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Discussion of Environmental Quality Standards (EQS) and their development for the monitoring of impacts from the use of pesticides and drugs at marine aquaculture sites

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Foreword

This series documents the scientific basis for the evaluation of aquatic resources and ecosystems in Canada. As such, it addresses the issues of the day in the time frames required and the documents it contains are not intended as definitive statements on the subjects addressed but rather as progress reports on ongoing investigations.

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ABSTRACT

Environmental Quality Standards (EQS) are numerical thresholds selected to protect ecosystems by limiting the release of a chemical to levels that will not result in irreparable harm or toxicity to sensitive aquatic species. They are an integral part of the design of an effective monitoring program and can have time (dispersion in water for bath pesticides) and spatial notions (allowable zone of deposition for in-feed drugs) embedded in their application process. EQS values exist for water and/or sediment compartments based on the targeted compounds n- Octanol/Water Partition Coefficient (K_{oW}). Water EQS can be divided into two main types: one related to maximum acute chemical (MAC-EQS) exposure and one to chronic exposure (AA-EQS). For sediment EQS there is no short-term versus long-term EQS considering the exposure route (i.e., organisms would be constantly exposed while living in the sediment).

In this document, we tested a process for EQS value inference for a few in-feed drugs (emamectin benzoate (EMB), ivermectin, teflubenzuron and lufenuron) and pesticides (azamethiphos and hydrogen peroxide) used in Canadian finfish aquaculture operations by relying on relevant and accessible toxicological data. These EQS values are proposed to illustrate the method used for threshold determination and are related to active ingredients. The selection of the final thresholds will have to be guided by the determination of clear management goals to be defined by policy makers. The following points summarize the main approach and recommendations of this working paper:

- There are two different approaches for EQS setting based on the quality and quantity of available toxicity data: the species sensitivity distributions (SSD) applied when a minimum of ten similar ecotoxicity end-points on a minimum of eight taxonomic groups are available, and the deterministic approach applied in situations where these data requirements are not met (European technical guidance document (CCME, 2007; TGD, 2018).
- The toxicity data of the in-feed drugs (EMB, ivermectin, teflubenzuron and lufenuron) do not meet the requirements for the completion of SSD (other than lufenuron as per previously completed SSD). Therefore, only a deterministic approach can be used to derive EQS as per the accessible data. This approach was also used for azamethiphos and hydrogen peroxide. However, a recommendation to test the feasibility of a SSD in the future is made for deriving MAC-EQS values with special considerations for dispersion timelines. This step will also have to be guided by inter-departmental regulatory considerations for pesticide usage.
- Quality assessment of available toxicity studies, both critical and supporting data as determined by regulatory bodies and/or international expert groups, was compiled. In addition, quality assessment of recent studies was completed using the published Criteria for Reporting and Evaluating ecotoxicity (CRED) and supporting guidance (Moermond et al., 2015; TGD, 2018) but will require additional considerations by groups of experts.
- Adjustments to assessment factors were guided by information on specific mode of action for chemicals such as azamethiphos, ivermectin, teflubenzuron, and lufenuron and whether data on identified sensitive target organisms were available. In addition, the selection of time-relevant toxicological data was also applied in the case of EQS values suggested for azamethiphos based on previous work on dispersion patterns.
- The EQS values presented in this document illustrate the process employed for their derivation and provide an overview of the toxicity data readily available. Enhanced access to confidential data provided to regulators for marketing authorisation will have to be facilitated to ensure the appropriate derivation of environmental standards. Ultimately, defining clear

management goals by policy makers and additional expert discussions will guide the selection of the final EQS thresholds and their regulatory usage.

INTRODUCTION, ROLES AND RESPONSIBILITIES, AND GENERAL DEFINITIONS

Fisheries and Oceans Canada (DFO) is in the process of developing new regulations that will be used to manage environmental impacts, including those on non-target organisms, from drugs and pesticides used in aquaculture, as committed to in the 2015 Aquaculture Activities Regulations (AAR) Regulatory Impact Analysis Statement (Canada Gazette, 2014). These regulations will only apply to drugs authorized for sale under the *Food and Drugs Act* and pesticides registered under the *Pest Control Products Act*. In the Canadian context, the term pesticide applies to a pest control product applied as a topical treatment or in-bath treatment (e.g., fully enclosed tarpaulin and well-boat). The term drug applies to in-feed antimicrobial products, such as oxytetracycline, used to control pathogens such as *Renibacterium salmoninarum*, and anti-parasitic products, for instance SLICE® (active ingredient[1] emamectin benzoate) or IMVIXA® (active ingredient lufenuron), used to control sea lice infestations. As with the existing Aquaculture Activities Regulations (AAR) regime, the regulatory framework for assessing pesticide and drug deposits will be applied on a site-by-site basis (not a bay or a group of farms) and will be dependent on the active ingredient[1]. The environmental impacts of drugs and pesticides used in aquaculture are currently managed by Environment and Climate Change Canada (ECCC) under the *Canadian Environmental Protection Act* (CEPA) and by DFO under s.36 of the *Fisheries Act*. The expectation by DFO and ECCC is that DFO will assume the lead role in enforcing compliance with s.36 of the *Fisheries Act* once the revised AAR come into effect.

This research document along with several others were presented during a formal peer review science advisory meeting (Canadian Science Advisory Secretariat) to develop advice that will be used to inform the design and operation of a monitoring program for drugs and pesticides used in aquaculture. The program will include pre-impact evaluation (predictive modelling) for deposit authorization and post-deposit sampling design and mitigation assessment for management effectiveness. Environmental Quality Standards (EQS) are regulatory thresholds, to support the proposed AAR post deposit pesticide and drug monitoring framework. The present document provides background, describes processes behind the development of EQS, and calculates EQS values to illustrate the procedures that could be used to generate thresholds. This paper is limited to the following compounds currently in use in Canada: the bath pesticides Salmosan® (azamethiphos) and Interox Paramove 50® (hydrogen peroxide), and in-feed drugs: SLICE® (emamectin benzoate), ivermectin, Calicide® (teflubenzuron), and IMVIXA® (lufenuron). For antibiotics and in contrast to the toxicological impact approach that has been suggested for other aquaculture drugs and pesticides in the regulation, the regulator has proposed to assess the impact from antimicrobial deposits by examining long-term impacts from chronic use of antimicrobials, specifically in the development of antimicrobial resistance in the environment. Where applicable, future considerations linked to the direct toxicity of antibiotics may need further examination.

[1] Active ingredient (a.i.) is defined as the component of drug or a pest control product to which the intended effects of the product are attributed and includes a synergist but does not include a solvent, diluent, emulsifier or other component that is not primarily responsible for those effects. The active ingredient typically comprises a small percent of the total weight of a product compared to the inactive ingredients (i.e., stabilizers, bulking agents and therapeutic enhancers), but not always. For example, hydrogen peroxide, the a.i. in the anti-parasitic product INTEROX® PARAMOVE® 50, is 50% by weight of total product.

HEALTH CANADA MANDATES WITHIN THE CONTEXT OF DRUGS AND PESTICIDES USAGE IN AQUACULTURE

Within the context of drugs used in aquaculture, DFO's authority lies under section 36 of the *Fisheries Act* with a focus on the deposit of deleterious substances and prevention of harm to the fish and fish habitat. Health Canada's Veterinary Drugs Directorate (VDD), as further detailed below, regulates the sale of drugs through their authorization/registration and evaluates the quality, safety, efficacy, and human food safety aspects of drugs, through the *Food and Drugs Act*. Health Canada's Pest Management Regulatory Agency (PMRA) regulates the registration and use of pest control products under the *Pest Control Product's Act*. Topical bath treatments (e.g., fully enclosed tarpaulin and well-boat) used in aquaculture are considered pesticides in Canada and must be registered with the PMRA prior to use.

Although not addressed directly under s.36 of the *Fisheries Act*, the use of in-feed anti-parasitic drugs in aquaculture may also have an impact on human health, either directly through food safety and drinking water or indirectly through drug release to the environment. Health Canada's VDD assesses the direct impact of veterinary drugs from multiple perspectives, including human safety, animal safety and human food safety. To evaluate an anti-parasitic veterinary drug with respect to human and food safety, human toxicological threshold values are calculated to ensure that any drug residue levels in food of animal origin pose no adverse health effects to humans who consume the product. These values are calculated based on extrapolations from laboratory animal toxicity studies in order to estimate potential risks to human safety. Firstly, the No Observed (Adverse) Effect Level (NOEL/NOAEL) values are determined by evaluating a range of laboratory animal toxicity studies. The lowest NOEL/NOAEL is then divided by an appropriate uncertainty factor (100 – 1000) to generate the acceptable daily intake (ADI) value for the veterinary drug (JECFA, 2006). This value represents the amount of drug that has been determined to be safe to consume, daily over a person's lifetime. The VDD establishes ADI values for drugs approved under the *Food and Drugs* Act for use in animals consumed as food. The ADI is the basis for establishing both the maximum residue limits (MRLs) and the pre-slaughter/pre-harvest withdrawal periods (JECFA, 2006). For aquaculture anti-parasitic drugs, the MRL value and withdrawal period stipulate the maximum amount of the drug residue permitted in edible fish tissues (muscle and skin) as well as the time necessary for residue levels to deplete to safe consumption levels following drug administration.

The Healthy Environments and Consumer Safety Branch of Health Canada conducts assessments of the potential environmental risk associated with environmental exposure to new substances in Food and Drugs Act (F&DA) products including veterinary drugs used in aquaculture. These environmental assessments are undertaken in accordance with the New Substances Notification Regulations (NSNR) under the Canadian Environmental Protection Act. Quantitative environmental assessments are conducted according to general risk assessment paradigms. A predicted no effect concentration (PNEC) is established using animal and non-animal data. Environmental concentrations are estimated using physical chemical data and exposure modelling. When available, monitoring data are used to refine or replace estimates. Predicted environmental concentrations are compared to the PNEC and the resulting quotient is considered to be an indication of risk. Risk quotients that exceed 1 are considered to be an indication of unacceptable risk.

The PMRA is the branch of Health Canada responsible for regulating pesticides under the authority of the *Pest Control Products Act*. In order for pesticides to be used in aquaculture, they must be registered under the *Pest Control Products Act*. The PMRA applies evidence-based scientific approaches to assess whether the health and environmental risks of pesticides proposed for registration are acceptable, and if the products have value. This same approach is used to regularly and systematically review whether pesticides already on the Canadian market

continue to meet modern scientific standards. The PMRA seeks to minimize health and environmental risks by facilitating access to new, lower-risk products in support of sustainable pest management practices. In collaboration with the Regulatory Operations and Regions Branch, the PMRA also promotes, monitors and enforces compliance with the *Pest Control Products Act* across Canada. The PMRA is committed to doing this in a collaborative, open and transparent manner (PMRA strategic plan 2016-2021).

The purpose of PMRA conducting an assessment of risks to human health is to define the nature of the risk (hazard) and to provide a measure of the likelihood and the magnitude of the risk associated with a defined exposure. The PMRA assessment follows a four-step process: (1) hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization. The main source of information for identifying hazards (toxic endpoints or adverse health effects) and for determining the relationship between dose and response are primarily animal toxicity studies; however, the Agency also considers data from alternative approaches to animal testing, such as in vitro studies.

The PMRA's environmental risk assessment process combines the results of the environmental toxicology (hazard) and environmental fate (exposure) assessments. The environmental fate data along with information on the application of the product are used to determine an estimated environmental concentration (EEC) in water and sediment. Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate (EECs) by an appropriate toxicity value (RQ = exposure/toxicity), which is then compared to the level of concern. Different toxicity endpoints may be considered as well as more realistic exposure scenarios which may include refinement to exposure modelling, monitoring data, and results from aquatic field studies such as an oceanic dye dispersion. Detailed information on the PMRA's completed and published human health and environmental risk assessments for hydrogen peroxide and azamethiphos, which are currently fully registered in Canada for aquaculture use, can be found in PRD2014-11 (PMRA, 2014) and PRD2016-25 (PMRA, 2016a), respectively.

EQS DETERMINATION AS PART OF THE DEVELOPMENT OF THE DFO'S REGULATORY FRAMEWORK

In a comparative study of environmental management programs for marine finfish aquaculture in Canada and other jurisdictions, Day et al. (2015) stated the following in relation to environmental management and monitoring programs:

"An effective monitoring program should have a set of acceptable limits that are specific to the managed activity (i.e., something that the aquaculture industry has control over yet closely linked with environmental sustainability) and should address stakeholder needs so as to be meaningful in a broader ecosystem context. These acceptable limits should be clearly identified and include, but not be limited to, setting specific Environmental Goals (EGs). An effective monitoring program should also have Environmental Quality Standards (EQS) and Environmental Quality Objectives (EQO) or Acceptable Zones of Effects (AZE), as well as Carrying Capacities (CC)".

Environmental Quality Standards (EQS) are intended to guide how the impact of chemical substances is managed in order to protect the structure and function of the aquatic ecosystems. These numerical thresholds are also used to prioritise management actions within remediation programs, and to identify the potential ecological impacts from chemical impacts prior to

authorizing a discharge (Ingersoll et al., 1996; Zabel and Cole, 1999). The purpose of environmental quality standards is to protect ecosystems by limiting the release of a particular chemical to levels that will not result in irreparable harm or toxicity to sensitive aquatic species. Ideally, EQSs encompass toxicity and impact data from multiple sources to avoid using only single toxicity endpoints that do not necessary address 'real-life' scenarios. Similarly, within the Canadian context, the Canadian Water Quality Guidelines for the Protection of Aquatic Life (CWQGs-PAL) are meant to protect all forms of aquatic life and all aspects of the aquatic life cycles, including the most sensitive life stage of the most sensitive species over the long term, from the negative effects of anthropogenically altered environmental parameters or exposures to substances via the water column (CCME, 2007). Predicted no effect concentrations (PNECs) derived as part of a risk assessment provide a key step in the derivation of an EQS and in most cases form the basis of most EQS values (Matthiessen et al., 2010; TGD, 2018). Procedures used for quality standard setting are very similar, including the application of assessment (i.e., assessment or uncertainty) factors (AFs) depending on the quality and quantity of available toxicity data. PNECs are often identical in value to EQS. In the terminology used in this document, we will not refer to PNECs but directly to EQS. The EQS values to be derived can be used as environmental thresholds in predictive modelling assessment (pre-impact assessment) and as compliance thresholds following post-deposit monitoring.

Many options/formulae are available to permit regulators to be as conservative as needed in EQS development. Regulators responsible for implementing an environmental impact standard can use EQS in a statutory or absolute context. The purpose of scientists in informing the development of an EQS is to advise regulators on the nature and importance of impacts, unresolved uncertainties, including steps that could be taken to address (e.g., conducting further ecotoxicity tests) or accommodate for them (i.e., through the application of precaution). Therefore, it is important to state that the values listed in this document are provided only to illustrate processes to derive EQS values and that ultimately the official adoption of thresholds will have to encompass more in-depth discussions with experts and regulators. A clear definition of management goals will also have to guide the threshold selection.

Within the Canadian context, the establishment of EQS should be consistent with DFO's overarching Framework for Aquaculture Risk Management (FARM). In accordance with the FARM steps, the development and implementation of EQS include:

- the identification of the chemical hazard;
- "hazard" assessment of toxicological impact (peer-reviewed, including recommendations of safety factors, precautionary measures, to address data quality and quantity);
- translation into a regulatory threshold (decision-making step considering the science, potential economic consequences, best-available technologies, etc.);
- use within a feedback monitoring program to assess efficacy of existing management actions; and
- communication of the final decision.

A good example of an approach with established EQS on drugs and pesticides used in aquaculture is the Scottish Environmental Protection Agency (SEPA) regulatory framework. Predicted or measured environmental concentrations of medicines are compared with the relevant EQS, over an Allowable Zone of Effects (AZE), to drive the consent setting process (authorization of use) for each medicine currently available. AZE is defined as "the area (or volume) of sea bed or receiving water in which SEPA will allow some exceedance of a relevant Environmental Quality Standard (EQS)" (SEPA, 2005 Annex H). For in-feed drugs, SEPA regulates fish farms by reference to two standards: a near-field standard (applies from the edge

of the cage up to 100 m) and a far-field standard (applies at and beyond 100 m from cage edge). Although not bound to the strict spatial values (to be ultimately determined by regulators with appropriate science input) when we refer to near-field and far-field throughout this document we are referring to similar notions as SEPA. These spatial notions as well as whether the AF is well justified are debated within the UKTAG for EMB (2020); the relevance of trigger values and the size of AZE will have to be further considered by regulators.

The use of EQS, within a tiered monitoring program, represents a cost-effective risk-based approach, whereby the exceedance of the EQS (based on reasonable cost chemical sampling) signals potential biological impacts (that would need to further validated or “ground-truth” through direct biological monitoring). The biological indicators are ultimately the “early warning” signs of potential higher–level harm at the population level. Management actions (e.g., stopping or changing conditions of pesticide or drug use) can be based on the exceedance of established EQS thresholds, the extent of early warning biological effects, in line with the precautionary approach. This highlights the fact that the application of EQS cannot be an end all process.

Assessing compliance between the chemical residue data measured in environmental matrices at a given site and corresponding EQSs is not a simple task (Amiard and Amiard-Triquet, 2015b). These procedures are described in the International Organization for Standardization guidance on the use of sampling data for decision making, based on the compliance with thresholds and classification systems (ISO, 2008). Linking the design of EQS to appropriate sampling strategies and chemical extraction techniques is fundamental for application within a regulatory framework including a clear communication on uncertainties related to bioavailability, toxicity profiles, and/or technical limitations. These aspects are also detailed in documents part of this CSAS process (Page et al., 2023; Wong et al., 2022).

As stated above, the EQS values are derived for active ingredients. In the EFSA (2015) guidance document on risk assessments for agricultural products for aquatic organisms in freshwater, it is stated that testing of formulated products shall be performed when the toxicity of the preparation cannot be predicted on the basis of data on the active substance and co-formulants might result in latency of effects and/or added effects. These points have not been clearly demonstrated for the compounds listed in this document, therefore, uncertainty remains regarding environmental effects of formulations.

We have based our approach, as further detailed below, on the European guidelines (TGD, 2018) considering their relevance to data poor situations and the existence of comparable EQS values within European legislations directly applicable to the products in consideration within this document. The Canadian water quality guidelines were considered (CCME, 1995; 2007) with some steps in the derivation protocols quite similar to the suggested approach in particular regarding data considerations. We have used in some cases similar data sets as European experts and have updated tables with more recent toxicity endpoints when applicable. A weight of evidence approach was used when suggesting assessment factors in the case of specific mode of actions and/or supporting information from similar compounds. The usage of this information and how factors are lowered is detailed in the sections related to each compound.

DERIVING EQS FOR THE AQUATIC ENVIRONMENT

Within the marine environment, EQS may be derived to encompass all three environmental compartments (i.e., water, sediment, biota). However, EQS are typically applied against chemical concentrations in specific environmental media, i.e., water, sediments, or biota (Table 1 in Lepper (2005)). An EQS for sediment may not be necessary if there is no indication that the substance partitions in the sediment. Similarly, EQS addressing the concentration of a substance in biota may not be required if the physical and chemical properties of the substance

along with other information suggest that the substance is unlikely to remain in the tissues of organisms. It is also possible that an EQS may not be relevant for any matrix- neither water, sediment nor biota if – based on the current scientific knowledge - there is no indication that a given substance is either present or poses a risk to a particular compartment (Lepper, 2005). Substances that are highly hydrophilic with a short half-life are not conducive to environmental monitoring (whether in water or sediment). Therefore a triage process is necessary. To avoid extensive testing of chemicals a log K_{oW} of ≥3 can be used as a trigger value for sediment effects assessment (TGD, 2003; Amiard and Amiard-Triquet, 2015b). The Canadian Environmental Protection Act (CEPA) recognizes log K_{oW} >= 5 as indicative of potential to persist and/or bioaccumulate (Beek et al., 2000); in addition, information on half-lives need to be considered.

To assess the potential for a chemical substance to be taken up by aquatic biota, direct measurements, models or standardized accumulation factors may be used: Bioaccumulation factor (BAF), Bioconcentration factor (BCF), and K_{oW}. Bioconcentration is the process by which a chemical substance is absorbed by an organism from the ambient environment only through its respiratory and dermal surfaces, i.e., chemical exposure in the diet is not included. Bioaccumulation is a process in which a chemical substance is absorbed in an organism by all routes of exposure as occurs in the natural environment, i.e., dietary and ambient environment sources (Arnot and Gobas, 2006). However, there is a lot of uncertainty in values reported in the literature, mainly due to differing statistical analyses and discrepancies of employed methodologies. A data quality assessment found that 45% of BCF values are subject to at least one major source of uncertainty and that measurement errors generally result in an underestimation of actual BCF values (Arnot and Gobas, 2006). A case study of organic chemicals on the Canadian Domestic Substances List indicated that empirical data were available for less than 4% of the chemicals that required evaluation and of these chemicals, 76% had less than three acceptable quality BCF or BAF values (Arnot and Gobas, 2006).

For the purpose of this document, only factors as used by Canadian regulatory agencies responsible for the screening and assessment of toxic substances will be considered. The following values are used by Environment Climate Change Canada's Toxic Substances Management Policy in defining substances that are persistent, bioaccumulative, toxic, and primarily the result of human activity (i.e., Track 1) (which are close to those used by the US Environmental Protection Administration, United Nations Environment Programme and the European Union). Therefore, EQS for biota should only be considered for substances that exceed the following partition factors:

Table 1. Partition factors used by the Canadian Environmental Protection Act (CEPA) to define substances that are persistent, bio-accumulative, toxic, and primarily the result of human activity (CEPA, 1999).

Bioaccumulation metric	Value (log)-CEPA, 1999
K_{oW}	≥100000 (5)
BCF	≥ 5000 (3.7)
BAF	≥ 5000 (3.7)

Table 2. Environmental protection objectives and triggers to derive environmental standards (reproduced from Lepper, 2005 with modifications to reflect the approach chosen).

Water (protection of the pelagic community)	**Sediments** (suspended particulate matter) (protection of the benthic community)	**Substance concentration in biota** (prey; protection of predators against secondary poisoning)
No trigger value applies. EQS are derived for **all** priority substances. For hydrophobic/adsorbing substances the EQS referring to the concentration in water are additionally reported as concentration in suspended particulate matter (SPM) when applicable.	EQS are derived for all substances with a log K_{oW} ≥ 3 The $EQS_{sediment}$ refers to suspended particulate matter when applicable and sediment.	EQS are derived for biota if: K_{oW} ≥100000 (5) BCF ≥ 5000 (3.7) BAF ≥ 5000 (3.7)

We can note also a paucity of data for most of the other compounds considered in this document. In addition, BCF values determined in laboratory conditions might not have the required environmental relevance. BAF and BCF determinations have to include considerations regarding uptake and depuration of chemotherapeutants in particular for filter feeders (Brooks et al., 2019) in addition to persistence in non-target organisms. For example for plant protection products (PPPs) European experts have concluded that currently, the risks of biomagnification and secondary poisoning of sediment-bound PPPs are not adequately addressed in the current risk assessment scheme. The panel on plant protection products recommended that for sediment organisms further development is required of such a risk assessment scheme based on existing contaminant food web transfer experiments and models (EFSA, 2015).

Some of the values available so far for the compounds considered in this manuscript are below the thresholds cited above to the exception of the BCF values for lufenuron for fish that raise concern. In fact, lufenuron potentially exceeds the K_{oW}, BCF, and BAF trigger values for considering biota within the EQS determination. The biota EQS will not be covered as part of this report but should be part of next considerations by scientists and regulators. Similarly, it is important to note that the EQS determination will have to be updated with new scientific knowledge, the need for more regulatory overlook and/or any revised information on bio-concentration and/or accumulation pathways. Justification for focusing on one compartment only or including both (water and sediment) will have to be re-considered for every compound in the light of any new available information.

DIFFERENT TYPES OF EQS BASED ON REGULATORY SIGNIFICANCE

In addition to be compartment specific (i.e., water versus sediment), EQS can be divided into two main types for water exposures: one related to acute chemical exposure and one to chronic exposure. The annual arithmetic mean concentration (AA-EQS) deals with protection against chronic effects and the maximum acceptable concentration EQS (MAC-EQS) deals with

protection against acute toxic effects. Notions of acute versus chronic are further discussed in some of the sections on data considerations and AFs.

The MAC-EQS is a concentration not to be exceeded any time. In conjunction, the AA-EQS and the MAC-EQS are intended to protect the structure and function of an aquatic ecosystem from the impact of chemical substances. For the derivation of the long-term "annual average" environmental quality standards (AA-EQS) chronic data (e.g., NOECs) are used in conjunction with acute toxicity data ($L(E)C_{50}$). In contrast, only acute toxicity data are required to derive the maximum acceptable concentration quality standard (MAC-EQS) (Lepper, 2005). Because sediment and biota are integrative matrices, representative of exposure over long periods, it is not appropriate nor environmentally relevant to derive MAC-EQSs for these compartments (Amiard and Amiard-Triquet, 2015a; TGD, 2018). In Scotland, for example, when regulating repeat short-duration discharges, the AA-EQS may be applied to provide protection from long-term intermittent (or pulsed) exposure.

PELAGIC AA-EQS

For this derivation combined marine and freshwater species toxicity data sets (with one toxicity value per species) may be used when the provisions for pooling data are met. As recommended in the Guidance Document No. 27 (TGD, 2018) detailing EQS determination under the European legislation, the two datasets have to be compared using statistical tests prior to data collation. If the two sets of data are not similar they cannot be pooled as further detailed in the document. Overall, the assessment factors for marine risk assessment are often resulting in quality standards more stringent than the standards derived for the freshwater environment. This is often justified by the requirement to account for additional uncertainty due to peculiarities of the marine ecosystem such as, e.g., greater species diversity or limited data availability for marine species and use of freshwater toxicity data as a surrogate (Lepper, 2015).

Table 3. Assessment factors to be applied to aquatic toxicity data for deriving environmental quality standards for pelagic communities (TGD, 2018).

Data set	**Assessment factor**
Lowest short-term $L(E)C_{50}$ from freshwater or saltwater representatives of three taxonomic groups (algae, crustaceans, and fish) of three trophic levels.	10,000
Lowest short-term $L(E)C_{50}$ from freshwater or saltwater representatives of three taxonomic groups (algae, crustaceans, and fish) of three trophic levels, plus two additional marine taxonomic groups (e.g., echinoderms, molluscs).	1000
One long-term result (e.g., EC_{10} or NOEC) (from freshwater or saltwater crustacean reproduction or fish growth studies).	1000
Two long term results (e.g., EC_{10} or NOEC) from freshwater or saltwater species	500

Data set	Assessment factor
representing two trophic levels (algae and/or crustaceans and/or fish).	
Lowest long-term results (e.g., EC_{10} or NOEC) from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish) representing three trophic levels.	100
Two long term results (e.g., EC_{10} or NOEC) from freshwater or saltwater species representing two trophic levels (algae and/or crustaceans and/or fish) plus one long-term result from an additional taxonomic group (e.g., echinoderms, molluscs).	50
Lowest long-term results (e.g., EC_{10} or NOEC) from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish) representing three trophic levels + two long-term results from additional marine taxonomic groups (e.g., echinoderms, molluscs).	10

Not all the footnotes related to the tables copied in this document have been copied as per the TGD (2018) document. The applicability of assessment factors was discussed for individual chemicals.

The TGD (2018) guidelines refer to a set of data with adequate representation of trophic levels (as per Table 3 above). For the CCME (Canadian Councils of Ministers of the Environment) guidelines (2007), similar groups are targeted with a set number of species for each category (fish, aquatic invertebrates, aquatic plants, and amphibians). The number of species determine whether guidelines of type A, type B1 or type B2 apply to a particular data set. Type A guidelines are derived using a species sensitivity distribution (SSD) approach when there are adequate primary and secondary toxicity data to satisfactorily fit a SSD curve. Type B guidelines are derived for substances that either have inadequate or insufficient toxicity data for the SSD approach, but for which enough toxicity data from a minimum number of primary and/or secondary studies are available (CCME, 2007). The different derivation approaches are further discussed in the EQS calculations section.

Acute toxicity data are not recommended for deriving long-term standards. However, because chronic toxicity data are largely missing for many substances, the calculation of AA-EQS may be based on data of acute toxicity tests by using assessment factors (AF); the AF values will depend on the number and quality of the toxicological data (SCHER, 2010; Amiard and Amiard-Triquet, 2015b). Some flexibility exists in varying the assessment factor; this includes one or more of the following (TGD, 2018):

- evidence from structurally similar compounds which may demonstrate that a higher or lower factor may be appropriate;
- knowledge of the mode of action as some substances by virtue of their structure may be known to act in a non-specific manner. A lower factor may therefore be considered. Equally

a known specific mode of action may lead to a higher factor if data on the most sensitive species/group are not available; and

- the assessment factors may be lowered if multiple data points are available for the most sensitive taxonomic group (i.e., the group showing acute toxicity more than 10 times lower than for the other groups).

For the Canadian water quality guidelines, preference is given to EC_x/LC_x low-effect threshold when available for deriving long-term exposure guidelines (CCME, 2007). As a side note, the usage of EC_{10} versus NOECs as endpoints has been debated by authors. Iwasaki et al. (2015) evaluated if the choice of NOEC or a 10% effect concentration (EC_{10}) affected the hazardous concentrations for five chemicals (HC5s) estimated from species sensitivity distributions (SSDs). Both EC_{10}-based and NOEC-based HC5s estimated for five substances were of the same order of magnitude, and their 95% confidence intervals overlapped considerably (Iwasaki et al., 2015). The choice of EC_x (e.g., EC_5, EC_{10}, or EC_{20}) or NOEC does not largely affect the resulting HC_5s (Iwasaki et al., 2015).

PELAGIC MAC-EQS

In the CCME guidelines (2007) MAC-EQS are referred to as short-term exposure guidelines; these guidelines identify benchmarks (i.e., maximum concentrations of substances or ranges for attributes) in the aquatic ecosystem that protect only a specified fraction of individuals from severe effects such as lethality for a defined short-term exposure period. Therefore, by design and by definition, these guidelines do not fulfill the guiding principle of protecting all components of the aquatic ecosystem all the time (CCME, 2007).

In principle, to derive a MAC-EQS for saltwater, the same approach as described for the EQS for pelagic communities can be applied. However, instead of using long-term NOECs, acute $L(E)C_{50}$ data will serve as input data. Combined acute toxicity data sets for marine and freshwater species may be used, if analyses show that the data can be pooled (TGD, 2018). Typically, field monitoring data are unlikely to have a useful part to play in informing the estimation of a MAC-EQS because they generally describe changes in biology arising from long-term exposure, so they are more relevant to chronic threshold derivation.

For exposures of short duration, acute toxicity data are relevant and the assessment factors to use are given in Table 4. Where there are at least three short term tests using species from three trophic levels (base set), an AF of 100 applied to the lowest $L(E)C_{50}$ is normally used to derive the MAC-EQS. Under some circumstances an AF less than 100 may be justified:

- 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 $L(E)C_{50}$ values is < 0.5) an AF<100 may be appropriate.
- For substances with a specific mode of action, the most sensitive taxa can be used with confidence. Where representatives of the most sensitive taxa are present in the acute dataset, an AF <100 may again be justified (TGD, 2018). Expert judgement and justification of the decision regarding the assessment factor chosen is therefore required (Lepper, 2005).

Table 4. Assessment factors to derive a maximum acceptable concentration quality standard for seawater (TGD, 2018).

Toxicity data	**Additional information**	**Assessment factor**
Base set not complete	-	-
At least one short-term $L(E)C_{50}$ from each of three trophic levels of the base set (fish, crustaceans, and algae)	-	1000
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 OR known model of toxic action and representative species for most sensitive taxonomic group included in data set	100
At least one short-term $L(E)C_{50}$ from each of three trophic levels of the base set (fish, crustaceans, and algae) + one short-term $L(E)C_{50}$ from an additional specific saltwater taxonomic group	-	500
At least one short-term $L(E)C_{50}$ from each of three trophic levels of the base set (fish, crustaceans, and algae) + one short-term $L(E)C_{50}$ from an additional specific saltwater taxonomic group	Acute toxicity data for different species do not have a higher standard deviation than a factor of 3 in both directions OR known model of toxic action and representative species for most sensitive taxonomic group included in data set	50
At least one short-term $L(E)C_{50}$ from each of three trophic levels of the base set (fish, crustaceans, and algae) + two or more short-term $L(E)C_{50}$s from additional specific saltwater taxonomic groups	-	100
At least one short-term $L(E)C_{50}$ from each of three	Acute toxicity data for different species do not have	10

Toxicity data	Additional information	Assessment factor
trophic levels of the base set (fish, crustaceans, and algae) + two or more short-term L(E)C_{50}s from additional specific saltwater taxonomic groups	a higher standard deviation than a factor of 3 in both directions OR known model of toxic action and representative species for most sensitive taxonomic group included in data set	

Not all the footnotes related to the tables copied in this document have been copied as per the TGD (2018) document. The applicability of assessment factors was discussed for individual chemicals.

BENTHIC EQS

Test results of organisms living in water may be used to derive EQS for sediment, as long as no tests for sediment dwelling organisms are available. Sediment-dwelling, or benthic organisms, are defined here as organisms that, during an important part of their life cycle, have their habitat on (epibenthos) or in the sediment (endobenthos) (EFSA, 2015). Legally binding sediment EQS should, however, preferably be based on results of toxicity tests with sediment organisms (Lepper, 2005). Ideally, results of long-term toxicity tests with sediment organisms are preferred for deriving sediment standards due to the generally long-term exposure of benthic organisms to sediment bound substances (TGD, 2018). If only results from short-term tests with sediment-dwelling organisms are available, appropriate assessment factors are applied to the lowest reliable value (EFSA, 2015; TGD, 2018).

Most sediment laboratory toxicity data are based on the use of spiked sediments in which clean sediment has been deliberately contaminated in the laboratory and test organisms introduced to this spiked sediment (TGD, 2018). Guidance specific to sediment toxicity tests including classical tests need to be used to judge on reliability and relevance. It should be kept in mind that laboratory experiments are likely to result in high levels of chemical availability because spiked sediments are rarely aged. This is in contrast with field or mesocosm data where chemical exposures are more likely to be closer to equilibrium. For these reasons, a bias in laboratory data toward higher toxicity (and more stringent standards) would be expected (TGD, 2018). In addition, there is no information on the effect of ageing for most of the drugs described in this paper; this is a significant knowledge gap in anticipating toxicity by using single mesocosm studies to derive EQS.

Sediment EQS have an associated spatial component; within the Scottish framework, “near-field” or “pen-edge” sediment EQS are often regulatory trigger values, which are intended to ensure sediment function is maintained and that the regulatory EQS is met at the edge of the allowable deposition zone, these are derived from the regulatory EQS. Sediment quality guidelines are numerical concentrations set with the intention to protect all forms of aquatic life and all aspects of their aquatic life cycles during an indefinite period of exposure to substances associated with bed sediments (CCME, 1995). Therefore, there is no short-term versus long-term EQS for sediment similarly to what is derived for water compartments.

Table 5. Assessment factors for derivations of the environmental quality standard for sediment (seawater) based on the lowest toxicity endpoints from long-term tests (spiked sediment tests) (TGD, 2018).

Available test results	**Assessment factor**
One acute freshwater or marine test ($L(E)C_{50}$)	10000
Two acute tests including a minimum of one marine test with an organism of a sensitive taxa (lowest $L(E)C_{50}$)	1000
One long-term freshwater sediment test	1000
Two long-term freshwater sediment tests with species representing different living and feeding conditions	500
One long-term freshwater and one saltwater sediment test representing different living and feeding conditions	100
Three long-term sediment tests with species representing different living and feeding conditions	50
Three long-term sediment tests with species representing different living and feeding conditions including a minimum of two tests with marine species	10

Not all the footnotes related to the tables copied in this document have been copied as per the TGD (2018) document. The applicability of assessment factors is discussed for individual chemicals.

As other combinations of data could occur (Van Vlaardingen and Verbruggen, 2007), the following additional guidance is offered:

- If two long-term tests with marine species representing different living and feeding conditions are available, but there are no freshwater tests, an assessment factor of 100 is applied.
- An assessment factor of 1000 might only be applied to a short-term toxicity test if the lowest value available is for a marine species.
- an assessment factor of 500 is applied if only one long-term marine but no freshwater test is available.

As per Canadian guidelines, the formal CCME protocol established for the derivation of numerical sediment quality guidelines (SQG) is applicable to the protection of both freshwater and marine (including estuarine) aquatic life associated with bed sediments (CCME, 1995). In deriving SQGs for the protection of aquatic life, all components of the aquatic ecosystem (e.g., bacteria, algae, macrophytes, invertebrates, fish) are considered, if the data are available. However, evaluation of the available data should focus on ecologically relevant species. Unless otherwise specified, SQGs refer to the total concentration of the substance in surficial sediments (i.e., the upper few centimetres) on a dry weight basis (CCME, 1995). The process for

developing Canadian SQGs follows the general framework that has been established for the derivation of water quality guidelines. The effect data set for the chemical under consideration must contain at least twenty (20) entries in the guideline derivation table prepared from the Biological Effects Database for Sediments (BEDS). The no-effect data set for the chemical under consideration must contain at least twenty (20) entries in the guideline derivation table prepared from BEDS. For the chemicals listed in this document the number of studies varied between 5 and 40 (with a significant number of repetitions in term of species (i.e., same species test: different times and/or different endpoints).

In the light of the knowledge gaps in bioavailability, sediment ageing, absence of mesocosm and/or field studies, and if policy makers deem that formal assessments of compliance using an EQS for sediment are necessary, a tiered assessment framework is recommended (TGD, 2018). In this framework, chemical analysis at Tier 1 provides a 'face value' assessment of compliance. This could use a benthic EQS based on data simulating worst-case conditions with EQS exceedance triggering a more detailed assessment (i.e., Tier 2) that accounts for bioavailability or uses biological data to assess whether the benthic community is actually impaired or not (TGD, 2018). A simple pass/fail approach to assessment is not always appropriate, especially as residual uncertainties in sediment standards can be high; it is recommended to use sediment standards as one of a number of lines of evidence (TGD, 2018).

APPROACHES FOR EQS CALCULATION

There are essentially two different approaches for EQS setting but they are similar in a couple of key areas: the application of safety factors while accounting for scientific uncertainty, and the dependency on the quality and quantity of available toxicity data. In determining the appropriate safety factor, expert judgement is required to disregard unreliable toxicity data and to assess whether data for the most sensitive species are available (Zabel and Cole, 1999). Two main approaches have been used worldwide to derive EQS, the deterministic and probabilistic methods (i.e., statistical extrapolation methods) (TGD, 2018).

EQS DETERMINATION BY STATISTICAL EXTRAPOLATION

The use of statistical extrapolation is one method for determining an EQS. Such a method involves the use of a species sensitivity distribution (SSD) curve in which all reliable toxicity data are ranked and a model fitted (Wagner and Lokke, 1995; Lepper, 2005; TGD, 2018). In order to conduct the statistical analysis required to run a SSD calculation, a minimum of 10 similar ecotoxicity end-points (i.e., EC_{50} or NOAEC) data on a minimum of eight taxonomic groups is required. The use of statistical extrapolation methods can be completed if all data requirements are met. Deviations from these recommendations can be made, on a case-by-case basis, through consideration of sensitive endpoints, sensitive species, mode of toxic action and/or knowledge from structure-activity considerations (Lepper, 2005). Ideally, toxicity data should be available for at least eight species of the potentially sensitive taxonomic group (most likely arthropods for insecticides; rooted macrophytes for herbicides). For substances for which a specific potential sensitive taxonomic group cannot be identified on basis of the available toxicity data for pelagic organisms, a minimum number of eight toxicity data for at least five different taxonomic/feeding groups may be selected (EFSA, 2015). It has also been suggested that the data set should be statistically and ecologically representative of the community (Forbes and Calow, 2002). This implies a significant knowledge of the environment (pelagic and benthic). It is necessary (and challenging) to acquire precise knowledge of the total number of taxa in a community including critical species, which, if eliminated, would result in major changes in the structure and/or function of the community (Wang et al., 2015).

Similarly to the European approach (TGD, 2018) described above, the CCME (2007) document requires a total at least 10 preferably 15 species for the application of a SSD for type A and type B1 marine guidelines as follows:

- at least three species of marine fish at least one of which is a temperate species;
- at least two studies on two or more marine species from different classes, at least one of which is a temperate species; and
- at least one study on a temperate marine vascular plant or marine algal species.

The chosen SSD model should sufficiently and adequately describe data and pass the appropriate goodness of fit test (CCME, 2007). Through the minimum toxicological data requirement, as well as the inclusion of primary and secondary studies, it is anticipated that generally at least 15 data points (different species) should be available with median values for comparable records (CCME, 2007). However, evaluation of the available data should focus on ecologically relevant species (CCME, 1995). In addition, true chronic studies covering sensitive life stages are required (CCME, 2007). When sufficiently large data sets are available the risk for errors is reduced while uncertainty on expected protection or impact prediction declines. When data sets are small, uncertainty is greater and consequently the more cautious deterministic approach (described below) is more appropriate (Belanger et al., 2017). A direction in the use of SSDs is the interest in using field data based on population abundance and biomass as alternatives to toxicity estimates in the laboratory (Leung et al., 2005). Overall, recommendations for the implementation of SSD approaches as per the European (TGD, 2018; EFSA, 2015) and the CCME approach (2007) are similar in nature with some differences in numbers of taxa/species.

EQS DETERMINATION USING A DETERMINISTIC APPROACH

The deterministic approach uses the lowest credible toxicity datum and applies an AF (which may be as low as 1 or has high as 10,000) to extrapolate an EQS, the AF allowing for uncertainties in the available data (TGD, 2018). An example of this in the Canadian context is the development of “Type A” and “Type B” CCME water quality guidelines. The magnitude of uncertainty factors will ultimately depend on the number of available ecotoxicological data (Van de Meent et al., 1990).

The European guidelines (TGD, 2018) use assessment factors similarly to CCME, with some differences in the conservative nature of AF for small data sets to allow for an early warning of potential effects. A high level of prescription/specificity is contained in the TGD (2018) allowing us to derive EQS for both water and sediments where paucity of data is dealt with in a very detailed manner. It is recognized that EQS and CCME guidelines are also subject to the same uncertainties (lab to field extrapolation, data quality, single chemical assessment vs synergistic/additive/antagonist effects of environmental chemical mixtures). Where an EQS is derived from a small or incomplete dataset in terms of community representation, the residual uncertainties can be large. Ideally, the minimum set should include data from three trophic levels, namely an alga (or an aquatic plant), an invertebrate and a fish (Oudin and Maupas, 1999). Incomplete sets can sometimes be accepted, according to expert judgement, but in such cases the derived thresholds might be considered as provisional (Babut et al., 2001). There is a considerable difference in the robustness and reliability of EQS derived from small data sets compared to those extrapolated from comprehensive ones. Because of this limitation, the usage of appropriate AF is fundamental. The consequences of using AF with a limited knowledge of environmental risk limits are two fold: (1) increasing the possibility of overestimating ecological effect; (2) usage might be insufficient to reduce the probability of causing harm to the environment, which thus will increase the possibility of underestimating ecological effect (Sijm et

al., 2001). If reliable no-effect-concentrations are available from field studies, it may only be necessary to apply a very small assessment factor (1-5) to account for differences between ecosystems (Zabel and Cole, 1999). However, some authors criticize this endpoint as being a fundamentally invalid interpretation of hypothesis testing (Crane and Newman, 2000). In fact, the effect at the NOEC concentration can still be present at 10 to 34% of the population tested as “no statistically significant effect” does not mean that there is no effect (Crane and Newman, 2000; Jager et al., 2006). The usage of more flexible derivation approaches could be guided by the statistical distribution of multiple NOECs and were recommended within the European context for future versions of SEQ-Eau (France) (Babut et al., 2003).

Some definitions, provided in Table 6, have been reproduced from SEPA (2013) for clarification. In addition, for context, the water quality CCME guidelines, for type B1 and type B2 are as follows:

- Type B1: For both long-term (equivalent to the AA-EQS described above) and short-term exposure (MAC-EQS) guidelines, the critical study, i.e., the lowest acceptable, appropriate toxicity endpoint, is divided by a safety factor of 10 to arrive at the respective guideline values.
- Type B2: The lowest acceptable endpoint (i.e., the most sensitive preferred low-effects endpoint) from a long-term exposure study will be the critical study used in the derivation of the type B2 long-term exposure guideline. The endpoint concentration from this critical study is divided by a safety factor of 10 unless scientific judgment dictates that this guideline is not sufficiently protective by experts then a safety factor of 20 can be used if the substance is non-persistent (i.e., t½ in water <8 weeks). If the substance is found to be persistent, the endpoint concentration is then divided by a safety factor of 100. For the short-term exposure type B2 guideline, the lowest endpoint is divided by a safety factor of 10.

Table 6. Some definitions (reproduced from SEPA, 2013).

Term	**Definition**
Acute Toxicity	Toxicity arising from exposure of an organism for a period which is short relative to the lifespan of the organism. This would be in the order of minutes for bacteria and usually up to four days for fish. The duration of an acute toxicity test is generally four days or less and mortality is the response most often measured.
Chronic Toxicity	Toxicity arising from exposure of an organism for a period which is a significant proportion of the lifespan of that organism, such as 10% or more. A chronic toxicity test is used to study the effects of continuous long-term exposure to a chemical or other potentially toxic material.
No Observed Effect Concentration (NOEC)	The highest concentration of a material in a toxicity test that has no statistically significant adverse effect on the exposed population of

Term	Definition
	the test organisms as compared with the controls.
Predicted No Effect Concentration (PNEC)	The environmental concentration of a chemical or substance which is regarded as a level below which the balance of probability is such that an unacceptable event will not occur.

In this document we will be using the deterministic approach as described in the TGD (2018) with further details in the following sections. Flexibility in applying the criteria described above will be exerted depending on the chemical. For example, the number and type of additional species that should be tested depends on what is known about the mode of action or selectivity of the pesticide (EFSA, 2005).

DATA CONSIDERATIONS

Data sets to be used for EQS determination should be reliable and relevant (Lepper, 2005). The two terms are defined in the European Technical Guidance Document (TGD, 2003) as follows: Reliability means that the inherent quality of the method used to conduct the test is high and that all relevant details to judge on the performance and the results of the test are described. Relevance means the extent to which a test is appropriate to give insight on a particular question addressed, for instance, in the effects assessment. Only reliable, relevant data should be considered valid for use in quality standard setting. Evaluations of the reliability and relevance of (eco)toxicity studies are subject to expert judgment. A few points regarding data considerations are summarized as follows:

- Not all data have an equal influence on EQS derivation. Critical data are ecotoxicity data (typically NOECs/EC_{10}s or LC/EC_{50}) for sensitive species and endpoints that are used as the basis for extrapolation and hence determine – or strongly influence - the value of the EQS. Supporting data are those data that are not described as critical data. They include data that are not among the most sensitive species/endpoints, studies that have estimated a non-standard summary statistic, e.g., a LOEC is reported but no NOEC, field or mesocosm experiments that are difficult to interpret, or where a study might be sound but is not fully reported. Supporting data are not used directly but can help inform the derivation of the standard by, for example, identifying sensitive taxa, determining if freshwater and saltwater datasets can be combined for derivation, averaging or aggregating the data in order to identify the critical data, and selecting an appropriate AF (TGD, 2018).
- As already stated, for the derivation of the long-term "annual average" environmental quality standards (AA-EQS), chronic data (e.g., NOECs) are preferred (long-term annual average EQS shall not be derived exclusively on the basis of acute toxicity data). However, acute toxicity data (L(E)C_{50}) may be used to check the plausibility of the long-term data and of the quality standard derived on the basis of these long-term data.
- Freshwater organisms may be used as surrogate species when determining an EQS for the marine environment provided that enough information exists to suggest that the sensitivity of the freshwater species towards the substance in question is representative of the anticipated sensitivity of the marine species. In cases where there is no compelling data to

suggest that the sensitivity of the marine species is equal to or less than that of the freshwater species, the use of a higher safety /uncertainty factor (AF) may be applied.

- Test results of organisms living in water may be used to derive EQS for sediment, as long as no tests for sediment dwelling organisms are available. Legally binding sediment EQS should, however, preferably be based on results of toxicity tests with sediment organisms (Lepper, 2005).
- 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 (Lepper, 2005; TGD, 2018).
- Data used for EQS derivation should be selected on the relevance of test conditions (pH, hardness, etc.) to the field when possible (Lepper, 2005; TGD, 2018).
- If multiple toxicity values or geometric means for different endpoints are available for one species, the most-sensitive endpoint is selected. NOECs when available can satisfy this criteria.
- The use of toxicity data from a test where an insufficient concentration range on the higher end has been tested (i.e., where the results are expressed as “toxic concentration is greater than x”) is generally acceptable, as they will not result in an under-protective guideline. These types of data are best used as supporting evidence for other studies and to help to fill minimum data requirements for guideline derivation (CCME, 2007).

STEPS USED FOR EQS DETERMINISTIC ESTIMATION

As part of the first step of the diagram below, knowledge on the chemical in question is important in particular the following characteristics (as listed in Lepper (2005) and TGD (2018)):

- Chemical and physical properties (including mode of action) in order to predict the major fate and behavioural pathways in the environment which may influence the eventual concentrations occurring in water, sediments or biota;
- Analysis (e.g., methodology limit of detection to assess whether the methods are adequate for the monitoring of the EQS);
- Behaviour in the environment, i.e., point of entry into the environment, method of application;
- Fate in the environment (e.g., in what form does it exist in the environment - complexed or dissolved including persistence of the substance in the environment and its main sink); and
- Environmental concentrations (e.g., to identify the extent of the contamination) and potential bioaccumulation.

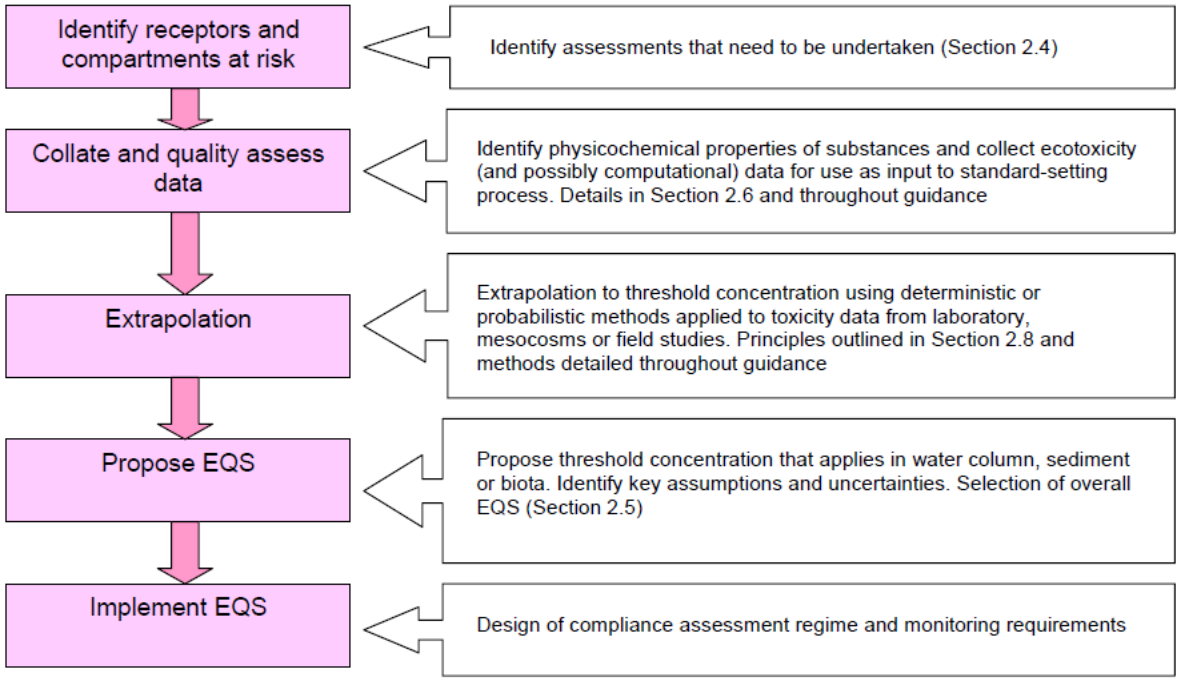

Figure 1. Steps of environmental quality standards determination (reproduced from TGD, 2011).

The approach used in this document is focused on parent compounds only. In most cases, parent compounds are often the most toxic (i.e., therapeutic action); in cases where a transformation product is potentially more toxic, concentrations are likely lower than the parent compound. It is important to highlight the knowledge gaps related to this aspect and re-explore EQS developments and additional steps if new information become available.

To implement this approach the following multi-step process was applied:

- **The selection of the appropriate compartments to target for EQS determination** (water/sediments). This triage is based on the K_{OW} of compounds as articulated in the earlier sections of the document.
- **Selecting and compiling all data available both in freshwater and seawater for every chemical**.

Data quality control: In preparation of this document a quality assurance assessment based on accessing peer review studies and collating data in line with other international jurisdictions (SEPA and US EPA) was completed. The more recent Moermond et al. (2016) CRED assessment tools were applied for some new critical data points but might need to be further confirmed by including more experts in the assessment. We have focused our selection on primary publications and accepted studies as per other regulatory agencies. Usability (i.e., reliability status) as determined by other regulatory agencies including assessments completed by PMRA was taken into consideration and any studies eliminated by SEPA or US EPA were not considered. The CCME water guidelines state the following: “A great deal of variability exists in the quality of published toxicity data. The evaluation of toxicological data should not follow a rigidly fixed format, but rather should incorporate scientific judgment and allow for special consideration on a case-by-case basis”.

Data compiling: In this data compiling exercise we have accessed primary references, technical reports, reports compiled by regulatory agencies, regulatory documents related to the establishment of thresholds (European Union, FAO, CCME, PMRA), as well as application data by private companies when available for consultation. We have benefited from the help of colleagues from PMRA and SEPA in accessing some confidential documentation. To keep an auditable track of any decision-making that went into the data consideration, the authors maintained a record of all ecotoxicological studies consulted in the preparation of the document and notes on the study reliability, whether or not they were included in the EQS inference process. In collating these data, toxicity endpoints were not standardized nor modified to account for the effect of any exposure and toxicity-modifying factors (ETMFs) such as hardness/alkalinity, organic matter, oxygen, pH and salinity as advised in the CCME guidelines (2007) because of the paucity of data on the influence of these factors. The tables provided in the Appendix contain most of the relevant data including data not deemed reliable as well as the data points applied directly to derive EQS including their reliability scores. We have kept values (even if high) in the tables to highlight to readers the differences in sensitivities of different taxa to the chemicals. In some cases, unnecessary repetition was avoided where the derived end-points for a particular organism were similar and thus captured by a single study. However, as further explained in the following sections, the tables provided in the annex section of this document do contain more than one value per species.

- **Separation of chronic versus acute data to derive the two different types of EQS (AA and MAC).** In most guidance documents some direction is provided on individual studies, whether these are to be considered as chronic studies or as acute studies; however, often expert judgement is required. What is to be considered chronic or acute will be dependent on: 1) the species considered, 2) the life stage, 3) the persistence of the compound, and 4) the studied endpoint and reported criterion, as well as the study duration. For most common species, toxicity studies with fish are considered acute if mortality is determined after 96 hours (standard acute test) or after 10-14 days (prolonged acute toxicity test). The most commonly accepted as chronic toxicity tests for fish are early life-stage tests (ELS), in which eggs or larvae are exposed and the effects on hatching, malformation and growth are considered (TGD, 2018). For daphnids, the standard exposure time for acute toxicity is 48 hours, but with regard to chronic toxicity, there is a factor of three difference between the tests with *Daphnia magna* (21 days) and *Ceriodaphnia dubia* (7 days), the latter having a much shorter reproduction time. For algae, the standard exposure time is 72 hours (TGD, 2018). In reality, ”true” chronic studies should cover all sensitive life stages. This is particularly relevant when deriving annual average quality standards input data where all reliable NOECs from chronic/long-term studies, preferably on full life-cycle or multi-generation studies should be used (Lepper, 2005). However, this is rarely the case. The absence of “true” chronic data (as per the definition above in Table 6) is an issue common to many chemicals and EQS determination process. For the purpose of this document, unless specified otherwise, acute and chronic have been separated based on length of exposure as per species known life cycles and guidelines (CCME, 2007; TGD, 2018). For most chronic tests in the toxicity tables, durations of tests are 21 days and more and discussed for every individual chemical. Expert judgement needs to be applied for some algal tests as 72 hours and 96 hours tests can be considered as long-term as stated in the Canadian water guidelines protocol (CCME, 2007). When applicable, discussion points on length of testing and associated chronic/acute uncertainties were added.
- **Identifying whether acute or chronic freshwater data can be combined with the corresponding seawater data to ensure consideration of both data sets for EQS derivation is appropriate.** The AFs applicable in the framework of the European regulations (TGD, 2003, 2018) have shown that seawater AFs are consistently higher than

freshwater AFs because fewer marine data are available. However, it remains questionable if marine species are more sensitive than freshwater species. In fact, the need to separate marine and freshwater standards remains a topic of discussion (Matthiessen et al., 2010; TGD, 2018), considering the possibility that salinity can influence both the physico-chemical nature of contaminants and organisms and that sensitivity differs between marine and freshwater organisms. A literature review (Klok et al., 2012) based on 3627 references concluded that there is no systematic difference in sensitivity to pesticides between fresh- and saltwater species. The consideration of both data sets is detailed in the tables provided in the Technical Guidance Document (TGD, 2018). The Canadian Water Quality Guidelines for the Protection of Aquatic Life (CCME, 2007) state that for substances for which no significant influence on chemical behaviour can be shown or reasonably anticipated, and where no differences in toxicity toward freshwater and marine organisms by comparison of similar taxonomic groups can be seen, toxicity data from freshwater organisms may be used in order to broaden the marine database. We have conducted the following: 1) F-tests were completed to test for equality of variance; 2) t-tests or Mann-Whitney tests (depending on normality of data) to compare all endpoints in freshwater and seawater independent of taxonomic groups represented; 3) we have compared similar taxonomic groups when enough data were available (as per CCME, 2007). Especially for compounds with a specific mode of action, it is important to identify particularly sensitive taxonomic groups and perform a separate statistical analysis for this specific group. If enough data are available to make a comparison for individual or related taxonomic groups (e.g., insects, crustaceans, arthropods, fish, vertebrates), this may help to determine if there are differences between saltwater and freshwater species (TGD, 2018). Eco-combined toxicity data sets (with one single toxicity value per species) of marine and freshwater species may be used when the provisions for pooling data are met (TGD, 2018). Data where exact concentrations are not provided (> or <) were not considered for the comparisons. TGD (2018) recommends the application of a logarithmic transformation of the data; this was also completed within this document. In the tables provided, more than one toxicity value per species are listed but only the lowest values (highlighted in grey in the annex tables) were used for comparisons or EQS inference (as per the TGD, 2018).

- **The inference of an EQS value based on the guidelines provided above, expert judgement and the application of appropriate AFs**. Perspectives in term of whether EQS values can be implemented (technical limitations) and/or realistic (as per field studies) are also discussed.

EQS DETERMINATION BY CHEMICAL

BATH PESTICIDES

Azamethiphos

Formulation and application

Azamethiphos is an organophosphate insecticide and the active ingredient in the formulation used in Canada and elsewhere. The Salmosan® formulation is a wet-able powder consisting of 47.5% azamethiphos and excipients sodium lauryl sulphate, kaolin light and silicic acid precipitated. Salmosan® is used as a bath treatment at 100 µg/L for 30-60 minutes in well boats and tarps. Four major transformation products were detected in laboratory studies: monomethyl ester CGA-18809, CGA-55016, CGA-51236 and GS-36533 (PMRA, 2016a). All four major transformation products are expected to disperse faster than they are formed and will undergo extremely rapid dilution rates in a period of less than three hours. These dilution rates far

exceed the rates at which the transformation products will be produced. As such, it was determined that there would be negligible exposure to non-target organisms from any of the transformation products of azamethiphos (PMRA, 2016a).

Solubility and mode of action

Azamethiphos is soluble in water (1.1 g/L) and has a low octanol-water partition coefficient (log K_{oW} = 1.05) (PMRA, 2016a). Azamethiphos is likely to remain in the aqueous phase on entering the environment and is not expected to bioaccumulate considering its solubility (PMRA, 2016a). We will derive an EQS for water only.

Azamethiphos acts by inhibition of the cholinesterase activity with toxicity towards a wide range of non-target organisms (Ernst et al., 2014) with crustaceans being the more sensitive group (Burridge et al., 2014).

Azamethiphos EQS in other jurisdictions

Within SEPA, operational EQS were applied as per the table below (SEPA, 2014; 2019c) with different time periods (three hours post-discharge and three days after the final discharge in any treatment period).

Table 7. Operational water quality standards for azamethiphos used by the Scottish Environmental Protection Agency (copied from SEPA, 2019c as per SEPA Policy 17 (1998)).

Timescale	Standard	Type
3 hours	250 ng/L	MAC
24 hours	150 ng/L	MAC
72 hours	40 ng/L	MAC

SEPA applies the 72-hour EQS in common with the 'mixing zone' concept applied to other point-source marine discharges, which for bath pesticides is defined as the lower of: 0.5 km^2, or 2% of loch area (SEPA, 2008). Areas for the majority of lochs and voes have been systematically defined in the Sea Loch Catalogue (Edwards and Sharples, 1986), if not defined, a suitable area for a similarly constrained receiving water should be determined and justified. The process of deriving the EQS values was completed as follows (SEPA, 1998).

For the 250 ng/L (after three hours): "McHenery provided data for a 5-h NOEC which, with the application of a x10 factor gives a maximum allowable concentration (MAC) after 3 h of 250 ng/L. This was accepted to be a more appropriate derivation following expert meetings (SEPA, 1998)".

For the 150 ng/L (after 24 hours): "Although there was no perceived requirement for a 24 h standard for the proposed regulatory strategy (3 hours and 72 hours are the only regulatory timelines), SEPA agreed to retain this threshold. McHenery in his report to Novartis suggested that the derivation of a 24 h standard used by the Veterinary Medicines Directorate was more appropriate: the 96-h EC_{50} for lobster larvae with an extrapolation factor of 10 giving a 24 h MAC of 150 ng/L (SEPA, 1998)".

For the 40 ng/L (after 72 hours): "Data provided by McHenery suggested a 70-h EC_{50} of 400 ng/L. Application of a 10-fold factor to this gives a 72-h MAC of 40 ng/L. This was accepted by experts at their December 15th, 1998 meeting (SEPA, 1998)".

Determination of the Pelagic MAC-EQS

Preconditions are met to use a SSD-based EQS if the database contains preferably more than 15, but at least 10 NOECs, for different species covering at least 8 taxonomic groups (Lepper, 2005; TGD, 2018). For azamethiphos, the data available as per Table 1-B in the appendix (seawater) cover eight taxonomic groups and include a total of nine NOEC/LOEC. However, most of them are related to the same species (four for lobster, two for sand shrimps, two for *Mysis* sp. and one for mussels). Similarly, the CCME (2007) document requires a total of six species for the application of a SSD for type A and type B1 marine guidelines with some requirements in term of species representability.

We will be using the deterministic approach to calculate the EQS. However, considering the fact that the number of taxonomic groups with toxicity data might allow probabilistic approaches, the authors wish to stress the importance of completing an SSD at a later time to test inferred EQS values. Considerations regarding the time/exposure constraints and how data should be divided for the application of a SSD will have to be taken into account.

Trials completed with tarp treatments have shown that concentrations of dye and pesticide are diluted by approximately a factor of 10 after 30 minutes, a factor of 100 after 1 hour and a factor of 1000 after three hours (Page et al., 2015). Discharges from well-boat treatments are quantitatively consistent with jet dynamics and are diluted more rapidly than from net-pen treatments (Page et al., 2015). An understanding of the exposure phase is very relevant to how the resulting MAC-EQS should be expressed (e.g., a 24-h or a 1-month peak) and applied (TGD, 2018). Considering dilution times as cited above (Page et al., 2014; 2015; Page and Burridge, 2014) the timelines used by SEPA seem reasonable in term of exposure patterns (3, 24 and 72 hours). We have used these timelines but modified the 72 hours threshold to 96 hours to better reflect timelines of the available toxicity data.

Deriving a MAC-EQS will be completed using the following approach: usage of toxicity values with time less than or equal 3 hours for the first EQS, usage of toxicity values with time less than or equal to 24 hours for the second EQS (including the tests ≤ 3 hours) and usage of toxicity values less than or equal to 96 hours for the third EQS (including the tests ≤ 3 hours and ≤ 24 hours). Tests clearly show that harmful effects are time sensitive and require an approach reflecting both the toxicity data differences according to time as well as the known dispersion timelines as per Canadian modelling studies (e.g., Page et al., 2014; 2015). Considering the inherent uncertainty associated with the exact occurrence of adverse effects in toxicity testing (dependent on the frequency of testing), questions remain regarding whether toxicity data can really reflect these subtle differences in timing. The longer-term test (10 days in our data set) will be used to derive the AA-EQS as further described below.

The determination of MAC-EQS requires the usage of acute data. Comparisons between the freshwater and seawater sets of acute toxicity data (Tables 1-A and 1-B in the Appendix, respectively) were not completed as the taxonomic groups considered are completely different. The freshwater data contain mostly fish endpoints for freshwater versus a significant representation from crustaceans in addition to molluscs, echinoderms, fish, algae and rotifers for seawater tests. A statistical comparison was also not feasible per taxonomic groups (fish for both data sets considering that the number of endpoints (when considering the lowest values) was only n=5 for the seawater dataset.

After limiting the toxicity test timelines to three hours or less, the lowest endpoint is based on the EC_{50} of *Metacarcinus edwardsii* (0.94 µg/L; (confidence interval: ± 0.15 µg/L)); however, when using the CRED risk assessment to assess the reliability of this study, this study was found to be unreliable due to a mortality in the controls greater than 35% and an EC_{50} value very close to the lowest quantity of Azamethiphos tested. This suggests that more trials with concentrations

between 0 and 1 ug/L might be required. Note that this evaluation is provisional and should be reassessed by more than one expert. The next lowest endpoint, reported in Burridge and Van Geest (2014), a study assessed by the PMRA to be acceptable, is **0.97 µg/L** and based on the 1-hour LOEC of *Crangon septemspinosa*. The data representation of taxa is as following: bacteria, fish, crustaceans, molluscs, and echinoderms. No algae short-term tests with less than 3 hours are available. EC_{50} values from bacterial tests may be used but they cannot substitute any of the other trophic levels (TGD, 2018). However, the 72-h test with freshwater diatoms (LC_{50} > 1000 µg/L) and the known toxicity mechanism of azamethiphos do not indicate concerns for this taxonomic group. As per the MAC-EQS guidelines in Table 4, the available data would require an AF of 50 but, given azamethiphos mode of action with crustaceans being the most sensitive group, it can be lowered to 10. The derived value will be 0.97 µg/L divided by an AF of 10 resulting in a **3h EQS of 0.097 µg/L (97 ng/L).**

For toxicity data with timelines less than or equal to 24 hours, the lowest toxicity endpoint, reported in the 2015 VMD report on azamethiphos and assessed by SEPA to be reliable with restrictions, is 0.36 µg/L, based on the 24-h EC_{50} of the stage IV larvae of *Homarus gammarus*. The available data includes toxicity data from three trophic levels (algae, crustaceans and fish) plus two or more tests from additional taxonomic groups (bacteria, echinoderms, rotifers, and molluscs) resulting in an AF of 10. The derived value will be 0.36 µg/L divided by an AF of 10, resulting in a **24-h EQS of 0.036 µg/L (36 ng/L)**.

For toxicity data with timelines less than or equal to 96 hours, the lowest toxicity endpoint is the same as the value used to derive the 24-h EQS: 0.36 µg/L, based on the 24-hour EC_{50} of the stage IV larvae of *Homarus gammarus* (VMD, 2015). This value is similar to endpoint values from timelines of 48 hours and 96 hours (a 0.45 µg/L LC_{50} on adult *Homarus americanus* and a 0.5 µg/L LC_{50} on stave IV and V *Homarus gammarus*, respectively). With the data set having the same representation of taxonomic groups as the 24h timeline (algae, crustaceans, fish, bacteria, echinoderms, rotifers, and molluscs), plus an additional test from the annelids group, the same AF of 10 can be used. The derived value will be 0.36 µg/L divided by an AF of 10, resulting in a **96-h EQS of 0.036 µg/L (36 ng/L)**.

The SEPA EQS values suggest differences in toxicity between the 24-hour and 72-hour thresholds; this is not the case for the values inferred as per this document. This is likely due to the fact that the SEPA values are based on literature data published prior to 1998 not including more recent reports (e.g., DFO, 2013; Burridge and Van Geest, 2014; Couillard and Burridge, 2015, etc.).

Determination of the Pelagic AA-EQS

Due to the dilution of azamethiphos, the hazard posed by the proposed end-use product is mostly of an acute nature and unlikely to pose risks for longer-term exposures. However, in the case of cumulative usage and/or longer-term applications an EQS needs to be derived. The data available are only of an acute nature if we consider timing < 14 days as acute. Considering the dilution patterns described in the literature (Page et al., 2015) we will include the 10 days as a reasonable long-term exposure.

The lowest value is related to lobster with a 10-day LC_{50} of 0.216 µg/L (Burridge and Van Geest, 2014). The PMRA experts assessed this study to be reliable. A lower endpoint is described below but was not added to the Appendix table as this study did not produce a final toxicity threshold; however, it cannot be ignored as further described in the following paragraph (L. Burridge, personal communication):

- A preliminary study was set up in 2012 exposing adult male lobsters to 0.078 µg/L of azamethiphos (in Salmosan® formulation) continuously for 10 days, in order to simulate

exposure to Salmosan® at a distance from farm sites with multiple treatments over a 10-day period. In addition to the direct effects of sublethal exposure to Salmosan®, effects on the ability of adult lobster to cope with simulated live transport and the persistence of the effects after a 24 h depuration period in clean seawater were also assessed. A single treated lobster died on day 10, while no other lobsters died during the 10-day treatment or during 24 h in running seawater post-treatment. However, more than 33% of the treated lobsters held under simulated shipping conditions were dead after 24 h compared to 2.6% of the shipped control lobsters. Treatment with azamethiphos significantly reduced acetylcholinesterase activity. Hepatosomatic index and hepatopancreas lipid content were increased and gonadosomatic index was reduced in male lobster exposed to azamethiphos. These effects persisted after 24-h depuration or shipping. This indicates that chronic exposure to low concentrations of the anti-sea lice pesticide azamethiphos induced sublethal effects in adult lobsters. Cholinesterase activity inhibition could lead to disturbance of critical behavioural functions (Burridge and Van Geest, 2014) suggesting some sublethal effects of azamethiphos at 0.078 µg/L.

The data available contain only one long-term result with a number of short-term tests representing more than three taxonomic groups. This requires the application of an AF of 1000. An assessment factor of 1000 is applied to a single long-term result if this result is generated for the taxonomic group showing the lowest short-term test as well (TGD, 2018). This is the case for lobster as a representative of the crustaceans where azamethiphos acute toxicity values are the lowest. Given the mode of action and the other information available it may be considered overly precautionary. TGD (2018) provides additional guidance on the applicability when two chronic studies are available and additional taxa (such as molluscs and echinoderms) have acute data that demonstrates they are less sensitive in reducing the AF from 500. However, no such additional guidance is provided when only one chronic study is available. The revision of the AF from 1000 to 500 should then be further discussed under expert review.

Based on the process described, the derived value will be 0.216 µg/L divided by an AF of 1000, resulting in an **AA-EQS of 0.216 ng/L. These concentrations are very low as per the dilution patterns described above; considerations of environmental relevance (realistic exposure phases) need to be part of the final decision making.**

In summary, the following EQS values were derived:

In water:

- MAC-EQS for 3 hours: 0.097 µg/L (97 ng/L)
- MAC-EQS for 24 hours: (timelines will have to be discussed): 0.036 µg/L (36 ng/L)
- MAC-EQS for 96 hours: 0.036 µg/L (36 ng/L)
- AA-EQS of 0.216 ng/L

As per Garcia-Rodriguez et al. (2008) it is possible to achieve a limit of detection (LOD) of 0.1 ng/L for azamethiphos in water rendering the potential application of the EQS thresholds executable.

Table 8. Summary of EQS values derived for azamethiphos.

EQS Type	Value	Three lowest endpoints	Assessment Factor; Rationale	Notes, limitations
3-hour MAC-EQS	97 ng/L	0.97 µg/L (1-h LOEC, *Crangon septemspinosa*; Burridge and Van Geest, 2014; Acceptable) 1.03 µg/L (30 min NOEC, *Homarus americanus*; Burridge et al., 2000; 2, Reliable with restrictions) 2.84 µg/L (30 min LC_{50}, *Metacarcinus edwardsii*; Gebauer et al., 2017; 2, Reliable with restrictions)	10; Available data include one short-term (< 3 hours) from three trophic levels (fish, crustaceans and bacteria), one short-term (< 3 hours) + a test from an additional saltwater taxonomic group (echinoderms) and more than one data point are available for the most sensitive taxonomic group (crustaceans)	Derived using seawater data only Toxicity values from bacterial tests may be used but they cannot substitute any of the other trophic levels of a base set; however, absence of short-term test for algae is not of concern considering the mode of action of azamethiphos
24-hour MAC-EQS	36 ng/L	0.36 µg/L (24-h EC_{50}, *Homarus gammarus* stage IV; VMD, 2015; 2, Reliable with restrictions) 0.9 µg/L (12-h LC_{50} at 12°C, *Homarus americanus* larvae; Pahl and Opitz, 1999; 2, Reliable with restrictions) 0.97 µg/L (1-h LOEC, *Crangon septemspinosa*; Burridge and Van Geest, 2014; Acceptable)	10; Available data include one short-term (< 24 hours) from three trophic levels (fish, crustaceans and algae) and two or more short-term (< 24 hours) tests from additional saltwater taxonomic groups (bacteria, rotifera, Mollusca, echinodermata)	Derived using seawater data only
96-hour MAC-EQS	36 ng/L	0.36 µg/L (24-h EC_{50}, stage IV *Homarus gammarus*; VMD, 2015; 2, Reliable with restrictions) 0.45 µg/L (48-h LC_{50}, adult *Homarus americanus* adult, Dounia et al., 2016; 2, Reliable with restrictions) 0.5 µg/L (96-h LC_{50}, stage VI and V *Homarus gammarus;* PMRA, 2016a; Reliable)	10; Available data include one short-term (< 96 hours) test from three trophic levels of the base set (fish, crustaceans, and algae) and two or more short-term (< 24 hours) tests from additional saltwater taxonomic groups (bacteria, rotifera, annelida, echinodermata, mollusca)	Derived using seawater data only

EQS Type	Value	Three lowest endpoints	Assessment Factor; Rationale	Notes, limitations
AA-EQS	0.216 ng/L	0.216 µg/L (10-d LC_{50}, *Homarus americanus*; Burridge and Van Geest, 2014; Acceptable)	1000; Available data include a single long-term result for a freshwater or saltwater crustacean or fish (crustacean) and this result was generated for the taxonomic group showing the lowest $L(E)C_{50}$ in the short-term algal, crustacean or fish tests (crustacean)	Derived using seawater data only Concentration is very low as per the dilution pattern of azamethiphos. The revision of the AF from 1000 (to 500) should be further discussed with additional expert review.

References and reliability assessments are stated between brackets.

Hydrogen peroxide

Formulation and application

Hydrogen peroxide (active ingredient of Paramove®) has a registered dosage of 1.2 - 1.8 g/L. Hydrogen peroxide has a half-life in seawater of about seven days (Haya et al., 2005) though half-life determinations are variable with reports in the literature ranging from minutes in freshwater to hours to days in coastal waters whether seawater was filtered or raw (i.e., containing organic matter) seawater (Lyons et al., 2014). These values are also influenced by the formulations used as further discussed below. Unlike other products, the background levels of hydrogen peroxide in seawater ranges from 0.5 to 14 µg/L (Haya et al., 2005).

Solubility and mode of action

Hydrogen peroxide is fully miscible in water and has a calculated K_{oW} of less than 1 (K_{oW} = -1.5) indicating a low potential for partitioning and accumulation in sediment and overall bioaccumulation. Therefore, only water EQS values will be determined. The transformation products from the degradation of hydrogen peroxide are water and oxygen. However, in degradation trials it was demonstrated that the concentration of Paramove® 50 hydrogen peroxide did not degrade significantly over a 3-h time period at different temperatures (5, 10, and 20°C). Relatively little degradation was observed even after 19 days (Page et al., 2015). Assessing chronic toxicity of hydrogen peroxide formulations will be required in the future.

Hydrogen peroxide does not have a targeted mode of action. The suggested mechanisms of action of hydrogen peroxide are mechanical paralysis through peroxidation by hydroxyl radicals of lipid and cellular organelle membranes, and inactivation of enzymes and DNA replication (Cotran et al., 1989).

Hydrogen peroxide EQS in other jurisdictions

Some PNEC values for single species are available as per an environmental assessment completed by Schmidt et al. (2006) for hydrogen peroxide usage in hatcheries (fish eggs treatments) as part of The International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) process. Values vary from 17 µg/L for *Microcystis* sp. to 68 µg/L for *Nitzchia closterium*, and up to 1,750 µg/L for

chinook salmon. The PNEC calculated for *Daphnia pulex* was of 120 µg/L (VICH phase II) (Schmidt et al., 2006).

In a summary report on conclusions of the risk assessment report of hydrogen peroxide prepared by Finland (European commission, 2003) in the context of Council Regulation (EEC) No. 793/93, the lowest long-term aquatic toxicity test result is the NOEC of 0.1 mg/L for algae with the usage of an assessment factor of 50 according to the TGD (2011). However, based on the data on natural background concentrations (typically <1 – 30 µg/L) it is obvious that this would overestimate the toxicity. An assessment factor of 10 was considered to be appropriate resulting in a PNEC-water of 10 µg/L (European Commission, 2003).

Determination of the Pelagic MAC-EQS

Similarly to azamethiphos, the authors wish to stress the importance of completing a SSD in the future to determine EQS values. The freshwater acute toxicity data for hydrogen peroxide include six taxonomic groups similarly to the marine data set. The number of data points are above 15 in both sets. However, the usable freshwater toxicity endpoints (fixed value versus > or <) include a high number of toxicity endpoints related to one species only (varying temperature and time exposures). Considerations on how these data should be collated for a potential SSD will have to be carefully deliberated.

After completion of the F-test, comparisons between the freshwater and seawater sets of data were completed by running Mann-Whitney rank sum tests (data not normally distributed). Data sets containing one single endpoint per species (lowest value) as per the approach described in the TGD (2018). No significant differences were found (P=0.097, Table 9) suggesting that data can be collated.

Table 9. Comparison of acute hydrogen peroxide freshwater and seawater acute pelagic toxicity endpoints (similar results after Log transformation).

-	**Freshwater Pelagic data**	**Seawater Pelagic data**	**P value (Mann-Whitney Rank test)**
Number of observations	N= 37	N= 24	P= 0.097
Median (µg/L)	28000	82000	

There are enough data points to compare Crustaceans tests in seawater (n=14) versus freshwater (n=10); there is no statistically significant difference (P=0.065); however, the P value is close to the significance level with a tendency for the freshwater endpoints to be lower for this taxa group. However, the lowest endpoint is seawater crustaceans highlighting that the range of sensitivities within this taxa group is quite large whether tests are related to amphipods, decapods or euphausiacea independent of the environment highlighting the limitation of this comparison.

The lowest endpoint available in the acute seawater toxicity data for hydrogen peroxide, as reported by EVS Environmental Consultants (1992), and cited in the USGS environmental assessment on hydrogen peroxide (Schmidt et al., 2006), as well as assessed by SEPA to be reliable with restrictions, is **240 µg/L**, based on a 96-hour LC_{50} of the krill species, *Euphausia pacifica* larvae. The available data include at least one short-term test from each of three trophic levels of the base set from both the freshwater and the saltwater data sets (algae, crustaceans, and fish) plus two or more short-term tests from additional saltwater taxonomic groups (annelids

and molluscs) resulting in an AF of 10. The derived value will be 240 µg/L divided by an AF of 10, resulting **MAC-EQS is 24 µg/L**.

Determination of the Pelagic AA-EQS

Due to the rapid degradation of hydrogen peroxide, the hazard posed by the proposed end-use product is mostly of an acute nature (PMRA, 2014). The continuous exposure regimen implied in the chronic studies listed in Table 2-C of the appendix would represent a high number of continuous treatments with little environmental dilutions which is an unlikely scenario.

The two lowest toxicity values are LOECs for two species of blue-green freshwater algae, both of which have been assessed by SEPA to be reliable with restrictions. The lowest endpoint, reported in Kavanagh (1992) and the EC (2003) document, is 100 µg/L, based on the 32-day LOEC of the algae species, *Anabaena flos-aquae*.

The available data includes two long-term results from freshwater species representing two trophic levels (algae and crustaceans) plus one long-term result from an additional taxonomic group (molluscs) resulting in an AF of 50. The derived value will be divided by an AF of 50, **resulting in an AA-EQS of 2 µg/L.**

When the tarp net pen treatment method is used, an aquatic dissipation time of 10 minutes was observed to reach a reduction in concentration of 90% (DT_{90}). Concentrations are further reduced by a factor of 100 after approximately 1 hour and a factor of one thousand after three hours (PMRA, 2014). When the wellboat treatment method is used, concentrations are also reduced by a factor of one thousand after 50 minutes (PMRA, 2014). Theoretically, at a starting concentration (tarped net pen) of 1200 mg/L, a reduction of 90% after 10 minutes would result in a concentration of 120 mg/L; this would be further reduced to 1.2 mg/L after 1 hour and 120 µg/L in three hours. In the light of dissipation time and toxicity testing, short exposures (1 to 3 hours) are environmentally relevant scenarios. Dispersion modelling for an area on the west coast of Norway estimated that concentrations as high as 10 mg/L H_2O_2 could occur several kilometres away from the treated farm up to 3 h after the discharge (Refseth et al., 2016). Local hydrodynamic conditions will determine how fast the concentration of H_2O_2 will be diluted and how far it will be transported horizontally and vertically. Results from dispersion modelling (Page et al., 2014; Refseth et al., 2016; Bechmann et al., 2019) and the current experiments indicate that treatment water with toxic concentrations of H_2O_2 (1.5 mg/L) could reach organisms living more than 1 km from a treated salmon farm. Lengths of exposure, dispersion characteristics per site, formulations employed need to be further discussed to ensure the relevance of the usage of a AA-EQS long-term threshold for hydrogen peroxide.

In summary, the following EQS values for hydrogen peroxide were derived:

In water:

- MAC-EQS: 24 µg/L
- AA-EQS of: 2 µg/L

Table 10. Summary of EQS values derived for hydrogen peroxide.

EQS Type	Value	Three lowest endpoints	Assessment Factor; Rationale	Notes, limitations
MAC-EQS	24 µg/L	240 µg/L (96-h LC_{50}, *Euphausia pacifica*; EVS Environmental Consultants, 1992 cited by Schmidt et al., 2006; 2, Reliable with restrictions) 470 µg/L (48-h NOEC, *Crassostrea gigas*, EVS Environmental Consultants, 1992; 2, Reliable with restrictions) 630 ug/L (72-h NOEC, *Skeletonema costatum*, Knight et al., 1995; 2, Reliable with restrictions)	10; Available data include at least one short-term test from each of three trophic levels of the base set from both freshwater and saltwater data sets (fish, crustaceans, and algae) + two short-term tests from additional saltwater taxonomic group (annelids and molluscs)	Derived using collated seawater and freshwater data Algal toxicity tests longer than ~24 hours are inappropriate for the derivation of a short-term guideline; this should be further discussed with experts and regulators
AA-EQS	2 µg/L	100 µg/L (32-d LOEC, *Anabaena flos-aquae*; Kavanagh, 1992; 2, Reliable with restrictions) 630 µg/L (21-d NOEC, *Daphnia magna*; Meinertz et al., 2008 ; 1, Reliable without restriction) 1000 µg/L (32-d LOEC, *Oscillatoria agardhii*; Kavanagh, 1992; 2, Reliable with restrictions)	50; Available data include two long-term results from two trophic groups (algae, crustaceans) plus one long-term result from an additional taxonomic group (molluscs)	Derived using freshwater data only Hydrogen peroxide degrades rapidly and continuous exposure regimen is an unlikely scenario (AA-EQS usage needs to be discussed).

References and reliability assessments are stated between brackets.

IN-FEED DRUGS

Emamectin Benzoate

Formulation and application

Emamectin benzoate (EMB) is a mixture of two avermectin homologues (Environment Canada, 2005). SLICE® is the formulation presently used in Canada. Emamectin is a member of the chemical class of avermectins, macrocyclic lactones, produced by fermentation of the soil actinomycete, *Streptomyces avermitilis*. Chemical modification of this fermentation product has yielded hundreds of analogues including ivermectin, abamectin, moxidectin and doramectin which are widely used for control of animal and human parasites as well as insects and mites on crops (Fisher, 1997). It is administered through feed pellets.

Solubility and mode of action

BCF for EMB for fish varies between 30 and 102 (EFSA, 2012). A recent study by Brooks et al. (2019) found a BCF (kinetic BCF) of 49 for blue mussels through water exposure. EMB has low water solubility and relatively high octanol-water partition coefficient (K_{oW} = 5 at pH:7) indicating that it has the potential to be absorbed to particulate material and that it will be tightly bound to marine sediments with little mobility (SEPA, 1999; Environment Canada, 2005). However, the fate and behaviour data also suggest that, although levels in the seawater are very low, they may form equilibrium with the emamectin benzoate in the sediment (SEPA, 2017). Therefore we will be determining an EQS for both the water and the sediment compartments. EMB mode of action is not specific to parasitic nematodes and arthropods and may potentially affect other non-target invertebrates when it reaches the environment (Garric et al., 2007).

EMB EQS in other jurisdictions

A deterministic approach has been used by Scottish experts for deriving the EMB EQS considering data limitations in obtaining a full representation of taxonomic groups for a robust SSD curve. EQS values were revisited in 2017 after one of Scotland's largest and most comprehensive marine research projects into aquaculture concluded that the Scottish salmon farm medicine was significantly impacting local marine environments (SEPA, 2018). One of the recommendations of the report is that more conservative standards should be proposed with EMB values of 0.120 and 0.012 µg/kg dry sediment for near field and far field, respectively. In addition, a MAC for the water column of 0.8 ng/L for the protection of all marine life (Table 11 below copied from SEPA (2017)). For that determination, aggregation of the new data with that used in 1999 and following Guidance Document No. 27 (TGD, 2018), short- and long-term marine PNECs and a long-term marine sediment PNEC were derived. From these, new EQS values were proposed (SEPA, 2017).

Using the lowest NOEC of 1.175 µg/kg, which was based on emergence in a 28-day study on midge larvae (*Chironomus riparius*) (EFSA, 2012; SEPA, 2017) and applying an AF of 100, a long-term marine sediment PNEC of 0.012 µg/kg (12 ng/kg) is derived. The AF has been selected on the basis that there is only one long-term chronic freshwater sediment end-point and three acute marine end-points for species with different life-cycles and feeding mechanisms. A trigger value or "near-field" EQS can be derived using an AF of 10 to the lowest sediment toxicity NOEC of 1.175 µg/kg to protect organisms inhabiting sediment below the cages. This results in a "near-field" sediment MAC EQS of 120 ng/kg (dry weight).

Table 11. Proposed environmental quality standards for the protection of marine communities (SEPA, 2017).

Substance	**Proposed EQS**			
	EQS-MAC marine water	**EQS-AA marine water**	**"Near-field" EQS-MAC for sediment**	**"Far-field" EQS-AA for sediment**
Emamectin benzoate	0.0008 µg/L (0.8 ng/L)	0.000435 µg/L (0.435 ng/L)	0.12 µg/kg dry weight (120 ng/kg dry weight)	0.012 µg/kg dry weight (12 ng/kg dry weight)

AA: Annual Average

MAC: Maximum Acceptable Concentration

In December 2019, SEPA issued a statement on the adoption of interim environmental standards for protecting the water environment until direction is issued on an EQS in relation to EMB (SEPA, 2019). Following the 2017 survey, subsequent analysis during 2018 of the environmental samples collected identified evidence of impacts on crustaceans. The impacts were proportional to the concentrations of emamectin benzoate in the seabed and were present at concentrations of the medicine below the current environmental standard (SEPA, 2019). A request was made to the UK Technical Advisory Group (UKTAG) to consider all the available scientific evidence and make recommendations on new standards. In November 2019, the UKTAG published a document advising that additional information has been supplied and will be included in a further review and as such no standard is being recommended at this time. However, UKTAG (UKTAG, 2020) did indicate that the evidence did not support a standard which was lower than that proposed in their consultation (23.5 ng/kg dry weight of sediment). The proposals for EQSs (which would apply outside the allowable mixing and/or deposition zones) proposed in the consultation in May 2019, are at present the most up to date proposed EQSs available. In addition UKTAG assessed the quality of the studies during their review and followed the TGD (2018) approach. Tables were updated as follows (SEPA, 2020).

Table 12. New interim benthic Scottish Environmental Protection Agency standards (SEPA, 2020).

What the standard applies to	Where the standard applies	How the standard is measured	What the standard is
Maximum concentration of in-feed sea lice medicine, emamectin benzoate	At mixing zone limit and beyond	ng per kg of marine sediment (dry weight)	23.5
	In mixing zone	ng per kg of marine sediment (dry weight)	235.0

Determination of the Pelagic MAC-EQS

After the F-test, comparisons between the freshwater and seawater acute toxicity data sets were completed by running Mann-Whitney rank sum tests (data not normally distributed) separating values independent of the taxonomic groups considered. There are not enough data to complete comparisons of toxicity data specific to taxonomic groups.

No significant differences between freshwater and seawater acute toxicity (lowest endpoints) data were observed (P=1.000, Table 11) suggesting that both sets of data can be collated. However, similarly to the SEPA report (SEPA, 2017) it is important to note that distribution of toxicity tests is skewed as per taxonomic representation.

Table 13. Comparison of acute emamectin benzoate freshwater and seawater pelagic toxicity endpoints (similar finding after Log transformation).

-	**Freshwater Pelagic data**	**Seawater Pelagic data**	**P value (Mann-Whitney Rank test)**
Number of observations	N= 7	N= 11	P=1.000
Median (µg/L)	49.00	21.50	

In the 2017 SEPA report on emamectin benzoate, the lowest reported toxicity endpoint was 0.04 µg/L, based on the results of a 96-hour LC_{50} on the mysid shrimp species, *Americamysis bahia*; however, in a 2019 report by the Chemical Task Team of the United Kingdom Technical Advisory Group (UKTAG CTT) the study was reassessed to be 4, unassignable, based on a lack of information. The UKTAG CTT cited a lower toxicity endpoint, as reported in EPP (2018a), and assessed to be reliable with restrictions, of **0.078 µg/L** based on the 96-hour LC_{50} on the same mysid species. The LC_{50} value is slightly extrapolated as per the 50% mortality range (UKTAG, 2019) and the NOEC generated (0.022 µg/L) was much lower than the tested concentrations and therefore not useable (as per TGD, 2018).

The available data includes at least one short-term L(E)C_{50} from each of three trophic levels of the base set (fish, crustaceans, and algae) plus two or more short-term L(E)C_{50}s from additional specific saltwater taxonomic groups, resulting in an AF of 10. The derived value is 0.078 µg/L divided by an AF of 10, resulting in a **MAC-EQS of 0.0078 µg/L (7.8 ng/L)**.

Determination of the Pelagic AA -EQS

There are not enough data available to statistically compare chronic seawater and freshwater data sets to determine differences in sensitivities, so data are collated by default.

The lowest toxicity endpoint, as reported by the US EPA (2009) is 0.0087 µg/L based on the 28-day NOEC for the mysid shrimp species, *Americamysis bahia* (similarly to SEPA (2017)). This report was found to contain too little information about the study and was assessed by UKTAG CTT as 4 – unassignable. The US EPA (US EPA, 2008 and 2009) also acknowledged that the study had limitations and reported highly erratic test concentrations and measurements made of dissolved and sorbed material; thus, true dissolved concentrations and toxicity parameters may be lower than reported. US EPA experts have used this value in the environmental risk assessment for EMB in the USA.

Therefore, the lowest toxicity endpoint, reported by EPP (2018b) as cited and assessed by the UKTAG CTT (2019) to be 2, reliable with restrictions, is **0.00944 µg/L** based on a 28-day EC_{10} of *Americamysis bahia*. The available data includes two long term results from freshwater or saltwater species representing two trophic levels (crustaceans, fish) plus one long-term result from an additional taxonomic group (molluscs) requiring an AF of 50 (TGD, 2018). The derived value will be 0.00944 µg/L divided by an AF of 50, resulting in an **AA-EQS of 0.19 ng/L**.

Determination of the Benthic EQS

There are not enough data available to statistically compare seawater and freshwater data sets for sediments as can be clearly illustrated by the aggregated values in the Table 3-D in the Appendix. The aggregation needs to be considered with caution.

The only reliable chronic sediment study available to SEPA (2017) and subsequent peer review was the 28-day emergence test with the freshwater midge *Chironomus riparius*. In the UKTAG

report (2020) three additional industry-generated chronic studies are available, two in the marine amphipod *Leptocheirus plumulosus* (EPP, 2018e; EAG, 2018) and one in the marine amphipod *Corophium volutator* (Scymaris, 2018). In addition, the industry conducted an additional acute toxicity study in the lugworm *Arenicola marina* (EPP, 2018c) and an acute toxicity study with the same *Corophium* amphipod species (EPP, 2018d) as the chronic study. However, results of long-term toxicity tests with sediment organisms are preferred for deriving sediment standards due to the generally long-term exposure of benthic organisms to sediment bound substances (TGD, 2018).

The new studies all followed accepted international or national (US EPA) guidelines except for the chronic *Corophium* study, the protocol for which was based on well-documented literature sources. In addition, given the new studies in marine organisms an assessment of the relevance of freshwater insect species for the marine environment is necessary (UKTAG, 2020). The available updated reliable and relevant chronic dataset includes studies in three species are as follows:

- 28-day chronic toxicity to freshwater midge *Chironomus riparius* (SEPA, 2017)
- 28-day chronic toxicity to the marine amphipod *Leptocheirus plumulosus* (EPP, 2018e)
- 28-day life cycle toxicity to the marine amphipod *Leptocheirus plumulosus* (EAG, 2018)
- 28/75-day chronic toxicity to the marine amphipod *Corophium volutator* (Scymaris, 2018)

According to TGD (2018), “one long term freshwater and one saltwater sediment test representing different living and feeding conditions” leads to an assessment factor of 100 while “three long term sediment tests with species representing different living and feed conditions” gives an assessment factor of 50 (Table 5). The presence of an additional marine test does not justify an AF of 10 considering that living conditions of amphipods are similar. The “default” position would be to apply an assessment factor of 100 to the chironomid data, on the basis that the life history of the midge is significantly different to that of the marine amphipods. However, based on the supporting sub-lethal effects data from the acute *Arenicola* study, and the fact that the freshwater data represent a taxon known to be sensitive to the substance’s mode of action, an AF of 50 is acceptable (UKTAG, 2020).

Therefore, the lowest toxicity endpoint, as reported by EFSA (2012) and assessed by SEPA to be reliable with restrictions, of 1.175 ug/kg dry weight based on the 28-day NOEC of the *Chironomus riparius* will be used with an AF of 50. The derived value is 1.175 ug/kg divided by an AF of 50, resulting in a **benthic EQS of 23.5 ng/kg for near-field** (presently SEPA threshold beyond the mixing zone).

As stated above, more conservative approaches (by dividing by 10) are suggested for the far-field (SEPA, 1999). The near field EQS is described as being used to trigger additional monitoring in the far field for compliance assessment by SEPA, it is not clear how assessment factors, and so the relationship between the near field and far field EQS, were decided in derivation of the SEPA, 1999 initial standards for which there is a factor of ten difference. It is likely that relationships between “Allowable Zone of Effect” (i.e., the seabed area immediately impacted in a fish farm cage) concentrations and the “far field” EQS compliance will vary from farm to farm depending on specific issues related to the farm itself and environmental factors of the local area, many of which could be modelled. A single “near field” EQS will likely ensure at all farms on the one hand adequate far field protection and on the other avoidance of wasted resources in unnecessary additional monitoring (UKTAG, 2020).

In term of field environmental values, the results of Ikonomou and Surridge (2013) show sedimentary EMB concentrations of 0.051 to 35 ng/g wet weight were measured within 50 to

100m from cages while Hamoutene et al. (2018) detected EMB in a production site with a range varying from 1.13 to 41.78 ng/g dry weight. In a latest survey of Scottish sites (Bloodworth et al., 2019) EMB concentrations generally followed a spatial gradient linked to distance from cages, with the highest concentrations found in the immediate vicinity of the cages. Approximately 7% of the samples beyond 100 m from the cages (where the EQS applies) were above the 1999 SEPA EQS (0.763 µg/kg wet weight), whilst 17% of cage edge samples were above the cage edge trigger value (7.630 µg/kg wet weight). This highlights that some of the field measurements in these surveys would exceed the thresholds as determined.

In summary, the derived EQS values for EMB are:

In water:

- MAC-EQS: 7.8 ng/L
- AA-EQS of 0.19 ng/L

In sediment:

- Benthic EQS: 0.0235 µg/kg: 23.5 ng/kg (far-field) (no other suggested threshold as per the UKTAG recommendations). This point should be further debated among experts and regulators.

The detection limits in sediment matrices (as per the methodology described in paper Wong et al., 2022) are method detection levels (MDL) of 0.063 ng/g for EMB and a LOQ (limit of quantification) of 0.203 ng/g. A lower limit of detection (LOD) (0.00068 ng/g) was determined as part of the method described in Hamoutene et al. (2018). Similarly, the analytical method used by SEPA has a LOD of 0.0034 µg/kg dry weight (Bloodworth et al., 2019; SEPA, 2019).There should be no technical limitations in detection in implementing the thresholds.

As for water detection, limits of quantification (LOQs) for EMB were 0.006 ng/L (ppt) as per Ikonomou and Surridge (2013) using a highly sensitive analytical method based on high-performance liquid chromatography/electrospray ionization-tandem mass spectrometry (LC/ESIMS/MS). This detection limit should not be a barrier to the implementation of the pelagic EQS threshold as defined.

Table 14. Summary of EQS values derived for emamectin benzoate.

EQS Type	Value	Three lowest endpoints	Assessment Factor; Rationale	Notes, limitations
MAC-EQS	7.8 ng/L	0.078 µg/L (96-h LC_{50}, *Americamysis bahia*; EPP, 2018a; 2, Reliable with restrictions) 0.12 µg/L (48-h EC_{50}, *Pseudocalanus elongatus*; Willis and Ling, 2003; 2, Reliable with restrictions) 0.23 ug/L (48-h EC_{50}, *Temora longicornis*; Willis and Ling, 2003; 2, Reliable with restrictions)	50; Available marine data include at least one short-term test from three trophic levels (fish, crustaceans, and bacteria) + one short-term test from an additional taxonomic group (molluscs), and representative species for most sensitive taxonomic group is included in the dataset (crustaceans)	Derived using collated seawater and freshwater data

EQS Type	Value	Three lowest endpoints	Assessment Factor; Rationale	Notes, limitations
AA-EQS	0.087 ng/L	0.00944 µg/L (28-d EC_{10}, *Americamysis bahia*; EPP, 2018b; 2, Reliable with restrictions) 0.018 µg/L (28-d NOEC, *Americamysis bahia*; US EPA, 2009; 2, Reliable with restrictions) 0.05 µg/L (7-d NOEC, *Acartia clausi*; Willis and Ling, 2003; 2, Reliable with restrictions)	100; Available data include long-term results from three freshwater or saltwater species representing three trophic levels (plants, insects, crustaceans and fish)	Derived using collated seawater and freshwater data
Benthic EQS	Far field only as per UKTAG (2020) recommendation: 23.5 ng/kg	1.175 µg/kg dry sediment (28-d NOEC, *Chironomus riparius*; EFSA, 2012; 2, Reliable with restrictions) 17.6 µg/kg dry sediment (28-d EC_{10}, *Leptocheirus plumulosus*; EPP, 2018e; 2, Reliable with restrictions). 19.9 µg/kg dry sediment (10-d NOEC, *Arenicola marina*; EPP, 2018c; 2, Reliable with restrictions)	50; Three long term sediment tests with species representing different living and feed conditions.	Derived using collated seawater and freshwater data The presence of an additional marine test does not justify an AF of 10 considering that living conditions of amphipods are similar.

References and reliability assessments are stated between brackets.

Ivermectin

Formulation and application

Ivermectin (commonly used formulation: Ivomec®) is an avermectin; it contains at least 80% of 22,23-dihydroavermectin B1a and not more than 20% of 22,23_dihydroavermectin B1b (Tway et al., 1981). A typical treatment (from June to November) with ivermectin ranges from 50 µg/kg of fish biomass when administered twice weekly within a 1-week interval to 200 µg/kg of fish biomass when treated every two weeks (Davies and Rodger, 2000).

Solubility and mode of action

Ivermectin is soluble in most organic solvents and has low solubility in water (SEPA, 1998b). It has a strong affinity to lipid, soil, and organic matter (Tomlin, 1997). The log of the octanol-water partition coefficient (K_{oW}) for ivermectin is 4.1 (Pub Chem, 2018). Based on this information we will derive an EQS for both the water and sediment compartments. In studies with zebrafish, BCF of 63–111 for ivermectin was determined (Rombke et al., 2018). Davies et al. (1997) calculated a BCF of 750 for mussels after exposure to ivermectin over a six-day period.

Ivermectin is a broad-spectrum anti-parasite medication part of the avermectins family of compounds. Ivermectin causes an influx of ions through the cell membrane of invertebrates by activation of specific ivermectin-sensitive ion channels (Davies and Rodger, 2000). This mode of action is not specific to parasitic nematodes and arthropods and ivermectin may, thus, affect other non-target invertebrates when it reaches the environment (Garric et al., 2007). More polar degradation products of Ivermectin (monosaccharide and aglycone), detected as transformation products in soil, have been found to be less toxic to daphnids than parent compounds (Halley et al., 1989a).

Ivermectin EQS in other jurisdictions

Ivermectin is not authorized for use in Irish aquaculture (Browne and Deegan, 2006). Similarly, Ivermectin is not currently authorized for use in Scottish aquaculture; however, it was used in the 1990's and tentative EQSs were proposed at the time. For the protection of freshwater life, an AA-EQS 0.01 ng/L and a MAC-EQS of 1 ng/L were suggested. These were derived by applying a safety factor of 100 and 10, respectively, to the 48-hour LC_{50} of 0.0158 µg/L for the water flea species *Daphnia magna* (SEPA, 1998 cited confidential data). For the protection of saltwater life, an AA-EQS of 1 ng/L and a MAC-EQS of 10 ng/L were proposed. These were derived by applying safety factors of 100 and 10, respectively, to a 96-hour LC_{50} of 0.07 µg/L for a mysid shrimp species *Neomysis integer* (Davies et al., 1997).

Determination of the Pelagic MAC-EQS

Using the lowest endpoints per species, and after testing for equality of variance we completed a t-test on the ivermectin freshwater and seawater acute toxicity data (P=0.027, Table 12).

Table 15. Comparison of acute ivermectin freshwater and seawater pelagic toxicity endpoints (data are normally distributed).

-	**Freshwater Pelagic data**	**Seawater Pelagic data**	**T-test**
Number of observations	N= 5	N= 10	P=0.027
Average (µg/L)	85.46	390.71	

Significant differences exist between the two data sets not allowing us to collate the data. We will be deriving a MAC-EQS using only the seawater data set. These comparisons must be taken with caution as the taxa representation differs between saltwater and freshwater datasets.

For the acute seawater data, the lowest endpoint, as reported by SSGA (1996) and cited and assessed by SEPA (1998b) as reliable with restrictions, is **0.07 µg/L**, based on the 96-hour LC_{50} of the mysid species, *Neomysis integer*. The seawater data set contains one short-term $L(E)C_{50}$ from one levels of the base set (crustaceans) plus more than two short-term $L(E)C_{50}$s from additional specific saltwater taxonomic species belonging to the mollusca taxa group. Although the seawater and freshwater datasets were not collated, the freshwater data can still be used to support the assessment factor. The available freshwater data includes at least one short-term endpoint from each of the three trophic levels of the base set (algae, crustaceans, and fish). Based on the available data, an AF of 10 can be used. The use of an AF of 10 is further justified considering the algae group (as per the freshwater tests) is not among the most sensitive groups to ivermectin exposure. Therefore, the derived value will be 0.07 µg/L divided by an AF of 10, resulting in a **MAC-EQS 0.007 µg/L (7 ng/L).** This value is equivalent to the one proposed within the SEPA document (SEPA, 1998b).

An important point to note on ivermectin water toxicity is that the water column exposure for ivermectin is likely not a relevant exposure route as ivermectin sorbs to organic matter and soil with a low potential of desorption (Krogh et al., 2008). Davies et al. (1997) conducted an initial assessment of the potential risk to the marine environment of dissolved ivermectin used on fish farms and concluded that the potential hazard via this route would be small with unlikely acute toxic effects. More information on the water column concentrations during different treatment scenarios might be required to further support the usage of this standard. Information on ivermectin mechanisms of action, eco-toxicological risks, and biological effects in targeted and non-targeted species remains unknown and requires further research (Bai and Ogbourne, 2016).

Determination of the Pelagic AA-EQS

Chronic tests were only available for freshwater species (only two data points). The lowest endpoint, as cited in Garric et al. (2007) is 0.0003 ng/L, based on a 21-day NOEC for *Daphnia magna.* The reliability of the Garric et al. (2007) study was assessed within this document using the CRED risk assessment and found to be reliable with restrictions; this assessment is supported by the inclusion of the data in the Environmental Risk Assessment of Ivermectin by Liebig et al. (2010). The Garric study on ivermectin water toxicity is based on concentrations determined through calculations with values below the detection limit of the compound. Any ecotoxicity study not supported by analytical data (i.e., endpoint concentrations reported as nominal values) would automatically be excluded from the most reliable studies to be used for EQS inference (TGD, 2018). However, studies can eventually be used (Lepper, 2005) if enough supporting information provide reliable ranges of toxicity as nominal concentrations will usually overestimate the final concentration (TGD, 2018).

In the light of the differences in sensitivity between freshwater and seawater species (previous table for acute endpoints) and the fact that the only chronic endpoint is a freshwater endpoint based on a nominal concentration we will use seawater acute endpoint to derive a pelagic EQS values at this stage.

The lowest short-term endpoint, as reported by SSGA (1996) and cited and assessed by SEPA (1998b) as reliable with restrictions, is 0.07 µg/L, based on the 96-hour LC_{50} of the mysid species, *Neomysis integer* (as outlined above). The saltwater acute dataset has representation from one taxonomic group (crustaceans) of one trophic level, plus two or more endpoints from additional marine taxonomic groups (molluscs). Although the seawater and freshwater datasets were not collated, the freshwater data can still be used to support the assessment factor. The available freshwater data includes at least one short-term endpoint from each of the three trophic levels of the base set (algae, crustaceans, and fish). Based on the available data, an AF of 1000 can be used; however, the assessment factor may be lowered if multiple data points are available for the most sensitive taxonomic group (i.e., the group showing acute toxicity more than 10 times lower than for the other groups) which seems to be the case for crustaceans and therefore, an AF of 100 will be used. The derived value will be 0.07 µg/L divided by an AF 100, resulting in an **AA-EQS of 0.0007 µg/L (0.7 ng/L)**.

Determination of the Benthic EQS

With only three data points (lowest and useable values) for the freshwater data set no comparisons can be completed on the benthic toxicity data sets for ivermectin.

After collating both freshwater and seawater data (this collation does not exclude the potential existence of differences between the two environments), the lowest seawater values (Table 4-E in the Appendix) are related to the *Arenicola marina* test (Thain et al., 1997) with a NOEC of 0.015 mg/kg. *A. marina* has been shown to be more sensitive to ivermectin via ingestion than

are other marine organisms for which published data are available (Burridge and Haya, 1993). In addition, in Thain et al. (1997) a reburial test with surviving worms indicated that prior exposure to concentrations of ivermectin above 0.008 mg/kg wet sediment adversely affected the ability of *A. marina* to subsequently burrow into clean sediment. *A. marina* produces casts of sediment which pass through the gut, primarily during feeding activity, but also as a consequence of burrow construction. Reduction in cast production not only implies a reduction of feed intake, but also a reduction in bioturbation of the sediment, and potentially, a reduction in aerobic metabolic processes in the sediment (Thain et al., 1997). The concentrations at which the behaviour of *A. marina* is changing are informative but were assigned a reliability score of 3 (not reliable) and are not considered in the EQS inference without a more in-depth dose-response and understanding of long-term consequences of reduction in casting and reburial.

The lowest freshwater value, as reported by Egeler et al. (2010), is 0.0031 mg/kg dry weight, based on the 10-day NOEC of the species *Chironomus riparius* (Egeler et al., 2010). The CRED risk assessment was used to assess the reliability of this study and it was found to be reliable. The NOEC for *Chironomus riparius* was related to larval dry weight (i.e., growth related). The collated data set includes three long-term sediment tests with species representing different living and feeding conditions (including two tests with the same marine species and considering 10 days exposures as chronic) resulting in an AF of 50. The derived value is 3.1 µg/kg dry weight divided by an AF of 50, resulting in a **near field benthic EQS of 0.062 µg/kg (62 ng/kg) dry sediment**. Further dividing the value by a factor of 10 results in a **far-field benthic EQS value of 0.0062 µg/kg (6.2 ng/kg) dry sediment**.

Cannavan et al. (2000) is one of the few studies that investigated the concentration of 22,23-dihydroavermectin B1a detected at a fish farm where ivermectin was orally administered. The mean concentration of 22,23-dihydroavermectin B1a detected in the six sediment cores taken directly under the cage block was 5.0 ng/g (or µg/kg) in the top 3 cm, 3.1 ng/g in the 3-6 cm layer, and 0.7 ng/g in the 6-9 cm layer (Cannavan et al., 2000). At depths below 9 cm, concentrations of 22,23-dihydroavermectin B1a were under the limit of quantitation with no detection in samples taken further than 31 m from the cage block (Cannavan et al., 2000). This suggests that the samples taken below the cages as per the aforementioned study would be lower than the suggested EQS.

In summary, the derived EQS values for ivermectin are:

In water (whether the water column exposure for ivermectin a relevant exposure route should be further debated):

- MAC-EQS: 7.0 ng/L
- AA-EQS of 0.7 ng/L

In sediment:

- Benthic EQS: 0.062 µg/kg dry sediment (near-field) and 0.0062 µg/kg dry sediment (6.2 ng/kg) (far-field)

If the detection limits in sediment matrices (as per the methodology described in Wong et al., 2022) are taken into account, the threshold values are lower than the limit of quantification (MDL of 1.23 ng/g and LOQ of 3.93 ng/g). Therefore there are potential technical limitations in detection as per the analytical method described in Wong et al. (2022). For water, the limit of detection (LOD) for ivermectin measurements is 0.2 ng/L as per Garric et al. (2007).

Table 16. Summary of EQS values derived for Ivermectin.

EQS Type	Value	Three lowest endpoints	Assessment Factor; Rationale	Notes, limitations
MAC-EQS	7 ng/L	0.07 µg/L (96-h LC_{50}, *Neomysis integer*; Davies et al., 1997; 2, Reliable with restrictions) 300 µg/L (96-h LC_{50}, *Pecten maximus*; SSGA, 1996 cited by SEPA, 1998b; 2, Reliable with restrictions) 380 µg/L (96-h LC_{50}, *Tapes semidecassata*; SSGA, 1996 cited by SEPA, 1998b; 2, Reliable with restrictions)	10; Available data includes at least one short-term endpoint representing three trophic levels of the base set (algae, crustaceans, and fish) plus one or more short-term endpoint from additional saltwater taxonomic species (molluscs)	EQS derived using only seawater data Seawater and freshwater data used to support AF usage Algae is not among the most sensitive taxonomic groups to ivermectin exposure, an application factor of 10 is justified for the derivation process.
AA-EQS	0. 7 ng/L	0.07 µg/L (96-h LC_{50}, *Neomysis integer*; Davies et al., 1997; 2, Reliable with restrictions) 300 µg/L (96-h LC_{50}, *Pecten maximus*; SSGA, 1996 cited by SEPA, 1998b; 2, Reliable with restrictions) 380 µg/L (96-h LC_{50}, *Tapes semidecassata*; SSGA, 1996 cited by SEPA, 1998b; 2, Reliable with restrictions)	100; With only one chronic, freshwater endpoint based on a nominal concentration, the lowest acute seawater endpoint was used to derive the annual average pelagic EQS value. The lowest short-term $L(E)C_{50}$ from the seawater dataset was selected. Available data includes at least one short-term endpoint representing three trophic levels of the base set (algae, crustaceans, and fish) plus one or more short-term endpoint from additional saltwater taxonomic species (molluscs)	EQS derived using only seawater data Seawater and freshwater data used to support AF usage Algae is not among the most sensitive taxonomic groups to ivermectin exposure, an application factor of 100 is justified for the derivation process.
Benthic EQS	Near field: 0.062 µg/kg dry sediment Far field (/10): 0.0062 µg/kg dry sediment	0.0031 mg/kg (10-d NOEC, *Chironomus riparius*; Egeler et al., 2010; 2, Reliable with restrictions) 0.015 mg/kg (10-d NOEC, *Arenicola marina*; Thain et al., 1997; 2. Reliable with restrictions) 0.018 mg/kg wet weight (10-d LC_{50}, *Arenicola marina*; SSGA, 1996	50; Available data include three long-term sediment tests with species representing different living and feeding positions (insects, nematodes, annelids, crustaceans, echinoderms) including a minimum of two tests with marine species (10-d exposures considered as chronic)	Derived using collated seawater and freshwater data Threshold values are lower than the limit of quantification (MDL of 1.23 ng/g and LOQ of 3.93 ng/g) and therefore there are

EQS Type	Value	Three lowest endpoints	Assessment Factor; Rationale	Notes, limitations
		cited by SEPA, 1998b; 2, Reliable with restrictions)		potential technical limitations in detection.

References and reliability assessments are stated between brackets.

Teflubenzuron

Formulation and application

The active ingredient in Calicide® is teflubenzuron (0.2%w/w). Teflubenzuron (CAS No. 83121-18-0) is an acyl urea insecticide. Medicated feed is prepared by coating commercial fish feed pellets with teflubenzuron (at least 95% chemically pure) as a powder to a concentration of 2 g/kg feed. Spraying the diet with fish oil increases the adherence of the material to the feed pellet. The intended oral dose is 10 mg teflubenzuron per kg of fish biomass once daily for seven consecutive days (FAO, 2016).

Solubility and mode of action

Teflubenzuron has low water solubility, a strong affinity to organic substrates in water and sediments, and it, along with its degradation products, have been found to be more persistent in sediment than in water alone (SEPA, 1998c). The solubility of 19 mg/L and partition coefficient (Log K_{oW}) of 4.3 also indicate a potential to persist in sediments (Tomlin, 1997). The BCF for teflubenzuron for fish is equivalent to 300 while Brooks et al. (2019) found a BCF value of 1304 for mussels (kinetic BCF) through water exposure. Half-lives for teflubenzuron are around 92 days and 7.3 days in soil, and water, respectively. Therefore, an EQS for both water and sediments will be determined.

Teflubenzuron is a chitin synthetase inhibitor that interferes with the production of the chitin exoskeleton and thus molting that occurs between life stages in the sea lice. Due to its very specific mode of action, teflubenzuron is relatively non-toxic to fish and algae, but is likely to have adverse effects on many non-target insects and crustacean where chitin synthesis is an important part of growth. The toxicity data gathered for teflubenzuron was lacking primary references and contained mostly reports that were classified as confidential and not accessible for consultation.

Teflubenzuron EQS in other jurisdictions

Teflubenzuron is not currently used in Scotland; the last usage was in 2013 prior to the marketing authorisation holder withdrawing the product from the market. The SEPA EQS were 10 mg/kg (dry weight) for near field (under cage) and 2.0 µg/kg for far field (SEPA, 2005). The 2.0 µg/kg for far field standard was derived from chronic life-cycle data as measured dry weight sediment concentrations on the 28-day NOEC to sediment dwelling amphipod *Corophium volutator* - a crustacean species (SEPA, 1999) using a x10 safety factor. The 10 mg/kg (dry weight) near field standard was derived from sediment toxicity data (nominal concentrations) for *Arenicola marina* using a x1000 safety factor. It was considered that this latest standard may be further refined and that the suitability of this value needed to be assessed (SEPA, 1999).

The SEPA threshold concentration of teflubenzuron in water is 0.03 µg/L (30 ng/L) as the maximum allowed concentration in a water body and 0.006 µg/L (6 ng/L) as an average allowable concentration in a water body (Henderson and Davies, 2000; SEPA, 2014). These standards were derived from chronic life-cycle data in a 27-day study for *Mysidopsis bahia* (Baird et al., 1997) and applying a x2 safety factor for the annual and a x10 safety factor for the

MAC. It is important to highlight the fact that we could not consult the Baird study as the document was classified as confidential and therefore cannot comment on details of this study (the reference was copied from the SEPA report).

For Norway, the recently suggested EQS for water and biota (submitted to the Norwegian Environment Agency) propose EQS-seawater values for teflubenzuron and diflubenzuron. For teflubenzuron, an annual average EQS and maximum allowable water concentration EQS of 2.5 ng/L and 12 ng/L, respectively, have been put forward. The AA-EQS was based on a mesocosm study completed on crustaceans resulting in a NOEC of 0.005 µg/L and suggested an AF of 2 (EFSA, 2008a). AA-EQS was set to 0.005/2 = 0.0025 µg/L (Miljødirektoratet, 2014). For sediments, the proposed EQS is 0.0004 µg/kg: 0.4 ng/kg (Miljødirektoratet, 2014). These EQS values have been proposed to the Norwegian Environment Agency (Miljødirektoratet, 2014) and have, to our knowledge, not officially been adopted by Norway (Macken et al., 2015).

However, studies examining the effects of teflubenzuron on non-target crustaceans have identified several knowledge gaps, among which include dosage levels that will induce mortality following long-term exposure of crustaceans to this therapeutant. In particular, there is a lack of known studies on the NOEC, EC_{50} or LOEC (Lowest-observed-effect Concentration) effects of teflubenzuron on American lobster.

Determination of the Pelagic MAC-EQS

When considering the lowest endpoints for every species, there are not enough endpoints in the acute toxicity dataset to compare freshwater and seawater sensitivities of organisms; therefore the seawater and freshwater data will be collated.

The lowest seawater toxicity endpoint, as reported in Macken et al. (2015), is 0.0032 µg/L (measured concentrations) based on the 7-day NOEC of the copepod species, *Tisbe battagliai*. The CRED risk assessment was used to assess the reliability of the study and it was found to be reliable. The available data include at least one short-term test from each of the three trophic levels of the base set (fish, crustaceans, plants) including two or more short term endpoints from an additional specific saltwater taxonomic group (crustaceans), resulting in an AF of 100. With the additional seawater data points being related to crustaceans, which are the most sensitive group, the AF may be lowered to 50. The derived value is 0.0032 µg/L divided by an AF 50, resulting in a **MAC-EQS of 0.06 ng/L**. This value is in accordance with the predicted no-effect concentration for seawater suggested by Macken et al. (2015) in the *Tisbe battagliai* study.

Both the target organism (the sea lice) and the non-target organism (*T. battagliai*) have similar life cycles and require chitin to develop through several morphologically different life stages (Macken et al., 2015). Teflubenzuron has low water solubility, is relatively hydrophobic and may therefore bind to particles and end up in the sediment. Because of its epibenthic nature, *T. battagliai* is a relevant test species to assess the environmental hazard of these test substances as it is present at the sediment–water interface and may be exposed to both water-soluble and particle-bound contaminants (Macken et al., 2015).

The EQS value obtained is lower than the one proposed to the Norwegian Agency as per the report Miljødirektoratet (2014) (12 ng/L) and the SEPA value (30 ng/L). The EQS derived in this document relied on more recent literature data (e.g., Macken et al., 2015) and the application of a different AF.

An important point on teflubenzuron water toxicity is that water column exposure is not likely a relevant exposure route as teflubenzuron has low water solubility and sorbs to organic substrates in water and sediment (SEPA, 1998c). This was demonstrated by Medeiros et al. (2013) in an acute toxicity study on freshwater pelagic organisms exposed to teflubenzuron both in the presence and absence of sediment. The results showed that the presence of sediment

caused up to a 78% reduction in estimated EC_{50} values (Medeiros et al., 2013). More information on the water column concentrations during different treatment scenarios may be required to further support the usage of this standard.

Determination of the Pelagic AA-EQS

To our knowledge, only one chronic marine and one chronic freshwater data were available for pelagic species. Based on the data available (two long-term results applicable to a sensitive taxonomic group), with additional short-term tests (fish and plants for freshwater) indicating that these groups are not the most sensitive group (TGD, 2018) the AF of 500 can be lowered to 100 and applicable. Assessment factors can be lowered if multiple data points are available for the most sensitive taxonomic group (TGD, 2018) especially in light of the drug specific mode of action. The lowest chronic endpoint, as reported by Drottar and Swigert (1996) and cited by EFSA (2008a), is 0.043 µg/L based on the 27-day NOEC for the mysid species *Mysidopsis bahia*. This study was assessed by EFSA experts to be reliable. The derived value will be 0.043 µg/L divided by an AF of 100, resulting in an **AA-EQS of 0.43 ng/L**. This value is lower than that proposed within the Norwegian context of 2.5 ng/L and the SEPA AA-EQS of 6 ng/L.

The AA-EQS value obtained through this process is higher than the MAC-EQS value obtained as per the usage of Macken et al. (2015) findings. When data are sparse or the ratio between acute effects and chronic effects is narrow, the estimated MAC-EQS can sometimes be more stringent than the AA-EQS. It is also possible that the effects observed in chronic studies are due to the initial contact with the test substance, rather than to prolonged exposure. The mortality calculated for the *Mysidopsis bahia* study (0.063 µg/L) is similar to the 7-day acute Mysid (juvenile) study where the LC_{50} was reported 0.057µg/L; this indicates that effects observed in the chronic study may be associated with acute effects at key points within the study (potentially during moulting). When the MAC-EQS is lower than the AA-EQS, a further analysis should be presented to discuss the possible causes. Since the effects of chronic exposure normally occur at lower concentrations than those of acute exposure, MAC-QS values below the AA-EQS has no toxicological logic. A recommendation of the TGD (2018) is to set a MAC-EQS equal to AA-EQS. We will keep both values in the document and add this recommendation in the summary table (Table 17).

Predictions regarding teflubenzuron toxicity are that effects would occur in sediment reworking species in the intermediate area around treated cages and that impacts may persist for up to 6 months as teflubenzuron degrades (SEPA, 1999). Teflubenzuron has been measured under field conditions. Measured levels of teflubenzuron in the water were the highest at the treatment site one day after treatment, three meters below the surface and equaled 0.0355 µg/L. Values were between 0.01-0.03 µg/L at 50 m offshore from the site and non-detectable at 50 m inshore and 100 m inshore (Cantox, 1997). As per these concentrations and based on the NOEC of *Mysidopsis bahia,* teflubenzuron in water is not expected to impact this species (Skretting, 2011).

Determination of the Benthic EQS

The data available on benthic organisms are quite limited. Four sediment toxicity results were found in the literature: a 28-day NOEC for *Chironomus riparius* (freshwater) with a result of 0.05 mg/kg dry sediment (EFSA, 2008a); a 28-day NOEC for *Corophium volutator* (amphipod/crustacean, seawater) of 17.3 µg/kg dry sediment (this data point was reported by Glass, 1997 and cited in SEPA, 2009 and used to calculate EQS values in SEPA but the original study was not available for consultation); a 10-day mortality study on *Capitella* sp. (polychaeta/annelida, seawater) of 25,000 µg/kg dry sediment; a 10 day *Arenicola* study (LC_{50} > 10000 mg/kg) (Table 5-D in the Appendix). However, the *Capitella* sp. study does not include a NOEC or EC_{10}, without these endpoints it can only be used as supporting information and is not

suitable for derivation of an EQS (TGD, 2018). Similarly, the *Arenicola* study is only a supporting data point.

Therefore, only two long-term studies exist for two different benthic animals representing different living and feeding conditions (one freshwater insect and one saltwater crustacean), requiring an AF of 100 (TGD, 2018). Therefore, using the lowest toxicity endpoint of 17.3 µg/kg dry sediment based on the 28-day NOEC, assessed by SEPA to be reliable with restrictions and dividing it by an AF of 100 results in a **near field benthic EQS of 0.173 µg/kg.** Further dividing the value by a factor of 10 results in a **far-field benthic EQS value of 0.017 µg/kg (17 ng/kg)**. These values are lower than the SEPA value but still higher than the Norwegian EQS value (we found no information on the inference of this proposed value) (0.4 ng/kg) cited in Macken et al. (2015) and not yet adopted by Norway.

In term of field studies, Langford et al. (2014) found median concentrations of 10.5 and 65.2 ng/g (µg/kg dry weight) after sampling sediment at two fish farms in Norway indicating values above the EQS of 0.173 ng/g.

In summary, the derived EQS values for teflubenzuron are:

In water:

- MAC-EQS: 0.06 ng/L. This value is lower than the AA-EQS; a recommendation would be to adopt a unique threshold.
- AA-EQS of 0.43 ng/L

In sediment:

- Benthic EQS: 0.173 µg/kg dry sediment (near-field) and 0.017 µg/kg dry sediment (far-field)

The current analytical methods for teflubenzuron by LC-MS can achieve limits of detection of 2 ng/L (ppt) in sea water (SEPA, 1999) rendering any of the EQS values selected impossible to implement. In addition to the questions raised above on environmental relevance the technical limitations represent another challenge suggesting the need to reconsider the water compartment EQS. The possibility of adopting the values suggested by SEPA or Norwegian experts could be an option. Residues of teflubenzuron in surface, ground and drinking water can also be determined by HPLC-UV with a LOQ of 0.1 µg/L, European experts concluded that the regulatory acceptable concentration for aquatic invertebrates is 0.0025 µg/L as per the Norwegian proposed standards. As a consequence a data gap was identified by EFSA for an analytical method to determine teflubenzuron residues in surface water with an LOQ of 0.0025 µg/L (EFSA, 2008a).

If we take into account the detection limits in sediment matrices (as per the methodology described in Wong et al., 2022) the threshold values for near and far-field are lower than the LOQ (0.36 to 1.89 ng/g depending on the type of sediment matrices).

Table 17. Summary of EQS values inferred for Teflubenzuron.

EQS Type	Value	Three lowest endpoints	Assessment Factor; Rationale	Notes, limitations
MAC-EQS	0.064 ng/L	0.0032 µg/L (7-d NOEC, *Tisbe battaglia*i; Macken et al., 2015 ; 2, Reliable with restrictions)	50; Available data include at least one short-term test from each of the three trophic levels of the base set (fish, crustaceans,	Derived using collated seawater and freshwater data

EQS Type	Value	Three lowest endpoints	Assessment Factor; Rationale	Notes, limitations
		0.01 µg/L (7-d LOEC, *Tisbe battagliai*; Macken et al., 2015 ; 2, Reliable with restrictions) 0.057 µg/L (7-d LC50, *Mysidopsis bahia*; Skretting ARC, 2011; 2, Reliable with restrictions)	plants) requiring an AF of 100 lowered to 50 due to the adequate representation of the most sensitive taxonomic group	This value is lower than the AA-EQS; a recommendation would be to adopt the AA-EQS as a unique threshold. Caution and additional interpretation are required to justify this potential adoption.
AA-EQS	0.43 ng/L	0.043 µg/L (27-d NOEC, *Mysidopsis bahia*; EFSA, 2008a; 2, Reliable with restrictions) 0.062 µg/L (21-d NOEC, *Daphnia magna*; EFSA, 2008a; 2, Reliable with restrictions)	100; Available data include two long-term results for freshwater or saltwater species representing a sensitive taxonomic group (crustaceans), with additional short-term tests on freshwater taxonomic groups (fish and plants) confirming they do not represent sensitive taxonomic groups	Derived using collated seawater and freshwater data
Benthic EQS	Near field: 0.173 µg/kg Far field (/10): 0.017 µg/kg	17.3 µg /kg dwt (28-d NOEC, *Corophium volutator*; SEPA, 1999; 2, Reliable with restrictions) 50 µg /kg dwt (28-d NOEC, *Chironomus riparius*; EFSA, 2008a; 2, Reliable with restrictions) 8400 µg /kg dwt (10-d sublethal effects level, *Capitella* sp. I; Mendez, 2005; 2, Reliable with restrictions)	100; One long-term freshwater and one saltwater sediment test representing different living and feeding conditions	Derived using collated seawater and freshwater data Both thresholds are lower than the detection limits in sediment matrices and therefore there are potential technical limitations in detection.

References and reliability assessments are stated between brackets.

Lufenuron

Formulation and application

The product (IMVIXA®) has been registered under emergency usage in Canada and is used only in freshwater (hatchery) prior to sea water introduction. The prescribed treatment is 5 mg (lufenuron) per kg body weight (BW) until 35 mg/kg BW have been delivered. Treatment must

last at least seven days and may be extended up to 14 days to ensure that the 35 mg/kg BW has been delivered. Administration of lufenuron occurs in the hatchery, thereby eliminating the most significant contribution of in-feed drug release to the environment (Poley et al., 2018). The drug protects fish whilst they are in seawater, facing continual sea-lice pressure. When treated fish are moved to marine sites, it is expected that one main route of entry into the environment will be in excreta from fish over an extended period with the released lufenuron present in feces (McHenery, 2016).

Solubility and mode of action

Lufenuron is a member of the benzoyl-phenyl-urea class of compounds and acts as a chitin synthesis inhibitor; it is classified as a growth regulator for animals with a chitin exoskeleton. As such it will not affect adult sea lice which no longer moult but should prevent sea lice from getting to the adult stage. Lufenuron also has low water solubility and high octanol-water partition coefficient (K_{oW}: 5.12), indicating that it has the potential to be absorbed to particulate material and surfaces and that it will be tightly bound to marine sediments with little or no mobility.

A study on 64 post-smolt salmon (*Salmo salar* L.) with a body weight of 107-185 g, housed in tanks with seawater, treated with [14C]-lufenuron show that fillet and pooled faecal samples extracted contain lufenuron after 178 days (Rath et al., 2017). Evidently, it is expected that the aqueous lufenuron concentrations in marine water will be reduced compared to that in freshwater due to dilution in the marine environment as well as decreasing excretion from fish on a per-day basis. Lufenuron in the marine environment would also undergo sorption to solids and partition to the sediment (McHenery, 2016). Its degradation half-life in water-sediment test systems ranges from 34 to 188 days (Brock et al., 2016; 2018). In bio-concentration studies with bluegill sunfish and fathead minnow, the BCF values for lufenuron were calculated to be 5,300 and 28,000, respectively (EFSA, 2008b). As stated above, the BCF values for lufenuron are above the thresholds (Table 2) and require that biota EQS should be part of next considerations by scientists and regulators.

Considering the K_{oW} and characteristics of lufenuron, we will be deriving an EQS for both the water and sediments compartments.

Lufenuron in other jurisdictions

Lufenuron has been approved for use in salmon aquaculture in Chile since November 2016 but has not been approved for use in treating salmon in the US, Scotland or Norway. It has been approved for clinical research trials in Canada and Norway and for Emergency Drug Release (EDR) in Canada (east and west coast).

Suggested regulatory acceptable concentrations for sediment-dwelling organisms (RACsed) in freshwater

The suggested values provided in Figure 2 were derived using the scientific findings of two main studies: Brock et al. (2016) and Brock et al. (2018). The study of Brock et al. (2016) was focussed on concentration-response relationships for lufenuron in sediment-spiked microcosms and in 28-day laboratory bioassays with standard freshwater benthic test species *C. riparius*, *H. azteca* and *Lumbriculus variegatus*. In the tests conducted by Brock et al. (2016), the plant protection formulated product, Match® was used. The acute toxicity tests in the study found the species *Daphnia magna* had a lower effect concentration when exposed to Match® in comparison to pure lufenuron (Brock et al., 2016). In Brock et al. (2018), 10-day and 28-day toxicity sediment-spiked laboratory bioassays with other benthic arthropods belonging to different taxonomic groups (Diptera, Ephemeroptera, Trichoptera, Megaloptera, Isopoda and Amphipoda) were completed. The values are expressed per weight of organic carbon (OC) in

dry sediment. In the field-collected sediment used for sediment toxicity testing 2.4% of the dry weight of the sediment was measured to be organic carbon (Brock et al., 2018). Brock et al. (2018) completed a full assessment as per figure 2. The Tier-1 (based on standard test species), Tier-2 (based on standard and additional test species) and Tier-3 (model ecosystem approach) regulatory acceptable concentrations (RACs) for sediment-spiked lufenuron did not differ substantially:

- The Tier-0 RAC_{sed} at equilibrium in Figure 2 is derived using a formula based on a RAC for seawater the pesticide properties and the Koc by selecting also the 21-d NOEC for Daphnia magna of 0.1 µg/L (EFSA, 2013; 2015; Brock et al., 2018). A short-coming of the equilibrium approach is that it neglects sediment ingestion as a relevant uptake pathway, as it only represents transfer occurring through passive partitioning between organic matter, water and lipids (EFSA, 2015).
- The Tier-1 is presently based the EFSA panel (EFSA, 2013) recommendation to use the 28-day sediment-spiked test with *Chironomus riparius* for substances with an insecticidal activity and the 28-day sediment-spiked *Lumbriculus* sp. test for active substances with a fungicidal activity with the application of an AF of 10.
- The Geo-mean approach is a Tier 2 option that can be used if, for taxa of the potentially most sensitive taxonomic group(s), more toxicity data are available than required for the Tier 1 assessment but less than required for the Species Sensitivity Distribution approach. When using the Geo-mean approach, the geometric mean $L(E)C_{50}$ value is calculated using all available $L(E)C_{50}$ values for different species belonging to the same taxonomic group (e.g., crustaceans, insects or oligochaete worms) and characterised by a comparable measurement endpoint (e.g., mortality and immobilisation) and test duration (e.g., 48 hours and 96 hours) (EFSA, 2015).
- The Tier-3 is the result of an SSD evaluation.

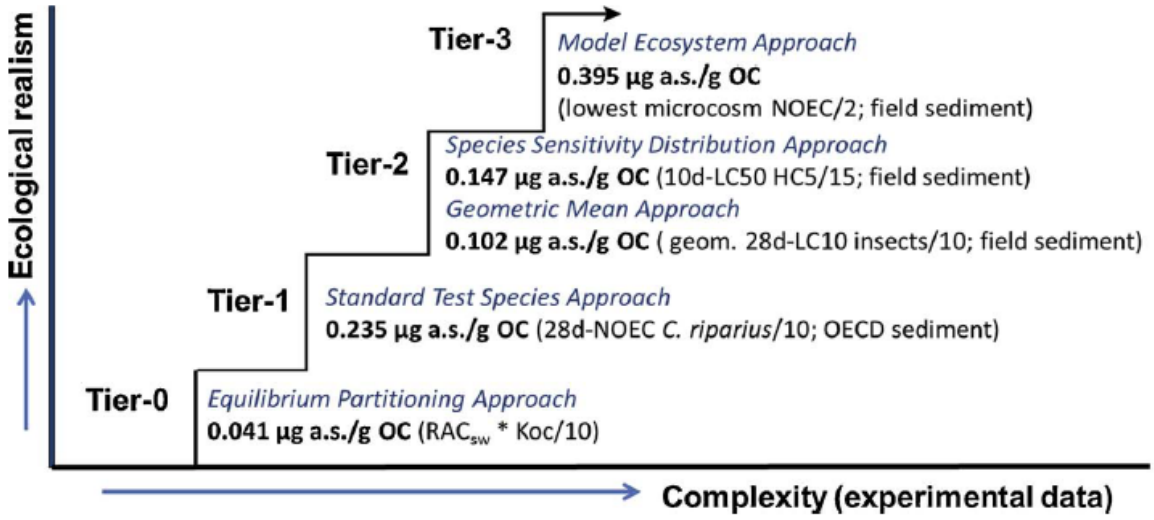

Figure 2. Overview of possible (RACsed) derived for several effect assessment tiers according to methods described in EFSA (2015) (copied from Brock et al., 2018).

Determination of the Pelagic MAC -EQS

The acute toxicity data available for lufenuron is only related to freshwater. The lowest acute endpoint, as reported by Syngenta and cited by the FAO (2008), is 1.1 µg/L based on the 48-

hour EC_{50} of the water flea species, *Daphnia magna* (Table 6-A in the Appendix). The study details are confidential and unavailable for consultation; however, it was used in the 2008 FAO evaluation of lufenuron and therefore considered reliable with restrictions.

The usage of *Daphnia magna* tests for inference of toxicity in the marine environment remains a controversial point. Within a study on offshore chemicals, Sverdup et al. (2002) concluded that for 25 of the 30 chemicals, *D. magna* was found to be less sensitive than the marine copepod by a factor > 2. This emphasises the importance of using marine data for environmental hazard classification as well as for environmental risk assessment purposes (Environment Canada, 1990; Sverdup et al., 2002). Poley et al. (2018) show that general effects of lufenuron on larvae and eggs of *L. salmonis* (representative of marine copepods) are similar to those previously observed for insects. However, authors still highlight the need to determine any taxa-specific effects of lufenuron on the chitin synthase which is the target of the benzoyl-phenyl-urea compounds considering it is multifunctional and that there is a large phylogenetic distance between copepods and insects.

The available toxicity data includes at least one short-term test from each of three trophic levels of the base set (fish, crustaceans and algae), with representative species for the most sensitive group included in the set (crustaceans), resulting in an AF of 100. The derived value will be 1.1 µg/L divided by an AF of 100, resulting in a **MAC-EQS of 0.011 µg/L (11 ng/L)**.

Determination of the Pelagic AA -EQS

Similarly to the MAC-EQS, the chronic data are limited and only related to freshwater endpoints representing two trophic levels: fish, crustaceans, and insects (Table 6-B in the Appendix).

The lowest chronic endpoint, as reported by Syngenta and cited by the FAO (2008), is 0.1 µg/L based on the 21-day NOEC of *Daphnia magna* (Table 6-B in the Appendix). The study details are confidential and unavailable for consultation; however, it was used in the 2008 FAO evaluation of lufenuron and therefore considered reliable with restrictions. The available toxicity data includes long-term results from freshwater species representing two trophic levels (insects/crustaceans and fish) requiring an AF of 500. However, assessment factors may be lowered if more than one data point is available for the most sensitive taxonomic group (TGD, 2011), especially in light of the drug specific mode of action, and therefore an AF of 100 will be applied. The derived value will be 0.1 µg/L (based on the NOEC for *Daphnia magna* similarly to the Tier- RAC selection) divided by an AF of 100, resulting in an **AA-EQS of 1 ng/L**.

In the spiked sediment trials conducted by Brock et al. (2016, 2018) the chemical analysis in water and sediment suggest that the majority of the spiked insecticide was not freely available in sediment pore water and overlying water after seven days of equilibrium following spiking. This confirms that pelagic exposure of non-target organisms is likely less environmentally relevant than the benthic one (Lopez-Mancisidor et al., 2008).

Determination of the Benthic EQS

The data related to lufenuron toxicity in sediments are based on a significant number of tests set in freshwater. Wheeler et al. (2002) used species sensitivity distributions to determine if freshwater datasets are adequately protective of saltwater species assemblages for 21 chemical substances. For pesticide and narcotic compounds, saltwater species tended to be more sensitive and a suitable uncertainty factor would need to be applied to surrogate freshwater data (Wheeler et al., 2002) requiring additional research.

The benthic EQS could be based on the values proposed in the Brock et al. (2018) assessment as per figure 2. The most conservative Tier 0 equals 0.984 µg/kg of dry sediment and the most relevant from an ecological point of view (for a freshwater ecosystem) is 9.48 µg/kg of dry

sediment. The Tier 2 value proposed by Brock et al. (2018) derived through a SSD approach (recommended path considering the number of tests completed within the study) would be appropriate. A deterministic approach would not be advisable considering the number of data points related to the sensitive groups likely targeted by lufenuron. The Tier 2 value is: **3.528 µg/kg of dry sediment**.

In summary, the derived EQS values for lufenuron are:

In water:

- MAC-EQS: 0.011 µg/L (11 ng/L)
- AA-EQS: 1.0 ng/L

In sediment:

- Suggested threshold as per the Brock et al. (2018) assessment (the Tier2 SSD): 3.528 µg/kg (for near field), to be divided by 10 for far-field: 0.353 µg/kg

The analytical methods described in Wong et al. (2022) yielded a MDL and LOQ for lufenuron of 0.067 and 0.217 ng/g, respectively. In Brock et al. (2016) the limits of detection and quantification of lufenuron in sediment were approximately 0.008 and 0.024 µg a.s./g OC/kg dry sediment, respectively. These values would not preclude the application of the thresholds cited above.

Table 18. Summary of EQS values derived for Lufenuron.

EQS Type	Value	Three lowest endpoints	Assessment Factor; Rationale	Notes, limitations
MAC-EQS	11 ng/L	1.1 µg/L (48-h EC_{50}, *Daphnia magna*; FAO, 2008; 2, Reliable with restrictions) 1.3 µg/L (48-h EC_{50}, *Daphnia magna*; FAO, 2008; 2, Reliable with restrictions; 2, Reliable with restrictions) 4 µg/L (48-h EC_{50}, *Daphnia magna*; FAO, 2008; 2, Reliable with restrictions)	100; Available data include at least one short-term L(E)C_{50} from each of the three trophic levels of the base set (fish, crustaceans, and algae), including representative species for the most sensitive taxonomic group (crustaceans)	Derived using freshwater data only
AA-EQS	1 ng/L	0.1 µg/L (21-d NOEC, *Daphnia magna*; FAO, 2008; 2, Reliable with restrictions) 2 µg/L (28-d NOEC, *Chironomus riparius*; FAO, 2008; 2, Reliable with restrictions) 4 µg/L (28-d NOEC, *Chironomus riparius*; FAO, 2008; 2, Reliable with restrictions)	100; Dataset includes long-term tests from freshwater species representing two trophic levels (insects/crustaceans and fish) and more than one data point is available for the most sensitive taxonomic group (insects/crustaceans).	Derived using freshwater data only EQS value should be taken with caution considering the absence of seawater data

EQS Type	Value	Three lowest endpoints	Assessment Factor; Rationale	Notes, limitations
Benthic EQS	3.528 µg/kg of dry sediment		The Tier 2 value proposed by Brock et al. (2018; 1, Reliable) inferred through an SSD approach (recommended path considering the number of tests completed within the study) would be appropriate. A deterministic approach is not advisable considering the number of data points related to the sensitive groups likely targeted by lufenuron. The Tier 2 value is: **3.528 µg/kg of dry sediment**	

While the data outlined in the previous sections have assisted in deriving standards, additional data that has been provided to regulators in Canada and in other jurisdictions for risk characterization and market authorization by regulators, were not accessible to the authors due to confidentiality issues. These data are likely to be highly relevant in determining environmental standards for this drug and therefore, should these data become accessible, the EQS derivation will need to be re-visited.

SUMMARY AND CONCLUSIONS

Environmental Quality Standards (EQS) are numerical thresholds employed with other regulatory tools to enable environmental protection by limiting the release of a particular chemical to levels that will not result in irreparable harm or toxicity to sensitive aquatic species. Water EQS can be divided into two main types: one related to maximum acute chemical (MAC-EQS) exposure and one to chronic exposure (AA-EQS). For sediment EQS there is no short-term versus long-term EQS considering the exposure route (i.e., organisms would be constantly exposed while living in the sediment).

In this document, an approach based on European guidelines (TGD, 2018) was tested to derive Environmental Quality Standards (EQS) for some drugs and pesticides used in Canadian finfish aquaculture operations. This was completed by relying on accessible and relevant toxicological data and the deterministic approach (TGD, 2018) including considerations from the Canadian water quality guidelines and an overall weight of evidence determination of assessment factors. This was selected based on the toxicological data status of emamectin benzoate (EMB), ivermectin, teflubenzuron and lufenuron where only a deterministic method can be used considering the number of toxicity endpoints available. This approach was also used for the two pesticides considered in this document: azamethiphos and hydrogen peroxide. However, a recommendation to test the feasibility of a species sensitivity distributions (SSD) in the future is made for deriving a MAC-EQS for azamethiphos and hydrogen peroxide with special considerations for dispersion timelines. This step will have to be guided by clear management objectives and inter-departmental regulatory considerations.

EQS values were derived for water and/or sediment compartments for the considered compounds based on their n-Octanol/Water Partition Coefficient (K_{oW}): azamethiphos (water only), hydrogen peroxide (water only), emamectin benzoate (EMB) (water and sediment), ivermectin (water and sediment), teflubenzuron (water and sediment) and lufenuron (water and

sediment). In addition, the inference of a benthic far-field threshold is suggested by dividing the proposed EQS value by 10.

In the toxicological data collation process, a quality assurance assessment based on accessing peer review studies and assembling data in line with other international jurisdictions (SEPA and US EPA) was completed. Usability (i.e., reliability status) as determined by other regulatory agencies was compiled and any studies eliminated by those regulatory bodies were not taken into account. Quality assessment was also completed for some recent studies but will require additional considerations by groups of experts.

Adjustments to assessment factors were guided by information on specific mode of action for chemicals such as azamethiphos, ivermectin, teflubenzuron, and lufenuron and whether data on identified sensitive target organisms were available. In addition, the selection of time relevant toxicological data was also applied in the case of EQS values suggested for azamethiphos based on previous work on dispersion patterns.

The EQS values presented in this document illustrate the process employed for the derivation and provide an overview of the toxicity data readily available and the knowledge gaps to be addressed. Enhanced access to confidential data provided to regulators for marketing authorisation will have to be facilitated to ensure the appropriate derivation of environmental standards. Ultimately, defining clear management goals by policy makers and additional expert discussions will guide the selection of the final EQS thresholds and their regulatory usage.

KNOWLEDGE GAPS

The data presented in this document highlight significant knowledge gaps in toxicological endpoints especially for in-feed drugs:

- Long-term studies with environmentally representative benthic marine species are lacking and require additional research.
- Studies on persistence of in-feed drugs are necessary to guide post-deposit monitoring sampling schemes and anticipation of cumulative impacts. In particular, the effect of cofounding conditions within the sediments: sediment types, oxygenation, pH and level of enrichment and/or presence of other drugs.
- In addition, field studies to confirm the environmental relevance of some of the EQS suggested within this document are needed; in particular ones related to the potential water exposures of in-feed drugs and expected aqueous concentrations of these products.
- The integration of relevant dispersion timelines for bath pesticides as well as footprint considerations for drugs and how thresholds should be applied spatially require more science input.
- Bioaccumulation studies and further considerations for biota sampling are needed to ensure exposure routes are adequately addressed (and EQS reconsidered when applicable).
- Most of the toxicological data cited in the tables presented in the annex are related to active ingredient testing (similarly to the inferred EQS values) there is a need to conduct additional research on formulations and their persistence. Similarly, more research on transformation products and their potential toxicity might be required.
- This document did not include antibiotics; however, toxicological studies to ensure lethal and sublethal (not limited to anti-microbial resistance) effects of widely used antibiotics should be completed in order to guide whether EQS values are warranted in the near future.
- This document focuses on EQS values linked to single chemicals. Considering that the environment will be the receptacle of more than one compound co-presence of toxicants should be considered to better anticipate synergistic or antagonistic toxicity mechanisms.

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APPENDIX I - SUMMARY OF AVAILABLE ECOTOXICITY DATA

BATH PESTICIDES

1. Azamethiphos

Table 1-A. Acute toxicity data for pelagic freshwater organisms exposed to azamethiphos.

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Fish - Non - Salmonid	*Carassius carassius* (Crucian carp)	LC_{50}	6000	96	Static	PMRA, 2016a*	Acceptable[A]
Fish - Non-Salmonid	*Cyprinus carpio* (Common carp)	LC_{50}	7100	96	Static	PMRA, 2016a*	Acceptable[A]
Fish - Non - Salmonid	*Ictalurus punctatus* (Channel catfish)	LC_{50}	3000	96	Static	PMRA, 2016a*	Acceptable[A]
Fish - Non - Salmonid	*Ictalurus punctatus* (Channel catfish)	LC_{50}	9200	96	Static	PMRA, 2016a*	Acceptable[A]
Fish - Non - Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	8000	96	Static	PMRA, 2016a*	Acceptable[A]
Fish - Non - Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	11 000	96	Static	PMRA, 2016a*	Acceptable[A]
Fish - Non - Salmonid	*Lebistes reticulatus* (Guppy)	LC_{50}	8000	96	Static	PMRA, 2016a*	Acceptable[A]
Fish - Non-Salmonid	*Leuciscus idus melanotus* (Golden orfe)	LC_{50}	4200	96	Static	PMRA, 2016a*	Acceptable[A]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	200	96	Static	PMRA, 2016a*	Acceptable[A]
Fish - Salmonid	*Salmo trutta* (Brown trout)	LC_{50}	290	96	Static	PMRA, 2016a*	Acceptable[A]

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1	Reliable without restriction	**C**	Reliablitly assessed by D. Hamoutene; evaluation is provisional and should be reassessed by more than one expert
2	Reliable with restriction	**D**	Reliability assessed by United Kingdom Technical Advisory Group Chemical Task Team
3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Table 1-B. Acute toxicity data for pelagic marine organisms exposed to azamethiphos.

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Algae	*Tetraselmis chuii*	EC_{50}	> 1000	72	Growth rate, cell count, and biomass	PMRA, 2016a*	Acceptable[A]
Algae	*Tetraselmis chuii*	NOEC	1000	15	-	VMD, 2015*	2[B]
Algae	*Phaeodactylum tricornutum*	EC_{50}	> 1000	72	Growth rate, cell count, and biomass	PMRA, 2016a*	Acceptable[A]
Algae	*Phaeodactylum tricornutum*	NOEC	1000	72	-	VMD, 2015*	2[B]
Algae	*Isochrysis galbana*	LC_{50}	1533	24	-	VMD, 2015*	2[B]
Algae	*Isochrysis galbana*	LC_{50}	2099	48	-	VMD, 2015*	2[B]
Algae	*Isochrysis galbana*	LC_{50}	2348	72	-	VMD, 2015*	2[B]
Algae	*Isochrysis galbana*	LC_{50}	3066	96	-	VMD, 2015*	2[B]
Bacteria	*Vibrio fischeri*	EC_{50}	11 000	15 min	Immobilization	Ernst et al., 2001	2[B]
Rotifera	*Brachionus plicatilis*	LC_{50}	> 10 000	24	-	Ernst et al., 2001	2[B]
Annelida - Polychaeta	*Polydora comuta*	LC_{50}	2310	96	Juvenile	Ernst et al., 2001	2[B]
Crustacea - Anostraca	*Artemia salina*	LC_{50}	> 10 000	24	-	Ernst et al., 2001	2[B]
Crustacea - Copepoda	*Temora longicornis*	LC_{50}	> 10	24	-	PMRA, 2016a*	Acceptable[A]
Crustacea - Amphipoda	*Hyale nilssoni*	LC_{50}	> 6.2	96	-	PMRA, 2016a*	Acceptable[A]
Crustacea - Amphipoda	*Hyale prevostii*	EC_{50}	2.4	24	-	VMD, 2015*	2[B]
Crustacea - Amphipoda	*Hyale prevostii*	EC_{50}	0.82	96	-	VMD, 2015*	2[B]
Crustacea - Amphipoda	*Eohaustorius estuarius*	LC_{50}	> 20	48	In 100 mg/L Rhodamine WT	Ernst et al., 2001	2[B]
Crustacea - Amphipoda	*Eohaustorius estuarius*	EC_{50}	3	48	In 100 mg/L Rhodamine WT	Ernst et al., 2001	2[B]
Crustacea - Mysida	Mysid sp.	LC_{50}	12.5	24	-	Burridge et al., 2014	2[B]

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4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Crustacea - Mysida	Mysid sp.	LC_{50}	> 85.5	1	1 hour exposure + 95 h monitoring	Burridge et al., 2014	2[B]
Crustacea - Mysida	Mysis sp.	LOEC	3.3	1	-	Burridge and Van Geest, 2014	Acceptable[A]
Crustacea - Mysida	Mysis sp.	LOEC	18.5	24	-	Burridge and Van Geest, 2014	Acceptable[A]
Crustacea - Mysida	*Mysis stenolepis*	LC_{50}	10.5	24	Water collected from sea louse treatment or effluent water	Ernst et al., 2014	2[B]
Crustacea - Mysida	*Mysidopsis bahia*	LC_{50}	2.1	96	-	PMRA, 2016a*	Acceptable[A]
Crustacea - Mysida	*Mysidopsis bahia*	LC_{50}	0.52	96	-	VMD, 2015*	2[B]
Crustacea - Decapoda	*Crangon septemspinosa* (Sand shrimp)	LC_{50}	19.2	24	Water collected from sea louse treatment or effluent water	Ernst et al., 2014	2[B]
Crustacea - Decapoda	*Crangon septemspinosa* (Sand shrimp)	LC_{50}	> 85.5	1	1 + 95 h monitoring	Burridge et al., 2014	2[B]
Crustacea - Decapoda	*Crangon septemspinosa* (Sand shrimp)	LC_{50}	191	24	-	Burridge et al., 2014	2[B]
Crustacea - Decapoda	*Crangon septemspinosa* (Sand shrimp)	LOEC	0.97	1	-	Burridge and Van Geest, 2014	Acceptable[A]
Crustacea - Decapoda	*Crangon septemspinosa* (Sand shrimp)	LOEC	71	24	-	Burridge and Van Geest, 2014	Acceptable[A]
Crustacea - Decapoda	*Metacarcinus edwardsii*	LC_{50}	2.84	30 min + 24 h recovery	-	Gebauer et al., 2017	2[B]
Crustacea - Decapoda	*Metacarcinus edwardsii*	EC_{50}	0.94	30 min + 24 h recovery	-	Gebauer et al., 2017	3[C]

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Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Crustacea - Decapoda	*Lithodes santolla*	LC_{50}	9.12	48	Larvae	VMD, 2015*	2[B]
Crustacea - Decapoda	*Homarus gammarus* (European lobster)	EC_{50}	0.36	24	Stage IV	VMD, 2015*	2[B]
Crustacea - Decapoda	*Homarus gammarus* (European lobster)	EC_{50}	1.25	48	Stage IV	VMD, 2015*	2[B]
Crustacea - Decapoda	*Homarus gammarus* (European lobster)	EC_{50}	0.52	96	Stage IV	VMD, 2015*	2[B]
Crustacea - Decapoda	*Homarus gammarus* (European lobster)	LC_{50}	0.5	96	Stage IV and V	PMRA, 2016a*	Fully Reliable[A]
Crustacea - Decapoda	*Homarus gammarus* (European lobster)	LC_{50}	3.2	5 x 1 h pulses with 5 d recovery between exposures	Larvae	PMRA, 2016a*	Acceptable[A]
Crustacea - Decapoda	*Homarus gammarus* (European lobster)	NOEC	1	5 x 1 h pulses with 5 d recovery between exposures	Larvae	PMRA, 2016a*	Acceptable[A]
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	>86.5	1 + 95 h monitoring	Stage I	Burridge et al., 2014	2[B]
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	8.9	24	Stage I	Burridge et al., 2014	2[B]
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LOEC	11.5	1	Stage I	Burridge and Van Geest, 2014	Acceptable[A]
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	3.57	48	Stage I	Burridge et al., 1999	2[B]
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	1.03	48	Stage II	Burridge et al., 1999	2[B]

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4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	33.9	5 min + 12 h recovery	Stage II; Static test, 10°C	Pahl and Opitz, 1999	2^{B}
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	27.01	30 min + 12 h recovery	Stage II; Static test, 10°C	Pahl and Opitz, 1999	2^{B}
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	26.5	1 h + 12 h recovery	Stage II; Static test, 10°C	Pahl and Opitz, 1999	2^{B}
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	5.4	6 h + 12 h recovery	Stage II; Static test, 10°C	Pahl and Opitz, 1999	2^{B}
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	1.33	12 h + 12 h recovery	Stage II; Static test, 12°C	Pahl and Opitz, 1999	2^{B}
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	50.4	5 min + 12 h recovery	Stage II; Static test, 12°C	Pahl and Opitz, 1999	2^{B}
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	37.7	30 min + 12 h recovery	Stage II; Static test, 12°C	Pahl and Opitz, 1999	2^{B}
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	20.7	1 h + 12 h recovery	Stage II; Static test, 12°C	Pahl and Opitz, 1999	2^{B}
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	3.5	6 h + 12 h recovery	Stage II; Static test, 12°C	Pahl and Opitz, 1999	2^{B}
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	0.9	12 h + 12 h recovery	Stage II; Static test, 12°C	Pahl and Opitz, 1999	2^{B}
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	2.29	48	Stage III	Burridge et al., 1999	2^{B}
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	2.12	48	Stage IV	Burridge et al., 1999	2^{B}
Crustacea - Decapoda	*Homarus americanus* (American lobster)	NOEC	11	30 min	Stage IV	Burridge et al., 2000	2^{B}

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3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	0.52	96	Stage IV	McHenery et al., 1991 cited by SEPA, 1997*	3[B] (Data used by SEPA to derive MAC values in 1999; however, SEPA experts later deemed the study not reliable)
Crustacea - Decapoda	*Homarus americanus* (American lobster)	EC_{50}	0.38	96	Stage IV	McHenery et al., 1991 cited by SEPA, 1997*	3[B] (Data used by SEPA to derive MAC values in 1997; however, SEPA experts later deemed the study not reliable)
Crustacea - Decapoda	*Homarus americanus* (American lobster)	NOEC	0.156	96	Stage IV	McHenery et al., 1991 cited by SEPA, 1997*	3[B] (Data used by SEPA to derive MAC values in 1997; however, SEPA experts later deemed the study not reliable)
Crustacea - Decapoda	*Homarus americanus* (American Lobster)	LC_{50}	0.61	48	Post and intermolt	Burridge et al., 2005	2[B]
Crustacea - Decapoda	*Homarus americanus* (American Lobster)	LC_{50}	3.24	48	Post and intermolt	Burridge et al., 2005	2[B]
Crustacea - Decapoda	*Homarus americanus* (American lobster)	NOEC	1.03	30 min	15 or 30 minutes, three times daily (3 days) with	Burridge et al., 2000	2[B]

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4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
					165 or 150 minutes between treatments		
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	24.8	1 + 95 h monitoring	Adult	Burridge et al., 2000	2[B]
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	2.8	24	Adult	Burridge et al., 2014	2[B]
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LOEC	2.9	1	Adult	Burridge and Van Geest, 2014	Acceptable[A]
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	1.39	48	Adult	Burridge et al., 1999	2[B]
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	1.08	48	Adult; 5 x 1-h pulses over 48 h	Burridge et al., 2000	2[B]
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	0.45	48	Adult	Dounia et al., 2016	2[B]
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	0.216	10 days	Adult	Burridge and Van Geest, 2014	Acceptable[A]
Mollusca - Bivalvia	*Mytilus edulis* (Blue mussel)	LC_{50}	> 10 000	24	-	PMRA, 2016a, VMD, 2015*	2[B]
Mollusca - Bivalvia	*Mytilus edulis* (Blue mussel)	LC_{50}	> 100 000	96	-	PMRA, 2016a*	Acceptable[A]
Mollusca - Bivalvia	*Mytilus edulis* (Blue mussel)	LC_{50}	> 100	5 x 1 h pulses	-	PMRA, 2016a*	Acceptable[A]

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Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Mollusca - Bivalvia	*Mytilus edulis* (Blue mussel)	LC_{50}	736	1	Semi-static conditions	VMD, 2015*	2[B]
Mollusca - Bivalvia	*Mytilus edulis* (Blue mussel)	LC_{50}	>100	96	-	SEPA, 1997*	2[B]
Mollusca - Bivalvia	*Mytilus edulis* (Blue mussel)	EC_{50}	29	24	-	VMD, 2015*	2[B]
Mollusca - Bivalvia	*Mytilus edulis* (Blue mussel)	NOEC	1.5	96	Behaviour	VMD, 2015*	2[B]
Mollusca - Bivalvia	*Mytilus edulis* (Blue mussel)	LC_{50}	46	24	-	VMD, 2015*	2[B]
Mollusca - Bivalvia	*Mytilus edulis* (Blue mussel)	EC_{50}	91	24	-	VMD, 2015*	2[B]
Mollusca - Bivalvia	*Mytilus edulis* (Blue mussel)	NOEC	10	96	-	VMD, 2015*	2[B]
Mollusca - Bivalvia	*Mytilus edulis* (Blue mussel)	LC_{50}	>10, <100	1	-	VMD, 2015*	2[B]
Mollusca - Bivalvia	*Crassostrea gigas* (Pacific oyster)	EC_{50}	> 1000	24	Embryo development	PMRA, 2016*	Acceptable[A]
Mollusca - Bivalvia	*Crassostrea gigas* (Pacific oyster)	NOEC	1000	24	Embryo	VMD, 2015*	2[B]
Mollusca - Bivalvia	Mussel	NOEC	> 10	24	No response to stimuli	SEPA, 1997*	2[B]
Mollusca - Gastropoda	*Patella vulgate* (Common Limpet)	LC_{50}	> 100	96	-	PMRA, 2016*	Acceptable[A]

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Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Mollusca - Gastropoda	*Patella vulgate* (Common Limpet)	EC_{50}	6.9	24	Adult	VMD, 2015*	2[B]
Mollusca - Gastropoda	*Patella vulgate* (Common Limpet)	EC_{50}	0.76	96	Adult; behaviour	VMD, 2015*	2[B]
Mollusca - Gastropoda	*Littorina littorea* (Common periwinkle)	LC_{50}	> 100	96	-	PMRA, 2016*	Acceptable[A]
Mollusca - Gastropoda	*Littorina littorea* (Common periwinkle)	EC_{50}	1.6	24	Adult	VMD, 2015*	2[B]
Mollusca - Gastropoda	*Littorina littorea* (Common periwinkle)	NOEC	25	24	Adult	VMD, 2015*	2[B]
Mollusca - Gastropoda	*Littorina littorea* (Common periwinkle)	EC_{50}	2.6	96	Adult	VMD, 2015*	2[B]
Mollusca - Gastropoda	*Littorina littorea* (Common periwinkle)	NOEC	1.5	96	Adult	VMD, 2015*	2[B]
Echinodermata	*Asterias rubens* (Common starfish)	LC_{50}	> 100	96	-	PMRA, 2016a*	Acceptable[A]
Echinodermata	*Asterias rubens* (Common starfish)	EC_{50}	14	96	-	VMD, 2015*	2[B]
Echinodermata	*Strongylocentrotus droebachiensis* (Green sea urchin)	LC_{50}	> 1000	96	96 h exposure followed by 96 h clean seawater	Ernst et al., 2001	2[B]
Echinodermata	*Lytechinus pictus* (Painted sea urchin)	EC_{50}	6840	20 min	Fertilization test	Ernst et al., 2001	2[B]

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Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Echinodermata	*Lytechinus pictus* (Painted sea urchin)	EC_{25}	3340	20 min	Fertilization test	Ernst et al., 2001	2[B]
Echinodermata	*Loxechinus albus* (Red sea urchin)	LC_{50}	> 456	48	-	VMD, 2015*	2[B]
Fish - Non-Salmonid	*Cyprinodon variegatus* (Sheepshead minnow)	LC_{50}	2200	96	-	PMRA, 2016a*	Acceptable[A]
Fish - Non-Salmonid	*Ctenolabrus rupestris* (Goldsinny wrasse)	LC_{50}	4180	1	Juvenile	PMRA, 2016a*	Acceptable[A]
Fish - Non-Salmonid	*Ctenolabrus rupestris* (Goldsinny wrasse)	LC_{50}	4140	1	Juvenile	VMD, 2015*	2[B]
Fish - Non-Salmonid	*Ctenolabrus rupestris* (Goldsinny wrasse)	LC_{50}	3350	1	Juvenile	VMD, 2015*	2[B]
Fish - Non-Salmonid	*Gasterosteus aculeatus* (Three-spined stickleback)	LC_{50}	190	96	-	Ernst et al., 2001	2[B]
Fish - Non-Salmonid	*Odontesthes regia* (Chilean silverside)	LC_{50}	4233	24	-	VMD, 2015*	2[B]
Fish - Non-Salmonid	*Odontesthes regia* (Chilean silverside)	LC_{50}	1700	48	-	VMD, 2015*	2[B]
Fish - Non-Salmonid	*Odontesthes regia* (Chilean silverside)	LC_{50}	29.38	96	-	VMD, 2015*	2[B]
Fish - Non-Salmonid	*Odontesthes regia* (Chilean silverside)	LC_{50}	213.9	72	-	VMD, 2015*	2[B]
Fish - Non-Salmonid	*Clupea harengus* (Atlantic herring)	LC_{50}	33.4	96	Yolk-sac larvae	VMD, 2015*	2[B]
Fish - Non-Salmonid	*Clupea harengus* (Atlantic herring)	LC_{50}	26.3	96	Post yolk-sac larvae	SEPA, 1997*	2[B]

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Table 1-C. Toxicity data for benthic organisms exposed to azamethiphos

Taxonomic group	Species	Endpoint	Value (µg/kg wet weight)	Test duration (days)	Notes	References	Reliability
Crustacea - Amphipoda	*Corophium volutator*	LC_{50}	182	10	-	Mayor et al., 2008	2^{B}

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4	Not assignable	**F**	Reliability assessed by FAO experts

2. Hydrogen peroxide

Table 2-A. Acute toxicity data for pelagic freshwater organisms exposed to hydrogen peroxide.

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Algae	*Chlorella vulgaris*	NOEC	100	72	Method: modified OECD 201	Degussa, 1991 cited by ECHA, 2003*	3[B]
Algae	*Chlorella vulgaris*	EC_{50}	2500	72	Method: modified OECD 201	Degussa, 1991 cited by ECHA, 2003*	3[B]
Algae	*Oscillatoria rubescens*	LOEC	350	29	-	Barroin and Feuillade, 1986	3[C] (Algae cultures were not replicated)
Algae	*Raphidocelis subcapitata*	EC_{50}	5380	96	Fluorescence	Gregor et al., 2008	2[B]
Algae	*Aphanothece clathrate*	EC_{50}	2270	96	Fluorescence	Gregor et al., 2008	2[B]
ghgrBacteria	*Anabaena spp.*	EC_{50}	9900	24	Reduced chlorophyll	Kay et al., 1982 cited by Schmidt et al., 2006*	2[B]
Bacteria	*Ankistrodesmus spp.*	EC_{50}	17 000	24	Reduced chlorophyll	Kay et al., 1982 cited by Schmidt et al., 2006*	2[B]
Bacteria	*Raphidiopsis spp.*	EC_{50}	6800	24	Reduced chlorophyll	Kay et al., 1982 cited by Schmidt et al., 2006*	2[B]
Bacteria	*Aphanizomenon flos-aquae*	EC_{50}	900	22	Inhibition of nitrogen fixation	Peterson et al., 1995	2[B]
Bacteria	*Aphanizomenon flos-aquae*	EC_{50}	3400	1.5	Inhibition of nitrogen fixation	Peterson et al., 1995	2[B]
Insecta	*Chironomid larvae*	LC_{50}	125 000	72	Larvae	Alexander et al., 1997	2[B]
Crustacea - Cladocera	*Daphnia* carinata	NOEC	3000	48	Mortality	Reichwaldt et al., 2012	2[B]
Crustacea - Cladocera	*Daphnia carinata*	LC_{50}	5600	48	Mortality	Reichwaldt et al., 2012	2[B]

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Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Crustacea - Cladocera	*Daphnia pulex*	NOEC	1000	48	-	Shurtleff, 1989a cited by ECHA, 2003*	2[B]
Crustacea - Cladocera	*Daphnia pulex*	LC_{50}	2400	48	-	Shurtleff, 1989a cited by ECHA, 2003*	2[B]
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	2320	24	DNA microarray analysis	Watanabe et al., 2006	2[B]
Crustacea - Cladocera	*Daphnia magna*	LC_{50}	1070	48	-	Environment Canada, 2010 (unpublished) cited by SEPA, 2019d*	2[B]
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	5370	24	-	Environment Canada, 2010 (unpublished) cited by SEPA, 2019d*	2[B]
Crustacea - Cladocera	*Daphnia magna*	LC_{50}	5370	48	-	Environment Canada, 2010 (unpublished) cited by SEPA, 2019d*	2[B]
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	3000 - 9600	24	-	Environment Canada, 2010 (unpublished) cited by SEPA, 2019d*	2[B]
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	7700	24	Immobilisation	Bringmann and Kuhn, 1982 cited by ECHA, 2003*	2[B]
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	2000 - 2600	24	-	Bringmann and Kuhn, 1982 cited by ECHA, 2003*	2[B]
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	2400	48	-	Shurtleff 1989a cited by Schmidt et al., 2006*	2[B]
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	2300	24	-	Trenel and Kuhn, 1982 cited by	2[B]

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Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
						Schmidt et al., 2006*	
Crustacea - Cladocera	*Ceriodaphnia dubia*	EC_{50}	8100 - 11 200	48	-	Analytical Laboratory Services, 2003 cited by Schmidt et al., 2006*	2[B]
Crustacea - Anomopoda	*Moina* sp.	NOEC	1500	48	Mortality	Reichwaldt et al., 2012	2[B]
Crustacea - Anomopoda	*Moina* sp.	LC_{50}	2000	48	Mortality	Reichwaldt et al., 2012	2[B]
Crustacea - Amphipoda	*Eulimnogammarus cyaneus*	LC_{50}	119 000	24	-	Fedoseeva and Stom, 2013	2[B]
Crustacea - Amphipoda	*Eulimnogammarus vittatus*	LC_{50}	238 000	24	-	Fedoseeva and Stom, 2013	2[B]
Crustacea - Amphipoda	*Gammarus lacustris*	LC_{50}	231 300	24	-	Fedoseeva and Stom, 2013	2[B]
Crustacea - Amphipoda	*Gammarus* sp.	EC_{50}	4400	96	Semi-static, nominal concentration	Kay et al., 1982	2[B]
Crustacea - Amphipoda	*Gmelinoides fasciatus*	LC_{50}	20 400	24	-	Fedoseeva and Stom, 2013	2[B]
Mollusca - Gastropoda	*Physa* sp.	EC_{50}	17 700	96	Semi-static, nominal concentration	Kay et al., 1982	2[B]
Fish - Non-Salmonid	*Poecilia reticulata* (Guppy)	NOEC	34 000	5	-	Quimby, 1981	2[B]
Fish - Non-Salmonid	*Leuciscus idus* (Ide)	LC_{50}	35 000	72	Static	Degussa, 1977 cited by ECHA, 2003*	2[B]
Fish - Non-Salmonid	*Rhamdia quelen* (South American catfish)	LC_{50}	82 540 (26 760 ug/L active ingredient)	96	Juvenile	Marchiori et al., 2017	2[B]
Fish - Non-Salmonid	*Ictalurus punctatus* (Channel catfish)	LC_{50}	> 5 000 000	Same value for 30 min, 1 h and 3 h	7°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Ictalurus punctatus* (Channel catfish)	LC_{50}	369 000	24	7°C	Rach et al., 1997	2[B]

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Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Fish - Non-Salmonid	*Ictalurus punctatus* (Channel catfish)	LC_{50}	> 5 000 000	Same value for 30 min, 1 h	12°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Ictalurus punctatus* (Channel catfish)	LC_{50}	1 520 000	3	12°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Ictalurus punctatus* (Channel catfish)	LC_{50}	76 600	24	12°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Ictalurus punctatus* (Channel catfish)	LC_{50}	> 5 000 000	30 min	17°C and 22°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Ictalurus punctatus* (Channel catfish)	LC_{50}	2 860 000	1	17°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Ictalurus punctatus* (Channel catfish)	LC_{50}	332 000	3	17 °C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Ictalurus punctatus* (Channel catfish)	LC_{50}	57 400	24	17 °C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Ictalurus punctatus* (Channel catfish)	LC_{50}	2 010 000	1	22°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Ictalurus punctatus* (Channel catfish)	LC_{50}	210 000	3	22°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Ictalurus punctatus* (Channel catfish)	LC_{50}	55 500	24	22°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Ictalurus punctatus* (Channel catfish)	NOEC	3 000 000	15	Mortality; 12°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Ictalurus punctatus* (Channel catfish)	NOEC	1 000 000	45 min	Mortality; 12°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Ictalurus punctatus* (Channel catfish)	LC_{50}	37 400	96	Semi-static, nominal	Kay et al., 1982	2[B]

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Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Fish - Non-Salmonid	*Ictalurus punctatus* (Channel catfish)	NOEC	28 000	3	Fry; 192 h post-exposure; higher endpoints reported at different life stages and time periods	Gaikowski et al., 1999	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	5 000 000	30 min	7°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	3 190 000	1	7°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	1 620 000	3	7°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	290 000	24	7°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	3 540 000	30 min	12°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	2 560 000	1	12°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	1 240 000	3	12°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	165 000	24	12°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	3 540 000	30 min	17°C	Rach et al., 1997	2[B]

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Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	2 180 000	1	17°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	683 000	3	17°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	152 000	24	17°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	2 010 000	30 min	22°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	1 460 000	1	22°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	406 000	3	22°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	71 500	24	22°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	NOEC	1 000 000	15 min and 45 min	Mortality; 12°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	NOEC	47 000	3	Fry and fingerling; 192 h post-exposure	Gaikowski et al., 1999	2[B]
Fish - Non-Salmonid	*Pimephales promelas* (Fathead minnow)	NOEC	1 000 000	15 min	Mortality; 12°C	Rach et al., 1997	2[B]

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Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Fish - Non-Salmonid	*Pimephales promelas* (Fathead minnow)	NOEC	500 000	45 min	Mortality; 12°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Pimephales promelas* (Fathead minnow)	NOEC	5000	96	Behaviour (nominal)	ECHA, 1989 cited by SEPA, 2019d*	2[B]
Fish - Non-Salmonid	*Pimephales promelas* (Fathead minnow)	NOEC	28 000	3	Fry; 192 h post-exposure	Gaikowski et al., 1999	2[B]
Fish - Non-Salmonid	*Pimephales promelas* (Fathead minnow)	LC_{50}	16 400	96	Semi-static	Shurtleff, 1989b cited by ECHA, 2003*	2[B]
Fish - Non-Salmonid	*Pimephales promelas* (Fathead minnow)	NOEC	4300	96	Semi-static	Solvay Chemicals Inc., 2015*	2[B]
Fish - Non-Salmonid	*Stizostedion vitreum* (Walleye)	NOEC	100 000	15 min	Mortality; 12°C	Rach et al., 1997	2[B]
Fish - Non-Salmonid	*Stizostedion vitreum* (Walleye)	LC_{50}	145 100	1 hour exposure + 12hours observation	-	Clayton and Summerfelt, 1996	2[B]
Fish - Non-Salmonid	*Stizostedion vitreum* (Walleye)	LC_{50}	142 800	1 hour + 96 hours	-	Clayton and Summerfelt, 1996	2[B]
Fish - Non-Salmonid	*Stizostedion vitreum* (Walleye)	LC_{50}	53 000	24	Medium water hardness; 3.8 cm size; different water hardness and fish sizes)	Tripi and Bowser, 2001	2[B]
Fish - Non-Salmonid	*Stizostedion vitreum* (Walleye)	NOEC	72 000	3	Fry; 192 h post-exposure	Gaikowski et al., 1999	2[B]
Fish - Non-Salmonid	*Esox masquinongy* (Muskellunge)	NOEC	54 000	3	Fry; 192 h post-exposure	Gaikowski et al., 1999	2[B]
Fish - Non-Salmonid	*Esox lucius* (Northern Pike)	NOEC	54 000	3	Fry; 192 h post-exposure	Gaikowski et al., 1999	2[B]
Fish - Non-Salmonid	*Scaphirhynchus albus* (Pallid sturgeon)	NOEC	28 000	3	Fry; 192 h post-exposure	Gaikowski et al., 1999	2[B]
Fish - Non-Salmonid	*Catostomus commersonii* (White sucker)	NOEC	28 000	3	Fry; 192 h post-exposure	Gaikowski et al., 1999	2[B]
Fish - Non-Salmonid	*Micropterus salmoides* (Largemouth bass)	NOEC	47 000	3	Fingerling; 192 h post-exposure	Gaikowski et al., 1999	2[B]

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Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Fish - Non-Salmonid	*Perca flavescens* (Yellow perch)	NOEC	43 000	3	Fry; 192 h post-exposure	Gaikowski et al., 1999	2[B]
Fish - Non-Salmonid	*Danio rerio* (Zebrafish)	LC_{50}	18 290	24	8 hours post fertilization	Chan et al., 2006	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	5 000 000	30 min	7°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	2 380 000	1	7°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	506 000	3	7°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	69 400	24	7°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	8 660 000	30 min	12°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	1 260 000	1	12°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	363 000	3	12°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	42 000	24	12°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	520 000	30 min	17°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	311 000	1	17°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	119 000	3	17°C	Rach et al., 1997	2[B]

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Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	34 000	24	17°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	393 000	30 min	22°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	218 000	1	22°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	102 000	3	22°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	31 300	24	22°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	NOEC	1 000 000	15 min	Sac fry; 12°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	NOEC	1 000 000	45 min	Sac fry; 12°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	NOEC	3 000 000	15 min	Swim up; 12°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	NOEC	500 000	45 min	Swim up; 12°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	NOEC	500 000	15 min	Fingerling, Small Adult, Large Adult; 12°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	NOEC	250 000	45 min	Fingerling, Large Adult; 12°C	Rach et al., 1997	2[B]

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Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	NOEC	10 000	45 min	Small adult; 12°C	Rach et al., 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	514 000	30 min	Fry	Arndt and Wagner, 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	322 000	1	Fry	Arndt and Wagner, 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	207 000	2	Fry	Arndt and Wagner, 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	574 000	30 min	Fingerling	Arndt and Wagner, 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	329 000	1	Fingerling	Arndt and Wagner, 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	189 000	2	Fingerling	Arndt and Wagner, 1997	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	NOEC	78 000	3	Fry	Gaikowski et al., 1999	2[B]
Fish - Salmonid	*Oncorhynchus clarkia* (Cutthroat trout)	LC_{50}	636 000	30 min	Fry	Arndt and Wagner, 1997	2[B]
Fish - Salmonid	*Oncorhynchus clarkia* (Cutthroat trout)	LC_{50}	377 000	1	Fry	Arndt and Wagner, 1997	2[B]
Fish - Salmonid	*Oncorhynchus clarkia* (Cutthroat trout)	LC_{50}	280 000	2	Fry	Arndt and Wagner, 1997	2[B]

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Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Fish - Salmonid	*Oncorhynchus clarkia* (Cutthroat trout)	LC_{50}	514 000	30 min	Fingerling	Arndt and Wagner, 1997	2^{B}
Fish - Salmonid	*Oncorhynchus clarkia* (Cutthroat trout)	LC_{50}	506 000	1	Fingerling	Arndt and Wagner, 1997	2^{B}
Fish - Salmonid	*Oncorhynchus clarkia* (Cutthroat trout)	LC_{50}	197 000	2	Fingerling	Arndt and Wagner, 1997	2^{B}
Fish - Salmonid	*Salmo trutta* (Brown trout)	NOEC	1 000 000	15 min	Mortality; 12°C	Rach et al., 1997	2^{B}
Fish - Salmonid	*Salmo trutta* (Brown trout)	NOEC	250 000	45 min	Mortality; 12°C	Rach et al., 1997	2^{B}
Fish - Salmonid	*Salvelinus namaycush* (Lake trout)	NOEC	3 000 000	15 min	Mortality; 12°C	Rach et al., 1997	2^{B}
Fish - Salmonid	*Salvelinus namaycush* (Lake trout)	NOEC	1 000 000	45 min	Mortality; 12°C	Rach et al., 1997	2^{B}
Fish - Salmonid	*Salvelinus namaycush* (Lake trout)	NOEC	113 000	3	Fingerling	Gaikowski et al., 1999	2^{B}
Fish - Salmonid	*Salmo salar* (Atlantic salmon)	NOEC	120 000	3	Fingerling	Gaikowski et al., 1999	2^{B}

*Data point retrieved from EC (2003); the reference (Degussa, 1991) is confidential and unavailable for verification.

*	Primary study unavailable for consultation	**A**	Reliability assessed by PMRA experts
_	Lowest reliable value available for species	**B**	Reliability assessed by SEPA experts
1	Reliable without restriction	**C**	Reliablitly assessed by D. Hamoutene; evaluation is provisional and should be reassessed by more than one expert
2	Reliable with restriction	**D**	Reliability assessed by United Kingdom Technical Advisory Group Chemical Task Team
3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Table 2-B. Acute toxicity data for pelagic marine organisms exposed to hydrogen peroxide.

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Algae	*Nitzschia closterium*	EC_{50}	850	72	Growth rate	Florence and Stauber, 1986	2[B]
Algae	*Nitzschia closterium*	EC_{50}	850	n/a	Duration not reported	PMRA, 2014*	Acceptable[A]
Algae	*Skeletonema costatum*	NOEC	630	72	-	Knight et al., 1995 cited by ECHA, 2003*	2[B]
Algae	*Skeletonema costatum*	EC_{50}	1380	72	-	Knight et al., 1995 cited by ECHA, 2003*	2[B]
Algae	*Chaetoceros gracilis*	EC_{50}	3200	72	-	ECHA, 2006 cited by SEPA, 2019d*	2[B]
Algae	*Chaetoceros gracilis*	NOEC	1900	72	-	ECHA, 2006 cited by SEPA, 2019d*	2[B]
Annelida – Polychaeta	*Capitella* sp.	LC_{50}	1 227 000	1	-	Fang et al., 2018	2[B]
Annelida – Polychaeta	Capitella sp.	LC_{50}	159 300	72	-	Fang et al., 2018	2[B]
Annelida – Polychaeta	Ophryotrocha sp.	LC_{50}	296 000	1	-	Fang et al., 2018	2[B]
Annelida – Polychaeta	*Ophryotrocha sp.*	LC_{50}	64 300	72	-	Fang et al., 2018	2[B]
Crustacea - Anostraca	*Artemia salina*	EC_{50}	168 000	96	-	Smit et al., 2008	1[C]
Crustacea - Anostraca	*Artemia salina*	LC_{50}	918 000	24	-	Matthews, 1994	2[B]
Crustacea - Siphonostomatoida	*Lepeophtheirus salmonis* (Salmon louse)	LC_{100}	1 250 000	20 min	-	Bruno and Raynard, 1994	2[B]
Crustacea - Siphonostomatoida	*Lepeophtheirus salmonis* (Salmon louse)	EC_{50}	216 000	30 min	Ls A strain	Helgesen et al., 2015	2[B]
Crustacea - Siphonostomatoida	*Lepeophtheirus salmonis* (Salmon louse)	EC_{50}	45 900	24	Ls A strain	Helgesen et al., 2015	2[B]
Crustacea - Siphonostomatoida	*Lepeophtheirus salmonis* (Salmon louse)	EC_{50}	1 767 000	30 min	Ls V F1 strain	Helgesen et al., 2015	2[B]

*	Primary study unavailable for consultation	**A**	Reliability assessed by PMRA experts
_	Lowest reliable value available for species	**B**	Reliability assessed by SEPA experts
1	Reliable without restriction	**C**	Reliablitly assessed by D. Hamoutene; evaluation is provisional and should be reassessed by more than one expert
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3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Crustacea - Siphonostomatoida	*Lepeophtheirus salmonis* (Salmon louse)	EC_{50}	138 000	24	Ls V F1 strain	Helgesen et al., 2015	2[B]
Crustacea - Euphausiacea	*Euphausia pacifica* (North Pacific krill)	LC_{50}	240	96	Larvae	EVS Environmental Consultants, 1992 cited by Schmidt et al., 2006*	2[B]
Crustacea - Amphipoda	*Rhepoxynius abronius* (Barnard)	LC_{50}	75 000	96	-	EVS Environmental Consultants, 1992*	2[B]
Crustacea - Copepoda	Copepoda	LC_{50}	42 000 - 75 000	1 + 5 h recovery	-	Burridge and Van Geest, 2014	2[C]
Crustacea - Copepoda	Copepoda	EC_{50}	5300	1 + 5 h recovery	Feeding behaviour	Burridge and Van Geest, 2014	2[C]
Crustacea - Calanoida	Calanus finmarchicus	LC_{50}	5992	24	Adult or stage V	Hansen et al., 2017	2[B]
Crustacea - Calanoida	Calanus finmarchicus	LC_{50}	3912	48	Adult or stage V	Hansen et al., 2017	2[B]
Crustacea - Calanoida	Calanus finmarchicus	LC_{50}	3824	72	Adult or stage V	Hansen et al., 2017	2[B]
Crustacea - Calanoida	Calanus finmarchicus	LC_{50}	2450	96	Adult or stage V	Hansen et al., 2017	2[B]
Crustacea - Amphipoda	*Gammarus* sp.	LC_{50}	> 350 000	48	LOC exceeded	PMRA, 2014*	Acceptable[A]
Crustacea - Mysida	*Mysis* sp.	LOEC	245 000	1	-	Burridge and Van Geest, 2014	2[C]
Crustacea - Mysida	*Mysis* sp.	LC_{50}	973 000	1 + 95 h recovery	-	Burridge et al., 2014	2[B]
Crustacea - Mysida	Mysid	LC_{50}	973 000	1	-	DFO, 2013	Acceptable[A]
Crustacea - Amphipoda	*Corophium volutator*	EC_{50}	46 000	96	-	Smit et al., 2008	1[C]
Crustacea - Decapoda	*Crangon*	LC_{50}	3 182 000	1	-	DFO, 2013	Acceptable[A]

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3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Crustacea - Decapoda	*Crangon crangon*	LOEC	680 000	5	Decrease in aerobic metabolic rate and intracellular pH	Abele-Oesschger et al., 1997	3[C] (Low number of animals tested, absence of a defined dose-reponse relationship)
Crustacea - Decapoda	*Crangon septemspinosa* (Sand shrimp)	LC_{50}	3 182 000	1	-	Burridge et al., 2014	2[B]
Crustacea - Decapoda	*Crangon septemspinosa* (Sand shrimp)	LOEC	223 000	1	-	Burridge and Van Geest, 2014	2[C]
Crustacea - Decapoda	*Penaeus monodon* (Giant tiger prawn)	LC_{50}	30 600	24	Post larvae	Srisapoom, 1999	2[B]
Crustacea - Decapoda	*Metacarcinus edwardsii*	EC_{50}	1 269 610	40 min + 48 h recovery	-	Gebauer et al., 2017	2[C]
Crustacea - Decapoda	*Metacarcinus edwardsii*	EC_{50}	1 130 190	40 min + 72 h recovery	-	Gebauer et al., 2017	2[C]
Crustacea - Decapoda	*Carcinus maenas* (European green crab)	EC_{50}	> 350 000	48	-	PMRA, 2014*	Acceptable[A]
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	> 3 750 000	1 + 95 h recovery	Adult	Burridge et al., 2014	2[B]
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LOEC	794 000	1	-	Burridge and Van Geest, 2014	2[C]
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LC_{50}	1 637 000	1 + 95 h recovery	Stage I	Burridge et al., 2014	2[B]
Crustacea - Decapoda	*Homarus americanus* (American lobster) Stage I	LOEC	186 000	1	-	Burridge and Van Geest, 2014	2[C]
Mollusca - Bivalvia	*Crassostrea gigas* (Pacific oyster)	NOEC	940	48	Mortality	EVS Environmental Consultants, 1992 cited by Schmidt et al., 2006*	2[B]
Mollusca - Bivalvia	*Crassostrea gigas* (Pacific oyster)	NOEC	470	48	Abnormal shell development	EVS Environmental Consultants, 1992 cited by Schmidt et al., 2006*	2[B]
Mollusca - Bivalvia	*Crassostrea gigas* (Pacific oyster)	EC_{50}	1200	48	Abnormal shell development	EVS Environmental Consultants, 1992	2[B]

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1	Reliable without restriction	**C**	Reliablitly assessed by D. Hamoutene; evaluation is provisional and should be reassessed by more than one expert
2	Reliable with restriction	**D**	Reliability assessed by United Kingdom Technical Advisory Group Chemical Task Team
3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
						cited by Schmidt et al., 2006*	
Fish - Non-salmonid	*Siganus fuscescens* (Black rabbitfish)	LC_{50}	224 000	24	-	Kanda et al., 1989	2[B]
Fish - Non-salmonid	*Siganus rivulatus* (Rivulated rabbitfish)	LC_{50}	> 700 000	1 + 72 h observation	Juvenile	Nasser et al., 2017	2[B]
Fish - Non-salmonid	*Tridentiger trigonocephalus* (Striped goby)	LC_{50}	155 000	24	-	Kanda et al., 1989	2[B]
Fish - Non-salmonid	*Trachurus japonicus* (Jack mackerel)	LC_{50}	89 000	24	-	Kanda et al., 1989	2[B]
Fish - Salmonid	*Oncorhynchus tshawytscha* (Chinook salmon)	LC_{50}	105 000	96	Juvenile	Boutillier, 1993 cited by Schmidt et al., 2006*	2[B]
Fish - Salmonid	*Oncorhynchus tshawytscha* (Chinook salmon)	LC_{0}	1 500 000	20 min	Juvenile; 14°C	Johnson et al., 1993	2[B]
Fish - Salmonid	*Oncorhynchus tshawytscha* (Chinook salmon)	LC_{100}	1 500 000	40 min	Juvenile; 11°C and 18°C	Johnson et al., 1993	2[B]
Fish - Salmonid	*Salmo salar* (Atlantic salmon)	LC_{50}	2 580 000	20 min	16°C	Kiemer and Black, 1997	2[C]
Fish - Salmonid	*Salmo salar* (Atlantic salmon)	LC_{50}	2 500 000	1	-	Thomassen and Poppe, 1992 cited by Schmidt et al., 2006*	2[B]

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2	Reliable with restriction	**D**	Reliability assessed by United Kingdom Technical Advisory Group Chemical Task Team
3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Table 2-C. Chronic toxicity data for pelagic freshwater organisms exposed to hydrogen peroxide.

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (days)	Notes	Reference	Reliability
Algae	*Anabaena flos-aquae*	LOEC	100	32	-	Kavanagh, 1992	2[B]
Algae	*Oscillatoria agardhii*	LOEC	1000	32	-	Kavanagh, 1992	2[B]
Crustacea - Cladocera	*Daphnia magna*	LOEC	> 1250	21	Reproduction	Meinertz et al., 2008	1[B]
Crustacea - Cladocera	*Daphnia magna*	NOEC	630	21	Reproduction	Meinertz et al., 2008	1[B]
Mollusca - Bivalvia	*Dreissena polymorpha* (Zebra mussel)	NOEC	2000	56	-	Klerks and Fraleigh, 1991 cited by ECHA, 2003*	3[B]
Mollusca - Bivalvia	*Dreissena polymorpha* (Zebra mussel)	EC_{50}	6000	20	-	Martin et al., 1993	2[B] (Despite reliability assessment by SEPA, there is a lack of clarity on how endpoint was calculated)

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1	Reliable without restriction	**C**	Reliablitly assessed by D. Hamoutene; evaluation is provisional and should be reassessed by more than one expert
2	Reliable with restriction	**D**	Reliability assessed by United Kingdom Technical Advisory Group Chemical Task Team
3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

IN-FEED PESTICIDES

3. Emamectin benzoate

Table 3-A. Acute toxicity data for pelagic freshwater organisms exposed to emamectin benzoate.

Taxonomic group	Species	Endpoint	Value (µg/L)	Test duration (hours)	Notes	References	Reliability
Algae	*Pseudokirchneriella subcapitata*	EC_{50}	7.2	96	Growth	EFSA, 2012*	2^{B}
Algae	*Pseudokirchneriella subcapitata*	EC_{50}	12.1	96	Growth inhibition	Maynard, 2003 cited by EFSA, 2009*	1^{B}
Bacteria	*Vibrio fischeri*	EC_{50}	> 6300	5, 15, 30 min	Bioluminescence	Hernando et al., 2007	2^{B}
Insecta	*Aedes albopictus*	LC_{50}	90	24	Mortality (Static)	Khan et al., 2011	3^{B}
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	1.0	48	Immobilization (Flow through)	SEPA, 2000*	2^{B}
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	11	48	-	EFSA, 2012*	1^{B}
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	3.5	48	-	EFSA, 2012*	1^{B}
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	>728	48	-	OPP, 2000 cited by Environment Canada, 2005*	2^{B}
Fish – Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	180	96	Mortality (Flow through)	OPP, 2000 cited by Environment Canada, 2005*	1^{B}
Fish – Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	NOEC	87	96	Flow through	OPP, 2000 cited by Environment Canada, 2005*	1^{B}
Fish – Non-Salmonid	*Cyprinus carpio* (Common carp)	LC_{50}	567	96	Mortality (Flow through)	EFSA, 2012*	1^{B}
Fish – Non-Salmonid	*Cyprinus carpio* (Common carp)	LC_{50}	200	96	-	EFSA, 2012*	3^{B}

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2	Reliable with restriction	**D**	Reliability assessed by United Kingdom Technical Advisory Group Chemical Task Team
3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic group	Species	Endpoint	Value (µg/L)	Test duration (hours)	Notes	References	Reliability
Fish – Non-Salmonid	*Pimephales promelas* (Fathead minnow)	LC_{50}	194	96	Mortality (Flow through)	OPP, 2000 cited by Environment Canada, 2005*	2^{B}
Fish – Non-Salmonid	*Pimephales promelas* (Fathead minnow)	NOEC	160	96	Flow-through	OPP, 2000 cited by Environment Canada, 2005*	2^{B}
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	174	96	Mortality (Flow through)	EFSA, 2012*	2^{B}
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	NOEC	49	96	-	OPP, 2000 cited by Environment Canada, 2005*	2^{B}

Table 3-B. Acute toxicity data for pelagic marine organisms exposed to emamectin benzoate.

Taxonomic group	Species	Endpoint	Value (µg/L)	Test duration	Notes	References	Reliability
Crustacea - Copepoda	*Acartia clausi*	EC_{50}	0.28	48	Immobilization; most sensitive life stage	Willis and Ling, 2003	2^{B}
Crustacea - Copepoda	*Pseudocalanus elongatus*	EC_{50}	0.12	48	Immobilization; most sensitive life stage	Willis and Ling, 2003	2^{B}
Crustacea - Copepoda	*Temora longicornis*	EC_{50}	0.23	48	Immobilization; most sensitive life stage	Willis and Ling, 2003	2^{B}
Crustacea - Cyclopoida	*Oithona similis*	EC_{50}	15.86	48	Immobilization; most sensitive life stage	Willis and Ling, 2003	2^{B}
Crustacea - Siphonostomatoida	*Lepeophtheirus salmonis* (Salmon louse)	EC_{50}	51.4	-	LS A Strain	Helgesen and Horsberg, 2013	2^{B}
Crustacea - Siphonostomatoida	*Lepeophtheirus salmonis* (Salmon louse)	EC_{50}	21.5	-	LS A Strain	Helgesen and Horsberg, 2013	2^{B}
Crustacea - Siphonostomatoida	*Lepeophtheirus salmonis* (Salmon louse)	EC_{50}	243	-	LS B Strain	Helgesen and Horsberg, 2013	2^{B}
Crustacea - Siphonostomatoida	*Lepeophtheirus salmonis* (Salmon louse)	EC_{50}	167	-	LS B Strain	Helgesen and Horsberg, 2013	2^{B}
Crustacea - Siphonostomatoida	*Lepeophtheirus salmonis* (Salmon louse)	EC_{50}	302	-	LS B Strain	Helgesen and Horsberg, 2013	2^{B}

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3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic group	Species	Endpoint	Value (µg/L)	Test duration	Notes	References	Reliability
Crustacea - Mysida	*Americamysis bahia*	LC_{50}	0.04	96	Mortality	SEPA, 2000*	4[B]
Crustacea - Mysida	*Americamysis bahia*	LC_{50}	0.078	96	Mortality	EPP, 2018a cited by UKTAG CTT, 2019*	2[D]
Crustacea - Mysida	*Americamysis bahia*	NOEC	0.0217	96	Mortality	EPP, 2018a cited by UKTAG CTT, 2019*	3[D]
Crustacea – Decapoda	*Crangon crangon*	LC_{50}	166	192	Mortality	SEPA, 2000*	2[B]
Crustacea - Decapoda	*Nephrops norvegicus* (Norway lobster)	LC_{50}	572	192	Mortality	SEPA, 2000*	2[B]
Mollusca - Bivalvia	*Crassostrea virginica* (Eastern oyster)	NOEC	260	96	Shell deposition	OPP, 2000 cited by Environment Canada, 2005*	2[B]
Mollusca - Bivalvia	*Crassostrea virginica* (Eastern oyster)	LC_{50}	670	96	-	OPP, 2000 cited by Environment Canada, 2005*	2[B]
Mollusca - Bivalvia	*Crassostrea virginica* (Eastern oyster)	EC_{50}	490	96	Immobilization	OPP, 2000 cited by Environment Canada, 2005*	2[B]
Fish – Non-Salmonid	*Cyprinodon variegatus* (Sheepshead minnow)	LC_{50}	1430	96	Mortality	OPP, 2000 cited by Environment Canada, 2005*	1[B]
Fish – Non-Salmonid	*Cyprinodon variegatus* (Sheepshead minnow)	NOEC	860	96	Mortality	OPP, 2000 cited by Environment Canada, 2005*	1[B]

*Primary studies are confidential and unavailable for verification.

Table 3-C. Chronic toxicity data for pelagic freshwater and marine organisms exposed to emamectin benzoate.

Taxonomic group	Species	Endpoint	Value (µg/L)	Test duration (days)	Notes	References	Reliability
Algae (Freshwater)	*Pseudokirchneriella subcapitata*	EC_{50}	> 3.9	5	Population abundance, growth inhibition	US EPA, 2009*	1[B]

*	Primary study unavailable for consultation	**A**	Reliability assessed by PMRA experts
_	Lowest reliable value available for species	**B**	Reliability assessed by SEPA experts
1	Reliable without restriction	**C**	Reliablitly assessed by D. Hamoutene; evaluation is provisional and should be reassessed by more than one expert
2	Reliable with restriction	**D**	Reliability assessed by United Kingdom Technical Advisory Group Chemical Task Team
3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic group	Species	Endpoint	Value (µg/L)	Test duration (days)	Notes	References	Reliability
Algae (Freshwater)	*Pseudokirchneriella subcapitata*	NOEC	> 3.9	5	Growth inhibition	US EPA, 2009*	1[B]
Plant (Freshwater)	*Lemna gibba* (Duckweed)	EC_{50}	> 94	14	-	US EPA, 2009*	2[B]
Plant (Freshwater)	*Lemna gibba* (Duckweed)	NOEC	94	14	Abundance	US EPA, 2009*	2[B]
Insecta (Freshwater)	*Chironomus riparius*	NOEC	1.25	28	Emergence	EFSA, 2012*	2[B]
Crustacea - Copepoda (Seawater)	*Acartia clausi*	LOEC	0.158	7	Egg production	Willis and Ling, 2003	2[B]
Crustacea - Copepoda (Seawater)	*Acartia clausi*	NOEC	0.05	7	Egg production	Willis and Ling, 2003	2[B]
Crustacea – Mysida (Seawater)	*Americamysis bahia*	NOEC	0.0087	28	-	US EPA, 2009*	4[D]
Crustacea – Mysida (Seawater)	*Americamysis bahia*	NOEC	0.018	28	-	US EPA, 2009*	2[B]
Crustacea – Mysida (Seawater)	*Americamysis bahia*	EC_{10}	0.00944	28	Reproduction	EPP, 2018b cited by UKTAG CTT, 2019*	2[D]
Crustacea - Cladocera (Freshwater)	*Daphnia magna*	LOEC	0.16	21	Reproduction	OPP, 2000 cited by Environment Canada, 2005*	2[B]
Crustacea - Cladocera (Freshwater)	*Daphnia magna*	NOEC	0.088	21	Reproduction	OPP, 2000 cited by Environment Canada, 2005*	2[B]
Crustacea - Decapoda (Seawater)	*Homarus americanus* (American lobster)	LC_{50}	644	7	Adult	Burridge et al., 2004	2[B]

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1	Reliable without restriction	**C**	Reliablitly assessed by D. Hamoutene; evaluation is provisional and should be reassessed by more than one expert
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3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic group	Species	Endpoint	Value (µg/L)	Test duration (days)	Notes	References	Reliability
Crustacea - Decapoda (Seawater)	*Homarus americanus* (American lobster)	LC_{50}	> 589	7	Juvenile	Burridge et al., 2004	2[B]
Mollusca - Bivalvia (Seawater)	*Crassostrea virginica* (Eastern oyster)	EC_{50}	490	Not reported	Shell deposition or embryo larvae	US EPA, 2009*	2[B]
Fish – Non-Salmonid (Freshwater)	*Pimephales promelas* (Fathead minnow)	NOEC	12	32	Growth - Early life stages	EFSA, 2012*	2[B]
Fish – Non-Salmonid (Freshwater)	*Pimephales promelas* (Fathead minnow)	NOEC	6.5	32	-	US EPA, 2009*	2[B]

Table 3-D. Toxicity data for benthic marine and freshwater organisms exposed to emamectin benzoate.

Taxonomic group	Species	Endpoint	Value (µg/kg dry weight; wet between brackets when applicable)	Test duration (days)	Notes	References	Reliability
Insecta (Freshwater)	*Chironomus riparius*	NOEC	1.175	28	Mortality	EFSA, 2012*	2[B]
Annelida - Polychaeta (Seawater)	*Hediste diversicolor* (Ragworm)	LC_{50}	1368 (wet)	10	Mortality	Mayor et al., 2008	2[C]
Annelida - Polychaeta (Seawater)	*Arenicola marina* (Lugworm)	LC_{50}	111 (wet)	10	Mortality	SEPA, 1999 cited by Environment Canada, 2005*	2[B]
Annelida - Polychaeta (Seawater)	*Arenicola marina* (Lugworm)	NOEC	56 (wet)	10	Mortality	SEPA, 1999 cited by Environment Canada, 2005*	2[B]
Annelida - Polychaeta (Seawater)	*Arenicola marina* (Lugworm)	LC_{50}	40.8	10	Mortality	EPP, 2018c cited by UKTAG CTT, 2019*	2[D]

*	Primary study unavailable for consultation	**A**	Reliability assessed by PMRA experts
_	Lowest reliable value available for species	**B**	Reliability assessed by SEPA experts
1	Reliable without restriction	**C**	Reliablitly assessed by D. Hamoutene; evaluation is provisional and should be reassessed by more than one expert
2	Reliable with restriction	**D**	Reliability assessed by United Kingdom Technical Advisory Group Chemical Task Team
3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic group	Species	Endpoint	Value (µg/kg dry weight; wet between brackets when applicable)	Test duration (days)	Notes	References	Reliability
Annelida - Polychaeta (Seawater)	*Arenicola marina* (Lugworm)	NOEC	19.9	10	Mortalitiy	EPP, 2018c cited by UKTAG CTT, 2019*	2[D]
Crustacea - Amphipoda (Seawater)	*Corophium volutator*	LC_{50}	193	10	-	SEPA, 2000*	2[B]
Crustacea - Amphipoda (Seawater)	*Corophium volutator*	NOEC	115	10	Mortality	SEPA, 2000*	2[B]
Crustacea - Amphipoda (Seawater)	*Corophium volutator*	LC_{50}	6.32	10	Carried out in absence of sediment (not used for EQS inference)	SEPA, 2000*	2[B]
Crustacea - Amphipoda (Seawater)	*Corophium volutator*	NOEC	3.2	10	Carried out in absence of sediment (not used for EQS inference)	SEPA, 2000*	2[B]
Crustacea - Amphipoda (Seawater)	*Corophium volutator*	LC_{50}	141.5	10	Mortality	EPP, 2018d cited by UKTAG CTT, 2019*	2[D]
Crustacea - Amphipoda (Seawater)	*Corophium volutator*	NOEC	99.4	10	Mortality	EPP, 2018d cited by UKTAG CTT, 2019*	2[D]
Crustacea - Amphipoda (Seawater)	*Corophium volutator*	NOEC	61.28	28	Survival, growth, reproduction	Scymaris Ltd, 2018 cited by UKTAG CTT, 2019*	2[D]
Crustacea - Amphipoda (Seawater)	*Eohaustorius estuarius*	LC_{50}	146 (185 wet)	10	Mortality	Kuo et al., 2010	1[C]
Crustacea - Amphipoda (Seawater)	*Leptocheirus plumulosus*	EC_{10}	17.6	28	Growth rate	EPP, 2018e cited by UKTAG CTT, 2019*	2[D]

*	Primary study unavailable for consultation	**A**	Reliability assessed by PMRA experts
_	Lowest reliable value available for species	**B**	Reliability assessed by SEPA experts
1	Reliable without restriction	**C**	Reliablitly assessed by D. Hamoutene; evaluation is provisional and should be reassessed by more than one expert
2	Reliable with restriction	**D**	Reliability assessed by United Kingdom Technical Advisory Group Chemical Task Team
3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic group	Species	Endpoint	Value (µg/kg dry weight; wet between brackets when applicable)	Test duration (days)	Notes	References	Reliability
Crustacea - Amphipoda (Seawater)	*Leptocheirus plumulosus*	EC_{10}	43	28	Reproduction	EAG, 2018 cited by UKTAG CTT, 2019*	2[D]
Crustacea - Decapoda (Seawater)	*Pandalus platyceros* (Spot prawn)	LC_{50}	735	30	Mortality, sublethal endpoints	Park, 2013	1[C]
Crustacea - Decapoda (Seawater)	*Pandalus platyceros* (Spot prawn)	LOEC	42 (wet)	8	Mortality, sublethal endpoints	Park, 2013	1[C]
Crustacea - Decapoda (Seawater)	*Pandalus platyceros* (Spot prawn)	EC_{20}	138 (wet)	8	Mortality, genetic changes	Veldhoen et al., 2012	2[B]

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1	Reliable without restriction	**C**	Reliablitly assessed by D. Hamoutene; evaluation is provisional and should be reassessed by more than one expert
2	Reliable with restriction	**D**	Reliability assessed by United Kingdom Technical Advisory Group Chemical Task Team
3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

4. Ivermectin

Table 4-A. Acute toxicity data for pelagic freshwater organisms exposed to ivermectin.

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Algae - Green	*Pseudokirchneriella subcapitata*	NOEC	391	72	Growth rate and yield	Garric et al., 2007	2[C]
Algae - Green	*Pseudokirchneriella subcapitata*	EC_{50}	1250	72	Growth rate and yield	Garric et al., 2007	2[C]
Crustacea - Cladocera	*Daphnia magna*	LC_{50}	0.025	48	Mortality	Halley et al., 1989a	4[B]
Crustacea - Cladocera	*Daphnia magna*	LC_{50}	0.0057	48	Mortality	Garric et al., 2007	2[C]
Crustacea - Cladocera	*Daphnia magna*	NOEC	0.01	48	Mortality	Halley et al., 1989a	4[B]
Crustacea - Cladocera	*Daphnia magna*	LC_{50}	0.0158	48	-	SEPA, 1998b*	2[B]
Crustacea - Cladocera	*Daphnia magna*	LC_{50}	0.0281	24	Nominal; Neonate	SEPA, 1998b*	2[B]
Crustacea - Cladocera	*Daphnia magna*	NOEC	0.0056	48	Nominal; Neonate	SEPA, 1998b*	2[B]
Crustacea - Cladocera	*Daphnia magna*	LC_{50}	0.015 - 0.03	48	-	Halley et al., 1989b*	4[B]
Mollusca - Gastropoda	*Biomphalaria glabrata* (Tropical snail)	LC_{50}	30	12 to 24	Nominal	Matha and Weiser, 1988	2[B]
Mollusca - Gastropoda	*Biomphalaria glabrata* (Tropical snail)	LC_{90}	42	12 to 24h	Nominal	Matha and Weiser, 1988	2[B]
Mollusca - Gastropoda	*Biomphalaria glabrata* (Tropical snail)	LC_{100}	55	12 to 24 h	Nominal	Matha and Weiser, 1988	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	4.8	96	Extrapolated value as LC50 was below lowest concentration (5.1 ppb)	Halley et al., 1989a	4[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	5.3	72 and 96	Nominal	SEPA, 1998b*	2[B]

*	Primary study unavailable for consultation	**A**	Reliability assessed by PMRA experts
_	Lowest reliable value available for species	**B**	Reliability assessed by SEPA experts
1	Reliable without restriction	**C**	Reliablitly assessed by D. Hamoutene; evaluation is provisional and should be reassessed by more than one expert
2	Reliable with restriction	**D**	Reliability assessed by United Kingdom Technical Advisory Group Chemical Task Team
3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	7.5	48	Nominal	SEPA, 1998b*	2[B]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	13.3	24	Nominal	SEPA, 1998b*	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	NOEC	0.9	96	-	Halley et al., 1989a	4[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	3	96	-	Halley et al., 1989a	4[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	3.3	96	Nominal	SEPA, 1998b*	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	9.4	24	Nominal	SEPA, 1998b*	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	4.7	48	Nominal	SEPA, 1998b*	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	4.2	72	Nominal	SEPA, 1998b*	2[B]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	NOEC	1.0	96	Nominal	SEPA, 1998b*	2[B]

Table 4-B. Acute toxicity data for pelagic marine organisms exposed to ivermectin.

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Nematoda	*Nematoda*	LC_{50}	> 10 000	96	Test sample of free living nematodes from a mid-estuarine site	Grant and Briggs, 1998	4[C]
Nematoda	*Nematoda*	LC_{10}	> 10 000	96	Test sample of free living nematodes from a mid-estuarine site	Grant and Briggs, 1998	4[C]
Annelida - Polychaeta	*Nereis diversicolor*	LC_{50}	7.75	96	-	Grant and Briggs, 1998	4[C]
Annelida - Polychaeta	*Nereis diversicolor*	LC_{10}	5.4	96	-	Grant and Briggs, 1998	4[C]
Crustacea - Anostraca	*Artemia salina*	LC_{50}	> 300	24	-	Grant and Briggs, 1998	4[C]

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_	Lowest reliable value available for species	**B**	Reliability assessed by SEPA experts
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2	Reliable with restriction	**D**	Reliability assessed by United Kingdom Technical Advisory Group Chemical Task Team
3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Crustacea - Anostraca	*Artemia salina*	LC_{10}	3	96	-	Grant and Briggs, 1998	4[C]
Crustacea - Amphipoda	*Gammarus* spp.	LC_{50}	0.033	96	A mixture of *G. duebeni* and *G. zaddachi* in a ratio of approximately 1:4	Grant and Briggs, 1998	4[C]
Crustacea - Amphipoda	*Gammarus* spp.	LC_{10}	0.0033	96	-	Grant and Briggs, 1998	4[C]
Crustacea - Mysida	*Neomysis integer*	LC_{50}	0.07	96	-	Davies et al., 1997	2[B]
Crustacea - Mysida	*Neomysis integer*	LC_{50}	0.026	48	-	Grant and Briggs, 1998	4[C]
Crustacea - Mysida	*Neomysis integer*	LC_{10}	0.0036	96	-	Grant and Briggs, 1998	4[C]
Crustacea - Mysida	*Neomysis integer*	LC_{50}	0.07	96	Measured	SSGA, 1996 cited by SEPA, 1998b*	2[B]
Crustacea - Isopoda	*Lekanesphaera rugicauda (*previously *Sphaeroma rugicauda)*	LC_{50}	348	96	-	Grant and Briggs, 1998	4[C]
Crustacea - Isopoda	*Lekanesphaera rugicauda (*previously *Sphaeroma rugicauda)*	LC_{10}	139	96	-	Grant and Briggs, 1998	4[C]
Crustacea - Decapoda	*Carcinus maenas* (European green crab)	LC_{50}	957	96	-	Grant and Briggs, 1998	4[C]
Crustacea - Decapoda	*Carcinus maenas* (European green crab)	LC_{10}	88	96	-	Grant and Briggs, 1998	4[C]
Crustacea - Decapoda	*Crangon septemspinosa* (Sand shrimp)	NOEC	21.5	96	-	Burridge and Haya, 1993	4[C]
Crustacea - Decapoda	*Palaemon varians* (Atlantic ditch shrimp)	LC_{50}	54	96	-	Grant and Briggs, 1998	4[C]
Crustacea - Decapoda	*Palaemon varians* (Atlantic ditch shrimp)	LC_{10}	9.4	96	-	Grant and Briggs, 1998	4[C]
Mollusca - Gastropoda	*Hydrobia ulvae* (Laver spire shell)	LC_{50}	> 10 000	96	-	Grant and Briggs, 1998	4[C]
Mollusca - Gastropoda	*Hydrobia ulvae* (Laver spire shell)	LC_{10}	> 10 000	96	-	Grant and Briggs, 1998	4[C]

*	Primary study unavailable for consultation	**A**	Reliability assessed by PMRA experts
_	Lowest reliable value available for species	**B**	Reliability assessed by SEPA experts
1	Reliable without restriction	**C**	Reliablitly assessed by D. Hamoutene; evaluation is provisional and should be reassessed by more than one expert
2	Reliable with restriction	**D**	Reliability assessed by United Kingdom Technical Advisory Group Chemical Task Team
3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Mollusca - Gastropoda	*Potamopyrgus jenkinsi* (New Zealand mud snail)	LC_{50}	< 9000	96	-	Grant and Briggs, 1998	4[C]
Mollusca - Gastrapoda	*Monodonta lineata* (Topshell)	LC_{50}	780	96	-	SSGA, 1996 cited by SEPA, 1998b*	2[B]
Mollusca - Gastropoda	*Nucella lapillus* (Dog whelk)	LC_{50}	390	96	-	SSGA, 1996 cited by SEPA, 1998b*	2[B]
Mollusca - Gastropoda	*Littorina littorea* (Periwinkle)	LC_{50}	580	96	-	SSGA, 1996 cited by SEPA, 1998b*	2[B]
Mollusca - Gastropoda	*Patella vulgate* (Common Limpet)	LC_{50}	600	96	-	SSGA, 1996 cited by SEPA, 1998b*	2[B]
Mollusca - General	*Potamopyrgus jenkinsi* (New Zealand mud snail)	LC_{10}	1800	96	Determined by inspection of data, rather than calculation	Grant and Briggs, 1998	4[C]
Mollusca - Pectinida	*Pecten maximus* (Scallop)	LC_{50}	300	96	-	SSGA, 1996 cited by SEPA, 1998b*	2[B]
Mollusca - Bivalvia	*Crassostrea gigas* (Pacific oyster)	LC_{50}	80 - 100	96	Larvae	SSGA, 1996 cited by SEPA, 1998b*	2[B]
Mollusca - Bivalvia	*Crassostrea gigas* (Pacific oyster)	LC_{50}	460	96	Spat	SSGA, 1996 cited by SEPA, 1998b*	2[B]
Mollusca - Bivalvia	*Mytilus edulis* (Blue mussel)	LC_{50}	400	96	-	SSGA, 1996 cited by SEPA, 1998b*	2[B]
Mollusca - Bivalvia	*Tapes semidecassata* (Carpet shell)	LC_{50}	380	96	Larvae	SSGA, 1996 cited by SEPA, 1998b*	2[B]
Mollusca - Bivalvia	*Tapes semidecassata* (Carpet shell)	LC_{50}	600	96	Spat	SSGA, 1996 cited by SEPA, 1998b*	2[B]
Fish - Salmonid	*Salmo salar* (Atlantic salmon)	LC_{50}	17	96	-	Kilmartin et al., 1997	3[C] (No tank replications in the immersion study)

Table 4-C. Chronic toxicity data for pelagic freshwater organisms exposed to ivermectin.

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (Days)	Notes	Reference	Reliability
Algae - Green	*Chlorella pyrenoidosa*	Sublethal Effects	9100	14	Growth neasured as mean dry weight	Halley et al., 1989a	4[B]

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3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (Days)	Notes	Reference	Reliability
Crustacea - Cladocera	*Daphnia magna*	NOEC	$3e10^{-7}$	21	Life traits (growth, reproduction, sex ratio); value based on nominal concentration	Garric et al., 2007	2[C]

Table 4-D. Toxicity data for benthic freshwater organisms exposed to ivermectin.

Taxonomic Group	Species	Endpoint	Value (mg/kg - dry weight)	Test Duration (days)	Notes	Reference	Reliability
Insecta	*Chironomus riparius*	NOEC	0.0031	10	Survival, growth	Egeler et al., 2010	2[C]
Insecta	*Chironomus riparius*	NOEC	0.053	51	Survival, growth, and emergence; Study carried out using dry dung rather than sediment	Schweitzer et al., 2010	2[C]
Nematoda - Rhabditida	*Caenorhabditis elegans*	NOEC	0.1	96 h	Reproduction	Liebig et al., 2010	1[C]
Annelida - Lumbriculida	*Lumbriculus variegatus*	NOEC	0.160	28	Survival	Egeler et al., 2010	2[C]
Annelida - Haplotaxida	*Eisenia foetida* (Earthworm/Red Wiggler; terrestrial)	LC_{50}	315 (Not clear if dry or wet weight)	28	Continuous light - not specified whether wet or dry weight	Halley et al., 1989b	4[B]
Annelida - Haplotaxida	*Eisenia foetida* (Earthworm/Red Wiggler; terrestrial)	NOEC	12 (Not clear if dry or wet weight)	28	Continuous light - not specified whether wet or dry weight	Halley et al., 1989b	4[B]
Crustacea - Cladocera	*Daphnia magna*	NOEC	0.263	51	Abundance and biomass; Study carried out using dry dung rather than sediment	Schweitzer et al., 2010	3[C] (High variability between replicates, potential exposures to ammonia through dung exposure that could have an effect on daphnia, some

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2	Reliable with restriction	**D**	Reliability assessed by United Kingdom Technical Advisory Group Chemical Task Team
3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic Group	Species	Endpoint	Value (mg/kg - dry weight)	Test Duration (days)	Notes	Reference	Reliability
							measurements below LOQ)

Table 4-E. Toxicity data for benthic marine organisms exposed to ivermectin.

Taxonomic Group	Species	Endpoint	Value (mg/kg - dry weight of sediment)	Test Duration (days)	Notes	Reference	Reliability
Annelida - Polychaeta	*Arenicola marina* (Lugworm)	NOEC	0.015	10	Mortality	Thain et al., 1997	2[C]
Annelida - Polychaeta	*Arenicola marina* (Lugworm)	LC_{50}	0.023	10	Mortality	Thain et al., 1997	2[C]
Annelida - Polychaeta	*Arenicola marina* (Lugworm)	LOEC	0.024	10	Mortality	Thain et al., 1997	2[C]
Annelida - Polychaeta	*Arenicola marina* (Lugworm)	EC (Behaviour Effects)	0.006	10	Reduction in rate of cast production	Thain et al., 1997	4[C]
Annelida - Polychaeta	*Arenicola marina* (Lugworm)	EC (Behaviour Effects)	≥ 0.01	10	Reduced the rate at which *A. marina* was able to burrow into clean sediment.	Thain et al., 1997	4[C]
Annelida - Polychaeta	*Arenicola marina* (Lugworm)	LC_{50}	0.018 (wet sediment)	10	Nominal	SSGA, 1996 cited by SEPA, 1998b*	2[B]
Crustacea - Amphipoda	*Corophium volutator*	LC_{50}	0.18	10	-	Davies et al., 1998	2[B]
Crustacea - Amphipoda	*Corophium volutator*	NOEC	0.05	10	-	Davies et al., 1998; SSGA, 1996 cited by SEPA, 1998b*	2[B]
Crustacea - Amphipoda	*Corophium volutator*	LOEC	0.1	10	-	Davies et al., 1998	2[B]
Crustacea - Amphipoda	*Corophium volutator*	LC_{50}	0.18 (dry sediment)	10	Nominal	SSGA, 1996 cited by SEPA, 1998b*	2[B]

*	Primary study unavailable for consultation	**A**	Reliability assessed by PMRA experts
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1	Reliable without restriction	**C**	Reliablitly assessed by D. Hamoutene; evaluation is provisional and should be reassessed by more than one expert
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Taxonomic Group	Species	Endpoint	Value (mg/kg - dry weight of sediment)	Test Duration (days)	Notes	Reference	Reliability
Crustacea - Amphipoda	*Corophium volutator*	LC_{50}	0.1 (wet sediment)	10	Nominal	SSGA, 1996 cited by SEPA, 1998b*	2^{B}
Crustacea - Amphipoda	*Corophium volutator*	NOEC	0.02 (wet sediment)	10	Nominal	SSGA, 1996 cited by SEPA, 1998b*	2^{B}
Echinoderms	*Asterias rubens* (Common starfish)	LC_{50}	23.6	10	-	Davies et al., 1998; SSGA, 1996 cited by SEPA, 1998b*	2^{B}
Echinoderms	*Asterias rubens* (Common starfish)	NOEC	5	10	-	Davies et al., 1998; SSGA, 1996 cited by SEPA, 1998b*	2^{B}
Echinoderms	*Asterias rubens* (Common starfish)	LOEC	10	10	-	SSGA, 1996 cited by SEPA, 1998b*	2^{B}
Echinoderms	*Asterias rubens* (Common starfish)	Sublethal Effects Level	20	10	Inability to turn over	Davies et al., 1998	2^{B}

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2	Reliable with restriction	**D**	Reliability assessed by United Kingdom Technical Advisory Group Chemical Task Team
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4	Not assignable	**F**	Reliability assessed by FAO experts

5. Teflubenzuron

Table 5-A. Acute toxicity data for pelagic freshwater organisms exposed to teflubenzuron.

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Plant	*Lemna minor* (Duckweed)	EC_{50}	1 176 160	7 days	Sediment absent	Medeiros et al., 2013	2[C]
Plant	*Lemna minor* (Duckweed)	EC_{50}	1 686 120	7 days	Sediment present	Medeiros et al., 2013	2[C]
Insecta - Hemiptera	*Anisops sardeus*	LC_{50}	249	24	-	Lahr et al., 2001	3[C] (Test requires more standardization)
Brachiopoda	*Streptocephalus sudanicus*	EC_{50}	23.6	24	Immobility	Lahr et al., 2001	3[C] (Test requires more standardization)
Brachiopoda	*Streptocephalus sudanicus*	EC_{50}	0.59	48	Immobility	Lahr et al., 2001	3[C] (Test requires more standardization)
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	0.26	48	Sediment absent	Medeiros et al., 2013	2[C]
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	1.19	48	Sediment present	Medeiros et al., 2013	2[C]
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	1.2	48	Immobilization	Koyangi et al., 1998	4[C]
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	0.33	48	Immobilization	EFSA, 2008a*	2[E]
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	> 1 000 000	24	Immobilization	SEPA, 1998c*	2[B]
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	0.47	48	Immobilization	SEPA, 1998c*	2[B]
Fish - Non-Salmonid	*Poecilia reticulata* (Guppy)	LC_{50}	2 580 130	96	Sediment absent	Medeiros et al., 2013	2[C]
Fish - Non-Salmonid	*Poecilia reticulata* (Guppy)	LC_{50}	3 486 130	96	Sediment present	Medeiros et al., 2013	2[C]

*	Primary study unavailable for consultation	**A**	Reliability assessed by PMRA experts
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2	Reliable with restriction	**D**	Reliability assessed by United Kingdom Technical Advisory Group Chemical Task Team
3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Table 5-B. Acute toxicity data for pelagic marine organisms exposed to teflubenzuron.

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Crustacea - Copepods	*Tisbe battagliai*	LC_{50}	230	24 h	Nauplii	Macken et al., 2015	1[C]
Crustacea - Copepods	*Tisbe battagliai*	LC_{50}	40	48 h	Nauplii	Macken et al., 2015	1[C]
Crustacea - Copepods	*Tisbe battagliai*	LOEC	0.01	7 days	-	Macken et al., 2015	1[C]
Crustacea - Copepods	*Tisbe battagliai*	NOEC	0.0032	7 days	-	Macken et al., 2015	1[C]
Crustacea - Mysida	*Mysidopsis bahia*	LC_{50}	0.057	7 days	Juvenile	Baird et al., 1996 cited by Skretting ARC, 2011*	2[B]
Crustacea - Mysida	*Mysidopsis bahia*	NOEC	0.037	n/a	Survival, growth and reproduction	Baird et al., 1996 cited by Skretting ARC, 2011*	2[B]
Crustacea - Mysida	*Mysidopsis bahia*	LC_{50}	0.17	96	27 day life cycle study	WRc, 1998c*	2[B]
Crustacea - Mysida	*Mysidopsis bahia*	LC_{50}	0.13	7 days	27 day life cycle study	WRc, 1998c*	2[B]
Crustacea - Decapoda	*Homarus americanus* (American lobster)	LOEC	≥ 2500	n/a	-	Cantox, Inc., 1997 cited by Skretting ARC, 2011*	2[B]

Table 5-C. Chronic toxicity data for pelagic marine and freshwater organisms exposed to teflubenzuron.

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (days)	Notes	Reference	Reliability
Crustacea - Mysida	*Mysidopsis bahia* (SW)	NOEC	0.043	27 days	Mortality, Reproduction, Growth	Drottar and Swigert, 1996 cited by EFSA, 2008a*	2[E]
Crustacea - Cladocera	*Daphnia magna* (FW)	NOEC	0.062	21 days	Length of parent daphnids	EFSA, 2008a*	2[E]

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1	Reliable without restriction	**C**	Reliablitly assessed by D. Hamoutene; evaluation is provisional and should be reassessed by more than one expert
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3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Table 5-D. Toxicity data for benthic marine and freshwater organisms exposed to teflubenzuron.

Taxonomic Group	Species	Endpoint	Value (µg/kg, dry)	Test Duration (days)	Notes	Reference	Reliability
Insects- Diptera (Freshwater)	*Chironomus riparius*	NOEC	50	28	Emergence ratio	EFSA, 2008a*	2[E]
Annelida - Polychaeta (Seawater)	*Arenicola marina* (Lugworm)	LC_{50}	> 10 000 mg/kg	10	Nominal	WRc, 1998c*	2[B]
Annelida – Polychaeta (Seawater)	*Capitella* sp. I and B	Sublethal Effects Level	41 800	10	Chaetal abnormalities	Mendez, 2006	2[C]
Annelida – Polychaeta (Seawater)	*Capitella* sp. B	Other Effects	25 000	10	40 % mortality	Mendez, 2006	2[C]
Annelida – Polychaeta (Seawater)	*Capitella* sp. I	Sublethal Effects Level	8 400	10	Reduction in feeding activity (further reduction as concentration increased from 8.4 - 41.8 µg/g (dry))	Mendez, 2006	2[C]
Crustacea – Amphipoda (Seawater)	*Corophium volutator*	NOEC	17.3	28	Life cycle	Glass, 1997 and Aufderheide et al., 1999 cited by SEPA, 1999*	2[B]

6. Lufenuron

Table 6-A. Acute toxicity data for pelagic freshwater organisms exposed to lufenuron.

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Algae	*Scenedesmus subspicatus* (Green algae)	EC_{50}	10 000	72	Growth Inhibition	Syngenta, 1989 (CGA 184699/0018) cited by FAO, 2008*	2[F]
Algae	*Selenastrum capricornutum*	EC_{50}	8 800	72	Growth	EFSA, 2008b*	2[E]

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3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	1.3	48	-	Syngenta, 1989 (CGA 184699/0013) cited by FAO, 2008*	2[F]
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	1.1	48	-	Syngenta, 1989 (CGA 184699/0015) cited by FAO, 2008*	2[F]
Crustacea - Cladocera	*Daphnia magna*	EC_{50}	4	48	Static test with sediment	Syngenta, 1989 (CGA 184699/0014) cited by FAO, 2008*	2[F]
Fish - Non-Salmonid	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}	> 29 000	96	-	Syngenta, 1989 (CGA 184699/0010) cited by FAO, 2008*	2[F]
Fish - Non-Salmonid	*Cyprinus carpio* (Carp)	LC_{50}	> 63 000	96	-	Syngenta, 1989 (CGA 184699/0012) cited by FAO, 2008*	2[F]
Fish - Non-Salmonid	Ictalurus punctatus (Catfish)	LC_{50}	> 45 000	96	-	Syngenta, 1989 (CGA 184699/0009) cited by FAO, 2008*	2[F]
Fish - Non-Salmonid	*Colossoma macropomum* (Tambaqui)	LC_{50}	610	24	Juveniles	Soares et al., 2016	2[C]
Fish - Non-Salmonid	*Colossoma macropomum* (Tambaqui)	LC_{90}	820	24	Juveniles	Soares et al., 2016	2[C]

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4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (hours)	Notes	Reference	Reliability
Fish - Non-Salmonid	*Colossoma macropomum* (Tambaqui)	LC_{50}	580	96	Juveniles	Soares et al., 2016	2[C]
Fish - Non-Salmonid	*Colossoma macropomum* (Tambaqui)	LC_{90}	780	96	Juveniles	Soares et al., 2016	2[C]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	> 73 000	96	-	Syngenta, 1989 (CGA 184699/0011) cited by FAO, 2008*	2[F]

Table 6-B. Chronic toxicity data for pelagic freshwater organisms exposed to lufenuron.

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (days)	Notes	Reference	Klimisch Score / Reliability
Insecta	*Chironomus riparius*	NOEC	2	28	Emergence	Syngenta, 1989 (CGA 184699/0566) cited by FAO, 2008*	2[F]
Insecta	*Chironomus riparius*	NOEC	4	28	Development	Syngenta, 1989 (CGA 184699/0566) cited by FAO, 2008*	2[F]
Crustacea - Cladocera	*Daphnia magna*	NOEC	0.1	21	-	Syngenta, 1989 (CGA 184699/0017) cited by FAO, 2008*	2[F]
Fish - Non-Salmonid	*Colossoma macropomum* (Tambaqui)	5% Mortality	100	120	Juveniles	Soares et al., 2016	2[C]

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3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic Group	Species	Endpoint	Value (µg/L)	Test Duration (days)	Notes	Reference	Klimisch Score / Reliability
Fish - Non-Salmonid	*Pimephales promelas* (Fathead minnow)	NOEC	20	2 generations	Egg hatch and survival in F1 generation	Syngenta, 1989 (184699/0757) cited by FAO, 2008*	2[F]
Fish - Salmonid	*Oncorhynchus mykiss* (Rainbow trout)	NOEC	69	21	-	Syngenta, 1989 (184699/0198) cited by FAO, 2008*	2[F]

Table 6-C. Toxicity data for benthic freshwater organisms exposed to lufenuron.

Taxonomic Group	Species	Endpoint	Value (µg/kg dry sediment; "indicates the units are µg/g OC)	Test Duration (days)	Notes	Reference	Reliability
Insecta - Trichoptera	*Sericostoma personatum*	NOEC	1.64"	10	-	Brock et al., 2018	1[C]
Insecta - Trichoptera	*Sericostoma personatum*	LC_{10}	0.04"	10	-	Brock et al., 2018	1[C]
Insecta - Trichoptera	*Sericostoma personatum*	LC_{20}	0.26"	10	-	Brock et al., 2018	1[C]
Insecta - Trichoptera	*Sericostoma personatum*	LC_{50}	7.6"	10	-	Brock et al., 2018	1[C]
Insecta - Trichoptera	*Sericostoma personatum*	EC_{50}	54"	10	Larvae	Jollie, 2016	2[C]
Insecta - Trichoptera	*Sericostoma personatum*	EC_{50}	7.9"	28	Larvae	Jollie, 2016	2[C]
Insecta - Megaloptera	*Sialis lutaria*	NOEC, LC_{10}, LC_{20}, LC_{50}	> 27.56"	Same value for both 10 and 28 days exposure for all endpoints	-	Brock et al., 2018	1[C]
Insecta - Ephemeroptera	*Caenis horaria*	NOEC	0.97"	10	-	Brock et al., 2018	1[C]

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2	Reliable with restriction	**D**	Reliability assessed by United Kingdom Technical Advisory Group Chemical Task Team
3	Not reliable	**E**	Reliability assessed by EFSA experts
4	Not assignable	**F**	Reliability assessed by FAO experts

Taxonomic Group	Species	Endpoint	Value (µg/kg dry sediment; "indicates the units are µg/g OC)	Test Duration (days)	Notes	Reference	Reliability
Insecta - Ephemeroptera	*Caenis horaria*	LC_{10}	1.42"	10	-	Brock et al., 2018	1[C]
Insecta - Ephemeroptera	*Caenis horaria*	LC_{20}	1.85"	10	-	Brock et al., 2018	1[C]
Insecta - Ephemeroptera	*Caenis horaria*	LC_{50}	2.89"	10	-	Brock et al., 2018	1[C]
Insecta - Ephemeroptera	*Caenis horaria*	NOEC	4.92"	28	-	Brock et al., 2018	1[C]
Insecta - Ephemeroptera	*Caenis horaria*	LC_{10}	1.12"	28	-	Brock et al., 2018	1[C]
Insecta - Ephemeroptera	*Caenis horaria*	LC_{20}	2.03"	28	-	Brock et al., 2018	1[C]
Insecta - Ephemeroptera	*Caenis horaria*	LC_{50}	5.7"	28	-	Brock et al., 2018	1[C]
Insecta - Ephemeroptera	*Ephemera danica*	NOEC	1.64"	28	-	Brock et al., 2018	1[C]
Insecta - Ephemeroptera	*Ephemera danica*	LC_{10}	1.94"	28	-	Brock et al., 2018	1[C]
Insecta - Ephemeroptera	*Ephemera danica*	LC_{20}	2.68"	28	-	Brock et al., 2018	1[C]
Insecta - Ephemeroptera	*Ephemera danica*	LC_{50}	4.72"	28	-	Brock et al., 2018	1[C]
Insecta - Diptera	*Chironomus riparius*	NOEC	3.32"	10	-	Brock et al., 2018	1[C]
Insecta - Diptera	*Chironomus riparius*	LC_{10}	2.99"	10	-	Brock et al., 2018	1[C]
Insecta - Diptera	*Chironomus riparius*	LC_{20}	3.43"	10	-	Brock et al., 2018	1[C]
Insecta - Diptera	*Chironomus riparius*	LC_{50}	4.37"	10	-	Brock et al., 2018	1[C]
Insecta - Diptera	*Chironomus riparius*	NOEC	30	10	Larval growth	Hooper et al., 2005	2[C]
Insecta - Diptera	*Chironomus riparius*	NOEC	60	10	Juvenile survival	Hooper et al., 2005	2[C]
Insecta - Diptera	*Chironomus riparius*	NOEC	0.15"	28	Survival of larvae	Brock et al., 2016	1[C]
Insecta - Diptera	*Chironomus riparius*	EC_{10}	0.49"	28	Survival of larvae	Brock et al., 2016	1[C]

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Taxonomic Group	Species	Endpoint	Value (µg/kg dry sediment; "indicates the units are µg/g OC)	Test Duration (days)	Notes	Reference	Reliability
Insecta - Diptera	*Chironomus riparius*	EC_{20}	0.88"	28	Survival of larvae	Brock et al., 2016	1[C]
Insecta - Diptera	*Chironomus riparius*	EC_{50}	2.7"	28	Survival of larvae	Brock et al., 2016	1[C]
Insecta - Diptera	*Chironomus riparius*	NOEC	3.32"	28	Emergence of adults	Brock et al., 2016	1[C]
Insecta - Diptera	*Chironomus riparius*	EC_{10}	0.51"	28	Emergence of adults	Brock et al., 2016	1[C]
Insecta - Diptera	*Chironomus riparius*	EC_{20}	0.81"	28	Emergence of adults	Brock et al., 2016	1[C]
Insecta - Diptera	*Chironomus riparius*	EC_{50}	3.18"	28	Emergence of adults	Brock et al., 2016	1[C]
Insecta - Diptera	*Chironomus riparius*	NOEC	2.35"	28	OECD Sediment	Brock et al., 2018	1[C]
Insecta - Diptera	*Chironomus riparius*	LC_{10}	4.18"	28	OECD Sediment	Brock et al., 2018	1[C]
Insecta - Diptera	*Chironomus riparius*	LC_{20}	4.44"	28	OECD Sediment	Brock et al., 2018	1[C]
Insecta - Diptera	*Chironomus riparius*	LC_{50}	4.86"	28	OECD Sediment	Brock et al., 2018	1[C]
Insecta - Diptera	*Chironomus riparius*	NOEC	40	28	Midge emergence	Syngenta, 1989 (CGA 184699/0566) cited by FAO, 2008*	2[F]
Insecta - Diptera	*Chironomus riparius*	NOEC	80	28	Midge development	Syngenta, 1989 (CGA 184699/0566) cited by FAO, 2008*	2[F]
Insecta - Diptera	*Chironomus dilutus*	NOEC	4.92"	10	-	Brock et al., 2018	1[C]
Insecta - Diptera	*Chironomus dilutus*	LC_{10}	4.77"	10	-	Brock et al., 2018	1[C]
Insecta - Diptera	*Chironomus dilutus*	LC_{20}	5.91"	10	-	Brock et al., 2018	1[C]
Insecta - Diptera	*Chironomus dilutus*	LC_{50}	8.7"	10	-	Brock et al., 2018	1[C]
Insecta - Diptera	*Chironomus dilutus*	EC_{50}	6.5"	10	Larvae	Jollie, 2018	2[C]
Insecta - Diptera	*Chironomus gr. thummi*	NOEC	3.32"	10	-	Brock et al., 2018	1[C]
Insecta - Diptera	*Chironomus gr. thummi*	LC_{10}	3.61"	10	-	Brock et al., 2018	1[C]
Insecta - Diptera	*Chironomus gr. thummi*	LC_{20}	4.77"	10	-	Brock et al., 2018	1[C]

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Taxonomic Group	Species	Endpoint	Value (µg/kg dry sediment; "indicates the units are µg/g OC)	Test Duration (days)	Notes	Reference	Reliability
Insecta - Diptera	*Chironomus gr. thummi*	LC_{50}	7.34"	10	-	Brock et al., 2018	1[C]
Insecta - Diptera	*Eisenia foetida* (Earthworm)	LC_{50}	> 1000 mg a.s./kg soil	14	Mortality and behaviour	Syngenta, 1989 (CGA 184699/0021) cited by FAO, 2008*	2[F]
Annelida - Lumbriculida	*Lumbriculus variegatus*	NOEC	790"	28	-	Brock et al., 2016	1[C]
Annelida - Lumbriculida	*Lumbriculus variegatus*	EC_{10}	211"	28	-	Brock et al., 2016	1[C]
Annelida - Lumbriculida	*Lumbriculus variegatus*	EC_{20}	371"	28	-	Brock et al., 2016	1[C]
Annelida - Lumbriculida	*Lumbriculus variegatus*	EC_{50}	1099"	28	-	Brock et al., 2016	1[C]
Annelida - Lumbriculida	*Lumbriculus variegatus*	NOEC	130"	28	-	Brock et al., 2016	1[C]
Annelida - Lumbriculida	*Lumbriculus variegatus*	EC_{10}	101"	28	-	Brock et al., 2016	1[C]
Annelida - Lumbriculida	*Lumbriculus variegatus*	EC_{20}	130"	28	-	Brock et al., 2016	1[C]
Annelida - Lumbriculida	*Lumbriculus variegatus*	EC_{50}	213"	28	-	Brock et al., 2016	1[C]
Crustacea - Amphipoda	*Hyalella azteca*	NOEC	3.32"	10	-	Brock et al., 2018	1[C]
Crustacea - Amphipoda	*Hyalella azteca*	LC_{10}	3.51"	10	-	Brock et al., 2018	1[C]
Crustacea - Amphipoda	*Hyalella azteca*	LC_{20}	6.57"	10	-	Brock et al., 2018	1[C]
Crustacea - Amphipoda	*Hyalella azteca*	LC_{50}	19.11"	10	-	Brock et al., 2018	1[C]
Crustacea - Amphipoda	*Hyalella azteca*	NOEC	0.97"	28	Adult survival; Weight adults	Brock et al., 2016	1[C]
Crustacea - Amphipoda	*Hyalella azteca*	EC_{10}	2.83"	28	Adult survival	Brock et al., 2016	1[C]
Crustacea - Amphipoda	*Hyalella azteca*	EC_{20}	3.18"	28	Adult survival	Brock et al., 2016	1[C]
Crustacea - Amphipoda	*Hyalella azteca*	EC_{50}	3.99"	28	Adult survival	Brock et al., 2016	1[C]
Crustacea - Amphipoda	*Hyalella azteca*	EC_{10}	2.82"	28	Weight adults	Brock et al., 2016	1[C]
Crustacea - Amphipoda	*Hyalella azteca*	EC_{20}	3.18"	28	Weight adults	Brock et al., 2016	1[C]
Crustacea - Amphipoda	*Hyalella azteca*	EC_{50}	3.99"	28	Weight adults	Brock et al., 2016	1[C]
Crustacea - Amphipoda	*Gammarus pulex*	NOEC	3.32"	10	-	Brock et al., 2018	1[C]
Crustacea - Amphipoda	*Gammarus pulex*	LC_{10}	4.84"	10	-	Brock et al., 2018	1[C]
Crustacea - Amphipoda	*Gammarus pulex*	LC_{20}	5.26"	10	-	Brock et al., 2018	1[C]

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Taxonomic Group	Species	Endpoint	Value (µg/kg dry sediment; "indicates the units are µg/g OC)	Test Duration (days)	Notes	Reference	Reliability
Crustacea - Amphipoda	*Gammarus pulex*	LC_{50}	6.05"	10	-	Brock et al., 2018	1[C]
Crustacea - Amphipoda	*Gammarus pulex*	NOEC	0.5"	28	-	Brock et al., 2018	1[C]
Crustacea - Amphipoda	*Gammarus pulex*	LC_{10}	3.79"	28	-	Brock et al., 2018	1[C]
Crustacea - Amphipoda	*Gammarus pulex*	LC_{20}	4.4"	28	-	Brock et al., 2018	1[C]
Crustacea - Amphipoda	*Gammarus pulex*	LC_{50}	5.5"	28	-	Brock et al., 2018	1[C]
Crustacea - Isopoda	*Asellus aquaticus*	NOEC	≥31.7"	10	-	Brock et al., 2018	1[C]
Crustacea - Isopoda	*Asellus aquaticus*	LC_{10}	29.72"	10	-	Brock et al., 2018	1[C]
Crustacea - Isopoda	*Asellus aquaticus*	LC_{20}	>31.7"	10	-	Brock et al., 2018	1[C]
Crustacea - Isopoda	*Asellus aquaticus*	LC_{50}	>31.7"	10	-	Brock et al., 2018	1[C]
Crustacea - Isopoda	*Asellus aquaticus*	NOEC	1.95"	28	-	Brock et al., 2018	1[C]
Crustacea - Isopoda	*Asellus aquaticus*	LC_{10}	0.1"	28	-	Brock et al., 2018	1[C]
Crustacea - Isopoda	*Asellus aquaticus*	LC_{20}	0.56"	28	-	Brock et al., 2018	1[C]
Crustacea - Isopoda	*Asellus aquaticus*	LC_{50}	10.92"	28	-	Brock et al., 2018	1[C]
Crustacea - Isopoda	*Asellus aquaticus*	LC_{50}	164.8	21	-	Deneer et al., 2013	2[C]
Crustacea - Isopoda	*Asellus aquaticus*	LC_{50}	6.59"	21	-	Jollie, 2016	2[C]
Crustacea - Isopoda	*Asellus aquaticus*	EC_{50}	8.1"	28	-	Workel, 2011	2[C]

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