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

Environment Directorate

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About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation composed of 29 industrialised countries in North America, Europe and the Pacific. The OECD works to co-ordinate and harmonize government policies, address issues of mutual concern, and respond to international problems.

The Pesticide Programme was created in 1992 within the OECD's Environmental Health and Safety Division to help OECD countries:

- harmonize their pesticide review procedures,
- share the work of evaluating pesticides, and
- reduce risks associated with pesticide use.

The Pesticide Programme is directed by a body called the Pesticide Forum, composed primarily of delegates from OECD Member countries, but also including representatives from the European Commission and other international organisations (e.g. United Nations Food and Agriculture Organization, United Nations Environment Programme, World Health Organization, Council of Europe), and observers from the pesticide industry and public interest organisations (NGO's).

In addition to the **Series on Pesticides**, the Environmental Health and Safety (EHS) Division publishes documents in five other series: **Testing and Assessment**; **Good Laboratory Practice and Compliance Monitoring**; **Risk Management**; **Harmonization of Regulatory Oversight in Biotechnology**; and **Chemical Accidents**. More information about the Environmental Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (see next page).

This publication was produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC). It was approved for derestriction by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, the governing body of the Environmental Health and Safety Division.

The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) was established in 1995 by UNEP, ILO, FAO, WHO, UNIDO and the OECD (the Participating Organizations), following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. UNITAR joined the IOMC in 1997 to become the seventh Participating Organization. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

Foreword

This report presents the results of an OECD survey to improve understanding of how Member countries regulate the broad class of chemical agents known as biocides or non-agricultural pesticides. The survey was conducted by the OECD Pesticide Programme in 1997-98.

The purpose of the survey was to provide information that would provide a basis for future efforts to increase international co-operation in biocides regulation. And in fact a programme of work on biocides was initiated within the Pesticide Programme at the end of 1998.

The Joint Meeting of the Chemicals Committee and the Working Party on Chemicals recommended that this document be made available to the public.

Contents

Executive Summary

This report presents the results of a survey conducted by the OECD Pesticide Programme in 1997-98 to (1) improve understanding of how Member countries regulate the broad class of chemical agents known as biocides or non-agricultural pesticides, and (2) provide information that could be used to prepare the way for future efforts to increase international co-operation in biocide regulation.

The survey focused on the following seven broad groups of biocides:

(i) disinfectants/sanitizers;
(ii) preservatives/microbiocides;
(iii) anti-fouling products;
(iv) wood preservatives and structural treatments;
(v) microbiocides for waste disposal and strip mine sites;
(vi) products used in aquatic non-food sites (e.g. molluscicides, algicides);
(vii) products used for vertebrate and invertebrate pest control.

It requested information on:

- how countries categorise biocides, the use categories regulated, whether they are regulated by notification or approval systems[1], the laws used and the government departments that have regulatory responsibilities.
- regulatory procedures for active ingredients and end-use products, conditions for approval, re-evaluation, decision-making criteria and the role of risk-benefit;
- data requirements, e.g. specific requirements for each use category, tiered approaches, data waiving.
- the need for and role of efficacy data in biocide approval, and whether countries address resistance development.
- how countries label biocides.
- approaches to human and environmental exposure assessment and risk assessment.
- whether countries have policies on minor uses and/or low risk products and the extent to which biological biocides exist.

Eighteen countries and the European Commission (EC) responded to the survey. The country responses reflect their national situations as of mid 1998. The response from the EC describes the approach to be used within Europe once the Biocidal Products Directive (98/8/EC) is integrated into the national laws of the EU countries (i.e. by 13 May 2000).

A summary of the main findings of the survey is given below. Most of the information provided relates to approval systems, since few countries reported on use categories regulated by notification.

The survey responses show a great variability among countries with respect to use categories regulated and the laws and government departments involved. There are big differences in the use categories

[1] ***"Notification"*** is a system in which a manufacturer/supplier must inform the appropriate national authority about their intention of placing a chemical on the market. Typically, the notifier must submit data for review by the national authority and there is usually a set time for the review period (e.g. 60 days). ***"Approval"*** (or registration) is a system in which a chemical can only be placed on the market when regulatory authority has given its permission.

regulated by an approval system. For some countries, one law will cover all use categories, while in others several and sometimes many pieces of legislation are involved. Although in most countries, one ministry or agency is responsible for a particular use category or group of categories, there are a few countries that have very complex systems. These countries may split responsibilities between different ministries and between different agencies within the same ministry for the approval not only of different product types but even for the same product type.

Regulatory procedures appear to be more similar. Most countries assess data on the active ingredient and the formulated end-use product in one procedure as an integrated package, but currently approval is only granted to the product. In a few countries, and in the forthcoming EU system, active ingredients have to be approved first before they can be used in products. Conditions for how a product should be used are usually attached to approvals. Most countries have decision-making criteria for (1) approval or notification and (2) classification and labelling. Risk-benefit generally plays a role in decision-making, and all countries indicate that they can deny approval of an active ingredient or end-use product.

Formalised data requirements generally exist for use categories regulated by an approval system. However, there is a great deal of variability among countries in (1) the amount of data required for any one use category, and (2) the size of the core data set (i.e. data always required) versus the number of conditional requirements. The way the data requirements are defined also varies. For example, some countries have specific requirements for a specific use category. Others have common core requirements for all use categories regulated under the same law. In the forthcoming EU system, there will be a core of data common to all use categories with additional data being required according to the nature and use of the product. About half the countries have a tiered approach to data requirements but this is usually applied on a case-by-case basis. Most countries can waive data if the applicant submits a justification acceptable to the regulatory authority.

Efficacy data are always required but not necessarily for all use categories regulated. Demonstrated efficacy is often important when deciding whether to approve a product. But at least one country believes that the market place will remove products that are not sufficiently effective.

The approved use of a particular product and the target pest should usually be specified on the label. All countries require that products be labelled for hazard, and most also require the labels to carry warnings or restrictions based on risk.

When assessing the potential risks associated with a biocide, all countries consider the type of people exposed, e.g. primary and secondary handlers. Some countries focus their concern on primary handlers and then take secondary handlers into account when relevant. Some countries also distinguish between industry, professional users and amateurs (e.g. home users). A number of examples of approaches for human exposure assessments are included.

Environmental exposure assessment of biocides appears to be less systematically performed than does human exposure assessment. Some countries perform environmental exposure assessments for all use categories regulated, while others perform them on a case-by-case basis. Still others have identified use categories for which an environmental exposure assessment should always be performed, and those for which they are not needed. All countries recognise the importance of use data in their assessment procedures, but they also recognise that collecting accurate information is difficult. Environmental monitoring data are not normally required, but are used when available. Exposure models are used by some countries and some examples are given.

Specific guidance for conducting environmental or human health risk assessments for biocides is not normally available. However, some countries have guidance for certain use categories and guidance is also being developed within the EU. Most countries perform risk assessments for materials treated with biocides (e.g. wood, the hulls of ships) or at least take this possibility into account in their assessment procedure.

Few countries have a formal policy for “minor uses”, and these policies are not necessarily specific to biocides. Reduced regulatory requirements exist in some countries (and will exist in the EU) for biocides identified as being of low risk. However, formal criteria for determining “low risk” products do not generally exist.

Finally about half the countries know of biological biocides (i.e. based on fungi, micro-organisms or viruses), and some formalised data requirements exist.

Introduction

1. This report presents the results of an OECD survey conducted in 1997-mid 1998 to (1) improve understanding of how Member countries regulate the broad class of chemical agents known as biocides or non-agricultural pesticides, and (2) provide information that could be used to prepare the way for future efforts to increase international co-operation in biocides regulation. The survey was done within the context of the OECD Pesticide Programme.

2. Eighteen countries (Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, New Zealand, the Netherlands, Portugal, Sweden, Switzerland, the UK, the US) and the European Commission responded to the survey. The response from the European Commission is designated as "EU" in this report. It should be noted that the Commission completed the OECD questionnaire based on the December 1996 version of the Directive concerning the placing of biocidal products on the market within the EU. Since responding to the questionnaire, the Directive 98/8/EC was adopted on 16 February 1998, but as there were no substantial changes, the EU responses presented in this report provide a good description of the future approach to be used within Europe. Although the Directive came into force in 1998, EU Member States had not integrated it into their national law at the time this survey was performed.[2] EU country responses therefore reflect their national situations as of mid 1998.

Scope of the survey

Product types considered to be biocides

3. A wide variety of product types (or use categories) may be categorised as biocides. This survey focused on the following seven broad groups of biocides:

(i) disinfectants/sanitizers;
(ii) preservatives/microbiocides;
(iii) anti-fouling products;
(iv) wood preservatives and structural treatments;
(v) microbiocides for waste disposal and strip mine sites;
(vi) products used in aquatic non-food sites (molluscicides, lampricides, algicides, disinfectants);
(vii) products used for vertebrate and invertebrate pest control.

4. Table I gives examples of the product types/use categories included in each group.

5. The survey did not cover plant protection pesticides used in either agriculture or non-agriculture (including forestry, vegetation control in rights of way, lawn care, etc.).

2. EU Member States must integrate Directive 98/8/EC into their national law by 13 May 2000.

Table I. Examples of Product Types/Use Categories for Biocides

Broad area	Product type/use category
i) Disinfectants/Sanitizers	1. Public health disinfectants and sanitizers for use in/on: a) hospitals b) medical equipment c) eating establishments d) air ducts e) mortuaries 2. Personal health care disinfectants, e.g.: a) denture cleaners b) disinfection of intact skin (antiseptics and skin cleansers) 3. Non public health (private) disinfectants/sanitizers/ bacteriostats for use on/in: a) dust mops b) laundries c) carpets d) bathrooms, kitchens e) air purifiers f) water beds 4. Veterinary area and domestic animal disinfection 5. Food/feed area disinfectants for use on/in, e.g.: a) agricultural premises and equipment such as beehives, barns, cattle feedlots b) industrial food storage and distribution such as egg-handling equipment c) food processing plants, dairies 6. Drinking water disinfectants for use in: a) human drinking water b) animal or poultry drinking water
ii) Preservatives/ Microbiocides	7. In-can preservatives 8. Industrial microbiocides/slimicides, e.g. for use in/on: a) textile mills b) pulp and paper mills c) oil industry (drilling muds, secondary oil recovering, etc.) d) cooling towers e) sterilizer process water 9. Material preservatives, e.g. for use in/on: a) paper b) leather c) rubber products d) masonry e) adhesives f) caulks g) textiles and specialty products h) diapers i) fuel oil j) carpets k) metal cutting fluids 10. Film preservatives, i.e. to protect properties of the surface of materials or objects such as paints, plastics, sealants, papers 11. Embalming fluids for the preservation and disinfection of human and animal corpses

Table I. Examples of Product Types/Use Categories for Biocides (cont.)

Broad area	Product type/use category
iii) Anti-fouling products	12. Underwater paints/treatments, antifoulants, e.g.: for use on/in: a) boats b) bilge water c) lobster pots d) marine structures e) fishing nets f) intake pipes
iv) Wood preservatives and structural treatments	13. Wood preservatives, e.g.: preventive industrial treatment, remedial, joinery, heavy duty, anti-sapstain 14. Structural pesticides (e.g. to control termites, carpenter ants, etc.)
v) Microbiocides for waste disposal and strip mine sites	For use in: 15. Sewage disposal areas 16. Refuse/solid waste sites 17. Control of microbes in strip mine acid
vi) Products for use in aquatic non-food sites	For use in: 18. Swimming pools 19. Hot baths 20. Spas 21. Ornamental ponds
vii) Products for use in vertebrate and invertebrate pest control	22. Rodenticides (e.g. domestic, storage areas, public health) 23. Avicides 24. Piscicides 25. Repellents (e.g. to repel deer, bears, dogs, insects, etc.) 26. Insecticides a) indoor (e.g. for household use, airplane cabins, etc.) b) outdoor (e.g. broadcast applications for mosquito control) 27. Insecticides/acaracides direct use on: a) humans b) clothes c) pets 28. Molluscicides 29. Other vertebrates (e.g. foxes, weasels, etc.)

Regulatory procedures covered

6. The survey focused on procedures involved in the ***notification, approval*** (or registration)***, labelling*** and ***risk assessment*** of biocides. Procedures pertaining to the manufacture, transport and disposal of biocides were not addressed.

7. In the context of the survey:

- 'notification' is a system in which a manufacturer/supplier must inform the appropriate national authority about their intention of placing a chemical on the market. Typically, the notifier must submit data for review by the national authority. There is usually a set time for the review period (e.g. 60 days). The national authority may decide on the classification and labelling of the chemical and may recommend/take control measures.

- *'approval'* (or registration) is a system in which a chemical can only be placed on the market when the regulatory authority has given its permission. Again, the national authority will review data submitted by the manufacturer/supplier but under this system the authorities have much more control over the use of the substance.

Survey Method

8. Information was collected from countries using a questionnaire which was developed in co-operation with Canada, Germany, Switzerland, the UK, the US, the EC and industry.

9. The questionnaire was divided into three parts. Part 1 requested information on regulatory procedures, with sections on:

1) categorisation of biocides, regulation and responsibilities;
2) data requirements;
3) regulatory procedures;
4) efficacy;
5) labelling;
6) human exposure assessments;
7) environmental exposure assessments;
8) risk assessment;
9) other issues (minor uses, low risk products and biological biocides).

10. Part 2 of the questionnaire had three sections: (1) Tier Testing, and (2) Specific Listing of Data Requirements for Approval Purposes. For the section on tier testing, countries were asked if they organised their data requirements in tiers (i.e. a stepped sequence for testing, in which tests in higher tiers are only required if triggers are met at earlier stages), and if so how they were organised.

11. For the specific listing of data requirements, countries were asked to complete a series of matrices showing their requirements for the following test areas:

1) chemical identity (active ingredient and biocidal product);
2) physical/chemical properties;
3) function, mode of action, and handling;
4) analytical methods;
5) efficacy of biocidal products;
6) fate and behaviour in the environment;
7) ecotoxicology;
8) residue chemistry;
9) toxicology - mammalian;
10) human exposure.

12. When responding to Part 2, countries were asked to complete a separate set of matrices where data requirements differ between product types/use categories. In addition, for each data element, countries were asked to indicate:

- whether the requirement is for the active ingredient, the biocidal product or both; and where appropriate, requirements for impurities and transformation products;
- the frequency it is required, i.e. always, conditionally (may be required if certain conditions are not met, including on a case-by-case basis), or not required; and
- whether compliance with the principles of Good Laboratory Practice (GLP) is required.

13. Countries could also complete a ‘remarks’ column, particularly in regard to requirements for particular test methods.

14. Part 3 of the survey requested contact names, i.e. people who could be contacted for clarification of survey responses, or for further information.

Presentation of Survey Results

15. Countries' responses to the questionnaire are collated in tables in the Annexes as follows:

Annex 1 : **Overview of Biocide Regulations.** This Annex includes responses to Part 1 of the questionnaire. The following tables are included:

- **Table 1:** Categorisation of biocides, regulations and responsibilities (and whether data requirements exist)
- **Table 2:** Overview of the regulatory procedures: active ingredients, end-use products, new and old biocides, duration of approvals and re-evaluation programmes
- **Table 3:** Overview of the regulatory procedures: conditions and impurities
- **Table 4:** Overview of the regulatory procedures: decision-making criteria and risk benefit
- **Table 5:** Overview of the regulatory procedures: denial of approval
- **Table 6:** Efficacy
- **Table 7:** Labelling
- **Table 8:** Human and environmental exposure assessments
- **Table 9:** Risk assessment
- **Table 10:** Minor uses, low risk products and biological biocides

Annex 2: **Country Biocide Use Categories.** This Annex provides information on the Canadian, Netherlands and EU biocide use categories.

Annex 3: **Data Waiving and Tier Testing.** This Annex collates responses on the extent of formalised data requirements and possibilities to waive data, from Part 1 of the questionnaire, and information on tier testing from Part 2.

Annex 4: **Detailed Information on Data Requirements.** In view of the large amount of information, Annex 4 has been prepared as a separate document.

Section 1 shows individual data requirements for each country collated from responses to Part 2 of the questionnaire. The country requirements are presented in the following seven sets of matrices:

- Disinfectants/sanitizers (use categories 1 to 6)
- Preservatives/microbiocides (use categories 7 to 11)
- Antifouling products (use category 12)
- Wood preservatives (use category 13)
- Structural pesticides (use category 14)
- Aquatic non-food sites (use categories 18 to 21)
- Vertebrate and invertebrate pest control (use categories 22 to 29)

Information on data requirements for microbiocides for waste disposal and strip mine sites (use categories 15 to 17) are not included since only Canada provided detailed information.

Section 2 summarises the information in Section 2 and shows the number of countries requiring each data element. The information is presented in the following seven sets of matrices:

- ◊ Disinfectants/sanitizers (use categories 1-3)
- ◊ Disinfectants/sanitizers (use categories 4-6)
- ◊ Preservatives/microbiocides (use categories 7-11)
- ◊ Antifouling products (12), Wood preservatives (13), Structural pesticides (14)
- ◊ Vertebrate and invertebrate pest control (use categories 22-25)
- ◊ Vertebrate and invertebrate pest control (use categories 26-29)

For both Sections 1 & 2, each set of matrices consists of separate tables for each of the 10 test areas.

Survey Results:
Overview of Biocide Regulations

Categorisation of biocides, regulations and responsibilities

Categorisation

16. Generally, Member countries used the use categories given in the survey when describing their regulatory procedures and data requirements. Germany, Sweden and Belgium used the EU categories, while Canada, Hungary, the Netherlands and the US used their own categories. Canada and the Netherlands provided conversion tables between their own system and the OECD. Information on the Canadian, Netherlands and EU categories is provided in Annex 2.

Use categories regulated

17. Information on which use categories are regulated by a system of approval (or registration) or notification in Member countries is given in Table 1 in Annex 1 and summarised in Table II below. Austria has not been included in Table II because at the moment, it has neither a notification nor an approval system in force for biocidal products (see details in Table 1, Annex 1).

18. Most countries only identified those use categories for which approval systems exist, commenting that the remaining categories are usually covered by general chemicals legislation. New Zealand also identified all categories covered by notification procedures. It should be noted that some countries may regulate more biocide products than those indicated in Table II since it is possible that not all authorities responsible for these products have responded to the questionnaire.

19. There appear to be big differences among countries with respect to which use categories are regulated by an approval system, although (1) all countries (except Austria) have approval systems for wood preservatives, and (2) most countries have approval systems for products used in vertebrate and invertebrate pest control.

20. Some countries appear to approve both the biocide active ingredient (or at least have a positive list of active ingredients that can be used) and the end-use product (Australia, Canada, France, USA, EU). Other countries approve only the end-use product (Belgium, Finland, Ireland, the Netherlands, New Zealand, Portugal, Sweden, Switzerland, UK). For Denmark, Germany, Greece and Hungary, whether they approve the active ingredient and/or the end-use product depends on the use category.

Relevant laws

21. For some countries, one law covers all biocide use categories that they regulate (Ireland, Netherlands, UK, and Australia - for biocides approved), while in others, several and sometimes many (Hungary) pieces of legislation are involved.

22. The type of laws covering disinfectants/sanitizers (OECD use categories 1-6) varies considerably from country to country. Countries such as the Netherlands, Portugal and USA regulate the majority of these products using pesticide legislation. Canada, Germany and Greece regulate them as medicines/drugs, while New Zealand and UK use chemicals/toxic substances regulations. For other countries (e.g. Australia, Belgium, Denmark, Sweden), a mixture of pesticide and non-pesticide legislation is used, depending on the use category.

Table II: Use categories for biocides for which approval (A) or notification (N) is required in Member countries[3]

Product type/use category	AUS	BEL	CAN	DEN	FIN	FR[4]	GER	GR	HUN	IRE	NZ	NL	POR	SWE	SWI	UK	USA[5]	EU
Disinfectants/sanitizers																		
1. Public health disinfectants & sanitizers		A	A	A[6]			note[7]	A	A	N	N			A[8]	A		A	
2. Personal health care disinfectants			A				A[9]	A[10]		N	N		A[11]	None	A		A	A[12]
3. Non public health (private) disinfectants/sanitizers/ bacteriostats		A	A				note[7]	A	A	N	N	A[13]		A[14]	A		A	
4. Veterinary area and domestic animal disinfection	A	A	A	A			A[15]	A[16]		N	N		A[17]	None	A			
5. Food/feed area disinfectants	A	A	A	A[18]		A[19]	None	A	A	N	N		A[20]	None	A		A	
6. Drinking water disinfectants		A	A[21]	A[22]			None	A	A	N	N		A[23]	A	A		A	

3. Although **Austria** responded to questionnaire it has not been included in Table II because, at the moment, Austria has neither a notification nor an approval system in force for biocidal products.
4. **France**: note that response was received only by the Ministry of Economy and Finance that regulates the products listed in this Table. No response to the biocides survey has been received from the Ministry of Agriculture. This Ministry authorises some products used for the cleaning and treatment of premises, materials and vehicules use for (a) transport and housing of domestic animals [OECD use category 4], and (b) preparation and transport of feed for domestic animals [OECD use category 5]. For responses received, whether the active ingredient and/or the end-use product is approved depends on the use.
5. **USA:** use categories different to OECD examples, i.e.: a) agricultural premises and equipment [corresponding to OECD use category 5a]; b) food handling/ storage establishments premises and equipment [OECD use categories1c, 5b, c]; c) commercial, institutional and industrial premises and equipment [corresponding broadly to OECD use category 1]; d) residential and public access premises [OECD use category 3]; e) medical premises and equipment [OECD use category 1a, b]; f) human drinking water systems [OECD use category 6a]; d) personal health care disinfectants [OECD use category 2].
6. **Denmark**: eating establishments only [OECD use category 1c].
7. **Germany**: approval for use in field of hygiene is applied on a voluntary basis.
8. **Sweden**: products against micro-organisms in chemical toilets, etc. only.
9. **Germany**: approval is only required for medicinal products (i.e. active substances/products for direct use on humans or animals).
10. **Greece**: personal health care products for use on human skin are considered as medicines.
11. **Portugal**: denture cleaners.
12. **EU**: use catgories different to OECD examples, i.e. (a) human hygiene biocidal products [OECD use category 2], (b) private area and public health area disinfectants and other biocidal products [OECD use categories 1, 3], (c) veterinary hygiene biocidal products [OECD use category 4], (d) food and feed area disinfectants [OECD use catgory 5], (e) drinking water disinfectants [OECD use category 6].
13. **Netherlands**: use categories in broad area of disinfectants/sanitisers are slightly different to those listed in table, i.e.: (D1) disinfectants outside the food industry and catering, exposure of users only; (D2) disinfectants for the food industry, catering, animal housing, etc.; (D3) disinfectants of material to which users are exposed.
14. **Sweden**: products against micro-organisms in chemical toilets, etc. only.
15. **Germany**: approval for medicinal products only. No approval or notification for other uses in this category.
16. **Greece**: disinfectants for use on animal skin are considered to be medicinal products.
17. **Portugal**: split between: (i) for external use in animals and (ii) for livestock (accommodation, transport).
18. **Denmark**: food processing plants only [OECD use category 5c].
19. **France**: food area disinfectants only.
20. **Portugal**: food industry animal products.
21. **Canada**: these products will require approval once the proposed legislation, the Drinking Water Materials Safety Act (DWMSA) is in place/effect.
22. **Denmark**: the treatment of drinking water for example by adding disinfectants has to be approved by the local authority.
23. **Portugal**: animal or poultry drinking water only [OECD use category 6b].

Table II: Use categories for biocides for which approval (A) or notification (N) is required in Member countries[3](cont.)

Product type/use category	AUS	BEL	CAN	DEN	FIN	FR[4]	GER	GR	HUN	IRE	NZ	NL	POR	SWE	SWI	UK	USA	EU
Preservatives/microbiocides																		
7. In-can preservatives		A	A				None			N	N			None				
8. Industrial microbiocides/slimicides	A[24]	A	A	A[25]	A[26]		None		A	N	N	A[27]		A[28]			A[29]	A[30]
9. Material preservatives		A	A				None	A[31]		N	N			A[32]				
10. Film preservatives		A	A				None			N	N			A				
11. Embalming fluids		A					None			N	N			None				
Antifouling products																		
12. Underwater paints/ treatments, antifoulants	A	A	A				None			A	A	A		A	A	A	A	A
Wood preservatives and structural treatments																		
13. Wood preservatives	A	A	A	A	A, N[33]	A[34]	A, N[35]	A	A	A	A	A	A	A	A	A	A	A
14. Structural pesticides	A		A		A		None		A		A		A	A		A		A[36]
Microbiocides for waste disposal and strip mine sites																		
15. Sewage disposal areas			A							N	N						A	
16. Refuse/solid waste sites			A							N	N							
17. Control of microbes in strip mine acid			A								N							

24. **Australia**: for use in cooling towers only, i.e. OECD use category 8d.
25. **Denmark:** Approval required for slimicides but not for use as preservatives for liquid-cooling processing systems, i.e. OECD use category 8d.
26. **Finland**: only for use in pulp and paper mills [8b] and cooling water systems [8d].
27. **Netherlands**: use categories in Netherlands differ to those listed, i.e. (D4) preservatives [broadly corresponding to the OECD use categories 7, 9, 10, 11] and (D5) industrial biocides (in cooling water, in liquids during production processes, e.g. paper industry [OECD use category 8].
28. **Sweden**: Approval required for slimicides but not for use as preservatives for liquid-cooling processing systems, i.e. OECD use category 8d.
29. **USA** use categories are different to OECD examples, i.e. material preservatives (generally corresponding to OECD use catogories 7, 9, 10); industrial preservatives and water systems (generally corresponding to OECD use category 8) and; embalming fluids (OECD use category 11).
30. **EU**: use categories slightly different than those of OECD.
31. **Greece**: only for use in/on leather [9b], textiles and specialty products [9g] and carpets [9j].
32. **Sweden**: Approval required for use on fibre, leather [9b], rubber and polymerised materials [9c], and masonry [9d] but not for metal working fluids [9k].
33. **Finland**: approval is required for wood preservatives such as heavy duty, antisapstain, remedial, while wood preservatives used as paint are notified.
34. **France**: for wood in contact with fruit and vegatables. Note that approval is need for the active ingredient but not for the end use product.
35. **Germany**: approval is required for construction products (i.e. load-bearing timber), while notification is required for non-load-bearing timber.
36. **EU**: if structrural pesticides are mainly insecticides, they are covered by the Directive and they have to be approved.

Table II: Use categories for biocides for which approval (A) or notification (N) is required in Member countries[3] (cont.)

Product type/use category	AUS	BEL	CAN	DEN	FIN	FR[4]	GER	GR	HUN	IRE	NZ	NL	POR	SWE	SWI	UK	USA	EU
Products for use in aquatic non-food sites																		
18. Swimming pools	A	A	A	A			None	A	A	A	N	A						
19. Hot baths	A	A	A				None	A	A		N						A	A
20. Spas	A	A	A				None	A			N							
21. Ornamental ponds	A	A	A				None	A		A	N							
Products for use in vertebrate and invertebrate pest control																		
22. Rodenticides	A	A	A	A	A[37]		A[38]	A	A	A	A		A	A		A		
23. Avicides	A	A	A				None	A		A	A			A		A		
24. Piscicides	A	A	A				None	A		A	A			A			A[39]	A
25. Repellents	A	A	A	A	A		A[40, 41]	A	A	A	A	A[42]	A	A		A		
26. Insecticides (indoor/outdoor)	A	A	A	A	A[43]		A[40, 41]	A	A	A	A		A	A		A		
27. Insecticides/acaracides for use on humans, clothes, pets	A	A	A	A			A[40]	A[44]	A	A[45]	A		A[46]	A		A		
28. Molluscicides	A	A	A	A			None[41]	A		A	A			A		A		
29. Other vertebrates	A	A	A				None	A		A	A			A		A		

37. **Finland**: different data requirements for indoor vs outdoor use for Environmental Fate, Ecotoxicology and Residue Chemistry.
38. **Germany**: approval (on voluntary basis) required only for products used according to the Federal Communicable Diseases Act. No approval/notification required for products to control mice, rats and other rodents. The use of rodenticides is also covered by the national legislation on plant protection products (crops as well as storage products).
39. In **US**, biocides are categorised by use sites (see Table 1, Annex 1). Therefore, the OECD use categories 22-29, do not appear as separate use categories in the USA, but are spread across US biocide use sites.
40. **Germany**: approval (voluntary) required only for products used according to the Federal Communicable Diseases Act. No approval or notification required for other products to control other arthropods.
41. **Germany**: The use of repellents [25], insecticides [26] and molluscicides [28] is also covered by the national legislation on plant protection products (crops as well as storage of plant products).
42. **Netherlands**: use categories slightly different than in table, i.e.: household products applied: indoors (H1) indoors on surfaces (H2), indoors as evaporators (H3), indoors as aerial spray (H4); repellents against mosquitos, applied on human skin [OECD use category 25]; (H6) moth repellents for textiles [OECD use category 25]; (H7) products against storage pests; (H8) rodenticides [OECD use category 22]; and, (V1) veterinary products applied in housings.
43. **Finland**: different data requirements for indoor insecticides and acaricides and outdoor insecticides.
44. **Greece**: for use only on clothes and pets [OECD use category 27b, c].
45. **Ireland**: only for use on clothes [27b].
46. **Portugal**: also identify separately products for external use on animals, and on use for livestock.

23. For preservatives/microbiocides (OECD use categories 7-11), about half of the countries who indicated that they regulate these products, do so as chemicals or toxic substances (Australia, Belgium, Finland, Germany, New Zealand, Switzerland, UK), while most of the others (Canada, Greece, the Netherlands, Sweden) apply pesticide legislation.

24. Antifouling products (OECD use category 12) are regulated as pesticides by some countries and as chemicals in others. Wood preservatives (OECD use category 13) are generally regulated as pesticides, although Finland and Switzerland consider them as chemicals. All countries regulating structural treatments (OECD use category 14) apply pesticide laws.

25. Canada is the only country that has an approval system for microbiocides for waste disposal and strip mine sites (OECD use categories 15-17) and applies pesticide legislation. In most countries, products for use in aquatic non-food sites (OECD use categories 18-21) are treated as pesticides. Pest control products (OECD use categories 22-29) are normally regulated as pesticides or medicines/drugs.

Responsible agencies

26. In most countries, one ministry or agency is responsible for a particular biocide use category or group of categories (i.e. no split responsibility) and in general, only a few national authorities are involved. However, some countries such as Finland, Germany, and Hungary, seem to have very complex systems and split responsibilities between different ministries and different agencies within same ministry for the registration not only of different biocide product types but even for the same product type.

Regulatory procedures

Active ingredients, end-use products, new and old biocides (Annex 1, Table 2)

27. Most countries assess data on the active ingredient(s) and the formulated end-use product in one procedure as an integrated package, but approval is usually only granted to the end-use product. In other countries, and in the forthcoming EU system, active ingredients have to be approved first (and placed on a 'positive list' as in the EU) before they can be used in products.

28. In Canada, there is a different approach to the treatment of active ingredients between different use categories. For all disinfectants regulated under the Food and Drugs Act, once an active ingredient is approved, all sources of that active are considered to be acceptable for use. However, for biocides regulated under the Pest Control Act, individual registration of all sources of an active ingredient is required, i.e. there is no generic registration process.

29. The approach to approval in Sweden should be noted. In Sweden, when an application for approval of a biocide is received, the need for the product is first reviewed. If there is considered to be no need, approval will not be given. If there is a need, then the human health and environmental risks of the active ingredient(s) will be evaluated. A risk-benefit analysis is then performed, and depending on the outcome, the product might get approval.

30. Generally the regulatory procedures for 'new' and 'old' biocides are the same. However, data requirements may differ slightly or even a lot. If the active ingredient(s) or the use category of the biocide product is new, a full dossier of information is usually required from industry. For products based on existing active ingredients, new data may not be required if access to data previously reviewed is possible and the approval procedure is generally very straight forward.

Duration of approvals and re-evaluation programmes (Annex 1, Table 2)

31. Canada, Denmark, the Netherlands and Sweden mention that they have fixed approval periods which range from four years (Denmark, for toxic or very toxic products) to 10 years. Also, in Finland the approval period varies depending on the product types/use categories but the maximum approval period is 10 years. However, approval may sometimes be given for an unlimited period for wood preservatives (OECD use category 13) and slimicides (OECD use category 8).

32. Ireland and the Netherlands refer to reviews of biocides, but only the UK and Sweden specifically mention a re-evaluation programme for older products.

Conditions and impurities (Annex 1, Table 3)

33. Conditions are usually attached to approvals and concern mainly the use of a product. Some countries also set conditions for marketing, advertisement, sale, supply, storage and distribution. Countries tend to require that the conditions appear on the label. Conditions are usually binding, but whether they apply to the manufacturer/supplier or to the user varies among countries. In most countries, conditions are enforced by state or local/regional inspectors. Not surprisingly, countries report that the control of private users is difficult.

34. Most countries control impurities in the active substances and have established standards or acceptable levels. Denmark (for disinfectants), Greece, Hungary, Portugal and Switzerland do not control impurities.

Decision-making criteria and risk-benefit (Annex 1, Table 4)

35. Most countries have decision-making criteria for approval and/or notification, although in some countries these criteria are (1) not fully elaborated (Finland, the Netherlands), (2) applied on a case-by-case basis (Belgium, USA), or (3) exist only for certain products (Switzerland, for antifoulants). Further more, there may be differences in criteria between use categories. For example, in Denmark, decisions for public health disinfectants/sanitizers for use in eating establishments and food processing plants are based on hazard (i.e. inherent properties), while for industrial wood protection products, decisions are based on a risk assessment.

36. Most countries also have decision-making criteria for classification and labelling, although they are usually not specific to biocides but are applicable for all chemicals. Most of the EU countries quoted the relevant EU Directives, although the UK mentioned that they have criteria established within the UK covering hazard, risk, target pests and use/user group restrictions. In New Zealand, the classification system is based on that of WHO. In the USA, classification criteria exist for acute health endpoints, carcinogens and some ecological endpoints. Labelling criteria also exist in regulations and in other advisory documents (since it is not feasible to develop regulations that could address all possible uses and situations).

37. Risk-benefit usually plays a role in decision-making. In Denmark, Sweden and the USA, risk-benefit balancing is central to approval and is always performed. For most countries however, it is not applied routinely, but only in certain situations and specifically if a product is considered to be harmful/very toxic or presents unacceptable risks. In these cases, most countries could approve the product if there is an absolute need (i.e. there are no alternative products). However, approval is usually then granted under tightly controlled conditions. Some countries authorise such a product only in the case of emergency.

Denial of approval (Annex 1, Table 5)

38. All countries can deny approval of an active ingredient or end-use product. The main reasons for denial are (1) insufficient efficacy, and (2) an unacceptable risk to people or to the environment. If the applicant presents a dossier with insufficient data, the responsible authorities usually wait for the missing data to be submitted. If the applicant fails to submit the missing data within a fixed time period, application is denied. As indicated above, Sweden denies approval if they feel that there is no need for the product on the market.

Efficacy (Annex 1, Table 6)

Requirement, role and development of efficacy data

39. All countries and the EU require efficacy data but not necessarily for all use categories they regulate. For example, Switzerland only considers efficacy for wood preservatives and disinfectants. Generally efficacy data are required to support label claims.

40. Most countries do not distinguish between public health and non-public health uses in requiring efficacy data, although in the USA under FIFRA, only efficacy data for public health products are reviewed (i.e. OECD categories 1, 4, 22, 23, 25, 26 and 29).

41. The importance that efficacy data play in approval varies among countries. In Germany, efficacy data seem to be the most important data with regard to whether a product is approved. In Canada, Denmark, Finland, the UK and the EU, demonstrated efficacy also seems to play an important part in decision-making for approval. However, Sweden for example, requires efficacy data, but do not consider them so important for the approval decision-making since they believe that the market place will remove products that are not sufficiently effective.

42. Efficacy data are normally generated by the applicant. However, there are a few countries where efficacy testing is done by state authorities or other independent organisations for some biocide products. For example, in Finland, the efficacy of wood impregnation chemicals is tested and assessed by the Nordic Wood Preservation Council, an independent efficacy control organisation, while the Agricultural Research Centre -funded much by the government- tests the efficacy of insecticides, rodenticides and repellents. In Germany, the efficacy testing of insecticides, acaricides and rodenticides in the field of hygiene is done by government authorities (the Federal Environmental Agency) and the testing of disinfectants by the Robert-Koch-Institute.

43. Although most countries evaluate efficacy data provided by the applicant, they have not developed standardised efficacy testing methods. Countries generally state that “tests simulating practical use conditions” are required. It seems that only the UK has done some work in this area. Although in the UK, no formal list of test methods is specified for efficacy testing, detailed guidance documents outlining the nature and extent of the testing required to gain approval have been produced for each of the product areas. These guidance documents are issued to approval holders and new applicants. Also in Australia, the Australian Wood Preservation Committee has recently published a

protocol ("Protocols for Assessment of Wood Preservatives") to provide procedures for determining biocidal efficacy of wood products.

Addressing resistance development

44. Most countries do not address the problem of resistance development (or reduced effectiveness) for biocides after notification/approval but the EU countries will do when they implement the Biocides Directive 98/8/EC. Although some countries report that they have not yet encountered problems with resistance (Greece, Sweden), other countries have already cancelled approvals because of resistance development (e.g. Finland in the case of bromadiole used for control of mice).

45. Some countries appear to have some experience regarding where resistance development may occur:

- Health Canada notes that the published literature show no evidence of the development of resistance of microbial pathogens to chemical disinfectants.
- In Finland, resistance to industrial wood preservatives and industrial slimicides has not been encountered during the past 15 years. However, for rodenticides used indoor and outdoor, repellents, indoor insecticides/acaricides, outdoor insecticides, the approval of some products have been cancelled due to the development of resistance.
- Hungary notes that resistance seldom occurs in the veterinary area, while New Zealand believes the opposite.

46. Management measures taken in cases of resistance depend on the situation. For example:

- Belgium (biocides for use in agriculture) may limit the number of applications, specify use, adapt the dose, withdraw authorisation.
- In Canada, for biocides regulated under the Pest Control Products Act, new studies may be required to confirm which pests are controlled/not controlled and the changes to the expected level of control as a result of resistance. Label revisions may be necessary to reflect changes in product performance.
- In Canada for disinfectants/sanitizers but not drinking water disinfectants the following procedure is used:
  1. A health hazard assessment may be conducted.
  2. The product is reviewed based on the current requirements for disinfectant drugs.
  3. A list of revisions/clarifications/actions that are required to bring the product into compliance is developed.
  4. An appropriate course of action is determined based on health hazard, product history, etc. in consultation with the Bureau of Drug Surveillance.
  5. The chosen course of action is implemented and appropriate individuals are contacted.

- Action taken in the UK could involve the incorporation of appropriate label warnings or provision of other labelling advice, or alternatively restrictions or removal of the active substance(s). Specific claims that a product put forward for approval will control resistant pest strains, must be quantified and supported by data. Where resistance is considered likely to be a problem, a strategy to help delay or reduce the likelihood of this development has to be proposed. When resistance is known to exist in specific use areas for the product, statements have to be made with regard to the effectiveness of the formulation under these conditions.
- Finland and Switzerland will reconsider approval and may withdraw authorisation.

47. The Netherlands does not undertake immediate action when resistance or reduced effectiveness is reported during use, but consider this information when products are re-evaluated for extension of the approval.

48. Although Australia has a resistance management programme for herbicides and agricultural fungicides, they do not have a formal programme for biocides. Their view is that resistance management strategies are generally developed and implemented by production industries/users/chemical manufactures rather than through government regulatory mechanisms.

Labelling (Annex 1, Table 7)

49. The majority of countries label biocides as biocides rather than as general chemicals, although this can depend on the use category. The US EPA does not require products to be labelled with the term "biocide". Instead, these products are labelled more specifically as disinfectants, preservatives, slimicides, wood preservatives, antifoulants, etc. Under the EU system, biocides will be classified, packaged and labelled according to Directive 88/379/EEC applicable to dangerous preparations. A Commission proposal amending this Directive is being discussed by the European Parliament and the Council, and will include biocides and agricultural pesticides.

50. All countries and the EU require the approved use of the product to be specified on the label, exceptions being Switzerland for disinfectants and the UK for antifouling products. Most countries usually require the target pest to also be specified.

51. All the countries and the EU require all biocide products that they regulate to be ***labelled for hazard***. Generally, the hazard areas to be included on the label are the same for all use categories regulated within a country, but they vary between countries. Most countries require information on human health toxicity (H) and physical-chemical properties (PC) to be included on the label. Only about half of the countries also require information on ecotoxicity (E) and/or environmental fate (F).

52. All the countries (except Canada) -for almost all the biocide product types that they regulate- and the EU require labels to carry ***warnings or restrictions based on risk***, and in general, environmental information in addition to human health and physical-chemical properties is required. Finland and Sweden also require warnings/restrictions to be included regarding risk connected to waste management (W) for some product groups. In Canada, warnings or restrictions for labelling are based on hazard(s).

53. Regarding whether ***directions*** or ***instructions*** for use are specified on the label or in a companion document, Australia, France, New Zealand, UK and EU require instructions to be specified only on the label. Other countries (e.g. Greece, Switzerland and partly Ireland) require instructions to be on the label and in a companion document. A third category are the countries that require instructions on either the label or in a companion document (e.g. Belgium, Canada, Hungary, Netherlands, Sweden, USA).

54. For most countries (around two-thirds), labels should carry ***instructions*** on application rates rather than guidance.

Exposure Assessments (Annex 1, Table 8)

Human

55. It appears that human exposure assessment is systematically performed in most of the responding countries and for most of the biocide product types that they regulate.

Exposures and users of concern

56. All countries, when assessing the potential risks associated with a biocide, consider the type of people who are exposed (e.g. primary handlers, secondary handlers[47]). Some countries (e.g., Australia, Canada, Denmark, Finland, Ireland, UK, USA) focus their concern mainly on primary handlers, while secondary handlers are taken into account, when relevant.

57. Some countries such as Ireland, Sweden and UK clearly distinguish between industry, professional users or handlers and "amateurs" (e.g. home use). Denmark (Environmental Protection Agency) only does this if relevant.

58. In the UK, exposure assessments also cover (1) bystanders who may be exposed during use of products and (2) consumers who could be exposed following use of products or indirectly via the environment. In Canada under the Canadian Environmental Protection Act (which covers a small subset of biocides), some consideration is given to exposure of the general public, i.e. exposure as a result of use and from environmental sources are broadly considered. For drinking water disinfectants, Canada is concerned with the persons who drink the water, not with the handlers of the disinfectants. The US EPA performs exposure assessments and non-dietary risk assessments for bystanders in the workplace or the home, if these persons are also likely to be exposed.

59. In Canada, exposure information on persons occupationally exposed to the product during manufacture has not been requested in the past, although applicants have occasionally submitted this information voluntarily. Canada also recognises that "home use products may require an exposure assessment for children as well as the person applying the product, if children are potentially exposed to the biocide".

Variables taken into consideration

60. Most countries seem to take into account the formulation types and application methods. However, whether they treat them differently depends on a number of factors, e.g. the intrinsic properties of the active ingredient and the formulated product being evaluated, the exposure anticipated and the risks arising. Most countries also consider the differences between product types/use categories, and some (Canada, Hungary, Ireland, New Zealand and the UK) mention that they also take account of different exposure sites (e.g. factory, hospital, home).

Examples of approaches for human exposure assessments

61. In Canada (Pest Management Regulatory Agency) the approach to human health assessments is usually tiered, requiring some exposure data to quantify exposure and depending on the exposure, some toxicity data. The risk assessment is then conducted comparing the exposure potential to a No Observable Effect Level (NOEL) of the most appropriate toxicity study relevant to the exposure pattern and toxic endpoint of concern. If the margins of safety (MOS) determined in the risk assessment are inadequate, then further measure may be required to refine the exposure assessment (e.g., dermal absorption data). This general approach pertains to new active ingredients

47. Primary handlers are persons handling end-use products containing biocides as the active ingredient. Secondary handlers are persons handling paints, adhesives, treated wood etc. to which the biocide has been added.

for most pesticides. New product registrations for existing active ingredients do not generally require a quantitative exposure assessment if the exposure potential is not expected to be greater than that of existing products.

62. For wood preservatives for pressure impregnation, Denmark has developed an exposure model based on the NOAEL (No Observable Adverse Effect Level).

63. In Finland (for all biocides regulated), all relevant exposure routes are assessed and usually include accidental situations (worst case). The estimated or measured concentrations of biocidal substances in working places are compared with the TLV-values (threshold limit values) when possible. Usually exposure can only be assessed qualitatively, not quantitatively.

64. In the UK (for all biocides regulated), estimates of exposure cover both normal use and foreseeable misues. Exposure data comes from two major sources, i.e. models or from data obtained during actual use of products. The UK has established an extensive programme of research to establish a realistic picture of exposure (both during typical and atypical working patterns) for all user groups using products subject to current UK regulations. In collecting these data they are also collecting information on subjective elements to gain a better understanding of the patterns of exposure and the impacts of controls such as the effectiveness of personal protective equipment.

Environment

65. Generally three approaches to environmental exposure assessment can be distinguished:

a) those countries who appear to perform environmental exposure assessments for all biocide product types that they regulate (e.g. Australia);
b) other countries who perform environmental exposure assessments on a case-by-case basis depending on the use (e.g. Belgium);
c) those countries who have identified those biocidal products for which an environmental exposure assessment should always be performed and those for which an assessment will not be necessary (e.g. Canada and Finland).

66. Portugal raised the problem that although the responsible authorities require information concerning the environment, animals and plants, in most cases such data are not available. Therefore, they believe that their absence is not a real reason to deny approval.

Usage data

67. All countries recognise the importance of usage data in their assessment procedure and for most countries it is a fundamental requirement (e.g. Australia, Belgium, Denmark, Germany, Greece, Hungary and USA). Other countries (Netherlands, Sweden) will ask for usage data if it is necessary (e.g. to run exposure models).

68. However, as emphasised by the UK and partly by the USA, there is a problem in collecting accurate information on the amount and patterns of use. This information is necessary to produce a better estimate of risk. Currently in the UK, usage data can only be obtained from the approval holders on a voluntary basis at the request of the Regulatory Authority. In the absence of these data, assessments are made on the basis of the best/most appropriate alternative information available from other sources. These estimates will inevitably be less accurate and tend towards a more cautionary assessment.

69. In Finland and Sweden for new industrial wood preservative and slimicide products, data on anticipated usage is provided in the application while for approved products, sales data are collected

every year. In the USA, the EPA obtain a certain amount of usage data for the product as a function of the labelling requirements. The feasibility of obtaining more specific usage data about factories for which biocides enter the environment through point source effluents is explored. It is recognised that it may not be fully practicable to require this information from the biocide registrant.

Monitoring data

70. Generally, in the assessment procedures, countries do not systematically require monitoring data but however, they take them into account when available (Belgium, Canada, Sweden). Only Ireland clearly states that "usage and monitoring data are requested" while Denmark, Canada, the Netherlands, Sweden and the UK may ask for monitoring data in specific cases.

71. In Canada, monitoring data can be requested to resolve outstanding concerns and may be applied as a condition of temporary or time-limited registration. The data gathered from monitoring can be used to determine if registration will be continued or if additional conditions will be imposed on registration of the product.

72. In the UK, where accurate usage data are not available, environmental monitoring may be required. This may be carried out either by the applicant as a condition of the approval, or by the appropriate monitoring/regulatory authority. These data can be used to determine effects on non-target organisms and to establish residue levels. A substantial database has been established for a number of active ingredients in this way.

Exposure models

73. Concerning the use of exposure models for environmental exposure assessment, three different groups of countries can be distinguished:

a) Countries such as Ireland and Greece that currently do not use models or such as the USA that perform only simple calculations and not elaborated modelling.

b) Countries such as Australia and the UK that use exposure models in addition to usage data and/or monitoring data for exposure assessments:

   - Australia uses simple fugacity models (Mackay level I) but the biocide use categories for which this model is used are not indicated in the Australian response.

   - The UK use generic models for key use patterns (e.g., antifouling products and the industrial use of wood preservatives) in order to estimate likely exposures to different compartments of the environment and to determine PEC and PEC/PNEC ratios. For example, certain modules of the EU EUSES package and emission scenarios from the EU risk assessment Technical Guidance Documents for new and existing industrial chemicals have been used. However, current experience in the UK indicates a marked disparity between model predictions and field levels determined by monitoring. Consequently, further research has been initiated to identify and validate suitable predictive models.

c) Countries such as Denmark, Finland, the Netherlands, Sweden, Switzerland that mostly base their exposure assessments on exposure models, for most or some specific biocide use categories:

   - In Denmark the general approach to environmental exposure assessment for wood preservatives, rodenticides, insecticides and molluscicides is to calculate local

predicted environmental concentrations (PECs) which can be expected in a reasonable worst case, e.g. when using the maximum dose given in the proposed use instructions.

- Finland base the environmental exposure assessment for slimicides on calculation models that are developed in Finland but the results are compared with similar model calculations made in Sweden, if available. The calculation models for wood preservatives are based on German models. The general approach to environmental exposure assessment is the same as in Denmark.

- The Netherlands has developed models specifically for biocides, but these are closely related to the models used for exposure assessments for chemicals in general (USES). These exposure models are mostly used to estimate the expected concentration in the environment (Predicted Environmental Concentration, PEC).

- Sweden uses the fugacity model, level III (Mackay) for PEC calculations, whenever appropriate, for all use categories regulated with an approval system.

- For antifouling products, Switzerland uses an exposure assessment scheme based on an exposure model "standard marina". The model has been developed at the Federal Office of Environment, Forests and Landscape using MASAS software for Apple/McIntosh.

Examples of approaches to environmental exposure assessments

74. In Australia (all biocides regulated by the National Registration Authority) the environmental fate of a chemical, or how it will be transported and degraded in the environment is considered. The exposure assessment is mainly based on the:

- biological, physical and chemical properties of the compound;
- method of application and;
- use pattern.

75. Canadian environmental exposure assessments for biocides regulated by the Pest Management Regulatory Authority are based on the following factors:

- the proposed Use Site Category (USC);
- the maximum application rate and the number of applications per year/season;
- the method of application;
- the formulation; and
- the result from laboratory studies on environmental chemistry and fate and field studies on the dissipation of the active ingredient(s) and major transformation products.

76. Further information on exposure scenarios for terrestrial and aquatic environments is provided in Annex 1, Table 8.

77. In New Zealand (for all biocides that are subject to an approval procedure), environmental exposure assessments involve a tiered evaluation of basic chemical and physical properties of the active ingredients, and where these data indicate that the proposed use pattern could result in significant environmental exposure, additional data is requested relating to the exposure route in question. These additional data can include laboratory studies, and where necessary, more extensive field studies.

78. Germany provided an extensive description for wood preservatives for construction products which is given Table 8 of Annex 1.

Risk Assessment (Annex 1, Table 9)

Guidance available

79. Most countries do not have specific written guidance for conducting environmental or health risk assessments for biocides. If risk assessment is part of their evaluation procedure for approval of a biocide, then similar approaches to "standard" ones for agricultural pesticides and/or chemical substances are followed, but adapted to the specific use category of a biocide.

80. The UK refers to "standard" approaches described in a number of publications from e.g. IPCS and EU (mainly Uniform Principles, Annex VI to Directive 91/414 EEC for the placing of plant protection products on the market). Belgium also refers to the latter approach.

81. Annex VI of the EU's Biocide Directive provides the general rules for the analysis of risks and decision making. A comprehensive risk assessment guidance is going to be prepared covering all the 23 biocide product types of the EU. This guidance will be unique to biocides. During the risk assessment, all the human populations concerned will be considered (professional users, non professional users and humans exposed directly or indirectly through the environment). Technical notes aimed to cover in as much in detail as possible all the possible use/exposure scenarios for each product types are under preparation.

82. At present, the USA have risk assessment guidance but it is not specific to biocides. Guidance used is not developed by product type, but by scientific discipline, e.g., carcinogen risk assessment, exposure risk assessment. It is expected that specific guidance will eventually be articulated for biocides, particularly for worker and occupational exposure and risk assessment, for environmental exposure and ecological risk assessment, and for dietary exposure to disinfectants and sanitizers.

83. In Canada, under CEPA (Canadian Environmental Protection Act), a risk assessment would be conducted on biocidal components of an imported non-biocidal product e.g., a biocide in an imported paint [Note: for a paint manufactured in Canada the added biocide would undergo a risk assessment under PCPA (Pest Management Regulatory Agency)]. The risk assessment under CEPA would be comparable to that which is done for commercial chemicals.

84. It appears, as emphasised by Canada, that one of the difficulties for a comprehensive and meaningful risk assessment is that the "data base available for toxicology and human exposure for biocides is often reduced compared to that available for agricultural chemicals. This is especially true for products registered some time ago".

85. Some countries have specific guidance for risk assessment of some biocides - mainly for wood preservatives, antifouling products and industrial slimicides (see Table III). It appears that the reason for developing specific risk assessment guidance for these specific use categories is that the regulatory authorities have more experience with them.

86. Table III shows that when developing specific risk assessment guidance for the specific biocide use categories mentioned above, (1) countries focus mainly on environmental risk assessment (e.g. Finland, the Netherlands); and (2) the main principles of the guidance are similar mostly to

guidance for industrial chemicals (e.g. Finland, The Netherlands) but they are adapted to the specific use of a biocide.

Table III: Examples of guidance for risk assessments

Wood preservatives	
Denmark	Unique risk assessment guidance document for environmental and human health for pressure impregnation products
Finland	Guidance documents are only used in environmental risk assessment. The main principles of the guidance for industrial chemicals are used but the detailed PEC/PNEC calculations are unique.
Netherlands	There is a guidance document only for environmental risk assessment. It is comparable with industrial chemicals, but adapted to specific use as a biocide.
Antifouling products	
Netherlands	There is a guidance document only for environmental risk assessment. It is comparable with industrial chemicals, but adapted to specific use as a biocide.
Sweden	• "Risk assessment of antifoulants" (prepared by Sweden/the Netherlands and published by the Council of Europe) • KemI report on antifouling products 2/93.
Switzerland	Unique risk assessment guidance.
Industrial slimicides	
Finland	Guidance documents are only used in environmental risk assessment. The main principles of the guidance for industrial chemicals are used but the detailed PEC/PNEC calculations are unique.
Sweden	• "Guidelines for the evaluation of Slimicides" (prepared by Sweden and published by the Council of Europe). • KemI report on risk assessment of Slimicides 9/95.

Treated materials

87. Most of the countries perform risk assessments for treated materials or at least take this possibility into account in their assessment procedure. Some countries (e.g. Australia, Ireland, the Netherlands, USA), intend to perform risk assessment in principle for all treated materials in relation to their function. Some other countries (e.g. Canada, UK) seem to have determined for which treated materials a risk assessment should be performed and for which treated materials a risk assessment is not required (see Table IV).

88. The treated materials for which countries decide to perform risk assessments vary from country to country. For example for textiles, a risk assessment is always performed in the Netherlands but is not required in Canada. However, most of the countries perform risk assessments for materials treated with wood preservatives and antifouling products. Specifically, for wood preservatives, a human health risk assessment is performed mainly for wood used indoors and an environmental risk assessment mainly for wood used outdoors.

89. The EU Biocide Directive considers that "treated materials are not within the scope of the proposed Directive, however Annex VI point 15 provides that the analysis of risks connected with the production and disposal of treated materials should be carried out".

Table IV: Examples of countries that have determined for which treated materials a risk assessment should be performed

Treated materials	Are risk assessments for treated materials performed?	
	Risk assessment for human health?	Risk assessment for the environment?
CANADA*		
• Wood treated with heavy duty, antisapstain or remedial wood preservatives • Antifouling paints and coatings	Yes	Yes
• Paints with biocidal claims, swimming pools, metal cutting fluids	Yes	No
• Textiles, leather, rubber, carpets	Yes; qualitative	No
UK		
• Vessels etc. treated with antifoulant	No	Yes
• Treated timber	Yes	Yes
• Furnishings etc. treated with insecticides	Yes	Yes, if appropriate (e.g., outdoor use)

* Generally, the use of a product or material with an antimicrobial pesticide in it, is not assessed unless the product or material has pesticidal claims. Specific post application end uses are assessed if the product applied has pesticidal properties (e.g. antifouling paints) or there is a high potential for exposure (e.g., swimming pool biocides, wood preservatives, textiles, etc.).

Minor uses, low risk products and biological biocides (Annex 1, Table 10)

Minor use

90. Only Belgium, Canada, Ireland and the USA indicated that they have a formal policy for "minor uses' but they are not necessarily specific to biocides. However, the USA report that in practice, they have already eased the financial burden of testing biocides by having a tiered approach, and because of this tiered approach, data required for approval of biocides do not exceed the guidelines put forward in the minor use policy.

91. The policies for minor use products may include: (1) no registration or cheaper registration fees (Belgium and Ireland), (2) funding of data generation for data gaps (Belgium), (3) systematic waivers of data requirements (Ireland), (4) extra time for industry to generate data and priority processing (USA).

92. Most other countries have no formal policy, and it seems that they have never dealt with the issue. Finland and the UK do not have a formal minor use policy, but they consider such products on a case-by-case basis. The EU Biocide Directive does not address the issue of minor use.

93. Some countries have a definition for 'minor use' which is based on the low volume of use and/or the small economic return for the applicants.

Low risk biocides

94. Only Denmark, Finland, Ireland, Sweden, the USA and the EU have reduced regulatory requirements for biocides identified as being of low risk. Australia indicated that reduced data for a low risk chemical may be accepted if low risk can be demonstrated. Canada indicated that although requirements are not reduced, they are working jointly with the USA on a process that will shorten the review process for reduced risk pesticides.

95. Most of these countries do not have formal criteria for determining "low risk" products. In Australia, Denmark and Sweden, the applicant should demonstrate the low risk of his biocidal product. In Finland, substances and products which are commonly used in food or in cosmetics and which are not classified as hazardous may be considered as low risk biocides. Ireland identifies compounds widely used for many purposes and for which low risks in practice have been established. The EU defines a "low risk" biocide as: "a biocide containing an active ingredient that is not classified as carcinogenic, mutagenic, toxic for reproduction, sensitising, bioaccumulative and not readily degradable". Furthermore, the definition of low risk biocidal products provides that they should contain only low risk active substance(s) and not contain substances of concern.

Biological biocides

96. About half of the responding countries knew of biocides based on fungi, micro-organisms or viruses. Most referred to biocide products based on the micro-organism *Bacillus thuringiensis* subspecies *israelensis*, which is mainly used as insecticide. Australia has already registered this product. Sweden has so far received two applications for products used in chemical toilets. These products were based on the micro-organisms *Bacillus licheniformis* and *Bacillus subtilis* but they did not get authorisation.

97. Germany, Ireland, the Netherlands, Portugal, Sweden and the EU indicated that they have formalised data requirements for biological biocides. Ireland, Sweden and the EU have requirements for products based on fungi, micro-organisms and viruses. However, it is not clear from the Irish and Dutch responses if the data requirements apply specifically to biological biocides. Sweden states that the requirements for biological biocides and biological agricultural pesticides are the same at present. Germany has data requirements only for genetically modified organisms, subject to guideline 90/220/EEC (especially Annex III a) and Portugal only for products based on micro-organisms.

98. Australia does not have formal data requirements, but it does have a policy document 'Guidelines for Registration of Biological Products'. The US EPA has formalised requirements only for microbial agricultural pesticides. Therefore, if an application for biological biocides is received it would be processed within the framework of the data/test methods required for microbial pesticides and then considered what information are needed for antimicrobial (biocidal) uses.

Survey Results:
Data Requirements

Extent of formalised data requirements and waiving of data

99. All countries (except Germany, Sweden and Switzerland) and the EU have established data requirements for those use categories that they regulate using an approval system (see Annex 1, Table 1). In Germany data requirements for some use categories are under preparation, while in Sweden, specific data requirements have only been developed for those use categories for which they have had submissions. For Switzerland, specific data requirements only exist for disinfectants (efficacy only), anti-fouling products and wood preservatives.

100. Table V indicates the number of countries with data requirements for biocide products. Note that where information has been grouped for several use categories (i.e. disinfectants/sanitizers, preservatives/microbiocides, aquatic food sites and pest control products) the countries listed in Table V have data requirements for one or more use category(ies) in a group but not necessarily all.

Table V. Countries with data requirements for various biocide products

Biocide broad areas or use categories	No. countries with data requirements	Countries
Disinfectants/sanitizers (use categories 1-6)	14 + EU	Australia, Belgium, Canada, Denmark, France, Germany, Greece, Hungary, Netherlands, New Zealand, Portugal, Sweden, Switzerland, USA, and EU
Preservatives/microbiocides (use categories 7-11)	10 + EU	Australia, Belgium, Canada, Finland, Greece, Hungary, Netherlands, New Zealand, Sweden, USA and EU
Antifouling products (use category 12)	10 + EU	Australia, Belgium, Canada, Ireland, Netherlands, New Zealand, Sweden, Switzerland, UK, USA and EU
Wood preservatives (use category 13)	17 + EU	Australia, Belgium, Canada, Denmark, Finland, France, Germany, Hungary, Ireland, Netherlands, New Zealand, Portugal, Sweden, Switzerland, UK, USA and EU
Structural pesticides (use category 14)	8 + EU	Australia, Canada, Finland, Hungary, New Zealand, Portugal, Sweden, UK
Microbiocides used for waste disposal and strip mine sites (use categories 15-17)	2	mainly Canada, although the US has some requirements for sewage disposal areas
Aquatic non-food sites (use categories 18-21)	10 + EU	Australia, Belgium, Canada, Denmark, Greece, Hungary, Ireland, Netherlands, New Zealand, USA and EU
Pest control products (use categories 22-29)	15 + EU	Australia, Belgium, Canada, Denmark, Finland, Germany, Greece, Hungary, Ireland, Netherlands, New Zealand, Portugal, Sweden, UK, USA and EU

101. All countries (except Greece, Hungary and the Netherlands) and the EU can waive data requirements on a case-by-case basis (see Annex 3, Table 1). Generally, the ability to waive data applies to all use categories regulated. However, in Canada, once DWMSA (Drinking Water Materials Safety Act) is in effect data waivers are not expected for disinfectants for human drinking water, and in Denmark, the possibility to waive data applies only to those biocides regulated by the Danish EPA and not for disinfectants regulated by the National Food Agency.

102. Some of the main reasons that countries give for waiving data are:

- the information is not needed due to the nature (intrinsic properties) of the biocide product or its proposed use (Canada, Finland, EU);
- the study is not technically feasible or scientifically justifiable (Canada, Finland, EU);
- limited exposure to the product (Finland, Germany)
- the substance can be contained so as to protect the environment and human life (Canada).

103. The waiving of data has to be initiated by the applicant, who should also submit a justification acceptable to the regulatory authority.

Tier Testing

104. Half of the countries and the EU have a tiered approach to data requirements for some or all (only the Netherlands and New Zealand) of the biocide use categories subject to approval (see Annex 3, Table 2).

105. In some countries (e.g. the Netherlands, New Zealand, the UK), the areas for which a tiered approach is applied are the same for all biocide product types. For example, in New Zealand, a tiered approach for the test areas of environmental fate, ecotoxicity, toxicology (mammalian) and human exposure is applied to all biocide products regulated by an approval system. In the Netherlands, a tiered approach is used in principle for all test areas in the OECD questionnaire (see Table I). For other countries, the areas where tiered testing is applied vary between use categories. Finland applies a tiered approach only for genotoxicity testing for structural pesticides, rodenticides (indoor), repellents, insecticides and acaricides (indoor) while for wood preservatives and industrial slimicides, a tiered approach is also used for mobility in soil, biodegradation and bioaccumulation.

106. No specific trend seems to exist between the biocide product types and the areas for which a tiered approach is applied.

107. In most countries, tier testing is done on a case-by-case basis. Only the Netherlands and the UK have formalised frameworks.

Detailed information on data requirements for approval

Collation and presentation of the information

108. Detailed information on countries' data requirements for the approval of biocides is provided in Sections 1 and 2 of Annex 4. Section 1 collates information on data requirements of individual countries. Section 2 summarises countries' responses and provides information on the number of countries requiring each data element. Information on data requirements for all use categories included in the survey is provided, with the exception of those under the broad category

'microbiocides for waste disposal and strip mine sites' (use categories 15 -17), where Canada was the only country with detailed requirements.

109. With respect to the situation within the EU, technical guidance documents for the practical operation of Directive 98/8/EC are under preparation which will (a) specify the detailed data requirements for each of the 23 product types listed in Annex V of the Directive, and (b) the detailed rule on how to carry out risk assessments for the chemical active substances and biocidal products. These technical notes will be finalised by May 2000 at the latest and only at that stage will detailed requirements at the EU level be agreed.

110. A guide to the large amount of information provided in Sections 1 and 2 and how it is organised and presented is given in the introduction to Annex 4.

Analysis of the responses

General comments

111. Perhaps the first comment that should be made with respect to data requirements is how much variability there is among and within countries.

112. The amount of data required for any one use category can vary tremendously among countries as illustrated in Figure 1 for wood preservatives (i.e. total number of data requirements for wood preservatives for the active ingredient and the biocidal product). Switzerland has the fewest requirements (less than 50) for wood preservatives, while Ireland can require over 300 data elements. The distribution of data requirements between core (always required) and conditional also varies. For wood preservatives, some countries (e.g. New Zealand) have a small core data set compared with the number of conditional requirements. In others, most data elements are core requirements (e.g. Belgium, Greece), and in yet others the requirements are more balanced between core and conditional (Australia, Portugal, EU). Similar patterns are seen for other use categories, and for test areas within a use category. Figures 2 and 3 show the number of data requirements for wood preservatives in the areas of environmental fate and toxicology. Figures 4, 5 and 6 show the number of data requirements for all test areas, for ecotoxicology and for toxicology for public health disinfectants (use category 1).

113. The way in which the data requirements are defined varies. Some countries (Australia, Canada, Finland, Hungary, the Netherlands, Germany, Sweden, Switzerland and the USA) have specific data requirements for a specific use category. In most of these countries, the different use categories are regulated under the same law. Other countries (Belgium, Denmark, Greece, Ireland, Portugal and the UK) have common core requirements for all biocide use categories regulated under the same law. New Zealand has the same core requirements for use categories regulated under different laws. The EU Biocide Directive has a common core of data for all use categories, and additional data may then be required according to the nature and use of the product. Data requirements in some countries will depend on where the end-use product is intended to be used. For example, Finland, the Netherlands and the USA clearly distinguish between indoor/outdoor uses, especially in the pest control area. Canada and Australia require residue data only for products which have food contact uses.

114. The test areas (e.g. physical/chemical properties, toxicology, ecotoxicology, etc.) included in countries' data requirements vary among countries for a particular broad area or use category and can also vary between broad areas/use categories for a particular country. This is illustrated in Table VI which gives a broad overview of the extent of data requirements established for the various test areas. In Table VI, no distinction is made between whether data are core (always required) or conditional requirements. In general, all countries have established requirements for chemical identity; physical/chemical properties; function, mode of action and handling; analytical methods; and

toxicology, for all biocides with the exception of disinfectants/sanitizers. Fewer countries have established data requirements for efficacy, environmental fate and behaviour, ecotoxicology, residue chemistry and human exposure.

Similarities among countries

115. Given that there is so much variability among countries and use categories in data requirements for biocides, two tables have been developed which indicate those data elements which are always or conditionally required by most (i.e. at least 70%) countries. Table VII provides information for the active ingredient, and Table VIII for the biocidal product. Both tables allow comparisons to be made among all use categories included in the survey, with the exception of microbiocides for waste disposal and strip mine sites (use categories 15-17).

116. Examination of Tables VII and VIII reveal the following:

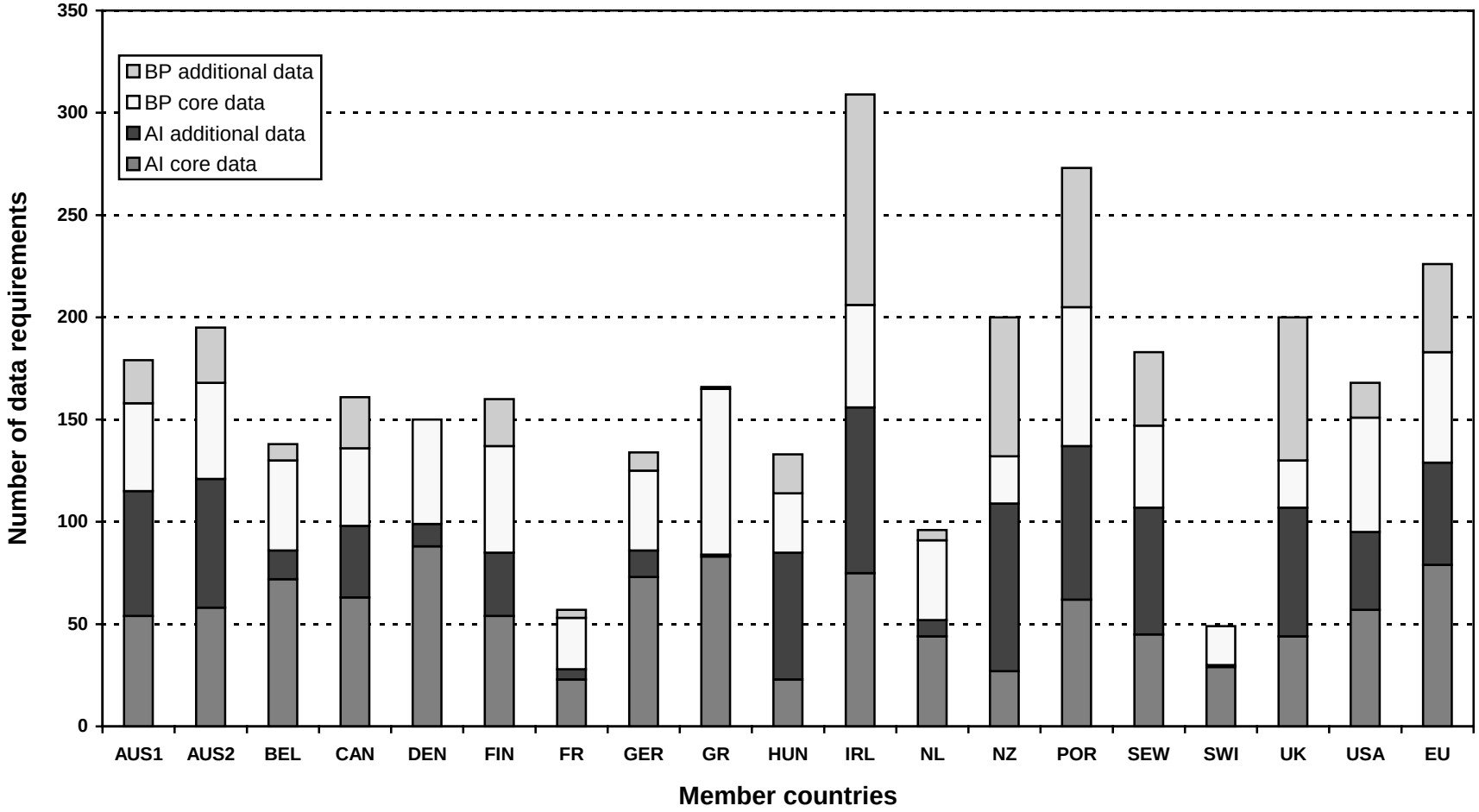
- The data on ***chemical identity*** that are always required by most countries (i.e. common requirements) are similar across all use categories for the active ingredient and for the biocidal product, although the number of common elements tends to be less for disinfectants/sanitizers. More data are commonly required for the active ingredient than for the biocidal product.
- For ***physical/chemical properties***, the common data elements are similar for the active ingredient, but again there is a tendency for fewer requirements for disinfectants/sanitizers. The common requirements for the biocidal product are similar across all use categories, although no common requirements were identified for products used in aquatic non-food sites (use categories 18-21). This suggests that requirements among countries vary considerably in this area. Most data are required for the active ingredient.
- Not surprisingly most data required on ***function, mode of action and handling*** are for the biocidal product. The common requirements for the product are similar across most use categories but with a tendency for fewer requirements for some disinfectants/sanitizers. No common requirements were identified for products used in aquatic non-food sites.
- Only one or two data elements for ***analytical methods*** are always required by most countries, although there are more conditional requirements for embalming fluids.
- Although responses to Part 1 of the questionnaire indicated that all countries and the EU require ***efficacy data***, but not necessarily for all use categories they regulate, there appear to be no data elements that are always required by at least 70% of the countries for either the active ingredient or the biocidal product. However, 50% of the countries require data on (a) dose/efficacy relationships for most products, and (b) evidence of effectiveness under working conditions for some use categories 4, 5, 6, 14, 22 and 25.
- Very few data on ***environmental fate and behaviour*** are always required by most countries for the active ingredient and none for the biocidal product. Information on hydrolysis rate is a common requirement for preservatives/microbiocides, antifoulants, wood preservatives and pest control products (except for repellents). There are no common requirements for disinfectants/sanitizers, structural treatments or products used in aquatic non-food sites.
- Common requirements on ***ecotoxicity*** are restricted to the active ingredient but even then only for antifoulants (fish studies) and pest control products (fish and avian studies). Data are conditionally required rather than always required.
- There are no common requirements for ***residue chemistry*** for either the active ingredient or the biocidal product.
- For ***toxicology***, the common data elements are similar for the active ingredient across all use categories and include data on acute effects, developmental and reproductive

toxicity and mutagenicity. More data are always required for products in the pest control area. For biocidal products, the common elements are restricted to data on acute effects.

- For ***human exposure***, no data elements are always required for most countries for either the active ingredient or the biocidal product. However, for the product some information is often conditionally required for some disinfectants (use categories 3-5), antifoulants, structural treatments and pest control products.

117. The information provided in Tables VII and VIII may be useful in work to harmonize countries' data requirements for biocides. In other areas of the OECD Pesticide Programme, work is underway to develop core sets of data requirements that could be adopted by all OECD countries as a foundation for registration of agricultural pesticides. Countries would be able to require additional data as necessary to address their individual situations, but the core data sets would establish a common basis for pesticide registration among OECD countries. A similar approach will probably be used for biocides.

Figure 1: Total no. data requirements per country for wood preservatives (use category 13) (sum of the 10 matrices)



AUS1: public health exposure; AUS2: occupational exposure

Figure 2: No. data requirements per country for enironmental fate and behaviour for wood preservatives (use category 13)

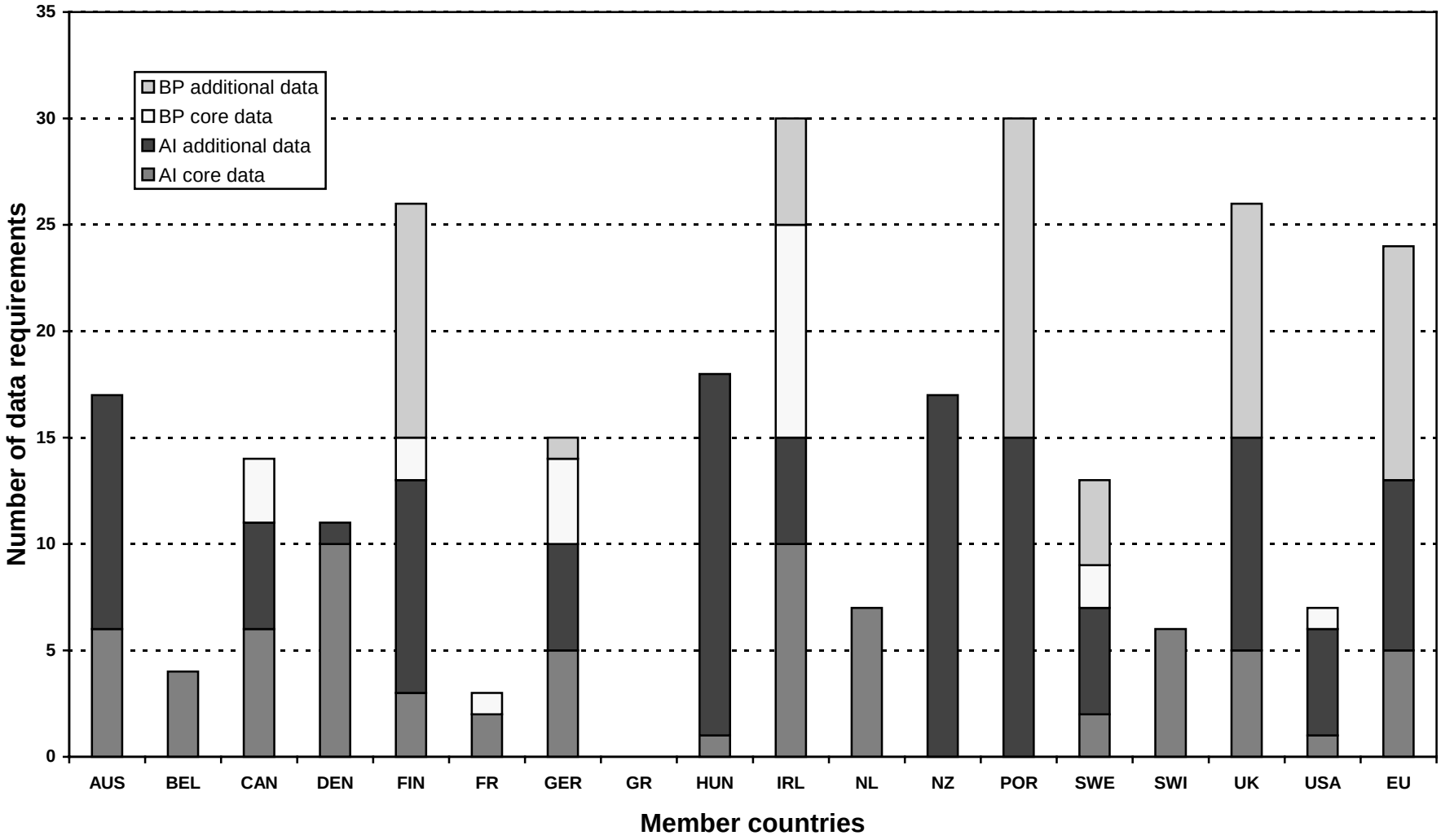
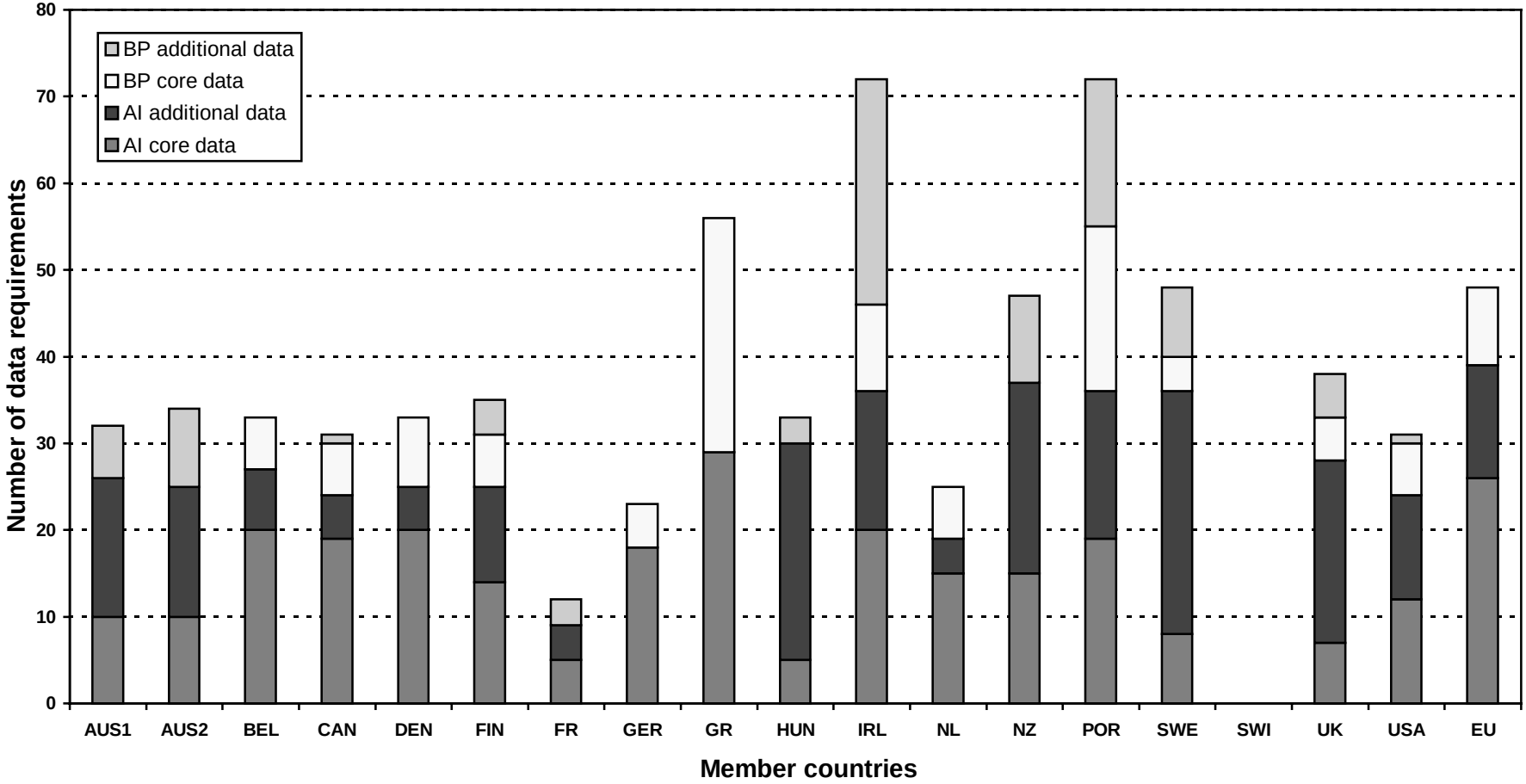


Figure 3: No. data requirements per country for toxicology for wood preservatives (use category 13)



AUS1: public health exposure; AUS2: occupational exposure

Figure 4: Total number of data requirements per country for public health disinfectants (use category 1) (sum of the 10 matrices)

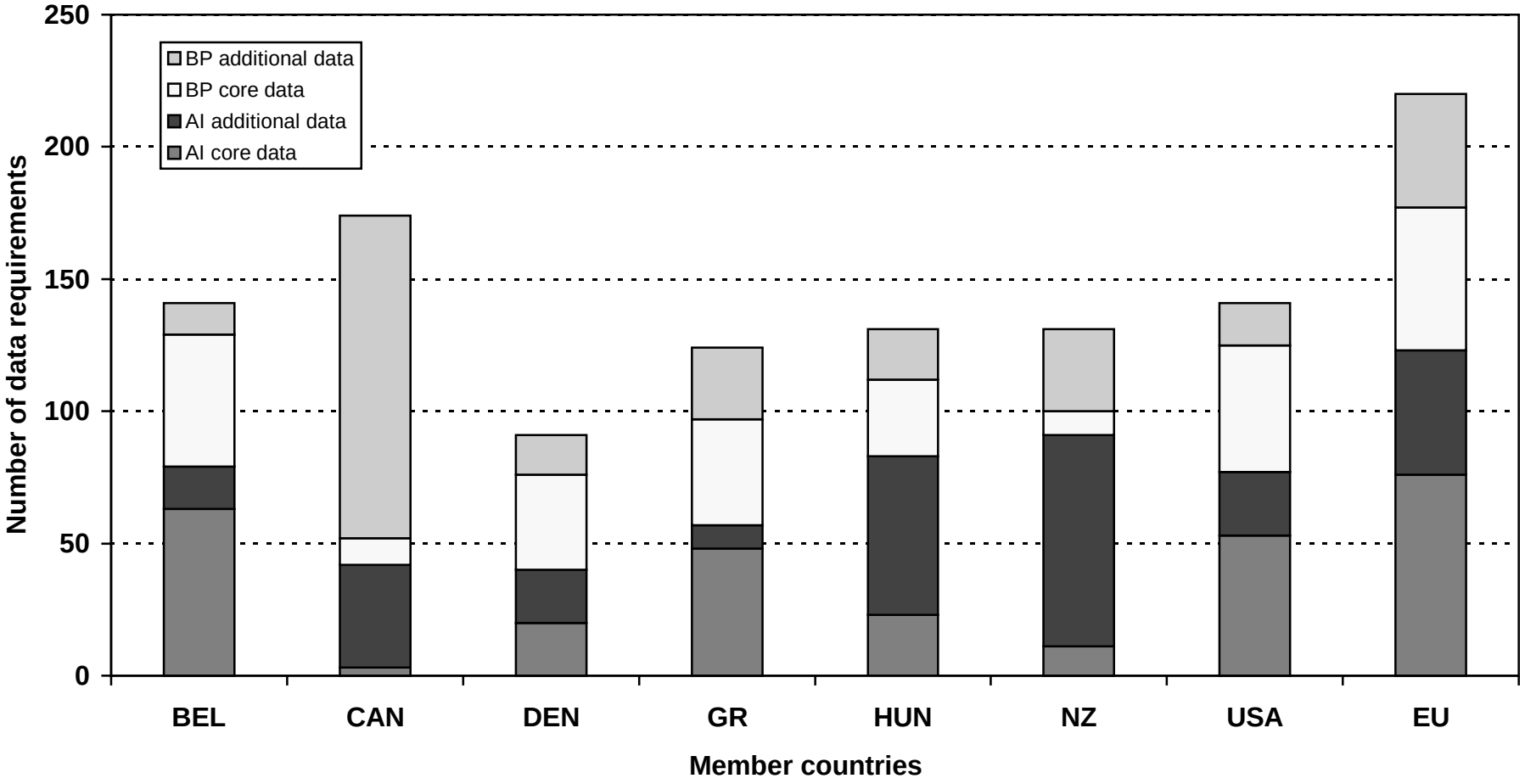


Figure 5: No. data requirements for ecotoxicology for public health disinfectants (use category 1)

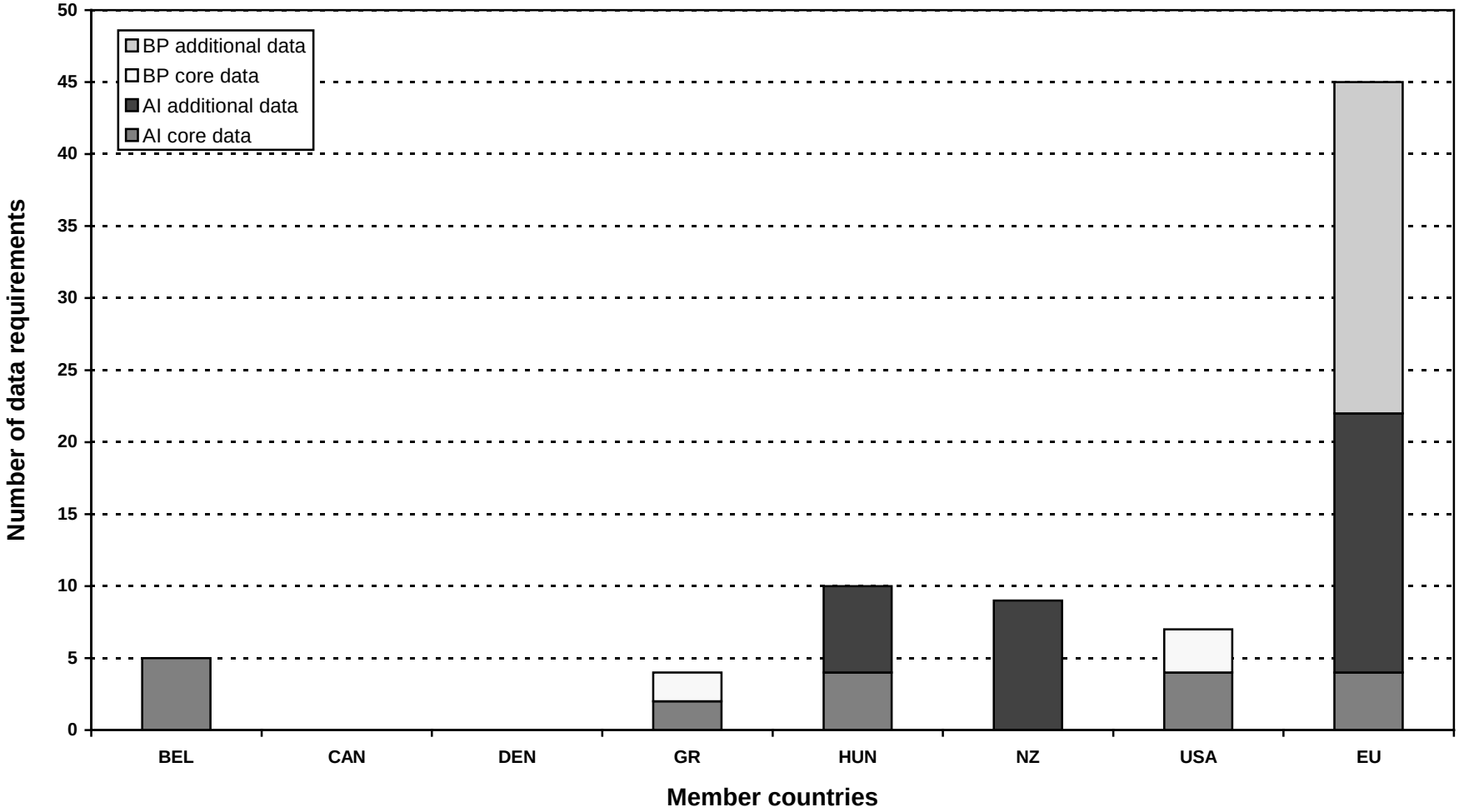


Figure 6: No. data requirements per country for toxicology for public health disinfectants (use category 1)

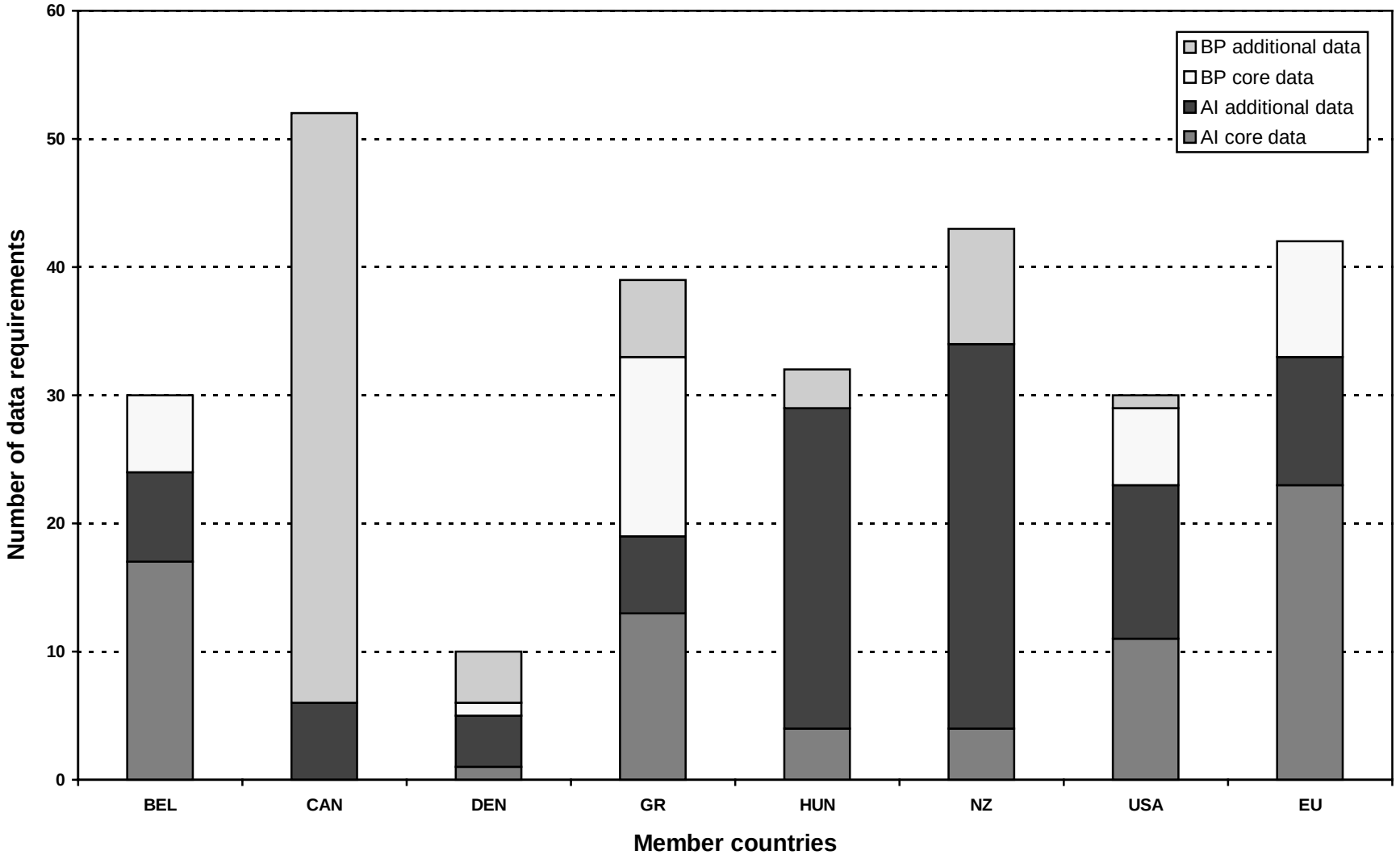


Table VI. Broad overview of extent of data requirements for the various test areas

	Disinfectants/ sanitizers	Preservatives/ microbiocides	Antifouling products	Wood preservatives	Structural pesticides	Aquatic non-food sites	Pest control
Number of countries with data requirements for the use category[1]							
No. countries with data requirements	14 + EU	10 + EU	10 + EU	17 + EU	8 + EU	10 + EU	15 + EU
Countries with data requirements in each of the test areas							
Chemical identity	no (GER, SWI)	all	all	all	all	all	all
Phys/chemical properties	no (GER)	all	all	all	all	all	no (GER)
Function, mode of action etc.	no (CAN, GER, SWI)	all	all	all	no (CAN)	all	no (GER)
Analytical methods	no (DEN, GER, SWI)	all	all	all	all	all	no (GER)
Efficacy	no (AUS, GER, NZ)	no (AUS)	no (AUS, SWI, US)	no (GER, USA)	no (AUS)	no (AUS, NZ, USA)	no (AUS, GER)
Fate and behaviour	no (CAN, GER, SWI)	no (AUS, GRE)	all	no (GRE)	no (FIN)	no (CAN)	no (GER, GRE)
Ecotoxicology	no (CAN, FR, GER, SWI)	no (AUS, BEL, NL)	all	yes	no (FIN)	no (CAN)	no (BEL, GER)
Residue chemistry	no (CAN, FR, GER, GRE, SWI)	no (AUS, BEL, CAN, GRE, NL)	no (BEL, CAN, NL, US)	no (AUS, BEL, CAN, FR, GER, GRE, SWE, SWI, USA)	no (CAN)	no (AUS, BEL, CAN, GRE, NL, USA)	no (BEL, GER)
Toxicology (mammalian)	no (SWI)	no (AUS)	no (SWI)	all (SWI)	all	all	all
Human exposure	no (CAN, DEN, FR, GRE, NL, NZ, SWI, EU)	no (BEL, GRE, HUN, NL, NZ, EU)	no (BEL, GRE, HUN, NL, NZ, EU)	no (BEL, FIN, FR, NL, SWI, EU)	no (FIN, HUN,)	no (BEL, GRE, HUN, NL, NZ, EU)	no (BEL, FIN, GRE, NL, EU)

Notes:

1. Where not all countries have data requirements for a particular test area, 'no' appears in the column. The countries listed in brackets are the countries who do not have requirements.
2. **Netherlands**: generally where it is indicated that the Netherlands has no data requirements this means that data are not normally required, but, however they do not rule out the possibility that data may be requested.
3. **Switzerland:** where it is indicated that Switzerland has no data requirements this means that these are not established in a specific formalised form, but data may be requested.
4. **EU**: data requirements for human exposure are under preparation.

Table VII. Data elements *always* (•) or *conditionally* (o) required by at least 70% of countries for the ACTIVE INGREDIENT

(Data elements always required by all countries are shown by shaded boxes)

Data *always* (•) or *conditionally* (o) required by at least 70% of countries	Disinfectants / sanitizers						Preservatives / microbiocides					Anti-fouling products	Wood preservatives and structural treatments		Products for use in aquatic non-food sites				Products for use in vertebrate and invertebrate pest control							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	18	19	20	21	22	23	24	25	26	27	28	29
MATRIX 1: CHEMICAL IDENTITY																										
Common name	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Chemical name (IUPAC) nomenclature	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
CAS and EEC numbers (if available)	•			•		•	•	•	•	•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•
Empirical and structural formula and mass molecular		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Trade name(s)	•		•			•	•	•	•	•	•	•	•		•	•	•	•	•		•	•	•	•	•	•
Method of manufacture							•	•		•	•						•	•			•		•		•	•
Specification of purity				•			•	•	•	•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•
Impurities and additives - identity, formation and range of each							•	•	•	•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•
Name of manufacturer	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Name of applicant	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•

Table VII. Data elements *always* (•) or *conditionally* (o) required by at least 70% of countries for the ACTIVE INGREDIENT (continued)

(Data elements always required by all countries are shown by shaded boxes)

Data *always* (•) or *conditionally* (o) required by at least 70% of countries	Disinfectants / sanitizers						Preservatives / microbiocides					Anti-fouling products	Wood preservatives and structural treatments		Products for use in aquatic non-food sites				Products for use in vertebrate and invertebrate pest control							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	18	19	20	21	22	23	24	25	26	27	28	29
MATRIX 2: PHYSICAL/CHEMICAL PROPERTIES																										
Colour		●	●	●		●	●	●	●	●	●	●		●	●	●	●	●	●	●	●	●	●	●	●	●
Physical state		●	●	●		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Odour						●	●	●	●	●	●				●	●	●	●			●		●		●	●
pH																							●			
Density			●			●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
UV-visible, IR, NMR, Mass Spectra			●			●	●			●	●	●			●		●	●					●		●	●
Melting point							●			●	●	●	●		●				●		●	●	●		●	●
Boiling point							●			●	●	●	●	●	●				●	●	●	●	●	●	●	●
Vapour pressure							●	●	●	●	●	●	●	●	●				●	●	●	●	●	●	●	●
Solubility in water as a function of pH and temperature	●	●	●	●		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Solubility in organic solvents			●			●	●	●		●	●	●	●		●	●	●	●	●		●	●	●	●	●	●
Octanol-water partition coefficient as a function of pH			●				●	●	●	●	●	●	●		●		●	●	●	●	●	●	●	●	●	●

Table VII. Data elements *always* (•) or *conditionally* (o) required by at least 70% of countries for the ACTIVE INGREDIENT (cont.)

(Data elements always required by all countries are shown by shaded boxes)

Data *always* (•) or *conditionally* (o) required by at least 70% of countries	Disinfectants / sanitizers						Preservatives / microbiocides					Anti-fouling products	Wood preservatives and structural treatments		Products for use in aquatic non-food sites				Products for use in vertebrate and invertebrate pest control							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	18	19	20	21	22	23	24	25	26	27	28	29
MATRIX 2: PHYSICAL/CHEMICAL PROPERTIES (cont.)																										
Thermal stability						•	•	•	•	•			•		•	•	•	•	•	•	•	•	•	•	•	•
Oxidizing properties																									•	•
Flammability																						•			•	•
Explosive properties																								•	•	•
Reactivity toward container						•											•									•
MATRIX 3: FUNCTION, MODE OF ACTION AND HANDLING																										
Function (e.g. algicide, fungicide, insecticide, molluscicide, repellent, disinfectant, etc.)							•		•	•	•						•	•		•	•	•	•	•	•	•
Mode of action on target organisms (e.g. contact poison, inhalation poison, fungitoxic, fungistatic, etc.)						•					•												•	•	•	•
Field of use (e.g. indoor, outdoor, public or non-public, etc.)											•															
Pests controlled/target organisms											•															
Products to be protected							•		•	•	•															•

Table VII. Data elements *always* (•) or *conditionally* (o) required by at least 70% of countries for the ACTIVE INGREDIENT (cont.)

(Data elements always required by all countries are shown by shaded boxes)

Data *always* (•) or *conditionally* (o) required by at least 70% of countries	Disinfectants / sanitizers						Preservatives / microbiocides					Anti-fouling products	Wood preservatives and structural treatments		Products for use in aquatic non-food sites				Products for use in vertebrate and invertebrate pest control							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	18	19	20	21	22	23	24	25	26	27	28	29
MATRIX 4: ANALYTICAL METHODS																										
Pure active ingredients and isomers, impurities and additives of the technical grade of the active ingredient or formulation						•	•			•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Active ingredients in food or feed (multiresidue methods) or treated product											o															
Composition of formulated product																										•
Residues in water, including potable water											o															
Residues in soil											o															
Residues in sediment											o								o	o	o	o	o	o		
Residues in biota (biological tissue such as plants, fish, birds, wild mammals, etc.)									o		o	o														
MATRIX 5: EFFICACY - no data elements are always required by at least 70% of countries																										

Table VII. Data elements *always* (•) or *conditionally* (o) required by at least 70% of countries for the ACTIVE INGREDIENT (cont.)

(Data elements always required by all countries are shown by shaded boxes)

Data *always* (•) or *conditionally* (o) required by at least 70% of countries	Disinfectants / sanitizers						Preservatives / microbiocides					Anti-fouling products	Wood preservatives and structural treatments		Products for use in aquatic non-food sites				Products for use in vertebrate and invertebrate pest control							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	18	19	20	21	22	23	24	25	26	27	28	29
MATRIX 6: FATE AND BEHAVIOUR IN THE ENVIRONMENT																										
ABIOTIC																										
Hydrolysis rate including identification of metabolites and breakdown products							●	●	●	●	●	●	●						●	●	●		●		●	●
Photodegradation in water including identification of metabolites and breakdown products											●															
Rate and route of photochemical degradation in air, identification of breakdown products											o			o												
BIOTIC																										
Soil metabolism, aerobic and anaerobic, to determine rate and route of degradation in representative soil types including metabolites and breakdown products											o															
Aquatic sediment metabolism, aerobic and anaerobic, including identification of breakdown products and metabolites								o			o	o													o	
Mobility/leaching in representative soil types and mobility of metabolites and breakdown products											o		o													

Table VII. Data elements *always* (•) or *conditionally* (o) required by at least 70% of countries for the ACTIVE INGREDIENT (cont.)

(Data elements always required by all countries are shown by shaded boxes)

Data *always* (•) or *conditionally* (o) required by at least 70% of countries	Disinfectants / sanitizers						Preservatives / microbiocides					Anti-fouling products	Wood preservatives and structural treatments		Products for use in aquatic non-food sites				Products for use in vertebrate and invertebrate pest control							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	18	19	20	21	22	23	24	25	26	27	28	29
MATRIX 6: FATE AND BEHAVIOUR IN THE ENVIRONMENT (cont.)																										
Adsorption/desorption in representative soil types including metabolites and breakdown products											o															
Adsorption/desorption screen											•															
Inherent biodegradability											o															
Aerobic aquatic biotransformation in natural water				o			o			o	o															

Table VII. Data elements *always* (•) or *conditionally* (o) required by at least 70% of countries for the ACTIVE INGREDIENT (cont.)

(Data elements always required by all countries are shown by shaded boxes)

Data *always* (•) or *conditionally* (o) required by at least 70% of countries	Disinfectants / sanitizers						Preservatives / microbiocides					Anti-fouling products	Wood preservatives and structural treatments		Products for use in aquatic non-food sites				Products for use in vertebrate and invertebrate pest control							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	18	19	20	21	22	23	24	25	26	27	28	29
MATRIX 7: ECOTOXICOLOGY																										
AVIAN TESTING																										
Avian acute oral LD50																				**o**	**o**					
Avian dietary toxicity LC50 - terrestrial bird (short-term toxicity)																			**o**	**o**		**o**	**o**			**o**
Avian dietary toxicity LC50-aquatic bird (short-term toxicity)																			**o**	**o**	**o**				**o**	**o**
Avian reproduction test - terrestrial bird																			**o**	**o**			**o**			**o**
AQUATIC TESTING																										
Fish acute toxicity LC50, freshwater; warmwater species																										**o**
Fish acute toxicity LC50, freshwater; cold water species																										
Marine or estuarine fish acute toxicity LC50/EC50																				**o**	**o**				**o**	**o**
Fish reproduction and growth rate												**o**								**o**	**o**				**o**	**o**
Daphnia life cycle (reproduction test)																									**o**	**o**
Fish life cycle/chronic toxicity to fish or fish early life stage												**o**								**o**	**o**				**o**	**o**
Fish bioconcentration												**o**								**o**	**o**		**o**		**o**	**o**
TESTING ON OTHER NON-TARGET SPECIES																										
Effects on earthworms																									**o**	

Table VII. Data elements *always* (•) or *conditionally* (o) required by at least 70% of countries for the ACTIVE INGREDIENT (cont.)

(Data elements always required by all countries are shown by shaded boxes)

Data *always* (•) or *conditionally* (o) required by at least 70% of countries	Disinfectants / sanitizers						Preservatives / microbiocides					Anti-fouling products	Wood preservatives and structural treatments		Products for use in aquatic non-food sites				Products for use in vertebrate and invertebrate pest control							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	18	19	20	21	22	23	24	25	26	27	28	29
MATRIX 8: RESIDUE CHEMISTRY - no data elements are always required by at least 70% of countries																										
MATRIX 9: TOXICOLOGY																										
ACUTE TESTING																										
Acute oral	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Acute dermal	•	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Acute inhalation	•	•	•	•		•	•	•	•	•	•		•	•			•	•	•	•	•	•	•	•	•	•
Acute dermal irritation	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Acute eye irritation			•			•	•	•	•	•	•	•	•	•	•	•	•		•	•	•	•	•	•	•	•
Skin sensitization			•	•		•	•			•	•	•	•	•			•	•	•	•	•	•	•	•	•	•
SUBCHRONIC TESTING																										
Repeated dose oral - 28 day				o		o												o								
Repeated dose inhalation - 28 day		o		o																						
Subchronic oral rat -90 day											o								•	•	•	•	•	•	•	•
Subchronic oral non-rodent -90 day																										
Subchronic dermal -90 day		o		o		o								o					o			o	o	o	o	o
Subchronic inhalation -90 day		o		o		o		o				o		o					o	o	o	o	o	o	o	o

Table VII. Data elements *always* (•) or *conditionally* (o) required by at least 70% of countries for the ACTIVE INGREDIENT (cont.)

(Data elements always required by all countries are shown by shaded boxes)

Data *always* (•) or *conditionally* (o) required by at least 70% of countries	Disinfectants / sanitizers						Preservatives / microbiocides					Anti-fouling products	Wood preservatives and structural treatments		Products for use in aquatic non-food sites				Products for use in vertebrate and invertebrate pest control							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	18	19	20	21	22	23	24	25	26	27	28	29
MATRIX 9: TOXICOLOGY (cont.)																										
DEVELOPMENT TOXICITY AND REPRODUCTION STUDIES																										
Teratogenicity rodent		•		•		•	•		•	•	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•
Multi-generation reproduction							•			•	•											•	•	•		
METABOLISM TESTING																										
Toxicokinetics/metabolism							•			•	•															
CHRONIC TESTING																										
Chronic toxicity rodent						•															•	•	•	•	•	
Chronic toxicity non- rodent											o															
Carcinogenicity - rat						•					o											•	•		•	
MUTAGENICITY																										
Testing for specific endpoints:	•		•			•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
• *In-vitro gene mutation study in bacteria (AMES TEST)*							•			•	•													•		•
• *In-vitro gene mutation assay in mammalian cells*											•															

Table VII. Data elements *always* (•) or *conditionally* (o) required by at least 70% of countries for the ACTIVE INGREDIENT (continued)

(Data elements always required by all countries are shown by shaded boxes)

Data *always* (•) or *conditionally* (o) required by at least 70% of countries	Disinfectants / sanitizers						Preservatives / microbiocides					Anti-fouling products	Wood preservatives and structural treatments		Products for use in aquatic non-food sites				Products for use in vertebrate and invertebrate pest control							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	18	19	20	21	22	23	24	25	26	27	28	29
MATRIX 9: TOXICOLOGY (cont.)																										
NEUROTOXICITY TESTING																										
Acute delayed neurotoxicity of organophosphates-hen														o					o			o	o	o		o
Subchronic neurotoxicity - rat -90 day														o												
Subchronic delayed neurotoxicity of organophoshospates - hen											o			o								o	o			
Postnatal developmental neurotoxicity		o					o			o	o															
MEDICAL DATA																										
Medical surveillance of manufacturing plant personnel														o												
Health records from industry and public/ users														o												
MATRIX 10: HUMAN EXPOSURE- no data elements are always required by at least 70% of countries																										

Table VIII. Data elements *always* (•) or *conditionally* (o) required by at least 70% of countries for the

BIOCIDAL PRODUCT

(Data elements always required by all countries are shown by shaded boxes)

Data *always* (•) or *conditionally* (o) required by at least 70% of countries	Disinfectants / sanitizers						Preservatives / microbiocides					Anti-fouling products	Wood preservatives and structural treatments		Products for use in aquatic non-food sites				Products for use in vertebrate and invertebrate pest control							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	18	19	20	21	22	23	24	25	26	27	28	29
MATRIX 1: CHEMICAL IDENTITY																										
Trade name	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Composition: names and amount of active ingredient(s), impurities, adjuvants, inert components	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Physical state (emulsifiable concentrate, wettable powder, solution, etc.)	●			●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Name of manufacturer	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Name of applicant	●	●	●	●	●	●	●	●	●	●	●	●	●		●	●	●	●	●	●	●	●	●	●	●	●

Table VIII. Data elements *always* (•) or *conditionally* (o) required by at least 70% of countries for the BIOCIDAL PRODUCT (cont.)

(Data elements always required by all countries are shown by shaded boxes)

Data *always* (•) or *conditionally* (o) required by at least 70% of countries	Disinfectants / sanitizers						Preservatives / microbiocides					Anti-fouling products	Wood preservatives and structural treatments		Products for use in aquatic non-food sites				Products for use in vertebrate and invertebrate pest control							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	18	19	20	21	22	23	24	25	26	27	28	29
MATRIX 2: PHYSICAL/CHEMICAL PROPERTIES																										
Colour			●	●		●					●				●	●	●	●			●	●	●	●	●	●
Physical state		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Odour						●									●	●	●	●								
pH			●			●					●		●		●	●	●	●	●	●	●	●	●	●	●	●
Density			●	●		●	●	●	●	●					●	●	●	●			●	●			●	●
Viscosity																										**o**
Flammability						●		●			●		●	●	●				●			●	●	●	●	●
Explosive properties						●		●			●								●			●	●			
Storage stability or stability in solvents used in formulation				●	●	●	●	●	●	●	●		●	●	●	●	●	●	●		●	●	●	●	●	●
Corrosion characteristics						●					●															
Flash point											**o**															

Table VIII. Data elements *always* (•) or *conditionally* (o) required by at least 70% of countries for the BIOCIDAL PRODUCT (cont.)

(Data elements <u>always</u> required by <u>all</u> countries are shown by shaded boxes)

Data *always* (•) or *conditionally* (o) required by at least 70% of countries	Disinfectants / sanitizers						Preservatives / microbiocides					Anti-fouling products	Wood preservatives and structural treatments		Products for use in aquatic non-food sites				Products for use in vertebrate and invertebrate pest control							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	18	19	20	21	22	23	24	25	26	27	28	29
MATRIX 3: FUNCTION, MODE OF ACTION AND HANDLING																										
Function (e.g. algicide, fungicide, insecticide, molluscicide, repellent, disinfectant, etc.)	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Mode of action on target organisms (e.g .contact poison, inhalation poison, fungitoxic, fungistatic, etc.)				●		●	●	●	●	●	●				●		●	●			●		●	●	●	●
Field of use (e.g. indoor, outdoor, public or non-public, etc.)	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Pests controlled/target organisms				●		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Products to be protected	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Application rate per unit treated area/ volume/ weight or concentration	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Concentration of active ingredient in material used		●		●		●	●	●	●	●	●	●	●		●	●	●	●	●	●	●	●	●	●	●	●
Timing of applications and duration of protection		●	●	●		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Use intervals (time between application of biocide and use of facility or commodity)							●		●	●	●	●			●		●	●		●	●		●	●	●	●
Proposed instructions for use	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

Table VIII. Data elements *always* (•) or *conditionally* (o) required by at least 70% of countries for the BIOCIDAL PRODUCT (cont.)

(Data elements always required by all countries are shown by shaded boxes)

Data *always* (•) or *conditionally* (o) required by at least 70% of countries	Disinfectants / sanitizers						Preservatives / microbiocides					Anti-fouling products	Wood preservatives and structural treatments		Products for use in aquatic non-food sites				Products for use in vertebrate and invertebrate pest control							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	18	19	20	21	22	23	24	25	26	27	28	29
MATRIX 3: FUNCTION, MODE OF ACTION AND HANDLING (cont.)																										
Site preparation and method of application	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Type of packaging				•	•	•	•	•	•	•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•
Procedures for cleaning application equipment						•	•	•	•	•	•				•	•	•						•	•		
Recommended methods and precautions for handling, storage, transport or fire (including reaction products)		•	•	•	•	•		•			•		•					•	•			•	•	•		
Emergency measures in case of accidents					•	•		•			•		•		•	•		•	•			•	•	•		
MATRIX 4: ANALYTICAL METHODS																										
Pure active ingredients and isomers, impurities and additives of the technical grade of the active ingredient or formulation				•			•			•	•						•	•			•					•
Composition of formulated product	•	•	•	•	•	•					•			•		•	•	•	•	•	•	•	•	•	•	•
MATRIX 5: ANALYTICAL METHODS, MATRIX 6: FATE AND BEHAVIOUR IN THE ENVIRONMENT, MATRIX 7: ECOTOXICOLOGY AND MATRIX 8: RESIDUE CHEMISTRY - no data elements are always required by at least 70% of countries																										

Table VIII. Data elements *always* (•) or *conditionally* (o) required by at least 70% of countries for the BIOCIDAL PRODUCT (cont.)

(Data elements always required by all countries are shown by shaded boxes)

Data *always* (•) or *conditionally* (o) required by at least 70% of countries	Disinfectants / sanitizers						Preservatives / microbiocides					Anti-fouling products	Wood preservatives and structural treatments		Products for use in aquatic non-food sites				Products for use in vertebrate and invertebrate pest control							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	18	19	20	21	22	23	24	25	26	27	28	29
MATRIX 9: TOXICOLOGY																										
ACUTE TESTING																										
Acute oral		●		●			●	●	●	●	●	●	●				●		●	●	●	●	●	●	●	●
Acute dermal		●		●			●	●	●	●	●	●	●				●		●	●	●	●	●	●	●	●
Acute inhalation		●		●			●	●	●	●	●						●		●		●	●	●	●		●
Acute dermal irritation		●		●			●	●	●	●	●	●					●		●	●	●	●	●	●	●	●
Acute eye irritation							●		●	●	●	●					●		●			●	●		●	●
Skin sensitization				●		●	●		●	●	●						●		●	●	●	●	●	●	●	●
MATRIX 10: HUMAN EXPOSURE - - no data elements are always required by at least 70% of countries																										

Annex 1

Overview of Biocide Regulations

TABLE 1: AUSTRALIA

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

- The main regulatory foci in Australia for biocides are the National Registration Scheme and the National Industrial Chemical (Notification and Assessment) Scheme, respectively administered by the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), and Worksafe Australia (WSA). The former is a formal approval scheme, while the latter is restricted to notification and assessment only. In general, non-agricultural pesticides are regulated under the NRA's approval scheme.
- ***Environment Australia*** conduct the environmental assessments and provide environmental advise to the NRA and WSA, and the ***Department of Human Servises and Health (HSH)*** undertakes similar activities in the area of public health.

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require -ments exist?
		active ingredient	end-use biocide			
(i) Disinfectants / sanitizers	1. Public health disinfectants and sanitizers 2. Personal health care disinfectants 3. Non public health (private) disinfectants /sanitizer / bacteriostats 6. Drinking water disinfectants			Not Agricultural or Veterinary Chemicals. These products are regulated by Australian laws relating to therapetic goods, dangerous goods, and chemical substances.	These laws are administered by the Department of Health and Family Services, Worksafe Australia and various State Government Departments	No information provided
	4. Veterinary area and domestic animal disinfection 5. Food/feed area disinfectants for use on/in agricultural premises, food storage and processing, dairies	APP	APP	Agricultural and Veterinary Chemicals Code (Ag/Vet Code)	National Registration Authority for Agricultural & Veterinary Chemicals (NRA)	Yes
(ii) Preservatives / microbiocides	7. In-can preservatives 8. Industrial microbiocides / slimicides for use in mills [8a, 8b] and oil industry [8c]. 9. Material preservatives for use in paper, leather etc. 10. Film Preservatives 11. Embalming fluids			Not Agricultural or Veterinary Chemicals. These products are regulated by Australian laws relating to therapetic goods, dangerous goods and chemical substances.	These laws are administered by the. Department of Health and Family Services, Worksafe Australia and various State Government Departments	No information provided
	8d. Industrial microbiocides / slimicides for use in cooling towers	APP	APP	Agricultural and Veterinary Chemicals Code		Yes

TABLE 1: AUSTRALIA (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(iii) Anti-fouling products	12. Underwater paints / treatments, antifoulants	APP	APP	Agricultural and Veterinary Chemicals Code	National Registration Authority for Agricultural & Veterinary Chemicals (NRA)	Yes
(iv) Wood preservatives and structural treatments	13. Wood preservatives 14. Structural pesticides	APP	APP	Agricultural and Veterinary Chemicals Code (Ag/Vet code)	National Registration Authority for Agricultural & Veterinary Chemicals (NRA)	Yes
(v) Microbiocides for waste disposal and strip mine sites	For use in: 15. Sewage disposal areas 16. Refuse /solid waste sites 17. Control of microbes in strip mine acid			Not Agricultural or Veterinary Chemicals. These products are regulated by Australian laws relating to therapetic goods, dangerous goods, and chemical substances.	These laws are administered by the Department of Health and Family. Services, Worksafe Australia and various State Government Departments	No information provided
(vi) Products for use in aquatic non-food sites	For use in: 18. Swimming pools 19. Hot baths 20. Spas 21. Ornamental ponds	APP	APP	Agricultural and Veterinary Chemicals Code	NRA	Yes
(vii) Products for use in vertebrate and invertebrate pest control	22. Rodenticides 23. Avicides 24. Piscicides 25. Repellents 26. Insecticides (indoor /outdoor) 27. Insecticides /acaracides direct use on humans /clothes /pets 28. Molluscicides 29. Other vertebrates	APP	APP	Agricultural and Veterinary Chemicals Code	NRA	Yes

TABLE 1: AUSTRIA

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

- At the moment, there is neither a notification nor an approval system in force for biocidal products in Austria. However, according to both laws cited below, persons/companies who place biocidal products on the market have the responsibility to comply with all relevant provisions of these laws. In addition, there are legal bodies established who monitor the compliance of the products on the market with the legal requirements.
- The bodies established for monitoring the compliance of the biocidal products with the requirements of the laws cited below have the legal right to demand from the persons/companies responsible for the individual product all data needed for the assessment of the compliance.

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(i) Disinfectants / sanitizers	Disinfectants for use: • in households • for premises, equipement, furniture and transport containers serving for handling and storage of food, food additives, and cosmetics.			Austrian Food Law	Federal Chancellery, Department VI	
(ii) Preservatives / microbiocides	• Preservatives for food or feed stocks					
(vii) Products for use in vertebrate and invertebrate pest control	• Rodenticides [22] • Insecticides [26] • Acaricides • Fungicides					
"Other biocides"	• All biocidal products falling under the scope of this survey, if they have one or more dangerous properties			Chemicals Law	• The Federal Chancellery, Department VI: in the case of very toxic, toxic and harmful properties. • The Federal Ministry of Environment, Youth and Family together with the Federal Chancellery VI: in the case of carcinogenic, teratogenic, mutagenic, corrosive, irritant and sensitizing properties. • The Federal Ministry of Environment, Youth and Family: in the case of explosive, flammable and toxic to the environment properties.	

TABLE 1: BELGIUM

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

Belgium has followed the European Union broad areas/uses categories in filling in the questionnaire. The numbers of OECD use categories, where correspondance is possible, are given in braquets.

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(i) Disinfectants and general biocidal products	• Veterinary hygiene biocidal products [4], including products against ecto-parasites on livestock and disinfectants for use on surfaces in veterianry surroundings (cowhouses, means of transport, tools [5a].	NONE	APP	Royal decree of 28/02/94 (published on 11/05/94) concerning the conservation, the placing on the market and the use of pesticides for veterinary use	Ministry of Small Enterprises and Agriculture • DG4 : Quality of Raw Materials and Vegetal Sector • IG41 : Raw Materials and Transformed Products	Yes
	• Private area and public health area disinfectants and other biocidal products [1, 3, 18-21] • Food and feed area disinfectants [5b, 5c] • Drinking water disinfectants [6]	NONE	APP	Royal decree June 5, 1975	• Ministry of Health Dept. : Risk Management (Administration) • Ministry of Health Hoge Gezondheidsraad Conseil Supérieur d'Hygiène (Scientific Evaluation)	Yes
(ii) Preservatives	• In-can preservatives [7] • Film preservatives [10] • Wood preservatives [13] • Fiber, leather, rubber and polymerized materials preservatives [9a, 9b, 9c] • Masonry preservatives [9d] • Preservatives for liquid-cooling and processing system [8d]. • Slimicides [8b, 8c] • Metalworking-fluid preservatives [9k].	NONE	APP	as above	as above	Yes

TABLE 1: BELGIUM (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(iii) Pest control	• Rodenticides [22] • Avicides [23] • Molluscicides [28] • Piscicides [24] • Insecticides, acaricides and products to control other arthropods [26 & 27] • Repellents and attractants [25]	NONE	APP	Royal decree June 5, 1975	• Ministry of Health Dept. : Risk Management (Administration) • Ministry of Health Hoge Gezondheidsraad Conseil Supérieur d'Hygiène (Scientific Evaluation)	Yes
(iv) Other biocidal products	• Preservatives for food or feedstocks • Antifouling products [12] • Embalming and taxidermist fluids [11] • Control of other vertebrates [29]	NONE	APP	as above	as above	Yes

TABLE 1: CANADA

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

- The Canadian Environmental Protection Act (CEPA), is a "safety net' or "residual legislation". As such it covers all substances that would not be subject to notice and toxic assessment under another federal legislation. It should be noted that CEPA covers only a very small subset of biocides in use in Canada.

- There are, at times, shared regulatory responsibilities under various laws which regulate various aspects of a biocide's life cycle. For example, in can preservatives for use in paints and coatings are registered as pesticides in Canada. The paint (containing the biocide) is regulated under the Hazardous Products Act.

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(i) Disinfectants / sanitizers	1. Public health disinfectants and sanitizers 2. Personal health care disinfectants 3. Non public health (private) disinfectants / sanitizer / bacteriostats 4. Veterinary area and domestic animal disinfection 5. Food/feed area disinfectants for use on/in agricultural premises, food storage and processing, dairies	APP	APP	Food & Drugs Act (FDA)	Health Protection Branch, Health Canada	Yes
	6. Drinking water disinfectants	APP	APP	Drinking Water Materials Safety Act	Health Protection Branch, Health Canada	No*
(ii) Preservatives / microbiocides	7. In-can preservatives 8. Industrial microbiocides / slimicides for use in mills and oil industry, in cooling towers 9. Material preservatives for use in paper, leather etc. 10. Film Preservatives	APP	APP	Pest Control Products Act (PCPA)	Pest Management Regulatory Agency	Yes
	11. Embalming fluids			Products of this type are not regulated as pesticides by the PMRA, nor are they regulated as drugs under the Food and Drugs Act. It is possible that they are regulated as workplace substances or commercial chemicals and there would be any data requirements other than a material safety data sheet or MSDS. Also, possible regulated under CEPA.		

* For disinfectants used in drinking water (use category #6), data requirements are under development but are not yet in force. These requirements are established in NSF standard 60 "Drinking Water Treatment Chemicals - Health Effects", which is a standard to be prescribed by future regulations make pursuant to the proposed Drinking Water Materials Safety Act. The NSF Standard 60 is a consensus health-based performance standard that was developed under the auspices of NSF International, a US-based, standard-development organization. A Joint Technical committee is responsible for its regular review and updating.

TABLE 1: CANADA (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(iii) Anti-fouling products	12. Underwater paints /treatments, antifoulants	APP	APP	Pest Control Products Act (PCPA)	Pest Management Regulatory Agency	Yes
(iv) Wood preservatives and structural treatments	13. Wood preservatives 14. Structural pesticides	APP	APP	Pest Control Products Act	Pest Management Regulatory Agency	Yes
(v) Microbiocides for waste disposal and strip mine sites	For use in: 15. Sewage disposal areas 16. Refuse /solid waste sites 17. Control of microbes in strip mine acid	APP	APP	Pest Control Products Act	Pest Management Regulatory Agency	Yes
(vi) Products for use in aquatic non-food sites	For use in: 18. Swimming pools 19. Hot baths 20. Spas 21. Ornamental ponds	APP	APP	Pest Control Products Act	Pest Management Regulatory Agency	Yes
(vii) Products for use in vertebrate and invertebrate pest control	22. Rodenticides 23. Avicides 24. Piscicides 25. Repellents 26. Insecticides (indoor/outdoor) 27. Insecticides/ acaracides direct use on humans /clothes /pets 28. Molluscicides 29. Other vertebrates	APP	APP	Pest Control Products Act	Pest Management Regulatory Agency	Yes

TABLE 1: DENMARK

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(i) Disinfectants / sanitizers	1c. Public health disinfectants and sanitizers for use in/on: eating establishments (including retail outlets) 5c. Food processing plants		APP	The Food etc. Act, no 310 of the 6th June 1973	The Danish Veterinary and Food Administration* under the Ministry of Food, Agriculture and Fisheries	Yes
	6. Drinking water disinfectants		APP		Disinfectants have to be approved by the local authority but normally in Denmark, drinking water is not treated with disinfectants.	No specific data required
	4. Veterinary area and domestic animal disinfection: vermin on domestic animals, including cage birds	APP	APP	• Consolidated Act from The Ministry of Environment and Energy No. 21 of January 16, 1996 on chemical substances and products • Statutory Order from The Ministry of Environment and Energy No. 722 of September, 1997 on pesticides	Danish Env. Prot. Agency	Yes
(ii) Preservatives / microbiocides	8. Slimicides [except 8d]	APP	APP	as above	as above	Yes
(iv) Wood preservatives and structural treatments	13. Wood preservatives	APP	APP	as above	as above	Yes
(vi) Products for use in aquatic non-food sites	For use in: 18. Swimming pools	APP	APP	as above	as above	Yes
(vii) Products for use in vertebrate and invertebrate pest control	22. Rodenticides 25. ***Repellents*** 26. Insecticides (indoor/outdoor) 27. Insecticides /acaracides direct use on humans /clothes /pets 28. Molluscicides	APP	APP	as above	as above	Yes
(iii) Anti-fouling products	14. Anti-fouling products	NONE	NONE	Anti-fouling products do not have to be approved but TBT (Tri-butyltin) based antifoulings are banned on boats smaller than 25 m in length		

* Due to reorganisations, the National Food Agency of Denmark and the Veterinary Service have been matched together into the Danish Veterinary and Food Administration, which is located under the Ministry of Food, Agriculture and Fisheries.

TABLE 1: FINLAND

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws♠	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(i) Disinfectants / sanitizers	• Disinfectants used for disinfection of intact skin [2b] • Disinfectants used in hospitals [1a] • Insecticides used directly on human skin [27a]		APP	These products are not regarded as biocides but as medicines, are controlled by the legislation on medicides and are covered by certain type of advance approval procedure.	National Agency for Medicines	Yes
	• Disinfectants, insecticides, acaricides etc. used directly on the animals (e.g. for control of fleas) [4 and 27c]		APP	These products are regarded as veterinary medicines and are controlled by the legislation on veterinary medicines.	National Agency for Medicines	Yes
	5. Food/feed area disinfectants	No approval procedures or positive list have been established yet		Food hygiene legislation: the products used as detergents or disinfectants in farms, food processing plants, dairies etc. are to be approved by the authorities. However, no approval procedures have been established so far.		
	6. Drinking water disinfectants	No approval procedures or positive list have been established yet		Health Protection Act	According to the Health Protection Act, the Ministry of Social Affairs and Health may give detailed rules on the chemicals used in disinfection or treatment of drinking water. However, no detailed rules have been given yet, because the relevant European standards are still under preparation.	
	• Other disinfectants			Many disinfectants are not cover by any special rules or procedures but only by general rules and regulations of chemicals legislation.		

TABLE 1: FINLAND (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws♠	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(ii) Preservatives / microbiocides	8. Industrial slimicides (for use in pulp and paper mills [8b] and in cooling water systems [8d])	NONE*	APP	Chemicals Act 744/89, Decree on Chemical Preservatives 123/94 and Decision of the Ministry of the Environment 256/94	• **Finnish Environment Institute** (under the Ministry of the Environment) (responsible authority, authorisations, environmental risk assessment, checking of the biological efficacy) • **National Product Control Agency for Welfare and Health** (Ministry of Social Affairs and Health) (evaluation of health effects) • **Ministry of Social Affairs and Health** (evaluation of safety measures for users)	Yes
	• Other preservatives			Many preservatives are not cover by any special rules or procedures but only by general rules and regulations of chemicals legislation.		
(iii) Anti-fouling products	12. Anti-fouling products			They are not cover by any special rules or procedures but only by general rules and regulations of chemicals legislation.		
(iv) Wood preservatives and structural treatments	13. Wood preservatives	NONE*	APP	as for industrial slimicides	as for industrial slimisides	Yes
	• Wood preservatives as a paint	NONE	NOTIF	as for industrial slimicides	as for industrial slimisides	Yes
	14. Structural pesticides	NONE*	APP	Pesticides Act (327/69, amendments) and Pesticide Statute (792/95)	• **Pesticide Board** (Ministry of Agriculture and Forestry) (Approval, conditions and restrictions for use) • **Plant Production Inspection Centre / Plant Protection Department** (Ministry of Agriculture and Forestry) (responsible authority, handling of applications, preparing of decisions, secretary of Pesticide Board)	Yes

TABLE 1: FINLAND (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws♠	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(iv) Wood preservatives and structural treatments (cont.)	14. Structural pesticides (cont.)			Pesticides Act (327/69, amendments) and Pesticide Statute (792/95)	• **Plant Production Inspection Centre / Agricultural Chemistry Department** (Chemical and physical control) • **National Product Control Agency for Welfare and Health** (Ministry of Social Affairs and Health) (Evaluation of Health Effects) • **Ministry of Social Affairs and Health** (Evaluation of effects on occupational hygiene) • **Agricultural Research Centre** (Ministry of Agriculture and Forestry) (Testing of biological efficacy and usefulness).	Yes
(v) Microbiocides for waste disposal and strip mine sites				They are not cover by any special rules or procedures but only by general rules and regulations of chemicals legislation.		
(vii) Products for use in aquatic non-food sites						
(vii) Products for use in vertebrate and invertebrate pest control	22. Rodenticides used indoor	NONE*	APP	as for structural pesticides	as for structural pesticides	Yes
	22. Rodenticides used outdoor (at landfields, other waste handling areas, parks etc.)	NONE*	APP	as for structural pesticides	as for structural pesticides and additionally: **Finnish Environment Institute** (Ministry of the Environment) (Evaluation of environmental effects)	Yes
	25. Repellents (e.g. to repel insects from human and domestic animals skin)	NONE*	APP	as for structural pesticides	same as for rodenticides used indoor	Yes
	26a. Indoor insecticides and acaricides	NONE*	APP	as for structural pesticides	same as for rodenticides used indoor	Yes

TABLE 1: FINLAND (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws♠	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(vii) Products for use in vertebrate and invertebrate pest control	26b. Outdoor insecticides (e.g. control of ants)	NONE*	APP	as above	same as for rodenticides used outdoor	Yes
	23. Avicides 29. Other vertebrates (e.g. foxes)	Not authorized or registered		The poisoning of e.g. birds or foxes is forbidden on the basis of the hunting legislation; in certain cases local health authorities may permit the use of a biocide for control of nuisance birds.		
	24. Piscicides	Not authorized or registered		The poisoning of fishes is forbidden on the basis of fishing legislation; in exceptional cases authorities may perform poisoning of fishes e.g. due to some fish disease in water courses.		

♠ In addition to the chemicals legislation and possible special legislation, the general environmental and product safety legislation may also affect the use, residues or the releases of certain biocides. E.g. the water discharges by industrial plants or waste water purification plants are controlled by environmental authorities, and thus in principle, also the biocides used in those plants may be controlled. In practice, however, the authorities seldom interfere specially to the use of biocides. The genearl rules concerning the product safety set requirements for e.g. the residues of biocides in the products and materials and thus they may indirectly affect the use of biocides in manufacturing processes.

* The active ingredients are only approved together with the products.

TABLE 1: FRANCE

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

- At this time, only few biocide product types are regulated by notification or approval in France.

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(i) Disinfectants / sanitizers	5. Food area disinfectants	APP	APP	Law (2 of November 1943) Decree n° 73-138 12 of February 1973	Ministry of Economy and Finances: • **Direction Générale de la Concurrence, de la Consommation et de la Répression des fraudes** (DGCCRF) for the authorisation of the active ingredient. • **Direction Générale de l' Alimentation** for the authorisation of the end-use product.	Yes
	• Treatment of premises, materials and vehicules used for: ◊ preparation and transport of feed for domestic animals [5] ◊ transport and housing of domestic animals ◊ harvesting, transport, storage, industrial transformation and marketing of products of vegetal or animal origin	???	???	???	Ministry of Agriculture	???
(iv) Wood preservatives and structural treatments	13. Wood preservatives, only for wood in contact with fruits and vegetables	APP	APP	Decree n° 92-631 8 July 1992	Ministry of Economy and Finances/ DGCCRF	Yes
	13. Other wood preservatives	They are controlled by a certification given by a commission applying rules defined in the legislation on consumer goods		Legislation on consumer goods.	Technical Center of Wood and Furniture Responsible for issuing the certification. The evaluation is based on the efficacity, toxicity and ecotoxicity of the products.	???

TABLE 1: FRANCE (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(v) Microbiocides for waste disposal and strip mine sites	• Collection, transport and tretment of household refuse and wastes of animal and vegetal origin	???		???	Ministry of Agriculture	???

TABLE 1: GERMANY

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

- **Germany** has followed the European Union broad areas/uses categories in filling in the questionnaire. The numbers of OECD use categories, where correspondance is possible, are given in braquets.
- In Germany at present, there is no specific legal regulation for the approval of non agricultural biocides, except for:
  - ◊ wood preservatives for load-bearing timber, which are regulated by the Construction Products Act;
  - ◊ some disinfectants and some pest control products (insecticides, acaricides and rodenticides) used in the field of hygiene, which are regulated by the Federal communicable Diseases Act (on voluntary basis);
  - ◊ medical products (i.e. products for direct use on humans or animals), which are regulated by the Medicines Act.
- Existing substances used in non agricultural biocidal products are covered by EU's Existing Chemicals Regulations and new ones by Chemicals Act (ChemG).
  For existing chemicals (most biocides are existing chemicals), industry has to submit basic data on all substances with a production volume of 1000 t/a or more. On the basis of this information, priority-setting is performed by the Commission of the EU. Priority substances are assessed according to rules set out in Technical Guidance Documents which are similar to those of the procedure for new chemicals. When constituents of biocides are new chemicals, they require notification under the Chemicals Act. As part of the notification, results of certain tests for ecotoxic effects and environmental fate have to be submitted. The substances are then assessed on the basis of these test results. The basic rules for the assessment are set out in the EU Commission's Technical Guidance Documents.

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(i) Disinfectants and general biocidal products	• Human hygiene biocidal products [2]: ◊ medicinal products	APP	APP	Medicines Act	Arzneimittel Institut, Robert-Koch Institut Berlin/BMG (Ministry of Health)	No environ-ment data
	◊ other products used for human hygiene purposes	NONE	NONE			
	• Private area and public health area disinfectants and other biocidal products [1, 3, 18-21] ◊ disinfectants used according to the Federal Communicable Diseases Act♥	APP*	APP*	Federal Communicable Diseases Act **(FCDA)** § 10c (BSeuchG vom 18.12.79 BGBI.I Nr. 75v. 25.12.1979, 2263) (7. amendment BGBI. Nr. 23, v. 25.04.1996; S.621)	• **BgVV** (Federal Institut for Health Protection Consumers and Veterinary Medicine)/**BMG**: responsible for health area. • **UBA** (Federal Environmental Agency)/**BMU** (Ministry of Environment): responsible for environmental area.	Yes

TABLE 1: GERMANY (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(i) Disinfectants and general biocidal products (cont.)	◊ other products for use in/for: swimming pools [18], aquaria [21], bathing and other waters [19, 20], air conditioning, chem. toilets, waste water, hospital water, soil and other substrates	NONE	NONE			
	• Veterinary hygiene biocidal products [4] ◊ medical products ♦	APP	APP	Medicines Act	• **BgVV/BMG**: responsible for health area • **UBA/BMU**: responsible for environmental area.	Yes
	◊ other veterinary hyg. biocidal products	NONE	NONE			
	• Food and feed area disinfectants [5] ∞ • Drinking water disinfectants [6]	NONE	NONE			
(ii) Preservatives	• In-can preservatives [7] • Film preservatives [10]	NONE	NONE			
	• Wood preservatives [13] ◊ construction products (load bearing timber)		APP	Landesbauordnung / Musterbauordnung (§20ff) (Guideline for construction)	• **DIBT** (German Institut for Construction Technology): responsible for approval • **BAM** (Federal Institut for Material Research and Testing)/BMW (Ministry of Economic Affairs): responsible for efficacy testing • **UBA/BMU**: responsible for environmental area • **BgVV/BMG**: responsible for health area	Yes
	◊ not load bearing timber: "RAL" products ◊ wood varnishing products		NOTIF	Agreement on a non-legislative (= volunatry) basis	• **BAM/BMW**: responsible for efficacy testing • **BgVV/BMG**: responsible for health area • **UBA/BMU**: responsible for environmental area	Yes

TABLE 1: GERMANY (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(ii) Preservatives (cont.)	◊ other not load bearing timber		NONE			No
	• Fiber, leather, rubber and polymerized materials preservatives [9a, 9b, 9c] • Masonry preservatives [9d]	NONE	NONE			No
	• Preservatives for liquid-cooling and processing system [8d]. • Slimicides [8b, 8c] • Metalworking-fluid preservatives	NONE	NONE			No
(iii) Pest Control	• Rodenticides [22] ◊ products used according to the Federal Communicable Diseases Act		APP*	• Federal Communicable Diseases Act (FCDA) § 10c; • National legislation on plant products.	• **BgVV/BMG**: responsible for toxicology and listing of products • **UBA/BMU**: responsible for ecotoxicology and efficacy testing	under prepara-tion
	◊ other products for the control of mice, rats, other rodents • Avicides [23] • Piscicides [24] • Molluscicides [28]	NONE	NONE			
	• Insecticides, acaricides and products to control other arthropods [26 & 27] ◊ Products used according to the Federal Communicable Diseases Act § 10c		APP*	**Use category 26:** • Federal Communicable Diseases Act § 10c; • National legislation on plant products. **Use category 27:** • Federal Communicable Diseases Act § 10c; and, • partly Medicines Act (for skin application) [27]	• **BgVV/BMG**: responsible for toxicology and listing of products • **UBA/BMU**: responsible for ecotoxicology and efficacy testing	under prepara-tion
	◊ other products used to control other arthropods	NONE	NONE			
	• Repellents and attractants [25] ◊ medicinal products		APP*	Federal Communicable Diseases Act § 10c and partly Medicines Act (for skin application)	Arzneimittel Institut, Robert-Koch Institut Berlin/BMG	under prepara-tion
	◊ other products	NONE	NONE			

TABLE 1: GERMANY (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(iv) Other biocidal products	• Preservatives for food or feedstocks • Antifouling products [12] • Embalming and taxidermist fluids [11] • Control of other vertebrates [29].	NONE	NONE			

♥ - Products mentioned in the actual BGA (Federal Health Office)-list were tested on composition, efficacy and lack of side-effects on human body. The enlisted products are admitted for measures ordered by the administration.

- An admitted fumigant for disinfection is listed in GefStoffV (Hazard Substances Ordinance) § 15d and Annex V, No. 5.

- DGHM (German Society for Hygienic and Microbiology)-list (recommandation). The enlisted products are admitted for measures by the administration (Medicines Act § 2, Art. 2, No 2). Products mentioned in the actual DGHM-list were tested on composition and efficacy and lack of side-effects on human body.

♦ DVG (German Society of Veterinary Surgeons)-list of disinfectants for animal farming which were tested on efficacy concerning to the guidelines of the DVG (recommendation).

∞ DGV-list of disinfectants for food industrial which were tested on efficacy concerning to the guidelines of the DVG (recommendation).

* Approval of these products for use in the field of hygiene is applied on voluntary basis. Only about 15% of the disinfection products which are found in the German market have been included in the list of approved products. In the label a note is included stating that the product has been tested and approved for the control of the target species indicated.

TABLE 1: GREECE

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(i) Disinfectants/ Sanitizers	1. Public health disinfectants and sanitizers for use in/on: hospitals, medical equipment etc. 2. Personal health care disinfectants, e.g. denture cleaners 3. Non public health (private) disinfectants/sanitizers/bacteriostats for use on/in: dust mops, laundries etc. 4. Veterinary area 5. Food/feed area disinfectants 6. Drinking water disinfectants for use in: human drinking water etc.	APP	APP	Ministerial decree YIB/OIK.7723/94 N.1316/83 N.1965/91	N.D.O.(EOF) National Drug Organisation 234, Messogion str., 15562 Holargos, Athens	Yes
(vi) Products for use in aquatic non -food sites	For use in: 18. Swimming pools 19. Hot baths 20. Spas 21. Ornamental ponds					
(ii) Preservatives / microbiocides	9. Material preservatives - leather [9b] - textile and speciality products [9g] - carpets [9j]		APP	721/77 OJ 298/A/7-10-1977	Ministry of Agriculture	Yes
(iv) Wood preservatives and structural treatments	13. Wood preservatives - seasoned wood - unseasoned wood - sapstain		APP	as above	as above	Yes

TABLE 1: GREECE (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(vii) Products for use in vertebrate and invertebrate pest control	22. Rodenticides (e.g. domestic, storage, public health) 23. Avicides 24. Piscicides 25. Repellents 26. Insecticides (indoor, outdoor) 27. Insecticides/acaricides direct use on: clothes, pets 28. Molluscicides 29. Other vertebrates		APP	721/77 OJ 298/A/7-10-1977	Ministry of Agriculture	Yes
(ii) Preservatives / microbiocides	Use categories 7-11 excluding OECD use category 9			Although the General Chemical State Laboratory is the Greek national Competent Authority for these products, the relevant legislative arrangements have not yet been established because we expect the approval of the European Union Parliament and Council concerning the biocides Directive.	General Chemical State Laboratory	
(iii) Antifouling products	12. Anti-fouling products					
(v) Microbiocides for waste disposal and strip mine sites	For use in: 18. Sewage disposal areas 19. Refuse/solid waste sites 20. Control of microbes in strip mine acid					

TABLE 1: HUNGARY

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

Hungary has followed its own broad areas and use categories in filling in the questionnaire. The numbers of OECD use categories, where correspondance is possible, are given in braquets.

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
Public health and not public health disinfectants/ sanitizers, and personal health care sanitizers	For use in/on: hospitals [1a], medical equipment [1b], air ducts [1d], mortuaries [1e], dust mops [3a], laundries [3b], carpets [3c], bathrooms [3d], air purifiers [3e] etc.		APP	1. Act XI of 1991 of the Parliament on the State Public Health Service. 2. Government Decree 233/1996 (XII 26) on rules concerning managing of hazardous substances and preparations 3. Decree 4/1997 (II 21) of the Minister of Welfare on the enforcement of the Government Decree 233/1996 (XII 26) on rules concerning managing of hazardous substances and preparations	Ministry of Health Medical Officer's Office National Center of Epidemiology Department of Disinfection *Resposibilities:* approval, efficacy assessment, health and environmental risk assessment	Yes
Public health and not public health disinfectants/ sanitizers used in the food area	For use in/on: eating establishments [1c], industrial food storage [5b], food processing plants and dairies [5c], textile mills [8a], pulp and paper mills [8b], cooling towers [8d], industrial food storage [5b]		APP	4. Act XC of 1995 of the Parliament on foodstuffs 5. Common Decree 1/1996 (I.9) of the Minister of Agriculture, Minister of Welfare, and Minister of Internal Trade on the Enforcement of the Act XC of 1995 of the Parliament on foodstuffs. • and also decrees 2 and 3	Ministry of Health Medical Officer's Office National Public Health Center National Inst. of Food Hugiene and Nutrition *Resposibilities:* approval, efficacy assessment, health and environmental risk assessment	Yes
Disinfectants/sanitizers in the veterinary area, food/feed disinfectants	For use on/in: agricultural premises [5a], feed preservatives [5b]		APP	6. Act XC of 1995 of the Parliament on Animal Health 7. Decree 22/1996 (VII 9) of the minister of Agriculture on animal health products 8. Act XCII of 1995 of the Parliament on production and marketing of feedstuffs	• Ministry of Agriculture and Reg. Development National Inst. for Agricultural Quality Control State Control Inst. for Veterinary Biologicals, Drugs and Feeds *Responsibilities:* approval, control functions	Yes

TABLE 1: HUNGARY (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
Disinfectants/sanitizers in the veterinary area, food/feed disinfectants (cont.)	For use on/in: agricultural premises [5a], feed preservatives [5b]		APP	9. Decree 25/1996 (IX 4) of the Minister of Agriculture on the enforcement of the Act XCII of 1995 of the Parliament regarding the production and marketing of feedstuffs 10. Decree 5/1988 (IV 26) of the Minister of Food and Agriculture on the enforcement of the Act II of 1988 of the Parliament on plant protection • and also decrees 2 and 3	• Ministry of Health (cont.) National Inst. of Food Hugiene and Nutrition *Responsibilities*: efficacy assessment, health and environmental risk assessment	Yes
Water disinfectants and sanitizers	Drinking water disinfectants for use in human or animal drinking water [6], swimming pools [18], hot baths [19].		APP	11. Ordinance 3/1971 (VII 17) of the Minister of Health concerning public health rules applicable to substances used in drinking water supply systems 12. Ordinance 28/1978 (V26) of the Council of Ministers amending certain legislation regarding pollutant discarge fines. • and also decrees 2 and 3	Ministry of Health Medical Officer's Office National Publ. Health Center National Inst. of Public Health *Resposibilities*: approval, efficacy assessment, health and environmental risk assessment	Yes
(ii) Preservatives/ microbiocides	For use on/in cosmetic products	APP		13. Decree 7/1994 (IV 20) of the Minister of Welfare on the health requirements to be fulfilled for the marketing of cosmetics • and also decrees 2 and 3	Ministry of Health Medical Officer's Office National Publ. Health Center National Inst. of Food Hygiene and Nutrition *Resposibilities*: approval, control functions	Yes

TABLE 1: HUNGARY (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(iv) Wood preservatives and structural treatments	For use on/in: • remedial, joinery [13] • preventive treatments [14]	APP	APP	decrees 2 and 3	• Sopron University of Forestry *Responsibilities*: approval, efficacy assessment • Ministry of Health Medical Officer's Office National Publ. Health Center National Inst. of Chemical Safety *Responsibilities:* coordination, health and environmental risk assessment	Yes
(vii) Products for use in vertebrate and invertebrate pest control	• Rodenticides [22] • Repellents [25] • Insecticides [26] (indoor/outdoor) • Insecticides/acaricides used on: humans, clothes, pets [27].	APP	APP	14. Decree 3/1969 (V 16) of the Minister of Health on marketing and use of insecticides, rodenticides and repellents • and also decrees 2, 3 and 15	Ministry of Health Medical Officer's Office National Center of Epidemiology Dept. of Vector Control *Resposibilities*: approval, efficacy assessment, health and environmental risk assessment	Yes

TABLE 1: IRELAND

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(iii) Anti-fouling products	12. Underwater paints/treatments, antifoulants	NONE	APP	European Communities (classification, packaging and labelling of pesticides) Regulations, 1994, Statutory Instrument 138 of 1994.	Pesticide Control Service Department of the Agriculture, Food and Forestry	Yes
(iv) Wood preservatives and structural treatments	13. Wood preservatives including use in remedial treatment, joinery, heavy duty, anti-sapstain	NONE	APP	as above	as above	Yes
(vi) Products for use in aquatic non -food sites	For use in: 18. Swimming pools 21. Ornamental ponds • Cooling waters	NONE	APP	as above	as above	Yes
(vii) Products for use in vertebrate and invertebrate pest control	22. Rodenticides 23. Avicides 24. Piscicides 25. Repellents 26. Insecticides 27b. Insecticides/acaricides for direct use on clothes 28. Molluscicides 29. Other vertebrates	NONE	APP	as above	as above	Yes
For all other biocides, i.e. use categories 1-6, 7-11, 15-16			NOTIF		Pesticide Control Service Department of the Agriculture, Food and Forestry	

TABLE 1: THE NETHERLANDS

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

The Netherlands has followed its own use categories in filling in the questionnaire. The numbers of OECD use categories, where correspondance is possible, are given in braquets.

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(i) **Disinfectants / sanitizers**	D.1 Disinfectants outside the food industry and catering, exposure of users only. D.2 Disinfectants for the food industry, catering, animal housing etc. D.3 Disinfectants of material to which users are exposed after application.		APP	Pesticides Act	The ministeries of: • Agriculture: some aspect of efficacy • Health: food safety and consumers safety • Social Affairs and Labour: worker protection • Environment: environmental safety are responsible for the pesticide law and the generic guidelines for the pesticides in the areas cited above. The **CTB** (Board for the authorisation of pesticides) is the responsible administration agency that has the mandate for the authorisation of pesticides on behalf of the involved ministries. The CTB and the four ministries are involved in the authorisation of all the 19 biocide product types.	Yes
(ii) Preservatives / microbiocides	D.4 Preservatives. D.5 Industrial biocides (in cooling water; in liquids during production processes, e.g. paper industry).					
(iii) Anti-fouling products	C.4 Anti-foulings [12]					
(iv) Wood preservatives and structural treatments	C.1 Wood preservatives applied outdoors or for wood to be used outdoors. C.2 Wood preservatives applied indoors or for wood to be used indoors. C.3 Wood preservatives on wooden packaging material in contact with food.					
(vi) Products for use in aquatic non -food sites	D.6 Products for swimming water [18]					

TABLE 1: THE NETHERLANDS (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(vii) Products for use in vertebrate and invertebrate pest control	H.1 Household products applied outdoors. H.2 Household products applied indoors on surfaces. H.3 Household products applied indoors as evaporators. H.4 Household products applied indoors as aerial spray. H.5 Repellents against mosquitos, applied on the human skin. H.6 Moth repellents for textile. H.7 Products against storage pests. H.8 Rodenticides [22]. V.1 Veterinary products applied in animal housings.		APP	Pesticides Act	Ministeries of: • Agriculture • Health Water protection (social affairs) • Environment (Administration Board for pesticide approval)	Yes

TABLE 1: NEW ZEALAND

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

- By default, any biocides that are not specifically defined as "pesticides" under the Pesticides Act (1979), are regulated under the Toxic Substances Act (1979), involving a ***notification*** process which includes the opportunity to classify and label these compounds and to establish controls.
- Those biocides that are "pesticides" are regulated through an *approval* scheme. Pesticides cover substances sold or used to control any unwanted mammal, bird, reptile, amphibian, fish, insect, arthropod, mollusc, nematode, plant, or fungus except those on man or animals, and includes substances intended for plant bacteria or plant virus control, and plant growth regulants.
- Compounds used on animals (e.g. insecticides/acaricides) are also *approved* under the Animal Remedies Act (1967) and those applied directly to humans are similarly *approved* under the Medicines Act (1981).

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?♥
		active ingredient	end-use biocide			
(i) Disinfectants / sanitizers	1. Public health disinfectants and sanitizers 2. Personal health care disinfectants 3. Non public health (private) disinfectants /sanitizer / bacteriostats 4. Veterinary area and domestic animal disinfection 5. Food/feed area disinfectants for use on/in agricultural premises, food storage and processing, dairies 6. Drinking water disinfectants	NONE	NOTIF	Toxic Substances Act 1979	The Toxic Substances Board, a statutory decison-making Board, served by the Ministry of Health [MOH(T)]	No
(ii) Preservatives / microbiocides	7. In-can preservatives 8. Industrial microbiocides 9. Material preservatives for use in paper, leather etc. 10. Film Preservatives 11. Embalming fluids	NONE	NOTIF	Toxic Substances Act 1979	The Toxic Substances Board, a statutory decison-making Board served by the Ministry of Health [MOH(T)]	No
(iii) Anti-fouling products	12. Antifoulants	NONE	APP	Pesticides Act 1979	The Pesticides Board, a statutory decison-making Board served by the Ministry of Agriculture [MAF(P)]	Yes

TABLE 1: NEW ZEALAND (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?♥
		active ingredient	end-use biocide			
(iv) Wood preservatives and structural treatments	13. Wood preservatives 14. Structural treatments	NONE	APP	Pesticides Act 1979	The Pesticides Board, a statutory decison-making Board served by the Ministry of Agriculture [MAF(P)]	Yes
(v) Microbiocides for waste disposal and strip mine sites	For use in: 15. Sewage disposal areas 16. Refuse/solid waste sites 17. Control of microbes in strip mine acid	NONE	NOTIF	Toxic Substances Act 1979	The Toxic Substances Board, a statutory decison-making Board served by the Ministry of Health [MOH(T)]	No
(vi) Products for use in aquatic non - food sites	For use in: 18. Swimming pools 19. Hot baths 20. Spas 21. Ornamental ponds	NONE	NOTIF	Toxic Substances Act 1979	[MOH(T)]	No
(vii) Products for use in vertebrate and invertebrate pest control	22. Rodenticides 23. Avicides 24. Piscicides 25. Repellents 26. Insecticides	NONE	APP	Pesticides Act 1979	[MAF(P)]	Yes
	27. Insecticides/acaracides direct use on: ◊ humans [27a]	NONE	APP	Medicines Act 1981	Therapeutants Section of the Ministry of Health	Yes
	◊ clothes [27b]	NONE	APP	Pesticides Act 1979	[MAF(P)]	Yes
	◊ pets [27c]	NONE	APP	Animal Remedies Act 1967	The Animal Remedies Board, a statutory decision -making Board, served by Ministry of Agriculture	Yes
	28. Molluscicides 29. Other vertebrates	NONE	APP	Pesticides Act 1979	[MAF(P)]	Yes

♥ For those biocides regulated under the Pesticides Act (1979), the Animal Remedies Act 1967, and the Medicines Act 1981, formal data requirements have been established, together with a tiered assessment process, as for plant protection products. For the others, specific information on identity and intended uses are required, with requirements for additional data being on a case-by-case basis.

TABLE 1: PORTUGAL

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

- The portuguese law on pesticides and the system of "approval", according to which a pesticide (including repellents) can only be placed on the market after authorization, has been in force since 1960. This law and all regulations followed, mainly concerned pesticide products for agriculture use.
- In 1988 the "Decreto-Lei 294/88, de 24/8" concerning classification, packaging and labelling of pesticide products was published. This law adopts the Directive 78/631/EEC.
- In 1990 the "Decreto-Lei 306/90 de 27/9" that categorized the pesticide products and the authorities which give the authorization was published. So Pesticides for agriculture use are authorized by "Direcção Geral da Protecção das Culturas"; Pesticides for Veterinary use are authorized by "Direcção Geral de Veterinária"; Wood Preservatives for "Direcção Geral das Florestas, now by Direcção Geral da Protecção das Culturas" and the pesticides for indoor and outdoor use (pest control = industrial use = professional use) and direct use on humans (including repellents) are authorized by "Direcção Geral da Saúde".
- All products to be authorized needed an evaluation and classification by a Committee called "Comissão Toxicológica dos Pesticidas".
- With the adoption of the Directive 91/414/EEC and its integration to the portuguese law (Decreto-lei 284/94 e Portaria 563/95), Portugal has finely separated the procedures for agriculture use and the other uses known as biocides. For these pesticides (biocides) we have the same legislation but we don't have the Committee anymore.
- In 1992 we had a new legislation for Veterinary Products that includes the veterinary disinfectants and other biocides as you can see later in responses to the questionnaire.

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(i) Disinfectants/ Sanitizers	2. Personal health care disinfectants: **only for denture cleaners**	NONE	APP	Medical device legislation	INFARMED	Yes
	4. Veterinary area and domestic animal disinfection ◊ For external use in animals ◊ For livestock (accomodation, transport) 5. Food/feed area disinfectants ◊ Food industry (animal products**)** 6. Drinking water disinfectants for use in animal or poultry drinking water [6b]	NONE	APP	National legislation: D.L. 62/91 of 91/2/1, ART. 2 AND ART. 18./Guidelines for file instruction	Direcção-Geral de Veterinária	Yes

TABLE 1: PORTUGAL (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(iv) Wood preservatives and structural treatments	13. Wood preservatives, e.g.: remedial, joinery, heavy duty, anti-sapstain 14. Structural pesticides (e.g. to control termites, carpenter ants)	NONE	APP	Decreto-Lei 131/97, de 30/5	Direcção Geral de Protecção das Culturas (DGPC)" ; The approval given by DGPC is confirmation by a inter-Ministerial Committee called *Comissão de Avaliação Toxicológica de Produtos Fitofarmacêuticos*	Yes
(vii) Products for use in vertebrate and invertebrate pest control	22. Rodenticides 25. Repellents 26. Insecticides (indoor/outdoor) 27. Insecticides/acaracides direct use on humans [27a] and clothes [27b]	NONE	APP	Portaria nº 17980 de 30/9/1960 Decreto-Lei nº 294/88 de 24/8 Decreto-Lei nº 306/90 de 27/9	Direcção-Geral da Saúde	Yes
	• For external use on animals	NONE	APP	National legislation: D.L. 62/91 of 91/2/1, ART. 2 AND ART. 18./Guidelines for file instruction	Direcção-Geral de Veterinária	Yes
	• For livestock (accomodation, transport) • For food industry (animal products)	NONE	APP	National legislation: D.L. 62/91 of 91/2/1, ART. 2 AND ART. 18./Guidelines for file instruction	Direcção-Geral de Veterinária	Yes

TABLE 1: SWEDEN

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

- **Sweden** has followed the European Union broad areas/uses categories in filling in the questionnaire. The numbers of OECD use categories where correspondence is possible are given in braquets.
- In the second column " product types/use categories": a) with **bold** fonts are cited the use categories which are subject to an approval and specific data requirements have been developed and; b) with **bold italics** are cited the use categories which are also subject to an approval procedure, the regulatory authorities have some experience because they got applications for authorisation, but no specific data requirements have been developed yet.
- In the last column "*data requirements*": a) with an "**s**" are cited data requirements which have been developed for the specific use category and; b) with an "***g"*** are cited data requirements which are generally applied and are mostly pulled out from the pesticides regulation, when specific data requirement are missing.

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(i) Disinfectants and general biocidal products	• Human hygiene biocidal products [2]	NONE	NONE	Ordinance on Cosmetics and Hygienic Products (SFS 1993:1283)	Medical Products Agency	No
	• Public health area and private area disinfectants and other biocidal products - only **products against microorganisms in chemical toilets etc.**	APP*	APP*	Ordinance on Pesticides (SFS 1985:836).	National Chemicals Inspectorate (KemI)	Yes[s @]
	• Veterinary hygiene biocidal products [4]	NONE	NONE	Act on Medical Products (SFS 1992:859)	Medical Products Agency	No
	• Food and feed area disinfectants [5]	NONE	NONE	Exempted from the Ordinance on Pesticides (KIFS 1989:7)	KemI	No
	• **Drinking water disinfectants** [6]	APP	APP	National Food Adm. Ordinance with Regulations and General Advice on drinking water (SLUFF 1989:30)	National Food Administration	Yes[s]
(ii) Preservatives/ Microbiocides	• In-can preservatives [7]	NONE	NONE	Exempted from the Ordinance on Pestcides (KIFS 1989:7)	KemI	No
	• Film preservatives [10]	APP	APP	Ordinance on Pesticides (SFS 1985:836)	KemI	Yes[g]
	• **Wood preservatives** [13]	APP	APP	Ordinance on Pesticides (SFS 1985:836)	KemI	Yes[s]

* Approval required only for those products cited in bold letters. The other products belonging to this use category are exempted from the Pesticides Ordinance according to the National Chemicals Inspectorat Regulations KIFS 1989:7.

@ "Guidelines on Documentation Requirements for Approval of Products Against Micro-organisms in Chemical Toilets".

TABLE 1: SWEDEN (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(ii) Preservatives/ Microbiocides (cont.)	• Fiber, ***leather,*** rubber *and* ***polymrerized material*** *preservatives* [9b, 9c]. • ***Mansonry preservatives*** [9d]	APP	APP	Ordinance on Pesticides (SFS 1985:836)	KemI	Yes[g]
	• **Slimicides** [8b, 8c]	APP	APP	Ordinance on Pesticides (SFS 1985:836)	KemI	Yes[s]
	• Metalworking-fluid preservatives [9k]	NONE	NONE	Exempted from the Ordinance on Pesticides (SFS 1985:836)	KemI	No
(iii) Pest Control Products	• **Rodenticides** [22]	APP	APP	Ordinance on Pesticides (SFS 1985:836)	KemI	Yes[s]
	• ***Avicides*** [23] • Molluscicides [28] • ***Piscicides*** [24] • Insecticides, acaricides and products to control other arthropods [26, 27]	APP	APP	Ordinance on Pesticides (SFS 1985:836)	KemI	Yes[g]
	• **Repellents and attractants** [25]	APP	APP	Ordinance on Pesticides (SFS 1985:836)	KemI	Yes[s]
(iv) Other biocidal products	• Preservatives for food and feedstocks	NONE	NONE	Food Act (SFS 1971:511) Feedstuffs Act (SFS 1985:295) National Food Adm. Ordinance with Regulations and General Advice on Food Additives (SLVFS 1995:31)	National Food Administration / National Agriculture and Forestry Administration	No
	• **Antifouling products** [12]	APP	APP	Ordinance on Pesticides (SFS 1985:836)	National Chemicals Inspectorate (KemI)	Yes[s]
	• **Structural Pesticides** [14]	APP	APP	Ordinance on Pesticides (SFS 1985:836)	KemI	Yes[s]
	• Embalming and taxidermist fluids [11] • Other vertebrates [29]	NONE	NONE	Ordinance on Pesticides (SFS 1985:836)	KemI	No

TABLE 1: SWITZERLAND

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

- All biocides need approval as far as human health is concerned ("Federal law on trade in toxic substances"). Antifoulings and wood preservatives need in addition approval on environmental grounds ("Federal law relating to the protection of the environment").
- With the exception of antifoulings, wood preservatives and disinfectants, Switzerland has not established data requirements for biocides in a specific formalised form. However, the possibility exists that data may be required.
- A new law covering chemicals in general is in preparation. It allows Switzerland to harmonize its legislation with the EU's Biocidal Products Directive.

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
(i) Disinfectants (only)	1. Public health disinfectants and sanitizers 2. Personal health care disinfectants 3. Non public health (private) disinfectants 4. Veterinary area and domestic animal disinfection 5. Food/feed area disinfectants for use on/in agricultural premises, food storage and processing, dairies 6. Drinking water disinfectants		APP	• Ordinance on disinfection and pest control • Federal law on trade in toxic substances	Federal Office of Public Health	Yes[s] (only for efficacy)
(iii) Anti-fouling products	12. Antifouling products		APP	• Ordinance relating to environmentally hazardous substances • Federal law on trade in toxic substances	• Federal Office of Environment, Forests and Landscape. • Federal Office of Public Health.	Yes[s]
(iv) Wood preservatives and structural treatments	13. Wood preservatives		APP	as above	as above	Yes[s]
• **Other biocides**			APP	Federal law on trade in toxic substances	Federal Office of Public Health.	Yes[g]

s, g specific and general data requirements respectively.

TABLE 1: UNITED KINGDOM

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

- Product groups 12, 13, 14, 22, 23, 25, 26, 27, 28, 29 are categorised as pesticides as defined by the Food and Environment Protection Act (FEPA) and the Control of Pesticides Regulations (COPR).
- The remaining product types are subject to the general controls on chemicals. These controls include the Chemicals (Hazard Information and Packaging) Regulations (CHIP), the Control of Substances Hazardous to Health Regulations (COSHH) and, if the active substance is defined as 'new' the Notification of New Substances Regulations (NONS).
- Approval of pesticides in the UK is given by the Ministers of 5 Government Departments acting jointly. These Departments are Agriculture, Fisheries and Food; Health; Environment; Scottish Office; Welsh Office.
  The actual administrative work is conducted by the two Regulatory Agencies. These are Pesticides Safety Directorate (PSD), who regulate agricultural pesticides and the Health and Safety Executive (HSE) who regulate non-agricultural pesticides.

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?♥
		active ingredient	end-use biocide			
(iii) Anti-fouling products	12. Antifouling products		APP	Control of Pesticides Regulations (COPR)* (1986) under the Food and Environment Protection Act (1985)	Health and Safety Executive (HSE)	Yes
(iv) Wood preservatives and structural treatments	13. Wood preservatives 14. Structural treatments		APP	COPR*	Health and Safety Executive (HSE)	Yes
(vii) Products for use in vertebrate and invertebrate pest control	22. Rodenticides 23. Avicides		APP	COPR*	Pesticides Safety Directorate (PSD)	Yes
	25. Repellents and attractants		APP	COPR*	• Pesticides Safety Directorate (PSD) • Health and Safety Executive (HSE)	Yes
	26. Insecticides (indoor/outdoor) 27. Insecticides/acaridices used on: humans, clothes, pets 28. Molluscicides		APP	COPR*	Health and Safety Executive (HSE)	Yes
	29. Other vertebrates			COPR*	Pesticides Safety Directorate (PSD)	Yes

♥ There is an agreed list of consolidated data requirements. However, approval is granted after consideration by an Independant Advisory Committee which has the right to request further data if it is considered necessary.

* In addition to this, products used at work are subject to the Control of Substances Hazardous to Health Regulations.

TABLE 1: USA

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

- The U.S. response addresses only biocides that are "pesticides" as defined by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Although the vast majority of "biocides" (as they were listed in the OECD questionnaire) would be categorized as pesticides, there are a few that are not. For example, personal health care disinfectants are not regulated as pesticides, but as drugs. Mortuary embalming fluids are exempted from regulation as pesticides.
- We recognize that the 7 broad areas of biocides OECD questionnaire categories comprise a broad set of non-agricultural pesticides. In the U.S. registration of ALL pesticides, non-agricultural, as well as plant protection products, is performed by the Office of Pesticide Programs. Data are required for all pesticides so that we can determine any potential for risk to health or the environment. Some of these data are also used for hazard labelling.
- The term "biocide" is not defined in any of our statutes or regulations. However, in the common parlance in the U.S. the term refers only to what would be Broad Areas (ii), (iii), (iv) and possibly (v), that is preservatives/microbiocides, anti-fouling products, wood preservatives and structural treatments, and microbiocides for waste disposal and strip mine sites, respectively.
- The term "biocide" is not generally used in the U.S. to refer to insecticides, rodenticides, piscicides, or vertebrate animal repellants, or to antimicrobial pesticides in Category (i) (disinfectants/sanitizers). Instead, these more specific terms are used, e.g., insecticide, disinfectant.
- Biocides that are pesticides may be regulated under several statutes. The main laws are:
  - ◊ The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), administered by EPA exclusively, governs the sale, distribution and use of pesticides generally through a licensing (approval) system.
  - ◊ The Federal Food, Drug and Cosmetic Act (FFDCA), administered by both EPA and the Food and Drug Administration, Department of Health and Human Services, regulates residues of substances, including pesticides, in food and feed. Responsibility for pesticide chemical residues in food is vested entirely within EPA unless EPA determines that FDA would be a more appropriate location. EPA intends to return to FDA jurisdiction a number of biocides that are pesticide chemicals for the purpose of regulating residues in food. EPA as a policy matter coordinates its regulatory activities under FIFRA and FFDCA with FDA.
- United States have followed their own broad areas/uses categories in filling in the questionnaire. The numbers of OECD use categories where correspondance is possible are given in braquets.

TABLE 1: USA (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
Agricultural premises and equipment [i-5a]	For use in • farm and farm animal/livestock premises (e.g. pens, houses, parlors, stalls, barns, etc.) • farm and farm animal/livestock equipment (e.g. utensils such as forks, shovels, scrapers; halters, ropes, other restraining equipment; racks, mangers, feeders, waterers, troughs, and food handling equipment such as milking equipment, etc.)	APP	APP	• Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) • Federal Food, Drug and Cosmetic Act (FFDCA)	Environmental Protection Agency/ Office of Pesticide Programs (EPA/OPP)	Yes under FIFRA
Food handling/ storage establishments premises and equipment [i - 1c, 5b, c]	For use in: • food/feed processing plants (e.g., dairy, egg, meat, poutry, fish/seafood etc.) • eating establishements (e.g. restaurants, cafeterias etc.) • food storage/distribution facilities (e.g. commercial transportation facilities/vehicles, shipping and storage containers; food stores markets; vending machines; etc.)	APP	APP	• FIFRA • FFDCA • Clean Water Act (CWA)	EPA/OPP	Yes under FIFRA and CWA (site specific permits for facilities)
Commercial, institutional and industrial premises and equipment [broadly i-1]	Premises is defined to include: ceilings, doors, doorknobs, fixtures, floors, light switches, stairs, wall, windows, and woodwork. The following areas are treated: • **Commercial** (e.g., hotels, motels, theaters, office buildings, airports, bus stations, train terminals, etc.);	APP	APP	FIFRA	EPA/OPP	Yes under FIFRA

TABLE 1: USA (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
Commercial, institutional and industrial premises and equipment (cont.)	• **Industrial** (e.g., factories, mills, industrial plants and areas, etc.); • **Institutional** (e.g., schools, colleges, camps, corridors, offices, auditoriums, institutions, etc.).			FIFRA	EPA/OPP	Yes under FIFRA
Residential and public access premises [i-3]	For use in: • residential (e.g., homes, apartments, mobile homes, shelters, etc.); • public areas (e.g., public areas, public buildings, or public rooms).			• FIFRA • FFDCA	EPA/OPP	Yes under FIFRA
Medical premises and equipment [i - 1a, b]	This use category includes premises and non-critical equipment in hospital or medical environments such as clinics, dental offices, nursing homes, sick rooms, morgues, or any other medical-related facility; and veterinary clinic/hospitals when efficacy is claimed against organisms that are pathogenic to both man and animal. Non-critical medical equipment includes those items and surfaces that do not contact the patient or only contact the patient's intact skin (i.e., furniture, telephones, carts, bedpans, basins, etc.)	APP	APP	• FIFRA • FFDCA (certain sterilants)	• EPA/OPP • Food and Drug Administration of Health and Human Services (FDA)	Yes under FIFRA
Human drinking water systems [i-6a]	Sites under this use category include public water systems, individual water systems, emergency water systems, and water purifier systems.	APP	APP	• FIFRA • FFDCA • Safe Drinking Water Act (it sets allowable ceilings for contami-nants in drinking water)	• EPA/OPP (Registration) • EPA/Office of Drinking Water (Clearances for intake in drinking water).	Yes ???

TABLE 1: USA (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
Personal health care disinfectants [i-2]	Personal health care disinfectants [i-2], e.g. denture cleaners, disinfection of intact skin.	APP??	APP??	FFDCA	U.S. Food and Drug Administration (FDA)	???
Material preservatives [ii-7, 9, 10]	This use category includes industrial process intermediate materials (dispersions, slurries, emulsions, solutions, etc.) and resulting products including paints, coatings, adhesives, textiles, paper, etc.	APP	APP	• FIFRA • FFDCA	• EPA/OPP • FDA	Yes under FIFRA and FFDCA
Industrial processes and water systems [ii-8 & v-15]	This use category includes freshwater supplies for commercial and industrial systems and processes and a variety of specialized applications such as: commercial and industrial processing water systems (e.g., cooling towers, evaporative condensers, air washers, heat exchangers, industrial scrubbing systems; pulp and paper mill systems, gas/oil recovery systems; drains, wastewater, and sewage systems [v-15], etc.); and specialized applications (e.g., immersion ultrasonic tank water, laboratory equipment water baths, photo processing wash water, recirculating electrodeposition systems, etc.).	APP	APP	• FIFRA • Clean Water Act (CWA)	• EPA/OPP (Registration) • EPA/ Office of Water (site-specific permits for effluents for industrial microbiocides, (NPDES permits))	Yes under FIFRA and CWA
Embalming fluids [ii-11]		NONE	NONE	Exempt from FIFRA regualtion		No

TABLE 1: USA (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
Anti-fouling coatings [iii-12]	Products in this category are antifouling paints for boat hulls and bottoms, crab and lobster pots, and underwater structures or equipment. Each use site has widespread environmental exposure. The category also includes antifouling treatment of structures and equipment used on fish farms and may have a potential for dietary exposure to humans.	APP	APP	• FIFRA • Organotin Antifouling Paint Control Act (1988) (OAPCA) It regulates the level of organotin in antifouling paints and prohibits the sale, distribution or use of paints with release rates greater than m4 micrograms/cm^2 on boats less than 25 m in length.	• EPA/OPP • Department of Commerce and Secretary of the Navy	Yes under FIFRA and OAPCA
Wood preservatives [iv-13]	Products in this category are wood preservatives for use on newly cut wood surfaces, kiln dried wood, milled wood and other building materials. An extremely wide variety of seasoned/unseasoned, indoor/ outdoor, terrestrial/marine/aquatic wood items and surfaces are treated with wood preservatives. The types of wood involved may include many items such as: fresh-cut logs or lumber; seasoned building materials; utility poles and fence posts and rails (prior to or after being placed in service); structural members; structures; dwellings; transportation vehicles; crop growing/ harvesting/ shipping/storage containers; lawn furniture; playground equipment; garden/landscape timbers; and log homes	APP	APP	• Federal Insecticide, Fungicide and Rodenticide (FIFRA) • Federal Food, Drug and Cosmetic Act (FFDCA)	• EPA/OPP (Registration under FIFRA and control of any contamination of food under FFDCA) • EPA/Office of Solid Waste (control of environmental contamination at wood treatment sites for wood preservatives).	Yes under FIFRA

TABLE 1: USA (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?
		active ingredient	end-use biocide			
Swimming pools [vi-18]	This use category encompasses hydrologically isolated and contained manmade bodies of water, including swimming pools, jacuzzis, and hot tubs. These use sites are constructed of or lined with impermeable materials, such as concrete; and have no direct inflow or outflow connection with environmental bodies of water such as oceans, lakes, rivers, streams or ponds.	APP	APP	FIFRA	EPA/OPP	Yes under FIFRA
Aquatic areas	These use sites are outdoor. Most uses have the potential to lead to contamination of potable water and are likely to require residue data. Widespread environmental exposure is possible from the uses for lakes, streams, rivers and reservoirs.	APP	APP	FIFRA and FFDCA	EPA/OPP	Yes under FIFRA

TABLE 1: EUROPEAN UNION

CATEGORISATION OF BIOCIDES, REGULATION, RESPONSIBILITIES

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?♥
		active ingredient	end-use biocide			
(i) Disinfectants and general biocidal products	• Human hygiene biocidal products [2] • Private area and public health area disinfectants and other biocidal products [1, 3, 18-21] • Veterinary hygiene biocidal products [4] • Food and feed area disinfectants [5] • Drinking water disinfectants [6]	APP	APP	Proposed Directive concerning the placing of biocidal products on the market.	• National competent authority/ies will be responsible for the authorization/ registration of biocidal products, whereas the decision on active substances to be used in biocidal products will be taken at Community level through a Committee procedure. Annex IA to the Directive will list the active substances posing only a low risk to humans, animals and the environment, Annex IB will list the"Basic substances", substances which major use is non biocidal but which have a minor use as biocides, and Annex I will list all other active substances. • Only active substances listed in the Annexes could be used in biocidal products. Common Principles for the evaluation of biocidal products (Annex VI of the proposed Directive) will ensure that evaluation of products will be made in a harmonized way.	Yes
(ii) Preservatives	• In-can preservatives [7] • Film preservatives [10] • Wood preservatives [13] • Fiber, leather, rubber and polymerized materials preservatives [9a, 9b, 9c] • Masonry preservatives [9d] • Preservatives for liquid-cooling and processing system [8d] • Slimicides [8b, 8c] • Metalworking-fluid preservatives [9k]					

TABLE 1: EUROPEAN UNION (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data require-ments exist?♥
		active ingredient	end-use biocide			
(iii) Pest control	• Rodenticides [22] • Avicides [23] • Molluscicides [28] • Piscicides [24] • Insecticides, acaricides and products to control other arthropods [26 & 27] • Repellents and attractants [25]	APP	APP	Proposed Directive concerning the placing of biocidal products on the market.	• Products authorized in one Member State shall be authorized in other Member States upon request (with some possible exception) with a system of mutual recognition of authorizations (article 4 to the Directive)	Yes
(iv) Other biocidal products	• Preservatives for food or feedstocks • Antifouling products [12] • Embalming and taxidermist fluids [11] • Control of other vertebrates					

♥ Currently, Annexes IIA, IIIA, IIB and IIIB represent an extensive list of data requirements for active substances and biocidal products. Technical guidance documents for the day-to-day implementation of the Directive are under preparation. One of them will identify the specific data requirements for the active substance and the relevant biocidal product for each product type.
This document will be prepared on the basis of Annex II A and II B which specify the common core of data always required for the active substance and biocidal product respectively, and from Annex III A and III B which specify the additional data to be submitted, according to the nature and use of the biocidal product.

TABLE 2. - OVERVIEW OF THE REGULATORY PROCEDURES:
Active ingredients, end-use products, new and old biocides, duration of approvals and re-evaluation programmes

Country	Are there separate regulatory procedures for the active ingredient (ai) and the end-use product (eup), and if so, how are these procedures linked?	Are the regulatory procedures the same for old and new biocides?	• Fixed duration of approval? • Is there a re-evaluation programme for old biocidal products?	'Approval' procedure depends on use category or is the same for different biocide use categories?
AUS	Biocides regulated (= approval procedure) by the National Authority for Agricultural & Veterinary Chemicals (NRA) (see Table 1, Annex 1)			
	The assessment of the **ai** and **eup** usually occurs during one procedure. The procedures for regulating biocides are the same for other categories of pesticides. The Ag Manual provides a summary of data requirements for assessment (Table B-1 Ag Manual).	Generally the same. However, data requirements may differ slightly.		Same
BEL	Biocides for non agricultural use, i.e. the use categories regulated by the Royal decree June 5, 1975 (see Table 1, Annex 1)			
	We authorise preparations not active ingredients as such.	Generally the same: • Biocides based on new active ingredients (not yet approved in Belgium) are fully evaluated. A full dossier for the active ingredients is required. • Biocides based on existing active ingredients (already approved in Belgium) are fully examined, but reference can be made to an ai. dossier already examined or to literature data.	Authorisation is given for a max. of 10 years. For re-approval the preparation is fully reviewed.	Depends on the product type/use category
	Biocides for use in agriculture, i.e. the use categories regulated under the Royal decree of 28/02/94 (see Table 1, Annex 1)			
	Only a preparation has to be authorised. An application has to be introduced at the General Inspection Raw Materials and Transformed Products, who examines the completeness of the dossier. Once complete, the dossier is submitted to the different experts of the Authorisation Committee. If environmental data were transmitted, those are first examined by a special Subcommittee of Ecotoxicologists, who give advice to the Authorisation Committee. The experts of the Authorisation Committee give their point of view concerning analysis, efficacy, toxicology and residues. This results eventually in an authorisation (or refusal).	Generally the same: • For biocides based on new active ingredients (not yet approved in Belgium) data required on: analysis, acute toxicity of the formulation, efficacy data, and residue data. • Especially for biocides with a new **ai**, data on toxicology, ecotoxicology, fate and behaviour in the environment can be requested.		

TABLE 2. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.):
Active ingredients, end-use products, new and old biocides, duration of approvals and re-evaluation programmes

Country	Are there separate regulatory procedures for the active ingredient (ai) and the end-use product (eup) and if so, how are these procedures linked?	Are the regulatory procedures the same for old and new biocides?	• Fixed duration of approval? • Is there a re-evaluation programme for old biocidal products?	'Approval' procedure depends on use category or is the same for different biocide use categories?
CAN	Biocide use categories 1-5 regulated (= approval procedure) under Food & Drugs Act (FDA) (see Table 1, Annex 1)			
	For drugs, pre-market applications for end-use products are required. Individual active ingredients are neither approved nor registered. Evaluation of the end-use product is considered to integrate evaluation of the active ingredients as they are present in the end-use formulation. Evaluation of the end-use product may include evaluation of information on specific active ingredients. Each application for an end-use product is evaluated individually and supporting data is required to relate directly to the end-use formulation. Provisions exist for cross referencing information from other end-use product files, with acceptable authorisation.	For the most part the same. However, the date of application can have a bearing on the type and quantity of data requested for evaluations.	• Full registration: up to 5 years Temporary registration: up to 1 year • No	Depends on the product type/use category
	Disinfectant products for human drinking water (part of use category 6)			
	Once DWMSA (Drinking Water Materials Safety Act) is in effect, disinfectant products for human drinking water will need to be certified as meeting NSF standard 60 by an accredited certification organisation before being allowed on the Canadian market. The certification organisation will perform analytical tests and a toxicological evaluation, on samples and data provided by the manufacturer, to determine compliance with the standard. The NSF standards addresses the health effects implications of treatment chemicals (including disinfectants used in drinking water) and related impurities. Both the treatment chemical and related impurities are considered contaminants. The questions covered by the standard are: Is the chemical safe at the normal maximum dose? Are the impurities below maximum acceptable levels?			
	Biocide use categories 7-29 regulated under Pest Control Products Act (PCPA) (see Table 1, Annex 1)			
	All end use products are required to contain a registered active ingredient. Furthermore, registrations of active ingredient are sources specific i.e. not all sources of active ingredient are considered to be equally safe. Typically, but not always, the application/petition to register a new active ingredient is accompanied by an application for the end use product. It is only with knowing the end uses that the PMRA can, accurately/with detail, outline the specific data required to assess safety and merit/efficacy.	For the most part the same. However, the date of application can have a bearing on the type and quantity of data requested for evaluations.	Full registration: up to 5 years Temporary registration: up to 1 year	

TABLE 2. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.):
Active ingredients, end-use products, new and old biocides, duration of approvals and re-evaluation programmes

Country	Are there separate regulatory procedures for the active ingredient (ai) and the end-use product (eup) and if so, how are these procedures linked?	Are the regulatory procedures the same for old and new biocides?	• Fixed duration of approval? • Is there a re-evaluation programme for old biocidal products?	'Approval' procedure depends on use category or is the same for different biocide use categories?
CAN (cont.)	Biocide use categories 7-29 regulated under Pest Control Products Act (PCPA) (see Table 1, Annex 1) (cont.)			
	For some active ingredients, there are many different manufacturers - called sources of active ingredient. For example: there are two manufacturers of pentachlorophenol supplying Canadian users with penta. Therefore there are two registrations for the two different sources of active ingredient. For some of the 163 anti-microbial active ingredients, there may be as many as 10 sources of active - each supported by an individual or shared database- with their own separate registrations. As well, there are many biocide active ingredients that are both the technical active ingredient as well as the end use product - simply because the technical is ready to use as an end use product for industrial applications. Pentachlorophenol is an example of a product that has a designation as both active and end use product. In this case only one application or petition would be required for the registration of the active ingredient and the end use product. It is the preference of the PMRA to receive applications for registration of the active ingredient with an application for the end use product. Sometimes when the active and end product are made by two different companies (frequently the case with anti-microbial pesticides), then synchronising the simultaneous arrival of applications from two different parties can be challenging.	For the most part the same. However, the date of application can have a bearing on the type and quantity of data requested for evaluations.	Full registration: up to 5 years Temporary registration: up to 1 year	
	Biocides notified under Canadian Environmental Protection Act (CEPA) (see Table 1, Annex 1)			
	Only **ai** is notified and assessed. Biocide end-use products are not under the scope of CEPA.	Biocides used in a way that is outside the definition of pesticide under PCPA are notified under CEPA		

TABLE 2. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.):
Active ingredients, end-use products, new and old biocides, duration of approvals and re-evaluation programmes

Country	Are there separate regulatory procedures for the active ingredient (ai) and the end-use product (eup) and if so, how are these procedures linked?	Are the regulatory procedures the same for old and new biocides?	• Fixed duration of approval? • Is there a re-evaluation programme for old biocidal products?	'Approval' procedure depends on use category or is the same for different biocide use categories?
DEN	Disinfectants regulated by the Danish Veterinary and Food Administration (see Table 1)			
	Products for disinfection are evaluated on the constituents and information on concentrations in the end-use product. The evaluation is made on the end-use product in order to validate toxicology and efficacy of the product. The approval for a certain product for disinfection is only given when information about toxicology, effect and labelling are sufficient.	Same		
	Biocides regulated by Danish Environment Protection Agency (see Table 1)			
	The approval system is linked to the product. The active substance is therefore assessed when an application for approval is received by the Danish EPA.	Same	8 years 4 years for products classified as toxic or very toxic	
FIN	All biocides which are subject to an approval procedure in Finland (see Table 1)			
	The approval is applied for the **eup** only; the active substances are never handled separately but always in connection with a product application. The applicant must submit a technical dossier on both the active substances and the product.	Generally the same: The existing ("old") and new products are handled in the same way, i.e. the procedure and the data requirements are the same. However, if there are no new data or any suspicions on the safety / efficacy of the existing product, the risk assessments are not necessarily repeated.	Usually 5-8 years for wood preservatives [13], and industrial slimicides [8b, 8d but may be for unlimited time in some cases]; Up to 10 years for structural treatments [14], and pest control products [22, 25, 26a and 26b)	Principally very similar for different biocidal product types
FR	Food area disinfectants regulated (= approval procedure) by the Ministry of Economy and Finances (see Table 1)			
	The active ingredients should be included in a positive list. For an **eup** containing an already authorised **ai**, the same approval procedure as in the case of pesticides for agricultural use is applied as appropriate. For products for domestic use, approval is granted only if they contain an **ai** which is included in a positive list; the **eup** does not need separate approval.	The regulatory (approval) procedure is the same for all active ingredients that are not yet authorised for the specific use category, independently whether the **ai** is old or new.		Depends on the product type/use category

TABLE 2. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.):
Active ingredients, end-use products, new and old biocides, duration of approvals and re-evaluation programmes

Country	Are there separate regulatory procedures for the active ingredient (ai) and the end-use product (eup) and if so, how are these procedures linked?	Are the regulatory procedures the same for old and new biocides?	• Fixed duration of approval? • Is there a re-evaluation programme for old biocidal products?	'Approval' procedure depends on use category or is the same for different biocide use categories?
FR (cont.)	Wood preservatives for wood in contact with fruits and vegetables regulated by the Ministry of Economy and Finances (see Table 1, Annex 1)			
	The active ingredients should be included in a positive list. The end-use products containing authorised active ingredients do not need individual authorisation and can be commercialised under prescribed conditions.	The regulatory (approval) procedure is the same for all active ingredients that are not yet authorised for the specific use category, independently whether the **ai** is old or new.		Depends on the product type/use category
GER	Wood preservatives for construction products and "RAL"-products (see Table 1, Annex 1)			
	Approval is applied to the **eup**.	Same		
	Disinfectants and pest control products use in the field of hygiene, regulated by the Federal Communicable Diseases Act (on voluntary base) (see Table 1, Annex 1)			
	The regulatory procedure is under preparation			
GR	Biocides use categories regulated by National Drug Organisation (see Table 1, Annex 1)			
	There is no separate procedure for the **ai** and **eup**. In Greece only end-use products are regulated.	Same		Same
	Biocides use categories regulated by the Ministry of Agriculture (see Table 1, Annex 1)			
	There is no separate procedure for the **ai** and **eup**. In Greece only end-use products are regulated.	No New biocides (not registered in Greece): a whole data package is required (physicochemical properties, toxicology, certain data on ecotoxicology, proposed label, sample of the product) and forwarded to the reviewers for assessment. Old biocides (already registered in Greece): According to this procedure, the same data as for "new" biocides are required but are not evaluated (administrative check only).		Same
HUN	All biocides which are subject to an approval procedure in Hungary (see Table 1, Annex 1)			
	The approval procedure is the same for the **ai** and the **eup** but toxicological classification and hazard characterisation may differ.	Generally the same. However, the quantity of data requested is less for old (well known) than for new biocides.		Depends on the product type/use category

TABLE 2. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.):
Active ingredients, end-use products, new and old biocides, duration of approvals and re-evaluation programmes

Country	Are there separate regulatory procedures for the active ingredient (ai) and the end-use product (eup) and if so, how are these procedures linked?	Are the regulatory procedures the same for old and new biocides?	• Fixed duration of approval? • Is there a re-evaluation programme for old biocidal products?	'Approval' procedure depends on use category or is the same for different biocide use categories?
IRL	All biocides which are subject to an approval procedure in Ireland (see Table 1, Annex 1)			
	No distinction is made between the active ingredient and the formulated product. Both are assessed as part of an integrated package.	No. All biocides which were placed on the market after 12 Dec. '95 are subject to a clearance/approval scheme. Products which were on the market prior to that date are subject to a notification scheme. The latter involves the submission of data pertaining to the product name, active ingredient and its content, field of use and other subsidiary information.	Notified products are subject to full review in accordance with a schedule by Minister	Same for different biocide use categories
NL	All 19 biocide use categories which are subject to approval procedure in the Netherlands (see Table 1, Annex 1)			
	Authorisation is given for specific individual products (the focus of the evaluation is on the **ai**).		Authorisation is given for a certain period, usually linked to the date of next re-evaluation	
NZ	All biocide use categories which are subject to an approval or notification procedure in New Zealand (see Table 1, Annex 1)			
	Biocide regulation is generally based on an assessment of the end-use product, with controls being divided into those associated with *notification* and those involving *approval*.			Same
POR	Biocide use categories regulated (= approval procedure) by the Direcção-Geral da Saúde (see Table 1, Annex 1)			
	When an applicant applies for an approval, two technical and toxicological dossiers for both active ingredient and end-use biocide must be presented.	Generally the same. However, if the active ingredient is new in Portugal (less than 10 years for the first approval) the applicant must present toxicological studies for both **ai** and **eup** (unless the active ingredient is not dangerous we don't need the last one, but an expert report).		
	Biocide use categories regulated by the Direcção-Geral de Veterinária (see Table 1, Annex 1)			
	The Direcção-Geral de Veterinária evaluates all the "veterinary" biocides but only the **eup**.			Essentially the same except for products used in non food producing animals.

TABLE 2. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.):
Active ingredients, end-use products, new and old biocides, duration of approvals and re-evaluation programmes

Country	Are there separate regulatory procedures for the active ingredient (ai) and the end-use product (eup) and if so, how are these procedures linked?	Are the regulatory procedures the same for old and new biocides?	• Fixed duration of approval? • Is there a re-evaluation programme for old biocidal products?	'Approval' procedure depends on use category or is the same for different biocide use categories?
POR (cont.)	Biocide use categories (wood preservatives) regulated by the Direcção Geral de Protecção das Culturas (see Table 1, Annex 1)			
	The applicant must present the technical data regarding toxicity to man and domestic animals, fate and behaviour in the environment, and ecotoxicity for both a.i. and e.u.p.	Generally the same. If the approval of the a.i. given to other applicant has more than 10 years, some technical data are not required.	• Authorisation is given for a max. of 5 years. • We have no re-evaluation programme.	It depends on use category: DGPC is the competent authority for granting the authorisations to wood preservatives.
SWE	All biocides which are subject to an approval procedure in Sweden (see Table 1, Annex 1)			
	When the National Chemicals Inspectorate receives an application for approval of a biocidal product, the need for the product is first assessed. If there is no need for the product no approval will be given. Secondly the health and environmental risks are evaluated from the studies of the active ingredient submitted by the applicants . A risk-benefit analysis is then done. After this the product might get an approval.	No • The new biocides (biocides with **ai** not being approved earlier) have to be fully assessed. • When the application for approval concerns a product containing an old **ai** and with the same area of use, the procedure for approval is very simple. • If, however, the area of use is different the procedure will take longer.	Authorisation is given for a max. of 5 years The product groups are reviewed every fifth year in order to look at new studies, new alternatives, plans for phasing out etc. The end-product of the review is re-approvals, restrictions, plans for phasing out certain **ai**.	Same
SWI	All biocides which are subject to an approval procedure in Switzerland (see Table 1, Annex 1)			
	The approval of the end-use product is based on the evaluation of the data of its ingredients.	Same		Same for different biocide use categories

TABLE 2. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.):
Active ingredients, end-use products, new and old biocides, duration of approvals and re-evaluation programmes

Country	Are there separate regulatory procedures for the active ingredient (ai) and the end-use product (eup) and if so, how are these procedures linked?	Are the regulatory procedures the same for old and new biocides?	• Fixed duration of approval? • Is there a re-evaluation programme for old biocidal products?	'Approval' procedure depends on use category or is the same for different biocide use categories?
UK	Biocides regulated by the "Control of Pesticides Regulations" (see Table 1, Annex 1)			
	Approvals are granted for specific products.	Depends on whether the active substance is new or whether the products fit into precedent categories created following previous approvals of products containing the active substance. • With a new active substance, data covering effects on human health, environment, physical chemistry and efficacy must be submitted and assessed. • For products based on existing active substances new data are not required if access to previously considered data is possible.	In addition to the these procedures for handling applications for approval, there is a review programme for older pesticide products. They are reviewed against modern safety standards and further data may be required to ensure safety for man and the environment and that the product is efficacious.	Same for different biocide use categories
USA	All biocides regulated (= approval procedure) by EPA/OPP under FIFRA (see Table 1, Annex 1)			
	Under FIFRA, pesticide active ingredients and end use products are subject to the same requirements for registration and labelling. Both active ingredient products (either technical grade active ingredients (TGAIs) or manufacturing use products (MUPs) and end-use products (**eups**) must furnish data supporting registration of specific uses of the product. Data requirements for active ingredients depend on the manufacturer's intended use of the MUP in **eups**, thus the data requirements are generally similar to those for the **eup** itself for a particular use.	FIFRA does not differentiate between existing active ingredients and new active ingredients. If a biocide is required to be registered with EPA under FIFRA, all products undergo the same process, varying only in the amount of data and the depth of assessment needed to address the risks and benefits.		Same requirements apply to all pesticides

TABLE 2. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.):

Active ingredients, end-use products, new and old biocides, duration of approvals and re-evaluation programmes

Country	Are there separate regulatory procedures for the active ingredient (ai) and the end-use product (eup) and if so, how are these procedures linked?	Are the regulatory procedures the same for old and new biocides?	• Fixed duration of approval? • Is there a re-evaluation programme for old biocidal products?	'Approval' procedure depends on use category or is the same for different biocide use categories?
EU	• The proposed Directive covers a wide range of product types (listed in annex V of the proposal), namely disinfectants, preservatives, pest control products and anti-foulants and ultimately only those active substances which are listed in Annex I, IA or IB of the Directive will be authorised for use in these biocidal products. Annex IB will list basic substances, Annex IA will list active substances for inclusion in low risk biocidal products and Annex I will list all other active substances (main group). Inclusion (or non-inclusion) in Annex I, IA and IB will be decided at community level, after an evaluation by Member States on the basis of data provided by industry. • For the inclusion of an active substance in Annex I or IA of the Directive, industry must submit to a rapporteur Member State a full dossier for an active substance and a biocidal product containing it. The rapporteur Member State will carry out the evaluation of the dossiers (risk assessment for the active substance) and will make a recommendation to the Commission of inclusion/non inclusion of the active substance in Annex I. The Commission will than make a decision of inclusion/non inclusion of the active substance in Annex I. If it is decided to include the active substance in Annex I, the rapporteur Member State, after the risk assessment of the product, can authorised in its territory the biocidal product containing the relevant active substance. Then it is foreseen a system of mutual recognition of authorisation (with some possible exceptions) with the possibility for industry to apply and obtain the registration of the same product in another Member State in a short time period. The procedure for the inclusion of a basic substance in Annex IB is the same with the only difference that there will not be authorisation of a biocidal product contained in basic substances. In fact basic substances are marketed and used as such or simply diluted, and once entered in Annex IB, they could be used throughout the whole Community without further authorisation at Member State level. • Following adoption of the Directive, existing active substances will be reviewed to ascertain whether or not they can be included in the Annex I, IA or IB list. This review will also require the submission of data by industry which will be again evaluated by Member States. The review programme will last for 10 years and will be subject to a future Commission Regulation. National laws will continue to apply for the registration of biocidal products containing only existing active substances, until they will be reviewed. • The Directive will also harmonize the national authorisation schemes for biocidal products, by use of the Common Principles (Annex VI), with these authorisations being mutually recognised in all Member States. Provisions for data protection (intellectual property rights), confidentiality and labelling are also included in the proposal.			

TABLE 3. - OVERVIEW OF THE REGULATORY PROCEDURES: Conditions and impurities

Country	How are controls enacted?				Impurities in active substances controlled?		
	Conditions attached to approvals?	**If yes, are they legally binding?**	**Conditions apply to user (u) or manufacturer/ supplier (m/s)?**	**How are conditions enforced?**		**If yes, how?**	**Are standards (or acceptable levels) of impurities established?**
AUS	Biocides regulated (= approval procedure) by the National Authority for Agricultural & Veterinary Chemicals (NRA) (see Table 1, Annex 1)						
	May be	Yes	Depending on the condition, they may apply to either the u or the m/s.	Through State control of use legislation and State enforcement officers	Yes	By reviewing details of the manufacturing process, and examining batch results from production batches under the NRA's Compliance Program	Yes
BEL	Biocides for non agricultural use, i.e. the use categories regulated by the Royal decree June 5, 1975 (see Table 1, Annex 1)						
	Yes	Yes			Yes	Detailed analytical report concerning the **ai** is required	Yes
	Biocides for use in agriculture, i.e. the use categories regulated under the Royal decree of 28/02/94 (see Table 1, Annex 1)						
	Conditions on use and labelling are attached to all approvals.	Yes	• Apply to the **u**: only the authorised uses are legal • Apply to **m/s**: the authorisation is only valid for the declared composition of the product, and any change must be notified.	By inspectors of the General Inspection Raw Materials and Transformed Products	Yes but not on a regular basis	• Data requirements contain full declaration of the impurities above 0,1 % of the technical **ai**, based on analysis results of 5 production batches. • Call for analysis standard of impurities, and analysis of product on the market by the State Laboratory	Yes FAO - criteria (max. content)
CAN	Biocide use categories 7-29 regulated (approval procedure) under Pest Control Products Act (PCPA) (see Table 1, Annex 1)						
	Registration can be granted with conditions.	Yes	Conditions of registration apply to the registrant or applicant for registration **(m/s)** i.e. it is their responsibility to ensure that they are met. If conditions of registration are not met, the registration will not be extended or will be refused.	Audit by federal officers; enforcement includes prosecution, monetary penalties, product seizure and detention, depending on the severity of the offence.	Yes	Under PCPA: Information related to the identity and quantity of impurities is requested as part of the pre-registration assessment process as well as part of specific follow-up activities related to meeting an acceptable standard for micro-contaminants. The identity and level of impurities are considered as part of the risk assessment process and a determination made if they present an unacceptable risk of harm.	Yes, under PCPA some standards are found in regulation, other are admini-strative i.e. prescribed in a regulatory directive.

TABLE 3. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.): Conditions and impurities

Country	How are controls enacted?				Impurities in active substances controlled?		
	Conditions attached to approvals?	**If yes, are they legally binding?**	**Conditions apply to user (u) or manufacturer/ supplier (m/s)?**	**How are conditions enforced?**		**If yes, how?**	**Are standards (or acceptable levels) of impurities established?**
CAN	Biocides notified under Canadian Environmental Protection Act (CEPA) (see Table 1, Annex 1)				Disinfectant products for human drinking water (part of use category 6)		
(cont.)	The Minister of Environment Canada has powers to impose conditions.	Yes	m/s		Yes	For drinking water disinfectants, impurities have to be below maximum acceptable levels (MALs) or the disinfectant will not be certified.	NSF std 60 stipulates how MALs are set.
DEN	Disinfectants regulated by the Danish Veterinary and Food Administration (see Table 1, Annex 1)						
	When a product is approved, conditions for approval and labelling are part of the approval.				No		No
	Biocides regulated by Danish Environment Protection Agency (see Table 1, Annex 1)						
	Conditions are set for marketing and use; Labels on products are also to be approved.	Yes; max. penalty is imprison-ment up to 2 years			Yes	By spot tests	Yes
FIN	All biocides which are subject to an approval procedure in Finland (see Table 1, Annex 1)						
	May be	Yes	The conditions may include restrictions concerning the users of the product (e.g. only for professional use). Also, for structural treatments and products for pest control, a special pesticide examination may be required from the buyers of the pesticide.	The marketing and use of approved biocides and the obeying of the conditions, rules and instructions given in the decision is supervised by the national, regional and local authorities.	Yes	In the application for approval the applicant must submit data on the identity and quantity and the known environmental and health effects of the impurities. If the composition of the product or the origin of the active substance is changed, the holder of the approval should notify the authorities. The authority will then consider if a new assessment is necessary. The impurities may also be regulated by a general restriction concerning a specific chemical which may be present in the biocide as an impurity	No (except in rare cases, e.g. creosote oil)

TABLE 3. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.): Conditions and impurities

Country	How are controls enacted?				Impurities in active substances controlled?		
	Conditions attached to approvals?	**If yes, are they legally binding?**	**Conditions apply to user (u) or manufacturer/ supplier (m/s)?**	**How are conditions enforced?**		**If yes, how?**	**Are standards (or acceptable levels) of impurities established?**
FR	Food area disinfectants and wood preservatives for wood in contact with fruits and vegetables regulated (= approval procedure) by the Ministry of Economy and Finances (see Table 1, Annex 1)						
	Conditions may be set especially for use instructions.						
GER	Wood preservatives for construction products and "RAL"-products and disinfectants and pest control products for use in the field of hygiene, regulated by the Federal Communicable Diseases Act (on voluntary base) and Medicines Act (see Table 1, Annex 1)						
	May be				Yes	Via safety data sheets.	No
GR	Biocides use categories regulated by National Drug Organisation (see Table 1, Annex 1)						
	Yes	Yes	Both	No specific procedure for the control on use. Conditions on users are enforced in some cases e.g. hospital disinfectants, but there are difficulties in the control of private users.	No	Impurities are addressed only in an indirect manner by submitting data on degree of purity of active(s). Generally no further characterisation of type(s) of impurity is given by the safety data sheet.	No
	Biocides use categories regulated by the Ministry of Agriculture (see Table 1, Annex 1)						
	Yes	Yes	Both	No specific procedure for the control of use.	No		No
HUN	All biocides which are subject to an approval procedure in Hungary (see Table 1, Annex 1)						
	No information provided				No		No
IRL	All biocides which are subject to an approval procedure in Ireland (see Table 1, Annex 1)						
	Conditions of use and dose rates are set and appear on the label.	Yes	Both		Yes	By specification verification carried out in the formulation laboratory.	Yes

TABLE 3. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.): Conditions and impurities

Country	How are controls enacted?				Impurities in active substances controlled?		
	Conditions attached to approvals?	**If yes, are they legally binding?**	**Conditions apply to user (u) or manufacturer/ supplier (m/s)?**	**How are conditions enforced?**		**If yes, how?**	**Are standards (or acceptable levels) of impurities established?**
NL	All 19 biocide use categories which are subject to an approval procedure in the Netherlands (see Table 1, Annex 1)						
	Conditions are set for the type of application, including concentration limits of **ai**, dosage, frequency of application.	?	u?	Conditions on users are enforced by inspectorates for specific domains (e.g. environment, labour protection, public health)	Yes	A certificate of analysis is required.	Yes, for certain impurities
NZ	All biocide use categories which are subject to an approval or notification procedure in New Zealand (see Table 1, Annex 1)						
	No information provided				Yes	Through the formal *approval* process (pesticides, animal remedies, medicines) where products with unacceptable levels of impurities would not be registered, or in the case of other *notified* biocides through product classification mechanisms (which can be used to restrict the availability of the biocide).	Yes, case-by-case
POR	Biocides use categories regulated (= approval procedure) by the Direcção-Geral da Saúde (see Table 1, Annex 1)						
	No information provided				No		Yes
	Biocides use categories regulated by the Direcção-Geral de Veterinária (see Table 1, Annex 1)						
	Yes	?	?	These products are used under veterinary surveillance and included in the National Residue Control Program.	No		Yes

TABLE 3. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.): Conditions and impurities

Country	How are controls enacted?				Impurities in active substances controlled?		
	Conditions attached to approvals?	**If yes, are they legally binding?**	**Conditions apply to user (u) or manufacturer/ supplier (m/s)?**	**How are conditions enforced?**		**If yes, how?**	**Are standards (or acceptable levels) of impurities established?**
POR (cont.)	Biocide use categories (wood preservatives) regulated by the Direcção Geral de Protecção das Culturas (see Table 1, Annex 1)						
	Conditions on use must be attached to the approval and should be stated on the label, which has to be approved by the competent authority.	• All the wood preservatives need an approval to be placed on the market; the control of wood preservatives is made by an official authority. • Some conditions apply to u and some other conditions to m/s.		By including it in the labels, and by the control measures made by official authority.	Yes	The content of impurities is not controlled in the laboratory; we accept the declarations from the manufacturer with the analysis certificate.	Yes, for some active ingredients.
SWE	All biocides which are subject to an approval procedure in Sweden (see Table 1, Annex 1)						
	Yes; each approved product will have an approved area of use.	Yes; fine or imprison-ment up to 1 year	Both	• By local authorities • The composition of a biocide product on the market may be checked by KemI.	Yes	Through the information on impurities included in the documentation for approval submitted by the applicant.	No
SWI	All biocides which are subject to an approval procedure in Switzerland (see Table 1, Annex 1)						
	Conditions on use may be attached to the approval and should be stated on the label.		m/s		No		
UK	Biocides regulated (= approval procedure) by the "Control of Pesticides Regulations" (see Table 1, Annex 1)						
	Conditions on advertisement, sale, supply, storage and use are attached to all approvals.	Yes	m/s		*No information provided*		

TABLE 3. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.): Conditions and impurities

Country	How are controls enacted?				Impurities in active substances controlled?		
	Conditions attached to approvals?	**If yes, are they legally binding?**	**Conditions apply to user (u) or manufacturer/ supplier (m/s)?**	**How are conditions enforced?**		**If yes, how?**	**Are standards (or acceptable levels) of impurities established?**
USA	All biocides regulated (= approval procedure) by EPA (see Table 1, Annex 1)						
	EPA has several means of placing controls on sale, distribution and use of pesticide biocides: • EPA may restrict the sale and distribution of a product, either by regulation or on a case-by-case basis. On a case-by-case basis, EPA may restrict products (or individual uses of a product) to use by certified (trained) applicators. Restrictions established by regulation may be of any type, and would apply to any product that meets the criteria for the restriction. • EPA may also put restrictions in place through the labelling of the product, because use of a product in a manner inconsistent with its labelling is a violation of law. Thus, EPA may require that a technical active ingredient biocide specify on the label the specific end uses to which the end-use product may be put, and the formulator is bound to produce an end-use product conforming to those use specifications. Similarly, the instructions, precautions and restrictions required on the end use labelling must be followed by users. These may include precautionary measures such as protective equipment, storage and disposal instructions, and use instructions relating to site, timing, dosage and frequency of application. The label is the principal means of enforcing binding conditions of use on users. • Even if EPA chooses not to regulate the pesticide by its registration (approval) scheme, it may by regulation regulate sale, distribution or use based upon risk considerations. • Under FFDCA, EPA establishes tolerances or otherwise regulates the amount of pesticide residues permitted in food, and thus, indirectly, the use of the pesticide product that results in residues. Regulations, particularly in the food processing area, often specify use conditions and restrictions to ensure that residues will not exceed permitted tolerances.				Yes	Impurities in biocide formulations are regulated through the registration (approval) process. A manufacturer must inform EPA of impurities that are known or potentially present in his product, its potential source (formulation process, equipment, carryover from source product), and its upper limit in the product if the impurity is toxicologically significant. Manufacturers must also describe their production or formulation processes in detail. EPA evaluates the impurities as part of the evaluation of the risks of the product proposed for approval, and may require that the manufacturer reduce impurities to acceptable levels before approval is granted.	Yes, on case-by-case basis
EU	Authorisation must stipulate the conditions relating to marketing and use of the biocidal product. In particular, use conditions include: the authorised uses (e.g. wood preservation) direction for use and dosage rate, direction for safe disposal of the biocidal product, precautionary measure to be taken during use, storage and transport of the biocidal product (e.g. use of personal protective clothing and equipment, measures for protection against fire), categories of users to which the biocidal product may be restricted. These conditions are legally binding and each Member State in its territory is responsible for the enforcement of the Directive.				Yes	Methods to be agreed by all Member States	Yes

TABLE 4. - OVERVIEW OF THE REGULATORY PROCEDURES: Decision-making criteria and risk benefit

Country	Does your country have decision-making criteria for:			Risk-benefit plays a part in decision making? Is risk-benefit more important for some products than others?
	notification or approval?	classification?	labelling?	
AUS	Biocides regulated (= approval procedure) by the Agricultural and Veterinary Chemicals Code (see Table 1, Annex 1)			
	Yes; section 14 of the Ag/Vet code gives the criteria for approval of pesticides (including biocides and veterinary drugs).	Hazard classification systems are controlled by different authorities such as NICNAS (National Industrial Chemicals Notification and Assessment Scheme) and Worksafe and State Dangerous Goods legislation.	Labelling requirements are specified in the Code of Practice for Labelling Agricultural Chemical Products.	
BEL	Biocides for non agricultural use, i.e. the use categories regulated by the Royal decree June 5, 1975 (see Table 1, Annex 1)			
	Yes; case-by-case (consideration of complete documentation of the application)	Yes; the decision-making criteria for classification and labelling are those laid down in the following legislative provisions of the European Union: • Directive 88/379/EEC and • Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.		Yes - Approval could be possible in case of need for the product if there are no substituting products, usually with severe application conditions.
	Biocides for use in agriculture, i.e. the use categories regulated under the Royal decree of 28/02/94 (see Table 1, Annex 1)			
	Yes; case-by-case (consideration of complete documentation of the application)	Yes; for classification and labelling the decision-making are those laid down in the following legislative provisions of the European Union : • Directive 78/631/EEC of 26 June 1978 on the approximation of laws of the Member States relating to the classification, packaging and labelling of dangerous substances. • Directive 67/548/EEC (see BEL, biocides for non agricultural use).		Yes Approval could be possible in case of need for the product (although high risk means strict application conditions).

TABLE 4. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.): Decision-making criteria and risk benefit

Country	Does your country have decision-making criteria for:			Risk-benefit plays a part in decision making? Is risk-benefit more important for some products than others?
	notification or approval?	classification?	labelling?	
CAN	Biocides use categories. 1-5 regulated under Food & Drugs Act (FDA) (see Table 1, Annex 1)			
	Yes	No	Yes; some of the labelling criteria are specified in a product monography.	
	Disinfectant products for human drinking water (part of use category 6)			
	Yes, once DWMSA (Drinking Water Materials Safety Act) in effect.		Yes, once DWMSA in effect.	Risk-benefit does not play a direct role in the decision making process for drinking water disinfectants.
	Biocides use categories 7-29 regulated (= approval procedure) under Pest Control Products Act (PCPA) (see Table 1, Annex 1)			
	Yes	Yes	Yes; some of the criteria are specified in a Regulatory Directive document e.g., Model Labels for Swimming Pool Products (use categories 18 and 20).	Products are evaluated for safety, merit (efficacy) and value. For submissions where there is a risk, the Agency considers if the risk can be managed and what impact (economic, on competition of the sector) there would be if the product was registered/not registered. A value assessment is considered under certain situations, e.g., the economic value of the commodity is high; the competitiveness of an industry is affected by the decision etc.
	Biocides notified under Canadian Environmental Protection Act (CEPA) (see Table 1, Annex 1)			
	Yes	No	No	A risk-benefit process is not applied in the scientific assessment of 'toxic' under section 11 of CEPA. However, it is taken into account when a control action is planned.
	Under section 11 of CEPA, there is a definition of toxic if it is determined to have an immediate or long- term harmful effect on the environment; constitute a danger to the environment on which human life depends; constitute a danger to human life or health. These criteria are used in the notification and approval process.			

TABLE 4. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.): Decision-making criteria and risk benefit

Country	Does your country have decision-making criteria for:			Risk-benefit plays a part in decision making? Is risk-benefit more important for some products than others?
	notification or approval?	classification?	labelling?	
DEN	Disinfectants regulated by the Danish Veterinary and Food Administration (see Table 1, Annex 1)			
	No disinfectant must be used in a retail outlet or food producing plant unless it has been approved by the Danish Veterinary and Food Administration. All chemicals must be labelled according to the law on chemicals (i.e. classification, hazards and risks). The conditions for the approval for a disinfectant (i.e. concentration and use restrictions) is stated on the label.			No
	Biocides regulated by Danish Environment Protection Agency (see Table 1, Annex 1)			
	Yes	According to EC-Directives		Yes, due to the substitution principle, which implies that an approval cannot be granted to a specific substance or product if substances, products or methods exist in the same field of application which present, or are assumed to present significantly less hazard to health or damage to the environment.
	For biocides which are subject to approval, the decision-making system is based on the hazard (inherent properties). For industrial wood protection products, the decision-making is based on a risk assessment. The decision-making is also based on the substitution principle (comparative assessment).			
FIN	All biocides which are subject to an approval procedure in Finland (see Table 1, Annex 1)			
	No	Yes	Yes	The risk-benefit-assessment is not applied routinely in the approval procedures of biocides but only in certain cases. If a product is considered to be harmful (e.g. very toxic), the existence and effects of alternative biocides and methods are usually studied before the final decision is made. If there are no substituting products or methods, the harmful product may be approved, usually with severe restrictions. On the other hand, if the harmful product is not regarded as essential, it is not approved.
	Approval: There are only general conditions for approval given in the main acts: a chemical must be suitable for the intended use, biologically effective, and when used according to the instructions the product or the material treated with it may not cause obvious harm to health or the environment.	General rules on chemicals classification are also applied to the biocides concerned.	General rules on chemicals labelling (i.e. risk and safety phrases, indications of danger) are also applied to the biocides concerned. Additionally, specific labelling rules apply for these biocides.	

TABLE 4. - OVERVIEW OF THE REGULATORY PROCEDURES: Decision-making criteria and risk benefit

Country	Does your country have decision-making criteria for:			Risk-benefit plays a part in decision making? Is risk-benefit more important for some products than others?
	notification or approval?	classification?	labelling?	
FR	Food area disinfectants and wood preservatives for wood in contact with fruits and vegetables regulated (= approval procedure) by the Ministry of Economy and Finances (see Table 1, Annex 1)			
		Yes; for classification and labelling the decision-making are those laid down in the following legislative provisions of the European Union: • Directive 78/631/EEC of 26 June 1978 on the approximation of laws of the Member States relating to the classification, packaging and labelling of dangerous substances. • Directive 67/548/EEC (see above BEL).		*No information provided*
GER	Wood preservatives for construction products and "RAL"-products and, disinfectants and pest control products for use in the field of hygiene, regulated by the Federal Communicable Diseases Act (see Table 1, Annex 1)			
	The decision-making criteria including a risk/benefit assessment for: • wood preservatives for construction products and "RAL"-products • disinfectants and pest control regulated by FCDA (Table 1) is under preparation.			Yes, on case-by-case basis
GR	Biocides use categories regulated by National Drug Organisation (see Table 1, Annex 1)			
			Yes; for labelling the final draft of the EC-Biocides Directive (article 20) and the Directive 88/379/EEC are followed.	No
	Biocides use categories regulated by the Ministry of Agriculture (see Table 1, Annex 1)			
	No	No	No	No
HUN	All biocides which are subject to an approval procedure in Hungary (see Table 1, Annex 1)			
	No	Yes	Yes	No
		Toxicity classification criteria for hazardous substances as well as labelling criteria are used: • Government Decree 233/1996 (XII 26) on rules concerning managing of hazardous substances and preparations • Decree 4/1997 (II 21) of the Minister of Welfare on the enforcement of the Government Decree 233/1996 (XII 26) on rules concerning managing of hazardous substances and preparations		

TABLE 4. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.): Decision-making criteria and risk benefit

Country	Does your country have decision-making criteria for:			Risk-benefit plays a part in decision making? Is risk-benefit more important for some products than others?
	notification or approval?	classification?	labelling?	
IRL	All biocides which are subject to an approval procedure in Ireland (see Table 1, Annex 1)			
		Yes; the decision-making criteria are those laid down in the various legislative provisions of the European Union pertaining to classification packaging and labelling of pesticides (Directive 78/631/EEC) in association with those laid down in Directive 67/548/EEC, supplemented by those specified in the relevant legislation (S.I. No. 138 of 1994)		Yes
NL	All 19 biocide use categories which are subject to approval procedure in the Netherlands (see Table 1, Annex 1)			
	Yes. However, criteria for approval have not been fully elaborated.	Yes	Yes	Risk-benefit does play a role in determining the protective measures to be taken. However, if a biocide will not meet the criteria for approval, no authorisation will be given, irrespective of the benefits. Exceptions are only possible in case of urgency.
NZ	All biocide use categories which are subject to an approval or notification procedure in New Zealand (see Table 1, Annex 1)			
	Criteria for requiring notification or approval are based on: • the intended use (in the case of biocides that fall under the definition of a pesticide, animal remedy or medicine); • the toxicity of the end-use product (in the case of other biocides).	Classification is generally based on the WHO hazard classification system, with compounds in the higher hazard groups being restricted in their availability.	Labelling requirements are generally based on the outcomes of the product assessments, and reflect warning and precautionary statements necessary to promote the safe and effective use of the product (i.e. occupational, consumer and environmental safety).	Approval and/or notification procedures both incorporate the assessment of risks, as indicated by estimates of potential exposure and assessments of hazards/toxicity. The level of risk associated with the use of a biocide influences the degree to which the compound is regulated or controlled (by labelling or restricted availability), and the benefits of use are also factored into the risk management decision.
POR	Biocides use categories regulated (= approval procedure) by the Direcção-Geral da Saúde (see Table 1, Annex 1)			
		• The EC-Directive 78/631/EEC for classification, packaging and labelling is followed. • Some other criteria were adopted by "Comissão Toxicológica de Pesticidas" for products intended to be used at home, e.g. the formulation type and presentation. We intend to apply a safety closure for children on indoor biocidal products.		*No information provided*

TABLE 4. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.): Decision-making criteria and risk benefit

Country	Does your country have decision-making criteria for:			Risk-benefit plays a part in decision making? Is risk-benefit more important for some products than others?
	notification or approval?	classification?	labelling?	
POR (cont.)	Biocides use categories regulated by the Direcção-Geral de Veterinária (see Table 1, Annex 1)			
	Yes	Yes		In the specific case of occurrence of some pest diseases in livestock animals, we consider the extreme necessity of using a certain pesticide for a very well determined purpose, we do evaluate the risk-benefit of the product intended to be useful and definitive. A period of treatment in a limited area can be established under the surveillance of veterinary services.
	All the requirements for market authorisation of a "veterinary" biocide apply to an approval procedure. After proper examination of the label which is proposed by the applicant, there are decision-making criteria. These criteria include all the precautions for the use of the product (target species, operator, environment, storage and consumer protection) and also the final classification. The classification is based on the LD50, oral and dermal in mice, of the active ingredient or preferably of the end-use product.			
	Biocide use categories (wood preservatives) regulated by the Direcção Geral de Protecção das Culturas (see Table 1, Annex 1)			
	Yes, the criteria for approval is based on the a.i. and e.u.p. safety evaluation for human, animals and environment	Yes, the Directive 78/631/EEC for classification, packaging and labelling is followed for this kind of biocides.		Yes, the risk-benefit is considered for the decision; for some products it is considered more important than for others, taking into consideration the toxicological and environmental properties, the risk evaluation and the importance of the use of the product.
SWE	All biocides which are subject to an approval procedure in Sweden (see Table 1, Annex 1)			
	A pesticide may only be approved if it is acceptable from the standpoint of health and environment protection. The risk for harmful effects on human health and the environment is dependent on the exposure as well as the intrinsic properties of a chemical substance or preparation. There are some general principles for identifying clearly unwanted properties in pesticides. However, in order to establish if a pesticide with clearly unwanted properties is unacceptable it is also necessary to perform an exposure assessment. Because of the wide variety of different exposure situations this assessment should be made on a case-by case basis. Pesticides with clearly unwanted properties which may - at potential levels of exposure - give rise to unacceptable risks will not be approved. For further information read KemI report No 4/92 "principles for identifying unacceptable pesticides".			Yes. A risk-benefit analysis is always made before approving a product. The benefits of the products must outweigh its risks.
SWI	Yes, but only for anti-fouling products.		Yes, but only for anti-fouling products.	No. It can be considered in special cases in the risk assessment process.

TABLE 4. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.): Decision-making criteria and risk benefit

Country	Does your country have decision-making criteria for:			Risk-benefit plays a part in decision making? Is risk-benefit more important for some products than others?
	notification or approval?	classification?	labelling?	
UK	Biocides regulated (= approval procedure) by the "Control of Pesticides Regulations" (see Table 1, Annex 1)			
	Assessment of safety for man or the environment is based on standard approaches to risk assessment using expert judgement. Expert judgement is also applied to determination of efficacy.	Classification and labelling are based on criteria established within the UK and covers hazard, risk, target pests and use/user group restrictions.		Yes, risk-benefit can play a part in the decision-making process. In considering applications for approval, the risks involved in the use of the product and its efficacy are considered first. If risks are considered to be unacceptable, but there is a clear need for the product, then an approval may be granted subject to very tightly controlled conditions regarding use. For products currently on the market for which there is evidence of effects on man or the environment from past use or where risks may be judged to be unacceptable against modern safety standards, approvals may again be allowed to continue subject to the tightly controlled conditions referred to above, whilst alternative strategies for pest-control and management are developed.

TABLE 4. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.): Decision-making criteria and risk benefit

Country	Does your country have decision-making criteria for:			Risk-benefit plays a part in decision making? Is risk-benefit more important for some products than others?
	notification or approval?	classification?	labelling?	
USA	All biocides regulated (= approval procedure) by EPA/OPP (see Table 1, Annex 1)			
	Approval - Yes Criteria for approval under FIFRA are contained generally in our regulations. However, each product is reviewed individually to determine whether the broad risk/benefit standard of FIFRA is met.	Yes, for acute end points, carcinogens, and some ecological end points. Toxicity and hazard classification criteria are established by regulation for acute toxicity end points, and for some ecological end points. These translate into labelling statements. There are classification criteria for carcinogens, but not for other chronic hazards. Cancer classifications are used for risk assessment purposes, but are not used for labelling purposes.	Yes Decision criteria for labelling purposes are contained both in regulations and in various other advisory documents. Since the labelling of each product is reviewed, it is not feasible to develop regulations that could address all possible biocide uses and situations. However, our regulations specify general requirements for all elements of the label; these are then applied and interpreted in specific situations for individual products.	Yes, risk/benefit balancing is central to approval under FIFRA. All biocides must meet the risk/benefit standard of FIFRA. In the case of public health pesticides, however, the public health risk/benefit process must be separate from other pesticides, and include specific consideration of the health risks posed by the disease vectors controlled by the pesticide. Under the FFDCA, approval of maximum residue levels (tolerances) is not a risk/benefit determination except in extremely limited circumstances, and then only for the purpose of retaining existing tolerances. For new tolerances, approval is entirely risk-based.
EU	All the biocide product types as categorised by EU (see Table 1, Annex 1)			
	Yes	Yes	Yes	Annex VI provides the general rules for the analysis of risks and the decision- making process. In the decision-making process for the authorisation of a biocidal product, an analysis of the risks posed to humans and the environment during the proposed use, and the benefits obtained is always carried out for each product type. If risks posed are considered unacceptable, an authorisation can be denied or subjected to specific restrictions. However a 10 years derogation, after the entry into force of the Directive, to the above general rule is granted to anti-fouling paints to be used on commercial naval seagoing vessels, as regard the effects on aquatic organisms.
	The principles for a harmonized evaluation of the dossiers and decision taken for the authorisation of a biocidal product by Member States are provided by Annex VI to the Directive, the Common Principles. A technical guidance document aimed to amplify and explain the Common Principles is under preparation. This document will give practical guidance for among other things assessing risks, effectiveness and unacceptable effects such as resistance.			

TABLE 5. - OVERVIEW OF THE REGULATORY PROCEDURES: Denial of approval

Country	Can approval of an active ingredient or end-use product be denied? If yes, under what circumstances?							
		Inadequate instructions on application/use of the product?	**Insufficient data (e.g. on human/env. risk, on efficacy)?**	**Insufficient efficacy?**	**Incompatibility with other regulatory frameworks?**	**Risk assessment shows an unacceptable risk to people or to environment?**	**Other**	**Answers depend on whether or not the product is used for public health purposes?**
AUS	Biocides regulated (= approval procedure) by the Agricultural and Veterinary Chemicals Code (see Table 1, Annex 1)							
	Yes	√	√	√	√	√	Approval to register an **ai** or **eup** can be denied if the **ai** or **eup** fails to meet the standards set out under section 14, of the Ag/Vet Code.	No
BEL	Biocides for non agricultural use, i.e. the use categories regulated by the Royal decree June 5, 1975 (see Table 1, Annex 1)							
	Yes			√		√		Yes; when a product is the only one effective under certain conditions, health hazards that are otherwise not accepted can be tolerated.
	Biocides for use in agriculture, i.e. the use categories regulated under the Royal decree of 28/02/94 (see Table 1, Annex 1)							
	Yes			√		√		
	Three possibilities after submission to the Committee : • approval; • wait: the Committee wishes to receive more information (analysis, efficacy data, adequate instructions for use, adaptation proposed dose, etc.) to complete the dossier; after reception of the information, the application is re-examined; • denial: authorisation refused, even if dossier completed: insufficient efficacy, unacceptable risk to human health or environment.							Not relevant for the Ministry of Small Enterprises and Agriculture.
CAN	Biocide use categories 1-5 regulated under Food & Drugs Act (FDA) (see Table 1, Annex 1)							
	Yes			√		√		No
	Products are assessed to determine if they are both safe and effective for purposes claimed. Approvals can be refused if either safety or product performance cannot be demonstrated or supported by scientific evidence.							

TABLE 5. - OVERVIEW OF THE REGULATORY PROCEDURES: Denial of approval

Country	Can approval of an active ingredient or end-use product be denied? If yes, under what circumstances?							
		Inadequate instructions on application/use of the product?	**Insufficient data (e.g. on human/env. risk, on efficacy)?**	**Insufficient efficacy?**	**Incompatibility with other regulatory frameworks?**	**Risk assessment shows an unacceptable risk to people or to environment?**	**Other**	**Answers depend on whether or not the product is used for public health purposes?**
CAN (cont.)	Disinfectant products for human drinking water (part of use category 6)							
	Yes	A drinking water disinfectant can be denied approval when it does not meet NSF standard 60. For example, when there is insufficient toxicological data, granting of certification may be refused.						No
	Biocides use categories 7-29 regulated (= approval procedure) under Pest Control Products Act (PCPA) (see Table 1, Annex 1)							
	Yes		√ If insufficient information has been provided to make a determi-nation of acceptable or unacceptable risk of harm.	√ If the applicant fails to establish that the product has value or merit for the purpose(s) claimed on the label.		√ If the product is found to represent an unacceptable risk of harm.	• If the application or the label does not comply with the legislation; • If the product does not require to be registered/ approved.	No
	Products regulated under Canadian Environmental Protection Act (CEPA) (see Table 1, Annex 1)							
	For products regulated under CEPA, approvals can also be denied due to unacceptable risk							
DEN	Disinfectants regulated by the Danish Veterinary and Food Administration (see Table 1, Annex 1)							
	Yes	√	√	√		√	When the hazard profile of the product shows that the product should not be allowed.	No
	Biocides regulated by Danish Environment Protection Agency (see Table 1, Annex 1)							
	Yes		√ If there is not enough information about toxicity, efficacy and labelling.	√ If the product is not efficient on the intended use.		√ If a risk assessment shows problems in relation to humans.	√ If the labelling do not meet mandatory demands.	No

TABLE 5. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.): Denial of approval

Country	Can approval of an active ingredient or end-use product be denied? If yes, under what circumstances?							
		Inadequate instructions on application/use of the product	**Insufficient data (e.g. on human/env. risk, on efficacy)?**	**Insufficient efficacy?**	**Incompatibility with other regulatory frameworks?**	**Risk assessment shows an unacceptable risk to people or to environment?**	**Other**	**Answers depend on whether or not the product is used for public health purposes?**
FIN	All biocides which are subject to an approval procedure in Finland (see Table 1, Annex 1)							
	Yes		√			√		No
			If the data on efficacy or risks to health or the environment are insufficient.					
FR	Food area disinfectants and wood preservatives for wood in contact with fruits and vegetables regulated (= approval procedure) by the Ministry of Economy and Finances (see Table 1, Annex 1)							
	Yes		√	√		√ (highly toxic)		Not relevant
GER	Wood preservatives for construction products and "RAL"-products (see Table 1, Annex 1)							
	Yes		√		√	√		
	Disinfectants and pest control products regulated (= approval procedure) by the Federal Communicable Diseases Act (on voluntary basis) and Medicines Act (see Table 1, Annex 1)							
	Yes			√		√		Yes - The regulations concern only their use for public health purposes.
GR	Biocide use categories regulated by National Drug Organisation (see Table 1, Annex 1)							
	Yes	√	√	√	√	√		No
	Biocide use categories regulated by the Ministry of Agriculture (see Table 1, Annex 1)							
	Yes		√			√		No

TABLE 5. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.): Denial of approval

Country	Can approval of an active ingredient or end-use product be denied? If yes, under what circumstances?							
		Inadequate instructions on application/use of the product	**Insufficient data (e.g. on human/env. risk, on efficacy)?**	**Insufficient efficacy?**	**Incompatibility with other regulatory frameworks?**	**Risk assessment shows an unacceptable risk to people or to environment?**	**Other**	**Answers depend on whether or not the product is used for public health purposes?**
HUN	All biocides which are subject to an approval procedure in Hungary (see Table 1, Annex 1)							
	Yes	√	√ Very often: insufficient data on human and environmental toxicity	√	√	√		No
IRL	All biocides which are subject to an approval procedure in Ireland (see Table 1, Annex 1)							
	Yes	√			√	√		No
NL	All 19 biocide use categories which are subject to approval procedure in the Netherlands (see Table 1, Annex 1)							
	Yes		√	√		√		No
NZ	All biocide use categories which are subject to an approval procedure in New Zealand (see Table 1, Annex 1)							
	Yes	√	√		√			No
		Approval is generally only granted (and labels accepted) once the regulatory authority is satisfied that the product can be used effectively and safely. This would include: • adequate instructions on how to apply the product; • sufficient data and label directions on efficacy; • compliance with other legislation and standards.						

TABLE 5. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.): Denial of approval

Country	Can approval of an active ingredient or end-use product be denied? If yes, under what circumstances?						
		Inadequate instructions on application/use of the product	**Insufficient data (e.g. on human/env. risk, on efficacy)?**	**Insufficient efficacy?**	**Incompatibility with other regulatory frameworks**	**Risk assessment shows an unacceptable risk to people or to environment**	**Other**	**Answers depend on whether or not the product is used for public health purposes?**
POR	Biocide use categories regulated (= approval procedure) by the Direcção-Geral da Saúde (see Table 1, Annex 1)						
	Yes	*No information provided*					Yes. Products used for public health purposes are authorised for pest control and only for professional use. They should be prepared by professionals (a product concentration can be approved).
	Biocide use categories regulated by the Direcção-Geral de Veterinária (see Table 1, Annex 1)						
	Yes	√	√	√	√	√		Yes
		Approval can be denied for all the above reasons and more precisely if the applicant for a market authorisation presents a technical file which is not compatible with the guidelines for it.						
	Biocide use categories (wood preservatives) regulated by the Direcção Geral de Protecção das Culturas							
	Yes	√	√ (with the exception of efficacy data)		√ (directives 91/173/EEC, 94/60/EEC and 89/677/EEC).	√		
SWE	All biocides which are subject to an approval procedure in Sweden (see Table 1, Annex 1)							
	Yes	√	√		√	√	Also, if there is no need for the product on the market.	No
SWI	All biocides which are subject to an approval procedure in Switzerland (see Table 1, Annex 1)							
	Yes		√ only for wood preservatives and disinfectants	√		√ for all biocides regulated in SWI		No
UK	Biocides regulated by the "Control of Pesticides Regulations" (see Table 1, Annex 1)							
	Yes			√		√		No
		Approval will be refused if the product cannot be shown to be capable of being used without significant risk to man or the environment or is not sufficiently efficacious.						

TABLE 5. - OVERVIEW OF THE REGULATORY PROCEDURES (cont.): Denial of approval

Country	Can approval of an active ingredient or end-use product be denied? If yes, under what circumstances?							
		Inadequate instructions application/use of the product?	**Insufficient data (e.g. on human/env. risk, on efficacy)?**	**Insufficient efficacy?**	**Incompatibility with other regulatory frameworks?**	**Risk assessment shows an unacceptable risk to people or to environment?**	**Other**	**Answers depend on whether or not the product is used for public health purposes?**
USA	All biocides regulated (= approval procedure) by EPA/OPP (see Table 1, Annex 1)							
	Yes	√	√	√		√		In part. - Assessment of public health biocides includes an efficacy component because lack of efficacy can pose serious risks.
	• **Inadequate instructions on how to apply the product** - YES, if the lack of instructions means that the product poses a risk to users or the environment not outweighed by benefits. • **Insufficient data on efficacy and insufficient efficacy** - YES. Although FIFRA requires that all biocides be efficacious, EPA reviews data only for public health biocides. Data for non-public health biocides are required to be maintained by the manufacturer and submitted if requested. • **Incompatibility with other regulatory frameworks?** - NO. Not solely on that basis. EPA must determine that there is a risk that is not outweighed by the benefits. Other regulatory frameworks are administered under different laws with different standards, and although those standards may mesh with the risk/benefit standard of FIFRA, EPA does not generally engage in a duplicative review process to determine whether the standards of other laws would support denial under FIFRA. For example, the Occupational Safety and Health Administration of the Department of Labor administers and enforces occupational safety standards in manufacturing facilities for pesticides. The Department of Transportation similarly regulates the transportation of pesticides that are hazardous by their standards. • **Risk assessment shows that it will present an unacceptable risk to people or to the environment** -YES. The primary reason for denial of a biocide approval under FIFRA is grounded in the risk/benefit standard of the law. No biocide that poses risks that are not outweighed by its benefits can be approved for sale and distribution. EPA may also deny a registration based upon technical or administrative grounds, for example, if the applicant fails to provide required information, or fails to satisfy data compensation requirements. Under the FFDCA, approval of a maximum residue level (tolerance) may be denied if the pesticide chemical residues in food would be unsafe. Failure to obtain a tolerance under FFDCA is also grounds for denial of approval under FIFRA.							
EU	All the biocide product types as categorised by EU (see Table 1, Annex 1)							
	Yes	√	√	√	√	√		No
	All the above conditions could lead to a denial of an authorisation for a biocidal product. Furthermore, the proposed Directive provides the concept of "comparative assessment" between active substances, with the possibility to remove or refuse an entry in the positive list if there exists, for the same product type, an active substance which presents significantly less risk for humans and the environment. Specific provisions rule the application of comparative assessment (article 10.5 to the Directive).							

TABLE 6: EFFICACY

Country	When required, how efficacy data are used in the regulatory procedure?	How do you address the problem of the development of resistance (or reduced effectiveness) after notification/approval?
AUS	Biocides regulated (= approval procedure) under the Agricultural and Veterinary Chemicals Code by the National Registration Authority (NRA) (see Table 1, Annex 1)	
	Efficacy data are required to show that the product, when used according to directions on the label is effective for the purposes claimed, and will not cause damage or harm to the plant, animal or other situation where it is applied. This requirement applies generally to all registrable products.	• No formal NRA program for biocide products is in place, however an NRA program is in place for herbicides and agricultural fungicides. • Resistance Management strategies are generally developed and implemented by production industries/users/chemical manufactures rather than through government regulatory mechanisms.
BEL	Biocides for non agricultural use , i.e. the use categories regulated by the Royal decree June 5, 1975 (see Table 1, Annex 1)	
	Test simulating practical use conditions are required.	Post-marketing follow-up is not performed. Plans, however, exist to review certain active ingredients on the basis of their toxicity. Similarly, concern regarding loss of efficacy might also be addressed in the future.
	Biocides for use in agriculture, i.e. the use categories regulated under the Royal decree of 28/02/94 (see Table 1, Annex 1)	
	Efficacy data are always needed: • **Disinfectants for veterinary use**: efficacy data are evaluated by the National Institute for Veterinary Research (NIDO), which delivers a certificate to the applier, who has to transmit this to the General Inspection, for discussion by the Authorisation Committee. • **Products for use against ecto-parasites**: efficacy data are examined by the experts of the Authorisation Committee (see Table 2).	If the Committee receives information concerning the development of resistance (pesticides : via the Service Research and Development of the Ministry of Small Enterprises and Agriculture; disinfectants : via the NIDO), a case-by-case study shows which products have to be considered. Possible measures: limitation of the number of applications, specification of the use, adaptation of the dose, withdrawal of the authorisation.
CAN	Biocide use categories 1-5 regulated under Food & Drugs Act (FDA) (see Table 1, Annex 1)	
	Efficacy data to support labelled claims is a pre-market requirement for disinfectants intended to be used: a) as a disinfectant on environmental surfaces and other inanimate objects for the mitigation or prevention of disease in humans or animals: i) in a facility used to manufacture, prepare or store food under the control of a manufacturing or other commercial facility and excludes anti-microbial products intended to preserve, prevent or treat damage, spoilage or disease on agricultural produce during its growth, harvest, transport, preservation or storage; **OR** ii) in patient care areas of health care facilities such as hospitals, nursing homes and medical, veterinary and dental clinics. General disinfectants which are used solely in non-patient care areas are subject only to the Pest Control Products Act (PCPA).	Health Canada maintains up-to-date information regarding development of resistance of microbial pathogens to chemical disinfectants by surveying the published scientific literature. However, at this time it appears that there is no documented evidence of the development of resistance of microbial pathogens to chemical disinfectants. Reporting of the development of resistance of microbial pathogens to chemical disinfectants is not required. In the event of receiving information indicating reduced effectiveness of a disinfectant drug product, the procedure is as follows: 1. A health hazard assessment may be conducted. 2. The product is reviewed based on the current requirements for disinfectant drugs. 3. A list of revisions/clarifications/actions that are required to bring the product into compliance is developed.

TABLE 6: EFFICACY (cont.)

Country	When required, how efficacy data are used in the regulatory procedure?	How do you address the problem of the development of resistance (or reduced effectiveness) after notification/approval?
CAN (cont.)	Biocide use categories 1-5 regulated (= approval procedure) under Food & Drugs Act (FDA) (see Table 1, Annex 1) (cont.)	
	NOTE: Although the general disinfectants are subject to the PCPA, as of April 1, 1997, reviews for these products will be reviewed and approved by the group that reviews and approves disinfectants characterised as drugs, under the Food and Drugs Act. (b) for the sterilisation and/or disinfection of medical devices, including, but not limited to contact lenses, hospital linens, and surgical, medical or dental instruments, such as endoscopes, catheters, aspirator tubes and thermometers. It is the responsibility of the manufacturer to ensure that he has supporting data to demonstrate efficacy of his product for all labelled claims according to the directions for use. Supporting data must be submitted with DIN applications (see Appendix A to Table 6). Supporting data may be requested for claims other than those indicated in Appendix A.	4. An appropriate course of action is determined based on health hazard, product history, etc. in consultation with the Bureau of Drug Surveillance. 5. The chosen course of action is implemented and appropriate individuals are contacted.
	Disinfectant products for human drinking water (part of use category 6)	
	For drinking water disinfectants, there are no immediate plans to use efficacy data. Eventually an efficacy standard will be prescribed for these disinfectants.	
	Biocides use categories 7-29 regulated under Pest Control Products Act (PCPA) (see Table 1, Annex 1)	
	Under the Pest Control Products Act, registration decision (approvals) are done based on safety, merit and value. Efficacy evaluations are conducted on all new uses (new use is defined as addition of a new pest, new site, new use site category of an active ingredient, new active ingredient which has not been previously assessed) to establish if a product works against the targeted pest(s). The assessment process also includes a verification of recommended rates/ dosages and the claimed level of control, i.e. disinfection versus sanitization; bacteriostat versus bactericide. The verification of the lowest needed dosage to achieve the level of control prescribed on the label, is seen as contributing to the reduction of exposure and risk to users and the environment.	For products regulated as pesticides, there is no requirement for reporting of resistance development to the PMRA. However, information does come to the attention of the PMRA from users of biocides, when products are not effective. New studies may be requested to confirm what pests are controlled/not controlled and changes to the expected level of control as a result of resistance. Label revisions may be necessary to reflect changes in product performance.

TABLE 6: EFFICACY (cont.)

Country	When required, how efficacy data are used in the regulatory procedure?	How do you address the problem of the development of resistance (or reduced effectiveness) after notification/approval?
DEN	Disinfectants regulated by the Danish Veterinary and Food Administration (see Table 1, Annex 1)	
	All disinfectants are validated on data from a "European suspension test" or similar.	The Danish Veterinary and Food Administration does not require information about reduced effectiveness/resistance and has no procedure if the problem should rise. The situation would be evaluated from case to case.
	Biocides regulated (= approval procedure) by Danish Environment Protection Agency (see Table 1, Annex 1)	
	Products which are to be used in Denmark and which are subject to approval have to be proven effective. For pest control the assessment of effectiveness is based on evaluation by pest control authorities. For wood preservatives the assessment is based on Nordic standards. For slimicides for paper pulp production the effectiveness is evaluated by the paper industry.	The holder of an approval shall notify any significant modifications or additions to information previously submitted to the Danish EPA. For products controlling rats the resistance problem is under constant supervision. Information is given to rat controllers to secure that new active substances are only taken into use, when the old rodenticides are no longer effective in the geographic area.
FIN	Industrial wood preservatives (heavy duty, anti-sapstain, remedial), Industrial slimicides (for use in pulp and paper mills and in cooling water systems)	All biocides which are subject to an approval procedure in Finland (see Table 1, Annex 1)
	The product can only be approved if it is suitable for the intended use, i.e. the applicant has demonstrated that the product is biologically effective and suitable for the intended use. There are, however, no standardised methods or fixed criteria for the efficacy. The efficacy of wood impregnation chemicals are tested and assessed by the Nordic Wood Preservation Council and the results of this non-obligatory inspection are utilised in the decision making. Also statements given by other objective expert institutions or organisations can be used to support the efficacy claims.	The general approach is that the development of resistance must be notified to the authorities and this information may lead to the cancelling of the approval. The usefulness of the product is also re-evaluated when re-approval is applied for. • **Industrial wood preservatives and industrial slimicides**: resistance has not been encountered during the 15 years the procedure has been in effect. • **Rodenticides used indoor and outdoor, repellents, indoor insecticides/acaricides, outdoor insecticides**: there have been cases that the Pesticide Board has cancelled the approval because of the development of resistance (e.g. bromadiolone used for the control of mice).
	Structural pesticides, Rodenticides used indoor and outdoor, Repellents, Indoor insecticides/acaricides, Outdoor insecticides	
	The Agricultural Research Centre tests in every case the biological efficacy and usefulness of biocides (insecticides, rodenticides, repellents). There is no difference between public health and non-public health biocides.	
FR	Food area disinfectants and wood preservatives for wood in contact with fruits and vegetables regulated by the Ministry of Economy and Finances (see Table 1, Annex 1)	
	Generally, the efficacy testing depends on the intended use of a product. For the products regulated by the Ministry of Economy and Finances is considered that they are used only by professionals.	*No information provided*

TABLE 6: EFFICACY (cont.)

Country	When required, how efficacy data are used in the regulatory procedure?	How do you address the problem of the development of resistance (or reduced effectiveness) after notification/approval?
GER	Wood preservatives for construction products and "RAL" - products	
	Efficacy is basic for the regulatory procedures.	If the effectiveness/efficacy is not guaranteed, the notification (registration) or approval has to be drawn away.
	Insecticides, acaricides and rodenticides in the field of hygiene, regulated (= approval procedure) by the Federal Communicable Diseases Act (on voluntary basis)	
	Efficacy data are the most important data for the approval of these products for vector control. The efficacy testing is done by government authorities, in this case by the Federal Environmental Agency, in the case of disinfectants the Robert-Koch-Institute. Testing of the products and procedures is based on the principle of vector extermination and includes laboratory and field tests to establish efficacy and practicability. The number of products which did not pass the test under the stringent conditions of extermination principle is approximately two times that of the products listed. These products and procedures which did not fulfil these requirements may, however, be well suited for prevention of infestation or for the control of pure nuisances in cases where a risk of spreading a disease does not exist, or as additional measures.	There is no reference institute in Germany to evaluate data on the resistance of target species of biocide uses.
GR	Biocide use categories regulated by the National Drug Organisation and the Ministry of Agriculture (see Table 1, Annex 1)	
	For new active ingredients efficacy data are required at a regular base. Public and non-public health uses are not treated differently.	Until now the problem has not been raised.
HUN	All biocides which are subject to an approval procedure in Hungary (see Table 1, Annex 1)	
	Efficacy data requirements are the same for biocides used in public health and non-public health.	Resistance occurs seldom in veterinary area. If so, change of the product type takes place.
IRL	All biocides which are subject to an approval procedure in Ireland (see Table 1, Annex 1)	
	Not required at present.	We do not address the problem of resistance.
NL	All 19 biocide use categories which are subject to approval procedure in the Netherlands (see Table 1, Annex 1)	
	No difference in efficacy requirements between professional use or use by the general public.	There are no specific methods to tackle the problem of resistance. When resistance or reduced effectiveness are reported during use, this will be considered when products are re-evaluated.

TABLE 6: EFFICACY (cont.)

Country	When required, how efficacy data are used in the regulatory procedure?	How do you address the problem of the development of resistance (or reduced effectiveness) after notification/approval?
NZ	All biocides which are subject to an approval procedure in New Zealand (see Table 1, Annex 1)	
	Efficacy data are required for biocides that are regulated under the Pesticides, Animal Remedies and Medicines Acts, (i.e. those that require *approval* rather than *notification*). These data are used to determine "Good Agricultural Practice" to ensure effective control of the pest organism without excessive use (and environmental contamination) of the product.	Resistance Management has not been considered to be a high priority for these biocides (as opposed to pesticides and veterinary compounds used in plant and animal production).
POR	Biocides use categories regulated (= approval procedure) by the Direcção-Geral de Veterinária (see Table 1, Annex 1)	
	Efficacy data are always required in our regulatory procedure.	There is a special annex in the guidelines for the elaboration of this process, which includes the problematic of resistance development of a certain substance or product. However, after approval of such a product, we can only count on the availability of the market authorisation holder to inform us if something happens meanwhile on this area or obtain some useful information through the veterinary pharmacovigilance system, when the complains are effective and proclaimed.
	Biocide use categories (wood preservatives) regulated by the Direcção Geral de Protecção das Culturas (see Table 1, Annex 1)	
	So far data on efficacy are not required.	Not evaluated in the case of wood preservatives**.**
SWE	All biocides which are subject to an approval procedure in Sweden (see Table 1, Annex 1)	
	According to the data requirements the manufacturer shall show that the product is efficient enough. This is not a big issue for KemI, since we believe that the market force will reject the products that are not efficient enough.	Since this problem has not yet appeared, no strategy has been developed. However, in the future when we are going to approve disinfectants according to the biocidal products directive a strategy has to be formed.
SWI	Disinfectants and wood preservatives	
	Efficacy is considered only for wood preservatives and disinfectants. For the remaining biocide use categories which are subject to an approval procedure in Switzerland, i.e., in-can preservatives, anti-fouling products, rodenticides, insecticides (indoor use) no data on efficacy are required.	• No data on development of resistance are to be reported. • After receiving information on reduced effectiveness approval will be reconsidered.

TABLE 6: EFFICACY (cont.)

Country	When required, how efficacy data are used in the regulatory procedure?	How do you address the problem of the development of resistance (or reduced effectiveness) after notification/approval?
UK	Biocides regulated (= approval procedure) by the "Control of Pesticides Regulations" (see Table 1, Annex 1)	
	Efficacy data are required to support the use of products in each of the product areas regulated under COPR. The same approach to evaluation of efficacy is adopted for each of these product areas in that the UK does not intend the evaluation process to be the basis for a product guarantee scheme. In the UK efficacy data are considered as part of the approval of non-agricultural pesticides on the basis of a flexible cost effective framework that requires a sufficient amount of data necessary to establish that a product is efficacious in relation to its conditions of approved use and that label claims are justified. Although no formal list of test methods are specified by the UK for efficacy testing in order to substantiate potential label claims made for the products under scope of COPR, detailed guidance documents outlining the nature and extent of testing required to gain approval have been produced by the UK Regulatory Authority for each of the product areas and are issued to approval holders and new applicants. In evaluation of efficacy data the UK Regulatory Authority will consider whether they demonstrate the efficacy of the product against the target pests when used normally in accordance with the conditions of approval. The data should demonstrate that use of the product (as directed by the label) will produce an acceptable level of effect, one that is consistent and results in a measurable beneficial effect over untreated controls. If the UK is not satisfied then either the product will not be recommended for approval or the label claims will be amended to reflect those which have been satisfied.	The potential for resistance would normally be highlighted and addressed during the routine review programme for an existing active substance although there may be other occasions when the UK Regulatory Authority may be asked to consider the problem (this could, for example, include times when concerns are raised with respect to the use of a pesticide or group of pesticides in particular situations e.g. use of pyrethroids for the control of fly problems in intensive animal units). Action taken could involve the incorporation of appropriate label warnings or provision of other labelling advice, or alternatively may involve the use of the active substance(s) in that situation being restricted or removed. However, in the course of considering applications for individual product approvals then where specific claims are made for the control of resistant pest strains then they must be quantified and supported by data. Where resistance is considered likely to be a problem, a strategy to help delay or reduce the likelihood of this development has to be proposed. When resistance is known to exist in specific areas of use for the product, statements have to be made with regard to the effectiveness of the formulation under these conditions.

TABLE 6: EFFICACY (cont.)

Country	When required, how efficacy data are used in the regulatory procedure?	How do you address the problem of the development of resistance (or reduced effectiveness) after notification/approval?
USA	Biocides regulated by EPA/OPP (see Table 1, Annex 1)	
	• Under FIFRA, all products are required to be efficacious. However, EPA reviews data only for **public health products**, i.e., OECD use categories 1, 4, 22, 23, 25, 26 and 29. • Under FFDCA efficacy is not a consideration.	*No information provided*
EU	All 23 biocide product types as categorised by EU (see Table 1, Annex 1)	
	The applicant must submit sufficient efficacy data to substantiate the label claim against the target organism/s in the normal conditions of use.	The principles for an harmonized evaluation of the dossiers and decision taken for the authorisation of a biocidal product by Member States are provided by Annex VI to the Directive, the Common Principles. A technical guidance document aimed to amplify and explain the Common Principles is under preparation. This document will give practical guidance, between other things, in assessing risks, effectiveness and unacceptable effects like, for example, resistance.

APPENDIX A to Table 6: Evaluation Criteria of the Drugs Directorate Guidelines for Disinfectant Drugs

Claim[1]	Device or Surface[2]	Efficacy[3]
Chemical Sterilant or Sporicide	Any device or surface	CGSB (AOAC) Sporicidal Test [4,5,6]
Tuberculocide	• Semi-critical devices • Non-critical devices or environmental surfaces in health care facilities.	• CGSB (AOAC) Tuberculocidal Test [4,5,6] • CGSB (AOAC) Tuberculocidal Test [4,5,6]
Virucide	Semi-critical devices	CGSB Testing of Virucides (Polio I virus) [4,5]
	Non-critical devices and environmental surfaces in health care facilities and food premises where food is manufactured, processed or kept.	• CGSB Testing of Virucides. If efficacy against Polio I has not been demonstrated, efficacy against specific viruses must be demonstrated and these viruses named on the label. • Efficacy data and specific directions for use required if HIV is involved.[4]
Fungicide	Semi-critical devices	CGSB (AOAC) Fungicidal Test [4]
	Non-critical devices and environmental surfaces in health care facilities and food premises where food is manufactured, processed or kept.	CGSB (AOAC) Fungicidal Test
Disinfectant	Semi-critical devices (High-level Disinfectant)	• CGSB (AOAC) Sporicidal test. Chemosterilant in not more than 10 hours [4,6] • CGSB (AOAC) Tuberculocidal test. Disinfectant contact time not less than that required for tuberculocidal activity.[4,6]
	Intermediate-Level Disinfectant	CGSB (AOAC) Tuberculocidal Test. Disinfectant contact time not less than that required for tuberculocidal activity. [4,7]
	Non-critical devices and environmental surfaces in health care facilities (Low-level Disinfectant)	CGSB (AOAC) Use Dilution Test must demonstrate efficacy against Salmonella, Staphylococcus and Pseudomonas.
	Environmental surfaces in premises where food is manufactured, processed or kept.	CGSB (AOAC) Use Dilution Test must demonstrate efficacy against Salmonella and Staphylococcus, as a minimum.

1. Except for the purpose of the pre-cleaning or storage of devices before or after sterilisation, only sporicidal claims are acceptable for critical devices.
2. The type of device (e.g., Spaulding classification (7, 14), Appendix I), environmental surface or area must be specified on the label, with examples, as appropriate.
3. These criteria are not directly applicable to gaseous sterilants or disinfectants for contact lenses.
4. Supporting data is to be submitted with the DIN application.
5. Virucidal data to support a claim for efficacy against HIV does not need to be submitted with the DIN application under these circumstances.
6. The titre of the inoculum must be sufficient to be able to demonstrate at least a 6 log kill.
7. The titre of the inoculum must be sufficient to be able to demonstrate at least a 4 log kill.

TABLE 7: LABELLING

PC: Physical/chemical properties, H: Human health toxicity, **E**: Ecotoxicology, **F**: Environmental fate, **W**: Waste management

Country	• Product types/use categories labelled • Are labelling requirements for biocides harmonized with the labelling requirements of non-biocide products?	How are biocides labelled?		Use specified? (Y/N)	Labelled for hazard?	Includes warnings/ restrictions based on risk?	Target pests indicated? (Y/N)	Instructions for use on label or in companion document? (L/CD)	Guidance or instructions on application rates? (G/I)
		Labelled as biocides	Covered by general chemical labelling						
AUS	Veterinary area and domestic animal disinfection [4]; Food/feed area disinfectants for use on/in agricultural premises, food storage and processing, dairies [5]; Industrial microbiocides / slimicides for use in cooling towers [8]; Underwater paints / treatments, anti-foulants [12]; Wood preservatives [13]; Structural pesticides [14]; Swimming pools [18]; Hot baths [19]; Spas [20]; Ornamental ponds [21]; Rodenticides [22]; Avicides [23]; Piscicides [24]; Repellents [25]; Insecticides (indoor, outdoor) [26]; Insecticides/ acaracides direct use on humans /clothes /pets [27]; Molluscicides [28]; Other vertebrates [29].		√	Y	PC, H, E, F	PC, H, E, F	Y	L	I
	The labelled risk and safety phrases are not harmonised between agricultural and industrial chemicals. However, all specific labelling requirements for biocides are harmonized with the labelling requirements of those non-biocide products defined as agricultural pesticides. The Ag Labelling Code describes Australia's specific labelling requirements for these products.								
AUT	• Disinfectants for use: - in households - for premises, equipment, furniture and transport containers serving for handling and storage of food, food additives, and cosmetics. • Preservatives for food or feed stocks • Rodenticides [22], Insecticides [26], Acaricides, Fungicides • All biocidal products falling under the scope of this survey, if they have one or more dangerous properties		√		PC, H	PC, H		L	G`

TABLE 7: LABELLING (cont.)

Country	• **Product types/use categories labelled** • **Are labelling requirements for biocides harmonized with the labelling requirements of non-biocide products?**	**How are biocides labelled?**		**Use specified?** (Y/N)	**Labelled for hazard?**	**Includes warnings/ restrictions based on risk?**	**Target pests indicated?** (Y/N)	**Instructions for use on label or in companion document?** (L/CD)	**Guidance or instructions on application rates?** (G/I)
		Labelled as biocides	Covered by general chemical labelling						
BEL	• Biocides for non agricultural use, i.e. the use categories regulated by the Royal decree June 5, 1975, are labelled according to Dir. 67/548/EEC, Dir. 88/379/EEC and Royal Decree June 5, 1975. The labelling for these products is harmonised with other no-biocide products, since is based on EC Directives or proposals.	√		Y	PC, H, E, F	PC, H, E, F	Y	L, CD	I
	• Biocides for use in agriculture, i.e. the use categories regulated under the Royal decree of 28/02/94. • The labelling is harmonised with pesticides.	Labelled as pesticides		Y	PC, H, E, F	PC, H, E, F	Y	L or CD	I
CAN	1 to 5 Disinfectants / sanitizers:	√		Y	PC, H	PC, H	Y	L	G
	6 Disinfectants would not have specified biocide labelling requirements under the proposed legislation. However, NSF standard 60 required the following: the product container shall be clearly identified with the manufacturer's name and address, product identification, net weight, lot number and, where applicable, any special precautions for handling, storage and use.								

TABLE 7: LABELLING (cont.)

Country	• Product types/use categories labelled • Are labelling requirements for biocides harmonized with the labelling requirements of non-biocide products?	How are biocides labelled?		Use specified? (Y/N)	Labelled for hazard?	Includes warnings/ restrictions based on risk?	Target pests indicated? (Y/N)	Instructions for use on label or in companion document? (L/CD)	Guidance or instructions on application rates? (G/I)
		Labelled as biocides	Covered by general chemical labelling						
CAN (cont.)	18. Swimming pools 19. Hot baths 20. Spas 21. Ornamental ponds 22. Rodenticides 27. Insecticides/acaricides (direct use on humans/clothes/pets) 28. Molluscicides	√		Y	PC, H	PC, H	Y	L	I
	7. In-can preservatives 9. Material preservatives 10. Film Preservatives	√		Y	PC, H	PC, H	Y	L or CD	I
	12. Anti-fouling products 14. Structural pesticides 23. Avicides 24. Piscicides 25. Repellents 26. Insecticides (indoor/outdoor) 29. Other vertebrates	√		Y	PC, H	PC, H, E, F	Y	L	I
	8. Industrial microbiocides/slimicides 13. Wood preservatives 15. Sewage disposal areas 16. Refuge/solid waste sites 17. Control of microbes in strip mine acid	√		Y	PC, H	PC, H, E, F	Y	L or CD	I

TABLE 7: LABELLING (cont.)

Country	• **Product types/use categories labelled** • **Are labelling requirements for biocides harmonized with the labelling requirements of non-biocide products?**	**How are biocides labelled?**		**Use specified?** (Y/N)	**Labelled for hazard?**	**Includes warnings/ restrictions based on risk?**	**Target pests indicated?** (Y/N)	**Instructions for use on label or in companion document?** (L/CD)	**Guidance or instructions on application rates?** (G/I)
		Labelled as biocides	Covered by general chemical labelling						
CAN (cont.)	Both biocides and agriculture use pesticides have the same labels requirements under the PCPA - as specified in section 27 of the PCP Regulations. Some harmonization with non biocide labelling requirement already exists (for all examples mentioned in the above question) e.g. labelling requirements for Transportation of Dangerous Goods. Further harmonization is being considered for products regulated as pesticides (biocides and agricultural pesticides) and those regulated as hazardous chemicals.								
DEN	• Disinfectants regulated by the Danish Veterinary and Food Administration		√	Y	H	H	N	L	N
	• Biocides regulated by Danish Environment Protection Agency For biocides subject to approval the labelling requirements are harmonised with those of plant protection products. For other biocides the labelling requirements follow the rules of EU-Directives on classification and labelling.	√		Y	PC, H, E	PC, H, E	Y	Y?	I

TABLE 7: LABELLING (cont.)

Country	• **Product types/use categories labelled** • **Are labelling requirements for biocides harmonized with the labelling requirements of non-biocide products?**	**How are biocides labelled?**		**Use specified?** (Y/N)	**Labelled for hazard?**	**Includes warnings/ restrictions based on risk?**	**Target pests indicated?** (Y/N)	**Instructions for use on label or in companion document?** (L/CD)	**Guidance or instructions on application rates?** (G/I)
		Labelled as biocides	Covered by general chemical labelling						
FIN	• Wood preservatives (heavy duty, anti-sapstain, remedial) [13]	√		Y	PC, H	PC, H, E, F, W	Y (only in general terms)	CD	I
	• Wood preservatives used as a paint	√		Y	PC, H	PC, H, E, F, W	Y (only in general terms)	L	I
	• Structural pesticides [14]	√		Y	PC, H	PC, H, W	Y	L CD (sometimes)	I
	• Industrial slimicides [8b, 8d]	√		Y	PC, H	PC, H, E, F, W	Y (sometimes)	CD	I
	• Indoor rodenticides [22]	√		Y	PC, H	PC, H, W	Y	L CD (sometimes)	I
	• Outdoor rodenticides [22]	√		Y	PC, H	PC, H, E, F, W	Y		
	• Repellents [25]	√		Y	PC, H	PC, H, W	Y (sometimes)		
	• Indoor insecticides and acaricides [26a]	√		Y	PC, H	PC, H, W	Y (sometimes)		
	• Outdoor insecticides [26b]	√		Y	PC, H	PC, H, E, F, W	Y (sometimes)		
	All the above product types are covered in Finland by general chemical labelling rules but in addition they are labelled as biocides. This means the hazard symbols and risk and safety phrases come from general chemicals legislation but in addition there are further phases (e.g. indication of intended use, reference to separate instructions of use and registration/authorisation decision number) required specifically for only biocides.								

TABLE 7: LABELLING (cont.)

Country	• **Product types/use categories labelled** • **Are labelling requirements for biocides harmonised with the labelling requirements of non-biocide products?**	**How are biocides labelled?**		**Use specified?** (Y/N)	**Labelled for hazard?**	**Includes warnings/ restrictions based on risk?**	**Target pests indicated?** (Y/N)	**Instructions for use on label or in companion document?** (L/CD)	**Guidance or instructions on application rates?** (G/I)
		Labelled as biocides	Covered by general chemical labelling						
FR	• Wood preservatives, for wood in contact with fruits and vegetables • Food area disinfectants	√		Y	PC, H EEC directives	PC, H EEC directives	N	L	I
	The labelling for the hazard of biocides is regulated by the decree of 28 March 1989, which transposes to the French legislation the EC Directive 78/631 of 26 June 1978 on the approximation of laws of the Member States relating to the classification, packaging and labelling of dangerous pesticides. However, this decree covers only the classification of certain substances based on calculations of the acute toxicity. Therefore, complementary classification criteria are applied according to the decree of 21 February 1990, which transposes the EC Directive 88/379 of 7 June 1988 on the classification, packaging and labelling of dangerous chemical substances.								
GER	• Wood preservatives for construction products and "RAL" products		√	Y	PC, H, E (Chemicals Act)	• risk phrases • safety phrases (according to the GefStoffV and additional phrases)	Y	CD	I
	• Disinfectants and products for pest control regulated by the FCDA § 10c The labelling requirements for the above biocide products are not harmonised with the labelling requirements of non-biocide products.		√	Y			Y	L (if possible)	
GR	• Biocides use categories regulated by National Drug Organisation. For labelling, the final draft of Biocides Directive (article 20) and the Directive 88/379/EC are followed.	√		Y	PC, H, E, F	PC, H, E, F	Y	L and CD	I

TABLE 7: LABELLING (cont.)

Country	• Product types/use categories labelled • Are labelling requirements for biocides harmonized with the labelling requirements of non-biocide products?	How are biocides labelled?		Use specified? (Y/N)	Labelled for hazard?	Includes warnings/ restrictions based on risk?	Target pests indicated? (Y/N)	Instructions for use on label or in companion document? (L/CD)	Guidance or instructions on application rates? (G/I)
		Labelled as biocides	Covered by general chemical labelling						
GR (cont.)	• Biocides use categories regulated by the Ministry of Agriculture. Labelling of biocides is harmonised with the labelling requirements of non-biocide products.	√		Y	PC, H, E, F	PC, H, E, F	Y	L and CD	I
HUN	• Wood preservatives [13] • Products for use in vertebrate and invertebrate control [22, 25, 26, 27]	√		Y	H	H	Y	L or CD	G or I
IRL	• All biocides regulated in Ireland (see Table 1)	√		Y	PC, H, E, F	PC, H, E, F	Y	L/ CD as appropriate	G/I
NL	• All biocides regulated in the Netherlands (see Table 1)	√		Y	Y (all test areas)	Y (all risk areas)	Y	L or CD	G mostly or I
	The labelling requirements are harmonised with the requirements for agricultural pesticides.								
NZ	12. Anti-fouling products 13. Wood preservatives		√	Y	PC, H	PC, H	Y	L	G
	22 to 29 Vertebrate/invertebrate pest control		√	Y	PC, H, E	PC, H, E	Y	L	G
	Biocide labelling with respect to human safety, particular occupational health, are based on those established for hazardous chemicals in general, while for those biocides that require *approval*, additional labelling for environmental and consumer safety are required.								

TABLE 7: LABELLING (cont.)

Country	• **Product types/use categories labelled** • **Are labelling requirements for biocides harmonized with the labelling requirements of non-biocide products?**	**How are biocides labelled?**		**Use specified?** (Y/N)	**Labelled for hazard?**	**Includes warnings/ restrictions based on risk?**	**Target pests indicated?** (Y/N)	**Instructions for use on label or in companion document?** (L/CD)	**Guidance or instructions on application rates?** (G/I)
		Labelled as biocides	Covered by general chemical labelling						
POR	• Pesticides for: - domestic/indoor use (insecticides [26], acaracides, rodenticides [22], repellents [25]) - "industrial use" / public health / professional use	√		Y	PC, H	PC, H	Y	L	G
	- direct use in humans	√		Y	PC, H	PC, H	Y	L and/or CD	G
	• Wood preservatives [13] • Pesticides for external use on food producing animal species • Disinfectants for use on food producing animal species • Pesticides for external use on pets, ornamental birds and their environment • Disinfectants for pets and ornamental birds	√		Y	PC, H	PC, H, E	Y	L	G
	At present, the labelling requirements for biocidal products are harmonised with the labelling of pesticides.								
SWE	• All biocides registered by KemI	As pesticides		Y	PC, H, E, F	PC, H, E, F	Y	L or CD	G
	The labelling for pesticides, both biocides and agricultural pesticides, are harmonized. However, these labels may differ from the labels of other chemicals and contain R-phrases developed specifically for pesticides.								
SWI	1-6 Disinfectants (not sanitizers)	√		Y	H		Y	L	G
	12. Anti-fouling products	√		Y	H		N	L and CD	I
	13. Wood preservatives	√		Y	E, H	E	Y	L and CD	I
	Biocides are labelled in the same way as general chemicals and agricultural pesticides for human health toxicity.								

TABLE 7: LABELLING (cont.)

Country	• Product types/use categories labelled • Are labelling requirements for biocides harmonized with the labelling requirements of non-biocide products?	How are biocides labelled?		Use specified? (Y/N)	Labelled for hazard?	Includes warnings/ restrictions based on risk?	Target pests indicated? (Y/N)	Instructions for use on label or in companion document? (L/CD)	Guidance or instructions on application rates? (G/I)
		Labelled as biocides	Covered by general chemical labelling						
UK	12. Anti-fouling products		√	*No information provided*					
	13. Wood preservatives 14. Structural treatments 22. Rodenticides 23. Avicides 25. Repellents 26. Insecticides 27. Insecticides/acaricides 28. Molluscicides 29. Other vertebrates	√		Y	PC, H, E	PC, H, E	Y	L	I
	⇒ Anti-fouling products (use category 12) are labelled in the same way as general chemicals. All other products are labelled using the same approach as for agricultural pesticides. ⇒ The criteria for some hazard end points (particularly acute toxicity and effects on the environment) differ slightly from those used for general chemicals, but in other cases are the same. ⇒ There is an element of risk-based labelling included in labels for pesticides whereas labelling for general chemicals is hazard based. ⇒ Many of the hazard and safety phrases used for labelling pesticides are read across from those used for general chemicals. ⇒ Requirements for specific types of product (e.g. labelling of aerosols) or type of effect (availability of carcinogens, mutagens and substances toxic to reproduction to the general public) are as for all chemicals.								

TABLE 7: LABELLING (cont.)

Country	• **Product types/use categories labelled** • **Are labelling requirements for biocides harmonized with the labelling requirements of non-biocide products?**	**How are biocides labelled?**		**Use specified?** (Y/N)	**Labelled for hazard?**	**Includes warnings/ restrictions based on risk?**	**Target pests indicated?** (Y/N)	**Instructions for use on label or in companion document?** (L/CD)	**Guidance or instructions on application rates?** (G/I)
		Labelled as biocides	Covered by general chemical labelling						
USA	• All biocides regulated by EPA		√	Y	PC H (primarily for acute toxicity), E F (sometimes, if the pesticide is known to leach or persist)	PC, H, E, F	Y Public health products are always required to specify the target pest by name. Biocides that are solely of aesthetic or economic significance (preservatives, processing systems, wood preservatives) may not list specific pests by name.	L or CD On label attached to product, or in labelling, defined to include materials that accompany the product in sale or distribution	I (all products are required to have specific application rates) and G (in addition, labelling often provides non-binding guidance on dosage ranges, or how to vary dosages depending on use factors.
	Most labelling requirements for warnings, restrictions, precautions, hazard, and use directions are the same for products having similar characteristic, toxicity, hazards, etc. For example, toxicity warnings are the same for agricultural and non-agricultural products. However, worker protection standards and associated labelling (personal protective equipment, restricted entry intervals) are limited to agricultural products.	Products are not required to be labelled with the term "biocide." Instead, they are labelled more specifically as disinfectants, preservatives, slimicides, wood preservatives, anti-foulants, etc.							
EU	• All the EU use categories as listed in Table 1.	√		Y	PC, H, E	PC, H, E, F	Y	L	I
	Biocides will be classified, packed and labelled in accordance to the provisions laid down in Directive 88/379/EEC, ruling the classification, packaging and labelling of dangerous preparations. A Commission proposal amending this Directive is under discussion in the European Parliament and the Council. It will lay down the general provision for the classification, packing and labelling of dangerous preparations, including biocides and agricultural pesticides. Other specific requirements are specified in article 20 of the proposed Directive.								

TABLE 8: HUMAN AND ENVIRONMENTAL EXPOSURE ASSESSMENTS

Country	Human exposure assessments	Environmental exposure assessments
AUS	Biocides regulated (= approval procedure) by the Agricultural and Veterinary Chemicals Code (see Table 1, Annex 1)	
	Occupational exposure assessment considers: ◊ primary handlers; ◊ secondary handlers where there is a close time correlation with the primary task, for instance moving freshly treated timber; ◊ different formulation types, differently; ◊ different occupational methods differently.	Environmental hazard assessments are conducted for biocides regulated under the National Registration and (for those not defined as a pesticide) Industrial Chemicals (Notification and Assessment) Schemes. In determining environmental exposure, Environment Australia (the advisory agency on environmental issues to the National Registration Authority) considers the environmental fate of a chemical, or how it will be transported and degraded in the environment. Important considerations are: • the biological, physical and chemical properties of the compound; • the method of application and; • the use pattern. **Usage data**, either prospective or retrospective, is a fundamental requirement for environmental assessment. Detailed descriptions of use patterns are also required as the basis for determining environmental exposure. Simple **fugacity models** (Mackay level 1) are also used to assess environmental exposure.
BEL	Biocides for non agricultural use, regulated by the Royal decree June 5, 1975 (see Table 1, Annex 1)	
	Exposure assessment is performed on case-by-case basis	Environmental exposure assessments are based in most of the cases on **usage data**, however, preference is given to real monitoring data.
	Biocides for use in agriculture, regulated under the Royal decree of 28/02/94 (see Table 1, Annex 1)	
	Exposure assessments are not yet performed.	In case of estimating environmental exposure (depending on the use), data generally comparable to those prescribed by Directive 91/414/EC will be required.

TABLE 8: HUMAN AND ENVIRONMENTAL EXPOSURE ASSESSMENTS (cont.)

<table>
<tr><th>Country</th><th>Human exposure assessments</th><th>Environmental exposure assessments</th></tr>
<tr><td rowspan="4">CAN</td><td colspan="2">Disinfectant products for human drinking water (part of use category 6)</td></tr>
<tr><td>For drinking water disinfectants, the standard to be prescribed (NSF standard 60) is concerned with the end use of the treated drinking water, that is the persons who will drink it, not with the handlers of the disinfectants.</td><td>For drinking water disinfectants, there are no immediate plans to conduct environmental exposure assessments. However, an assessment will be performed for disinfectants considered “new substances”, as defined under the Canadian Environmental Protection Act (CEPA).</td></tr>
<tr><td colspan="2">All the biocides regulated by the Pest Management Regulatory Agency (see Table 1, Annex 1)</td></tr>
<tr><td>Generally, the exposure assessment portion of the human health assessment is conducted the same way for all biocides. The Occupational Exposure Assessment Section (OEAS) of the Pest Management Regulatory Agency, requests registrants to provide exposure data for individuals handling the end-use product, and for some instances of secondary exposure (as per the following table) in order to assess the safety of the product.
Table 1. Biocides use where an exposure assessment is conducted:
<table>
<tr><th>Anti-microbial Type</th><th>Manufacture of biocide</th><th>Pesticide application/addition of pesticide to system</th><th>Post-application</th></tr>
<tr><td>Material preservative</td><td>No</td><td>Yes</td><td>No (except metalworking fluids)</td></tr>
<tr><td>Swimming pools</td><td>No</td><td>Yes</td><td>Yes</td></tr>
<tr><td>Wood preservatives</td><td>No</td><td>Yes</td><td>Yes</td></tr>
<tr><td>Cooling water</td><td>No</td><td>Yes</td><td>No</td></tr>
<tr><td>Oil field recovery water</td><td>No</td><td>Yes</td><td>No</td></tr>
<tr><td>Anti-fouling paints</td><td>No</td><td>No (refers to the addition of the biocide to the paint batch)</td><td>Yes</td></tr>
</table></td><td>Canadian environmental exposure assessments are based on the following factors:
1. The proposed Use Site Category (USC)
2. The maximum application rate and the number of application per year/season;
3. The method of application;
4. The formulation; and
5. The result from laboratory studies on environmental chemistry and fate and field studies on the dissipation of the active ingredient(s) and major transformation products.
The Pest Management Regulatory Agency (PMRA), Health Canada, has defined 33 Use Site Categories (USC) for pesticides. These categories can be subdivided into agricultural/forestry, industrial and societal groups. Products that fulfil the criteria for a biocide’ could be placed in fourteen of the 33 PMRA USC based on the proposed use(s) of the product.
Data requirements for each Use Site Category were determined on the basis of the potential exposure of the biocide to different compartments of the environment. These are summarised in the what are called DACO tables specific to a USC.
Studies that are listed as required data (designated R) must be submitted for all products in the USC. Conditional required data (designated CR) are determined by the properties of the product and the intended use. Exposure scenarios are conducted for terrestrial and aquatic environments. For multiple applications, the persistence of the compound is taken into consideration. The DT50 values from laboratory or field studies are employed to determine the maximum environmental concentration of the active ingredient(s).</td></tr>
</table>

TABLE 8: HUMAN AND ENVIRONMENTAL EXPOSURE ASSESSMENTS (cont.)

Country	Human exposure assessments	Environmental exposure assessments
CAN (cont.)	All the biocides regulated (= approval procedure) by the Pest Management Regulatory Agency (PCPA) (cont.)	
	However, exposure information on persons occupationally exposed to the product when it is manufactured has not been requested in the past. Registrants have voluntarily submitted this information on occasion. Generally, the use of a product or material with an anti-microbial pesticide in it is not assessed unless the product or material has pesticidal claims. Usually only the use of the end use product (i.e. the product which is actually used) is assessed. Specific post application end - uses are assessed if the product applied has pesticidal properties (e.g., anti-fouling paints) or there is a high potential for exposure (e.g., swimming pool biocides, wood preservatives, textiles etc.). The approach for assessing exposure is not different for different formulation types or application sites, however it is understood that different formulation types and application sites will have different exposure potentials. Home use products may require an exposure assessment for children as well as the person applying the product, if children are potentially exposed to the biocide. The approach to human health assessments in general is tiered, requiring some exposure data to quantify exposure. The risk assessment is then conducted comparing the exposure potential to a No Observable Effect Level (NOEL) of the most appropriate toxicity study, relevant to the exposure pattern and toxic endpoint of concern. If the margins of safety (MOS) determined in the risk assessment are inadequate, then further measure may be required to refine the exposure assessment (e.g., dermal absorption data). This general approach pertains to new active ingredients for most pesticides. New product registrations for existing active ingredients do not generally require a quantitative exposure assessment if the exposure potential is not expected to be greater than that of existing products. There is some consideration given to exposure to the general public, under CEPA. Exposure as a result of use and from environmental sources are broadly considered under CEPA.	For the terrestrial scenarios, values from Hoerger and Kenaga (Hoerger, F. And Kenaga, E.E. 1972. Pesticide Residues on Plants: Correlation of Representative Data as Basis for Estimation of Their Magnitude in the Environment. In: Coulston, F. and Korte, F. (eds.) *Global Aspects of Chemistry, Toxicology and Technology as Applied to the Environment*, Vol.I. Thieme, Stuttgart, and Academic Press, New York. pp. 9-28) are used for residues on food. If empirical data are available for residues on food sources used by species that would be found in the areas of intended use, these values are used in the exposure assessment. For the aquatic scenarios, the sources of contamination of open aquatic environments are runoff, drift, direct over spray (for forestry), and leaching from treated products (e.g., heavy duty wood preservatives and anti-fouling coatings). In general, mitigating label statements are included on the label where there are concerns regarding persistence (i.e., lack of breakdown via hydrolysis, photolysis or biotransformation), mobility (i.e., leaching, surface runoff or volatilization), accumulation (i.e., lack of dissipation with a potential for carryover), or impact on non-target organisms (e.g., algae, aquatic invertebrates, fish, beneficial insects, birds, mammals and plants). The PMRA is currently evaluating spray models for aerial and ground applications. Such models would be used for determining buffer zones. Monitoring data are not normally submitted, however, these data would be used in the environmental assessment if they were provided be the applicant. Monitoring data can be requested to resolve outstanding concerns and may be applied as a condition of temporary or time-limited registration. The data gathered from monitoring can be used to determine if registration will be continued or if additional conditions will be imposed on registration of the product. For more information related to environmental assessments for products regulated as pesticides under PCPA, there are two guidance documents: Guidelines for Determining Environmental Chemistry and Fate of Pesticides (T-1-255, October 1987) and Suggested Guidelines for Environmental Toxicology Studies. Under CEPA, the primary focus is the assessment of the effects on the aquatic environment. Other environmental factors could be considered, such as effects on wildlife or climate change issues. Important data elements include inherent toxicity, persistence and bioaccumulation. Environmental exposure is also estimated. Usage data are requested under CEPA. Use /monitoring data are not requested.

TABLE 8: HUMAN AND ENVIRONMENTAL EXPOSURE ASSESSMENTS (cont.)

Country	Human exposure assessments	Environmental exposure assessments
DEN	Disinfectants regulated by the Danish Veterinary and Food Administration (see Table 1, Annex 1)	
	The toxicological evaluation for each ingredient in a disinfectant is based upon acceptable daily intake (ADI). The evaluation is based on active ingredient concentration in the **eup**.	Environmental exposure is not validated separately for the types of disinfectants described in Table 1.
	Biocides regulated by Danish Environment Protection Agency (see Table 1, Annex 1)	
	• The assessment involves primary handlers. In some situations also the risks for secondary handlers are evaluated. • If relevant, we can distinguish between industry, professionals and the general public. • Different application methods are evaluated if the product gives rise to concern.	• Generally, **usage data** are required. If the product gives rise to concern monitoring data might be used. • For wood preservation by industrial processes (pressure treatment) **exposure models** might be used. Specifically, for assessing the environmental risks associated with preservatives used in the pressure impregnation of wood a procedure is developed by the Danish Environmental Protection Agency, which took into account the proposed EU biocide directive. According to this procedure it is assessed the: ◊ persistence, mobility and bioaccumulation ◊ effects on aquatic and Terrestrial Organisms based on: - the determination of the Predicted No Effect Concentration (PNEC) for every impact area; - the predicted Environmental Concentration (PEC) for each sub-environment (fresh water, salt water and soil).
FIN	• **Structural pesticides and products for pest control** as regulated in Finland (see Table 1) Human exposure assessment is focused mainly on applicators (both professional and amateur users). Toxic or very toxic products are accepted only for professional users, as also products with a formulation type considered hazardous (e.g. anticoagulant rodenticides with dust formation). • **Industrial wood preservatives, wood preservatives used as a paint and industrial slimicides** The main concern is focused on primary handlers. Secondary handling (e.g. exposure to sawdust when working treated wood) and consumers exposure are taken into consideration, when relevant. The products of these groups, excluding the wood preservatives used as paints, may not be used by general public.	• **Industrial wood preservatives and slimicides** The general approach to environmental exposure assessment is to calculate examples of local predicted environmental concentrations (PECs) which can be expected in a reasonable worst case, e.g. when using the maximum dose given in the proposed instructions for use. For new products, data on anticipated usage is provided in the application. For approved products, data on sold amounts is collected every year. There is only scare monitoring data available for these chemicals. The environmental exposure assessment is based on simple calculations (**models**). The calculation models for slimicides are developed in FEI but the results are compared with similar model calculations made in Sweden, if available. The calculation models for wood preservatives are based on German models (Bringenzu, S. 1992. Konzepts für die Prüfung und Bewertung der Umweltverträglichkeit von Holzschutzmitteln. Texte 13/92. Umweltbundesamt. Berlin, Germany. 85 pp. + 27 pp. appendices).

TABLE 8: HUMAN AND ENVIRONMENTAL EXPOSURE ASSESSMENTS (cont.)

Country	Human exposure assessments	Environmental exposure assessments
FIN (cont.)	• **For both the above broad categories**: Different formulation types and application methods are handled in a case-by-case basis. All relevant exposure routes are assessed and special consideration on user exposure is taken if the product is used in open systems (e.g. applied by spraying). Human exposure assessment usually includes accidental situations (worst case). The estimated or measured concentrations of biocidal substances in working places are compared with the TLV-values (threshold limit values) when possible. Usually exposure can only be assessed qualitatively, not quantitatively. These remarks are applicable to all biocidal product types regulated in Finland (see Table 1).	• **Rodenticides used indoor, repellents and, insecticides and acaricides used indoor** For these products, no environmental exposure assessment is made. However, if needed in exceptional cases it is possible to ask for usage or exposure data. • **Rodenticides and insecticides used outdoor** The environmental exposure is assessed but there are no actual methods or models e.g. for the calculation of PECs. Concerning rodenticides special attention is paid to the risk of bioaccumulation/biomagnification and secondary poisoning.
FR	Food area disinfectants and wood preservatives for wood in contact with fruits and vegetables regulated (= approval procedure) by the Ministry of Economy and Finances (see Table 1, Annex 1)	
	No information provided	*No information provided*
GER	Wood preservatives for construction products	
	No information provided	To estimate the environmental exposure the following data are required: a) Data on the chemical structural of the active ingredients and other environmental relevant components of the **eup**, on application concentrations, rates and modes. b) Exposure concentrations of the active ingredients and of the other components of an end-use product, which can be environmental relevant, are requested. Specifically, they are asked for: ◊ maximum saturation concentration; ◊ evaporation of treated wood, determined by a suitable methodology; ◊ indoor concentration; ◊ leaching from treated wood according to DIN EN 84 and DIN ENV 1250-2.

TABLE 8: HUMAN AND ENVIRONMENTAL EXPOSURE ASSESSMENTS (cont.)

<table>
<tr><th>Country</th><th>Human exposure assessments</th><th>Environmental exposure assessments</th></tr>
<tr><td rowspan="4">GER (cont.)</td><td colspan="2">Wood preservatives for construction products (cont.)</td></tr>
<tr><td>No information provided</td><td>c) The data summarised in the following table (DG1, 2, 3, 4 are the four different danger groups):
<table>
<tr><th>#</th><th>Data</th><th>DG1</th><th>DG2</th><th>DG3</th><th>DG4</th></tr>
<tr><td colspan="6">GENERAL DATA</td></tr>
<tr><td>1</td><td>Water solubility at pH 7</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>2</td><td>Water solubility at pH 4</td><td></td><td></td><td>X</td><td>X</td></tr>
<tr><td>3</td><td>pKa</td><td></td><td></td><td>X</td><td>X</td></tr>
<tr><td>4</td><td>Vapour pressure</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>5</td><td>Pow</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td colspan="6">SOIL/ WATER/ SLUDGE OF SEWAGE TREATMENT PLANS</td></tr>
<tr><td>6</td><td>Hydrolysis</td><td></td><td></td><td>X</td><td>X</td></tr>
<tr><td>7</td><td>Leaching from treated wood</td><td></td><td></td><td>X</td><td>X</td></tr>
<tr><td>8</td><td>Adsorption/ Desorption in soil</td><td></td><td></td><td>X</td><td>X</td></tr>
<tr><td>9</td><td>Distribution in water / sediment/ sludge</td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="6">AIR (Vapour pressure > 10^{-3} [Pa])</td></tr>
<tr><td>10</td><td>Evaporation from treated wood</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>11</td><td>Photolysis</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>12</td><td>Photochemical-oxidation decomposition</td><td colspan="4">Conditionally, depending on the results of 6, 10 and 11</td></tr>
</table></td></tr>
<tr><td colspan="2">Disinfectants and pest control products regulated (= approval procedure) by the Federal Communicable Diseases Act (on voluntary basis) (see Table 1, Annex 1)</td></tr>
<tr><td></td><td>The work is under preparation</td></tr>
<tr><td>GR</td><td>Biocide use categories regulated by the Ministry of Agriculture (see Table 1, Annex 1)</td><td>All biocide use categories regulated by National Drug Organisation and the Ministry of Agriculture (see Table 1, Annex 1)</td></tr>
<tr><td></td><td>The biocides regulated by the Ministry of Agriculture are divided into two categories:
⇒ wood preservatives
⇒ all the other product types/use categories
Human exposure assessments are different for these two categories due to the specific use and intrinsic properties of wood preservatives.</td><td>Presently neither monitoring nor exposure models are used in making the environmental exposure assessments. The only data used for the environmental exposure assessment are those provided by the applicant and/or the literature.</td></tr>
</table>

TABLE 8: HUMAN AND ENVIRONMENTAL EXPOSURE ASSESSMENTS (cont.)

Country	Human exposure assessments	Environmental exposure assessments
HUN	All biocides which are subject to an approval procedure in Hungary (see Table 1, Annex 1)	
	In the human exposure assessment the potential toxicity of the product, the type of people (primary handlers or secondary handlers, professional users or home users) and the exposure sites (factory or home) are considered. Formulation types and application methods are also important factors.	In the environmental exposure assessment **usage data** may be required. Inter alia, the following basic documents are used for environmental exposure assessments as well as risk assessment: ⇒ Council Directive 94/43/EC establishing Annex VI to Directive 91/414/EEC concerning the placing of plant protection products on the market. ⇒ Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No. 1488/94 on Risk Assessment for Existing Substances. European Commission, 1996-1997.
IRL	All biocides which are subject to an approval procedure in Ireland (see Table 1, Annex 1)	
	⇒ Both primary and secondary handlers are taken into consideration but the primary concern is for primary handlers. ⇒ We distinguish between industry, professional users or handlers, and amateurs. ⇒ We do not subdivide exposure sites (e.g. factory, hospital, home, etc.) ⇒ Whether we treat the different formulation types differently depends on the intrinsic properties of the active ingredient and the formulated product being evaluated, the exposure anticipated and the risks arising. ⇒ Whether we treat different application methods differently or whether there are differences in approach between different product types/use categories, depends on the intrinsic properties and proposed manner of use of active ingredient and the formulated product being evaluated, the exposure anticipated and the risk arising.	For the environmental exposure assessment **usage and monitoring data** are requested. Exposure models are not used.
NL	All 19 biocide use categories which are subject to approval procedure in the Netherlands (see Table 1, Annex 1)	
	No information provided	Mostly **exposure models** are used to estimate the expected concentration in the environment (= Predicted Environmental Concentration, PEC). The PEC is compared with the Predicted No-Effect Concentration (PNEC). The models used have been specifically developed for biocides, but are closely related to the models used for exposure assessments for chemicals in general (USES). **Usage data** will be asked if they are necessary to run the model. **Monitoring data** are not asked, but monitoring is sometimes done for specific situations.

Country	Human exposure assessments	Environmental exposure assessments
NZ	All biocide use categories which are subject to an approval procedure in New Zealand (see Table 1, Annex 1)	
	When assessing the potential risks associated with a biocide all the following factors are taken into account: ⇒ the type of people who are concerned, e.g. primary handlers, secondary handlers ⇒ industry, professional users or handlers, and 'amateurs' (e.g. home use) ⇒ exposure sites (e.g. factory, hospital, home, etc.) ⇒ different formulation types (e.g. oil, dust, liquids, solids, pressurised gas, etc.) ⇒ different application methods (e.g. aerosol spray, high pressure spray, pourable liquid, solid, etc.) ⇒ the differences of product types/use categories Risk management decisions are made on a case-by-case basis for each product or group of products with similar characteristics and use patterns.	Environmental exposure assessments involve a tiered evaluation of basic chemical and physical properties of the active ingredients, and where these data indicate that the proposed use pattern could result in significant environmental exposure, additional data is requested relating to the exposure route in question. These additional data can include laboratory studies, and where necessary, more extensive field studies.
POR	Biocide use categories regulated (= approval procedure) by the Direcção-Geral de Veterinária (see Table 1, Annex 1)	
	We are concerned mainly for the primary handlers, handling end-use biocide products and for the final consumer of the treated foodstuff of animal origin. The so-called "veterinary" biocides are generally used under professional advice, recommendation or even prescription. However, they are mainly used by amateurs in their own homes or on their livestocks and the industry. Different formulations also have different precautions in their labels concerning usage, storage, dilution, special care, etc. The most important warnings are: the correct use of a product for a certain purpose, the protection of the user, the correct disposal of the unused product and its container in the environment, the protection of the people who come in every day contact with the treated targets (animals and industrial devices) and the respect for the established withdrawal period for consumer protection purposes.	We generally ask for information concerning the environment, animals and plants. However, in most of the cases such data and studies are not available. Therefore, their absence is not a real reason to deny approval. For environmental risk assessment of veterinary medical products other than GMO-containing and immunological products a exposure model is used.
	Biocide use categories (wood preservatives) regulated by the Direcção Geral de Protecção das Culturas (see Table 1, Annex 1)	
	Yes, we do some simple human exposure assessment, but without mathematical models.	Yes, an exposure assessment is always carried out**.**

TABLE 8: HUMAN AND ENVIRONMENTAL EXPOSURE ASSESSMENTS (cont.)

Country	Human exposure assessments	Environmental exposure assessments
SWE	All biocides which are subject to an approval procedure in Sweden (see Table 1, Annex 1)	
	For human exposure assessment: ⇒ the type of people who are exposed (e.g. primary handlers, secondary handlers) is considered. ⇒ we distinguish between industry, professional users or handlers, and 'amateurs' (e.g. home use). ⇒ we treat different formulation types (e.g. oil, dust, liquids, solids, pressurised gas, etc.) differently. ⇒ we treat different application methods (e.g. aerosol spray, high pressure spray, pourable liquid, solid, etc.) differently. ⇒ we do have differences in approach between different product types/use categories, depending on human exposure scenarios. • **Slimicides as one example:** The exposure situation for people who may come in contact with Slimicides in the paper and pulp industry varies, depending on the method or refilling, dosage equipment and the conditions relating to different paper machines. However, it can generally be assumed that handling and application is performed in a relatively closed manner. A major dilution of the slimicide proceeds after dosaging into the system. Hence, the potential risk for exposure is mainly limited to repeated momentary contact with the concentrated product when handling it and repeated momentary contact with water vapour and aerosols while dosaging it into the process water. Physical factors that contribute to the exposure risk are: the volatility of the active ingredient, the partition coefficient for water/air and also the maximum and average concentration of the substance in the white water. The calculations and/or measurements of these factors must then be related to the hazards assessment of the active ingredient and the probability for exposure.	In environmental exposure assessment, usage data can be asked. Also, monitoring data can be used, if available. Exposure models are used and specifically: calculations of Predicted Environmental Concentration (PEC), the fugacity model and level III (Mackay). • **Slimicides as one example:** When the exposure assessment is made for slimicides some of the applicants have performed monitoring studies to view the existence of active ingredients in the out-going water from the paper mill. Others have only made calculations to make possible to predict the concentration in the effluent. Therefore, in order to conduct a fair comparison between the different slimicidal active ingredients, KemI performs calculations of predicted environmental concentrations, PEC, according to three different scenarios. For more information read KemI report no 9/95 "risk assessment of Slimicides".
SWI	All biocides which are subject to an approval procedure in Switzerland (see Table 1)	Anti-fouling products
	Exposure assessments are not done systematically, therefore no detailed criteria are established.	For anti-fouling products we use an exposure assessment scheme based on an exposure model "standard marina". The model has been developed at our Federal Office of Environment, Forests and Landscape using MASAS software for Apple/McIntosh. ⇒ The input data are: degradation, leaching rates, log Pow, log Koc, water solubility. ⇒ The output data are: time dependent PEC in water and sediment.

TABLE 8: HUMAN AND ENVIRONMENTAL EXPOSURE ASSESSMENTS (cont.)

Country	Human exposure assessments	Environmental exposure assessments
UK	Biocides regulated (= approval procedure) by the "Control of Pesticides Regulations" (see Table 1, Annex 1)	
	Exposure assessment covers exposure to all human populations who may be exposed to the product during use or as a likely consequence of that use. As such it includes primary handlers, secondary handlers who could be exposed to significant amounts of product (e.g. workers handling significant amounts of timber treated with wood preservative immediately after treatment), bystanders who may be exposed during use of products and consumers who could be exposed following use of products or indirectly via the environment. Estimates of exposure will cover both normal use and 'foreseeable misuse'. Exposure estimates also cover different user groups (industrial, professional and the general public), exposure scenarios (in industry, occasional use in home, continuous use in home/other occupied premises like hospitals/prisons). The exposure assessment will also take account of product formulation and method of application and how these may affect the risk assessment. Exposure data comes from two major sources. These are from models or from data obtained during actual use of products. The UK has established an extensive programme of research to establish a realistic picture of exposure (both during typical and atypical working patterns) for all user groups using products subject to current UK regulations. In collecting these data we are also collecting information on subjective elements to gain a better understanding of the patterns of exposure and the impacts of controls such as the effectiveness of personal protective equipment.	An environmental exposure assessment comprises, wherever possible, a combination of the following data, including the use of models. ⇒ **Usage data** The UK agrees that usage data are very important in the development of environmental risk assessments. In order to produce a better estimate of risk following the use of products, information on the amount and patterns of use are necessary. However, currently, this information can only be obtained from the approval holders on a voluntary basis at the request of the Regulatory Authority. In the absence of these data, assessments are made on the basis of the best/most appropriate alternative information available from other sources. These estimates will inevitably be less accurate and tend towards a more cautionary assessment. ⇒ **Monitoring data** Where accurate usage data are not available, and sometimes in addition, environmental monitoring may be required. This may be carried out either by the applicant as a condition of the approval, or by the appropriate monitoring/regulatory authority. These data can be used to determine effects on non-target organisms and to establish residues levels. A substantial database has been established on a number of active ingredients in this way. ⇒ **Models** For key use patterns (e.g. anti-fouling products and the industrial use of wood preservatives) generic models are used to estimate likely exposures to different compartments of the environment and to determine PEC and PEC/PNEC ratios (for example, certain modules of the EU EUSES package and EURATGD guidelines on emission scenarios have been used). However, current experience in the UK indicates a marked disparity between model predictions and field levels determined by monitoring. Consequently, further research has been initiated to identify and validate suitable predictive models.

TABLE 8: HUMAN AND ENVIRONMENTAL EXPOSURE ASSESSMENTS (cont.)

Country	Human exposure assessments	Environmental exposure assessments
USA	All biocides regulated by EPA/OPP (see Table 1, Annex 1)	
	Exposure assessments are performed in OPP for exposure of workers or home owners, handling biocidal pesticides or articles treated with such pesticides. If EPA determines that bystanders in the workplace or the home are also likely to be exposed, EPA performs exposure assessments for them as well with the goal of assessing non dietary risk to these persons. EPA has developed an intricate set of classifications for purposes of exposure assessment - primary handlers are those handling the biocide itself and secondary handlers handle the treated article. The data, however, are required using a straightforward scheme which does not draw these distinctions. Exposure will differ as a function of the application method and formulation type. However, once the data are collected for the application methods and formulation types for which a product will be used when registered, EPA distinguishs the varieties of exposures to applicators, homeowners, etc. by means of assumptions about the duration and frequency of use of the product, the size and ventilation capacity of the facility in which it is used, and other relevant parameters.	Environmental exposure assessments for biocides are in their beginning stages in many respects in EPA. EPA obtains a certain amount of usage data for the product as a function of the labelling requirements under 40CFR Part 156.10. We are exploring the feasibility of obtaining more specific usage data about factories for which biocides enter the environment through point source effluents. It may not be fully practical to require this information of the registrant of the biocide. Monitoring data are not typically required for point source effluents with non agricultural uses. Modelling is not typically performed, although simple calculations are performed.
EU	All the biocide product types as categorised by EU (see Table 1, Annex 1)	
	Annex VI provide the general rules for the analysis of risks and decision making process. During the risk assessment, all the human populations concerned will be considered (professional users, non professional users and humans exposed directly or indirectly through the environment). As already quoted in answer to question 3.3, technical notes aimed to cover as in details as possible all the possible use/exposure scenario for each product types are under preparation. They will be used by members states as guidance for an harmonized approach in the risk assessment to Humans.	The environmental exposure assessments will always be carried out taking into consideration all factors affecting the life cycle of a biocidal product. These will be related to the manufacture of the biocidal product, the used of the biocidal product and related treated material, the disposal of the excess product, container and treated material. For the estimation of the environmental concentrations, special consideration will be given to adequately measured exposure data when available. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied.

TABLE 9: RISK ASSESSMENT

Country	Does your country have guidance(s) for the risk assessment of biocides?	Risk assessment guidance: same as for agricultural pesticides?	Risk assessment guidance: same as for industrial chemicals?	Risk assessment guidance: unique?	Remarks	Are risk assessments for treated materials performed? Risk assessment for human health?	Are risk assessments for treated materials performed? Risk assessment for the environment?
AUS	Biocides regulated (= approval procedure) by the Agricultural and Veterinary Chemicals Code (see Table 1, Annex 1)						
	No				There are no specific guidelines for risk assessment of biocides. Risk assessment is undertaken as part of the whole evaluation process.	Yes	Yes*
						* The environmental aspect of the assessment of biocides is exposure based and therefore must give close attention to use patterns, including materials to which biocides will be applied and the rates at which biocides will be lost from those materials to enter the environment.	
BEL	Biocides for non agricultural use , i.e. the use categories regulated by the Royal decree June 5, 1975 (see Table 1, Annex 1)						
	No				In principle the ratio hazard/exposure is estimated, similarly to the procedure followed for agricultural pesticides and chemical substances. For the hazard assessment, uncertainty factors are taken into account.	Yes	Yes
	Biocides for use in agriculture, i.e. the use categories regulated under the Royal decree of 28/02/94 (see Table 1, Annex 1)						
	No				The assessment is carried out on a case-by-case basis. No guidance is available. Data are evaluated following the Uniform Principles of Directive 91/414. The labelling of all components of the formulation, according to Directive 67/548/EEC is also considered.	Yes	Yes
CAN	Biocide use categories 1-5 regulated under Food & Drugs Act (FDA) (see Table 1, Annex 1)					◊ Treated wood products treated with heavy duty, anti-sapstain or remedial wood preservatives ◊ Anti-fouling paints and coatings	
	No				For products regulated as disinfectant drugs, risk assessments are not routinely done for each product applying for a Drug Identification Number (DIN). The potential risk of a product is usually dictated by its intended use e.g. disinfection of low risk areas. Potential risk can also be dictated by lack of efficacy or performance.	Yes	Yes
						◊ Paints with biocidal claims ◊ Swimming pools ◊ Metal cutting fluids	
	Disinfectant products for human drinking water (part of use category 6)						
	No				For drinking water disinfectants, there are no specific guidance documents for evaluating risk. The NSF standard 60 is the preferred tool to deal with risk-benefit considerations.	Yes	No

TABLE 9: RISK ASSESSMENT (cont.)

Country	Does your country have guidance(s)for the risk assessment of biocides?	Risk assessment guidance			Remarks	Are risk assessments for treated materials performed?	
		same as for agricultural pesticides?	same as for industrial chemicals?	unique?		Risk assessment for human health?	Risk assessment for the environment?
CAN (cont.)	Biocides use categories 7-29 regulated (= approval procedure) under Pest Control Products Act (PCPA) (see Table 1, Annex 1)					◊ Textiles, leather, rubber, carpets ◊ Paper, plastics, fuel oil ◊ Caulks, adhesives, sealant	
	No	√			There are no specific guidance on environmental or health risk assessment for biocides. However, the Pest Management Regulatory Agency (PMRA) does perform risk assessments for biocides regulated under the PCPA with a standard process, but this process is not documented.	No	No
	The same approach is taken for risk assessment for biocides as for agricultural pesticides. However, depending on factors such as the hazard level and exposure potential of the biocide varying approaches to data requirements and risk assessment may be used. The data base available for toxicology and human exposure for biocides is often reduced compared to that available for agricultural chemicals. This is especially true for products registered some time ago.						
DEN	Disinfectants regulated by the Danish Veterinary and Food Administration (see Table 1, Annex 1)						
	No					No	No
	Wood preservatives-pressure regulated by Danish Environment Protection Agency (see Table 1, Annex 1)						
	Yes			√		Yes	Yes
FIN	Industrial wood preservatives and Industrial slimicides (see Table 1, Annex 1)					Wood treated with wood preservatives (other than those used as paints)	
	Yes		√	√	Guidance documents are only used in environmental risk assessment. The main principles of the guidance for industrial chemicals are used but the detailed PEC/PNEC calculations are unique.	Yes; if the treated wood is used indoors. No comprehensive risk assessment is performed for treated wood used outdoors.	Yes
						Paper and paperboard	
						Only in exceptional cases.	No

TABLE 9: RISK ASSESSMENT (cont.)

Country	Does your country have guidance(s) for the risk assessment of biocides?	Risk assessment guidance:			Remarks	Are risk assessments for treated materials performed?	
		same as for agricultural pesticides?	same as for industrial chemicals?	unique?		Risk assessment for human health?	Risk assessment for the environment?
FR	Wood preservatives, for wood in contact with fruits and vegetables						
	No			√	Although, there is no specific guidance for the risk assessments, tests for fixation on wood are required.	Yes	
GER	Wood preservatives; disinfectants and; pest control products regulated by the Federal Communicable Diseases Act (FCDA) (on voluntary basis) (see Table 1, Annex 1)						
	No				*A guidance document is under preparation*	*Under Preparation*	
GR	Biocide use categories regulated (= approval procedure) by the National Drug Organisation and the Ministry of Agriculture (see Table 1, Annex 1)						
	No					No	No
HUN	All biocides which are subject to an approval procedure in Hungary (see Table 1, Annex 1)						
	No					No	No
IRL	All biocides which are subject to an approval procedure in Ireland (see Table 1, Annex 1)						
	Yes	√			We do not distinguish between new and existing chemicals	Appropriate treated products	
						Yes	Yes
NL	Most biocide use categories regulated at present in the Netherlands (see Table 1, Annex 1)					In principle for all treated materials in relation to their functions. Mostly: anti-foulings, wood preservatives and textile preservatives.	
	Yes; only environmental risk assessment		√		The risk assessment guidance is comparable with industrial chemicals, but adapted to specific use as a biocide.	Yes	Yes, but not elaborated. Exposure data or models are not (always) present. Omissions will be filled in.

TABLE 9: RISK ASSESSMENT (cont.)

Country	Does your country have guidance(s) for the risk assessment of biocides?	Risk assessment guidance:			Remarks	Are risk assessments for treated materials performed?	
		same as for agricultural pesticides?	same as for industrial chemicals?	unique?		Risk assessment for human health?	Risk assessment for the environment?
NZ	All biocides which are subject to an approval or notification procedure in New Zealand (see Table 1, Annex 1)						
	No	√ (For compounds requiring *approval*)			While **no formal risk assessment guidelines** have been established, the *approval* and *notification* schemes are based on risk assessment principles, generally involving tiered evaluation of exposure and toxicity data, sufficient to support a risk management decision on suitable control/labelling measures.	*No information provided*	
POR	Biocides use categories regulated (= approval procedure) by the Direcção-Geral da Saúde (see Table 1, Annex 1)						
	No information provided						
	Biocides use categories regulated by the Direcção-Geral de Veterinária (see Table 1, Annex 1)						
	Yes					◊ Livestock animals and devices ◊ Animal food industry devices	
						Yes	Yes
						◊ Pets	
						No	No
	Biocide use categories (wood preservatives) regulated by the Direcção Geral de Protecção das Culturas (see Table 1, Annex 1)						
	No					Yes	Yes, the exposure assessment is always combined with results of toxicity studies to perform an adequate risk assessment.
SWE	Slimicides					Slimicides	
	Yes			√	• "Guidelines for the evaluation of Slimicides" (prepared by Sweden and published by the Council of Europe). • KemI report on risk assessment of Slimicides 9/95.	No	No

TABLE 9: RISK ASSESSMENT (cont.)

Country	Does your country have guidance(s) for the risk assessment of biocides?	Risk assessment guidance			Remarks	Are risk assessments for treated materials performed?	
		same as for agricultural pesticides?	same as for industrial chemicals?	unique?		Risk assessment for human health?	Risk assessment for the environment?
SWE (cont.)	Anti-fouling paints					Anti-fouling paints - leaching of biocides	
	Yes			√	• "Risk assessment of anti-foulants" (prepared by Sweden/the Netherlands and published by the Council of Europe) • KemI report on anti-fouling products 2/93.	No	Yes
	Wood preservatives, Repellents, Rodenticides					Wood preservatives-treated wood	
	No			√	In the data requirement certain criteria are set up. The approvals are also based on risk assessments guidelines. However, they cannot be called complete guidance but a guidance under development.	Yes	Yes
SWI	Anti-fouling products					Anti-fouling products	
	Yes			√		No	Yes
	Other biocide products which are subject to an approval procedure in Switzerland (see Table 1, Annex 1)					Treated wood indoor	
	No					Yes	No
UK	Biocides regulated (= approval procedure) by the "Control of Pesticides Regulations" (see Table 1, Annex 1)					Vessels etc. treated with anti-foulant	
	No				Written guidance for conducting risk assessments is not available. Procedures rely on expert judgement and are based on standard approaches as described in a number of publications from e.g. IPCS and EU. These approaches are similar to those used for agricultural pesticides and general chemicals.	No	Yes
						Treated timber	
						Yes	Yes
						Furnishings etc. treated with insecticides	
						Yes	No

TABLE 9: RISK ASSESSMENT (cont.)

Country	Does your country have guidance(s) for the risk assessment of biocides?	Risk assessment guidance			Remarks	Are risk assessments for treated materials performed?	
		same as for agricultural pesticides?	same as for industrial chemicals?	unique?		Risk assessment for human health?	Risk assessment for the environment?
USA	Biocides regulated by EPA/OPP (see Table 1, Annex 1)						
	Yes; but not specific to biocides	The same for all products. However, for the special situations flagged beside, specific guidance will be needed for biocides.			Risk assessment guidance is not categorised by product type, but by scientific discipline, e.g., carcinogen risk assessment, exposure risk assessment. In all likelihood, specific guidance will eventually be articulated for biocides, particularly for worker and occupational exposure and risk assessment, for environmental exposure and ecological risk assessment, and for dietary exposure to disinfectants and sanitizers.	Yes	Yes, if appropriate (e.g., outdoor use)
EU	All the 23 biocide product types as categorised by EU (see Table 1, Annex 1)						
	Yes; it will be available for all the 23 product types of EU.	It will be unique, even if based on the same principles as those used for agricultural pesticides (Uniform principles, Annex VI to Directive 91/414/EEC) and industrial new and existing chemicals (Directive 93/67/EEC and Regulation (EC) 1488/94).			Annex VI provides the general rules for the analysis of risks and decision making process. During the risk assessment, all human populations concerned will be considered (professional users, non professional users and humans exposed directly or indirectly through the environment. Technical notes aimed to cover as in details as possible all the possible use/exposure scenario for each product types are under preparation. They will be used by members states as guidance for an harmonized approach in the risk assessment to Humans and the Environment.	Treated materials are not within the scope of the proposed Directive, however Annex VI point 15 provides that the analysis of risks connected with the production and disposal of treated materials should be carried out.	

TABLE 10: MINOR USES, LOW RISK PRODUCTS, BIOLOGICAL BIOCIDES

Country	Minor uses • **Does your country have a policy for "minor use" biocides"?** • **How do you define a minor use?**	Low risk products • **Reduced regulatory requirements for biocides of low risk?** • **If yes, what are your criteria for determining low risk?**	Biological biocides **Do you know of any biocides based on fungi, micro-organisms or viruses?**	**Does your country have formalised data requirements for the notification or approval of these products?** Biocides based on fungi	Biocides based on micro-organisms	Biocides based on viruses
AUS	Biocides regulated (= approval procedure) by the Agricultural and Veterinary Chemicals Code (see Table 1, Annex 1)					
	• There is no formal policy for "minor use" biocides. Applications for approval are often handled under the permits system. Procedures to facilitate co-operative arrangements for data development and/or to meet data requirements for minor uses are under consideration. • The definition of a minor use is given on p8 "Permits for Agricultural and Veterinary Chemical Products".	• No • Whilst there are no formal criteria for determining low risk, flexibility is implemented on a case-by case basis. Data is assessed when a submission is received. Reduced data for a low risk chemical may be accepted if low risk can be demonstrated.	Yes The NRA has registered a microbial product (Vectobac/*Bacillus thuringiensis israeliensis*) for vector control (category 26). The Rabbit Haemorhagic Disease Virus (more recently known in Australia as the rabbit Calicivirus) is an example of an agricultural viral biocide. It performs a similar function as the myxoma virus (formerly used to control rabbits but no longer effective due to resistance). Some new research is being undertaken into a disseminating virus expressing a sterility agent for vertebrate pest control, news release "CSIRO Develops Virus to Control Fertility in Pests", although the organism is not strictly a biocide. Research into a fungal biocide option, *Metarhizhium anisopliae*, for structural protection (against termites) is underway although any commercialisation remains years away.	No	No	No Whilst we have no formalised data requirements (d.r.) for biological biocides the NRA has a policy document "Guidelines for Registration of Biological Products".
BEL	Biocides for non agricultural use, i.e. the use categories regulated by the Royal decree June 5, 1975 (see Table 1, Annex 1)					
	No	No	No	Data requirements are under preparation for agricul. pesticides.		

TABLE 10: MINOR USES, LOW RISK PRODUCTS, BIOLOGICAL BIOCIDES (cont.)

Country	Minor uses • **Does your country have a policy for "minor use" biocides"?** • **How do you define a minor use?**	Low risk products • **Reduced regulatory requirements for biocides of low risk?** • **If yes, what are your criteria for determining low risk?**	Biological biocides **Do you know of any biocides based on fungi, micro-organisms or viruses?**	**Does your country have formalised data requirements for the notification or approval of these products?**		
				Biocides based on fungi	Biocides based on micro-organisms	Biocides based on viruses
BEL (cont.)	Biocides for use in agriculture, i.e. the use categories regulated under the Royal decree of 28/02/94 (see Table 1, Annex 1)					
	• Minor use policy exists in general, but has as yet never been applied on biocides (no application for minor biocide use): no registration fee, funding of data generation (if a gap exists). • Use with little (no) economical interest for enterprises.	No	No	No	No	No
CAN	Human drinking water disinfectants	• No • Although regulatory requirements are not reduced, Canada is working jointly with the USA on a process that will shorten the review process for reduced risk pesticides regulated under the PCPA.	No			
	• No • There is no definition for minor use , as it would pertain to drinking water disinfectants.					
	Biocides use categories 7-29, regulated under PCPA					
	• There is a minor use policy and program. It is not specific to biocides, but is applicable to all products where there is low volume of use and a small economic return for registrants. To date, minor use registrants have been granted for only non biocide products.					
	Biocides notified under CEPA (see Table 2)					
	• There is a tiered approach system where the data requirements vary depending on the yearly quantity or specific category. • Under CEPA, it is defined only for products destined to be exported. In addition, a low volume criteria has been established of less than 20 Kg per year for a totally new chemical/substance and less than 1000 Kg for polymers or substances already available on the Non-Domestic Substances List (NDSL).					

TABLE 10: MINOR USES, LOW RISK PRODUCTS, BIOLOGICAL BIOCIDES (cont.)

Country	Minor uses • **Does your country have a policy for "minor use" biocides"?** • **How do you define a minor use?**	Low risk products • **Reduced regulatory requirements for biocides of low risk?** • **If yes, what are your criteria for determining low risk?**	Biological biocides **Do you know of any biocides based on fungi, micro-organisms or viruses?**	**Does your country have formalised data requirements for the notification or approval of these products?**		
				Biocides based on fungi	Biocides based on micro-organisms	Biocides based on viruses
DEN	Disinfectants regulated by the Danish Veterinary and Food Administration (see Table 1, Annex 1)					
	No	No	No	No	No	No
	Biocides regulated by the Danish Environmental Protection Agency (see Table 1, Annex 1)					
	No	No	Yes; some algecides	No	No	No
FIN	All biocide use categories regulated (= approval procedure) in Finland (see Table 1, Annex 1)					
	• There is no systematic approach for minor use biocides (case-by-case basis). • A product used only for a very specific purpose, e.g. for the control of one rare harmful organism and therefore its annual use amounts are limited.	• Yes There is no written criteria for defining a low risk product; the question is handled on case-by-case basis. E.g., substances and products which are commonly used in food or in cosmetics and which are not classified as hazardous may be considered as low risk biocides. Also, the application method and use area (i.e. exposure) is taken into account (e.g. repellent candles). The procedure can be simplified by not asking statements from all authorities. Usually the documentation requirements are also waived in the case of low risk products.	Yes; products containing bacillus thuringiensis used as insecticides (in livestock shelters etc.).	No	No	No

TABLE 10: MINOR USES, LOW RISK PRODUCTS, BIOLOGICAL BIOCIDES (cont.)

Country	Minor uses • **Does your country have a policy for "minor use" biocides"?** • **How do you define a minor use?**	Low risk products • **Reduced regulatory requirements for biocides of low risk?** • **If yes, what are your criteria for determining low risk?**	Biological biocides **Do you know of any biocides based on fungi, micro-organisms or viruses?**	**Does your country have formalised data requirements for the notification or approval of these products?**		
				Biocides based on fungi	Biocides based on micro-organisms	Biocides based on viruses
FR	*No information provided*					
GER	All biocide use categories regulated in Germany (see Table 1, Annex 1)					
	No	No at present	Yes, bacillus thuringiensis subspecies israelensis for the control of larvae.	No	Yes	No
GR	All biocide use categories regulated (= approval procedure) in Greece (see Table 1, Annex 1)					
	No	No	No	No	No	No
H	All biocide use categories regulated in Hungary (see Table 1, Annex 1)					
	No	No	No	No	No	No
IRL	All biocide use categories regulated in Ireland (see Table 1, Annex 1)					
	• Yes - Cheaper registration fees - Systematic waivers • Scale of use	• Yes • Compounds widely used for many purposes and for which low risks in practice has been established.	No	Yes	Yes	Yes
NL	All 19 biocide use categories which are subject to approval procedure in the Netherlands (see Table 1, Annex 1)					
	No	• No; not all biocide categories have the same data requirements. In addition, under the Pesticides Act the possibility to make exceptions exists. • However, no criteria or general rules are documented.	Yes; bacillus thuringiensis.	Yes	Yes	Yes

TABLE 10: MINOR USES, LOW RISK PRODUCTS, BIOLOGICAL BIOCIDES (cont.)

Country	Minor uses • **Does your country have a policy for "minor use" biocides"?** • **How do you define a minor use?**	Low risk products • **Reduced regulatory requirements for biocides of low risk?** • **If yes, what are your criteria for determining low risk?**	Biological biocides **Do you know of any biocides based on fungi, micro-organisms or viruses?**	**Does your country have formalised data requirements for the notification or approval of these products?**		
				Biocides based on fungi	Biocides based on micro-organisms	Biocides based on viruses
NZ	All biocide use categories which are subject to approval procedure in New Zealand (see Table 1, Annex 1)					
	• No policy has been yet finalised. • No criteria have yet been established.	No	No	No	No	No
POR	Biocides regulated by the Direcção-Geral de Veterinária (see Table 1, Annex 1)					
	• All biocide products for veterinary use are evaluated exactly the same way. Presently, no fees have been collected from industry. The evaluation procedure is based on the compiled data provided by the industry for each product, which is subject to an authorisation before to be placed in the market. • We define of minor use those products, which are intended to be used only in pets or in ornamental and exotic bird.	No	Yes; bacillus thuringiensis.	No	Yes	No
	Biocide use categories (wood preservatives) regulated by the Direcção Geral de Protecção das Culturas (see Table 1, Annex 1)					
	All biocide products for wood preservation are evaluated exactly in the same way.	Not yet. There are no wood preservatives classified as low risk products.	No, for wood preservatives	No, we have not formalised data requirements for biological biocides. We have formalised them for no biological biocides.		

TABLE 10: MINOR USES, LOW RISK PRODUCTS, BIOLOGICAL BIOCIDES (cont.)

Country	Minor uses • **Does your country have a policy for "minor use" biocides"?** • **How do you define a minor use?**	Low risk products • **Reduced regulatory requirements for biocides of low risk?** • **If yes, what are your criteria for determining low risk?**	Biological biocides **Do you know of any biocides based on fungi, micro-organisms or viruses?**	**Does your country have formalised data requirements for the notification or approval of these products?**		
				Biocides based on fungi	Biocides based on micro-organisms	Biocides based on viruses
SWE	All biocides which are subject to an approval procedure in Sweden (see Table 1, Annex 1)					
	• No applications have been received for "minor use". With regards to biocides, the National Chemicals Inspectorate may issue waivers of the provision. • No definition is available.	• Yes • We have not set criteria. Depending on the area of use decisions are made on a case-by-case basis. It is up to manufacturer to argue that his/her product is of low risk and why. Finally KemI makes the decisions.	Yes; until now two applications have been received but the products were not registered. They were both products against micro-organisms in chemical toilets and based on the micro-organisms Bacillus licheniformis and Bacillis subtilis.	Yes	Yes	Yes Biological Pesticides may not be offered for sale or used without being approved by the National Chemicals Inspectorate according to the act (1991:639) on preliminary examination of biological pesticides. The term biological pesticide includes: micro-organisms, viruses, nematodes, insects and arachinida. The data requirements are formalised. However, the requirements are so far the same for both biocides and plant protection products.
SWI	All biocides which are subject to an approval procedure in Switzerland (see Table 1, Annex 1)					
	No	No	No	No	No	No
UK	Biocides regulated by the "Control of Pesticides Regulations" (see Table 1, Annex 1)					
	No, there is no policy, but such products have been considered on a case-by-case basis.	No	Yes; bacillus thuringiensis var istraelensis.	No	No	No

TABLE 10: MINOR USES, LOW RISK PRODUCTS, BIOLOGICAL BIOCIDES (cont.)

Country	Minor uses • **Does your country have a policy for "minor use" biocides"?** • **How do you define a minor use?**	Low risk products • **Reduced regulatory requirements for biocides of low risk?** • **If yes, what are your criteria for determining low risk?**	Biological biocides **Do you know of any biocides based on fungi, micro-organisms or viruses?**	**Does your country have formalised data requirements for the notification or approval of these products?** Biocides based on fungi	Biocides based on micro-organisms	Biocides based on viruses
USA	All biocides regulated by EPA/OPP (see Table 1, Annex 1)					
	• Yes. We have a well established minor use policy for **plant protection products** that has two aspects. First, giving industry extra time to generate data needed for registration if the data are extensive and costly in proportion to the market share of the chemical. Second, we work with the industry and a part of the US Department of agriculture which helps generate certain test data, generally residue chemistry data, on minor crops. **The first part of the policy/program applies to biocides as well, but not the second.** In practice, we have already done a lot to ease the financial burden of testing biocides by having a tiered approach for both human health (for assessment of risk to workers) and environmental fate and effects. We have also tried to limit the cost of toxicology testing for dietary burdens of disinfectants and sanitizers. (However, we still retain a requirement for extensive toxicology testing for a few high impact uses, such as swimming pool water). Because of this carefully tiered approach, generally, data required for registration of anti-microbials or biocides does not exceed the guidelines set forth in the minor use policy. Priority processing: Minor uses in general are given priority processing if they meet criteria for a minor use. Biocides are not singled out from other minor uses. EPA is directed to review minor use approvals as expeditiously as possible, with a goal of 12 months.	Yes, EPA has issued on its "reduced risk" program (PR Notice 97-3).	No	OPP considers that the data required for microbial pesticides are based on the special microbial tests applicable to these organisms. Were we to receive an application for biological biocides, we would work within the framework of the data/test methods required for microbial pesticides and then consider what information are needed for anti-microbial uses.		

TABLE 10: MINOR USES, LOW RISK PRODUCTS, BIOLOGICAL BIOCIDES (cont.)

Country	Minor uses • **Does your country have a policy for "minor use" biocides"?** • **How do you define a minor use?**	Low risk products • **Reduced regulatory requirements for biocides of low risk?** • **If yes, what are your criteria for determining low risk?**	Biological biocides **Do you know of any biocides based on fungi, micro-organisms or viruses?**	**Does your country have formalised data requirements for the notification or approval of these products?** Biocides based on fungi	Biocides based on micro-organisms	Biocides based on viruses
USA (cont.)	All biocides regulated by EPA/OPP (see Table 1, Annex 1) (cont.)					
	Exclusive use of data: Companies who register for minor uses are granted additional periods of exclusive use of data if they submit within certain timeframes. Time concessions for data submission: Minor uses are granted time concessions in submitting certain data if other uses are being supported. These can be either a delay in submitting required data, or the right to a longer submission time if a waiver is refused. In addition, minor uses may rely on data supporting a product whose approval has been cancelled. Fee waivers: Minor uses are granted fee waivers in re-registration. and in many cases for establishment of maximum residue levels (tolerances). Organisation focus: A special minor use program has been established organisationally in EPA to handle minor uses. This is paralleled by a minor use program in the U.S. Department of Agriculture, which, under a specific revolving fund, is authorised to make grants to cover up to half the cost of minor use data development. • Minor use is defined in FIFRA to be either: ⇒ use on a crop with a national acreage of less than 300,000 acres; or ⇒ Any other use which, based on criteria in FIFRA, does not provide sufficient economic incentive to support registration or re-registration, which may include public health pesticides.	Yes, EPA has issued on its "reduced risk" program (PR Notice 97-3).	No	OPP considers that the data required for microbial pesticides are based on the special microbial tests applicable to these organisms. Were we to receive an application for biological biocides, we would work within the framework of the data/test methods required for microbial pesticides and then consider what information are needed for anti-microbial uses.		

TABLE 10: MINOR USES, LOW RISK PRODUCTS, BIOLOGICAL BIOCIDES (cont.)

Country	Minor uses • Does your country have a policy for "minor use" biocides"? • How do you define a minor use?	Low risk products • Reduced regulatory requirements for biocides of low risk? • If yes, what are your criteria for determining low risk?	Biological biocides Do you know of any biocides based on fungi, micro-organisms or viruses?	Does your country have formalised data requirements for the notification or approval of these products?		
				Biocides based on fungi	Biocides based on micro-organisms	Biocides based on viruses
EU	All the biocide product types as categorised by EU (see Table 1, Annex 1)					
	The minor use concept is not foreseen in the proposed directive.	• Yes • Active substances can be used in low risk biocidal products only if they pose a low risks to humans, animals and the environments. To be considered a low risk active substance it should not be classified as carcinogenic, mutagenic, toxic for reproduction, sensitising , bioaccumulative and not readily degradable (Article 10.1 to the Directive). Furthermore, the definition of low risk biocidal products provide that they should contain only low risk active substance(s) and not contain substances of concern [Article 2.1(b)].	Yes; the proposed directive covers also products based on micro-organisms, with an authorisation process comparable to chemicals.	Yes	Yes	Yes

Annex 2

Country Biocide Use Categories

Canadian Use-Site Categories for Conventional Chemical Pesticides

Products that fulfil the criteria for a "biocide" could be placed in sixteen (indicated by shaded rows) of the 33 PRMA USC based on the proposed use(s) of the product.
(see also Canadian Cross Reference Table)

Use-Site Category	Definition	Exclusions
AGRICULTURE/FORESTRY		
1. Aquaculture – Insecticides – Herbicides – IGRs – Antifouling products	Plants or animals produced in an aquatic (marine or fresh water) environment for human consumption. Including, antifouling products for nets and pens	• for hydroponics, see Greenhouse Food Crops (USC # 5) and Greenhouse Non-Food Crops (USC # 6)
2. Aquatic Non-Food Sites – Insecticides – Herbicides – Piscicides – Molluscides – Algicides – Lampricides	Outdoor natural and man-made environments (marine or fresh water), including, but not limited to: • non-food algae • weeds • lamprey eels • fish • aquatic life stages of insects • zebra mussels and other mollusks • includes once-through treatment of industrial water systems for zebra mussel control	• Industrial Process Fluids (USC # 17) • Underwater Structures and Materials (USC # 22) • Swimming Pools (USC # 29) • Other Indoor Surfaces, Water and Air (USC # 19) • treatments of drinking water in municipal systems and private wells
3. Empty Food Storage Areas – Insecticides – Herbicides – Rodenticides – Disinfectants – Plant Growth Regulators (PGRs) – Insect Growth Regulators (IGRs)	Empty commercial premises where food is to be stored or grown, including, but not limited to: • disinfection of potato storage bins on farms and cooperatives • empty food storage or packaging areas • empty greenhouses and mushroom houses devoid of growth media	• disinfection or sanitization of all other commercial food storage areas subject to the Food and Drugs Act
4. Forests and Woodlots – Insecticides – Herbicides – Fungicides – PGRs – IGRs	Forested areas, including, but not limited to: • plantations • forest nurseries • Christmas tree plantations and nurseries • site preparation • seed production (seed orchard) • conifer release	• Ornamental Outdoor (USC # 27) • Greenhouse Non-Food (USC # 6)
5. Greenhouse Food Crops – Insecticides – Herbicides – Fungicides – PGRs – IGRs	Edible crops growing in greenhouses including, but not limited to: • mushrooms growing in mushroom houses • indoor hydroponically grown food plants • greenhouses cleared of edible crops, but containing soil and growth media	• for treatment of empty greenhouses and empty mushroom houses devoid of growth media, see Empty Food Storage Areas (USC # 3) • disinfection or sanitization of greenhouses or mushroom houses where a food crop is growing is subject to the Food and Drugs Act

Canadian Use-Site Categories for Conventional Chemical Pesticides (cont.)

Use-Site Category	Definition	Exclusions
AGRICULTURE/FORESTRY (cont.)		
6. Greenhouse Non-Food Crops – Insecticides – Herbicides – Fungicides – PGRs – IGRs	Non-food crops growing in greenhouses, including, but not limited to: • non-food crops growing hydroponically indoors	• for treatment of empty greenhouses devoid of growth media, see Empty Food Storage Areas (USC # 3)
7. Industrial Oil Seed Crops and Fibre Crops – Insecticides – Herbicides – Fungicides – PGRs – IGRs	Terrestrial plants being commercially grown only for seed production, including , but not limited to: • seed crops	
8. Livestock for Food – Insecticides – Insecticides feed-through – Insect Repellents – IGRs	Terrestrial animals and bees raised as a source of food for human consumption, including, but not limited to: • milk • meat • meat by-products • honey Also including: • topical application for ectoparasite control	• all methods other than topical application for the control of ectoparasites. All disease control agents, no matter how they are applied, subject to the Food and Drugs Act • for other treatments of animals, see Aquaculture (USC # 1) and Companion Animals (USC # 24)
9. Livestock Non-Food – Insecticides	Terrestrial animals raised for uses other than as food for human consumption, including, but not limited to: • fur-bearing animals	• Companion Animals (USC # 24) • Livestock for Food (USC # 8) • all methods other than topical application for the control of ectoparasites • All disease control agents, no matter how they are reapplied, subject to the Food and Drugs Act
10. Seed Treatments Food and Feed – Insecticides – Fungicides – Bactericides	Seed for food or feed in a commercial application facility or on a farm to prevent insect infestation or infectious diseases. Includes the planting of treated seed either indoors or outdoors. Including, but not limited to: • seed potatoes • rootstock • bulbs • cuttings • true seed	

Canadian Use-Site Categories for Conventional Chemical Pesticides (cont.)

Use-Site Category	Definition	Exclusions
AGRICULTURE/FORESTRY (cont.)		
11. Seed Treatments Non-Food – Insecticides – Fungicides – Bactericides	Seed for non-food in a commercial application facility or on a farm to prevent insect infestation or infectious diseases. Includes the planting of treated seed either indoors or outdoors. Including, but not limited to: • seed potatoes • rootstock • bulbs • cuttings • true seed	
12. Stored Food and Feed – Insecticides – Fungicides – Rodenticides – PGRs – IGRs	Stored bulk food, including, but not limited to: • grains in elevators, ships' holds, etc. • post-harvest treatment of crops (e.g., fruits, potatoes, etc.) • stored packaged food and feed • stored bulk feed • food processing areas, food processing plants, restaurants and other areas where food is present during treatment	
13. Terrestrial Feed Crops – Insecticides – Herbicides – Fungicides – PGRs – IGRs	Crops grown outdoors as a source of feed for livestock, including direct treatment of crops or the soil during one or more of the various growth stages including pre-plant and pre-emergence.	• for crops treated after harvest, see Stored Food and Feed (USC # 12)
14. Terrestrial Food Crops – Insecticides – Herbicides – Fungicides – PGRs – IGRs	Crops grown outdoors as a source of food for human consumption, including direct treatment of crops or the soil during one or more of the various growth stages including pre-plant and pre-emergence. Including, but not limited to: • non-bearing stages of plants (e.g., pre- and post-bloom fruit trees, non-bearing strawberries, etc.) • crops grown for seeds for subsequent planting • cranberries • tobacco • land to be used for future crop growth (e.g., fallow land)	

Canadian Use-Site Categories for Conventional Chemical Pesticides (cont.)

Use-Site Category	Definition	Exclusions
INDUSTRY		
15. Indoor Hard Surfaces – Hard Surface Disinfectants – Sanitizers	Indoor hard surfaces (e.g., counters, sinks, toilets and floors) in non-food areas and also in areas such as kitchens where there may be food contact. Food contamination must be avoided by appropriate label precautions.	The following antimicrobial controls are still subject to the Food and Drugs Act: • food processing and meat packaging • medical instruments • medical care facilities (e.g., hospitals and veterinary clinics) • drinking water devices
16. Industrial and Domestic Vegetation Control for Non-Food Sites – Herbicides – PGRs	Terrestrial vegetation sites on non-agricultural lands, including, but not limited to: industrial sites parking lots tennis courts rights-of-way driveways and patios	• for agricultural land to be used for a Terrestrial Food or Feed Crop in subsequent years, see Terrestrial Food Crops (USC #14) and Terrestrial Feed Crops (USC #13)
17. Industrial Process Fluids – Slimicides	Industrial process fluids, including, but not limited to: • water cooling towers (open, once-through and closed systems) • pulp and paper • drilling muds	• for slime control in other sites see Swimming Pools (USC #29) and Aquaculture (USC #1) • for ornamental ponds, see Aquatic Non-Food Sites (USC #2) • Material (USC #18)
18. Material – Material Preservatives	Products used or added to manufacture or processing to preserve the material or its function, including, but not limited to: • metal cutting fluid • leather • textiles • fuel • paint • canvas • caulking	• Underwater Structures and Materials (USC #22) • Wood (USC #23)
19. Other Indoor Surfaces, Water and Air – Slimicides – Disinfectants – Sanitizers	Including, but not limited to: • laundry • air ducts • air • water beds • humidifiers • building-related-illness treatment Food contamination must be avoided by appropriate label precautions	
20. Structural – Insecticides – Fungicides – Rodenticides – IGRs	Residential, farm, and office buildings, air, land and sea transport vehicles, ships and other commercial structures not associated with commercial food production or storage. Food contamination must be avoided by appropriate label precautions	• Indoor Hard Surfaces (USC #15) • for termite control, see Structures and Surrounding Soil (USC #21) • products for disinfectant treatments of food storage and processing areas subject to the Food and Drugs Act

Canadian Use-Site Categories for Conventional Chemical Pesticides (cont.)

Use-Site Category	Definition	Exclusions
INDUSTRY (cont.)		
21. Structures and Surrounding Soil – Termiticides	Structures and surrounding soil for preventive treatment or control of termite infestations	• Structural (USC #20)
22. Underwater Structures and Materials – Antifouling coatings	Structures intended for underwater use, including, but not limited to: • lobster traps • boat hulls • fishing nets • intake pipes	• for wood preservation of underwater structures, piers and docks, see Wood (USC #23) • aquaculture pens and nets
23. Wood – Heavy duty wood preservatives (HDWP) – Anti-sapstains – Millwork and joinery products – Remedial treatment products – Wood stains and coatings	Preservation and protection of wood and wood products. Including, but not limited to, HDWPs for wood used in underwater structures.	• Underwater Structures and Materials (USC #22) • Structural (USC #20) • Structures and Surrounding Soil (USC #21)
SOCIETY		
24. Companion Animals – Insecticides – Fungicides – Molluscides – Algicides – IGRs	Indoor and outdoor companion animals and aquatic life forms. control of pests is solely by topical application or directly to aquarium water.	• Livestock for Food (USC #8) and Non-Food (USC #9) • all other prescribed veterinary drugs • all methods other than topical application for the control of ectoparasites. All disease control agents, no matter how they are applied, subject to the Food and Drugs Act • for products to be used on pet sleeping areas, see Structural (USC #20)
25. Human Habitat and Recreational Areas – Insecticides	Commercial treatment of urban or rural habitation and recreational areas. Including, but not limited to control of: • adult biting flies • black flies • mosquitoes • other insects	• for aquatic larval stages, see Aquatic Non-Food (USC # 2)
26. Human Skin, Clothing and Proximal Sites – Insecticides – Insect Repellents	Direct application, placement in close proximity to humans (e.g., coils and candles); impregnation into, or a spraying onto materials (e.g., clothing, tablecloths and canvas).	• products intended to repel or control ectoparasites (e.g., lice) subject to Food and Drugs Act

Canadian Use-Site Categories for Conventional Chemical Pesticides (cont.)

Use-Site Category	Definition	Exclusions
SOCIETY (cont.)		
27. Ornamentals Outdoor – Insecticides – Herbicides – Fungicides – PGRs – IGRs	Non-food plants growing outdoors, including, but not limited to: • flowers • trees • shrubs • seed crops on non-agricultural land	• for grass, lawns, turf soil, sod farms, see Turf (USC # 30)
28. Indoor Plants and Plantscapes – Insecticides – Herbicides – Fungicides – PGRs – IGRs	Plants grown indoors, including, but not limited to: • shopping malls • commercial buildings • residences	• see also Terrestrial Food Crops (USC # 14)
29. Swimming Pools – Algicides – Bactericides	Water in public or private swimming pools, hot tubs, and spas.	• for ornamental ponds, see Aquatic Non-Food (USC # 2)
30. Turf – Insecticides – Herbicides – Fungicides – PGRs – IGRs	Grass sites, including, but not limited to: • lawns • golf courses • parks • recreational areas • sod farms • turf soil	• for natural grassland and pastures, see Terrestrial Feed Crops (USC # 13) • Residential Outdoors (USC # 33)
31. Various Indoor and Outdoor Sites – Animal Repellents	Products used indoors or outdoors in small quantities to repel dogs, cats, birds, bears, and other vertebrate pests.	• Terrestrial Food Crops (USC # 14) • Terrestrial Feed Crops (USC # 13)
32. Various Outdoor Sites – Vertebrate Pest Control Products – Rodenticides – Avicides	Commercial products used outdoors to control animal pests, including, but not limited to: • gophers • coyotes • wolves • birds	• Terrestrial Food Crops (USC # 14) • Terrestrial Feed Crops (USC # 13)
33. Residential Outdoors – Insecticides – IGRs	Control of domestic home and yard nuisance insects and ticks, including but not limited to: • wasps • hornets • icks • leas • mosquitoes and black flies	• any food use • for termite control, see Structures and Surrounding Soil (USC # 21) • for insect repellents, see Human Skin, Clothing and Proximal Sites (USC # 26) • Turf (USCs # 30) • Ornamental Outdoors (USC # 27)

CANADA

Cross Reference of OECD and Pest Management Regulatory Agency (PMRA) Use Site Categories

No.	OECD Product Type/Use Category	PMRA USC No.	Canadian Name of Use Site Category (USC)/Relevant Authority
1	Public Health Disinfectants and Sanitizers		Bureau of Pharmaceutical Assessment, Health Canada
2	Personal Health Care Disinfectants		Bureau of Pharmaceutical Assessment, Health Canada
3	Non Public Health (Private) Disinfectants/Sanitizers/Bacteriostats		Bureau of Pharmaceutical Assessment, Health Canada
4	Veterinary Area and Domestic Disinfection		Bureau of Veterinary Drugs, Health Canada
5	Food/Feed Area Disinfectants		Bureau of Veterinary Drugs, Health Canada
6	Drinking Water Disinfectants		Environmental Health Directorate, Health Canada
7	In-can Preservatives	18	Material / PMRA, Health Canada
8	Industrial microbiocides/slimicides	17	Industrial Process Fluids / PMRA, Health Canada
9	Material preservatives	18	Material / PMRA, Health Canada
10	Film preservatives	18	Material / PMRA, Health Canada
12	Underwater paints/treatments and antifoulants	1	Aquaculture / PMRA, Health Canada
		2	Aquatic Non-Food Sites / PMRA, Health Canada
		22	Underwater Structures and Materials / PMRA, Health Canada
13	Wood preservatives	23	Wood / PMRA, Health Canada
14	Structural pesticides	21	Structures and Surrounding Soil / PMRA, Health Canada
15	Sewage disposal areas	17?	(*most similar to)* Industrial Process Fluids / PMRA, Health Canada
16	Refuse/solid waste sites	16?	(*most similar to)* Industrial and Domestic Vegetation Control for Non-Food Sites / PMRA, Health Canada
17	Control of microbes in strip mine acid	16?	(*most similar to)* Industrial and Domestic Vegetation Control for Non-Food Sites / PMRA, Health Canada

CANADA

Cross Reference of OECD and Pest Management Regulatory Agency (PMRA) Use Site Categories (cont.)

No.	OECD Product Type/Use Category	PMRA USC No.	Canadian Name of Use Site Category (USC)/Relevant Authority
18	Swimming Pools	29	Swimming Pools / PMRA, Health Canada
19	Hot baths	29	Swimming Pools / PMRA, Health Canada
20	Spas	29	Swimming Pools / PMRA, Health Canada
21	Ornamental ponds	29	Swimming Pools / PMRA, Health Canada
22	Rodenticides	3	Empty Food Storage Areas / PMRA, Health Canada
		20	Structural / PMRA, Health Canada
		32	Various Outdoor Sites / PMRA, Health Canada
23	Avicides	32	Various Outdoor Sites / PMRA, Health Canada
24	Piscicides	2	Aquatic Non-Food Sites / PMRA, Health Canada
25	Repellents (vertebrate)	31	Various Indoor and Outdoor Sites / PMRA, Health Canada
26	a.Insectidices (indoor)	20	Structural / PMRA, Health Canada
	b.Insectidices (outdoor residence)	26	Human Skin / PMRA, Health Canada
	c.Insecticides (outdoor expanses)	25 27 33	Human Habitat and Recreational Areas Ornamental Outdoor Residential Outdoor / PMRA, Health Canada
27	Insecticides	26	Human Skin / PMRA, Health Canada
28	Molluscides	2	Aquatic Non-Food Sites / PMRA, Health Canada
		22	Underwater Structures and Materials / PMRA, Health Canada
29	Other vertebrates	32	Various Outdoor Sites / PMRA, Health Canada

CONVERSION TABLE OF THE NETHERLANDS

(*product types distinguished by OECD in relation to the classification of groups of biocides in the Netherlands with respect to registration of biocides)*

OECD broad grouping of biocides		Biocides use categories of the Netherlands
(i) Disinfectants /sanitizers	D.1	Disinfectants outside the food industry and catering, exposure of users only
	D.2	Disinfectants for the food industry, catering, animal housing etc.
	D.3	Disinfectants of material to which users are exposed after application
(ii) Preservatives / microbiocides	D.4	Preservatives
	D.5	Industrial biocides (in cooling water; in liquids during production processes, e.g. paper industry).
(iii) Anti-fouling products	C.4	Anti-fouling products
(iv) Wood preservatives and structural treatments	C.1	Wood preservatives applied outdoors or for wood to be used outdoors
	C.2	Wood preservatives applied indoors or for wood to be used indoors
	C.3	Wood preservatives on wooden packaging material in contact with food
(v) Microbiocides for waste disposal and strip mine sites	-	-
(vi) Products used in aquatic non-food sites (molluscicides, lampricides, algicides, disinfectants)	D.6	Products for swimming water
(vii) Products used for vertebrate and invertebrate pest control	H.1	Household products applied outdoors
	H.2	Household products applied indoors on surfaces
	H.3	Household products applied indoors as evaporators
	H.4	Household products applied indoors as aerial spray
	H.5	Repellents against mosquito's, applied on the human skin
	H.6	Moth repellents for textile
	H.7	Products against storage pests
	H.8	Rodenticides
	V.1	Veterinary products applied in animal housings

EU Biocidal Product Types/Use Categories

Broad grouping	Product types/use categories	Description of biocidal product types (Annex V to the Directive)
Disinfectants and general biocidal products	1. Human hygiene biocidal products	Products in this group are biocidal products used for human hygiene purposes.
	2. Private area and public health area disinfectants and other biocidal products	Products used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feed contact in private, public and industrial areas, including hospitals, as well as products used as algaecides. Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air-conditioning systems; walls and floors in health and other institutions; chemical toilets, waste water, hospital waste, soil or other substrates (in playgrounds).
	3. Veterinary hygiene biocidal products	Products in this group are biocidal products used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported.
	4. Food and feed area disinfectants	Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food, feed or drink (including drinking water) for humans and animals.
	5. Drinking water disinfectants	Products used for the disinfection of drinking water (for both humans and animals).
Preservatives	6. In-can preservatives	Products used for the preservation of manufactured products, other than foodstuffs or feedingstuffs, in containers by the control of microbial deterioration to ensure their shelf life.
	7. Film preservatives	Products used for the preservation of films or coatings by the control of microbial deterioration in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealant, wall adhesives, binders, papers, art works.
	8. Wood preservatives	Products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms. This product type includes both preventive and curative products.
	9. Fiber, leather, rubber and polymerized materials preservatives	Products used for the preservation of fibrous or polymerized materials, such as leather, rubber or paper or textile products and rubber by the control of microbiological deterioration.
	10. Masonry preservatives	Products used for preservation and remedial treatment of masonry or other construction materials other than wood by the control of microbiological and algal attack.

EU Biocidal Product Types/Use Categories (cont.)

Broad grouping	Product types/use categories	Description of biocidal product types (Annex V to the Directive)
Preservatives (cont.)	11. Preservatives for liquid-cooling and processing system	Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels. Products used for the preservation of drinking water are not included in this product type.
	12. Slimicides	Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.
	13. Metalworking-fluid preservatives	Products used for the preservation of metalworking fluids by the control of microbial deterioration.
Pest control	14. Rodenticides	Products used for the control of mice, rats or other rodents.
	15. Avicides	Products used for the control of birds.
	16. Molluscicides	Products used for the control of mollusks.
	17. Piscicides	Products used for the control of fish; these products exclude products for the treatment of fish diseases.
	18. Insecticides, acaricides and products to control other arthropods	Products used for the control of arthropods (e.g. insects, arachnids and crustaceans).
	19. Repellents and attractants	Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly.
Other biocidal products	20. Preservatives for food or feedstocks	Products used for the preservation of food or feedstocks by the control of harmful organisms.
	21. Antifouling products	Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.
	22. Embalming and taxidermist fluids	Products used for the disinfection and preservation of human or animal corpses, or parts thereof.
	23. Control of other vertebrates	Products used for the control of vermin.

ANNEX 3

Data Waiving and Tier Testing

TABLE 1: WAIVING OF DATA REQUIREMENTS

Country	Flexibility to waive data requirements?	Written criteria for waiving data requirements or case-by-case basis?
AUS	Biocides regulated (= approval procedure) by the National Authority for Agricultural & Veterinary Chemicals (NRA) (see Table 1, Annex 1)	
	Yes	The NRA has the flexibility to waive data requirements provided the conditions for approval of a pesticide can be met. These conditions are set out in the legislation. The NRA does not have detailed written criteria for waiving data requirements; flexibility is employed on a case-by case basis. A summary of broad criteria for product application types is given in the NRA's Requirements Manual for Agricultural Chemicals (Ag Manual) p29. The NRA reserves the right to adjust the requirements up or down for a particular product application according to use.
BEL	Biocides for non agricultural use, i.e. the use categories regulated by the Royal decree June 5, 1975 (see Table 1, Annex 1)	
	Yes	Case by case basis
	Biocides for use in agriculture, i.e. the use categories regulated (approval procedure) under the Royal decree of 28/02/94 (see Table 1, Annex 1)	
	Yes	Case-by-case basis, depending on the chemical nature and the use of the product.
CAN	Biocides regulated under the FDA & PCPA (see Table 1, Annex 1)	
	Yes	For certain types of products and under certain conditions data can be waived.
	Products containing biocides regulated under CEPA (see Table 1, Annex 1)	
	Yes	Under CEPA, criteria for waiving data are specified in ss26(4) of CEPA. Judgement is made on a case by case basis, if the criteria are met. Basis for waivers are generally based on: the information is not needed; substance can be contained so as to protect the environment and human life; not feasible to generate the test data.
	Disinfectants for human drinking water (part of use category 6)	
	No	For products in use category 6, flexibility is not readily available. Once in force, requirements will only be changeable through amendments to the regulations, or through amendments to the standard.
DEN	Disinfectants regulated (approval procedure) by the National Food Agency of Denmark (see Table 1, Annex 1)	
	No	
	Biocides regulated by the Danish Env. Prot. Agency (see Table 1, Annex 1)	
	Yes	The application form for biocidal products is the same as for plant protection products, i.e. the data requirements are identical. Waivers are decided on case-by-case basis.
FIN	All biocides which are subject to an approval procedure in Finland (see Table 1, Annex 1)	
	Yes	It is mostly done on a case-by-case basis. According to the general rules, it is possible not to submit a study if the performance of the study is not technically possible or scientifically justifiable. These exceptions have to be motivated by the applicant. Furthermore, there are some generally accepted rules based on intrinsic properties of chemicals to waive a certain study (e.g. highly corrosive substances need not to be tested for eye and skin irritation). In some cases, the limited exposure to the product may be accepted as a ground for waiving a certain study. Low-risk biocides as repellent candles used outdoor and containing citronella oil can be approved without any toxicological or ecotoxicological studies. In addition, in some exceptional cases, when a chemical is generally used for other purposes than as a biocide and its properties are already well known (e.g. hydrogen peroxide, boric acid) the data requirements may be waived. On the other hand, if there are strong reasons for concern (e.g. a suspect of great risk) it is always possible to require additional data (including new studies) on health or environmental effects etc.

TABLE 1: WAIVING OF DATA REQUIREMENTS (cont.)

Country	Flexibility to waive data requirements?	Written criteria for waiving data requirements or case-by-case basis?
FR	Food area disinfectants and wood preservatives for wood in contact with fruits and vegetables regulated by the Ministry of Economy and Finances (see Table 1, Annex 1)	
	Yes	The data required vary according to toxicological profile of the substance. This guides the experts to request on a case-by case basis the necessary information for a thorough evaluation of the product with respect to human health risks.
GER	Wood preservatives for construction products and "RAL"-product	
	Yes	There is a case-by-case decision depending on the exposure.
	Disinfectants and pest control products regulated by the Federal Communicable Diseases Act (FCDA) (on voluntary basis) (see Table 1, Annex 1)	
	Yes	There no established and formalised data requirements. Therefore, decisions for waiving of data requirements are taken on a case-by-case basis.
GR	Biocide use categories regulated (= approval procedure) by the National Drug Organisation and the Ministry of Agriculture (see Table 1, Annex 1)	
	No	There is no the flexibility to waive data requirements.
HUN	All biocides which are subject to an approval procedure in Hungary (see Table 1, Annex 1)	
	No	
IRL	All biocides which are subject to an approval procedure in Ireland (see Table 1, Annex 1)	
	Yes	Data requirements may be waived on a case-by-case basis depending on whether such data are considered fundamental for the clearance process.
NL	All the nineteen biocides use categories which are subject to an approval procedure in the Netherlands (see Table 1, Annex 1)	
	No	There is no flexibility to waive data requirements.
NZ	All biocides which are subject to an approval procedure in New Zealand (see Table 1, Annex 1)	
	Yes	There is such flexibility on case-by-case basis.
POR	Biocides use categories regulated by the Direcção-Geral da Saúde (see Table 1, Annex 1)	
	Yes	If the composition is the same or almost the same, a "letter of access" from the first applicant is only needed.
	Biocides use categories regulated by the Direcção-Geral de Veterinária (see Table 1, Annex 1)	
	Yes	The criteria of waiving data requirements are set on a case-by-case basis. For example, in the particular case of biocides to be used in non food-producing species, some data concerning the toxicological studies can be waived. This sometimes also occurs for old substances whose efficacy or toxicological profile is well known but not documented. However, taking into consideration the straight link between veterinary products and human health we always try to demand as much data as we do recognise as technically possible.
	Biocide use categories (wood preservatives) regulated by the Direcção Geral de Protecção das Culturas (see Table 1, Annex 1)	
	Yes	If the composition is the same, a "letter of access" from the first applicant is only needed; for old substances whose toxicological profile is well known some toxicological studies can be waived.

TABLE 1: WAIVING OF DATA REQUIREMENTS (cont.)

Country	Flexibility to waive data requirements?	
		Written criteria for waiving data requirements or case-by-case basis?
SWE	All biocides which are subject to an approval procedure in Sweden (see Table 1, Annex 1)	
	Yes	Firstly, the data requirements for both plant protection products and biocides have been the same for a long time. A couple of years ago "new" requirements were developed for the most common biocidal groups, i.e. biocides that we had received most applications for approval, e.g. slimicides, wood preservatives, antifouling products, anti-mosquito repellents and rodenticides. For the other biocidal products, the "old " data requirements (for both plant protection and biocides) are used but with considerations to the new product groups. A case-by-case judgement is made for these groups.
SWI	All biocides which are subject to an approval procedure in Switzerland (see Table 1)	
	Yes	On a case-by-case basis.
UK	Biocides regulated by the "Control of Pesticides Regulations" (see Table 1, Annex 1)	
	Yes	There is the flexibility to waive data requirements but there are no specific written criteria. Decisions are made on a case-by-case basis and may make use of reasoned cases based on scientific justification or read-across to other, similar, products.
USA	Biocides regulated (= approval procedure) by EPA/OPP (see Table 1, Annex 1)	
	Yes	This is done on a case-by-case basis. Note that most of the data requirements themselves are accompanied with descriptions of the conditions under which they must be submitted. By publishing normative criteria for requirements and conditional or tiered requirements, the Agency minimizes the need for waivers of data required.
EU	All 23 biocide product types as categorised by EU (see Table 1, Annex 1)	
	Yes	Article 8(5) and introductions of Annexes II and III provide that information which is not necessary owing to the nature of the biocidal product or its proposed uses need not to be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases, a justification, acceptable to the competent authority must be submitted. During the preparation of the document quoted in the answer to question 2.1, on the basis of the above mentioned principles, standard justifications for waiving of data will be drafted. When the final document on data requirements will be agreed by all Member States, derogation will be granted on a case-by-case basis.

TABLE 2: DATA REQUIREMENTS ORGANISED IN TIERS

Country	Data requirements for a specific product type/use category organised in tiers?			
		For which areas?	**Tier testing formalised or on a case-by-case basis?**	• **Description of a model of tier structure** • **Other remarks on data requirements**
AUS	Biocides regulated (= approval procedure) by the National Authority for Agricultural & Veterinary Chemicals (NRA) (see Table 1, Annex 1)			
	No			
BEL	Biocides for non agricultural use, i.e. the use categories regulated by the Royal decree June 5, 1975 (see Table 1, Annex 1)			
	No			
	Biocides for use in agriculture, i.e. the use categories regulated under the Royal decree of 28/02/94 (see Table 1, Annex 1)			
	No			
CAN	Biocides regulated under FDA (see Table 1, Annex 1)			
	No			For products regulated as disinfectant drugs, the efficacy data requirements are based on intended use (claim and device/surface), and are not organised in tiers
	Disinfectants for human drinking water (part of use category 6)			
	Yes	Toxicity testing requirements.		The Standard to be prescribed (NSF Standard 60) has grouped toxicity testing requirements in four tiers, based on the anticipated human exposure to the chemical itself or it impurities. The four tiers are based on the following normalized contaminant concentrations: Level I >10 ppb Level II ≥ 10 ppb and <50 ppb Level III ≥ 50 ppb and < 1000 ppb Level IV ≥ 1000 ppb
	Biocides regulated as pesticides under PCPA (see Table 1, Annex 1)			
	Yes	For products regulated as pesticides, data requirements in the occupational and bystander exposure area are organised in tiers for all product types/use categories.	Case-by-case	• **First tier**: generally involves comparing generic exposure data from published databases with no-observed effect levels from toxicology studies relevant to the use pattern under consideration to see whether the predicted exposure leads to an acceptable margin safety. Several databases have been developed, such as the North American Pesticides Handlers Exposure Database (PHED), the U.K. Predictive Operator Exposure Model (POEM), the German model and the Dutch Model. • **Second tier**: involves using dermal absorption data (if available) to refine the estimate of absorbed dose. Exposure mitigation measures (e.g. protective clothing) can also be taken into account. • **Third tier**: a field study should be considered for use patterns for which no acceptable generic data are available, or when margins of safety are inadequate based on generic exposure and dermal absorption data, if it is judged that generating additional exposure data alone will improve the quality of the risk assessment. It may be better to consider a biological monitoring approach, as absorbed dose data, interpreted with the aid of pharmacokinetics data, are likely to be more accurate than the estimate of absorption given by exposure data and correction for dermal absorption. If the risk assessment still indicates excessive exposure, further risk mitigation factors may be considered to reduce the absorbed dose to an acceptable level.

TABLE 2: DATA REQUIREMENTS ORGANISED IN TIERS (cont.)

Country	Data requirements for a specific product type/use category organised in tiers?			
		For which areas?	**Tier testing formalised or on a case-by-case basis?**	• **Description of a model of tier structure** • **Other remarks on data requirements**
DEN	Disinfectants regulated (= approval procedure) by the National Food Agency of Denmark (see Table 1, Annex 1)			
	No			
	Biocides regulated by the Danish Env. Prot. Agency (see Table 1, Annex 1)			
	Yes	• Toxicity • Fate • Ecotoxicology	Generally on a case-by-case evaluation. However, some cases are almost formalised: where products which are well known as low risk products i.e. some plant oil products, they have only to be effective to the claimed use.	• **Toxicity:** The choice of route of administration other than oral will depend upon the nature of the substance or the product. In mutagenicity testing requirements we have the normal tiered system as outlined in the data requirement in the Directive. Requirements for testing for carcinogenicity might be dependant on the outcome of mutagenicity studies. • **Fate**: Mobility in soil - adsorption test are followed by column leaching test, lysimeter and field test. • **Ecotoxicology**: Toxicity towards aquatic organisms - laboratory studies followed by micro/mesocosm studies.
FIN	Industrial slimicides for use in pulp and paper mills and cooling water systems			
	Yes	• Biodegradation • Bioaccumulation • Genotoxicity	Tier testing is formalised for biodegradation and bioaccumulation. For genotoxicity, tier testing is decided on a case-by-case basis.	• Additional studies on **biodegradation** are always required, if the compound is not readily degradable. E.g. OECD guidelines number 302 A - C (Inherent biodegradability). A study on degradation in soil is required if the active substance is slowly degradable and may reach the soil. The degradation should be studied in at least three soil types. E.g. OECD guideline number 304 A (Inherent biodegradability test in soil). • A study on **bioaccumulation** in fish is required, if the partition coefficient n-octanol/ water is over 1 000. E.g. OECD guideline number 305 E (Flow-through fish test). Additional studies on bioaccumulation are required if the bioaccumulation factor for fish is > 100. E.g. tests with other species or model ecosystem tests with several species. • **Genotoxicity studies** at gene and chromosome level are always required. At least two different in vitro tests, e.g. EEC guideline number B.14. or OECD guideline number 471 (Salmonella typhimurium, Reverse mutation assay) **and** EEC B.10. or OECD 473 (In vitro Mammalian Cytogenetic Test). In addition those in vivo studies considered necessary should be attached. For example, due to a positive result in an in vitro test, one of the following tests may be required: EEC B.11. or OECD 475 (In-vivo mammalian bone marrow cytogenetic test - chromosomal analysis) **or** EEC B.12 or OECD 474 (Micronucleus test).

TABLE 2: DATA REQUIREMENTS ORGANISED IN TIERS (cont.)

Country	Data requirements for a specific product type/use category organised in tiers?			
		For which areas?	**Tier testing formalised or on a case-by-case basis?**	• **Description of a model of tier structure** • **Other remarks on data requirements**
FIN (cont.)	Industrial wood preservatives (heavy duty, anti-sapstain, remedial)			
	Yes	• Mobility in soil • Biodegradation • Bioaccumulation • Genotoxicity	Tier testing is formalised for mobility in soil, biodegradation and bioaccumulation. For genotoxicity, tier testing is decided on a case-by-case basis.	• A study on **mobility in soil**: Required if the active substance can be mobile in the soil (e.g. K_{oc} < 500) on the basis of the screening test on adsorption/desorption, and it is not readily degradable chemically or biologically. E.g. soil column, soil thin layer chromatography or lysimeter tests. • **Biodegradation, Bioaccumulation** and **Genotoxicity** as above for industrial slimicides
	Wood preservatives used as a paint			
	No			
	Structural Pesticides, Rodenticides (indoor), Repellents, Insecticides and Acaricides (indoor)			
	Yes	• Genotoxicity	For genotoxicity, tier testing is decided on a case-by-case basis.	• **Genotoxicity studies** as for industrial slimicides
	Rodenticides (outdoor), Insecticides (outdoor)			
	Yes	• Bioaccumulation • Genotoxicity	Tier testing is formalised for bioaccumulation. For genotoxicity, tier testing is decided on case-by-case.	• **Bioaccumulation and Genotoxicity studies** as for industrial slimicides
FR	Food area disinfectants and wood preservatives for wood in contact with fruits and vegetables regulated (= approval procedure) by the Ministry of Economy and Finances (see Table 1)			
	No information provided			
GER	Wood preservatives for construction products and "RAL"-products; disinfectants (see Table 1, Annex 1)			
	No		Data requirements are generally not organised in tiers but optionally practised case-by-case	

TABLE 2: DATA REQUIREMENTS ORGANISED IN TIERS (cont.)

Country	Data requirements for a specific product type/use category organised in tiers?			
		For which areas?	**Tier testing formalised or on a case-by-case basis?**	• **Description of a model of tier structure** • **Other remarks on data requirements**
GER (cont.)	Disinfectants and pest control products used in the field of hygiene, regulated by the Medicines Act & Federal Communicable Diseases Act (on voluntary base) (see Table 1, Annex 1)			
	Yes	• Toxicology • Human exposure • Environment	Case-by-case basis	
GR	Biocides use categories regulated (= approval procedure) by the National Drug Organisation and the Ministry of Agriculture (see Table 1, Annex 1)			
	No			
HUN	All biocides which are subject to an approval procedure in Hungary (see Table 1, Annex 1)			
IRL	All biocides which are subject to an approval procedure in Ireland (see Table 1, Annex 1)			
	No			
NL	All 19 biocide use categories which are subject to an approval procedure in the Netherlands (see Table 1, Annex 1)			
	Yes	In principle tier testing is applied for data requirements included in all the 10 Matrices of the OECD questionnaire.	Tier testing is formalised in general. However, after a first evaluation of the "complete" dossier, it is decided - on a case-by-case basis- for which aspects additional data are required.	• The data requirements (matrices 1-10 of the Part 2 of the OECD questionnaire) indicated for the 19 product types are minimal requirements. Those minimal requirements are necessary with respect to the completeness of the dossiers in the completeness check. Based upon a first evaluation of a dossier, additional data requirements (matrices 1-10) are established. In that respect, when filling in the Part 2 of the questionnaire, the code "NR = not required" is not used, since the possibility to ask additional data requirements cannot be excluded. • Many triggers are not formalised. However, besides the indicated conditions for conditionally required data elements- triggers for data requirements are often related to risk assessments. • For instance with respect to: ◊ **Human Exposure** (Matrix 10): In case of lack of a margin of safety in a worst case risk assessment for the applicator it may be necessary to ask for dermal penetration data or applicator exposure data in order to improve the risk assessment. ◊ **Fate and behaviour in the environment** (Matrix 6) **& Ecotoxicology** (Matrix 7**)**: (Semi)field testing may be triggered in relation to risk assessments. ◊ **Toxicology (mammalian)** (Matrix 9): The results of in-vitro mutagenicity tests may trigger in-vivo mutagenicity tests and further a carginogenicity test.

TABLE 2: DATA REQUIREMENTS ORGANISED IN TIERS (cont.)

Country	Data requirements for a specific product type/use category organised in tiers?			
		For which areas?	**Tier testing formalised or on a case-by-case basis?**	• **Description of a model of tier structure** • **Other remarks on data requirements**
NZ	All biocide use categories which are subject to an approval procedure in New Zealand (see Table 1, Annex 1)			
	Yes	• Fate • Ecotoxicology • Toxicology (mammalian) • Human exposure	Case-by-case basis	For those biocides regulated under the Pesticides Act (1979), the Animal Remedies Act 1967, and the Medicines Act 1981, formal data requirements have been established, together with a tiered assessment process, as for plant protection products. For the others, specific information on identity and intended uses are required, with requirements for additional data being on a case-by-case basis.
POR	All biocides use categories which are subject to an approval procedure in Portugal (see Table 1, Annex 1)			
	No			
SWE	Slimicides as categorised in Sweden (see Table 1, Annex 1)			
	Yes	• Genotoxicity	Case-by-case basis	If positive in the in-vitro system, in-vivo tests may not be required.
	Anti-fouling products, Wood preservatives, Rodenticides, Mosquito repellents for use on skin (see Table 1, Annex 1)			
	No			
SWI	Biocides which are subject to an approval procedure in Switzerland (see Table 1, Annex 1)			
	No			• <u>Human health</u>: Concerning toxicological studies for biocides Art. 6 of the "Federal Law on Trade in Toxic Substances" (Swiss Toxicity Law) requires "appropriate test certificates concerning the toxicity and degree of hazard of the substance. In practice this means that all available studies and test documents relevant for the evaluation of the hazard and risk assessment of the biocide have to be submitted". In most cases applicants submit fairly substantial documents, which have been prepared at international standards. Toxicological studies with biocidal end-use <u>products</u> are not systematically required. The approval of a product is based on the data of its individual ingredients. As far as toxicological studies with new active ingredients are concerned, the data requirements of the proposed EC Biocidal Products Directive can be considered as a guidance for the registration in Switzerland, with some flexibility on a case by case basis. • <u>Residues on food</u>: Data on the magnitude of the residues on food are required, when the biocide is intended for treatment of material that gets in contact with food, e.g. treatment of store rooms.

TABLE 2: DATA REQUIREMENTS ORGANISED IN TIERS (cont.)

Country	Data requirements for a specific product type/use category organised in tiers?			
		For which areas?	**Tier testing formalised or on a case-by-case basis?**	• **Description of a model of tier structure** • **Other remarks on data requirements**
UK	Biocides regulated (= approval procedure) by the "Control of Pesticides Regulations" (see Table 1, Annex 1)			
	Yes	• Fate • Ecotoxicology • Toxicology (mammalian)	There is a basic framework for tier testing, but further data can also be required on a case-by-case basis.	
USA	Biocides regulated by EPA/OPP & FDA (see Table 1, Annex 1)			
	No information provided			
EU	All 23 biocide product types as categorised by EU (see Table 1, Annex 1)			
	Yes			Technical guidance notes will specify the data requirements for each product types and for the relevant active substance. A tiered approach which will take into account the hazard proprieties of both the active substance and the product, and the proposed use/exposure scenario will drive the compilation of these documents. The precise stepped strategy for testing is under discussion.