Canadian Water Quality Guidelines for the Protection of Aquatic Life

PROTOCOL

A Protocol for the Derivation of Water Quality Guidelines for the Protection of Aquatic Life 2007

PART I. GENERAL OVERVIEW

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Introduction

The composition of aquatic assemblages and various physiological processes of aquatic plants and animals vary naturally with physical, chemical, geological, and hydrological conditions of the environment. Ecological attributes also fluctuate in response to elevated concentrations of natural and anthropogenic substances. Canadian Water Quality Guidelines for the Protection of Aquatic Life (CWQGs-PAL) are nationally approved limits of substances and other attributes (such as pH and temperature) in the water column where no adverse toxic effects are expected to aquatic plants and animals. The guidelines are one of a set of management tools developed to ensure that societal stresses, particularly the introduction of toxic substances, do not lead to the degradation of Canadian fresh and marine waters.

Background

Environmental toxicology and chemistry is a growing and evolving field; therefore, management approaches to address environmental issues should be flexible and adaptive. As a result, there is a need to periodically review the protocol outlining the derivation of CWQGs-PAL. Since the publication of the original protocol in 1991 (CCME 1991, 1999) through the Canadian Council of Ministers of the Environment (CCME), knowledge of aquatic toxicology and the environmental impact of toxic substances has advanced to a point where it is possible to better address certain issues involved in the derivation of water quality guidelines. Consequently, this revised protocol framework was developed. Using the existing Protocol for the Derivation of Water Quality Guidelines for the Protection of Aquatic Life (CCME 1991) as a basis, this revised protocol framework also incorporates new developments in the field of aquatic toxicology.

Canadian Environmental Quality Guidelines
Canadian Council of Ministers of the Environment, 2007

CCME Guiding Principles

Guiding principles of the CWQGs-PAL (freshwater and marine) are as follows:

- Guidelines are generic national recommendations that are based on the most current scientific information available at the time of their derivation (i.e., they do not directly consider site-specific, technological, socioeconomic, or management factors that may influence their implementation).

- Guidelines 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 (e.g., pH, temperature, and dissolved oxygen) or exposures to substances via the water column.

- In deriving these science-based guidelines, all higher components of the aquatic ecosystem (e.g., algae, macrophytes, invertebrates, and vertebrates [fish, amphibians, etc.]) and their aquatic life stages are considered, if the data are available.

- National guidelines can be the basis for the derivation of site-specific guidelines (i.e., derived with site-specific scientific data) and objectives (i.e., derived with site-specific scientific data as well as consideration of technological, site-specific socioeconomic, or management factors).

- Provincial jurisdictions may aim for greater or lesser levels of protection (i.e., certainty and margins of safety) depending on circumstances within each jurisdiction.

CCME has outlined several procedures to modify the national water quality guidelines to site-specific water quality guidelines or objectives to account for unique conditions and/or requirements at the site under investigation (CCME 1991, CCME 2003).

Guidelines for long-term and short-term exposure periods will be derived. Two derivation approaches to setting guidelines are recommended depending on the data available (See appropriate sections in Part II, Guideline Derivation).

Long-term exposure guidelines identify benchmarks (i.e., maximum concentrations of substances or ranges for attributes) in the aquatic ecosystem that are intended to protect all forms of aquatic life (all species, all life stages) for indefinite exposure periods. These guidelines adhere to the guiding principles.

Short-term exposure 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. These guidelines are estimators of severe effects to the aquatic ecosystem and are intended to give guidance on the impacts of severe, but transient, situations (e.g., spill events to aquatic receiving environments and infrequent releases of short-lived/nonpersistent substances).

Generally, guidelines are set separately for freshwater and marine environments because of the fundamental differences in the chemistry of these two types of water bodies, which often result in different toxic effects elicited by these substances. However, 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.

In the derivation of the guideline value, the influence of exposure and toxicity-modifying factors (ETMFs) (such as pH, temperature, hardness [Ca^{2+}, Mg^{2+}], organic matter, oxygen, other substances) is incorporated to the extent possible, provided that the scientific information to do so is available.

The concentration of a substance in the ambient environment is caused by natural factors, human actions, or a combination of both. Ambient concentrations are variable in space and time. For substances that occur naturally, it can become important to distinguish between the concentration that is due only to natural causes (i.e., the natural background concentration) and the concentration that is due, at least in part, to anthropogenic causes. The natural background concentration of naturally occurring substances is a very site-specific matter and cannot be incorporated into a nationally applicable guideline value. The national guideline is derived considering all acceptable and applicable toxicological

data from a variety of toxicological studies. These location-independent toxicological studies will have been performed with different species, with different histories, and under different exposure conditions, so it is possible that the recommended national guideline value will fall below (or outside) the natural background concentration (or natural condition) of a particular site of interest. While this fact does not invalidate the derivation process of a national guideline, it points out the need for the user to understand the derivation process and to know how to properly apply national guideline values. In some situations it may be necessary or advantageous to derive a site-specific guideline (or objective). It is the general recommendation that, where the site-specific natural background concentration of a substance exceeds the national guideline value derived primarily from laboratory toxicity data, the natural background concentrations should be taken as the site-specific guideline value unless another appropriate site-specific guideline value is derived according to recommended methods (e.g., CCME 2003). This advice is based on the assumption that the biological community present at a site has adapted to the local conditions, including a naturally elevated level of the substance of concern. This, however, does not imply that the community may be able to adjust to an additional, anthropogenically created exposure to this substance without showing negative effects. Further site-specific study would be required.

Unless otherwise specified, a guideline generally refers to the total concentration of the substance in the unfiltered sample. Application to extremely turbid samples should be considered on a case-by-case basis. Total concentrations will apply unless it can be demonstrated that (a) the relationship between variable fractions and their toxicity is firmly established and (b) analytical techniques have been developed that unequivocally identify the toxic fraction of a variable in a consistent manner using routine field-verified measurements.

Some substances (e.g., metals) exhibit a complex environmental chemistry and toxicology and, therefore, create unique challenges in their guideline derivation and environmental management. In order to give users the best possible guidance, where possible, two water quality guidelines for these substances should be derived related to potential toxicity. The first, which does not factor in bioavailability and is thus highly conservative, is based on the total measured concentration in the unfiltered sample (i.e., total recoverable concentration). This is referred to as the total guideline. The second, which factors in bioavailability, and is thus more realistic, is based on the relevant physical and chemical speciation-specific fractions (i.e., the fractions toxic to aquatic organisms). This is referred to as the bioavailable guideline. These guidelines should, where appropriate, focus on the bioavailable and thus potentially toxic forms of substances related to (a) the form of the substance as it enters the environment, as well as to the forms it acquires while circulating through the environment; (b) the abiotic environmental conditions affecting the substance (i.e., water and sediment chemistry, climatological conditions, etc.); and (c) the biotic environment (i.e., selective uptake and excretion by organisms, aquatic species sensitivity, exposure routes, etc.).

Note that substances are not toxic unless they are available to organisms at a sufficient dose in a bioavailable form. Bioavailability is defined as the portion of a substance such as a chemical that is immediately available for uptake by organisms. Bioavailability of different substances can change over time. Bioaccessibility refers to the fraction of a substance such as a chemical present in the environment that may be available for uptake by organisms over the long term. This fraction includes the portion of the chemical that is currently bioavailable as well as the portion that may become bioavailable over time (e.g., as and if conditions change). Actual uptake of a substance by an organism is termed bioabsorbtion. Bioreactivity refers to the portion of a chemical within an organism that is actually able to cause toxicity; it comprises the bioabsorbed fraction minus the fraction that is depurated, internally sequestered, or used by the organism for its own needs.

Selection of Substances for Guideline Development

The CCME Water Quality Task Group selects substances for water quality guideline development after consultation with federal, provincial, and territorial jurisdictions. Variables of national concern are given priority for guideline development. Regional concerns may also be given priority based on sector and spatial scales.

The Guideline Development Process

The development of a CWQG-PAL should follow, where possible and as much as possible, the process outlined in this document. However, deviations from this process are acceptable where scientifically warranted and approved by the Water Quality Task Group (for example, a CWQG-PAL for an ambient water quality parameter such as pH or temperature may require a modified approach compared to a chemical substance). The general development of a CWQG-PAL consists of seven distinct steps (Figure 1). In step 1, the available toxicity data are compiled, evaluated, and sorted according to media (freshwater or marine) and suitability for guideline derivation.

In step 2, the factors that modify the environmental exposure and the expression of the actual toxicity of the particular substance (or parameter) in question are identified and their influence is evaluated and prioritized. Examples of these ETMFs are pH, temperature, hardness/alkalinity (Ca^{2+}, Mg^{2+},, and carbonate ion), organic matter, oxygen, and counter-ions (i.e., the anion or cation linked to the ion of interest). This step and the next deal with bioavailability and bioaccessibility.

In step 3, the influences of the most important ETMFs are, to the extent possible, quantified.

The available toxicity data are standardized in step 4 to account for the ETMFs quantified in the previous step. Where possible and appropriate, these data are based on the bioreactivity of the bioabsorbed fraction of a substance. The standardization (i.e., normalization) of the toxicity data can be according to the most sensitive (i.e., realistic worst-case scenario, e.g., lowest hardness, lowest dissolved organic matter [DOM], and/or lowest/highest temperature and pH tested) and/or most appropriate situation (e.g., average temperature or pH tested). This standardization will allow a more accurate comparison and evaluation of the available toxicity data and will result in more appropriate guidelines.

The respective guideline is derived in step 5, using the specific derivation procedure (see Part II) selected on the basis of the availability and quality of toxicity data. Separate guidelines will be developed, where possible, for marine and freshwater environments, for short- and long-term exposures, and for total (total guideline) and chemical speciation-specific concentrations (bioavailable guideline). Depending on the quality and quantity of the available information, different types of guidelines are produced.

If the toxicity data were standardized in step 4, then the guideline derived in step 5 is for either the most sensitive or most appropriate environmental condition. In order to improve the applicability of these guideline values to other environmental conditions, they are expanded in step 6. The expansion is done by employing the reverse procedure of the standardization method(s) applied in step 4.

Step 7 entails the internal and external reviews of the guideline(s) and the final approval.

In addition, during the derivation of guidelines for naturally occurring substances, a scoping and compilation of the range of the natural background values across Canada is recommended. While such a compilation and analysis of background concentration is not necessary for the derivation of the guideline, this information will be useful in assessing the significance of a guideline exceedance and the relevance of site-specific guideline development. Comparison of the recommended guideline value(s) to the diversity of natural background concentrations across Canada may give indications on the applicability of the guideline at different sites and the potential necessity and advantages for a user of deriving a site-specific guideline. For this, the recommended, and/or, if possible, the most appropriate applicable national guideline value (i.e., with the ETMFs incorporated and considered), is compared to the different natural background values of the substance. If a further refinement is deemed necessary or desirable, a site-specific guideline or site-specific objective may be developed.

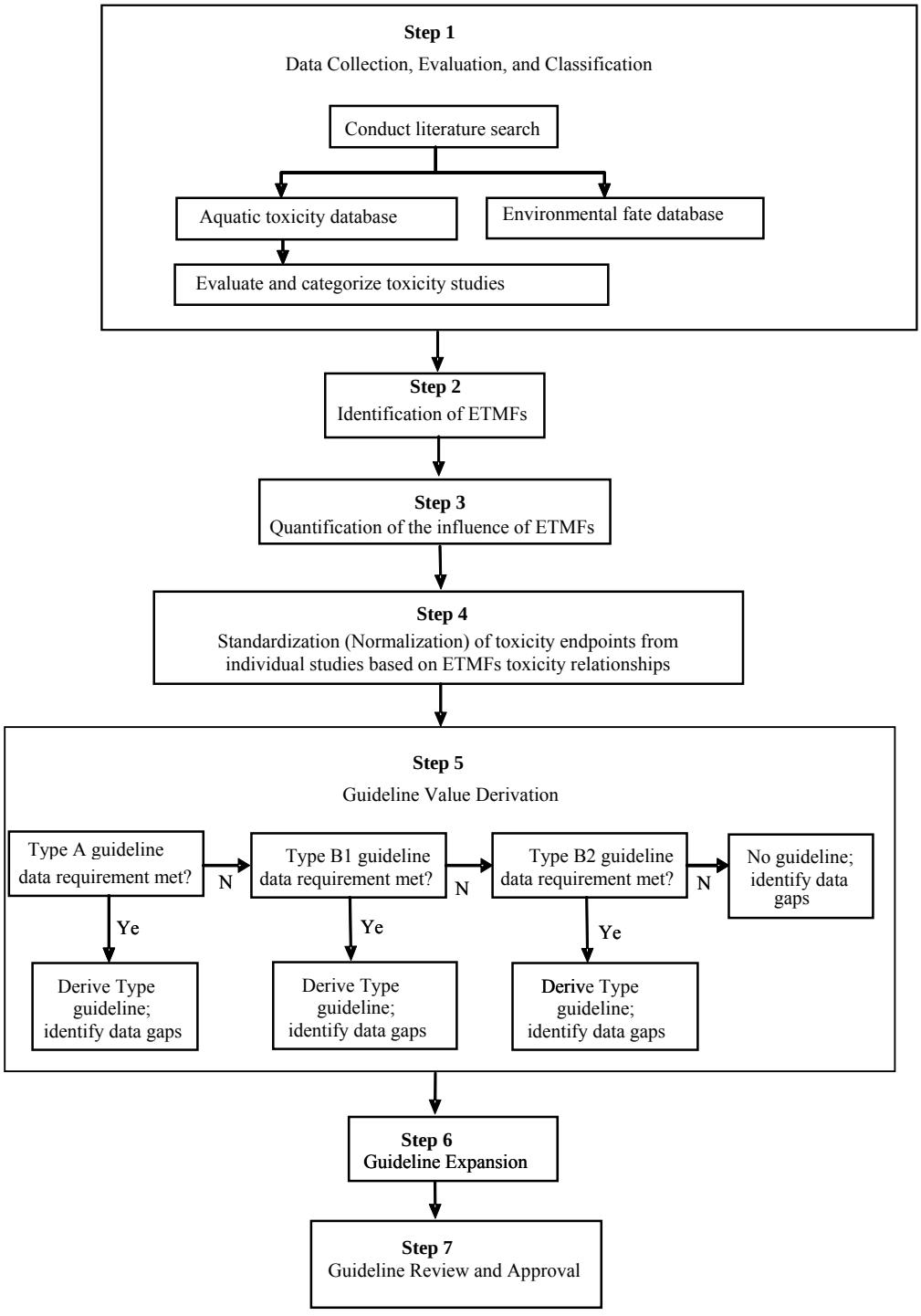

Figure 1. Steps for developing a Canadian Water Quality Guideline for the Protection of Aquatic Life.

Review, Approval, and Publication of Guidelines

In support of the derivation procedure for CWQGs-PAL, a detailed scientific supporting document is generally prepared discussing the environmental fate and behaviour and the aquatic toxicity of the variable of concern and the derivation and justification of the recommended guideline value(s). Based on this scientific supporting document, a concise fact sheet, summarizing the key facts and describing the recommended guideline(s), is prepared. On behalf of the CCME Water Quality Task Group, the National Guidelines and Standards Office of Environment Canada provides technical support for guideline development. The documents are subject to review by the CCME Water Quality Task Group and other scientific and technical experts and released for public comment.

The CCME Water Quality Task Group recommends approval and publishing of the final CWQG fact sheet to the CCME Environmental Planning and Protection Committee (EPPC).

Definition of Freshwater and Marine Systems

Guidelines are set separately for freshwater and marine systems. Freshwater is defined as water with total dissolved salt content equal to or lower than 1000 ppm (1 $g \cdot L^{-1}$, $1^0/_{00}$ [parts per thousand]).

Marine water is defined as water with total dissolved salt concentration greater than 5000 ppm (5 $g \cdot L^{-1}$, $5^0/_{00}$). Marine water (open ocean) generally has a dissolved salt concentration of approximately 34–35 $g \cdot L^{-1}$ ($34–35^0/_{00}$), but near shore marine water can have considerably lower concentrations (often approximately 28 $g \cdot L^{-1}$).

When total dissolved salt concentrations are $1–5^0/_{00}$ (e.g., in some brackish waters), the water quality guideline protecting the most sensitive condition, be it for freshwater or marine, should be applied, unless sufficient data are available on resident aquatic species and environmental conditions to justify a different choice.

The same definitions also apply in the categorization of toxicity data as applicable for the derivation of the freshwater and marine guidelines. Toxicity tests conducted in low-salinity brackish water (e.g., when the total dissolved salt concentrations are $1–5^0/_{00}$) are categorized according to best scientific judgment.

In this protocol, marine species include those species found in estuarine, coastal, and open ocean habitats, any of which may be used to derive a guideline.

Definition of Short- and Long-Term Exposures

Guidelines are set for both short-term and long-term exposures. Short-term exposure guidelines are meant to estimate severe effects and to protect most species against lethality during intermittent and transient events (e.g., spill events to aquatic-receiving environments, infrequent releases of short-lived/nonpersistent substances.). In contrast, long-term exposure guidelines are meant to protect against all negative effects during indefinite exposures.

Types of Guidelines

In this protocol, two approaches for deriving water quality guidelines are provided, depending on the availability and quality of data for the substance. The first, and more preferred, approach, is based on the statistical distribution of all the available and acceptable toxicity data. Guidelines derived from this approach are called Type A guidelines. The second approach is based on the extrapolation from the lowest available and acceptable toxicity endpoint. Guidelines derived from this approach are called Type B guidelines. Each approach requires a defined minimum amount of environmental and toxicological data.

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 (i.e., Type A guideline), but for which enough toxicity data from a minimum number of primary and/or secondary studies are available.

Type B guidelines are divided into Type B1 and Type B2 guidelines, based on the quantity and quality of available toxicity data. At present, there is no protocol for deriving guidelines when the minimum toxicity data requirement for a Type B guideline is not met.

Use of Guidelines in Water Quality Management

CWQGs-PAL are developed to provide basic scientific information about the effects of water quality variables and natural and anthropogenic substances on aquatic life. This information can be used to assess water quality issues and to establish, where needed, site-specific water quality guidelines (i.e., a science-only–based benchmark) and objectives (i.e., a science- and policy-based benchmark).

CWQGs-PAL are national in scope, which means they are based on generic, rather than site-specific, environmental fate and behaviour and toxicity data. In most instances, CWQGs-PAL are sufficient to assess water quality issues in the environment. However, as sites and ecosystems vary in aquatic species composition and environmental characteristics (such as pH, water hardness, temperature regimes, chemical composition, etc.), the actual site-specific toxicity and environmental impact exhibited by the parameter of concern of a CWQG-PAL varies as well. This can result in a situation where the national CWQG-PAL is potentially over- or even under-protective at a particular site. Therefore, the need to develop site-specific water quality guidelines or objectives may arise if (a) there are site-specific conditions that are unique and require considerations to deal with existing water quality issues or to provide preventative watershed protection, and (b) an industry announces a new project that could have a severe effect on water quality in a basin. For instance, where the natural background concentration of a naturally occurring substance exceeds the guideline value, then a site-specific guideline or objective may be required. The environmental manager responsible for such a site may require a benchmark that is more appropriate for this site, i.e., a Site-Specific Water Quality Guideline for the Protection of Aquatic Life (SS-WQG-PAL) or a Site-Specific Water Quality Objective for the Protection of Aquatic Life (SS-WQO-PAL).

The development of an SS-WQG-PAL requires extensive knowledge of the substance of concern, as well as of the physical, chemical, and biological properties of the water body. Furthermore, the development of an SS-WQO-PAL may also require knowledge of the social and economic characteristics of the local area. CCME (2003) has provided science-based guidance to modify national water quality guidelines to site-specific water quality objectives. When the need for developing site-specific objectives is recognized, those charged with developing objectives (e.g., Environment Canada, Indian and Northern Affairs Canada, provincial and territorial governments, and water management agencies) must decide what factors are to be considered and what uses are to be protected. The responsible authority then obtains the necessary information, formulates the objectives, and presents them for approval to their appropriate jurisdiction.

As a minimum, science-based water quality guidelines and objectives should protect the traditional, existing, and potential uses of a water body. Where water bodies are considered to be of exceptional value, or where they support valuable biological resources, degradation of the existing water quality should always be avoided. Similarly, modifications of guidelines to site-specific objectives should not be made on the basis of degraded aquatic ecosystem characteristics that have arisen as a direct negative result of previous human activities.

References

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PART II. GUIDELINE DERIVATION

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Overview

Part II of this Protocol for the Derivation of Water Quality Guidelines for the Protection of Aquatic Life deals with the methodological details of guideline derivation. This part is subdivided into sections that deal with specific technical details.

Section 1 provides the general approach to the collection of data and defines the evaluation and categorization of the data, the exposure periods, and the minimum data requirements. This captures step 1 in Figure 1.

Section 2 provides the approach for incorporating important exposure and toxicity-modifying factors (ETMFs) into the guideline derivation process, where appropriate. This captures steps 2, 3, and 4 in Figure 1. It also describes how guidelines can be expanded (i.e., step 6) to apply to other situations than the one to which the toxicity data were standardized in step 4.

Section 3 presents the various derivation processes for the water quality guideline depending on the quantity and quality of available toxicological data. This is step 5 in Figure 1.

Part II. Guideline Derivation

Section 1. Data Gathering and Evaluation

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Introduction

This section deals with

- the gathering of relevant data
- the evaluation of those data
- the minimum physical, chemical, and toxicological data set requirements necessary to proceed with the derivation of a CWQG-PAL.

It is not required to have complete information on each of the following points. However, the intent is to be able to identify the major environmental pathways and fate of a substance in in the aquatic environment. Specifically, the following should be determined:

- solubility of the substance in the various aquatic environments (freshwater and marine, hard versus soft water, pH and temperature influence, etc.)
- mobility of the substance and the compartments of the aquatic environment in which it is most likely to be present
- kinds of chemical and biological reactions that take place during transport and after deposition
- eventual chemical form under various environmental conditions
- persistence of the substance in water, sediment, and biota
- toxic interactions with other substance (i.e., parameters affecting exposure and toxicity).

Comprehensive information for each substance selected is desirable, but not necessary, for the development of a guideline. Relevant stakeholders (e.g., chemical producers and manufacturers, importers, and regulatory authorities) are contacted and a literature search is conducted to obtain information on the following:

- physical and chemical data
- ambient environmental concentrations (and, where applicable and possible, information on whether elevated levels are due to natural or anthropogenic causes)
- environmental fate processes, persistence, and behaviour of the substance in water, soil, sediment, air, and aquatic biota
- routes of exposure and uptake by aquatic organisms
- mode of toxic action and related toxicokinetics
- toxicity to aquatic biota after short- and long-term exposures
- bioavailability, including the conditions under which the variable is bioavailable
- bioaccumulation potential
- toxic interactions, behaviour in mixtures, and interactions with other variables (i.e., parameters affecting exposure and toxicity)
- essentiality (if applicable)
- analytical and toxicological testing methods (including current detection limits)
- breakdown of products and by-products
- additional information (e.g., guidelines, objectives, criteria, standards, etc. from other jurisdictions).

Physical, Chemical, and Biological Data

The literature review and stakeholder communication should provide information on the following types of data to allow for the derivation of a guideline. Where significant portions of these data are lacking, best scientific judgment shall determine whether the guideline shall be of a lower type. Data gaps must be clearly identified.

Ambient Concentrations

Where applicable and possible, information on ambient concentrations in the Canadian environment should be provided, including whether concentrations are natural or are elevated anthropogenically.

Environmental Behaviour, Fate, and Persistence

It is important to understand the basic physical and chemical behaviour of the substance in the aquatic environment, such as water solubility and precipitation, chemical speciation, and chemical reactivity. The mobility of the substance and the compartments (i.e., water, sediment, biota, soil, and air) in which the substance is most likely to be present should be identified. Potential fate processes include volatilization, hydrolysis, oxidation, photolysis, speciation, aerobic and anaerobic biotransformation (e.g., methylation/demethylation), long-range transport, soil and sediment sorption/desorption, bioaccumulation, and, for a few organic substances, biomagnification. The chemical speciation and the factors influencing changes in speciation are especially important for metals. These variables should be described in detail.

When possible and applicable, the residence time of the substance should be expressed in terms of its particular residence half-life in water, sediment, biota, soil, and air, while considering potential degradation and speciation. Understanding the actual residence time (i.e., persistence) can be especially important for the potentially bioavailable metal fractions in water, sediment, and biota.

Exposure and Route of Uptake

It must be kept in mind that CWQGs-PAL are tools for the assessment and management of substances in the water column. That is, the guidelines are related to the concentration of the substance in the water.

Aquatic organisms are exposed to substances via uptake directly from the water and diet. For many substances, water exposure is likely the dominant uptake route. However, for some substances, exposure from bedded or suspended solids, as well as other dietary sources, may be equally or more important. For example, the organo-forms of selenium and mercury, as well as chlorinated pesticides such as DDT, are accumulated primarily via the diet, resulting in toxic responses. For these substances, the sediment quality guidelines and the tissue residue guidelines are important. Therefore, in the derivation of water quality guidelines for a specific substance, caution must be exercised to clearly differentiate between toxicity studies with water, diet, or both as the main exposure route. Toxicity studies where the route of uptake is mainly through the diet cannot be used for the derivation of a water quality guideline. Guideline derivation should focus primarily on studies in which exposure was principally via water. As diet is likely a minor route in short-term exposures, the critical analysis of this aspect of a toxicity study has more relevance in the derivation of long-term exposure guidelines. The main exposure route(s) must be clearly stated in the guideline document in order to assist in the appropriate use of the guideline value.

For this reason, in the evaluation of toxicity tests, it should be stated if organisms were fed during the study. This will allow evaluating whether food availability influences the toxicity of the substance. Food availability can influence toxicity by providing organic carbon to which substances can bind, thus reducing water column toxicity; by serving as an additional source of potentially toxic substances; and/or by keeping the organisms healthier than if they were not fed and thus better able to withstand toxic stress. Similarly, the particulate matter or dissolved organic carbon content (DOC) of the test water should be noted and evaluated.

Toxicological Information

The toxicological information must be relevant for the derivation of a water quality guideline, i.e., it must

relate to a negative effect on an aquatic organism or population and it must be ecologically significant. In cases where the organisms are semi-aquatic or have a partial aquatic life stage, the negative effect must result from exposure in the aquatic environment. For invertebrates, acceptable data are for fully aquatic forms such as Crustacea (plankton, benthic), insect larvae (e.g., Ephemeroptera, Plecoptera, Trichoptera, Chironomidae), Mollusca, etc., or for the aquatic life-stage of semi-aquatic insects (e.g., beetles [Coleoptera] and some Hemiptera) that can leave the aquatic environment. Data on the nonaquatic life stage of these insects will not be considered.

Effects endpoints used in the derivation of water quality guidelines include the traditional endpoints (i.e., growth, reproduction, and survival), as well as nontraditional endpoints (e.g., behaviour [predator avoidance, swimming ability, swimming speed, etc.] and physiological changes), but only if the ecological relevance of these nontraditional endpoints can be demonstrated. Nontraditional endpoints will be evaluated for use on a case-by-case basis, using as criteria whether the measured impact has the potential to have a strong negative influence on ecological competitiveness at a population level, as well as the overall reliability and reproducibility of the laboratory test.

Ecological relevance pertains to whether physical abilities (e.g., swimming speed, orientation ability, and migratory fitness), physical traits (e.g., fin size/shape), physiological abilities (e.g., egg laying), physiological traits (e.g., production of a certain enzyme), and/or behavioural tendencies (e.g., swimming in groups) of organisms are important enough to influence a species' ecological competitiveness. Characteristics that are of high ecological relevance are those that have a strong positive or negative influence on survival, reproductive ability, and growth (e.g., stunting, high fertility, and organ failure). Nontraditional toxicological endpoints are often difficult to link to ecological relevance because the adverse effects they test do not have a primary impact on survival, reproductive ability, or growth.

As some elements (e.g., copper and zinc) are essential for the physiological and metabolic processes of organisms, care must be taken in the analysis and evaluation of toxicological studies of these elements. Observed negative effects associated with such a substance may be due to over-exposure, as well as under-exposure (i.e., deficiency of an essential element). It is, therefore, important to understand the range of concentration of a substance that is harmful, as well as essential to an organism.

Information on toxic interactions and the behaviour of a substance in mixtures is important, but unfortunately often still too incomplete to be incorporated into guideline development. However, where possible (i.e., where sufficient data and appropriate methods are available), information on toxic interactions and the behaviour of a substance in mixtures will be incorporated.

Mode of Toxic Action

Toxicity can occur as a result of direct physical damage to an external biological surface (e.g., eyes, scales, and respiratory surface) or alterations to physiological processes while inside an organism. Guidelines are derived for waterborne concentrations, so an understanding of the relevance of waterborne concentrations to the overall mode of action and resulting toxicity (especially toxicokinetic aspects) is necessary.

Bioavailability

The bioavailability, or access that a substance has to the biological processes of an organism and, therefore, the toxicity of substances, can depend on chemical speciation (especially for, but not limited to, metals) and water chemistry (e.g., presence of organic matter, pH, etc.). Conditions under which the substance in question is bioavailable and how a change in conditions can or might change the bioaccessibility of the substance need to be investigated and are key factors to consider in guideline development. The interactions with other variables, i.e., the parameters affecting speciation and/or toxicity are important considerations.

Toxicological studies need to be conducted under conditions where the substance is bioavailable, otherwise toxicity will be underestimated. Studies conducted under conditions where the substance is not readily available (e.g., due to binding to organic or inorganic ligands) must be examined on a case-by-case basis. If the bioavailable and non-bioavailable fractions are not well characterized, identified, and quantified, these studies should not be considered acceptable for guideline development.

The bioavailability issue is particularly relevant to metals. The conditions under which the metal is bioavailable and bioreactive should be examined. Studies may report metal concentrations as total,

filtered, dissolved, free, or bioavailable, and particular attention should be given to the analytical methodology. The metal fraction (and species) used in the toxicity testing process should be clearly articulated if a study is used in guideline development.

It should be pointed out that, from geochemical, biological, and analytical perspectives, the term "bioavailable fraction" is context-specific (i.e., not generalizable) and quantitatively elusive (Meyer 2002). Until it is possible to quantify in a scientifically defensible manner the bioavailable fraction of a substance in the environment, CWQGs-PAL will be derived based on chemical speciation-specific approaches. This may include the total and/or filtered fraction or a chemical species.

Bioaccumulation

Mechanisms of bioaccumulation of naturally occurring inorganic substances (i.e., accumulation via water and food) are different than for organic substances. While the bioaccumulation of organic substances (including organo-metals) depends mainly on hydrophobicity, molecular size, lipid content of the exposed organism (allowing the use of predictive models that employ the octanol–water partition coefficient [K_{ow}] approach to estimate bioaccumulation within an individual), and persistence, the bioaccumulation of naturally occurring inorganic substances in aquatic systems depends largely on speciation, on the properties of the surrounding medium, and on specific physiological mechanisms of uptake of organisms.

While the notion of bioaccumulation is important in aquatic toxicology, it is not considered to be part of the protocol for the derivation of CWQGs-PAL, as this protocol deals with the concentration of the substance in the water column and the toxic effects resulting from direct exposure. However, the ability and likelihood of a substance to bioaccumulate should be discussed in the guideline document, with routes of exposure limited to water. It must be noted that bioaccumulation does not necessarily result in toxicity; such depends on bioreactivity within organisms. Because the bioaccumulative potential of a substance depends on many factors and is situation-specific, no defining criteria are provided to categorize a substance as a bioaccumulator. If necessary, the substance will be assessed on a case-by-case basis. Similarly, while biomagnification is important in many anthropogenically created organic compounds, it does not seem to be prevalent in most naturally occurring substances (exceptions are methylmercury, organo-selenium compounds, and, potentially, some other organo-metallics). These issues of bioaccumulation and biomagnification are not addressed formally in the derivation sections, but should be considered in a case-by-case approach during the guideline derivation of particular substances, if appropriate and/or required. Bioaccumulation and biomagnification are, furthermore, more appropriately taken into account in the derivation of other types of guidelines (e.g., tissue residue guidelines).

Additional Information

The following additional information is not essential, but is useful for conducting a review of the potential hazard of a chemical and should be provided where appropriate and when readily available:

- production, releases, and uses
- organoleptic effects (taste, odour, and fish and shellfish flesh tainting)
- sources to the aquatic environment
- genotoxicity, mutagenicity, carcinogenicity, endocrine effects, and teratogenicity
- sensitivity of birds and wildlife consuming aquatic organisms
- analytical methods and detection limits
- potential break-down products and associated toxicity
- guideline values used in other jurisdictions.

Evaluation of Toxicological Data

Each relevant toxicological study found in the literature search and received from stakeholders is evaluated to ensure that acceptable laboratory practices were used in the design and execution of the experiment. Each study is then classified as primary, secondary, or unacceptable, based on criteria given below.

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. Studies need not necessarily follow standard protocols for toxicity testing; nonstandard testing procedures should be evaluated for yielding results usable for guideline development. The data included in the data set must be checked for appropriateness with respect to the substance in question and must meet the criteria elaborated below

to ensure a consistent scientific evaluation for each substance. The following information should be considered crucial for evaluation purposes:

- test conditions/design (e.g., flow-through, renewal, static, single species study, community study, mesocosm, etc.)
- test concentrations
- test containers
- temperature, hardness Ca^{2+} and Mg^{2+}), alkalinity,, pH, dissolved oxygen, salinity, organic matter, adjuvants (chelators), and carrier solvents
- solubility limit of substance in relation of tested concentrations
- experimental design (i.e., analytical methodology, quality control/ quality assurance, controls, and number of replicates)
- description of statistics used in evaluating the data.

Where possible and necessary, the influence of environmental factors on the expression of toxicity should be evaluated (i.e., ETMFs).

A variety of standardized test protocols have been developed nationally and internationally for fish, invertebrates, and plants. When appropriate, these protocols should be consulted during the evaluation process. Special attention should be given to the standardized test methods developed and published by Environment Canada as part of the Biological Test Method series (http://www.etc-cte.ec.gc.ca/organization/bmd/bmd_publist_e.html) e.g., EC 1990a, 1998) and the guidance document EC 1999b. Other useful sources, not only for toxicity testing, but also for analytical methods and data interpretation, are recent text books in aquatic toxicology and publications such as EC 2005, 1994; ASTM 2004; OECD 1993; USEPA 1985a, 1985b, 1985c, 1995, 2002a, 2002b. These should be consulted when necessary.

When consulting test protocols, evaluating toxicological information, and deriving guidelines, it is important to be aware of the following limitations:

- The study may have been performed prior to the development of an appropriate standardized test protocol. This does not necessarily invalidate the study.
- Standardized test protocols consider only a few well-studied aquatic species and biological processes.
- Our ability to extrapolate toxicological results from one aquatic species to another (i.e., comparative ecotoxicology) is limited.
- There may be limited knowledge of the effects of metabolites and other environmentally transformed products of the parent chemicals.
- Protocols developed so far do not take into account cumulative, synergistic, or antagonistic effects of chemicals or compensatory responses of organisms (such as acclimation, adaptation, or reduced density-dependent mortality among juveniles).
- The predictability of laboratory exposures and effects to aquatic ecosystems is still challenging.

Toxicity tests deviating from standard test protocols should be examined for their merit, and best scientific judgment should be used in deciding if the toxicity test is acceptable for use in guideline derivation.

Toxicological Data Quality Categorization

Toxicological data are to be categorized as primary, secondary, or unacceptable data based on suitability, usefulness, and reliability. Both primary and secondary data can be used in the derivation processes for guideline development, although the emphasis should be placed on primary data when possible. Unacceptable data are deemed not suitable for guideline development.

Toxicity endpoints obtained through regression-based statistical data evaluation (i.e., EC_x values identifying no- or low-effects thresholds) are preferred over endpoints obtained through hypothesis-based statistical data evaluation (i.e., NOEC [no-observed-effect-concentration] and LOEC [lowest-observed-effect-concentration] values). When the desired regression-based EC_x values are not presented in a toxicological study of interest, but sufficient information is provided, the desired EC_x values should be calculated for guideline derivation where feasible.

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. However, scientific judgment must be applied in their evaluation as primary or secondary data and in how many such data points should be included in the guideline derivation. Issues to consider are the percentage of "greater than" data points compared to the whole data set and how they compare to other data. It must be reasonable to assume that the tested organism is insensitive toward the tested

substance. The toxic threshold must be clearly above identified thresholds for sensitive organisms. Examples include toxicity studies for pesticides on nontarget organisms (i.e., plant toxicity studies with insecticides or piscicides and vertebrate/invertebrate toxicity studies with herbicides). These studies can be used to fill the minimum data set requirements and in the actual guideline derivation.

The use of toxicity data from tests where an insufficient concentration range on the lower end has been tested (i.e., where the results are expressed as "toxic concentration is less than *x*") is not acceptable, as they may result in an under-protective guideline.

Primary Data

Primary data are those that are based on toxicity tests that are scientifically defensible. Toxicity tests must employ currently acceptable laboratory or field practices of exposure and environmental controls. Other types of tests using more novel approaches will be evaluated on a case-by-case basis.

As a minimum requirement for primary data, substance concentrations must be measured at the beginning and end of the exposure period. Calculated substance concentrations or measurements taken in stock solutions are unacceptable in primary data. Test concentrations must be below the water solubility limit of the substance. Measurements of abiotic variables such as temperature, pH, dissolved oxygen, water hardness (including Ca^{2+} and Mg^{2+} concentrations)), salinity, dissolved organic matter (DOM), and the presence of other relevant substances should be reported so that any factors (ETMFs) that may affect toxicity can be included in the evaluation process.

In order that any toxicity test generates primary data, appropriate replicates and dilution steps need to be completed. Generally, static laboratory tests are not classified as primary data unless it can be shown that substance concentrations did not change during the test and that appropriate environmental conditions for the test species were maintained.

For a study to produce primary data, the study design should consider sensitive endpoints. Preferred test endpoints from a partial or full life-cycle test include a determination of effects on embryonic development, hatching, or germination success; survival of juvenile stages, growth, reproduction; and survival of adults. Additional test endpoints, such as behavioural or endocrine-disrupting effects, can be included if it can be shown that these effects are a result of exposure to the parameter in question, lead to an ecologically relevant negative impact, and are scientifically sound.

For studies to be deemed to produce primary data, response and survival of controls (both positive [reference toxicants] and negative [uncontaminated conditions]) must be measured and reported, and should be appropriate for the life stage of the tested species used. For standard test species (e.g., fathead minnow [*Pimephales promelas*], *Daphnia magna*, etc.), accepted control mortality rates should be considered for comparison to the treatment levels or concentrations. For nonstandard test species, the control mortality rate of the test should be used for comparison against the treatment levels or concentrations, provided the species has undergone previous reference toxicant testing to determine acceptability of the species' response.

A clear dose–response relationship should be demonstrated in the study. Studies with limited treatment levels may be considered if other toxicological studies support the effect level.

Controlled microcosm and mesocosm studies are acceptable and are ranked according to the applicable categorization criteria. A clear dose–response relationship should be experimentally established and effects reasonably apportioned to the substance. As field studies generally have too many uncontrollable and recordable variables, they should not be used in guideline derivation. However, while not directly contributing to the actual guideline value derivation, field studies can play a significant role in evaluating and validating toxicological endpoints obtained in the laboratory and the final guideline.

Statistical procedures used to analyze the data must be reported and be of an acceptable scientific standard.

Secondary Data

Secondary data are those that originate from studies where primary data cannot be generated, but are still of acceptable quality and documentation. Toxicity tests may employ a wider array of methodologies (e.g., measuring toxicity while test species are exposed to additional stresses such as low temperatures, lack of food, or high salinity). All relevant environmental variables that modify toxicity should be measured and reported. The survival of controls must be measured and reported.

Static tests, calculated substance concentrations, and measurements taken in stock solutions are generally acceptable. Test concentrations must be below the water solubility limit of the substance. Evaluation criteria include the nature of the substance (e.g., volatility, complexation/chelating potential [especially for metals], stock solution analysis, nominal stock solution, and dilution series).

Appropriate test replication is necessary; however, pseudo-replication may be acceptable for secondary data. Pseudo-replication refers to taking multiple measurements on the same experimental unit and treating each measurement as an independent data point. For example, a common form of pseudo-replication in aquatic toxicity testing is to have just one aquarium for each treatment in a test and then treat each fish exposed within that aquarium as a replicate. A true replicate is the smallest experimental unit to which a treatment is independently applied. Therefore, it is the aquarium in this example that is the replicate.

Preferred test endpoints include those listed for primary data as well as pathological, behavioural (if their ecological relevance can be shown, but not as clearly as for primary data), and physiological effects.

Unacceptable Data

Toxicity data that do not meet the criteria of primary or secondary data are unacceptable for guideline derivation purposes. Unacceptable data cannot be used to fulfill minimum data set requirements for any derivation procedure; these data should be discussed and the reasons for their rejection clearly stated.

Data that are initially classified as unacceptable because insufficient information was reported in the study to assess the adequacy of the test design, procedures, or results, etc., may be upgraded to secondary or primary classification if ancillary information is available from related studies or obtained directly from the author(s).

Preferred Endpoints

For the purpose of the development of the long-term exposure guidelines, a threshold level for no negative effect is generally defined as an effect level on 10% or less of the exposed individuals of a species (i.e., EC_{10}), unless a more appropriate no-effects threshold is defined for the test species in a generally accepted standardized test protocol (i.e., the most appropriate EC_x representing a no-effects threshold for the species). The default level of 10% is chosen to allow comparison of results and support statistical robustness. Similarly, a threshold level for negative effects is generally defined as an effect level on more than 15–20% of the exposed individuals of a species (i.e., low-effect level: EC_{15}–EC_{20}). Accepted endpoints can be lethal or nonlethal.

The accepted endpoints for the development of short-term exposure guidelines are LC_{50} or equivalent (i.e., EC_{50} for immobility).

Long-term exposure guidelines are preferentially derived from no-effect level data. Low-effect data are added to the no-effect data set to satisfy the minimum data requirement and to improve the results of the guideline derivation analysis using the SSD approach (Type A long-term exposure guideline). This means that no-effect and low-effect data can be used to fulfill the minimum data requirements for a Type A long-term exposure guideline; however, only low-effect data can be used to fulfill the minimum data requirements for a Type B long-term exposure guideline. The accepted effect levels for the endpoints used in the derivation of the guidelines according to the derivation procedures are listed in their respective sections.

Generally, the preferred endpoints for developing long-term exposure guidelines are the respective EC_x of a standard (e.g., published by EC, OECD, USEPA, or ASTM,) or another test otherwise deemed acceptable, where the EC_x value has been derived by regression analysis of the toxicological data and it has been demonstrated to be at or near the no-effects threshold. However, it is understood that this information may not always be readily available in sufficient quantity to meet the minimum data requirement. Other endpoints are considered acceptable in a tiered approach as described in the respective sections on guideline derivation.

Exposure Period Definition

Guidelines will be set to provide protection for short- and long-term exposure periods. The intended goal of long-term guidelines is the protection and maintenance of all forms of aquatic life and all aquatic life stages in the aquatic environment for indefinite exposure periods. Short-term exposure guidelines provide estimates of relatively short-lived, severe effects to the aquatic ecosystem and are intended to provide a benchmark for the onset of serious effects. They are

not intended to provide complete protection against all negative effects for all forms of aquatic life.

Professional judgment must be used to evaluate exposure periods not discussed in detail here for their appropriateness and acceptability for short- and long-term exposure guideline development on a case-by-case basis.

Short Term

In general, exposure periods of 96 hours or less are considered appropriate for the derivation of a short-term exposure guideline.

Fish and Amphibians
For fish and amphibians, the effect level for the derivation of a short-term guideline is an LC_{50}. Examples of standard toxicity tests for this category are the 96-h rainbow trout (*Oncorhychus mykiss*) LC_{50} (EC 1990a), the 96-h threespine stickleback (*Gasterosteus aculeatus*) LC_{50} (EC 1990b), or the 96-h fathead minnow (*Pimephales promelas*) LC_{50} (EC 1992b).

Aquatic Invertebrates
For aquatic invertebrates, the effect level for the derivation of a short-term guideline is a short-term LC_{50} or equivalent (i.e., EC_{50} for immobility). Examples of standard toxicity tests for this category are the 48-h *Daphnia magna* LC_{50} (EC 1990c).

Aquatic Plants
Because of the general lack of data on aquatic plants, these tests will be considered on a case-by-case basis.

Algae
Because of the rapid cell division rate (reproduction rate) in algae, they usually (but not always) have a high resiliency during short-term exposures. Therefore, algal toxicity tests with exposure periods longer than approximately 24 hours are generally considered inappropriate for inclusion in the derivation of a short-term guideline. Algal tests with exposure periods shorter than 24 hours and severe effects should be included in the short-term dataset, but each test must be considered and evaluated on a case-by-case basis and ecological relevance must be emphasized. . Algal tests equal to or less than 48 hours may be included in the derivation of the short-term guideline if plant requirements are not met with algal studies equal to or less than 24 hours.

Long Term

The following exposure periods are generally considered long-term. Shorter exposure periods may be classified on a case-by-case basis by best scientific judgment as long-term exposures and used in the derivation of the long-term exposure guidelines.

Fish and Amphibians
For fish and amphibians, exposure periods involving juvenile or adult stages of ≥ 21 days in duration, or periods involving eggs and larvae of ≥ 7 days, are considered long-term. An example of a standard toxicity test in this category is the fathead minnow 7-day larval growth and survival test (EC 1992b; USEPA 2002a).

Aquatic Invertebrates
Acceptable data for aquatic invertebrates include nonlethal endpoints from test durations of ≥ 96-h for shorter-lived invertebrates (e.g., *Ceriodaphnia dubia*) (EC 1992a; USEPA 2002b), nonlethal endpoints of ≥ 7 days duration for longer-lived invertebrates (e.g., crayfish), and lethal endpoints from tests of ≥ 21 days duration for longer-lived invertebrates. Lethal endpoints from shorter-lived invertebrates from tests with <21-day exposure periods will be considered on a case-by-case basis.

Plants
Acceptable data for plants are restricted to aquatic and semi-aquatic plants. Plants that are normally found in the riparian zone will be considered on a case-by-case basis. Plants that would normally be found in terrestrial environments are excluded. The exposure of the plants to the test substance must be through the water column. All tests for *Lemna* sp. following standard test protocols (e.g., EC 1999a) are generally considered long-term exposures and are acceptable in the derivation of long-term guidelines. Data for other species will be considered on a case-by-case basis.

Algae
All toxicity tests with algae with exposure durations of longer than 24 hours are considered long-term exposure tests because of the length of the algal life cycle compared to the duration of the exposure. Algal tests with exposure periods shorter than 24 hours and severe effects will be considered on a case-by-case basis. For example, growth and inhibition tests (72-h) and 96-h cell density counts with *Pseudokirchneriella subcapitata* (formerly *Selenastrum capricornutum*) following standard test protocols (e.g., EC 1992c) are acceptable for long-term guideline derivation.

Minimum Toxicological Data Requirements

Each derivation method has a minimum toxicological data requirement as specified in the detailed methodologies (Part II, Sections 3.1, 3.2, and 3.3). The minima depend on the classification of the guideline and whether the guideline is for freshwater or marine environments or for short- or long-term exposures. Tables 1–4 summarize the minimum data requirements depending on classification, receiving environment, and duration.

Unless exceptional circumstances require guideline derivation with a modified data set (e.g., substituted, reduced, or expanded), the minimum physical, chemical, and toxicological data (and where applicable, statistical) requirements to permit guideline development must be met.

Data from fish, aquatic invertebrates, aquatic plants, and algae are to be included in the guideline derivation process. Guidelines may be derived from studies involving species not required in the respective minimum data set (e.g., ., amphibians)), provided that the appropriate minimum data set requirements are met and appropriate rationale is provided. Data must be classified as primary or secondary.

Studies on Canadian species are preferred; however, studies with species that are nonresident to Canada can be used if it can be demonstrated that they are acceptable surrogate species for Canadian resident species (e.g., fall within the same taxonomic group) and the studies were conducted under exposure conditions representative of Canadian waters.

As substances can elicit different toxic effects in freshwater and marine environments because of the fundamental differences in the chemistry of these two types of water bodies, freshwater toxicity data are generally used to derive the freshwater guideline and marine toxicity data are generally used to derive the marine guideline. However, to compensate for the paucity of marine toxicity data for many substances, 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 on a case-by-case basis in order to broaden the marine database.

Despite the greater taxonomic diversity of invertebrates compared to vertebrates, and the greater taxonomic diversity of marine ecosystems compared to freshwater ecosystems, the minimum data requirements for vertebrates are equal to or higher than for invertebrates, and are equal for freshwater ecosystems and marine ecosystems. The respective minimum data requirements are a compromise between the scientific desire for an extensive data set resembling the taxonomic diversity and the reality of data availability, and societal and policy considerations.

In freshwater systems, salmonids are generally considered to be among the most sensitive fish and are routinely tested. They are, therefore, included in the minimum data requirement. With respect to invertebrates, Ephemeroptera (mayfly), Plecoptera (stonefly), and Trichoptera (caddisfly) often represent the sensitive end of the insect community spectrum with respect to contaminant exposure and water quality parameters (Versteeg et al. 1999). However, because these insects, as well as amphibians, are not routinely used in toxicity tests, they are not included in the minimum data requirement.

Table 1. Minimum data set requirements for the derivation of a long-term exposure guideline for freshwater environments.

Group	Guideline		
	Type A	**Type B1**	**Type B2**
Fish	Three species, including at least one salmonid and one non-salmonid.		Two species, including at least one salmonid and one non-salmonid.
Aquatic Invertebrates	Three aquatic or semi-aquatic invertebrates, at least one of which must be a planktonic crustacean. For semi-aquatic invertebrates, the life stages tested must be aquatic. It is desirable, but not necessary, that one of the aquatic invertebrate species be either a mayfly, caddisfly, or stonefly.		Two aquatic or semi-aquatic invertebrates, at least one of which must be a planktonic crustacean. For semi-aquatic invertebrates, the life stages tested must be aquatic. It is desirable, but not necessary, that one of the aquatic invertebrate species be either a mayfly, caddisfly, or stonefly.
Aquatic Plants	At least one study on a freshwater vascular plant or freshwater algal species. If a toxicity study indicates that a plant or algal species is among the most sensitive species in the data set, then this substance is considered to be phyto-toxic and three studies on nontarget freshwater plant or algal species are required.		Toxicity data for plants are highly desirable, but not necessary. If a toxicity study indicates that a plant or algal species is among the most sensitive species in the data set, then this substance is considered to be phyto-toxic and two studies on nontarget freshwater plant or algal species are required.
Amphibians	Toxicity data for amphibians are highly desirable, but not necessary. Data must represent fully aquatic stages.		Toxicity data for amphibians are highly desirable, but not necessary. Data must represent fully aquatic stages.
Preferred Endpoints	The acceptable endpoints representing the no-effects threshold and EC_{10}/IC_{10} for a species are plotted. The other, less preferred, endpoints may be added sequentially to the data set to fulfill the minimum data requirement condition and improve the result of the modelling for the guideline derivation if the more preferred endpoint for a given species is not available. The preference ranking is done in the following order: Most appropriate EC_x/IC_x representing a no-effects threshold > EC_{10}/IC_{10} > EC_{11-25}/IC_{11-25} > MATC > NOEC > LOEC > EC_{26-49}/IC_{26-49} > nonlethal EC_{50}/IC_{50}. Multiple comparable records for the same endpoint are to be combined by the geometric mean of these records to represent the averaged species effects endpoint.	The most preferred acceptable endpoint representing a low-effects threshold for a species is used as the critical study; the next less preferred endpoint will be used sequentially only if the more preferred endpoint for a given species is not available. The preference ranking is done in the following order: Most appropriate EC_x/IC_x representing a low-effects threshold > EC_{15-25}/IC_{15-25} > LOEC > MATC > EC_{26-49}/IC_{26-49} > nonlethal EC_{50}/IC_{50} > LC_{50}.	
Data Quality Requirement	Primary and secondary no-effects and low-effects level data are acceptable to meet the minimum data set requirement. Both primary and secondary data will be plotted. A chosen model should sufficiently and adequately describe data and pass the appropriate goodness-of-fit test.	The minimum data requirement must be met with primary data. The value used to set the guideline must be primary. Only low-effect data can be used to fulfill the minimum data requirement.	Secondary data are acceptable. The value used to set the guideline may be secondary. Only low-effect data can be used to fulfill the minimum data requirement.

Table 2. Minimum data set requirements for the derivation of a long-term exposure guideline for marine environments. (Marine species include those species found in estuarine, coastal, and open ocean habitats, any of which may be used to derive a guideline.)

Group	Guideline		
	Type A	**Type B1**	**Type B2**
Fish	At least three studies on three or more marine fish species, at least one of which is a temperate species.		At least two studies on two or more marine fish species, at least one of which is a temperate species.
Aquatic Invertebrates	At least **two** studies on **two** or more marine species from different classes, at least **one** of which is a temperate species.		At least **two** studies on **two** or more marine species.
Plants	At least one study on a temperate marine vascular plant or marine algal species. If a toxicity study indicates that a plant or algal species is among the most sensitive species in the data set, then this substance is considered to be phyto-toxic and three studies on nontarget marine plant or algal species are required.	At least one study on a temperate marine vascular plant or marine algal species. If a toxicity study indicates that a plant or algal species is among the most sensitive species in the data set, then this substance is considered to be phyto-toxic and two studies on nontarget marine plant or algal species are required.	If a toxicity study indicates that a plant or algal species is among the most sensitive species in the data set, then this substance is considered to be phyto-toxic and two studies on nontarget marine plant or algal species are required.
Preferred Endpoints	The acceptable endpoints representing the no-effects threshold and EC_{10}/IC_{10} for a species are plotted. The other, less preferred, endpoints may be added sequentially to the data set to fulfill the minimum data requirement condition and improve the result of the modelling for the guideline derivation if the more preferred endpoint for a given species is not available. The preference ranking is done in the following order: Most appropriate EC_x/IC_x representing a no-effects threshold > EC_{10}/IC_{10} > $EC_{11\text{-}25}/IC_{11\text{-}25}$ > MATC > NOEC > LOEC > $EC_{26\text{-}49}/IC_{26\text{-}49}$ > nonlethal EC_{50}/IC_{50}. Multiple comparable records for the same endpoint are to be combined by the geometric mean of these records to represent the averaged species effects endpoint.	The most preferred acceptable endpoint representing a low-effects threshold for a species is used as the critical study; the next less preferred endpoint will be used sequentially only if the more preferred endpoint for a given species is not available. The preference ranking is done in the following order: Most appropriate EC_x/IC_x representing a low-effects threshold > $EC_{15\text{-}25}/IC_{15\text{-}25}$ > LOEC > MATC $EC_{26\text{-}49}/IC_{26\text{-}49}$ > nonlethal EC_{50}/IC_{50} > LC_{50}.	
Data Quality Requirement	Primary and secondary no-effects and low-effects level data are acceptable to meet the minimum data set requirement. Both primary and secondary data will be plotted. A chosen model should sufficiently and adequately describe data and pass the appropriate goodness-of-fit test.	The minimum data requirement must be met with primary data. The value used to set the guideline must be primary. Only low-effect data can be used to fulfill the minimum data requirement.	Secondary data are acceptable. The value used to set the guideline may be secondary. Only low-effect data can be used to fulfill the minimum data requirement.

Table 3. Minimum data set requirements for the derivation of a short-term exposure guideline for freshwater environments.

Group	Guideline		
	Type A	**Type B1**	**Type B2**
Fish	Three species, including at least one salmonid and one non-salmonid.		Two species, including at least one salmonid and one non-salmonid.
Aquatic Invertebrates	Three aquatic or semi-aquatic invertebrates, at least one of which must be a planktonic crustacean. For semi-aquatic invertebrates, the life stages tested must be aquatic. It is desirable, but not necessary, that one of the aquatic invertebrate species be either a mayfly, caddisfly, or stonefly.		Two aquatic or semi-aquatic invertebrates, at least one of which must be a planktonic crustacean. For semi-aquatic invertebrates, the life stages tested must be aquatic. It is desirable, but not necessary, that one of the aquatic invertebrate species be either a mayfly, caddisfly, or stonefly.
Plants	Toxicity data for aquatic plants or algae are highly desirable, but not necessary. However, if a toxicity study indicates that a plant or algal species is among the most sensitive species in the data set, then this substance is considered to be phyto-toxic and two studies on nontarget freshwater plant or algal species are required.		
Amphibians	Toxicity data for amphibians are highly desirable, but not necessary. Data must represent fully aquatic stages.		
Preferred Endpoints	Acceptable LC_{50} or equivalent (e.g., EC_{50} for immobility in small invertebrates).		
Data Quality Requirement	Primary and secondary LC_{50} (or equivalents) data are acceptable to meet the minimum data set requirement. Both primary and secondary data will be plotted. A chosen model should sufficiently and adequately describe data and pass the appropriate goodness-of-fit test.	The minimum data requirement must be met with primary LC_{50} (or equivalents) data. The value used to set the guideline must be primary.	The minimum data requirement must be met with primary LC_{50} (or equivalents) data. Secondary data are acceptable. The value used to set the guideline may be secondary.

Table 4. Minimum data set requirements for the derivation of a short-term exposure guideline for marine environments. (Marine species include those species found in estuarine, coastal, and open ocean habitats, any of which may be used to derive a guideline.)

Group	Guideline		
	Type A	**Type B1**	**Type B2**
Fish	At least three studies on three or more marine fish species, at least one of which is a temperate species.		At least two studies on two or more marine fish species, at least one of which is a temperate species.
Aquatic Invertebrates	At least two studies on two or more marine species from different classes, at least one of which is a temperate species.		At least two studies on two or more marine species.
Plants	At least **one** study on a temperate marine vascular plant or marine algal species. If a toxicity study indicates that a plant or algal species is among the most sensitive species in the data set, then this substance is considered to be phyto-toxic and two studies on nontarget marine plant or algal species are required.		Toxicity data for marine plants are highly desirable, but not necessary. If a toxicity study indicates that a plant or algal species is among the most sensitive species in the data set, then this substance is considered to be phyto-toxic and two studies on nontarget marine plant or algal species are required.
Preferred Endpoints	Acceptable LC_{50} or equivalent (e.g., EC_{50} for immobility in small invertebrates).		
Data Quality Requirement	Primary and secondary LC_{50} (or equivalents) data are acceptable to meet the minimum data set requirement. Both primary and secondary data will be plotted. A chosen model should sufficiently and adequately describe data and pass the appropriate goodness-of-fit test.	The minimum data requirement must be met with primary LC_{50} (or equivalents) data. The value used to set the guideline must be primary.	The minimum data requirement must be met with primary LC_{50} (or equivalents) data. Secondary data are acceptable. The value used to set the guideline may be secondary.

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Part II. Guideline Derivation

Section 2. Incorporating Exposure and Toxicity-Modifying Factors

Contents

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Introduction

A variety of environmental factors and physical, chemical, and biological interactions modify the exposure and behaviour of chemical substances and thus toxicity to aquatic plants and animals. Modifying factors may be grouped as follows:

- substance–ion interactions (e.g., hardness/alkalinity, pH, salinity, and other anions or cations)
- substance–organic matter interactions (e.g., humic substances and turbidity impact)
- substance–substance interactions
- temperature and other physical influences (e.g., light intensity, water turbulence, turbidity impacts, etc.).

Where possible, these exposure and toxicity-modifying factors (ETMFs) are important to identify, document, and account for in the guideline derivation procedure. In order to expand the applicability of the CWQGs, guidance on how these ETMFs alter the toxicity and the guideline value must be given. The guideline derivation of substances such as cadmium, copper, and ammonia has, in the past, taken into account the hardness, pH, and/or temperature of the water to predict an impact to aquatic biota. Dissolved organic matter, alkalinity, and a variety of other factors have also been identified as important modifiers of aquatic toxicity.

The incorporation of ETMFs will result in a range of situation-specific guidelines. The user can then select the guidelines that are the most appropriate to use for the particular site characteristics or situation in question.

Development of guideline equations and matrices will likely be the most often used derivation route, as these can be derived independently from the other parameters and, if necessary, with only a limited data set. This approach can be tailored to the specific needs and data availability of the substance and can range from a simple, single parameter equation to complex, multi-factor equations and matrices. These in turn can then be combined to derive models. While providing national guidance on the substance, the incorporation of the functional relationship between toxicity and toxicity-modifying environmental factors readily allows application of the guideline on a site-specific level and prepares and aids in the development of site-specific guidelines or objectives. It will provide valuable, yet easy to apply, guidance.

New models and science that describe the relationships between concentration and toxicity by considering these modifiers should be taken into account when deriving a guideline. This section describes general approaches and models that can be used to adjust observed toxicity data to the most

appropriate conditions, e.g., most sensitive (hardness, DOM, and temperature) or most commonly occurring (pH and temperature) conditions. The selected conditions should be what are deemed to be scientifically the most appropriate approach.

Approach

The first step in evaluating ETMFs consists primarily of a detailed search of the toxicology literature for the substance in question with the goal of identifying studies that examined toxicity-modifying factors, grouping of these studies, and analyzing them thoroughly.

After evaluation of all factors and the information available on them, the most pertinent ones (i.e., the factors that influence the expressed toxicity of the substance in question the most) are identified.

The next step entails quantifying, where possible, the influence of the most pertinent ETMFs identified. This can be done through either the use of simple equations and/or matrices or the use of complex equations or models (e.g., Biotic Ligand Model), where appropriate. The extent and magnitude of influence that the selected parameters will have on the final guideline values depends on the amount and depth of data available and the level of understanding of the interaction between these factors and the substance.

The Biotic Ligand Model (BLM) (Paquin et al. 2002) is a tool used to evaluate quantitatively the manner in which several water chemistry parameters affect the speciation and bioavailability of metals in aquatic systems. In this, it is a promising approach in the derivation of CWQGs-PAL for metals, especially of acute guidelines. So far, it is validated for a small but growing number of metals. While initially developed only for freshwater systems and acute toxicity, it is now expanding to chronic toxicity and marine waters. The BLM can be used in the standardization of the data before a guideline is derived and in the expansion and application of the guideline to specific environmental conditions.

Once the impact of the most important ETMF or ETMFs is quantified, the toxicity data set can be standardized (normalized) as much as possible to the most appropriate conditions. This fully or partially standardized toxicity data set is used to derive the appropriate guidelines as described in Part II, Sections 3.1, 3.2, and 3.3.

The reverse of the applied standardization method can be applied to the resulting guidelines in order to obtain guideline values that are more appropriate and pertinent to situations or sites with specific environmental characteristics. The issue of introducing bias in the guideline when back-transforming data is recognized and should be examined on a case-by-case basis.

Application of Canadian Water Quality Guidelines for Mixtures

It must be emphasized that CWQGs-PAL are generally derived using single-substance toxicity tests and are usually not designed to deal with mixtures. Exceptions are guidelines that are explicitly developed for a group of substances (e.g., polychlorinated dioxin/furan congeners and polychlorinated biphenyl congeners). Therefore, the application of CWQGs-PAL to mixtures of two or more substances can be problematic. More information on the toxic interaction of substances is required to resolve this issue satisfactorily. However, to describe the toxicological behaviour of a mixture, different approaches can be used. The so-called “concentration addition” model can be applied if the substances involved have the same mode of toxic action and behave additively in their toxicity. The “independent action” model can be applied if the substances involved have different modes of toxic action, but do not behave in an antagonistic or synergistic manner in their toxicity (Greco et al. 1992). Neither model adequately addresses antagonistic or synergistic interactions.

It has been shown that mixtures composed of 3 to 30 substances with the same, as well as different, modes of toxic action can elicit significant toxic responses even when they are present at their individual EC_{01} concentrations. EC_{01} values and NOECs generally do not indicate concentrations of no environmental concern with respect to multiple mixtures of pollutants (Vighi et al. 2003). In extension, while a CWQG-PAL determines the safe level of the substance to protect the aquatic environment when acting singly, it cannot automatically be assumed that this is also the scientifically sound “zero-effect level” when multiple contaminants are present. It is, therefore, recommended to examine the potential of whole effluent toxicity measurements and the development of site-specific water quality guidelines or objectives when multiple substances at concentrations close to their individual CWQG/Os are present.

Further current discussions on mixtures can be found, for example, in Backhaus et al. (2003), Borgert et al. (2004), and Junghans et al. (2006).

Additional Guidance

For most substances, single maximum values, which are not to be exceeded, are recommended as the respective CWQGs-PAL. These maximum values are considered to be estimated no-effect concentrations, extrapolated from the existing appropriate toxicological data sets according to nationally agreed-upon procedures described herein.

The respective guideline document will specify to which chemical fraction (i.e., chemical species) of the total concentration of the substance the recommended guideline value applies. A chemical species is a specific form of a substance (e.g., molecule, element, metal, composite ion, etc.) defined as to isotopic composition (e.g., ^{204}Pb or ^{206}Pb), electronic or oxidation state (e.g., Pb(II) or Pb(0)), or molecular structure (e.g., $Pb(OH)^{+}$ or $Pb(HS)_2$). Chemical speciation refers to the distribution of a substance among defined chemical species in a system. However, if not specified, a guideline value refers to the total measured concentration of the substance in the unfiltered sample. While this may, at times, be over-protective (as the bioavailability issue is not addressed), it was deemed preferable to being under-protective.

The guideline can be applied to the filtered fraction (often also referred to as the dissolved concentration) if it can be demonstrated that the relationship between this fraction and its toxicity is firmly established. Although the filtered fraction is considered to represent a better estimate of the bioavailable fraction of the substance (which cannot reliably be quantified, as it is dependent on the particular system [environmental conditions and organisms involved]) than the total measured concentration, the total concentration symbolizes an often more appropriate solution for a conservative guideline derivation. It includes the already dissolved fraction, as well as the fraction that may in some cases become soluble when environmental conditions change. Ambient physical and chemical conditions often differ greatly from one location to another, or from effluent conditions. There is no guarantee that the particulate or bound fraction of a substance at one site will not dissolve at another site (i.e., bioaccessibility must be considered). Furthermore, while the bioavailability of a substance bound to a particulate (and, consequently, the toxicity of the particulate [i.e., nondissolved] fraction) is lower than the dissolved fraction, it is not zero, and should, therefore, be considered.

Speciation

Speciation is the determination of various physical and chemical forms of a substance. Physical speciation represents the different states of a substance in the environment (hydrated [i.e., filtered/dissolved], labile particulate, refractory particulate, organically complexed, labile dissolved, colloidal, or total). Chemical speciation refers to the identity of the chemical species in solution (e.g., Cr^{3+}, $Cr_2O_7^{2-}$, or CrO_4^{2-}). Speciation is an important concept in the aquatic environment because of the continual interactions between substances and various biogeochemical factors (such as DOM, pH, temperature, ligands, etc.) that modify the chemical species present in solution and, therefore, can have an impact on the bioavailability and toxicity of the substance in the aquatic media. The solubility and the persistence of the fraction should be assessed in order to predict the deleterious effects encountered over short and long terms in the aquatic environment.

Analytical Methodology

The analytical quantification of substances in the aquatic environment can often be very complex. Substances of importance for guideline development (e.g., metals, pesticides, and toxic by-products) are often found in trace amounts, and few analytical apparati are set to attain such low detection limits. Also, only a few techniques are known today to differentiate reliably, especially at environmental levels, between the different species of a substance, rendering the study of speciation in the aquatic environment difficult. Contamination, sampling procedure, sample preservation, storage, pre-concentration, and filtration may all be sources of errors rendering the task of achieving precision and accuracy complex. A thorough investigation of the data (technique and reliability) must be performed before considering the measured concentrations as acceptable values for a guideline derivation.

Mode of Toxic Action

An understanding of the mode of toxic action is essential in order to allow for proper evaluation of the toxicity test results and future incorporation of mixture exposure.

Special Considerations for Naturally Occurring Substances

Natural Background Concentrations

The level of a naturally occurring substance originating from natural sources is defined as the natural background concentration and varies according to the geological setting and the natural processes occurring in the surrounding environment. It is, therefore, important to consider the variability associated with this characteristic across the country, as certain areas can have naturally elevated concentrations. These concentrations may be higher than what the more sensitive aquatic organisms are able to tolerate. Sensitive species or sensitive members of a species that cannot acclimate or adapt will not exist in such areas, and testing with naïve (i.e., nontolerant) laboratory species will not be environmentally relevant for such situations. This issue must be considered at the time of the guideline derivation and the application of the water quality guideline in a given environment.

Essentiality

The essentiality of naturally occurring substances (i.e., elements) is a factor to be considered during guideline derivation. Essentiality of an element means that the absence or deficiency of the element results in the impairment of life functions, and that the impairment can be prevented or corrected only by supplementation of physiological levels of this element and not by others (Chowdhury and Chandra 1987). Therefore, essential elements differ from nonessential elements and other non-nutritive chemicals, as negative effects on organisms are observed when insufficient levels (i.e., levels below the compensation limit of accumulation/assimilation of the organism) of the essential element are present in the environment. This deficiency varies between organisms, between aquatic species, and within aquatic species based on their respective locale (adaptation). As organisms have adapted to their natural habitat, it can be assumed that the natural background concentrations of essential elements at a given locale fulfill the requirements of essentiality to organisms there. Organisms requiring levels of essential elements in greater quantities than those naturally present in a particular environment (natural background concentrations) are not expected to be present in this environment to begin with or, if present, would suffer from deficiency not caused by anthropogenic influences.

In order to prevent anthropogenically created adverse health effects to organisms caused by a deficiency of essential elements, recommended threshold levels for these elements should not fall below the level required by the organism at a particular site needing the highest concentration to remain healthy (i.e., the organism with the highest deficiency threshold). This necessitates the caveat that if a toxicity-derived guideline value is below the natural background concentration at a certain locale, this background number would be taken as the guideline value. This will prevent recommending a guideline value that could lead to potential deficiency effects.

Consequently, guideline derivation procedures for essential and nonessential elements are the same.

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Part II. Guideline Derivation

Section 3.1. Type A Guidelines

Statistical Derivation Approach

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General Approach

For substances with adequate data (below), the recommended guideline derivation method involves modelling the cumulative species sensitivity distribution (SSD) with estimating the 95% confidence interval. The guideline is defined as the intercept of the 5th percentile of the SSD. **It is the intention of the CCME Water Quality Task Group to evaluate and, if need be, revisit the guideline derivation approach outlined in this section once this approach has been applied in the derivation of several guidelines.**

A thorough discussion of the use of SSD approach in ecotoxicology can be found in Posthuma et al. (2002).

In this approach, the long-term exposure guideline is extrapolated primarily and preferentially from no-effects threshold data, while the short-term exposure guideline is extrapolated from severe-effects threshold data.

The SSD approach can be used to derive Type A guidelines for the long- and short-term exposure durations for both freshwater and marine environments, as long as the respective minimum toxicological data requirements and the statistical curve modelling conditions are met. If possible, guidelines should be set for the most appropriate environmental conditions (e.g., most sensitive or most common conditions) after as much toxicity data as possible have been adjusted to that condition according to ETMFs (Part II, Section 2).

Preferred Endpoints

Type A Long-Term Exposure Guideline

The preferred endpoint in the derivation of the Type A long-term exposure guidelines is the most appropriate acceptable long-term exposure EC_x of a standard test (e.g., published by EC, OECD, USEPA, or ASTM), or another test otherwise deemed acceptable, where the EC_x value has been derived by regression analysis of the toxicological data and it has been demonstrated to be at or near the no-effects threshold. Though the preferred endpoint for long-term exposure studies is the no-effect EC_x, it is understood that it may not always be available in sufficient quantity to meet the minimum data requirement. The less preferred endpoints may be added to the data set sequentially in the following order if the more preferred endpoint for a given species is not available.

The preference ranking is done in the following order from the most preferred acceptable to the least preferred acceptable endpoint: most appropriate EC_x/IC_x representing a no-effects threshold > EC_{10}/IC_{10} > EC_{11-25}/IC_{11-25} > MATC > NOEC > LOEC > nonlethal EC_{26-49}/IC_{26-49} > nonlethal EC_{50}/IC_{50}.

This is done to satisfy the minimum data requirement condition and for developing more reliable long-term exposure guidelines using the SSD approach.

The acceptable effects endpoints can be the traditional endpoints (i.e., growth, reproduction, and survival), as well as nontraditional endpoints (e.g., behaviour and physiological changes), but only if the ecological relevance of these nontraditional endpoints can be demonstrated.

The low-effects endpoints (i.e. up to EC_{25}) can be lethality endpoints.

For a given effect, only the most sensitive preferred and acceptable effects endpoint for a species will be included in the analysis. As indicated above, if it is not available, the next most preferred endpoint will be included in the analysis. Only the most sensitive endpoint of the acceptable effects on a species will be included in the analysis, i.e., in the compiled data set to derive the SSD curve, a species is represented by only one effect. If there is more than one comparable record for a preferred endpoint, then the species effects endpoint is to be represented by the geometric mean of these records.

It is recognized that with a wide variety of acceptable effect endpoints this approach may lead to a distribution curve containing data from nonlethal and lethal, but long-term, toxicity tests, showing effects from 0% to 50% of a population. However, it is deemed important to include all the relevant data for the different species in the derivation of the guideline value. Using as much relevant data as possible is also important because toxicological studies can be scarce for many substances and organisms. It is important to identify and clearly label these different effect data points (i.e., identify species, effect, endpoint, and data classification) in any summary compilation and graphical representations of the distribution so they can be distinguished and, if necessary analyzed, relative to different patterns and anomalies.

Type A Short-Term Exposure Guideline

The accepted endpoints for the development of the Type A short-term (generally $\leq$96h) exposure guidelines are LC_{50} or equivalent (i.e., EC_{50} for immobility).

Accepted Effects

This protocol allows for the use of multiple effects endpoints per species in an SSD (i.e., the most sensitive point for each of the traditional effects such as growth, reproduction, and survival), as well as endpoints for other effects, such as behaviour, or physiological. If there is more than one comparable record for a preferred endpoint, then the species effects endpoint is to be represented by the geometric mean of these records.

Minimum Requirements for a Type A Guideline Guideline

The minimum toxicological data set requirement stipulates the requisite number of studies on fish, invertebrates, and plants, depending on the receiving environment (marine or freshwater) according to Tables 1–4 in Part II, Section 1.

In addition to the toxicological minimum requirement, there is also a statistical requirement related to the ability to fit a model that sufficiently and adequately describes the curvilinear relationship (e.g., sigmoidal) between concentration and cumulative percentage of species. Sufficient and adequate description of data is tested with the appropriate statistical goodness-of-fit test for the model.

While no minimum requirement is set with respect to the number of data points necessary to allow the fitting of a model, it is recognized that statistical power increases with the increasing number of data points. Through the minimum toxicological data requirement, (requiring several fish, invertebrate, and plant studies), as well as the inclusion of primary and secondary studies, it is anticipated that generally at least 10 to 15 data points should be available, recognizing that there will be occasions when more or less data may be needed or acceptable to produce an adequate curve.

Where the minimum toxicological data requirements cannot be met, or where no model adequately fits the data as determined by an appropriate goodness-of-fit

test, a Type A guideline cannot be derived and the derivation procedure for a Type B1 or Type B2 guideline (Part II, Section 3.2 and Section 3.3, respectively) should be used.

The toxicity data set used may be subject to modifications to normalize/standardize for environmental conditions, exposure conditions, or other sources of extraneous variance (Part II, Section 2).

Derivation Methodology

General

A regression-based approach is used in the derivation of the Type A guideline. An SSD is created, and one of several regression models is fit to this distribution. A description of most of the appropriate models can be found in Zajdlik (2005). The curve fitting may be done by means of nonlinear regression (e.g., Moore and Caux 1997; Nyholm et al. 1992) or linear regression on data that have been statistically transformed (Bailer and Oris 1997; Cox 1987). The following general guidance is provided to assist with this task.

Data are first collected, according to the requirements identified in Part II, Section 1. Data are then categorized and classified as being for short- or long-term exposure and for marine or freshwater guideline derivation. To the extent possible, concentration data should be standardized for ETMFs to reflect the concentration that would elicit the response in the most appropriate condition, according to Part II, Section 2.

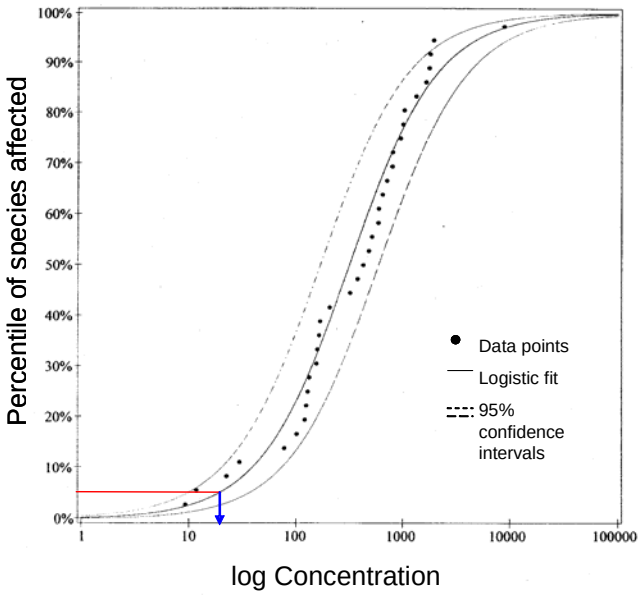
For substances for which there is a clear difference in the toxicological sensitivity across taxa due to the different mode of toxic action (e.g., plants are more sensitive to an herbicide than fish), the data set may display a bimodal (or multimodal) distribution. In this situation, on a case-by-case basis, separate SSD curves may be plotted and the most sensitive taxonomic level can be used to derive the guideline. However substantial additional data would be required to derive an independent SSD for a single taxonomic level.

The choice of model is critical when estimating low toxic effects because the resulting estimate often involves extrapolation from the response data and is therefore model-dependent. The regression-based approach requires that there be some flexibility for guideline derivation in order to integrate biological/toxicological issues with statistical ones. A rationale that is scientifically based and is consistent with CCME guiding principles (see Part I) is then required.

The choice of model to fit the data will vary according to the data at hand. General rules, from Zajdlik (2005), are as follows:

- Consider biological issues and data distribution.
- Choose a suitable model or models (e.g., 3 parameter logistic [a < 0] for symmetric data with a steeper slope of ascent).
- Using the model(s), enter and plot individual concentration–response data.
- Use the appropriate statistic (e.g., *G* test, *F* test; p < 5%, etc.) to determine goodness of fit to select the best model.
- Create the fitted SSD curve.
- Use the best model to derive the appropriate water quality guideline value.

Figure 2. Schematic of a relationship between concentration of a substance and the percent of species affected, illustrating the derivation of the water quality guideline as the intercept of the 5th percentile and the fitted curve. Also shown are the upper and lower 95% confidence limits.



Generally, for both the long- and short-term exposure guidelines, the guideline is defined as the intercept of the 5th percentile of the y-axis with the fitted SSD curve (see Figure 2). However, there are certain exceptions as described below under the heading Protection Clause.

Recommended Models

The following models are recommended (following Zajdlik [2006]) for fitting the SSD and determining a 5th percentile from the toxicological data:

- Burr Type III Cumulative Density Function (CDF)
- Gumbel CDF
- Logistic CDF
- Lognormal CDF
- Normal CDF
- Weibull CDF.

No prioritization of the models is given because the curve-fitting analysis to the available toxicity data should determine the most appropriate model. Other models (not mentioned above) can be employed if they are deemed appropriate.

Guidance on fitting models is provided by Zajdlik (2006) as well as other literature (Burr 1942; Berkson 1944; Gumbel 1958; Aldenberg and Slob 1993; van Ewik and Hoekstra 1993; OECD 1995; EC 2005).

The parameters of a distribution (or model) must be estimated before the model may be used to estimate the lower 5th percentile, even before settling on a final model. In some cases, parameters may be estimated manually. An example is the normal distribution where the sample location and scale parameters are the mean and standard deviation, respectively, of the SSD data set. Estimating parameters for most distributions requires computer software.

Computer Software

Computer software may take two forms: (1) software that directly estimates the parameters of a distribution or (2) software that allows the user to input a function to be optimized. Of the two forms, only the first is generally employed. The second form requires advanced knowledge of statistics and optimization. Every major statistical package has the second capability, while direct estimation of parameters of a distribution is generally available in most major statistical packages for a generous variety of distributions.

Goodness of Fit

Once parameters are estimated, graphical assessments of goodness of fit are required. This is necessary to ensure that the fitted model adequately describes the data and that the extrapolation to the guideline value is statistically sound and scientifically defensible.

Some formal goodness-of-fit tests are generally available, such as the Anderson-Darling, chi-square, and Kolmogorov-Smirnov tests.

However, selecting the final fitted model distributions for use in the guideline derivation based solely on the goodness-of-fit test statistics is not recommended. Best professional judgment must also be applied because, for example, sample size influences the goodness-of-fit test results and different goodness-of-fit test statistics give different rank orders. Graphical tools (e.g., cumulative distribution function plots, observed versus model values plots, plots of residuals, quantile–quantile plots, etc.) are useful in this evaluation. It must also be verified that the modelled distribution is (at least theoretically) plausible.

Choosing a Model

D'Agostino and Stephens (1986) provide useful reference information to guide the selection of a model based on goodness-of-fit tests. Modellers should use graphical techniques in conjunction with formal methods, along with a general understanding of ecotoxicological principles, in order to choose the best-fitting model and to decide when even the best-fitting model inadequately represents an SSD.

One numeric criterion that could be used to choose between contending models is a comparison of a test statistic for the various candidate models. When using the Kolmogorov-Smirnov or Anderson-Darling tests, the model corresponding to the smallest value indicates the best-fitting model. The term "best", however is a function of the test. For example, while the Kolmogorov-Smirnov test is best at detecting location shifts, this may not be the most suitable criterion for identifying the most appropriate best model for choosing a model for estimating environmental quality guidelines, where a good fit of the tails is paramount.

Even the best-fitting model(s) may poorly describe the SSD (Zajdlik 2006), so acceptance of a model need not always rely on statistical tests. A huge data set, as well as the presence of bimodal (or multimodal)

distributions, (e.g., that occur when different taxa or trophic levels have different sensitivities [as seen, for example, in selectively acting pesticides]) will reduce the ability of any model to adequately fit the data. The ability to reject or accept a model can be limited with small or large sample sizes, respectively.

Fulfillment of the Guiding Principle by Long-term Exposure Guideline

Using the SSD approach in the derivation of long-term exposure guidelines may raise the question whether the resulting guideline is fulfilling the guiding principle of protecting all species all the time.

In the SSD, the likelihood of a data point falling below a certain percentile on the y-axis is a function of sample size (i.e., the number of species and endpoints in the SSD in relation to the percentile). For example, with a data set of over 20 data points, at least one data point would fall below the 5th percentile. Therefore, setting the guideline at the 5th percentile alone could be interpreted as allowing for the impairment (and, theoretically, potential loss) of up to 5% of possible species, depending on the severity of the effects endpoints plotted. This issue is of particular relevance when plotting moderate- or severe-effect level data, but is less important when plotting low- or no-effect level data. Some proponents of the SSD approach argue that enough redundancy exists within aquatic communities to allow some loss (e.g., Posthuma et al., 2002). This in itself, however, is not considered acceptable to deem the resulting guideline as fulfilling the guiding principle.

Therefore, additional safeguards are taken in the development of the guideline when using the SSD approach:

- Data for all available species are plotted.
- The lowest acceptable endpoint for appropriate, different negative effects per species is plotted.
- No-effect data are preferentially and primarily plotted.
- There is the potential of invoking the protection clause (see below).

While the intercept of the 5th percentile to the fitted curve is often lower than the lowest observed low-effect toxicity value (especially for data sets with fewer than approximately 15 data points), the larger the data set, the higher the probability that a low-effect data point will fall below this value, thereby implying that this species may not be sufficiently protected (depending on the kind and severity of effect associated with this data point). Although the guideline is derived preferentially with a no-effect data set (which can include some effects data, especially at the upper part of the concentration range), the potential, therefore, exists that a low-effect or even a severe-effect endpoint may in fact be below the recommended guideline value. Consequently, in certain situations, the protection clause may be invoked.

Protection Clause

The protection clause is created to ensure that the guideline is fulfilling the guiding principles of CCME with respect to the intended level of protection. It applies only to the long-term exposure guideline and should only be invoked if there is a strong reason to question that the Type A long-term exposure guideline based on the 5th percentile intercept to the fitted curve is achieving the intended level of protection.

The protection clause may be invoked if an acceptable single (or, if applicable, geometric mean) no-effect or low-effect level endpoint (e.g., EC_x for growth, reproduction, survival, or behaviour) for a species at risk (as defined by the Committee on the Status of Endangered Wildlife in Canada [COSEWIC]) is lower than the proposed guideline (i.e., is below the 5th percentile intercept to the fitted curve), then that endpoint becomes the recommended guideline value. If this endpoint is a moderate- or severe-effect level endpoint for a species at risk (i.e., EC_x with $x \geq 50\%$, or a lethality endpoint [LC_x]), then the guideline value shall be determined on a case-by-case basis (e.g., by using an appropriate safety factor) (Chapman et al. 1998).

Similarly, if an acceptable single (or, if applicable, geometric mean) lethal-effects endpoint (i.e., LC_x, where $x \geq 15\%$) for any species is lower than the proposed guideline (i.e., is below the 5th percentile intercept to the fitted curve), then that endpoint becomes the recommended guideline value.

Furthermore, special consideration will be required if multiple endpoints for a single taxon (e.g., fish, invertebrates, or plant/algae) and/or an elevated number of secondary studies are clustered around the 5th percentile. Best scientific judgment should be used in deciding when this situation is present (e.g., due consideration should be given to the percentage of data points in question to the whole data set) and in

determining the best path forward to address this situation.

To allow for flexibility in the regional or site-specific implementation, if it can be demonstrated that a data point below the recommended guideline is for a species at risk within a given province/territory or region/site, for a species of commercial or recreational importance, or for an "ecologically important" species, then jurisdictions may use that data point as the basis for deriving the applicable guideline value.

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Part II. Guideline Derivation

Section 3.2. Type B1 Guidelines

Lowest Endpoint Derivation Approach

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Preferred Acceptable Endpoints 1
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General Approach

The guideline derivation method described in this section is a modified version of the method traditionally used to derive CWQGs-PAL (CCME, 1991). It is a generic method of wide applicability that can be used when data are inadequate to derive a Type A guideline (Part II, Section 3.1).

In this approach, the long-term exposure guideline is extrapolated from low-effects threshold data, while the short-term exposure guideline is extrapolated from severe-effects threshold data.

The method can be used to generate Type B1 guidelines for long- or short-term exposures and for both marine and freshwater environments. These guidelines can be upgraded to Type A guidelines when the minimum physical, chemical and toxicological data requirements and statistical requirement are met. If possible, guidelines should be set for the most appropriate environmental condition (e.g., most sensitive or most common conditions) after as much toxicity data as possible have been adjusted to that condition according to ETMFs (Part II, Section 2).

Preferred Acceptable Endpoints

The acceptable effects endpoints can be the traditional endpoints (i.e., growth, reproduction, and survival), as well as nontraditional endpoints (e.g., behaviour and physiological changes), but only if the ecological relevance of these nontraditional endpoints can be demonstrated.

Type B1 Long-Term Exposure Guideline

The preferred acceptable endpoint for developing the Type B1 long-term exposure guidelines is the most appropriate EC_x of a long-term exposure standard test (e.g., published by EC, OECD, USEPA, or ASTM), or another test otherwise deemed acceptable, where the EC_x value has been derived by regression analysis of the toxicological data and it has been demonstrated to be at or near the low-effect threshold. Though the preferred endpoint for long-term exposure studies is the EC_x, it may not always be available.

Other endpoints are considered acceptable in a tiered approach for developing long-term exposure guidelines in the following order: Ranking of the most preferred acceptable to the least preferred acceptable endpoint: Most appropriate EC_x/IC_x representing a low-effects threshold > $EC_{15\text{-}25}/IC_{15\text{-}25}$ > LOEC > MATC > nonlethal $EC_{26\text{-}49}/IC_{26\text{-}49}$ > nonlethal EC_{50}/IC_{50}.

The low-effects endpoints (i.e. up to EC_{25}) can be lethality endpoints.

The most sensitive acceptable and preferred effects endpoint for the most sensitive species will be the critical study used in the derivation of the guideline. If it is not available (i.e., it is not in the available data set), the next most preferred and acceptable endpoint will be used.

Type B1 Short-Term Exposure Guideline

The accepted endpoints for the development of the Type B1 short-term exposure guidelines are LC_{50} or equivalent (i.e., EC_{50} for immobility) of a short-term exposure standard test (e.g., published by EC, OECD, USEPA, or ASTM,), or another test otherwise deemed acceptable, where the EC_{50} value has been derived by regression analysis of the toxicological data. The lowest scientifically defensible acceptable effects concentration from a short-term exposure study will be the critical study for the derivation of the short-term exposure Type B1 guideline.

Data Requirements

In order to proceed with the derivation process for a Type B1 guideline, the appropriate minimum physical, chemical, and toxicological data requirements (i.e., the requisite number of studies on fish, invertebrates, and plants, depending on the receiving environment [marine or freshwater]) must be met according to Tables 1–4 (Part I, Section 1).

All data required to fulfill the minimum toxicological data set must be of primary quality in order for a Type B1 guideline derivation to proceed. The guideline must be derived from a primary quality data value.

Where there are insufficient physical and chemical data, or where the minimum toxicological data requirements cannot be met, a Type B1 guideline cannot be derived and the derivation procedure for a Type B2 guideline (Part II, Section 3.3) should be used.

The toxicity data set used may be subject to modifications to normalize/standardize for environmental conditions, exposure conditions, or other sources of extraneous variance (Part II, Section 2).

Derivation Methodology

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 B1 long-term exposure guideline. The lowest acceptable endpoint (i.e., the most sensitive LC_{50} or equivalent endpoint) from a short-term exposure study will be the critical study used in the derivation of the Type B1 short-term exposure guideline.

For both long-term and short-term exposure 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.

This precautionary safety factor has been chosen to account for differences in sensitivity to a chemical variable due to differences in species (intra- and interspecies), exposure conditions (laboratory versus field, varying environmental conditions), and test endpoints, as well as a paucity of toxicological data, cumulative exposures, and policy requirements (in particular, extrapolating from a low-effect toxicological threshold to a protective environmental management benchmark). While this safety factor may be considered as arbitrary, fixed, and too conservative for many substances (Chapman et al. 1998), the Type B1 guideline derivation approach is used for substances where only a limited amount of toxicological information is available.

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CCME (Canadian Council of Ministers of the Environment). 1991. Appendix IX — A protocol for the derivation of water quality guidelines for the protection of aquatic life (April 1991). In: Canadian water quality guidelines, Canadian Council of Resource and Environment Ministers, 1987. Prepared by the Task Force on Water Quality Guidelines. [Updated and reprinted with minor revisions and editorial changes in Canadian environmental quality guidelines, Chapter 4, Canadian Council of Ministers of the Environment, 1999, Winnipeg.]

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Part II. Guideline Derivation

Section 3.3. Type B2 Guidelines

Lowest Endpoint Derivation Approach

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General Approach

The guideline derivation method described in this section is a modified version of the method traditionally used to derive CWQGs-PAL (CCME, 1991). It is a generic method of wide applicability that can be used when data are inadequate to derive a Type A guideline (Part II, Section 3.1) or a Type B1 guideline (Part II, Section 3.2).

In this approach, the long-term exposure guideline is extrapolated from low-effects threshold data, while the short-term exposure guideline is extrapolated from severe-effects threshold data.

The method can be used to generate Type B2 guidelines for long- or short-term exposures and for both marine and freshwater environments. These guidelines can be upgraded to Type A or Type B1 guidelines when the minimum physical, chemical, or toxicological data are met. If possible, guidelines should be set for the most appropriate environmental condition (e.g., most sensitive or most common conditions) after as much toxicity data as possible have been adjusted to that condition according to ETMFs (Part II, Section 2).

Preferred Acceptable Endpoints

The acceptable effects endpoints can be the traditional endpoints (i.e., growth, reproduction, and survival), as well as nontraditional endpoints (e.g., behaviour and physiological changes), but only if the ecological relevance of these nontraditional endpoints can be demonstrated.

Type B2 Long-Term Exposure Guideline

The preferred acceptable endpoint for developing the Type B2 long-term exposure guidelines is the most appropriate EC_x of a long-term exposure standard test (e.g., published by EC, OECD, USEPA, or ASTM,) or another test otherwise deemed acceptable, where the EC_x value has been derived by regression analysis of the toxicological data and it has been demonstrated to be at or near the low-effect threshold. Though the preferred endpoint for long-term exposure studies is the EC_x, it may not always be available.

Other endpoints are considered acceptable in a tiered approach for developing long-term exposure guidelines in the following order: Ranking of the most preferred acceptable to the least preferred acceptable endpoint: Most appropriate EC_x/IC_x representing a low-effects threshold > $EC_{15\text{-}25}/IC_{15\text{-}25}$ > LOEC > MATC > $EC_{26\text{-}49}/IC_{26\text{-}49}$ > nonlethal EC_{50}/IC_{50} > LC_{50}.

The effects endpoints can be lethality endpoints.

The most sensitive preferred and acceptable effects endpoint for the most sensitive species will be the critical study used in the derivation of the guideline. If it is not available (i.e., it is not in the available data set), the next most preferred and acceptable endpoint will be used.

Long-term exposure studies generally show effects occurring at lower concentrations than short-term exposure studies for the same endpoint and species. It is possible that effect concentrations (including EC_{50} and LC_{50}) from short-term exposure studies from one

species can be below the effect concentrations from long-term exposure studies from the same species. Examples are studies performed by different laboratories, at different times, or with different populations/strains of the same species or of a second species.

While an acceptable corresponding long-term exposure effects concentration of the first species would be below its short-term exposure effects concentration, this value may not always be available (i.e., no appropriate long-term exposure study has so far been performed with this species). In such a case, the long-term exposure guideline derived from only long-term exposure studies may not be sufficiently protective for the first species.

This situation may occur more frequently for substances with fairly limited data sets, i.e., candidate substances for the Type B2 guideline derivation. While it is preferred to derive the Type B2 long-term exposure guidelines from the lowest acceptable endpoint from a long-term exposure study, scientific judgment must be used to decide if the resulting guideline is sufficiently protective.

If it is deemed that the resulting long-term exposure guideline would not be sufficiently protective, a suitable lowest-effects concentration short-term exposure study can be used as the critical study for the derivation of the long-term exposure guideline. This decision, however, must be scientifically defensible.

The selection of the suitable lowest-effects concentration short-term exposure study as a critical study is a case-by-case scientific decision. Because long-term exposure studies can be considered more reliable, generally, even if there is a short-term exposure study lower than a long-term exposure study for the most sensitive species, then the long-term exposure study should be taken as the critical study. Early-life stage (ELS) studies are an exception, to be evaluated on a case-by-case basis. However, if there is no long-term study for this species, and its short-term exposure study is below the long-term exposure study of another species, then the short-term exposure study result for this species should be taken as the critical study.

Type B2 Short-Term Exposure Guideline

The accepted endpoints for the development of Type B2 short-term exposure guidelines are LC_{50} or equivalent (i.e., EC_{50} for immobility) of a short-term exposure standard test (e.g., published by EC, OECD, USEPA, or ASTM), or another test otherwise deemed acceptable, where the LC_{50}/EC_{50} value has been derived by regression analysis of the toxicological data. The lowest scientifically defensible acceptable effects concentration from a short-term exposure study will be the critical study for the derivation of the short-term exposure Type B2 guideline.

Data Requirements

In order to proceed with the derivation process for a Type B2 guideline, the appropriate minimum physical, chemical, and toxicological data requirements (i.e., the requisite number of studies on fish, invertebrates and plants, depending on the receiving environment [marine or freshwater]) must be met according to Tables 1–4 in Part I, Section 1.

The minimum toxicological data set can be met with secondary data. If the minimum data requirement cannot be met with a combination of primary and/or secondary data, then no Type B2 guideline will be set. The guideline can also be derived from a secondary quality data value.

The toxicity data set used may be subject to modifications to normalize/standardize for environmental conditions, exposure conditions, or other sources of extraneous variance (Part II, Section 2).

Derivation Methodology

Long-Term Exposure Type B2 Guideline

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 to derive the long-term exposure guideline value. However, if scientific judgment dictates that this guideline would not be sufficiently protective (e.g., when a suitable lowest-effects concentration short-term exposure study is below a suitable lowest-effects concentration long-term exposure study), a suitable lowest-effects concentration short-term exposure study can be used as the critical study for the derivation of the long-term exposure guideline. The endpoint concentration from this critical study is then divided by a safety factor of 20 to derive the long-term exposure guideline value if the substance is

nonpersistent (i.e., $t_{½}$ in water <8 weeks). If the substance is found to be persistent, the endpoint concentration from the critical study is then divided by a safety factor of 100 to derive the long-term exposure guideline value.

These precautionary safety factors have been chosen to account for differences in sensitivity to a chemical variable due to differences in species (intra- and interspecies), exposure conditions (laboratory versus field, varying environmental conditions), and test endpoints, as well as a paucity of toxicological data, cumulative exposures, and policy requirements (in particular, extrapolating from a low-effect toxicological threshold to a protective environmental management benchmark). While these safety factors may be considered as arbitrary, fixed, and too conservative for many substances (Chapman et al. 1998), the Type B2 guideline derivation approach is used for substances where only a very limited amount of toxicological information is available.

Short-Term Exposure Type B2 Guideline

The lowest scientifically defensible acceptable effects concentration (i.e., the most sensitive LC_{50} or equivalent endpoint) from a short-term exposure study will be the critical study for the derivation of the short-term exposure Type B2 guideline. The endpoint concentration from this critical study is divided by a safety factor of 10 to derive the short-term exposure guideline value.

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CCME (Canadian Council of Ministers of the Environment). 1991. Appendix IX — A protocol for the derivation of water quality guidelines for the protection of aquatic life (April 1991). In: Canadian water quality guidelines, Canadian Council of Resource and Environment Ministers, 1987. Prepared by the Task Force on Water Quality Guidelines. [Updated and reprinted with minor revisions and editorial changes in Canadian environmental quality guidelines, Chapter 4, Canadian Council of Ministers of the Environment, 1999, Winnipeg.]

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For further scientific information, contact:

Environment Canada
National Guidelines and Standards Division
351 St. Joseph Blvd.
Hull, QC K1A 0H3
Phone: (819) 953-1550
Facsimile: (819) 956-5602
E-mail: ceqg-rcqe@ec.gc.ca
Internet: http://www.ec.gc.ca

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