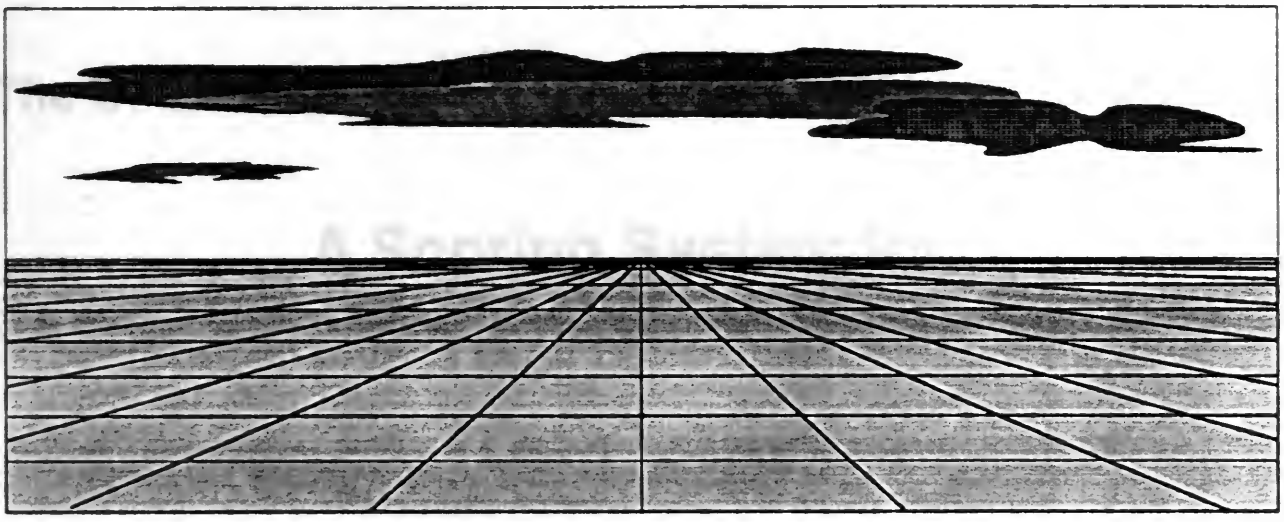
The Ontario Ministry of the Environment Scoring System



A Scoring System for Assessing Environmental Contaminants

Hazardous Contaminants Coordination Branch
Ontario Ministry of the Environment

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Contents

Preamble

There are thousands of chemical substances which can potentially be released into the various environmental compartments. It is not possible to evaluate the impact of all of these chemicals on the environment and on living organisms all at once. It therefore is helpful if a screening mechanism is developed to reduce to a manageable size the number of chemicals subject to monitoring and subsequent intensive examination and standards development. In this publication a method for scoring environmental contaminants is described, the objective of which is the relative assessment of chemical substances according to their ability to partition into multiple media, persist or bioaccumulate and/or have adverse effects on biota. Substances can then be screened or prioritized based on these scores.

This scoring system is an adaption of the Vector Scoring System developed by the Ontario Ministry of the Environment for evaluating the exposure potential and toxicity characteristics of numerous chemicals. It is based on the use of a set of scoring parameters, each corresponding to a physical/chemical property or an effect which is relevant to the assessment of a contaminant's potential environmental or health effects. The scores assigned reflect the relative severity of effect associated with each parameter.

Concern levels or cut-off scores may be set for some or all of the parameters such that those substances receiving scores equal to or above these concern levels would be designated as being of particular concern. Priorities may also be assigned using combinations of scores or weighting of scores. The selection of the concern levels and the method, if any, by which the scores are combined or weighted depends on the needs of the user and the objectives of the particular program. As an example, the concern levels used for promoting substances to the Ontario Effluent Monitoring Priority Pollutants List are provided in Appendix B.

The Ministry is currently using this scoring system as a basis for identifying chemicals for multimedia standards and water quality guidelines development, for selecting chemicals of high priority for air emission control (Clean Air Program - "CAP") and waste management (hazardous waste listing, Regulation 309), and for identifying chemicals for effluent monitoring purposes (Municipal-Industrial Strategy for Abatement - "MISA"). This system has also been adopted for use in the establishment of the Canada/U.S. Great Lakes Water Quality Agreement priority lists.

For further information, please contact the Risk Identification Unit, Standards Development Section, Hazardous Contaminants Coordination Branch, Ontario Ministry of the Environment, 135 St. Clair Avenue West, Toronto, Ontario M4V 1P5.

ONTARIO MINISTRY OF THE ENVIRONMENT SCORING SYSTEM

INTRODUCTION

The following generally accepted parameters have been developed to determine the concern level for a chemical in the environment. These parameters are a subgroup of the parameters in a methodology, developed for the Ministry of the Environment for assessing the relative environmental hazards of chemical contaminants. The magnitude of the score assigned to each parameter reflects the level of concern arising from that property of a chemical.

1. Environmental Behaviour Parameters

Range of scores: 0-10 for all parameters a. to c.

a) Environmental Transport
b) Environmental Persistence
c) Bioaccumulation

2. Toxicity Parameters

Range of scores: 0-10 for all parameters a. to g.

a) Acute Lethality
b) Sub-Lethal Effects on Non-Mammalian Animals
c) Sub-Lethal Effects on Plants
d) Sub-Lethal Effects on Mammals
e) Teratogenicity
f) Genotoxicity/Mutagenicity
g) Carcinogenicity

In addition to the numerical value assigned to a parameter, various symbols are used to indicate special concerns regarding the source of, or confidence in, the underlying data:

- If the data required are not available, an asterisk (*) is assigned to that parameter rather than a numerical score.

- If the data used are questionable (e.g., data not completely meeting the specifications of a criterion, data lacking in documentation, data derived with outdated methods), a score is assigned to the parameter, but it is "tagged" with a "Q" to indicate doubt regarding the confidence in the data. An example of the use of this tag would be when saltwater species data was used in the absence of data for a freshwater species.

- If the data used in the assignment of a parameter score is "limited", the score for that parameter is "tagged" with an "L". This indicates that a score was assigned, but due to the nature of the really available data, confidence in the score was less than if a more comprehensive data set had been used. In many instances, additional data would either remove the "L" designation and confirm the score, or result in a higher score.

  "L" was also used if, in the absence of a freshwater fish BCF, log kow was used to score bioaccumulation.

- If the data used are perceived as representing a worst-case scenario (e.g., toxicity data from intravenous administration), the score for that parameter is "tagged" with a "W".

- If the data used in the assignment of a parameter score are estimated from environmental modelling techniques or structure-activity relationships, the score for that parameter is "tagged" with an "E".

These "tags" may be taken into consideration when the chemical is reviewed.

PARAMETERS

1. Environmental Behaviour Parameters

(a) ENVIRONMENTAL TRANSPORT

Rationale

This parameter describes the transport of chemicals between environmental media. The environmental transport of a chemical is an important factor in evaluating its potential environmental and health hazards. Inter-media transport can be observed during field studies or by undertaking microcosm studies in a laboratory, but relatively few substances have been studied using such techniques. One way to estimate the environmental transport characteristics of a chemical is to use a simple mathematical model such as the Fugacity Level I model (MacKay and Paterson).

The Fugacity Level I model estimates the equilibrium distribution of a chemical released to the environment. The environmental media considered are air, water, soil, sediment and aquatic biota. The model requires information about the chemical's physicochemical properties, i.e. molecular weight, solubility, vapour pressure, and octanol-water partition coefficient.

Scoring Criteria

The criteria for this parameter use results from environmental models. In addition, there are criteria for substances that are largely associated with fine particles (generally less than 10 um in size). Examples are fine particles associated with incinerator processes.

The scoring criteria for this parameter are as follows:

PARAMETER SCORE	CRITERIA
10	Three or more media each contain ≥ 5% of the total amount released or substance is inorganic and is adsorbed to particles <10um in diameter when released.
7	Two media each contain ≥ 5% of the total amount released.
4	No one medium contains > 95%, and only one medium contains ≥ 5% of the total amount released.
0	Any single medium contains > 95% of the total amount released.

Suggested Information Sources

Lyman et al., 1982 -

A comprehensive reference of published values and estimation methods for various physical and chemical properties.

Verschueren, 1983 -

A handbook of environmental data for organic chemicals.

ENVIROFATE and ISHOW databases -

Contain solubility, vapour pressure, partition coefficients for many chemicals.

ICF Inc., 1985 -

Contains tabulations of physical, chemical and fate data for many organic substances and elements.

Mills et al., 1982 -

A compilation of physical, chemical and fate data for many organic substances.

Mackay and Shiu, 1981 -

A compilation of physical and chemical parameters for organic substances.

Kenaga and Goring, 1980 -

A compilation of solubility, sorption and K_{ow} data.

Clayton and Clayton, 1981 -

A comprehensive reference of information on industrial chemicals.

Karickhoff, 1984 -

Discussion of sorption processes in general and K_{ow}/K_{oc} values in particular.

Amoore and Hautala, 1983 -

Information on volatilities of industrial chemicals.

Neely and Blau, 1985 -

Contains physical, chemical and fate data and estimation methods.

(b) ENVIRONMENTAL PERSISTENCE

Rationale

This parameter describes the tendency for a chemical to persist in the environment. Substances in the environment can be subjected to a variety of processes including sorption, oxidation, hydrolysis, photodegradation and biodegradation. The net result of such processes may be expressed as the overall persistence of a substance in the environment. When quantified, persistence is usually expressed as the length of time required for one-half of the original amount of a substance to be degraded. It is analogous to parameters which may be presented as "rate of loss in natural systems", "overall half-life", or "50% recovery time". It is also similar to the "persistence" parameter calculated by fugacity models.

Half-lives of chemicals may vary from seconds to thousands of years (ICF Inc., 1985). Short half-lives generally indicate a lower level of concern. For example, environmental releases of substances with half-lives of less than a few days often will not result in significant accumulation in the environment. Conversely, those with half-lives of several months or longer can lead to substantial exposure or accumulation in the food chain.

Scoring Criteria

The criteria for this parameter are based on half-life values.

If half-life data are available, they will usually pertain to specific media as opposed to general environmental persistence. This information provides an indication of levels of concern regarding specific media. In such cases, it is recommended that the media providing the highest score be used.

If persistence values have not been reported and cannot be estimated by using environmental models, other types of information may offer guidance in developing a score for this parameter. For example, structure-activity relationships (SARs) may provide general indications of persistence for relatively unknown substances structurally similar to more familiar substances. To assess the potential biodegradability of substances in wastewater treatment plants, test methods such as the static-culture-flask and shaker-flask techniques have been used (for example, see Tabak et al., 1981). The results of these tests in general show good agreement with published work on biodegradability. Substances not degraded under test conditions cannot be presumed to be immune to microbial action in the environment. Accordingly, scores derived from SARs or biodegradability tests should be tagged with E, Q, or W.

PARAMETER SCORE	CRITERIA
10	Half-life greater than 100 days
7	Half-life of more than 50 but less than or equal to 100 days
4	Half-life of more than 10 but less than or equal to 50 days
0	Half-life of less than or equal to 10 days

Suggested Information Sources

ICF Inc., 1985 -
Includes compilation of half-lives in several media for organic substances.

Mills *et al.*, 1982 -
Includes compilation of half-lives in aquatic media for organic substances.

Verschueren, 1983 -
Includes half-lives and biodegradability test results for organic substances.

NRCC - National Research Council of Canada Associate Committee on Scientific Criteria for Environmental Quality - These publications include data on biodegradability for specific substances.

ENVIROFATE database -
Contains data on biodegradation rates for chemicals released to the environment.

Tabak *et al.*, 1981 -
Includes results of biodegradability studies for more than 100 organic substances.

(c) BIOACCUMULATION

Rationale

This parameter describes the tendency for a substance to accumulate in biological systems. In the current context, the term bioaccumulation is intended to convey the ability of a substance to accumulate in the tissues of organisms. The tendency for certain groups or classes of chemicals to bioaccumulate is well documented. This process has also been referred to as bioconcentration or biomagnification and some authors have assigned various distinct definitions to these terms but for purposes of this assessment those differences are relatively unimportant.

One of the parameters frequently used to express bioaccumulation is the bioconcentration factor (BCF). Most BCF values pertain to fish or other aquatic organisms and are calculated as the ratio of the concentration of a substance in the organism (or some specific tissue) on a wet weight basis to the concentration of the substance in the water at steady state (Veith *et al.*, 1980). For organic substances, values of BCF range from about 1 to more than 1,000,000 (Lyman *et al.*, 1982).

Bioaccumulation factors have also been determined for some terrestrial vertebrates but these data are less abundant and more difficult to locate than those for aquatic organisms. It is recommended for this assessment that data collection efforts first focus on BCF values for aquatic organisms.

The tendency of substances to bioaccumulate in tissue frequently has been related to hydrophobicity or lipophilicity (Veith *et al*, 1980). As a result, various regression equations have been suggested for predicting BCF values for aquatic organisms based on the octanol-water partition coefficient (K_{ow}) and other physico-chemical properties. To date, those that use K_{ow} values have been the most widely investigated and most successful (Lyman *et al*., 1982; Geyer *et al*., 1984).

Scoring Criteria

Scoring criteria for this parameter are defined in terms of either BCF or log K_{ow}. The correlation between the two sets of criteria is based upon the following relationship developed from experimental data on 84 chemicals (Veith *et al*., 1980):

$$\log BCF = 0.76 \log K_{ow} - 0.23$$

Other equations have been developed based upon various groups of chemicals. If an equation is available that is more directly applicable to a substance being evaluated, that equation can be used.

The bioaccumulation of compounds with relatively high K_{ow} values is influenced by the degree to which a compound dissociates in water. Equations for estimating bioaccumulation that include a dissociation term have not been reported. For this parameter, dissociation has not been considered in the determination of scores. This should tend to produce somewhat higher scores than warranted for some organic substances. BCF values can be estimated only to within an order of magnitude using most of the correlations developed to date, and laboratory test situations are incapable of duplicating field situations (Lyman *et al*., 1982). Therefore, the consideration of dissociation effects may be unimportant, for this evaluation.

If scores based on both the BCF and the K_{ow} can be determined, preference should be given to the measured BCF values rather than those estimated based on K_{ow}.

PARAMETER SCORE	CRITERIA BCF	log Kow
10	>15000	>6.0
7	>500 - 15000	>4.0 - 6.0
4	>20 - 500	>2.0 - 4.0
0	$\leq$ 20	$\leq$ 2.0

Suggested Information Sources

Lyman et al., 1982 -
Contains BCF and K_{ow} data and estimation methods.

Geyer et al., 1984 -
Examines relationship between BCF and K_{ow}.

Kenaga and Goring, 1980 -
Includes K_{ow} and BCF data for aquatic environments.

Verschueren, 1983 -
Includes BCF and K_{ow} data for organic substances.

Veith et al., 1980 -
Includes BCF and K_{ow} values.

AQUIRE database -
Contains BCF data for aquatic organisms.

Mackay, 1982 -
Examines correlations of BCFs.

Garten and Trabalka, 1983 -
Contains BCF data for data for aquatic and terrestrial organisms.

ICF Inc., 1985 -
Includes BCF data.

Hansch and Leo, 1979 -
Describes how to estimate K_{ow} values.

2. Toxicity Parameters

Parameters "a" through "h" were selected to describe the toxicological properties of chemicals. Information on acute lethality of chemicals to all targets in the environment is included in parameter "a". The sub-lethal effects of chemicals on ecological systems (plants and animals) are described in parameters "b" and "c". Parameters "d" through "f" are primarily designed to describe potential adverse effects on human health.

When data are lacking on the effects of a chemical on a specific environmental target (e.g., humans, fish or wildlife) the best available information should be used. Unless specific data are available on species differences in responses to the chemical, it is assumed that all species respond in an equivalent manner and the most sensitive would be used in scoring. Differences in response among species, or other differences between experimental and "real-world" exposure situations (e.g., data from high level experimental exposures extrapolated to much lower levels) are not considered in this assessment.

There are several general topics, including route and duration of exposure and validity of testing procedures, that apply equally to all of the toxicity parameters. These are discussed below and will only be briefly referred to in the descriptions of each parameter.

Route of Exposure

Route of exposure is an important factor in the judgement of the applicability and validity of the effects observed under controlled experimental conditions (Grice, 1984; Willes et al., 1985). In terrestrial animals, oral, inhalation and dermal routes of exposure are considered the most representative of "real-world" exposures. In aquatic species, the usual route of exposure is through water. In plants, exposures usually occur through soils or from the atmosphere. In all test systems, data derived by direct application of chemicals to biological systems (e.g., direct injections into tissues) that by-pass normal absorption and uptake systems may indicate the potential for the production of adverse effects but their relevance to normal exposures should be carefully evaluated. In addition, the use of vehicles (e.g., dimethylsulfoxide) in dermal exposure studies can substantially increase the uptake of chemicals through the skin and, although the results would indicate a worst-case assessment of potential effects, their relevance to usual dermal exposure is questionable. In all of the toxicity elements the scorer must exercise judgement in the use of data derived from unusual exposure routes. If such data are the only information available they may be used, but, at the very least the scores assigned require appropriate "flags" (e.g., Q or W or E).

Duration of Exposure

The duration of exposure is important in the assessment of potential effects of chemicals on the environment and health (Hushon and Kornreich, 1984). Acute lethality is usually assessed following a single exposure (e.g., LD_{50}, LC_{50}), or following a short duration of exposure (e.g., acute tolerance tests or 96-hour LC_{50} tests in aquatic species). The assessment of long term effects usually involve multiple exposures for the major portion of the lifespan of the test system (FDA, 1982). This is usually considered a minimum of one year in terrestrial animals (FDA, 1982), but may be as short as a few days in certain short-lived aquatic and plant test systems.

In the assessment of long term effects of chemicals, judgement is required to determine if the duration of exposure and observation in the studies was adequate both to achieve a steady state level of the chemical in the system and to encompass the latency period for the development of adverse effects. The biological half-life of the test chemical can assist in judging whether steady state levels of the chemical in the test system were achieved. For example, a minimum of 3.5 half-lives are generally required to reach 99% of the steady state body burden (FDA, 1982; Willes et al., 1985).

The latency period between the initiation of exposure and the development of particular adverse effects depends on the type of effects produced, in addition to the time required to achieve a steady state body level. Effects related to general narcotic actions of chemicals generally have much shorter latency periods (e.g., several hours) compared to cancer where latency periods range from months to years (Grice 1984; Willes et al., 1985).

If adequate long term exposure data are not available, scores for toxicity elements addressing long term effects may be estimated from shorter term exposure data. In terrestrial animals, data from exposures of 90+ days may provide reasonable estimates of certain long-term effects, although the validity of extrapolating such data to predict chronic effects requires considerable judgement. Judgement is even more critical when estimates of potential chronic effects are made by extrapolation of data from various short-term in vivo or in vitro test systems (Grice, 1984; Willes et al., 1985). It is not possible nor desirable to overly complicate a scoring system by incorporating all the uncertainties of extrapolating data from shorter to longer exposure scenarios. Therefore, as a general rule, when effects related to long term exposure are estimated from short term exposure data, the scores derived require appropriate "flags" (e.g., W, Q or E) indicating uncertainty in the assigned score.

Validity of Testing Procedures

The assignment of scores to the various toxicity parameters requires that the scorer assess the validity of the procedures followed in the collection of the toxicological data. It is beyond the scope of this scoring system to provide details of adequate procedures for the myriad of ever-changing tests available. The following references outline current standard procedures used in the collection of toxicological data: Grice et al., (1975); IARC (1980); FDA (1982); EPA (1984); NTP (1984); OSTP (1985). The validity of new testing procedures can usually be determined from publications by recognized authority centres around the world (e.g., Health and Welfare Canada, U.S. EPA, U.S. FDA, WHO, OECD, IARC).

(a) ACUTE LETHALITY

Rationale

This parameter describes the acute lethality of a chemical to terrestrial and aquatic animals. Non-lethal or reversible effects are not included in this element.

Acute effects other than lethality (e.g., irritation, allergic reactions, general narcosis, etc.) are considered in other toxicity elements. Criteria for phytotoxicity are not included in this element because of the difficulties in assessing lethality in plants.

Scoring Criteria

Scoring criteria for acute oral and dermal LD_{50}s and inhalation and aquatic LC_{50}s are similar to those utilized by the Transportation of Dangerous Goods Act (DOT, 1984) and the State of Michigan Critical Materials Registry (Michigan, 1979). Scores of six down to zero for oral and dermal LD_{50}s are comparable to the extremely toxic to relatively non-toxic scales outlined in the literature (Hodge and Sterner, 1949; Gleason *et al.*, 1977; Doull *et al.*, 1980). The criteria for scores of 8 to 10 would identify chemicals with greater toxicity than those included in the scales referred to above. These more stringent criteria were adopted to ensure chemicals with extreme acute lethality are clearly identified by the scoring system.

The scoring criteria for inhalation LC_{50}s are derived from the oral LD_{50} criteria, assuming a 60 kg individual respires 20 m^3 of air daily and that the contaminants have equal biological availability via the oral and inhalation routes of exposure. The aquatic toxicity LC_{50} data would usually be derived from 96-hour exposures.

Scoring criteria for this parameter are as follows:

PARAMETER SCORE	CRITERIA Oral LD_{50} mg/kg	Dermal LD_{50} mg/kg	Inhalation LC_{50} mg/m^3	Aquatic LC_{50} mg/L
10	≤0.5	≤0.5	≤1.5	≤0.1
8	>0.5 - 5	>0.5 - 5	>1.5 - 15	>0.1 - 1
6	>5 - 50	>5 - 50	>15 - 150	>1 - 10
4	>50 - 500	>50 - 500	>150 - 1500	>10 - 100
2	>500 - 5000	>500 - 5000	>1500 - 15000	>100 - 1000
0	>5000	>5000	>15000	>1000

Suggested Information Sources

ACQUIRE database -

This database contains acute lethality values for aquatic and terrestrial species.

Hayes, 1982 -

Contains information on the toxicology of pesticides and associated chemicals with particular reference to effects in humans.

Ketchen and Porter, 1979 -

These Critical Material Data sheets summarize information on the toxic potential of individual chemicals, including acute lethality data, in terrestrial species.

Merck Index -

The Merck Index lists indices of toxicity for many chemicals in terrestrial species.

MEDLINE database -

A computerized database presenting titles and abstracts of published, worldwide, biomedical literature.

Clayton & Clayton, 1981 -

Summarizes the toxic characteristics of a large number of industrial chemicals, primarily in terrestrial species.

(b) SUB-LETHAL EFFECTS ON NON-MAMMALIAN SPECIES

Rationale

This parameter describes potential effects from long-term exposures of non-mammalian species to chemicals. The effects-data may be expressed as median effect concentration (EC_{50}), maximum aquatic toxic concentration (MATC) or no-observed-adverse-effect-concentration (NOAEC).

The most frequently reported data of these types are EC_{50} values for fish or other aquatic organisms such as daphnia. Associated with an EC_{50} value is the species studied, the endpoint(s) observed, and the duration of exposure. Common endpoints are immobilization, loss of equilibrium, effects on reproduction and other sub-lethal effects. As with other parameters, if different indicators of effects are available, the most sensitive would be used, unless scorer judgement indicates otherwise.

As with mammalian toxicity, duration of exposure is important to the interpretation of the results. For aquatic organisms, either full or partial life-cycle tests are preferred for the

assessment of reproductive effects. Such tests may last as few as seven days or extend beyond a year depending on the life cycle. For terrestrial animals, periods of exposure usually last several months. For other types of effects, results from 96-hour exposures generally have more credence than shorter exposures. In addition, preference should be given to tests on freshwater species native or introduced to North America.

Scoring Criteria

Based on published results of the effects of many substances on aquatic organisms, the NOAEC values that appear in the score definitions are a factor of 100 lower than EC_{50} values (Konemann and Visser, 1983). Maximum Aquatic Toxic Concentration (MATC) values are 10 times lower than EC_{50} values.

The scoring criteria for this parameter are as follows:

PARAMETER SCORE	CRITERIA - AQUATIC ORGANISMS	TERRESTRIAL ORGANISMS
10	EC_{50} $\leq$0.02 mg/L; OR MATC $\leq$0.002 mg/L; OR NOAEC $\leq$0.0002 mg/L in different genera.	Adverse effects at $\leq$1 mg/kg for sub-chronic exposure OR $\leq$0.5 mg/kg for chronic exposure, in different genera.
8	EC_{50} $\leq$0.02 mg/L; OR MATC $\leq$0.002 mg/L OR NOAEC $\leq$0.0002 mg/L in one genera only.	Adverse effects at $\leq$1 mg/kg for sub-chronic exposure OR $\leq$0.5 mg/kg chronic exposure, in one genus only.
6	EC_{50} <0.2 - 0.02 mg/L; OR MATC <0.02 - 0.002 mg/L; OR NOAEC <0.002 - 0.0002 mg/L.	Adverse effects at >1-10 mg/kg for sub-chronic exposure OR >0.5-5 mg/kg for chronic exposure.
4	EC_{50} <2 - 0.2 mg/L; OR MATC <0.2 - 0.02 mg/L; OR NOAEC <0.02 - 0.002 mg/L.	Adverse or non-adverse effects at >10-100 mg/kg for sub-chronic exposure OR >5-50 mg/kg for chronic exposure.
2	EC_{50} <20 - 2 mg/L; OR MATC <2 - 0.2 mg/L; OR NOAEC <0.2 - 0.02 mg/L.	Adverse or non-adverse effects at >100-1000 mg/kg for sub-chronic exposure OR >50-500 mg/kg for chronic exposure
0	EC_{50} $\geq$20 mg/L; OR MATC $\geq$ 2 mg/L; OR NOAEC $\geq$0.2 mg/L.	Adverse or non-adverse effects at $\geq$1000 mg/kg for sub-chronic exposure exposure, $\geq$500 mg/kg for chronic exposure

Suggested Information Sources

AQUIRE database -

AQUIRE has EC_{50} and/or NOAEC data for aquatic organisms for some organic chemicals.

Most information required for this element must be sought from primary sources identified through literature searches.

(c) SUB-LETHAL EFFECTS ON PLANTS

Rationale

Sub-lethal effects on plants are highly varied depending on the toxicant. The relative significance of the injury or effect depends on the commodity and its use. These can be divided into three categories.

A The appearance is important, but growth and yield are of much less importance. This is relevant for ornamentals, flower crops, leafy vegetables and fruit.

B The impact on growth and yield are the most significant, and visible injury to the foliage, though unsightly, is of less importance. This is relevant for vegetables, fruits, seeds and storage organs such as tubers.

C There are no visible injurious effects but the longevity of the commodity has been altered. This is of greatest significance in flower crops and storage of fruit and vegetables.

The toxic effects can generally be assayed using short term tests with indicator plants. The possible effects include a wide spectrum of responses: inhibition of germination, inhibition of seedling growth, growth abnormalities, reduction in either root or shoot growth, etc. Long term tests with annual plants may be used to assess chronic effects such as decreased yield or decreased competitiveness (NAS, 1975).

The most commonly tested aquatic plants are algae and duckweed (Lemna minor) (U.S. EPA, 1978). Several test methods have been developed that use algae (for example, the U.S. EPA Algal Assay Bottle Test). Duckweed has been used to assess the effects of substances on aquatic macrophytes, (EPA, 1978).

Effects on the genetic make up of the organism may be assayed using other short term tests with plant material. These include gene mutations, DNA repair, primary DNA damage and chromosomal abberations (Sandhu, 1980). Some examples of genetic mutation assays using plants are the measurement of chromosomal aberrations in root tip cells, the Tradescantia micronucleus assay

(Sandhu, 1980) and the use of Arabidopsis for measuring the frequency of mutational events at the embryo stage (Revel, 1980).

Scoring Criteria

The score definitions for aquatic plants are very similar to those used in parameters which address sub-lethal effects on aquatic animals.

Various biomonitors have been used for different contaminants with each species displaying characteristic symptoms for a given pollutant. Some of these tests have been standardized to a substantial degree while others are only qualitative indicators. Standardized sampling methods have also been devised for substances that accumulate in vegetation and that are toxic to animals. Lichens are also used for a variety of contaminants, both as indicators by presence or absence, or are used as accumulators.

Standardized tests have been reported for relatively few substances. In some cases, the scoring system can accommodate results expressed in concentration units (mg/L for substance in water, mg/m^3 for gaseous contaminants, and mg/kg for substances in the soil), but in most instances, the length of exposure time is very important. It is thus necessary to link the persistence or the number of releases or the length of exposure to this element in some way through the use of appropriate combining rules.

Precautions. Soil extraction procedures are critical in determining the level of a toxicant, e.g. the total amount removed by acid extraction may no be meaningful in relation to plant bioavailability.

The scoring criteria for this element are as follows:

PARAMETER SCORE	MEDIUM**	CRITERIA* <5% EFFECT OR NOAEL	>5-50% EFFECT OR EC_{50}	>50% EFFECT
10	WATER	<0.001	<0.01	<0.1
	AIR & SOIL	<0.01	<0.1	<1
8	WATER	0.001-0.01	0.01-0.1	0.1-1
	AIR & SOIL	0.01-0.1	0.1-1	1-10
6	WATER	>0.01-0.1	>0.1-1	>1-10
	AIR & SOIL	>0.1-1	>1-10	>10-100
4	WATER	>0.1-1	>1-10	>10-100
	AIR & SOIL	>1-10	>10-100	>100-1000
2	WATER	>1-10	>10-100	>100-1000
	AIR & SOIL	>10-100	>100-1000	>1000-10000
0	WATER	>10	>100	>1000
	AIR & SOIL	>100	>1000	>10000

*Effects considered: Reduction in growth, total biomass or photsynthesis

**Units: Water - mg/L
Air - mg/m^3
Soil - mg/kg

Suggested Information Sources

Manning and Feder, 1980-
Discusses the use of plants as monitors of pollution.

Lepp, 1981 -

Discusses effects of heavy metals in plants.

Martin and Coughtrey, 1982 -

Discusses effects of heavy metals on biota as indicatators of pollution.

NRCC -

Publications of the Associate Committee on Scientific Criteria for Environmental Chemistry includes data on effects on plants.

Levitt, 1980 -

Reviews environmental stress on plants.

Ormrod, 1978 -

Reviews effects of pollution on horticulture.

Information will have to be sought from primary sources for many of the toxicants.

(d) SUB-LETHAL EFFECTS ON MAMMALS

Rationale

This parameter describes potential longer-term effects of chemicals in mammals. The effects are directed primarily at human health, although the actual data used will largely be from laboratory animals. Other scoring systems (see Hushon and Kornreich, 1984) generally score chemicals for sub-lethal toxicity based on specific effects (e.g., separate scores for carcinogenicity, mutagenicity, teratogenicity, etc.), but most do not address systemic toxic effects. The toxic effects included in this parameter are restricted to sub-lethal systemic effects, but do not include carcinogenic, mutagenic or teratogenic effects since these are included in other parameters.

Scoring Criteria

If data are not available on the effects following a suitable duration of exposure, either

appropriate "tags" (W, Q or E) should be used, or, preferably, the criteria should be divided by an appropriate extrapolation factor to adjust for potential effects that would not develop during shorter exposure studies. Criteria used in the development of scores for this parameter would be derived from sub-chronic (generally 90-day exposure) or chronic (usually 1 year or more) exposure studies in any mammalian species (refer to the general discussion of exposure duration). If the data were derived from sub-chronic studies, it is recommended that the NOAEL be divided by a 10-fold extrapolation factor (see FDA, 1982; Dourson and Stara, 1983). If the only data available involved even shorter term exposures (e.g., 14 days), it is recommended that a 100-fold extrapolation factor be used. Considerable judgement will be required in the utilization of such extrapolation factors, considering issues such as the biological half-life of the chemical, the biological characteristics of the test system from which the data was derived, and knowledge of the usual consequences of the type(s) of lesions produced.

The scoring criteria for this parameter do not provide for differences in the type of toxic response observed. For example, if the effects associated with exposure are irreversible, the consequences of exposure are much more serious than if the effects reverse following cessation of exposure. For the purposes of this assessment, all effects are considered as equal but details of differences in the severity of the effects would be carefully noted.

Examples of the various end-points included as chronic systemic effects are as follows:

Reproduction toxicity
- Adverse effects on reproduction as they affect the survival, development and well-being of the species, including interference with gonadal functions but excluding teratogenic effects.

General toxicity
- General depressions in body weight and body weight gains, general behavioural alterations and increases in diseases secondary to chemical exposure.
- Gross or microscopic alterations indicative of disease from toxic events.
- Adverse or deleterious effects on organ systems or functions, alterations in secretions of exocrine and endocrine glands, alterations in the brain and peripheral nervous systems.
- Treatment related biochemical effects.

If data are available on more than one of these effects, the effect occurring at the lowest exposure level in the most sensitive test system should be used in scoring. In addition,

structure-activity relationships may provide estimates of the occurrence of chronic effects if data on the actual compound are lacking. Structure-activity relationships appear reasonably predictive for certain types of effects (e.g., narcotic effects), however, little predictive value is obtained for other effects using available methods. In the future, the accuracy of structure-activity relationships in predicting effects between different chemicals may improve. Even with present methodologies, however, an estimation of potential effects may prove more valuable than accepting a judgement of inadequate information. Such estimates, however, would be appropriately "flagged" with a Q or E.

The scoring system for this parameter is as follows:

PARAMETER SCORE	CRITERIA[1] ORAL NOAEL mg/kg	INHALATION NOAEL mg/m^3
10	$\leq$0.1	$\leq$0.3
8	>0.1 - 1	>0.3 - 3
6	>1 - 10	>3 - 30
4	>10 - 100	>30 - 300
2	>100 - 1000	>300 - 3000
0	>1000	>3000

1 Criteria are based on data from exposures of 90 days or more in duration. If data from studies of 28-<90 days duration are used, divide the data values by 10. If data from studies of <28 days duration are used, divide the data values by 100.

Suggested Information Sources

Most of the information on the toxic effects associated with chronic exposure to chemicals would be obtained from original scientific publications which could be accessed through the MEDLINE and TOXLINE databases. Additional sources of summary data include Ketchen and Porter (1979), Clayton and Clayton (1981), RTECS database, and Verschueren (1983). It should be emphasized however, that the judgement of the validity of a NOEL from summary data is difficult and that original publications should be consulted.

(f) TERATOGENICITY

Rationale

This parameter describes the potential teratogenic effects of chemicals on mammalian systems. Toxic effects on reproduction in plants, non-mammalian and mammalian systems, as distinct from developmental defects, are described in parameters b, c, and d. The production of terata by exposure to chemical contaminants can seriously compromise the development and survival of offspring. Such effects are usually irreversible, although current understanding is that they have an exposure threshold (EPA, 1984).

The criteria for these effects are as outlined by the U.S. Environmental Protection Agency (EPA, 1984). Teratogenic effects include frank developmental malformations detrimental to the survival, future development, or well-being of newborn. They do not include developmental anomalies and aberrations that appear to be secondary to embryo-, feto- and maternal toxicity (see EPA, 1984; Khera, 1981). Many such effects are known to recover as development proceeds (e.g., reversible delayed ossification of various parts of the skeleton, delayed development of specific organs, delayed eye opening, delayed vaginal opening, reduced body weight) (Khera, 1981). In some cases, exposure of pregnant females to chemicals can result in malnutrition due to decreased feed intake. Malnutrition has been shown to delay embryo and fetal development, reduce birth weights and, in severe cases, produce irreversible neurological and metabolic abnormalities (EPA, 1984; Khera, 1984). These differences in the apparent severity between frank terata and minor developmental anomalies from chemicals are reflected in the scoring criteria for this element.

Behavioural teratology is a rapidly developing sub-field of teratology and includes effects related to alterations in the behaviour of the offspring as they mature. In some cases behavioural effects may not be evident until maturity (e.g., effects on sexual behaviour). Other effects may only be temporary and actually disappear at some later stage of development. No specific criteria have been included in this parameter for behavioural teratogenic effects and judgement must be exercised to determine how such effects "fit" into the criteria provided. As the significance of such effects is better understood, alterations in the criteria for this parameter may be required to encompass the increase in knowledge.

Scoring Criteria

Working from the assumption that teratogenic effects exhibit exposure thresholds (Khera, 1981; EPA, 1984), scoring criteria are based on gradations in exposure levels associated with effects. Since teratogenic effects are viewed as more serious than developmental anomalies as outlined above, higher scores are applied to chemicals showing evidence of frank teratogenicity. Chemicals producing developmental anomalies and aberrations are assigned lower scores (e.g., delayed

ossification of bone, decreased fetal weights, decreased birth weights, prolonged gestation, decreased survival without abnormalities, developmental effects that reverse during postnatal development).

Duration of exposure is particularly critical in assessing teratogenic effects. To adequately assess the potential for such effects from a chemical exposure should occur at least through the period of organogenesis (e.g., usually from late in the first trimester through early in the third trimester of gestation). In addition, the levels of exposure studied should be sufficient to elicit a range of effects in the dams, from toxicity at the higher exposures to no-observable effects at the lower exposures (Grice et al. 1975; EPA, 1984; Khera, 1981).

The general requirements regarding route of exposure discussed earlier also apply to teratogenicity assessments.

The scoring criteria for this parameter are as follows:

PARAMETER SCORE	CRITERIA
10	- Teratogenic effects observed without overt maternal toxicity at maternal exposures ≤0.1 mg/kg/day during organogenesis, or equivalent exposure[1]
8	- Teratogenic effects observed without maternal toxicity at maternal exposures >0.1 - 1 mg/kg/day during organogenesis or equivalent exposure
6	- Teratogenic effects or developmental anomalies observed at maternal exposures >1 - 10 mg/kg/day during organogenesis or equivalent exposure
4	- Teratogenic effects or developmental anomalies observed at maternal exposures >10 - 50 mg/kg/day during organogenesis or equivalent exposure
2	- Teratogenic effects or developmental anomalies obsreved at maternal exposures >50 - 1000 mg/kg/day during organogenesis or equivalent exposure
0	- No terata observed, or observed only at maternal exposures of ≥1000 mg/kg/day or equivalent exposure

1 Equivalent exposure by inhalation or dermal routes, assuming 100% absorption and that effects after dermal exposure would occur at comparable doses to oral exposure. Total dose via inhalation is to be converted to an approximate daily oral dose equivalent by the use of appropriate factors (e.g. ppm-to-mg/m^3 conversion factor and physiological standards such as: a 60 kg adult human respires 20 m^3 of air per day; a 275 g female rat respires 0.17 m^3 of air per day).

Information Sources

Most of the information on the teratogenic effects associated with exposure to chemicals can be obtained from original scientific publications which can be accessed through the MEDLINE and TOXLINE databases. Additional sources of summary data include Ketchen and Porter (1979), Clayton and Clayton (1981), RTECS database, and Verschueren (1983). Care should be exercised in using the RTECS date base since only studies showing positive effects associated with exposure are reported. It must also be emphasized that the judgement of the validity of teratogenic effects (e.g., the evaluation of frank developmental anomalies versus developmental aberrations) from summary data is difficult and that original publications should be consulted.

GENOTOXICITY/MUTAGENICITY

Rationale

This parameter describes the mutagenic and genotoxic potential of a chemical. Such effects in themselves are indicative of potential hazards of chemicals to health and the environment. In addition, the strength of such evidence is valuable in the interpretation of other potential hazards from chemicals (e.g., carcinogenicity).

Genotoxic or mutagenic effects on somatic or germ cells are considered equal potential hazards. Evidence of heritable mutations (i.e., mutations in germ cells) was regarded as more indicative of the test system studied and ability of a chemical to distribute to germ cells (i.e., the disposition of the chemical in vivo) rather than of a greater potential hazard. In addition, assessment of the potential for germ cell mutations requires specific tests (e.g., dominant lethal test, mouse heritable translocation assay) and results from such tests are not available for large numbers of chemicals. Therefore, specific scoring criteria for germ cell mutations would increase the dependency of the resulting prioritization of chemicals on the information available rather than indicators of potential hazard. In the scoring criteria used, chemicals for which evidence of germ cell mutations are available would receive high scores, however, not preferentially higher than chemicals with evidence of somatic mutations only.

Scoring Criteria

The criteria assign higher scores to chemicals with adequate evidence of mutagenic/genotoxic effects derived from short-term tests. The primary objective is to score the potential of a chemical to produce such effects.

Chemicals producing direct mutagenic/genotoxic effects in the absence of overt toxicity are assigned the highest scores (e.g., the chemical or its activated metabolite(s) directly acts on genetic material to produce mutations or genotoxic effects). Clastogenic effects produced by

chemicals that do not directly interact with genetic material are scored in the next category. Chemicals causing mutagenic or genotoxic effects indirectly by interfering with various cellular systems would receive lower scores. Scores of two or four should be assigned to chemicals having positive evidence from certain test systems but clear evidence of lack of effects in other test systems.

It is assumed that all test data will be derived under optimal experimental conditions (e.g., using validated test procedures, including appropriate S-9 metabolic activating systems, adequately controlling for unusual chemical/physical characteristics of the test chemicals). Acceptable tests include, but are not necessarily limited to, the following:

a) *in vitro* gene mutation

- *Salmonella*/mammalian microsome assay
- CHO/HGPRT - assay
- L5178Y TK - assay
- Haploid *Saccharomyces* assay

b) *in vitro* mammalian chromosomal aberrations

- metaphase analysis in mammalian cells exposed *in vitro* (not including sister chromatid exchange and micronuclei)

c) *in vivo* mammalian chromosomal aberrations

- rodent bone marrow micronucleus assay
- rodent bone marrow metaphase analysis (not including sister chromatid exchange)

d) *in vivo* mammalian gene mutation or indicator tests in a second somatic tissue

- rodent liver unscheduled DNA synthesis
- rodent sister chromatid exchange

Data from other tests may be used with appropriate justification. There will be many chemicals for which adequate information for this parameter is lacking or incomplete. The use of structure-activity relationships in developing scores for this parameter may be a viable alternative in the future, however, at present such concepts are only in their formative stages (FDA, 1982; NTP, 1984; OSTP, 1985) Consequently, considerable expertise and judgement are required to assign scores based on structure-activity information, and such scores would require appropriate "flags" to signify the level of confidence in the data used (e.g., W, Q, E).

The scoring criteria for this parameter are as follows:

PARAMETER SCORE	CRITERIA
10	Conclusive evidence of mutagenicity or genotoxicity in recognized prokaryotic or eukaryotic test systems at exposure levels not producing overt toxic effects (*in vivo* and *in vitro* eukaryotic data are positive or are absent).
8	Evidence of clastogenic effects (general DNA damage, strand breaks, sister chromatid exchange), intercalations or crosslinks but no evidence of increased incidences of mutations or direct interactions with genetic material
6	Does not interact directly with DNA, but interferes with cellular mechanisms such as DNA synthesis and DNA repair. Effects may be observed at exposure levels associated with overt toxicity unrelated to genetic effects
4	Mutagen/genotoxin in prokaryotic systems only; *in vitro* eukaryotic data exist, and the results are negative.
2	Mutagen/genotoxin *in vitro* only; *in vivo* data exist, and the results are negative.
0	No evidence of mutagenic or genotoxic effects in a adequate battery of test systems.

Suggested Information Sources

Information on the genotoxicity/mutagenicity of chemicals would generally be obtained from original publications and review articles as identified through MEDLINE or TOXLINE databases or through the GenTox Information Service. Information may also be available from various summary data sources including Bowman (1982), Fairchild (1978), Fishbein (1979), Ketchen and Porter (1979), Kirsch-Volders (1983), Sax *et al.* (1981), Souerman (1983), Sontag (1981), and Stich and San (1984). It is difficult to judge the validity of genotoxicity/mutagenicity tests from summary data, however, and original publications should be consulted where possible.

(g) CARCINOGENICITY

Rationale

This parameter describes the potential of chemicals to cause cancer. Detailed assessment of the

dose-response relationships, types of cancers produced, the validity of extrapolating carcinogenicity data among species and the processes of risk identification, assessment and management are beyond the sophistication of this assessment.

There is general agreement that radiation, biological, physical and chemical agents can cause cancer. In addition, the biochemical and molecular process of cancer development, as it is understood, is similar among mammalian species (NTP, 1984; OSTP, 1985). It is evident that the development of cancer is a multi-stage process involving interactions of agents with genetic material (the genome). The induction of tumorigenic phenotypes through interactions with the genome may occur directly through the induction of somatic mutations or indirectly by alterations in gene expression. A number of factors affect the occurrence of these events, including age, sex, genetic differences, strain and species differences, diet, dose rate, route of exposure, interactions with other agents and a variety of environmental conditions (NTP, 1984; OSTP, 1985). Furthermore, the production of these effects by a chemical may be by direct action of the chemical or its metabolites (e.g., direct acting, genotoxic carcinogens) or indirect through actions of the chemical on systems that secondarily produce tumorigenic phenotypes (e.g., non-genotoxic or epigenetic mechanism). Although the detailed mechanism(s) of cancer production are not fully understood, it is evident that once the required modification in the genome occurs (known as initiation), the process is irreversible and self-propagating. A wide range of factors affect the initiation process, however, and many of these are believed to be reversible (IRLG, 1979; NTP, 1984; OSTP, 1985).

Although the exact mechanisms of the various stages of carcinogenesis are not fully understood, it is apparent that the events leading to the initiation of cells are dose-related (i.e., the frequency of occurrence of initiation increases with exposure). Once initiation has occurred, however, the subsequent development of tumours is independent of the exposure level (IRLG, 1979). This information is important to the scoring of the carcinogenic potential of a chemical.

Based on this brief summary of what is known about the process of carcinogenesis (refer to IRLG, 1979, NTP, 1984 and OSTP, 1985, for more detailed discussions), the scoring criteria for this element differentiate between direct acting and indirect acting carcinogens. It is important that the scoring system not merely reflect the completeness of the data base (e.g., only a few chemicals have been adequately studied from an epidemiological point of view in human populations to assess their carcinogenicity). For many chemicals, epidemiological studies to assess their carcinogenic potential will never be conducted and complete reliance will have to be placed on animal bioassay data for their evaluation. If the data from animal bioassays are viewed sufficiently strong, "epidemiologically proven" and "potential human" carcinogens (i.e, positive in animal bioassays) are given equal weight in the scoring system.

Scoring Criteria

The following definitions of carcinogenicity are used in scoring this parameter (Tomatis, 1979):

- Evidence of carcinogenicity is positive when an increase in malignant tumours is caused in more than one species or strain, in multiple experiments with varying routes or levels of exposure or to an unusual degree with respect to type, site, incidence or latency period.

- Evidence of carcinogenicity is negative when no tumour induction is observed in at least two adequate and appropriate animal studies in different species or in both animal and epidemiology studies.

- Evidence of carcinogenicity is inconclusive when neither of the above two conditions apply, usually because the observations are inadequate, of unacceptable quality or excessively limited. Contradictory results from different test systems may also lead to an inconclusive assessment. Such conditions are recorded as either positive or negative for carcinogenicity and tagged with either Q or W depending on the interpretation of the information by the scorer.

There is a great deal of controversy regarding the potency ranking of carcinogens, particularly when attempting to denote the potency of a chemical to cause cancer in man from data derived from animal cancer bioassays. Animal bioassays utilize high exposure levels (known as the Maximum Tolerated Dose or MTD protocol, see NTP, 1984; OSTP, 1985). Judgements of carcinogenic potency based on information derived from such high levels of exposure may have little relationship to potencies at lower levels of exposure comparable to those found in the environment. Consequently, the basis for potency ranking is not considered adequately developed for use in a scoring system. However, if procedures for such ranking were found reliable, they would form a reasonable basis for the scoring of the carcinogenic potential of chemicals.

Important information to assist in the interpretation of animal cancer bioassay data vis-a-vis the potential of a chemical to cause cancer in humans can be derived from assessments of its mutagenicity/genotoxicity.

The scoring scheme for this parameter is as follows:

PARAMETER SCORE	CRITERIA
10	Direct acting human carcinogen or potential human carcinogen (based on animal bioassay data) with evidence of direct interactions with genetic material. Acts as an electrophile or direct alkylating agent, produces DNA adducts, induces cell transformation, etc.
8	Indirect acting (epigenetic) human carcinogen or potential human carcinogen (based on animal bioassay data) with evidence that it does not interact with genetic material
6	Carcinogenic in animal bioassay tests at levels of exposure shown to saturate enzymes involved in the metabolism of the compound or at exposure levels shown to cause histopathological lesions known to predispose animals to the development of cancers at sites where the lesions are observed (e.g., ATPAse deficient liver foci in rodents). Adequate evidence must be available demonstrating that no interactions occur with genetic material and that the chemical does not induce cell transformation.
4	Positive tumorigenic agent (benign tumours) in humans or animals. Evidence must be available of lack of interactions with genetic material. Includes chemicals that act solely as promoters and those that cause cell transformation *in vitro* without evidence in other systems
2	Tumorigenic in only one animal species and negative in other(s) (all studies considered adequate)
0	Not tumorigenic in an adequate animal bioassay in at least two species and must not interact with genetic material

Information Sources

Information on the carcinogenicity of chemicals would generally be obtained from original publications and review articles as identified through IARC Monographs or MEDLINE, TOXLINE databases or National Toxicology Program (NTP) publications. Information may also be available from various summary data sources including Bowman (1982), Fairchild (1978), Fishbein (1979), Ketchen and Porter (1979), Kirsch-Volders (1983), Sax *et al* (1981), Souerman (1983), Sontag (1981), and Stich and San (1984). However, it is difficult to judge the validity of carcinogenicity data from summary data and original publications should be consulted.

MOE SCORING SYSTEM SUMMARY CHART

ELEMENT NAME	ENDPOINT & UNITS	SCORING CRITERIA 0	4	7	10
Environmental Transport	Percent partitioning, measured or predicted	Any single medium contains >95% of the total amount released	No one medium contains >95%, and only one medium contains ≥5% of the total amount released	Two media each contain ≥5% of the total amount released	Three or more media each contain ≥5% of the total amount released or Substance is inorganic and is adsorbed to particles <10um in diameter when released
Environmental Persistence	$t_{1/2}$ (days)	<10	10 to <50	50 to <100	≥100
Bio-accumulation	BCF Log k_{ow}	≤20 ≤2.0	>20 to 500 >2.0 to 4.0	>500 to 15000 >4.0 to 6.0	>15000 >6.0

ELEMENT NAME	ENDPOINT & UNITS	0	2	4	6	8	10
Acute Lethality	oral LD_{50} mg/kg	>5000	>500-5000	>50-500	>5-50	>0.5-5	≤0.5
	dermal LD_{50} mg/kg	>5000	>500-5000	>50-500	>5-50	>0.5-5	≤0.5
	inhal. LD_{50} mg/m^3	>15000	>1500-15000	>150-1500	>15-150	>1.5-15	≤1.5
	aquatic LC_{50} mg/L	>1000	>100-1000	>10-100	>1-10	>0.1-1	≤0.1
Sublethal Effects, Non-Mammals	aquatic EC_{50}, mg/L MATC, mg/L NOAEC,mg/L	 ≥20 ≥2 ≥0.2	 2-<20 0.2-<2 0.02-<0.2	 0.2-<2 0.02-<0.2 0.002-<0.02	 0.02-<0.2 0.002-<0.02 0.0002-<0.002	 <0.02* <0.002* <0.0002*	 <0.02* <0.002* <0.0002*
	terrestrial subchronic NOEL mg/kg chronic NOEL mg/kg	 ≥1000 ≥500	 100-<1000 50-<500	 10-<100 5-<50	 1-<10 0.5-<5	 <1* <0.5* *in one genus	 <1* <0.5* *in different genera
Sublethal Effects, Plants	Water, mg/L Air, mg/m^3 Soil, mg/kg						
	% Growth Reduction: ≤5 (=NOAEL) water air soil	 >10 >100 >100	 >1-10 >10-100 >10-100	 >0.1-1 >1-10 >1-10	 >0.01-0.1 >0.1-1 >0.1-1	 0.001-0.01 0.01-0.1 0.01-0.1	 <0.001 <0.01 <0.01
	>5-50(=EC_{50}) water air soil	 >100 >1000 >1000	 >10-100 >100-1000 >100-1000	 >1-10 >10-100 >10-100	 >0.1-1 >1-10 >1-10	 0.01-0.1 0.1-1 0.1-1	 <0.01 <0.1 <0.1
	>50 water air soil	 >1000 >10000 >10000	 >100-1000 >1000-10000 >1000-10000	 >10-100 >100-1000 >100-1000	 >1-10 >10-100 >10-100	 0.1-1 1-10 1-10	 <0.1 <1 <1
Sublethal Effects, Mammals*	oral NOEL mg/kg	>1000	>100-1000	>10-100	>1-10	>0.1-1	≤0.1
	inhal. NOEL mg/m^3	>3000	>300-3000	>30-300	>3-30	>0.3-3	≤0.3
Teratogenicity	mg/kg/day	no terata, or terata only at >1000	terata or developmental anomalies at >50-1000	terata or developmental anomalies at >10-50	terata or developmental anomalies at >1-10	terata at >0.1-1, without overt maternal toxicity	terata at ≤0.1 without overt maternal toxicity
Genotoxicity /Mutagenicity	in vivo and in vitro cell assays	not genotoxic or mutagenic; negative results in vivo and in vitro	mutagenic in in vitro assays only; negative in vivo	mutagenic in prokaryotic cells only; negative results in eukaryotic cell assays	causes DNA induction or repair, with no direct interaction with nuclear material	causes clastogenic effects, sister chromatid exchange, crosslinks; no evidence of mutation	mutagenic in vivo (no negative results from in vivo assays)
Carcinogenicity	human and animal bioassay data	no tumours in adequate studies on at least two species, and does not interact with genetic material	tumours in only one animal species, negative results in others	causes benign tumours in more than one species, and does not interact with genetic material; promotor only; or causes cell transformation in vitro only (negative evidence in vivo)	tumourigenic in bioassays at doses causing metabolic enzyme saturation, or associated with lesions that predispose to tumours. No interaction with genetic material	indirect-acting carcinogen, no interaction with genetic material	direct-acting carcinogen that interacts with genetic material

* NOTE: The Sublethal Effects, Mammals criteria are based on studies of ≥90 days duration. If only shorter-term subchronic studies are available, the data are modified as follows, for scoring purposes:

Study duration 28-89 days - divide result by 10;
Study duration ≤28 days - divide result by 100.

13/09/89

Appendix A
Guidelines for Using Score Qualifiers and Criteria

I. General Description of Score Qualifiers

Insufficient Information for Scoring (*)

The insufficient data (*) tag is used where there are no data for a particular parameter or exposure route available, following a Level II (bibliographic database) search. Any individual oral, inhalational, dermal or aquatic score and tag fields are left blank if no information for them is available after a Level I (factual database and reference text) search.

Limited Data (L)

The limited data (L) tag is used when the data available is of limited scope.

Worst-Case Designation (W)

The worst-case tag (W) is used when a score is based on data obtained from a study reporting an unusual endpoint or using a route of administration which would overestimate the hazard.

(W)-tagged scores may decrease when additional data becomes available during a subsequent detailed assessment.

Questionable Data (Q)

The questionable-data tag (Q) is used to indicate that the data used does not fully match the criteria description, was obtained from situations of questionable relevance to the Ontario environment, or is otherwise questionable due to deficiencies in study or analytical methodology.

(Q)-tagged scores may increase or decrease when additional data becomes available during a subsequent detailed assessment.

Estimated Data (E)

The estimated data tag (E) is used when a value is derived from a model such as a QSAR or fugacity model. In most cases this type of data is acceptable only if "real" data is absent. An exception is in scoring persistence (see section II, below).

Hierarchy of Tags

Only a single tag is to be assigned to a score. The order of precedence is: Q = W > E > L. For example, if a score is based on estimated data and also warrants a (W) tag, the tag assigned would be (W).

II. Persistence Criteria

Types of Data Preferred

Biodegradation data best reflecting the conditions in the ambient environment is preferable over data derived from studies using media such as activated sludge. The order of preference is:

environmental data (e.g. river die-away, half-life in soils) > some shaker flask studies > QSAR estimates > BOD.

When QSAR results in the form "$t_{1/2}$ > x" are used for scoring, the score is assigned as if $t_{1/2}$=2x.

If data from the studies mentioned above are available, scoring is not based on other types of studies even if they represent a worst-case. If preferred data is not available, the obtainable data is used and a (Q) tag is assigned.

Limited Database

When data on persistence are available for one medium only, an (L) tag is assigned.

III. Bioaccumulation Criteria

Use of Log P in the Absence of BCF Data

When log P values are used in the absence of bioaccumulation factors (BCFs) for scoring bioaccumulation, an (L) tag is assigned.

Use of BCFs for Unusual Species

When bioaccumulation is scored on the basis of a BCF for an unusual species, e.g. an aquatic organism other than a freshwater fish, a (Q) tag is assigned.

IV. Acute Lethality Criteria

Route of Administration (Terrestrial Species)

When acute lethality is being scored, the score is based on intravenous, subcutaneous or intraperitoneal route data only if oral, dermal or inhalational route data are not available. A (W) tag is assigned in these cases, and scores are determined by using the oral LD_{50} criteria.

Aquatic Toxicity Ratings

When an overall acute lethality score is based only on an "aquatic toxicity rating" range, an (L) tag is assigned.

Saltwater Studies

Freshwater species studies are preferred over saltwater studies. If an aquatic LC_{50} score must be based on a saltwater study (i.e. no freshwater data exist), a (Q) tag is assigned.

Scoring Acute Lethality in the Absence of LD_{50}/LC_{50}s

When only LD_{Lo} or LC_{Lo} data are available, the data are scored as if they were for LD/LC_{50}s and a (W) tag is assigned.

When only LD_{100} or LC_{100} data are available, the data are scored as if they were for LD/LC_{50}s and a (Q) tag is assigned.

V. Sublethal Effects Criteria

Route of Administration (Mammalian Studies)

When sublethal effects are being scored, the score is based on intravenous, subcutaneous and intraperitoneal route data only if oral, dermal or inhalational route data are not available. A (W) tag is assigned in these cases, and scores are determined using the oral exposure criteria.

Duration of Study (Mammalian Studies)

The criteria are based on data from exposures of 90 days or more in duration. If such data is lacking, the results of shorter-term studies are used, tagged as questionable data (Q), and scored based on a modification of the data as described below. The rationale for this is that over a shorter period of time,

higher concentrations of a toxin may be tolerated by an organism than over a extended period. The order of preference is ≥90 days, 28-89 days, <28 days duration.

If data from studies of 28 to 89 days exposure duration are used, the data values are divided by 10. If data from studies of less than 28 days exposure duration are used, the data values are divided by 100.

Estimating NOAEL when only LOAELs are available (Mammalian Studies)

In cases where only LOAELs are available, or in cases where some studies give LOAEL figures lower than the NOAELs reported in other studies, scores are based on the lowest LOAEL divided by a safety factor of 10, and are tagged (Q).

Limited Database

When a sublethal effects score is based on only one piece of data or on data for only one species, an (L) tag is assigned.

VI. Genotoxicity / Mutagenicity Criteria

Absence of Eukaryotic or In Vivo *Data*

If positive prokaryotic in vitro (e.g. Ames salmonella) assays are available, but positive or negative eukaryotic or in vivo data are absent, a score of 4 is assigned, with a (Q) tag.

A (Q) tag is also applied when a score of 6 or greater is assigned in the absence of in vivo data.

Limited Database

When the score is based on only one piece of data or on data for only one species strain, an (L) tag is assigned.

VII. Carcinogenicity Criteria

Limited Database

When the score is based on only one piece of data or on data for only one species strain, an (L) tag is assigned.

Appendix B
Concern Levels for Promotion to the Ontario Effluent Monitoring Priority Pollutants List (EMPPL)

The minimum parameter scores leading to promotion of a substance to the EMPPL are as follows:

Persistence	7*
Bioaccumulation	7
Acute Lethality	6
Sublethal Toxicity, non-mammals	6
Sublethal Toxicity, plants	6
Sublethal Toxicity, mammals	6
Mutagenicity/Genotoxicity	6
Teratogenicity	2
Carcinogenicity	2

* - A persistence score equal to or greater than 7 alone does not cause promotion to the EMPPL, but may support promotion based on other parameters.