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Aquatic Risks of Plant Protection Products: A Comparison of Different Hazard Assessment Strategies for Surface Waters in Switzerland

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Summary

Background In Switzerland the assessment of surface water quality with respect to contaminations by plant protection products (PPP) is based on the Swiss water protection law (Schweizer Bundesgesetz vom 24. Januar 1991 über den Schutz der Gewässer, Gewässerschutzgesetz, GSchG, SR 814.20), as well as on the Swiss water protection ordinance (Gewässerschutzverordnung vom 28. Oktober 1998, GSchV, SR 814.201). According to GSchV a general quality criterion of 0.1 µg/l exists for single organic pesticides (plant protection products and biocidal products) in Swiss running waters. Other values remain subject to reserve on the basis of individual substance assessments in the context of the authorisation procedure. In the European Union, the protection of water bodies is regulated under the Water Framework Directive (2000/60/EC, WFD). In addition, the aquatic risk of PPP is already being assessed during the PPP authorisation procedure under the ordinance on the placing of plant protection products on the Swiss market (Verordnung vom 18. Mai 2005 über das Inverkehrbringen von Pflanzenschutzmitteln, Pflanzenschutzmittelverordnung, PSMV, SR 916.161) and in the EU under the Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market.

Aims and Approaches The goal of this project was to propose an appropriate method for the derivation of Environmental Quality Standards (EQS) for active substances (AS) from PPP in Swiss surface waters, consistent with the aims of the Swiss legislation on water protection (GSchG and GSchV). For this purpose the approaches currently applied in the EU were (i) identified by query and review, (ii) reviewed with regard to their underlying protection goals and methods and (iii) applied in case studies to six AS currently used in PPPs in Switzerland: the herbicides Diuron, Mecoprop and Terbuthylazine, the fungicide Carbendazim and the insecticides Diazinon and Imidacloprid. The resulting EQS values were compared with EQS values derived for the same AS by other authorities as well as with the regulatory acceptable concentrations (RACs) that can be calculated from the PPP authorisation documents.

Results The review demonstrated that minor differences exist between the ecotoxicological protection goals underlying the three guidance documents currently used for deriving EQS under the Water Framework Directive (WFD), the draft Technical Guidance Document for EQS (TGD for EQS), its predecessor („Lepper method“) and the Dutch guidance document for the implementation of the WFD, and those described in the Swiss water protection law (GSchG) and in the Swiss Water Protection Ordinance (GSchV). With some additional provisions concerning the data selection however, the approaches of the WFD are compatible with the GSchG, therefore the selection of relevant toxicity data should be guided not only by their relevance under the WFD but also by the protection goals from the GSchG and the GSchV.

A review of the methods showed that the three approaches are very similar. The few minor distinctions, led to small differences regarding the EQS values derived in the case studies for the selected AS. However, EQS values never differed by more than a factor of 3, if the use of different data sets and/or different “expert judgement“ in the evaluation of data could be ruled out. The influence of this - so called - “expert judgement” on resulting EQS values was

significant, mostly due to differences in weighting the available data and/or the selection of the assessment factor (AF). Differences in “expert judgement” resulted in EQS values that differed by a factor up to 20. The largest difference was found between the EQS derived according to the WFD and RACs calculated from the PPP authorisation documents. RACs were always higher than the EQS, by up to a factor of 230. The key cause seems to be the consideration of recovery during PPP authorisation, which is neither compatible with the protection goals of the GSchG and the GSchV nor with the WFD.

Conclusions and recommendations The EQS derived for the selected AS ranged between 0.01 µg/l and 1000 µg/l. Clearly, EQS are significantly higher than the general value of 0.1 µg/l for some AS, while being significantly lower for other AS. Consequently, effect based EQS for PPP are needed for a comprehensive ecotoxicological water quality assessment in Switzerland. For EQS derivation PPP authorisation data are highly relevant and should be included in the data set where appropriate. The hazard assessment procedures of the PSMV, however, have not shown to be compatible with the GSchG. It is recommended that EQS should be derived according to the TGD for EQS, but the protection goals underlying the GSchG and the GSchV should be used as additional guidance during the selection of relevant data. It is further recommended that the Klimisch scoring system for the assessment of data reliability should be revised or amended, since it does not seem to ensure consistent validation between different hazard assessors. In addition, the importance of implementing mixture toxicity approaches into regulatory frameworks has been recognised internationally. Hence, it should be evaluated in the future, how this can be done with respect to EQS. Finally, a scheme for EQS derivation for AS from PPP has been proposed, that is specifically designed to balance the influence of “expert judgement“.

Zusammenfassung

Hintergrund Die Beurteilung der Wasserqualität von Oberflächengewässern in Bezug auf Pflanzenschutzmittel basiert in der Schweiz auf dem Schweizer Bundesgesetz vom 24. Januar 1991 über den Schutz der Gewässer (Gewässerschutzgesetz, GSchG, SR 814.20) und auf der Gewässerschutzverordnung vom 28. Oktober 1998 (GSchV, SR 814.201). In Schweizer Fliessgewässern gilt gemäss GSchV für organische Pestizide (Biozidprodukte und Pflanzenschutzmittel) eine Anforderung an die Wasserqualität von 0.1 µg/L je Einzelstoff. Vorbehalten bleiben andere Werte aufgrund von Einzelstoffbeurteilungen im Rahmen des Zulassungsverfahrens. In der Europäischen Union wird der Schutz der Gewässer durch die Wasserrahmenrichtlinie (2000/60/EC, WRRL) geregelt. Wichtig in diesem Zusammenhang ist aber auch, dass für Pflanzenschutzmittel (PSM) bereits eine Risikobewertung im Rahmen der Pflanzenschutzmittelzulassung erfolgt: in der Schweiz gemäss der Schweizerischen Verordnung vom 18. Mai 2005 über das Inverkehrbringen von Pflanzenschutzmitteln (Pflanzenschutzmittelverordnung, PSMV, SR 916.161) und in der EU unter der Richtlinie des Rates vom 15. Juli 1991 über das Inverkehrbringen von Pflanzenschutzmitteln (91/414/EWG).

Ziele und Methoden Das Projekt zielt darauf ab, eine Methode für die Ableitung von Umweltqualitätsnormen (UQN) für Wirkstoffe (WS) in PSM in Schweizer Oberflächengewässern vorzuschlagen, welche den Zielen der Schweizer Gewässerschutzgesetzgebung entspricht. Dafür wurden die derzeit angewandten Ansätze (i) zunächst mittels einer Umfrage identifiziert und (ii) eine Bestandsaufnahme ihrer Schutzziele und Methoden gemacht, um sie schliesslich (iii) in Fallstudien auf die folgenden sechs WS anzuwenden, welche zur Zeit in PSM in der Schweiz angewendet werden: die Herbizide Diuron, Mecoprop und Terbuthylazin, das Fungizid Carbendazim, sowie die Insektizide Diazinon und Imidacloprid. Die resultierenden UQN wurden anschliessend sowohl mit UQN verglichen, die von anderen Behörden abgeleitet wurden, als auch mit den regulatorisch akzeptablen Werten (RACs), die aus den Zulassungsdossiers der PSM-Zulassung in der Schweiz abgeleitet werden können.

Ergebnisse Die Bestandsaufnahme der derzeitig unter der WRRL angewandten Ansätze hat gezeigt, dass sich die ökotoxikologischen Schutzziele der drei technischen Vorschriften zur Ableitung von UQN unter der WRRL nur in einigen Punkten von den Schutzzielen des GSchG und der GSchV unterscheiden. Die UQN Ansätze der WRRL sind mit dem GSchG vereinbar, wenn die Auswahl der nach WRRL relevanten Toxizitätsstudien auf der Grundlage der Schutzziele aus GSchG und GSchV ergänzt wird.

Die drei in den Fallstudien untersuchten Ansätze waren der Entwurf der technischen Vorschrift für UQN gemäss WRRL (“TGD for EQS”), deren Vorgängerdokument („Lepper Methode“) sowie die niederländische technische Vorschrift zur Umsetzung der WRRL. Eine vergleichende Bestandsaufnahme hat gezeigt, dass die Methoden der drei Ansätze sehr ähnlich sind. Es konnten zwar kleinere methodische Unterschiede festgestellt werden, die zu geringen Variationen bei den UQN führten, die UQN haben sich aber in keinem Fall um mehr als einen Faktor 3 voneinander unterschieden, wenn Unterschiede im Datensatz und durch die „Expertenentscheidung“ von unterschiedlichen Gefahrenbewertern ausgeschlossen werden kann. Grössere Unterschiede bei den UQN wurden durch den

Einfluss der sogenannten “Expertenentscheidung” beobachtet. Durch eine andere Gewichtung der Daten oder die Wahl eines anderen Sicherheitsfaktors konnten die UQN um bis zu einem Faktor von 20 variieren.

Die grössten Unterschiede wurden jedoch zwischen den UQN und den RACs beobachtet. Die RACs waren immer höher als die UQN, in einem Fall sogar um einen Faktor von 230. Eine Schlüsselrolle scheint zu spielen, dass im Rahmen der PSM-Zulassung die Erholung von Populationen berücksichtigt wird, was hingegen weder mit den Schutzzielen der GSchV noch mit der WRRL vereinbar ist.

Schlussfolgerungen und Empfehlungen Die für die ausgewählten WS abgeleiteten UQN variierten im Bereich zwischen 0.01 µg/l und 1000 µg/l. Offensichtlich sind die UQN für einige Wirkstoffe signifikant höher und für andere signifikant tiefer als der generelle Wert von 0.1 µg/l. Diese Erkenntnis bestätigt, dass für eine umfassende ökotoxikologische Bewertung der Gewässerqualität effektbasierte UQN benötigt werden. Für die Ableitung von UQN für PSM haben die Daten aus der Pflanzenschutzmittelzulassung eine hohe Relevanz und sie sollten daher berücksichtigt werden. Die Methoden zur Gefährdungsbeurteilung gemäss PSMV haben sich jedoch als nicht kompatibel mit dem GSchG erwiesen. Es wird daher empfohlen, die UQN nach dem TGD for EQS abzuleiten. Dabei sollen jedoch die im GSchG und in der GSchV genannten Schutzziele zur Auswahl der relevanten Daten herangezogen werden. Es wird weiterhin empfohlen, die Klimisch Kriterien zur Beurteilung der Datenqualität zu überarbeiten oder zu ergänzen, da es sich gezeigt hat, dass sie keine konsistente Validierung gewährleisten können. Aktuelle internationale Entwicklungen deuten darauf hin, dass die Berücksichtigung von Gemischtoxizität auch im regulatorischen Kontext wichtig ist. Daher wird empfohlen, zu überprüfen, wie Gemischtoxizität in Bezug auf UQN zukünftig berücksichtigt werden kann. Schliesslich wird ein Schema zur Herleitung von UQN für WS aus PSM vorgeschlagen, dass den Einfluss von „Expertenentscheidungen“ auf UQN ausgleichen helfen soll.

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Abbreviations

AA-EQS	Annual Average Environmental Quality Standard (long-term EQS)
AF	Assessment Factor
AS	Active Substance in a PPP
AQK	Acute Quality Criterion (proposed by Chèvre and co-workers in 2006; the commonly used expression for MAC-EQS in Switzerland)
BP	Biocidal Products
CQK	Chronic Quality Criterion (proposed by Chèvre and co-workers in 2006; the commonly used expression for AA-EQS in Switzerland)
DAR	Draft Assessment Report
EAC	Ecologically Acceptable Concentration
EFSA	European Food Safety Authority
ERLs	Environmental Risk Limits (in the Netherlands)
EU_RAR	EU Risk Assessment Report
EQS	Environmental Quality Standard (official English expression in the EU; identical with →UQN)
FOAG	Swiss Federal Office for Agriculture
FOEN	Swiss Federal Office for the Environment
GSchG	Swiss water protection law (Gewässerschutzgesetz)
GSchV	Swiss Water Protection Ordinance (Gewässerschutzverordnung)
ICPR	International Commission for the Protection of the Rhine
LOEC	Lowest Observed Effect Concentration: the lowest tested concentration at which the observed effect is significantly different to the controls
MAC-EQS	Maximum Acceptable Concentration (short-term EQS)
MATC	Maximum Allowable Toxicant Concentration: the geometric mean of NOEC and LOEC
NOEAEC	No Observed Ecological Adverse Effect Concentration
NOEC	No Observed Effect Concentration: The highest tested concentration for which the observed effect is not significantly different to the controls
OZ	Swiss Centre for Applied Ecotoxicology (Ökotoxzentrum)
PBT	Persistent, Bioaccumulative and Toxic Substances
PEC	Predicted Environmental Concentration

PNEC	Predicted No Effect Concentration
PPP	Plant Protection Product (formulations consisting of the AS and other substances e.g. safeners, synergists, co-formulants and additional actives)
PSMV	Swiss Ordinance for Plant Protection Products
RAC	Regulatory Acceptable Concentration
REACH	Registration Evaluation and Authorisation of Chemicals (Regulation (EC) No 1907/2006)
RIVM	National Institute for Public Health and the Environment of the Netherlands
RMS	Rapporteur Member State
SSD	Species Sensitivity Distribution
TER	Toxicity/Exposure Ratio
TGD for EQS	Technical Guidance Document for Environmental Quality Standards
TGD on RA	Technical Guidance Document on Risk Assessment
TWA	Time Weighted Average Concentration
UP	Uniform Principles of Directive 91/414/EEC
UQN	Umweltqualitätsnorm (official German expression in the EU; identical with →EQS)
vPvB	very Persistent and very Bioaccumulative Substances
WFD	Water Framework Directive (2000/60/EC)
WRRL	Wasserrahmenrichtlinie (official German expression in the EU for the WFD)
WQK	“Wasser Qualitätsziel”: Water Quality Criterion (proposed by Chèvre and co-workers in 2006; the commonly used expression for EQS in Switzerland)

Terminology[1]

Adverse effect	Change in the morphology, physiology, growth, development, reproduction, or life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences.
Assessment	Evaluation or appraisal of an analysis of facts and the inference of possible consequences concerning a particular object or process.
Assessment end-point	Quantitative/qualitative expression of a specific factor with which a risk may be associated as determined through an appropriate risk assessment.
Assessment factor	Numerical adjustment used to extrapolate from experimentally determined (dose-response) relationships to estimate the agent exposure below which an adverse effect is not likely to occur.
Dose–response assessment	Analysis of the relationship between the total amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population and the changes developed in that organism, system, or (sub)population in reaction to that agent, and inferences derived from such an analysis with respect to the entire population.
Effect	Change in the state or dynamics of an organism, system, or (sub)population caused by the exposure to an agent.
Effect assessment	Combination of analysis and inference of possible consequences of the exposure to a particular agent based on knowledge of the dose-effect relationship associated with that agent in a specific target organism, system, or (sub)population.
Expert judgement	Opinion of an authoritative person on a particular subject.
Exposure	Concentration or amount of a particular agent that reaches a target organism, system, or (sub)population in a specific frequency for a defined duration.

[1] This terminology is taken from the IPCS Risk Assessment Terminology by the International Program on Chemical Safety (ICPS) developed in the ICPS Harmonisation Project, published by the WHO in 2004 (http://www.who.int/ipcs/methods/harmonization/areas/ipcsterminologyparts1and2.pdf)

Exposure assessment	Evaluation of the exposure of an organism, system, or (sub)population to an agent (and its derivatives). Exposure assessment is the third step in the process of risk assessment.
Hazard	Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system, or (sub)population is exposed to that agent.
Hazard assessment	A process designed to determine the possible adverse effects of an agent or situation to which an organism, system, or (sub)population could be exposed. The process includes hazard identification and hazard characterization. The process focuses on the hazard, in contrast to risk assessment, where exposure assessment is a distinct additional step.
Hazard characterization	The qualitative and, wherever possible, quantitative description of the inherent property of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose-response assessment and its attendant uncertainties. Hazard characterization is the second stage in the process of hazard assessment and the second of four steps in risk assessment.
Hazard identification	The identification of the type and nature of adverse effects that an agent has an inherent capacity to cause in an organism, system, or (sub)population. Hazard identification is the first stage in hazard assessment and the first of four steps in risk assessment.
Measurement end-point	Measurable (ecological) characteristic that is related to the valued characteristic chosen as an assessment point.
Risk	The probability of an adverse effect in an organism, system, or (sub)population caused under specified circumstances by exposure to an agent.
Risk assessment	A process intended to calculate or estimate the risk to a given target organism, system, or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system. The risk assessment process includes four steps: hazard identification, hazard characterization (related term: Dose–response assessment), exposure assessment, and risk characterization. It is the first component in a risk analysis process.

Risk characterization	The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system, or (sub)population, under defined exposure conditions. Risk characterization is the fourth step in the risk assessment process.
Toxicity	Inherent property of an agent to cause an adverse biological effect.
Uncertainty	Imperfect knowledge concerning the present or future state of an organism, system, or (sub)population under consideration.
Validation	Process by which the reliability and relevance of a particular approach, method, process or assessment is established for a defined purpose. Different parties define “Reliability” as establishing the reproducibility of the outcome of the approach, method, process, or assessment over time. “Relevance” is defined as establishing the meaningfulness and usefulness of the approach, method, process, or assessment for the defined purpose.

1. Background and objectives

In Switzerland the assessment of the surface water quality with respect to contaminations with plant protection products (PPP) is based on the Swiss water protection law (Schweizer Bundesgesetz vom 24. Januar 1991 über den Schutz der Gewässer, Gewässerschutzgesetz, GSchG, SR 814.20 [1]) as well as on the Swiss water protection ordinance (Gewässerschutzverordnung vom 28. Oktober 1998, GSchV, SR 814.201 [2]). According to GSchV for Swiss running waters a general quality criterion of 0.1 µg/l exists for single organic pesticides (plant protection products and biocidal products). However, it is also stated that other values remain subject to reserve on the basis of individual substance assessments in the context of the admission procedure [2]. In the European Union the protection of water bodies is regulated under the Water Framework Directive (2000/60/EC, WFD [3]). However, it is also important to note, that the aquatic risk of PPP is already being assessed during the PPP authorisation procedure under the ordinance on the placing of plant protection products on the market in Switzerland (Verordnung vom 18. Mai 2005 über das Inverkehrbringen von Pflanzenschutzmitteln, Pflanzenschutzmittelverordnung, PSMV, SR 916.161 [4]) and in the EU under Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [5].

To date no legally binding effect based values exist for AS of PPP in Swiss surface waters in the context of the Swiss water protection law. Nonetheless, in scientific literature some values have been published: In a previous project by Chèvre and co-workers acute and chronic water quality criteria (AQK and CQK) for PPP in Swiss surface waters [6, 7] have been derived by an approach that was partly based on the EU Technical Guidance Document on Risk Assessment (TGD on RA) [8]. The derived values have not been implemented into Swiss regulations but are nevertheless used for risk assessments for surface waters by some cantons [9, 10]. Additionally, in a very recent publication by Knauer and FOAG co-workers [11] „ecotoxicological characteristics (PNECs)“ were proposed for some pesticides which were stated to be based on the provisions of the PSMV.

A method to derive effect based environmental quality standards (EQS) which is in accordance with the Swiss water protection legislation (GSchG and GSchV) might be needed in the future, as there is a broad interest to assess monitoring data against the ecotoxicological protection goals of the Swiss Water protection legislation. Therefore, FOEN initiated this situation analysis on EQS setting in neighbouring countries and the compatibility of existing approaches with the Swiss water protection legislation.

1.1. Existing guidance documents for the derivation of EQS for active substances in PPP

In the EU the derivation of EQS is driven by the WFD [3]. Article 16 of the WFD lays down the community strategy for the establishment of harmonised quality standards and emission controls for the priority substances posing a significant risk to, or via, the aquatic environment. The setting of quality standards applicable to the concentrations of the priority substances in surface water is one important element of the strategy to achieve the protection objectives of the WFD [3].

Since 2003 several guidance documents on risk assessment have been developed in the EU in which the derivation of numerical values for quality standards for substances is described. The connection between these guidance documents is illustrated in Figure 1.1.

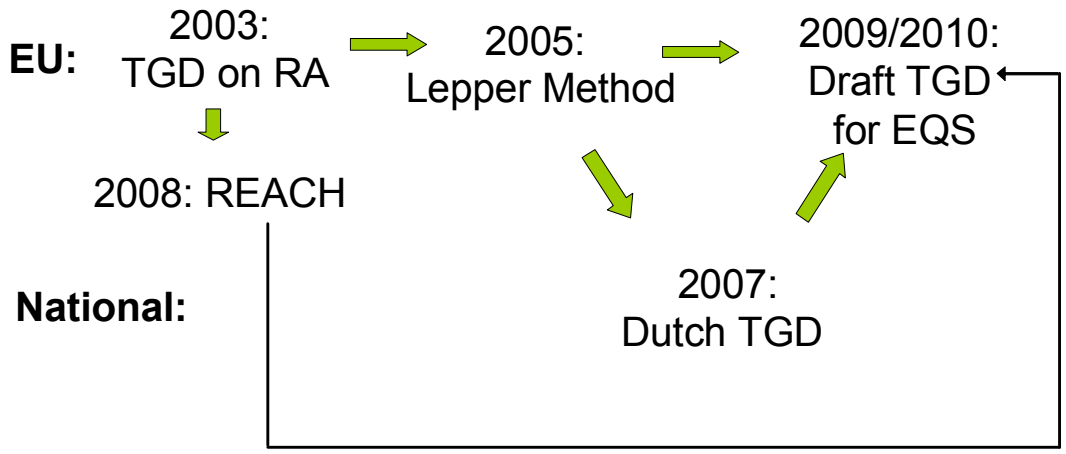

Figure 1.1: Development of Technical Guidance Documents for hazard assessment in the European Union.

In this figure only the relevant national guidance documents were included, which were identified by the query (chapter 3.1). Since the query was restricted to the neighbouring countries of Switzerland and the Netherlands, other national guidance documents which also influenced the Draft TGD for EQS, such as the guidance document by the UK, were not considered. This omission should not indicate that these guidance documents were less important for the development of the TGD for EQS than the Dutch TGD.

The first guidance document, on which all following guidance documents were based, was the TGD on RA [8]. In this guidance document, methods to derive Predicted No Effect Concentrations (PNECs) are described. The derived PNECs were intended to be used in prospective as well as in retrospective risk assessments.

In the process of the replacement of the former regulations for new (Directive 93/67/EEC) and existing substances (Commission Regulation (EC) No 1488/94) by the REACH (Regulation (EC) No 1907/2006) [12], a new guidance document for the prospective risk assessment of industrial chemicals was developed [13].

In the context of the WFD a project was performed by P. Lepper of the Fraunhofer-Institute for Molecular Biology and Applied Ecology to develop a concept for the derivation of environmental quality standards (EQS) [14]. This concept was subsequently updated by Lepper in 2005 [15]. In the EU, guidance documents for the derivation of EQS under the WFD were developed also on the national level. In the Netherlands a guidance document [16] was prepared in 2007 to incorporate the guidance of Lepper [15] into the national framework for the derivation of environmental quality standards, which was officially based on the TDG on RA [8] until then. Currently a draft version for a Technical Guidance Document for Deriving Environmental Quality Standards (TGD for EQS) [17] is in the commenting phase. The TGD for EQS is intended to be consistent as far as possible with the guidance documents developed for the ecotoxicological hazard assessment under REACH [13].

In the context of deriving EQS for AS from PPP also the Swiss ordinance for placing plant protection products on the market (PSMV [4]) is of interest, since under this ordinance the hazard of these AS for the aquatic environment is already being assessed. The PSMV is to a large

extent in accordance with the Council Directive 91/414/EEC [5] which regulates the placing of plant protection products on the market in the EU. The Council Directive 91/414/EEC as well as the PSMV will be replaced in June 2011 [18]. However, the parts in which the hazard assessment for the aquatic environment is regulated remained generally unchanged. Hence, in this report the current legislation was reviewed.

1.2. Project aims

The project is intended to give a situation analysis on the derivation of EQS for PPP. The aims of the project were to:

- compare the protection goals and risk assessment methods used to derive the numerical values for PPP or their AS under the different legislations at the EU and the national level
- check the compatibility of different EQS derivation methods with the purpose of the Swiss water protection law (GSchG)
- identify methods which are based on the same protection goals as the goals given in the Swiss water protection law (GSchG)
- illustrate and interpret the numerical consequences of the selected approaches
- determine the factors with the highest impact on the resulting numerical value within the approaches
- propose a method for the derivation of environmental quality standards (EQS) for Swiss surface waters.

This report is intended to be a background document for Swiss decision makers. **It has to be kept in mind that the EQS derived in the case studies of this report need further quality assessment before use (c.f. chapter 6).**

1.3. General approach

After a review of the current surface water protection in Switzerland, the currently applied guidelines for EQS derivation of PPP were identified. For this purpose a query was performed in the neighbouring countries of Switzerland as well as in the Netherlands. The Netherlands were included in the query because Switzerland and the Netherlands are both members of the International Commission for the Protection of the Rhine (ICPR). In a second step the identified methodologies were reviewed and compared. Finally, the most important of the identified methodologies were applied in case studies to six selected AS used in PPP. For each case study, the EQS derived according to the different guidelines were compared with each other, with EQS derived by other authorities, as well as with the regulatory acceptable concentrations (RACs) that can be calculated from the PPP authorisation documents.

2. Surface water protection in Switzerland

2.1. Protection goals

The purpose of the Swiss water protection law of 1991 (GSchG [1]) is to protect waters against harmful effects (Art. 1). In the context of establishing environmental quality standards (EQS), it aims in particular to maintain:

- the health of humans, animals and plants
- the natural biotopes of indigenous fauna and flora
- waters suitable to sustain natural fish populations.

An additional important purpose is to guarantee the supply and economic use of drinking water (Art. 1 character b). Although this has to be considered when quality standards for surface waters will be set, this protection goal will not be discussed any further in this document that focuses on ecological objectives.

Art. 6 GSchG states that it is prohibited to introduce or infiltrate into a water body any substances which may pollute such waters, either directly or indirectly.

The water protection law thus provides for comprehensive protection:

Water bodies are to be safeguarded against adverse impacts of all kinds so as to ensure that they can serve a wide variety of functions. The GSchG applies to all surface and subterranean waters (Art. 2 GSchG). According to the message of the federal council (dated 29 April 1987, BBl 1987 II 1104) concerning this subject, the protection has to cover all natural and artificial public and private waters including their sources.

Ecological goals for surface waters, and the associated water quality requirements, are specified in the Swiss Water Protection Ordinance (GSchV [2]):

Annex 1 GSchV defines ecological objectives for water bodies. These objectives have to be taken into account for all measures taken under this Ordinance (Art 1 GSchV). For surface waters it is required that pollutants which could enter the water as a result of human activities do not:

- accumulate in plants, animals, micro-organisms, suspended matter or sediments
- have any harmful effects on the biocoenoses of plants, animals and micro-organisms and on the utilisation of the water
- interfere with the biological processes making possible the fulfilment of the basic physiological needs of plant and animal life, such as the metabolic processes, the reproductive processes and the olfactory orientation of animals.

Additionally, the GSchV also requires that pollutants which might enter the water as a result of human activities should occur in the water body [2]:

- in concentrations that are within the range of natural concentrations where they are already present naturally
- only in near-zero concentrations where they are not naturally present.

The latter two requirements are based on relevant international agreements (such as the Convention for the Protection of the Marine Environment of the North-East Atlantic, OSPAR Convention), including those which aim to prevent and eliminate pollution of the marine environment by ceasing or phasing out discharges, emissions and losses of priority hazardous substances, with the ultimate aim of achieving concentrations in the marine environment near background values for naturally occurring substances and close to zero for man-made synthetic substances.

2.2. How can the protection goals be implemented?

General requirements for the surface water quality are defined in Annex 2 GSchV [2].

If the authorities establish that a water body does not fulfil the requirements on water quality according to Annex 2 GSchV or that the specific use of the water body cannot be guaranteed, they shall:

- determine and assess the type and extent of the pollution
- determine the causes of the pollution
- assess the effectiveness of possible measures
- ensure that the necessary measures are undertaken based on the relevant provisions (Art. 47 GSchV).

The numerical requirements specified in Annex 2 apply to every type of water body after thorough mixing of the wastewater discharged in the water body. Particular natural conditions such as water discharge from marshy areas, rare high-water peaks or rare low-water events remain subject to reserve.

However, as mentioned before, numerical values for organic micropollutants are generally missing, with the exception of organic pesticides (biocidal products, BP, and plant protection products, PPP). For organic pesticides a general value of 0.1 µg/l per individual substance is defined; with the possibility that other values remain subject to reserve on the basis of individual substance assessment in the context of the authorisation procedure.

The general value of 0.1 µg/l is not an ecologically based EQS, but was simply derived from the drinking water requirements as defined in the European Union [19] and in Switzerland [20]. For many AS used in PPP this value is below the concentration range at which harmful effects in aquatic organisms might occur. However, for some AS this value will most probably be higher than an ecotoxicity-based EQS in water bodies. Consequently, if the hazard assessment indicates that EQS have to be lower than 0.1 µg/l, this general numerical value is neither totally in line with the purpose of the GSchG [1] with respect to maintain the health of persons, animals and plants, nor with the ecological objectives for water bodies as defined in Annex 1 GSchV [2], i.e. not having any harmful effects on the biocoenoses of plants, animals and micro-organisms.

It has to be pointed out that the definition of ecologically acceptable concentrations, such as EQS values, but also the general value of 0.1 µg/l per individual substance used in PPP, are not in line with the ecological objectives for water bodies as defined in Annex 1 GSchV (i.e. occurring in the water body only in near-zero concentrations where they are not naturally present [2]).

However, this corresponds to the concept behind Annex 1 and Annex 2 GSchV: Annex 1 contains the long-term ecological goals (ultimate aim) comparable with the very good status in the Water Framework Directive (WFD [3]). The requirements in Annex 2 have to be fulfilled and can be interpreted as short- and medium-term objectives on the way to the goals outlined in Annex 1. Thus, the requirements in Annex 2 GSchV are comparable with those that are defining the good ecological status in the WFD, with some small differences, which are discussed in more detail in chapter 3.9.

3. Hazard Assessment under different legislations and underlying protection goals

Plant protection products (PPP) are deliberately released into the environment to control pests that harm agricultural crops. Aquatic ecosystems may be contaminated with PPP as a result of spray-drift, leaching, runoff, and/or accidental spills. Because aquatic ecosystems contain species related to the target organisms of the PPP, there is a potential risk of adverse effects on non-target species when PPP are applied [21]. Therefore, PPP and their AS are subject to risk assessment procedures during the authorisation procedure of the PPP under the Council Directive 91/414/EEC. However, they may also be regulated under other legislations. For example, if an AS is part of a biocidal product, a hazard assessment is also done under the Swiss biocidal products ordinance (Verordnung über das Inverkehrbringen von und den Umgang mit Biozidprodukten, Biozidprodukteverordnung (VBP) vom 18.5.2005) in Switzerland and under the biocide directive (Directive 98/8/EC) [22], in the EU. All the aforementioned hazard assessments are part of prospective risk assessments, but the hazard of PPP and their AS is assessed also in retrospective risk assessments, e.g. for the derivation of EQS under the WFD. One reason for the necessity of a retrospective risk assessment are the multiple sources through which AS used in PPP can enter the water body, either as part of a PPP or a biocidal product.

3.1. Query on the derivation of EQS selection of guidance documents for the methodological review

In order to compare and evaluate the methods used to assess the risk of PPPs or their AS in surface waters a query was performed. The following national authorities were approached (Table 3.1).

The query comprised 13 questions regarding the adopted guidance documents and the applied methods, the data sources, the eligible endpoints, the data validation, the political process to bring EQS into force, the number of previously and currently derived EQS for PPPs, and the derived EQS values for the PPPs that were selected for the case studies. The detailed results of the query can be found in Appendix 2.

Table 3.1: Authorities approached for the query.

Country	Authority
Austria (AT)	BAW - Federal Agency for Water Management, Institute for Water Quality
France (FR)	INERIS - French National Institute for Industrial Environment and Risks, Ecotoxicological Risk Assessment Unit
Germany (DE)	UBA - Federal Environment Agency, Substances Hazardous to Water – Ecotoxicological Laboratory
Italy (IT)	ISS - National Institute of Health, Department Environment and Health
The Netherlands (NL)	RIVM - National Institute for Public Health and the Environment, Expert Centre for Substances

The query revealed that in all participating countries, EQS are already being derived based on a method which was developed explicitly for the implementation of the WFD [3] (see Table 3.2 and chapter 2.1 in Appendix 2). Five out of five countries use at least the method proposed by Lepper [15] in 2005. Moreover, four out of five countries additionally consider the draft TGD for EQS [17], which is based to a large extent on the TGD on RA [8], the Lepper method [15] and the REACH guidance [23]. A number of items from the Dutch guidance [16], which elaborated further on the TGD on RA [8] and Lepper [15], have been taken forward to this draft. This Dutch guidance document is the only noticeable national guidance document for EQS derivation revealed by the query.

Table 3.2: Documents according to which EQS are derived.

Document	Country				
	AT	FR	DE	IT	NL
TGD for EQS [17]	(x) [1]	x	x		x
Lepper 2005 [15]	x	(x) [2]	x	x	x
TGD, 2003 [8]	x	(x) [2]	x	x	x
National internal guidance					x [3]
Other guidance document				(x) [4]	

[1] AT: Only one exercise of EQS derivation has been done; future assessments will consider the new TGD for EQS

[2] FR: Lepper manual and TGD 2003 are not deemed to be used anymore after publication of TGD for EQS

[3] NL: The Dutch guideline 2007 [16], based on the TGD on RA [8], the Lepper Method [15] and existing national guidance

[4] IT: COMMPS report. Study on the prioritisation of substances dangerous to the aquatic environment. EC 1999 (used in IT until 2006 as main document, currently mainly as a data source)

The following legislations including their guidance documents on environmental hazard assessment as well as other hazard assessment approaches shall be compared in the subsequent chapters with respect to the derivation of effect-based environmental concentrations for the aquatic environment in the context of a retrospective risk assessment:

- Directive 2000/60/EC. The Water Framework Directive establishes a legal framework to protect and restore clean water across Europe and to ensure its long-term, sustainable use [3]. The Directive aims to ensure a good ecological and chemical status of surface water bodies across Europe. This goal is implemented by defining permissible concentration limits (i.e. EQS) for specific pollutants of EU relevance (chapter 3.2).
- Guidance document from the Netherlands. Based on the query on the EQS derivation procedure in various European countries the guidance document from the Netherlands [16] was selected for comparison (chapter 3.3).
- International Commission for the Protection of the Rhine (ICPR). For the benefit of the Rhine and of all of its tributaries the members of the ICPR successfully co-operate. Focal points of work are sustainable development of the Rhine, its alluvial areas and the good state of all waters in the watershed. In this context, EQS for Rhine relevant pollutants have been derived [24] (chapter 3.4).
- Chèvre *et al*., 2006. In Switzerland quality criteria for some AS used in PPP derived according to a method by Chèvre and co-workers [6, 7] are used by some cantons for assessing the risk of PPP in surface waters. Hence, the steps proposed by Chèvre and co-workers for deriving quality criteria for PPPs [6, 7] are also shortly described (chapter 3.5).
- Hazard assessment for industrial chemicals and biocides: REACH and biocidal products authorisation. For the sake of completeness, the hazard assessment for industrial chemicals and biocides is shortly described.
- Hazard assessment under the PPP authorisation. The evaluation, marketing and use of pesticides (herbicides, insecticides, fungicides etc.) in plant protection are regulated under the Ordinance on the placing of plant protection products on the market in Switzerland (Verordnung vom 18. Mai 2005 über das Inverkehrbringen von Pflanzenschutzmitteln, Pflanzenschutzmittelverordnung, PSMV, SR 916.161) and under the Council Directive 91/414/EEC in the EU. A comprehensive risk assessment and authorisation procedure for AS and products containing these substances is laid out [5] based on the guidance on aquatic ecotoxicology published in the Sanco Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC [25], which is used under the PPP authorisation in the EU and Switzerland (chapter 3.7).

3.2. Hazard assessment under the Water Framework Directive (Directive 2000/60/EC)

3.2.1. Objectives

The Water Framework Directive (WFD, Directive 2000/60/EC [3]) establishes a legal framework to protect and restore clean water across Europe and ensure its long-term, sustainable use. The Directive aims to ensure the good chemical status (as defined in Art. 2 of the WFD) of both surface water and groundwater bodies across Europe. For surface waters this goal is defined by EQS for specific pollutants of EU relevance.

These EQS are established under the new Priority Substances Directive [26], published in December 2008. EQS for the first list of 33 substances identified by the EU as Priority Substances and Priority Hazardous Substances are derived at the European level and apply to all Member States. The Annex II to this new directive replaces Annex X of the WFD referring to the list of priority substances. In addition, the WFD establishes the principles to be applied by the Member States to develop EQS for Specific Pollutants that are 'discharged in significant quantities'. These are also known as Annex VIII substances of the WFD.

According to Art. 4 WFD, the Member States shall implement the necessary measures to prevent deterioration of the status of all bodies of surface water. Body of surface water means a discrete and significant element of surface water such as a lake, a reservoir, a stream, river or canal, part of a stream, a transitional water or a stretch of coastal water [3].

The objective of achieving good water status should be pursued for each river basin, so that measures in respect of surface water and ground waters belonging to the same ecological, hydrological and hydro geological system are coordinated. River basin means the area of land from which all surface run-off flows through a sequence of streams, rivers and possibly lakes into the sea at a single river mouth, estuary or delta [3].

Also ecological objectives are defined in Art. 1 of the WFD with the ultimate aim of achieving concentrations in the marine environment near background values for naturally occurring substances and close to zero for man-made synthetic substances.

The chemical status assessment is used alongside the ecological status assessment to determine the overall quality of a water body [3].

3.2.2. Derivation of EQS

In the context of the WFD a project was performed by Lepper of the Fraunhofer-Institute for Molecular Biology and Applied Ecology to develop a methodology to derive environmental quality standards (EQS) [14], which was based on the TGD on RA [8]. This concept was subsequently updated by Lepper in 2005 [15] and applied to derive the EQS for the first list of the 33 priority substances. An expert group on EQS chaired by the Joint Research Centre and UK as a member state were commissioned to update this methodology according to the more recent regulation progress (e.g. REACH). The result is currently being worked out as a Technical Guidance Document for Deriving Environmental Quality Standards (TGD for EQS [17]).

In order to cover both long- and short-term effects resulting from exposure, two water column EQS will normally be required [17]:

- a long-term standard, expressed as an annual average concentration (AA-EQS) and preferably based on chronic toxicity data and
- a short-term standard, referred to as a maximum acceptable concentration EQS (MAC-EQS) which is based on acute toxicity data.

The AA-EQS is the concentration which should not be exceeded when compared to the annual average of the measured concentrations. It is comparable to the CQK ("Chronisches Qualitätskriterium"), which is used by some Swiss cantons since their publication by Chèvre and co-workers in 2006 [6, 7].

Where EQS are derived for biota and sediment, they are always expressed as a long-term standard. It is not appropriate to derive a short-term standard for these compartments because exposure will typically be over long periods of time. Whilst derivation of the AA-EQS typically employs chronic toxicity data, the MAC-EQS always relies on acute data. Where the derivation of the MAC-EQS leads to a lower value than the AA-EQS, the MAC-EQS is set equal to the AA-EQS. This procedure is summarised in Table 3.3.

Table 3.3: Summary of MAC-EQS recommendation based on relationship with AA-EQS [17].

Relationship between estimated AA and MAC	Recommendation
MAC-EQS < AA-EQS	Set MAC-EQS equal to AA-EQS
MAC-EQS > AA-EQS	Derive MAC-EQS

3.2.2.1. Evaluation of available information

The data used for the derivation of EQS have to undergo an assessment of their relevance and reliability, before they can be used for deriving EQS. The data reliability is generally assessed according to the Klimisch system [17], which classifies the data into four score categories:

1 = reliable without restrictions: 'studies or data [...] generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline...or in which all parameters described are closely related/comparable to a guideline method.'

2 = reliable with restrictions: 'studies or data [...](mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.'

3 = not reliable: 'studies or data [...] in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g., un-physiologic pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an "expert judgement".

4 = not assignable: 'studies or data [...] which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.).'

Only data with the Klimisch scores 1 and 2 are considered to be reliable with regard to EQS derivation. However, there are some exceptions, since data are also considered valid if (i) they were generated and assessed under community regulations or directives, (ii) they were peer reviewed by (inter)national organizations (if the source is judged to be reliable enough), (iii) the study was performed under the criteria for good laboratory practice and the data have been submitted under a regulatory regime, and (iv) data judged as being reliable in DARs. It should be noted however, that not all valid data are relevant for EQS derivation. As pointed out in the TGD for EQS [17], not all studies on plant protection products are suitable for EQS development because the exposure regimes are designed to simulate specific exposure scenarios.

More detailed guidance on the data reliability assessment is given in the Appendix 1 of the TGD for EQS [17].

Relevant endpoints are e.g. (Table A 1.2 in Appendix 1): (i) survivorship of adults, (ii) growth, (iii) time taken to develop, (iv) reproductive output, (v) behavioural effects, if relevant for the competitive fitness of the population, and (vi) avoidance reactions, if usual habitats are likely to be avoided by the population. The focus clearly lies on the effect on the population level. The relevance of physiological endpoints such as histopathological endpoints, plasma protein levels or cell proliferation is unclear.

The query on the methods used for EQS derivation (Appendix 2) comprised also an assessment of the most commonly used endpoints in the context of EQS derivation (Table 3.4).

Table 3.4: Endpoints used for EQS derivation as assessed by the query.

Agreed endpoints	Country				
	AT [1]	FR	DE	IT	NL
growth (weight, length, growth rate, biomass)	A	A, F	x	x	A, I, F
number (cells, population)		A	x	x	A, I
mortality	I, F	I, F	x	x	I, F
immobilization	I	I	x	x	I
reproduction	I, F	I, F		x	I, F
hatching (rate, time, percentage)		I, F	x	x	I, F
sex ratio			x	x	F
development (egg, embryo, life stage)		F	x	x	I, F
malformations (teratogenicity)		I	x	x	F
proliferation (cells)				x	A, Prot.
filtration rate		I		x	I
carbon uptake (algae)		A		x	A
reburial (of e.g. certain crustacean species)		I		x	I
discussed endpoints					
histopathological endpoints			x		
behavioural responses (swimming behaviour, antenna motility, etc.)			x		

[1] AT: Only the most frequently used endpoints are mentioned; A: Algae; I: Invertebrate; F: Fish; Prot.: Protista

NB: It should be noted that the group of 'invertebrates' consists of many different species groups. Insects, crustaceans, molluscs etc. are treated as different taxa. Thus, where “I” is marked above, this does not necessarily apply to all invertebrates. Further, it must be noted that other groups such as amphibians are also considered. Not all endpoints are common to all taxa, but might be relevant if a study describing these endpoints is retrieved. Relevance for population level is then considered on a case by case basis.

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3.2.3. Deriving an AA-EQS

The AA-EQS can be derived in three different ways [17]:

- deterministic approach using the Assessment Factor (AF) method
- probabilistic approach using the Species Sensitivity Distribution (SSD) method
- using results from model ecosystem and field studies.

If the conditions to use the SSD method for the derivation of EQS are met, it should always be used. If all methods can be performed, the final EQS should preferably be based on the results from the SSD method or from model ecosystem-studies, since these entail a more robust approach towards assessing ecosystem effects [17]:

- The SSD gives a robust estimate of the range of sensitivities to be encountered in an ecosystem, but it is still based on single species data, and species-interactions at the ecosystem level are not covered.
- In the case of mesocosm studies, it is often not possible to disentangle the exact cause-effect relationships, but they may point to long-term effects on the ecosystem that cannot be shown in single-species laboratory studies (i.e. indirect effects, predator-prey interactions).

Nonetheless, for the final setting of the EQS the results from all three approaches have to be considered, if the available data allow for it.

A concise overview of the data requirements and AF for the derivation of an AA-EQS according to the TGD for EQS is given in Table 3.5 and the respective footnotes.

Table 3.5: Overview of the required data and the respective AF for the derivation of an AA-EQS according to the TGD for EQS [17].

Available data	Assessment factor
At least one short-term L(E)C50 from each of three trophic levels (fish, invertebrates (preferred *Daphnia*) and algae) (i.e. base set)	1000 [a)]
One long-term EC10 or NOEC (either fish or *Daphnia*)	100 [b)]
Two long-term results (e.g. EC10 or NOECs) from species representing two trophic levels (fish and/or *Daphnia* and/or algae)	50 [c)]
Long-term results (e.g. EC10 or NOECs) from at least three species (normally fish, *Daphnia* and algae) representing three trophic levels	10 [d)]
Species sensitivity distribution (SSD) method [e)]	5-1 (to be fully justified case by case)
Field data or model ecosystems	Reviewed on a case by case basis [f)]

a) The use of a factor of 1000 on short-term toxicity data is a conservative and protective factor and is designed to ensure that substances with the potential to cause adverse effects are identified. It assumes that the uncertainties identified above make a significant contribution to the overall uncertainty. For any given substance there may be evidence that this is not so, or that one

particular component of the uncertainty is more important than any other. In these circumstances it may be necessary to vary this factor. This variation may lead to a raised or lowered assessment factor depending on the available evidence. A factor lower than 100 should not be used in deriving an AA-$EQS_{freshwater, eco}$ from short-term toxicity data.

Variation from a factor of 1000 should not be regarded as normal and should be fully supported by accompanying evidence.

b) An assessment factor of 100 is applied to a single long-term result (e.g. EC10 or NOECs) (fish or Daphnia) if this result was generated for the trophic level showing the lowest L(E)C50 in the short-term tests. If the only available long-term result (e.g. EC10 or NOECs) is from a species (standard or non-standard organism) which does not have the lowest L(E)C50 from the short-term tests, applying an assessment factor of 100 is not regarded as protective of other more sensitive species. Thus the hazard assessment is based on the short-term data and an assessment factor of 1000 applied. However, the resulting QS based on short-term data may not be higher than the QS based on the long-term result available. An assessment factor of 100 can also be applied to the lowest of two long-term results (e.g. EC10 or NOECs) covering two trophic levels when such results have not been generated from that showing the lowest L(E)C50 of the short-term tests. This should, however, not apply in cases where the acutely most sensitive species has an L(E)C50 value lower than the lowest long-term result (e.g. EC10 or NOECs) value. In such cases the QS might be derived by using an assessment factor of 100 to the lowest L(E)C50 of the short-term tests.

c) An assessment factor of 50 applies to the lowest of two long-term results (e.g. EC10 or NOECs) covering two trophic levels when such results have been generated covering that level showing the lowest L(E)C50 in the short-term tests. It also applies to the lowest of three long-term results (e.g. EC10 or NOECs) covering three trophic levels when such results have not been generated from that trophic level showing the lowest L(E)C50 in the short-term tests. This should however not apply in cases where the acutely most sensitive species has an L(E)C50 value lower than the lowest long-term result (e.g. EC10 or NOECs) value. In such cases the EQS might be derived by using an assessment factor of 100 to the lowest L(E)C50 of the short-term tests.

d) An assessment factor of 10 will normally only be applied when long-term toxicity results (e.g. EC10 or NOECs) are available from at least three species across three trophic levels (e.g. fish, Daphnia, and algae or a non-standard organism instead of a standard organism). When examining the results of long-term toxicity studies, the AA-EQS should be calculated from the lowest available long-term result. Extrapolation to the ecosystem can be made with much greater confidence, and thus a reduction of the assessment factor to 10 is possible. This is only sufficient, however, if the species tested can be considered to represent one of the more sensitive groups. This would normally only be possible to determine if data were available on at least three species across three trophic levels. It may sometimes be possible to determine with high probability that the most sensitive species has been examined, i.e. that a further long-term result (e.g. EC10 or NOECs) from a different taxonomic group would not be lower than the data already available. In those circumstances, a factor of 10 applied to the lowest long-term result (e.g. EC10 or NOECs) from only two species would also be appropriate. This is particularly important if the substance does not have a potential to bioaccumulate. If it is not possible to make this judgement, then an assessment factor of 50 should be applied to take into account any interspecies variation in sensitivity. A factor of 10 cannot be decreased on the basis of laboratory studies. (However, this only refers to the deterministic approach. If the SSD approach is used, which is also based on laboratory data, a lower assessment factor than 10 can be used (1-5).)

e) Minimum data requirements: 10 NOECs (preferably more than 15 NOECs) for different species covering at least the 8 taxonomic groups: fish (species frequently tested include salmonids, minnows, bluegill sunfish, channel catfish, etc.), a second family in the phylum chordata (e.g. fish, amphibian, etc.), a crustacean (e.g. cladoceran, copepod, ostracod, isopod, amphipod, crayfish, etc.), an insect (e.g. mayfly, dragonfly, damselfly, stonefly, caddisfly, mosquito, midge, etc.), a family in a phylum other than arthropoda or chordata (e.g. rotifera, annelida, mollusca, etc.), a family in any order of insect or any phylum not already represented, algae, higher plants

f) The assessment factor to be used on mesocosm studies or (semi-) field data will need to be reviewed on a case-by-case basis.

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3.2.3.1. Extrapolation using the assessment factor (AF) method

The most commonly applied approach is the assessment factor (AF) method, in which the lowest observed toxicity value for a given substance is divided by an AF which should reflect the uncertainty connected to the representativeness of the available ecotoxicity data for the toxic effects the substance exerts in ecosystems. The more chronic ecotoxicity values from taxonomic groups from different trophic levels are available, the lower the AF becomes. Usually, the minimal number of data needed for the AF method is the "base set", which consists of one acute EC50 value for each of the following taxa: algae, daphnids and fish. For substances with small datasets, the deterministic approach or assessment factor method (AF method) is the only realistic option for the derivation of EQS because the data requirements of the SSD method (cf. section 3.2.3.2) are too demanding.

3.2.3.2. Extrapolation using SSDs

The species sensitivity distribution method is based on statistical calculations and usually requires experimentally determined NOEC or EC10 values from chronic studies for a number of species from different taxonomic groups. This method aims at calculating a concentration that is assumed to protect a certain percentage (e.g. 95%) of the species of the ecosystem against toxic effects. The TGD for EQS [17] refers to the REACH guidance [13] and to the book on SSDs by Posthuma et al. [27] for details on the method.

The main underlying assumptions of the statistical extrapolation methods are as follows:

- the distribution of species sensitivities follows a theoretical distribution function
- the group of species tested in the laboratory is a random sample of this distribution.

Mathematically, SSDs correspond to cumulative frequency distributions fitted by a sigmoidal regression model, which allows for the calculation of the concentration at which a given percentage of species is affected by the substance (**Figure 3.1**). Long-term toxicity data are log-transformed and fitted to the distribution function. Although there are several suitable regression models that can be used for SSDs, the log-normal function is recommended [17].

It is impossible to calculate from an SSD a concentration at which no species is affected, because the upper and the lower end of the SSD approaches 100% and 0% infinitely. Therefore, usually 5% of the affected species is set as a cut-off criterion, which is called the HC5 (concentration hazardous for 5% of the species).

In order to be representative for all species in ecosystems, a certain amount of representatives from different taxonomic groups have to be included. An EQS should be protective for the wide range of surface waters and communities that can occur within Europe. Given this broad scope of protection of the WFD, the requirements of the REACH guidance [13] with respect to the number of taxa and species to be included in the dataset are followed [17]. The output from a SSD-based EQS is considered reliable if the database contains preferably more than 15, but at least 10 NOEC/EC10, from different species covering at least eight taxonomic groups. For estimating an AA-EQS, the taxa summarised in Table 3.6 normally need to be represented.

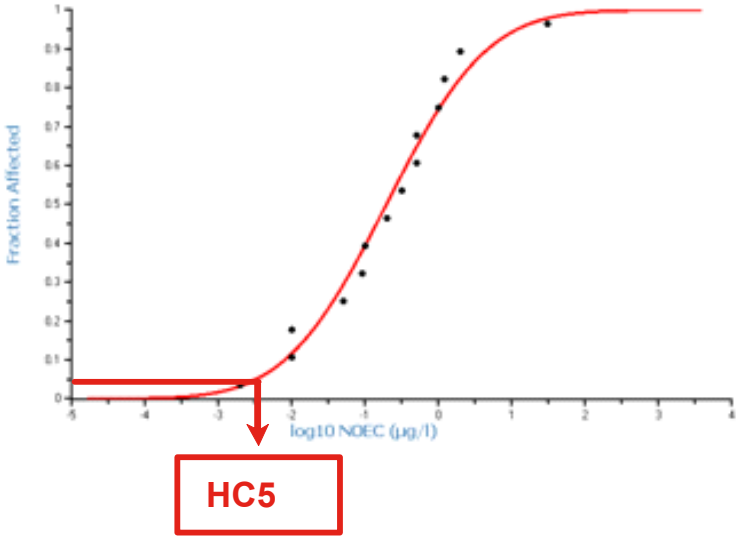

Figure 3.1: Example for deriving HC5 from a SSD.

Table 3.6: Minimum species requirements when using the SSD method.

fish (species frequently tested include salmonids, minnows, bluegill sunfish, channel catfish, etc.)
a second family in the phylum Chordata (fish, amphibian, etc.)
a crustacean (e.g. cladoceran, copepod, ostracod, isopod, amphipod, crayfish, etc.)
an insect (e.g. mayfly, dragonfly, damselfly, stonefly, caddisfly, mosquito, midge, etc.)
a family in a phylum other than Arthropoda or Chordata (e.g. Rotifera, Annelida, Mollusca, etc.)
a family in any order of insect or any phylum not already represented
algae
higher plants

For substances exerting a specific mode of action a stepwise approach should be followed. First an SSD should be constructed with the entire data set to examine the relative sensitivities of the taxa. For substances with a specific mode of action “breaks” in the distribution are often observed, resulting in a poor model fit. Therefore, in the second step an SSD comprising only the particularly sensitive species should be made. It is essential to note however, that also for the SSD with the most sensitive taxa also the minimum number of 10 data points is required. It has to be pointed out that the SSD on the most sensitive taxonomic groups may only be performed in case that the data requirements for an SSD with all required taxa are fulfilled. Only if there is other evidence for the existence of a specifically sensitive group, e.g. read across from a structurally similar substance, the SSD for the sensitive taxa can be constructed in the first place.

By default, an AF of 5 is used on the HC5 when an AA-EQS is derived from a SSD. Depending on the evaluation of the uncertainties around the derivation of the HC5, the AF can be reduced to minimally 1. Guidance on the determination of the assessment factor is given in Table 3.7 [17].

Table 3.7: Issues to consider when determining the size of the AF in the SSD method.

an AF of 5 is used by default, if nothing is specified
the overall quality of the database and the endpoints covered, e.g., if all the data are generated from "true" chronic studies (e.g., covering all sensitive life stages)
the diversity and representativity of the taxonomic groups covered by the database, and the extent to which differences in the life forms, feeding strategies and trophic levels of the organisms are represented
knowledge on presumed mode of action of the chemical (covering also long-term exposure)
statistical uncertainties around the 5th percentile estimate, e.g., reflected in the goodness of fit or the size of confidence interval around the 5th percentile, and consideration of different levels of confidence (e.g. by a comparison between the median estimate of the HC5 (50% confidence level) with the lower estimate of the HC5 (95% confidence level))
comparisons between field and mesocosm studies, where available, and the 5th percentile and mesocosm/field studies to evaluate the robustness of the laboratory to field extrapolation

Due to their assumed lower uncertainty, which is resembled in the lower AF proposed for the final derivation of the EQS, EQS derived by the SSD approach are generally preferred when compared to EQS derived by the AF approach. An advantage of these methods is that they use the whole sensitivity distribution of species in an ecosystem to derive an EQS instead of taking always the lowest long-term NOEC. However, such methods can also be criticised. Among the most common drawbacks, the reasons being put forward are [13, 28]:

- the lack of transparency by using this method compared to the standard approach
- the question of representativity of the selected test species
- the comparability of different endpoints
- the arbitrary choice of a specific percentile and a statistical confidence level
- SSDs cannot give results on the combined effects of different additional stressors (e.g. natural light regimes) and the test substance under environmental conditions.

3.2.3.3. Use of field and semi-field studies for derivation of the AA-EQS

The third approach derives EQS based on the results of micro- or mesocosm studies. In these studies the effects of a given substance in a relatively small-scale, simulated ecosystem are studied. The relevance of these studies for EQS setting highly depends on the representativeness of the given micro- or mesocosm for the ecosystem which is at the focus of EQS setting. Also in this approach, an AF is finally applied to derive an EQS: on the determined lowest reliable and relevant NOEC. There is extensive guidance on the assessment of the reliability and the evaluation of endpoints from mesocosm studies [29]. The main issue is to link the exposure regime in the experiment to the purpose of EQS-derivation, i.e. setting standards for prolonged or peak exposure. Nonetheless, EQS based on micro- and mesocosm data are mostly influenced by the "expert judgement" of the hazard assessor, since the guidance given in the respective TGDs is not clear on this point [8, 15-17].

Field studies and simulated ecosystem studies such as microcosm and mesocosm experiments (e.g. ponds and streams) are frequently used to assess the environmental risks posed by PPP. They can be a valuable tool to assess the impact of a chemical on populations or communities of aquatic ecosystems under more realistic environmental conditions than is achievable with standard single-species laboratory studies. If such studies are available, and they fulfil the criteria regarding reliability and relevance as defined below, they may be used either as the basis of AA-EQS derivation or, when an SSD is used, to help select the size of AF applied to the HC5 [17]. In this context it has to be kept in mind though, that field and semi-field studies in most cases cannot give evidence on the toxicity against fish, since fish are usually not included in these studies.

According to the REACH guidance [13], the AF applied to mesocosm studies or (semi-)field data will need to be reviewed on a case-by-case basis, but no guidance is given with respect to the range of AF to be applied.

Brock *et al.* [21] compared micro- and mesocosm experiments for several chemicals in which long-term exposure was simulated. They estimated a geographical extrapolation factor based on the ratio of the upper and lower limit of the 95% confidence interval of NOECs for toxic effects. These factors ranged between 1.4 and 5.4. This suggests that, where there is (a) only a single model ecosystem study, and (b) sensitive taxa are included in the study of a compound with a specific mode of action, an assessment factor of 5 would account for variation in the NOECs. When additional, confirmative mesocosm studies are available, the AF may be lowered [17].

In determining the size of the AF to be applied to microcosm and mesocosm studies, the following criteria should be considered (Table 3.8) [17]:

Table 3.8: Consideration with respect to the determination of the size of AF to be applied to microcosm and mesocosm studies.

What is the overall quality of the micro- or mesocosm study/studies from which the NOEC has been derived?
What is the relationship between the mode of action of the investigated substance and the species represented in the available micro- or mesocosm studies? Are sensitive species represented?
Do the available micro- or mesocosm studies cover vulnerable species or representatives of taxonomic groups (e.g. families, orders) of vulnerable species that are part of the aquatic ecosystems to be protected?
Do the available micro- or mesocosm studies represent the range of flow regimes that should be protected by the EQS? Consider specific populations of species inhabiting the lotic and lentic water types to be protected.
Do the available micro- or mesocosm studies represent the range of trophic statuses of water bodies that should be protected by the EQS?

However, there may be some features that are of particular importance to EQS derivation since the objectives of risk assessment under Council Directive 91/414/EEC and EQSs under the WFD are not entirely compatible [17]:

- For AA-EQS derivation, exposure in the test system must be properly characterised. Therefore a prerequisite for using a field or mesocosm study is that the concentration

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of the substance is measured over the course of the experiment, so that time-weighted average concentrations (TWA) within a well-defined time window can be calculated for persistent AS.

- All effects observed (and all NOECs derived), must be related to the respective TWA[2] concentration. It is not acceptable to use the initial concentration as the basis for assessment unless there is evidence that this level of exposure has been maintained.
- This means that for AA-EQS derivation mesocosm studies with rapidly dissipating compounds (with half-lives of hours) cannot be used unless steps have been taken to replenish the test substance at intervals consistent with the substance's half-life in the environment.
- In risk assessment of PPP, the potential for recovery following removal of the chemical stressor is normally taken into account. This principle does not apply in EQS derivation, i.e. a temporary impact is not normally tolerated, especially when deriving an AA-EQS which is intended to protect against long-term exposure when recovery conditions might never actually occur.
- The scope of protection of an EQS under the WFD is broader than that of the "acceptable concentration" in the hazard assessment of PPP. The EQS must be protective for all types of surface waters and communities, not just the type covered by a particular mesocosm or field study. Therefore, it has to be assessed whether the test system can be considered as representative for the full range of water bodies that might be subject to PPP exposure.
- In general, the more similar the test system is to the field situation, the higher its relevance for risk assessment and EQS setting. Differences between experimental mesocosms and the field can result in either an over- or underestimation of the response of the field ecosystem.

3.2.4. Deriving a MAC-EQS

For deriving a MAC-EQS, the REACH guidance for effects assessment of substances with intermittent release is adopted (cf. section 3.6.1.3).

3.2.4.1. Extrapolation using the AF method

For exposures of short duration, acute toxicity data are relevant and the AF values to be used are given in Table 3.9.

[2] Time Weighted Average concentration based on frequent determinations of the exposure concentration during the biotest

Table 3.9: Assessment factors to derive MAC-EQS.

Available data	Additional information	Assessment factor
Base set not complete	-	- [1)]
At least one short-term L(E)C_{50} from each of three trophic levels of the base set (fish, crustaceans and algae)	-	100
At least one short-term L(E)C_{50} from each of three trophic levels of the base set (fish, crustaceans and algae)	Acute toxicity data for different species do not have a higher standard deviation than a factor of 3 in both directions [2)] OR known mode of toxic action and representative species for most sensitive taxonomic group included in data set	10 [3)]

1) When the base set is not complete, a MAC-EQS cannot be derived. It should be considered if the base set could be completed with non-testing data. Non-testing data should not be used as critical data in the derivation of the MAC-EQS.

2) To assess the span of the acute toxicity data, all reliable acute toxicity data collected are used, with a minimum of three LC_{50} or EC_{50} values, for species representing each of the base set trophic levels (algae, *Daphnia*, fish). If the standard deviation of the log transformed L(E)C_{50} values is <0.5, an assessment factor of 10 could be applied, otherwise an assessment factor of 100 should be applied.

3) Lowest assessment factor to be applied.

3.2.4.2. Extrapolation using the SSD approach

The same approach as described in section 3.2.3.2 can be applied. However, instead of long-term NOECs, acute L(E)C_{50} data are the appropriate input data. Combined acute toxicity data sets for marine and freshwater species may be used, unless an evaluation of the freshwater and saltwater toxicity data indicates that the data cannot be pooled. This pooling of salt and freshwater data has newly been introduced into the TGD for EQS and was not foreseen in the TGD on RA [8], the Lepper guidance document [15] and the Dutch TGD [16]. Because L(E)C_{50} instead of NOECs are used for deriving the MAC-EQS, the default assessment factor for a MAC-EQS derived from an SSD is 10 instead of 5.

3.2.4.3. Use of simulated ecosystem studies in deriving a MAC-EQS

For determining the MAC-EQS, experiments simulating short-term exposure are most relevant.

For substances for which the mode of action and/or the most sensitive taxa are unknown, an assessment factor ranging from 1-5 is applied to the lowest threshold concentrations from the available mesocosms, with the same considerations as given for the derivation of the AA-EQS (cf. section 3.2.3.3).

Brock *et al.* [21] compared the outcome of six mesocosm studies that simulated short-term exposure with the insecticides chlorpyrifos and lambda-cyhalothrin. They looked at the spread (i.e. the ratio of the upper and lower limit of the 95% confidence interval) of the threshold concentrations for toxic effects. The spreads were 2.9 for chlorpyrifos and 2.6 for

lambda-cyhalothrin. They concluded that for a substance with a specific mode of toxic action, an AF of 3 can be applied to the threshold level for effects of a single valid study to ensure that more severe effects do not occur in various field situations. According to the TGD for EQS, this factor can be put on the NOEC and lowered depending on the number of available mesocosms [17]. Again it has to be considered, that field and semi-field studies in most cases cannot give evidence on the toxicity against fish, since fish are usually not included in these studies.

3.2.5. Deriving EQS for water abstracted for drinking water

In addition to potential exposure through the consumption of fishery products, a second route for human exposure to substances in water is through drinking water. Therefore the WFD requires quality standards to protect humans against this route of exposure. In principle, existing drinking water standards are adopted, e.g. EU drinking water standards from Drinking Water Directive 98/83/EC [19] and the World Health Organization (WHO) drinking water standards. These drinking water standards are used to set the EQS for those water bodies used for the abstraction of drinking water.

A treatment factor should be applied to the drinking water standard so that the EQS relates to the 'raw' water (i.e. it is an 'environmental' standard). If no existing drinking water standards are available (either Directive 98/83/EC [19] or WHO standards) a standard for drinking water abstraction from surface water may be derived.

3.2.6. Derivation of biota standards

One of the factors leading to unmanageable water column standards is the very low concentrations that may be estimated for some substances, especially those with very low water solubility or a tendency to bioaccumulate through the food web. If these substances pose a significant risk through indirect toxicity (i.e. secondary poisoning resulting from food-chain transfer incl. human fish consumption) and their analysis is more feasible in other environmental matrices, such as biota and/or sediments, then a biota standard may be required alongside or instead of the water column EQS [17]. This is typically the case for hydrophobic substances. In line with the requirements of the EQS Directive [26], these biota standards are presented as possible alternatives to a water column standard. The WFD requires biota EQS to protect:

- humans from adverse effects resulting from the consumption of chemical-contaminated food (fish, molluscs, crustaceans, etc.)
- top predators, such as birds and mammals, from risks of secondary poisoning due to consuming toxic chemicals in their prey
- benthic and pelagic predators (e.g. predatory fish) that may also be at risk from secondary poisoning.

Since the collection of data of chronic avian or mammalian toxicity is not the key focus in the current project to derive EQS for the aquatic environment, the procedures to derive biota standards are not explained in details in this report.

3.3. Guidance document from the Netherlands (van Vlaardingen and Verbruggen, 2007)

Based on the query of the Ecotox Centre from 2010 on the EQS derivation procedure in various European countries (cf. section 3 and Appendix 2) the guidance from the Netherlands [16] was selected as an additional document for comparison.[3]

The guidance for the derivation of environmental risk limits (ERLs) within the framework of 'International and national environmental quality standards for substances in the Netherlands' (INS) has been performed for the account of the Directorate-General for Environmental Protection, Directorate for Chemicals, Waste and Radiation, in the context of the project 'International and national environmental quality standards for substances in the Netherlands', RIVM-project no. 601782 [16].

The guidance document is based on Lepper [15] and on the EU TGD from 2003 [8]. Different ERLs, describing four levels of protection [16]:

- the maximum permissible concentration (MPC) for water, soil, groundwater, sediment and air, both for ecosystems and for humans (corresponding to the AA-EQS)
- the maximum acceptable concentration for ecosystems (MAC_{eco}) for surface water (freshwater and marine) (corresponding to the MAC-EQS)
- the serious risk concentration (SRC) for water, soil, groundwater and sediment, both for ecosystems (SRC_{eco}) and humans (SRC_{human})
- the negligible concentration (NC) for water, soil, groundwater, sediment and air (i.e. the MPC / 100).

These ERLs serve as advisory values for the setting of EQS values. The term EQS is used to designate all legally and non-legally binding standards that are used in Dutch environmental policy [16].

3.3.1. Data collection and evaluation

Before any data are collected, the availability of EU-RAR (EU Risk Assessment Report) documents for the compounds of interest or whether the compound is on the list of priority substances of the WFD should be checked:

- For compounds for which an EU-RAR is in draft, no risk limits will be derived.
- For compounds for which a finalised EU-RAR is available, the PNECs are recalculated to MPCs, making use of the Dutch characteristics for soil, sediment and suspended matter.
- For compounds that are priority substances in the Water Framework Directive, AA-EQS values for freshwater, marine water, freshwater sediment and marine sediment

[3] Please note that the Dutch TGD will be updated to reflect the final TGD for EQS once this is officially accepted by the European Comission.

are available in principle, plus a MAC-EQS for freshwater. The data validated in the WFD fact sheets should be used to derive the SRC_{eco}.

Concerning the derivation of ERLs for PPP, the following procedure applies [16]:

The toxicity data that are used to derive ERLs for PPP comprise both all publicly available literature data and all confidential data. The confidential data for plant protection products should be made available by the Dutch Board for Authorisation of Pesticides (CTB). If more than one registration dossier for the same compound (active substance) is available, data from all registration dossiers should be taken into account when deriving ERLs. Any relevant information provided by companies can also be evaluated for use in the ERL derivation.

3.3.2. Derivation of the maximum permissible concentration (MPC)

MPC values for freshwater are derived by the assessment factor method, or, if possible, by applying an SSD with the same procedures as used for the derivation of AA-EQS values (cf. section 3.2.3). It is interesting to note that according to the Dutch TGD the long-term EQS (MPC) may only be derived when the base-set is complete. However, because of the broader scope of this TGD, in exceptional cases (e.g. in cases where data for the whole base-set are not legally required) there is the possibility of deriving a MPC based on an EC_{50} for Daphnia and an AF of 1000.

3.3.3. Derivation of the maximum acceptable concentration for ecosystems (MAC_{eco})

MAC_{eco} values for freshwater are derived by the assessment factor method, or, if possible, by applying an SSD with the same procedures as used for the derivation of MAC-EQS values (cf. section 3.2.4).

When using the assessment factor method, Table 3.9 applies. However, an assessment factor of 1000 is used for substances with the potential to bioaccumulate, because Lepper [15] states that a factor of 100 may not always be justified for substances which bioaccumulate. [4]

3.3.4. Derivation of the serious risk concentration (SRC)

For derivation of the SRC_{eco} both acute and chronic toxicity data should be tabulated. In general, the SRC_{eco} is the geometric mean of all available chronic toxicity data. When no or few chronic data are available, a comparison is made with the geometric mean of acute toxicity data [16].

In principle, an acute-to-chronic ratio (ACR) of 10 is applied to the acute toxicity data to compare acute $L(E)C_{50}$ values with chronic NOEC (or EC10) values.

For the aquatic compartment, comparison between chronic data and acute data is not performed, when chronic data are available for at least three species, which should represent the three specified trophic levels from the base set of the TGD [8]: algae, *Daphnia* and fish.

[4] According to a comment by Els Smit (RIVM-NL) an evaluation on this topic for the draft TGD for EQS has led to the conclusion that an additional factor is not needed [30]

3.3.5. Derivation of the negligible concentration (NC)

The following definition is given for the negligible concentration (NC) [16]:

The target value (i.e. EQS) is in principle set at the level of negligible concentration (NC) and is the guideline for the long-term environmental quality to be achieved. The NC has been set to a factor of 100 below the MPC, which defines a safety margin allowing for combination toxicity. The following points of departure have been used to derive target values:

- protection of the ecological function: risks to ecosystems must be negligible
- protection of functional properties of the environment: the use functions must be safeguarded.

3.3.6. Summary on the guidance document from the Netherlands

Since the guidance document from the Netherlands is based on Lepper [15] and on the EU TGD from 2003 [8], it is in line with the TGD for EQS [17].

Maximum permissible concentrations (MPC) and maximum acceptable concentrations (MAC) are derived with the same methods as foreseen for the derivation of AA-EQS and MAC-EQS values.

Some additional points comprise the derivation of the negligible concentration (NC) and the serious risk concentration (SRC).

3.4. International Commission for the Protection of the Rhine (IKSR)

For the benefit of the Rhine and of all of its tributaries the members of the ICPR successfully co-operate. Focal points of work are sustainable development of the Rhine, its alluvial areas and the good state of all waters in the watershed. In this context EQS for Rhine relevant pollutants have been derived [24]. The methodology was adopted from Lepper [15] and is therefore in-line with the procedures described in section 3.2.

3.5. Effect-Based Quality Criteria (Chèvre and co-workers)

The methodology presented by Chèvre and co-workers [7] was developed in a project on the derivation of robust EQS values to assess the quality of surface water for both single substances and mixtures.

The determination of EQS is based on species sensitivity distribution (SSD). This method has the advantage to take all the available ecotoxicological values into account during calculation. However, for many pesticides, less than 10 NOECs as required by the TGD for EQS [17] are available to determine SSD. For this reason, and based on the mixture theory, pesticides were grouped based on their mode of toxic action and were handled together. Shortly, one pesticide with sufficient chronic data available is used as reference to extrapolate the curves for the other pesticides that have less data (Figure 3.2).

This approach was statistically tested for six groups of pesticides, namely triazines, phenylureas, chloroacetanilids, phenoxy acids, acylalanines & oxazolidinones, and organophosphates (Chèvre *et al.* 2006 [6]). The extrapolation used was considered as valid for most of the cases.

Compared to the other three methods, the authors do not consider the Assessment Factor method as valid in this approach. This is due to the fact that the relationship of PNEC values derived by the Assessment Factor method cannot be explained mechanistically even when the pesticides have a similar mode of action.

The subsequent four technical details have been followed:

- The validity of the data used to build the SSD was carefully checked in the original literature. When this was not feasible, the data were not used.
- When more than one data were available for one species (similar test conditions) these data were weighted (instead of being averaged geometrically).
- A log-logistic model was used to fit the SSDs.
- Within this approach, the EQS has been taken equivalent to the HC5-95% instead of using the HC5 divided by an assessment factor. Using the confidence intervals for calculation was considered as more robust than using an arbitrary assessment factor.

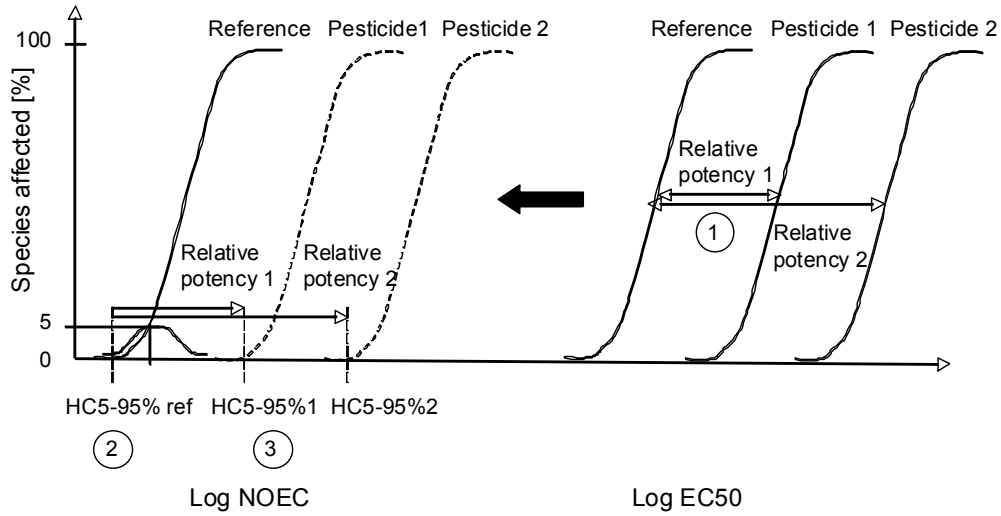

Figure 3.2: Three steps approach for deriving water quality criteria according to N. Chèvre and co-workers [7].

Here the hazardous concentration 5%-95% (HC5-95%) for each compound in a mixture of substances with a similar mode of action. Step 1: Derivation of the relative potency i for each compound i of the mixture based on the SSD-EC_{50} curves of compound i (SSD-EC_{50i}) and the reference ref (SSD-EC_{50ref}). Step 2: Derivation of the HC5-95%ref based on the SSD-NOEC for the reference (SSD-$NOEC_{ref}$). Step 3: Prediction of the SSD-$NOEC_i$ curves and HC5-95%$_i$ for each compound i in the mixture based on its Relative Potency i (RP_i) and the HC5-95%$_{ref}$. For further information see Chèvre *et al.* 2006 [7].

3.6. Hazard assessment for industrial chemicals and biocides: REACH and biocidal products authorisation

The EU Technical Guidance Document on Risk Assessment (TGD on RA) from 2003 [8] was used for the risk assessment for new and existing chemicals and also in support of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market.

After the REACH Regulation [12] had entered into force the evaluation of new and existing chemicals was replaced by the REACH Registration process. For the implementation of REACH, guidance documents were prepared for the hazard assessment [31] and the characterisation of dose [concentration]-response for the environment [13]. The TGD on RA [8] is still the current guidance document for the hazard assessment of biocidal products.

3.6.1. REACH

3.6.1.1. Required data

PNEC derivation under REACH is required for substances manufactured or imported in amounts of >10 t per year. However, if the substance neither poses a physicochemical, toxicological and environmental hazard nor is identified as a PBT substance no risk assessment has to be performed. Hence, in such cases no PNEC would have to be calculated. For each tonnage level standard data requirements have been specified in REACH (Annex VII-X, in conjunction with Annex XI). For environmentally relevant substances >100 t per year the REACH registration process will provide a reasonable amount of acute and chronic data, which can be used for the derivation for EQS under the EU WFD (cf. section 3.2). PNEC(s) should be reconsidered if further information becomes available at higher tonnage levels [13].

For substances >1 t per year, acute toxicity data for *Daphnia* and Alga are available. For substances >10 t per year, the full acute base set (incl. fish) is available. For substances >100 t chronic toxicity data will be available (Long-term toxicity testing shall be proposed by the registrant, if the chemical safety assessment according to Annex I of the REACH regulation indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s) depends on the results of the chemical safety assessment [12]):

- long-term toxicity testing on invertebrates (preferred species Daphnia)
- long-term toxicity testing on fish
- fish early-life stage (FELS) toxicity test
- fish short-term toxicity test on embryo and sac-fry stages
- fish, juvenile growth test.

REACH also requires that any other relevant hazard information that is available (i.e. from other available tests and non-test methods) is taken into account [13].

- New data for ecotoxicological properties have to be generated in compliance with GLP. The required tests are specified in two regulations ([32], [33]).

- Already available information has to be evaluated amongst others according to the Klimisch [34] approach.

Since the available data for most industrial chemicals under REACH do not fulfil the requirement for a SSD, the assessment factor methods are the most frequently used under REACH and in the respective REACH guidance document [13] mainly these methods are described.

3.6.1.2. Derivation of PNECs

For the derivation of PNECs two different methods dependent on the data availability are applied [13]:

- calculation of PNEC using assessment factors
- calculation of PNEC using statistical extrapolation techniques (SSD).

The procedures for estimating an AA-EQS under the WFD are essentially the same as the procedures described for the derivation of a PNEC under REACH [13]. Therefore, to derive a PNEC the same AF are used as described in Table 3.5 in section 3.2.3. A detailed strategy for further testing in order to refine the PNEC has been developed for the aquatic compartment and was published in the EU TGD [8]:

3.6.1.3. Derivation of PNECs for substances with intermittent release

The PNEC-values derived for freshwater or marine waters are based on the implicit assumption that the environmental exposure is constant, e.g. arising from a constant or frequent release.

However, in many cases, discharges will be limited in time, e.g. in case of emissions from batch productions. In such cases, the environmental exposure will also be limited in time, and it is assumed that when exposure stops rapidly, populations can tolerate higher concentrations than when it is long lasting [13].

In these cases, short-term $L(E)C_{50}$ values are used to derive a $PNEC_{water,intermittent}$. The $PNEC_{water,intermittent}$ for such situations is normally derived by application of an assessment factor of 100 to the lowest $L(E)C_{50}$ of at least three short-term tests from three trophic levels. The assessment factor is designed to take account of the uncertainty that exists in extrapolating from the results of short-term laboratory toxicity tests to short-term effects that can be anticipated in the ecosystems [13].

A similar approach is used in the TGD for EQS for the derivation of a MAC-EQS (cf. Section 3.2.4).

3.6.2. Hazard Assessment for Biocidal products: TGD on RA

As mentioned in chapter 1.1, the TGD on RA [8] is the basic guidance document on which all the newer guidance documents on the aquatic environmental hazard assessment are based: the TGD for EQS [17], its predecessor the Lepper method [15], the Dutch TGD [16] and the respective REACH guidance document [13]. Hence, it follows the same principles that were described above. Like under REACH, PNEC for constant exposure as well as a PNEC for substances with intermittent release are derived. The methods for the derivation of PNECs are the same as in all the aforementioned guidance documents (including the selection of the AF), i.e. AF, SSD and micro/mesocosm experiments. The minimum data requirement for the derivation of a PNEC are acute EC_{50} values for algae, daphnids and fish (the so called base set).

3.7. Hazard assessment in the context of the PPP authorisation process

3.7.1. General considerations

In Switzerland the PPP authorisation process is regulated under the PSMV [4]: Verordnung über das Inverkehrbringen von Pflanzenschutzmitteln (Der Schweizerische Bundesrat - Pflanzenschutzmittelverordnung, PSMV vom 18. Mai 2005, SR 916.161). The PSMV is very similar to the Council Directive 91/414/EEC [5] which regulates the authorisation of PPP in the EU. Both legislations were revised and the revised legislations will come into force in June (EU) and July (CH) 2011. In the EU the Council Directive will be replaced by the Regulation (EC) No 1107/2009 [18]. A regulation on uniform principles for risk assessment for plant protection products, as referred to in Article 36 of Regulation (EC) No 1107/2009 will also have to be prepared until 14 June 2011. The current guidance on aquatic ecotoxicology is published in the Sanco Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC [25].

Since the supporting documents to Regulation (EC) No 1107/2009 and to the new Swiss regulation are not yet prepared, the present review is solely based on the current Directive 91/414/EEC [5] and its supporting documents. Council Directive 97/57/EC [35] established Annex VI, the so-called Uniform Principles, for Directive 91/414/EEC, which are also part of the PSMV (Annex VI).

To prevent unacceptable effects on ecosystems is one of the major goals of the environmental risk assessment fulfilled as part of the PPP authorisation process. During the authorisation process no EQS values are derived. Nonetheless a thorough risk assessment is performed in the area of aquatic organisms. The authorisation procedure is important in the context of this report as the numerical consequences of the differences between the protection goals of the PSMV, the WFD and the Swiss Water Protection legislation can be illustrated by the comparison of the hazard assessment under the PPP authorisation with the EQS/PNEC derivation following other guidelines. Furthermore, it defines the available set of ecotoxicity data already evaluated by authorities that can be used for EQS derivation. Therefore, the PPP authorisation process is briefly presented in this chapter. To be in line with the other guidelines presented in this report, we focus on the hazard assessment part of the PPP authorisation. However, some principles of the risk assessment method will be mentioned without the aim to fully cover this topic.

The hazard assessment performed under the PPP authorisation follows a different sequence than the hazard assessments described in the TGD for EQS, the Dutch TGD, the REACH guidance document or the technical guidance document used for the hazard assessment of biocidal products [8]. While in all the aforementioned guidance documents a concentration value (EQS or PNEC) is derived at which no adverse effects are expected to occur in the environment by applying an AF on the most reliable and relevant effects data, this is not explicitly done in the procedures outlined in the guidance on aquatic ecotoxicology [25] used under the PPP authorisation. With the application of the AF, the uncertainty connected to the extrapolation from the effects observed in the effects assessment to the effects that can be expected to actually occur in the field should be taken into account. In the hazard assessment under the PPP authorisation, this uncertainty is considered at a later step, namely during the evaluation of the toxicity/exposure ratio (TER): if this ratio is below a defined "trigger value", the risk of the occurrence of unacceptable effects on ecosystems is considered too high. Hence, the trigger value fulfils the same function as the assessment factor. This connection has already been proposed by Brock and co-workers, who compared the methods used under the PPP authorisation with the methods under the water framework directive [21]. Knauer and co-workers have adopted this harmonizing approach in an article on the aquatic risk assessment of PPP under the PSMV in Switzerland [11], to be able to derive and present ecotoxicological characteristics for 24 AS used in PPP [5]. They are also termed regulatory acceptable concentrations (RACs, see chapter 3.7.5) and can be used for a direct comparison of the hazard assessment under the pesticide authorisation with other hazard assessment, e.g. the EQS derived under the WFD.

3.7.2. Environmental objectives

The general principles of the environmental objectives are laid down in Annex VI C – Decision Making – of the Council Directive 91/414/EEC [5] and of the PSMV (Anhang 6, C-1, Absatz 3 und 5):

- It shall be ensured that the authorized amounts, in terms of rates and number of applications, are the minimum necessary to achieve the desired effect even where higher amounts **would not result in unacceptable risks to human or animal health or to the environment**. The **authorized amounts must be** differentiated according to, and be **appropriate to, the agricultural, plant health or environmental (including climatic) conditions** in the various areas for which an authorization is granted.
- Since the evaluation is to be based on data concerning a limited number of representative species, it shall be ensured that use of plant protection products **does not have any long-term repercussions for the abundance and diversity of non-target species**.

[5] However, no PNECs are given for the AS used in the case studies presented in this report.

3.7.3. Principles of hazard assessment within the context of the PSMV and the Directive 91/414/EEC

The hazard assessment under the PPP authorisation follows a tiered approach (Figure 3.3). At each tier the risk of adverse effects is evaluated based on the TER and the respective trigger value. At the first tier the hazard is assessed based on standardised biotests on acute and chronic toxicity [25]:

- Acute toxicity (mostly EC_{50}/LC_{50}) data for fish and invertebrates are divided by the maximum predicted environmental concentration (PEC_{max}) to generate acute toxicity exposure ratios (TER_{acute}). The trigger values as given in Annex VI of Directive 91/414/EEC and PSMV are at least 100 for the most sensitive animal species, which are numbers that can be considered as assessment factors (AF).
- In addition, the chronic NOEC values are divided by either the PEC_{max} or the predicted time-weighted average concentration (PEC_{TWA}) values to derive chronic TER ($TER_{long\text{-}term}$). The use of the PEC_{TWA} values is an option for the refinement of the TER with respect to the exposure site. For the PEC_{TWA} values, usually a period of 21 and 28 d is taken into account to assess the risks to invertebrates and fish, respectively, but shorter time frames also may be chosen (e.g. dependent on time-to-effect information derived from toxicity tests). Data from long-term studies using stable exposure conditions, i.e. flow-through systems, are preferred.
- Tests with algae and higher plants (e.g. *Lemna spec.*) are considered chronic and the trigger value for the ratio between the EC_{50} and the maximum predicted environmental concentration (PEC_{max}) is 10 for the appropriate algal species[6].
- The PEC_{max} is used to calculate the $TER_{long\text{-}term}$ if it concerns a long-term static test (e.g., the 28 d *C. riparius* test in a water–sediment system in which the water is spiked) or if evidence suggests that in the long-term test, the time-to-effect period is short for relevant chronic endpoints like reproduction. In other cases, PEC_{TWA} values are used.
- The $TER_{long\text{-}term}$ should be at least 10 for the most sensitive animal species; the lower-tier risks to algae / aquatic plants are assessed by the TER_{acute} method only.

TER values are compared to the trigger values. If the TER is below the trigger, then the risk is not acceptable and has to be refined either by higher tier exposure or effect assessments. If the TER is above the trigger, then the substance passed the risk assessment and the risk is considered to be acceptable.

Higher-tier effect assessments may comprise laboratory toxicity tests with additional species, modified exposure studies with standard test species, population-level laboratory studies, indoor microcosm experiments, and outdoor mesocosm experiments [21].

[6] It is interesting to note, that in the guidance documents under the Biocide directive, REACH and the WFD and EC50 value for algae is alway considered as an acute value (i.e. the AF is at least 100). According to a comment by Els Smit (RIVM-NL) on this report [30], under the new regulation 1107/2009/EC for algae the EC10/NOEC (with a trigger value of 10) will be used instead of the EC50. Hence, this difference between the hazard assessment under the PPP authorisation and the hazard assessments under ther other three mentioned legislations might be overcome soon.

According to the Sanco Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC [25] the lower-tier AFs may be reduced if additional sensitive species are tested. The most frequently used higher-tier effect assessment procedures for the authorisation of PPPs are [21]:

- the species sensitivity distribution (SSD) approach
- the model ecosystem approach.

If the standard risk assessment indicates that one species of the basic set is considerably more sensitive, an SSD should be constructed that is representative for the sensitive taxonomic group. For the construction of a SSD, toxicity data for at least 8 different species from the sensitive taxonomic group are recommended. Brock *et al.* [21] summarised the data requirements as defined by the Guidance Document on Higher tier Aquatic Risk Assessment for Pesticides (HARAP [36]) as follows (Table 3.10).

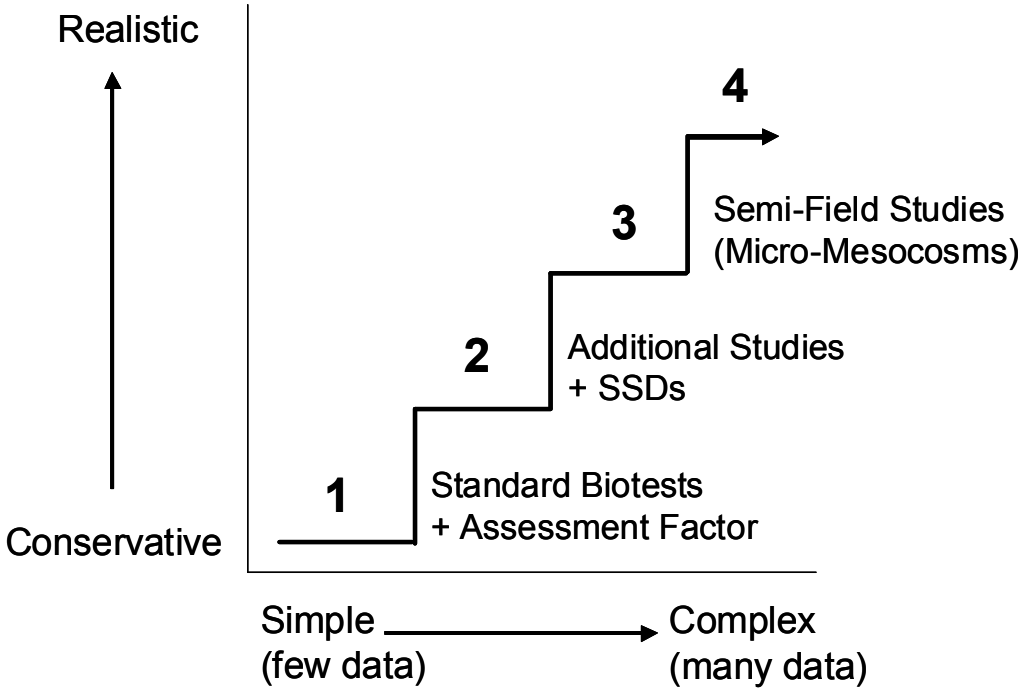

Figure 3.3: Tiered approach of the hazard assessment under the PPP authorisation. Adapted from [11].

Table 3.10: Data requirements for an SSD for PPP as defined by HARAP [36] and summarised by Brock et al. [21].

Type of PPP	No. of species of the sensitive taxonomic group
herbicides	≥8 vascular plants and algae
insecticides	≥8 arthropods
PPPs, where fish are the most sensitive species	≥5 (lower number because of animal welfare considerations)
PPPs with biocidal properties, such as several fungicides for which the basic set of standard test species shows a more or less equal sensitivity	≥8 different taxonomic groups (not specified by HARAP [36])

The third tier comprises field studies. Annex III of Directive 91/414/EEC and PSMV states that where the TER_{acute} is <100 for fish and *Daphnia*, less than 10 for alga or $TER_{long\text{-}term}$ is <10 for fish and *Daphnia*, "expert judgement" should be used to decide whether a microcosm or mesocosm study is necessary.

When evaluating micro- and mesocosms, important assessment endpoints are the $NOEC_{population}$, the $NOEC_{micro/mesocosm}$ (based on the most sensitive measurement endpoint/population), the $NOEC_{community}$ (usually based on multivariate analysis of community responses), and the no observed ecological adverse effect concentration, NOEAEC (usually based on the recovery potential of sensitive populations [25] [29]). The NOEAEC is defined as being the concentration at or below which no long-lasting adverse effects were observed in a particular higher-tier study (e.g. mesocosm). No long-lasting effects are defined as those effects on individuals that have no or only transient effects on populations and communities and are considered of minor ecological relevance (e.g., effects that are not shown to have long-term effects on population growth, taking into account the life-history characteristics of the organisms concerned) [25].

According to the Sanco Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC [25] these assessment endpoints can be used to derive an ecologically acceptable concentration (EAC). The EAC aims to take into account the spatiotemporal extrapolation of the results of the specific model ecosystem experiment, including information concerning the potential recovery of sensitive populations. The derivation of an EAC usually follows a case-by-case approach based on "expert judgement" [21].

Only the first tier hazard assessment is compulsory. If a PPP passed the first tier risk assessment (i.e. one safe use has been demonstrated), no further effects data are required. Therefore, the set of available data can differ for different PPP.

3.7.4. Data validation

In general the Sanco Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC document in line with Directive 91/414/EEC requires that the notifier should submit all available data which may be relevant for decision making. Data generated to fulfil data requirements should be from tests that were performed under GLP (Klimisch 1 [34]). If published data from the literature are used to fulfil data requirements (i) they must be derived in compliance with GLP or (ii) the notifier must justify why such data should be accepted.

3.7.5. Regulatory acceptable concentration (RAC)

During the aquatic risk assessment performed in the context of PPP authorization, toxicity exposure ratios (TER values) are usually calculated. The TER is thereby the quotient of the toxicity (e.g. EC_{50}, NOEC) and the exposure data (PEC value) and is compared to the appropriate trigger value. The risk assessment is passed when all TER values calculated in the highest tier exceed the corresponding trigger values.

A similar approach to perform an aquatic risk assessment under the PPP authorization legislation is to calculate the regulatory acceptable concentration (RAC), which is the most relevant toxicity endpoint (e.g. NOEC, EC_{50}, NOEAEC from a mesocosm study, HC_5 from an SSD EAC from all available ecotoxicity data) divided by the appropriate trigger value, and to compare these RACs directly with the relevant PEC value from the exposure site of the risk equation. In this case, the risk assessment is passed when the predicted exposure concentration is below the RAC.

3.8. Comparison of the different approaches to derive EQS

3.8.1. Comparison of hazard assessment under PPP authorisation and the WFD

The main differences between the hazard assessment under the WFD [17] and the hazard assessment under the PPP authorisation [35] [25] are summarised in Table 3.11.

Due to the applied exposure and risk assessment in the PPP authorisation process and the definition of ecologically acceptable concentrations based on NOEAEC values (community recovery principle), the risk assessment methods from Directive 91/414/EEC are not suitable to derive EQS values.

Nevertheless the TGD for EQS [17] concludes that: "although a risk assessment under 91/414/EEC should not be used directly to set an EQS, the list of endpoints produced for the review process and published on the internet by the Commission, provides a valuable data set. These data must, however, be supplemented with other ecotoxicity data where they are available, and also meet quality criteria."

Table 3.11: Main differences between the WFD and the PPP authorisation taken from the TGD for EQS [17] and Brock et al. [21].

The WFD follows a general approach and largely makes use of retrospective exposure assessments (monitoring data). The UP follows a prospective approach, and the risk assessment is based on specific uses of PPPs in certain crops.
The 91/414/EEC assessment is based on a field margin ditch, pond or stream scenario close to the point of application, whereas the WFD seeks to provide protection to all water bodies, including lakes, rivers, transitional and coastal waters.
The 91/414/EEC assessment makes an allowance for recovery from impacts. This does not feature at all in the Annex V methodology under WFD.
Under 91/414/EEC the risk is expressed as a Toxicity Exposure Ratio (TER), based on a direct comparison of toxicity values (without assessment factors) to predictions of concentrations in the environment (PEC). Hence risk assessment under 91/414/EEC does not use AFs applied to the toxicity side of the risk equation, but to the risk quotient, yielding a TER.
Both the WFD and the UP allow the SSD approach; however, different criteria are used in the construction of the SSD (number of taxa and taxonomic groups).
Algal toxicity data are dealt with differently. This can lead to different outcomes when algae are the critical data determining the threshold.
Under 91/414/EEC, acute toxicity data are never used to extrapolate to chronic toxicity values; risk assessment for chronic exposure is carried out using only chronic toxicity data.
There will not always be an evaluation of risks to sediment biota or risks from secondary poisoning, both of which may be required as part of QS development.

3.8.2. Comparison of the guidance document from the Netherlands and the TGD for EQS

Since the guidance document from the Netherlands is based on Lepper [15] and on the EU TGD from 2003 [8], it is in line with the TGD for EQS [17].

Maximum permissible concentrations (MPC) and maximum acceptable concentrations (MAC) are derived with the same methods as foreseen for the derivation of AA-EQS and MAC-EQS values.

Some additional points comprise the derivation of the negligible concentration (NC) and the serious risk concentration (SRC).

Despite its major similarity to the TGD for EQS the Dutch guidance document differs in some technical details [17]. The most prominent differences are:

- A different terminology is used: MPC and MAC instead of AA-EQS and MAC-EQS. The only reason for this deviating terminology is a strict discrimination between scientifically derived proposals and finally implemented EQS values. Hence, for the sake of consistency, the terminology of the TGD for EQS [17] will also be used for the EQS derived according to the Dutch guidance document.
- An AA-EQS can only be derived if at least one chronic NOEC is available.

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- The AF for deriving the MAC-EQS of substances with the potential to bioaccumulate is 1000 instead of the default AF of 100, because Lepper states that a factor of 100 may not always be justified for substances which bioaccumulate. [7]
- Salt and freshwater data may not be pooled.

3.8.3. Comparison of the Lepper method and the TGD for EQS

Although the TGD for EQS [17] is based on the Lepper method [15] for the derivation of EQS in water bodies, some technical differences exist. The most prominent differences are:

- If the base set is incomplete neither a MAC-EQS nor an AA-EQS can be derived according to the Lepper method.
- While according to the TGD for EQS an AA-EQS can be derived on the acute data alone, according to the Lepper method it can only be derived if at least one chronic NOEC is available.
- Salt and freshwater data may not be pooled.

3.8.4. Summary

While no significant methodological differences exist between the three guidance documents used under the WFD (the TGD for EQS, its predecessor the Lepper method and the Dutch TGD), which themselves are consistent with the guidance documents used under REACH and for the hazard assessment of biocidal products, the hazard assessment used under the PPP authorisation distinctly differs in several points (Table 3.11). The differences possibly having the highest influence on the result of the hazard assessment are: (i) the different use of data on algal toxicity (the use of the EC_{50} instead of the NOEC)[8], (ii) different data requirements for the SSD method (less data required under the PPP authorisation) and most notably (iii) recovery which is considered under the PPP authorisation but not under the WFD.

In the following chapter, the results of the compatibility assessment of the WFD and PPP authorisation methods for hazard assessment with the Swiss Water Protection law are compiled.

[7] According to a comment by Els Smit (RIVM-NL) an evaluation on this topic for the draft TGD on EQS has led to the conclusion that an additional factor is not needed [30].

[8] According to a comment by Els Smit (RIVM-NL) on this report [30], under the new regulation 1107/2009/EC for algae the EC10/NOEC (with a trigger value of 10) will be used instead of the EC50. Hence, this difference between the hazard assessment under the PPP authorisation and the hazard assessments under ther other three mentioned legislations might be overcome soon.

3.9. Compatibility of existing guidance documents for hazard assessment under the WFD and under the PPP authorisation with the Swiss water protection law

The protection goals of the different legislative documents can comparatively be summarized as follows (Table 3.12). It is important to note, that the Annexes 1 and 2 of the Swiss water protection ordinance (GSchV) have different legal statuses. Annex 1 defines the long-term ecological goals (ultimate aim) that should be considered when taking actions according to the GSchV. Annex 2 specifies water quality requirements that trigger action by authorities e.g. mitigation measures.

3.9.1. Protection goals under the WFD

The Water Framework Directive (WFD, Directive 2000/60/EC [3]) establishes a legal framework to protect and restore clean water across Europe and ensure its long-term, sustainable use. The Directive aims to ensure the good ecological and chemical status of surface water bodies across Europe. For surface waters this goal is defined by limits on the concentration of specific pollutants (i.e. EQS) of EU relevance.

A number of objectives are defined in the WFD concerning the protection of the water quality. The key ones at European level are general protection of the aquatic ecology, specific protection of unique and valuable habitats, protection of drinking water resources, and protection of bathing water. All these objectives must be integrated for each river basin. It is clear that the last three (special habitats, drinking water areas and bathing water) apply only to specific water bodies (those which are (i) supporting special wetlands, (ii) have been identified for drinking water abstraction and (iii) are generally used as bathing areas). In contrast, ecological protection should apply to all waters: the central requirement of the WFD is that the environment should be protected to a high level in its entirety.

For this reason, a general requirement for ecological protection, and a general minimum chemical standard, was introduced for all surface waters:

- Good ecological status is defined in Annex V of the Water Framework Proposal, in terms of the quality of the biological community (i.e. the structure and functioning of aquatic ecosystems), the hydrological characteristics and the chemical characteristics. The good ecological status is assessed with respect to (i) the composition and abundance of plant species, (ii) the diversity and abundance of invertebrate taxa and the abundance of the disturbance-sensitive fish species. Hence, the level of protection lies on the population and community level.
- Good chemical status is defined in terms of compliance with all the quality standards established for priority chemical substances at European level (i.e. EQS). The Directive also provides a mechanism for renewing these EQS and establishing new ones by means of a prioritisation mechanism for hazardous chemicals. This will ensure at least a minimum chemical quality, particularly in relation to very toxic substances, everywhere in the Community.

Table 3.12: Comparison of protection goals - overview.

Legislation	Level of Protection: individual level (I), population (P), community (C)		Time dimension	Special provisions		
	phrasing	Inter-pretation	Short (S) and/or long-term (L)	Olfactory Orientation of Animals	Fish spaw-ning grounds	Near zero concen-trations
GSchG (CH)	(i) health of humans, animals and plants; (ii) conservation of natural habitats, (iii) maintenance of waters to sustain natural fish populations	(I, P)	(S, L)	-	x	-
GschV (CH) – annex 1[1]	(i) prevention of any harmful effects on the biocoenoses of plants, animals and micro-organisms, (ii) prevention of interference with the biological processes, (iii) making possible the fulfilment of the basic physiological needs of plant and animal life, such as the metabolic processes, the reproductive processes and the olfactory orientation of animals, (iv) near zero concentrations of not naturally occurring substances	(I, P, C)	(S, L)	x	implied	x
GschV (CH) - annex 2[2]	preservation of fish-spawning grounds	(P)	(S, L)	-	x	-
GschV (CH) – annex 2 proposed new version	no impairment of reproduction and development of sensitive plants, animals and microorganisms	(P)	(S, L)	-	implied	-
WFD (EU)	(i) good ecological status (quality of the structure and functioning of aquatic ecosystems), (ii) composition and abundance of plants, (iii) diversity and abundance of invertebrate taxa, (iv) abundance of the disturbance-sensitive fish species	(P, C)	(S, L)	-	implied	only for marine and coastal waters, NL: x

Legislation	Level of Protection: individual level (I), population (P), community (C)		Time dimension	Special provisions		
	phrasing	Inter-pretation	Short (S) and/or long-term (L)	Olfactory Orientation of Animals	Fish spawning grounds	Near zero concentrations
91/414/EEC (EU), PSMV (CH version 15.09.2010)	Main text: (i) ensure a high level of protection of both human and animal health and the environment (ii) no unacceptable influence on the environment with regard to: its fate and distribution in the environment, particularly contamination of water including drinking water and groundwater and its impact on non-target species Annex 6: (iii) no long-term repercussions for the abundance and diversity of non-target species Aquatic guidance document (Sanco [38]): (iv) no decrease in biodiversity (v) no impact on ecosystem functioning and functionality (vi) no decrease in perceived aesthetic value or appearance of the water body	(P, C)	(L) short-term effects only for fish	-	-	-
1107/2009/EC (EU)	Main text: (i) ensure a high level of protection of both human and animal health and the environment (ii) no unacceptable effects on the environment with regard to: fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation, impact on non-target species, **including the ongoing behaviour of those species and its impact on biodiversity and the ecosystem**	(P, C)	(L)	maybe implied	-	-

[1] defines only the general goal for water quality but has no legal binding with respect to e.g. mitigation measures

[2] specific requirements that trigger legal action (e.g. mitigation measures)

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The requirement of the WFD that the ecological protection should apply to all waters is in line with the area of validity of the Swiss water act as defined in Art. 2 GSchG: "the present law shall apply to all surface and subterranean waters" [1]. However, as Ralf Schulz and Sebastian Stehle from the University Koblenz-Landau in Germany [28] as well as Tobias Frische and Jörn Wogram from the UBA in Germany [37] point out, it is important to reflect that the effective spatial application depends on the monitoring sites, i.e. the water bodies in which compliance with the protection goals is actually checked. Under the WFD (Annex II) [3] the regulations for an operational monitoring target at bigger flowing waters (catchment area ≥10 km^2 or surface area ≥0.5 km^2).Additionally the requirements of the WFD are in line with the purpose of the Swiss water protection law (GSchG), i.e. to protect waters against harmful effects. In the context of EQS the main focus of the GSchG lies on:

- the health of humans, animals and plants (i.e. focus on the individual)
- the conservation of natural habitats for indigenous animals and plants (i.e. focus on the population)
- the maintenance of waters to sustain natural fish populations (i.e. focus on the population).

This indirectly implies also the protection on the community level.

The protection goals behind the EQS derivation following the WFD are in line with the ones outlined in Annex 1:

- Other pollutants which could enter the water as a result of human activities should not have any harmful effects on the biocoenoses of plants, animals and micro-organisms (i.e. community level) and on the utilisation of the water.
- Other pollutants which could enter the water as a result of human activities should not interfere with the biological processes making possible the fulfilment of the basic physiological needs of plant and animal life, such as the metabolic processes (individual level), the reproductive processes (population level) and the olfactory orientation of animals (individual level).

and Annex 2 of the GSchV [2]:

- The water quality must be such that fish-spawning grounds are preserved.

as well as with the proposed new version of Annex 2 [38]:

- The water quality must be such that substances, which can pollute water bodies also in low concentrations and enter the water bodies through human activities (micropollutants), do not impair the reproduction (population level) and development (population level) of sensitive plants, animals and microorganisms.

The reference to metabolic processes and the olfactory orientation of animals implies that also endpoints that are not directly linked to reproductive success may be relevant for EQS setting, and hence it can be concluded that the focus of the GSchG and GSchV (Annex 1) is not only on effects on populations, but also on effects that manifest themselves primarily at the individual level.

The fact that in contrast to the WFD the focus of the protection goals of the GSchG and the GSchV (Annex 1) not only lies on the population level but also on the individual level may affect the EQS derivation. This can be illustrated at 2 examples: Diuron and MTBE.

Diuron

Diuron is an active substance used in herbicides. Belonging to the chemical group of phenylurea herbicides, it inhibits the photosynthesis. In 2005 EQS values were derived for Diuron in accordance with Article 16 of the Water Framework Directive (2000/60/EC) [3] applying the Lepper method [15]. Algae proved to be the most sensitive taxonomic group and hence the EQS values were based on algal toxicity [39]. For algal toxicity the data used for the derivation of the EQS values were restricted to values for the inhibition of the growth rate (population level). Hence, studies on the inhibition of photosynthesis (individual level) were not considered. If the EQS derivation would be based on the protection goals of the GSchG and the GSchV (Annex 1), data on photosynthesis would also have to be considered, since an inhibition of the photosynthesis would affect the health of the algae (GSchG) and would show an interference with metabolic processes (GSchV - Annex 1). Although Annex 1 does not trigger legal action, the ecological targets described in Annex 1 have to be considered with all measures under the GSchV [2].

It is not possible to decide, whether the consideration of data on photosynthesis would have led to lower EQS than the ones derived of 0.2 µg/l (AA-EQS) and 1.8 µg/l (MAC-EQS), since the document only lists data on algae growth [39]. However, two studies on algal photosynthesis inhibition published in 2005 report NOEC/EC10 values that are in the range of 0.1-0.2 µg/l [40, 41] and would hence lead to lower EQS. It has to be pointed out though, that the data were not assessed for their validity - a Klimisch assessment of these studies is still missing.

MTBE

During a risk assessment for MTBE published by the European Chemicals Bureau in 2002 concern was raised that MTBE might cause avoiding behaviour in fish. The risk assessment was performed according to a predecessor [42] of the TGD on RA [8]. Although the aquatic toxicity of MTBE was quite low ($PNEC_{aquatic}$ of 2.6 mg/l and PNEC aquatic_intermittent of 13.6 mg/l), the rather low human taste thresholds of 2.5-680 µg/l MTBE in water indicated that the PNECs might not be protective enough against avoiding behaviour of fish. As a consequence, a clarifying study was performed, in which the swimming behaviour of eels was tested under an exposure of 30 µg/l MTBE [43]. The study did not show avoidance behaviour but an attraction behaviour caused by MTBE. This was explained with the known feeding strategy of eels which is based on a preference behaviour towards organic molecules which are indicative for decaying organic material [43]. Since no avoidance was observed, it was concluded, that a reduction of the $PNECs_{aquatic}$ was not necessary. When considering the protection goals from the GSchV (Annex 1) though, it has to be clarified whether this attraction behaviour could be relevant for EQS setting with respect to the olfactory orientation of animals (individual level).

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3.9.2. Protection goals under the PPP authorisation

Annex VI of the Council Directive 91/414/EEC and the PSMV [44] defines that it shall be ensured that the use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species. This remains unchanged in the new Swiss and EU PPP legislation which will come into force in June 2011. It is interesting to note however, that in the main text of 1107/2009/EC [18], the new EU legislation, the approval criteria have slightly been changed compared to the approval criteria under 91/414/EEC. In article 4 point 3 (e) it says that a PPP (ii) shall have no impact on non-target species, including the ongoing behaviour of those species and (iii) it shouldn't have an impact on biodiversity and the ecosystem.

Moreover, the following unacceptable effects of contaminants are defined in the Sanco Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC [25]:

- decrease in biodiversity
    - overall species richness and densities
    - population densities of ecological key species
    - population densities of indicator species
- impact on ecosystem functioning and functionality
    - water quality parameters (e.g. increase of toxic algae; oxygen depletion)
    - harvestable resources (e.g. fish)
- decrease in perceived aesthetic value or appearance of the water body
    - disappearance of species with a popular appeal (e.g. dragonflies; water lilies)
    - visual mortality of individuals of fish, frogs, water fowl and other vertebrates.

Since the new guidance document is not available yet, it cannot be judged whether there will be any relevant changes with respect to the protection goals under the PPP legislation.

There are a lot of similarities between the protection goals under the PPP authorization and the protection goals under the Swiss water protection law. Both aim at the protection of structure and functioning of ecosystems by protecting against effects on the population and community level. Moreover, the special focus on fish can be found under the Swiss water protection law as well as under the PPP authorization. However, a distinct difference lies in the temporal dimension: short-term effects are acceptable under the PPP authorization (as long as they have no long-term repercussions or cause death of fish) while the Swiss water protection law implies the protection against short- as well as long-term effects, since the GSchG aims at protecting the health of humans, animals and plants, as well as their physiological needs.

3.9.3. Summary

GSchV and WFD have very similar protection goals:

- protection on the population and community level, but
- GSchV extends the goals to the individual level, i.e. olfactory orientation and the protection of metabolic processes.

GSchG focuses primarily on the health of the plants or animals, which can be interpreted in the way that the relevance of an effect for the population is not mandatory but that all effects observed on the individual level are relevant effects (e.g. physiological endpoints like inhibition of photosynthesis, histopathological effects and blood plasma levels). This indirectly also implies the protection on the population and community level which are protected under the WFD. It can be concluded that the Swiss water protection law is compatible with the WFD with respect to the protection on the population and community level but goes even further than the WFD, since its protection goals also encompass effects on the individual level.

Like in the WFD the focus of the PPP authorisation also lies on the population and community level, but the focus is more on the sustainability of the populations. Further more, short-term effects are tolerated under 91/414/EEC, as long as they do not lead to any long-term repercussions or cause the death of fish. It can be concluded that the protection goals of the PPP authorisation are not compatible with the Swiss water protection law since short-term effects are tolerated.

3.9.4. Conclusion

It can be concluded that EQS values defined in accordance with the WFD seem to be generally in compliance with the purpose of the Swiss water protection law. However, to ensure complete compliance the set of relevant endpoints might have to be widened to include also effects which manifest themselves mainly on the individual level with an unproven relevance to the population level.

The general agreement is additionally expressed by the proposed amendment of Annex 2 GSchV phrasing the general protection goal of the Swiss law in the area of micropollutants [45, 46]:

> ”Substances that could pollute waters even at low concentrations and that end-up in waters by human activity (micropollutants) do not affect the reproduction and development of sensitive plant and animal species and microorganisms.”

It can be concluded that the WFD and its TGD for EQS is compatible with the GSchG and the GSchV, if the protection goals that are unique for the GSchG and the GSchV are additionally considered when selecting the relevant data for the EQS setting.

4. Case studies

Based on the review and the query, the following guidelines were selected for the case studies: Lepper 2005 [15], draft TGD for EQS [17], and the Dutch guidance document for the derivation of EQS [16]. In general, the selected guidelines use the same methods. However, they differ in the detailed guidance they give for the actual EQS derivation. Therefore, the detailed methods were compared, before the case studies were actually performed. The data for the case studies were compiled (i) directly from different data bases (ECOTOX[9], PESTICIDEINFO[10], HSDB[11], EU[12], EFSA[13], INERIS[14], FOOTPRINT[15], webTOX[16], eChemPortal[17], WFD UK TAG[18], OPP[19], AGRITOX[20], RIVM[21], UK pesticides[22]), (ii) from the scientific literature (Sciencedirect[23], Web of science[24] and/or Scopus[25]), and (iii) from regulatory documents (DAR, EFSA conclusion, national EQS derivations).

The compiled data were analysed with respect to their relevance for EQS derivation and their reliability according to the different guidelines. Subsequently, the long- and short-term EQS were derived. If the EQS differed between the guidelines, it was noted and discussed. If applicable, the derived EQS were compared to EQS values derived by other authorities. In case where there were differences in the EQS derivation by the different authorities, these were discussed.

[9] The ECOTOXicology database http://cfpub.epa.gov/ecotox/quick_query.htm

[10] Pesticide Action Network (PAN) Pesticide Database (http://www.pesticideinfo.org/)

[11] Hazardous Substance Data Bank (http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB)

[12] EU pesticides database(http://ec.europa.eu/sanco_pesticides/public/index.cfm)EUpesticides database

[13] European Food Safety Authority (http://www.efsa.europa.eu/en/scdocs.htm)

[14] European Food Safety Authority (http://www.efsa.europa.eu/en/scdocs.htm)

[15] Functional TOOls for Pesticide RIsk assessmenNt and management (http://www.eu-footprint.org/ppdb.html)

[16] ETOX: Information System Ecotoxicology and Environmental Quality Targets (http://webetox.uba.de/webETOX/index.do?language=en)

[17] The Global Portal to Information on Chemical Substances (http://webnet3.oecd.org/echemportal/ParticipatingDb.aspx)

[18] UKTAG - Water Framework Directive Site (http://www.wfduk.org/LibraryPublicDocs/)

[19] Integrated pest management (http://www.ipmcenters.org/Ecotox/DataAccess.cfm)

[20] AGRITOX - Base de données sur les substances actives phytopharmaceutiques (http://www.dive.afssa.fr/agritox/php/fiches.php)

[21] National Institute for Public Health and the Environment (Netherlands) (http://www.rivm.nl/en/)

[22] Pesticides in UK (http://www.pesticides.gov.uk/psd_evaluation_all.asp)

[23] (http://www.sciencedirect.com/)

[24] (http://apps.isiknowledge.com/)

[25] http://www.scopus.com/home.url

4.1. Selection of active substances

For the case studies AS used in PPP were selected according to the following criteria:

- availability of ecotoxicity data
- availability of data from PPP registration (e.g., draft assessment reports (DAR), EFSA conclusion)
- balance between representatives from different pesticide classes (herbicides, fungicides, insecticides)
- different primary modes of action
- environmental relevance for Switzerland.

The resulting set of AS for the case studies is given in Table 4.1. It comprises the three herbicides Diuron, Mecoprop-P and Terbuthylazine, the fungicide Carbendazim as well as the two insecticides Imidacloprid and Diazinon. For all substances registration data from the European authorisation process are available. For some of these substances (Mecoprop-P, Carbendazim, Imidacloprid and Diazinon) also EQS have already been derived in some European member states and the complete reports are available. This leads to an even bigger data set. While the PPP registration is mainly based on data supplied by the notifier, the data sets for EQS derivation are supplemented by data from publicly available literature from peer reviewed scientific journals. All PPPs are listed in Annex 1 of the Swiss ordinance for plant protection products (PSMV) [4]. Most of the selected PPPs have a long history of application and were commercialised before 1980. Only Imidacloprid was commercialised in the 1990s.

Table 4.1: Selected PPP for the case studies: Identity, primary mode of action, commercialisation, available regulatory documents.

PPP Class	PPP	CAS-No. [4]	CIPAC-No. [4]	Substance class	Primary mode of action	Commercia-lisation [47]	Available regulatory documents
Herbicides	Diuron	330-54-1	100	Phenylurea	Inhibition of the e⁻ transport in PSII [48]	1950s	DAR (EU)
	Mecoprop-P	16484-77-8	475	Phenoxyacetic acids	Auxin analogue with inhibition of root and shoot growth[26] [48]	1950s	DAR (EU), Review report (EU), Environment Agency (UK), ICPR
	Terbuthylazine	5915-41-3	234	Triazines	Inhibition of the e⁻ transport in PSII [48]	1960s	DAR (EU)
Fungicides	Carbendazim	10605-21-7	263	Benzimidazol-carbamates	Inhibition of β-tubulin synthesis [47]	1970s	Review report (EU), RIVM (NL)
Insecticides	Diazinon[27]	333-41-5	15	Organophos-phates	Inhibition of acetylcholinesterase [47]	1950s	DAR (EU), Environment Agency (UK)
	Imidacloprid	138261-41-3	582	Neonicotinoids	Antagonistic action by binding to postsynaptic nicotinic receptors in the central nervous system of insects [47]	1990s	DAR (EU), EFSA Conclusion (EU), RIVM (NL)

[26] This mechanism of action does not apply to algae - Junghans and co-workers have observed unspecific action through narcosis for a unicellular green alga [49]

[27] Marked for re-evaluation in Swiss plant protection products ordinance since 25.05.2008

4.2. Comparison of case study results with EQS derived by other authorities as well as with RAC values

In the case studies AA-EQS and MAC-EQS were derived for the six selected AS Diazinon, Imidacloprid, Diuron, Terbuthylazine, Mecoprop/Mecoprop-P, and Carbendazim by applying the following three methods: the Lepper Method [15] (referred as "LP" in Table 4.2 and Table 4.3), the draft TGD for EQS [17] (referred as "TG" in Table 4.2 and Table 4.3) and the Dutch national guidance document by van Vlaardingen and Verbruggen [16] (referred as "NL" in Table 4.2 and Table 4.3. An overview of the resulting AA-EQS and MAC-EQS is given in Table 4.2 and Table 4.3, respectively. Where available, the derived EQS were compared with EQS derived by other authorities as well as with the regulatory acceptable concentrations (RACs) that can be calculated from the authorisation documents prepared during the PPP authorisation.

The most prominent findings from the comparison of the different EQS are summarized in the following paragraphs.

Table 4.2: Comparison of the AA-EQS derived in the case studies with the AA-EQS derived by other authorities as well as with the regulatory acceptable concentrations (RACs) that can be derived from the PPP authorisation documents.

	AA-EQS (µg/l)									RAC (µg/l)	
	Derived in this project			Derived by other authorities / projects							
Substance	LP	TG	NL	EA (UK)	RIVM (NL)	ICPR	EU	Chèvre et al. 2006	OZ	CH	NL [50]
Diazinon	0.015	0.015	0.015	0.01				0.0027		n.d.	
Imidacloprid	n.p.	0.0134	0.0134		0.067					3.1	1.47
Diuron	0.046	0.046	0.046				0.2	0.15	0.02	n.d.	
Terbuthylazine	n.p.	0.12	n.p.[26]					0.38		1.2	
Mecoprop	180	180	180			18				n.d.	
Mecoprop-P	5.5	5.5	5.5	5.5						160	
Carbendazim	0.03	0.03	0.03		0.6				0.34	n.d.	

n.p.: data not sufficient for EQS derivation; n.d.: not determined; OZ: determined by the ecotox centre according to [17]

[26] According to a comment by Els Smit (RIVM-NL) a value would have been derived by the RIVM [30]. Although according to the Dutch TGD a long-term EQS may not be derived if the base set is incomplete (the acute toxicity to daphnids is missing), they would have regarded the requirement of a complete base-set fulfilled, because a chronic NOEC for *Daphnia magna* is available. Based on the data set used in this report a long-term EQS (MPC/AA-EQS) of 0.12 µg/l would result.

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Table 4.3: Comparison of the MAC-EQS derived in the case studies with the MAC-EQS derived by other authorities as well as with the regulatory acceptable concentrations (RACs) that can be derived from the PPP authorisation documents.

	MAC-EQS (µg/l)									RAC (µg/l)	
	Derived in this project										
Substance	LP	TG	NL	EA (UK)	RIVM (NL)	ICPR	EU	Chèvre et al. 2006	OZ	CH	NL.[50]
Diazinon	0.0049-0.049	0.015-0.049	0.015	0.02				0.14		n.d.	
Imidacloprid	n.p.	0.0134-0.1	0.0134-0.1		0.2					3.1	1.47
Diuron	0.01-0.1	0.046-0.1	0.046-0.1				1.8	1.3	0.06	n.d.	
Terbuthylazin	n.p.	n.p.	n.p.[27]					3.1		1.2	
Mecoprop	60-600	180-600	180-600			160				n.d.	
Mecoprop-P	2.4-24	5.5-24	5.5-24	24						160	
Carbendazim	0.07-0.7	0.07-0.7	0.07-0.7		0.6				0.56	n.d.	

n.p.: data not sufficient for EQS derivation; n.d.: not determined; OZ: determined by the ecotox centre according to [17]

4.3. Comparison of EQS derived in the case studies according to the three selected methods

- Not for all PPP AA-EQS and MAC-EQS values could be derived according to all methods applied in the case studies.
- The AA-EQS derived in the case studies according to the three methods (Figure 4.1) are very similar - only for Imidacloprid and Terbuthylazine differences were observed. For

[27] According to a comment by Els Smit (RIVM-NL) a value would have been derived by the RIVM [30]. Although according to the Dutch TGD a short-term EQS may not be derived if the base set is incomplete (the acute toxicity to daphnids is missing), they would have regarded the requirement of a complete base-set fulfilled, because a chronic NOEC for *Daphnia magna* is available, which shows that *Daphnia magna* is not the most sensitive species. Because of the known mechanism of action and the fact that algae and aquatic plants are much more sensitive than the other taxonomic groups present in the data set, they would have concluded that with the data on primary producers the most sensitive taxonomic group is present in the data set. Based on the data set used in this report a short-term EQS (MAC) between 0.12 and 1.02 µg/l would result.

these substances the data availability was not sufficient to derive AA-EQS according to all three methods.

- When the data availability was sufficient to derive AA-EQS according to all three methods, the derived values were identical.
- More differences were observed for the MAC-EQS derived in the case studies (Figure 4.2), especially for the values derived according to the Lepper method (LP) when compared to the TGD for EQS (TG) and the Dutch guidance document (NL).
- Please note that for the MAC-EQS only concentration ranges were determined. Therefore, for each method an upper as well as a lower MAC-EQS is given. A clearly defined value would result if “expert judgement” were applied, however, for the purpose of the project we decided not to perform this step. The guidance is not very specific with respect to the AF used for deriving the MAC-EQS based on the assessment factor method. While for the AA-EQS the AF method gives distinct AF, for the MAC-EQS the hazard assessor can lower the default AF of 100 to an AF of minimally 10 under certain conditions. However, any other value between 100 and 10 may also result according to “expert judgement”.
- Only for Diazinon a distinctive value resulted according to the Dutch TGD, because the high potential for bioaccumulation did not allow the lowering of the AF from 100 to 10. Since the resulting MAC-EQS was lower than the AA-EQS, the MAC-EQS was set equal to the AA-EQS.
- For Terbuthylazine no MAC-EQS could be determined, because the base-set was not complete.
- For none of the case studies the data were sufficient to derive the EQS with the SSD method. All EQS were derived using the assessment factor (AF) method.

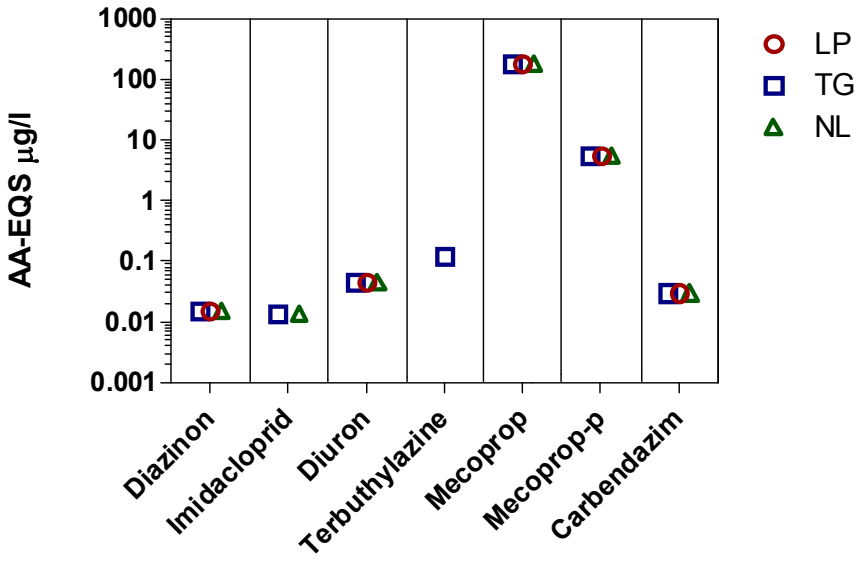

Figure 4.1: AA-EQS values derived in the case studies for the six selected active substances.
For Imidacloprid the AA-EQS could not be determined according to the method by Lepper and for Terbuthylazine the only successful method was the draft TGD for EQS.

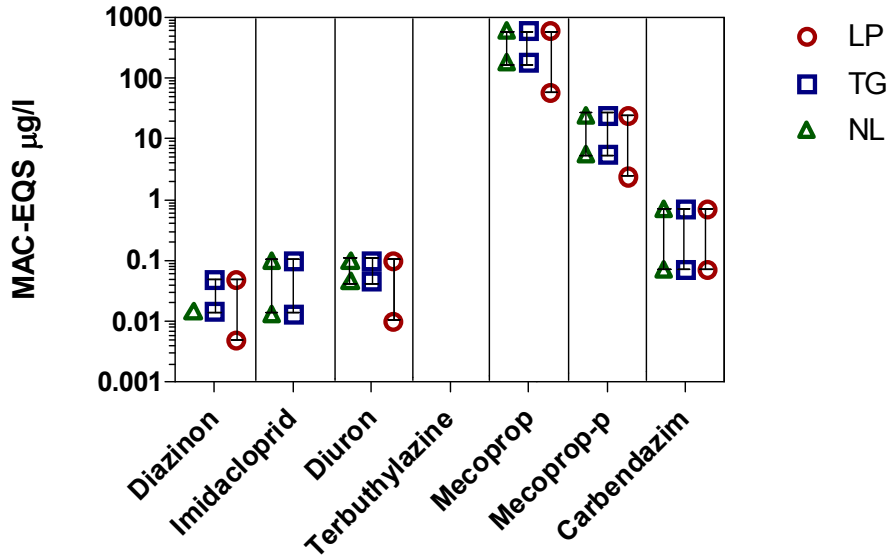

Figure 4.2: MAC-EQS values derived in the case studies for the six selected active substances.
Please note that for the MAC-EQS concentration ranges were determined. Therefore, for each method an upper as well as a lower MAC-EQS is given. For Terbuthylazine no MAC-EQS could be determined. Only for Diazinon a distinctive value resulted according to the Dutch TGD.

4.4. Comparison of EQS derived in the case studies with EQS derived by other authorities

- The AA-EQS derived in the case studies differed in five out of six cases from the AA-EQS derived by other authorities. The differences were within factors of 1.5-20 (Figure 4.3).

The MAC-EQS differed within a similar range (Figure 4.4). Please note that a comparison between the MAC-EQS derived in the case studies and the MAC-EQS derived by other authorities is difficult, because in the case studies the MAC-EQS were given in the concentration ranges and not in distinct values.

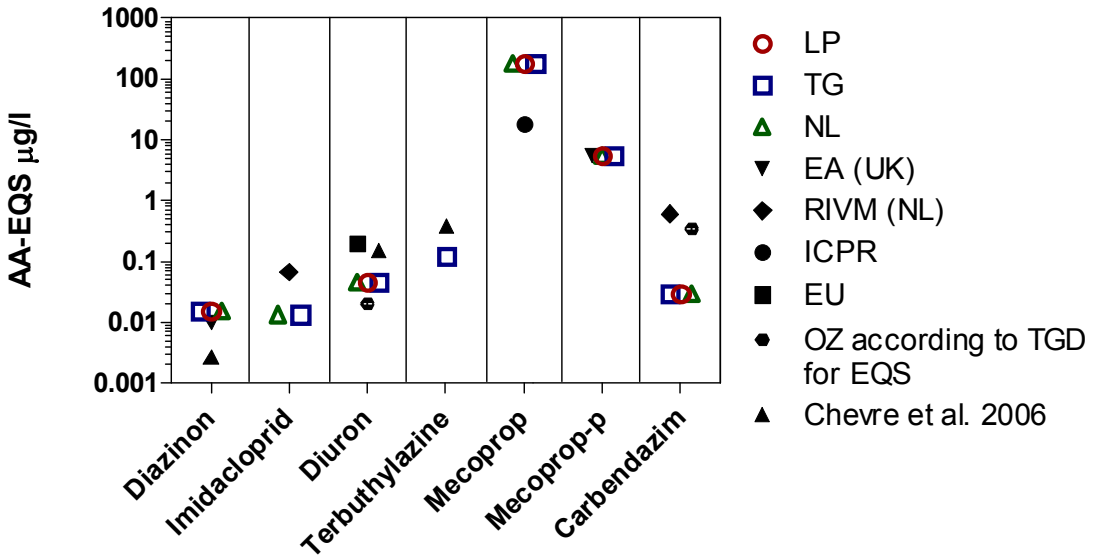

Figure 4.3: AA-EQS values derived in the case studies for the six selected active substances compared to the AA-EQS values derived by other authorities.

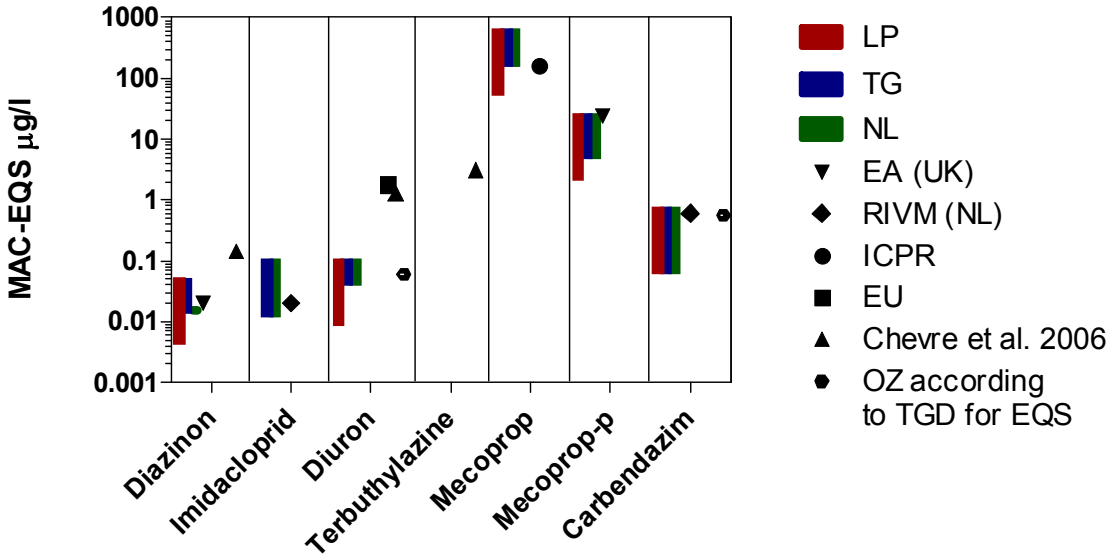

Figure 4.4: MAC-EQS values derived in the case studies for the six selected active substances compared to the MAC-EQS values derived by other authorities.

Please note that for the MAC-EQS concentration ranges were determined. Therefore, for each method an upper as well as a lower MAC-EQS is given. For Terbuthylazine no MAC-EQS could be determined. Only for Diazinon a distinctive value resulted according to the Dutch TGD.

4.5. Comparison of EQS derived in the case studies with the RACs

- Where available, the RACs are always higher than the derived EQS, irrespective of (i) the method used, (ii) the hazard assessor, and (iii) whether compared to the AA-EQS (Figure 4.5) or to the MAC-EQS (Figure 4.6).
- The comparison of the RACs derived for Imidacloprid in Switzerland and in The Netherlands shows that also RACs may differ depending on the hazard assessor.

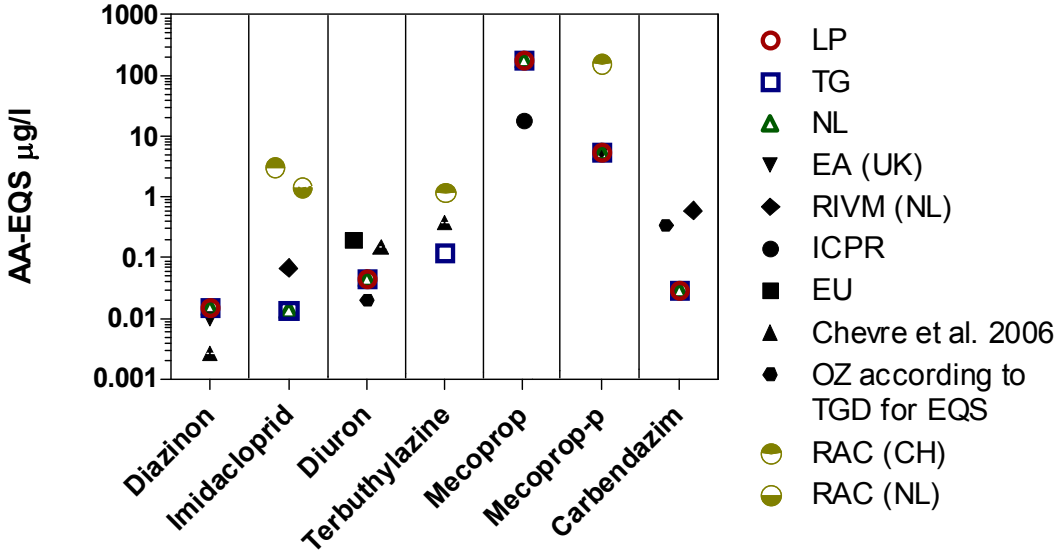

Figure 4.5: AA-EQS values derived in the case studies for the six selected active substances and AA-EQS values derived by other authorities compared to the RAC values derived during the PPP authorisation (values supplied by the FOAG and from [50]).

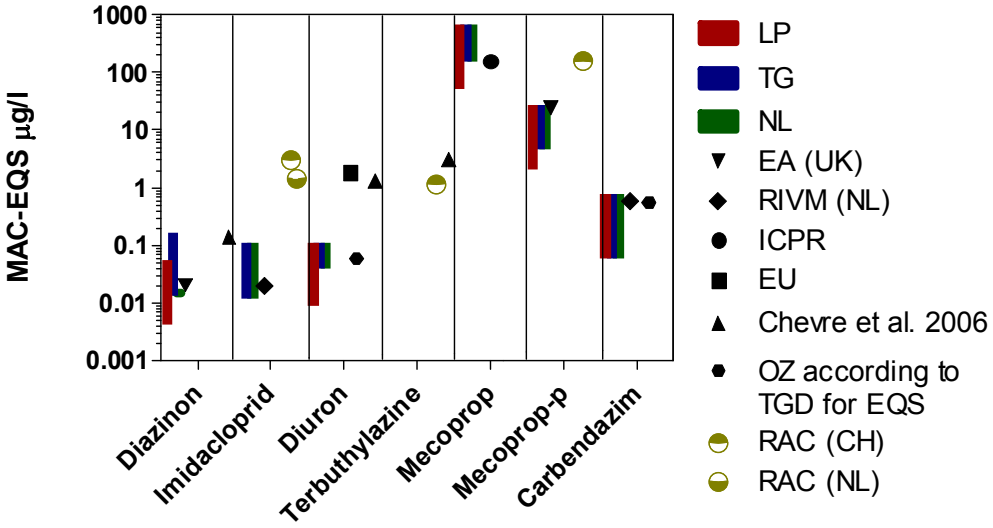

Figure 4.6: MAC-EQS values derived in the case studies for the six selected active substances and MAC-EQS values derived by other authorities compared to the RAC values derived during the PPP authorisation (values supplied by the FOAG) and from [50]).

Please note that for the MAC-EQS concentration ranges were determined. Therefore, for each method an upper as well as a lower MAC-EQS is given. For Terbuthylazine no MAC-EQS could be determined. Only for Diazinon a distinctive value resulted according to the Dutch TGD.

4.6. Comparison of EQS derived in the case studies according to the three selected methods with the general value of 0.1 µg/l

- For two of the six PPP (Mecoprop and Terbuthylazine) the derived AA-EQS are higher than the general value of 0.1 µg/l from the GSchV [2] (Figure 4.7).
- For Carbendazim the AA-EQS derived in the case studies is lower than 0.1 µg/l but the long-term EQS value derived by the RIVM in the Netherlands as well as the draft AA-EQS proposal derived by the Swiss Centre for Applied Ecotoxicology according to the draft TGD for EQS are both higher than 0.1 µg/l.
- For the other three PPP (Diazinon, Imidacloprid and Diuron) the derived AA-EQS are lower than the general value from the GSchV [2] of 0.1 µg/l.
- Even when compared to the short-term toxicity the general value from the GSchV [2] of 0.1 µg/l can be higher than the EQS. At least for Diazinon the MAC-EQS derived in the case studies, as well as the MAC-EQS derived by the Environment Agency (UK) were below 0.1 µg/l (Figure 4.8). Also for Imidacloprid and Diuron this may apply, since their MAC-EQS tend to be lower than 0.1 µg/l.

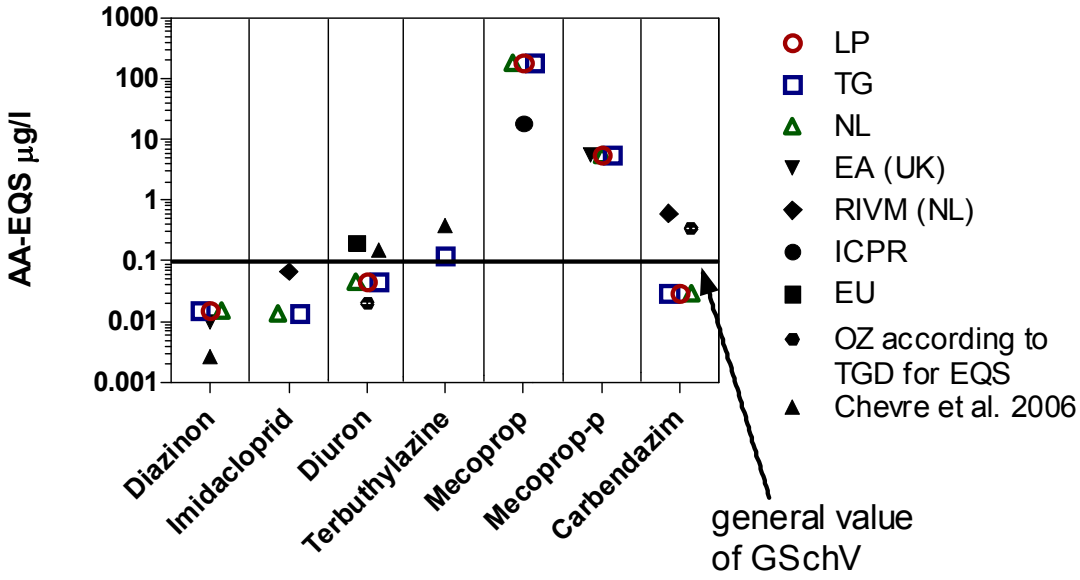

Figure 4.7: AA-EQS values derived in the case studies for the six selected active substances and AA-EQS values derived by other authorities compared to the general value of 0.1µg/l from the GSchV.

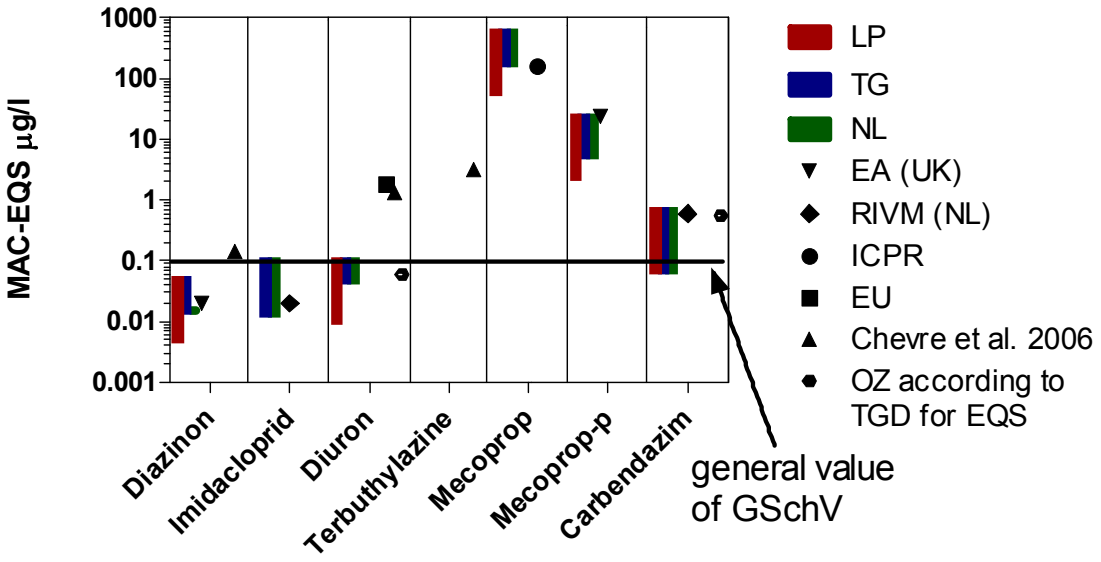

Figure 4.8: MAC-EQS values derived in the case studies for the six selected active substances and MAC-EQS values derived by other authorities compared to the general value of 0.1 µg/l from the GSchV.

Please note that for the MAC-EQS concentration ranges were determined. Therefore, for each method an upper as well as a lower MAC-EQS is given. For Terbuthylazine no MAC-EQS could be determined. Only for Diazinon a distinctive value resulted according to the Dutch TGD.

4.7. Factors influencing the outcome of the EQS derivation

The results from the case studies highlight several factors influencing the outcome of the EQS derivation, which are discussed in the following paragraphs.

4.7.1. The influence of the guidance document used

When the three different guidelines used under the WFD [15-17] are applied by the same hazard assessor on the same data set, the differences between the resulting EQS are small. However, three differences were identified which affected the outcome of the case studies.

For Diazinon, Diuron and Mecoprop differences in the MAC-EQS resulted, because both in the TGD for EQS [17] as well as in the Dutch guideline [15] the MAC-EQS is set to the value of the AA-EQS in cases where the MAC-EQS derivation would lead to a value lower than the AA-EQS. The maximal difference between the EQS was a factor of 3.

Another difference lies in the importance of the “base set”. For Terbuthylazine the AA-EQS could only be derived according to the TGD for EQS [17], since an acute EC_{50} for daphnid toxicity was

missing. According to the Lepper method [15] and the Dutch guidance document [16] a complete base set is needed. [28]

It can be concluded that the influence of the guidance document on the EQS derivation is rather small, since the three guidelines use to a large extent the same methods. Small deviations between the derived EQS can result from minor differences in the guidelines but never exceeded a factor of 3 in the case studies.

4.7.2. The influence of "expert judgement"

In the query a consensus was observed that "expert judgement" with respect to data evaluation and determination of the assessment factor has a great influence on the EQS derivation (c.f. Appendix 2). Indeed, this was confirmed when comparing the EQS derived in the case studies with EQS derived by other authorities.

For Imidacloprid the AA-EQS derived in the case studies and the AA-EQS derived by the RIVM (NL) are based on the same NOEC. Despite using the same guidance document [16] and the same data set, in the case studies an AF of 50 was chosen to be applied on the lowest NOEC of 0.67 µg/l for the insect *Chironimus tentans* while the RIVM used an AF of 10. The crucial point for selecting different AF was the crustacean *Cypretta seuratti,* for which the lowest acute EC_{50} value was found (1.0 µg/l). In the chronic data set the only NOEC for crustaceans was found for *Daphnia magna*, for which the acute EC50 was much higher than for *Cypretta seuratti* (85000 µg/l). It was argued in the case studies, that the most sensitive taxonomic group might not be present in the chronic data set and hence the AF has to be 50 instead of 10.

The example of the Imidacloprid toxicity can also be used to highlight the influence of the data availability. In chapter 9 of Appendix 1 (Case Studies) the EQS for Imidacloprid were assessed again with an extended data set. Data, which were previously not judged as reliable, because they were assigned a Klimisch score of 3 or 4, were added to the data set. The extended data set changed the selection of the AF, since with *Epeorus longimanus* also in the acute data set an insect was the most sensitive species showing an EC_{50} of 0.65 µg/l. Accordingly, for the extended data set an AF of 10 was applied on the NOEC for *Chironimus tentans* and the AA-EQS increased from 0.0134 µg/l to 0.067 µg/l.

Also for Carbendazim several interesting influences of "expert judgement" can be observed. Three AA-EQS are available for Carbendazim: 0.03 µg/l (case studies), 0.6 µg/l (RIVM NL) and 0.34 µg/l (derived by the Swiss Centre for Applied Ecotoxicology according to the draft TGD for EQS). All three derivations are based on the same dataset.

In the case studies the AA-EQS was based on the lowest available NOEC for *Daphnia magna* of 1.5 µg/l. Although also higher NOECs for *Daphnia magna* were available, it was argued that the life stage used in this specific study was responsible for the differences in the toxicity and this value represents the lowest NOEC for the most sensitive life stage of *Daphnia magna*. The RIVM

[28] It is interesting to note that according to a comment by Els Smit (RIVM-NL) [30] based on expert judgement RIVM would have regarded the requirement of a complete base-set fulfilled, because a chronic NOEC for *Daphnia magna* is available.

[51] however did not judge the differences in the life stages of the daphnids used in the studies as relevant and calculated the geometric mean of the values for the most similar life stages. This resulted in a value higher than the NOEC for the next most sensitive species *Dugesia lugubris* (3.4 µg/l). Hence, the AA-EQS derived by the RIVM for the AF method was 0.34 µg/l using an AF of 10. Also the Swiss Centre for Applied Ecotoxicology followed this approach when deriving independent EQS proposals according to the TGD for EQS.

While in the case studies as well for the independent EQS proposals by the Swiss Centre for Applied Ecotoxicology the data for deriving the AA-EQS based on an SSD were judged as being insufficient, the RIVM report [51] also lists an AA-EQS for Carbendazim from the SSD approach of 0.24 µg/l (HC5 of 0.71 µg/l with an AF of 3). This was done due to "expert judgement". It was argued that the mesocosm studies showed that macrophytes, the only missing mandatory taxonomic group, are rather insensitive towards Carbendazim.

For Carbendazim additionally two mesocosm studies were available, for which the lowest NOEC was 0.179 µg/l (average exposure concentration). The RIVM judged the mesocosm studies as relevant and reliable. Nonetheless, they noted that there is remaining uncertainty with respect to the sensitivity of fish which cannot be answered by the mesocosms [29]. Therefore they chose an AF of 3 and derived an AA-EQS of 0.60 µg/l which was then proposed as the overall AA-EQS for Carbendazim. In the derivation by the Swiss Centre for Applied Ecotoxicology the two mesocosm studies were not regarded as relevant for the ecotoxicity of Carbendazim, since no fish species were included in the mesocosms. However, the data from single species tests indicate that fish belong to the more sensitive taxa for Carbendazim. Instead the AA-EQS derived with the AF method based on *Dugesia lugubris* was proposed as the overall AA-EQS for Carbendazim. In the case studies the overall AA-EQS was also calculated with the AF method, but was based on the lowest NOEC observed for *Daphnia magna*.

It was shown that solely due to "expert judgement" the AA-EQS for Carbendazim can differ by a factor as high as 20 between 0.03 µg/l and 0.60 µg/l. Hence, it can be concluded that "expert judgement" has a stronger influence on the derived EQS values than the selection of the guidance document for EQS derivation. The Sanco Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC is excluded from this statement, since the details of the RAC derivation were not available and could hence not be evaluated with respect to "expert judgement".

[29] citation from the RIVM report (page 15) [51] : "However, fish are not present in the cosms, while the available data indicate that fish may be very sensitive. A valid 96-h LC50 of 7 µg/L is available for yolk-sac fry of *Ictalurus punctatus* (see Appendix 2). In view of the life stage, this test duration is chronic but since the endpoint is an LC50 rather than a NOEC, it cannot be added to the chronic dataset. It indicates, however, that there is remaining uncertainty as to whether the cosm data do fully cover the potentially sensitive species. Therefore an **assessment factor of 3** is kept on the lowest NOEC, resulting in an MPC_{cosms}**of 0.60 µg/L**" [103]."

4.7.3. The influence of the chemical identity

For Mecoprop ecotoxicity data are available for the two stereo-isomers Mecoprop and Mecoprop-P. The data indicate that the two isomers have a different potency. While for Mecoprop an AA-EQS of 180 µg/l was derived, the value for Mecoprop-P was only 5.5 µg/l. Hence, when collecting the data for EQS derivation, the chemical identity of the PPP applied in the respective ecotoxicity tests should be carefully evaluated. However, this has also an implication for the priority setting of PPP for which EQS should be derived. Usually, priorities are set according to the frequency of detections of the PPP in water samples. In the case of stereo-isomers like Mecoprop the isomers can usually not be discriminated in routine monitoring programs. In such a case, a further analysis of the predominant isomer would be necessary. If this should proof to be impossible, another possibility would be to use the precautionary principle by deriving EQS for both isomers and setting the EQS for the racemic mixture to the EQS of the most critical isomer.

5. Conclusions

5.1. All countries participating in the query use WFD compatible methods for the derivation of EQS or other effect based quality criteria

There are no fundamental differences between the three guidance documents, despite the fact that the Dutch approach comprises the derivation of the so-called negligible concentrations (NC), an approach that considers the possible occurrence of mixture toxicity. Although the three approaches are very similar, there are a lot of subtle differences between these guidelines, which are described in detail in chapter 1 of the Case Study Report (c.f. Appendix 1). There is a general trend to include more specific advice on special cases, the newer the guidance document is. This trend is likely to be driven by the number of EQS derivations being performed and the pitfalls encountered along this process.

It can be concluded that (i) in all neighbouring countries of Switzerland as well as in the Netherlands EQS are being derived for PPPs, (ii) they are generally based on ecotoxicological effects data, and (iii) for this purpose methods are used that are compatible with, or driven by the WFD [3]. Hence, when considering complementing the general value of 0.1 µg/l from the Swiss water protection ordinance [2] as the current quality criterion for PPP in flowing waters with a value based on ecotoxicological effects data, the methods developed in the EU for the implementation of the WFD [3] are highly relevant. This is especially important, if it is intended to derive EQS values which are consistent with the values derived in countries situated at the same river basins as Switzerland.

5.2. The draft guidance document for EQS derivation of the EU is compatible with the purpose of the Swiss water protection law

After having determined the high relevance of the WFD [3] for the EQS derivation in Switzerland, the compatibility of the respective guidance documents with the purpose of the Swiss water protection law [1] was evaluated.

The crucial issue in this context are the protection goals underlying the Swiss water protection law (GSchG [1]) including the Swiss water protection ordinance (GSchV [2]) on the one hand and the WFD [3] on the other hand. A detailed analysis can be found in chapter 3.9.

EQS values defined in accordance with the WFD seem to be generally in compliance with the purpose of the Swiss water protection law. All protection goals of the WFD [3] are also found in the GSchG [1] (specifically in the Annexes 1 and 2 of the GSchV [2]): the protection on the population and community level - both against short-term effects as well as against long-term effects. This temporal compliance between the protection goals of the Swiss water protection law and the WFD is important to note since the protection goals of the PPP authorisation generally only comprise long-term effects.

From the GSchG [1] however, some additional protection goals can be deduced: the protection of animals and plants[30, 31] against effects on the individual level and the conservation of water bodies in which the spawning of fish can take place (Annex 2 of the GSchV) [32]. Although not mentioned in a similarly specific way, in the WFD [3] water bodies in which the spawning of fish can take place are also protected as a result of protecting the structure and functioning of ecosystems as well as the hydrological characteristics of the water bodies (c.f. chapter 3.9). The protection on the individual level though has no counterpart in the WFD. Although effects on the individual level may be used for EQS derivation, their relevance on the population level has to be shown on a case by case basis [17].

Annex 1 of the GSchV [2] additionally protects the olfactory orientation of animals[31] and aims at near zero concentrations for not naturally occurring substances [33]. The aim of near zero concentrations of not naturally occurring substances can be found in the WFD [3] only with respect to marine and coastal waters. Hence, these two protection goals have no counterpart in the WFD [3]. It has to be kept in mind however, that the protection goals of Annex 1 of the GSchV do not trigger legal action (e.g. mitigation measures) in case of infraction, but only the more detailed protection goals named in Annex 2 are legally binding. Therefore, the lack of these two protection goals does not make GSchV [2] and WFD [3] incompatible.

[30] GSchG, p. 1, 1. section: general regulations, Art. 1 Aim: „This law aims at the protection of waters against adverse effects. It serves in particular: a. the health of humans, animals and plants..."
[31] GSchV, Annex 1 (Art. 1), section 1 surface waters, paragraph 3: „The water quality shall be as such, that....c. other substances, which can pollute waters and enter the water through human activities,... do not impair the biological processes for the maintenance of the basic physiological needs of plants and animals, e.g. metabolic processes, reproduction, olfactory orientation of animals,..."
[32] GSchV, Annex 2, section 1 surface waters, paragraph 3 general requirements: „The water quality must be as such, that....b. water bodies, in which the spawning of fish can take place, are conserved."
[33] GSchV, Annex 1 (Art. 1), section 1 surface waters, paragraph 3: „The water quality shall be as such, that....c. other substances, which can pollute waters and enter the water through human activities,... be present in the waters only in near zero concentrations, if they are not occurrung naturally in these waters."

Nonetheless, all measures taken under the GSchV must take ecological objectives for bodies of water (Annex 1) into account (Art 1 GschV). Thus, the protection goals named in Annex 1 of the GSchV [2] may serve as an argument for extending the endpoints judged as relevant within the context of the WFD [3] and the draft TGD for EQS [17] to effects on the individual level (e.g. physiological effects like inhibition of photosynthesis and olfactory orientation of animals). Concerning the aim of near zero concentrations it could be considered to adopt the approach of the negligible concentration from the Dutch TGD [16].

It can be concluded that the draft TGD for EQS [17], as the relevant technical guidance document for the implementation of the WFD [17], and the GSchG [1] (including Annexes 1 and 2 of the GSchV [2]) are compatible. The existing differences in the protection goals will only lead to a different weighting in exceptional cases during the process of EQS derivation. However, to ensure complete compliance the set of relevant endpoints might have to be widened to include also effects that manifest themselves mainly on the individual level, and may hence not be relevant for the population level, or their relevance for the population level has not yet been shown. The specific protection goals from the GSchG and the GSchV may give guidance to the hazard assessor concerning the selection of the relevant data.

5.3. Critical differences between the PPP authorisation and the WFD

For the six AS used in the case studies the highest quantitative difference was observed when comparing the EQS derived according to guidance documents designed for the implementation of the WFD and RAC values derived during the authorisation procedure for PPP (Figure 4.5 and Figure 4.6 in chapter 4.5). The RACs for Imidacloprid were higher than the derived AA-EQS by more than a factor of 230 (CH) and 109 (NL). For Mecoprop-P a factor of 30 was observed. For Terbuthylazine the difference is a bit smaller, but the RAC is still higher than the derived AA-EQS by a factor of 10.

A detailed overview of the differences between the PPP authorisation and the WFD is given in chapter 3.8.1 The main difference between the TGD for EQS [17] and the Sanco Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC [25] under the PSMV is the recovery from initial adverse effects that is accepted under the PPP authorisation. In contrast to that, recovery is not considered under the WFD. This may explain at least the differences between the RAC and the EQS for Imidacloprid, since the Swiss RAC was based on the NOEAEC of a mesocosm study and not on its NOEC. Another important difference lies in the different exposure assumptions: while the focus of the PSMV lies on the ditches at the edge of the field, the WFD seeks to protect all water bodies (c.f. table 3.11 in chapter 3.8.1.). This difference may affect the hazard assessment, e.g. when mesocosm studies are designed based on the ditch scenario with a single application of the test substance, or when single species lab studies are altered to reflect different exposure conditions like pulse exposure or water-sediment systems.

The hazard assessment under the PSMV is tiered, i.e. only when the risk assessment for the specific exposure scenario indicates an unacceptable risk, higher tier hazard assessment methods like the SSD approach or specifically designed micro- or mesocosm studies are performed. The exposure scenarios become more specific with each tier until an acceptable risk

results. In contrast to that, if the data allow for it all three approaches have to be performed when deriving EQS according to the TGD for EQS [17].

Another difference is the dataset used for the hazard assessment. While under the WFD all available reliable and relevant data have to be considered, the hazard assessment under the PSMV is usually based on the data specifically generated for the authorisation under GLP (Klimisch Score 1). Data from publicly available studies like scientific publications usually cannot replace original GLP-study reports to fulfil the data requirements. They can only be submitted as additional data but at least in the Annexes of 91/414/EEC, a comprehensive open literature search is not mandatory. It is possible however, that this will change under the new regulation 1107/2009/EC [30].

Finally, also the data requirements differ. If a PPP is known to specifically act as a herbicide, the availability of ecotoxicity data from taxonomic groups other than primary producers has a lower relevance when compared to the TGD for EQS [17]. In such a case e.g. SSDs can be performed solely on the data of primary producers, even when for less than the requested eight taxonomic groups data are available (see table 3.10 in chapter 3.7.3 and chapter 3.8.1).

5.4. Data validation and “expert judgement”

It has been shown that the results of the hazard assessment strongly rely on the assessment of the data quality. This assessment must be based on scientific arguments such as the ones proposed by Klimisch and co-workers [34], but it will finally rely on “expert judgement” and thus it is sensitive to scientific and cognitive variations [52]. Duchemin and co-workers [53] showed that scoring the reliability of 22 standard and non standard studies by 10 assessors led to more or less large variations. The results showed that the GLP quality assurance system may serve as a warranty that the study was conducted according to scientific standards. However, GLP is no warranty of scientific reliability as it has already been discussed by Becker and co-workers [54] and Myers and co-workers [55]. It mainly ensures that the execution of the study can be reconstructed in large detail. The study by Duchemin and co-workers [52, 53] further showed that most variations observed in the trial resulted from classifying the data between the categories reliable with or without restrictions (K2 or K1) or from classifying them between the categories reliable with restrictions and unreliable (K2 or K3). Errors between the categories K2 and K3 are regarded by the authors as the most critical errors since they decide whether a data point is correctly excluded from or correctly included in the set of critical data. They further pointed out that the Klimisch criteria do not necessarily force the assessor to reflect upon all parameters necessary to demonstrate reliability. This is reflected in the technical guidance documents [15-17] by giving guidance on the necessary information for each common standard test. Nonetheless, Duchemin and co-workers concluded that the validity assessment is also a question of the risk assessor’s confidence in the report or publication which may itself depend on the knowledge the assessor has with regard to the substance. As an example the authors give a report that lacks important information on the stability of the substance and hence can only be classified as reliable when further information on the stability is made available by other reports. As pointed out by Els Smit [30] also the size of the data set can have a strong influence on the validity assessment: with a small data set, the assessor might become less stringent, because otherwise an EQS cannot be derived. Duchemin and co-workers [52, 53] came to the conclusion

that in extreme cases the call for collegial assessment might become necessary to evaluate the reliability of some data.

Not only the assessment of the data validity was shown by Duchemin and co-workers to vary due to “expert judgement” [52]. They suggest that “expert judgement” will apply to three levels during the assessment of the environmental hazard: (1) the evaluation of the data validity, (2) the choice of different assessment factors for the same data set due to regulatory, cultural or experience differences of the assessors and (3) the choice of the critical data (assessment of data relevance).

The results of the present study underline this finding - all three factors could be identified as reasons for differences in EQS values due to “expert judgement”.

6. Recommendations for the derivation of EQS for PPP in Switzerland and outlook

6.1. The TGD for EQS is recommended for the derivation of EQS for AS from PPP in Switzerland

The TGD for EQS [17] is an important guidance document for the implementation of the WFD in the European Union and will be the EU master guidance document for EQS derivation for substances including PPP as soon as it is finalised. Since it is used for EQS derivation in the neighbouring countries of Switzerland, it will affect Switzerland, e.g., through the river basin management of the Rhine (ICPR). Hence, the TGD for EQS [17] will have a high relevance for Swiss running waters in the future and should be considered when implementing methods to derive EQS for AS from PPP in Switzerland.

With minor differences, the protection goals underlying the WFD [3] and its TGD for EQS [17] are in line with the protection goals of the GSchG [1] and the GSchV [2]. The detected differences had no influence on the derived EQS values in the case studies. However, to ensure complete compliance, the set of relevant endpoints might have to be widened to include also effects that manifest themselves mainly on the individual level, and may hence not be relevant for the population level (or their relevance has not been shown yet). It is recommended that the specific protection goals from the GSchG and the GSchV should give guidance to the hazard assessor during the selection of relevant studies.

It is further recommended to adopt the approach of the Dutch TGD to derive neglible concentrations (NC) by dividing the AA-EQS by 100 [16]. With this approach the ultimate protection goal of near zero concentrations (GSchV, Annex 1 [2]) can be approached. Moreover, with this NC approach the risk of the occurrence of mixture toxicity due to exposure towards more than one AS from PPP can be minimised.

Several studies have shown that the consideration of mixture toxicity is an important issue in ecotoxicology (Kortenkamp et al. [56] and references therein). It has also been demonstrated that EQS for single substances, may not be protective enough for surface waters. A study conducted in Dutch surface waters [57] was able to show for some water samples that the AA-EQS is not protective when several substances are present. At present several national and

international activities are taking place concerning the assessment and regulation of mixture toxicity (e.g. from Council of the European Union [58], the Society for Environmental Toxicology and Chemistry [59]). It is recommended to follow these activities in order to be able to assess the actual risk of mixture toxicity in the Swiss surface water bodies more precisely.

6.2. Data from the PPP authorisation are highly relevant for the EQS setting, but the hazard assessment procedures of the PSMV have shown to be not compatible with the GSchG

The large quantitative difference of the EQS derived according to guidance documents by the WFD with the RAC values calculated during the PPP authorisation process show that the hazard assessment performed during the PPP authorisation is not compatible with the WFD and is hence also not fulfilling the purpose for water quality criteria under the GSchG [21]. The key issue seems to be recovery, which is considered during PPP authorisation but is not compatible with the protection goals of the GSchG [21] and the GSchV [2].

Although a hazard assessment under the PPP authorisation should not be used directly to set an EQS, the list of endpoints produced for the review process and published on the internet by the Commission provides a valuable data set. These data must however, be supplemented with other ecotoxicity data where they are available, and also meet quality criteria. It should also be considered whether the data submitted for PPP authorisation are relevant for EQS-setting, since the exposure regime in the studies might reflect situations that are typical for the proposed use of the product.

6.3. The protection goals of the PPP authorisation are currently under revision

The protection goals underlying the PPP authorisation, which now are quite similar to the protection goals of the WFD (mainly the protection of the structure and functioning of ecosystems) may change with the revision of the Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001[25]) leading in the future to a new interpretation of protection goals for PPP. In the current process of revising this document it is suggested to replace the general protection goals by specific protection goal options that can be agreed with risk managers and other stakeholders via a consultation process in order to provide the framework within which appropriate risk assessment methodology can be developed for pesticides [60], i.e. these protection goals should be defined based on the „ecosystem services“ concept.

The „ecosystem services“ concept is based on the benefits people obtain from ecosystems [61]. Ecosystems are valuated in terms of what they do in relation to the support of human well-being ([62] as cited in [61]). Legislative requirements and criteria of naturalness are only regarded as a component of quality, but not as an exclusive goal [61]. Closeness to the natural state can be incorporated but is defined by the societies‘ desire for such a state.

The PPR Panel intends to use this general concept as input for the dialogue between risk managers and risk assessors during the problem formulation phase for the next steps of the

revision of the Guidance Document for Aquatic Ecotoxicology for which the Panel received the mandate in 2009 (EFSA-Q-2009-00001).

6.4. The Klimisch scoring system needs to be revised or amended

When performing the data validity assessment in the case studies, it became clear that the Klimisch criteria [34] are not informative enough for a thorough assessment of the data. In the case studies, the Klimisch criteria were applied very strictly and hence most data published in scientific journals were judged Klimisch 4 because methodological information in the scientific publications was not deemed sufficient to judge the data validity. Some of these studies however, were included nonetheless, because they were assessed Klimisch 2 by another authority (e.g. RIVM for Imidacloprid). Hence, the assessment of the data validity based on Klimisch scores alone can lead to a high influence of "expert judgement". This has also been shown by Duchemin and co-workers [52, 53] who concluded that the Klimisch scoring system in its current form cannot guarantee consistent validation between assessors.

The suitability of the Klimisch criteria for the assessment of the study reliability has not been very much discussed in published literature, so far [52]. Hobbs et al. [63] aimed to build a guide that could be implemented for almost any type of studies while Breton et al. [64] aimed to automate the analysis of fish, daphnids and algae OECD standard tests by a computer program. According to Duchemin et al. [52] both approaches are still needing improvements but can be regarded as valuable first steps towards a more systematic and reproducible data validation.

6.5. The general quality criterion from GSchV should be complemented by effect based EQS

The EQS derived for the selected AS ranged between 0.01 µg/l and 1000 µg/l. These, for some AS very high, deviations from the general value of 0.1 µg/l confirm, that for a comprehensive ecotoxicological assessment of the water quality effect based EQS for PPP are needed in Switzerland to complement the general value of 0.1 µg/l.

6.6. The influence of "expert judgement" should be balanced

EQS derivations can lead to different results, even if the same guidance document and the same data set is used. For the AA-EQS for Carbendazim differences of a factor of 20 were observed, which could be explained solely by the different weighting of the data by the different hazard assessors. Hence, "expert judgement" seems to have a major influence on the EQS derivation, although the guidance documents are quite detailed.

Considering the results obtained in this project, it is recommended to complement the general quality criterion of 0.1 µg/l for pesticides with effect based quality criteria according to the TGD for EQS [17], wherever possible. To balance the observed high influence of "expert judgement" on the EQS derivation, a balanced procedure for the derivation of EQS for AS used in PPP in Switzerland is proposed in (Figure 6.1).

The exchange with other hazard assessors in the field of EQS setting has substantially increased the quality of EQS derived by the Swiss Centre for Applied Ecotoxicology in the past. Especially the working group E (WG E) and the Multilateral Meeting (ML-Meeting) have been shown to be valuable platforms on EU level. It is recommended that these platforms should also be used for knowledge exchange concerning the derivation of EQS for AS used in PPP.

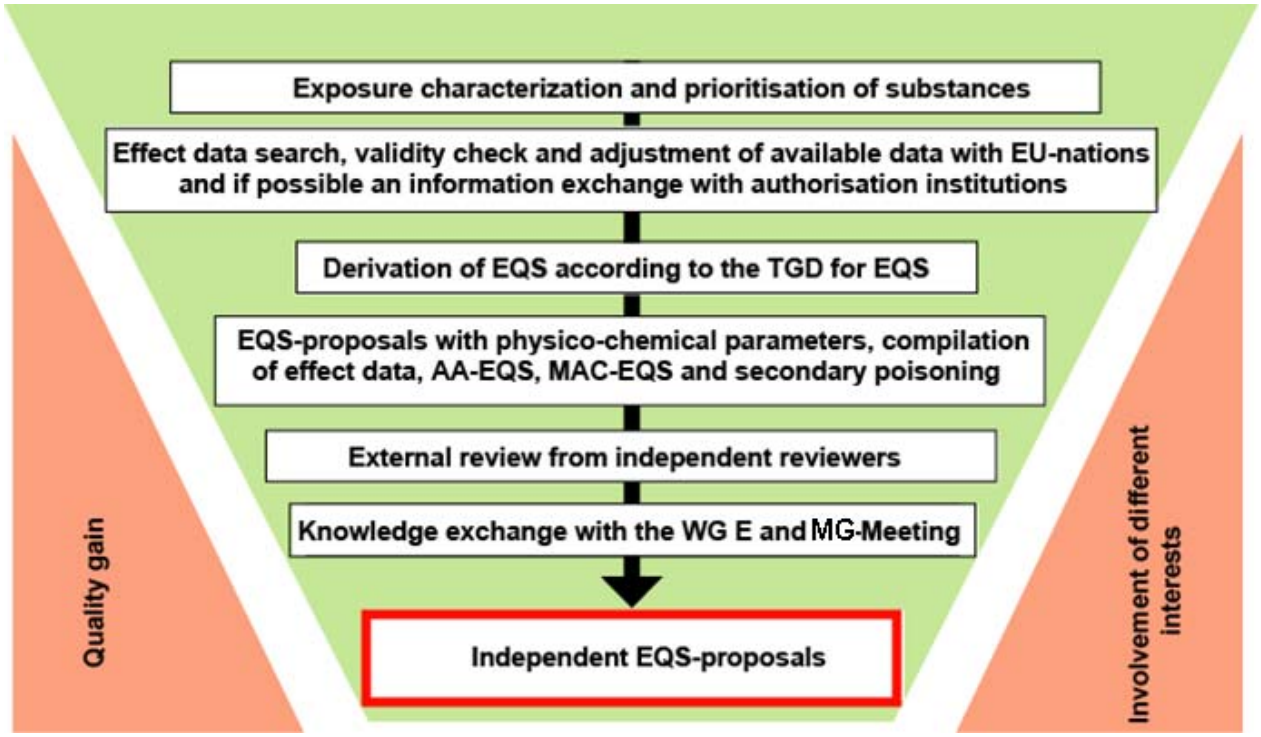

Figure 6.1: Proposal for a balanced derivation of EQS in Switzerland.
The working group E (WG E) and the Multilateral Meeting (MG-Meeting) are platforms at which the EQS assessors from the different EU nations perform an information exchange on EQS derivation and discuss the EQS derivations for priority substances.

7. References

1. Switzerland (1991). Federal Law on the Protection of Waters (Water Protection Law, GSchG) of 24 January 1991 (State of 1 August 2008). SR 814.20.

2. Switzerland (1998). Water Protection Ordinance (GSchV) of 28 October 1998 (State of 1 July 2008). SR 814.201.

3. European Union (2000). Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 Establishing a Framework for Community Action in the Field of Water Policy. OJ L 327, 22.12.2000.

4. Switzerland (2005). Verordnung vom 18. Mai 2005 über das Inverkehrbringen von Pflanzenschutzmitteln (Pflanzenschutzmittelverordnung, PSMV). SR 916.161.

5. Council of the European Communities (1991). Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market Official Journal L 230 , 19/08/1991 P. 0001 - 0032.

6. Chèvre, N., et al. (2006). Pestizide in Schweizer Oberflächengewässern: Wirkungsbasierte Qualitätskriterien. Gas Wasser Abwasser. 4/2006.

7. Chèvre, N., et al. (2006). Including mixtures in the determination of water quality criteria for herbicides in surface water. Environmental Science and Technology. 40(2): p. 426-435.

8. Commission of the European Communities (2003). Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and of the Council concerning the Placing of Biocidal Products on the Market.

9. Amt für Umwelt und Energie des Kantons St.Gallen (AFU) Abteilung Abwasser und Gewässerqualität (2008). Pestizide in St.Galler Fliessgewässern Auswertung der Messkampagnen 2002 und 2006: St. Gallen, Switzerland.

10. Huser, M. (2009). Pflanzenschutzmittelbelastung von Baselbieter Oberflächengewässern. Bau und Umweltschutzdirektion Kanton Basel-Landschaft - Amt für Umweltschutz und Energie. Liestal, Switzerland.

11. Knauer, K., et al. (2010). Aquatische Risikobewertung von Pflanzenschutzmitteln. Agrarforschung Schweiz 1(10): p. 372-377.

12. Commission of the European Communities (2006). 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. OJ L 396, 30.12.2006, consolidated version of 20.02.2009.

13. European Chemicals Agency (2008). Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.10: Characterisation of dose [concentration]-response for environment.

14. Lepper, P. (2002). Final Report of the Study Contract No. B4-3040/2000/30637/MAR/E1: Identification of quality standards for priority substances in the field of water policy. Towards the Derivation of Quality Standards for Priority Substances in the Context of the Water Framework Directive. (4 September 2002).

15. Lepper, P. (2005). Manual on the Methodological Framework to Derive Environmental Quality Standards for Priority Substances in accordance with Article 16 of the Water Framework Directive (2000/60/EC) Fraunhofer-Institute Molecular Biology and Applied Ecology. Schmallenberg, Germany.

16. van Vlaardingen, P.L.A. and E.M.J. Verbruggen (2007). Guidance for the Derivation of Environmental Risk Limits within the Framework of 'International and National Environmental Quality Standards for Substances in the Netherlands' (INS) National Institute for Public Health and the Environment RIVM report 601782001/2007. Bilthoven, the Netherlands.

17. Commission of the European Communities (2010). Chemicals and the Water Framework Directive: Technical guidance for deriving environmental quality standards Draft 2010 (29/01/2010).

18. European Parliament and Council of the European Union (2009). Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009.

19. Council of the European Communities (1998). Council Directive 98/83/EC of 3 November 1998 on the Quality of Water Intended for Human Consumption. Official Journal L 330 , 5/12/1998.

20. Switzerland, E. (2009). Verordnung des EDI über Fremd- und Inhaltsstoffe in Lebensmitteln (Fremd- und Inhaltsstoffverordnung, FIV) vom 26. Juni 1995 (Stand 1. October 2009). SR 817.021.23.

21. Brock, T., et al. (2006). Aquatic Risks of Pesticides, Ecological Protection Goals, and Common Aims in European Union Legislation. Integrated Environmental Assessment and Management. 2(4): p. e20-e46.

22. European Parliament and Council of the European Union (1998). Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 Concerning the Placing of Biocidal Products on the Market. OJ L 123/1, 24.04.1998.

23. European Chemicals Agency (2008). Guidance on Information Requirements and Chemical Safety Assessment. http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm.

24. International Commission for the Protection of the Rhine (ICPR) (2009). Ableitung von Umweltqualitätsnormen für die Rhein-relevanten Stoffe. Bericht Nr. 164 vom Juli 2009.

25. European Commission Health & Consumer Protection Directorate-General (2002). Working Document - Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC. Sanco/3268/2001 rev.4 (final). 17 October 2002.

26. European Union (2008). Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council. OJ L 348, 24.12.2008.

27. Posthuma, L., G.W. Suter, and T.P. Traas (2002). Species Sensitivity Distributions in Ecotoxicology. Boca Raton, FL, USA: Lewis.

28. Schulz, R. and S. Stehle (2010). External Review for Report "Aquatic Risk of Plant Protection Products: A Comparison of Different Hazard Assessment Strategies for Surface Waters in Switzerland, version 08 Nov 2010.

29. De Jong, F.M.W., et al. (2008). Guidance for summarizing and evaluating aquatic micro- and mesocosm studies. RIVM Report 601506009, Bilthoven, the Netherlands, 59 p.

30. Smit, E. (2010). Comments by Els Smit, RIVM-NL, on the report "Aquatic Risks of Plant Protection Products: A Comparison of Different Hazard Assessment Strategies for Surface Waters in Switzerland" version 8 November 2010.

31. European Chemicals Agency (2008). Guidance on Information Requirements and Chemical Safety Assessment. Part B: Hazard Assessment. October 2008 (version 1.1).

32. Council of the European Communities (2008). Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods persuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Official Journal L 142 , 31/5/2008.

33. Comission of the European Communities (2009). Commission Regulation (EC) No 761/2009 of 23 July 2009 amending, for the purpose of its adaptation to technical progress, Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). OJ L 220, 24.08.2009.

34. Klimisch, H.J., M. Andreae, and U. Tillmann (1997). A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data. Regulatory Toxicology and Pharmacology. 25(1): p. 1-5.

35. Council of the European Communities (1997). Council Directive 97/57/EC of 22 September 1997 establishing Annex VI to Directive 91/414/EEC concerning the placing of plant protection products on the market. Official Journal L 265 , 27/09/1997 P

36. Campbell, P., et al. (1999). Guidance Document on Higher Tier Aquatic Risk Assessment for Pesticides (HARAP). SETAC, Brussels.

37. Frische, T. and J. Wogram (2010). Fachliche Stellungnahme zum Report "Aquatic Risks of Plant Protection Products: A Comparison of Different Hazard Assessment Strategies for Surface Waters in Switzerland" (Version vom 08.11.2010).

38. Bundesamt für Umwelt BAFU (2009). Proposed new version of Annex 2 of the Swiss water protection ordinance dating 18 November 2009.

39. Anonymus (2005). Common Implementation Strategy for the Water Framework Directive. Environmental Quality Standards (EQS). Substance Data Sheet Priority Substance No. 13 Diuron CAS-No. 330-54-1. Final version. Brussels, 15 January 2005.

40. Bengtson Nash, S.M., et al. (2005). The selection of a model microalgal species as biomaterial for a novel aquatic phytotoxicity assay. Aquatic Toxicology. 72(4): p. 315-326.

41. Podola, B. and M. Melkonian (2005). Selective real-time herbicide monitoring by an array chip biosensor employing diverse microalgae. Journal of Applied Phycology. 17(3): p. 261-271.

42. European Comission (1996). Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances. pp. 740. Luxembourg: European Commission, Office for Official Publications of the European Communities.

43. European Chemicals Bureau (2002). Addendum to the Environmental Risk Assessment for tert-Butyl methyl ether (MTBE) - CAS-No. 1634-04-4. http://ecb.jrc.ec.europa.eu/esis/.

44. Council of the European Communities (2005). Council Directive 2005/25/EC of 14 March 2005 amending Annex VI to Directive 91/414/EEC as regards plant protection products containing micro-organisms Official Journal L 090 (08/04/2005): p. 0001 - 0034.

45. Switzerland (2009). Water Protection Ordinance (GSchV), amendment, draft of 18 November 2009.

46. Federal Office for the Environment (2009). Eintrag von organischen Spurenstoffen in die Gewässer. Erläuternder Bericht zur Änderung der Gewässerschutzverordnung (GSchV). Entwurf vom 18. November 2009.

47. Tomlin, C.D.S., ed. The Pesticide Manual. 14th ed. 2006, British Crop Protection Council: Alton, Hampshire, UK.

48. Devine, M., S.O. Duke, and C. Fedtke (1993). Physiology of herbicide action. London: Prentice-Hall.

49. Junghans, M., et al. (2006). Application and Validation of Approaches for the Predictive Hazard Assessment of Realistic Pesticide Mixtures. Aquatic Toxicology. 76(2): p. 93-110.

50. Kalf, D. (2010). Pesticides in the Dutch part of the River Rhine basin: Vision on harmonizing pesticide regulation with the Water Framework Directive. http://www.iksr.org/fileadmin/user_upload/Dokumente_de/Symposien_u._Workshops/Pesticides_in_the_Dutch_part_of_the_River_Rhine_basin-DenisKalf-EN.pdf.

51. Dang, Z. and E. Smit (2008). Environmental risk limits for carbendazim, in Letter report 601716014/2008. RIVM - National Institute for Public Health and the Environment: Bilthoven, the Netherlands.

52. Duchemin, M.B., et al. (2010). External Review Aquatic Risks of Plant Protection Products: A Comparison of Different Hazard Assessment Strategies for Surface Waters in Switzerland.

53. Duchemin, M.B., et al. (2010). Reliability Assessment Process of Standard Data for the Environmental Risk Assessment for the Purpose of Regulations of Chemicals. SETAC, Seville. MO 446.

54. Becker, R.A., et al. (2009). Good laboratory practices and safety assessments. Environmental Health Perspectives. 117(11).

55. Myers, J.P., et al. (2009). Good laboratory practices: Myers et al. respond. Environmental Health Perspectives. 117(11).

56. Kortenkamp, A., T. Backhaus, and M. Faust (2009). State of the Art Report on Mixture Toxicity - Final Report. http://ec.europa.eu/environment/chemicals/effects.htm.

57. Baas, J. and B. Kooijman (2010). Chemical Contamination and the Ecological Quality of Surface Waters. Environmental Pollution. 58: p. 1603-1607.

58. Council of the European Union (2009). Council Conclusions on Combination Effects of Chemicals. ENVIRONMENT Council meeting Brussels, 22 December 2009. ENVIRONMENT Council meeting Brussels, 22 December 2009. http://ec.europa.eu/environment/chemicals/effects.htm.

59. SETAC (2011). Prospective and Retrospective Environmental Risk Assessment of Chemical Mixtures - Moving from Research to Regulation. 3rd SETAC Europe Special Science Symposium. 2.-3. February 2011, Brussels.

60. EFSA (2010). Scientific Opinion on the Development of Specific Protection Goal Options for Environmental Risk Assessment of Pesticides, in Particular in Relation to the Revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002) EFSA Journal 8(10): p. 1821 http://www.efsa.europa.eu/en/scdocs/scdoc/1821.htm.

61. Paetzold, A., P.H. Warren, and L.L. Maltby (2010). A framework for assessing ecological quality based on ecosystem services. Ecological Complexity. 7(3): p. 273-281.

62. Millenium Ecosystem Assessment (2003). Ecosystems and Human Well-being - A Framework for Assessment. Island Press, Washington, DC, USA.

63. Hobbs, D.A., M.S. Warne, and S.J. Markich (2005). Evaluation of criteria used to assess the quality of aquatic toxicity data. Integrated Environmental Assessment and Management. 1(3): p. 174-180.

64. Breton, R.L., et al. (2009). A new quality assurance system for the evaluation of ecotoxicity studies submitted under the new substances notification regulations in Canada. Integrated Environmental Assessment and Management. 5(1): p. 127-137.

Appendix 1

Case Study Report

1. Data collection and methods

1.1. Data search

The following databases were considered as data sources.

Short name in excel file, web link	Full name (web link)
ECOTOX	The ECOTOXicology database (http://cfpub.epa.gov/ecotox/quick_query.htm)
PESTICIDEINFO	Pesticide Action Network (PAN) Pesticide Database (http://www.pesticideinfo.org/)
HSDB	Hazardous Substance Data Bank (http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB)
EU	EU pesticides database
EFSA	European Food Safety Authority (http://www.efsa.europa.eu/en/scdocs.htm)
INERIS	Institut National de l'EnviRonnement industriel et des rISques (http://www.ineris.fr/)
FOOTPRINT	Functional TOOls for Pesticide RIsk assessmenNt and management (http://www.eu-footprint.org/ppdb.html)
webTOX	ETOX: Information System Ecotoxicology and Environmental Quality Targets (http://webetox.uba.de/webETOX/index.do?language=en)
eChemPortal §	The Global Portal to Information on Chemical Substances (http://webnet3.oecd.org/echemportal/ParticipatingDb.aspx)
WFD UK TAG	UKTAG - Water Framework Directive Site (http://www.wfduk.org/LibraryPublicDocs/)
OPP	Integrated pest management (http://www.ipmcenters.org/Ecotox/DataAccess.cfm)
AGRITOX	AGRITOX - Base de données sur les substances actives phytopharmaceutiques (http://www.dive.afssa.fr/agritox/php/fiches.php)
RIVM	National Institute for Public Health and the Environment (Netherlands) (http://www.rivm.nl/en/)
UK pesticides	Pesticides in UK (http://www.pesticides.gov.uk/psd_evaluation_all.asp)
Web of science*	Key words used: Pesticide name + toxicity + aquatic 2006-2010 (http://apps.isiknowledge.com/

Sciencedirect*	Key words used: Pesticide name + toxicity + aquatic 2006-2010 (http://www.sciencedirect.com/)

* The two literature databases were checked to ensure that no particular sensitive endpoints or effects (for example olfactory or endocrine effects) were missing in the consulted databases.

§ List of databases currently participating in eChemPortal:

CESAR	Canada's Existing Substances Assessment Repository (http://www.chemicalsubstanceschimiques.gc.ca/about-apropos/assess-eval/caes-ecse/index-eng.php)
CHRIP	Information on Biodegradation and Bioconcentration of the Existing Chemical Substances in the Chemical Risk information platform (CHRIP) (http://www.safe.nite.go.jp/english/kizon/KIZON_start_hazkizon.html)
EnviChem	Data Bank of Environmental Properties of Chemicals (http://www.ymparisto.fi/default.asp?contentid=141944&lan=en)
ESIS	European chemical substances information system (ESIS) (http://ecb.jrc.it/ESIS/)
GHS-J	The Result of the GHS Classification by the Japanese Government (http://www.safe.nite.go.jp/english/ghs_index.html)
HPVIS	High Production Volume Information System (HPVIS) (http://www.epa.gov/hpvis/)
HSDB	Hazardous Substance Data Bank (http://www.toxnet.nlm.nih.gov/)
HSNO CCID	New Zealand Hazardous Substances and New Organisms Chemical Classification Information Database (http://www.ermanz.govt.nz/hs/compliance/chemicals.html)
INCHEM	Chemical Safety Information from Intergovernmental Organizations - INCHEM (http://www.inchem.org/)
JECDB	Japan Existing Chemical Data Base (http://dra4.nihs.go.jp/mhlw_data/jsp/SearchPageENG.jsp)
NICNAS PEC	Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Priority Existing Chemical Assessment Reports (http://www.nicnas.gov.au/Publications/CAR/PEC.asp)
OECD HPV	Organisation for Economic Cooperation and Development (OECD) Existing Chemicals Database (http://www.oecd.org/env/existingchemicals/data)
SIDS UNEP	OECD Initial Assessment Reports for HPV Chemicals including Screening Information Data Sets (SIDS) as maintained by United Nations Environment Programme (UNEP) Chemicals (http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html)
UK CCRMP Outputs	UK Coordinated Chemicals Risk Management Programme Publications (http://publications.environment-agency.gov.uk/)

US EPA IRIS	United States Environmental Protection Agency Integrated Risk Information System (http://www.epa.gov/iris)
US EPA SRS	United States Environmental Protection Agency Substance Registry Services (http://www.epa.gov/srs)

1.2. Data selection

In order to compare the data selection criteria described by the different selected guidelines, the validity of the data to be used in the calculations was evaluated according to the three different guidance documents, Lepper 2005 (and TGD 2003 therein) [1], TGD for EQS [2], and The Dutch guideline 2007 (named in this report as EQS NL) [3]. Additionally, registration data, which were validated according to the directive 91/414/EEC were shown. No data have been eliminated *a priori* from the database.

In this report, the validity of ecotoxicity data is identified according to the respective followed guidance document, following the codes:

- **LP:** indicates the value is valid for **Lepper 2005,**
- **TG:** indicates the value is valid for **TGD for EQS,**
- **NL:** indicates the value is valid for **EQS NL,**
- **SN:** registration values valid according to the directive **91/414/EEC, (c.f. chapter 3.7 of the main part of the report).**

The described notation has been used in this report e.g. from Table A 1.1 to Table A 1.9. For the specific validity criteria (relevance and reliability) see section 1.3. It is important to note that the Sanco guidance document on aquatic ecotoxicology in the context of the Council Directive 91/414/EEC (c.f. chapter 3.7 of the main part of the report) does not indicate how to calculate Environmental Quality Standard (EQS) values. Nonetheless, DAR EQS values are accepted for derivation of EQS values, see Table A 1.1, since the data valid under the Council Directive 91/414/EEC are also valid for EQS derivation in the context of the WFD. Therefore, this guidance document will not be further mentioned in this section; as a consequence, “all guidance documents” means Lepper 2005, TGD for EQS and EQS NL guidance documents.

1.3. General requirements/criteria

A short summary of the requirements the data have to fulfil to be considered reliable and relevant for the derivation of EQS according to the different guidance documents is given.

Table 1.1 presents the criteria the data have to fulfil to be considered reliable, and thus might be used to derive EQS. As indicated, not all the guidance documents apply the same criteria.

Table A 1.2 shows a few endpoints considered as “relevant” by the different guidelines. As stated in all guidance documents, the list is not complete: generally any endpoint which “can be related to ecologically significant hazards” or which is based on “effects that can be linked to population

sustainability" is accepted [2]. For a more complete list, see Annex 1 of the TGD for EQS, section 1.9.2 (test endpoint).

Table A 1.1: Short summary of the criteria for data validation (data reliability).

Specific requirement	**Guidance document**
Klimisch score: 1 reliable without restrictions (K1 in tables) 2 reliable with restrictions (K2 in tables) 3 not reliable (K3 in tables) 4 not assignable (K4 in tables)	LP, TG, NL
Data generated or assessed under community regulations or directives	LP, TG, (NL)[34]
Peer reviewed data retrieved from (inter)national organizations	TG, LP (if source is reliable enough)
Studies performed according to GLP, unless not relevant to QS development (i.e. unusual exposure regime or very short test duration)	TG
DAR values	LP, TG, NL, SN

Table A 1.2: Short summary of accepted specific endpoints (data relevance).

Endpoints	**Guidance document**
Survivorship of adults	LP, TG, NL
Time taken to develop (particularly to reach reproductive age)	LP, TG, NL
Reproductive output	LP, TG, NL
Behaviours if the effect may impair the competitive fitness of the population	LP, TG, NL
Avoidance reactions may also be relevant if populations are likely to avoid a contaminated habitat where they would normally be present	LP, TG

From the mentioned guidance documents, the TGD for EQS is the only one that states the difference between "critical" and "supportive" data, considering all data to be important in order to understand the toxicity of a chemical. Table A 1.3, taken from TGD for EQS, summarizes the difference between "critical" and "supportive" data.

Often, several values are available for one particular species and one particular endpoint. Table A 1.4 presents the principles for aggregating multiple values as defined in the selected guidance

[34] after a Klimisch assessment

documents. The idea can be illustrated by the statement: “One value per species and endpoint is selected for use in the assessment. Where multiple data are available for the same species/endpoint, individual toxicity data may be aggregated“[2].

Table A 1.3: Summary statistics derived from toxicity studies and their use in EQS derivation. Adapted from table 9 in TGD for EQS.

Start of citation

Test type	Criterion	Use in EQS derivation?	Action
acute test	EC10 or LC10	No [a]	▪ Tabulate value; may be valuable as additional information
acute test	EC50 or LC50	Yes	▪ Tabulate value
acute test	ECx or LCx	No	▪ Tabulate value; may be valuable as additional information
acute test	LOEC	No	▪ Omit if NOEC is also available from same experiment ▪ Else: tabulate value; may be valuable as additional information
acute test	MATC[35]	No	▪ Omit if NOEC is also available from same experiment ▪ Else: tabulate value; may be valuable as additional information
acute test	NOEC	No [a]	▪ Tabulate value; may be valuable as additional information
acute test	TLm	Yes	▪ Tabulate as LC50 [b]
chronic test	EC10 or LC10	Yes	▪ Tabulate value
chronic test	EC50 or LC50	No [a]	▪ Tabulate value; may be valuable as additional information
chronic test	ECx (x < 10)	No	▪ Omit if NOEC is also available from same experiment ▪ If more than one ECx value is available, try to establish an EC10 from a reliable dose-response relationship ▪ Else: tabulate value; may be valuable as additional information
chronic test	ECx (10 < x < 20)	Yes	▪ Omit if NOEC is also available from same experiment ▪ If more than one ECx value is available, try to establish an EC10 from a reliable dose-response relationship ▪ Tabulate value if the ECx is the lowest effect concentration measured. Calculate NOEC = ECx/2 (TGD guidance) and tabulate this NOEC [c]
chronic test	ECx (x ≥ 20)	No	▪ Tabulate value; may be valuable as additional information ▪ If more than one ECx value is available, try to establish an EC10 from a reliable dose-response relationship

[35] The MATC is the geometric mean of NOEC and LOEC.

Test type	Criterion	Use in EQS derivation?	Action
chronic test	LOEC	No	▪ Omit if NOEC is also available from same experiment ▪ Else: (i) if percentage effect is known, see ECx in this table for further guidance ▪ Else: (ii) if percentage effect is unknown: tabulate value; may be valuable as additional information
chronic test	MATC - single value, no further information	Yes	▪ Omit if NOEC is also available from same experiment ▪ Else, if no further information is available, calculate NOEC = MATC/√2 (TGD guidance) and tabulate this NOEC [d]
chronic test	MATC - reported as a range	Yes	▪ Omit if NOEC is also available from same experiment ▪ Else, if no further information is available, tabulate the lowest value of the range as NOEC [e]
chronic test	MATC – spacing factor is given [f]	Yes	▪ Omit if NOEC is also available from same experiment ▪ Else, if no further information is available, calculate NOEC = MATC/√(spacing factor)[f] and tabulate this NOEC [g]
chronic test	NOEC	Yes	▪ Omit LOEC if it is also available from same experiment

Notes

a) For toxicity tests with algae and *Lemna* sp., both the EC50 and the EC10 or NOEC are used in the EQS derivation, if available.
b) A footnote should be added to the toxicity data table stating that the TLm is used as LC50.
c) A footnote should be added to the toxicity data table stating that the NOEC is calculated as ECx/2.
d) A footnote should be added to the toxicity data table stating that the NOEC is calculated as MATC/√2.
e) A footnote should be added to the toxicity data table stating that the lowest value of the MATC range is taken as NOEC.
f) The spacing factor is the factor of difference between two subsequent testing concentrations employed in the toxicity experiment.
g) A footnote should be added to the toxicity data table stating that the NOEC is calculated as MATC/(√spacing factor).

End of citation, [2].

Table A 1.4: Aggregation of multiple data for one species.

GENERAL CRITERIA	GUIDANCE DOCUMENT
Identify particularly sensitive species and/or endpoints that may be lost upon averaging data to single values.	LP, TG, NL
Investigate multiple values for the same endpoint on a case-by-case basis and seek to explain differences between results.	LP, TG, NL
If multiple toxicity values or geometric means for different endpoints are available for one species, the most-sensitive endpoint is selected as long as it is relevant to population sustainability. If multiple valid toxicity data for one species are left that cannot be averaged, the *lowest* value is selected.	TG, NL
Where valid data show high variation that can be explained, grouping of data is considered, e.g. by pH ranges. If an effect of test conditions is expected to be the cause of variation in toxicity values (hardness of test water, life stage of the test animal, etc.), averaging of data per species should not be performed.	LP, TG, NL
If the variation in test results of different life stages of a test animal is such that averaging data would cause significant underprotection of sensitive life stages, only the data for the most sensitive life stage should be selected. In other words, it is important that sensitive life stages are protected.	TG, NL
Calculate the geometric mean of multiple comparable toxicity values for the same species and the same endpoint. This applies to both acute and chronic data.	LP, TG, NL

All sentences in Table A 1.4 are cited from the TGD for EQS [2].

1.4. Specific requirements for derivation of EQS using Assessment Factors (AF) method

The main requirements and differences in the AF methodology depending on the guidance documents are summarized in the Tables A 1.5 to 1.8. Shortly, to apply the AF methodology the following steps need to be followed:

1. Construction of the BASE SET
2. Verification the BASE SET is complete (see Table A 1.5)
3. Collecting all other data (long or short-term)
4. Application of the appropriate AF (see Table **A 1.6:** Table A 1.6 for AA-EQS and Table A 1.7 and Table A 1.8 for MAC-EQS)

The first requirement for the EQS derivation by the AF method involves the creation of a base data set, which is supposed to be representative of an aquatic community. It includes a primary producer (algae) and primary and secondary consumers (invertebrates, normally *Daphnia* and fish).

For all the guidance documents, two types of EQS can be derived with the AF method: annual average (AA-EQS) or maximum allowed concentration (MAC-EQS). Data used for the derivation of AA-EQS are both long-term and short-term, while only short-term data are employed for MAC-

EQS. Usually, short-term experiments last only for a short time (e.g. 24, 48, 72 or 96 h) with respect to the life-cycle of the tested organism, and long-term experiments on the other hand are representative of the life-cycle or evaluate sensitive life-stage such as hatching. It is not possible to define a "standard" duration for short- and long-term studies due to their dependence on the duration of the organism's life. For example, algae reproduction is very fast (hours) and both short- and long-term studies have the same duration, i.e. usually 3-4 days. For algae short- and long-term data are distinguished by the effect level: the EC50 is considered a short-term value while the EC10 and the NOEC are considered long-term values. For experiments with *Lemna* spec. the same distinction is made. For crustaceans, usually short-term studies last 2 days, while long-term can last 7 days (*Ceriodaphina dubia*) or 21 days (*Daphnia magna*) depending on the duration of their life-cycle.

Generally, depending on the type of data available, as well as on the number of available short-term and long-term data, an appropriate AF is applied to the data which is representative of the highest toxicity. Details on the appropriate AF are provided on Table A 1.5 to Table A 1.8. Please note that in Table A 1.6 long-term results mean both NOEC and EC10 values. The directive 91/414/EEC (c.f. chapter 3.7 of the main part of the report) does not give any details on how to derivate the EQS, and is therefore not mentioned in the following tables.

It is interesting to note that according to TGD for EQS, it is possible to derive an AA-EQS even if L(E)C50 for *Daphnia sp.* is missing, but this it is not the case for EQS NL.[36]

Table A 1.5: Specific criteria for the base set (representative of the aquatic community).

Base set	**Guidance document**
Algae	LP, TG, NL
Cyanophytes (blue green algae)	TG, NL (for both, only when algae values are missing)
Macrophytes	LP, TG (only when algae or Cyanophytes are missing)
Daphnia sp.	LP, TG, NL
Ceriodaphnia dubia	NL (instead of *Daphnia sp.*), TG
Ceriodaphnia sp., *Gammarus sp.*	TG (instead of *Daphnia sp.*)
Fish	LP, TG, NL

Table A 1.6: Specific differences in the AF methodology for AA-EQS derivation

GENERAL CRITERIA	**GUIDANCE DOCUMENT**
BASE SET NOT COMPLETE (MISSING VALUE REGARDING TABLE A 1.5)	
No AA-EQS derivation	LP

[36] According to a comment by Els Smit (RIVM-NL) [133], the RIVM would in practice also make exceptions to this rule, e.g. when a chronic NOEC is available for *Daphnia magna*.

If there is evidence that the missing trophic level would not be the potentially most sensitive species (*e.g. Daphnia* in case of a herbicide) or when it can be assumed that the available species are potentially sensitive (*i.e.* insect and *Daphnia* data in case of an insecticide, where algae are missing), the assessment scheme can be followed as if the base set were complete, [2].	TG
[…] at least an acute toxicity study with *Daphnia* is available, the MPC[37] is derived by applying an assessment factor of 1000 to the L(E)C50 for *Daphnia*. […] no MPC is derived […] when the base set is incomplete and when a short-term study with *Daphnia* is not available, [3] [38].	NL
NO LONG-TERM RESULTS	
No AA-EQS can be derived based ONLY on acute data	NL
AA-EQS derivation based on the lowest L(E)C50 with AF 1000.	LP[39], TG
1000 ≤ AF ≤ 100 is possible based on evidence.	LP, TG
AF < 100 may be acceptable only for substances with intermittent release.	LP
1 LONG-TERM RESULT	
An assessment factor of 100 is applied to a single long-term result [...] (fish or *Daphnia*) if this result was generated for the trophic level showing the lowest L(E)C50 in the short-term tests, [2].	LP, TG, NL
An assessment factor of 100 is applied to the lowest chronic value [...] if chronic data are available for only one trophic level of the base set, which has to be either *Daphnia* or fish (no other species). The lowest long-term result [...] should be from the same trophic level as that of the lowest acute L(E)C50. If this is not the case, a factor of 1000 is also applied to the lowest L(E)C50. The two results are compared: lowest L(E)C50/1000 versus long-term result/100; the lowest value is selected, [2].	TG, NL
If the only available long-term result [...] is from a species (standard or non-standard organism) which does not have the lowest L(E)C50 from the short-term tests, applying an assessment factor of 100 is not regarded as protective of other more sensitive species. Thus the hazard assessment is based on the short-term data and an assessment factor of 1000 applied. However, the resulting QS based on short-term data may not be higher than the QS based on the long-term result available, [2].	LP, TG, NL
AF of 100, when only algal NOEC is present, is accepted if the algal acute toxicity is the highest, AND the NOEC from the same species of the lowest L(E)C50 is present, AND a second algal NOEC is present.	TG
2 LONG-TERM RESULTS	

[37] In the Dutch guidance document, MPC corresponds to AA-QS.

[38] According to a comment by Els Smit (RIVM-NL) [133] in practice RIVM would make exceptions to this rule, e.g. if a chronic NOEC/EC10 is available for the missing taxonomic group.

[39] Lepper is not quite clear on this. In one section the derivation of an AA-EQS based on acute data alone is possible, while in another section he writes that this should not be done. We decided that it is meant that it is possible according to Lepper.

An assessment factor of 50 applies to the lowest of two long-term results [...] covering two trophic levels when such results have been generated covering that level showing the lowest L(E)C50 in the short-term tests, [2].	LP, TG, NL
An assessment factor of 100 can also be applied to the lowest of two long-term results [...] covering two trophic levels when such results have not been generated from that showing the lowest L(E)C50 of the short-term tests. This should, however, not apply in cases where the acutely most sensitive species has an L(E)C50 value lower than the lowest long-term result value. In such cases the QS might be derived by using an assessment factor of 100 to the lowest L(E)C50 of the short-term tests, [2].	LP, TG, NL
If the trophic level for the lowest acute L(E)C50 is not included in the chronic data [...] then: • an assessment factor of 100 is applied to the lowest NOEC or EC10 if the lowest L(E)C50 is higher than the lowest NOEC or EC10; • an assessment factor of 100 is applied to the lowest L(E)C50 if the lowest L(E)C50 is lower than the lowest NOEC or EC10.	TG, NL
It may sometimes be possible to determine with high probability that the most sensitive species has been examined, i.e. that a further long-term result [...] from a different taxonomic group would not be lower than the data already available. In those circumstances, a factor of 10 applied to the lowest long-term result [...] from only two species would also be appropriate. This is particularly important if the substance does not have a potential to bioaccumulate, [2].	LP, TG, NL
3 (OR MORE) LONG-TERM RESULTS	
An assessment factor of 10 will normally only be applied when long-term toxicity results [...] are available from at least three species across three trophic levels (e.g. fish, Daphnia, and algae or a non-standard organism instead of a standard organism), [2].	LP, TG, NL
An assessment factor of 100 applies to the lowest of three long-term results [...] covering three trophic levels when such results have not been generated from that trophic level showing the lowest L(E)C50 in the short-term tests. This should however not apply in cases where the acutely most sensitive species has an L(E)C50 value lower than the lowest long-term result [...] value. In such cases the QS might be derived by using an assessment factor of 100 to the lowest L(E)C50 of the short-term tests, [2].	LP, TG, NL
An assessment factor of 10 is applied to the lowest chronic NOEC or EC10 if chronic data are available from all three trophic levels of the base set. The trophic levels of NOECs and/or EC10s should include the trophic level of the lowest acute L(E)C50. If acute toxicity data are available for trophic levels not covered in the chronic toxicity data, and the trophic level of the lowest L(E)C50 is not included in that of the NOECs and/or EC10s then: • an assessment factor of 50 is applied to the lowest NOEC or EC10 if the lowest L(E)C50 is higher than the lowest NOEC or EC10; • an assessment factor of 100 is applied to the lowest L(E)C50 if the lowest L(E)C50 is lower than the lowest NOEC or EC10, [2].	TG, NL
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Insect growth regulators For this specific type of pesticides, *Daphnia* may not be the most sensitive species. Within the context of pesticide authorisation, it is advised that insects should be tested when for an insecticide the toxicity to *Daphnia* is low (i.e. 48 h EC50 > 1 mg/L, 21 d NOEC > 0.1 mg/L; EC, 2002). This means that where the presence of acute and chronic data for algae, *Daphnia* and fish normally allows for an AF of 10, in this case additional information from insects is considered necessary, [2].	TG
Bacterial studies Long term result "values derived from bacterial studies may not be used in the derivation of the AA-$EQS_{freshwater,eco}$ using assessment factors. EC50 values from bacterial tests may be used but they cannot substitute any of the other trophic levels (acute data on algae, *Daphnia*, fish) for completion of the base set", [2].	TG, NL
Blue-green algae "data from (both chronic and acute) tests with cyanobacteria are considered as additional algal data and are treated in the same way (*i.e.* if they represent the lowest endpoint, the AF will be based on cyanobacteria, even when data for green algae are present). They can also be used to complete the base set where there are no algal data", [2].	TG, NL

1.4.1. Specific requirements for derivation of MAC-EQS

When deriving MAC-EQS using the AF method, an AF of minimum 10 should be applied according to all guidance documents.

Lepper 2005 does not give a table but refers to section 3.3.2 of part II of the TGD 2003. Nevertheless, it specifies that an AF of 100 is normally applied to the lowest L(E)C50. Exceptions include substances

- with potential to bioaccumulate; AF "100 may not be always be justified",
- with a non-specific mode of action; an AF lower than 100 could be appropriate.

In both TGD for EQS and EQS NL there is a table where the appropriate AF is indicated. Since these tables are different they have been copied in this report, see Table A 1.7 and Table A 1.8.[40]

[40] Please note that the Dutch TGD will be updated to reflect the new WFD-guidance once this is officially accepted by the European Commission [133]

Table A 1.7: AF to be used in MAC-EQS in TGD for EQS.

Start of citation

Toxicity data	Additional information	Assessment factor
Base set not complete	–	_ [a]
At least one short-term L(E)C50 from each of three trophic levels of the base set (fish, crustaceans and algae)		100
At least one short-term L(E)C50 from each of three trophic levels of the base set (fish, crustaceans and algae)	Acute toxicity data for different species do not have a higher standard deviation than a factor of 3 in both directions[b] OR known mode of toxic action and representative species for most sensitive taxonomic group included in data set	10[c]

Notes.

[a] When the base set is not complete, a MAC-EQS$_{freshwater,eco}$ cannot be derived. It should be considered if the base set could be completed with non-testing data (See Section 2.6.). Non-testing data should not be used as critical data in the derivation of the MAC-EQS$_{freshwater,eco}$.

[b] To assess the span of the acute toxicity data, all reliable acute toxicity data collected are used, with a minimum of three LC50 or EC50 values, for species representing each of the base set trophic levels (algae, *Daphnia*, fish). If the standard deviation of the log transformed L(E)C50 values is < 0.5, an assessment factor of 10 could be applied, otherwise an assessment factor of 100 should be applied.

[c] Lowest assessment factor to be applied.

[…]

Where there are at least 3 short-term tests using species from three trophic levels (base set), an AF of 100 applied to the lowest L(E)C50 is normally used to derive the MAC-EQS$_{freshwater,eco}$. Under some circumstances an AF less than 100 may be justified, e.g.

- For substances which do not have a specific mode of action (e.g. acting by narcosis only), if the available data show that interspecies variations are low (standard deviation of the log transformed L(E)C50 values is < 0.5) an AF<100 may be appropriate.
- For substances with a specific mode of action, the most sensitive taxa can be predicted with confidence. Where representatives of the most sensitive taxa are present in the acute dataset, an AF <100 may again be justified.
- Where there is a good understanding of the relationship between acute and chronic toxicity (e.g. acute: chronic ratios for a range of species), the AF used to estimate the MAC may be selected to reflect this, or at least to ensure the MAC is not lower than the AA.
- Acute toxicity data for different species do not have a higher standard deviation than a factor of 3 in both directions OR known mode of toxic action and representative species for most sensitive taxonomic group included in data set
- In no case should an AF lower than 10 be applied to a short-term L(E)C50 value.

End of citation, [2].

Table A 1.8: AF to be used in MAC-EQS in EQS NL.

Start of citation

Toxicity data	Additional information	Assessment factor
Base set not complete	–	– [a)]
At least one short-term L(E)C50 from each of three trophic levels of the base set (fish, *Daphnia* and algae)	Potential to bioaccumulate[b)]	1000
At least one short-term L(E)C50 from each of three trophic levels of the base set (fish, *Daphnia* and algae)	Potential to bioaccumulate[b)]; AND known non-specific mode of action and low interspecies variation OR known mode of toxic action and most sensitive species included in data set	100
At least one short-term L(E)C50 from each of three trophic levels of the base set (fish, *Daphnia* and algae)	No potential to bioaccumulate[c)];	100
At least one short-term L(E)C50 from each of three trophic levels of the base set (fish, *Daphnia* and algae)	No potential to bioaccumulate[c)]; AND Acute toxicity data for different species do not differ by more than a factor of 2 to 3[d)] OR known mode of toxic action and representative species for most sensitive species included in data set	10 [e)]

Notes.

[a)] When the base set is not complete, a MAC_{eco}, water can not be derived.

[b)] Potential to bioaccumulate is defined as the substance having an experimental BCF ≥ 100 L/kgww^{-1} or an experimental BMF > 1 $kg_{ww}.kg_{ww}^{-1}$ or, if BCF and BMF are absent, a log *K*ow ≥ 3.

[c)] No potential to bioaccumulate is defined as the substance having an experimental BCF < 100 L.kgww^{-1} and an experimental BMF ≤ 1 $kg_{ww}.kg_{ww}^{-1}$ or, if BCF and BMF are absent, a log *K*ow < 3.

[d)] This guidance has been added within the INS framework. To assess the span of the acute toxicity data, all reliable acute toxicity data collected are used, with a minimum of three LC50 or EC50 values, for species representing each of the base set trophic levels (algae, *Daphnia*, fish). If the ratio of the highest and lowest L(E)C50 value is ≤ 3, an assessment factor of 10 should be applied, otherwise an assessment factor of 100 should be applied.

[e)] Lowest assessment factor to be applied.

End of citation, [3].

1.4.2. Further requirements to be fulfilled once both AA and MAC-EQS have been derived

In addition to the previous requirements, Lepper 2005 introduces the notion of using “acute data to check the plausibility of long-term data” and “acute data to check the QS derived on the basis of long-term data”. Furthermore, it states that “any MAC-EQS which is higher than 12 times the AA-EQS may be meaningless in the regulatory practice of compliance checking” [1]. According to Lepper 2005, the substance concentration has to be monitored regularly, for example, once a month. So, if the MAC-EQS is higher than 12 times the AA-EQS, the allowed concentration peaks would on average be higher than the annual average, and the protection goal not fulfilled.

For both TGD 2005 and EQS NL this does not apply, since the MAC-EQS has to be set equal to AA-EQS in case that it is lower than AA-EQS.

1.5. Specific Species Sensitivity Distribution (SSD) criteria

The SSD methodology is based on statistical extrapolation: “to construct an SSD, toxicity data are log-transformed and fitted to a distribution function from which a percentile (normally the 5th percentile; often referred to as the HC5) of that distribution is used as the basis for an EQS. Several distribution functions have been proposed [2]”. To derive EQS using the SSD method, all guidance documents require a minimum of 10 NOECs (preferably more than 15 NOECs) for different species covering at least 8 taxonomic groups[41]. This is due to protection goals: “ideally the dataset for an SSD should be statistically and ecologically representative of the community of interest (Posthuma *et al*., 2002)”, [2]. According to all guidance documents, these taxonomic groups should be:

- Fish (species frequently tested include salmonids, minnows, bluegill sunfish, channel catfish, etc.)
- A second family in the phylum Chordata (e.g. fish, amphibian, etc.)
- A crustacean (e.g. cladoceran, copepod, ostracod, isopod, amphipod, crayfish etc.)
- An insect (e.g. mayfly, dragonfly, damselfly, stonefly, caddisfly, mosquito, midge, etc.)
- A family in a phylum other than Arthropoda or Chordata (e.g. Rotifera, Annelida, Mollusca, etc.)
- A family in any order of insect or any phylum not already represented
- Algae
- Higher plants

Both AA-EQS and MAC-EQS can be derived using the SSD method; in the first case only long-term results are used, in the latter only short-term results. In Table A 1.9 general criteria for the

[41] Fish, amphibians, crustaceans, insects, molluscs, annelids, macrophytes, algae, birds, mammals, rotifer, gastropoda and bacteria, [2].
In table 29, EQS NL lists some commonly tested species with their corresponding taxa: bacteria, cyanobacteria, archaebacteria, algae, protozoa, macrophyta, fungi, cnidaria, ctenophora, platyhelminthes, gastrotricha, rotifera, nematoda, mollusca, annelida, arachnida, pycnoginida, crustacea, myriapoda, insecta, echinodermata, pisces, amphibia, reptilia, aves, mammalian, [3] .

derivation of both AA-EQS and MAC-EQS using the SSD method are illustrated; specific criteria to be used only in the derivation of AA-EQS or MAC-EQS are listed at the end of the Table A.1.9.

Table A 1.9: Specific differences in the SSD methodology.

GENERAL CRITERIA	**GUIDANCE DOCUMENT**
Different distributions like e.g. log logistic, log normal or others may be used, but it should be clearly explained, [1].	LP
The choice of a distribution function other than the log-normal or log-logistic distribution should be clearly explained, [2].	TG
The Anderson–Darling goodness of fit test can be used in addition to the Kolmogorov-Smirnov-test, as a criterion for the choice of a parametric distribution for comprehensive data sets, because it gives more weight to the tails of the distribution, [1].	LP
Whatever the fit to a distribution, results should be discussed with regards to the graphical representation of the species distribution and the different p-values[42] that were obtained with each test, [1].	LP, TG
The use of other distributions (not log-logistic) is favoured only after detailed analysis has shown that the log-normal distribution results in an inadequate fit (see next two sections). Moreover, other distributions may only be used if statistical uncertainty of the fit (at least goodness of fit and confidence interval around the estimated percentile) can be estimated with the software calculating the distributions, [3].	NL
The SSD method should not be used in cases where the data do not fit a distribution, [1].	LP
CALCULATION OF HC5	
"The method of Aldenberg and Jaworska (2000) is considered most appropriate because it enables the calculation of a confidence interval (normally the 90% interval) for the HC5. This method is used in the ETX-computer program [134]", [2].	TG, NL
If the data do not fit any distribution, the left tail of the distribution (the lowest effect concentrations) should be analysed more carefully. If a subgroup of species can be identified as particularly sensitive and if the number of data on this subgroup is sufficient, the distribution can be fit to this subgroup, [1].	LP, TG (only if supported by mechanistic explanation)
SSDS FOR SUBSTANCES WITH A SPECIFIC MODE OF ACTION	

[42] p-value ≈ probability value - expressing the probability of wrongly rejecting a statistical hypothesis if it is in fact true (e.g. $p < 0.05$, meaning a probability of < 5%).

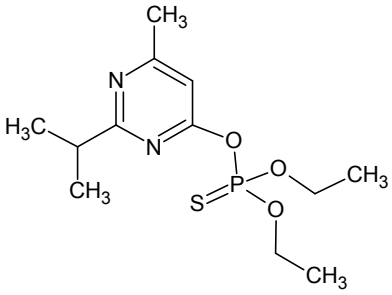
Especially if the substance in question exerts (or is suspected to have) a specific mode of action, SSDs should not only be set up for the entire database but as well for the most sensitive taxonomic group(s). For substances with a specific mode of action it may in most instances be more appropriate to derive a quality standard on the basis of the SSD of the most sensitive group. However, any decision should be discussed and justified, [1].	LP
For a substance exerting a specific mode of action, SSDs should be constructed using only those taxa that are expected to be particularly sensitive if: the entire dataset (i.e. all taxa, so that the relative sensitivities of taxa can be examined) and the SSD distribution shows a bimodality and if the number of data for the subgroup is sufficient (at least 10).	TG, NL
AF TO BE APPLIED WHEN DERIVING AA-EQS: 5-1 (5 DEFAULT) - ISSUES TO CONSIDER	
The overall quality of the database and the end-points covered, e.g., if all the data are generated from ”true” chronic studies (e.g., covering all sensitive life stages), [1].	LP, TG, NL
The diversity and representativeness of the taxonomic groups covered by the database, including also the variation represented relating to differences in the life forms, feeding strategies and trophic levels of the organisms, [1].	LP, TG, NL
The mode of action of the chemical, [1].	LP, NL, TG (covering also long-term exposure)
Statistical uncertainties around the 5th percentile estimate, e.g., reflected in the goodness of fit or the size of confidence interval around the 5th percentile, [1].	LP, TG, NL
and consideration of different levels of confidence (e.g. by a comparison between the median estimate of the HC5 with the lower estimate (90% confidence interval) of the HC5), [2].	TG, NL
Comparisons between field and mesocosm studies and the 5th percentile and mesocosm/ field studies to evaluate the laboratory to field extrapolation, [1].	LP, TG, NL
AF TO BE APPLIED WHEN DERIVING MAC-EQS: 10 - ISSUES TO CONSIDER	
This AF should normally be 10, unless other lines of evidence (e.g. acute EC50:acute EC10 (or NOEC) ratios are narrow) suggest that a higher or lower one is appropriate [2].	LP, TG, NL

In the following sections, the results of the case studies for each of the selected substances are presented.

2. Diazinon

2.1. General data

Table A 1.10: Diazinon, general data.

IUPAC name	Diethoxy-[(2-isopropyl-6-methyl-4-pyrimidinyl)oxy]-thioxophosphorane	
CAS registry number	333-41-5	
EU number	206-373-8	
Molecular formula	$C_{12}H_{21}N_2O_3PS$	
Code SMILES	S=P(OC1=NC(=NC(=C1)C)C(C)C)(OCC)OCC	
Pesticide class	Insecticide	
Molecular weigh	304.34 [g/mol]	
BCF	Between 3 and 274.4 ± 17.7, [5]	
$LogK_{OW}$	3.1–4.0 [5]	
EU classification	Xn; R22 – N; R50/53[43]	

Diazinon is moderately lipophilic (log Kow 3.1–4.0), and hence will tend to partition into sediment and biota. Its primary mode of action is through the inhibition of cholinesterase in the nervous system; invertebrates are particularly sensitive [5]. In its endocrine disruptor classification, the EU places it in category 2: “at least some *in vitro* evidence of biological activity related to endocrine disruption”.

Table A 1.11 summarizes the database search results for diazinon. The data search using Web of Science was performed using the following key words:

- Diazinon aquatic toxicity (61 results)

The goal was to check if any particular sensitive endpoint or effect were detected in recent studies, i.e. studies not included in the different databases. After an examination of the resulting papers, no publication was considered as “relevant” to be included in the dataset regarding specific endpoints, especially because the concentrations used in the experiments were too high (mg/l range) when compared to environmentally relevant concentrations.

Analogously, the keywords for Sciencedirect were:

Diazinon toxicity (1’021 results)

Diazinon toxicity + aquatic toxicity (438 results)

[43] Xn: Harmful, R22: Harmful if swallowed, N: Dangerous for the environment, R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Table A 1.11: Diazinon, result of the database search.

Database name	Results	Database name	Results
ECOTOX	Available data	eChemPortal	Available data
PESTICIDEINFO	Available data (data from ECOTOX)	WFD UK TAG	Available data
HSDB	No ecotox data	OPP	Available data
EU	Available data	AGRITOX	Available data
EFSA	No ecotox data	RIVM	Not in the database
INERIS	Available data	UK pesticides	Available data
FOOTPRINT	Available data	Web of science	Available data
webTOX	Available data	Sciencedirect	Available data

The resulting publications refer to studies with concentration in the range of mg/l, *i.e.* too high when compared to the ones usually present in the environment. After evaluation, none of these publications have been considered as “relevant”.

2.2. Derivation of EQS values

Three methods have been considered for the EQS derivation: assessment factor, species sensitivity distribution methods, and interpretation of simulated ecosystem studies.

In Table A 1.12 and Table A 1.13, the acute (L(E)C50) and chronic (NOEC and EC10) values for diazinon are listed. All short- and long-term results which are reliable and relevant for at least one directive have been included.

To show the effect of non-standard end-points, two data have been included in the tables: the NOEC in *Salmo salar* (fish) for the olfactory system of 0.1 µg/l; and for hormonal effects of 0.3 µg/l (LC50, decrease of steroid in the plasma after 5 days, according to one source or 4-5 hours according to a second source, see Table A 1.12). These were the lowest toxicity values for fish.

Table A 1.12: Diazinon, reliable and relevant short-term toxicity values.

Taxonomic group	Species scientific name	Endpoint	Test duration [d]	Conc. [µg/l] (Purity %)	Source	Reliable (Relevant) according to
ALG	*Scenedesmus subspicatus*	EC50 (POP/GRT)	4	8'540 (92.8%)	EFSA (EU DAR), [6]	LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Scenedesmus capricornutum*	EC50 (POP/GRT)	7	6'400 (87.7%)	EFSA (EU DAR), [7]	LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Ceriodaphnia dubia*	EC50 (MOR/MORT)	2	0.49 (GM)	UK Report, [8]	LP, TG, NL (LP, TG, NL, SN)
CRU	*Daphnia magna*	EC50 (MOR/MORT)	2	0.78 [44] (Tech)	EFSA (EU DAR), [9]	LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Daphnia magna*	EC50 (MOR/MORT)	2	0.96	EFSA (EU DAR), [10]	LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Daphnia magna*	EC50 (ITX/IMBL)	2	1.4 (Diazol 60 EC)	EFSA (EU DAR), [11]	LP, TG, NL, SN (LP, TG, NL, SN)
FIS	*Lepomis macrochirus*	LC50 (MOR/MORT)	4	462 (GM)	EU DAR	(LP, TG, NL, SN)
FIS	*Lepomis macrochirus*	LC50 (MOR/MORT)	4	270	EFSA conclusion	LP, TG, NL, SN (LP, TG, NL, SN)
FIS	*Salmo salar*	EC50 (PHY[45])	5d [12], 4-5h [13]	0.3	Diazinon 333-41-5.pdf; UK Report (K1)	LP, TG, NL (None); LP, TG, NL (None)

ALG = algae; CRU = crustaceans; FIS = fish

[44] Purity specified as "Technical"
[45] Decrease of steroids concentration in plasma

The acute toxicity values presented in the following table were reported in the EU DAR for *Lepomis macrochirus* and used for the GM (geometric mean). These are reported literature data for which the reliability could not be assessed.

Reference	**96 hour LC50 (95% confidence limits) mg/L**
Sachsse, 1972	16 (10- 25.5)
Allison & Hermanutz, 1977	0.46 (0.31- 067)
Dennis *et al.*, 1980 & Meier *et al.*, 1979	0.12
Johnson & Finley, 1980 & Mayer & Ellersieck, 1986	0.17 (0.12-0.22)
Beliles, 1965	0.14 (0.10 – 0.19)

Therefore, in the review report of the EU DAR it was recommended to perform a new study on the toxicity of diazinon for a warm water fish species. This study was performed and mentioned in the EFSA conclusion, and the new EC50 value for *Lepomis macrochirus* was 0.27 mg/l.

Acute toxicity values reported in the UK report for *Ceriodaphnia dubia* and used for the geometric means were: 0.26, 0.50 and 0.92 µg/l. These are all EC50 values (MOR/MORT), with test duration of 2 days, reported by the UK report as K2 [8].

Table A 1.13: Diazinon, reliable and relevant long-term toxicity values.

Taxonomic group	Species scientific name	Endpoint	Test duration [d]	Conc. [µg/l] (Purity %)	Source	Reliable (Relevant) according to
ALG	*Scenedesmus capricornutum*	NOEC (POP/cell counts)	7	< 60 (87.7%)	EFSA (EU DAR), [7]	LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Scenedesmus subspicatus*	NOEC (POP/GRT)	4	1'000 (92.8%)	EFSA (EU DAR), [6]	LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Ceriodaphnia dubia*	NOEC (ITX/IMBL)	2	0.080 (88.0%)	EFSA (EU DAR), [14]	LP, TG, NL, SN (None[46])
CRU	*Daphnia magna*	NOEC (REP, GRT rate, life cycle)	21	0.17 (87.7%)	EFSA (EU DAR), [9]	LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Daphnia magna*	NOEC (MOR/MORT)	21	0.15[47]	UK Report (K2), [15]	LP, TG, NL (LP, TG, NL, SN)

[46] Please notice that nor Lepper 2005, nor TGD for EQS nor EQS NL do not consider 2 day exposure as "long-term" result for crustaceans; in particular for *Ceriodaphnia dubia* a minum of 7 days is required, see TDG pg 186.
[47] Mean number of broods, total young per female

FIS	*Pimephales promelas*	NOEC (MOR/MORT)	34	92	EFSA (EU DAR), [16]	LP, TG, NL, SN (LP, TG, NL, SN)
FIS	*Pimephales promelas*	NOEC (DEV[48])	up to 274	< 3.2	UK Report (P, K1), [17]	LP, TG, NL (LP, TG, NL, SN)
FIS	*Salvelinus fontinalis*	NOEC (MOR/MORT)	91 173	2.4 > 9.6	UK Report (K1), [17]	LP, TG, NL (LP, TG, NL, SN)
FIS	*Salmo salar*	NOEC (PHY[49])	4-5 (h)	0.1	UK Report (K1), [13]	LP, TG, NL (None)
FIS	*Salvelinus fontinalis*	NOEC (DEV[50])	122	< 0.55	UK Report (K2), [17]	LP, TG, NL (LP, TG, NL)
FIS	*Salvelinus fontinalis*	NOEC (DEV[51])	173	2.4	UK Report (K1), [17]	LP, TG, NL (LP, TG, NL)

ALG = algae; CRU = crustaceans; FIS = fish

2.2.1. Derivation using AF method

According to the AF method, when the base data set is complete and at least three long-term species values (NOECs) are available, an assessment factor of 10 is applied to the lowest NOEC value. The section 1.5 presents further details on AF to be applied. Furthermore, the NOEC of the most sensitive organism based on the acute data (*Daphnia magna*) is present in Table A 1.12, so an AF of 10 can be applied.

Even if the lowest available NOEC was 0.08 µg/l, it is not considered as chronic by the different guidelines since the test only lasted 2 days. In addition, the validity of the second lowest NOEC, 0.1 µg/l, can also be questioned, as avoidance tests cannot easily be linked "to population sustainability", [2]. In consequence, when the guidelines are strictly applied the lowest NOEC is 0.15 µg/l.

The proposed **AA-EQS** is therefore **0.015 µg/l**, calculated as 0.15 NOEC µg/l for *Daphnia magna* and an AF of 10.

2.2.2. Derivation using SSD method

The data available for this method are listed in A 1.13. As explained in section 1.5, the SSD method requires a minimum of 10 long-term results (preferably more than 15) for different species covering at least 8 taxonomic groups. For diazinon, there are not enough reliable and relevant long-term results: at maximum 7 long-term results for 3 taxa have been found.

[48] Hatching success of eggs and deformation of spinal cord
[49] Physiology, sensitivity to olfactory system
[50] Growth and weight of progeny of exposed parents
[51] Deformation of spinal cord

2.2.3. Interpretation of simulated ecosystem studies

Mesocosm studies are available in the DAR for diazinon. They were described as follows:

"There were 9 treatment groups (including controls), 0. 2.0, 4.4, 9.7, 21, 47, 103, 227, and 500 µg a.s./l, each with two replicates. Diazinon (purity: 88%; batch n°FL-880045, 790701-ML 5755) was applied directly as an aqueous solution followed by gentle stirring of the water column on three occasions at seven days intervals. Measurements were made every four weeks for water (physical and chemical parameters) phytoplankton, periphyton and macroinvertebrates. The study was terminated 84 days (approximately three months) after the first application [18]."

A second mesocosm study was performed on twenty-one ponds (approximately 450 m^2 surface area, 2.2 m water depth with sediments on the bottom). Seventeen ponds were treated with "AG 500 (470 g a.s/ha; batch n° FL-861807). A total of six applications over a seven week period" were performed [18].

As the general conclusion the **"Ecological Acceptable Concentration** (EAC) as defined by the HARAP guidance document (Campbell *et al.* 1999) was considered to be **9.2 µg/l**. Effects at this concentration were followed by full recovery (after 10 weeks for cladocerans, and 2-4 weeks for affected macroinvertebrate taxa). Whilst full population recovery at 16 and 33 µg/l was observed for almost all species, the impacts were greater in both magnitude and to a wider number of macroinvertebrates and emergent insect species, than what was observed at 9.2 µg/l. Time for recovery of macroinvertebrates at 33 µg/l (2-8 weeks) was generally slower than at lower test concentrations" [18].

2.3. Derivation of MAC-EQS values

Three methods have been considered for the EQS derivation: the assessment factor method, the species sensitivity distribution method, and the interpretation of simulated ecosystem studies.

2.3.1. Derivation using AF method

The lowest short-term result is 0.49 µg/l (GM, LC50, *Ceriodaphnia dubia*). The appropriate AF has to be chosen depending on (i) the potential to bioaccumulate, (ii) whether the mode of action is known, (iii) the number of data available (in this case 5 at maximum) and (iv) the selected guidance document. The BCF has been calculated to vary between 3 and 274.4, while the $\log K_{OW}$ is between 3.1 and 4.0 [5].

Lepper 2005 states that usually an AF of 100 should be applied. For substances with the potential to bioaccumulate an AF of "100 may not always be justified". A higher AF might have to be considered. For substances with a non-specific mode of action however, an AF lower than 100 could be appropriate. In consequence, depending on "expert judgement" the **MAC-EQS** varies between **0.0049** and **0.049 µg/l**.

TGD for EQS does not specifically consider the case of bioaccumulation. According to Table A 1.7, an AF between 100 and 10 can be applied. The lower AF can be applied if the mode of action is known and if the most affected species is present in the database, or if the range of the acute toxicity data is lower than a factor of 3. For diazinon, the standard deviation of the log

transformed L(E)C50 is above 2. This is higher than 0.5, which is the threshold value of the TGD for EQS for a specific mode of action. Hence, for diazinon a non-specific mode of action can be excluded. It remains to be decided by "expert judgement" if the presence of two species of invertebrates (daphnids, insects) in the reliable and relevant data set is considered to be sufficient for the representation of the most affected species. Therefore, depending on the "expert judgement" taken, the **MAC-EQS** can vary between **0.0049** (better 0.015 µg/l[52]) and **0.049 µg/l**.

According to the BCF threshold value set by **EQS NL** diazinon bioaccumulates. Therefore, an AF of 100 should be applied. In consequence the MAC-EQS is **0.0049 µg/l**, which is lower than the AA-EQS, and thus it should be **set equal to** the **AA-EQS** value, i.e. **0.015 µg/l**.

2.3.2. Derivation using SSD method

For diazinon, there are not enough reliable and relevant short-term results available since only five short-term results for three taxa have been considered as reliable and relevant.

2.4. Comparison with other EQS

2.4.1. Diazinon SSD curves according to UK report

In the diazinon UK report several long- and short-term results are used to fit a curve similar to an SSD, which however is clearly stated not to be an SSD. In order to compare our calculated values with the UK results, we calculated SSD curves for diazinon based on all data reported in the tables of the UK report, i.e. we considered the data as reliable and applied the guidance rules on how to discriminate among them, e.g. by calculation of the geometric mean. The chosen long- and short-term data are reported in Table A 1.14 and in Table A 1.15.

Table A 1.14: Diazinon, acute toxicity values for SSD based on UK report tabulated values.

Taxonomic group	Species scientific name	Endpoint	Test duration (d)	Conc (µg/l)	UK Report, Klimisch (ref.)
ALG	*Scenedesmus capricornutum*	EC50	7	3'700	[19]
CRU	*Ceriodaphnia dubia*	EC50 (MOR/MORT)	2	0.49 (GM)	K2, [8]
CRU	*Daphnia magna*	EC50 (MOR/MORT)	2	1.03 (GM, ITX)	[19]
CRU	*Daphnia pulex*	EC50	2	0.65	[20-22]
CRU	*Daphnia sp.*	LC50 (MOR/MORT)	2	0.9	[23]
CRU	*Gammarus fasciatus*	LC50 (MOR/MORT)	4	0.2	P [21]
CRU	*Gammarus pseudolimnaeus*	LC50 (MOR/MORT)	30	0.27	P [24]

[52] For TDG 2010, if MAC-QS is lower than AA-QS it has to be set equal to AA-QS.

CRU	*Hyalella azteca*	LC50 (MOR/MORT)	4	4	P [25]
FIS	*Anguilla anguilla*	LC50 (MOR/MORT)	4	80	P [26]
FIS	*Jordanella floridae*	LC50 (MOR/MORT)	4	1'600	P [17]
FIS	*Lepomis macrochirus*	LC50 (MOR/MORT)	4	221 (GM)	[17, 19, 21]
FIS	*Oncorhynchus mykiss*	LC50 (MOR/MORT)	4	584 (GM)	P [21, 27]
FIS	*Pimephales promelas*	LC50 (MOR/MORT)	4	6'140 (GM)	[28]
FIS	*Poecilia reticulata*	LC50 (MOR/MORT)	1	1'100	[19]
FIS	*Salvelinus fontinalis*	LC50 (MOR/MORT)	1	770	P [17]
AMP	*Rana clamitans*	LC50 (MOR/MORT)	16	5	P [29]
ANE	*Lumbricus variegatus*	L(E)C50		9'980	[30]
INS	*Chironomus tentans*	LC50 (MOR/MORT)	4	19.1	P [31]
INS	*Hydropsyche angustipennis*	LC50 (MOR/MORT)	7	1.0	P [32]
INS	*Pteronarcys californica*	LC50 (MOR/MORT)	4	25	P, [32]
MOL	*Pomacea paludosa*	L(E)C50	1	2'950	[33]
PLA	*Dugesia tigrina*	L(E)C50		11'640	[30]

The abbreviation (P) stands for publication and the Klimisch criteria should be 4.
ALG = algae; AMP = Amphibians; ANE = annelids; CRU = crustaceans; FIS = fish; INS = insects; MOL = molluscs; PLA = platyhelminthes.

Table A 1.15: Diazinon, long-term toxicity values for SSD based on UK report tabulated values.

Taxonomic group	Species scientific name	Endpoint	Test duration (d)	Conc (µg/l)	UK Report, Klimisch (ref.)
ALG	*Scenedesmus capricornutum*	NOEC (NR)	7	60	-, [22]
ALG	Mixed population	No Effect (NR)	14	1'000	P, [34]
ALG	*Scenedesmus quadricauda*	No Effect (GRO/REPR)	10	> 1'000	P, [35]
CRU	*Ceriodaphnia dubia*	NOEC (REP/GREP)	7	0.22	P, [36]
CRU	*Daphnia magna*	NOEC (MOR/MORT)	21	0.15[53]	K2, [15]

[53] Mean number of broods, total young per female

CRU	*Gammarus pseudolimnaeus*	NOEC (NR)	30	0.2	-, [24]
FIS	*Brachydanio rerio*	NOEC (PHY/GRO)	56	40	P, [37]
FIS	*Jordanella floridae*	NOEC (REP)	120	< 14	P, [38]
FIS	*Oncorhynchus mykiss*	NOEC (GRO)	28	> 200	P, [37]
FIS	*Pimephales promelas*	NOEC (DEV[54])	up to 274	< 3.2	P, K1, [17]
FIS	*Salmo salar*	NOEC[55]	56	0.1	K1, [13]
FIS	*Salvelinus fontinalis*	NOEC (DEV[56])	122	< 0.55	K2, [17]
INS (Stonefly)	*Acroneuria lycorias*	NOEC (NR)	30	0.83	P, [24]
INS (Midge)	*Chironomus tentans*	LOEC (DEV/GDVP[57])	7	0.003	K4, [39]
INS (Mayfly)	*Ephemerelia subvaria*	NOEC (NR)	30	0.42	P, [24]
INS (Caddisfly)	*Hydropsyche bettoni*	NOEC (NR)	30	1.79	P, [24]
INS (Dragonfly)	*Ophiogomphus rupinsulensis*	NOEC (NR)	30	1.29	P, [24]
INS (Stonefly)	*Pteronarcys dorsata*	NOEC (NR)	30	3.29	P, [24]
ROT	*Brachionus calyciflorus*	NOEC (REP)	2	8'000	P, [40]

The abbreviation (P) stands for publication and the Klimisch criteria should be 4.
ALG = algae; AMP = Amphibians; ANE = annelids; CRU = crustaceans; FIS = fish; INS = insects; MAC = macrophytes; MOL = molluscs; PLA = platyhelminthes; PRO = protozoa ; ROT = rotifera.

[54] Hatching success of eggs, deformation of spinal cord
[55] Physiology, sensitivity to olfactory system
[56] Growth and weight of progeny of exposed parents
[57] Significant delay in egg hatch, increased duration of the larvae stage, slightly depressed pupation and emergence of adults, and lengthened time from eggs to adults by 33.6%.

Table A 1.16: Diazinon, comparison of the number of long- and short-term data used by UK report in the SSD.

Taxa	Number of species in UK report curve (chronic)	Number of species in UK report table (chronic)	Number of species in UK report curve (acute)	Number of species in UK report table (acute)
Algae	3	3	1	1
Amphibians	0	0	1	1
Annelids	0	0	1	1
CRU	5	3	20	6
FIS	9	6	21	8
Insects	7	6	6	3
Molluscs	0	0	1	1
Rotifer	1	1	0	0
Platyhelminthes	0	0	1	1
Higher plants	0	0	0	0
Tot number species (taxa)	**25 (5)**	**18 (5)**	**52 (8)**	**22 (8)**

Using the values tabulated in the UK report, two SSD curves were calculated using the ETX 2.0 software [4]. Tables A 1.17 to A 1.19 report the HC5 values extrapolated from the SSD fit (both acute and chronic), as well as the results of the acceptance tests. Figures A 1.1 and A 1.2 illustrate the curves. Note that it is not possible to calculate an SSD chronic for only the most sensitive species (*a priori* crustaceans), as not enough data are available. Briefly, the acceptance tests highlight if the hypothesis of normality for the SSD curve (postulated with the ETX tool) can be accepted or not.

Table A 1.17: Diazinon, extrapolated HC5 chronic and acute SSD.

Name	HC5 (chronic) [µg/l]	HC5 (acute) [µg/l]
Lower estimate	0.0004	0.0062
Median estimate	0.0076	0.0820
Upper estimate	0.0514	0.4988

Table A 1.18: Diazinon, results of the SSD acceptance tests chronic.

Acceptance test name, n=19	Significance level 0.1	Significance level 0.05	Significance level 0.025	Significance level 0.01
Anderson-Darling	Accepted	Accepted	Accepted	Accepted
Kolmogorov-Smirnov	Accepted	Accepted	Accepted	Accepted
Cramer von Mises	Accepted	Accepted	Accepted	Accepted

Table A 1.19: Diazinon, results of the SSD acceptance tests acute.

Acceptance test name, n=22	Significance level 0.1	Significance level 0.05	Significance level 0.025	Significance level 0.01
Anderson-Darling	Rejected	Accepted	Accepted	Accepted
Kolmogorov-Smirnov	Accepted	Accepted	Accepted	Accepted
Cramer von Mises	Accepted	Accepted	Accepted	Accepted

Following these analyses, we can propose an AA-EQS equal to **0.0015 µg/l** (HC5 chronic /5 ->0.076/5), while the proposed MAC-EQS is equal to **0.0082 µg/l** (HC5 acute /10 -> 0.0820/10). The TGD for EQS proposes a default assessment factor of 5 and 10 for chronic and acute SSD respectively. For chronic SSD it may be decreased to 1, but we had no reason to do it here.

As seen in Figure A 1.2, the most sensitive taxonomic group is crustaceans. In consequence a second SSD using only these data have been created. The fit results are presented in Figure A 1.3, Tables A 1.20 and A 1.21.

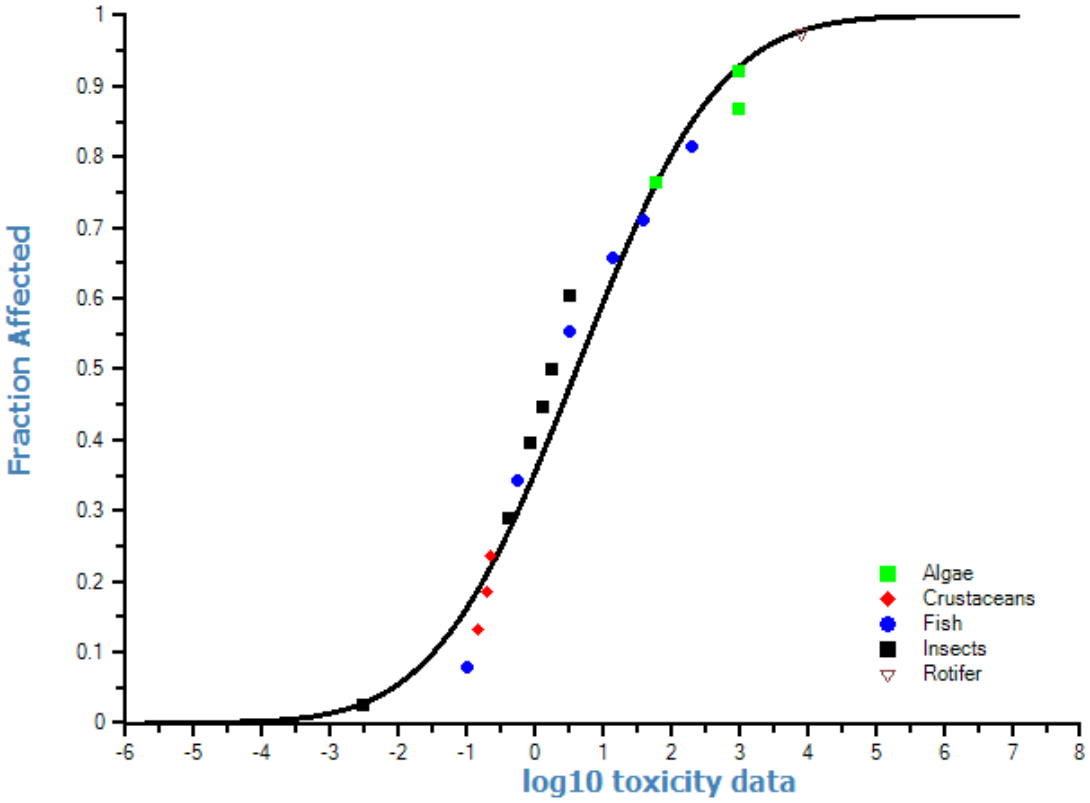


Figure A 1.1: Diazinon chronic SSD curve calculated with UK report data.

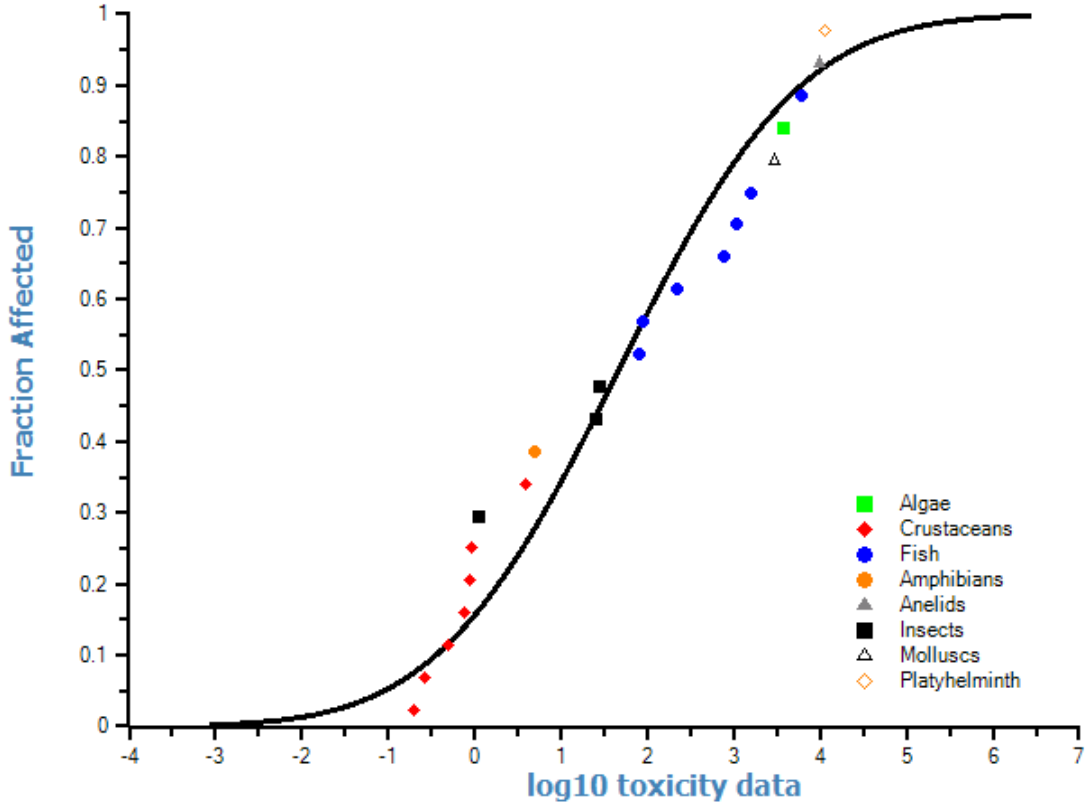


Figure A 1.2: Diazinon acute SSD curve calculated with UK report.

Table A 1.20: Diazinon, extrapolated HC5 crustaceans**.**

Name	HC5 (acute) [µg/l]
Lower estimate	0.0242
Median estimate	0.1245
Upper estimate	0.2763

Table A 1.21: Diazinon, results of the SSD acceptance tests.

Acceptance test name	Significance level 0.1	Significance level 0.05	Significance level 0.025	Significance level 0.01
Anderson-Darling	Accepted	Accepted	Accepted	Accepted
Kolmogorov-Smirnov	Accepted	Accepted	Accepted	Accepted
Cramer von Mises	Accepted	Accepted	Accepted	Accepted

Based only on the acute data for crustaceans, the proposed MAC-EQS is HC5/AF and equals **0.0125 µg/l** calculated from 0.125 µg/l and an AF of 10. This value is higher than the result from the curve constructed fitting all acute results, which is 0.0082 µg/l. In this case, using the most sensitive species only lead to a less protective EQS value, which was quite unexpected.

However, this can be explained based on statistics. The distribution with all the species is at least bimodal, and the fit is therefore worse than with a unimodal distribution as it can be visually seen from Figures A 1.2 and A 1.3 respectively. Due to this bimodality, the curve based on all the species is therefore more flat than the one with only crustaceans, also seen on the figures. However, statistically it is less good, which can also be observed in the large confidence interval of the HC5 for the SSD chronic with all the species.

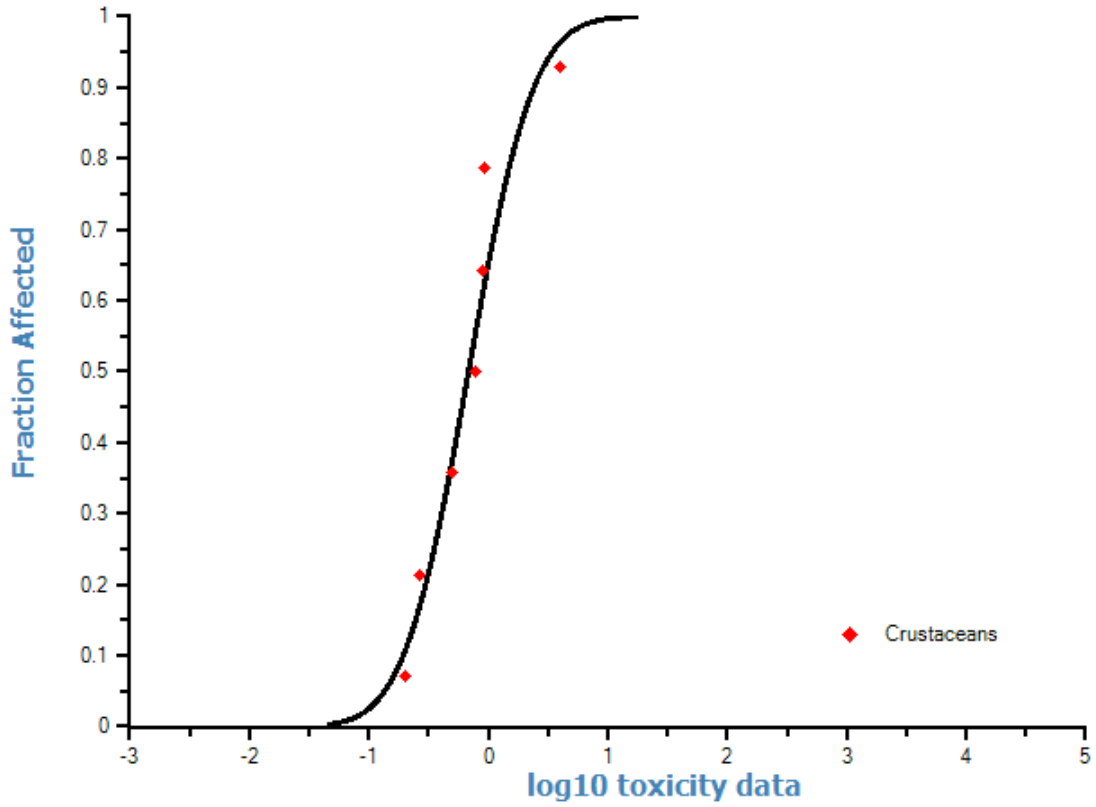


Figure A 1.3: Diazinon acute crustaceans SSD curve calculated with UK report data.

2.5. Diazinon summary of the proposed EQS

Table A 1.22 presents a comparison of all EQS data proposed for diazinon. It summarizes the acute and chronic EQS values resulting from the application of the considered methods. It should be remembered that both TGD for EQS and EQS NL set MAC-EQS values equal to AA-EQS values in case the former are lower than the latter as computation result.

Table A 1.22: Diazinon, summary EQS results.

Data	Type of EQS	Guidance document	Value to be divided by AF (µg/l)	AF	Proposed EQS (µg/l)	See paragraph #, page #
Extrapolated EQS based on reliable and relevant data in accord with the guidance documents as in column 3						
D. magna, NOEC	AA –QS	LP, TG, NL	0.15	10	0.015	2.2.1, 90
Ceriodaphnia dubia, LC50	MAC-EQS	LP	0.49	100 10	0.0049 0.049	2.3.1, 91
Ceriodaphnia dubia, LC50	MAC-EQS	TG	0.49	100 10	0.015 0.049	2.3.1, 91
Ceriodaphnia dubia, LC50	MAC-EQS	NL	0.49	100	0.015	2.3.1, 91
	Negligible concentration	NL	AA-EQS	100	1.5 E-4	---
EQS based on SSD when all the data in the UK report are considered (both reliable and non reliable)						
Chronic	AA-EQS	LP, TG, NL	0.0076	5	0.0015	2.4, 92
Acute	MAC-EQS	LP, TG, NL	0.0820	10	0.0082	2.4, 92
Acute, crustaceans	MAC-EQS	LP, TG, NL	0.1245	10	0.0125	2.4, 92

2.6. Comparison with EQS UK

The proposed chronic EQS value according to AF method is equal to 0.015 µg/l, as detailed in section 2.2.1. As already mentioned, it is more than 600 times lower than the proposed DAR value.

It is important to understand that these two values are estimated with two very different concepts: the first one is an extrapolation of laboratory experiments, while the second is based on mesocosm studies and considered the recovery of the population. Both concepts might be criticized. For example, extrapolations use arbitrary assessment factors and are therefore far from a real situation. Mesocosm studies are closer to real conditions, however on the other hand the mesocosm studies are conducted under very specific exposure conditions (e.g. repeated treatments), which do not always correspond to real exposure (e.g. continuous concentrations).

In the official UK report, the proposed AA and MAC-EQS are 0.01 and 0.2 µg/l respectively. The rational behind the values presented in Table A 1.23 is discussed below. The text was extracted from the respective UK:

Table A 1.23: Diazinon, proposed or existing EQS value according to the UK report on diazinon.

Data	Type of EQS	Value to be divided by (µg/l)	AF	Proposed EQS (µg/l)
UK report proposed EQS				
Salmo salar	AA –QS	0.1	10	0.01
Gammarus fasciatus	MAC-EQS	0.2	10	0.02
Existing EQS cited by UK report				
D. magna	AA –QS	0.15	5	0.03
D. magna	MAC-EQS	0.15	2	0.1

Start of citation UK report.

"Long-term PNEC for freshwaters

Reliable chronic data are available for invertebrates and fish. Recent studies have revealed significant reductions in olfactory responses of male Atlantic salmon (*Salmo salar*) following short-term exposure to 0.3 µg l^{-1} diazinon, with a no observed effect concentration (NOEC) of 0.1 µg l^{-1}. Although the exposure period was only 30 minutes, effects on reproductive steroid concentrations, the sensitivity of the olfactory epithelium and sperm volumes were observed, with important long-term implications for reproductive success. These data are supported by similar NOECs for reproduction in the crustaceans *Ceriodaphnia dubia*, *Daphnia magna* and *Gammarus pseudolimnaeus*. The standard assessment factor of 10 applied to the Atlantic salmon NOEC of 0.1 µg l^{-1} is recommended, resulting in a $PNEC_{freshwater\_it}$ of 0.01 µg l^{-1}.

This is similar to the existing EQS of 0.03 µg l^{-1} for sheep dip insecticides (the combined concentrations of diazinon, chlorfenvinphos, propetamphos, coumaphos and fenchlorphos) based on a *Daphnia magna* NOEC of 0.15 µg l^{-1}, to which an assessment factor of 5 was applied.

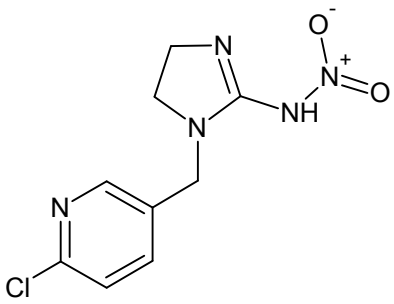
Short-term PNEC for freshwaters Good quality data are available from acute studies with eight taxa including fish, insects and crustaceans. The most sensitive of the insects and crustaceans are at least an order of magnitude more sensitive than the most sensitive fish species. The lowest reliable effects concentration is a 96-hour LC50 of 0.2 µg l^{-1} to the freshwater shrimp *Gammarus fasciatus*. The specific mode of action of diazinon, coupled with the indications that this species is likely to be among the most sensitive taxa, allows a reduced assessment factor (10) to be applied instead of the default value of 100, resulting in a $PNEC_{freshwater\_st}$ of 0.02 µg l^{-1}.

This is five times lower than the existing EQS of 0.1 µg l^{-1} for sheep dip insecticides (the combined concentrations of diazinon, chlorfenvinphos, propetamphos, coumaphos and fenchlorphos) generated using a smaller assessment factor (2) applied to the same critical data, as permitted by the method used to derive the EQS". *End of citation* [5]

3. Imidacloprid

3.1. General data

Table A 1.24: Imidacloprid, general data.

IUPAC name	(E)-1-(6Chloro-3-pyridinylmethyl)-N-nitoimidazolidin-2-ylideneamine	
CAS registry number	138261-41-3	
EU number	428-040-8	
Molecular formula	$C_9H_{10}ClN_5O_2$	
Code SMILES	C1CN(C(=N1)N[N+](=O)[O-])CC2=CN=C(C=C2)Cl	
Pesticide class	Systemic insecticide	
Molecular weigh	255.70 [g/mol]	
BCF max	3.2 [INERIS]	
$LogK_{OW}$	0.57 [INERIS]	
EU classification	Xn; R22 – N; R50-53[58]	

Imidacloprid binds to postsynaptic nicotinic receptors in the insect central nervous system [41].

The following table summarizes the database search results for imidacloprid.

Table A 1.25: Imidacloprid, result of the database search.

Database name	Results	Database name	Results
ECOTOX	Available data	eChemPortal	Available data
PESTICIDEINFO	No ecotox data	WFD UK TAG	Not in the database
HSDB	Available data	OPP	Available data
EU	No ecotox data	AGRITOX	Available data
EFSA	Available data	RIVM	Available data
INERIS	Available data	UK pesticides	Available data
FOOTPRINT	Present, forbidden access	Web of science	Available data
webTOX	Not in the database	Sciencedirect	Available data

[58] Xn: Harmful, R22: Harmful if swallowed, N: Dangerous for the environment, R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

In order to check if no particular sensitive endpoint or effect were detected in recent studies, i.e. studies not included in the different database, data searches using Web of Science and Science Direct were performed using the following key words:

- Imidacloprid aquatic toxicity

Ten results were considered as relevant but not reliable.

3.2. Derivation of EQS values

Three methods have been considered for the EQS derivation: assessment factor, species sensitivity distribution methods, and interpretation of simulated ecosystem studies.

In Tables A 1.26 and A 1.27 the acute (L(E)C50) and chronic (NOEC and EC10) values for imidacloprid are listed. All short- and long-term results which are valid for at least one guidance document have been included.

Table A 1.26: Imidacloprid, acute toxicity values.

Taxonomic group	Species scientific name	Endpoint	Test duration [d]	Conc. [µg/l] (Purity %)	Source	Reliable (Relevant) according to
ALG[59]	*Anabaena flos-aquae*	EC50 (POP/GRT rate)	4	32'800[60] (21.6%)	RIVM (K2), [42]	LP, TG, NL (LP, TG, NL, SN)
ALG	*Scenedesmus subspicatus*	EC50 (POP/BMAS, GRT rate)	3	> 10'000	RIVM (K3), [43]; EFSA [44]	None (LP, TG, NL, SN); LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Selenastrum capricornutum*	EC50 (POP/BMAS, GRT rate)	3	> 10'000 (98.6%)	RIVM (K3), [43]; EFSA, [45]	None (LP, TG, NL, SN); LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Daphnia magna*	EC50 (ITX/IMBL)	2	85'000 (95.4%)	RIVM (K2), [43]; EFSA, [46]	LP, TG, NL (LP, TG, NL, SN); LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Daphnia magna*	EC50 (REP/PROG)	21	> 7'300	EFSA, [47]	LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Chydorus sphaericus*	EC50 (ITX/IMBL)	2	832	RIVM (K2), [48]	LP, TG, NL (LP, TG, NL, SN)

[59] Cyanobacteria
[60] Test compound NTN 33893 2F, results given in mg as/L.

CRU	*Cypretta seuratti*	EC50 (ITX/IMBL)	2	1.0	RIVM (K2), [48]	LP, TG, NL (LP, TG, NL, SN)
CRU	*Cypridopsis vidua*	LC50 (MOR/MORT)	2	273	RIVM (K2), [48]	LP, TG, NL (LP, TG, NL, SN)
CRU	*Cypridopsis vidua*	EC50 (ITX/IMBL)	2	10	RIVM (K2), [48]	LP, TG, NL (LP, TG, NL, SN)
CRU	*Hyalella azteca*	LC50 (MOR/MORT)	4	526 (tg[§])	RIVM (K2), [42, 43]; EFSA, [49]	LP, TG, NL (LP, TG, NL, SN); LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Hyalella azteca*	EC50 (ITX/IMBL)	4	55 (tg[§])	RIVM (K2), [42],	LP, TG, NL (LP, TG, NL, SN)
CRU	*Ilyocypris dentifera*	LC50 (MOR/MORT)	2	214 (tg[§])	RIVM (K2), [48]	LP, TG, NL (LP, TG, NL, SN)
CRU	*Ilyocypris dentifera*	EC50 (ITX/IMBL)	2	3.0 (tg[§])	RIVM (K2), [48]	LP, TG, NL (LP, TG, NL, SN)
FIS	*Oncorhynchus mykiss*	LC50 (MOR/MORT)	4	> 83'000 (95.0%)	RIVM (K2), [43]	LP, TG, NL (LP, TG, NL, SN)
FIS	*Oncorhynchus mykiss*	LC50 (MOR/MORT)	4	> 211'000 (95.3%)	RIVM (K3), [43]; EFSA, [50]	None (LP, TG, NL, SN); LP, TG, NL, SN (LP, TG, NL, SN)
FIS	*Lepomis macrochirus*	LC50 (MOR/MORT)	4	> 105'000 (97.4%)	RIVM (K2), [42]	LP, TG, NL (LP, TG, NL, SN)
FIS	*Leuciscus idus melanotus*	LC50 (MOR/MORT)	4	237'000 (95.3%)	RIVM (K3), [43]; EFSA, [51]	None (LP, TG, NL, SN); LP, TG, NL, SN (LP, TG, NL, SN)
INS	*Chironomus tentans*	LC50 (MOR/MORT)	4	10.5 (95.0%)	RIVM (K2), [42]	LP, TG, NL (LP, TG, NL, SN)
INS	*Chironomus tentans*	LC50 (MOR/MORT)	10	3.17	EFSA, [52]	LP, TG, NL, SN (LP, TG, NL, SN)
INS	*Chironomus riparius*	LC50 (MOR/MORT)	4	55.2 (99.9%)	RIVM (K3), [43]; EFSA, [53]	None (LP, TG, NL, SN); LP, TG, NL, SN (LP, TG, NL, SN)
INS	*Simulium vittatum*	LC50 (MOR/MORT)	2	6.75 (≥ 98%)	RIVM (K1), [54]	LP, TG, NL (LP, TG, NL, SN)

INS	*Simulium vittatum*	LC50 (MOR/MORT)	2	6.25 (≥ 898%)	RIVM (K1), [54]	LP, TG, NL (LP, TG, NL, SN)
INS	*Simulium vittatum*	LC50 (MOR/MORT)	2	9.54 (≥ 98%)	RIVM (K1), [54]	LP, TG, NL (LP, TG, NL, SN)
INS	*Simulium vittatum*	LC50 (MOR/MORT)	2	8.10 (GM)	RIVM (K1), [54]	LP, TG, NL (LP, TG, NL, SN)

[§]Technical grade; ALG = algae; CRU = crustaceans; FIS = fish; INS = insects

Table A 1.27: Imidacloprid, chronic values.

Taxonomic group	Species scientific name	Endpoint	Test duration [d]	Conc. [µg/l] (Purity %)	Source	Reliable (Relevant) according to
ALG[61]	*Anabaena flos-aquae*	NOEC (POP/ GRT rate)	4	24'900[62] (21.6%)	RIVM (K2), [42]	LP, TG, NL (LP, TG, NL, SN)
ALG	*Navicula pelliculosa*	NOEC	7	6'690[63] (21.6%)	RIVM (K2), [42]	LP, TG, NL (LP, TG, NL, SN)
ALG	*Selenastrum capricornutum*	NOEC (POP/ GRT rate)	3	>10'000 (98.6%)	EFSA	LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Pseudokirchneriella subcapitata*	NOEC (POP/ GRT rate)	3	< 100'000 (98.6%)	RIVM (K3), [43]; EFSA	None (LP, TG, NL, SN); LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Scenedesmus subspicatus*	NOEC (POP/ GRT rate)	3	10'000 (98.6%)	RIVM (K3), [43], EFSA	None (LP, TG, NL, SN); LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Scenedesmus subspicatus*	NOEC (POP/ GRT rate)	4	>10'000 (92.8%)	RIVM (K3), [44]; EFSA	None (LP, TG, NL, SN); LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Daphnia magna*	NOEC (REP)	21	1'800 (95.4%)	EFSA (K2), [43]	LP, TG, NL, SN (LP, TG, NL, SN)
FIS	*Oncorhynchus mykiss*	NOEC (GRT)	98	1'200 (tg[§])	RIVM (K2), [42]	LP, TG, NL (LP, TG, NL, SN)

[61] Cyanobacteria
[62] Test compound NTN 33893 2F, results given in mg as/L.
[63] Test compound NTN 33893 2F, results given in mg as/L.

INS	*Chironomus tentans*	NOEC (GRT)	10	0.67 (95.0%)	RIVM (K2), [42]	LP, TG, NL (LP, TG, NL, SN)

[§]Technical grade; ALG = algae; CRU = crustaceans; INS = Insects; FIS = fish

3.2.1. Derivation using AF method

The base data set is not complete for Lepper 2005, because algal values are missing. The cyanobacteria EC50 does not count as an algae for Lepper 2005, like it does for the TGD for EQS and EQS NL (see Table A 1.5). As a consequence, no AA-EQS derivation is possible for Lepper 2005 [1].

For both TGD for EQS [2] and EQS NL [3] the NOEC of the most sensitive organism based on the acute data, *Cypretta seuratti* (lowest L(E)C50), is not represented in the chronic data (Table A 1.27).

In consequence an AF of 50 instead of 10 was applied to the lowest NOEC value presented in Table A 1.6. Therefore, the proposed **AA-EQS** is **0.0134 µg/l**, calculated as 0.67 µg/l for the NOEC *Chironomus tentans* divided by the assessment factor of 50.

Please note that the short- and long-term results present in the EU DAR, which should have been considered valid without further evaluation, were evaluated by the RIVM and most of them considered as not reliable (K3).

3.2.2. Derivation using SSD method

The available chronic data are listed in Table A 1.27. As explained in section 1.5, the SSD method requires a minimum of 10 NOECs (preferably more than 15 NOECs) for different species covering at least eight taxonomic groups.

For imidacloprid, there are not sufficient reliable and relevant long-term results, with maximum nine long-term results for four taxa being found.

3.2.3. Interpretation of simulated ecosystem studies

No long-term mesocosms studies have been found. Further discussion is presented in the section 3.3.3.

3.3. Derivation of MAC-EQS values

Three methods have been considered for the EQS derivation: the assessment factor method, the species sensitivity distribution method, and a microcosm study reported by RIVM [55].

3.3.1. Derivation using AF method

The lowest short-term result is 1.0 µg/l for *Cypretta seuratti*, a crustacean. The appropriate AF has to be chosen depending on (i) the potential to bioaccumulate, (ii) whether the mode of action is known, (iii) the number of data available, and (iv) the selected guidance document.

Because there seems to be no potential for bioaccumulation, an AF between 100 and 10 can be applied according to all guidance documents, with 100 as standard factor and 10 as lower value, since the mode of action is known and the most sensitive species (insects) is present in the dataset.

It is relevant to note that a large difference exists between the LC50 (mortality) and the EC50 (immobilisation) for the same species (*Cypretta seuratti* and *Ilyocypris dentifera,* ratio varies between 27 and 71 respectively).

The proposed **MAC-EQS** is therefore between **0.01** and **0.1 µg/l**, depending on "expert judgement".

3.3.2. Derivation using SSD method

For imidacloprid, there are not sufficient reliable and relevant long-term results, with maximum 16 short-term results for four taxa being considered as reliable and relevant.

Due to the number of data available, despite the required number of taxa not being fulfilled, we decided to extrapolate the SSD curve. The acute data present in Table A 1.26 were inserted in ETX 2.0 software [4], the results are displayed in Table A 1.28 as the HC5 values, in Table A 1.29 as the acceptance tests (normality of the distribution), and in Figure A 1.4 as the acute SSD curve.

The proposed MAC-EQS calculated as HC5/AF (0.3458/10) results in **0.035 µg/l**.

Table A 1.28: Imidacloprid, extrapolated HC5 acute SSD.

Name	HC5 (acute)
Lower estimate	0.0072
Median estimate	0.3458
Upper estimate	4.1284

Table A 1.29: Imidacloprid, results of the acute SSD acceptance tests.

Acceptance test name (n=15)	Significance level 0.1	Significance level 0.05	Significance level 0.025	Significance level 0.01
Anderson-Darling (n ≥ 8)	Accepted	Accepted	Accepted	Accepted
Kolmogorov-Smirnov (n ≥ 20)	Accepted	Accepted	Accepted	Accepted
Cramer von Mises (n ≥ 20)	Accepted	Accepted	Accepted	Accepted

After visual inspection the curve is clearly bimodal, thus a second SSD has been extrapolated using only crustaceans' short-term data. The Figure A 1.5 illustrates the curve, the Table A 1.30 presents the HC5 values and the Table A 1.31 the results of the acceptance tests.

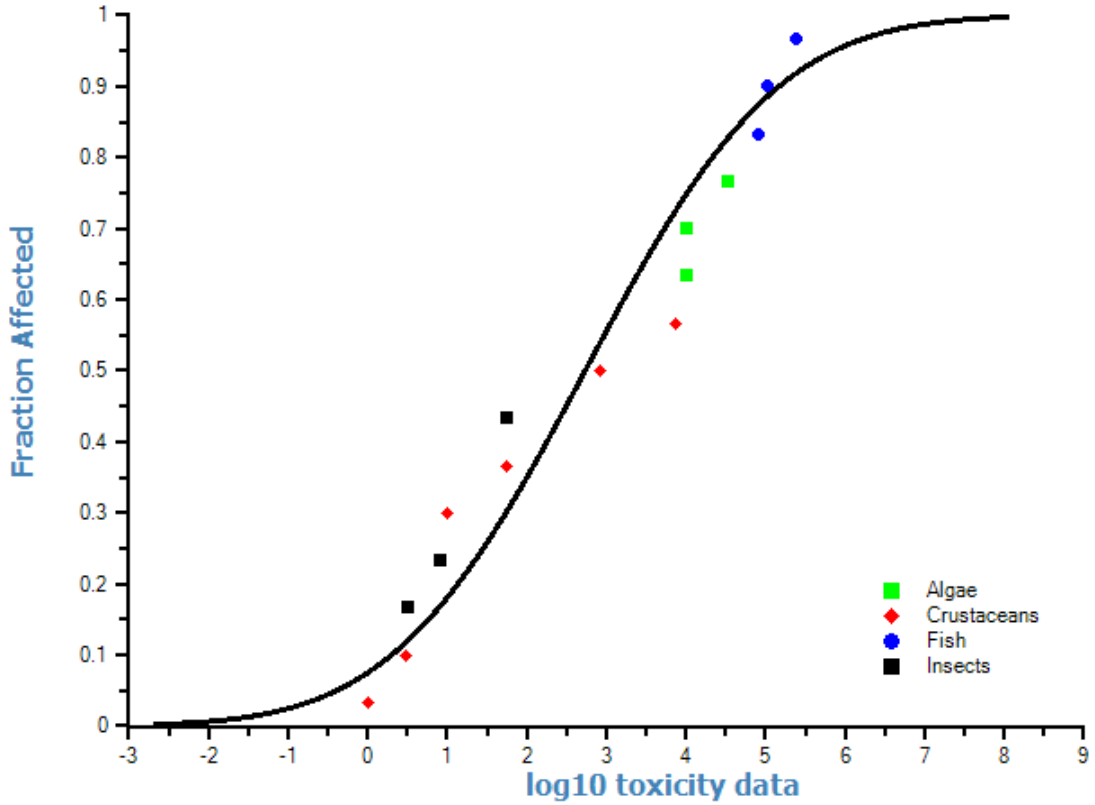


Figure A 1.4: Imidacloprid: acute SSD curve.

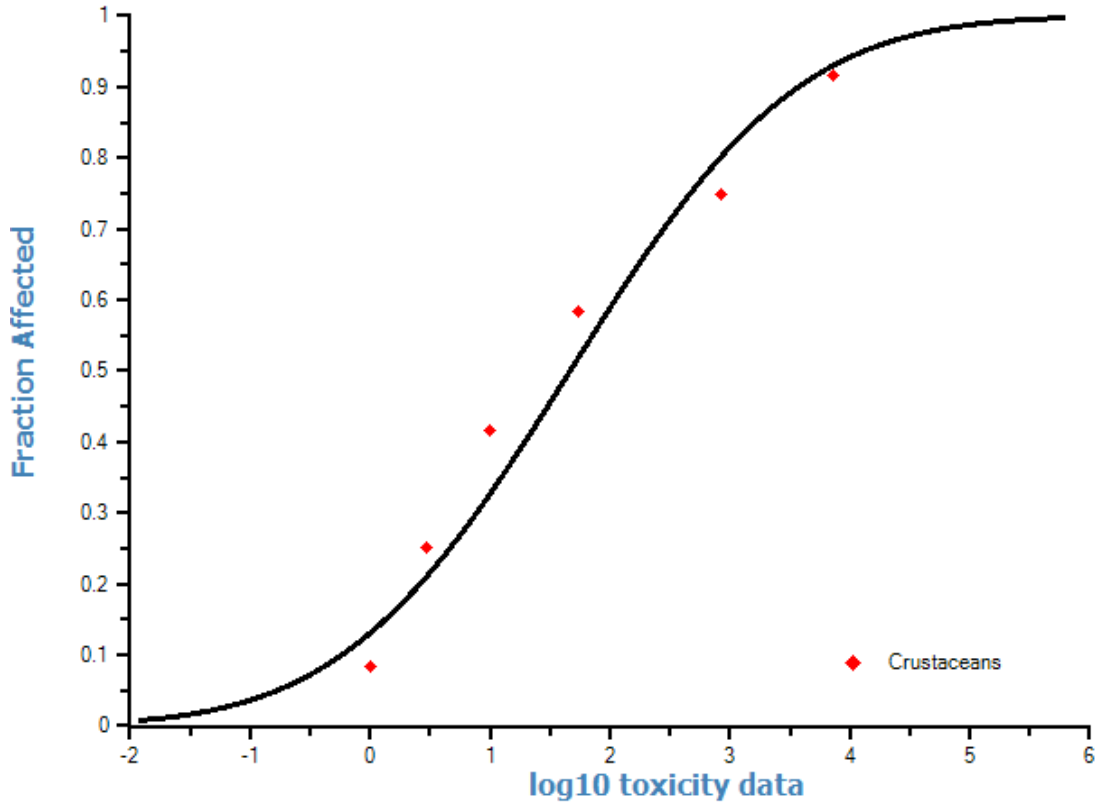


Figure A 1.5: Imidacloprid: acute SSD curve extrapolated using only crustacean data.

Table A 1.30: Imidacloprid, extrapolated HC5 acute SSD (crustaceans data only).

Name	HC5 (acute crustaceans only)
Lower estimate	0.0001
Median estimate	0.1164
Upper estimate	2.3282

Table A 1.31: Imidacloprid, results of the acute crustaceans SSD acceptance tests.

Acceptance test name (n=7)	Significance level 0.1	Significance level 0.05	Significance level 0.025	Significance level 0.01
Anderson-Darling (n ≥ 8)	Accepted	Accepted	Accepted	Accepted
Kolmogorov-Smirnov (n ≥ 20)	Accepted	Accepted	Accepted	Accepted
Cramer von Mises (n ≥ 20)	Accepted	Accepted	Accepted	Accepted

The proposed MAC-EQS as HC5/AF equals **0.012 µg/l** (0.1164/10).

3.3.3. Interpretation of simulated ecosystem studies

A microcosm study with natural populations of algae, invertebrates and zooplankton is described in the RIVM report [55, 56], as follows.

"Test system

Thirteen microcosms of 2.0-2.2 m diameter, 10 cm natural sediment and 1.0 m water, total 3100-3800 l, Aachen, Germany, sediment not specified. Organisms were added with the sediment and phytoplankton and zooplankton were obtained from natural ponds. Ponds were left to establish during 6 months. Application took place on May 2 and 23, 2001, Treatments, 0, 0.6, 1.5, 3.8, 9.4 and 23.5 a.s. µg/L in duplicate, untreated in triplicate. The substance was sprayed on the pond surface.

Analytical sampling

Concentration was measured in the application solutions, and in initial concentrations in pond water samplings, and regularly during the experiment in water and sediment.

Effect parameters zooplankton, phytoplankton, chlorophyll-a, emerging insects and macrozoobenthos (by artificial substrate and sediment) were regularly monitored.

[...] Biological observations

Insects (caught by the emergence traps) were the most significantly affected organisms, from 1.5 µg/L upwards. Effects were found on community parameters such as taxa richness, diversity, similarity and principal response. Chironomidae and Baetidae were the most sensitive taxa. No effects were found at 0.6 µg/L, which can be seen as the NOEC. Indirect effects are found on algae, but only the NOEAEC (defined as recovery within 8 weeks after last application) of 23.5 µg/L is reported. For zooplankton NOEC of 9.4 µg/L is reported for copepods and cladocerans, for macrozoobenthos the NOEC for the most sensitive species (*Chaoborus* spp.) is 9.4 µg/L.

[...] Criteria for a suitable (semi)field study

These criteria result in an overall assessment of the study reliability. The study is considered to be less reliable (Ri 2) mainly due to the lack of details in the available summary. The RMS and the notifier appointed the 0.6 µg/L-treatments as the NOEC. The notifier and RMS did not agree on the level of the NOEAEC. Both RMS and notifier agreed on a small TER trigger, because uncertainty of the NOEC is considered to be relatively low. The notifier proposes a factor of two as TER trigger.

Conclusion

For ERL-derivation, the NOEC based on the **0.6 µg/L**-treatment with an actual initial concentration similar to the nominal concentration is used. Experimental ponds were exposed to imidacloprid in two peaks and actual concentrations declined rather rapid. Therefore, the results of the underlying study can be used for derivation of the **MAC**, but the study is not suitable for derivation of the MPC[64]" [55].

To derive a MAC-EQS, the RIVM used this value of 0.6 µg/l divided by an assessment factor of 3, which gave a value of 0.2 µg/l and is different from the notifier's proposed factor (2).

Microcosm or mesocosm studies reported by EFSA (EU DAR):

FIRST STUDY:

"Assessment of the potential ecological and biological effects of NTN 33893 on aquatic ecosystem as measured in fibreglass pond systems".

Since this study was not considered to be acceptable, no further details will be given.

SECOND STUDY:

See study reported by RIVM

Contrary to RIVM, EFSA (EU DAR) accept the proposed AF of 2.

THIRD STUDY:

"Biological effects and fate of imidacloprid SL 200 in outdoor microcosm ponds". Unpublished report Date 25.2.2005 WAT2005-348, Brock T.C.M. (2005)

EFSA conclusion: "The variability in insect species sensitivity not being fully addressed in this study, we maintain our proposal of a safety factor of 2 on the NOEC/NOEAEC of 0.6 µg/l."

FOURTH STUDY:

"Fate of imidacloprid SL 200 in outdoor microcosms, Bayer Crop-Science AG, unpublished report No.HBF/MT 11, Date: 2001-02-20 WAS2003-257.

[64] MPC = maximum permitted concentration, equivalent to AA-QS

Guidelines: OECD guidance document “freshwater lentic field tests (outdoor microcosms and mesocosms)”, June 2000 (Draft). Guidance documents on testing procedures for pesticides in Fresh-water microcosms (SETAC-Europe Workshop, Monks Woos, UK, July 1991). Deviations: not mentioned.”

The study used two replicates for one concentration and one control pond:

“The test substance was applied once [...]. The treatment level was 6.0 µg /L per application. [...] The microcosms were investigated for a period of 70 days after treatment. [...] the results of the treated microcosms demonstrate a steady decline of imidacloprid in the water after the application. [...] after the application, the active substance disappeared constantly and steadily with a half-life of 5.7 days (water) in both tested systems and 8.5 days (water plus sediments) in the tank system”.

3.4. Imidacloprid summary of the proposed EQS

The following table summarizes the acute and chronic EQS values resulting from the application of the methods considered. No AA-EQS or MAC-EQS values were proposed according to Lepper 2005 because the base data set is not complete since algal values are missing.

Table A 1.32: Imidacloprid, summary EQS results.

Data	Type of EQS	Guidance document	Value to be divided by AF (µg/l)	AF	Proposed EQS (µg/l)	See paragraph #, page #
EQS derived using reliable and relevant data in agreement with the guidance documents						
Chironomus tentans, NOEC	AA –QS	TG, NL	0.67	50	0.0134	3.2.1, 105
Cypretta seuratti, LC50	MAC-EQS	TG, NL	1	100 10	0.0134 0.1	3.3.1, 105
	Negligible concentration	NL	AA-EQS	100	1.34E-4	
EQS derived using all data but criteria for SSD not met for the guidance documents						
SSD acute	MAC-EQS		0.3458	10	0.035	3.3.2, 106
SSD acute (crustaceans)	MAC-EQS		0.1164	10	0.012	3.3.2, 106

The EFSA (EU DAR) does not propose a MAC or an AA-EQS value, but evaluates the risk assessment based on TER, *i.e.* PEC/PNEC ratio.

The Table A 1.33 summarizes the EQS values proposed by RIVM.

Table A 1.33: Imidacloprid, summary of the EQS results present in RIVM report.

Data	Type of EQS	Value to be divided by AF (µg/l)	AF	Proposed EQS (µg/l)
Chironomus tentans, NOEC	AA–QS	0.67	10	0.067
Cypretta seuratti, LC50	MAC-EQS	1	10	0.1
Chironomids and Baetidae, NOEC, mesocosm	MAC-EQS	0.6	3	0.2

For the derivation of AA-EQS, the RIVM does neither agree with the TGD for EQS nor with the EQS NL in two points [3]:

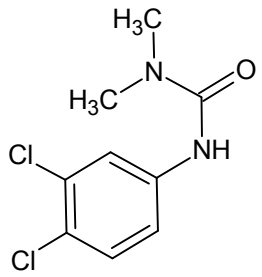
1. In the RIVM imidacloprid report the base set is considered incomplete, missing algae values. Nevertheless it states that the risk assessment can be performed as if the base set is complete because 1) only algal acute toxicity are missing, and 2) algal species are not the most sensitive based on chronic results. The RIVM report dates of 2008. In The Dutch guideline (2007), it is clearly stated that: "*Cyanobacteria (blue-green algae or Cyanophyta) belong to the trophic level of primary producers. This means that results from (both chronic and acute) tests with cyanobacteria can replace results with algae when applying the assessment factor scheme. Therefore, the results of these studies can be used to complete the base set, in cases where there is no study for algae. 'Additionally, blue-green algae should be counted among the primary producers due to their autotrophic nutrition' (cited from TGD)*" [3]. Therefore it is not clear why RIVM claims that the base set is not complete in the imidacloprid report.

2. RIVM applies an AF of 10 to the lower NOEC instead of 100. An AF of 100 is recommended when none of the long-term results corresponds to the lowest acute data, i.e. long-term toxicity is not evaluated for the most sensitive acute species (Table A 1.6). This discrepancy could be due to "expert judgement", however the reasons for this decision were not found in the report.

4. Diuron

4.1. General data

Table A 1.34: Diuron, general data.

IUPAC name	3-(3,4-dichlorophenyl)-1,1-dimethylurea	
CAS registry number	330-54-1	
EC number	206-354-4	
Molecular formula	$C_9H_{10}Cl_2N_2O$	
Code SMILES	Clc1ccc(NC(=O)N(C)C)cc1Cl	
Pesticide class	Herbicide, Phenylurea	
Molecular weight	233.09 [g/mol]	
BCF max	15-85 laboratory, 190-300 field study [57]	
$LogK_{OW}$	2.87 [EU DAR]	
EU classification	Carc. Cat. 3; R40 - Xn; R22-48/22 - N; R50-53[65]	

Diuron is a systemic herbicide, absorbed via the roots. It is strongly inhibiting the photosynthesis, by blocking the electron flow in photosystem II [58]. In its endocrine disruptor classification, the EU community places it in category 2: “at least some *in vitro* evidence of biological activity related to endocrine disruption”.

The following table summarizes the database search results for diuron.

Table A 1.35: Diuron, result of the database search.

Database name	Results	Database name	Results
ECOTOX	Available data	eChemPortal	Available data
PESTICIDEINFO	Data from ECOTOX	WFD UK TAG	Not present in database
HSDB	Available data	OPP	Available data
EU	No ecotox data	AGRITOX	Not present in database
EFSA	Not present in database	RIVM	Not present in database
INERIS	Available data	UK pesticides	Available data
FOOTPRINT	Present, forbidden access	Web of science	Available data
webTOX	Available data	Sciencedirect	Available data

[65] R40: limited evidence of a cancinogenic effect Xn: Harmful, R22: Harmful if swallowed, R48/22: Harmful: danger of serious damage to health by prolonged exposure if swallowed. N: Dangerous for the environment, R50/53: Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment.

Data search using Web of science were performed using the following key words,

- Diuron aquatic toxicity (164 results)

The goal was to check if no particular sensitive endpoint or effect were detected in recent studies, i.e. studies not included in the different databases.

No reliable results were found.

Analogously, for Sciencedirect:

- Diuron toxicity (1334 results)
- Diuron toxicity + aquatic toxicity (573 results)

No reliable results were found.

4.2. Derivation of EQS values

Three methods have been considered for the EQS derivation: the assessment factor method, the species sensitivity distribution method, and interpretation of simulated ecosystem studies.

In Table A 1.36 and Table A 1.37 the acute (L(E)C50) and chronic (NOEC and EC10) values for diuron are listed. All short- and long-term results which are valid for at least one guidance document have been included.

Table A 1.36: Diuron, acute toxicity values.

Taxonomic group	Species scientific name	Endpoint	Test duration [d]	Conc. [µg/l] (Purity %)	Source	Reliable (Relevant) according to
ALG[66]	*Anabaena flos-aquae*	EC50 (POP/BMAS)	3	23.2 (98.7%)	EU DAR, [59]	LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Scenedesmus subspicatus*	EC50 (POP/BMAS)	3	1.0[67] (80%)	EU DAR, [60]	LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Selenastrum capricornutum*	EC50 (POP/ BMAS)	5	2.9 (96.8%)	EU DAR, [61]	LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Daphnia magna*	EC50 (ITX/IMBL)	2	1'400 (98.8%)[68]	EU DAR, [62]	LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Hyalella azteca*	LC50 (MOR/MORT)	21	420 (79.2%)	EU DAR, [63]	LP, TG, NL, SN (LP, TG, NL, SN)

[66] Cyanobacteria
[67] Corrected to measured concentration
[68] The test followed the guideline, apart from that feeding was performed and no analytical verification of test concentration was performed. However, the data are considered valid.

FIS	*Cyprinodon variegates*	LC50 (MOR/MORT)	4	6'700 (99%)	EU DAR, [64]	LP, TG, NL, SN (LP, TG, NL, SN)
FIS	*Oncorhynchus mykiss*	LC50 (MOR/MORT)	4	14'700 (98.2%)	EU DAR, [65]	LP, TG, NL, SN (LP, TG, NL, SN)
FIS	*Oncorhynchus mykiss*	LC50 (MOR/MORT)	28	4'010 (98.2%)[69]	EU DAR, [66]	LP, TG, NL, SN (LP, TG, NL, SN)
INS	*Chironomus riparius*	LC50 (MOR/MORT)	41	> 4'000 (79.2%)	EU DAR, [57]	LP, TG, NL, SN (LP, TG, NL, SN)
MAC	*Lemna gibba*	EC50 (frond area)	0-7	18.3 (98.7%)	EU DAR, [67]	LP, TG, NL, SN (LP, TG, NL, SN)

ALG = algae; CRU = crustaceans; FIS = fish; INS = Insects; MAC = Macrophytes

Table A 1.37: Diuron, chronic values.

Taxonomic group	Species scientific name	Endpoint	Test duration [d]	Conc. [µg/l] (Purity %)	Source	Reliable (Relevant) according to
ALG[70]	*Anabaena flos-aquae*	NOEC	3	10 (98.7%)	EU DAR, [59]	LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Selenastrum capricornutum*	NOEC	5	1.3 (96.8%)	EU DAR, [61]	LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Scenedesmus subspicatus*	NOEC (POP/ BMAS)	3	0.46 (98.5%)	EU DAR, [60]	LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Daphnia magna*	NOEC (REP)	21	56 (98%)	EU DAR, [62]	LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Daphnia magna*	NOEC (GRT)	21	96[71] (98%)	EU DAR, [62]	LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Hyalella azteca*	NOEC (MOR/MORT)	21	60 (79.2%)	EU DAR [63]	LP, TG, NL, SN (LP, TG, NL, SN)
FIS	*Oncorhynchus mykiss*	NOEC (MOR/MORT)	28	410 (98.2%)	EU DAR [68]	LP, TG, NL, SN (LP, TG, NL, SN)

[69] The long term LC50 was 4.01 mg test substance (ts)/L, whereas the acute value LC50 (96 hr) was 14.7 mg/L. Further the increasing intoxication during the test period at 1.97 mg ts/L indicates that extension of the experiment for 1 or 2 weeks further would have resulted in a significantly lower long term LC50

[70] Cyanobacteria

[71] EU DAR uses this value for EQS derivation.

FIS	*Cyprinodon variegatus*	NOEC (MOR/MORT)	38	1'700 (96.8%)[72]	EU DAR [68]	LP, TG, NL, SN (LP, TG, NL, SN)
INS	*Chironomus riparius*	NOEC (MOR/MORT)	41	> 4'000 (79.2%)	EU DAR, [57]	LP, TG, NL, SN (LP, TG, NL, SN)
MAC	*Lemna gibba*	NOEC (frond area)	0-7	3.4 (98.7%)	EU DAR, [67]	LP, TG, NL, SN (LP, TG, NL, SN)

ALG = algae; CRU = crustaceans; FIS = fish; INS = Insects; MAC = Macrophytes

4.2.1. Derivation using AF method

In case the base data set is complete and at least three long-term species values (NOECs) are available, generally an assessment factor of 10 is applied to the lowest NOEC value. For this compound the dataset is complete for all guidelines.

The species with the highest sensitivity to diuron in the set of acute data is *Scenedesmus subspicatus* since its NOEC is present (Table A 1.37). An AF of 10 can be applied to the lowest NOEC value, i.e. 0.46 µg/l (*Scenedesmus subspicatus*). For all guidelines, the proposed **AA-EQS** is **0.046 µg/l**.

4.2.2. Derivation using SSD method

The available data are listed in Table A 1.37. As explained in section1.5, the SSD method requires a minimum of 10 NOECs (preferably more than 15 NOECs) for different species covering at least 8 taxonomic groups.

For diuron, there are not sufficient reliable and relevant long-term results available, with maximum nine long-term results for five taxa found.

4.2.3. Interpretation of simulated ecosystem studies

Two relevant but not reliable micro/mesocosms studies are available:

- Knauer, K; Leimgruber, A; Hommen, U; Knauert, S; 2010; Co-tolerance of phytoplankton communities to photosynthesis II inhibitors Aquatic Toxicology 96(4); 256-263
- Knauert, S; Singer, H; Hollender, J; Knauer, K; 2010; Phytotoxicity of atrazine, isoproturon, and diuron to submersed macrophytes in outdoor mesocosms ; Environmental Pollution 158(1); 167-174.

Therefore the method was not applicable for diuron.

[72] The trend that the measured concentrations generally exceeded the nominal indicates that the method is not exact, however, they are within ± 20% of the nominals. Hence, it would have been in accordance with guidelines to use the nominal concentration.

4.3. Derivation of MAC-EQS values

Two methods have been considered for the EQS derivation: the assessment factor and the species sensitivity distribution method.

4.3.1. Derivation using AF method

Table A 1.36 shows all the short-term data considered reliable and relevant. The base set is complete and diuron has a BCF factor of maximum of 85 or 300 [L/kg_{ww}] in laboratory and in one field study respectively [57]. Depending on the trusted value the AF can change drastically. Since only one field study states that diuron BCF ≥ 100 [L/kg_{ww}], and many studies state the opposite, in the present report it is assumed that it does not bioaccumulate.

Since the mode of action of diuron is known, an AF < 100 might be appropriate. However, data on only a few representatives (3) of the most sensitive taxa are present, which make the choice of the AF difficult.

The lowest relevant value is the EC50 of 1.0 µg/l for *Scenedesmus subspicatus*. If we consider an AF between 10 and 100, the **MAC-EQS** is therefore between **0.1 µg/l** and **0.01 µg/l**.

It is interesting to note that this last value is lower than the proposed AA-EQS of 0.046 µg/l, which is contradictory. The TGD for EQS and EQS NL clearly state to set MAC-EQS equal to AA-EQS, in case the latter is lower than the former [3]. The factor of 100 is therefore clearly too high, however it is difficult to fix a value for the factor, and each decision would be based on "expert judgement".

4.3.2. Derivation using SSD method

For diuron, there are not sufficient reliable and relevant long-term results, with maximum nine short-term results for five taxa considered as reliable and relevant.

4.3.3. Interpretation of simulated ecosystem studies

No values from micro/mesocosms studies are available, thus this method is not applicable for diuron.

4.4. Diuron: summary of the proposed EQS

The following table summarizes the acute and chronic EQS values resulting from the application of the methods considered.

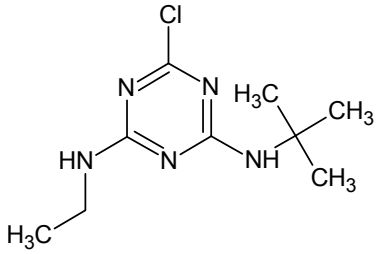
Table A 1.38: Diuron, summary EQS results.

Data	Type of EQS	Guidance document	Value to be divided by AF (µg/l)	AF	Proposed EQS (µg/l)	See paragraph #, page #
EQS derived using reliable and relevant data in agreement with the guidance documents						
Scenedesmus subspicatus, NOEC	AA –QS	LP, TG, NL	0.46	10	0.046	4.2.1, 115
Scenedesmus subspicatus, EC50	MAC-EQS	LP	1	100 10	0.01 0.1	4.3.1, 116
Scenedesmus subspicatus, EC50	MAC-EQS	TG, NL	1	100 10	0.046 0.1	4.3.1, 116
	Negligible concentration	NL	AA-EQS	100	4.6 E-4	---

5. Terbuthylazine

5.1. General data

Table A 1.39: Terbuthylazine, general data.

IUPAC name	N-tert-butyl-6-chloro-N'-ethyl-1,3,5-triazine-2,4-diamine	
CAS registry number	5915-41-3	
EC number	227-637-9	
Molecular formula	$C_9H_{16}ClN_5$	
Code SMILES	CCNC1=NC(=NC(=N1)Cl)NC(C)(C)C	
Pesticide class	Herbicide	
Molecular weigh	229.7 g/mol	
BCF max	34 [EFSA, EU DAR, [69]]	
$LogK_{OW}$	3.4 [EFSA, EU DAR, [70]]	
EU classification[73]	Xn; R22- N; R50-53[74]	

"Terbuthylazine is mainly taken up via plant roots, although entering the leaves is possible. The site of application is located in the chloroplasts of leaf meristems where interference with the electron transport of Photosystem II ("Hill-reaction") takes place leading to inhibition of photosynthesis" [71].

Table A 1.40: Terbuthylazine, result of the database search.

Database name	Results	Database name	Results
ECOTOX	Available data	eChemPortal	Available data
PESTICIDEINFO	Data from ECOTOX	WFD UK TAG	Not present in database
HSDB	Available data	OPP	Available data
EU	Not present in database	AGRITOX	Not present in database
EFSA	Available data	RIVM	Not present in database
INERIS	No ecotox data	UK pesticides	Not present in database
FOOTPRINT	Available data	Web of science	Available data
webTOX	Not present in database	Sciencedirect	Available data

[73] No classification found in the European Chemical Substances Information System; classification provided by BMG via Dr. Andreas Häner.
[74] Xn: Harmful, R22: Harmful if swallowed, N: Dangerous for the environment, R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

After web data search, the three following scientific papers have been classified as “relevant”. However, since the data given in each of these publications is not sufficient for a Klimisch assessment and they have not been “peer reviewed” by (inter)national organizations nor their validity assessed by an international organization, their Klimisch score was set to K4. Hence, it was not possible to include their results in the following discussion.

1. Cedergreen, N., Spliid, N.H., and Streibig, J.C., (2004). Species-specific sensitivity of aquatic macrophytes towards two herbicides, Ecotoxicology and Environmental Safety 58:314-323
2. Munkegaard, M., Abbaspoor, M., Cedergreen, (2008). Organophosphorous insecticides as herbicide synergists on the green algae *Pseudokirchneriella subcapitata* and the aquatic plant *Lemna minor*, Ecotoxicology 17:29-35
3. Nitschke, L., Wilk, A., Schussler, W., Metzner, G. and Lind, G., (1999), Biodegradation in laboratory activated sludge plants and aquatic toxicity of herbicides, Chemosphere 39:2313-2323.

5.2. Derivation of EQS values

Three methods have been considered for the EQS derivation: the assessment factor method, the species sensitivity distribution method, and the interpretation of simulated ecosystem studies.

In Tables A 1.41 and A 1.42 the acute (L(E)C50) and chronic (NOEC and EC10) values for terbuthylazine are listed. All short- and long-term results which are valid for at least one guidance document have been included.

Table A 1.41: Terbuthylazine, acute toxicity values.

Taxonomic group	Species scientific name	Endpoint	Test duration [d]	Conc. [µg/l] (Purity %)	Source	Reliable (Relevant) according to
ALG[75]	*Anabaena flos-aquae*	EC50 (POP/BMAS)	2-5	18 (98%)	EFSA, [72]	LP, TG, NL, SN (LP, TG, NL, SN)
ALG[76]	*Navicula pelliculosa*	EC50 (POP/BMAS)	4	> 25 (96.4%)	EFSA, [73]	LP, TG, NL, SN (LP, TG, NL, SN)
ALG[77]	*Microcystis aeruginosa*	EC50 (POP/GRT rate)	5	10.2 (98%)	EFSA, [74]	LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Scenedesmus subspicatus*	EC50 (POP/ BMAS)	3	16 (96.4%)	EFSA, [73]	LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Pseudokirchneriella subcapitata*	EC50 (POP/ BMAS)	3	12 (96.6%)	EFSA, [75]	LP, TG, NL, SN (LP, TG, NL, SN)

[75] Cyanobacteria
[76] Diatoms
[77] Cyanobacteria

FIS	*Oncorhynchus mykiss*	LC50 (MOR/MORT)	4	2'200 (96.8%)	EFSA, [76]	LP, TG, NL, SN (LP, TG, NL, SN)
FIS	*Cyprinus carpio*	LC50 (MOR/MORT)	4	> 5'700 (96.8%)	EFSA, [76]	LP, TG, NL, SN (LP, TG, NL, SN)
FIS	*Lepomis macrochirus*	LC50 (MOR/MORT)	4	~ 6'800 (97%)	EFSA, [77]	LP, TG, NL, SN (LP, TG, NL, SN)
MAC	*Lemna gibba*	EC50 (frond area)	7	12.8 (97.7%)	EFSA, [78]	LP, TG, NL, SN (LP, TG, NL, SN)

ALG = algae; CRU = crustaceans; FIS = fish; INS = Insects; MAC = Macrophytes

Table A 1.42: Terbuthylazine, long-term values.

Taxonomic group	Species scientific name	Endpoint	Test duration [d]	Conc. [µg/l] (Purity %)	Source	Reliable (Relevant) according to
ALG[78]	*Anabaena flos-aquae*	NOEC (POP/BMAS)	2-5	8.9 (98%)	EFSA, [72]	LP, TG, NL, SN (LP, TG, NL, SN)
ALG[79]	*Navicula pelliculosa*	NOEC (POP/BMAS)	4	10 (96.4%)	EFSA [73]	LP, TG, NL, SN (LP, TG, NL, SN)
ALG[80]	*Microcystis aeruginosa*	NOEC (POP/ BMAS & GRT rate)	5	3.96[81] (98%)	EFSA, [74]	LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Scenedesmus subspicatus*	NOEC (POP/ BMAS)	3	3.3 (96.4%)	EFSA [73]	LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Pseudokirchneriella subcapitata*	NOEC (POP/ BMAS)	3	1.2 (96.6%)	EFSA, [75]	LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Daphnia magna*	NOEC (GRT)	21	19 (96.8%)	EFSA, [79]	LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Daphnia magna*	NOEC (ITX/IMB)	21	17 (96.5%)	EFSA, [80]	LP, TG, NL, SN (LP, TG, NL, SN)
FIS	*Oncorhynchus mykiss*	NOEC (Hatching, growth[82])	90	90 (96.8%)	EFSA, [81]	LP, TG, NL, SN (LP, TG, NL, SN)
FIS	*Oncorhynchus mykiss*	NOEC juvenile (GRT)	21	310 (99%)	EFSA, [82]	LP, TG, NL, SN (LP, TG, NL, SN)

[78] Cyanobacteria
[79] Diatoms
[80] Cyanobacteria
[81] The reported value is 39.6 i.e. higher than the corresponding EC50 for biomass; which is reported as 102 µg/l below the experiment and as 10.2 µg/l in the summary table. Since the EC50 growth rate is 16 µg/l and the EC50 biomass is usually lower than the corresponding growth rate, we believe the corrected NOEC value to be 3.96.
[82] Early fife-stage

INS	*Chironomus riparius*	NOEC (Development)	28	500 (99+96.8%)	EFSA, [83]	LP, TG, NL, SN (LP, TG, NL, SN)

ALG = algae; CRU = crustaceans; FIS = fish; INS = Insects

5.2.1. Derivation using AF method

The base data set is not complete, since the acute values are missing for *Daphnia sp*. and the two experiments reported in the DAR have been classified as not suitable for risk assessment.

No AA-EQS derivation is possible for **Lepper 2005**.

For the **TGD for EQS**, the assessment can be followed as if the dataset was complete because the missing species is not the potentially most sensitive one, as detailed in Table A 1.6. Indeed, in the summary table of the report (B.9.2.52, page 61) it is written that: "no definitive acute endpoint for aquatic invertebrate was identified; however, the submitted studies are of adequate quality to demonstrate that aquatic invertebrates are less acutely sensitive to terbuthylazine than fish and algae" [69]. The species with the highest sensitivity to terbuthylazine in the acute data is *Microcystis aeruginosa*. Since its NOEC is present, as detailed in Table A 1.42, an AF of 10 can be applied to the lowest NOEC value, i.e. 1.2 µg/l (*Pseudokirchneriella subcapitata*). Therefore, the proposed **EQS** is **0.12 µg/l**.

For **EQS NL**, no AA-EQS is possible, since *Daphnia sp.* values were not present in the base set (Table A 1.6).

5.2.2. Derivation using SSD method

The available data for the SSD method are listed in Table A 1.42. As explained in section 1.5, the SSD method requires a minimum of 10 NOECs (preferably more than 15 NOECs) for different species covering at least eight taxonomic groups.

For terbuthylazine, there are not sufficient reliable and relevant long-term results, since maximum eight long-term results for five taxa have been found.

5.2.3. Interpretation of simulated ecosystem studies

Three micro/mesocosms studies have been reported by EFSA, described as follows. In the mesocosm and microcosm studies cited below, the text formatting (bold and the underline) has been reported as given in the original EFSA (EU DAR) documents. According to reviewers, study one and three are "not suitable for risk assessment purposes" and study two is "of limited use", thus no EQS have been derived on the basis of these studies.

FIRST STUDY:

Start of citation

"Effect of terbuthylazine in aquatic outdoor microcosms (SYS)

Terbuthylazine, purity >99% […] The eight test substance compartments were treated once with terbuthylazine at nominal concentration of 5, 10, 20, 30, 50, 100, 200 and 400 µg a.s./L […] by

pipetting the test substance to the water surface. Treatment occurred on 06/07/93. The control systems received the formulation additives only but no active ingredient. The treatments were randomly assigned to the test systems and resulted in the following combinations of concentrations (µg a.s./L): 30; 400; 0/ 0; 10; 100 /0; 50; 20/ 5; 0; 200. The remaining tank which hat not been separated was treated at concentration of 10 µg a.s./L. Subsequently, biotic and abiotic parameters were recorded in each test system over a period of **430 days** (July 1993-September 1994). […]

Summary:

The Notifier has proposed that the NOEC is 10 µg a.s./L (initial concentration), based on transient of the effects observed in some phytoplankton species at initial terbuthylazine concentration between 20 and 50 µg a.s./L, and the lasting effect on macrophytes in the 4 µg a.s./L treatment. The Notifier also proposes that the NOEAEC (No Observed Ecologically Adverse Effect Concentration) is 30 µg a.s./L. **The Rapporteur cannot agree with the Notifier proposal until the results have been re-presented.**

[…] The study was not conducted in a GPL compliant laboratory; it is noted that it was conducted after the implementation of GPL. At present, given the number of concerns the Rapporteur has, and the fact that the results are not presented in a manner that allows clear interpretation, **the Rapporteur does not consider this study to be suitable for risk assessment purposes**".

End of citation [84]

SECOND STUDY:

Start of citation

Effects of terbuthylazine on aquatic macrophytes (SYN)

The effect of terbuthylazine on the photosynthesis of *Elodea Canadensis*, *Hydrilla verticillata*, *Myriophyllum verticillatum*, *Myriophyllum spicatum*, *Potamogeton densus* and *Chara hispida* was investigated using two different test designs: (a) direct measurement of the oxygen production over 25 minutes and (b) calculation of the "daily" oxygen production (during a 14 hours light-period). Furthermore, the effects of the growth of *Lemna gibba* were determined after a 21-day exposure period to terbuthylazine.

In **test (a)**, […] five concentrations between nominal 0.005 and 0.5 mg a.s./L were employed in the tests (the range of concentrations was individually adapted for each species to achieve 50%-inhibitiion of photosynthesis). […] with one replicate per treatment level and five replicates for the blank control. […]

In **test (b)**, […] five concentrations between nominal 0.005 and 0.5 mg a.s./L were employed in the tests (the range of concentrations was individually adapted for each species to achieve 50%-inhibitiion of photosynthesis).

Lemna gibba was exposed to eight terbuthylazine concentrations (nominal: 0.00025, 0.00125, 0.005, 0.0125, 0.025, 0.05, 0.05 and 0.25 mg a.s./L) for 21 days. […]

[…] The Notifier has concluded that the nominal EC50 values for the effects of terbuthylazine on aquatic plants ranged from 0.023 to 0.063 mg a.s./L.

The study was not performed in a GLP compliant laboratory or to a recognised test guideline. No chemical analysis was performed and therefore it is not possible to confirm the maintenance of the test concentrations. It is noted that the toxicity endpoints were derived for parameters which are not normally assessed (photosynthesis) as opposed to more conventional parameters such as growth rate and biomass. The plants used in the study were simply 'shoot-tips' and therefore it is difficult to assess whether the effects would be comparable for rooted plants. The Rapporteur considers the study to be of limited use for risk assessment, however it is useful to demonstrate the relative sensitivity of the aquatic macrophytes tested i.e. *Myriophyllum spicatum* being the most sensitive under the conditions of the study".

End of citation [85]

THIRD STUDY:

Start of citation

"**Standardized indoor aquatic microcosm study to assess the effect of application of 14C-radiolabelled 'Terbuthylazine 500AC' on a defined community of algal species and aquatic invertebrates**. […]

Rapporteur's evaluation

The Notifier has proposed a NOEC for all species tested of 22 µg/l based on the fact that there were no effects on phyto- or fauna-plankton species.

The rapporteur agrees that there appears not to have been any treatment related effects in the density of algae, growth rate and biomass of *Elodea nuttallii* and zooplankton population replicated in both series. The concentrations tested (up to 22 µg/l) failed to induce significant effects in the test parameters measured; hence it is difficult to distinguish whether the study was sensitive enough to pick up any potential effects. Ideally, a test concentration which resulted in significant effects should have been included. Under the condition of the study the NOEC for *Elodea nuttallii* (the only aquatic macrophyte tested) was 20.25 µg a.s./L (initial measured concentration) and the NOEC for *Ceriodaphnia dubia* and *Brachionus calyciflorus* (the only two zooplankton species tested) was also 20.25 a.s./L (initial measured concentration). Given the behaviour of the algae control groups and the effect of grazing pressure by the invertebrates the Rapporteur cannot conclude a NOEC for algae species tested.

As discussed above, the Rapporteur has a number of concerns with the study and currently the Rapporteur does not consider the study to be suitable for algae risk assessment"

End of citation [86]

5.3. Derivation of MAC-EQS values

Two methods have been considered for the EQS derivation: assessment factor and species sensitivity distribution methods.

5.3.1. Derivation using AF method

The Table A 1.41 shows all the short-term data considered reliable and relevant.

Since microcrustacea values are missing, the base set is not complete, and no MAC-EQS value can be derived. However, in the summary table (B.9.2.52, pg 61) [69] it is written that: “no definitive acute endpoint for aquatic invertebrates was identified; however, the submitted studies are of adequate quality to demonstrate that aquatic invertebrates are less acutely sensitive to terbuthylazine than fish and algae” (EFSA).

If we consider that the most sensitive species are present (algae), a MAC-EQS between 0.102[83] and 1.02 (10.2/AF between 10 and 100) could be proposed.

5.3.2. Derivation using SSD method

For terbuthylazine, there are not sufficient reliable and relevant short-term results.

5.4. Terbuthylazine: summary of the proposed EQS

The following table summarises the acute and chronic EQS values resulting from the application of the methods considered. No AA-EQS value was proposed according to Lepper 2005 and the Dutch guideline 2007, as well as no MAC-EQS (for all guidance documents) because the base data set is not complete; and *Daphnia sp.* values are missing. Also the negligible concentration is missing, since no AA-EQS could be derived according to the Dutch guideline 2007.

Table A 1.43: Terbuthylazine, summary EQS results.

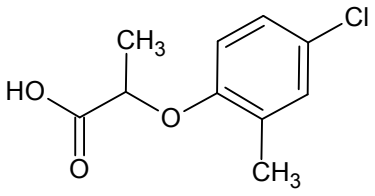
Data	Type of EQS	Guidance document	Value to be divided by AF (µg/l)	AF	Proposed EQS (µg/l)	See paragraph #, page #
EQS derived using reliable and relevant data in agreement with the guidance documents						
Pseudokirchneriella subcapitata, NOEC	AA –QS	TG	1.2	10	0.12	5.2.1, 121
No values for *Daphnia sp.*	MAC-EQS	LP, TG, NL	---	---		5.3.1, 123
	Negligible concentration	NL	---	---		---

[83] For TGD for EQS and EQS NL if MAC-QS is lower than AA-QS, then MAC-QS is equal to AA-QS.

6. Mecoprop

6.1. General data

Table A 1.44: Mecoprop, general data.

IUPAC Name	(RS)-2-(4-Chloro-o-methylphenoxy)propanoic acid	
CAS registry number	93-65-2 (7085-19-0)	
EC number	202-264-4	
Chemical formula	$C_{10}H_{11}ClO_3$	
SMILES code	O=C(O)C(Oc(c(cc(c1)Cl)C)c1)C	
Molecular weight	214.6 [g/mol]	
Pesticide class	Herbicide, phenoxyacetic acid	
BCF max	5.5 [L/kg_{ww}] [87]	
LogK_{ow}	3.3 ([87], ChemID Plus 2006)	
EU classification	Xn; R22- Xi; R41 – N; R50-53[84]	

Mecoprop is present as acid form and as different salts. In the present report, according to the Science Report HOEP670085/SR19 (2007) written by the Environmental Agency (WFD UK TAG) it is assumed that mecoprop in the environment "will usually dissociate in the acid form" [87]. When necessary, all salt values have been converted to acid equivalents and considered for the EQS. In the following table, the result of several database searches is listed.

Table A 1.45: Mecoprop, results of the database search.

Short name in excel file, web link	Result for mecoprop	Short name in excel file, web link	Result for mecoprop
ECOTOX	Available data	eChemPortal	Available data
PESTICIDEINFO	Available data (data from ECOTOX)	WFD UK TAG	Data mixed with Mecoprop-P
HSDB	No ecotox data	OPP	Available data
EU	Available data	AGRITOX	Available data
EFSA	No ecotox data	RIVM	Not in the database
INERIS	Available data	UK pesticides	Available data
FOOTPRINT	Present, forbidden access	Web of science	Available data

[84] Xn: Harmful, R22: Harmful if swallowed, Xi: Irritant, R41: risk of serious damage to eyes, N: Dangerous for the environment, R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

webTOX	Available data	Sciencedirect	Available data

The data search using both Web of Science and Sciencedirect was performed in the time span of the last five years, i.e. from 2006 to 2010, in order to include relevant and reliable data that may have not yet been included in the above mentioned databases. The goal was to check if no particularly sensitive endpoint or effect were detected in recent studies, i.e. studies not included in the different databases.

The following key words were used on Web of Science:

- Mecoprop toxicity (no relevant and reliable results)
- Mecoprop algae (no relevant and reliable results)
- Mecoprop (2 potentially relevant results)
  - Marrs RH, Frost AJ, Plant RA, Lunnis P, Brighton crop protection conference: weeds – 1991, Volumes 1-3, Pages 891-900. *A study of repeat applications of Mecoprop to plant-communities in mesocosms.*

    No longer available on Nebis
  - Bermingham S, Fisher PJ, Martin A, Lappin-Scott H, Microbial ecology, 1998, Volume 35, Pages 199-204. *The effect of the herbicide mecoprop on Heliscus lungdunensis and its influence on the preferential feeding of Gammarus pseudolimnaeus.*

    The article has been retrieved and evaluated as “not relevant”, since the concentration range used in the experiments was too high (between 1 mg/l and 3’000 mg/l) when compared to environmentally relevant concentrations.

Analogously, for Sciencedirect:

- Mecoprop toxicity (1 potentially relevant result out of 177)
  - Kennepohl E, Munro IC, Bus JS, Hayes Handbook of Pesticides Toxicology, chapter 84. Phenoxy herbicides (2,4-D)

    Although mecoprop is cited, in the book chapter only 2,4-D is evaluated, therefore not relevant.

6.2. Derivation of long-term EQS values (AA-EQS)

Three methods have been considered for the EQS derivation: the assessment factor method, the species sensitivity distribution method, and interpretation of simulated ecosystem studies.

6.2.1. Derivation using AF method

The basic data set for AF (at least acute values for algae, crustaceans or *Daphnia magna* and fish) is detailed in Table A 1.46.

Table A 1.46: Mecoprop, acute toxicity values.

Taxonomic group	Species scientific name	Endpoint	Test duration [d]	Conc. [µg/l] (Purity %)	Source	Reliable (Relevant) according to
ALG	*Scenedesmus subspicatus*	EC50 (POP/BMAS)	3	237'000	EU DAR	LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Scenedesmus subspicatus*	EC50 (GRT/rate)	3	322'000	EU DAR	LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Scenedesmus subspicatus*	EC50 (POP/BMAS)	3	>180'000	UK report (K2) [88]	LP, TG, NL (LP, TG, NL, SN)
ALG	*Pseudokirchneriella subcapitata*	EC50 (GRT)	4	711'000 (GM)	UK	LP, TG (LP, TG, NL, SN)
ALG	*Chlorella pyrenoidosa*	EC50 (GRT)	4	220'000	UK; IKRS	LP, TG (LP, TG, NL, SN); LP, TG (LP, TG, NL, SN)
CRU	*Daphnia magna*	EC50 (NR)	2	>200'000	UK report (K2) [89]; INERIS (valid)	LP, TG, NL (LP, TG, NL, SN); LP, TG, NL (LP, TG, NL, SN)
CRU	*Daphnia magna*	EC50 (ITX/IMBL)	1	>100'000	UK report (K2) [88]	LP, TG, NL (LP, TG, NL, SN)
CRU	*Daphnia magna*	EC50 (REP)	3	100'000 (91.6%)	UK	LP, TG (LP, TG, NL, SN)
FIS	*Oncorhynchus mykiss*	LC50 (MOR/MORT)	4	240'000 (91.6%)	UK report (K1) [90]; INERIS (valid)	LP, TG, NL (LP, TG, NL, SN); LP, TG, NL (LP, TG, NL, SN)
FIS	*Poecilia reticulata*	LC50 (MOR/MORT)	21-28	1'100'000 (92.0%)	UK, [91]	LP, TG (LP, TG, NL, SN)
MAC	*Lemna minor*	EC50 (POP/BMAS)	7	6'000 (98.0%)	UK report (K2) [88]; INERIS (valid)	LP, TG, NL (LP, TG, NL, SN); LP, TG, NL (LP, TG, NL, SN)
MAC	*Lemna minor*	EC50 (POP/BMAS)	7	56'200 (calc[§])	EU DAR	LP, TG, NL, SN (LP, TG, NL, SN)
MAC	*Lemna minor*	EC50 (GRT/rate)	7	40'200 (calc[§])	EU DAR	LP, TG, NL, SN (LP, TG, NL, SN)

[§]The test substance was Mecoprop 640D, a mecoprop dimethylamine salt formulation containing 643.5 g/l mecoprop and density

1140.6 g/l, [EU DAR]. The values are given as mecoprop acid equivalent by EU DAR.

ALG = algae; CRU = crustaceans; FIS = fish; INS = Insects; MAC = Macrophytes

Table A 1.47: Mecoprop, chronic ecotoxicity values.

Taxonomic group	Species scientific name	Endpoint	Test duration [d]	Conc. [µg/l] (Purity %)	Source	Reliable (Relevant) according to
ALG	*Scenedesmus subspicatus*	NOEC (GRT/BMAS or GRT rate)	4	68'000	EU DAR	LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Pseudokirchneriella subcapitata*	NOEC (GRT)	4	21'000	UK	LP, TG (LP, TG, NL, SN)
ALG	*Chlorella pyrenoidosa*	NOEC (POP/PGRT)	4	56'000	UK	LP, TG (LP, TG, NL, SN)
CRU	*Daphnia magna*	NOEC (REP)	28	22'200 (91.6%)	UK report (K1) [89]; INERIS (valid)	LP, TG, NL (LP, TG, NL, SN); LP, TG, NL (LP, TG, NL, SN)
CRU	*Daphnia magna*	NOEC	21	22'200	INERIS (valid)	LP, TG, NL (LP, TG, NL, SN)
FIS	*Oncorhynchus mykiss*	NOEC (MOR/MORT)	21	89'621[85] (91.6%)	UK report (K1) [92]	LP, TG, NL (LP, TG, NL, SN)
FIS	*Oncorhynchus mykiss*	NOEC (NR)	21	109'000	INERIS (valid)	LP, TG, NL (LP, TG, NL, SN)
MAC	*Lemna minor*	NOEC (GRT/rate)	7	1'800 (calc§)	EU DAR	LP, TG, NL, SN (LP, TG, NL, SN)
MAC	*Lemna minor*	EC10 (GRT/inhibition)	7	4'500	UK report (K2) [88]	TG, NL (TG, NL)

§The test substance was Mecoprop 640D, a mecoprop dimethylamine salt formulation containing 643.5 g/l mecopropo and density 1140.6 g/l, [EU DAR]. The values are given as mecoprop acid equivalent by EU DAR.

ALG = algae; CRU = crustaceans; FIS = fish; INS = Insects; MAC = Macrophytes

A dataset is considered as complete for all three methods if it contains at least three acute data,

[85] The UK report uses the value of 89'621 (MCPP a.e, purity 91.6%, K1) and claims it has been used in EU DAR 1999. INERIS (Sanco 2003) propose a value of 109'000 µg/l (MCPP, unknown purity). Since the purity of UK report value is known, no geometric mean has been performed.

i.e. algae, invertebrates (specifically *Daphnia magna* for Lepper 2005) and fish, as detailed in Table 1.5.

If at least three long-term species values (NOECs) are available, usually an assessment factor of 10 is applied to the lowest NOEC value.

Following the procedures for the different guidance documents, all of them resulted in a proposed **EQS** of **180 µg/l,** calculated as the NOEC 1'800 µg/l divided by AF of 10.

The lowest value is obtained with the macrophyte *Lemna minor*, which is not surprising since mecoprop is toxic to roots elongation. This value of 180 µg/l was also obtained following the directive 91/414/EEC, with the lowest value indicated in the DAR report.

As a remark, although the lowest tabulated value (1'800 µg/l) has been reported in the EU DAR and is considered valid, it is important to keep in mind that this toxicity value has been back calculated as pure mecoprop from the toxicity value determined by testing a formulation (further details in the notes of tables 9 and 10 of the report). It is also relevant to note the difference in toxicity for the EC50 (POP/BMAS) comparing a tested value of 6'000 µg/l (98%, UK report K2, and INERIS) and the same endpoint recalculated from the tested formulation toxicity, which is 56'200 µg/l (EU DAR). Unfortunately, no experimental details are available to verify the presence of other differences.

6.2.2. Derivation using the SSD method

The SSD method requires a minimum of 10 NOECs (preferably more than 15 NOECs) for different species covering at least eight taxonomic groups. For mecoprop, the number of species with a valid NOEC value was of maximum six for four taxonomic groups; the exact number depends on the guidance document (see Table A 1.9). Therefore the methodology is not applicable.

6.2.3. Interpretation of simulated ecosystem studies

No values from micro/mesocosms studies were available, thus this method is not applicable.

6.3. Derivation of acute QS values (MAC-EQS)

Three methods have been considered for the EQS derivation: the assessment factor method, the species sensitivity distribution method, and the interpretation of simulated ecosystem studies.

6.3.1. Extrapolation using AF method

The Table A 1.46 shows all the short-term data considered reliable and relevant. The base set is complete and mecoprop has a BCF factor of maximum 5.5 [L/kg_{ww}], so for all guidance documents an AF ≤ 100 can be applied. Where representatives of the most sensitive taxa are present in the acute dataset, "an AF <100 may again be justified" [2], which is accepted also by EQS NL [3]. Lepper 2005 only states that if the mode of action is known, a lower factor than 100 can be appropriate without giving more details.

Since the mode of action of mecoprop is known, an AF < 100 may be appropriate. However, data on only one representative of the most sensitive taxa is present, which makes the choice of the AF difficult.

The lowest relevant value is the EC50 of 6'000 µg/l for *Lemna minor*. If we consider an AF between 10 and 100, the **MAC-EQS** is therefore between **600 µg/l** and **60 µg/l**.

It is interesting to note that this last value is lower than the proposed AA-EQS of 180 µg/l, which is incoherent. The TGD for EQS and EQS NL clearly state to set MAC-EQS equal to AA-EQS, in case the latter is lower than the former [3]. The factor of 100 is therefore considered to be too high, however it is difficult to fix the factor and a decision would be based on "expert judgement".

6.3.2. Extrapolation using SSD method

The SSD method requires a minimum of 10 L(E)Cs (preferably more than 15 L(E)Cs) for different species covering at least eight taxonomic groups. For mecoprop, there are not enough reliable L(E)C50 species nor taxa available. Thus according to all guidance documents the method cannot be applied.

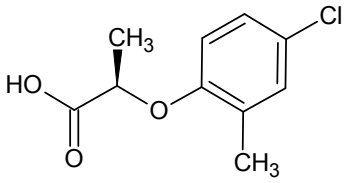
6.3.3. Interpretation of simulated ecosystem studies

No values from micro/mesocosm studies are available therefore this method is not applicable.

7. Mecoprop-P

7.1. General data

Table A 1.48: Mecoprop-P, general data.

IUPAC Name	(2R)-2-(4-Chloro-o-methylphenoxy)propanoic acid	
CAS registry number	16484-77-8	
Chemical formula	$C_{10}H_{11}ClO_3$	
EC number	202-264-4	
SMILES code	O=C(O)C(Oc(c(cc(c1)Cl)C)c1)C	
Molecular weight	214.6 [g/mol]	
Pesticide class	Herbicide, phenoxyacetic acid	
BCF max	5.5 [L/kg_{ww}] [87]	
LogK_{ow}	3.3 ([87], ChemID Plus 2006)	
EU classification	Xn; R22- Xi; R41 – N; R50-53[86]	

The following databases have been considered as data sources.

Table A 1.49: Mecoprop-P, results of the database search.

Short name in excel file, web link	Result for Mecoprop-P	Short name in excel file, web link	Result for Mecoprop-P
ECOTOX	Not present in the database	eChemPortal[§]	Present, (no ecotox data)
PESTICIDEINFO	Present, no data	WFD UK TAG	Data mixed with mecoprop
HSDB	Not present in the database	OPP	Available data
EU	Ecotoxicity tested mainly on mecoprop	AGRITOX	Available data
EFSA	Not present in the database	RIVM	Not present in the database
INERIS	Present, no ecotox data	UK pesticides	Available data
FOOTPRINT	Present, forbidden access	Web of science	Available data
webTOX	No present	Sciencedirect	Available data

[86] Xn: Harmful, R22: Harmful if swallowed, Xi: Irritant, R41: risk of serious damage to eyes, N: Dangerous for the environment, R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

For results of the web search, see results for mecoprop see paragraph 6.1.

7.2. Derivation of EQS values

Three methods have been considered for the EQS derivation: the assessment factor method, the species sensitivity distribution method, and the interpretation of simulated ecosystem studies.

7.2.1. Derivation using Assessment Factor (AF) method

Basic data set for AF: acute values for algae, crustaceans or *Daphnia magna* and fish.

Table A 1.50: Mecoprop-P, short-term values.

Taxonomic group	Species scientific name	Endpoint	Test duration [d]	Conc. [µg/l] (Purity %)	Source	Reliable (Relevant) according to
ALG	*Navicula pelliculosa*	EC50 (POP/PGRT)	5	240	UK report (K1) [93]	LP, TG, NL (LP, TG, NL)
ALG	*Selenastrum capricornutum*	EC50 (POP/ABND)	5	340	UK report (K1) [94]	LP, TG, NL (LP, TG, NL)
ALG	*Anabaena flos-aquae*	EC50 (GRT/rate)	0-3	28'900[87] (76.6%)	EU DAR [95]	LP, TG, NL, SN (LP, TG, NL, SN)
CRU	*Daphnia magna*	EC50 (ITX/IMBL)	2	>91'000[88] (87.9%)	UK report (K1) [96]	LP, TG, NL (LP, TG, NL)
FIS	*Lepomis macrochirus*	EC50 (MOR/MORT)	4	>50'000 (91.4%)	UK report (K1) [97]	LP, TG, NL (LP, TG, NL)
FIS	*Oncorhynchus mykiss*	EC50 (MOR/MORT)	4	>93'000	UK report (K1) [98]	LP, TG, NL (LP, TG, NL)
MAC	*Lemna minor*	EC50 (GRT/inhibition)	7	1'900	UK report (K1) [99]	LP, TG, NL (LP, TG, NL)

ALG = algae; CRU = crustaceans; FIS = fish; MAC = Macrophytes

[87] Only indicative because the probit fit to the data was not good, see EU-DAR repot page 18.
[88] Valid but not usable as it is.

Table A 1.51: Mecoprop-P, long-term values.

Taxonomic group	Species scientific name	Endpoint	Test duration [d]	Conc. [µg/l] (Purity %)	Source	Reliable (Relevant) according to
ALG	*Navicula pelliculosa*	NOEC (POP/PGRT)	5	55	UK report (K1) [93]	LP, TG, NL (LP, TG, NL)
ALG	*Selenastrum capricornutum*	EC10 (POP/ABND)	5	55	UK report (K1) [94]	TG, NL (TG, NL)
ALG[89]	*Anabaena flos-aquae*	NOEC (GRT/rate)	0-3	5'956[90] (76.6%)	EU DAR [95]	LP, TG, NL, SN (LP, TG, NL, SN)
ALG	*Pseudokirchneriella subcapitata*	NOEC (POP/BMAS)	3	27'000 (92.2%)	UK report (K1) [100]	LP, TG, NL (LP, TG, NL)
CRU	*Daphnia magna*	NOEC (REP)	21	50'000 (92.2%)	UK report (K1) [101]	LP, TG, NL (LP, TG, NL)
FIS	*Oncorhynchus mykiss*	NOEC (MOR/MORT)	28	50'000 (92.7%)	UK report (K1) [102]	LP, TG, NL (LP, TG, NL)
MAC	*Lemna gibba*	EC10 (reduction frond number)	5	530	UK report (K1) [99]	TG, NL (TG, NL)
MAC	*Lemna minor*	LOEC	14	440[91]	INERIS (valid)	LP, TG, NL (None)

ALG = algae; CRU = crustaceans; FIS = fish; MAC = Macrophytes

The base set is complete according to all the selected guidance documents, even if data for *Daphnia magna* and *Lepomis macrochirus* cannot be used to derive EQS since they indicate only the lower limit.

The lowest long-term toxicity (55 µg/l, algae *Navicula pelliculosa*) corresponds to the lowest short-term toxicity value. In this case, for all guidance documents the **AA-EQS** proposed is **5.5 µg/l**, calculated by 55 µg/l divided by an AF of 10.

[89] Cyanobacteria
[90] Only indicative because the probit fit to the data was not good, see EU-DAR repot page 18.
[91] INERIS uses this LOEC value to propose an EQS of 22 µg/l (440/20) for mecoprop and Mecoprop-P since ecotoxicity data are mixed. The proposed AF (20) comes from note d of table 16 page 101 of E.C. (2003). Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) N° 1488/94 on Risk Assessment for existing substances, Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. Luxembourg, Office for Official Publications of the European Communities.

7.2.2. Derivation using Sensitive Species Distribution (SSD) method

The SSD method requires a minimum of 10 L(C)C50s (preferably more than 15) for different species covering at least eight taxonomic groups. For Mecoprop-P, there are neither sufficient data nor the required number of taxa available; therefore the methodology is not applicable.

7.2.3. Derivation of simulated ecosystem studies

Two values of micro/mesocosm studies have been found in the "Reregistration Eligibility Decision (RED) for Mecoprop-P (mcpp)" written by the United States Environmental Protection Agency (EPA) in 2007 (Table A 1.52). However, no conclusion can be derived from these data as the NOAEC is always lower than a given concentration.

Table A 1.52: Mecoprop-P, micro/mesocosms results.

Taxonomic group	Species scientific name	Endpoint	Test duration (d)	Conc (µg/l)	Source	Valid according to
Algae	*Skeletonema costatum* (SW)	NOAEC	> 7	< 9	US EPA	LP, TG
Macrophytes	*Lemna gibba*	NOAEC	> 7	< 440	US EPA	LP, TG

7.3. Derivation of MAC-EQS values

7.3.1. Derivation using AF method

To derive a MAC-EQS an AF of 100 is applied to the lowest L(E)C50; when the mode of action is known (Mecoprop-P is toxic to roots elongation) an AF < 100 may be appropriate, as described in section 2.

The most sensitive taxa to Mecoprop-P are macrophytes, but surprisingly the lowest L(E)C50 value tabulated in Table A 1.50 does not correspond to an aquatic plant, but to an algae: 240 µg/l for *Navicula pelliculosa* in contrast to 1'900 µg/l for *Lemna minor*.

If we consider an AF between 10 and 100, the **MAC-EQS** is therefore between **24 µg/l** and **2.4 µg/l**. This last value is lower than the proposed AA-EQS of 5.5 µg/l, which was unexpected. Furthermore, the TGD for EQS and the EQS NL clearly state to set MAC-EQS equal to AA-EQS, in case the latter is lower than the former. The factor of 100 is therefore clearly too high, but again, it is difficult to fix the factor and each decision would be arbitrary and based on "expert judgement".

7.3.2. Derivation using SSD method

The SSD method requires a minimum of 10 L(E)C50s (preferably more than 15 L(E)C50s) for different species covering at least eight taxonomic groups. For Mecoprop-P, there are L(E)C50 values for several species depending on the selection criteria used, however the requirement for at least eight taxonomic groups is not fulfilled and the method cannot be applied (TGD for EQS, section 3.2.4.1 of the main document).

7.3.3. Interpretation of simulated ecosystem studies

No values from micro/mesocosm studies are available, thus this method was not applicable for Mecoprop-P.

7.4. Mecoprop and Mecoprop-P: summary of the proposed EQS

The following table summarises the acute and chronic EQS values resulting from the application of the considered methods. It is relevant to remember that both TGD for EQS and EQS NL set values of MAC-EQS equal to AA-EQS in case the former are lower than the latter.

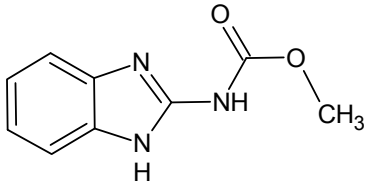
Table A 1.53: Mecoprop and Mecoprop-P, summary EQS results.

Data	Type of EQS	Guidance document	Value to be divided by AF (µg/l)	AF	Proposed EQS (µg/l)	See paragraph #, page #
Mecoprop						
EQS derived using reliable and relevant data in agreement with the guidance documents						
Lemna minor, NOEC	AA-EQS	LP, TG, NL	1'800	10	180	6.2.1, 126
Lemna minor, EC50	MAC-EQS	LP	6'000	100 10	60 600	6.3.1, 129
Lemna minor, EC50	MAC-EQS	TG, NL	6'000	100 10	180 600	6.3.1, 129
	Negligible concentration	NL	AA-EQS	100	1.8	---
Mecoprop-P						
EQS derived using reliable and relevant data in agreement with the guidance documents						
Navicula pelliculosa, NOEC	AA–QS	LP, TG, NL	55	10	5.5	7.2.1, 132
Navicula pelliculosa, LC50	MAC-EQS	LP	240	100 10	2.4 24	7.3.1, 134
Navicula pelliculosa, LC50	MAC-EQS	TG, NL	240	100 10	5.5 24	7.3.1, 134
	Negligible concentration	NL	AA-EQS	100	5.5E-2	---

8. Carbendazim

8.1. General data

Table A 1.54: Carbendazim, general data.

IUPAC name	Methyl benzimidazol-2-ylcarbamate	
CAS registry number	10605-21-7	
EC number	234-232-0	
Molecular formula	$C_9H_9N_3O_2$	
Code SMILES	COC(=O)NC1=NC2=CC=CC=C2N1	
Pesticide class	Fungicide	
Molecular weigh	191.21 g/mol [EC, 1997]	
BCF max	4-27 [INERIS]	
$LogK_{OW}$	1.5 [EC, 1997]	
EU classification	Mutagenic cat. 2; R46 - Repr. Cat. 2; R60-61 - N; R50-53[92]	

Carbendazim is a “systemic fungicide with protective and curative action. It is absorbed through the roots and green tissues, with translocation acropetally. It acts by inhibiting the development of the germ tubes, the formation of appressoria, and the growth of mycelia” [103].

The Table A 1.55 summarises the database search results for carbendazim.

Table A 1.56: Carbendazim, result of the database search.

Database name	Results	Database name	Results
ECOTOX	Available data	eChemPortal	Available data
PESTICIDEINFO	Data from ECOTOX	WFD UK TAG	Not present in database
HSDB	Available data	OPP	Available data
EU	No ecotox data	AGRITOX	Not present in database
EFSA	Not present in database	RIVM	Not present in database
INERIS	Available data	UK pesticides	Available data
FOOTPRINT	Available data	Web of science	Available data
webTOX	Available data	Sciencedirect	Available data

[92] R46: May cause heritable genetic damage; R60: May impair fertility; R61: May cause harm to unborn child; N: Dangerous for the environment, R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

After the data search, the work of van Wijngaarden *et al.* has been classified as "relevant".

- van Wijngaarden R.P.A., Crum S.J.H., Decreane K., Hattink J., van Kammen, A., (1998) Toxicity of Derosal (active ingredient carbendazim) to aquatic invertebrates, Chemosphere 37(4):673-683

However, since it has not been "peer reviewed" by (inter)national organization and there is not enough data in the publication to assess its Klimisch score, it was not possible to include its results in the following discussion.

8.2. Derivation of EQS values

Three methods have been considered for the EQS derivation: the assessment factor method, the species sensitivity distribution method, and the interpretation of simulated ecosystem studies.

In Tables A 1.57 and A 1.58 the acute (L(E)C50) and chronic (NOEC and EC10) values for carbendazim are listed. All short- and long-term results which are valid for at least one guidance document have been included.

Table A 1.57: Carbendazim, acute toxicity values.

Taxonomic group	Species scientific name	Endpoint	Test duration [d]	Conc. [µg/l] (Purity %)	Source	Reliable (Relevant) according to
ALG	*Chlorella pyrenoidosa*	EC50 (GRT/inhib)	2	340 (97.4%)	RIVM (K2), [104]	LP, TG, NL (LP, TG, NL, SN)
ALG	*Scenedesmus subspicatus*	EC50	3	> 8'000	EU database; RIVM (K4), [105]	LP, TG, NL, SN (Unkn); None (Unkn)
ALG	*Pseudokirchneriella subcapitata*	EC50	3	1.3	RIVM (K3), [105, 106]	None (Unkn)
ALG	*Pseudokirchneriella subcapitata*	EC50	3	7.7	RIVM (K4), [105]	None (Unkn)
CRU	*Daphnia magna*	EC50	2	150	EU database; RIVM (K2) [105, 107]	LP, TG, NL, SN (Unkn); LP, TG, NL (Unkn)
CRU	*Daphnia magna*[93]	EC50 (ITX/IMBL)	4	87[§]	RIVM (K2), [108]	LP, TG, NL (LP, TG, NL, SN)
CRU	*Gammarus pulex*[94]	LC50	4	55[§]	RIVM (K2), [108]	LP, TG, NL (LP,

[93] Species < 1.5 mm
[94] Juvenile

		(MOR/MORT)				TG, NL, SN)
FIS	*Cyprinus carpio*	LC50 (MOR/MORT)	4	440	EU database; RIVM (K2), [105, 107]	LP, TG, NL, SN (LP, TG, NL, SN); LP, TG, NL (LP, TG, NL, SN)
FIS	*Ictalurus punctatus*[95]	LC50 (MOR/MORT)	4	7 (99%)	RIVM (K2), [109]	LP, TG, NL (LP, TG, NL, SN)
FIS	*Ictalurus punctatus*[96]	LC50 (MOR/MORT)	4	10 (99%)	RIVM (K2), [105, 109]	LP, TG, NL (LP, TG, NL, SN)
FIS	*Lepomis macrochirus*[97]	LC50 (MOR/MORT)	4	> 3'200 (99%)	RIVM (K2), [105, 107]	LP, TG, NL (LP, TG, NL, SN)
FIS	*Lepomis macrochirus*	NOEC (MOR/MORT)	4	> 17'250 (99%)	RIVM (K2), [105, 110]	LP, TG, NL (LP, TG, NL, SN)
FIS	*Oncorhynchus mykiss*	LC50 (MOR/MORT)	4	830	EU database; RIVM (K2), [105, 107]	LP, TG, NL, SN (LP, TG, NL, SN); LP, TG, NL (LP, TG, NL, SN)
FIS	*Oncorhynchus mykiss* [98]	LC50 (MOR/MORT)	4	145 (99%)	RIVM (K2), [109]	LP, TG, NL (LP, TG, NL, SN)
FIS	*Salmo trutta*	LC50 (MOR/MORT)	4	390 (50%)	RIVM (K2), [105, 111]	LP, TG, NL (LP, TG, NL, SN)
ANE[99]	*Dero digitata*	LC50 (MOR/MORT)	2	980[§]	RIVM (K2), [108]	LP, TG, NL (LP, TG, NL, SN)
ANE[100]	*Stylaria lacustris*	LC50 (MOR/MORT)	4	821[§]	RIVM (K2), [108]	LP, TG, NL (LP, TG, NL, SN)
INS	*Chaoborus obscuripes*[101]	EC50 (ability to stay in susp)	---	< 3.44 E+6[§]	RIVM (K2), [108]	LP, TG, NL (LP, TG, NL, SN)
PRO	*Tetrahymena pyriformis*	EC50 (GRT)	1.5	6'380	RIVM (K2), [112]	LP, TG, NL (LP, TG, NL, SN)
PLA[102]	*Dugesia lugubris*	LC50	4	134[§]	RIVM (K2), [108]	LP, TG, NL

[95] Alevin (Yolk-sac fry), i.e. first stage of fish after hatching, they are not capable of moving and and continue to grow by absorbing their yolk sac.
[96] Juvenile.
[97] Juvenile; 0.2g.
[98] Alevin (Yolk-sac fry), i.e. first stage of fish after hatching, they are not capable of moving and and continue to grow by absorbing their yolk sac.
[99] Clitellata
[100] Clitellata
[101] Larvae
[102] Turbellaria

		(MOR/MORT)				(LP, TG, NL, SN)

[§]Tested compound Derosal, results given as active substance. Reference 21 corresponds to DAR 2007

ALG = algae; ANE = annelids; CRU = crustaceans; FIS = fish; INS = insects; MAC = macrophytes; MOL = molluscs; PLA = platyhelminthes; PRO = protozoa.

Table A 1.58: Carbendazim, chronic values.

Taxonomic group	Species scientific name	Endpoint	Test duration [d]	Conc. [µg/l] (Purity %)	Source	Reliable (Relevant) according to
ALG	*Pseudokirchneriella subcapitata*	NOEC	3	500	RIVM (K3) [105, 106]	None (Unkn)
ALG	*Pseudokirchneriella subcapitata*	NOEC	3	2'500	RIVM (K4) [105]	None (Unkn)
ALG	*Scenedesmus subspicatus*	NOEC (POP/ GRT)	3	10'000	RIVM (K2) [105, 113]	LP, TG, NL (LP, TG, NL, SN)
CRU	*Daphnia magna*	NOEC (REP)	21	1.5	EU database; RIVM (K2) [105]	LP, TG, NL, SN (LP, TG, NL, SN); LP, TG, NL (LP, TG, NL, SN)
FIS	*Oncorhynchus mykiss*	NOEC (Early life cycle, embryo mortality)	79	11	EU database; RIVM (K2), [105, 114]	LP, TG, NL, SN (LP, TG, NL, SN); LP, TG, NL (LP, TG, NL, SN)
FIS	*Cyprinus carpio*	NOEC (MOR/MORT)	24	1'000	EU database; RIVM (K2), [115]	LP, TG, NL, SN (LP, TG, NL, SN); LP, TG, NL (LP, TG, NL, SN)
ANE[103]	*Stylaria lacustris*	LC50 (MOR/MORT)	7	21[§]	RIVM (K2), [108]	LP, TG, NL (LP, TG, NL, SN)
MOL[104]	*Bithynia tentaculata*[105]	NOEC (REP)	28	103[§]	RIVM (K2), [108]	LP, TG, NL (LP, TG, NL, SN)
MOL[106]	*Planorbis planorbis*[107]	NOEC (REP)	28	301[§]	RIVM (K2), [108]	LP, TG, NL (LP, TG, NL, SN)

[103] Clitellata
[104] Gastropoda
[105] Number egg clutches
[106] Gastropoda
[107] increased number of egg clutches

INS	*Chironomus riparius*	NOEC (Emergence)	28	13.3[108]	EU database; RIVM (K2), [105]	LP, TG, NL, SN (LP, TG, NL, SN); LP, TG, NL (LP, TG, NL, SN)
PRO	*Tetrahymena pyriformis*	NOEC (GRT)	1.5	< 5'000	RIVM (K2), [112]	LP, TG, NL (LP, TG, NL, SN)
PLA[109]	*Dugesia lugubris*[110]	LC50 (MOR/MORT)	21	3.4[§]	RIVM (K2), [108]	LP, TG, NL (LP, TG, NL, SN)

[§]Tested compound Derosal, results given as active substance; Reference 21 corresponds to DAR 2007

ALG = algae; ANE = annelids; CRU = crustaceans; FIS = fish; INS = insects; MAC = macrophytes; MOL = molluscs; PLA = platyhelminthes; PRO = protozoa.

8.2.1. Derivation using AF method

If the base data set is complete and at least three long-term species values (NOECs) are available, generally an assessment factor of 10 is applied to the lowest NOEC value. In this case study, the dataset is complete for all guidance documents.

The species with the highest sensitivity to carbendazim in the set of acute data is *Ictalurus punctatus* (fish). Since the most sensitive taxa in the long-term result is different from fish, an AF of 10 cannot be applied to the lowest NOEC value. Therefore the proposed **AA-EQS** is **0.03 µg/l**, calculated as 1.5 µg/l (NOEC, *Daphnia magna*) divided by an AF of 50.

8.2.2. Derivation using SSD method

The data are listed in Table A 1.58. As explained in section 1.5, the SSD method requires a minimum of 10 NOECs (preferably more than 15 NOECs) for different species covering at least eight taxonomic groups.

For carbendazim, there are sufficient reliable and relevant long-term results, with maximum 12 long-term results for nine taxa, including more than one taxonomic group for fish. however one of the requested taxa is not represented: higher plants.

Due to the number of available data, even if not all required taxa were present, we decided to extrapolate the SSD curve. Chronic data present in Table A 1.58 were inserted in ETX 2.0 software [4] and the results are displayed in Table A 1.59 as HC5 values, in Table A 1.60, as acceptance tests (normality of the distribution), and the SSD curve in Figure A 1.6.

[108] Calculated a.s. value, test substance 500 SC-formulation
[109] Turbellaria
[110] Neonates

Table A 1.59: Carbendazim, extrapolated HC5 chronic SSD.

Name	HC5 (acute)
Lower estimate	0.0124
Median estimate	0.4904
Upper estimate	3.9320

Table A 1.60: Carbendazim, results of the acute SSD acceptance tests.

Acceptance test name (n=10)	Significance level 0.1	Significance level 0.05	Significance level 0.025	Significance level 0.01
Anderson-Darling (n ≥ 8)	Accepted	Accepted	Accepted	Accepted
Kolmogorov-Smirnov (n ≥ 20)	Accepted	Accepted	Accepted	Accepted
Cramer von Mises (n ≥ 20)	Accepted	Accepted	Accepted	Accepted

The proposed AA-EQS as HC5/AF equals **0.098 µg/l** (0.4904/5).

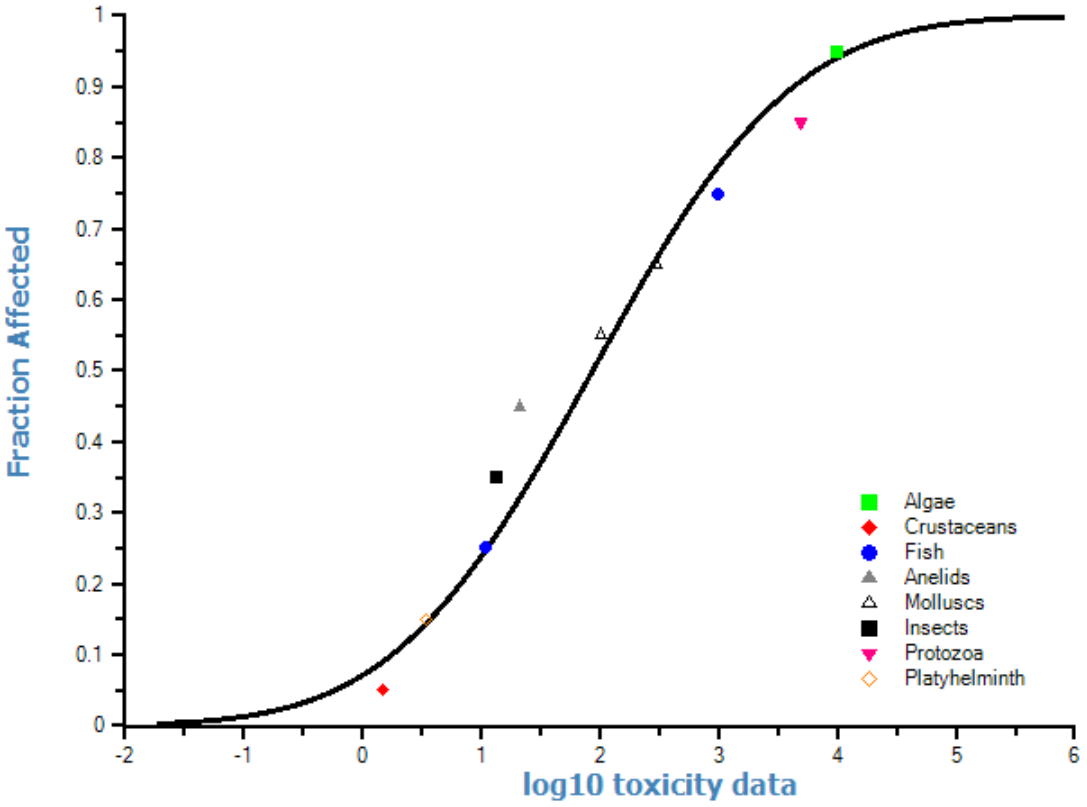


Figure A 1.6: Carbendazim, chronic SSD curve.

8.2.3. Interpretation of simulated ecosystem studies

Two reliable and relevant micro/mesocosm studies have been reported by RIVM. The following paragraphs summarise their main characteristics and outcomes.

FIRST STUDY:

"Microcosm study with natural population of algae, zooplankton and macroinvertebrate"

Indoor microcosm, 4 weeks of exposure to the formulation Derosal, effects followed during 11 weeks.

"For individual species, the lowest NOEC is found for *Acroperus harpae* (3.3 µg/l). [...]

Evaluation of the scientific reliability of the field study

Criteria for a suitable (semi) field study

1. Does the test system represent a realistic freshwater community? Yes, natural population of algae, macrophytes, micro and macroinvertebrates were present. No fish.
2. Is the description of the experiment set-up adequate and unambiguous? Yes.
3. Is the exposure regime adequately described? Unclear. Not all data are reported, but results indicate that measured concentrations are close to nominal during the 4 weeks exposure period.
4. Are the investigated endpoints sensitive in accordance with the mechanism of action of the compound? Unclear. Carbendazim is a fungicide. Laboratory data show that the substance is toxic to a number of different invertebrate species.
5. Is it possible to evaluate the observed effects statistically? Yes, statistical significant results are reported for community and individual species.

The criteria result in an overall assessment of the study reliability. The study is considered to be less reliable mainly due to the lack of raw exposure and effect data and (Ri 2).

Since in this study a chronic exposure of 4 weeks is maintained, the results can be used for derivation of a MPC_{ECO}. Based on this mesocosm study, a **NOEC of 3.3 µg/l** can be used"[111] [116].

SECOND STUDY:

"Mesocosm study with natural population of algae, zooplankton and macroinvertebrate"

Outdoor mesocosm, 1 application of carbendazim, mixing during 4h, effects followed for 4 weeks.

"**Evaluation of the scientific reliability of the field study**

[111] Ri 2 = K2 and MPC_{ECO} = AA-QS

Criteria for a suitable (semi) field study

1. Does the test system represent a realistic freshwater community? No, macrophytes, macroinvertebrates and fish are not included.
2. Is the description of the experiment set-up adequate and unambiguous? Yes.
3. Is the exposure regime adequately described? Unclear. Not all data are reported, but results indicate that measured concentrations are 30% of nominal shortly after exposure (start and 29 d reported).
4. Are the investigated endpoints sensitive in accordance with the working mechanism of the compound? Unclear. Carbendazim is a fungicide. Laboratory data show that the substance is toxic to a number of different invertebrate species.
5. Is it possible to evaluate the observed effects statistically? Yes, statistical significant results are reported or can be read from figures for community and individual species-groups.

The criteria result in an overall assessment of the study reliability. The study is considered to be less reliable mainly due to the lack of raw exposure and effect data and (Ri 2).

Since in this study one dose is given, and the actual dose differs considerable from the nominal dose, the actual value of 2.17 µg/l could be used to underpin a MAC-value, with the restriction that the value refers to zooplankton (and algae) only. Since the compound disappears only slowly, it could be considered to use the average exposure concentration of **1.79 µg/l** as indicative for an **MPC**, with the same restriction concerning the species" [117][112].

8.3. Derivation of MAC-EQS values

Two methods have been considered for the EQS derivation: the assessment factor and the species sensitivity distribution method.

8.3.1. Derivation using AF method

Table A 1.57 shows all the short-term data considered reliable and relevant. The base set is complete, the mode of action is known and representatives of the most sensitive species are present. Therefore, an AF < 100 may be applied.

Unfortunately for this substance the lowest relevant and reliable value is not easy to define. According to Table A 1.56 and A.1.57**,** data from DAR documents should be considered as reliable. In this document on carbendazim, RIVM tested the reliability of all the considered data, indicating that some results included in the DAR are considered as not reliable (K3) or not classifiable (K4) due to lack of sufficient information. As can be seen in Table A 1.57, the two lowest L(E)C50 fall in this category, as follows:

1. *Pseudokirchneriella subcapitata*, EC50 1.3 µg/l, RIVM (K3) & DAR

[112] Ri 2 = K2 and MPC_{ECO} = AA-QS

The second most sensitive result is a reliable (and relevant) result (K2):

2. *Ictalurus punctatus*, (fish) LC50 7 µg/l, RIVM (K2).

Since we consider the LC50 in fish as reliable, the **MAC-EQS** varies between **0.07** and **0.7 µg/l** depending on the AF applied.

8.3.2. Derivation using SSD method

For carbendazim, there are not sufficient reliable and relevant short-term results available. Although at maximum 11 short-term results for eight taxa are available (including more than two taxonomic groups for fish), higher plants and insects are not represented.

Due to the number of data available, even though the required number and kind of taxa is not fulfilled, we decided to extrapolate the SSD curve. Acute data presented in Table A 1.57 were inserted into ETX 2.0 software [4] and the results are displayed in Table A 1.61 as HC5 values, in Table A 1.62 as acceptance tests, and the acute SSD curve in Figure A 1.7.

Table A 1.61: Carbendazim, extrapolated HC5 acute SSD.

Name	HC5 (acute)
Lower estimate	1.69
Median estimate	12.2
Upper estimate	38.9

Table A 1.62: Carbendazim, results of the acute SSD acceptance tests.

Acceptance test name (n=14)	Significance level 0.1	Significance level 0.05	Significance level 0.025	Significance level 0.01
Anderson-Darling (n ≥ 8)	Accepted	Accepted	Accepted	Accepted
Kolmogorov-Smirnov (n ≥ 20)	Accepted	Accepted	Accepted	Accepted
Cramer von Mises (n ≥ 20)	Accepted	Accepted	Accepted	Accepted

The proposed MAC-EQS was calculated as HC5/AF (12.2/10) and equals **1.22 µg/l**.

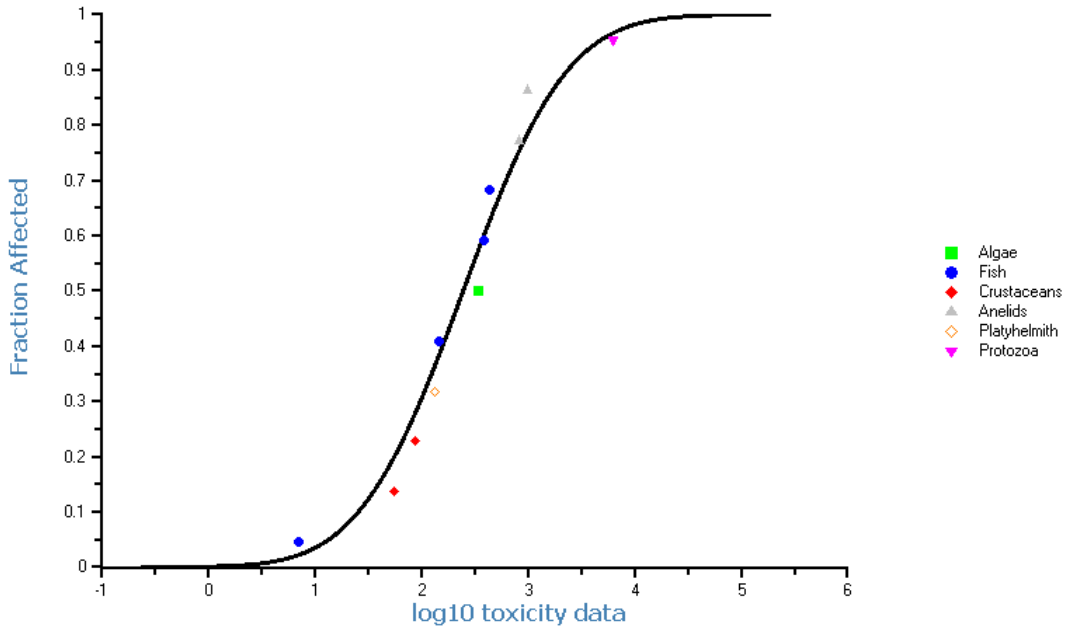


Figure A 1.7: Carbendazim, acute SSD curve.

8.3.3. Interpretation of simulated ecosystem studies

See section 8.2.3.

8.4. Carbendazim: summary of the proposed EQS

The following table summarises the acute and chronic EQS values resulting from the application of the considered methods.

Table A 1.63: Carbendazim, summary EQS results.

Data	Type of EQS	Guidance document	Value to be divided by AF (µg/l)	AF	Proposed EQS (µg/l)	See paragraph #, page #
EQS derived using reliable and relevant data, derivation fulfilling the criteria of guidance document						
Daphnia magna, NOEC	AA –QS	LP, TG, NL	1.5	50	0.03	8.2.1, 140
Ictalurus punctatus, LC50	MAC-EQS	LP, TG, NL	7	100 10	0.07 0.7	8.3.1, 143
EQS derived using reliable and relevant data, derivation not fulfilling the criteria of guidance document						
SSD chronic	AA-EQS		0.49	5	0.098	8.2.2, 140
SSD acute	MAC-EQS		0.34	10	1.22	8.3.2, 144

The following table summarises the EQS values proposed by RIVM.

Table A 1.64: Carbendazim, summary of RIVM EQS results.

Data	Type of EQS	Value to be divided by AF (µg/l)	AF	Proposed EQS (µg/l)
Dugesia lugubris, NOEC	AA–QS	3.4	10	0.34
SSD chronic	AA-EQS	0.71	3	0.24
NOEC, mesocosm Slijkerman	AA-EQS	1.79	3	0.60
Ictalurus punctatus, LC50	MAC-EQS	10	100	0.60

It is interesting to note that RIVM didn't consider the NOEC for *Daphnia magna* (1.5 µg/l) as the lowest chronic data. Instead they used the "geometric mean of 190, 390, 130, 150, 180, 350, 87, 460, 690 µg/L, parameter immobilisation or mortality for *D. magna*; data for >3 mm animals (adults) omitted and most sensitive endpoint selected for <1.5 mm", [103]. Therefore, they calculated an average value for different endpoints, which is not in accordance with the TGD for EQS and ESQ-NL guidelines.

For SSD, they obtained a HC5 of 0.71 µg/L by considering the 10 NOEC values listed in their Table 6. Among these, there are geometric means from values we did not consider appropriate to include in the average calculation.

Finally, in the MAC-EQS derivation, RIVM does not consider the LC50 (*Ictalurus punctatus*) value for the most sensitive life-stage (Alevin, 7 µg/l), because this endpoint was considered as "chronic". However, they also did not include it in the "long-term" data, because it is a LC50. Therefore to extrapolate MAC-EQS the LC50 for the juvenile *Ictalurus punctatus* (10 µg/l) was used.

A short summary of RIVM explanation on their derivation of EQS values, as further detailed in their full report, is cited as follows:

"For carbendazim, a complete base set for toxicity to freshwater organisms is available. Moreover, long-term NOECs of at least three species representing three trophic levels are available. Therefore, the MPC_{ECO}, water is derived using an assessment factor of 10 on the lowest NOEC, i.e. the 21-d NOEC for *Dugesia lugubris* of 3.4 µg/L. The initial MPC_{ECO}, water based on laboratory tests is 3.4/10 = 0.34 µg/L. NOECs of 3.3 and 1.79 µg/L are available from micro/mesocosm studies, that are considered valid for derivation of the MPC (see 3.3.1.2). From a comparison of mesocosm studies with the insecticides chlorpyrifos and lambda-cyhalothrin, it can be concluded that an assessment factor of 3 may be necessary to cover variation at the level of the NOEAEC in case one reliable study is available (De Jong et al., 2008, based on Brock et al., 2006).

Lepper (2005) argues that the scope of protection of an environmental quality standard under the Water Frame Directive is broader than that of the "acceptable concentration" under Directive 91/414. It should be considered that the quality standard must be protective for all types of surface waters and communities that are addressed by the respective standard. Mesocosm

studies performed in the context of 91/414 are normally focused on agricultural ditches that can be characterised as eutrophic shallow water bodies. Environmental quality standards under the WFD, however, must assure protection also for water bodies that significantly differ from this paradigm (Lepper, 2005). It is therefore in principle proposed to use an assessment factor of 3 on the NOEC instead of on the NOEAEC.

In addition, the variation between mesocosms is not studied in as much detail for fungicides as e.g. for insecticides. In this case, two studies available which both cover a wide range of tested species, including Turbellaria and Cladocera, which appeared to be most sensitive in the laboratory studies. The NOEC for *Dugesia lugubris*, the species with the lowest laboratory NOEC, was established as 3.3 µg/L in the microcosm experiment. However, fish are not present in the cosms, while the available data indicate that fish may be very sensitive. A valid 96-h LC50 of 7 µg/L is available for yolk-sac fry of *Ictalurus punctatus* (see Appendix 2). In view of the life stage, this test duration is chronic but since the endpoint is an LC50 rather than a NOEC, it cannot be added to the chronic dataset. It indicates, however, that there is remaining uncertainty as to whether the cosm data do fully cover the potentially sensitive species. Therefore an **assessment factor of 3** is kept on the lowest NOEC, resulting in an **of 0.60 µg/L**" [103].

"For comparison, the MPC_{ECO} water is also derived applying Species Sensitivity Distribution (SSD) to the Chronic data. (…)

The median estimate of the HC5 is 0.71 µg/L (90% CI 0.032 - 4.1 µg/L), calculated with ETX 2.0 (Van Vlaardingen et al., 2004). (…)

In view of the above listed points, there are reasons to apply an assessment factor to the HC5, mainly because of the small dataset, the visual lack of fit, and the large confidence interval. The remaining uncertainty is assumed to be covered by **a factor of 3**, leading to a **MPC_{HC5} of 0.24 µg/L**. In the present case, the available information indicates that MPCHC5 is rather conservative. The MPC_{COSM} is 0.60 µg/L, which is over a factor of 5 lower than the lowest laboratory NOEC. It is considered justified to use the MPC_{COSM} and set the MPC_{ECO}, water to 0.60 µg/L" [103].

"The MAC_{ECO}, water may be derived from the acute toxicity data. Fourteen short-term values for three trophic levels are available, carbendazim has no potential to bioaccumulate (BCF <100 L/kg), the mode of action for the tested species is non-specific and the interspecies variation is high. Therefore, an assessment factor of 100 is applied to the lowest L(E)C50, i.e. the EC50 for *Ictalurus punctatus*: 10 µg/L. Therefore, the MAC_{ECO} is initially derived as 10 / 100 = 0.1 µg/L. However, because the MPC_{WATER} (0.60 µg/L) is higher, the MAC_{ECO}, water is put level with the MPC_{WATER} and becomes 0.60 µg/L" [103]."

9. Imidacloprid: EQS using all relevant data

In this chapter, all relevant data were considered in order to show the influence of data selection on the EQS derivation. In Table A 1.75, the proposed EQS values based on the selected data (reliable and relevant or only relevant), the methodology (AF or SSD) and the guidance documents used for the derivation (LP, TG and NL) are summarized.

9.1. Derivation of EQS values

Two methods have been considered for the EQS derivation: the assessment factor and species sensitivity distribution method.

The Table A 1.65 and Table A 1.66 list the short-term (L(E)C50) and long-term (NOEC and EC10) values used in EQS derivation. These tables are equivalent to Table A 1.26 and Table A 1. 27 (reliable and relevant values) extended with all the relevant but not reliable values.

Table A 1.65: Imidacloprid, reliable short-term toxicity values.

Taxonomic group	Species scientific name	Endpoint	Test duration [d]	Conc. [µg/l] (Purity %)	Source
ALG[113]	*Anabaena flos-aquae*	EC50 (POP/GRT rate)	4	32'800 (21.6%)	RIVM (K2), [42]
ALG	*Desmodesmus subspicatus*	EC50 (POP/ GRT inhib)	3	> 389	[118]
ALG	*Scenedesmus subspicatus*	EC50 (POP/BMAS, GRT rate)	3	> 10'000	RIVM (K3), [43]; EFSA [44]
ALG	*Pseudokirchneriella subcapitata*	EC50 (POP/ GRT inhib)	3	> 1'000 (Confidor)	[119]
ALG	*Selenastrum capricornutum*	EC50 (POP/ BMAS, GRT rate)	3	> 10'000 (98.6%)	RIVM (K3), [43]; EFSA, [45]
CRU	*Daphnia magna*	EC50 (ITX/IMBL)	2	56.60	[118]
CRU	*Chydorus sphaericus*	EC50 (ITX/IMBL)	2	832	RIVM (K2), [48]
CRU	*Cypretta seuratti*	EC50 (ITX/IMBL)	2	1.0	RIVM (K2), [48]
CRU	*Gammarus fossarum*	LC50 (ITX/IMBL)	2	0.80 (Confidor)	[120]
CRU	*Cypridopsis vidua*	EC50 (ITX/IMBL)	2	3	RIVM (K2), [48]
CRU	*Hyalella azteca*	EC50 (ITX/IMBL)	4	55 (tg[§])	RIVM (K2), [42],
CRU	*Ilyocypris dentifera*	EC50 (ITX/IMBL)	2	3.0 (tg[§])	RIVM (K2), [48]
FIS	*Oncorhynchus mykiss*	LC50 (MOR/MORT)	4	> 83'000 (95.0%)	RIVM (K2), [43]

[113] Cyanobacteria

FIS	*Cyprinodon variegatus*	LC50 (MOR/MORT)	4	161'000 (96.2%)	[121]
FIS	*Lepomis macrochirus*	LC50 (MOR/MORT)	4	> 105'000 (97.4%)	RIVM (K2), [42]
FIS	*Leuciscus idus melanotus*	LC50 (MOR/MORT)	4	237'000 (95.3%)	RIVM (K3), [43]; EFSA, [51]
FIS	*Danio rerio*	LC50 (MOR/MORT)	4	241'000 (95.3%)	[118]
AMP	*Rana hallowell*	LC50 (MOR/MORT)	4	129000 (>95%)	[122]
AMP	*Rana limnocharis*	LC50 (MOR/MORT)	4	82000 (>95%)	[122]
AMP	*Rana nigromaculata*	LC50 (MOR/MORT)	4	129000	[122]
INS	*Chironomus tentans*	LC50 (MOR/MORT)	10	3.17 (95.0%)	EFSA, [52]
INS	*Chironomus riparius*	EC50 (ITX/IMBL)	4	12.94 (confidor)	[123]
INS	*Aedes aegypti*	LC50 (MOR/MORT)	2	44.50	[124]
INS	*Aedes albopictus*	LC50 (MOR/MORT)	1	300	[125]
INS	*Cheumatopsyche brevilineata*	EC50 (ITX/IMBL)	2	6.64	[126]
INS	*Culex quinquefasciatus*	LC50 (MOR/MORT)	1	300	[125]
INS	*Epeorus longimanus*	LC50 (MOR/MORT)	4	0.65	[127]
INS	*Simulium vittatum*	LC50 (MOR/MORT)	2	8.10 (GM)	RIVM (K1), [54]
INS	*Pteronarcys dorsata*	LC50 (MOR/MORT)	14	70.10	[128]
INS	*Sericostoma vittatum*	EC50 (ITX/IMBL)	2	47.22	[123]
WOR	*Agamermis unka*	LC50 (MOR/MORT)	1	1'580	[129]
WOR	*Lumbriculus variegatus*	EC50 (ITX/IMBL)	4	6.20	[127]
WOR	*Tubifex tubifex*	EC50 (BEH/NMVM)	1	90	[130]

[§]Technical grade; ALG = algae; AMP = amphibians; CRU = crustaceans; FIS = fish; INS = insects; WOR = worms

Table A 1.66: Imidacloprid, reliable long-term toxicity values.

Species group	Species scientific name	Endpoint	Test duration [d]	Conc. [µg/l] (Purity %)	Source
ALG[114]	*Anabaena flos-aquae*	NOEC (POP/ GRT rate)	4	24'900[115] (21.6%)	RIVM (K2), [42]
ALG	*Navicula pelliculosa*	NOEC	7	6'690[116] (21.6%)	RIVM (K2), [42]
ALG	*Pseudokirchneriella subcapitata*	NOEC (POP/ GRT rate)	3	< 100'000 (98.6%)	RIVM (K3), [43]; EFSA
ALG	*Desmodesmus subspicatus*	NOEC (POP/ GRT rate)	3	10'000 (98.6%)	RIVM (K3), [43], EFSA
ALG	*Desmodesmus subspicatus*	EC10 (POP/ GRT)	3	106'000	[118]
CRU	*Daphnia magna*	NOEC (REP)	21	1'800 (95.4%)	EFSA (K2), [43]
CRU	*Hyalella azteca*	NOEC (GRT)	28	3.53 (admire)	[131]
FIS	*Oncorhynchus mykiss*	NOEC (GRT)	98	1'200 (tg[§])	RIVM (K2), [42]
AMP	*Rana nigromaculata*	NOEC (GEN/MNUC)	7	2000	[122]
INS	*Epeorus longimanus*	NOEC (FDB/FCNS)		1.12	[127]
INS	*Pteronarcys dorsata*	NOEC (MOR/MORT)	14	12	[128]
INS	*Sericostoma vittatum*	NOEC	6	1.9 (Confidor)	[123]
INS	*Chironomus riparius*	NOEC (GRT)	10	>0.40 (Confidor)	[123]
INS	*Chironomus tentans*	NOEC (GRT)	10	0.67 (95.0%)	RIVM (K2), [42]
WOR	*Lumbriculus variegatus*	NOEC	1	9.67	[127]
MOL	*Marisa cornuarietis*	NOEC (MOR/MORT)	>9	>50	[132]

[§]Technical grade; ALG = algae; AMP = amphibians; CRU = crustaceans; FIS = fish; INS = insects; WOR = worms

9.1.1. Derivation using AF method

When the taxonomic group with the lowest NOEC value corresponds to the most sensitive taxonomic group based on the acute data, an AF of 10 can be applied to this lowest NOEC value. The lowest NOEC value on *Chironomus riparius* is not acceptable for the derivation of EQS, for being a value "higher than" 0.40 µg/l. In consequence, the proposed **AA-EQS** is **0.067 µg/l**, calculated as 0.67 µg/l (NOEC *Chironomus tentans*) divided by 10, i.e. based on the second most sensitive long-term result. When using only the reliable data, the lowest NOEC is also the NOEC for the insect *Chironomus riparius*, but in this case an assessment factor of 50

[114] Cyanobacteria
[115] Test compound NTN 33893 2F, results given in mg as/L.
[116] Test compound NTN 33893 2F, results given in mg as/L.

was used since the crustacean *Cypretta seuratti*, which was the most sensitive species in the reliable acute toxicity data set, was not present in the data set with reliable chronic data.

9.1.2. Derivation using SSD method

The SSD method requires a minimum of 10 NOECs (preferably more than 15 NOECs) for different species covering at least eight taxonomic groups.

For imidacloprid, there are only seven taxonomic groups, i.e. not enough to fully satisfy the criteria for SSD methodology. Nonetheless, the SSD curve has been calculated for comparison with the AF method.

The proposed AA-EQS as HC5/AF equals **0.020 µg/l** (0.1009/5).

Table A 1.67: Imidacloprid, extrapolated HC5 long-term SSD.

Name	HC5 (acute) [µg/l]
Lower estimate	0.0023
Median estimate	0.1009
Upper estimate	1.1669

Table A 1.68: Imidacloprid, results of the long-term SSD acceptance tests.

Acceptance test name (n=16)	Significance level 0.1	Significance level 0.05	Significance level 0.025	Significance level 0.01
Anderson-Darling (n ≥ 8)	Accepted	Accepted	Accepted	Accepted
Kolmogorov-Smirnov (n ≥ 20)	Accepted	Accepted	Accepted	Accepted
Cramer von Mises (n ≥ 20)	Accepted	Accepted	Accepted	Accepted

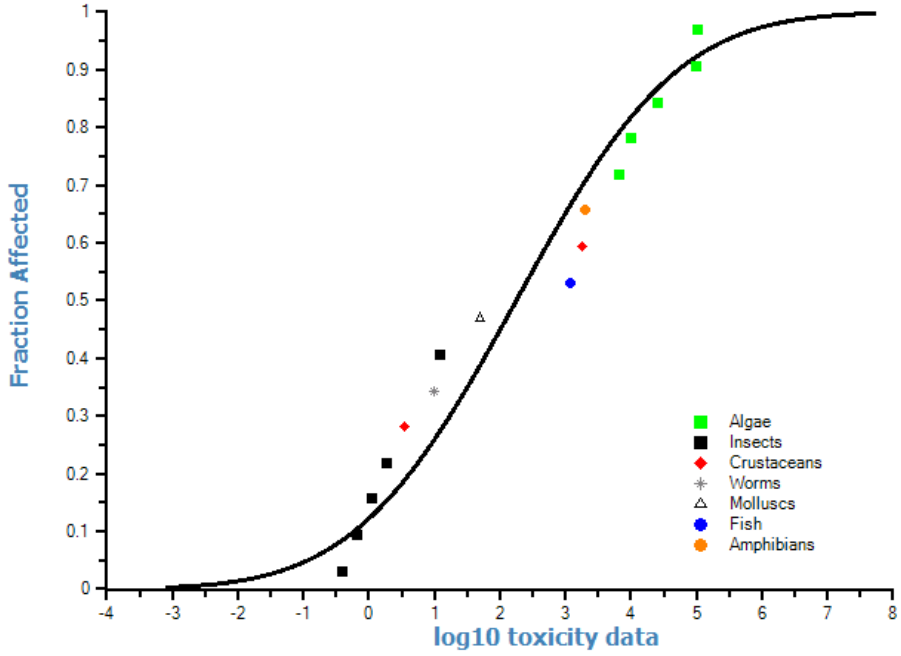


Figure A 1.8: Imidacloprid: long-term SSD curve.

After visual analysis, the curve is clearly bimodal, therefore a second SSD has been extrapolated using crustaceans and insects' long-term data, as presented in Figure A 8.1, Table A 1.69 for the HC5 values and Table A 1.70 for the results of the acceptance tests.

The proposed AA-EQS as HC5/AF equals **0.0065 µg/l**, calculated as 0.0325 µg/l divided by the AF of 5.

Table A 1.69: Imidacloprid, extrapolated HC5 from crustaceans and insects long-term SSD.

Name	HC5 (acute) [µg/l]
Lower estimate	0.0003
Median estimate	0.0325
Upper estimate	0.3307

Table A 1.70: Imidacloprid, results of the crustaceans and insects' long-term SSD acceptance tests.

Acceptance test name (n=7)	Significance level 0.1	Significance level 0.05	Significance level 0.025	Significance level 0.01
Anderson-Darling (n ≥ 8)	Rejected	Accepted	Accepted	Accepted
Kolmogorov-Smirnov (n ≥ 20)	Accepted	Accepted	Accepted	Accepted
Cramer von Mises (n ≥ 20)	Accepted	Accepted	Accepted	Accepted

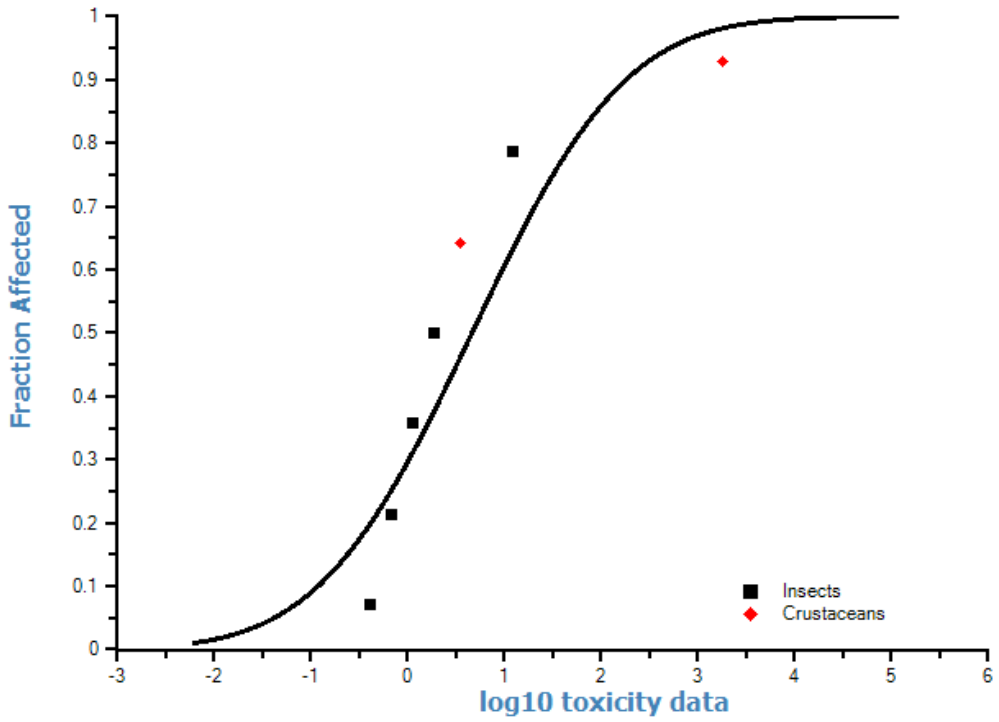


Figure A 1.9: Imidacloprid: crustaceans and insects long-term SSD curve.

9.2. Derivation of MAC-EQS values

Two methods were considered for the EQS derivation: the assessment factor and the species sensitivity distribution method.

9.2.1. Derivation using AF method

The lowest short-term result was the LC50 of 0.65 µg/l for the insect *Epeorus longimanus*. An AF between 100 and 10 can be applied, with 100 as the standard factor and 10 as the lower value, since the mode of action is known and the most sensitive species (insects) is present in the dataset. The proposed MAC-EQS values should be between 0.0065 and 0.065 µg/l, depending on "expert judgement", but since MAC-EQS should not be lower than AA-EQS the MAC-EQS is set equal to AA-EQS.

The proposed **MAC-EQS** is **0.067 µg/l**.

9.2.2. SSD for MAC-EQS

For SSD 30 short-term results for four taxa have been considered as reliable and relevant.

Due to the number of data available, even if the required number of taxa is not fulfilled we decided to extrapolate the SSD curve. The acute data presented in Table A 1.66 were inserted in ETX 2.0 software [4], and the results are displayed in Table A 1.71 for the HC5 values, in Table A 1.72 for acceptance tests, and in Figure A 1.10 for the acute SSD curve.

The proposed MAC-EQS is HC5/AF equal to **0.032 µg/l**, calculated as 0.3223 µg/l divided by the AF of 10.

At visual inspection the curve is clearly bimodal, thus a second SSD has been extrapolated using crustaceans and insects' short-term data, see Figure A 1.11 for the curve, Table A 1.73 for the HC5 values and Table A 1.74 for the results of the acceptance tests.

The proposed MAC-EQS as HC5/AF equals **0.041 µg/l** (0.4116/10).

Table A 1.71: Imidacloprid, extrapolated HC5 acute SSD.

Name	HC5 (acute) [µg/l]
Lower estimate	0.0339
Median estimate	0.3223
Upper estimate	1.7446

Table A 1.72: Imidacloprid, results of the acute SSD acceptance tests.

Acceptance test name (n=33)	Significance level 0.1	Significance level 0.05	Significance level 0.025	Significance level 0.01
Anderson-Darling (n ≥ 8)	Rejected	Rejected	Rejected	Accepted
Kolmogorov-Smirnov (n ≥ 20)	Accepted	Accepted	Accepted	Accepted
Cramer von Mises (n ≥ 20)	Rejected	Accepted	Accepted	Accepted

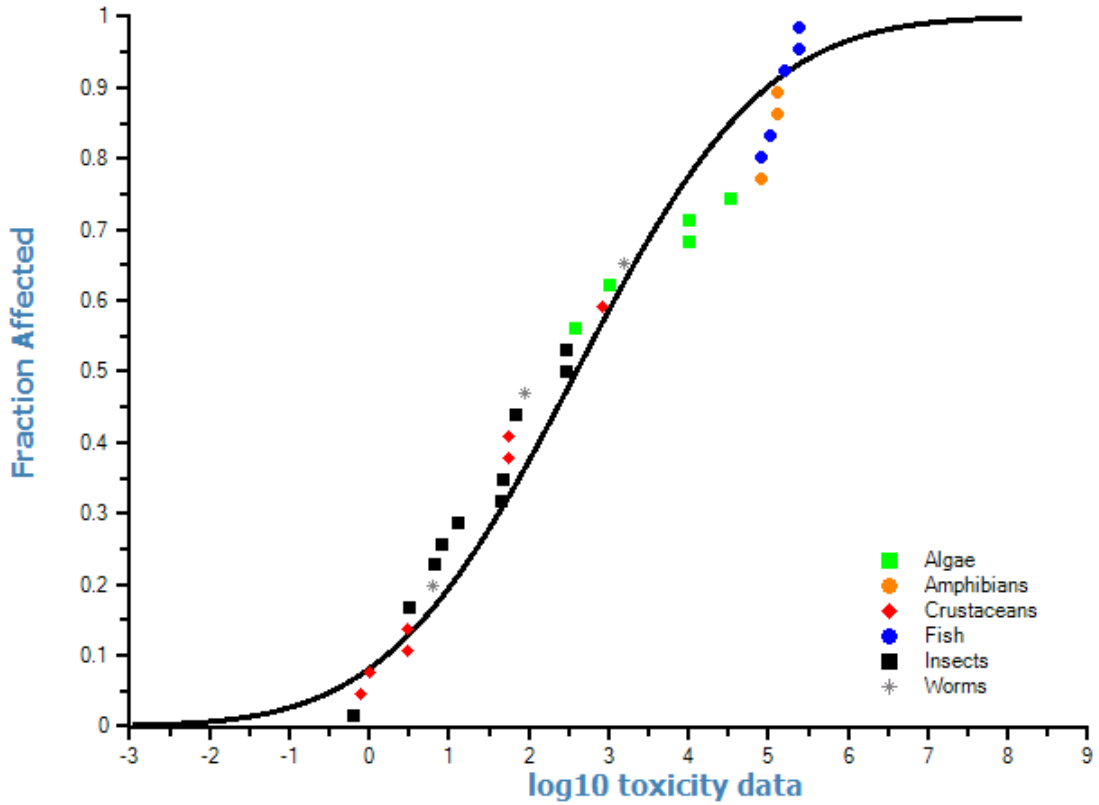


Figure A 1.10: Imidacloprid: acute SSD curve relevant, reliable and non reliable data.

Table A 1.73: Imidacloprid, extrapolated HC5 acute SSD (crustaceans and insects).

Name	HC5 (acute only) [µg/l]
Lower estimate	0.0698
Median estimate	0.4116
Upper estimate	1.3287

Table A 1.74: Imidacloprid, results of the acute crustaceans and insects SSD acceptance tests.

Acceptance test name (n=17)	Significance level 0.1	Significance level 0.05	Significance level 0.025	Significance level 0.01
Anderson-Darling (n ≥ 8)	Accepted	Accepted	Accepted	Accepted
Kolmogorov-Smirnov (n ≥ 20)	Accepted	Accepted	Accepted	Accepted
Cramer von Mises (n ≥ 20)	Accepted	Accepted	Accepted	Accepted

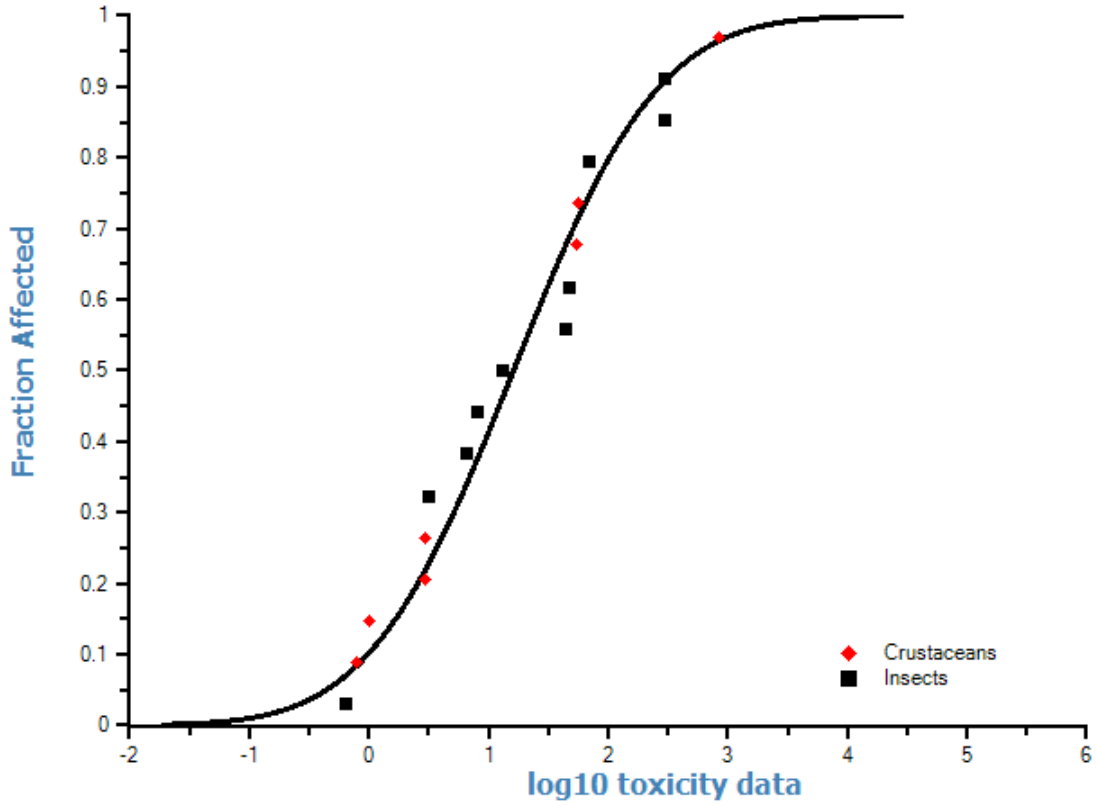


Figure A 1.11: Imidacloprid: acute SSD curve extrapolated using crustaceans and insects data.

9.3. Imidacloprid: summary of the proposed EQS

The following table summarizes the acute and chronic EQS values resulting from the application of the AF and SSD methodology on relevant and reliable data and on relevant data only. The third column indicates for which guidance documents the requirements of the corresponding methodology are fulfilled.

In this section, short- and long-term results which are relevant but not reliable have been added to the relevant and reliable data used previously for the derivation of imidacloprid EQS.

After the inclusion of insect short-term data in Table A 1.65, the most sensitive taxonomic group becomes insects. For reliable and relevant data it was crustaceans.

Despite the addition of new long-term results, the lowest long-term data acceptable for EQS derivation remained the one for *Chironomus tentans*, the same as when both reliable and relevant data were considered.

When the most sensitive taxonomic group in the long-term and the short-term results are the same, an AF of 10 can be applied to the lowest long-term result. On the contrary, when the most sensitive taxonomic group in the acute data is not the taxonomic group showing the higher sensitivity in the long-term data, an AF of 50 should be applied, [2, 3].

As a result of the different AF to be applied (10 instead of 50) to the same long-term result, the AA-EQS is higher when considering relevant data instead of only reliable and relevant data.

Furthermore, since according to TG and NL the MAC-EQS cannot be lower than the AA-EQS, also the MAC-EQS is higher when considering relevant instead of reliable and relevant data.

Table A 1.75: Imidacloprid, summary of the proposed EQS.

Data	Type of EQS	Requirements guidance document fulfilled	Value to be divided by AF (µg/l)	AF	Proposed EQS (µg/l)	See paragraph #, page #
Reliable and relevant data according to the guidance documents						
Chironomus tentans, NOEC	AA –QS	TG, NL	0.67	50	0.0134	3.2.1, 105
Cypretta seuratti, LC50	MAC-EQS	TG, NL	1	100 10	0.0134 0.1	3.3.1, 105
Reliable and relevant data according to the guidance documents but requirements for SSD not fulfilled						
SSD acute	MAC-EQS		0.3458	10	0.035	3.3.2, 106
SSD acute (crustaceans)	MAC-EQS		0.1164	10	0.012	3.3.2, 106
Relevant data according to the guidance documents						
Chironomus tentans, NOEC	AA –QS	LP, TG, NL	0.67	10	0.067	9.1.2, 151
Epeorus longimanus, LC50	MAC-EQS	LP	0.65	100 10	0.0065 0.065	9.2.1, 153
Epeorus longimanus, LC50	MAC-EQS	TG, NL	0.65	100 10	0.067 0.067	9.2.1, 153
SSD acute	MAC-EQS	LP, TG, NL	0.32	10	0.032	9.2.2, 153
SSD acute (crustaceans and insects)	MAC-EQS	LP, TG, NL	0.41	10	0.041	9.2.2, 153
Relevant data according to the guidance documents but requirements for SSD not fulfilled						
SSD chronic	AA-EQS		0.1009	5	0.020	9.1.2, 151
SSD chronic (crustaceans and insects)	AA-EQS		0.0325	5	0.0065	9.1.2, 151

	Reliable and relevant data	Relevant data
Most sensitive taxonomic group in the short-term dataset	Crustaceans	Insects
Most sensitive taxonomic group in the long-term dataset	Insects	Insects
AF to be applied	50	10
Lowest chronic data [µg/l]	0.67 (*Chironomus tentans*)	0.67 (*Chironomus tentans*)
Proposed AA-EQS [µg/l]	0.0134	0.067

10. References

[1] Lepper P. Manual on the Methodological Framework to Derive Environmental Quality Standards for Priority Substances in accordance with Article 16 of the Water Framework Directive (2000/60/EC). Schmallenberg, Germany: Fraunhofer-Institute Molecular Biology and Applied Ecology, 2005.

[2] Paya Perez A, Whitehouse P, Wilkinson H, Rodriguez Romero J, David M. Technical Guidance Document for deriving Environmental Quality Standards. EU and WFD, 2010.

[3] van Vlaardingen PLA, Verbruggen EMJ. Guidance for the derivation of environmental risk limits within the framework of 'International and national environmental quality standards for substances in the Netherlands' (INS). In: 601782001/2007 Rr, editor. Bilthoven, the Netherlands: National Institute for Public Health and the Environment, 2007.

[4] Van Vlaardingen P, Traas TP, Aldenberg T. ETX-2000, Normal Distribution Based Hazardous Concentration and Potentially Affected Fraction. Bilthoven, The Netherlands: Rijksinstituut voor Volksgezondheid en Milieu, 2003.

[5] Lepper P, Sorokin N, Atkinson C, Hope S-J, Rule K, Comber S. Proposed EQS for Water Framework Directive Annex VIII substances: diazinon. Almondsbury, Bristol, BS32 4UD: Environment Agency, Rio House, Waterside Drive, Aztec West, 2007.

[6] Oldersma H, Hanstveit A, Pullens M. The effect of the product diazinon technical 92.8% on the growth of green algae (*Scenedesmus subspicatus*). EFSA DAR, 1984.

[7] Hughes J. The toxicity of diazinon technical to *Selenastrum capricornutum*. U.S. Environmental Protection Agency, Office of Pesticide Programs registration standard, 1988.

[8] Bailey HC, Miller JL, Miller MJ, Wiborg LC, Deanovic L, Shed T. Joint acute toxicity of diazinon and chlorpyrifos to *Ceriodaphnia dubia*. Environmental Toxicology and Chemistry 1997;16:2304.

[9] Surprenant DC. The chronic toxicity of 14C-diazinon technical to *Daphnia magna* under flow-through conditions. EFSA DAR, 1988.

[10] Vilkas AG. Acute toxicity of diazinon technical to the water flea *Daphnia magna* Straus. EFSA DAR, 1976.

[11] Albuquerque R. Diazol 60EC: acute toxicity to *Daphnia magna*. EFSA DAR, 2002.

[12] Okkerman P, van der Putte I. Endocrine Disrupters: Study on gathering information on 435 substances with insufficient data.: NKH: RPS BKH consulting Engineers, 2002. p.52 excl. Annexes.

[13] Moore A, Waring CP. Sublethal effects of the pesticide diazinon on olfactory function in mature male Atlantic salmon parr. Journal of Fish Biology 1996;48:758.

[14] Le Lievre MK. Diazinon technical - acute toxicity to Ceriodaphnids (*Ceriodaphnia dubia*) under static condition. EFSA DAR, 1991.

[15] Fernandez-Casalderrey A, Ferrando MD, Andreu-Moliner E. Chronic toxicity of diazinon to *Daphnia magna*: effects on survival, reproduction and growth. Toxicological and Environmental Chemistry 1995;49:25.

[16] Surprenant DC. The toxicity of diazinon technical to fathead minnow (*Pimephales promelas*) embryos and larvae. EFSA DAR, 1988.

[17] Allison DT, Hermanutz RO. Toxicity of diazinon to brook trout and fathead minnows. In: Washington DUEPA, editor, vol. EPA-600/3-77-060, 1977.

[18] EU Council Directive 91/414/EEC. Diazinon, report and proposed decision. Ministério da agricultura do desenvolvimento rural e das pescas direcçao das culturas, 2005. p.Volume 3.

[19] Office of Pesticide Programs. Pesticide Ecotoxicity Database. Washington, DC: US EPA Environmental Fate and Effects Division, 2000.

[20] Ankley GT, Dierkes JR, Jensen DA, Peterson GS. Piperonyl butoxide as a tool in aquatic toxicological research with organophosphate insecticides. Ecotoxicology and Environmental Safety 1991;21:266.

[21] Mayer FL, Ellersieck MR. Manual of acute toxicity: Interpretation and data base for 410 chemicals and 66 species of freshwater animals. Washington, DC; USA: US Department of the Interior, Fish and Wildlife Service, 1986.

[22] Nikunen E, Leinonen R, Kultamaa A. Environmental properties of chemicals. Helsinki, Finland: National Board of Waters and the Environment, 1990.

[23] Van Hooidonk C, Van Der Holst JPJ. Desk study on the environmental load of organophosphorus compounds. Brussels, Belgium: Commission of the European Communities, 1981.

[24] Verschueren K. New York: Van Nostrand Reinhold: Handbook of Environmental Data on Organic Chemicals, 1996.

[25] Collyard SA, Ankley GT, Hoke RA, Goldenstein T. Influence of age on the relative sensitivity of *Hyalella azteca* to diazinon, alkylphenol ethoxylates, copper, cadmium and zinc. Archives of Environmental Contamination and Toxicology 1994;26:110.

[26] Ferrando MD, Sancho E, Andreu-Moliner E. Comparative acute toxicities of selected pesticides to *Anguilla anguilla*. Journal of Environmental Science and Health 1991;B26:491–498.

[27] Office of Pesticide Programs. Pesticide ecotoxicity database. Washington, DC: US EPA Environmental Fate and Effects Division, 2000.

[28] Jarvinen AW, Tanner DK. Toxicity of selected controlled release and corresponding unformulated technical grade pesticides to the fathead minnow *Pimephales promelas*. Environmental Pollution (Series A) 1982;27:179.

[29] Harris ML, Bishop CA, Struger J, Ripley B, Bogart JP. The functional integrity of northern leopard frog (*Rana pipiens*) and green frog (*Rana calamitans*) populations in orchard wetlands. II. Effects of pesticides and eutrophic conditions on early life stage development. Environmental Toxicology and Chemistry 1998;17:1351–1363.

[30] Philipps GL. Memorandum dated 29 April to R. Sehar. Duluth, MN, USA: US Environmental Protection Agency, 1988.

[31] Lydy MJ, Austin KR. Toxicity assessment of pesticide mixtures typical of the Sacramento-San Joaquin Delta using *Chironomus tentans*. Archives of Environmental Contamination and Toxicology, 48, 49–55. Archives of Environmental Contamination and Toxicology 2004;48:49.

[32] Van der Geest HG, Greve GD, De Haas EM, Scheper BB, Kraak MHS, Stuijfzand SC, Augustijn KH, Admiraal W. Survival and behavioral responses of larvae of the caddisfly *Hydropsyche angustipennis* to copper and diazinon. Environmental Toxicology and Chemistry 1999;19:1965.

[33] Call D. Validation study of a protocol for testing the acute toxicity of pesticides to invertebrates using the apple snail (*Pomacea paludosa*). Superior, WI: University of Wisconsin-Superior: US EPA Cooperative Agreement, 1993.

[34] Murray HE, Guthrie RK. Effects of carbaryl, diazinon and malathion on native aquatic populations of microorganisms. Bulletin of Environmental Contamination and Toxicology 1980;24:535–542.

[35] Stadnyk L, Cambell RS, Johnson BT. Pesticide effect on growth and ^{14}C assimilation in a freshwater alga. Bulletin of Environmental Contamination and Toxicology 1971;6:1.

[36] Norberg-King TJ. Memorandum dated 31 August to C. Stephan. Duluth, MN: US Environmental Protection Agency, 1987.

[37] Bresch H. Early life stages test in zebra fish versus a growth test in rainbow trout to evaluate toxic effects. Bulletin of Environmental Contamination and Toxicology 1991;46:641–648.

[38] Allison DT. Use of exposure units for estimating aquatic toxicity of organophosphate pesticides. vol. EPA-600/3-77-077: Washington, DC: US Environmental Protection Agency, 1977.

[39] Morgan HG. Sublethal effects of diazinon on stream invertebrates. Guelph, Ontario, Canada: University of Guelph, 1977.

[40] Snell TW, Moffat BD. A 2-d life-cycle test with the rotifer *Brachionus calyciflorus*. Environmental Toxicology and Chemistry 1992;11:1249–1257.

[41] Tomlin C. e-Pesticide Manual 2002-2003, 2003.

[42] Anatra-Cordone M, Durkin P. Imidacloprid- human health and ecological risk assessment. USDA Forest service, 2005.

[43] EC. Imidacloprid, Draft Assessment Report. Rapporteur Member State: Germany, 2006.

[44] Heimbach F. Growth inhibition of green algae (*Scenedesmus subcapicatus*) caused by NTN 33893. Leverkusen, Germany: Private industry report, 1986.

[45] Dorgerloh M. Imidacloprid - Influence on the growth of the green alga, *Selenastrum capricornutum*. Private report, Bayer Cropscience AG, 2000.

[46] Young B, Hicks S. Acute toxicity of NTN 33893 to *Daphnia magna*. Bayer Corporation, 1990.

[47] Young B, Blakemore G. 21-Day chronic static renewal toxicity of NTN 33893 to *Daphnia magna*. Bayer Corporation, 1990.

[48] Sanchez-Bayo F, Goka K. Influence of light in acute toxicity bioassays of imidacloprid and zinc pyrithione to zooplankton crustaceans. Aquatic Toxicology 2006;78:262.

[49] England D, Bucksath J. Acute toxicity of NTN 33893 to *Hyalella azteca*.: BAY, 1991.

[50] Grau R. The acute toxicity of NTN 33893 techn. to rainbow trout (*Salmo gairdneiri*) in a static test. Bayer CropScience AG, 1988.

[51] Grau R. The acute toxicity of NTN 33893 techn. to golden orfe (*Leuciscus idus melanotus*) in a static test.: Bayer CropScience AG, 1987.

[52] Gagliano G. Growth and survival of the midge (*Chironomus tentans*) exposed to NTN 33893 technical under static renewal conditions.: Bayer, 1991.

[53] Dorgerloh M, Sommer H. Acute toxicity of Imidacloprid (tech.) to larvae of *Chironomus riparius*. Private report, Bayer Cropscience AG, 2002.

[54] Overmyer J, Manson B, Armbrust K. Acute toxicity of imidacloprid and fipronil to a non target aquatic insect, *Simulium vittatum* Zetterstedt cytospecies IS-7. Bulletin of Environmental Contamination and Toxicology 2005;74:872.

[55] Posthuma-Doodeman CJAM. Environmental risk limits for imidacloprid. Letter report 601716018/2008. Bilthoven, the Netherlands: RIVM - National Institute for Public Health and the Environment, 2008.

[56] Ratte H, Memmert A. Biological effects and fate of imidacloprid SL 200 in outdoor microcosm ponds. RCC Ltd, 2003.

[57] Heimbach F. Influence of Diuron WP 80 on development and emergence of larvae of *Chironomus riparius*. Unpublished report, Bayer AG, 1992.

[58] Metz JG, Pakrasi HB, Seibert M, Arntzer CJ. Evidence for a dual function of the herbicide-binding D1 protein in photosystem II. FEBS Letters 1986;205:269.

[59] Memmert U. Toxicity of Diuron techn. to *Anabaena flos-aquae* (Cyanothyta) in a 72-hour algal growth test.: Private report, RCC Ltd., 1998.

[60] Dengler D. Testing of toxic effects of the Karmex DF (80% diuron) on the single cell green alga *Desmodesmus subspicatus* (formerly *Scenedesmus subspicatus*). Arbeitsgemeinschaft GAB Biotechnologie GmbH und IFU Umweltanalytik GmbH, 2003.

[61] Blasberg J, Hicks S, Bucksath J. Acute toxicity of diuron to *Selenastrum capricornutum* Printz. ABC Laboratory Project ID, final report No. 39335, ABC Laboratory Inc., 1991.

[62] Heimbach F. Acute toxicity of Diuron to water flea. Unpublished report Hb-DM-7 Bayer AG, 1983.

[63] Galiano G, Bowers L. Influence of diuron (WP 80) on the amphipod (*Hyalella azteca*) in a water sediment system under static conditions. Unpublished Miles report. Bayer AG, 1993.

[64] Drottar K. Acute toxicity of HR-16, 035 to sheepshead minnow (*Cyprinodon variegatus*). Private report, Du Pont, 1985.

[65] Dorgerloh M. Diuron techn.-prolonged toxicity to rainbow trout in a semi-static test. Private report, Bayer AG, 1993.

[66] Dorgerloh M. Diuron techn.-prolonged toxicity (28 days) to rainbow trout in a semi-static test. Private report no. DOM 93009 Bayer AG, 1993.

[67] Dorgerloh M. Diuron-toxicity (7 days) to *Lemna gibba* G3.: Private report no. DOM 99054. Bayer AG, 1999.

[68] Dorgerloh M. Diuron techn.-acute toxicity to rainbow trout *Oncorhynchus mykiss* in a static test. Private report no E280 0692-7. Bayer AG, 1993.

[69] EC. Terbuthylazine. Report and proposed decision of the United Kingdom made to the European Commission under article 8 of 91/414/EEC (Terbuthylazine_DAR_15_Vol3_B9_part2_public). York, UK: Pesticides safety directorate, 2007.

[70] Kettner R. Octanol/water partition coefficient of GS 13529. Basel, CH: Novartis Crop protection AG, 1999.

[71] EC. Terbuthylazine. Report and proposed decision of the United Kingdom made to the European Commission under article 8 of 91/414/EEC (Terbuthylazine_DAR_01_Vol1_public). York, UK: Pesticides safety directorate, 2007.

[72] Migchielsen a. Cyanobacteria growth inhibition test with terbuthylazine technical. Private report, Oxon, 2002.

[73] Grade R. Report on the growth inhibition test of GS 13529 tech, to green algae (*Scenedesmus subspicatus*). Private report, Syngenta, 1993.

[74] Migchielsen Mb. Fresh water algal growth inhibition test with terbuthylazine technical. Private report, Oxon, 2002.

[75] Kelly C. Private report, Oxon, 1996.

[76] Wallace, Woodyer. Private report, Syngenta, 2002.

[77] Douglas, Handley, Macdonald. Private report, Oxon, 1988.

[78] Dengler D. Private report, Oxon, 2001.

[79] Shillabeer N, Maynard S, Woodyer J. Private report, Syngenta, 2002.

[80] Bell G. Private report, Oxon, 1995.

[81] Rufli H. Private report, Syngenta, 1996.

[82] Ritter. Private report, Syngenta, 1990.

[83] Memmert U. Private report, Syngenta, 1998.

[84] Huber W. Private report, Syngenta, 1996.

[85] Huber W. Private report, Syngenta, 1994.

[86] Bogers. Private report, Oxon, 1999.

[87] Johnson I, Aldous E, Atkinson C, Hope S-J, Sorokin N. Proposed EQS for Water Framework Directive Annex VIII substances: mecoprop. Almondsbury, Bristol, BS32 4UD: Environment Agency, 2007.

[88] Nitschke L, Wilk A, Schussler W, Metzner G, Lind G. Biodegradation in laboratory activated sludge plants and aquatic toxicity of herbicides. Chemosphere 1999;39:2313.

[89] Mullerschon H. Influence of MCPP (as DMA salt) on the reproduction of *Daphnia magna*. CCR Project No. 167703 Report. Unpublished. [Cited in EU DAR 1999]. 1990.

[90] Bogers M. MCPP (as DMA salt) 96 hour acute toxicity study (LC50) in the rainbow trout (flow through). RCC Notox Project 018213 Report. Unpublished. [Cited in EU DAR 1999]. 1990.

[91] Alabaster JS. Survival of fish in 164 herbicides, insecticides, fungicides, wetting agents and miscellaneous substances. International Pesticides Control 1969;11:29.

[92] Bogers M. MCPP (as DMA salt) 21-day prolonged toxicity study in the rainbow trout (flow through). RCC Notox Project 018224 Report. Unpublished. [Cited in EU DAR 1999]. 1990.

[93] Hoberg J. MCPP-p-DMAS: toxicity to the freshwater diatom, *Navicula pelliculosa*. Final Report – Laboratory Project Number 92-10-4463, 10566.1191.6211.440. Unpublished study prepared by Springborn Laboratories., 1992.

[94] Hoberg J. MCPP-p-DMAS: toxicity to the freshwater green alga, *Selenastrum capricornutum*.: Final Report – Laboratory Project Number 92-2-4113, 10566.1191.6211.430 574.0. Unpublished study prepared by Springborn Laboratories., 1992.

[95] European Commission. Review report for the active substance Mecoprop-P. European Commission, 2003.

[96] Bell. Mecoprop-P: acute toxicity to *Daphnia magna*. Unpublished. [Cited in EU DAR 1999]. 1994.

[97] Munk R. Report on the study of the acute toxicity of Mecoprop-P. Bluegill (*Lepomis macrochirus*). Unpublished. [Cited in EU DAR 1999]. 1989.

[98] Kirsch P, Munk R. Report on the study of the acute toxicity of Mecoprop-P DMA salt on rainbow trout (*Oncorhynchus mykiss*). Unpublished. [Cited in EU DAR 1999]. 1992.

[99] Hoberg J. MCPP-p-DMAS: toxicity to the duckweed *Lemna gibba*. Final Report – Laboratory Project Number 92-3-4174, 10566.1191.6211.410, 574.1. Unpublished study prepared by Springborn Laboratories., 1992.

[100] Dohmen GP. Effect of Mecoprop-P on the growth of the green alga *Pseudokirchneriella subcapitata* using the 72-hour growth inhibition test according to OECD 201. BASF Report No. 88/420. Unpublished. [Cited in EU DAR 1999]. 1993.

[101] Dohmen GP. Effects of Mecoprop-P on the reproduction of *Daphnia magna* Straus in a chronic toxicity test.: BASF Report 3728. Unpublished. [Cited in EU DAR 1999], 1993.

[102] Munk R. Sublethal toxic effects on the rainbow trout (*Oncorhynchus mykiss* Walbaum 1792) of Mecoprop-P-acid in a flow through system (28 days); OECD 204. BASF Project No. 42F0002/915134 Report. Unpublished. [Cited in EU DAR 1999]. 1993.

[103] Dang Z, Smit E. Environmental risk limits for carbendazim. Letter report 601716014/2008. Bilthoven, the Netherlands: RIVM - National Institute for Public Health and the Environment, 2008.

[104] Canton J. The toxicity of benomyl, thiophanate-methyl, and BCM to four freshwater organisms. Bulletin of Environmental Contamination and Toxicology 1976;16:214.

[105] DAR EC. Draft Assessment Report (DAR) Carbendazim. Rapporteur member state Germany, with addendum 2000, 1997.

[106] Douglas, Handley. See RIVM report, 1987.

[107] Fisher. See RIVM report, 1988.

[108] Van Wijngaaeden R, Crum S, Decraene K, Hattink J, Van Kammen A. Toxicity of Derosal (active ingredient carbendazim) to aquatic invertebrates. Chemosphere 1998;37:673.

[109] Palawski D, Knowles C. Toxicological studies of benomyl and carbendazim in rainbow trout, channel catfish and bluegills. Environmental Toxicology and Chemistry 1986;5:1039.

[110] Hutton. See RIVM report, 1984.

[111] Fisher. See RIVM report, 1981.

[112] Rankin P, Surak J, Thompson N. Effect of benomyl and benomyl hydrolysis products on tetrahymena pyriformis. Food and Cosmetics Toxicology 1976;15:187.

[113] Heusel. See RIVM report, 1991.

[114] Baer. See RIVM report, 1993.

[115] Lakota S, Zbigniew J, Raszka A. Effect of carbendazim on fish. I. Acute toxicity of MBC to carp fry (*Cyprinus carpio L.*). Zoological Pol 1993;37:88.

[116] Cuppen J, Van den Brink P. Impact of the fungicide carbendazim in freshwater microcosms. I. Water quality, Breakdown of particulate organic matter and responses of macroinvertebrates. Aquatic Toxicology 2000;48:233.

[117] Slijkerman D, Baird D, Conrad A, Jak R, Van Straalen N. Assessing structural and functional plankton responses to carbendazim toxicity. Environmental Toxicology and Chemistry 2004;23:455.

[118] Tišler T, Jemec A, Mozetič B, Trebše P. Hazard identification of imidacloprid to aquatic environment. Chemosphere 2009;76:907.

[119] Kungolos A, C E, Tsiridis V, Tsiropoulos N. Evaluation of toxic and interactive toxic effects of three agrochemicals and copper using a battery of microbiotests. Science of the Total Environment 2009;407:4610.

[120] Lukančič S, Žibrat U, Mezek T, Jerebic A, Simčič T, Brancelj A. Effects of Exposing Two Non-Target Crustacean Species, *Asellus aquaticus* L., and *Gammarus fossarum* Koch., to Atrazine and Imidacloprid. Bulletin of Environmental Contamination and Toxicology 2010;84:85.

[121] Ward G. See EFSA report, 1990.

[122] Feng S, Kong Z, Wang X, Zhao L, Peng P. Acute Toxicity and Genotoxicity of Two Novel Pesticides on Amphibian, *Rana N. Hallowell*. Chemosphere 2004;56:457.

[123] Pestana J, Loureiro S, Baird D, AMVM S. Fear and loathing in the benthos: Responses of aquatic insect larvae to the pesticides imidacloprid in the presence of chemical signals of predation risks. Aquatic Toxicology 2009;93:138.

[124] Song MY, Stark JD, Brown JJ. Comparative toxicity of four insecticides, including imidacloprid and tebufenozide, to four aquatic arthropods. Environmental Toxicology and Chemistry 1997;16:2494.

[125] Liu H, Cupp E, Guo A, Liu N. Insecticide Resistance in Alabama and Florida Mosquito Strains of *Aedes albopictus*. Journal of Medical Entomology 2004;41:946.

[126] Yokoyama A, Ohtsu K, Iwafune T, Nagai T, Ishihara S, Kobara Y, Horio Y, Horio T, Endo S. Sensitivity difference to insecticides of a riverine caddisfly, *Cheumatopsyche brevilineata* (Trichoptera: Hydropsychidae), depending on the larval stages and strains. Pesticide Science 2009;34:21.

[127] Alexander AC, Culp JM, Liber K, Cessna A. Effects of Insecticide Exposure on Feeding Inhibition in Mayflies and Oligochaetes. Environmental Toxicology and Chemistry 2007;26.

[128] Kreutzweiser DP, Good KP, Chartrand DT, Scarr TA, Thompson DG. Toxicity of the Systemic Insecticide, Imidacloprid, to Forest Stream Insects and Microbial Communities. Bulletin of Environmental Contamination and Toxicology 2008;80:211.

[129] Choo HY, Kim HH, Kaya HK. Effects of Selected Chemical Pesticides on *Agamermis unka* (Nematoda: Mermithidae), a Parasite of the Brown Plant Hopper, *Nilaparvata lugens* Biocontrol Science and Technology 1998;8:413.

[130] Gerhardt A. Screening the Toxicity of Ni, Cd, Cu, Ivermectin, and Imidacloprid in a Short-Term Automated Behavioral Toxicity Test with *Tubifex tubifex* (Muller 1774) (Oligochaeta). Human and Ecological Risk Assessment: An International Journal 2009;15:27.

[131] Stoughton S, Liber K, Culp J, Cessna A. Acute and chronic toxicity of imidacloprid to the aquatic invertebrates *Chironomus tentans* and Hyalella azteca under constant- and pulse-

exposure conditions. Archives of Environmental Contamination and Toxicology 2008;54:662.

[132] Sawasdee B, Köhler H. Embryo toxicity of pesticides and heavy metals to the ramshorn snail, *Marisa cornuarietis* (Prosobranchia). Chemosphere 2009;75:1539.

[133] Smit, E. (2010). Comments by Els Smit, RIVM-NL, on the report "Aquatic Risks of Plant Protection Products: A Comparison of Different Hazard Assessment Strategies for Surface Waters in Switzerland" version 8 November 2010.

[134] Van Vlaardingen, P., T.P. Traas, and T. Aldenberg (2003). ETX-2000, Normal Distribution Based Hazardous Concentration and Potentially Affected Fraction. Rijksinstituut voor Volksgezondheid en Milieu: Bilthoven, The Netherlands.

Appendix 2

Results of the query concerning EQS derivations for PPP in selected EU countries

1. Query outline

The Ecotox Centre performed a query in order to compare and evaluate the methods used to assess the risk of PPPs in surface waters, taking into consideration the EU and the national guidelines of selected EU countries.

The following national authorities were interrogated:

Country	Authority
Austria (AT)	BAW - Federal Agency for Water Management, Institute for Water Quality
France (FR)	INERIS - French National Institute for Industrial Environment and Risks, Ecotoxicological Risk Assessment Unit
Germany (DE)	UBA – Federal Environment Agency, Substances Hazardous to Water – Ecotoxicological Laboratory
Italy (IT)	ISS - National Institute of Health, Department Environment and Health
The Netherlands (NL)	RIVM - National Institute for Public Health and the Environment, Expert Centre for Substances

2. Answers to the questions

2.1. Which guidance document(s) are currently used for EQS derivation of PPPs in your country?

Document	Country				
	AT	FR	DE	IT	NL
TGD for EQS [1]	(x) [1]	x	x		x
Lepper 2005 [2]	x	(x) [2]	x	x	x
TGD, 2003 [3]	x	(x) [2]	x	x	x
National internal guidance					x [3]
Other guidance document				(x) [4]	

[1] AT: Only one exercise of EQS derivation has been done; future assessments will consider the new TGD for EQS

[2] FR: Lepper manual and TGD 2003 are not deemed to be used anymore after publication of TGD for EQS

[3] NL: The Dutch guideline 2007 [4], based on the Lepper Method

[4] IT: COMMPS report. Study on the prioritisation of substances dangerous to the aquatic environment. EC 1999 (used in IT until 2006 as main document, currently mainly as a data source)

2.2. Which databases are used for EQS derivation?

Document	Country				
	AT	FR	DE	IT	NL
ECOTOX	x	x	x		x
EU DARs		x	x		x
FOOTPRINT		x			x
ETOX		x	x		
PAN Pesticides Database		x			x
OPP		x			x
INERIS Environmental database		x	x	x	
ESIS/IUCLID DS	x	x	x		x
ICS (UBA)		x	x		
eChemPortal		x			
Other	x	x	x	x	

Databases are used to obtain references; only references that can be evaluated are used. Endpoints that cannot be checked are included, but not used.

2.3. Is public literature used?

All countries use public literature as data source.

2.4. Are data from databases and public literature evaluated before use?

Country	Comment
AT	According to: Lepper 2002. Towards the Derivation of Quality Standards for Priority Substances in the Context of the Water Framework Directive. Final Report: Identification of quality standards for priority substances in the field of water policy
FR	Validation of data by INERIS experts, with reference to standardized guidelines (e.g. OECD guidelines), the use of TGD and use of “expert judgement”
DE	Only relevant data and available sources. Data previously evaluated by other organizations (i.e. US EPA, Office of Pesticides) are sometimes directly taken/accepted
IT	The quality of the source is evaluated. Data previously evaluated (i.e. EU reports) taken directly
NL	All retrieved and useful literature is quality assessed according to Klimisch criteria, see Dutch guidance on standard setting

All retrieved and useful literature is quality assessed according to Klimisch criteria.

2.5. Which EQS are derived?

EQS	Country				
	AT	FR	DE	IT	NL
AA-EQS: Annual Average concentration Environmental Quality Standard	x [1]	x	x	x	x
MAC-EQS: Maximum Allowable Concentration Environmental Quality Standard		x	(x) [2]	x	x
PNEC: Predicted No-Effect Concentration					
HC: Hazardous Concentration			x		x
EQS_{biota}: takes into account secondary poisoning via bioaccumulation and biomagnification		x	x		
Other: DE: $EQS_{drinking\ water}$, IT: $EQS_{Sediment}$			x	x	

[1] AT: On the EU level, the decision to include MAC-EQS in the legislative document was made after finalization of the national EQS exercise, therefore for specific pollutants no MAC-EQS were derived

[2] DE: MAC-EQS values have been derived until now, but for the future the trend is to derive AA-EQS only

PNEC is not a standard used in standard setting but a risk limit derived in risk assessment. There are some differences between standards and risk limits in interpretation, status and legislation.

HC5 is the basis for a PNEC or EQS, when enough data are available. Thus, if the data allow, the HC5 is derived together with the other options (AF method, mesocosm). Final choice depends on “expert judgement”

HC50 is used as basis for Serious Risk Concentration, an EQS which serves remediation purposes, especially for sediment and soil.

EQS_{biota} is proposed in Directive 2008/105/EC [5]

2.6. Which methods are used for EQS derivation?

Methods	Country				
	AT	FR	DE	IT	NL
AF Assessment Factor Method	x	x	x	x	x
SSD Species Sensitivity Distributions		x	x		x
Simulated Ecosystem Studies (Micro/Mesocosms)		x	(x) [1]		x
Other					

[1] DE: Results from micro / mesocosms studies were mostly used as supporting information only

2.7. Which endpoints are used for EQS derivation?

Agreed endpoints	Country				
	AT [1]	FR	DE	IT	NL
growth (weight, length, growth rate, biomass)	A	A, F	x	x	A, I, F
number (cells, population)		A	x	x	A, I
mortality	I, F	I, F	x	x	I, F
immobilization	I	I	x	x	I
reproduction	I, F	I, F		x	I, F
hatching (rate, time, percentage)		I, F	x	x	I, F
sex ratio			x	x	F
development (egg, embryo, life stage)		F	x	x	I, F
malformations (teratogenicity)		I	x	x	F
proliferation (cells)				x	A, Prot.
filtration rate		I		x	I
carbon uptake (algae)		A		x	A
reburial (of e.g. certain crustacean species)		I		x	I
Discussed endpoints					
histopathological endpoints			x		
behavioural responses (swimming behaviour, antenna motility, etc.)			x		

A: Algae; I: Invertebrate; F: Fish; Prot.: Protista

[1] AT: Only the most frequently used endpoints are mentioned

It should be noted that the group of 'invertebrates' consists of many different species groups. Insects, crustaceans, molluscs etc. are treated as different taxa. Thus, where “I” is marked above, this does not necessarily apply to all invertebrates. Further, it must be noted that other groups such as amphibians are also considered. Not all endpoints are common to all taxa, but might be relevant if a study describing these endpoints is retrieved. Relevance for population level is then considered on a case by case basis.

2.8. Is secondary poisoning taken into account in EQS derivation?

Country	Comment
AT	It strongly depends on the data availability
FR	Taken into account, if relevant according to the TGD for EQS
DE	EQS_{biota} if trigger BCF >100
IT	Protection of Human Health is considered
NL	Birds and mammals values are recalculated to water concentrations

2.9. In which step of EQS derivation do you see the greatest influence of "expert judgement"?

Methods	Country				
	AT	FR	DE	IT	NL
Data evaluation	x	x	x		x
Determination of AF		x		x	x
Metals issues		x			
Endocrine disruptors	x				

2.10. Are EQS further discussed after derivation?

Country	Comment
AT	Proposed EQS were discussed in Bund-Länder working groups
FR	An external group of 4 experts working in ERA area validate INERIS EQS proposals before they are proposed to the ministry in charge of the environment (MEEDDM)
DE	LAWA EK Stoffe (primarily monitoring aspects), but no scientific committee is established
IT	Discussion with National Scientific Institutes
NL	Draft reports are discussed with scientific committee with members from academia, government and other stakeholders (industry, NGO)

All countries: yes

2.11. How many PPPs have been evaluated for EQS derivation until now?

Country	Amount of PPPs
AT	10 (one exercise of EQS derivation, 2003/2005)
FR	25 pesticides for which EQS has been validated externally
DE	-
IT	20, plus the PPPs included in the list of EU Priority Substances (2008/105/EC)
NL	Over 30 PPPs recently (i.e. 2007 and later)

2.12. How many PPPs are currently being evaluated for EQS derivation?

Country	Amount of PPPs
AT	Decision depends on results from planned (2010/2011) monitoring study of PPPs in surface waters
FR	23 pesticides for which a $PNEC_{aqua}$ has been derived are to be studied for derivation of an EQS in 2010 but the list is not available yet
DE	Around 10
IT	-
NL	At the moment an evaluation of some organotins is made.

2.13. Derived EQS (AA-EQS)?

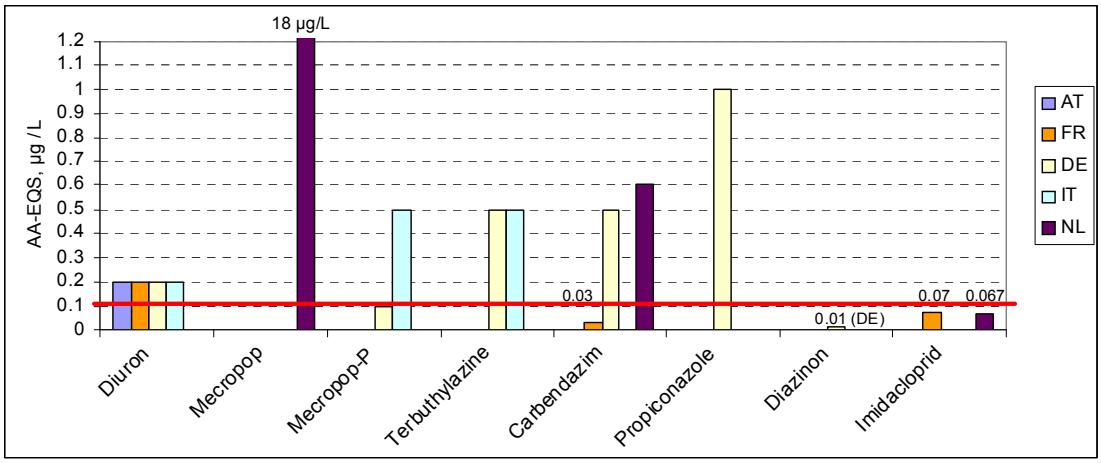


Figure A 2.1.: AA-EQS values for the selected PPP in the interviewed countries.
Used method was AF, except for the NL value for carbendazim which was based on mesocosm results-

FR: values for carbendazim and imidacloprid stand for $QS_{water, eco}$ (instead of AA-EQS)

The deviations from the general value of 0.1 µg/l indicate, that for a comprehensive ecotoxicological assessment of the water quality effect based EQS for PPP are needed.

3. Main conclusions from the query

Guidance documents: most of the countries used the new TGD for EQS [1], Lepper 2005 [2] and the TGD 2003 [3]

Endpoints: most of the countries use the agreed endpoints for EQS derivation

"Expert judgement" was indicated to be more relevant for data evaluation and determination of AF

Differences between derived EQS were observed between different countries, e.g. for Carbendazim

The general quality criterion of 0.1 µg/l currently adopted in Switzerland was not always safe / precautionary enough when compared to the AA-EQS values derived by the other countries

The query performed by the OZ has revealed that the different national authorities use different data sources for the derivation of EQS. The validation of all these data is crucial for a harmonised derivation of EQS. Therefore, all available data should be checked with the procedures as described in section 3.2.2.1.

Moreover, different endpoints are considered relevant by the respective national authorities to derive EQS (c.f. section 2.7). It can be assumed that the choice of endpoints will be harmonised, if the TGD for EQS [1] will be finalised.

4. References

[1] Commission of the European Communities (2010). Chemicals and the Water Framework Directive: Technical guidance for deriving environmental quality standards Draft 2010 (29/01/2010).

[2] Lepper P. Manual on the Methodological Framework to Derive Environmental Quality Standards for Priority Substances in accordance with Article 16 of the Water Framework Directive (2000/60/EC). Schmallenberg, Germany: Fraunhofer-Institute Molecular Biology and Applied Ecology, 2005.

[3] Commission of the European Communities. Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, 2003.

[4] van Vlaardingen PLA, Verbruggen EMJ. Guidance for the derivation of environmental risk limits within the framework of 'International and national environmental quality standards for substances in the Netherlands' (INS). In: 601782001/2007 Rr, editor. Bilthoven, the Netherlands: National Institute for Public Health and the Environment, 2007.

[5]. European Union (2008). Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council. OJ L 348, 24.12.2008.