UN/SCEGHS/15/INF.29

COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

Fifteenth session,
Geneva, 9-11 July 2008
Item 2 (c) of the provisional agenda

UPDATING OF THE SECOND REVISED EDITION OF THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

Environmental hazards

Annex to the progress report on terrestrial environmental hazards:
Detailed review of existing classification and labelling systems

Transmitted by the Organisation for Economic Co-operation and Development (OECD)

This document contains the annex to the progress report on terrestrial environmental hazards (UN/SCEGHS/15/INF.28).

ANNEX

REPORT TO THE UN SUB-COMMITTEE OF EXPERTS ON THE GHS: TERRESTRIAL ENVIRONMENTAL HAZARDS

Classification of hazards to the terrestrial environment
A review

Contents

Tables

1. Introduction

The following document is a summary of the existing classification systems for terrestrial hazards.

It contains information from the Andean Community, Argentina, Basel Convention, Canada, European Union, New Zealand, Mexico and the U.S.A.

2. Andean Community (Ecuador, Bolivia, Colombia and Peru) – Pesticides

The information has been collected primarily from the "Manual Técnico Andino para el Registro y Control de Plaguicidas Químicos de Uso Agrícola" (Technical Andean Handbook for the Registration and Control of Chemical Pesticides for Agricultural Use).

2.1 OF THE ACTIVE INGREDIENT IN TECHNICAL GRADE

Containing chemical elements and their natural or manufactured compounds, including impurities and related compounds unavoidable to result from the manufacturing process.

2.1.1 Toxic effects on mammals

Requested to agricultural pesticides subject to been registered. Methods recommended follow.

Acute toxicity

(i) Oral

Relevant data on parameters other than oral LD_{50} must be reported. The following methods are recommended:

- Guideline OECD 401 (February 1987) for oral LD_{50}
- EU B.1 methods for toxicological studies: LD_{50} acute oral
- Guideline OECD 420: acute oral toxicity – fixed dose method
- Guideline OECD 423: acute oral toxicity – acute toxic class method
- Guideline OECD 425: acute oral toxicity – up and down procedure

(ii) Dermic

Relevant data on parameters other than dermal LD_{50} must be reported. The following methods are recommended:

- Any of the methods recommended
- Guideline OECD 402 (February 1987) for toxicological studies: LD_{50} dermal
- UE B.3 methods for the determination of DL_{50} dermal

(iii) Inhalatory

(iv) Cutaneous and eye irritation

(v) Sensibilisation

Sub-chronic toxicity (13 to 90 days)

(i) Accumulative oral
(ii) Oral administration to rodents and non-rodents
(iii) Other pathways (if precedent): inhalation, dermic

Chronic toxicity

(i) Long-term oral (2 years).

Carcinogenicity

Mutagenicity

Assays for genetic mutations, assays for cromosomic aberrations, assays to determine effects on DNA.

Toxicological compatibility: potentation, synergism, additivity (for mixtures of active ingredients)

Effects on reproduction

(i) Teratogenecity
(ii) Studies of at least two generations of mammals

Metabolism in mammals

(i) Studies on oral and dermal administration
(ii) Explanation on metabolic routes

Mandatory medical information

Additional studies

(i) Studies on neurotoxicity

(ii) Toxic effects of metabolites of toxicological importance, from treated plants, when these are different from the ones identified by studies on animals

(iii) Special studies, justified

Biodegradation (toxic kinetics)

2.1.2 *Toxic effects on other species*

-Terrestrial ecosystems: vertebrates (birds and mammals); invertebrates (bees); soil organisms (earthworms, micro-organisms, non-target plants).

-Aquatic ecosystems: (…)

Effects on birds

Information on acute dietary and oral effects will be required to those products that will be applied to non-confined spaces or for those that will be exposed in open spaces after the application (for example, seeds) and those that will be applied in closed spaces.

Information on chronic effects is further described on the original document.

(i) Acute toxicity to pheasant quail, wild duck or other validated species
Guidelines FIFRA Nº 71-1 and EPA OPPTS Nº 850.2100.

(ii) Short term toxicity (toxicity on one species eight days) in pheasant, quail, wild duck or any other validates species
Guidelines OECD Nº5, FIFRA Nº 71-2 and EPA OPPTS Nº850.2200

(iii) Effects on the reproduction of pheasant, quail, wild duck or any other validates species
This information will be required if the pesticide, its metabolites or degradation products, by their proposed use, would result in one or more of the following criteria:

a. Birds are subject to multiple or continuous exposure, specially before or during breeding season
b. The persistence of the products, its metabolites or degradation products are stable in the environment and potentially toxic amounts of them could persist in the feed source
c. If they accumulate in plant or animal tissues. Relevant indicators of toxicity are: n-octanol/water partition coefficient, metabolic or accumulation studies, and also if the structure of the product is similar to other substances of know bioaccumulation
d. All information derived of studies on reproduction of mammals that could indicate a potentially adverse effect on reproduction.

Guidelines OECD Nº206, FIFRA 71-4 and EPA OPPTS Nº 850.2300

2.1.3 *Effects on species other than the target species*

Acute toxicity to bees (oral and contact)
Guidelines OECD Nº213 and 214, FIFRA 141-1 and EPA OPPTS Nº 850.3020

Acute toxicity to beneficial arthropods (i.e., predators)
Guidelines EPPO PP 1/180(2), PP 1/142(2), PP 1/151(2) or other internationally accepted.

Toxicity to earthworms, Eisenia foetida or any other validates species
Guidelines OECD Nº207 and EPA OPPTS Nº 850.6200

Toxicity to soil micro-organisms (nitrifying)
Guidelines OECD Nº 216 and 217 and EPA OPPTS Nº 850.5100

2.1.4 *Other studies*

Design of field experiments: simulated and real for the study of specific effects when justifiable
FIFRA 71-5 for birds and mammals, 72-7 and 165-5 for aquatic organisms, EPA OPPTS Nº 850.1950, 850.1900, 850.1925.

2.2 TOXICOLOGICAL DATA OF THE FORMULATED PRODUCT

It mainly refers to the properties and studies on acute toxicity, sensibilization tests; eye, dermal and oral irritation; and genotoxic potential.

2.2.1 *Acute toxicity to mammals*

For classification purposes, oral and dermal LD_{50} are required, together with the inhalatory LC_{50} when required and the Ames test when genotoxicy is suspected on any of the components of the formulation.

2.3 DATA ON THE EFFECTS OF THE FORMULATED PRODUCT ON THE ENVIRONMENT

Used for ERA of biocides considering toxic effects on non-mammal species (birds, bees and aquatic organism); mammal species and on the environment (in soil: residues, leaching, degradability; and in water)

2.4 PICTOGRAMS

These are examples of used pictograms in Ecuador:

"Do not allow animals on the treated zone"
"Toxic for bees"
"Do not contaminate watercourses"

2.5 REFERENTIAL VALUES FOR THE ECOTOXICOLOGICAL EVALUATION

2.5.1 *Evaluation of terrestrial environmental risk: birds*

Avian species used as indicators

Table 1 Avian species used as indicators. Pesticides. (Ecuador-Andean Community)

Common name	Scientific name
Mallard duck	ANAS PLATYRHYNCHOS
Bobwhite quail	COLINUS VIRGINIANUS
Japanese quail	COTURNIX COTURNIX JAPONICA
Ring – necked pheasant	PHASIANUS COLCHICUS

Categorisation for oral LD_{50} (quail)

Table 2 Categorisation for oral LD_{50} (quail). Pesticides (Ecuador-Andean Community)

LD_{50} (mg/kg)	Category
< 10	Extremely toxic

10 - 50	Highly toxic
51 - 500	Moderately toxic
501 – 2 000	Slightly toxic
> 2 000	Practically non-toxic

US EPA (6)

Categorisation for LC_{50} (quail/duck)

Table 3 Categorisation for LC_{50} (quail/duck). Pesticides (Ecuador-Andean Community)

LC_{50} (ppm; mg/kg)	**Category**
< 50	Extremely toxic
51 - 500	Highly toxic
501 – 1 000	Moderately toxic
1 001 – 5 000	Slightly toxic
> 5 000	Practically non-toxic

US EPA (6)

Critical levels and risk ratios for terrestrial ecotoxicological evaluation of pesticides

Table 4 Critical levels and risk rations for terrestrial ecotoxicological evaluation of pesticides (Ecuador-Andean Community)

Risk assumption	**Risk ratio**	**Interest level**
High acute	EEC / CL_{50} or DL_{50}/day	0.5
Restricted use acute	EEC / CL_{50} or DL_{50}/day (or DL_{50} < 50 mg/kg)	0.2
Acute for species in danger	EEC / CL_{50} or DL_{50}/day	0.1
Chronic	EEC / NOEC	1

EEC: Estimated Environmental Concentration

3. Argentina – phytosanitary products

3.1 TOXIC EFFECTS ON BIRDS

3.1.1 Acute oral toxicity

In pheasant, quail, wild duck or any other species validated with a lipophilic xenobiotic compound.

3.1.2 Short term toxicity

Studies on one species for eight days (pheseant, quail, wild duck or any species validated by a lipophilic xenobiotic compound).

3.1.3 Effects on reproduction

In pheasant, quail, wild duck or any other species validated with a lipophilic xenobiotic compound.

This study would be required if the product, its metabolites or degradation products, for their suggested use, would result on one or more of the following criteria:

- birds are subject to multiple or a continuous exposure, specially before or during breeding season;

- the persistence of the product, its metabolites or degradation products, were environmentally stable and potentially toxic amounts of any of them could persist in their food source;

- the product, its metabolites or degradation products accumulate in plant or animal tissues. Relevant accumulation indicators are: octanol/water partition coefficient, accumulation or metabolic studies, as well as if the structure of the product is similar to any other chemical substance with known bioaccumulation. An octanol/water coefficient equal or higher to 1,000 or accumulation studies with values equal of higher than 100 are regarded as evidence of accumulation;

- any other information obtained as a result of studies on mammals reproduction that might indicate there could be an adverse effect.

3.2 TOXIC EFFECTS ON OTHER ORGANISMS OTHER THAN THE TARGET ORGANISM

3.2.1 Acute toxicity in honey bees

Oral and contact LD_{50}, validated by contemporary control with dimetoate. This study would be required in the use of the product results on honey bee exposure. On a case by case basis and only in the dangerousness of the product requires so and with a technical justification it would be viable to request simulation field assays (group mortality and bee tramp count, seven days).

3.2.2 Acute toxicity to beneficial arthropods (i.e., predators)

No specific relevant information.

3.2.3 Toxicity to earthworms (Eisetia foetida or any other validated species)

LC_{50} on soil (in mg/kg of soil). Contemporary control with un-treated soil. This study will be required when there is a possibility that the product can be present in the base soil when used.

3.2.4 Toxicity to soil micro-organisms (nitrifying)

Required when the product can be present in the base soil when used.

Specific experimental conditions will be designed whenever the results of the assays can not result on a full risk control of the phytosanitary product in relation to its use.

3.3 ECOTOXICOLOGICAL CLASSIFICATION OF FORMULATED PRODUCTS / ACTIVE PRINCIPLES

3.3.1 Toxicity to birds

Table 5 Toxicity to birds. Phytosanitary products (Argentina)

LC_{50} dietary (ppm)	LD_{50} oral, single dose (mm/kg)	Category
> 5 000	> 2 000	Practically non-toxic
1 001 – 5 000	501 – 2 000	Slightly toxic
501 – 1 000	51 - 500	Moderately toxic
51 - 500	10 - 50	Very toxic
< 50	< 10	Extremely toxic

As it will be shown later on this document, this classification is in agreement with Canadian classification (acute dietary).

3.3.2 *Toxicity to honey bees*

Table 6 Toxicity to honey bees. Phytosanitary products (Argentina)

LD_{50} (mg/bee)[1]	Category
< 1	Highly toxic
1 - 10	Moderately toxic
10 - 100	Slightly toxic
> 100	Virtually non-toxic

[1]Units in mg/bee as shown in official document although these should be µg/bee

4. Basel Convention

For the purposes of this Convention:

"Wastes" are substances or objects which are disposed of or are intended to be disposed of or are required to be disposed of by the provisions of national law;(…)"

Article 1 mentions the criteria to consider wastes as "hazardous wastes", we regard that only bullet a) and b) of the point 1 make sense in our framework, i.e.:

Article 1

Scope of the Convention

1. "The following wastes that are subject to transboundary movement shall be "hazardous wastes" for the purposes of this Convention":

(a) "Wastes that belong to any category contained in Annex I, unless they do not possess any of the characteristics contained in Annex III; and

(b) "Wastes that are not covered under paragraph (a) but are defined as, or are considered to be, hazardous wastes by the domestic legislation of the Party of export, import or transit(...)"

Annex III shows a list of hazardous characteristics:

Annex III

List of hazardous characteristics

UN Class[1]	Code	Characteristics
9	H12	Ecotoxic
		Substances or wastes which if released present or may present immediate or delayed adverse impacts to the environment by means of bioaccumulation and/or toxic effects upon biotic systems.
9	H13	Capable, by any means, after disposal, of yielding another material, e.g., leachate, which possesses any of the characteristics listed above.

The potential hazards posed by certain types of wastes are not yet fully documented; tests to define quantitatively these hazards do not exist. Further research is necessary in order to develop means to characterise potential hazards posed to man and/or the environment by these wastes. Standardized tests have been derived with respect to pure substances and materials. Many countries have developed national tests which can be applied to materials listed in Annex I, in order to decide if these materials exhibit any of the characteristics listed in this Annex.
There is no distinction between aquatic or terrestrial environment in Annex III. This annex also considerers the difference between acute and chronic hazards. Therefore, any classification and labelling system based on acute and/or chronic hazard criteria for aquatic and/or terrestrial environment would be in agreement with the content of this Convention.

5. Canada - pesticides

The hazard is communicated in print on the pesticide product label along with risk management and risk avoidance statements.

Most of the Canadian system for terrestrial hazards is identical with the system used by the U.S. EPA.

5.1 HONEY BEES

Categories obtained from Atkins *et al.* (1981), are used to assess the relative acute oral and contact toxicities of pesticides to honey bees or to decide if further testing is required:

Group 1 - Highly Toxic: LD_{50} 0.001-1.99 ug active ingredient/bee.
Severe losses may be expected if the compound is used when bees are present at treatment time or within a few days thereafter.

Group 2 - Moderately Toxic: LD_{50} 2.00-10.99 ug active ingredient/bee.
Can be used around bees depending on dosage, timing, and method of application, but should not be applied directly on bees in the field or at the colonies.

Group 3 - Relatively Nontoxic: $LD_{50} > 10.99$ ug active ingredient/bee.
Can be used around bees with a minimum of injury.

5.2 BIRDS AND MAMMALS

Classifications are from the EPA Standard Evaluation Procedure Documents for birds and mammals.

[1] *Corresponds to the hazard classification system included in the United Nations Recommendations on the Transport of Dangerous Goods (ST/SG/AC.10/1Rev.5, United Nations, New York, 1988).*

5.2.1 *Acute oral*

Table 7 U.S. EPA Standard evaluation procedure for birds and mammals. Acute oral. (Canada)

LD_{50} (mg a.i./kg bw)	**Toxicity Classification**
< 10	very highly toxic
10 - 50	highly toxic
51 - 500	moderately toxic
501 – 2 000	slightly toxic
> 2 000	Practically non- toxic

5.2.2 *Acute dietary*

Table 8 U.S. EPA Standard evaluation procedure for birds and mammals. Acute dietary. (Canada)

LC_{50} (mg a.i./kg diet)	**Toxicity Classification**
< 50	very highly toxic
51 - 500	highly toxic
501 – 1 000	moderately toxic
1 001 – 5 000	slightly toxic
> 5 000	practically non-toxic

6. European Union – chemicals, biocides and pesticides

The EU system based on risk phrases is not currently applied as the criteria for terrestrial hazards have not been developed yet. According to the currently available information, the proposed new EU Classification, Labelling and Packaging (CLP) Regulation will not include labelling elements concerning terrestrial hazards, as it is based on the current GHS.

6.1 RISK PHRASES

Table 9 Classification, packaging and labelling of dangerous substances (Commission Directive 67/548/EEC and subsequent Directives adapting Directive 67/548/EEC to technical progress) (EU)

	Chemicals	Pesticides	Biocides
R 54 Toxic to flora	Properties based on hazard No classification criteria	Properties based on hazard No classification criteria	Properties based on hazard No classification criteria
R 55 Toxic to fauna	Properties based on hazard No classification criteria	Properties based on hazard No classification criteria	Properties based on hazard No classification criteria
R 56 Toxic to soil organisms	Properties based on hazard No classification criteria	Properties based on hazard No classification criteria	Properties based on hazard No classification criteria
R 57 Toxic to bees	Properties based on hazard No classification criteria	Properties based on hazard No classification criteria	Properties based on hazard No classification criteria

R 58 May cause long term adverse effects in the environment	Properties based on hazard No classification criteria	Properties based on hazard No classification criteria	Properties based on hazard No classification criteria

6.2 STANDARD PHRASES FOR THE SAFETY PRECAUTIONS FOR THE PROTECTION OF THE ENVIRONMENT

Table 10 Placing of Plant Protection Products on the market (Council Directive 91/414/EEC and subsequent amendments) (EU)

	Chemicals	Pesticides	Biocides
SPe 1 To protect groundwater/soil organisms do not apply this or any other product containing … more than….	-	Properties based on risk assessment Toxicity Exposure Ratio (TER) < trigger value as set in Annex VI to Directive 91/414/EC	-
SPe 3 To protect aquatic organisms/non target plants/arthropods/insects respect an unsprayed buffer zone of …. To non-agricultural land /surface water bodies	-	Properties based on risk assessment TER < trigger value as set in Annex VI to Directive 91/414/EC	-
SPe 4 To protect aquatic organisms/non-target plants do not apply on impermeable surfaces such as asphalt, concrete, cobblestones, railway tracks and others situation with a high risk of run-off	-	Properties based on risk assessment TER < trigger value as set in Annex VI to Directive 91/414/EC	-
SPe 5 *To protect bird mammals, the product must be entirely incorporated in the soil, insure that the product is also fully incorporated at the end of rows*	-	Properties based on risk assessment TER < trigger value as set in Annex VI to Directive 91/414/EC	-
SPe 6 *To protect bird/mammals remove spillages*	-	Properties based on risk assessment TER < trigger value as set in Annex VI to Directive 91/414/EC	-
SPe 7 *Do not apply during the bird breeding period*		Properties based on risk assessment TER < trigger value as set in Annex VI to Directive 91/414/EC	
SPe 8 *Dangerous to bees/To protect bees and others pollinating insects do not apply to crop plants when in flower/ Do not use where bees are actively foraging/remove or cover beehives during applications and for…..after treatment/Do not apply when flowering weeds are present/Remove weeds before flowering/Do not apply before…..*	-	Properties based on risk assessment (Hazard Quotient (HQ) oral or contact > 50)	-

7. New Zealand – Hazardous substances

The New Zealand "User Guide to the HSNO Thresholds and Classifications" (2) used as base for writing this section is under review at the time of issuing this report.

7.1 INTRODUCTION

The "Hazardous Substances (Classification) Regulations 2001 includes, under item 11, the "Subclasses and categories for ecotoxic substances":

(1) "Ecotoxic substances are divided into the subclasses 9.1, 9.2, 9.3, and 9.4, and each subclass is divided into 1 or more categories.
(2) An ecotoxic substance is classified as having a particular hazard classification if it meets the criteria set out in the table Schedule 6 for that hazard classification"

"Schedule 6" gives the classification criteria for ecotoxic substances (aquatic and terrestrial) according to the criteria set out in the table of the schedule.

Table 11 Summary table. Hazard classification ("Hazardous Substance (Classification) Regulations 2001", New Zealand)

Hazard classification	Criteria for each hazard classification
9.2A Substances that are very ecotoxic in the soil environment	A substance for which data indicate a soil ecotoxicity value less than or equal to 1 miligram of the substance per kilogram dry weight of soil
9.2B Substances that are ecotoxic in the soil environment	A substance for which data indicate a soil ecotoxicity value greater than 1 miligram, but less than or equal to 10 milligrams, of the substance per kilogram dry weight of soil
9.2C Substances that are harmful in the soil environment	A substance for which data indicate a soil ecotoxicity value greater than 10 miligrams, but less than or equal to 100 miligrams, of the substance per kilogram dry weight of soil, where the soil DT_{50} is greater than 30 days
9.2D Substances that are slightly harmful in the soil environment	A substance for which data indicate a soil ecotoxicity value greater than 10 miligrams, but less than or equal to 100 miligrams, but less than or equal to 100 milligrams, of the substance per kilogram dry weight of soil, where the soil DT_{50} is less than or equal to 30 days
9.3A Substances that are very ecotoxic to terrestrial vertebrates	(a) a substance for which data indicate an acute avian or mammalian oral or dermal LD_{50} less than or equal to 50 milligrams of the substance per kilogram of bodyweight; or (b) a substance for which data indicate an acute avian or mammalian LC_{50} less than or equal to 500 parts per million of the substance in the diet.
9.3B Substances that are ecotoxic to terrestrial vertebrates	(a) a substance for which data indicate an acute avian or mammalian oral or dermal LD_{50} greater than 50 milligrams, but less than or equal to 500 milligrams, of the substance per kilogram of bodyweight; or (b) a substance for which data indicate an acute avian or mammalian LC_{50} greater than 500 parts per million, but less than or equal to 1 000 parts per million, of the substance in the diet.
9.3C Substances that are harmful to terrestrial vertebrates	(a) a substance for which data indicate an acute avian or mammalian oral or dermal LD_{50} greater than 500 milligrams, but less than or equal to 2 000 milligrams, of the substance per kilogram of bodyweight; or (b) a substance for which data indicate an acute avian or mammalian LC_{50} greater than 1 000 parts per million, but less than or equal to 5 000 parts per million, of the substance in the

	diet; or (c) a substance for which data indicate a chronic avian or mammalian MATC of less than 100 parts per million of the substance in the diet, but does not meet the criteria for hazard classification 9.3A or 9.3B
9.4A Substances that are very ecotoxic to terrestrial vertebrates	A substance for which data indicate a contact or oral LD_{50} less than 2 micrograms of substance per terrestrial invertebrate.
9.4B Substances that are ecotoxic to terrestrial invertebrates	A substance for which data indicate a contact or oral LD_{50} greater than or equal to 2 micrograms, but less than 11 micrograms, of substance per terrestrial invertebrate.
9.4C Substances that are harmful to terrestrial invertebrates	A substance for which data indicate a contact or oral LD_{50} greater than or equal to 11 micrograms, but less than or equal to 25 micrograms, of substance per terrestrial invertebrate.

On the "User guide to the HSNO thresholds and classifications" (Aug 2001), there are guidelines on terrestrial hazard classification. A summary of the document follows.

7.1.1 Threshold

A substance with ecotoxic properties is not hazardous for the purposes of the Act unless:

- the substance is ecotoxic to soil organisms because:

- data for the substance indicates that a plant or soil invertebrate EC_{50} is 100 milligrams or less of the substance per kilogram dry weight of soil over a 14-day exposure period, as a result of exposure to the substance;

or

- data for the substance indicates that a 25% reduction of microbial respiration or microbial nitrification at 100 miligrams or less of the substance per kilogram dry weight of soil after a 28-day exposure period, as a result of exposure to the substance.

7.1.2 Classification

The HSNO (Hazardous Substances and New Organisms Act) classification criteria for substances with ecotoxic properties under Schedule 6 identify four classification categories for substances which are ecotoxic to the soil environment (Subclass 9.2).

A subclass 9.2 classification and the subsequent Category apply to any substance which meets the following criteria:

(i) Category 9.2A- Substances that are very ecotoxic in the soil environment:
A substance for which data indicate a soil ecotoxicity value less than or equal to 1 milligram of the substance per kilogram dry weight of soil.

(ii) Category 9.2B . Substances that are ecotoxic in the soil environment:
A substance for which data indicate a soil ecotoxicity value greater than 1 milligram, but less than or equal to 10 milligrams, of the substance per kilogram dry weight of soil.

(iii) Category 9.2C. Substances that are harmful in the soil environment:

A substance for which data indicate a soil ecotoxicity value greater than 10 milligrams, but less than or equal to 100 milligrams, of the substance per kilogram dry weight of soil, where the soil DT_{50} is greater than 30 days.

(iv) Category 9.2D. Substances that are slightly harmful in the soil environment:
A substance for which data indicate a soil ecotoxicity value greater than 10 milligrams, but less than or equal to 100 milligrams, of the substance per kilogram dry weight of soil, where the soil DT_{50} is less than or equal to 30 days.

The classification scheme for soil effects outlined above is presented in tabular form in Table 8.

Table 12 Classification scheme for soil effects (New Zealand)

HSNO Category	Measure (mg/kg dry weight soil)
Category 9.2A (very ecotoxic in the soil environment)	Soil ecotoxicity value ≤ 1
Category 9.2B (ecotoxic in the soil environment)	1 > Soil ecotoxicity value ≤ 10
Category 9.2C (harmful in the soil environment)	10 > Soil ecotoxicity value ≤ 100 AND Soil DT_{50} >30 days
Category 9.2D (slightly harmful in the soil environment)	10 > Soil ecotoxicity value ≤ 100 AND Soil DT_{50} ≤ 30 days

7.1.3 Definitions

Data: includes values that are directly measured, calculated, or estimated for any of the measures given.

EC_{50}: a median effect concentration, being a statistically derived concentration of a substance that can be expected to cause:

(a) an adverse reaction in 50% of organisms
or
(b) a 50% reduction in growth or in the growth rate of the organisms

Soil DT_{50}: the half-life in soil, which is the time required to reduce the original concentration of the substance in the soil by 50%.

Soil ecotoxicity value: the lower value in units of milligrams of a substance per kilogram (dry weight) of soil from:

(a) plant or soil invertebrate EC_{50} data after 14 days exposure to the substance
or
(b) data that demonstrate a 25% reduction in soil micro-organism respiration or nitrification after 28 days exposure to the substance

7.1.4 Acceptable test methodologies

The following test methodologies (Table 13) are deemed to meet the requirements for testing the soil effect thresholds.

Table 13 Test methodologies

Test Protocol	OECD Code	USEPA OPPTS code	USEPA OPP code	USEPA OTS code	European Community	SETAC
Earthworm toxicity	207	850.6200	none	795.150	EC Method C.8	
Terrestrial plant, growth test	208					
Terrestrial plant, seedling emergence		850.4100	122-1	None		
Terrestrial plant, vegetative vigour		850.4150	122-1	None		
Soil microbial community test		850.5100	none	797.3700		Soil micro-organism test
Nitrogen transformation test	216					
Carbon transformation test	217					

7.1.5 *Mitigating factors / data interpretation*

Absence of measured data

While it should be noted that no measured is available, classification of substance into a HSNO hazard classification Category can still occur using a weight of evidence approach that acknowledges all other data that is available on the substance. If this approach is used, any assumptions made and the weight of evidence approach for hazard classification should be clearly documented.

If there is no measured (direct) data or indirect data on the substance, the substance can not be assigned a definitive hazard classification.

Earthworm tests

While the units used for deriving test data (EC_{50} as mg/kg soil dry weight) are consistent with the proposed threshold, variations exist where data can be presented as an LC_{50} value (lethality) or as a NOEC (USEPA).

The development of a conversion factor between an earthworm NOEC and an EC_{50} should not be necessary since the protocols deriving a NOEC value also specify that EC_{50} and LC_{50} data be calculated. Therefore, the EC_{50} value is used for assessing whether a substance triggers the threshold.

In contrast, the OECD protocol does not derive an EC_{50} value, with reference only given to a LC_{50}. While a single conversion factor will not be accurate for all chemicals, some conservative guidance can be obtained from standardised risk assessment procedures which include a conversion factor of 10 when comparing between lethal concentrations and "safe" concentrations (EPPO 1998). While the EC_{50} defines an effect concentration rather than the "safe" concentration, the factor of 10 would nevertheless represent the conservative end of the range of values for extrapolating from an LC_{50} to EC_{50}. In situations where evidence for a specific substance(s) demonstrates that a reduced factor is valid, the reduced value should be acceptable. As the OECD earthworm test requires a description of obvious physical or pathological symptoms or distinct changes in behaviour observed in the test animals, evidence for a lower factor could include the absence of obvious physical, pathological or behavioural changes.

Plant tests

The protocols for assessing plant ecotoxicity differ from the threshold in the following ways:

• The OECD test data can be derived as a LC_{50} and as an EC_{50}

• A conversion factor for an LC_{50} to EC_{50} should not need to be developed since the OECD protocol requires both the LC_{50} and an EC_{50} to be derived. However, in situations where the LC_{50} is described in isolation from the EC_{50}. As noted for the conversion of earthworm data, a factor of 10 should represent a conservative extrapolation from an LC_{50} to EC_{50}

• The U.S. EPA Terrestrial Plant Tests (seedling emergence and percent vigour); derive a percent effect level (rather than EC_{50}) in units of grams or pounds per acre (rather than mg/kg soil dry weight); and

• This difference between the proposed threshold and the USEPA Terrestrial Plant Tests approach of deriving a percent effect level in units of grams or pounds per acre limits its comparability to the threshold. While risk assessment procedures are available for extrapolating from field application rates to expected soil concentrations (EPPO, 1998), the validity of using these approaches for qualitative laboratory test predictions is questionable. Furthermore, the variety of factors that can influence the final soil concentration (eg formulation and percentage crop cover) suggests that any extrapolation would need to be developed on a case-by-case basis. An additional difficulty with extrapolating for the vegetative vigour test is that application is on postemergent plants and, therefore, a component of exposure is through direct surface contact rather than via soil exposure.

Micro-organism tests

The following variations from the micro-organism threshold are noted:

• The protocols enable data to be expressed as an EC_{50} as an alternative to, or in addition to, the EC_{25}:

Developing a conversion factor for extrapolating between soil micro-organism ecotoxicity values such as an EC_{50} to an EC_{25} is difficult to justify scientifically. An analogous scenario exists in the EU where an EC_{50} value is specified for aquatic hazard classification. If an ecotoxicity value is expressed not as an EC_{50} but as an EC_{10}, EC_{90}, etc, this latter data is used as a direct surrogate for the EC50 where the ecotoxicity value concentration is 'well below a classification limit'. In situations where the ecotoxicity value is close to a classification limit, an *ad hoc* evaluation is performed (Pedersen *et al*, 1995). The use of EC_{50} as a surrogate for EC_{25} would be a conservative approach.

• The U.S. EPA protocol uses units of µg/g dry soil (rather than mg/kg soil dry weight), and,

• The U.S. EPA units of µg/g dry soil do not need a conversion factor since the units are directly comparable to mg/kg soil dry weight.

• For pesticides which have predictable environmental concentrations, testing is conducted based on an application rate(s) rather than a concentration series for deriving an EC_{50}.

Generally effects should be judged as especially serious if the decline in the overall number and/or biomass is > 50% or if the recovery time exceeds the interval between two field exposures. Where soil micro-organism tests are conducted based on a field application rate rather than for derivation of an EC_{50}, the data will only be directly comparable in situations where:

• The soil concentration used was < 100 mg/kg and ≥ 25 % effect was noted (in which case the substance triggers the threshold), or

• The concentration used was > 100 mg/kg and < 25 % effect was noted (in which case the substance does not trigger the threshold).

Indirect methods

The relatively small database that is available describing the effects of chemicals on soil organisms has restricted the development of QSAR for this environmental compartment. Nevertheless, there has been a focus on the development of indirect methods based on extrapolations from effect levels in aquatic organisms.

These methods have arisen from the observations that the effect concentrations of chemicals in sediment have been correlated to interstitial water concentrations, and that effect concentrations in interstitial water are often similar to effect concentrations in water-only exposures. Therefore, it is equated that the predicted concentrations in interstitial or pore water can be coupled with aquatic ecotoxicity data can quantify the hazard to soil organisms.

While these indirect techniques appear to have potential for hazard assessment, they have not become widely established methods in chemical registration programs for qualitatively assessing soil ecotoxicity. Smrchek and Zeeman, 1998, noted that the techniques were "an interesting, yet somewhat controversial, method of ultimately establishing hazard criteria for terrestrial soil organisms". The major difficulties with the approach include:

• The identification of suitable aquatic surrogates for soil organisms. Torstensson and Pettersson, (1996) found no simple correlation between the ecotoxicity values for the standardised aquatic (*Daphnia*) and soil (earthworm) invertebrate test organisms;

• The interstitial water concentrations can not always be readily predicted since bioavailability of the chemical in the soil environment is influenced by a variety of factors;

• The extrapolation from effects on aquatic species only considers effects on soil organisms due to exposure to the pore water of the soil. In reality, other exposure routes may become significant.

An example of the principles of the indirect method is described in Ingersoll (1995), with the estimation of a sediment effect concentration (mg substance/kg sediment dry weight) from an effect level in water (µg/l). The water effect level was multiplied by the partitioning coefficient between sediment and interstitial water to estimate the sediment effect concentration. This approach can be translated to derivation of a soil EC_{50} from an aquatic EC_{50} as:

Soil-organism EC_{50} (mg substance/kg sediment dry weight)
= Kp (l/g) X Aquatic EC_{50} (mg substance/l)

where Kp is the partitioning coefficient between sediment and interstitial water (l/g).

7.1.6 Hazard cut-off values

It is acknowledged that certain percentage levels of a substance are unlikely to result in an adverse ecological effect when released to the environment. Therefore, ERMA New Zealand considers the following levels as acceptable percentage cut-offs at the threshold effect trigger level. That is, the substance is below the threshold for soil effects if it meets the following requirement.

Condition	Endpoint
The substance is present at less than 1% and DT_{50} in soil is <30 days	Soil ecotoxicity

unless the substance soil ecotoxicity value is less than 0.1 mg/kg (that is highly ecotoxic)	

The generic hazard cut-off level does not apply if it can be shown that the substance causes a terrestrial soil hazard that will be evident below the generic hazard cut-off level.

If the substance is a mixture, and it contains components that in their own right trigger the soil ecotoxicity threshold(s) and are classified as ecotoxic to the soil environment, every component must meet this requirement (concentration less than 1% w/w) for the substance as a mixture to be considered non-ecotoxic. Alternatively if data on the substance as a mixture shows the mixture is not ecotoxic to the soil environment, then it is considered non-ecotoxic for the soil environment.

Where multiple values for a substance/substance as a mixture are available, the most sensitive value should be used.

7.1.7 Minimum data sets: industrial substances, veterinary medicines, pesticides

The HSNO Act covers many types of substances with varying degrees of hazardous properties. These substances also have different uses and circumstances of use. The risk associated with a hazardous substance is a function of the degrees of hazard of the substance and the level and duration of exposure to these hazards.

Further information on this can be found on pp 35-37 of Part VII on "User Guide to the HSNO Thresholds and Classifications" (2).

7.1.8 Classification of substances

Similar principles and mixture rules apply for classification of soil ecotoxicity as for aquatic ecotoxicity are used.

Once a substance triggers a threshold, it is then classified. While this is relatively straightforward for single substances (pure substances), substances as mixtures may be more complex. The process for classification of soil ecotoxicity endpoints (and therefore whether the substance as a mixture triggers a threshold), is as follows:

(a) Where test data are available for the complete mixture, the classification of the mixture will always be based on that data;

(b) Where test data are not available for the mixture itself, then bridging principles should be considered to see whether they permit classification of the mixture;

(c) Where test data are not available for the mixture itself, and the available information is not sufficient to allow application of the bridging principles, the agreed method(s) for estimating the hazards based on the information known will be applied to classify the mixture (Additivity Formula or Summation of Classified Components Approach);

(d) Where a substance as a mixture contains components with no useable information on soil effects, classification should be based on the known components only.
It should also be noted that the following data sources can be used for classification to a soil ecotoxicity category:

• Data shows that the chemical structure of the new substance is similar to an existing scheduled substance under the *Toxic Substances Regulations 1983* or an approved substance with ecotoxic

properties under the HSNO Act 1996 (either as structure activity relationship or a structure property relationship), or

• Data from an *in vitro* study indicates the result is equivalent to results from an organism-based study.

Mixture components

If the substance as a mixture contains any components (including impurities and additives) that have been identified and are themselves classified (or would be classified) under the HSNO legislation, then they shall be considered during classification of the substance as a mixture if they exceed the cut-off value/concentration limit for a given endpoint.

Synergistic / antagonistic effects

(a) If the applicant is aware of any available information about possible synergistic effects that may enhance the ecotoxicity of the substance as a mixture, this must be considered.

(b) Similarly if the applicant is aware of any available information that antagonistic effects may occur such that the substance as a mixture classification is lower than indicated from the calculated value, this should be noted. For example, encapsulation of a substance as a mixture can lower the ecotoxicity of the substance, or the amount of substance in the container is unlikely to result in an ecotoxic effect.

Test data available for the complete substance

When a substance or substance as a mixture has been directly tested, this result should be used in determining whether the substance as a mixture triggers the soil ecotoxicity effect level.
It should be noted, however, that the additional properties that, when combined with soil ecotoxicity, give rise to concern for longer-term effects (that is, degradation time in soil), can not be directly tested for mixtures as these properties are strictly related to single substances.

Therefore in order to classify a substance where there is ecotoxicity data on the mixture as a whole, information used to classify components for longer-term effects (lack of degradability) should be used as follows:

• EC_{50} of the tested mixture is ≤1 mg/kg dry weight soil:
Classify as Category 9.2A

• EC_{50} of the tested mixture is >1 and ≤10 mg/kg dry weight soil:
Classify as Category 9.2B

• EC_{50} of the tested mixture is >10 and ≤100 mg/kg dry weight soil, and the sum of percentages of components classified as 9.2A, 9.2B and 9.2C whose DT_{50} >30 days is greater than 25%:
Classify as Category 9.2C

• EC_{50} of the tested mixture is >10 and ≤100 mg/kg dry weight soil, and the sum of percentages of components classified as 9.2A, 9.2B and 9.2C whose DT_{50} >30 days is less than 25%: Classify as Category 9.2D

• EC_{50} of the tested mixture is >10 and ≤100 mg/ kg dry weight soil, and the sum of percentages of components classified as 9.2A, 9.2B and 9.2C and 9.2D whose DT_{50} <30 days is greater than 25%: Classify as Category 9.2D

• EC_{50} of the tested mixture is >100 mg/ kg dry weight soil, and the sum of percentages of components classified as 9.2A, 9.2B and 9.2C and 9.2D whose DT_{50} <30 days is greater than 25%:

Substance not classified, not hazardous

• EC_{50} of the tested mixture is >100 mg/ kg dry weight soil, and the sum of percentages of components classified as 9.2A, 9.2B and 9.2C and 9.2D whose DT_{50} <30 days is less than 25%:
Substance not classified, not hazardous

Test data not available for the complete substance as a mixture

If the substance as a mixture has not been tested to determine its soil ecotoxicity, but there are sufficient data on the individual components and similar tested mixtures to adequately characterise the hazards of the mixture, this data should be used in accordance with the following bridging rules:

(a) Dilution

(i) If a substance as a mixture is diluted with a diluent which has an equivalent or lower soil hazard classification than the least ecotoxic original component and which is not expected to affect the soil hazards of other components, then the new mixture may be classified as equivalent to the original mixture or substance.

(ii) If the mixture is diluted with water or other totally non-ecotoxic material, the ecotoxicity of the mixture can be calculated from the original mixture or substance.

(b) Batching

The soil hazard classification of one batch of substance as a mixture can be assumed to be substantially equivalent to that of another batch of the same commercial product and produced by or under the control of the same manufacturer. If there is reason to believe there is significant variation such that the soil hazard classification of the batch has changed, then this batch is a new substance requiring an application to the Authority.

(c) Concentration of Highly Ecotoxic Mixtures

If a substance as a mixture is classified as very ecotoxic to the soil environment (that is 9.2A), and components of the mixture that are classified as 9.2A in their own right are further concentrated, the more concentrated mixture should be classified as 9.2A without additional testing.

(d) Interpolation within one ecotoxicity class

If mixtures X and Y are in the same classification Category and mixture Z is made in which the ecotoxicologically active components have concentrations intermediate to those in mixtures X and Y, then mixture Z is assumed to be in the same classification Category as X and Y. Note that the identity of the components is the same in all three mixtures.

(e) Substantially similar mixtures
For example
Mixture One: components A + B
Mixture Two: components C + B

The concentration of component B is the same for both mixtures and the concentration of component A equals that of component C. If the data on the soil ecotoxicity of A and C are available and substantially equivalent (same hazard Class and not expected to affect the

ecotoxicity of component B), and Mixture One has already been tested, there is no need to test Mixture Two. That is Mixture One and Mixture Two would be classified in the same Category.

Classification of mixtures when test data on the mixture is not available and the bridging principles above are not applicable

Some preparations contain relatively small concentrations of extremely hazardous substances, for example, some pesticide active ingredients.

Options for dealing with these extremely hazardous ingredients in mixtures must deal with the issue of how to characterise the ecotoxicity of the entire preparation, even though data may not be available for the less hazardous components.

If the mixture contains highly ecotoxic components ($EC_{50} \leq 0.1$mg/kg), and acute ecotoxicity data of all relevant components are known, then the additivity formula below should be applied. The additivity formula may also be used for mixtures containing highly ecotoxic components whose ecotoxicities are well characterized and would be expected to dominate the ecotoxicity of the mixture and if there is convincing information to conclude that all other components, including those for which there is no specific acute ecotoxicity data available, are of low or no ecotoxicity and do not significantly contribute to the aquatic environmental hazard of the mixture.

Additivity Formula

$$\frac{100}{EC_{50mix}} = \sum_{\eta} \frac{C_i}{EC_{50i}}$$

where:
C_i = concentration of component i (weight percentage)
EC_{50i} = (mg/kg dry weight soil) EC_{50} for component i
η = number of components
Concentration of non-ecotoxic components such as water may be neglected.

When applying the additivity formula, it is preferable to calculate the ecotoxicity of the mixture using, for each substance, ecotoxicity values that relate to the same species (plant or soil invertebrate or soil micro-organism EC_{25}) and then to use the highest ecotoxicity (lowest value) obtained (that is, use the most sensitive of the three species).

When ecotoxicity data for each component are not available in the same species, the ecotoxicity value of each component should be selected in the same manner that ecotoxicity values are selected for the classification of substances, ie, the higher ecotoxicity (from the most sensitive test organism) is used. The calculated acute ecotoxicity of the mixture may then be used to classify the mixture as 9.2A, 9.2B, 9.2C or 9.2D using the same criteria for pure substances.

Examples

- Calculated EC_{50} of the mixture ≤1mg/kg dry weight soil:
Classify as 9.2A

- Calculated EC_{50} of the mixture 1 ≤10mg/kg dry weight soil:
Classify as 9.2B

- Calculated EC_{50} of the mixture is >10 and ≤100 mg/kg dry weight soil, and the sum of percentages of components classified as 9.2A, 9.2B and 9.2C whose DT_{50} >30 days is greater than 25%:

Classify as Category 9.2C

- Calculated EC_{50} of the mixture is >10 and ≤100 mg/kg dry weight soil, and the sum of percentages of components classified as 9.2A, 9.2B and 9.2C whose DT_{50} >30 days is less than 25%:

Classify as Category 9.2D

- Calculated EC_{50} of the mixture is >10 and ≤100 mg/kg dry weight soil, and the sum of percentages of components classified as 9.2A, 9.2B and 9.2C and 9.2D whose DT_{50} <30 days is greater than 25%:

Classify as Category 9.2D

- Calculated EC_{50} of the mixture is >100 mg/kg dry weight soil, and the sum of percentages of components classified as 9.2A, 9.2B and 9.2C and 9.2D whose DT_{50} <30 days is greater than 25%:

Substance not classified, not hazardous

- Calculated EC_{50} of the mixture is >100 mg/kg dry weight soil, and the sum of percentages of components classified as 9.2A, 9.2B and 9.2C and 9.2D whose DT_{50} <30 days is less than 25%:

Substance not classified, not hazardous

Summation of Classified Components Approach

If soil ecotoxicity data are not available for all relevant components of the mixture the classification should be based on summation of the classification of its components. Details of the summation approach are described in the next paragraphs.

In case of the substance classification classes, the underlying ecotoxicity criteria differ by a factor of 10 in moving from one Class to another. Substances with a classification in a high ecotoxicity band may therefore contribute to the classification of a mixture in a lower band.

The calculation of these classification classes therefore needs to consider the contribution of all substances classified together.

Classification procedure

In general a more severe classification for mixtures overrides a less severe classification, for example a classification with 9.2A overrides a classification with 9.2B. As a consequence the classification procedure is already completed if the results of the classification is 9.2A. A more severe classification than 9.2A is not possible therefore it is not necessary to undergo the further classification procedure.

First all components classified as 9.2A are considered. If the sum of these components is greater than 25% the whole mixture is classified as 9.2A. If the result of the calculation is a classification of the mixture as 9.2A, the classification process is completed.

In cases where the mixture is not classified as 9.2A, classification of the mixture as 9.2B is considered. A mixture is classified as 9.2B if ten times the sum of all components classified as 9.2A plus the sum of all components classified as 9.2B is greater than 25%. If the result of the calculation is classification of the mixture as Class 9.2B, the classification process is completed.

In cases where the mixture is not classified either as 9.2A or 9.2B, classification of the mixture as 9.2C is considered. A mixture is classified as 9.2C if 100 times the sum of all components classified as 9.2A plus 10 times the sum of all components classified as 9.2B plus the sum of all components classified as 9.2C is greater than 25%.

If the mixture is still not classified in 9.2A, 9.2B or 9.2C, classification of the mixture as 9.2D should be considered. A mixture is classified as 9.2D if the sum of the percentages of components classified as 9.2A, 9.2B, 9.2C and 9.2D is greater than 25%.

The classification of mixtures for soil based on this summation of classified components is summarised in tabular form in Table 14.

Table 14 Classification of a Mixture for Ecotoxic Soil Hazards, based on Summation of Classified Components (New Zealand)

Sum of components classified as		Mixture is classified as
9.2A x M		9.2A
(M x 10 x 9.2A) + 9. 2B	>25%	9.2B
(M x 100 x 9.2A)+ (10 x 9.2B) + 9.2C	>25%	9.2C
9.2A + 9.2B + 9.2C + 9.2D	>25%	9.2D

Where M = multiplying factor

Mixtures with highly ecotoxic components

In applying the summation of classified components approach, more weight should be given to highly ecotoxic components. When a mixture contains components classified as 9.2A, the tiered approach described above should be applied using a weighted sum by multiplying the concentrations of 9.2A components by a factor, instead of merely adding up the percentages.

The multiplying factors to be applied to the component are summarised in tabular form in Table 15. If $0.1 < EC_{50} \leq 1$, no multiplying factor is needed.

Table 15 Multiplying Factors for Highly Ecotoxic Components of Mixtures (New Zealand)

EC_{50} value (mg/kg dry weight soil)	Multiplying factor (M)
$0.01 < EC_{50} \leq 0.1$	10
$0.001 < EC_{50} \leq 0.01$	100
$0.0001 < EC_{50} \leq 0.001$	1 000
$0.00001 < EC_{50} \leq 0.0001$	10 000
(continue in factor 10 intervals)	

For example

Component	EC_{50} (mg/kg dry weight soil)	Individual Substance (100%) Classification	Concentration in mixture (%)	Multiplying Factor
B	5	9.2B	5	-
P	0.002	9.2A	0.05	100
Q	0.9	9.2A	1	-
T	50	9.2C	40	-
U	Not Classified	Not Classified	53.95	-

Therefore from the above table, it can be observed that component P is extremely ecotoxic. The total percentage of components classified as 9.2A is 1.05%. The weighted sum of 9.2A

components using the multiplier is 6% (1 + (0.05 X 100)). This is below 25% so the mixture is not classified as 9.2A.

Consideration of components classified as 9.2A and 9.2B results in a total percentage of 65% (10(6% of 9.2A) + (5% of 9.2B)). Therefore as this is above 25%, the mixture is classified as 9.2B.

A general rule of thumb for percentage levels and subsequent classification of the mixture containing these extremely ecotoxic substances, based on the above method, is outlined below. This is general guideline only and the above calculation should be carried out for ultimate classification of the substance.

EC_{50}

Band 1: 0.1-0.01 mg/l
Band 2: 0.01-0.001 mg/l
Band 3: 0.001-0.0001 mg/l
Band 4: <0.0001 mg/l

Σ(% Band 1 in mixture)	> 0.25%	Classify as 9.2A
Σ(% Band 1 in mixture)	> 0.025%	Classify as 9.2B
Σ(% Band 1 in mixture)	> 0.0025%	Classify as 9.2C
Σ(% Band 2 in mixture)	> 0.025%	Classify as 9.2A
Σ(% Band 2 in mixture)	> 0.0025%	Classify as 9.2B
Σ(% Band 3 in mixture)	> 0.0025%	Classify as 9.2A
Σ(% Band 4 in mixture)	no limit	Classify as 9.2A

Classification of mixtures with components without any useable information

If the substance as a mixture contains components present at concentrations of 1% or greater, but no information is available on soil effects for those component(s), the mixture cannot be attributed a definitive hazard classification.

The substance as a mixture can, however, be classified based on the soil ecotoxicity of known components only. This classification would need to be highlighted as:

> "X percent of the mixture consists of component(s) of unknown hazards to the soil environment"

If there is no information about the soil ecotoxicity of the components but the substance has been classified as an aquatic hazard (9.1A, 9.1B, 9.1C or 9.1D), then a precautionary approach may be applied such that a similar hazard classification may apply to the terrestrial environment (9.2A, 9.2B, 9.2C or 9.2D).

Conversely if the classification mixture rules for aquatic ecotoxic effects indicate the substance is not hazardous to the aquatic environment, and no other information in the data package indicates a terrestrial hazard (such as corrosiveness), then it may be considered not hazardous to soil organisms.

7.2 TERRESTRIAL VERTEBRATE TOXICITY – SUBCLASS 9.3

7.2.1 Thresholds

Schedule 6 of the threshold criteria defined in the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001 state:

2(1) A substance with ecotoxic properties is not hazardous for the purposes of the Act unless –

(c) the substance is ecotoxic to terrestrial vertebrates because:

(i) data for the substance indicates an acute avian or mammalian oral or dermal LD_{50} of 2 000 milligrams or less of the substance per kilogram body weight, as a result of exposure to the substance;

or

(ii) data for the substance indicates an acute avian or mammalian LC_{50} of 5 000 parts or less of the substance per million in the diet, as a result of exposure to the substance;

or

(iii) data for the substance indicates a chronic avian or mammalian MATC of 100 parts or less of the substance per million in the diet, as a result of exposure to the substance.

7.2.2 Classification

The HSNO classification criteria for substances with ecotoxicity properties under Schedule 6 identifies three classification categories for substances which are ecotoxic to terrestrial vertebrates (Subclass 9.3).

A subclass 9.3 classification and the subsequent Category apply to any substance which meets the following criteria:

(i) Category 9.3A- Substances that are very ecotoxic to terrestrial vertebrates:
(a) A substance for which data indicate an acute avian or mammalian LD_{50} less than or equal to 50 milligrams of the substance per kilogram of bodyweight; or
(b) A substance for which data indicate an acute avian or mammalian LC_{50} less than or equal to 500 parts per million of the substance in the diet.

(ii) Category 9.3B . Substance that are ecotoxic to terrestrial vertebrates:
(a) A substance for which data indicate an acute avian or mammalian LD_{50} greater than 50 milligrams, but less than or equal to 500 milligrams, of the substance per kilogram of bodyweight; or
(b) A substance for which data indicate an acute avian or mammalian LC_{50} greater than 500 parts per million, but less than or equal to 1000 parts per million, of the substance in the diet.

(iii) Category 9.3C . Substances that are harmful to terrestrial vertebrates:
(a) A substance for which data indicate an acute avian or mammalian LD_{50} greater than 500 milligrams, but less than or equal to 2000 milligrams, of the substance per kilogram of bodyweight; or

(b) A substance for which data indicate an acute avian or mammalian LC_{50} greater than 1000 parts per million, but less than or equal to 5000 parts per million, in the diet; or
(c) A substance for which data indicate a chronic avian or mammalian MATC of less than 100 parts per million of the substance in the diet**,** but which does not meet the criteria for hazard classification 9.3A or 9.3B.

The classification scheme for terrestrial vertebrates outlined above is presented in tabular form in Table 16:

Table 16 Classification scheme for terrestrial vertebrates (New Zealand)

HSNO Category	Measure
Category 9.3A (very ecotoxic to terrestrial vertebrates)	(a) $LD_{50} \leq 50$ mg/kg bw; or (b) LC50 ≤ 500 ppm in the diet
Category 9.3B (ecotoxic to terrestrial vertebrates)	(a) $50 < LD_{50} \leq 500$ mg/kg bw; or (b) $500 < LC_{50} \leq 1000$ ppm in the diet
Category 9.3C (harmful to terrestrial vertebrates)	(a) $500 < LD_{50} \leq 2000$ mg/kg bw or (b) $1000 < LC_{50} \leq 5000$ ppm in the diet; or (c) a chronic MATC of less than 100 ppm in the diet but which does not meet the criteria for Categories 9.3A and 9.3B

7.2.3 Definitions

Data: includes values that are directly measured, calculated, or estimated for any of the measures given

LC_{50}: the median lethal concentration, being a statistically derived concentration of a substance that can be expected to cause death in 50% of organisms exposed for a specified time

LD_{50}: a median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of organisms

LOEC: the lowest observed effect concentration, being the lowest concentration of a substance that produces a significant ecotoxic effect in an organism or organism population

MATC: the maximum acceptable toxicant concentration, being the geometric mean of the NOEC and LOEC where the NOEC and LOEC are derived from the same study

NOEC: the no observed effect concentration, being the highest concentration of a substance that does not produce a significant ecotoxic effect in an organism or in an organism population

Significant ecotoxic effect: an ecotoxicologically significant change in an organism or in an organism population observed during the study where the probability that the change is different from any recognised background history of change or from the value in a recognised unexposed control organism or organism population is greater than 0.95 (equivalent of P (probability) of 0.05 or less).

7.2.4 Acceptable test methodologies

Acute terrestrial vertebrate effect thresholds

The following test methodologies are deemed to meet the requirements for testing the acute terrestrial vertebrate effect thresholds (Table 17).

Table 17 Test methodologies for testing acute terrestrial vertebrate effect thresholds (New Zealand)

Test Protocol	OECD Code	USEPA OPPTS code	USEPA OPP code	USEPA OTS code	European Community
Acute oral mammalian toxicity	401	870.1100	81-1	798.1175	EC Method B.1.
Acute oral avian toxicity		850.2100	71-2	797.2050	
Acute dietary avian toxicity	205	850.2200	71-1	797.2175	

Chronic terrestrial vertebrate effects thresholds

The following test methodologies are deemed to meet the requirements for testing the chronic terrestrial vertebrate effects thresholds (Table 18).

Table 18 Test methodologies for testing chronic terrestrial vertebrate effect thresholds (New Zealand)

Test Methodologies	OECD Code	USEPA OPPTS code	USEPA OPP code	USEPA OTS code	European Community
Rodent sub-chronic oral toxicity	408	870.3100	82-1	798.2650	B.26
Non-rodent sub-chronic oral toxicity	409	870.3150	82-1		B.27
Avian Reproduction Test	206	850.2300	71-4	797.2130 797.2150	

7.2.5 *Mitigating factors / data interpretation*

Absence of measured data

Hazard classification for a substance or substance as a mixture that has measured data is outlined in Section 5.1.8 of the "User Guide to the HSNO. Thresholds and Classifications" (2).

ERMA New Zealand recognises that measured data will not be available for all hazard effect endpoints for all substances or substances as mixtures. The *HSNO (Minimum Degrees of Hazard) Regulations 2001* also acknowledges that data includes:

> "values that are directly measured, calculated, or estimated for any of the measures given"

Therefore while it should be noted that no measured data is available, classification of substance into a HSNO hazard classification Category can still occur using a weight of evidence approach that acknowledges all other data that is available on the substance. If this approach is used, any assumptions made and the weight of evidence approach for hazard classification should be clearly documented.

If there is no measured (direct) data or indirect data on the substance, the substance can not be assigned a definitive hazard classification.

Values expressed as NOEL, NOAEL or NOEC rather than a MATC

The MATC has a relationship to the NOEC, being bounded by the NOEC and LOEC. Therefore, the NOEC gives a conservative estimate of the MATC, and so if the NOEC for a substance does not trigger the threshold, it can be assumed that the MATC will also not trigger the threshold.

The quantitative prediction of the MATC from a NOEC value is more problematic. In some circumstances the MATC is given as a point estimate (rather than as the range from NOEC to LOEC), calculated as the geometric mean of the NOEC and LOEC. However, none of the test

guidelines require doses to be in a specified concentration series. As a result, an up-front conversion factor cannot be used based on the maximum differences between the NOEC and LOEC. If the original data package is available, the MATC can be derived by calculating from the NOEC and LOEC values (as the geometric mean).

MATC values expressed in units of ppm diet or mg/kg body weight, while the chronic threshold is limited to ppm diet

The expression of the MATC in mg/kg body weight is inconsistent with the chronic threshold ((1(c)(iii) above). Equations to determine the average food intake per body weight for standard test species are provided by the USEPA *Wildlife Exposure Factors Handbook*, 1993 (United States Environmental Protection Agency; Office of Research and Development, Vol. EPA/600/R-93/187) and are listed below. In order to accurately determine the food intake for a species, the body weight must be provided within the test report. Given the below conversion factors and the body weight of the animal, the units of dose can be converted from mg/kg body weight to ppm diet (mg/kg).

Food Intake (FI) rates (grams dry matter/day) from metabolisable energy from diets of general composition and field (or free-living) metabolic rates (Nagy, 1987) for birds and mammals are shown in Table19.

Table 19 Food intake rates from metabolisable energy (birds and mammals) (New Zealand)

Vertebrate Class	Food intake = (diet composition*body $^{\text{weightField Metabolic Rate}}$)
All birds	FI (g/day) = 0.648 * body weight (g)$^{0.651}$ FI (kg/day) = 0.0582 * body weight (kg)$^{0.651}$
Passerines (perching birds)	FI (g/day) = 0.398* body weight (g)$^{0.850}$
Non passerines	FI (g/day) = 0.301 * body weight (g)$^{0.751}$
Seabirds	FI (g/day) = 0.495 * body weight (g)$^{0.704}$
All mammals	FI (g/day) = 0.235 * body weight (g)$^{0.822}$ FI (kg/day) = 0.0687 * body weight (kg)$^{0.822}$
Rodents	FI (g/day) = 0.621 * body weight (g)$^{0.564}$
Herbivores	FI (g/day) = 0.577 * body weight (g)$^{0.727}$

Example
Converting a MATC of 40 mg atrazine/kg body weight/day from the OPPTS 870.3100 90 Day Oral Toxicity for Rodents Test (average rodent body weight taken as 0.250 kg) to units of ppm diet.

Step 1: converting mg/kg bodyweight/day to exposure as mg/day
= mg chemical/kg body weight/day * body weight (kg)
= 40 mg atrazine/kg bodyweight/day * 0.250 kg
= 10 mg/day

Step 2: calculating rodent food intake (kg/day) (using equation for all mammals)
= diet composition * body weight
= 0.0687 * 0.250 kg0.822
= 0.022 kg diet/day-1

Step 3: converting mg/day to ppm (as mg substance/kg diet)
= (mg/day) / (kg diet/day)
= (10 mg/day) / (0.022 kg diet/day)
= 454.5 mg/kg diet-1 (ppm).

Therefore, an MATC of 40 mg/kg body weight for 0.25 kg rodents can be considered equivalent to 454 ppm diet.

7.2.6 *Hazard cut-off levels*

It is acknowledged that certain percentage levels of a substance are unlikely to result in an adverse ecological effect when released to the environment. Therefore, ERMA New Zealand considers the following levels as acceptable percentage cut-offs at the threshold effect trigger level. If the following criteria are met, then the substance is not considered to trigger the threshold, that is the substance is not hazardous to the terrestrial vertebrates.

Condition	Endpoint
The substance is present at less than 1% and DT_{50} in soil < 30 days	Terrestrial vertebrate ecotoxicity

The generic hazard cut-off level does not apply if it can be shown that the substance causes a terrestrial vertebrate hazard that will be evident below the generic hazard cut-off level.

If the substance is a mixture, and it contains components that in their own right trigger the terrestrial vertebrate threshold(s) and are classified as ecotoxic to terrestrial vertebrates, for the substance as a mixture to be considered non-toxic, every component must meet this requirement (concentration less than 1% w/w). Alternatively data if on the substance as a mixture shows the mixture is not ecotoxic to the terrestrial vertebrates, then it is not ecotoxic to terrestrial vertebrates.

7.2.7 *Minimum data sets*

There is an overlap between tests that may be required for assessing terrestrial vertebrate ecotoxicity, and the tests that may be required for assessing human toxicity. Therefore the requirements for terrestrial vertebrate ecotoxicity data, and the comparable requirements for mammalian tests for human toxicity are described.

The HSNO Act covers many types of substances with varying degrees of hazardous properties. These substances also have different uses and circumstances of use. The risk associated with a hazardous substance is a function of the degrees of hazard of the substance and the level and duration of exposure to these hazards

Different types of hazardous substances present different levels of risk and will therefore require different types and levels of information for consideration of applications for approval.

Different levels of information could relate to the quantity, extent, or degree of detail of information, as applicable to the application involved. In recognition of this international risk based approach for when testing is required, and to prevent unnecessary testing of ecotoxicity endpoints when other methods of data interpretation can be used to calculate a hazard classification for a substance, the following minimum data sets may be used. It should be noted that there may be instances when the Authority will require additional data generation where there is uncertainty in the likely effect within the New Zealand environment.

For further guidance please refer to pp 49-52, Part VII of “User Guide to the HSNO Thresholds and Classifications” (2).

7.2.8 *Classification of substances*

Similar principles and mixture rules apply for classification of terrestrial vertebrate ecotoxicity as for aquatic ecotoxicity are used.

Once a substance triggers a threshold, it is then classified. While this is relatively straightforward for single substances (pure substances), substances as mixtures may be more complex. The process for classification of terrestrial vertebrate endpoints (and therefore whether the substance as a mixture triggers a threshold), is as follows:

(a) Where test data are available for the complete mixture, the classification of the mixture will always be based on that data;

(b) Where test data are not available for the mixture itself, then bridging principles should be considered to see whether they permit classification of the mixture;

(c) Where test data are not available for the mixture itself, and the available information is not sufficient to allow application of the bridging principles, the agreed method(s) for estimating the hazards based on the information known will be applied to classify the mixture (additivity formula or summation of classified components approach);

(d) Where a substance as a mixture contains components with no useable information on either acute or chronic terrestrial vertebrate effects, classification should be based on the known components only.

It should also be noted that the following data sources may be used for classification to a terrestrial vertebrate ecotoxicity category:

- data shows that the chemical structure of the new substance is similar to an existing scheduled substance under the *Toxic Substances Regulations 1983* or an approved substance with ecotoxic properties under the HSNO Act 1996 (either as structure activity relationship or a structure property relationship), or

- data from an in vitro study indicates the result is equivalent to results from an organism based study.

When any of the rules in Section 5.8 are applied, if a substance (or substance as a mixture) is classified as 9.3A, 9.3B, 9.3C or 9.3D, then an application to the Authority is required.

Mixture components

If the substance as a mixture contains any components (including impurities and additives) that have been identified and are themselves classified (or would be classified) under the HSNO legislation, then they shall be considered during classification of the substance as a mixture if they exceed the cut-off value/concentration limit for a given endpoint.

Synergestic / antagonistic effects

(a) If the applicant is aware of any available information about possible synergistic effects that may enhance the ecotoxicity of the substance as a mixture, this must be considered.

(b) Similarly if the applicant is aware of any available information that antagonistic effects may occur such that the substance as a mixture classification is lower than indicated from the calculated value, this should be noted. For example, encapsulation of a substance as a mixture can lower the ecotoxicity of the substance, or the amount of substance in the container is unlikely to result in an ecotoxic effect.