyclic Aromatic Hydrocarbons
IED	European Industrial Emissions Directive
sous	*Strategie Omgaan Met Stoffen – beleidsvernieuwing stoffen* (strategy for handling substances – policy innovation for substances)
TEB	*Totaal-Effluent Beoordeling* (total effluent assessment)
UVR	*Uitvoeringsbesluit Rijkswateren* (implementation decree on national water bodies)
VIB	*Veiligheids Informatie Blad* (Safety Information Sheet)
Wabo	*Wet algemene bepalingen omgevingsrecht* (Environmental Licensing (General Provisions) Act)
Wm	*Wet milieubeheer* (Environmental Management Act)
SVHC	Substances of Very High Concern

6 Annexes

6.1 Use of data for GAM assessment

Sources of information on substances include the ECHA[42] site, where data on both physical and ecological properties of a large number of substances can be found, as well as information on use and safety. It is important, however, to always screen the information. To ensure that toxicity data is sufficiently reliable, it must have a classification of at least 1 or 2.

The corresponding guidance document describes a method for how and where substance data can be found. Definitions are given as well as an explanation of how data is to be handled before using it as input for GAM assessment by a company.

For a more convenient application of the GAM, an Excel program has been created for mixtures. This can also be used to determine the GAM classification of individual substances.

6.2 A step-by-step approach to decontamination

The GAM steps are shown in Figure 1. The first step of the assessment is screening as to whether the substances to be assessed can be considered SVHC or whether the mixtures to be assessed contain substances that are considered SVHC in a concentration of 0.1/M%. The GAM results in an approach Z(1) for non-readily biodegradable SVHC, and in an approach Z(2) for readily biodegradable SVHC. Emphasis for SVHC is initially on substitution. If that is not possible, emissions into water must be reduced as much as possible (target of zero emissions).

Substances that are not considered SVHC are first of all assessed with respect to their biodegradability. If a substance is readily biodegradable, it is tested to determine whether it can give rise to bioaccumulation in the aquatic environment (log Kow > 4). Substances with a log Kow > 4 may cause effects in the long term. These substances follow the same route as non-readily biodegradable substances. The substances are then classified with regard to their toxicity. Based on chronic or acute toxicity data[43], substances are classified into categories with a corresponding decontamination effort (A1 to A3). Substances with a relatively low level of toxicity that are not classified into categories 1 to 3 are then assessed with respect to their solubility. It is not possible to properly determine the toxicity of substances that are not easily soluble. These substances will have to be assessed in terms of their bioaccumulative potential, given their possible long-term effects. Substances with a log Kow > 4 are classified into category A(4). Substances with a solubility > 1 mg/l can be said to have a low level of toxicity; while their toxicity can be determined, these substances do not come into categories 1 to 3. These substances and substances with a log Kow ≤ 4 are classified into category B(4) and into category C(1) if the substance occurs naturally.

A similar classification based on toxicity data is used for readily biodegradable substances. The criteria are somewhat less limiting because no long-term effects are expected (log Kow < 4 and the substances are readily biodegradable). This results in classification into categories B(1 to 3), for substances with a low level of toxicity into category B(5), and for substances that occur naturally in surface water into C(2).

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[42] http://echa.europa.eu/nl/information-on-chemicals/registered-substances
[43] classification depends on which of the two represents the greatest hazard

If no or insufficient data is available on a substance as required for input for the GAM assessment, a worst-case approach is followed.

6.2.1 Heavy metals

Heavy metals occupy a special position because they are not biodegradable. They are automatically classified into the A category. This approach differs from the GAM method from 2000. Some heavy metals (Hg, Cd, As, Ni ..) are SVHC and are classified into category Z(1).

6.2.2 Substances that occur naturally

Implementation of the GAM may result in the choice *'substance that occurs naturally'*. These include macro-ions that occur naturally in the receiving surface water, such as sulphate, chloride, phosphate, nitrate, sodium, etc.

Some other substances also occur naturally, including petroleum and heavy metals. It is generally recognised that the discharge of these substances is to be avoided. These are, therefore, not considered natural substances in the implementation of the GAM. Substances synthesised by humans are, of course, no natural substances.

6.3 Examples of GAM classification

<u>Classification into category Z(1)</u>

Benzo(b)fluoranthene is a substance in this category and is on the SVHC list. This substance is not biodegradable and therefore classified into category Z(1). This means that it must be substituted wherever possible. Ships used to use coal tar, which contains this and other harmful PAH compounds. For that reason, coal tar was substituted by other coatings, such as epoxy. The production of steel requires cokes. The production of cokes from coal releases PAH compounds, including benzo(b)fluoranthene, the emissions of which must be regulated by means of BAT. The permit for this part must be evaluated every five years.

<u>Classification into category Z(2)</u>

Benzene is a substance in this category and is on the SVHC list. This substance is biodegradable and therefore classified into category Z(2). This means that it must be substituted wherever possible. However, this is not always feasible in practice. It is a raw material in the industry that cannot always be substituted just like that. That means that emissions of this substance must be tackled using an optimal BAT approach. This approach must be evaluated every five years.

<u>Classification into category A</u>

The substance 2,4-dichloronitrobenzene is an intermediary for the production of pesticides. As stated on the ECHA site, this substance is not readily biodegradable. Its aquatic toxicity is between 1 and 10 mg/l. On the CLP inventory list, the substance is classified as H411 aqua chronic 2. Its log Kow is 3.05. Based on this data, the substance is to be classified into category A2. This has the following consequences for licensing: approach at the source, possibly combined with additional purification.

<u>Classification into category B</u>

The substance 2,6-difluorobenzonitrile is a raw material used for the production of pesticides. As stated on the ECHA site, this substance is not readily biodegradable. Its log Kow is 1.88. According to this source of information, the NOEC value of the substance for zebrafish is 44.8mg/l. The LC 50 value for zebrafish is 113 mg/l. According to the GAM diagram, the substance cannot be assigned an H classification for aquatic toxicity. The CLP inventory list within ECHA also does not include an H-sentence for aquatic toxicity. The substance’s solubility at 20 degrees Celsius is 1.87 mg/l. The substance does not occur naturally. For these reasons, it is classified into category B4. In accordance with the criteria in par. 3.2.4, permits are granted on condition that an appropriate method for reducing pollution is used.

Classification into category C

Phosphoric acid has numerous applications. The substance’s toxicity is determined by its pH. According to ECHA, the lethal pH for fish is 3-3.25. It is important, therefore, that discharges are as pH neutral as possible. Phosphoric acid is not biodegradable and readily soluble in water (log Kow < 0.) No H classification for aquatic toxicity is given. It is generally known that the salts in phosphoric acid contribute to the eutrophication of surface water. Phosphates also occur naturally. The GAM classification is C1. Discharges of this substance are subject to neutralisation of pH and application of the discharge test. Measures in case of extensive discharges may include biological or chemical dephosphatisation or biological purification.

Substitution of substances

An important aspect in the substitution of substances in addition to the GAM assessment is the quantity of the substance that will be needed. Another issue is how a GAM classification into, say, the B category relates to a GAM classification into the A category. Is use of an A substance always more polluting than use of a B substance? This depends on such factors as a substance's toxicity. A B1 substance is much more toxic than an A4 substance. Despite the fact that a B1 substance degrades by 70% within 28 days, the use of a B1 substance may have acute effects due to its much higher toxicity. In this case, an *integrated* assessment will have to be made based on the quantity of the substance needed, the GAM classification based on the properties of the substance, the available purification facilities, and any required additional facilities and related effects for the receiving water (testing based on the discharge test). The use of a B substance is not necessarily more beneficial than the use of an A substance. In such integrated assessments, the local prerequisites also determine the final ruling.

6.4 Explanation of the calculation rules for the aquatic hazard level of mixtures

This appendix describes the calculation rules for determining the aquatic hazard level of mixtures. The method is based on the CLP Regulation.

The flowchart below presents three steps that ultimately lead from environmental data of individual substances to the GAM classification of a mixture. The first step considers in what concentrations substances are present in a mixture and whether, based on that, they must be included in the assessment. This is necessary because both CLP and SVHC policy have abandoned the 0.1% (w/w) limit (see par. 6.4.2.). The second step comprises the CLP classification of each substance based on the toxicity data (details in par. 6.4.3). In the final step, the classification of individual substances in a mixture is converted into the GAM classification of that mixture using calculation rules (see par. 6.4.4).

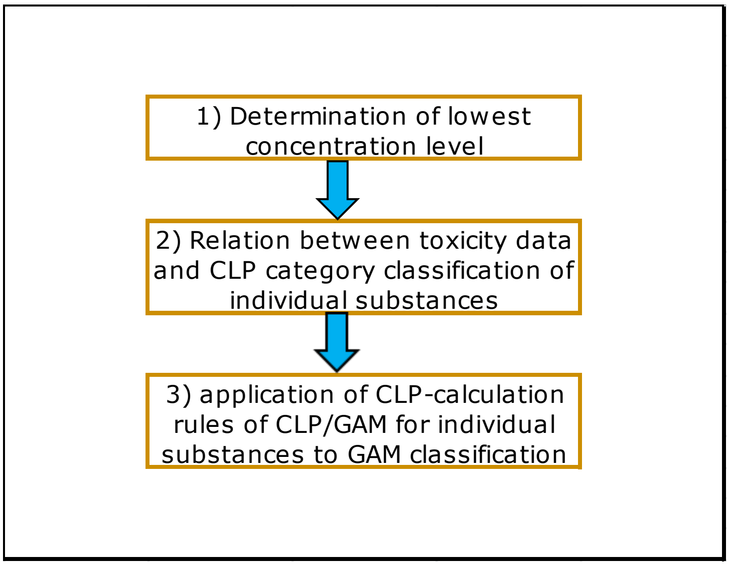

Figure: 3 Steps in the classification of a mixture into a GAM category

It is not easy to determine the GAM classification of mixtures. For that reason, a digital Excel tool has been developed: the GAM tool. This tool determines the GAM classification based on the properties of the components and the percentage at which they occur in the mixture. This enables a more rapid and transparent determination of the GAM classification of a mixture. This tool uses the steps in the above figure. It can also be used to determine the GAM classification of individual substances.

6.4.1 Data on the mixture

The assessment of mixtures requires information at component level of all substances in the mixture to get an idea of the aquatic hazard of that mixture. Such information is usually stated on MSDSs or safety information sheets. For determining the aquatic hazard of mixtures, the GAM is designed to link up with the methodology of the European CLP Regulation (Classification, Labelling and Packaging) wherever possible. This regulation includes the lower limits above which a substance is to be included in an MSDS.

6.4.2 Methodology for concentration limits under CLP Regulation

The CLP Regulation prescribes when a component present in a mixture must be stated on an MSDS. This must be done using weighting factors based on a substance's toxicity. The more toxic a substance, the higher its weighting factor and as such it must be stated as a component of the

mixture from lower concentrations upwards.
The table below indicates how the weighting factor is applied to determine the concentration limit at which the substance is relevant under the CLP Regulation.

Table 2.* *Concentration limits under CLP per category [1])

Category of substances	Concentration limit (% m/m) [2])
Acute toxicity 1 (H400)	0.1/M[3]
Chronic toxicity 1 (H410)	0.1/M
Other substances	1

[1]) See Article 10 of CLP Regulation, par. 4; Annex I to CLP table 1.1 chapter 4.1.3.1 (p. 529) of the 'Guidance on the application of the CLP' (June 2015)
[2]) m/m percentage by weight
[3]) M: value of the weighting factor (M-factor), see par. 6.4.2.1

To implement SVHC policy, a weighting factor (M-factor) is used, analogous to the CLP approach, which is related to toxicity in order to determine when a substance as a component in a mixture is to be considered in the assessment of the aquatic hazard of the mixture.
SVHC substances include a number of highly toxic substances. For that reason, the concentration limit uses a percentage by weight of 0.1/M %. This approach is in the spirit of the CLP Regulation.
The table below provides an overview of the concentration limits above which a substance as a component in a mixture is to be considered in the assessment of the aquatic hazard of the mixture.

Table 3.* *GAM concentration limits [1])

SVHC[44]	(0.1/M)%	GAM categories Z1 and Z2
Acute toxicity 1 (H400)	(0.1/M)%	GAM categories A1 and B1
Chronic toxicity 1 (H410)	(0.1/M)%	GAM categories A1 and B1
Other substances	1%	Other GAM categories

[1]) A substance must be included in the assessment of the aquatic hazard of a mixture if the concentration of that substance is greater than or equal to the concentration limit given in the table.

The practical application of the concentration limit is explained in more detail in the following example.

Example

A producer markets a mixture consisting of four component substances: O, P, Q and R (see next table). It is known from the literature that the mixture is pollutant to a concentration of 0.003% w/w with mercury. The question is whether and to what level of detail the producer must declare the composition. The following table indicates to what level substances must be included in the assessment of the toxicity of a mixture and in the declaration of its composition.

Substance	Composition (% w/w)	Biodegradability	L(E)C50 [mg/l]	NOEC [mg/l]	Classification into toxicity category	M-factor	Concentration limit [% w/w]
O	20	Not readily biodegradable	0.1	0.01	NOEC ≤ 0.01 mg/l and LC50 ≤ 0.1 mg/l	10	0.01
P	20	Readily biodegradable	1	0.5	LC50 >0.1 mg/l and NOEC > 0.01 mg/l	1	0.1
Q	30	Not readily biodegradable	0.5	0.01	NOEC ≤ 0.01 mg/l and LC50 ≤ 0.1 mg/l	10	0.01
R	29,997	Readily biodegradable	2	0.6	LC50 >0.1 mg/l and NOEC > 0.01 mg/l	1	1
mercury	0.003	Not readily biodegradable	0.005	0.0006	NOEC ≤ 0,001 mg/l and LC50 ≤ 0.01 mg/l	100	0.001

[44]Whether substances are to be considered SVHC can be found on http://www.rivm.nl/rvs/Stoffenlijsten/Zeer_Zorgwekkende_Stoffen and http://echa.europa.eu/nl/candidate-list-table

6.4.2.1 Determining the M-factor of individual substances

The weighting factor (M-factor) is determined on the basis of a substance's acute and chronic toxicity. Chronic toxicity further distinguishes between 'not readily biodegradable' and 'readily biodegradable'. The table below indicates which M-factor is used for which level of toxicity.

Table 4. M-factor depending on acute or chronic toxicity in accordance with CLP

Acute toxicity	**M-factor***	**Chronic toxicity**	**M-factor**	
LC-50 value [mg/l]		NOEC value [mg/l]	NRB**	RB***
L(E)C50 > 0.1	1	NOEC> 0.01	1	1
0.01< L(E)C50 ≤ 0.1	10	0.001< NOEC ≤ 0.01	10	1
0.001< L(E)C50 ≤ 0.01	100	0.0001< NOEC ≤ 0.001	100	10
0.0001< L(E)C50 ≤ 0.001	1000	0.00001< NOEC ≤ 0.0001	1000	100
0.00001< L(E)C50 ≤ 0.0001	10000	0.000001< NOEC ≤ 0.00001	10000	1000
0.000001< L(E)C50 ≤ 0.00001	100000	0.0000001< NOEC ≤ 0.000001	100000	10000
(and onwards by a factor of 10)		(and onwards by a factor of 10)		

* See Chapter 4 of Annex I to the CLP Regulation

** NRB Not Readily Biodegradable (in accordance with OECD 301 tests).

*** RB Readily biodegradable (in accordance with OECD 301 tests).

6.4.3 Classification of individual substances into CLP categories

The CLP Regulation distinguishes between four chronic toxicity classes (category 1 to 4) and one acute toxicity class (acute 1). The GAM uses the same principles for the classification of substances and mixtures (see Figure 1 in paragraph 2.2). The first three categories are based on measured toxicity. Category 4 comprises substances that, based on toxicity, cannot yet be categorised because the actual effect concentration cannot be determined (solubility < effect concentration). Exposure is limited by solubility. This is the case, for example, with mineral oil. Because it is not clear whether toxic effects will occur as a result of, for instance, bioaccumulation, additional screening for log Kow takes place. Not readily biodegradable substances with a Log Kow > 4 may have toxic effects in this way and are classified into category 4. Other substances need not be classified based on toxicity. The new GAM has a similar classification to the old GAM. Table 5 presents the CLP categories for toxicity and the corresponding GAM categories.

Table 5 From CLP classification for toxicity [1]) to GAM classification

CLP toxicity category	Chronic Readily biodegradable	Chronic Not readily biodegradable	Acute	GAM category	Comments
Category 1	NOEC ≤ 0.01 [mg/l]	NOEC > 0.1 mg/l]	LC50 ≤ 1 [mg/l]	A1 (NRB) or B1 (RB)	
Category 2 (chronic)	NOEC ≤ 0.1 [mg/l]	NOEC ≤ 1 [mg/l]	LC50 ≤ 10 [mg/l]*	A2 (NRB) or B2 (RB)	
Category 3 (chronic)	NOEC ≤ 1 [mg/l]	NOEC ≤ 10 [mg/l]	LC50 ≤ 100 [mg/l]*	A3 (NRB or B3 (RB)	
Category 4 (chronic)		NOEC cannot be determined [2]) and solubility < 1 mg/l and log Kow > 4	LC50 cannot be determined 2) and solubility < 1 mg/l and log Kow > 4*	A4	Classification based on bioaccumulative potential (log Kow) and solubility
Other		NOEC > 10 [mg/l] or cannot be determined and log Kow ≤ 4, or solubility ≥ 1 mg/l	LC50 > 100 [mg/l] or cannot be determined and log Kow ≤ 100, or solubility ≥ 1 mg/l *	B4; C2; B5; C2	Distinction based on whether or not the substance occurs naturally in surface water[45]

[1]) Annex I CLP table 4.1.0
[2]) Solubility < 1 mg/l, toxic effect concentration < solubility, so that toxicity cannot be determined
* CLP has no categories 2, 3 and 4 based on acute toxicity. Data is included in table 4 and GAM to be able to make a classification in the absence of chronic data. As for the chronic categories, a difference between toxicity categories by a factor of 10 is used.
NRB = Not Readily Biodegradable
RB = Readily Biodegradable

6.4.4 Application of calculation rules in the GAM for mixtures

Depending on the classification of individual components, the CLP also has calculation rules for the classification of mixtures. This is based on three principles:

- Classification based on mixtures tested;
- Classification based on extrapolation principles;
- Application of the 'addition method for classified components' and/or a 'summation formula'.

For the GAM described in this report it was decided to consider the biodegradability of a substance as a guiding principle. No biodegradability and bioaccumulation tests are used for mixtures, as these are usually difficult to interpret and may only be relevant to individual substances[46].

[46] 4.1.3.3.2 CLP

Table 6. Classification into toxicity categories in accordance with CLP [2]) and related calculation rules

Category	CLP-calculation rules for classification of mixtures		Remark	GAM-classification
CLP-category 1 (H410; H400)	M-factor has to be taken into account (M might be > 1) **M*C-cat-1 >= 25%**	**(I)**		A1; B1
CLP-category 2 (H411)	M-factor =1 **M*C-cat-1*10 + C-cat-2 >= 25%**	**(II)**	Cat-2 is 10 times less toxic Cat-1	A2; B2
CLP-category 3	M-factor =1 **M*C-cat-1*100 + M*C-cat-2*10 + C-cat-3 >= 25%**	**(III)**	Cat-3 is 10 times less toxic than cat-2 en 100 times less toxic than Cat-1	A3; B3 A3; B3
CLP-category 4	M-factor =1 **C-cat-1 + C-cat-2 + C-cat-3 + C-cat-4 >= 25%**	**(IV)**	Due to low solubility toxicity of Cat-4 substances canot be determined	A4
Other			Proven toxicity lower than toxicity of cat-3 substances	B4; B5; C1; C2

[2]) See Table 4.1.2 of Annex I to the CLP Regulation.

Classification of mixtures is based on calculation rules. The starting point is the individual classification of substances based on toxicity. Individual substances can be classified into category 1 (A1;B1), 2 (A2;B2) or 3 (A3,B3). The calculation rules take the sum concentration of all substances in the same category as the starting point. If, for instance, two A1 substances are present in a mixture in concentrations of 10% and 20% respectively, a concentration of 30% will have to be filled in for category A1 in the calculation rule. The calculation rules for category 1 to 3 of the CLP Regulation (see table above) have been adopted in the GAM in their entirety. The calculation rule for category 4 has been slightly adjusted. This is explained in more detail in Appendix 6.5.

The variables in the calculation rules are the added substance concentration in each category and the related M-factor, based on a substance's toxicity. In addition, there are additional (weighting) factors used to assign extra weight to the concentration of substances from a higher toxicity category in the calculation rule for classification into a lower category (see table 7).

Because of the weighting factors that are distinguished for the different toxicity categories, low concentrations in heavier categories (not sufficient for classification into that heavier category) may be sufficient for classifying the mixture into a lighter category. Categories 1 to 3 differ roughly by a factor of 10 in toxicity.

The following table illustrates how concentrations in the higher toxicity categories affect the classification of lower categories.

Table 7. Criteria per category

category → classification based on calculation rule ↓	Classification into category 1	Classification into category 2	Classification into category 3	Classification into category 4
1 $\sum_{k=1}^{n}(Mk)*C_{1,k(A1,B1)}$	≥ 25%	2.5%≤C1< 25%	0.25%≤C1< 2.5%	
2 $10*\sum_{k=1}^{n}(Mk)*C_{1,k(A1,B1)} + \sum_{k=1}^{n} C_{2,k(A2,B2)}$		≥ 25%	2.5% ≤ C2 < 25%	
3 $100*\sum_{k=1}^{n}(Mk)*C_{1,k(A1,B1)} + 10*\sum_{k=1}^{n} C_{2,k(A2,B2)} + \sum_{k=1}^{n} C_{3,k(A3,B3)}$			≥ 25%	
4 $100*\sum_{k=1}^{n}(Mk)*C_{1,k(A1,B1)} + 10*\sum_{k=1}^{n} C_{2,k(A2,B2)} + \sum_{k=1}^{n} C_{3,k(A3,B3)} + \sum_{k=1}^{n} C_{4,k(A4)}$				≥ 25%

The calculation rules for each GAM category and the related testing criteria are included in Table 8 in this appendix.

6.4.5 Testing diagram of the aquatic hazard level of mixtures

The testing diagram below (Table 8) gives practical details on testing the aquatic hazard of mixtures in accordance with the CLP Regulation.

Table 8. General assessment methodology for mixtures based on concentration C (expressed as percentage by weight) of substances in mixtures

Result of classification → **Calculation rules per category** [1]) ↓	**Z1**	**Z2**	**A1**	**A2**	**A3**	**A4**	**B4**	**C1= C2**	**B1**	**B2**	**B3**	**B5= B4**
Z1 Σ M*Cz_1	≥0.1 %						<0.1%					
Z2 Σ M*Cz_2		≥0.1 %					<0.1%					
A1 Σ M*C_1			≥25 %	2.5%≤ C_x < 25%	0.25%≤ C_x < 2.5%		<0.25 %					
A2 Σ M*C_{A1} *10 + Σ C_{A2}				≥25%	2.5%≤ C_x < 25		<2.5%					
A3 Σ M*C_{A1} *100 + Σ C_{A2} *10 + Σ C_{A3}					≥25%		<25%					
A4 Σ M*C_{A1} *100 + Σ C_{A2} *10 + Σ C_{A3} + Σ C_{A4}						≥25%	<25%					
B4 Σ C_{B4}							≥1%					
C1 = C2								100%				
B1 Σ M*C_{B1}									≥25%	2.5% ≤ C_x < 25%	0.25% ≤ C_x < 2.5%	< 0.25 %
B2 Σ M*C_{B1} *10 + Σ C_{B2}										≥25%	2.5% ≤ C_x < 25%	<2.5 %
B3 Σ M*C_{B1} *100 + Σ C_{B2}*10 + Σ C_{B3}											≥25%	<25 %
B5 Σ C_{B5}												≥1%

[1]) where Σ M*Cz_1 = $\sum_{k=1}^{n}(Mk)$*$Cz_{1,k}$; where Σ M*Cz_2 = $\sum_{k=1}^{n}(Mk)$*$Cz_{2,k}$; Σ M*C_{A1} = $\sum_{k=1}^{n}(Mk)$*C_{A1};
Σ C_{A2} = $\sum_{k=1}^{n}$ $C_{A2,k}$; Σ C_{A3} = $\sum_{k=1}^{n}$ $C_{A3,k}$ en Σ C_{A4} = $\sum_{k=1}^{n}$ $C_{A4,k}$; Σ M*C_{B1} = $\sum_{k=1}^{n}(Mk)$*$C_{B1,k}$;
Σ C_{B2} = $\sum_{k=1}^{n}$ $C_{B2,k}$; Σ C_{B3} = $\sum_{k=1}^{n}$ $C_{B3,k}$; Σ C_{B4} = $\sum_{k=1}^{n}$ $C_{B4,k}$; Σ C_{B5} = $\sum_{k=1}^{n}$ $C_{B5,k}$

To be able to apply the above diagram, it is essential to know the following:

- The GAM calculation rules based on the CLP Regulation are given in the left-hand column;
- The aquatic hazard of the mixture follows from the top row;
- The highest aquatic hazard is the guiding principle for classifying a mixture.

This means that the diagram is gone through from left to right and from top to bottom. The starting point is the substance with the highest aquatic hazard level. Depending on the number of differently classified substances, one or more calculation rules must be followed. The calculation rule that yields the greatest aquatic hazard is decisive for the mixture’s classification.

An Excel tool has been developed for practical application by businesses. This has been used for determining the GAM classification of three mixtures.

6.4.6 Practical examples of classification of mixtures

The GAM classification of three mixtures was determined using the GAM tool, taking data from the ECHA database. The required information is summarised in the table below.

Table 9 Overview of relevant substance data for GAM assessment of mixtures

mixture	substance (%)	SVHC substance?	CAS number	H Zin Aq CLP	readily bio-degradable?	LC50 fish Acute [mg/l]	LC 50 invertebr acute [mg/l]	NOEC fish [mg/l]	NOEC invertebr Chr [mg/l]	NOEC Alg Chr [mg/l]	Hzin derived	Soluble in water (%)	Log Kow	GAM
Aroma	Mesitylene 79%	n	108-67-8		n	12.52	6	-			411	46.2	3.42	
	Toluene 10%	n	108-88-3		j			1.4	0.74	10	411		2.73	
	Benzene 0.095 %	svhc	71-43-2	412				0.8	3	100			2.13	
Metalux	Phosphoric acid 70%	n	7664-38-2		n									C1
	Sulphuric acid 29 %	n	7664-93-9		n									C1
	Copper sulphate 1%	n	7758-98-7		n	0.3	0.1			0.2				
Metal additive	Bis[bis(2-hydroxyethyl)ammonium] sulphate[1] 7%	n	20261-60-3		n	>100	>100	>100	100	>100		>1000	-1.31	
	Phosphoric acid 50%	n	7664-38-2		n								<<0	C1
	Sulphuric acid 25 %	n	7758-98-7		n								<<0	C1
	Tributylamine 1%	n	102-82-9	H411	J	>10	8	n.k.[2]	n.k.	<1.378[3]			3.378	

1 Information on bis(2-hydroxyethyl)ammonium acetate (cas 23251-72-1) was used in this table (similar substance). The ECHA database held no information on the actual substance.
2 n.k. = not known
3 LOEC value given

Mixture: Aroma

The figure below is the result of the calculation with the GAM tool for the mixture *Aroma*. The GAM classification of the mixture is shown at the bottom. Despite the fact that benzene – an SVHC substance – is present, the mixture is classified as A2. If the benzene content were to exceed 0.1%, the mixture would be classified as Z2. The mixture is for the most part not biodegradable. For the substance to be classified as A2, a phase separator must be used, followed by, for example, biological purification or a stripper.

Name of mixture:	Aroma
Give the number of different components the mixture is consisting of?	3

Name of substance	(insert CAS-nr.)	Does it concern a substance that has been classified before?	Composition by weight-percentage (%)	Does it concern a designated SVHC or a substance that meets the SVHC-criteria? ***	Is the substance readily biodegradable?*	Is CLP H-classification for aquatic toxicity available?	Enter H-classification	Are chronic toxicity data available?	Is a complete chronic toxicity dataset available?	Enter lowest chronic NOEC-value [mg/l]	Are acute toxicity data available?	Enter lowest LC-50 value [mg/l]	M-factor	Solubility [mg/l]	Log Kow	Does substance naturally occur in aquatic environment **?	GAM-classification for individual substance ****
mesitylene	(106-67-8)	no	79.000%	no	no	no		no			yes	6	1		3.42		A2
toluene	(108-88-3)	no	10.000%	no	yes	no		yes	yes	0.74			1		2.73		B3
benzene	(71-43-2)	no	0.095%	yes	yes	yes	H412						1		2.13		Z2

GAM classification: A2

The GAM classification of the mixture is: A2

result based on calculation rules for mixtures:				
classification	result calculation rule		criteria	
Z1	0.000%	≥	0.10%	
Z2	0.095%	≥	0.10%	
A1	0.000%	≥	25.00%	
A2	79.000%	≥	25.00%	<<==
A3	790.000%	≥	25.00%	
A4	790.000%	≥	25.00%	
B4	0.000%	≥	1.00%	
C1	0.000%	=	100%	
B1	0.000%	≥	25.00%	
B2	0.000%	≥	25.00%	
B3	10.000%	≥	25.00%	
B5	0.000%	≥	1.00%	
C2	0.000%	=	100%	

degradable part of the mixture	11.33%
non degradable part:	88.67%

sum of Z2 < 0.001/M; Z2 ==> B4

LEGENDA:

- cells (to be filled) needed for GAM classification
- (filled-in) cells
- cells (te be filled) NOT needed for GAM category but desired for the environmental profile of the substance

The underlying GAM assessment using the calculation module, with calculation rules based on the CLP, works as follows:

- It follows from table 3 ‘determination of M-factor’ that, based on the environmental data for mesitylene, toluene and benzene, the M-factor is 1.
- It follows from table 4 ‘classification of individual substances CLP for toxicity’ that, based on the environmental data, mesitylene falls into CLP Category 2 and GAM category A2, and toluene into category 3 and GAM category B3.
- In Table 8, the heaviest categories always take precedence (Z over A and A classifications over B classifications). Vertically from top to bottom are the GAM categories of the individual substances. The classification of the mixture is determined horizontally.

- Benzene, a substance of very high concern, is a Z2 substance. So the classification of the individual substance is Z2. The M-factor for benzene is 1. Benzene is the only SVHC in the mixture, and because the benzene content in the mixture < 0.1/M%, benzene in the mixture is classified as B4.
- Mesitylene is an A2 substance. Mesitylene is the only A2 substance in the mixture. The calculation rule for A2 substances in the mixture yields: $\Sigma\ M^*C_{A1}\ ^*10 + \ \Sigma\ C_{A2}$ = $M^*10^*C_{A1}+ C_{A2}$. Or M*10*0 + 79.9 % = 79.9%. This is more than 25%. This results in classification A2 for the mixture.
- Toluene is a B3 substance (see above figure). Its content is 10%. Toluene is the only B3 substance in the mixture, which means that the calculation rule for the mixture is $100^*\Sigma\ M^*C_{B1} + 10^*\Sigma\ C_{B2} + \Sigma\ C_{B3}$ = $M^*100^*C_{B1}+10^*C_{B2}+C_{B3}$ = 0+0+10% = 10%. This is less than 25%. This yields a GAM classification of B5 for the mixture.

• Ultimately, the most stringent classification for the mixture from Table 8 applies, i.e. classification A2.

The different steps are represented in the following overview:

Legend:
- (red) Most stringent and determining classification for mixture
- (pink) Result calculation rule meets criteria for classification

component	compo-sition	Classi-fication of individual compounds	M-factor	sumconcen-tration per GAM-class (%)	Classi-fication	Calculation rules	Result
mesitylene (106-67-8)	79.00%	A2	1	0.000%	<= Z1 =>	Σ Mi*$C_{Z1,i}$ (%)	0.00%
toluene (108-88-3)	10.00%	B3	1	0.095%	<= Z2 =>	Σ Mi*$C_{Z2,i}$ (%)	0.095%
benzene (71-43-2)	0.10%	Z2	1	0.000%	<= A1 =>	Σ Mi*$C_{A1,i}$ (%)	0.00%
				79.000%	<= A2 =>	10*ΣMi*$C_{A1,i}$ +$\Sigma C_{A2,i}$ (%)	79.00%
				0.000%	<= A3 =>	100*ΣMi*$C_{A1,i}$ +10*$\Sigma C_{A2,i}$+$\Sigma C_{A3,i}$ (%)	790.00%
				0.000%	<= A4 =>	100*ΣMi*$C_{A1,i}$ +10*$\Sigma C_{A2,i}$+$\Sigma C_{A3,i}$ +$\Sigma C_{A4,i}$ (%)	790.00%
				0.000%	<= B4 =>	$\Sigma C_{B4,i}$ (%)	0.00%
				0.000%	<= C1 =>	$\Sigma C_{1,i}$ (%)	0.00%
				0.000%	<= B1 =>	Σ Mi*$CB_{1,i}$ (%)	0.00%
				0.000%	<= B2 =>	10*ΣMi*$CB_{1,i}$ +$\Sigma CB_{2,i}$ (%)	0.00%
				10.000%	<= B3 =>	100*ΣMi*$CB_{1,i}$ +10*$\Sigma CB_{2,i}$+$\Sigma CB_{3,i}$ (%)	10.00%
				0.000%	<= B5 =>	$\Sigma C_{B5,i}$ (%)	0.00%
				0.000%	<= C2 =>	$\Sigma C_{2,i}$ (%)	0.00%

Classi-fication
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V

GAM CLASSIFICATION OF MIXTURE

CRITERIA:	Cat 1			Cat 2	Cat 3	Cat 4	other cat		Cat 1	Cat 2	Cat 3	other cat	
	Z1	Z2	A1	A2	A3	A4	B4	C1	B1	B2	B3	B5	C2
<= Z1 =>	≥ 0.1%						< 0.1%					< 0.1%	
<= Z2 =>		≥ 0.1%					< 0.1%					< 0.1%	
<= A1 =>			≥ 25%	2.5% ≤ Cx < 25%	0.25% ≤ Cx < 2.5%		< 0.25%						
<= A2 =>				≥ 25%	2.5% ≤ Cx < 25%		< 2.5%						
<= A3 =>					≥ 25%		< 25%						
<= A4 =>						≥ 25%	< 25%						
<= B4 =>							≥ 1%						
<= C1 =>								100%					
<= B1 =>									≥ 25%	2.5% ≤ Cx ≤ 25%	0.25% ≤ Cx ≤ 2.5%	< 0.25%	
<= B2 =>										≥ 25%	2.5% ≤ Cx ≤ 25%	< 2.5%	
<= B3 =>											≥ 25%	< 25%	
<= B5 =>												≥ 1%	
<= C2 =>													100%

Mixture: Metalux

There are a number of remarkable aspects to this mixture. The GAM classifications of phosphoric acid and sulphuric acid are known. These substances contain the naturally occurring macro-ions phosphate and sulphate. The mixture contains very strong acids. As such, the pH of the water to be discharged must be between certain limits (6.5 < pH < 10). Phosphates and sulphates are substances that occur naturally. The mixture is classified as A2. The decision on the permit will have to consider whether the discharge of copper is permitted or whether separate purification is required, for instance using an ONO installat ion or adsorption to sludge in a biological purification plant.

Name of mixture:	Metalux
Give the number of different components the mixture is consisting of?	3

Name of substance (insert CAS-nr.)	Does it concern a substance that has been classified before?	give the result of GAM classi-fication ****	Composition by weight-percentage (%)	Does it concern a designated SVHC or a substance that meets the SVHC-criteria? ***	Is the substance readily biodegradable?*	Is CLP H-classification for aquatic toxicity available?	Are chronic toxicity data available?	Is a com-plete chronic toxicity dataset available?	Give lowest chronic NOEC-value [mg/l]	Are acute toxicity data available?	Give lowest LC-50 value [mg/l]	M-factor	Solubility [mg/l]	Log Kow	Does substance naturally occur in aquatic environ-ment **?	GAM-classification for individual substance ****
phosphoric acid (7764-38-2)	yes	C1	70.000%									1				C1
sulphuric acid (7764-93-9)	yes	C1	29.000%									1				C1
copper sulphate (7758-98-7)	no		1.000%	no	no	no	yes	no	0.2	yes	0.1	10		3		A1

GAM classification:	A2	The GAM classification of the mixture is:	A2

result based on calculation rules for mixtures:				
classification	result calculation rule		criteria	
Z1	0.000%	≥	0.10%	
Z2	0.000%	≥	0.10%	
A1	10.000%	≥	25.00%	
A2	100.000%	≥	25.00%	<<==
A3	1000.000%	≥	25.00%	
A4	1000.000%	≥	25.00%	
B4	0.000%	≥	1.00%	
C1	99.000%	=	100%	
B1	0.000%	≥	25.00%	
B2	0.000%	≥	25.00%	
B3	0.000%	≥	25.00%	
B5	0.000%	≥	1.00%	
C2	0.000%	=	100%	

degradable part of the mixture	0.00%
non degradable part:	100.00%

LEGENDA:

- cells (to be filled) needed for GAM classification
- (filled-in) cells
- cells (te be filled) NOT needed for GAM category but desired for the environmental profile of the substance

The following overview presents the results of the calculation rules and testing against the criteria for GAM classification of the mixture:

Legend:
- (red) Most stringent and determining classification for mixture
- (pink) Result calculation rule meets criteria for classification

component	compo-sition	Classi-fication of individual compounds	M-factor	sumconcen-tration per GAM-class (%)	Classi-fication	Calculation rules	Result
phosphoric acid (7764-	70.00%	C1	1	0.000%	<= Z1 =>	$\sum Mi*C_{Z1,i}$ (%)	0.00%
sulphuric acid (7764-	29.00%	C1	1	0.000%	<= Z2 =>	$\sum Mi*C_{Z2,i}$ (%)	0.000%
copper sulphate (7758-98-7)	1.00%	A1	10	1.000%	<= A1 =>	$\sum Mi*C_{A1,i}$ (%)	10.00%
				0.000%	<= A2 =>	$10*\sum Mi*C_{A1,i} + \sum C_{A2,i}$ (%)	100.00%
				0.000%	<= A3 =>	$100*\sum Mi*C_{A1,i} + 10*\sum C_{A2,i} + \sum C_{A3,i}$ (%)	1000.00%
				0.000%	<= A4 =>	$100*\sum Mi*C_{A1,i} + 10*\sum C_{A2,i} + \sum C_{A3,i} + \sum C_{A4,i}$ (%)	1000.00%
				0.000%	<= B4 =>	$\sum C_{B4,i}$ (%)	0.00%
				99.000%	<= C1 =>	$\sum C_{1,i}$ (%)	99.00%
				0.000%	<= B1 =>	$\sum Mi*CB_{1,i}$ (%)	0.00%
				0.000%	<= B2 =>	$10*\sum Mi*CB_{1,i} + \sum CB_{2,i}$ (%)	0.00%
				0.000%	<= B3 =>	$100*\sum Mi*CB_{1,i} + 10*\sum CB_{2,i} + \sum CB_{3,i}$ (%)	0.00%
				0.000%	<= B5 =>	$\sum C_{B5,i}$ (%)	0.00%
				0.000%	<= C2 =>	$\sum C_{2,i}$ (%)	0.00%

Classi-fication
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V

GAM CLASSIFICATION OF MIXTURE

CRITERIA:	Cat 1			Cat 2	Cat 3	Cat 4	other cat		Cat 1	Cat 2	Cat 3	other cat	
	Z1	Z2	A1	A2	A3	A4	B4	C1	B1	B2	B3	B5	C2
<= Z1 =>	≥ 0.1%						< 0.1%					< 0.1%	
<= Z2 =>		≥ 0.1%					< 0.1%					< 0.1%	
<= A1 =>			≥ 25%	2.5% ≤ Cx < 25%	0.25% ≤ Cx < 2.5%		< 0.25%						
<= A2 =>				≥ 25%	2.5% ≤ Cx < 25%		< 2.5%						
<= A3 =>					≥ 25%		< 25%						
<= A4 =>						≥ 25%	< 25%						
<= B4 =>							≥ 1%						
<= C1 =>								100%					
<= B1 =>									≥ 25%	2.5% ≤ Cx ≤ 25%	0.25% ≤ Cx ≤ 2.5%	< 0.25%	
<= B2 =>										≥ 25%	2.5% ≤ Cx ≤ 25%	< 2.5%	
<= B3 =>											≥ 25%	< 25%	
<= B5 =>												≥ 1%	
<= C2 =>													100%

Surteq 459 mixture

There are a number of remarkable aspects to this mixture. The GAM classifications of phosphoric acid and sulphuric acid are known. The mixture also contains a quaternary ammonium sulphate compound. ECHA holds no environmental data on this compound. In that case, the data on a compound that most closely resembles it may be used. The acetate variety was opted for. This compound does not meet the criterion ‘readily biodegradable’, as it is only 63% biodegradable. The ECHA database states that this substance is inherently biodegradable. As such, the substance is assessed to be poorly biodegradable. The mixture itself is classified as B5. In practice, treatment in a biological purification plant as a technique is acceptable in this case, provided the acids are sufficiently neutralised.

Name of mixture: **metal additives**

Give the number of different components the mixture is consisting of? **4**

Name of substance (insert CAS-nr.)	Does it concern a substance that has been classified before?	give the result of GAM classi-fication ****	Composition by weight-percentage (%)	Does it concern a designated SVHC or a substance that meets the SVHC-criteria? ***	Is the substance readily biodegradable?*	Is CLP H-classification for aquatic toxicity available?	Enter H-classification	Are chronic toxicity data available?	Is a com-plete chronic toxicity dataset available?	Enter lowest chronic NOEC-value [mg/l]	Are acute toxicity data available?	Enter lowest LC-50 value [mg/l]	M-factor	Solubility [mg/l]	Log Kow	Does substance naturally occur in aquatic environ-ment **?	GAM-classification for individual substance ****
bis[bis[(2-hydroxyethyl)ammonium]sulphate (108-67-8)	no		7.000%	no	no	no		yes	yes	101			1	1000	-1.31	no	B4
phosphoric acid (7664-38-2)	yes	C1	50.000%										1				C1
sulphuric acid (7758-98-7)	yes	C1	25.000%										1				C1
tributylamine (102-82-9)	no		1.000%	no	yes	yes	H411						1		3.38		B2

GAM classification: **B4**

The GAM classification of the mixture is: **B4**

result based on calculation rules for mixtures:

classification	result calculation rule		criteria	
Z1	0.000%	≥	0.10%	
Z2	0.000%	≥	0.10%	
A1	0.000%	≥	25.00%	
A2	0.000%	≥	25.00%	
A3	0.000%	≥	25.00%	
A4	0.000%	≥	25.00%	
B4	7.000%	≥	1.00%	<<==
C1	75.000%	=	100%	
B1	0.000%	≥	25.00%	
B2	1.000%	≥	25.00%	
B3	10.000%	≥	25.00%	
B5	0.000%	≥	1.00%	
C2	0.000%	=	100%	

degradable part of the mixture	1.20%
non degradable part:	98.80%

based on criteria classification in B4 of B5 in an option; based on degradability the total mixture is classified in: B4

LEGENDA:

- cells (to be filled) needed for GAM classification
- (filled-in) cells
- cells (te be filled) NOT needed for GAM category but desired for the environmental profile of the substance

The following overview presents the results of the calculation rules and testing against the criteria for GAM classification of the mixture:

Legend:
- (red) Most stringent and determining classification for mixture
- (pink) Result calculation rule meets criteria for classification

component	compo-sition	Classi-fication of individual compounds	M-factor
bis[bis[(2-hydroxyethyl)ammonium]sulphate	7.00%	B4	1
phosphoric acid (7664-38-2)	50.00%	C1	1
sulphuric acid (7758-98-7)	25.00%	C1	1
tributylamine (102-82-9)	1.00%	B2	1

sumconcen-tration per GAM-class (%)	Classi-fication	Calculation rules	Result
0.000%	<= Z1 =>	$\Sigma\ Mi*C_{Z1,i}$ (%)	0.00%
0.000%	<= Z2 =>	$\Sigma\ Mi*C_{Z2,i}$ (%)	0.000%
0.000%	<= A1 =>	$\Sigma\ Mi*C_{A1,i}$ (%)	0.00%
0.000%	<= A2 =>	$10*\Sigma Mi*C_{A1,i} + \Sigma C_{A2,i}$ (%)	0.00%
0.000%	<= A3 =>	$100*\Sigma Mi*C_{A1,i} + 10*\Sigma C_{A2,i} + \Sigma C_{A3,i}$ (%)	0.00%
0.000%	<= A4 =>	$100*\Sigma Mi*C_{A1,i} + 10*\Sigma C_{A2,i} + \Sigma C_{A3,i} + \Sigma C_{A4,i}$ (%)	0.00%
7.000%	<= B4 =>	$\Sigma C_{B4,i}$ (%)	7.00%
75.000%	<= C1 =>	$\Sigma C_{1,i}$ (%)	75.00%
0.000%	<= B1 =>	$\Sigma\ Mi*CB_{1,i}$ (%)	0.00%
1.000%	<= B2 =>	$10*\Sigma Mi*CB_{1,i} + \Sigma CB_{2,i}$ (%)	1.00%
0.000%	<= B3 =>	$100*\Sigma Mi*CB_{1,i} + 10*\Sigma CB_{2,i} + \Sigma CB_{3,i}$ (%)	10.00%
0.000%	<= B5 =>	$\Sigma C_{B5,i}$ (%)	0.00%
0.000%	<= C2 =>	$\Sigma C_{2,i}$ (%)	0.00%

Classi-fication
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V

GAM CLASSIFICATION OF MIXTURE

CRITERIA	Cat 1			Cat 2	Cat 3	Cat 4	other cat		Cat 1	Cat 2	Cat 3	other cat	
	Z1	Z2	A1	A2	A3	A4	B4	C1	B1	B2	B3	B5	C2
<= Z1 =>	≥ 0.1%						< 0.1%					< 0.1%	
<= Z2 =>		≥ 0.1%					< 0.1%					< 0.1%	
<= A1 =>			≥ 25%	2.5% ≤ Cx < 25%	0.25% ≤ Cx < 2.5%		< 0.25%						
<= A2 =>				≥ 25%	2.5% ≤ Cx < 25%		< 2.5%						
<= A3 =>					≥ 25%		< 25%						
<= A4 =>						≥ 25%	< 25%						
<= B4 =>							≥ 1%						
<= C1 =>								100%					
<= B1 =>									≥ 25%	2.5% ≤ Cx ≤ 25%	0.25% ≤ Cx ≤ 2.5%	< 0.25%	
<= B2 =>										≥ 25%	2.5% ≤ Cx ≤ 25%	< 2.5%	
<= B3 =>											≥ 25%	< 25%	
<= B5 =>												≥ 1%	
<= C2 =>													100%

6.5 Calculation rules for category 4 and other substances in GAM

The criteria for classification in category 4 and other substances and the related GAM classification of each substance are presented in Table 10.

Table 10 Criteria for classification into category 4 and category Other.***

CLP toxicity category	**Chronic:** **Readily biodegradable**	**Chronic:** **Not readily biodegradable**	**Acute:**	**aquatic hazard**
Category 4		NOEC cannot be determined 2) and solubility < 1 mg/l and log Kow > 4	LC50 cannot be determined 2) and solubility < 1 mg/l and log Kow > 4 1	Low hazard to aquatic organisms may result in harmful effects in the aquatic environment in the long term. (GAM classification: A4)
Other	NOEC > 10 [mg/l] or cannot be determined and log Kow ≤ 4	NOEC > 10 [mg/l] or cannot be determined and log Kow ≤ 4, or solubility < 1 mg/l	LC50 > 100 [mg/l] or cannot be determined and log Kow ≤ 4, or solubility < mg/l 1)	Low hazard to aquatic organisms (GAM classification: B4 * and C1 ** (NRB) and B5* and C2 ** (RB)

1) CLP has no category 4 based on acute toxicity. In order to make a classification in the absence of chronic data, these criteria have nonetheless been included in the GAM.
* not naturally occurring in water
** naturally occurring in water
*** Annex I CLP Table 4.1.0
NRB = Not Readily Biodegradable
RB = Readily Biodegradable

If a mixture cannot be classified based on calculation rules I to III from Table 6, this results in a classification into category 4 or the category Other.

Examples[47]

Elaboration of example

A mixture contains 3 components X (A2; content 2%), Y (A3; content 3%) and Z (A4; content 2%).

Calculation rule II gives the following for classification in category 3:

$M*100*C_{1(A1;B1)} + 10*C_{2(A2;B2)} + C_{3(A3;B3)} >= 25\%$. This results in:

100*0 + 10*2% + 3% >= 25% ==> 23% < 25% ==> classification does NOT meet category 3 criteria, so this mixture must be classified in category 4 or category Other.

Then it must be tested whether the criteria for category 4 are met.

CLP calculation rule IV for category 4 states:

cat-1(A1) + cat-2 (A2)+ cat-3 (A3) + cat-4 (A4) ≥ 25% [48]

Example Cat-4

The mixture contains 3 components P (A2; content 2%), Q (A3; content 3%) and R (A4; content 2%).

Using CLP calculation rule IV, this yields:

$C_{1(A1)} + C_{2(A2)} + C_{3(A3)} + C_{4(A4)} >= 25\%$. This results in:

0 + 2% + 3% >= 25% ==> 5% < 25% ==> classification does NOT meet category 4 criteria.

The calculation rule does not yield the expected result; the criteria for category 3 are not met and because an A4 component is present, you would expect a higher score than based on calculation rule III. But calculation rule IV shows differently. The result is lower than the score for category 3.

[47] Application of the substance information from REACH and CLP also uses information supplied by companies. By ticking the disclaimer on the CLP and ECHA sites, the user (licensor or other company) confirms they are aware of this.
[48] This calculation rule concerns substances whose toxicity cannot be determined and for which a subsequent check on bioaccumulative potential is required. This only applies to A substances. B substances meet the criterion log Kow ≤ 4.

For mixtures that do NOT meet the classification criteria for category 3, calculation rule IV often yields an outcome < 25%, even if A4 components are present. This precludes classification into category 4. This once again underlines the need to draft a revised calculation rule.

This results in the following calculation rule for classification into category 4:

M*100* C(A1) + 10*C(A2) + C(A3) + CA4 >= 25%. **(V)**[49]

The difference between the result of calculation rule III and calculation rule V for classification into category 4 (GAM classification A4) is, therefore, based solely on the concentration of substances classified as A4. In the presence of an A4 component, the result is always higher than based on calculation rule III.

Elaboration of example

A mixture contains 3 components D (A2; content 2%), E (A3; content 3%) and F (A4; content 2%).

Calculation rule III gives the following for classification in category 4:
$M*100*C_{1(A1)} + 10*C_{2(A2)} + C_{3(A3)} + C_{4(A4)} >= 25\%$. This results in:
100*0 + 10*2% + 3% + 2% >= 25% ==> 25% ==> classification meets category A4 criteria.

If the A4 concentration in the example is lower or non-existent, application of calculation rule V automatically yields a classification into the category Other. This concerns GAM classes (B4; B5) or (C1; C2). These categories do not distinguish between toxicity but between biodegradability ((C1; B4 = not readily biodegradable)(B5 and C2 = readily biodegradable)). In all cases, the lower limit for declaration on the MSDS is 1%, and for classification C8 and C13, the mixture as a whole must entirely (=100%) occur naturally in surface water.

Example

A mixture contains the following substances:

Substance X	(1%; classification A1);
Substance Y	(4%; classification A3: 4%)
Substance Z	(10%; classification A4: 10%)
Substance U	(25%; classification B4)
Substance V	(60%; classification C1).

Based on the calculation rules given above, this yields:

Classification A1: 1% < 25% ==> does NOT meet the criteria for classification A1;
Classification A2: 1*10*1% + 0% = 10% < 25% does NOT meet the criteria for classification A2;
Classification A3: $100*M*1\% + 10*C_{A2} + C_{A3} = 100*1*1 + 10*0 + 4\% = 104\%$ ==> meets the criteria for classification A3;
Classification A4: $100*1*C_{A1}+ 10*C_{A2} + C_{A3} + C_{A4}= 100*1*1\% +10*0 + 4\% + 10\% = 114\% > 25\%$ ==> meets the criteria for classification A4;
Classification B4: $C_{B4} = 25\% > 1\%$ ==> meets the criteria for classification B4
Classification C1: $C_{C1} = 60\% < 100\%$ ==> does NOT meet the criteria for classification C1.

The most stringent classification determines the classification of the mixture, which means that the mixture is to be classified as A3. Despite the high levels of U and V (together representing 85% of the mixture), these substances are not decisive in the classification of the mixture.

[49] Alternatively, including a factor of 10 for the weighting factors for toxicity could be opted for, but that would automatically mean that the entire mixture (even if no A4 substance were present) would be assessed as A4. This is in contrast to the need to differentiate between category 4 and the category Other.