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Number 9

Report of the Survey of OECD Member Countries' Approaches
to the Regulation of Biocides

Part 2 of Annex 4 - Detailed Information on Data Requirements

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Data requirements for Structural pesticides

DATA REQUIREMENTS FOR APPROVAL OF STRUCTURAL PESTICIDES (use category 14)

MATRIX 1. CHEMICAL IDENTITY

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
IDENTITY OF THE ACTIVE INGREDIENT										
Common name	AI	A*	A [§]	A	A*	A _{CL}	A [♥] _{CL}	C	A	A
Chemical name (IUPAC) nomenclature	AI	A [♥]	A [@]	A [♥]	A	A	A [♥]	A	A	A
CAS and EEC numbers (if available)	AI	A [♥]	A [♣] _{CAS}	A [♣]	C	C	A [♥]	A	A	A
Empirical and structural formula and mass molecular	AI	A [♥]	A [♣]	A		C	A	A	A	A
Trade name(s)	AI	A	A	A	A		NR	A	A	NR
Method of manufacture	AI	A	A	A	NR		NR	A	C	A
Specification of purity	AI	A	A	A	C	A	A	A	A	A
Impurities and additives - identity, formation and range of each	AI	A [§]	A [♣]	A	NR	A _{CL}	NR	A	A	A
Name of manufacturer	AI	A	A	A	A	A	NR	A	A	A
Name of applicant	AI	A	A	A	A		A	A	A	A
Other										
<i>Country's patent status</i>	AI		A							
<i>Strength or concentration</i>	AI		A					A		
<i>Authorisation from the manufacturer</i>	AI			A				A	A	
<i>Origin of the natural active substance</i>	AI									A
<i>Exposure data in conformity with the Annex VII A to Directive 92/32/EEC</i>	AI									A

MATRIX 1. CHEMICAL IDENTITY - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
IDENTITY OF THE BIOCIDAL PRODUCT										
Trade name	BP	A	A	A _{CL}	A [§]	A _{CL}	A _{CL}	A	A	A
Composition: names and amount of -active ingredient(s), impurities, components	BP	A	A [§]	A _{CL}	A*	A _{CL}	A [♥] _{CL}	A	A _{CL}	A _{CL}
Physical state (emulsifiable concentrate, wettable powder, solution, etc.)	BP	A	A	A	A	A _{CL}	A _{CL}	A	A	A _{CL}
Name of manufacturer	BP	A	A	A	A	A	A _{CL}	A	NR	A
Name of applicant	BP	A	A	A _{CL}	A	A _{CL}	A _{CL}	A	A	A
Other										
Address, tel. no, fax no. of manufacturer	BP		A					A		
Contact person	BP		A							
Country's distributor	BP		A							
Referenced submissions	BP		A							
Package sizes available	BP		A					A		
Draft of proposed Canadian label	BP		A							
Description of formulation process	BP		A							
Marketing Company	BP								A	
Approval Holder	BP							A	A	
Authorisation from the manufacturer	BP			A						
CAS and EEC numbers and classification (according to general classification rules) of the other ingredients than the active ingredient(s)	BP			A				A		
Impurities and additives - identity, formation and range of each	BP							A	C _{CL}	

MATRIX 1. CHEMICAL IDENTITY - STRUCTURAL PESTICIDES

@	Canada: Both the CAS and IUPAC name are required for the active. Also, the CAS chemical name must be provided for impurities.
π	EU: Data requirements for structural pesticides if they are mainly insecticides
♣	Impurities always required
♥	Impurities and Transformation products always required
§	Impurities conditionally required
*	Impurities and Transformation products conditionally required
CL	Classification & Labelling
CAS	CAS numbers

DATA REQUIREMENTS FOR APPROVAL OF STRUCTURAL PESTICIDES (use category 14)**MATRIX 2. PHYSICAL/CHEMICAL PROPERTIES**

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
Colour	AI	A	A	A		A	A [♦]	C	A	A
	BP	A	C	A	A	A	A	NR	C	A
Physical state	AI	A	A	A		A	A [♦]	A	A _{CL}	A
	BP	A	A	A	A	A _{CL}	A	NR	A _{CL}	A
Odour	AI	A	A	A		C	A	C	NR	NR
	BP	A	C	A	A	C _{CL}	A	NR	NR	NR
pH	AI	A	C	NR		C	A	A	C _{CL}	NR
	BP	A	C	A _{CL}	A	A _{CL}	A	C	C _{CL}	A
Density	AI	A	A	A		C	A	A	A	A
	BP	A	A	A	C	C _{CL}	A	C	C	A
UV-visible, IR, NMR, Mass Spectra	AI	A	C [@]	A	C		A	C	A	A
	BP	C	NR	NR	C		A	NR	NR	NR
Melting point	AI	A	C	A	C	A	A	A	C	A
	BP	C	NR	NR		C _{CL}	C	NR	NR	NR
Boiling point	AI	A	C	A	C	A	A	A	A _{CL}	A
	BP	C	NR	NR		C _{CL}	C	NR	NR	NR
Vapour pressure	AI	A	C	A	C	A _{CL}	A	A	A	A
	BP	C	NR	NR		C _{CL}	NR	NR	NR	NR
Solubility in water as a function of pH and temperature	AI	A	A	A	A	C _{CL}	A	A	A	A
	BP	C	NR	NR		C _{CL}	NR	NR	NR	NR

MATRIX 2. PHYSICAL/CHEMICAL PROPERTIES - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
Solubility in organic solvents	AI	A	A	A	A	C _{CL}	A	A	NR	C
	BP	C	NR	NR		C _{CL}	C	NR	NR	NR
Octanol-water partition coefficient as a function of pH	AI	A	C	A	C	A _{CL}	C	A	A	A
	BP	C	NR	NR			C	NR	NR	NR
Dissociation constant in water	AI	A	C	A	C	C _{CL}	C*	A	A	NR
	BP	C	NR	NR			C	NR	NR	NR
Thermal stability	AI	A	A	A	A	C _{CL}	C	A	NR	A
	BP	A	NR	NR	A	C _{CL}	A	C	NR	A
Stability in air	AI	A	A	A		C _{CL}	C	A	NR	C
	BP	A	NR	NR	A	C _{CL}	A	C	NR	NR
Stability in presence of metal ions or sunlight as a function of temperature	AI	A	C	NR			C	C	NR	NR
	BP	C	NR	NR	A		A	C	NR	A
Viscosity	AI	C	NR	NR		C	C	C	C _{CL}	NR
	BP	C	C	A	C	C _{CL}	C	NR	C _{CL}	NR
Surface tension	AI	C	NR	A			C	C	C _{CL}	A
	BP	C	NR	A	NR		C	NR	C _{CL}	NR
Dielectric breakdown voltage	AI	C	NR	NR	NR		C	NR	NR	NR
	BP	C	C	NR	NR		C	NR	NR	NR
Oxidising properties	AI	A	NR	A			C	C	A _{CL}	A _{CL}
	BP	A	C	A _{CL}	C	C _{CL}	C _{CL}	C	C _{CL}	A _{CL}

MATRIX 2. PHYSICAL/CHEMICAL PROPERTIES - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
Flammability	AI	A	NR	A			A _{CL} [♥]	A	A _{CL}	A _{CL}
	BP	A	C	A _{CL}	A	C _{CL}	A _{CL} [♥]	A	A _{CL}	A _{CL}
Explosive properties	AI	A	NR	A			A _{CL} [♥]	A	A _{CL}	A _{CL}
	BP	A	C	A _{CL}	A	C _{CL}	A _{CL} [♥]	A	C _{CL}	A _{CL}
Storage stability or stability in solvents used in formulation	AI	A	NR	NR			A _{CL}	A	NR	NR
	BP	A	A	A	A	C _{CL}	A _{CL}	A	C	A
Corrosion characteristics	AI	A	NR	NR			A	C	NR	A _{CL}
	BP	A	C	NR	A	C _{CL}	A _{CL}	A	NR	A _{CL}
Reactivity toward container	AI	A	NR	NR			A	C	NR	A
	BP	A	C	NR	C	C _{CL}	A	C	C	A
Miscibility or suspensibility of product with water or other solvents	AI	A	NR	NR			A _{CL}	C	NR	NR
	BP	A	C	A	C	C _{CL}	A _{CL}	C	NR	A _{CL}
Flash point	AI	A	NR	A			A	C	A _{CL}	A
	BP	A	C	A	C	C _{CL}	A	C	C _{CL}	A
Wettability	AI	C	NR	NR			C	C	NR	NR
	BP	A	NR	A	C		C _{CL}	C	NR	A
Wet sieve and dry sieve test	AI	C	NR	NR			NR	C	NR	NR
	BP	A	NR	A	C	C	NR	C	NR	NR
Other										
<i>Particle size</i>	AI			NR						
	BP			C				A	C _{CL}	

MATRIX 2. PHYSICAL/CHEMICAL PROPERTIES - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
Particle size during the application of a product	AI									
	BP							A		
Refraction index	AI			C						
	BP			NR						
Henry's law constant (volatility)	AI							A		
	BP									
Fat solubility	AI			A				A		
	BP			NR						
Physical or chemical compatibility / incompatibility with other preparations	AI									
	BP							A		
Formulation type	AI									
	BP							A		
Hydrolysis as function of pH	AI									
	BP							A		
Decomposition or other reaction during combustion	AI			A						
	BP			NR						
Persistent foaming, flowability, pourability and dustability	AI									NR
	BP									A

π EU: Data requirements for structural pesticides if they are mainly insecticides

@ **Canada:** UV/VIS is conditionally required for AI; NR for BP. Mass Spec. is A for pure active and impurities; NR for BP.

♠ Transformation products always required

♥ Impurities and transformation products always required

♦ Transformation products conditionally required

* Impurities and Transformation products conditionally required

CL Classification & Labelling

DATA REQUIREMENTS FOR APPROVAL OF STRUCTURAL PESTICIDES (use category 14)**MATRIX 3. FUNCTION, MODE OF ACTION AND HANDLING**

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
Function (e.g. algicide, fungicide, insecticide, molluscicide, repellent, disinfectant, etc.)	AI	A	C	NR			A _{CL}	NR	A	A
	BP	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}
Mode of action on target organisms (e.g. .contact poison, inhalation poison, fungitoxic, fungistatic, etc.)	AI		C	NR	A		A _{CL}	NR	A	A
	BP	A		A	C _{CL}	C	A _{CL}	A	NR	A _{CL}
Field of use (e.g. indoor, outdoor, public or non-public)	AI			NR			A _{CL}	NR	NR	A
	BP	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}
Pests controlled/target organisms	AI			NR	C		A _{CL}	NR	NR	A
	BP	A _{CL}	A _{CL}	A	C	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}
Products to be protected	AI		A	NR	A		C _{CL}	NR	NR	A
	BP	A _{CL}	A _{CL}	NR	A	A _{CL}	A _{CL}	A	C _{CL}	A _{CL}
Application rate per unit treated area/volume/weight or concentration	AI			NR			A _{CL}	NR	NR	A
	BP	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}
Concentration of active ingredient in material used	AI		A	NR	NR		A _{CL}	NR	NR	NR
	BP	A _{CL}	A	NR	NR	A _{CL}	A _{CL}	A	A _{CL}	NR
Timing of applications and duration of protection	AI			NR			C _{CL}	NR	NR	NR
	BP	A _{CL}	C _{CL}	A _{CL}	A	A _{CL}	A _{CL}	A	C _{CL}	A _{CL}
Use intervals (time between application of biocide and use of facility or commodity)	AI			NR			A _{CL}	NR	NR	NR
	BP	A _{CL}	C _{CL}	C _{CL}	C _{CL}	A _{CL}	C _{CL}	A	C _{CL}	A _{CL}

MATRIX 3. FUNCTION, MODE OF ACTION AND HANDLING - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
Proposed instructions for use	AI		A _{CL}	NR			NR	NR	NR	NR
	BP	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}
Site preparation and method of application	AI			NR			NR	NR	NR	NR
	BP	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}
Type of packaging	AI			NR			C _{CL}	NR	NR	A
	BP	A	A	A	A _{CL}	A _{CL}	A _{CL}	A	A	A _{CL}
Procedures for cleaning application equipment	AI			NR			C _{CL}	NR	NR	NR
	BP	A		NR	A _{CL}	C _{CL}	A _{CL}	A	NR	A _{CL}
Recommended methods and precautions for handling, storage, transport or fire (including reaction products)	AI		C _{CL}	NR			C _{CL}	NR	NR	A
	BP	A _{CL}	C _{CL}	A _{CL}	A _{CL}	C _{CL}	A _{CL}	A	NR	A _{CL}
Emergency measures in case of accidents	AI		C _{CL}	NR			A _{CL}	NR		A
	BP	A	C _{CL}	A _{CL}	A _{CL}	C _{CL}	A _{CL}	A		A _{CL}
Other										
<i>Fixation time on wood</i>	AI									
	BP							C		
<i>Information on resistance and development of strategies to cope with</i>	AI							A		A
	BP									A
<i>Quantities (manufactured or imported) placed in market every year</i>	AI			NR						A
	BP			A				A		NR
<i>Function of the other ingredients than the active ingredient(s) in the biocidal product</i>	BP							C		

MATRIX 3. FUNCTION, MODE OF ACTION AND HANDLING - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
<i>Undesirable secondary effects for example on useful organisms</i>	AI									
	BP							A		
<i>Disposal statement</i>	AI									
	BP							A		
<i>Advise and instructions for the disposal of unfinished products or contaminated packages</i>	BP							A		
<i>Instructions for the disposal of treated wood</i>	BP									
<i>Information on the possibility of destruction with: controlled waste disposal, incineration, waste water treatment plans or other techniques.</i>	AI									
	BP							A		
<i>Information on any possibility of rendering the active organism non-infective after release in or into the following: air, water, soil.</i>	BP							C		
<i>Directions or restrictions for treated materials</i>	AI									
	BP							A		
<i>Proposal for labelling and instructions for use</i>	AI		A	NR						
	BP		A	A _{CL}						
<i>Prior approval, use in other countries</i>	AI			NR						
	BP			C						
<i>Safety data sheet</i>	AI		A	NR						
	BP			A				A		
<i>Miscibility with other biocides</i>	AI			NR						
	BP		C _{CL}	A						

MATRIX 3. FUNCTION, MODE OF ACTION AND HANDLING - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
<i>Classification of the product according to general classification rules for chemicals</i>	AI		A _{CL}	NR						
	BP		A _{CL}	A _{CL}				A		
<i>Pack size</i>	AI		A							
	BP		A					A	A	
<i>Intended user</i>	AI									
	BP		A _{CL}						A	

π EU: Data requirements for structural pesticides if they are mainly insecticides

CL Classification & Labelling

DATA REQUIREMENTS FOR APPROVAL OF STRUCTURAL PESTICIDES (use category 14)**MATRIX 4. ANALYTICAL METHODS**

Entries in the “BP” rows refer to formulates other than the active ingredients for which a concern may arise.

Type of Data/Information		AUS	CAN ^δ	FIN	HUN	NZ	POR	SWE	UK	EU ^π
Pure active ingredients and isomers, impurities and additives of the technical grade of the active ingredient or formulation	AI	A ^{♦♦}	A [*]	A [*]	A [*]	A	A	C	A	A
	BP	A ^{♦♦}	A [*]	A [*]		C	A	C	C	A
Active ingredients in food or feed(multi-residue methods) or treated product	AI	A ^{♦♦}		A [*]	A	C	A _{CL}	NR	NR	C
	BP	A ^{♦♦}		NR		C	A _{CL}	NR	NR	A
Composition of formulated product	AI	A [*]		NR			A _{CL} [§]	NR	A _{CL}	NR
	BP	A [*]		A	A	A	A _{CL} [§]	A	C _{CL}	A
Residues in water, including potable water	AI	NR	C [*]	A [♦]		C	C _{CL}	A	A [♦]	A
	BP	NR		NR	A/C		C _{CL}	A	NR	A
Residues in air	AI	NR		NR		C	C _{CL}	NR	C [♦]	A
	BP	NR		NR	NR		C _{CL}	NR	NR	A
Residues in soil	AI	C [♦]	A [*]	A [♦]	C	C	C _{CL}	C	C [♦]	A
	BP	NR		NR	C		C _{CL}	C	NR	A
Residues in sediment	AI	NR	C [*]	C	C	C	C _{CL}	C	C [♦]	C
	BP	NR		NR	C		C _{CL}	C	NR	C
Residues in biota (biological tissue such as plants, fish, birds, wild mammals, etc.)	AI	NR	C [*]	A [♦]	C	C	C _{CL}	A	C [♦]	C
	BP	NR		NR	C		C _{CL}	A	NR	C

MATRIX 4. ANALYTICAL METHODS - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN ^δ	FIN	HUN	NZ	POR	SWE	UK	EU ^π
Residues in human body fluids	AI	NR		NR	NR	C	C* _{CL}	NR	NR	A
	BP	NR		NR			C* _{CL}	NR	NR	A

δ **Canada:** Active in TGAI: Validated methodologies for specifically identifying and quantifying the active ingredients and each impurity present at or above 0.1% by weight, or those of toxicological significance at any level above the practical limit of quantitation, are required. A method capable, must also be provided. Corresponding supporting raw data for all specified components from five (5) batches is required.

Active in Formulation: A validated analytical method suitable for enforcement purposes must be provided for each active ingredient in a end-use product with a requirement for specific determination of stereoisomers, when applicable. Raw data demonstrating the lack of interference of formulation components must also be provided. If potential exists for the formulators/formulating process to create or enhance the presence of an impurity of toxicological concern, validated methodology and corresponding raw data from the analysis of five (5) batches are required.

π **EU:** Data requirements for structural pesticides if they are mainly insecticides

♣ Impurities always required

§ Impurities conditionally required

♦ Transformation products conditionally required

* Impurities and Transformation products conditionally required

CL Classification & Labelling

DATA REQUIREMENTS FOR APPROVAL OF STRUCTURAL PESTICIDES (use category 14)**MATRIX 5. EFFICACY OF FORMULATIONS**

Type of Data/Information		AUS ^ζ	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
Effects on quality of treated substance	AI	see note	NR	NR			C [♦] _{CL}	C	NR	NR
	BP		C	NR	C	A _{CL}	A [♦] _{CL}	C	NR	NR
Dose/efficacy relationships (minimum inhibition-concentration scale)	AI		NR	NR	A/C		A _{CL}	C	A	NR
	BP		NR	A _{CL}		A _{CL}	A _{CL}	C	C	A
Evidence of effectiveness under working conditions	AI		NR	NR	NR		C _{CL}	A	NR	NR
	BP		C	A		A _{CL}	A _{CL}	A	C	A

ζ **Australia:** Although, Australia stated that efficacy data are required for all registerable products, information on what data are required has not been provided

π **EU:** Data requirements for structural pesticides if they are mainly insecticides

♦ Transformation products conditionally required

* Impurities and transformation products conditionally required

CL Classification & Labelling

DATA REQUIREMENTS FOR APPROVAL OF STRUCTURAL PESTICIDES (use category 14)

MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
ABIOTIC										
Hydrolysis rate including identification of metabolites and breakdown products	AI	A	A*	NR	C	C _{CL}	C	NR	A [♦]	A
	BP						C _{CL}	A	C [♦]	NR
Photodegradation in water including identification of metabolites and breakdown products	AI	C	NR		C	C _{CL}	C	NR	C [♦]	A
	BP						C _{CL}	C	C [♦]	NR
Photodegradation on soil including identification of metabolites and breakdown products	AI	C	NR		C	C _{CL}	C	NR	C [♦]	NR
	BP						C _{CL}	C	C [♦]	NR
Rate and route of photochemical degradation in air, identification of breakdown products	AI	C	C*		C	C _{CL}	C	NR	C [♦]	C
	BP						C _{CL}	C	NR	NR
Other										
Information on emission to the air	AI									
	BP							A		
BIOTIC										
Soil metabolism, aerobic and anaerobic, to determine rate and route of degradation in representative soil types including metabolites and breakdown products	AI	A	A* _{ae} NR _{ana}	NR	A/C	C _{CL}	C	C	C [♦]	C
	BP						C _{CL}	NR	C [♦]	C
Aquatic sediment metabolism, aerobic and anaerobic, including identification of breakdown products and metabolites	AI	C	NR		C	C _{CL}	C		C [♦]	C
	BP						C _{CL}	NR	C [♦]	C

MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
BIOTIC (cont.)										
Mobility/leaching in representative soil types and mobility of metabolites and breakdown products	AI	A	C*	NR	C	C _{CL}	C	C	C [♦]	C
	BP						C _{CL}	NR	C [♦]	C
Adsorption/desorption in representative soil types including metabolites and breakdown products	AI	A	C*		C	C _{CL}	C	C	A [♦]	C
	BP						C _{CL}	NR	C [♦]	C
Laboratory volatility	AI	C	C*		C		NR	A	A	NR
	BP						NR	NR	NR	NR
Special degradation of biocides in effluents	AI	C	NR		C	C _{CL}	C _{CL}	NR	NR	NR
	BP						C _{CL}	NR	NR	C
Adsorption/desorption screen	AI	A	NR		C	C _{CL}	C	C	C	A
	BP						C _{CL}	NR	NR	C
Ready biodegradability	AI	C	NR		C	C _{CL}	C _{CL}	C	C	A
	BP						C _{CL}	NR	C	NR
Inherent biodegradability	AI	C	NR		C	C _{CL}	C _{CL}	NR	C	A
	BP						C _{CL}	NR	NR	NR
Aerobic aquatic biotransformation in natural water	AI	C	C*		C	C _{CL}	C _{CL}	NR	C	C
	BP						C _{CL}	C	C	C
LEACHING										
Leaching from treated wood	AI	A		NR	C	C _{CL}	C _{CL}	A	A	C
	BP		NR				C _{CL}	A	C	C
Leaching from anti-fouling paint	AI	NR			C	C _{CL}	C _{CL}		A	C
	BP		NR				C _{CL}		C	C

MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
FIELD TESTING										
Small plot field tests or terrestrial field studies	AI	C		NR	C	C _{CL}		NR		NR
	BP		A*					C		C
Aquatic field studies	AI	C			C	C _{CL}		NR		NR
	BP		C*					NR		C

π EU: Data requirements for structural pesticides if they are mainly insecticides

♣ Impurities always required

◆ Transformation products conditionally required

* Impurities and Transformation products conditionally required

CL Classification & Labelling

ae aerobic

ana anaerobic

DATA REQUIREMENTS FOR APPROVAL OF STRUCTURAL PESTICIDES (use category 14)**MATRIX 7. ECOTOXICOLOGY**

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
AVIAN TESTING										
Avian acute oral LD50	AI	C	NR	NR	A	C _{CL}	C _{CL}	NR	C	C
	BP					C _{CL}	C _{CL}	NR	C	C
Avian dietary toxicity LC50 - terrestrial bird (short-term toxicity)	AI	C	NR		C	C _{CL}	NR	NR	C	C
	BP					C _{CL}	NR	NR	C	NR
Avian dietary toxicity LC50 - aquatic bird (short-term toxicity)	AI	C	NR		NR	C _{CL}	NR	NR	C	C
	BP					C _{CL}	NR	NR	C	NR
Avian reproduction test - terrestrial bird	AI	C	NR		NR	C _{CL}	NR	NR	C	C
	BP						NR	NR	C	NR
Avian reproduction test - aquatic bird	AI	C	NR		NR	C _{CL}	NR	NR	C	C
	BP						NR	NR	C	NR
Avian field testing	AI	C			C		NR		NR	?
	BP		NR			C _{CL}	NR		NR	C
Acceptance of bait, treated items by birds	AI	C	NR		NR		NR		NR	?
	BP					C	NR		C	C
AQUATIC TESTING (not including algae)										
Fish acute toxicity LC50, freshwater; warm water species	AI	C	C*	NR	A	C _{CL}	C _{CL}	C	C _{CL}	A
	BP					C _{CL}	C _{CL}	C	C _{CL}	C
Fish acute toxicity LC50, freshwater; cold water species	AI	C	C*		C	C _{CL}	C _{CL}	A	A _{CL}	A
	BP					C _{CL}	C _{CL}	A	C _{CL}	C

MATRIX 7. ECOTOXICOLOGY - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
AQUATIC TESTING (not including algae) (cont.)										
Daphnia acute immobilization test	AI	C	C*	NR	A	C _{CL}	C _{CL}	A	A _{CL}	?
	BP					C _{CL}	C _{CL}	A	C _{CL}	?
Marine or estuarine fish acute toxicity LC50/EC50	AI	C	C*		C	C _{CL}	NR	NR	C _{CL}	C
	BP					C _{CL}	NR	NR	C _{CL}	C
Daphnia life cycle (reproduction test)	AI	C			A	C _{CL}	NR	A	C _{CL}	C
	BP					C _{CL}	NR	A	C _{CL}	C
Fish reproduction and growth rate	AI	C	NR		NR	C _{CL}	NR	NR	C	C
	BP					C _{CL}	NR	NR	C	C
Fish life cycle/chronic toxicity to fish or fish early life stage	AI	C	NR		NR	C _{CL}	NR	NR	C	C
	BP					C _{CL}	NR	NR	C	C
Fish bioconcentration	AI	C	C*		NR	C _{CL}	NR	A	C	C
	BP					C _{CL}	NR	NR	C	C
Acute toxicity to marine invertebrates	AI	C			NR		C _{CL}	NR	C _{CL}	NR
	BP						C _{CL}	NR	C _{CL}	C
<i>Acute (crustacean, e.g. shrimp)</i>	AI		C*							
	BP							A		
Chronic toxicity to marine invertebrates	AI	C	NR		NR		NR	NR	C _{CL}	NR
	BP						NR	NR	C _{CL}	C
Field studies	AI	C	NR		C		C _{CL}	NR	C	?
	BP						C _{CL}	NR	C	C

MATRIX 7. ECOTOXICOLOGY - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
AQUATIC TESTING (not including algae) (cont.)										
Other aquatic tests				NR						
Bioconcentration depuration(bivalve or crustacean)	AI		C*					C		
	BP									
Bioaccumulation	AI							C		
	BP									
Test on sediment dwelling species	AI							C		
	BP									
Short term toxicity test daphnia	AI							A		
	BP									
PHYTOTOXICITY TO NON-TARGET PLANTS										
Algae, growth inhibition - freshwater	AI	C	C*	NR	NR/C	C _{CL}	C _{CL}		C _{CL}	A
	BP						C _{CL}		C _{CL}	C
Algae, growth inhibition - marine	AI	C	NR		NR	C _{CL}	C _{CL}		C _{CL}	A
	BP						C _{CL}		C _{CL}	C
Aquatic plant growth	AI	C	NR		NR		NR		C	C
	BP					C _{CL}	NR		C	C
Seed germination/seedling emergence	AI	C	NR		NR		NR		NR	C
	BP					C _{CL}	NR		NR	C
Other on-target plant tests	AI				NR					C
	BP									C
Short term toxicity test algae	AI							A		
	BP									

MATRIX 7. ECOTOXICOLOGY - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
TESTING ON OTHER NON-TARGET SPECIES										
Effects on earthworms	AI	C	NR	NR	NR	C _{CL}	C _{CL}		C	C
	BP					C _{CL}	C _{CL}		C	C
Effects on beneficial insects	AI	C	NR		NR		NR		C	C
	BP					C _{CL}	NR		C _{CL}	C
Effects on terrestrial vertebrates other than birds	AI	C	NR		NR	C _{CL}	C _{CL}		C	C
	BP					C _{CL}	C _{CL}		C _{CL}	C
Activated sludge, respiration inhibition test	AI	C	NR		NR	C _{CL}	NR		A	C
	BP					C _{CL}	NR		C	C
Other	AI									C
	BP									C
<i>Evaluation of the environmental fate and effects of other ingredients, than a.i. in the product or in the a.i. (e.g. impurities, metabolites solvents and other additives)</i>	AI									
	BP							C		

π EU: Data requirements for structural pesticides if they are mainly insecticides

* Impurities and Transformation products conditionally required.

CL Classification and Labelling

DATA REQUIREMENTS FOR APPROVAL OF STRUCTURAL PESTICIDES (use category 14)**MATRIX 8. RESIDUE CHEMISTRY**

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π	
IDENTIFICATION OF RESIDUES											
Nature of the residue in/on treated material or animal	AI	C [♦]	NR	C	C	C	A [♥] _{CL}	NR	C	C	
	BP	NR		C			A [♥] _{CL}		NR	C	
MAGNITUDE OF THE RESIDUE ON/ IN THE TREATED MATERIAL OR ANIMAL											
Wood	AI	NR	NR	NR	NR	C		NR	NR		
	BP	NR		NR		C			C		
Wool	AI	NR		NR	NR	C			NR		
	BP	NR		NR		C			NR		
Livestock	AI	C [♦]		C	NR				NR	C	
	BP	NR		C						C	
Consumer residues	AI								C [♦]		
	BP								C [♦]		
All food producing species	AI						A [♥] _{CL}				
	BP						A [♥] _{CL}				
As listed on the label/use directions	AI					C					
	BP					C					
Fish	AI	C [♦]		NR	NR	C	A [♥] _{CL}				C
	BP	NR		NR			A [♥] _{CL}				C

MATRIX 8. RESIDUE CHEMISTRY - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π	
MAGNITUDE OF THE RESIDUE ON/ IN THE TREATED MATERIAL OR ANIMAL (cont.)											
Freezer or storage stability tests for any of the above magnitude of the residue tests	AI	C [♦]	NR	NR	NR	C	C _{CL}	NR			
	BP	NR		NR		C	A _{CL}			C	
Other											
Surfaces which contact directly with food animal derivatives	AI						A [♥] _{CL}				
	BP						A [♥] _{CL}				
Dislodgeable residue from treated furnishings	AI									NR	
	BP									C	
OTHER REQUIREMENTS											
Proposed tolerance or maximum residue levels	AI	C [♦]	NR	NR	C	C	A _{CL}	NR	NR	C	
	BP	NR		NR			A _{CL}		NR	C	
Effects of preparation on residues (e.g. cooking, processing)	AI	C [♦]		NR	NR		A [♠] _{CL}			NR	C
	BP	NR		NR		C	A [♠] _{CL}			NR	C
Effects on odour, taste and quality of food due to residues	AI	C [♦]		NR	C		A _{CL}			NR	C
	BP	NR		NR		C	A _{CL}			NR	C

π EU: Data requirements for structural pesticides if they are mainly insecticides

♠ Transformation products always required

♥ Impurities and Transformation products always required

* Impurities and Transformation products conditionally required

♦ Transformation products conditionally required

CL Classification & Labelling

DATA REQUIREMENTS FOR APPROVAL OF STRUCTURAL PESTICIDES (use category 14)

MATRIX 9. TOXICOLOGY

Type of Data/Information		AUS	CAN	FIN ^α	HUN	NZ	POR	SWE	UK	EU ^π
ACUTE TESTING										
Acute oral	AI	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A*	A	A _{CL}	A _{CL}
	BP	C _{CL}	A _{CL}	A _{CL}		C _{CL}	A*	A	A _{CL}	A _{CL}
Acute dermal	AI	A _{CL}	A _{CL}	A _{CL}	C	A _{CL}	A*	A	A _{CL}	A _{CL}
	BP	C _{CL}	A _{CL}	A _{CL}		C _{CL}	A*	A	A _{CL}	A _{CL}
Acute inhalation	AI	A _{CL}	A _{CL}	A _{CL}	C	A _{CL}	A*	A	C _{CL}	A _{CL}
	BP	C _{CL}	A _{CL}	A _{CL}		C _{CL}	A*	A	C _{CL}	A _{CL}
Acute dermal irritation	AI	A _{CL}	A _{CL}	C _{CL}	A	A _{CL}	A*	A	A _{CL}	A _{CL}
	BP	C _{CL}	A _{CL}	C _{CL}	C	C _{CL}	A*	C	A _{CL}	A _{CL}
Acute eye irritation	AI	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A*	A	A _{CL}	A _{CL}
	BP	C _{CL}	A _{CL}	A	C	C _{CL}	A*	A	A _{CL}	A _{CL}
Skin sensitisation	AI	A _{CL}	A _{CL}	A _{CL}	C	A _{CL}	A*	A	A _{CL}	A _{CL}
	BP	C _{CL}	A _{CL}	NR _{CL}	C	C _{CL}	A*	C	A _{CL}	A _{CL}
Potentiation/interactions of multiple active ingredients or products	AI	C		NR	NR	C _{CL}	A*	C	NR	NR
	BP			NR			A*	C	NR	A
Other										
<i>Information on dermal absorption</i>	AI									A
	BP									A

MATRIX 9. TOXICOLOGY - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN	FIN ^α	HUN	NZ	POR	SWE	UK	EU ^π
SUBCHRONIC TESTING										
Repeated dose oral - 28 day	AI	C _{CL}		NR	C	C _{CL}	C	C	C _{CL}	A _{CL}
	BP			NR			C _{CL}	NR	NR _{CL}	NR
Repeated dose inhalation - 28 day	AI	C _{CL}		NR	NR	C _{CL}	C	A	C _{CL}	C _{CL}
	BP			NR			C _{CL}	NR	NR _{CL}	NR
Subchronic oral rat -90 day	AI	A _{CL}	A	A _{CL}	NR/C	A _{CL}	A _{CL}	C	C _{CL}	A _{CL}
	BP			NR _{CL}			A _{CL}	NR	NR _{CL}	NR
Subchronic oral non-rodent -90 day	AI	A _{CL}	A	A _{CL}	C	C _{CL}	A _{CL}	C	NR	A _{CL}
	BP			NR _{CL}			A _{CL}	NR	NR	NR
Subchronic dermal -90 day	AI	C _{CL}	C	C _{CL}	C	C _{CL}	C	C	C _{CL}	C _{CL}
	BP			NR _{CL}			C _{CL}	NR	NR _{CL}	NR
Subchronic inhalation -90 day	AI	C _{CL}	C	C _{CL}	NR	C _{CL}	C	C	C _{CL}	C _{CL}
	BP			NR _{CL}			C _{CL}	NR	NR _{CL}	NR
Repeated dose dermal toxicity -21/28 day	AI	C _{CL}	C	NR	C	C _{CL}	A _{CL}	C	NR	NR
	BP			NR			A _{CL}	NR	NR	NR
Other										
<i>A short term study by the most useful route may be required if there is evidence of or known potential for synergism among any of the ingredients.</i>	BP		C							

MATRIX 9. TOXICOLOGY - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN	FIN ^α	HUN	NZ	POR	SWE	UK	EU ^π
DEVELOPMENT TOXICITY AND REPRODUCTION STUDIES										
Teratogenicity rodent	AI	A _{CL}	A	A _{CL}	C	A _{CL}	A _{CL}	C	C _{CL}	A _{CL}
	BP			NR _{CL}			A _{CL}	NR	NR _{CL}	NR
Teratogenicity-second species	AI	A _{CL}	A	C _{CL}	C	A _{CL}	A _{CL}	C	C _{CL}	A _{CL}
	BP			NR _{CL}			A _{CL}	NR	NR _{CL}	NR
Multi-generation reproduction	AI	A _{CL}	A	A _{CL}	C	C _{CL}	A _{CL}	C	C _{CL}	A _{CL}
	BP			NR _{CL}			A _{CL}	NR	NR _{CL}	NR
Reproductive screen	AI	NR		NR	C	C _{CL}	C	C	NR	NR
	BP			NR			C _{CL}	NR	NR	NR
METABOLISM TESTING										
Toxicokinetics/metabolism	AI	A	A*	A	C	A _{CL}	C	A	C	A
	BP			NR			A _{CL}	NR	NR	NR
CHRONIC TESTING										
Chronic toxicity rodent	AI	A _{CL}	A	A _{CL}	C	A _{CL}	A _{CL}	C	NR	A _{CL}
	BP			NR _{CL}			A _{CL}	NR	NR	NR
Chronic toxicity non-rodent	AI	A _{CL}		A _{CL}	C	A _{CL}	A _{CL}	C	NR	A _{CL}
	BP			NR _{CL}			A _{CL}	NR	NR	NR
Carcinogenicity - rat	AI	A _{CL}	A	A _{CL}	C	C _{CL}	A _{CL}	C	C _{CL}	A _{CL}
	BP			NR _{CL}			A _{CL}	NR	NR _{CL}	NR
Carcinogenicity - second species	AI	A _{CL}		NR			C _{CL}	C		
	BP			NR			C _{CL}	NR		

MATRIX 9. TOXICOLOGY - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN	FIN ^α	HUN	NZ	POR	SWE	UK	EU ^π
CHRONIC TESTING (cont.)										
<i>Mouse</i>	AI		A			C _{CL}			C _{CL}	
	BP								NR _{CL}	
<i>Other mammalian species</i>	AI									A _{CL}
	BP									NR
<i>Other chronic test</i>	AI							C		
	BP							NR		
MUTAGENICITY										
Testing for specific endpoints	AI	A	A	A/C _{CL}	A	A	A	C	A	A _{CL}
	BP			NR _{CL}				NR		NR
<i>In-vitro gene mutation in bacteria (AMES TEST)</i>	AI	A _{CL}		A/C _{CL}		A _{CL}	A _{CL}		A _{CL}	A _{CL}
	BP			NR _{CL}			A _{CL}		NR _{CL}	NR
<i>In-vitro gene mutation assay in mammalian cells</i>	AI					A _{CL}			C _{CL}	A _{CL}
	BP								NR _{CL}	NR
<i>Microbial or mammalian point mutation [= point mutations (with and without microsomal activation) in procaryotic and/or eucartoyic cells in vitro]</i>	AI		A							
	BP									
<i>In-vitro cytogenetics study in mammalian cells</i>	AI			A/C _{CL}					A _{CL}	A _{CL}
	BP			NR _{CL}					NR _{CL}	NR
<i>In-vitro chromosomal aberrations</i>	AI	A _{CL}	A			A _{CL}				
	BP									

MATRIX 9. TOXICOLOGY - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS	CAN	FIN ^α	HUN	NZ	POR	SWE	UK	EU ^π
MUTAGENICITY (cont.)										
<i>In-vivo mutagenicity study (bone marrow assay for chromosomal damage or micronucleus test)</i>	AI									C _{CL}
	BP									NR
<i>In-vivo study to examine whether mutagenicity or evidence of DNA damage can be demonstrated in tissue other than bone marrow (= in-vivo assay in second tissue, e.g. liver UDS)</i>	AI								C _{CL}	C _{CL}
	BP								NR _{CL}	NR
<i>Assessment of possible germ cell effects (= dominant lethal)</i>	AI									C _{CL}
	BP									NR
<i>In-vivo chromosomal aberrations</i>	AI	A _{CL}	A						C _{CL}	
	BP								NR _{CL}	
NEUROTOXICITY TESTING										
Acute neurotoxicity - rat	AI	C _{CL}		NR	C	C _{CL}	C _{CL}	C	NR	C
	BP			NR			C _{CL}	NR	NR	NR
Acute delayed neurotoxicity of organophosphates-hen	AI	C _{CL}	C	C _{CL}	C	C _{CL}	C _{CL}	C	C	C
	BP			NR _{CL}			C _{CL}	NR	NR	NR
28 day delayed neurotoxicity	AI	C _{CL}		NR	C	C _{CL}	C	C	NR	C
	BP			NR			C _{CL}	NR	NR	NR
Subchronic neurotoxicity - rat -90 day	AI	C _{CL}	C	NR	C	C _{CL}	C	C	NR	C
	BP			NR			C _{CL}	NR	NR	NR
Subchronic delayed neurotoxicity of hen - organophosphates	AI	C _{CL}		NR	C	C _{CL}	C	C	C	C
	BP			NR			C _{CL}	NR	NR	NR

MATRIX 9. TOXICOLOGY - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS ^ζ	CAN	FIN ^α	HUN	NZ	POR	SWE	UK	EU ^π
NEUROTOXICITY TESTING (cont.)										
Postnatal developmental neurotoxicity	AI	NR	C	NR	C	C _{CL}	C	C	NR	C
	BP			NR			C _{CL}	NR	NR	NR
<i>Other</i>										
<i>Acute delayed neurotoxicity - rat</i>	AI		C							
	BP									
OTHER TESTING										
Toxic effects in livestock and pets	AI		A	NR	C	C _{CL}	A _{CL}	NR	NR	C
	BP			NR		C _{CL}	A _{CL}	NR	NR	NR
Antidote	AI	NR		A	C	C _{CL}	A _{CL}	C	NR	A
	BP			A _{CL}			C _{CL}	C	NR	A
MEDICAL DATA										
Medical surveillance of manufacturing plant personnel	AI	C _{CL} C* _{CL}		C	C	C _{CL}	C	C	C	A
	BP	C* _{CL}		C		C _{CL}	C	C	C	NR
Clinical cases and poisoning incidents	AI	C _{CL} C* _{CL}		C	A	C _{CL}	C	C	C	A
	BP	C* _{CL}		C		C _{CL}	C	C	C	NR
Health records from industry and public users	AI	C _{CL} NR		C	C	C _{CL}	C	C	C	A
	BP			C		C _{CL}	C	C	C	NR
Observations of exposure of the general population or epidemiological studies	AI	C _{CL} ^N R		C			C _{CL}	C	C	A
	BP			C			C _{CL}	C	C	NR

MATRIX 9. TOXICOLOGY - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS ^ζ	CAN	FIN ^α	HUN	NZ	POR	SWE	UK	EU ^π
MEDICAL DATA (cont.)										
Other										
<i>Epidemiological studies of occupational users</i>	AI	C* _{CL}								
	BP	C* _{CL}								
<i>Evaluation of the toxicity of other ingredients than a.i. in the product or in the a.i. (e.g. impurities, metabolites, solvents and other additives)</i>	AI			C						
	BP			C						

ζ **Australia:** with a) regular fonts are listed data requirements for public health exposure and b) *italics* are listed d.r. for occupational exposure

α **Finland:** Data on toxicology of impurities or transformation products is required on a case-by-case basis

π **EU:** Data requirements for structural pesticides if they are mainly insecticides

* Impurities and Transformation products conditionally required

CL Classification & Labelling

DATA REQUIREMENTS FOR APPROVAL OF STRUCTURAL PESTICIDES (use category 14)**MATRIX 10. HUMAN EXPOSURE**

Type of Data/Information		AUS ^ζ	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
Wetting, adherence and distribution to target areas or in products	AI	NR C*		NR	NR		C _{CL}	C	NR	
	BP	NR C*	NR				C _{CL}	C	NR	
Dermal penetration	AI	C A*					C _{CL}	C	C	
	BP	C A*	C			C _{CL}	C _{CL}	C	C	
Dermal exposure for applicator	AI	NR A*					C _{CL}	A		
	BP	C A* _{CL}	A			C _{CL}	C _{CL}	A	C	
Dermal exposure for bystanders	AI	NR C					C _{CL}	C		
	BP	NR C _{CL}	C			C _{CL}	C _{CL}	C	C	
Dermal exposure for people handling treated article	AI	C C*					C _{CL}	C		
	BP	NR C* _{CL}	C			C _{CL}	C _{CL}	C	C	
Inhalation exposure for applicator	AI	NR A*					C _{CL}	A		
	BP	C A* _{CL}	A			C _{CL}	C _{CL}	A	C	

MATRIX 10. HUMAN EXPOSURE - STRUCTURAL PESTICIDES (cont.)

Type of Data/Information		AUS ^ξ	CAN	FIN	HUN	NZ	POR	SWE	UK	EU ^π
Inhalation exposure for bystanders	AI	NR C		NR	NR		C _{CL}	C		
	BP	NR C _{CL}	C			C _{CL}	C _{CL}	C	C	
Inhalation exposure for people handling treated article	AI	C C					C _{CL}			
	BP	NR C* _{CL}	C			C _{CL}	C _{CL}		C	
Indoor surface dissipation	AI	NR C*					C _{CL}			
	BP	NR C* _{CL}	NR			C _{CL}	C		C	
Other										
Worker re-entry to treated areas	AI	A*								
	BP	A* _{CL}								
Glove clothing penetration data	AI									
	BP		C							
Package integrity study	AI									
	BP		C							
Product use information	AI									
	BP		C							
Description of human activity	AI									
	BP		C							

MATRIX 10. HUMAN EXPOSURE - STRUCTURAL PESTICIDES

- ζ **Australia:** Data requirements for public health and occupational exposure; occupational exposure requirements are presented in italics where different than the public health.
- π **European Union:** The specific data requirements on humans, animals and the environment exposure to be submitted for each of 23 EU product types and according to the use pattern are under preparation.
- * Impurities and Transformation products conditionally required.
- CL Classification & Labelling.

**Data requirements for
Products used in aquatic
non-food sites**

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (use categories 18-21)

MATRIX 1. CHEMICAL IDENTITY

Type of Data/Information		AUS	BEL	CAN	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^³	NZ	USA	EU
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
IDENTITY OF THE ACTIVE INGREDIENT												
Common name	AI	A*	A	A [§]	A [♥] _{CL}	A _{CL}	A*	A* _{CL}	A	A _{CL}	A	A
Chemical name (IUPAC) nomenclature	AI	A [♥]	A	A [@]	A [♥]	A	A	A* _{CL}		C [§]	A	A
CAS and EEC numbers (if available)	AI	A [♥]	A	A [♣] _{CAS}	A [♥]	C	C	A* _{CL}	A	C	A	A
Empirical and structural formula and mass molecular	AI	A [♥]	A	A [♣]	A [♥]	A		A* _{CL}	A	C	A	A
Trade name(s)	AI	A	A	A	A	A _{CL}	A	C _{CL}	A	A _{CL}	A	NR
Method of manufacture	AI	A	A	A	A	NR	NR	A _{CL}		C	A	A
Specification of purity	AI	A	A	A	A	C	C	A _{CL}	A	C	A	A
Impurities and additives - identity, formation and range of each	AI	A [§]	A	A [♣]	A	C	NR	A _{CL}	A	C _{CL} [§]	A	A
Name of manufacturer	AI	A	A	A	A	A	A	A _{CL}	A	A	A	A
Name of applicant	AI	A	A	A	A	A	A	A _{CL}	A	A	A	A
Other												
Strength or concentration	AI			A								
Origin of the natural active substance	AI			A		A						A
Information on authorisation already given in other countries or for other uses	AI		A									
Development code number(s) of producer	AI		A	A								
Description of starting materials for the manufacture	AI		A	A							A	
Guaranteed minimum concentration	AI		A	A								

MATRIX 1. CHEMICAL IDENTITY - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information	AUS	BEL	CAN	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^ϑ	NZ	USA	EU	
	18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21	
IDENTITY OF THE ACTIVE INGREDIENT (cont.)												
Exposure data in conformity with Annex VII A to Directive 92/32/EEC	AI										A	
Discussion of the formation of impurities of toxicological concern	AI		A							A		
IDENTITY OF THE BIOCIDAL PRODUCT												
Trade name	BP	A	A	A	A _{CL}	A [§]	A [§]	A _{CL}	A	A _{CL}	A	A
Composition: names and amount of -active ingredient(s), impurities, adjuvants, inert s components	BP	A	A	A	A _(CL)		A*	A _{CL}	A	A _{CL}	A	A _{CL}
Physical state (emulsifiable concentrate, wettable powder, solution, etc.)	BP	A	A		A _{CL}		A	A _{CL}	A	A _{CL}	A	A _{CL}
Name of manufacturer	BP	A	A	A	A _{CL}		A	A _{CL}	A		A	A
Name of applicant	BP	A	A	A	A		A	A _{CL}	A	A _{CL}	A	A
Other												
Address, tel. no., fax no. of manufact.	BP		A							A		
Contact person	BP		A									
Country's distributor	BP		A									
Referenced submissions	BP		A									
Packages sizes available	BP		A									
Draft of proposed country's label	BP		A									
CAS number of the other ingredients than the active ingredient(s)	BP	A								A		
Commercial name of the other ingredients than the active ingredient(s)	BP	A								A		

MATRIX 1. CHEMICAL IDENTITY - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS	BEL	CAN	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^³	NZ	USA	EU
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
IDENTITY OF THE BIOCIDAL PRODUCT (cont.)												
Information on authorisation already given in other countries or for other uses	BP		A									
Description of starting materials	BP										A	
Description of production process	BP										A	
Description of formulation process	BP										A	
Description of formation of impurities	BP										A	
Certificate of chemical analysis	BP								A			

@ **Canada:** Both the CAS and IUPAC name are required for the active. Also, the CAS chemical name must be provided for impurities.

η **Denmark:** Data requirements only for swimming pools [use category 18].

β **Hungary:** Data requirements only for swimming pools [use category 18] and hot spas [use category 19].

³ **The Netherlands:** The data requirements listed cover only the category 18 and are the minimal requirements that are necessary for the completeness of the dossiers. Based upon a first evaluation of a dossier additional requirements are established. In this respect the code "NR" is not used in the specific listing of data requirements since the possibility cannot be excluded that a particular question has to be asked as additional data requirement.

ψ **Ireland:** Data requirements only for swimming pools [use category 18] and ornamental ponds [use category 21].

♣ Impurities always required.

♥ Impurities and Transformation products always required.

§ Impurities conditionally required.

♦ Transformation products conditionally required.

* Impurities and Transformation products conditionally required.

CL Classification & Labelling.

(CL) Conditionally used for Classification and Labelling.

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (use categories 18-21)**MATRIX 2. PHYSICAL/CHEMICAL PROPERTIES**

Type of Data/Information		AUS	BEL	CAN	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^³	NZ	USA	EU
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
Colour	AI	A	A	A	A	A		A		A	A	A
	BP	A	A	A	A	A	A	A		A		A
Physical state	AI	A	A	A	A	A		A _{CL}		A	A	A
	BP	A	A	A	A	A	A	A _{CL}	A	A	A	A
Odour	AI	A	A	A	A	A		A		A	A	NR
	BP	A	A	A	A	A	A	A		A		NR
pH	AI	A		C	A	A		A _{CL}			A	NR
	BP	A	A	C	A	A	A	A _{CL}	C	C _{CL}	A	A
Density	AI	A	A	A	A	A		A _{CL}			A	A
	BP	A	A	A	A	A	C	C _{CL}	C	A	A	A
UV-visible, IR, NMR, Mass Spectra	AI	A	A	C [@]	A	A	C	A _{CL}	A		A	A
	BP	C		NR			C	C _{CL}				NR
Melting point	AI	A	A	C	A	A	C	A _{CL}	A		C	A
	BP	C		NR		A		C _{CL}		C _{CL}		NR
Boiling point	AI	A	A	C	A	A	C	A _{CL}	A		C	A
	BP	C		NR		A		C _{CL}		C _{CL}		NR
Vapour pressure	AI	A	A	C	A	C	C	A _{CL}	A	C _{CL}	A	A
	BP	C		NR		C		C _{CL}				NR

MATRIX 2. PHYSICAL/CHEMICAL PROPERTIES - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS	BEL	CAN	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^ϑ	NZ	USA	EU
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
Solubility in water as a function of pH and temperature	AI	A	A	A	A	A	A	A _{CL}	A	C _{CL}	A	A
	BP	C		NR		C		C _{CL}				NR
Solubility in organic solvents	AI	A	A	A	A	A	A	A _{CL}	A	C _{CL}	A	C
	BP	C		NR		C		C _{CL}				NR
Octanol-water partition coefficient as a function of pH	AI	A	A	C	A	A	C	A _{CL}	A	C _{CL}	A	A
	BP	C		NR	^{CL}	C		C _{CL}				NR
Dissociation constant in water components	AI	A		C	A	A	C	A _{CL}	A	C _{CL}	A	NR
	BP	C		NR		C		C _{CL}				NR
Thermal stability	AI	A	A [♣]	A	A	A	A	A _{CL}	A	C _{CL}	A	A
	BP	A		NR		A	A	C _{CL}				A
Stability in air	AI	A		A	A	A		A _{CL}		C _{CL}	A	C
	BP	A		NR		A	A	C _{CL}				NR
Stability in presence of metal ions or sunlight as a function of temperature	AI	A		C	A	A		A	A		A	NR
	BP	C		NR		A	A	C				A
Viscosity	AI	C		NR	A	A		C _{CL}			A	NR
	BP	C	A	C		A	C	C _{CL}		C _{CL}	C	NR
Surface tension	AI	C	A	NR	A	A		C _{CL}			NR	A
	BP	C		NR		A	NR	C _{CL}			NR	NR
Dielectric breakdown voltage	AI	C		NR			NR	C				NR
	BP	C		C			NR	C			C	NR

MATRIX 2. PHYSICAL/CHEMICAL PROPERTIES - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS	BEL	CAN	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^ρ	NZ	USA	EU
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
Oxidising properties	AI	A	A	NR	A	A		A _{CL}		C _{CL}	C	A _{CL}
	BP	A	A	C	A _{CL}	A	C	C _{CL}		C _{CL}	C	A _{CL}
Flammability	AI	A	A	NR	A	A		A _{CL}		C _{CL}	C	A _{CL}
	BP	A	A	C	A _{CL}	A	A	A _{CL}	A	C _{CL}	C	A _{CL}
Explosive properties	AI	A	A	NR	A	A		A _{CL}		C _{CL}	C	A _{CL}
	BP	A	A	C	A _{CL}	A	A	C _{CL}	A	C _{CL}	C	A _{CL}
Storage stability or stability in solvents used in formulation	AI	A	A [♣]	NR	A	A		A _{CL}	A	C _{CL}	C	NR
	BP	A	A	A	A _{CL}	A	A	A _{CL}	A	C _{CL}	C	A
Corrosion characteristics	AI	A		NR	A	A		A _{CL}		C _{CL}	A	A _{CL}
	BP	A		C	A	A	A	C _{CL}	A	C _{CL}	A	A _{CL}
Reactivity toward container	AI	A	A	NR		A		C _{CL}			A	A
	BP	A		C	A	A	C	C _{CL}		C _{CL}	C	A
Miscibility or suspensibility of product with water or other solvents	AI	A		NR		A		C _{CL}			C	NR
	BP	A		C	A		C	C _{CL}			C	A _{CL}
Flash point	AI	A		NR		A		C _{CL}		C _{CL}	C	A
	BP	A		C	A	A	C	C _{CL}	C _{CL}	C _{CL}	C	A
Wettability	AI	C		NR		A		C			NR	NR
	BP	A	A	NR	A	A	C	C _{CL}			NR	A
Wet sieve and dry sieve test	AI	C		NR				C			NR	NR
	BP	A		NR	A		C	C _{CL}		C	NR	NR

MATRIX 2. PHYSICAL/CHEMICAL PROPERTIES - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS	BEL	CAN	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^ρ	NZ	USA	EU
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
Other				NR								
<i>Particle size</i>	AI											
	BP		A						C			
<i>Particle size during the application of a product</i>	AI											
	BP								C			
<i>Henry's law constant (volatility)</i>	AI								A			
	BP											
<i>Decomposition or other reactions during combustion</i>	AI		A									
	BP											
<i>Physical or chemical compatibility /incompatibility with other preparations</i>	AI											
	BP		C						A			
<i>Hydrolysis as function of pH</i>	AI											
	BP								A			
<i>Suspension capacity</i>	AI											
	BP								A			
<i>Persistent foaming, flowability, pourability and dustability</i>	AI											NR
	BP											A
<i>Emulsifiability and emulsion stability</i>	AI											
	BP								A			

MATRIX 2. PHYSICAL/CHEMICAL PROPERTIES - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

- | | | |
|---|--|---|
| @ | Canada: UV/VIS is conditionally required for AI; NR for BP. Mass Spec is A for pure active and impurities; NR for BP. | |
| η | Denmark: Data requirements only for swimming pools [use category 18]. | |
| β | Hungary: Data requirements only for swimming pools [use category 18] and hot spas [use category 19]. | |
| ψ | Ireland: Data requirements only for swimming pools [use category 18] and ornamental ponds [use category 21]. | |
| ə | The Netherlands: The data requirements listed cover only the category 18 and are the minimal requirements that are necessary for the completeness of the dossiers. Based upon a first evaluation of a dossier additional requirements are established. In this respect the code “NR” is not used in the specific listing of data requirements since the possibility cannot be excluded that a particular question has to be asked as additional data requirement. | |
| ♠ | Transformation products always required. | ◆ Transformation products conditionally required. |
| ♥ | Impurities and transformation products always required. | CL Classification & Labelling |
| § | Impurities conditionally required. | |

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (use categories 18-21)**MATRIX 3. FUNCTION, MODE OF ACTION AND HANDLING**

Type of Data/Information		AUS	BEL	CAN	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^ϑ	NZ	USA	EU
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
Function (e.g. algicide, fungicide, insecticide, molluscicide, repellent, disinfectant, etc.)	AI	A	A	A	A			A _{CL}			A	A
	BP	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A	A _{CL}
Mode of action on target organisms (e.g. contact poison, inhalation poison, fungitoxic, fungistatic, etc.)	AI		A	C	A		A	A _{CL}			A	A
	BP	A	A	NR	A _{CL}	A _{CL}	C _{CL}	A _{CL}	A		A	A _{CL}
Field of use (e.g. indoor, outdoor, public or non-public, etc.)	AI		A	NR				A _{CL}			A	A
	BP	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A	A _{CL}
Pests controlled/target organisms	AI		A	NR			C	A _{CL}			A	A
	BP	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	C	A _{CL}	A	C _{CL}	A	A _{CL}
Products to be protected	AI		A	A			A	A _{CL}			A	A
	BP	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A	C _{CL}	A	A _{CL}
Application rate per unit treated area/ volume/weight or concentration	AI			NR				A _{CL}			NR	A
	BP	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A	A _{CL}	A	A _{CL}
Concentration of active ingredient in material used	AI			NR			NR	A _{CL}			A	NR
	BP	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	NR	A _{CL}	A	A _{CL}	A	NR
Timing of applications and duration of protection	AI			NR				A _{CL}			NR	NR
	BP	A _{CL}	A	C _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A	C _{CL}	A	A _{CL}
Use intervals (time between application of biocide and use of facility or commodity)	AI			NR				A _{CL}			NR	NR
	BP	A _{CL}	A	C _{CL}	A _{CL}	A _{CL}	C _{CL}	A _{CL}	A	C _{CL}	A	A _{CL}

MATRIX 3. FUNCTION, MODE OF ACTION AND HANDLING - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS	BEL	CAN	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^ϑ	NZ	USA	EU
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
Proposed instructions for use	AI			A _{CL}				A _{CL}			NR	NR
	BP	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A	A _{CL}
Site preparation and method of application	AI			NR				A _{CL}			NR	NR
	BP	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A	C _{CL}	A	A _{CL}
Type of packaging	AI			A				A _{CL}			NR	A
	BP	A		A	A	A _{CL}	A _{CL}	A _{CL}	A	C _{CL}	A	A _{CL}
Procedures for cleaning application equipment	AI			NR				C _{CL}			NR	NR
	BP	A	A	NR	A _{CL}	A _{CL}	A _{CL}	C _{CL}	A	C _{CL}	A	A _{CL}
Recommended methods and precautions for handling, storage, transport or fire (including reaction products)	AI			C _{CL}				A _{CL}			NR	A
	BP	A _{CL}		C _{CL}		A _{CL}	A _{CL}	A _{CL}	A _{CL}	C _{CL}	A	A _{CL}
Emergency measures in case of accidents	AI			C _{CL}				A _{CL}	A		NR	A
	BP	A		C _{CL}	A _{CL}	A _{CL}	A _{CL}	A _{CL}	A _{CL}	C _{CL}	A	A _{CL}
Other										C _{CL}		
Information on resistance and development of strategies to cope with	AI		A									A
	BP		A									A
Quantities (manufactured or imported) placed in market every year	AI		A									A
	BP											NR
Function of the other ingredients than the active ingredient(s) in the biocidal product	BP		A	A								
Undesirable secondary effects for example on useful organisms	AI		A									
	BP		A									

MATRIX 3. FUNCTION, MODE OF ACTION AND HANDLING - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS	BEL	CAN	DEN ^η	GR	HUN ^β	IRL ^ψ	NL [⊃]	NZ	USA	EU
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
Information on the possibility of destruction with: controlled waste disposal, incineration, waste water treatment plans or other techniques	BP		@									
Information on the possibility to re-use or recycle the product	BP		@									
Information on any possibility of rendering the active organism non-infective after release in or into the following: air, water, soil			@									
Disposal statement, how to dispose of (remains of) the product	AI			C _{CL}								
	BP			C _{CL}					A			
Handling of product by general public or by professional users	AI			A _{CL}								
	BP			A _{CL}		A _{CL}			A _{CL}			

η **Denmark:** Data requirements only for swimming pools [use category 18].

β **Hungary:** Data requirements only for swimming pools [use category 18] and hot spas [use category 19].

ψ **Ireland:** Data requirements only for swimming pools [use category 18] and ornamental ponds [use category 21].

⊃ **The Netherlands:** The data requirements listed cover only the category 18 and are the minimal requirements that are necessary for the completeness of the dossiers. Based upon a first evaluation of a dossier additional requirements are established. In this respect the code "NR" is not used in the specific listing of data requirements since the possibility cannot be excluded that a particular question has to be asked as additional data requirement.

CL Classification & Labelling.

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (use categories 18-21)**MATRIX 4. ANALYTICAL METHODS**

Entries in the “BP” rows refer to formulations other than the active ingredients for which a concern may arise.

Type of Data/Information		AUS	BEL	CAN ^δ	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^³	NZ	USA	EU
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
Pure active ingredients and isomers, impurities and additives of the technical grade of the active ingredient or formulation	AI	A	A*	A*	A		A*	A [♥] _{CL}		C	A*	A
	BP	A	A*	A*		NR		A [♥] _{CL}			A*	A
Active ingredients in food or feed (multi-residue methods) or treated product	AI	A	C [♦]		A		A	C* _{CL}	C [♦]		NR	C
	BP	A	C [♦]			NR		C* _{CL}			NR	A
Composition of formulated product	AI	A	A					NR		C	A*	NR
	BP	A	A			A	A	A* _{CL}			A*	A
Residues in water, including potable water	AI	NR	C [♦]		A			A [♥] _{CL}	A	C	C*	A
	BP	NR	C [♦]			NR	A/C	A [♥] _{CL}			C*	A
Residues in air	AI	NR	C [♦]		A			C* _{CL}			NR	A
	BP	NR	C [♦]			NR	NR	C* _{CL}			NR	A
Residues in soil	AI	NR	C [♦]		A		C	C* _{CL}		C	C*	A
	BP	NR	C [♦]			NR	C	C* _{CL}			NR	A
Residues in sediment	AI	NR	C [♦]		C		C	C* _{CL}			C*	C
	BP	NR	C [♦]			NR	C	C* _{CL}			NR	C
Residues in biota (biological tissue such as plants, fish, birds, wild mammals, etc.)	AI	NR	C [♦]		A		C	C* _{CL}	C [♦]		C*	C
	BP	NR	C [♦]			NR	C	C* _{CL}			NR	C

MATRIX 4. ANALYTICAL METHODS - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS	BEL	CAN ^δ	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^ϑ	NZ	USA	EU
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
Residues in human body fluids	AI	NR	C [♦]		A		NR	C* _{CL}			C*	A
	BP	NR	C [♦]			NR		C* _{CL}			NR	A

δ **Canada:** Active in TGAI: Validated methodologies for specifically identifying and quantifying the active ingredients and each impurity present at or above 0.1% by weight, or those of toxicological significance at any level above the practical limit of quantitation, are required. A method capable, must also be provided. Corresponding supporting raw data for all specified components from five (5) batches is required.

Active in Formulation: A validated analytical method suitable for enforcement purposes must be provided for each active ingredient in a end-use product with a requirement for specific determination of stereoisomers, when applicable. Raw data demonstrating the lack of interference of formulation components must also be provided. If potential exists for the formulators/formulating process to create or enhance the presence of an impurity of toxicological concern, validated methodology and corresponding raw data from the analysis of five (5) batches are required.

η **Denmark:** Data requirements only for swimming pools [use category 18].

β **Hungary:** Data requirements only for swimming pools [use category 18] and hot spas [use category 19].

ψ **Ireland:** Data requirements only for swimming pools [use category 18] and ornamental ponds [use category 21].

ϑ **The Netherlands:** The data requirements listed cover only the category 18 and are the minimal requirements that are necessary for the completeness of the dossiers. Based upon a first evaluation of a dossier additional requirements are established. In this respect the code “NR” is not used in the specific listing of data requirements since the possibility cannot be excluded that a particular question has to be asked as additional data requirement.

♣ Impurities always required.

♥ Impurities and Transformation products always required.

§ Impurities conditionally required.

♦ Transformation products conditionally required.

* Impurities and Transformation products conditionally required.

CL Classification & Labelling.

tp treated product

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (use categories 18-21)**MATRIX 5. EFFICACY OF FORMULATIONS**

Type of Data/Information		AUS ^ζ	BEL	CAN	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^³	NZ	USA	EU
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
Effects on quality of treated substance	AI	see note		NR				C* _{CL}		NR	NR	NR
	BP			A	A	NR	C	C* _{CL}				NR
Dose/efficacy relationships (minimum inhibition-concentration scale)	AI		A	NR		NR	A/C	C _{CL}				NR
	BP			C	A	A _{CL}		C _{CL}	A			A
Evidence of effectiveness under working conditions	AI			NR			NR	C				NR
	BP			A	A	NR		C				A
<i>Other</i>												
<i>Laboratory studies</i>	AI											
	BP			C								

ζ **Australia:** Although, Australia stated that efficacy data are required for all registerable products, information on what data are required has not been provided.

η **Denmark:** Data requirements only for swimming pools [use category 18].

β **Hungary:** Data requirements only for swimming pools [use category 18] and hot spas [use category 19].

ψ **Ireland:** Data requirements only for swimming pools [use category 18] and ornamental ponds [use category 21].

³ **The Netherlands:** The data requirements listed cover only the category 18 and are the minimal requirements that are necessary for the completeness of the dossiers. Based upon a first evaluation of a dossier additional requirements are established. In this respect the code “NR” is not used in the specific listing of data requirements since the possibility cannot be excluded that a particular question has to be asked as additional data requirement.

♦ Transformation products conditionally required.

* Impurities and transformation products conditionally required.

CL Classification & Labelling.

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (use categories 18-21)**MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT**

Type of Data/Information			AUS ^ζ	BEL	CAN	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^ϑ	NZ	USA ^μ	EU
			18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
ABIOTIC													
Hydrolysis rate including identification of metabolites and breakdown products	AI	A	A	NR	A		C	A* _{CL}	A	C _{CL}	A	A	
	BP					NR		A* _{CL}			NR	NR	
Photodegradation in water including identification of metabolites and breakdown products	AI	C	A		A		C	A* _{CL}	A	C _{CL}	A	A	
	BP					NR		A* _{CL}			NR	NR	
Photodegradation on soil including identification of metabolites and breakdown products	AI	C	C		A		C	A* _{CL}		C _{CL}		NR	
	BP					NR		A* _{CL}				NR	
Rate and route of photochemical degradation in air, identification of breakdown products	AI	C	C				C	A* _{CL}		C _{CL}		C	
	BP					NR		A* _{CL}				NR	
BIOTIC													
Soil metabolism, aerobic and anaerobic, to determine rate and route of degradation in representative soil types including metabolites and breakdown products	AI	C	C	NR	A		A/C	A* _{CL}		C _{CL}		C	
	BP		C			NR		A* _{CL}				C	
Aquatic sediment metabolism, aerobic and anaerobic, including identification of breakdown products and metabolites	AI	C	C		C		C	A* _{CL}	C	C _{CL}	A	C	
	BP		C			NR		A* _{CL}			NR	C	
Mobility/leaching in representative soil types and mobility of metabolites and breakdown products	AI	C	C		A		C	A* _{CL}		C _{CL}		C	
	BP		C			NR		A* _{CL}				C	
Adsorption/desorption in representative soil types including metabolites and breakdown products	AI	C	C		A		C	A* _{CL}		C _{CL}	A	C	
	BP		C			NR		A* _{CL}			NR	C	

MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information			AUS ^ζ	BEL	CAN	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^³	NZ	USA ^μ	EU
			18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
BIOTIC (cont.)													
Laboratory volatility	AI	C		NR	A		C	C*					NR
	BP					NR		C*					NR
Special degradation of biocides in effluents	AI	C					C	C* _{CL}		C _{CL}			NR
	BP					NR		C* _{CL}					C
Adsorption/desorption screen	AI	C	A				C	C*	A	C _{CL}			A
	BP		C			NR		C*					C
Ready biodegradability	AI	C	A		A		C	A* _{CL}	C	C _{CL}			A
	BP		C		CL	A _{CL}		A* _{CL}					NR
Inherent biodegradability	AI	C	C		A		C	C* _{CL}	C	C _{CL}			A
	BP		C					C* _{CL}					NR
Aerobic aquatic biotransformation in natural water	AI	C	C				C		C	C _{CL}			C
	BP		C										C
Other													
Effect on waste water	AI								A				
	BP												
LEACHING													
Leaching from treated wood	AI	NR	C	NR	A		C	C* _{CL}					C
	BP		C					C* _{CL}					C
Leaching from anti-fouling paint	AI	NR	C				C	A ^{♣♦} _{CL}					C
	BP		C					A ^{♣♦} _{CL}					C

MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS ^ζ	BEL	CAN	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^ε	NZ	USA ^μ	EU
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
FIELD TESTING												
Small plot field tests or terrestrial field studies	AI	C		NR			C	C*		C _{CL}		NR
	BP					NR		C*				C
Aquatic field studies	AI	C					C	C*		C _{CL}	NR	NR
	BP					NR		C*			A	C

^ζ **Australia:** Australia has not developed specific and detailed environmental data requirements; rather, the Australian approach to environmental assessment is one of general rather than specific guidance, with data requirements determined on a case-by-case basis, depending on exposure. Australia's environmental data requirements for assessment of biocides are flexible, with the key criteria being the nature and extent of environmental exposure expected to arise through manufacture, use and disposal of the biocide.

Accordingly, Australia has chosen indicative examples for the environmental data requirements based on experience, rather than filling out separate matrices for a large number of categories. To address all categories would be a largely hypothetical exercise as Australia has little or no experience with many of them, particularly in non-agricultural situations.

Australia has only filled out the active ingredient column in matrices 6 and 7, as most testing will be done on the active. In most cases, we have marked requirements as conditional as it is very difficult to completely rule out particular requirements, even though they may be very unlikely. Similarly, for nearly all items the possibility remains that environmental data may be required for the biocidal product, impurities, or transformation products, even though in most situations such data would not be required.

^η **Denmark:** Data requirements only for swimming pools [use category 18].

^β **Hungary:** Data requirements only for swimming pools [use category 18] and hot spas [use category 19].

^ψ **Ireland:** Data requirements only for swimming pools [use category 18] and ornamental ponds [use category 21].

^ε **The Netherlands:** The data requirements listed cover only the category 18 and are the minimal requirements that are necessary for the completeness of the dossiers. Based upon a first evaluation of a dossier additional requirements are established. In this respect the code "NR" is not used in the specific listing of data requirements since the possibility cannot be excluded that a particular question has to be asked as additional data requirement.

^μ **USA:** There are also data requirements for algicides in rivers and lakes. These data requirements are cited with *italics* when they are different from those of the use categories 18-21.

♣ Impurities always required.

* Impurities and Transformation products conditionally required.

◆ Transformation products conditionally required.

CL Classification & Labelling.

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (use categories 18-21)**MATRIX 7. ECOTOXICOLOGY**

Type of Data/Information		AUS ^ζ		BEL	CAN	DEN ^η		GR	HUN ^β		IRL ^ψ	NL ^ϑ		NZ	USA ^μ		EU
		18-21		18-21	18-21	18		18-21	18, 19		18, 21	18		18-21	18-21		18-21
AVIAN TESTING																	
Avian acute oral LD50	AI	C		NR	A		A	C* _{CL}		C _{CL}	A	C					
	BP							C* _{CL}			NR	C					
Avian dietary toxicity LC50 - terrestrial bird (short-term toxicity)	AI	C			A/C		C	C* _{CL}		C	A	C					
	BP							C* _{CL}			NR	NR					
Avian dietary toxicity LC50 - aquatic bird (short-term toxicity)	AI	C			A/C		NR	C* _{CL}		C	A	C					
	BP							C* _{CL}			NR	NR					
Avian reproduction test - terrestrial bird	AI	C			A/C		NR	C* _{CL}				C					
	BP							C* _{CL}				NR					
Avian reproduction test - aquatic bird	AI	C			A/C		NR	C* _{CL}				C					
	BP							C* _{CL}				NR					
Avian field testing	AI	C					C	C* _{CL}		C		?					
	BP							C* _{CL}				C					
Acceptance of bait, treated items by birds	AI	C			C		NR	C* _{CL}		C _{CL}		?					
	BP							C* _{CL}				C					
AQUATIC TESTING (not including algae)																	
Fish acute toxicity LC50, freshwater; warm water species	AI	A	C	NR	A		A	C* _{CL}	C	C _{CL}	A	A					
	BP		C		CL			C* _{CL}			A	C					
Fish acute toxicity LC50, freshwater; cold water species	AI	A	A		A	A _{CL}	C	C* _{CL}	C	C _{CL}	A	A					
	BP		C			A _{CL}		C* _{CL}			A	C					

MATRIX 7. ECOTOXICOLOGY - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS ^ζ	BEL	CAN	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^ϑ	NZ	USA ^μ	EU
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
AQUATIC TESTING (not including algae) (cont.)												
Daphnia acute immobilization test	AI	A	A	NR	A	A _{CL}	A	C* _{CL}		C _{CL}	A	?
	BP		C		^{CL}	A _{CL}		C* _{CL}			A	?
Marine or estuarine fish acute toxicity LC50/EC50	AI	C	C			NR	C	C* _{CL}			A	C
	BP		C			NR		C* _{CL}			A	C
Daphnia life cycle(reproduction test)	AI	C	C		A	NR	A	C* _{CL}			A	C
	BP		C			NR		C* _{CL}			NR	C
Fish reproduction and growth rate	AI	C	C		A/C	NR	NR	C* _{CL}			A	C
	BP		C			NR		C* _{CL}			NR	C
Fish life cycle/chronic toxicity to fish or fish early life stage	AI	C	C		A/C	NR	NR	C* _{CL}			A	C
	BP		C			NR		C* _{CL}			NR	C
Fish bioconcentration	AI	C	C		A	NR	NR	C* _{CL}			C	C
	BP		C		^{CL}	NR		C* _{CL}			NR	C
Acute toxicity to marine invertebrates	AI	C	C			NR	NR	C* _{CL}			C	NR
	BP		C			NR		C* _{CL}			C	C
Chronic toxicity to marine invertebrates	AI	C				NR	NR	C* _{CL}				NR
	BP					NR		C* _{CL}				C
Field studies	AI	C				NR	C				NR	?
	BP					NR					C	C

MATRIX 7. ECOTOXICOLOGY - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS ^ζ	BEL	CAN	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^ϑ	NZ	USA ^μ	EU	
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21	
AQUATIC TESTING (not including algae) (cont.)													
Other aquatic tests	AI	C	C	NR								?	
	BP											?	
Bioaccumulation	AI		C										
	BP												
Test on sediment dwelling species	AI		C		C								
	BP												
Short term toxicity test Daphnia	AI		C						C				
	BP												
PHYTOTOXICITY TO NON-TARGET PLANTS													
Algae, growth inhibition - freshwater	AI	C	A	NR	A		NR/C	C* _{CL}			A	A	
	BP		C		CL			C* _{CL}			A	C	
Algae, growth inhibition - marine	AI	C	C				NR	C* _{CL}			A	A	
	BP		C					C* _{CL}			A	C	
Aquatic plant growth	AI	C					NR	C* _{CL}			A	C	
	BP							C* _{CL}			A	C	
Seed germination/seedling emergence	AI	C					NR	C* _{CL}			NR	C	
	BP							C* _{CL}			A	C	
Other on-target plant tests	AI												C
	BP						NR						C
All data prescribed by Directive 91/414 can be asked for(or justification)	AI												
	BP												
Short term toxicity test algae	AI									C			
	BP												

MATRIX 7. ECOTOXICOLOGY - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS ^ζ	BEL	CAN	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^θ	NZ	USA ^μ	EU
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
TESTING ON OTHER NON-TARGET SPECIES												
Effects on earthworms	AI	C	C	NR	A		NR	C [§] _{CL}				C
	BP		C					C [§] _{CL}				C
Effects on beneficial insects	AI	C					NR	C [§] _{CL}				C
	BP							C [§] _{CL}				C
<i>Bees</i>	AI				A							
	BP				CL							
Effects on terrestrial vertebrates other than birds	AI	C					NR	C [§] _{CL}		C _{CL}		C
	BP							C [§] _{CL}				C
Activated sludge, respiration inhibition test	AI	C	C		C		NR	C [§] _{CL}				
	BP		C					C [§] _{CL}				
<i>Other</i>												C
<i>Acute testing on a non-aquatic, non-target species</i>	AI		C									
	BP											

MATRIX 7. ECOTOXICOLOGY - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

- ζ **Australia:** Australia has not developed specific and detailed environmental data requirements; rather, the Australian approach to environmental assessment is one of general rather than specific guidance, with data requirements determined on a case-by-case basis, depending on exposure. Australia's environmental data requirements for assessment of biocides are flexible, with the key criteria being the nature and extent of environmental exposure expected to arise through manufacture, use and disposal of the biocide.
- Accordingly we have chosen indicative examples for the environmental data requirements based on experience, rather than filling out separate matrices for a large number of categories. To address all categories would be a largely hypothetical exercise as we have little or no experience with many of them, particularly in non-agricultural situations.
- We have only filled out the active ingredient column in matrices 6 and 7, as most testing will be done on the active. In most cases, we have marked requirements as conditional as it is very difficult to completely rule out particular requirements, even though they may be very unlikely. Similarly, for nearly all items the possibility remains that environmental data may be required for the biocidal product, impurities, or transformation products, even though in most situations such data would not be required.
- η **Denmark:** Data requirements only for swimming pools [use category 18].
- β **Hungary:** Data requirements only for swimming pools [use category 18] and hot spas [use category 19].
- ψ **Ireland:** Data requirements only for swimming pools [use category 18] and ornamental ponds [use category 21].
- ε **The Netherlands:** The data requirements listed cover only the category 18 and are the minimal requirements that are necessary for the completeness of the dossiers. Based upon a first evaluation of a dossier additional requirements are established. In this respect the code "NR" is not used in the specific listing of data requirements since the possibility cannot be excluded that a particular question has to be asked as additional data requirement.
- μ **USA:** There are also data requirements for algicides in rivers and lakes. These data requirements are cited with *italics* when they are different from those of the use categories 18-21.
- ♣ Impurities always required.
- ♦ Transformation products conditionally required.
- * Impurities and Transformation products conditionally required.
- § Impurities conditionally required.
- CL Classification & Labelling.

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (use categories 18-21)**MATRIX 8. RESIDUE CHEMISTRY**

Type of Data/Information		AUS	BEL	CAN ^δ	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^ϑ	NZ	USA	EU
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
IDENTIFICATION OF RESIDUES												
Nature of the residue in/on treated material or animal	AI	NR	NR	NR	A	NR	C	C* _{CL}	see note	C	NR	C
	BP				A	NR		C* _{CL}	note			C
MAGNITUDE OF THE RESIDUE ON/ IN THE TREATED MATERIAL OR ANIMAL												
Wood	AI	NR	NR	NR	C		NR	C _{CL}	see note		NR	
	BP							C _{CL}				
Wool	AI						NR	NR				
	BP							NR				
Livestock:	AI						NR			C		C
	BP											C
• Consumer residues	AI											
	BP				A							
• Animals kept for food production and pets	AI							C* _{CL}				
	BP							C* _{CL}				
Fish	AI						NR	C* _{CL}				C
	BP							C* _{CL}				C
Freezer or storage stability tests for any of the above magnitude of the residue tests	AI						NR	NR				
	BP							NR				C

MATRIX 8. RESIDUE CHEMISTRY - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS	BEL	CAN ^δ	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^ε	NZ	USA	EU
		18-21	18-21	18-21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
OTHER REQUIREMENTS												
Proposed tolerance or maximum residue levels	AI	NR	NR	NR				A [♥]	see note	C		C
	BP					NR		A [♥]				C
Effects of preparation on residues (e.g. cooking, processing)	AI							C*				C
	BP					NR		C*				C
Effects on odour, taste and quality of food due to residues	AI							C*		C		C
	BP					NR		C*				C

δ **Canada:** There are not data requirements, since these products are considered to have no-food contact uses.

η **Denmark:** Data requirements only for swimming pools [use category 18].

β **Hungary:** Data requirements only for swimming pools [use category 18] and hot spas [use category 19].

ψ **Ireland:** Data requirements only for swimming pools [use category 18] and ornamental ponds [use category 21].

ε **The Netherlands regulate** only the category 18 (swimming pools) by an approval system. However, data requirements on residue chemistry are not necessary for the completeness of the dossiers. Based upon a first evaluation of a dossier additional requirements are established. In this respect the code "NR" is not used in the specific listing of data requirements since the possibility cannot be excluded that a particular question has to be asked as additional data requirement.

μ **USA:** There are also data requirements for algicides in rivers and lakes. These data requirements are cited with *italics* when they are different from those of the use categories 18-21.

♥ Impurities and Transformation products always required.

* Impurities and Transformation products conditionally required.

CL Classification & Labelling.

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (use categories 18-21)**MATRIX 9. TOXICOLOGY**

Type of Data/Information		AUS ^ζ	BEL ^σ	CAN ^δ	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^ϑ	NZ	USA ^μ	EU
		18-20 21	18-21	21	18	18-21	18, 19	18, 21	18	18-21	18-20	18-21
ACUTE TESTING												
Acute oral	AI	A _{CL}	A	A _{CL}	A	A _{CL}	A	A* _{CL}	A	A _{CL}	A	A _{CL}
	BP	C _{CL}	A	A _{CL}	A _{CL}	A _{CL}		A* _{CL}	A _{CL}	C _{CL}	A	A _{CL}
Acute dermal	AI	A _{CL}	A	A _{CL}	A	A _{CL}	C	A* _{CL}	A	A _{CL}	A	A _{CL}
	BP	C _{CL}	A	A _{CL}	A _{CL}	A _{CL}		A* _{CL}	A _{CL}	C _{CL}	A	A _{CL}
Acute inhalation	AI	C _{CL}	A	A _{CL}	A	A _{CL}	C	A* _{CL}		A _{CL}	A	A _{CL}
	BP	C _{CL}	A	A _{CL}	A _{CL}	A _{CL}		A* _{CL}	A _{CL}	C _{CL}	A	A _{CL}
Acute dermal irritation	AI	A _{CL}	A	A _{CL}	A	A _{CL}	A	A* _{CL}	A	A _{CL}	A	A _{CL}
	BP	C _{CL}	A	A _{CL}	A _{CL}	A _{CL}	C	A* _{CL}	A _{CL}	C _{CL}	A	A _{CL}
Acute eye irritation	AI	A _{CL}	A	A _{CL}	A	A _{CL}	A	C* _{CL}	A	C _{CL}	A	A _{CL}
	BP	C _{CL}	A	A _{CL}	A _{CL}	A _{CL}	C	C* _{CL}	A _{CL}	C _{CL}	A	A _{CL}
Skin sensitisation	AI	A _{CL}	A	A _{CL}	A	A _{CL}	C	A* _{CL}		C _{CL}	A	A _{CL}
	BP	C _{CL}	A	A _{CL}	^{CL}	A _{CL}	C	A* _{CL}	A _{CL}	C _{CL}	A	A _{CL}
Potentiation/interactions of multiple active ingredients or products	AI	C					NR	C* _{CL}		C _{CL}	NR	NR
	BP					A _{CL}		C* _{CL}			NR	A
Other												
<i>Information on dermal absorption</i>	AI											A
	BP											A

MATRIX 9. TOXICOLOGY - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS ^ζ	BEL ^σ	CAN ^δ	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^³	NZ	USA ^μ	EU
		18-20 21	18-21	21	18	18-21	18, 19	18, 21	18	18-21	18-20	18-21
SUBCHRONIC TESTING												
Repeated dose oral - 28 day	AI	A _{CL} C _{CL}	C			C	C	C* _{CL}		C _{CL}	NR	A _{CL}
	BP					C		C* _{CL}			NR	NR
Repeated dose inhalation - 28 day	AI	C _{CL}				C	NR	C* _{CL}		C _{CL}	NR	C _{CL}
	BP					C		C* _{CL}			NR	NR
Subchronic oral rat -90 day	AI	C _{CL} NR	A	A	A	C	NR/C	A* _{CL}	C	C _{CL}	A	A _{CL}
	BP					C		A* _{CL}			NR	NR
Subchronic oral non-rodent -90 day	AI	C _{CL} NR	A	A	A	C	C	C* _{CL}		C _{CL}	C	A _{CL}
	BP					C		C* _{CL}			NR	NR
Subchronic dermal -90 day	AI	NR		C	C	C	C	C* _{CL}		C _{CL}	A	C _{CL}
	BP					C		C* _{CL}			NR	NR
Subchronic inhalation -90 day	AI	NR		C	C	C	NR	C* _{CL}	C	C _{CL}	C	C _{CL}
	BP					C		C* _{CL}			NR	NR
Repeated dose dermal toxicity -21/28 day	AI	C _{CL}		C			C	C* _{CL}	C	C _{CL}	NR	NR
	BP							C* _{CL}	C		NR	NR
Other												
<i>A short study by the most useful route may be required if there is evidence of or known potential for synergism among any of the ingredients</i>	AI											
	BP			C								

MATRIX 9. TOXICOLOGY - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS ^ζ	BEL ^σ	CAN ^δ	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^³	NZ	USA ^μ	EU
		18-20 21	18-21	21	18	18-21	18, 19	18, 21	18	18-21	18-20	18-21
DEVELOPMENT TOXICITY AND REPRODUCTION STUDIES												
Teratogenicity rodent	AI	A _{CL}	A	A	A	A _{CL}	A _{CL}	A* _{CL}	A _{CL}	C _{CL}	A	A _{CL}
	BP				CL	A _{CL}		C* _{CL}			NR	NR
Teratogenicity-second species	AI	C _{CL}		A	A			C* _{CL}		C _{CL}	A	A _{CL}
	BP				CL			C* _{CL}			NR	NR
Multi-generation reproduction	AI	C _{CL}	A	A	A		A _{CL}	A* _{CL}	A _{CL}	C _{CL}	A	A _{CL}
	BP				CL			C* _{CL}			NR	NR
Reproductive screen	AI	NR						A* _{CL}		C _{CL}	NR	NR
	BP							C* _{CL}			NR	NR
METABOLISM TESTING												
Toxicokinetics/metabolism	AI	C	A	A*	A		A		A	C _{CL}	A	A
	BP										NR	NR
CHRONIC TESTING												
Chronic toxicity rodent	AI	NR	A	A	A	A _{CL}	C			C _{CL}	A	A _{CL}
	BP				CL	A _{CL}					NR	NR
Chronic toxicity non-rodent	AI	NR	C		A	A _{CL}		A* _{CL}		C _{CL}	A	A _{CL}
	BP				CL	A _{CL}		C* _{CL}			NR	NR

MATRIX 9. TOXICOLOGY - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS ^ζ	BEL ^σ	CAN ^δ	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^³	NZ	USA ^μ	EU
		18-20 21	18-21	21	18	18-21	18, 19	18, 21	18	18-21	18-20	18-21
CHRONIC TESTING (cont.)												
Carcinogenicity - rat	AI	NR	A	A	A	A _{CL}	C _{CL}	A* _{CL}	C _{CL}	C _{CL}	A	A _{CL}
	BP				CL	A _{CL}		C* _{CL}			NR	NR
Carcinogenicity - second species	AI	NR			A	NR				C _{CL}		
	BP				CL	NR						
<i>Mouse</i>	AI		A	A							A	
	BP										NR	
<i>Dog</i>	AI							C* _{CL}				
	BP							C* _{CL}				
<i>Other mammalian species</i>	AI											A _{CL}
	BP											NR
MUTAGENICITY												
Testing for specific endpoints:	AI	A _{CL}	A	A	A	A	A	A* _{CL}	A _{CL}	C _{CL}	A	A _{CL}
	BP				CL	A					NR	
<i>In-vitro gene mutation study in bacteria (AMES TEST)</i>	AI	A _{CL}	A						A _{CL}	C _{CL}	A	A _{CL}
	BP										NR	NR
<i>In-vitro gene mutation assay in mammalian cells</i>	AI		A						A _{CL}	C _{CL}		A _{CL}
	BP											NR
<i>Microbial or mammalian point mutation [= point mutations (with and without microsomal activation) in procaryotic and/or eucaryotic cells in vitro]</i>	AI			A				A* _{CL}				
	BP							C* _{CL}				

MATRIX 9. TOXICOLOGY - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS ^ζ	BEL ^σ	CAN ^δ	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^³	NZ	USA ^μ	EU
		18-20 21	18-21	21	18	18-21	18, 19	18, 21	18	18-21	18-20	18-21
MUTAGENICITY (cont.)												
<i>In-vitro</i> cytogenicity study in mammalian cells	AI		A									A _{CL}
	BP											NR
<i>In-vitro</i> chromosomal aberrations	AI	A _{CL}		A					A _{CL}	C _{CL}		
	BP											
<i>In-vivo</i> mutagenicity study (bone marrow assay from chromosomal damage or micronucleus test)	AI		C									C _{CL}
	BP											NR
<i>In-vivo</i> study to examine whether mutagenicity or evidence of DNA damage can be demonstrated in tissue other than bone marrow	AI		C									C _{CL}
	BP											NR
Assessment of possible germ cell effects (= dominant lethal)	AI		C					A* _{CL}				C _{CL}
	BP							C* _{CL}				NR
<i>In-vivo</i> chromosomal aberrations	AI			A				A* _{CL}				
	BP							C* _{CL}				

MATRIX 9. TOXICOLOGY - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS ^ζ	BEL ^σ	CAN ^δ	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^³	NZ	USA ^μ	EU
		18-20 21	18-21	21	18	18-21	18, 19	18, 21	18	18-21	18-20	18-21
NEUROTOXICITY TESTING												
Acute neurotoxicity - rat	AI	C _{CL}				A _{CL}		A* _{CL}		C _{CL}	A	C
	BP					A _{CL}		C* _{CL}			NR	NR
Acute delayed neurotoxicity of organophosphates-hen	AI	C _{CL}	A	C	A		C	C* _{CL}	A	C _{CL}	NR	C
	BP				CL			C* _{CL}			NR	NR
28 day delayed neurotoxicity	AI	C _{CL}					C	C* _{CL}		C _{CL}	NR	C
	BP							C* _{CL}			NR	NR
Subchronic neurotoxicity - rat -90 day	AI	NR		C		NR	C	C* _{CL}		C _{CL}	A	C
	BP							C* _{CL}			NR	NR
Subchronic delayed neurotoxicity of organophosphates - hen	AI	NR	C		A	NR	C	C* _{CL}		C _{CL}	A	C
	BP				CL			C* _{CL}			NR	NR
Postnatal developmental neurotoxicity	AI	NR					C	NR		C _{CL}	C	C
	BP							NR			NR	NR
Other												
<i>Study of the effects of transformation products</i>	AI		C									
<i>Statement with respect to (absence of) neurotoxicity</i>	AI											
	BP								A			
<i>Acute delayed neurotoxicity - rat</i>	AI			C								
	BP											

MATRIX 9. TOXICOLOGY - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS ^ζ	BEL ^σ	CAN ^δ	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^³	NZ	USA ^μ	EU
		18-20 21	18-21	21	18	18-21	18, 19	18, 21	18	18-21	18-20	18-21
OTHER TESTING												
Toxic effects in livestock and pets	AI		A	A		A _{CL}	C	A* _{CL}		C _{CL}	NR	C
	BP				A _{CL}	A _{CL}		C* _{CL}		C _{CL}	NR	NR
Antidote	AI	NR	A			A _{CL}	C	A* _{CL}		C _{CL}	NR	A
	BP				A _{CL}	A _{CL}		A* _{CL}			NR	A
Other												
Eye abnormalities (cataracts)	AI								C			
	BP											
MEDICAL DATA												
Medical surveillance of manufacturing plant personnel	AI	C _{CL} C* _{CL}			A	NR	C	A* _{CL}		C _{CL}	NR	A
	BP	C* _{CL}				NR		A* _{CL}		C _{CL}	NR	NR
Clinical cases and poisoning incidents	AI	C _{CL} C* _{CL}			C	NR	A	A* _{CL}	A	C _{CL}	NR	A
	BP	C* _{CL}				NR		A* _{CL}		C _{CL}	NR	NR
Health records from industry and public users	AI	C _{CL} NR			C	NR	C	A* _{CL}		C _{CL}	NR	A
	BP	NR				NR		A* _{CL}		C _{CL}	NR	NR
Observations of exposure of the general population or epidemiological studies	AI	C _{CL}			C	NR		C* _{CL}	A		NR	A
	BP					NR		C* _{CL}			NR	NR

MATRIX 9. TOXICOLOGY - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS ^ζ	BEL ^σ	CAN ^δ	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^ε	NZ	USA ^μ	EU
		18-20 21	18-21	21	18	18-21	18, 19	18, 21	18	18-21	18-20	18-21
Other												
Epidemiological studies of occupational users	AI	C* _{CL}										
	BP	C* _{CL}										

- ζ **Australia:** The data requirements for the use category 21 are cited with *italics* where different from the categories 18-20. With **bold** fonts are listed data required only in the case of **Occupational Exposure**.
- σ **Belgium:** The data requirements listed under “Acute Testing” are equally required for the active ingredient(s), non-active ingredient(s) and end-use biocidal product. A study of chronic toxicity for the non-active ingredient(s) in the formulated product is also required.
- δ **Canada:** The data requirements listed cover only the use category 21: Ornamental ponds.
- η **Denmark:** Data requirements only for swimming pools [use category 18].
- β **Hungary:** Data requirements only for swimming pools [use category 18] and hot spas [use category 19].
- ψ **Ireland:** Data requirements only for swimming pools [use category 18] and ornamental ponds [use category 21].
- ε **The Netherlands:** The data requirements listed cover only the category 18 and are the minimal requirements that are necessary for the completeness of the dossiers. Based upon a first evaluation of a dossier additional requirements are established. In this respect the code “NR” is not used in the specific listing of data requirements since the possibility cannot be excluded that a particular question has to be asked as additional data requirement.
- μ **USA:** The data requirements listed cover the use categories 18, 19 and 20 as well as algicides for outdoor aquatic uses in lakes, rivers or streams.
- ◆ Transformation products conditionally required.
- * Impurities and Transformation products conditionally required.
- CL Classification & Labelling.

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (use categories 18-21)**MATRIX 10. HUMAN EXPOSURE**

Type of Data/Information		AUS ^ζ	BEL	CAN ^δ	DEN ^η	GR	HUN ^β	IRL ^ψ	NL ^ϑ	NZ	USA	EU ^π
		18-21	18-21	18, 20 21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
Wetting, adherence and distribution to target areas or in products	AI	NR C*	NR			NR	NR	C _{CL}	see note	NR	NR	
	BP	NR C*		NR				C _{CL}			NR	
Dermal penetration	AI	C A*				NR	NR	C _{CL}			NR	
	BP	C A*		A C	A			C _{CL}			NR	
Dermal exposure for applicator	AI	NR A*				NR	NR	C _{CL}			NR	
	BP	C A* _{CL}		C A	A			C _{CL}			C	
Dermal exposure for bystanders	AI	NR C				NR	NR	C _{CL}			NR	
	BP	NR C _{CL}		A NR				C _{CL}			NR	
Dermal exposure for people handling treated article	AI	C C*				NR	NR	C _{CL}			NR	
	BP	NR C* _{CL}		NR				C _{CL}			NR	

MATRIX 10. HUMAN EXPOSURE - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS ^ζ	BEL	CAN ^δ	DEN ^η	GR	HUN ^β	IRL	NL ^θ	NZ	USA	EU ^π
		18-21	18-21	18, 20 21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
Inhalation exposure for applicator	AI	NR A*	NR			NR	NR	C _{CL}	see note	NR	NR	
	BP	C A* _{CL}		C A	A			C _{CL}			C	
Inhalation exposure for bystanders	AI	NR C				NR	NR	C _{CL}			NR	
	BP	NR C _{CL}		NR				C _{CL}			NR	
Inhalation exposure for people handling treated article	AI	C C				NR	NR	C _{CL}			NR	
	BP	NR C* _{CL}		NR				C _{CL}			NR	
Indoor surface dissipation	AI	NR C*				NR	NR	C _{CL}			NR	
	BP	NR C* _{CL}		NR				C _{CL}			NR	
Other												
Worker re-entry to treated areas	AI	A*										
	BP	A* _{CL}										
Glove clothing penetration data	AI											
	BP			C								
Product use information	AI										NR	
	BP			A							A	

MATRIX 10. HUMAN EXPOSURE - PRODUCTS FOR USE IN AQUATIC NON-FOOD SITES (cont.)

Type of Data/Information		AUS ^ζ	BEL	CAN ^δ	DEN ^η	GR	HUN ^β	IRL	NL ^ε	NZ	USA	EU ^π
		18-21	18-21	18, 20 21	18	18-21	18, 19	18, 21	18	18-21	18-21	18-21
<i>Applicator biological monitoring</i>	AI		NR						see note	NR	NR	
	BP			C							C	
<i>Bystander biological monitoring</i>	AI										NR	
	BP			C							C	
<i>Description of human activity</i>	AI										NR	
	BP			A							A	
<i>Package integrity study</i>	AI											
	BP	C		C								

ζ **Australia:** The data requirements listed cover the use categories 18-21 for both public health (regular fonts) and occupational exposure (*italics*).

δ **Canada:** Data requirements for the use categories 18, 20 and 21; the d.r. for the latter category are cited with *italics* where different from the other two.

η **Denmark:** Data requirements only for swimming pools [use category 18].

β **Hungary:** Data requirements only for swimming pools [use category 18] and hot spas [use category 19].

ψ **Ireland:** Data requirements only for swimming pools [use category 18] and ornamental ponds [use category 21].

ε **The Netherlands regulate** only the category 18 (swimming pools) by an approval system. However, data requirements on human exposure are not necessary for the completeness of the dossiers. Based upon a first evaluation of a dossier additional requirements are established. In this respect the code “NR” is not used in the specific listing of data requirements since the possibility cannot be excluded that a particular question has to be asked as additional data requirement.

π **European Union:** The specific data requirements on humans, animals and the environment exposure to be submitted for each of 23 EU product types and according to the use pattern are under preparation.

* Impurities and Transformation products conditionally required.

CL Classification & Labelling.

**Data requirements for
Products used in vertebrate
and invertebrate pest control**

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL
(use categories 22-29)

MATRIX 1. CHEMICAL IDENTITY

Type of Data/Information	AUS	BEL	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ε	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA	EU	
	22-29	22-29	22-29	22 25-28	22 25-26	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22 25-27	22, 25	22-29 except 24	22-29	22-29	
IDENTITY OF THE ACTIVE INGREDIENT																	
Common name	AI	A [*]	A	A [§]	A [♥] _{CL}	A	A	A [♣]	A [*]	A [*] _{CL}	A	A _{CL}	A [♥] _{CL}	C	A	A	A
Chemical name (IUPAC) nomenclature	AI	A [♥]	A	A [@]	A [♥]	A [♥]	A	A [♣]	A	A [*] _{CL}		A	A [♥]	A _{CL} A	A	A	A
CAS and EEC numbers (if available)	AI	A [♥]	A	A [♣] _C AS	A [♥]	A [♣]	C	NR	C	A [*] _{CL}	A	C	A [♥]	A	A	A	A
Empirical and structural formula and molecular mass	AI	A [♥]	A	A [♣]	A [♥]	A		A [♣]		A [*] _{CL}	A	C	A	A	A	A	A
Trade name(s)	AI	A	A	A	A	A	A	A	A	C _{CL}	A		NR	A	A	A	NR
Method of manufacture	AI	A	A	A	A	A		NR	NR	A _{CL}			NR	A	C	A	A
Specification of purity	AI	A	A	A	A	A		A [♣]	C	A _{CL}	A	A	A	A	A	A	A
Impurities and additives - identity, formation and range of each	AI	A [§]	A	A [♣]	A	A		A [♣]	NR	A _{CL}	A	A _{CL}	NR	A _{CL} A	A	A	A
Name of manufacturer	AI	A	A	A	A	A		A	A	A _{CL}	A	A	NR	A	A	A	A
Name of applicant	AI	A	A	A	A	A		A	A	A _{CL}	A		A	A	A	A	A
Other																	
Country's patent status	AI			A													
Strength or concentration	AI			A													
Information on authorisation already in other countries or for other uses	AI		A														
Origin of the natural active substance	AI			A													A
Exposure data in conformity with the Annex VII A to Directive 92/32/EEC	AI																A

MATRIX 1. CHEMICAL IDENTITY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information	AUS	BEL	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ξ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA	EU	
	22-29	22-29	22-29	22 25-28	22, 25 26	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22 25-27	22, 25	22-29 except 24	22-29	22-29	
IDENTITY OF THE ACTIVE INGREDIENT (cont.)																	
Authorisation from the manufacturer	AI				A									A			
Development code number(s) of producer	AI		A	A													
Description of starting materials for the manufacture	AI		A	A											A		
Guaranteed minimum concentration	AI		A	A													
Discussion of the formation of impurities of toxicological concern	AI			A											A		
IDENTITY OF THE BIOCIDAL PRODUCT																	
Trade name	BP	A	A	A	A _{CL}	A _{CL}	A	A	A [§]	A _{CL}	A	A _{CL}	A _{CL}	A _{CL} A	A	A	A
Composition: names and amount of - active ingredient(s), impurities, adjuvants, inert components	BP	A	A	A [§]	A _{CL}	A _{CL}	A	A	A*	A _{CL}	A	A _{CL}	A [♥] _{CL}	A _{CL} A	A _{CL}	A	A _{CL}
Physical state (emulsifiable concentrate, wettable powder, solution, etc.)	BP	A	A	A	A _{CL}	A		A	A	A _{CL}	A	A _{CL}	A _{CL}	A	A	A	A _{CL}
Name of manufacturer	BP	A	A	A	A _{CL}	A	C	A	A	A _{CL}	A	A	A _{CL}	A _{CL} A	NR	A	A
Name of applicant	BP	A	A	A	A	A _{CL}	A	A	A	A _{CL}	A	A _{CL}	A _{CL}	A _{CL} A	A	A	A
Other																	
Address, tel. no., fax no., of manufacturer	BP			A			A									A	
Contact person	BP			A													
Country's distributor	BP			A													

MATRIX 1. CHEMICAL IDENTITY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS	BEL	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ζ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA	EU
		22-29	22-29	22-29	22 25-28	22 25-26	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22 25-27	22, 25	22-29 except 24	22-29	22-29
IDENTITY OF THE BIOCIDAL PRODUCT (cont.)																	
Referenced submissions	BP			A													
Package size available	BP			A													
Draft of proposed label	BP			A													
Description of starting materials	BP			A												A	
Description of production process	BP															A	
Description of formulation process	BP			A												A	
Description of formation of impurities	BP															A	
Marketing Company	BP														A		
Approval Holder	BP														A		
Autorisation from the manufacturer	BP					A											
CAS number of the other ingredients than the active ingredient(s)	BP		A			A										A	
Commercial name of the other ingredients than the active ingredient(s)	BP		A													A	
Impurities and additives - identity, formation and range of each	BP														C _{CL}	A	
Information on authorisation already given in other countries or for other uses	BP		A														
Certificate of chemical analysis	BP										A						

MATRIX 1. CHEMICAL IDENTITY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

@	Canada: Both the CAS and IUPAC names are required for the active. Also, the CAS chemical name must be provided for impurities.
η	Denmark: The data requirements listed cover the use categories: 22 (rodenticides); 25 (repellents); 26 (insecticides, indoor/outdoor); 27 (insecticides/acaricides, humans/clothes/pets); and, 28 (molluscicides).
α	Finland: The data requirements listed cover the following use categories: rodenticides (indoor, outdoor) [22], repellents [25], insecticides/acaricides (indoor) [26a] and insecticides (outdoor) [26b].
κ	Germany has an approval procedure on voluntary basis for the following use categories: rodenticides [OECD use category 22]; repellents and attractants [25]; and, insecticides and acaricides [26 & 27]. For these products the data requirements are under preparation. Currently, data only on Toxicology (Matrix 9) and Human Exposure (Matrix 10) are formalised. The data requirements listed above cover all these use categories but they are not yet formalised.
φ	Greece: The data requirements cover the use categories 22-29 except the 27a (insecticides/acaricides for direct use on humans).
β	Hungary: The data requirements listed cover the use categories: 22 (rodenticides), 25 (repellents), 26 (insecticides), and 27 (insecticides/acaricides),.
θ	Ireland: Data requirements for the OECD use categories 22-29 but excluding 27a and 27c (direct application to humans and pets or other animals, respectively).
ε	The Netherlands have different use categories for products for vertebrate and invertebrate pest control than those used in the survey. The data requirements listed are common for the following use categories: H1) household products applied outdoors; H2) household products applied indoors on surfaces; H3) household products applied indoors as evaporators; H4) household products applied indoors as aerial spray; H5) repellents against mosquitoes, applied on the human skin [includ. in category 25]; H6) moth repellents for textile [includ. in category 25]; H7) products against storage pests; H8) rodenticides; and, V1) veterinary products applied in animal housing. The data requirements listed are minimal requirements that are necessary for the completeness of the dossiers. Based upon a first evaluation of a dossier additional requirements are established. In this respect the code "NR" is not used in the specific listing of data requirements since the possibility cannot be excluded that a particular question has to be asked as additional data requirement.
τ	Portugal: Data requirements for the OECD use categories 22, 25, 26, 27a, 27b, as well as for products for external use in animals, live stock, animal accommodation and transport, food industry (animal products).
ρ	Sweden: Regulates all the OECD use categories for pest control products, i.e. use categories 22-29 by an approval system. However, formalised data requirements exist only for rodenticides (use category 22) (presented in regular fonts) and mosquito repellents for use on skin (part of the use category 25) (presented in <i>italics</i> if different from those of the rodenticides).
ω	United Kingdom: Data requirements for OECD use categories 22-29, excluding only the use category 24 (piscicides).
♣	Impurities always required.
♥	Impurities and Transformation products always required.
§	Impurities conditionally required.
*	Impurities and Transformation products conditionally required.
CL	Classification & Labelling
CAS	CAS numbers

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL
(use categories 22-29)

MATRIX 2. PHYSICAL/CHEMICAL PROPERTIES

Type of Data/Information		AUS	BEL	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ε	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA	EU
		22-29	22-29	22-29	22-25-28	22-25-26	22-25-27	22-29 except 27a	22-25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22-25-27	22, 25	22-29 except 24	22-29	22-29
Colour	AI	A	A	A	A	A	NR	A _{CL}		A		A	A [♦]	C	A	A	A
	BP	A	A	C	A	A		A _{CL}	A	A		A	A	NR	C		A
Physical state	AI	A	A	A	A	A		A		A _{CL}		A	A [♦]	A	A _{CL}	A	A
	BP	A	A	A	A	A		A	A	A _{CL}	A	A _{CL}	A	NR	A _{CL}	A	A
Odour	AI	A	A	A	A	A		A		A		C	A	C	NR	A	NR
	BP	A	A	C	A	A		A	A	A		C _{CL}	A	NR	NR		NR
pH	AI	A		NR	A	NR		A		A _{CL}		C	A	A	C _{CL}	A	NR
	BP	A	A	C	A	A _{CL}		A	A	A _{CL}	C	A _{CL}	A	C	C _{CL}	A	A
Density	AI	A	A	A	A	A		A		A _{CL}		C	A	A	A	A	A
	BP	A	A	A	A	A		A	C	C _{CL}	C	C _{CL}	A	C	C	A	A
UV-visible, IR, NMR, Mass Spectra	AI	A	A	C [@]	A	A		NR	C	A _{CL}	A		A	C	A	A	A
	BP	C		NR		NR		NR	C	C _{CL}			A	NR	NR		NR
Melting point	AI	A	A	C	A	A		A	C	A _{CL}	A	A	A	A	C	C	A
	BP	C		NR		NR		A		C _{CL}		C _{CL}	C	NR	NR		NR
Boiling point	AI	A	A	C	A	A		A	C	A _{CL}	A	A	A	A	A _{CL}	C	A
	BP	C		NR		NR		A		C _{CL}		C _{CL}	C	NR	NR		NR
Vapour pressure	AI	A	A	C	A	A		A	C	A _{CL}	A	A _{CL}	A	A	A	A	A
	BP	C		NR		NR		A		C _{CL}		C _{CL}	NR	NR	NR		NR

MATRIX 2. PHYSICAL/CHEMICAL PROPERTIES - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS	BEL	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ρ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA	EU
		22-29	22-29	22-29	22 25-28	22 25-26	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22 25-27	22, 25	22-29 except 24	22-29	22-29
Solubility in water as a function of pH and temperature	AI	A	A	A	A	A	NR	A	A	A _{CL}	A	C _{CL}	A	A	A	A	A
	BP	C		NR		NR		A		C _{CL}		C _{CL}	NR	NR	NR		NR
Solubility in organic solvents	AI	A	A	A	A	A		A	A	A _{CL}	A	C _{CL}	A	A	NR	A	C
	BP	C		NR		NR		A		C _{CL}		C _{CL}	C	NR	NR		NR
Octanol-water partition coefficient as a function of pH	AI	A	A	C	A	A		A	C	A _{CL}	A	A _{CL}	C	A	A	A	A
	BP	C		NR	^{CL}	NR		A		C _{CL}			C	NR	NR		NR
Dissociation constant in water	AI	A		C	A	A		A	C	A _{CL}	A	C _{CL}	C*	A	A	A	NR
	BP	C		NR		NR		A		C _{CL}			C	NR	NR		NR
Thermal stability	AI	A	A [▲]	A	A	A		A	A	A _{CL}	A	C _{CL}	C	A	NR	A	A
	BP	A		NR		NR		A	A	C _{CL}		C _{CL}	A	C	NR		A
Stability in air	AI	A		A	A	A		A		A _{CL}		C _{CL}	C	A	NR	A	C
	BP	A		NR		NR		A	A	C _{CL}		C _{CL}	A	C	NR		NR
Stability in presence of metal ions or sunlight as a function of temperature	AI	A		C	A	NR		A		A	A		C	C	NR	A	NR
	BP	C		NR		NR		A	A	C			A	C	NR		A
Viscosity	AI	C		NR	A	NR		A		C _{CL}		C	C	C	C _{CL}	A	NR
	BP	C	A	C		A		A	C	C _{CL}		C _{CL}	C	NR	C _{CL}	C	NR
Surface tension	AI	C	A	NR	A	A		A		C _{CL}			C	C	C _{CL}	NR	A
	BP	C		NR		A		A	NR	C _{CL}			C	NR	C _{CL}	NR	NR
Dielectric breakdown voltage	AI	C		NR		NR		NR	NR	C			C	NR	NR		NR
	BP	C		C		NR		NR	NR	C			C	NR	NR	C	NR

MATRIX 2. PHYSICAL/CHEMICAL PROPERTIES - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS	BEL	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ρ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA	EU
		22-29	22-29	22-29	22-25-28	22-25-26	22-25-27	22-29 except 27a	22-25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22-25-27	22, 25	22-29 except 24	22-29	22-29
Oxidizing properties	AI	A	A	NR	A	A	NR	A _{CL}		A _{CL}			C	C	A _{CL}	C	A _{CL}
	BP	A	A	C	A _{CL}	A _{CL}		A _{CL}	C	C _{CL}		C _{CL}	C _{CL}	C _{CL}	C _{CL}	C	A _{CL}
Flammability	AI	A	A	NR	A	A		A _{CL}		A _{CL}			A [♥] _{CL}	A	A _{CL}	C	A _{CL}
	BP	A	A	C	A _{CL}	A _{CL}		A _{CL}	A	A _{CL}	A	C _{CL}	A [♥] _{CL}	A _{CL}	A _{CL}	C	A _{CL}
Explosive properties	AI	A	A	NR	A	A		A _{CL}					A [♥] _{CL}	A	A _{CL}	C	A _{CL}
	BP	A	A	C	A _{CL}	A _{CL}		A _{CL}	A	A _{CL}	A	C _{CL}	A [♥] _{CL}	A _{CL}	C _{CL}	C	A _{CL}
Storage stability or stability in solvents used in formulation	AI	A	A [♠]	NR	A	NR		A _{CL}		C _{CL}	A		A _{CL}	A	NR	C	NR
	BP	A	A	A	A _{CL}	A		A _{CL}	A	A _{CL}	A	C _{CL}	A _{CL}	A	C	C	A
Corrosion characteristics	AI	A		NR	A	NR		A _{CL}		A _{CL}			A	C	NR	A	A _{CL}
	BP	A		C	A	NR		A _{CL}	A	C _{CL}	A	C _{CL}	A _{CL}	C	NR	A	A _{CL}
Reactivity toward container	AI	A	A	NR		NR		A		C _{CL}			A	C	NR	A	A
	BP	A		C	A	NR		A	C	C _{CL}		C _{CL}	A	C	C	C	A
Miscibility or suspensibility of product with water or other solvents	AI	A		NR		NR		A		C _{CL}			A _{CL}	C	NR	C	NR
	BP	A		C	A	A		A	C	C _{CL}		C _{CL}	A _{CL}	C	NR	C	A _{CL}
Flash point	AI	A		NR		A		A		C _{CL}			A	C	A _{CL}	C	A
	BP	A		C	A	A		A	C	C _{CL}	C _{CL}	C _{CL}	A	C	C _{CL}	C	A
Wettability	AI	C		NR		NR		A		C			C	C	NR	NR	NR
	BP	A	A	NR	A	A		A	C	C _{CL}			C _{CL}	C	NR	NR	A

MATRIX 2. PHYSICAL/CHEMICAL PROPERTIES - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS	BEL	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ρ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA	EU
		22-29	22-29	22-29	22-25-28	22-25-26	22-25-27	22-29 except 27a	22-25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22-25-27	22, 25	22-29 except 24	22-29	22-29
Wet sieve and dry sieve test	AI	C		NR		NR	NR	A		C			NR	NR	NR	NR	NR
	BP	A		NR	A	A		A	C	C _{CL}		C	NR	NR	NR	NR	NR
Other				NR													
<i>Persistent foaming, flowability, pourability and dustability</i>	AI																NR
	BP																A
<i>Particle size</i>	AI					NR											
	BP		A			C					C				C _{CL}		
<i>Particle size during the application of a product</i>	AI																
	BP										C						
<i>Refraction index</i>	AI					C											
	BP					NR											
<i>Henry's law constant (volatility)</i>	AI										A						
	BP																
<i>Fat solubility</i>	AI					A											
	BP					NR											
<i>Decomposition or other reaction during combustion</i>	AI		A			A											
	BP					NR											
<i>Water content</i>	AI							A									
	BP							A									

MATRIX 2. PHYSICAL/CHEMICAL PROPERTIES - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS	BEL	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ρ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA	EU
		22-29	22-29	22-29	22-25-28	22-25-26	22-25-27	22-29 except 27a	22-25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22-25-27	22, 25	22-29 except 24	22-29	22-29
Physical or chemical compatibility /incompatibility with other preparations	AI						NR										
	BP		C								A						
Hydrolysis as function of pH	AI										A						
	BP																
Suspension capacity	AI																
	BP										A						
Emulsifiability and emulsion stability	AI																
	BP										A						

@ **Canada:** UV/VIS is conditionally required for AI; NR for BP. Mass Spec is A for pure active and impurities; NR for BP.

η **Denmark:** The data requirements listed cover the use categories: 22 (rodenticides); 25 (repellents); 26 (insecticides, indoor/outdoor); 27 (insecticides/acaricides, humans/clothes/pets); and, 28 (Molluscicides).

α **Finland:** The data requirements listed cover the following use categories: rodenticides (indoor, outdoor) [22]; repellents [25]; insecticides/acaricides (indoor) [26a]; and, insecticides (outdoor) [26b].

κ **Germany** has an approval procedure **on voluntary basis** for the following use categories: rodenticides [OECD use category 22]; repellents and attractants [25]; and, insecticides and acaricides [26 & 27]. For these products the data requirements are under preparation. Currently, data only on Toxicology (Matrix 9) and Human Exposure (Matrix 10) are formalised (under the voluntary scheme). No data on physical/chemical properties are presently required. Only risk phrases (R and S) which are best on some of the above tests need to be provided (according to EU legislation 67/548/EEC on classification, packaging and labelling of dangerous substances).

φ **Greece:** The data requirements cover the use categories 22-29 except the 27a (insecticides/acaricides for direct use on humans).

β **Hungary:** The data requirements listed cover the use categories: 22 (rodenticides); 25 (repellents); 26 (insecticides); and, 27 (insecticides/acaricides).

δ **Ireland:** Data requirements for the OECD use categories 22-29 but excluding the 27a and 27c (insecticides/acaricides for direct application to humans, pets or other animals).

MATRIX 2. PHYSICAL/CHEMICAL PROPERTIES - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

- ⊗ **The Netherlands** has different use categories for products used for vertebrate and invertebrate pest control than those used in the survey. The data requirements listed are common for the following uses categories: H1) household products applied outdoors; H2) household products applied indoors on surfaces; H3) household products applied indoors as evaporators; H4) household products applied indoors as aerial spray; H5) repellents against mosquitoes, applied on the human skin; H6) moth repellents for textile; H7) products against storage pests; H8) rodenticides; and, V1) veterinary products applied in animal housings.
- The data requirements listed are minimal requirements that are necessary for the completeness of the dossiers. Based upon a first evaluation of a dossier additional requirements are established. In this respect the code “NR” is not used in the specific listing of data requirements since the possibility cannot be excluded that a particular question has to be asked as additional data requirement.
- τ **Portugal:** Data requirements for the OECD use categories 22, 25, 26, 27a, 27b, as well as for products for external use in animals, livestock , animal accommodation and transport, food industry (animal products).
- ρ **Sweden:** Regulates all the OECD use categories for pest control products, i.e. use categories 22-29 by an approval system. However, formalised data requirements exist only for rodenticides (use category 22) (presented in regular fonts) and mosquito repellents for use on skin (part of the use category 25) (presented in *italics* if different from those of the rodenticides).
- ω **United Kingdom:** Data requirements for OECD use categories 22-29 , excluding only the use category 24 (piscicides).
- ♠ Transformation products always required.
- ♥ Impurities and transformation products always required.
- ♦ Transformation products conditionally required.
- § Impurities conditionally required.
- CL Classification & Labelling.

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL
(use categories 22-29)

MATRIX 3. FUNCTION, MODE OF ACTION AND HANDLING

Type of Data/Information		AUS	BEL	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ³	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA	EU
		22-29	22-29	22-29	22 25-28	22 25-26	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22 25-27	22, 25	22-29 except 24	22-29	22-29
Function (e.g. algicide, fungicide, insecticide, molluscicide, repellent, disinfectant, etc.)	AI	A	A	A	A	NR		A _{CL}		A _{CL}			A _{CL}	NR	A	A	A
	BP	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}	A	A _{CL}	A	A _{CL}
Mode of action on target organisms (e.g. contact poison, inhalation poison, fungitoxic, fungistatic, etc.)	AI		A	C	A	NR		A _{CL}	A	A _{CL}			A _{CL}	NR	A	A	A
	BP	A	A	NR	A _{CL}	A	A	A _{CL}	C _{CL}	A _{CL}	A	C	A _{CL}	A	NR	A	A _{CL}
Field of use (e.g. indoor, outdoor, public or non-public, etc)	AI		A	NR		NR		A _{CL}		A _{CL}			A _{CL}	NR	NR	A	A
	BP	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}	A _{CL} A	A _{CL}	A	A _{CL}
Pests controlled/target organisms	AI		A	NR		NR		A _{CL}	C	A _{CL}			A _{CL}	NR	NR	A	A
	BP	A _{CL}	A	A _{CL}	A _{CL}	A	A	A _{CL}	C	A _{CL}	A	A _{CL}	A _{CL}	A _{CL} A	A _{CL}	A	A _{CL}
Products to be protected	AI		A	A		NR		A _{CL}	A	A _{CL}			C _{CL}	NR	NR	A	A
	BP	A _{CL}	A	A _{CL}	A _{CL}	NR	A	A _{CL}	A	A _{CL}	A	A _{CL}	A _{CL}	A _{CL} A	C _{CL}	A	A _{CL}
Application rate per unit treated area/volume/weight or concentration	AI			NR		NR		A _{CL}		A _{CL}			A _{CL}	NR	NR	NR	A
	BP	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A	A _{CL}	A	A _{CL}	A _{CL}	C	A _{CL}	A	A _{CL}
Concentration of active ingredient in material used	AI			A		NR		A _{CL}	NR	A _{CL}			A _{CL}	NR	NR	A	NR
	BP	A _{CL}	A	A	A _{CL}	NR	A	A _{CL}	NR	A _{CL}	A	A _{CL}	A _{CL}	NR	A _{CL}	A	NR
Timing of applications and duration of protection	AI			NR		NR		A _{CL}		A _{CL}			C _{CL}	NR	NR	NR	NR
	BP	A _{CL}	A	C _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A	A _{CL}	A	A _{CL}	A _{CL}	C	C _{CL}	A	A _{CL}

**MATRIX 3. FUNCTION, MODE OF ACTION AND HANDLING - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE
PEST CONTROL (cont.)**

Type of Data/Information		AUS	BEL	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ξ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA	EU
		22-29	22-29	22-29	22-25-28	22-25-26	22-25-27	22-29 except 27a	22-25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22-25-27	22, 25	22-29 except 24	22-29	22-29
Use intervals (time between application of biocide and use of facility or commodity)	AI			NR		NR		A _{CL}		A _{CL}			A _{CL}	NR	NR	NR	NR
	BP	A _{CL}	A	C _{CL}	A _{CL}	C _{CL}	A	A _{CL}	C _{CL}	A _{CL}	A	A _{CL}	C _{CL}	C	C _{CL}	A	A _{CL}
Proposed instructions for use	AI			A _{CL}		NR		A _{CL}		A _{CL}			NR	NR	NR	NR	NR
	BP	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}	A _{CL} A	A _{CL}	A	A _{CL}
Site preparation and method of application	AI			NR		NR		A _{CL}		A _{CL}			NR	NR	NR	NR	NR
	BP	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}	A	A _{CL}	A	A _{CL}
Type of packaging	AI			NR		NR		A _{CL}		A _{CL}			C _{CL}	NR	NR	NR	A
	BP	A		A	A	A		A _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}	A	A	A	A _{CL}
Procedures for cleaning application equipment	AI			NR		NR		A _{CL}		C _{CL}			C _{CL}	NR	NR	NR	NR
	BP	A	A	NR	A _{CL}	NR	A	A _{CL}	A _{CL}	C _{CL}	A	C _{CL}	A _{CL}	C	NR	A	A _{CL}
Recommended methods and precautions for handling, storage, transport or fire (including reaction products)	AI			C _{CL}		NR		A _{CL}		A _{CL}			C _{CL}	NR	NR	NR	A
	BP	A _{CL}		C _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	A _{CL}	C _{CL}	A _{CL}	A _{CL} A	NR	A	A _{CL}
Emergency measures in case of accidents	AI			C _{CL}		NR		A _{CL}		A _{CL}	A		A _{CL}	NR		NR	A
	BP	A		C _{CL}	A _{CL}	A _{CL}	A	A _{CL}	A _{CL}	A _{CL}	A _{CL}	C _{CL}	A _{CL}	A		A	A _{CL}

**MATRIX 3. FUNCTION, MODE OF ACTION AND HANDLING - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE
PEST CONTROL (cont.)**

Type of Data/Information		AUS	BEL	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ξ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA	EU
		22-29	22-29	22-29	22-25-28	22-25-26	22-25-27	22-29 except 27a	22-25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22-25-27	22, 25	22-29 except 24	22-29	22-29
Other																	
Information on resistance and development of strategies to cope with	AI		A														A
	BP		A	C													A
Quantities (manufactured or imported) placed in market every year	AI		A			NR											A
	BP					A											NR
Function of the other ingredients than the active ingredient(s) in the biocidal product	BP		A	A													
Undesirable secondary effects for example on useful organisms	AI		A	A													
	BP		A														
Information on the possibility of destruction with: controlled waste disposal, incineration, waste water treatment plans or other techniques	BP		@				A										
Information on the possibility to re-use or recycle the product	BP		@														
Information on any possibility of rendering the active organism non-infective after release in or into the following: air, water, soil	BP		@														
Disposal statement, how to dispose of (remains of) the product	AI			C _{CL}													
	BP			C _{CL}			A				A						
Safety data sheet	AI			A		NR											
	BP					A											

**MATRIX 3. FUNCTION, MODE OF ACTION AND HANDLING - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE
PEST CONTROL (cont.)**

Type of Data/Information		AUS	BEL	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ξ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA	EU
		22-29	22-29	22-29	22 25-28	22 25-26	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22 25-27	22, 25	22-29 except 24	22-29	22-29
Prior approval, use in other countries	AI					NR											
	BP					C											
Miscibility with other biocides	AI					NR											
	BP			C _{CL}		A											
Proposal for labelling and instructions for use	AI			A		NR											
	BP			A		A _{CL}											
Classification of the product according to general classification rules for chemicals	AI			A _{CL}		NR											
	BP			A _{CL}		A _{CL}											
Pack size	AI			A													
	BP			A											A		
Intended User (e.g. professional or non-professional use)	AI																
	BP			A _{CL}							A _{CL}				A		

η **Denmark:** The data requirements listed cover the use categories: 22 (rodenticides); 25 (repellents); 26 (insecticides, indoor/outdoor); 27 (insecticides/acaricides, humans/clothes/pets); and, 28 (molluscicides).

α **Finland:** The data requirements listed cover the following use categories: rodenticides (indoor, outdoor) [22]; repellents [25]; insecticides/acaricides (indoor) [26a]; and, insecticides (outdoor) [26b].

κ **Germany** has an approval procedure on voluntary basis for the following use categories: rodenticides {OECD use category 22}; repellents and attractants [25]; and, insecticides and acaricides [26 & 27]. For these products the data requirements are under preparation. Currently, data only on Toxicology (Matrix 9) and Human Exposure (Matrix 10) are formalised (under the voluntary scheme). The above listed data cover all these categories but they are not yet formalised.

φ **Greece:** The data requirements cover the use categories 22-29 except the 27a (insecticides/acaricides for direct use on humans).

β **Hungary:** The data requirements listed cover the use categories: 22 (rodenticides); 25 (repellents); 26 (insecticides); and, 27 (insecticides/acaricides).

MATRIX 3. FUNCTION, MODE OF ACTION AND HANDLING - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

- ð **Ireland:** Data requirements for the OECD use categories 22-29 but excluding the 27a and 27c (insecticides/acaricides direct application to humans, pets or other animals).
- ə **The Netherlands** has different use categories for products used for vertebrate and invertebrate pest control than those used in the survey. The data requirements listed are common for the following uses categories: H1) household products applied outdoors; H2) household products applied indoors on surfaces; H3) household products applied indoors as evaporators; H4) household products applied indoors as aerial spray; H5) repellents against mosquitoes, applied on the human skin; H6) moth repellents for textile; H7) products against storage pests; H8) rodenticides; and, V1) veterinary products applied in animal housings.
 The data requirements listed are minimal requirements that are necessary for the completeness of the dossiers. Based upon a first evaluation of a dossier additional requirements are established. In this respect the code “NR” is not used in the specific listing of data requirements since the possibility cannot be excluded that a particular question has to be asked as additional data requirement.
- ρ **Sweden:** Regulates all the OECD use categories for pest control products, i.e. use categories 22-29 by an approval system. However, formalised data requirements exist only for rodenticides (use category 22) (presented in regular fonts) and mosquito repellents for use on skin (part of the use category 25) (presented in *italics* if different from those of the rodenticides).
- τ **Portugal:** Data requirements for the use categories 22, 25, 26, 27a, and 27b, as well as for products for external use in animals, livestock, animal accommodation and transport, food industry (animal products).
- ω **United Kingdom:** Data requirements for OECD use categories 22-29 , excluding only the use category 24 (piscicides).
- @ **Belgium:** This information will be required as soon as the EU Biocide Directive will be adopted.
- CL Classification & Labelling

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL
(use categories 22-29)

MATRIX 4. ANALYTICAL METHODS

Entries in the “BP” rows refer to formulates other than the active ingredients for which a concern may arise.

Type of Data/Information		AUS ^ζ	BEL	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ε	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA	EU
		22-29	22-29	22-29	22-25-28	22-25-26	22-25-27	22-29 except 27a	22-25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22-25-27	22, 25	22-29 except 24	22-29	22-29
Pure active ingredients and isomers, impurities and additives of the technical grade of the active ingredient or formulation	AI	A ^{♣♦} A [§] A ^{♣♦}	A*	Appendix A to Matrix 4	A	A*	NR	NR	A*	A [♥] _{CL}		A	A	C	A	A*	A
	BP	A ^{♣♦} A [§] A ^{♣♦}	A*			A*		NR		A [♥] _{CL}		C	A	C	C	A*	A
Active ingredients in food or feed (multi_residue methods) or treated product	AI	A ^{♣♦} A A*	C [♦]		A	A*		NR	A	C* _{CL}	C [♦] NR C [♦]	C	A _{CL}	NR	NR	C*	C
	BP	A ^{♣♦} A A*	C [♦]			NR		NR		C* _{CL}		C	A _{CL}	NR	NR	C*	A
Composition of formulated product	AI	A* A A*	A			NR		A [♣]		NR			A [§] _{CL}	NR	A _{CL}	A*	NR
	BP	A* A A*	A			A		A [♣]	A	A* _{CL}		A	A [§] _{CL}	A	C _{CL}	A*	A

MATRIX 4. ANALYTICAL METHODS - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS ^ζ	BEL	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^θ	NL ^ρ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA	EU
		22-29	22-29	22-29 except 27	22 25-28	22 25-26	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22 25-27	22, 25	22-29 except 24	22-29	22-29
Residues in water, including potable water	AI	NR NR C [♦]	C [♦]	Appendix A to Matrix 4	A	A [♦]	NR	NR		A [♥] _{CL}	A [♥] _{CL}	C	C _{CL}	NR C	A [♦]	C*	A
	BP	NR	C [♦]			NR		NR	A/C	A [♥] _{CL}			C _{CL}	NR C	NR	C*	A
Residues in air	AI	NR	C [♦]		A	NR		NR		C* _{CL}		C	C _{CL}	NR C	C [♦]	NR	A
	BP	NR	C [♦]			NR		NR	NR	C* _{CL}			C _{CL}	NR C	NR	NR	A
Residues in soil	AI	NR	C [♦]		A	A [♦]		NR	C	C* _{CL}		C	C _{CL}	NR C	C [♦]	C*	A
	BP	NR	C [♦]			NR		NR	C	C* _{CL}			C _{CL}	NR C	NR	NR	A
Residues in sediment	AI	NR	C [♦]		C	C		NR	C	C* _{CL}		C	C _{CL}	NR C	C [♦]	C*	C
	BP	NR	C [♦]			NR		NR	C	C* _{CL}			C _{CL}	NR C	NR	NR	C
Residues in biota (biological tissue such as plants, fish, birds, wild mammals, etc.)	AI	NR	C [♦]		A	A [♦]		NR	C	C* _{CL}	C [♦]	C	C _{CL}	NR C	C [♦]	C*	C
	BP	NR	C [♦]			NR		NR	C	C* _{CL}			C _{CL}	NR C	NR	NR	C
Residues in human body fluids	AI	NR	C [♦]		A	NR		NR	NR	C* _{CL}		C	C* _{CL}	NR C	NR	C*	A
	BP	NR	C [♦]			NR		NR		C* _{CL}			C* _{CL}	NR C	NR	NR	A

MATRIX 4. ANALYTICAL METHODS - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

- ζ **Australia:** data requirements for use categories 22-29. The data requirements (d.r.) for use categories 22-25 and 27-29 are cited with regular fonts; the d.r. for mothproof agents for carpets (included in use category 26a) are cited with *italics*; and, the d.r. for insecticides used outdoors (use category 26b) are cited with **bold** fonts.
- η **Denmark:** The data requirements listed cover the use categories: 22 (rodenticides); 25 (repellents); 26 (insecticides, indoor/outdoor); 27 (insecticides/acaricides, humans/clothes/pets); and, 28 (molluscicides).
- α **Finland:** The data requirements listed cover the following use categories: rodenticides (indoor, outdoor) [22]; repellents [25]; insecticides/acaricides (indoor) [26a]; and, insecticides (outdoor) [26b].
- κ **Germany** has an approval procedure on voluntary basis for the following use categories: rodenticides [OECD use category 22]; repellents and attractants [25]; and, insecticides and acaricides [26 & 27]. For these products the data requirements are under preparation. Currently, data only on Toxicology (Matrix 9) and Human Exposure (Matrix 10) are formalised (under the voluntary scheme).
- φ **Greece:** The data requirements cover the use categories 22-29 except the 27a (insecticides/acaricides for direct use on humans).
- β **Hungary:** The data requirements listed cover the use categories: 22 (rodenticides); 25 (repellents); 26 (insecticides); and, 27 (insecticides/acaricides).
- ∂ **Ireland:** Data requirements for the OECD use categories 22-29 but excluding the 27a and 27b (insecticides/acaricides direct application to humans, pets or other animals, respectively).
- ε **The Netherlands** has different use categories for products for vertebrate and invertebrate pest control than those used in the survey: H1) household products applied outdoors; H2) household products applied indoors on surfaces; H3) household products applied indoors as evaporators; H4) household products applied indoors as aerial spray; H5) repellents against mosquitoes, applied on the human skin; H6) moth repellents for textile; H7) products against storage pests; H8) rodenticides; and, V1) veterinary products applied in animal housings. Data requirements cited: a) with regular fonts are applicable to the use categories H2 - H5 and H8; b) with *italics* are applicable only for the use category H1; and, c) with **bold** fonts only for the use categories H6, H7 and V1.
- The data requirements listed are minimal requirements that are necessary for the completeness of the dossiers. Based upon a first evaluation of a dossier additional requirements are established. In this respect the code "NR" is not used in the specific listing of data requirements since the possibility cannot be excluded that a particular question has to be asked as additional data requirement.
- τ **Portugal:** Data requirements for the use categories 22, 25, 26, 27a, 27b, as well as for products for external use in animals, livestock, animal accommodation and transport, food industry (animal products).
- ρ **Sweden:** Regulates all the OECD use categories for pest control products, i.e. use categories 22-29 by an approval system. However, formalised data requirements exist only for rodenticides (use category 22) (presented in regular fonts) and mosquito repellents for use on skin (part of the use category 25) (presented in *italics* if different from those of rodenticides).
- ω **United Kingdom:** Data requirements for OECD use categories 22-29, excluding only the use category 24 (piscicides).
- ♣ Impurities always required
- ♥ Impurities and Transformation products always required
- ♦ Transformation products conditionally required
- * Impurities and Transformation products conditionally required

CL Classification & Labelling
tp treated product

COUNTRY: CANADA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL
(use categories 22-29, excluding 27)

APPENDIX A to MATRIX 4. ANALYTICAL METHODS

Type of Data/Information		Rodenticides (22)	Avicides (23)	Piscicides (24)	Repellents (25)	Insecticides (Outdoor residences) (26b ₁)	Insecticides (Outdoor expanses) (26b ₂)	Molluscicides (28)	Other vertebrates (29)
Pure active ingredients and isomers, impurities and additives of the technical grade of the active ingredient or formulation δ	AI	A*	A*	A*	A*	A*	A*	A*	A*
	BP	A*	A*	A*	A*	A*	A*	A*	A*
Active ingredients in food or feed (multi- residue methods) or treated product	AI								
	BP								
Composition of formulated product	AI								
	BP								
Residues in water, including potable water	AI	C*	C*	A*	C*	C*	A*	A*	C*
	BP								
Residues in air	AI								
	BP								
Residues in soil	AI	C*	C*	C*	C*	A*	A*	C*	C*
	BP								
Residues in sediment	AI	C*	C*	A*	C*	C*	A*	A*	C*
	BP								

COUNTRY: CANADA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL**APPENDIX A to MATRIX 4. ANALYTICAL METHODS (cont.)**

Type of Data/Information		Rodenticides (22)	Avicides (23)	Piscicides (24)	Repellents (25)	Insecticides (Outdoor residences) (26b ₁)	Insecticides (Outdoor expanses) (26b ₂)	Molluscicides (28)	Other vertebrates (29)
Residues in biota (biological tissue such as plants, fish, birds, wild mammals, etc.)	AI	C*	A*	A*	A*	A*	A*	A*	A*
	BP								
Residues in human body fluids	AI								
	BP								

δ Active in TGAI: Validated methodologies for specifically identifying and quantifying the active ingredients and each impurity present at or above 0.1% by weight, or those of toxicological significance at any level above the practical limit of quantitation, are required. A method capable of separating stereoisomers, must also be provided. Corresponding supporting raw data for all specified components from five (5) batches is required.

Active in Formulation: A validated analytical method suitable for enforcement purposes must be provided for each active ingredient in a end-use product with a requirement for specific determination of stereoisomers, when applicable. Raw data demonstrating the lack of interference of formulation components must also be provided. If potential exists for the formulators/formulating process to create or enhance the presence of an impurity of toxicological concern, validated methodology and corresponding raw data from the analysis of five (5) batches are required.

♣ Impurities always required

* Impurities and Transformation products conditionally required

CL Classification & Labelling

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL
(use categories 22-29)

MATRIX 5. EFFICACY OF FORMULATIONS

Type of Data/Information		AUS ^ζ	BEL	CAN ^δ	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ³	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU
		22-29	22-29	22 25-29	22 25-28	22 25-26	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22 25-27	22, 25	22-29 except 24	22, 23 25, 26 29	22-29
Effects on quality of treated substance	AI	see note		NR		NR	Not yet formalised (Under preparat- ion)	NR		C* _{CL}			C [♦] _{CL}	C	NR	NR	NR
	BP			C	A	NR		NR	C	C* _{CL}		A _{CL}	A [♦] _{CL}	C	NR	NR	NR
Dose/efficacy relationships (minimum inhibition-concentration scale)	AI			NR		NR		NR	A/C	C _{CL}			A _{CL}	C	A	A	NR
	BP		A	C	A	A _{CL}		NR		C _{CL}	A A	A _{CL}	A _{CL}	C	C	A	A
Evidence of effectiveness under working conditions	AI			NR		NR		C	NR	C			C _{CL}	A	NR	NR	NR
	BP			C	A	A		C		C	A NR	A _{CL}	A _{CL}	A	C	A	A
<i>Other</i>	AI																
	BP			C													

ζ **Australia:** Although, Australia stated that efficacy data are required for all registerable products, information on what data are required has not been provided.

δ **Canada:** Regulates all the OECD use categories for pest control products, i.e. use categories 22-29. However, data on efficacy are required only for the use categories 22 and 25-29. Efficacy trials must be carried out using the proposed formulations. Impurities and transformation products are qualified and quantified elsewhere in required supporting data.

η **Denmark:** The data requirements listed cover the use categories: 22 (rodenticides); 25 (repellents); 26 (insecticides, indoor/outdoor); 27 (insecticides/acaricides, humans/clothes/pets); and, 28 (Molluscicides).

α **Finland:** The data requirements listed cover the following use categories: rodenticides (indoor, outdoor) [22]; repellents [25]; insecticides/acaricides (indoor) [26a]; and, insecticides (outdoor) [26b].

κ **Germany** has an approval procedure on voluntary basis for the following use categories: rodenticides [OECD use category 22]; repellents and attractants [25]; and, insecticides and acaricides [26 & 27]. For these products the data requirements are under preparation. Currently, data only on Toxicology (Matrix 9) and Human Exposure (Matrix 10) are formalised (under the voluntary scheme).

φ **Greece:** The data requirements cover the use categories 22-29 except the 27a (insecticides/acaricides for direct use on humans).

MATRIX 5. EFFICACY OF FORMULATIONS - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

- β **Hungary:** The data requirements listed cover the use categories: 22 (rodenticides); 25 (repellents); 26 (insecticides); and, 27 (insecticides/acaricides).
- ð **Ireland:** Data requirements for the OECD use categories 22-29 but excluding 27a and 27c (insecticides/acaricides for direct application to humans and pets or other animals, respectively).
- ε **The Netherlands** has different use categories for products for vertebrate and invertebrate pest control than those used in the survey: H1) household products applied outdoors; H2) household products applied indoors on surfaces; H3) household products applied indoors as evaporators; H4) household products applied indoors as aerial spray; H5) repellents against mosquitoes, applied on the human skin [includ. in OECD use category 25]; H6) moth repellents for textile [includ. in OECD use category 25]; H7) products against storage pests; H8) rodenticides [OECD use category 22]; and, V1) veterinary products applied in animal housings. Data requirements cited: a) with regular fonts refer to use categories H1, H2, H4, H7-9; and, b) with *italics* to use categories H3, H5 and H6.
- The data requirements listed are minimal requirements that are necessary for the completeness of the dossiers. Based upon a first evaluation of a dossier additional requirements are established. In this respect the code “NR” is not used in the specific listing of data requirements since the possibility cannot be excluded that a particular question has to be asked as additional data requirement.
- τ **Portugal:** Data requirements for the use categories 22, 25, 26, 27a, 27b, as well as for products for external use in animals, livestock , animal accommodation and transport, food industry (animal products).
- ρ **Sweden:** Regulates all the OECD use categories for pest control products, i.e. use categories 22-29 by an approval system. However, formalised data requirements exist only for rodenticides (use category 22) and mosquito repellents for use on skin (includ. in the use category 25).
- ω **United Kingdom:** Data requirements for use categories 22-29 , excluding only the use category 24 (piscicides).
- μ **USA** regulates all the OECD pest control use categories, i.e. 22-29. Efficacy testing is required only for those use categories that are related to public health, i.e. rodenticides [use category 22], avicides [23], repellents [25], insecticides (indoor/outdoor) [26] and other vertebrates [29].
- ♦ Transformation products conditionally required.
- * Impurities and transformation products conditionally required.
- CL Classification & Labelling.

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL
(use categories 22-29)

MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT

Type of Data/Information		AUS ^ζ	BEL	CAN ^δ	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ε	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU
		22-29 except 27	22-29	22-29 except 27	22 25-28	22, 26b outdoor	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22 25-27	22	22-29 except 24	22-29	22-29
ABIOTIC																	
Hydrolysis rate including identification of metabolites and breakdown products	AI	A	A	Appendix A to Matrix 6	A	A	NR	NR	C	A* _{CL}	Appendix B to Matrix 6	C _{CL}	C	A _{CL}	A [♦]	A A A	A
	BP					NR				A* _{CL}			C _{CL}	NR	C [♦]	NR NR NR	NR
Photodegradation in water including identification of metabolites and breakdown products	AI	C	A		A	C			C	A* _{CL}		C _{CL}	C	C _{CL}	C [♦]	A C	A
	BP					NR				A* _{CL}			C _{CL}	NR	C [♦]	NR NR	NR
Photodegradation on soil including identification of metabolites and breakdown products	AI	C			A	C			C	A* _{CL}		C _{CL}	C	NR	C [♦]		NR
	BP					NR				A* _{CL}			C _{CL}	NR	C [♦]		NR
Rate and route of photochemical degradation in air, identification of breakdown products	AI	C				NR			C	A* _{CL}		C _{CL}	C	NR	C [♦]		C
	BP					NR				A* _{CL}			C _{CL}	NR	NR		NR
BIOTIC																	
Soil metabolism, aerobic and anaerobic, to determine rate and route of degradation in representative soil types including metabolites and breakdown products	AI	C			A	C	NR	NR	A/C	A* _{CL}		C _{CL}	C	C	C [♦]		C
	BP					NR				A* _{CL}		C _{CL}	C	C [♦]		C	

**MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE
PEST CONTROL (cont.)**

Type of Data/Information		AUS ^ζ	BEL	CAN ^δ	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^θ	NL ^ρ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU	
		22-29 except 27	22-29	22-29 except 27	22 25-28	22, 26b outdoor	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22 25-27	22	22-29 except 24	22-29	22-29	
BIOTIC (cont.)																		
Aquatic sediment metabolism, aerobic and anaerobic, including identification of breakdown products and metabolites	AI	C		Appendix A to Matrix 6	C	NR	NR	NR	C	A* _{CL}	Appendix B to Matrix 6	C _{CL}	C	NR	C [♦]	A C	C	
	BP					NR				A* _{CL}			C _{CL}	NR	C [♦]	NR NR	C	
Mobility/leaching in representative soil types and mobility of metabolites and breakdown products	AI	C			A	C			C	A* _{CL}		C _{CL}	C	C	C [♦]		C	
	BP					NR				A* _{CL}			C _{CL}	NR	C [♦]		C	
Adsorption/desorption in representative soil types including metabolites and breakdown products	AI	C	A		A	C			C	A* _{CL}		C _{CL}	C	C	A [♦]	A C	C	
	BP					NR				A* _{CL}			C _{CL}	NR	C [♦]	NR NR	C	
Laboratory volatility	AI	C			A	NR			C	C*				NR	C	A		NR
	BP					NR				C*				NR	NR	NR		NR
Special degradation of biocides in effluents	AI	C				NR			C	C* _{CL}		C _{CL}	C _{CL}	C _{CL}	A	NR		NR
	BP					NR				C* _{CL}				C _{CL}	C	NR		C
Adsorption/desorption screen	AI	C				C			C	C*		C _{CL}	C _{CL}	C	C	C		A
	BP					NR				C*				C _{CL}	NR	NR		C
Ready biodegradability	AI	C	A		A	C			C	A* _{CL}		C _{CL}	C _{CL}	C _{CL}	A _{CL}	C		A
	BP				^{CL}	NR				A* _{CL}				C _{CL}	C	C		NR
Inherent biodegradability	AI	C			A	NR			C	C* _{CL}		C _{CL}	C _{CL}	C _{CL}	C _{CL}	C		A
	BP					NR				C* _{CL}				C _{CL}	C	NR		NR

**MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE
PEST CONTROL (cont.)**

Type of Data/Information	AUS ^ζ		BEL	CAN ^δ	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^θ	NL ^ρ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU			
	22-29 except 27		22-29	22-29 except 27	22 25-28	22, 26b outdoor	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {VI}	22-29	22 25-27	22	22-29 except 24	22-29	22-29			
BIOTIC (cont.)																				
Aerobic aquatic biotransformation in natural water	AI	C		Appendix A to Matrix 6		NR	NR	NR	C		Appendix B to Matrix 6	C _{CL}	C _{CL}	C	C		C			
	BP					NR						C _{CL}	NR	C		C				
LEACHING																				
Leaching from treated wood	AI	NR			A	NR	NR	NR	C	C* _{CL}		C _{CL}	C _{CL}	CL	A		C			
	BP					NR				C* _{CL}			C _{CL}		C		C			
Leaching from anti-fouling paint	AI	NR				NR				C		A ^{♣♦} _{CL}		C _{CL}	C _{CL}	CL	A	NR	C	
	BP					NR						A ^{♣♦} _{CL}			C _{CL}		C	A	C	
Other	AI														C					
	BP														C					
FIELD TESTING																				
Small plot field tests or terrestrial field studies	AI	C				NR	NR	NR	C			C _{CL}		NR			NR			
	BP					NR								NR			C			
Aquatic field studies	AI	C NR				NR				C			C _{CL}		NR			NR		
	BP					NR									NR			C		
Other																				
Field monitoring	AI																	CL		
	BP																			

**MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE
PEST CONTROL (cont.)**

- ζ **Australia:** Regulates all the OECD use categories for pest control products, i.e. use categories 22-29. Data for environmental fate are required for use categories 22-29 excluding 27. The entries in regular fonts cover these use categories (i.e., 22-26 and 28-29) while the entries in *italics* correspond only to the use categories [22] rodenticides and 29 [other vertebrates], if their d.r. are different from the other categories.
- Australia has not developed specific and detailed environmental data requirements; rather, the Australian approach to environmental assessment is one of general rather than specific guidance, with data requirements determined on a case-by-case basis, depending on exposure. Australia's environmental data requirements for assessment of biocides are flexible, with the key criteria being the nature and extent of environmental exposure expected to arise through manufacture, use and disposal of the biocide.
- Accordingly, Australia has chosen indicative examples for the environmental data requirements based on experience, rather than filling out separate matrices for a large number of categories. To address all categories would be a largely hypothetical exercise as we have little or no experience with many of them, particularly in non-agricultural situations.
- Australia has only filled out the active ingredient column in matrices 6 and 7, as most testing will be done on the active. In most cases, Australia has marked requirements as conditional as it is very difficult to completely rule out particular requirements, even though they may be very unlikely. Similarly, for nearly all items the possibility remains that environmental data may be required for the biocidal product, impurities, or transformation products, even though in most situations such data would not be required.
- δ **Canada:** There are different data requirements for the use categories 22, 23, 24, 25, 26a, 26b, 28 and 29, which are listed in the Appendix A to Matrix 6.
- η **Denmark:** The data requirements listed cover the use categories: 22 (rodenticides); 25 (repellents); 26 (insecticides, indoor/outdoor); 27 (insecticides/acaricides, humans/clothes/pets); and, 28 (Molluscicides).
- α **Finland:** Regulates the following use categories by an approval system: rodenticides (indoor, outdoor) [22], repellents [25], insecticides/acaricides (indoor) [26a] and insecticides (outdoor) [26b]. However, data requirements for environmental fate exist only for rodenticides outdoor and insecticides outdoor, which are listed here.
- κ **Germany** has an approval procedure on voluntary basis for the following use categories: rodenticides [OECD use category 22]; repellents and attractants [25]; and, insecticides and acaricides [26 & 27]. For these products the data requirements are under preparation. Currently, data only on Toxicology (Matrix 9) and Human Exposure (Matrix 10) are formalised (under the voluntary scheme).
- φ **Greece:** The data requirements cover the use categories 22-29 except the 27a (insecticides/acaricides for direct use on humans).
- β **Hungary:** The data requirements listed cover the use categories: 22 (rodenticides), 25 (repellents), 26 (insecticides), and 27 (insecticides/acaricides).
- θ **Ireland:** Data requirements for the OECD use categories 22-29 but excluding the 27a and 27c (insecticides/acaricides for direct application to humans, pets or other animals, respectively).
- ε **The Netherlands** have different use categories for products for vertebrate and invertebrate pest control than those used in the survey: H1) household products applied outdoors; H2) household products applied indoors on surfaces; H3) household products applied indoors as evaporators; H4) household products applied indoors as aerial spray; H5) repellents against mosquito, applied on the human skin [includ. in OECD use category 25]; H6) moth repellents for textile [includ. in OECD use category 25]; H7) products against storage pests; H8) rodenticides [OECD use category 22]; and, V1) veterinary products applied in animal housings. The data requirements for these categories are listed in the Appendix B to the MATRIX 6.
- τ **Portugal:** Data requirements for the OECD use categories 22, 25, 26, 27a, 27b, as well as for products for external use in animals, live stock, animal accommodation and transport, food industry (animal products).
- ρ **Sweden:** Regulates all the OECD use categories for pest control products, i.e. use categories 22-29 by an approval system. However, formalised data requirements (d.r.) for environmental fate exist only for rodenticides (use category 22).

**MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE
PEST CONTROL (cont.)**

- ω **United Kingdom:** Data requirements for use categories 22-29, excluding only the use category 24 (piscicides).
- μ **USA:** i) with regular fonts are listed common data requirements for the use categories 22, 23, 25, 26a, 27 and 29; ii) with *italics* are listed data requirements for piscicides (24) and insecticides outdoor (26b); and; iii) with **bold** fonts are listed data requirements for molluscicides (28).
- ♣ Impurities always required.
- ♦ Transformation products conditionally required.
- * Impurities and Transformation products conditionally required.
- CL Classification & Labelling.

COUNTRY: CANADA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL
(use category 22-29 excluding 27)

APPENDIX A to MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT

Type of Data/Information Use Category		Rodenticides (22)	Avicides (23)	Piscicides (24)	Repellents (25)	Insecticides outdoor residences (26b ₁)	Insecticides outdoor expanses (26b ₂)	Molluscicides (28)	Other vertebrates (29)
ABIOTIC									
Hydrolysis rate including identification of metabolites and breakdown products	AI	A*	A*	A*	A*	A*	A*	A*	A*
	BP								
Photodegradation in water including identification of metabolites and breakdown products	AI	NR	NR	A*	NR	C*	A*	A*	NR
	BP								
Photodegradation on soil including identification of metabolites and breakdown products	AI	NR	NR	C*	NR	C*	A*	C*	NR
	BP								
Rate and route of photochemical degradation in air, identification of breakdown products	AI	C*	NR	C*	NR	NR	C*	C*	NR
	BP								
BIOTIC									
Soil metabolism, aerobic and anaerobic, to determine rate and route of degradation in representative soil types including metabolites and breakdown products	AI	C* aerobic NR anaerobic	C* aerobic NR anaerobic	C* aerobic NR anaerobic	C* aerobic NR anaerobic	A* aerobic NR anaerobic	A* aerobic C* anaerobic	C* aerobic C* anaerobic	C* aerobic NR anaerobic
	BP								
Aquatic sediment metabolism, aerobic and anaerobic, including identification of breakdown products and metabolites	AI	NR	NR	C*	NR	NR	C* aerobic A § anaerobic	C* aerobic C anaerobic	NR
	BP								

COUNTRY: CANADA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL

APPENDIX A to MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT (cont.)

Type of Data/Information Use Category		Rodenticides (22)	Avicides (23)	Piscicides (24)	Repellents (25)	Insecticides outdoor residences (26b ₁)	Insecticides outdoor expanses (26b ₂)	Molluscicides (28)	Other vertebrates (29)
BIOTIC (cont.)									
Mobility/leaching in representative soil types and mobility of metabolites and breakdown products	AI	NR	NR	C*	NR	C*	C*	C*	NR
	BP								
Adsorption/desorption in representative soil types including metabolites and breakdown products	AI	C*	C*	A*	C*	C*	C*	A*	C*
	BP								
Laboratory volatility	AI	NR	NR	C*	NR	C*	C*	C*	NR
	BP								
Special degradation of biocides in effluents	AI	NR	NR	NR	NR	NR	NR	NR	NR
	BP								
Adsorption/desorption screen	AI	NR	NR	NR	NR	NR	NR	NR	NR
	BP								
Ready biodegradability	AI	NR	NR	NR	NR	NR	NR	NR	NR
	BP								
Inherent biodegradability	AI	NR	NR	NR	NR	NR	NR	NR	NR
	BP								
Aerobic aquatic biotransformation in natural water	AI	C*	C*	A*	C*	C*	A*	A*	C*
	BP								

COUNTRY: CANADA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL

APPENDIX A to MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT (cont.)

Type of Data/Information Use Category		Rodenticides (22)	Avicides (23)	Piscicides (24)	Repellents (25)	Insecticides outdoor residences (26b ₁)	Insecticides outdoor expanses (26b ₂)	Molluscicides (28)	Other vertebrates (29)
BIOTIC (cont.)									
Other									
<i>Anaerobic aquatic sediment metabolism at low temperature (3-5°C), including identification of breakdown products and metabolites</i>	AI	NR	NR	C*	NR	NR	C*	C*	NR
	BP								
LEACHING									
Leaching from treated wood (special study related to use-pattern)	AI								
	BP	NR	NR	NR	NR	NR	NR	C	NR
Leaching from anti-fouling paint (special study related to use-pattern or formulation)	AI								
	BP	NR	NR	NR	NR	NR	NR	C	NR
FIELD TESTING									
Small plot field tests or terrestrial field studies	AI								
	BP	C*	NR	C*	NR	NR	A*	NR	NR
Aquatic field studies	AI								
	BP	C*	NR	A*	NR	NR	A*	A*	NR

* Impurities and Transformation products conditionally required.

§ Impurities conditionally required.

COUNTRY: **The NETHERLANDS****DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL****APPENDIX B to MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT**

Type of Data/Information Use Category		Household outdoors	Household indoors on surfaces	Household indoors as evaporators	Household indoors as aerial spray	Repellents against mosquitos	Moth repellents for textile	Products against storage pests	Rodenticides	Veterinary products animal housings
ABIOTIC										
Hydrolysis rate including identification of metabolites and breakdown products	AI	A	A	A	A	A	A	A	A	A
	BP									
Photodegradation in water including identification of metabolites and breakdown products	AI						A			
	BP									
Photodegradation on soil including identification of metabolites and breakdown products	AI									
	BP									
Rate and route of photochemical degradation in air, identification of breakdown products	AI									
	BP									
Other										
<i>Information on emission to the air</i>	AI		A	A						
	BP									

COUNTRY: The NETHERLANDS

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL

APPENDIX B to MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT (cont.)

Type of Data/Information Use Category		Household outdoors	Household indoors on surfaces	Household indoors as evaporators	Household indoors as aerial spray	Repellents against mosquitos	Moth repellents for textile	Products against storage pests	Rodenticides	Veterinary products animal housings
BIOTIC										
Soil metabolism, aerobic and anaerobic, to determine rate and route of degradation in representative soil types including metabolites and breakdown products	AI	A							C	C
	BP									
Aquatic sediment metabolism, aerobic and anaerobic, including identification of breakdown products and metabolites	AI	A					A	A		A
	BP									
Mobility/leaching in representative soil types and mobility of metabolites and breakdown products	AI								C	C
	BP									
Adsorption/desorption in representative soil types including metabolites and breakdown products	AI								C	C
	BP									
Laboratory volatility	AI									
	BP									
Special degradation of biocides in effluents	AI									
	BP									
Adsorption/desorption screen	AI						A			
	BP									

COUNTRY: The NETHERLANDS

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL

APPENDIX B to MATRIX 6. FATE AND BEHAVIOUR IN THE ENVIRONMENT (cont.)

Type of Data/Information Use Category		Household outdoors	Household indoors on surfaces	Household indoors as evaporators	Household indoors as aerial spray	Repellents against mosquitos	Moth repellents for textile	Products against storage pests	Rodenticides	Veterinary products animal housings
BIOTIC (cont.)										
Ready biodegradability	AI	A					A			A
	BP									
Inherent biodegradability	AI	A					A	A		A
	BP									
Aerobic aquatic biotransformation in natural water	AI	A					A	A		A
	BP									
<i>Other</i>										
<i>Effect on waste water</i>	AI						A		C	
	BP									
LEACHING										
Leaching from treated wood	AI									
	BP									
Leaching from anti-fouling paint	AI									
	BP									
FIELD TESTING										
Small plot field tests or terrestrial field studies	AI									
	BP									
Aquatic field studies	AI									
	BP									

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL
(use categories 22-29)

MATRIX 7. ECOTOXICOLOGY

Type of Data/Information		AUS ^ζ	BEL	CAN ^δ	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^³	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU
		22-29 except 27	22-29	22-29 except 27	22 25-28	22, 26b outdoor	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1, 6, 7} {VI} {H8}	22-29	22 25-27	22	22-29 except 24	22-29	22-29
AVIAN TESTING																	
Avian acute oral LD50	AI	C A	C	Appendix A to Matrix 7	A	A	NR	A _{CL}	A	C* _{CL}	C	C _{CL}	C _{CL}	A _{CL}	C	A A	C
	BP					C		A _{CL}		C* _{CL}		C _{CL}	C _{CL}	C	C	NR NR	C
Avian dietary toxicity LC50 - terrestrial bird (short-term toxicity)	AI	C	C		A/C	C		NR	C	C* _{CL}	C	C _{CL}	NR	C	C	A	C
	BP					NR		NR		C* _{CL}		C _{CL}	NR	C	C	NR	NR
Avian dietary toxicity LC50 - aquatic bird (short-term toxicity)	AI	C	C		A/C	C		NR	NR	C* _{CL}	C	C _{CL}	NR	C	C	A	C
	BP					NR		NR		C* _{CL}		C _{CL}	NR	C	C	NR	NR
Avian reproduction test - terrestrial bird	AI	C	C		A/C	C		NR	NR	C* _{CL}	C	C _{CL}	NR	C	C		C
	BP					NR		NR		C* _{CL}			NR	C	C		NR
Avian reproduction test - aquatic bird	AI	C			A/C	C		NR	NR	C* _{CL}		C _{CL}	NR	C	C		C
	BP					NR		NR		C* _{CL}			NR	C	C		NR
Avian field testing	AI	C				C		NR	C	C* _{CL}			NR	NR	NR		?
	BP					C		NR		C* _{CL}		C _{CL}	NR	NR	NR		C
Acceptance of bait, treated items by birds	AI	C			C	C		NR	NR	C* _{CL}			NR	NR	NR		?
	BP					C		NR		C* _{CL}		C	NR	NR	C		C

MATRIX 7. ECOTOXICOLOGY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS ^ζ		BEL	CAN ^δ	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^³	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU
		22-29 except 27		22-29	22-29 except 27	22 25-28	22, 26b outdoor	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1, 6, 7} {VI} {H8}	22-29	22 25-27	22	22-29 except 24	22-29	22-29
AQUATIC TESTING (not including algae)																		
Fish acute toxicity LC50, freshwater; warm water species	AI	C	C	Appendix A to Matrix 7	A	C _{CL}	NR	NR	A	C* _{CL}	A NR	C _{CL}	C _{CL}	C _{CL}	C _{CL}	A A A	A	
	BP		C		^{CL}	NR _{CL}	NR		C* _{CL}		C _{CL}	C _{CL}	C	C _{CL}	A A A	C		
Fish acute toxicity LC50, freshwater; cold water species	AI	C	A		A	C _{CL}	A _{CL}	C	C* _{CL}	A NR	C _{CL}	C _{CL}	A	A _{CL}	A A A	A		
	BP		C			NR _{CL}	A _{CL}		C* _{CL}		C _{CL}	C _{CL}	A	C _{CL}	A A A	C		
Daphnia acute immobilization test	AI	C	A		A	A _{CL}	A _{CL}	A	C* _{CL}	A NR	C _{CL}	C _{CL}	A _{CL}	A _{CL}	A A A	?		
	BP		C		^{CL}	NR _{CL}	A _{CL}		C* _{CL}		C _{CL}	C _{CL}	A	C _{CL}	A A A	?		
Marine or estuarine fish acute toxicity LC50/EC50	AI	C	C			NR	NR	C	C* _{CL}		C _{CL}	NR	NR _{CL}	C _{CL}	C A	C		
	BP					NR	NR		C* _{CL}		C _{CL}	NR	NR	C _{CL}	C A	C		
Daphnia life cycle (reproduction test)	AI	C	C		A	C _{CL}	NR	A	C* _{CL}		C _{CL}	NR	A	C _{CL}	A A	C		
	BP		C			C _{CL}	NR		C* _{CL}		C _{CL}	NR	A	C _{CL}	NR NR	C		

MATRIX 7. ECOTOXICOLOGY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS ^ζ	BEL	CAN ^δ	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^θ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU
		22-29 except 27	22-29	22-29 except 27	22 25-28	22, 26b outdoor	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1, 6, 7} {VI} {H8}	22-29	22 25-27	22	22-29 except 24	22-29	22-29
AQUATIC TESTING (not including algae) (cont.)																	
Fish reproduction and growth rate	AI	C	C	Appendix A to Matrix 7	A/C	NR	NR	NR	NR	C* _{CL}		C _{CL}	NR	NR _{CL}	C	A C	C
	BP		C			NR		NR		C* _{CL}		C _{CL}	NR	NR	C	NR NR	C
Fish life cycle/chronic toxicity to fish or fish early life stage	AI	C	C		A/C	NR		NR	NR	C* _{CL}		C _{CL}	NR	NR	C	A C	C
	BP		C			NR		NR		C* _{CL}		C _{CL}	NR	NR	C	NR NR	C
Fish bioconcentration	AI	C	C		A	C		NR	NR	C* _{CL}		C _{CL}	NR	A _{CL}	C	C C	C
	BP		C		CL	NR		NR		C* _{CL}		C _{CL}	NR	A	C	NR NR	C
Acute toxicity to marine invertebrates	AI	C	C			NR		NR	NR	C* _{CL}			C _{CL}	NR	C _{CL}	C A	NR
	BP					NR		NR		C* _{CL}			C _{CL}	NR	C _{CL}	C A	C
Chronic toxicity to marine invertebrates	AI	C				NR		NR	NR	C* _{CL}			NR	NR	C _{CL}		NR
	BP					NR		NR		C* _{CL}			NR	NR	C _{CL}		C
Field studies	AI	C				NR		NR	C				C _{CL}	NR	C	NR	?
	BP					NR		NR					C _{CL}	NR	C	C	C

MATRIX 7. ECOTOXICOLOGY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information	AUS ^ζ		BEL	CAN ^δ	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^θ	NL ^ε	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU	
	22-29 except 27	22-29	22-29 except 27	22-25-28	22, 26b outdoor	22-25-27	22-29 except 27a	22-25-27	22-29 except 27a,c	{H1, 6, 7} {VI} {H8}	22-29	22-25-27	22	22-29 except 24	22-29	22-29		
AQUATIC TESTING (not including algae) (cont.)																		
Other aquatic tests				Appendix A to Matrix 7			NR											
Bioaccumulation	AI		C															
	BP																	
Test on sediment dwelling species	AI		C		C													
	BP																	
PHYTOTOXICITY TO NON-TARGET PLANTS																		
Algae, growth inhibition -freshwater	AI	C	A	Appendix A to Matrix 7	A	A _{CL}	NR	NR	NR/C	C* _{CL}	A _{NR}	C _{CL}	C _{CL}	A _{CL}	C _{CL}	A _A	A	
	BP		C		CL	NR		NR		C* _{CL}			C _{CL}	A	C _{CL}	A _A	C	
Algae, growth inhibition - marine	AI	C	C			NR		NR	NR	C* _{CL}		C _{CL}	C _{CL}	NR _{CL}	C _{CL}	A _A	A	
	BP		C			NR		NR		C* _{CL}		C _{CL}	NR	C _{CL}	A _A	C		
Aquatic plant growth	AI	C				NR		NR	NR	C* _{CL}			NR	NR	C	A _A	C	
	BP					NR		NR		C* _{CL}		C _{CL}	NR	NR	C	A _A	C	
Seed germination/seedling emergence	AI	C				NR		A	NR	C* _{CL}			NR	NR	NR	NR _{NR}	C	
	BP					NR		A		C* _{CL}		C _{CL}	NR	NR	NR	A _A	C	
Other on-target plant tests	AI					NR			NR									C
	BP																	C

MATRIX 7. ECOTOXICOLOGY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS ^ζ	BEL	CAN ^δ	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^θ	NL ^ε	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU
		22-29 except 27	22-29	22-29 except 27	22 25-28	22, 26b outdoor	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1, 6, 7} {VI} {H8}	22-29	22 25-27	22	22-29 except 24	22-29	22-29
TESTING ON OTHER NON-TARGET SPECIES																	
Effects on earthworms	AI	C	C	Appendix A to Matrix 7	A	NR	NR	NR	NR	C _{CL} ^s	C	C _{CL}	C _{CL}	NR _{CL}	C		C
	BP		C			NR		NR		C _{CL} ^s		C _{CL}	C _{CL}	NR	C		C
Effects on beneficial insects	AI	C			A	NR		NR	NR	C _{CL} ^s			NR	NR	C		C
	BP				CL	NR		NR		C _{CL} ^s		C _{CL}	NR	NR	C _{CL}		C
Effects on terrestrial vertebrates other than birds	AI	C				C		A _{CL}	NR	C _{CL} ^s		C _{CL}	C _{CL}	NR	C		C
	BP					NR		A _{CL}		C _{CL} ^s		C _{CL}	C _{CL}	NR	C _{CL}		C
Activated sludge, respiration inhibition test	AI	C	C		C	NR		NR	NR	C _{CL} ^s		C _{CL}	NR	A	A		C
	BP		C			NR		NR		C _{CL} ^s		C _{CL}	NR	C	C		C
Other	AI																C
	BP																C
Acute testing on a non-aquatic, non-target species	AI		C														
	BP																
Effect on nitrification	AI										C						
	BP																

MATRIX 7. ECOTOXICOLOGY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

ζ **Australia:** Regulates all the OECD use categories for pest control products, i.e. use categories 22-29. Data for ecotoxicology are required for use categories 22-29 excluding 27. The entries in regular fonts cover these use categories (i.e., 22-26 and 28-29) while the entries in *italics* correspond only to the use categories [22] rodenticides and 29 [other vertebrates], if their d.r. are different from the other categories.

Australia has not developed specific and detailed environmental data requirements; rather, the Australian approach to environmental assessment is one of general rather than specific guidance, with data requirements determined on a case-by-case basis, depending on exposure. Australia's environmental data requirements for assessment of biocides are flexible, with the key criteria being the nature and extent of environmental exposure expected to arise through manufacture, use and disposal of the biocide.

Accordingly, Australia has chosen indicative examples for the environmental data requirements based on experience, rather than filling out separate matrices for a large number of categories. To address all categories would be a largely hypothetical exercise as Australia has little or no experience with many of them, particularly in non-agricultural situations.

Australia has only filled out the active ingredient column in matrices 6 and 7, as most testing will be done on the active. In most cases, Australia has marked requirements as conditional as it is very difficult to completely rule out particular requirements, even though they may be very unlikely. Similarly, for nearly all items the possibility remains that environmental data may be required for the biocidal product, impurities, or transformation products, even though in most situations such data would not be required.

δ **Canada:** Regulates all the OECD use categories for pest control products, i.e. use categories 22-29. Data requirements for ecotoxicology exists for all these categories except the 27 [insecticides/acaricides for use on humans, clothes, pets]. The use category 26 is divided differently from the OECD: 26a [insecticides outdoor residences] and 26b [outdoor expanses]. The data requirements are listed in the Appendix A to Matrix 7.

η **Denmark:** The data requirements listed cover the use categories: 22 (rodenticides); 25 (repellents); 26 (insecticides, indoor/outdoor); 27 (insecticides/acaricides, humans/clothes/pets); and, 28 (molluscicides).

α **Finland:** Regulates the following use categories: rodenticides (indoor, outdoor) [22]; repellents [25]; insecticides/acaricides (indoor) [26a]; and, insecticides (outdoor) [26b]. However, data requirements for ecotoxicology exist only for rodenticides outdoor and insecticides outdoor and they are listed here.

κ **Germany** has an approval procedure on voluntary basis for the following use categories: Rodenticides [OECD use category 22]; repellents and attractants [25]; and, insecticides and acaricides [26 & 27]. For these products the data requirements are under preparation. Currently, data only on Toxicology (Matrix 9) and Human Exposure (Matrix 10) are formalised (under the voluntary scheme).

φ **Greece:** The data requirements cover the use categories 22-29 except the 27a (insecticides/acaricides for direct use on humans).

β **Hungary:** The data requirements listed cover the use categories: 22 (rodenticides), 25 (repellents), 26 (insecticides), and 27 (insecticides/acaricides).

∂ **Ireland:** Data requirements for the OECD use categories 22-29 but excluding the 27a and 27c (insecticides/acaricides for direct application to human pets or other animals, respectively).

ς **The Netherlands** has different use categories for products for vertebrate and invertebrate pest control from those used in the survey: : H1) household products applied outdoors; H2) household products applied indoors on surfaces; H3) household products applied indoors as evaporators; H4) household products applied indoors as aerial spray; H5) repellents against mosquitoes, applied on the human skin [includ. in OECD use category 25]; H6) moth repellents for textile [includ. in OECD use category 25]; H7) products against storage pests; H8) rodenticides [OECD use category 22]; and, V1) veterinary products applied in animal housings. However, only the use categories H1, H6, H7, H8 and V1 have data requirements for ecotoxicology: a) with regular fonts are listed data for the use categories H1, H6, H7 and V1; and, b) with *italics* are listed d.r. for the category H8.

The data requirements listed are minimal requirements that are necessary for the completeness of the dossiers. Based upon a first evaluation of a dossier additional requirements are established. In this respect the code "NR" is not used in the specific listing of data requirements since the possibility cannot be excluded that a particular question has to be asked as additional data requirement.

MATRIX 7. ECOTOXICOLOGY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

- τ **Portugal:** Data requirements for the use categories 22, 25, 26, 27a and 27b, as well as for products for external use in animals, livestock, animal accommodation and transport, food industry (animal products).
- ρ **Sweden:** Regulates all the OECD use categories for pest control products, i.e. use categories 22-29 by an approval system. However, formalised data requirements for ecotoxicology exist only for rodenticides (use category 22).
- ω **United Kingdom:** Data requirements for use categories 22-29, excluding only the use category 24 (piscicides).
- μ **USA:** i) with normal fonts are listed common data requirements for the use categories 22, 23, 25, 26a, 27 and 29; ii) with *italics* are listed data requirements for piscicides (24) and insecticides outdoor (26b) and; iii) with **bold fonts** are listed data requirements for molluscicides (28).
- ♣ Impurities always required.
- ♦ Transformation products conditionally required.
- * Impurities and Transformation products conditionally required.
- § Impurities conditionally required.
- CL Classification & Labelling.

COUNTRY: CANADA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL
(use categories 22-29, excluding 27)

APPENDIX A to MATRIX 7. ECOTOXICOLOGY

Type of Data/Information Use Category		Rodenticides (22)	Avicides (23)	Piscicides (24)	Repellents (25)	Insecticides outdoor residences (26b ₁)	Insecticides outdoor expances (26b ₂)	Molluscicides (28)	Other vertebrates (29)
AVIAN TESTING									
Avian acute oral LD50	AI	C*	C*	C*	C*	A*	A*	C*	C*
	BP								
Avian dietary toxicity LC50 - terrestrial bird (short-term toxicity)	AI	C*	C*	NR	C*	A*	A*	NR	C*
	BP								
Avian dietary toxicity LC50 - aquatic bird (short-term toxicity) - <i>Mallard duck</i>	AI	C*	C*	C*	C*	A*	A*	C*	C*
	BP								
Avian reproduction test - terrestrial bird (<i>Bobwhite quail</i>)	AI	C*	C*	NR	C*	C*	C*	NR	C*
	BP								
Avian reproduction test - aquatic bird (<i>Mallard duck</i>)	AI	C*	C*	C*	C*	C*	C*	C*	C*
	BP								
Avian field testing	AI								
	BP	C*	C*	C*	C*	C*	C*	C*	C*
Acceptance of bait, treated items by birds	AI	NR	NR	NR	NR	NR	NR	NR	NR
	BP								

COUNTRY: CANADA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL

APPENDIX A to MATRIX 7. ECOTOXICOLOGY (cont.)

Type of Data/Information Use Category		Rodenticides (22)	Avicides (23)	Piscicides (24)	Repellents (25)	Insecticides outdoor residences (26b ₁)	Insecticides outdoor expanses (26b ₂)	Molluscicides (28)	Other vertebrates (29)
AVIAN TESTING (cont.)									
Other									
Special studies related to the intended use-pattern	AI	C*	C*	C*	C*	C*	C*	C*	C*
	BP								
Laboratory studies with end-use products	AI			C*					
	BP	C*	C*		C*	C*	C*	C*	C*
AQUATIC TESTING (not including algae)									
Fish acute toxicity LC50, freshwater; warm water species (<i>Bluegill sunfish</i>)	AI	C*	C*	C*	C*	C*	A*	C*	C*
	BP								
Fish acute toxicity LC50, freshwater; cold water species (<i>Rainbow trout</i>)	AI	C*	C*	C*	C*	C*	A*	C*	C*
	BP								
Daphnia acute immobilization test	AI	C*	C*	C*	C*	C*	A*	C*	C*
	BP								
Marine or estuarine fish acute toxicity LC50/EC50	AI	C*	C*	C*	C*	NR	C*	C*	C*
	BP								
Daphnia life cycle (reproduction test)	AI								
	BP								

COUNTRY: CANADA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL

APPENDIX A to MATRIX 7. ECOTOXICOLOGY (cont.)

Type of Data/Information Use Category		Rodenticides (22)	Avicides (23)	Piscicides (24)	Repellents (25)	Insecticides outdoor residences (26b ₁)	Insecticides outdoor expanses (26b ₂)	Molluscicides (28)	Other vertebrates (29)
AQUATIC TESTING (not including algae) (cont.)									
Fish reproduction and growth rate	AI	C*	C*	C*	C*	C*	C*	C*	C*
	BP								
Fish life cycle/chronic toxicity to fish or fish early life stage	AI	C*	C*	C*	C*	C*	C*	C*	C*
	BP								
Fish bioconcentration	AI	C*	C*	C*	C*	C*	C*	C*	C*
	BP								
Acute toxicity to marine invertebrates - <i>Crustacean, e.g. shrimp</i> - <i>Mollusc embryo larvae</i> - <i>Mollusc shell deposition</i>	AI	NR	NR	C*	NR	NR	C*	C*	NR
	BP								
Chronic toxicity to marine invertebrates:									
- <i>Mollusc or crustacean</i>	AI	NR	NR	C*	NR	NR	C*	C*	NR
	BP								
- <i>Daphnia sp. Chronic</i>	AI	C*	C*	C*	C*	C*	C*	C*	C*
	BP								
Field studies	AI	NR	NR	C*	NR	NR	C		NR
	BP							C*	

COUNTRY: CANADA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL

APPENDIX A to MATRIX 7. ECOTOXICOLOGY (cont.)

Type of Data/Information Use Category		Rodenticides (22)	Avicides (23)	Piscicides (24)	Repellents (25)	Insecticides outdoor residences (26b ₁)	Insecticides outdoor expanses (26b ₂)	Molluscicides (28)	Other vertebrates (29)
AQUATIC TESTING (not including algae) (cont.)									
<i>Other aquatic tests</i>									
<i>Laboratory studies with end-use product</i>	AI	NR	NR	C*	NR	NR	C*		NR
	BP							C*	
<i>Bioconcentration Depuration (bivale or crustacean)</i>	AI	NR	NR	C*	NR	NR	C*	C*	NR
	BP								
PHYTOTOXICITY TO NON-TARGET PLANTS									
Algae, growth inhibition - freshwater	AI	C*	C*	C*	C*	C*	A*	C	C*
	BP								
Algae, growth inhibition - marine	AI	C*	NR	C*	NR	NR	C*	C	NR
	BP								
Aquatic plant growth (<i>Aquatic vascular plants -Lemma</i>)	AI	C*	C*	C*	C*	C*	A*	C	C*
	BP								
Seed germination/seedling emergence (<i>Terrestrial vascular plants</i>)	AI	C*	C*	NR	C*	C*	A*		C*
	BP								

COUNTRY: CANADA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL

APPENDIX A to MATRIX 7. ECOTOXICOLOGY (cont.)

Type of Data/Information Use Category		Rodenticides (22)	Avicides (23)	Piscicides (24)	Repellents (25)	Insecticides outdoor residences (26b ₁)	Insecticides outdoor expanses (26b ₂)	Molluscicides (28)	Other vertebrates (29)
TESTING ON OTHER NON-TARGET SPECIES									
Effects on earthworms	AI	NR	NR	NR	NR	NR	A*		NR
	BP								
Effects on beneficial insects - Acute contact bees/pollinators - Acute oral bees/pollinators - Hive study (including bee bread) - Predators - Parasites - Other terrestrial invertebrates	AI	NR	NR	NR	NR	NR	C*		NR
	BP								
Effects on terrestrial vertebrates other than birds	AI	NR	NR	NR	NR				NR
	BP								
Activated sludge, respiration inhibition test	AI	NR	NR	NR	NR	NR	NR		NR
	BP								

* Impurities and Transformation products conditionally required.

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL
(use categories 22-29)

MATRIX 8. RESIDUE CHEMISTRY

Type of Data/Information			AUS ^ζ	BEL	CAN ^δ	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^θ	NL ^³	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU				
			26b	22-29	22-29	22 25-28	22, 26a indoor 25	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {V1}	22-29	22 25-27	22	22-29 except 24	22, 24 & cockroach control [incl. 26a]	22-29				
IDENTIFICATION OF RESIDUES																						
Nature of the residue in/on treated material or animal	AI	C [♦]	NR	NR	A	C	NR	NR	C	C* _{CL}	Appendix A to Matrix 8	C	A [♥] _{CL}	NR	C	A	C					
	BP	NR			A	C				C* _{CL}			A [♥] _{CL}	NR	NR	NR	C					
Other																						
Risk of secondary poisoning	AI																					
	BP																					
MAGNITUDE OF THE RESIDUE ON/ IN THE TREATED MATERIAL OR ANIMAL																						
Wood	AI	NR	NR	NR	C	NR	NR	NR	NR	C _{CL}		C			NR	NR	?					
	BP	NR				NR				C _{CL}		C			C	NR	?					
Wool	AI	NR				NR			NR	NR		C			NR	NR	?					
	BP	NR				NR				NR		C			NR	NR	?					
Livestock:	AI	C [♦]				NR			NR						NR				NR	C	C	
	BP	NR				NR														NR	C	
• Consumer residues	AI																			C [♦]		
	BP					A														C [♦]		

MATRIX 8. RESIDUE CHEMISTRY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS ^ζ	BEL	CAN ^δ	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^θ	NL ^ϑ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU
		26b	22-29	22-29	22 25-28	22, 26a indoor 25	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {V1}	22-29	22 25-27	22	22-29 except 24	22, 24 & cockroach control [incl. 26a]	22-29
MAGNITUDE OF THE RESIDUE ON/ IN THE TREATED MATERIAL OR ANIMAL (cont.)																	
• Animals kept for food production and pets	AI		NR	NR			NR	NR		C* _{CL}	Appendix A to Matrix 8						
	BP									C* _{CL}							
• All food producing species	AI												A [♥] _{CL}				
	BP												A [♥] _{CL}				
• As listed on the label/use directions	AI											C					
	BP											C					
Fish	AI	C [♦]				NR			NR	C* _{CL}		C	A [♥] _{CL}			NR	C
	BP	NR				NR				C* _{CL}			A [♥] _{CL}			NR	C
Freezer or storage stability tests for any of the above magnitude of the residue tests	AI	C [♦]				NR			NR	NR		C	C _{CL}			NR	?
	BP	NR				NR				NR		C	A _{CL}			A	C
Other																	
Surfaces which contact directly with food animal derivatives	AI												A [♥] _{CL}				
	BP												A [♥] _{CL}				
Dislodgeable residue from treated furnishings	AI														NR		
	BP														C		
Data on migration to (raw materials for) foodstuffs and animal feed and the residues found as a result to this	AI																
	BP																

MATRIX 8. RESIDUE CHEMISTRY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information	AUS ^ζ		BEL	CAN ^δ	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ε	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU
	26b		22-29	22-29	22 25-28	22, 26a indoor 25	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {V1}	22-29	22 25-27	22	22-29 except 24	22, 24 & cockroach control [incl. 26a]	22-29
OTHER REQUIREMENTS																	
Proposed tolerance or maximum residue levels	AI	C [♦]	NR	NR		NR	NR	NR	C	A [♥]	Appendix A to Matrix 8	C	A _{CL}	NR	NR		C
	BP	NR				NR				A [♥]			A _{CL}	NR	NR		C
Effects of preparation on residues (e.g. cooking, processing)	AI	C [♦]				NR				C*			A [♠] _{CL}	NR	NR		C
	BP	NR				NR				C*		C	A [♠] _{CL}	NR	NR		C
Effects on odor, taste and quality of food due to residues	AI	C [♦]				NR				C*			A _{CL}	NR	NR		C
	BP	NR				NR				C*		C	A _{CL}	NR	NR		C

- ζ **Australia:** Regulates all the OECD use categories for pest control products, i.e. use categories 22-29. However, data for residues are required only for the use category 26b: insecticides outdoor.
- δ **Canada:** Regulates all the OECD use categories for pest control products, i.e. use categories 22-29. However, there are no data requirements for residues, since these products are considered to have non-food contact uses.
- η **Denmark:** The data requirements listed cover the use categories: 22 (rodenticides); 25 (repellents); 26 (insecticides, indoor/outdoor); 27 (insecticides/acaricides, humans/clothes/pets); and, 28 (molluscicides).
- α **Finland:** Regulates the following use categories: rodenticides (indoor, outdoor) [22]; repellents [25]; insecticides/acaricides (indoor) [26a]; and, insecticides (outdoor) [26b]. However, data requirements for residues exist only for rodenticides (indoor), repellents [25] and insecticides/acaricides (indoor) [26a] and they are listed here.
- κ **Germany** has an approval procedure **on voluntary basis** for the following use categories: rodenticides [OECD use category 22]; repellents and attractants [25]; and, insecticides and acaricides [26 & 27]. For these products the data requirements are under preparation. Currently, data only on Toxicology (Matrix 9) and Human Exposure (Matrix 10) are formalised (under the voluntary scheme).
- φ **Greece:** The data requirements cover the use categories 22-29 except the 27a (insecticides/acaricides for direct use on humans).
- β **Hungary:** The data requirements listed cover the use categories: 22 (rodenticides); 25 (repellents); 26 (insecticides); and, 27 (insecticides/acaricides).
- δ **Ireland:** Data requirements for the use categories 22-29 but excluding the 27a and 27c (insecticides/acaricides for direct application to humans, pets or other animals, respectively).

MATRIX 8. RESIDUE CHEMISTRY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

- ⊗ **The Netherlands** has different use categories for products for vertebrate and invertebrate pest control from those used in the survey: H1) household products applied outdoors; H2) household products applied indoors on surfaces; H3) household products applied indoors as evaporators; H4) household products applied indoors as aerial spray; H5) repellents against mosquitos, applied on the human skin [includ. in OECD use category 25]; H6) moth repellents for textile [includ. in OECD use category 25]; H7) products against storage pests; H8) rodenticides [OECD use category 22]; and, V1) veterinary products applied in animal housings. Data requirements for residues exist only for the use categories H2, H3, H4, H6, H7 and V1 and are listed in the APPENDIX A to the MATRIX 8.
- τ **Portugal:** Data requirements for the OECD use categories 22, 25, 26, 27a, 27b, as well as for products for external use in animals, live stock, animal accommodation and transport, food industry (animal products).
- ρ **Sweden:** Regulates all the OECD use categories for pest control products, i.e. use categories 22-29 by an approval system. However, formalised data requirements for residues exist only for rodenticides (use category 22).
- ω **United Kingdom:** Data requirements for OECD use categories 22-29, excluding only the use category 24 (piscicides).
- μ **USA:** Regulates all the OECD use categories for pest control products, i.e. use categories 22-29. However, data requirements for residues exist only for rodenticides [use category 22], piscicides [use category 24] and cockroach control [included in the use category 26a] and they are listed here.
- ♣ Impurities always required
- ♠ Transformation products always required
- ♥ Impurities and Transformation products always required
- * Impurities and Transformation products conditionally required
- ♦ Transformation products conditionally required
- CL Classification & Labelling

COUNTRY: The NETHERLANDS

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL

APPENDIX A to MATRIX 8. RESIDUE CHEMISTRY

Type of Data/Information		Use category								
		Household outdoors [▽]	Household indoors on surfaces	Household indoors as evaporators	Household indoors as aerial spray	Repellents against mosquitos [▽]	Moth repellents for textile	Products against storage pests	Rodenticides [▽]	Veterinary products animal housings
IDENTIFICATION OF RESIDUES										
Nature of the residue in/on treated material or animal	AI									
	BP									
MAGNITUDE OF THE RESIDUE ON/ IN THE TREATED MATERIAL OR ANIMAL										
Wood	AI									
	BP									
Wool	AI									
	BP									
Livestock : (depends on claim for biocidal product)	AI									A
	BP									
• Plant products	AI							A		
	BP									
Fish	AI									
	BP									
Freezer or storage stability tests for any of the above magnitude of the residue tests	AI									
	BP									

COUNTRY: The NETHERLANDS

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL

APPENDIX A to MATRIX 8. RESIDUE CHEMISTRY (cont.)

Type of Data/Information	Use category									
	Household outdoors ∇	Household indoors on surfaces	Household indoors as evaporators	Household indoors as aerial spray	Repellents against mosquitos ∇	Moth repellents for textile	Products against storage pests	Rodenticides ∇	Veterinary products animal housings	
MAGNITUDE OF THE RESIDUE ON/ IN THE TREATED MATERIAL OR ANIMAL (cont.)										
Other										
Data on migration to (raw materials for) foodstuffs and animal feed and the residues found as a result to this	AI		C	C	C		C			
	BP									
OTHER REQUIREMENTS										
Proposed tolerance or maximum residue levels	AI		C	C	C		C	C		C
	BP									
Effects of preparation on residues (e.g. cooking, processing)	AI									
	BP									
Effects on odor, taste and quality of food due to residues	AI									
	BP									
Other										
Transfer of residues from vegetable products to animal products (milk, meat, eggs)	AI		C	C	C			C		
	BP									

[∇] There are no data requirements

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL
(use categories 22-29)

MATRIX 9. TOXICOLOGY

Type of Data/Information		AUS ^ζ	BEL ^σ	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ρ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU
		22-29	22-29	22-29	22 25-28	22 25-26	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {V1}	22-29	22 25-27	22, 25	22-29 except 24	22-29	22-29
ACUTE TESTING																	
Acute oral	AI	Appendix A to Matrix 9	A	A _{CL}	A	A _{CL}	A* _{CL}	A _{CL}	A	A* _{CL}	A	A _{CL}	A*	A A	A _{CL}	A	A _{CL}
	BP		A	A _{CL}	A _{CL}	A _{CL}	A* _{CL}	A _{CL}		A* _{CL}	A _{CL}	C _{CL}	A*	A _{CL} A	A _{CL}	A	A _{CL}
Acute dermal	AI		A	A _{CL}	A	A _{CL}	A [§] _{CL}	A _{CL}	C	A* _{CL}	A	A _{CL}	A*	A A	A _{CL}	A	A _{CL}
	BP		A	A _{CL}	A _{CL}	A _{CL}	A [§] _{CL}	A _{CL}		A* _{CL}	A _{CL}	C _{CL}	A*	A _{CL} A	A _{CL}	A	A _{CL}
Acute inhalation	AI		A	A _{CL}	A	A _{CL}	A [§] _{CL}	A _{CL}	C	A* _{CL}		A _{CL}	A*	C A	C _{CL}	A	A _{CL}
	BP		A	A _{CL}	A _{CL}	A _{CL}	A [§] _{CL}	A _{CL}		A* _{CL}	A _{CL}	C _{CL}	A*	C _{CL} A	C _{CL}	A	A _{CL}
Acute dermal irritation	AI		A	A _{CL}	A	C _{CL}	A [§] _{CL}	A _{CL}	A	A* _{CL}	A	A _{CL}	A*	A A	A _{CL}	A	A _{CL}
	BP		A	A _{CL}	A _{CL}	C _{CL}	A [§] _{CL}	A _{CL}	C	A* _{CL}	A _{CL}	C _{CL}	A*	A _{CL} A	A _{CL}	A	A _{CL}
Acute eye irritation	AI		A	A _{CL}	A	A _{CL}	C [§] _{CL}	A _{CL}	A	C* _{CL}	A	A _{CL}	A*	A A	A _{CL}	A	A _{CL}
	BP		A	A _{CL}	A _{CL}	A	C [§] _{CL}	A _{CL}	C	C* _{CL}	A _{CL}	C _{CL}	A*	A _{CL} A	A _{CL}	A	A _{CL}

MATRIX 9. TOXICOLOGY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS ^ζ	BEL ^σ	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ρ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU	
		22-29	22-29	22-29	22 25-28	22 25-26	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {V1}	22-29	22 25-27	22, 25	22-29 except 24	22-29	22-29	
ACUTE TESTING (cont.)																		
Skin sensitization	AI	Appendix A to Matrix 9	A	A _{CL}	A	A _{CL}	A [§] _{CL}	A _{CL}	C	A* _{CL}		A _{CL}	A*	A _A	A _{CL}	A	A _{CL}	
	BP		A	A _{CL}	A _{CL}	NR _{CL}	A [§] _{CL}	A _{CL}	C	A* _{CL}	A _{CL}	C _{CL}	A*	A _{CL} NR	A _{CL}	A	A _{CL}	
Potentiation/interactions of multiple active ingredients or products	AI					NR	C [§]	A _{CL}	NR	C* _{CL}		C _{CL}	A*	NR	NR	NR	NR	
	BP					NR	C [§]	A _{CL}		C* _{CL}			A*	NR	NR	NR	A	
Other																		
Information on dermal absorption	AI																	A
	BP																	A
SUBCHRONIC TESTING																		
Repeated dose oral - 28 day	AI		C			NR	C	A _{CL}	C	C* _{CL}		C _{CL}	C	A _A	C _{CL}	NR	A _{CL}	
	BP					NR	NR	A _{CL}		C* _{CL}			C _{CL}	NR _{CL} C	NR _{CL}	NR	NR	
Repeated dose inhalation - 28 day	AI					NR	C	A _{CL}	NR	C* _{CL}		C _{CL}	C	C _A	C _{CL}	NR	C _{CL}	
	BP					NR	NR	A _{CL}		C* _{CL}			C _{CL}	NR _{CL} C	NR _{CL}	NR	NR	
Subchronic oral rat -90 day	AI		A	A	A	A _{CL}	A	A _{CL}	NR/C	A* _{CL}	C	A _{CL}	A _{CL}	C _C	C _{CL}	C _A	A _{CL}	
	BP					NR _{CL}	C	A _{CL}		A* _{CL}			A _{CL}	NR _{CL} C	NR _{CL}	NR	NR	

MATRIX 9. TOXICOLOGY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS ^ζ	BEL ^σ	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ε	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU
		22-29	22-29	22-29	22-25-28	22-25-26	22-25-27	22-29 except 27a	22-25-27	22-29 except 27a,c	{H1-8} {V1}	22-29	22-25-27	22, 25	22-29 except 24	22-29	22-29
SUBCHRONIC TESTING (cont.)																	
Subchronic oral non-rodent -90 day	AI	Appendix A to Matrix 9	A	A	A	A _{CL}	C	A _{CL}	C	C* _{CL}	C	C _{CL}	A _{CL}	C _C	NR	C	A _{CL}
	BP					NR _{CL}	NR	A _{CL}		C* _{CL}			A _{CL}	NR _{CL} C	NR	NR	NR
Subchronic dermal -90 day	AI			C	C	C _{CL}	C	A _{CL}	C	C* _{CL}		C _{CL}	C	C _C	C _{CL}	A	C _{CL}
	BP					NR _{CL}	NR	A _{CL}		C* _{CL}			C _{CL}	NR _{CL} C	NR _{CL}	NR	NR
Subchronic inhalation -90 day	AI			C	C	C _{CL}	C	A _{CL}	NR	C* _{CL}	C	C _{CL}	C	C _C	C _{CL}	C	C _{CL}
	BP					NR _{CL}	NR	A _{CL}		C* _{CL}			C _{CL}	NR _{CL} NR	NR _{CL}	NR	NR
Repeated dose dermal toxicity -21/28 day	AI			C		NR	C	A _{CL}	C	C* _{CL}	C	C _{CL}	A _{CL}	C _C	NR	NR	NR
	BP					NR	NR	A _{CL}		C* _{CL}	C		A _{CL}	NR _{CL} C	NR	NR	NR
Other																	
A short term study by the most useful route may be required if there is evidence of or known potential for synergism among any of the ingredients	AI																
	BP			C													

MATRIX 9. TOXICOLOGY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS ^ζ	BEL ^σ	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ρ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU
		22-29	22-29	22-29	22-25-28	22-25-26	22-25-27	22-29 except 27a	22-25-27	22-29 except 27a,c	{H1-8} {V1}	22-29	22-25-27	22, 25	22-29 except 24	22-29	22-29
DEVELOPMENT TOXICITY AND REPRODUCTION STUDIES																	
Teratogenicity rodent	AI	Appendix A to Matrix 9	A	A	A	A _{CL}	A _{CL}	A _{CL}	C	A* _{CL}	A _{CL}	A _{CL}	A _{CL}	A _C	C _{CL}	A	A _{CL}
	BP				CL	NR _{CL}	NR _{CL}	A _{CL}		C* _{CL}			A _{CL}	NR _{CL} C	NR _{CL}	NR	NR
Teratogenicity-second species	AI			A	A	C _{CL}	C _{CL}	A _{CL}	C	C* _{CL}		A _{CL}	A _{CL}	A _C	C _{CL}	C _A	A _{CL}
	BP				CL	NR _{CL}	NR _{CL}	A _{CL}		C* _{CL}			A _{CL}	NR _{CL} NR	NR _{CL}	NR	NR
Multi-generation reproduction	AI		A	A	A	A _{CL}	A _{CL}	A _{CL}	C	A* _{CL}	A _{CL}	C _{CL}	A _{CL}	C _C	C _{CL}	C	A _{CL}
	BP				CL	NR _{CL}	NR _{CL}	A _{CL}		C* _{CL}			A _{CL}	NR _{CL} NR	NR _{CL}	NR	NR
Reproductive screen	AI					NR	NR	NR	C	A* _{CL}		C _{CL}	C	C _C	NR	NR	NR
	BP					NR	NR	NR		C* _{CL}			C _{CL}	NR	NR	NR	NR
Other																	
Sperm analysis	AI						C										
	BP																
Postnatal behaviour	AI						C										
	BP																
Hormonal effects	AI						C										
	BP																

MATRIX 9. TOXICOLOGY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS ^ζ	BEL ^σ	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ρ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU	
		22-29	22-29	22-29	22 25-28	22 25-26	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {V1}	22-29	22 25-27	22, 25	22-29 except 24	22-29	22-29	
METABOLISM TESTING																		
Toxicokinetics/metabolism	AI	Appendix A to Matrix 9	A	A*	A	A	A [§]	NR	C		A	A _{CL}	C	A _C	C	C _A	A	
	BP					NR	NR	NR					A _{CL}	NR _{CL} NR	NR	NR	NR	
CHRONIC TESTING																		
Chronic toxicity rodent	AI		A	A	A	A _{CL}	A	A _{CL}	C	A* _{CL}	C (C)	A _{CL}	A _{CL}	C _C	NR	C _A	A _{CL}	
	BP				^{CL}	NR _{CL}	NR	A _{CL}		C* _{CL}			A _{CL}	NR _{CL} NR	NR	NR	NR	
Chronic toxicity non-rodent	AI		C		A	A _{CL}	C	A _{CL}	C	A* _{CL}		A _{CL}	A _{CL}	C _C	NR	C _A	A _{CL}	
	BP				^{CL}	NR _{CL}	NR	A _{CL}		C* _{CL}			A _{CL}	NR _{CL} NR	NR	NR	NR	
Carcinogenicity - rat	AI		A	A	A	A _{CL}	A _{CL}	A _{CL}	C	C* _{CL}	C _{CL}	C _{CL}	A _{CL}	C _A	C _{CL}	C _A	A _{CL}	
	BP				^{CL}	NR _{CL}	NR _{CL}	A _{CL}		C* _{CL}			A _{CL}	NR _{CL} NR	NR _{CL}	NR	NR	
Carcinogenicity - second species:	AI				A	NR		NR					C _{CL}	C _{CL}				
	BP				^{CL}	NR		NR					C _{CL}					
• <i>Mouse</i>	AI		A	A				C _{CL}							C _{NR}	C _{CL}	C _A	
	BP							NR _{CL}							NR _{CL} NR	NR _{CL}	NR	

MATRIX 9. TOXICOLOGY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS ^ζ	BEL ^σ	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ρ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU	
		22-29	22-29	22-29	22 25-28	22 25-26	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {V1}	22-29	22 25-27	22, 25	22-29 except 24	22-29	22-29	
CHRONIC TESTING (cont.)																		
• Dog	AI	Appendix A to Matrix 9								C* _{CL}								
	BP									C* _{CL}								
• Other mammalian species	AI																A _{CL}	
	BP																NR	
Other chronic test	AI													C C				
	BP													NR				
MUTAGENICITY																		
Testing for specific endpoints:	AI		A	A	A	C	A* _{CL}	NR	A	A	A	A	A	A	A	A	A	
	BP				CL		NR _{CL}	NR								NR		
• In-vitro gene mutation in bacteria (AMES TEST)	AI		A			A/C _{CL}					A _{CL}	A _{CL}	A _{CL}		A _{CL}	A	A _{CL}	
	BP					NR _{CL}							A _{CL}		NR _{CL}	NR	NR	
• In-vitro mutation assay in mammalian cells (=gene mutations)	AI		A								A _{CL}	A _{CL}		A NR	C _{CL}		A _{CL}	
	BP													NR _{CL} NR	NR _{CL}		NR	
• Microbial or mammalian point mutation [= point mutations (with and without microsomal activation) in procaryotic and/or eucaryotic cells in vitro]	AI			A							A* _{CL}							
	BP										C* _{CL}							

MATRIX 9. TOXICOLOGY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS ^ζ	BEL ^σ	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ρ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU
		22-29	22-29	22-29	22-25-28	22-25-26	22-25-27	22-29 except 27a	22-25-27	22-29 except 27a,c	{H1-8} {V1}	22-29	22-25-27	22, 25	22-29 except 24	22-29	22-29
MUTAGENICITY (cont.)																	
• In-vitro cytogenicity study in mammalian cells	AI	Appendix A to Matrix 9	A			A/C _{CL}									A _{CL}	A	A _{CL}
	BP					NR _{CL}									NR _{CL}	NR	NR
• In-vitro chromosomal aberrations	AI			A							A _{CL}	A		A NR			
	BP													NR _{CL} NR			
• In-vivo mutagenicity study (bone marrow assay for chromosomal damage or micronucleus test)	AI		C													A	C _{CL}
	BP															NR	NR
• In-vivo study to examine whether mutagenicity or evidence of DNA damage can be demonstrated in tissue other than bone marrow (= in-vivo assay in second tissue eg liver UDS)	AI		C												C _{CL}		C _{CL}
	BP														NR _{CL}		NR
• Assessment of possible germ cell effects (= dominant lethal)	AI		C							A* _{CL}							C _{CL}
	BP									C* _{CL}							NR
• In-vivo chromosomal aberrations	AI			A						A* _{CL}					C _{CL}		
	BP									C* _{CL}					NR _{CL}		

MATRIX 9. TOXICOLOGY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data /Information		AUS ^ζ	BEL ^σ	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^ρ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU
		22-29	22-29	22-29	22-25-28	22-25-26	22-25-27	22-29 except 27a	22-25-27	22-29 except 27a,c	{H1-8} {V1}	22-29	22-25-27	22, 25	22-29 except 24	22-29	22-29
NEUROTOXICITY TESTING																	
Acute neurotoxicity - rat	AI	Appendix A to Matrix 9				NR	C [§]	A _{CL}	C	A* _{CL}		C _{CL}	C _{CL}	C _C	NR	A	C
	BP					NR	NR	A _{CL}		C* _{CL}			C _{CL}	NR	NR	NR	NR
Acute delayed neurotoxicity of organophosphates-hen	AI		A	C	A	C _{CL}	C [§]	A _{CL}	C	C* _{CL}	A	C _{CL}	C _{CL}	C _C	C	NR	C
	BP				CL	NR _{CL}	NR	A _{CL}		C* _{CL}			C _{CL}	NR	NR	NR	NR
28 day delayed neurotoxicity	AI					NR	C [§]	A _{CL}	C	C* _{CL}		C _{CL}	C	C _C	NR	NR	C
	BP					NR	NR	A _{CL}		C* _{CL}			C _{CL}	NR	NR	NR	NR
Subchronic neurotoxicity - rat -90 day	AI			C		NR	C	A _{CL}	C	C* _{CL}		C _{CL}	C	C _C	NR	A	C
	BP					NR	NR	A _{CL}		C* _{CL}			C _{CL}	NR	NR	NR	NR
Subchronic delayed neurotoxicity of organophosphates - hen	AI		C		A	NR	C	A _{CL}	C	C* _{CL}		C _{CL}	C	C _C	C	A	C
	BP				CL	NR	NR	A _{CL}		C* _{CL}			C _{CL}	NR	NR	NR	NR
Postnatal developmental neurotoxicity	AI			C		NR	C	A _{CL}	C	NR		C _{CL}	C	C _C	NR	C	C
	BP					NR	NR	A _{CL}		NR			C _{CL}	NR	NR	NR	NR

MATRIX 9. TOXICOLOGY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data /Information		AUS ^ζ	BEL ^σ	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^θ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU
		22-29	22-29	22-29	22 25-28	22 25-26	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {V1}	22-29	22 25-27	22, 25	22-29 except 24	22-29	22-29
Other neurotoxicity testing		Appendix A to Matrix 9															
Study of the effects of transformation products	AI		C														
Acute delayed neurotoxicity - rat	AI			C													
	BP																
Statement with respect to (absence of) neurotoxicity	AI										A						
	BP																
OTHER TESTING																	
Toxic effects in livestock and pets	AI		A	A		NR	C		C	A* _{CL}		C _{CL}	A _{CL}	C NR	NR	NR	C
	BP				A _{CL}	NR	NR			C* _{CL}		C _{CL}	A _{CL}	C NR	NR	NR	NR
Antidote	AI		A			A	C	A _{CL}	C	A* _{CL}		C _{CL}	A _{CL}	A NR	NR	NR	A
	BP				A _{CL}	A _{CL}	NR	A _{CL}		A* _{CL}			C _{CL}	A NR	NR	NR	A
Other																	
Eye abnormalities (cataracts)	AI										C						
	BP																

MATRIX 9. TOXICOLOGY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data /Information		AUS ^ζ	BEL ^σ	CAN	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL ^θ	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA ^μ	EU
		22-29	22-29	22-29	22 25-28	22 25-26	22 25-27	22-29 except 27a	22 25-27	22-29 except 27a,c	{H1-8} {V1}	22-29	22 25-27	22, 25	22-29 except 24	22-29	22-29
MEDICAL DATA																	
Medical surveillance of manufacturing plant personnel	AI	Appendix A to Matrix 9			A	C	A [*]	NR	C	A [*] _{CL}		C _{CL}	C	C _{NR}	C	NR	A
	BP					C	A [*]	NR		A [*] _{CL}		C _{CL}	C	C _{CL} _{NR}	C	NR	NR
Clinical cases and poisoning incidents	AI				C	C	A [*]	NR	A	A [*] _{CL}	A	C _{CL}	C	A _{NR}	C	NR	A
	BP					C	A [*]	NR		A [*] _{CL}		C _{CL}	C	A _{NR}	C	NR	NR
Health records from industry and public/users	AI				C	C	A [*]	NR	C	A [*] _{CL}		C _{CL}	C	A _{NR}	C	NR	A
	BP					C	A [*]	NR		A [*] _{CL}		C _{CL}	C	A _{CL} _{NR}	C	NR	NR
Observations of exposure of the general population or epidemiological studies	AI				C	C	C [§]	NR		C [*] _{CL}	A		C _{CL}	C _{NR}	C	NR	A
	BP					C	C [§]	NR		C [*] _{CL}			C _{CL}	C _{NR}	C	NR	NR
Other																	
Evaluation of the toxicity of other ingredients than a.i. in the product or in the a.i. (e.g. impurities, metabolites, solvents and other additives)	AI					C											
	BP					C											

MATRIX 9. TOXICOLOGY - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

- ζ **Australia** has data requirements for use categories 22-29 which are given in APPENDIX A to Matrix 9.
- σ **Belgium:** The data requirements listed under “Acute Testing” are equally required for the active ingredient(s), non-active ingredient(s) and end-use biocidal product. A study of chronic toxicity for the non-active ingredient(s) in the formulated product is also required.
- η **Denmark:** The data requirements listed cover the use categories: 22 (rodenticides); 25 (repellents); 26 (insecticides, indoor/outdoor); 27 (insecticides/acaricides, humans/clothes/pets); and, 28 (molluscicides).
- α **Finland:** The data requirements listed cover the following use categories: rodenticides (indoor, outdoor) [22]; repellents [25]; insecticides/acaricides (indoor) [26a]; and, insecticides (outdoor) [26b].
- κ **Germany** has an approval procedure on voluntary basis for the following use categories: rodenticides [OECD use category 22]; repellents and attractants [25]; and, insecticides and acaricides [26 & 27]. For these products the data requirements are under preparation. Currently, data only on Toxicology (Matrix 9) and Human Exposure (Matrix 10) are formalised (under the voluntary scheme).
- φ **Greece:** The data requirements cover the use categories 22-29 except the 27a (insecticides/acaricides for direct use on humans).
- β **Hungary:** The data requirements listed cover the use categories: 22 (rodenticides); 25 (repellents); 26 (insecticides); and, 27 (insecticides/acaricides).
- ð **Ireland:** Data requirements for the OECD use categories 22-29 but excluding the 27a and 27c (insecticides/acaricides for direct application to humans and pets or other animals, respectively).
- ε **The Netherlands** have different use categories for products for vertebrate and invertebrate pest control from those used in the survey. The d.r. listed above with regular fonts are common for the following uses categories: H1) household products applied outdoors; H2) household products applied indoors on surfaces; H3) household products applied indoors as evaporators; H4) household products applied indoors as aerial spray; H5) repellents against mosquitoes, applied on the human skin; H6) moth repellents for textile; H7) products against storage pests; H8) rodenticides; and, V1) veterinary products applied in animal housings. The d.r. which are additionally asked only for the category H7 are cited with *italics*; for the category H5 with **bold** fonts; and, for the category H8 within parenthesis.
- The data requirements listed are minimal requirements that are necessary for the completeness of the dossiers. Based upon a first evaluation of a dossier additional requirements are established. In this respect the code “NR” is not used in the specific listing of data requirements since the possibility cannot be excluded that a particular question has to be asked as additional data requirement.
- τ **Portugal:** Data requirements for the use categories 22, 25, 26, 27a, 27b, as well as for products for external use in animals, livestock, animal accommodation and transport, food industry (animal products).
- ρ **Sweden:** Regulates all the OECD use categories for pest control products, i.e. use categories 22-29 by an approval system. However, formalised data requirements (d.r.) for toxicology exist only for rodenticides (use category 22) (cited with regular fonts) and mosquito repellents for use on skin (part of the use category 25) (cited with *italics*).
- ω **United Kingdom:** Data requirements for use categories 22-29, excluding only the use category 24 (piscicides).
- μ **USA:** i) with normal fonts are listed common data requirements for the use categories 22, 23, 24, 25, 26a, 26b, 27, 28, 29; and, ii) with **bold fonts** are listed data requirements for molluscicides (28) only when they are different from the others.
- ♣ Impurities always required.
- § Impurities conditionally required.
- ♦ Transformation products conditionally required.
- * Impurities and Transformation products conditionally required.
- CL Classification and Labelling.

COUNTRY: AUSTRALIA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL**(use categories 22-29)****APPENDIX A to MATRIX 9. TOXICOLOGY**

Type of Data/Information		Use Categories			
		22, 23, 24 28, 29	26	25 and 27a,b (for use on humans)	27c (for use on pets)
ACUTE TESTING					
Acute oral	AI	A _{CL}	A _{CL}	A _{CL}	A _{CL}
	BP	A _{CL}	C _{CL}	C _{CL}	C _{CL}
Acute dermal	AI	A _{CL}	A _{CL}	A _{CL}	A _{CL}
	BP	C _{CL}	C _{CL}	C _{CL}	C _{CL}
Acute inhalation	AI	C _{CL}	A _{CL}	C _{CL}	C _{CL}
	BP	C _{CL}	C _{CL}	C _{CL}	C _{CL}
Acute dermal irritation	AI	A _{CL}	A _{CL}	A _{CL}	A _{CL}
	BP	C _{CL}	C _{CL}	C _{CL}	C _{CL}
Acute eye irritation	AI	A _{CL}	A _{CL}	A _{CL}	A _{CL}
	BP	C _{CL}	C _{CL}	C _{CL}	C _{CL}
Skin sensitization	AI	A _{CL}	A _{CL}	A _{CL}	A _{CL}
	BP	C _{CL}	C _{CL}	C _{CL}	C _{CL}
Potentiation/interactions of multiple active ingredients or products	AI	C	C	C	C
	BP				

COUNTRY: AUSTRALIA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL**APPENDIX A to MATRIX 9. TOXICOLOGY (cont.)**

Type of Data/Information		Use Categories			
		22, 23, 24 28, 29	26	25 and 27a,b (for use on humans)	27c (for use on pets)
SUBCHRONIC TESTING					
Repeated dose oral - 28 day	AI	C _{CL}	C _{CL}	C _{CL}	A _{CL}
	BP				
Repeated dose inhalation - 28 day	AI	C _{CL}	C _{CL}	C _{CL}	C _{CL}
	BP				
Subchronic oral rat -90 day	AI	A _{CL}	A _{CL}	A _{CL}	C _{CL}
	BP				
Subchronic oral non-rodent -90 day	AI	A _{CL}	A _{CL}	A _{CL}	C _{CL}
	BP				
Subchronic dermal -90 day	AI	C _{CL}	C _{CL}	C _{CL}	NR
	BP				
Subchronic inhalation -90 day	AI	C _{CL}	C _{CL}	C _{CL}	NR
	BP				
Repeated dose dermal toxicity -21/28 day	AI	C _{CL}	C _{CL}	C _{CL}	C _{CL}
	BP				

COUNTRY: AUSTRALIA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL**APPENDIX A to MATRIX 9. TOXICOLOGY (cont.)**

Type of Data/Information		Use Categories			
		22, 23, 24 28, 29	26	25 and 27a,b (for use on humans)	27c (for use on pets)
DEVELOPMENT TOXICITY AND REPRODUCTION STUDIES					
Teratogenicity rodent	AI	A _{CL}	A _{CL}	A _{CL}	A _{CL}
	BP				
Teratogenicity-second species	AI	C _{CL}	A _{CL}	A _{CL}	C _{CL}
	BP				
Multi-generation reproduction	AI	C _{CL}	A _{CL}	A _{CL}	C _{CL}
	BP				
Reproductive screen	AI	NR	NR	NR	NR
	BP				
METABOLISM TESTING					
Toxicokinetics/metabolism	AI	C	A	C	C
	BP				
CHRONIC TESTING					
Chronic toxicity rodent	AI	NR	A _{CL}	A _{CL}	NR
	BP				
Chronic toxicity non-rodent	AI	NR	A _{CL}	A _{CL}	NR
	BP				

COUNTRY: AUSTRALIA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL

APPENDIX A to MATRIX 9. TOXICOLOGY (cont.)

Type of Data/Information		Use Categories			
		22, 23, 24 28, 29	26	25 and 27a,b (for use on humans)	27c (for use on pets)
CHRONIC TESTING (cont.)					
Carcinogenicity - rat	AI	NR	A _{CL}	A _{CL}	NR
	BP				
Carcinogenicity - second species	AI	NR	A _{CL}	A _{CL}	NR
	BP				
MUTAGENICITY					
Testing for specific endpoints:					
<i>Bacterial gene mutation</i>	AI	A _{CL}	A _{CL}	A _{CL}	A _{CL}
	BP				
<i>Chromosomal aberrations in mammals</i>	AI	A _{CL}	A _{CL}	A _{CL}	A _{CL}
	BP				
NEUROTOXICITY TESTING					
Acute neurotoxicity - rat	AI	C _{CL}	C _{CL}	C _{CL}	C _{CL}
	BP				
Acute delayed neurotoxicity of organophosphates-hen	AI	C _{CL}	C _{CL}	C _{CL}	C _{CL}
	BP				

COUNTRY: AUSTRALIA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL**APPENDIX A to MATRIX 9. TOXICOLOGY (cont.)**

Type of Data/Information		Use Categories			
		22, 23, 24 28, 29	26	25 and 27a,b (for use on humans)	27c (for use on pets)
NEUROTOXICITY TESTING (cont.)					
28 day delayed neurotoxicity	AI	C _{CL}	C _{CL}	C _{CL}	C _{CL}
	BP				
Subchronic neurotoxicity - rat -90 day	AI	NR	C _{CL}	C _{CL}	NR
	BP				
Subchronic delayed neurotoxicity of organophosphates - hen	AI	NR	C _{CL}	C _{CL}	NR
	BP				
Postnatal developmental neurotoxicity	AI	NR	NR	NR	NR
	BP				
OTHER TESTING					
Toxic effects in livestock and pets	AI				
	BP				
Antidote	AI	A	NR	NR	NR
	BP				

COUNTRY: AUSTRALIA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL

APPENDIX A to MATRIX 9. TOXICOLOGY (cont.)

Type of Data/Information		Use Categories			
		22, 23, 24 28, 29	26	25 and 27a,b (for use on humans)	27c (for use on pets)
MEDICAL DATA ^ζ					
Medical surveillance of manufacturing plant personnel	AI	C _{CL} C* _{CL}	C _{CL} C* _{CL}	C _{CL} C* _{CL}	C _{CL} C* _{CL}
	BP	C* _{CL}	C* _{CL}	C* _{CL}	C* _{CL}
Clinical cases and poisoning incidents	AI	C _{CL} C* _{CL}	C _{CL} C* _{CL}	C _{CL} C* _{CL}	C _{CL} C* _{CL}
	BP	C* _{CL}	C* _{CL}	C* _{CL}	C* _{CL}
Health records from industry and public/ users	AI	C _{CL} NR	C _{CL} NR	C _{CL} NR	C _{CL} NR
	BP	NR	NR	NR	NR
Observations of exposure of the general population or epidemiological studies	AI	C _{CL}	C _{CL}	C _{CL}	C _{CL}
	BP				
Other					
<i>Epidemiological studies of occupational users</i>	AI	C* _{CL}	C* _{CL}	C* _{CL}	C* _{CL}
	BP	C* _{CL}	C* _{CL}	C* _{CL}	C* _{CL}

ζ with regular fonts are listed data required for public health exposure and with *italics* are listed data required in the case of occupational exposure.

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL
(use categories 22-29)

MATRIX 10. HUMAN EXPOSURE

Type of Data/Information		AUS ^ζ	BEL	CAN ^δ	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^δ	NL	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA	EU ^π
		22-29	22-29	22-29	22-25-28	22-25-26	22-25-27	22-29 except 27a	22-25-27	22-29 except 27a,c	{H1-8} {V1}	22-29	22-25-27	22	22-29 except 24	22-29	22-29
Wetting, adherence and distribution to target areas or in products	AI	NR C*	NR	Appendix A to Matrix 10		NR	C [§]	NR	NR	C _{CL}	NR		C _{CL}	C _{CL}	NR	NR	
	BP	NR C*				NR	C [§]	NR		C _{CL}			C _{CL}		NR	NR	
Dermal penetration	AI	C A*				NR	C [§]	NR	NR	C _{CL}			C _{CL}	C _{CL}	C	NR	
	BP	C A*			A	NR	C [§]	NR		C _{CL}		C _{CL}	C _{CL}	^{CL}	C	NR	
Dermal exposure for applicator	AI	NR A*				NR	C [§]	NR	NR	C _{CL}			C _{CL}	C _{CL}		NR	
	BP	C A* _{CL}			A	NR	C [§]	NR		C _{CL}		C _{CL}	C _{CL}	^{CL}	C	C	
Dermal exposure for bystanders	AI	NR C				NR	C [§]	NR	NR	C _{CL}			C _{CL}	C _{CL}		NR	
	BP	NR C _{CL}				NR	C [§]	NR		C _{CL}		C _{CL}	C _{CL}	^{CL}	C	C	
Dermal exposure for people handling treated article	AI	C C*				NR	C [§]	NR	NR	C _{CL}			C _{CL}	C _{CL}		NR	
	BP	NR C* _{CL}				NR	C [§]	NR		C _{CL}		C _{CL}	C _{CL}	^{CL}	C	C	

MATRIX 10. HUMAN EXPOSURE - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS ^ζ	BEL	CAN ^δ	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^θ	NL	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA	EU ^π
		22-29	22-29	22-29	22-25-28	22-25-26	22-25-27	22-29 except 27a	22-25-27	22-29 except 27a,c	{H1-8} {V1}	22-29	22-25-27	22	22-29 except 24	22-29	22-29
Inhalation exposure for applicator	AI	NR A*	NR	Appendix A to Matrix 10		NR	C [§]	NR	NR	C _{CL}	NR		C _{CL}	C _{CL}		NR	
	BP	C A* _{CL}			A	NR	C [§]	NR		C _{CL}		C _{CL}	C _{CL}	^{CL}	C	C	
Inhalation exposure for bystanders	AI	NR C				NR	C [§]	NR	NR	C _{CL}			C _{CL}	C _{CL}		NR	
	BP	NR C _{CL}				NR	C [§]	NR		C _{CL}		C _{CL}	C _{CL}	^{CL}	C	C	
Inhalation exposure for people handling treated article	AI	C C				NR	C [§]	NR	NR	C _{CL}			C _{CL}	C _{CL}		NR	
	BP	NR C* _{CL}				NR	C [§]	NR		C _{CL}		C _{CL}	C _{CL}	^{CL}	C	C	
Indoor surface dissipation	AI	NR C*				NR	C	NR	NR	C _{CL}			C _{CL}	C _{CL}		NR	
	BP	NR C* _{CL}				NR	C	NR		C _{CL}		C _{CL}	C		C	C	
Other																	
Product use information	AI															NR	
	BP															A	
Applicator biological monitoring	AI															NR	
	BP															C	

MATRIX 10. HUMAN EXPOSURE - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

Type of Data/Information		AUS ^ζ	BEL	CAN ^δ	DEN ^η	FIN ^α	GER ^κ	GR ^φ	HUN ^β	IRL ^θ	NL	NZ	POR ^τ	SWE ^ρ	UK ^ω	USA	EU ^π
		22-29	22-29	22-29	22-25-28	22-25-26	22-25-27	22-29 except 27a	22-25-27	22-29 except 27a,c	{H1-8} {V1}	22-29	22-25-27	22	22-29 except 24	22-29	22-29
<i>Bystander biological monitoring</i>	AI			Appendix A to Matrix 10							NR					NR	
	BP															C	
<i>Description of human activity</i>	AI															NR	
	BP															A	
<i>Worker re-entry to treated areas</i>	AI	A*															
	BP	A* _{CL}															
<i>Glove Clothing Penetration Data</i>	AI																
	BP																
<i>Package Integrity Study</i>	AI																
	BP																

ζ **Australia:** Data requirements for both public health (regular fonts) and occupational exposure (*italics*) for the use categories 22-29.

δ **Canada:** The data requirements are given in Appendix A to Matrix 10.

η **Denmark:** The data requirements listed cover the use categories: 22 (rodenticides); 25 (repellents); 26 (insecticides, indoor/outdoor); 27 (insecticides/acaricides, humans/clothes/pets); and, 28 (molluscicides).

α **Finland:** The data requirements listed cover the following use categories: rodenticides (indoor, outdoor) [22]; repellents [25]; insecticides/acaricides (indoor) [26a]; and, insecticides (outdoor) [26b].

κ **Germany** has an approval procedure on voluntary basis for the following use categories: rodenticides [OECD use category 22]; repellents and attractants [25]; and, insecticides and acaricides [26 & 27]. For these products the data requirements are under preparation. Currently, data only on Toxicology (Matrix 9) and Human Exposure (Matrix 10) are formalised (under the voluntary scheme).

φ **Greece:** The data requirements cover the use categories 22-29 except the 27a (insecticides/acaricides for direct use on humans).

MATRIX 10. HUMAN EXPOSURE - PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL (cont.)

- β **Hungary:** The data requirements listed cover the use categories: 22 (rodenticides); 25 (repellents); 26 (insecticides); and, 27 (insecticides/acaricides).
- ð **Ireland:** Data requirements for the OECD use categories 22-29 but excluding the 27a and 27b (insecticides/acaricides for direct application to humans, pets or other animals, respectively).
- ε **The Netherlands** has different use categories for products for vertebrate and invertebrate pest control from those used in the survey: H1) household products applied outdoors; H2) household products applied indoors on surfaces; H3) household products applied indoors as evaporators; H4) household products applied indoors as aerial spray; H5) repellents against mosquitos, applied on the human skin [incl. in OECD use category 25]; H6) moth repellents for textile [incl. in OECD use category 25]; H7) products against storage pests; H8) rodenticides [OECD use category 22]; and, V1) veterinary products applied in animal housings. There are no data requirements for any of these categories concerning human exposure.
- τ **Portugal:** Data requirements for the use categories 22, 25, 26, 27a, 27b, as well as for products for external use in animals, livestock, animal accommodation and transport, food industry (animal products).
- ρ **Sweden:** Data requirements only for rodenticides (use category 22).
- ω **United Kingdom:** Data requirements for use categories 22-29, excluding only the use category 24 (piscicides).
- π **European Union:** The specific data requirements on human, animals and the environment exposure are under preparation.
- ♣ Impurities always required
- ♠ Transformation products always required
- ♥ Impurities and Transformation products always required
- * Impurities and Transformation products conditionally required
- ♦ Transformation products conditionally required
- CL Classification and Labelling

COUNTRY: CANADA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL
(use categories 22-29)

APPENDIX A to MATRIX 10. HUMAN EXPOSURE

Type of Data/Information		Rodenticides (22)	Avicides (23)	Piscicides (24)	Repellents (25)	Insecticides (26)	Insecticides/ acaracides (27)	Molluscicides (28)	Other vertebrates (29)
Wetting, adherence and distribution to target areas or in products	AI								
	BP	NR	NR	NR	NR	NR	NR	NR	NR
Dermal penetration	AI								
	BP	C	C	C	C	C	C	C	C
Dermal exposure for applicator	AI								
	BP	A	C	A	C	A	A	A	C
Dermal exposure for bystanders	AI								
	BP	C	NR	C	C	C	C	NR	NR
Dermal exposure for people handling treated article	AI								
	BP	C	NR	C	C	C	C	C	NR
Inhalation exposure for applicator	AI								
	BP	A	C	A	C	A	C	C	C
Inhalation exposure for bystanders	AI								
	BP	C	NR	NR	C	C	NR	NR	NR

COUNTRY: CANADA

DATA REQUIREMENTS FOR APPROVAL OF PRODUCTS FOR USE IN VERTEBRATE AND INVERTEBRATE PEST CONTROL

APPENDIX A to MATRIX 10. HUMAN EXPOSURE (cont.)

Type of Data/Information		Rodenticides (22)	Avicides (23)	Piscicides (24)	Repellents (25)	Insecticides (26)	Insecticides/ acaracides (27)	Molluscicides (28)	Other vertebrates (29)
Inhalation exposure for people handling treated article	AI								
	BP	C	NR	NR	NR	NR	NR	NR	NR
Indoor surface dissipation	AI								
	BP	C	NR	NR	C	C	NR	NR	NR
Other									
<i>Glove clothing penetration data</i>	AI								
	BP	C	C	C	C	C	C	C	C
<i>Leaching and/or migration studies from clothing and materials</i>	AI								
	BP					C			
<i>Package integrity study</i>	AI								
	BP	C	C	C	C	C	C	C	C

