

Overview of Biocide Regulations in OECD Member Countries

This document provides an overview of biocide regulation in OECD Member countries indicating for each Member country:

- how biocides are categorised,
- the biocide product types regulated,
- the relevant laws,
- the responsible Ministries/Agencies, and
- whether data requirements exist.

The document is a part of *the Survey of OECD Member Countries' Approaches to Regulation of Biocides* which was performed in 1997-98 and reflects the national procedures that were in place in mid-1998.

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 requirements 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 therapeutic 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 requirements exist?
		active ingredient	end-use biocide			
(i) Disinfectants / sanitizers	Disinfectants for use: <ul style="list-style-type: none"> • in households • for premises, equipment, 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	<ul style="list-style-type: none"> • Preservatives for food or feed stocks 					
(vii) Products for use in vertebrate and invertebrate pest control	<ul style="list-style-type: none"> • Rodenticides [22] • Insecticides [26] • Acaricides • Fungicides 					
“Other biocides”	<ul style="list-style-type: none"> • All biocidal products falling under the scope of this survey, if they have one or more dangerous properties 			Chemicals Law	<ul style="list-style-type: none"> • The Federal Chancellery, Department VI: in the case of very toxic, toxic and harmful properties. <ul style="list-style-type: none"> • 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 brackets.

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data requirements exist?
		active ingredient	end-use biocide			
(i) Disinfectants and general biocidal products	<ul style="list-style-type: none"> • Veterinary hygiene biocidal products [4], including products against ecto-parasites on livestock and disinfectants for use on surfaces in veterinary 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 <ul style="list-style-type: none"> • DG4 : Quality of Raw Materials and Vegetal Sector • IG41 : Raw Materials and Transformed Products 	Yes
	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Ministry of Health Dept. : Risk Management (Administration) • Ministry of Health Hoge Gezondheidsraad Conseil Supérieur d'Hygiène (Scientific Evaluation) 	Yes
(ii) Preservatives	<ul style="list-style-type: none"> • 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 requirements exist?
		active ingredient	end-use biocide			
(iii) Pest control	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Ministry of Health Dept. : Risk Management (Administration) • Ministry of Health Hoge Gezondheidsraad Conseil Supérieur d'Hygiène (Scientific Evaluation) 	Yes
(iv) Other biocidal products	<ul style="list-style-type: none"> • 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 requirements 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 requirements 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/ acaricides 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 requirements 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	<ul style="list-style-type: none"> 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. <i>Repellents</i> 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 requirements exist?
		active ingredient	end-use biocide			
(i) Disinfectants / sanitizers	<ul style="list-style-type: none"> 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 medicines and are covered by certain type of advance approval procedure.	National Agency for Medicines	Yes
	<ul style="list-style-type: none"> 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.	
	<ul style="list-style-type: none"> 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 requirements 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	<ul style="list-style-type: none"> • 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
	<ul style="list-style-type: none"> • 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 slimicides	Yes
	<ul style="list-style-type: none"> • Wood preservatives as a paint 	NONE	NOTIF	as for industrial slimicides	as for industrial slimicides	Yes
	14. Structural pesticides	NONE*	APP	Pesticides Act (327/69, amendments) and Pesticide Statute (792/95)	<ul style="list-style-type: none"> • Pesticide Board (Ministry of Agriculture and Forestry) (Approval, conditions and restrictions for use) <ul style="list-style-type: none"> • 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 requirements 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)	<ul style="list-style-type: none"> • 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 <u>indoor</u>	Yes
	26a. Indoor insecticides and acaricides	NONE*	APP	as for structural pesticides	same as for rodenticides used <u>indoor</u>	Yes

TABLE 1: FINLAND (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws [♠]	Responsible agency(s)/ministry(s)	Data requirements 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 <u>outdoor</u>	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 general 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 requirements 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: <ul style="list-style-type: none"> • 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
	<ul style="list-style-type: none"> • Treatment of premises, materials and vehicules used for: <ul style="list-style-type: none"> ◊ 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 efficacy, 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 requirements exist?
		active ingredient	end-use biocide			
(v) Microbiocides for waste disposal and strip mine sites	<ul style="list-style-type: none"> Collection, transport and treatment 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 requirements exist?
		active ingredient	end-use biocide			
(i) Disinfectants and general biocidal products	<ul style="list-style-type: none"> • Human hygiene biocidal products [2]: <ul style="list-style-type: none"> ◇ medicinal products 	APP	APP	Medicines Act	Arzneimittel Institut, Robert-Koch Institut Berlin/BMG (Ministry of Health)	No environment data
	<ul style="list-style-type: none"> ◇ other products used for human hygiene purposes 	NONE	NONE			
	<ul style="list-style-type: none"> • Private area and public health area disinfectants and other biocidal products [1, 3, 18-21] <ul style="list-style-type: none"> ◇ disinfectants used according to the Federal Communicable Diseases Act 	APP*	APP*	Federal Communicable Diseases Act (FCDA) § 10c (BSeuchG vom 18.12.79 BGBl.I Nr. 75v. 25.12.1979, 2263) (7. amendment BGBl. Nr. 23, v. 25.04.1996; S.621)	<ul style="list-style-type: none"> • 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 requirements 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			
	<ul style="list-style-type: none"> • Veterinary hygiene biocidal products [4] ◇ medical products 	APP	APP	Medicines Act	<ul style="list-style-type: none"> • BgVV/BMG: responsible for health area • UBA/BMU: responsible for environmental area. 	Yes
	◇ other veterinary hyg. biocidal products	NONE	NONE			
	<ul style="list-style-type: none"> • Food and feed area disinfectants [5] • Drinking water disinfectants [6] 	NONE	NONE			
(ii) Preservatives	<ul style="list-style-type: none"> • In-can preservatives [7] • Film preservatives [10] 	NONE	NONE			
	<ul style="list-style-type: none"> • Wood preservatives [13] ◇ construction products (load bearing timber) 		APP	Landesbauordnung / Musterbauordnung (§20ff) (Guideline for construction)	<ul style="list-style-type: none"> • 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
	<ul style="list-style-type: none"> ◇ not load bearing timber: “RAL” products ◇ wood varnishing products 		NOTIF	Agreement on a non-legislative (= volunatry) basis	<ul style="list-style-type: none"> • 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 requirements exist?
		active ingredient	end-use biocide			
(ii) Preservatives (cont.)	◊ other not load bearing timber		NONE			No
	<ul style="list-style-type: none"> Fiber, leather, rubber and polymerized materials preservatives [9a, 9b, 9c] Masonry preservatives [9d] 	NONE	NONE			No
	<ul style="list-style-type: none"> Preservatives for liquid-cooling and processing system [8d]. Slimicides [8b, 8c] Metalworking-fluid preservatives 	NONE	NONE			No
(iii) Pest Control	<ul style="list-style-type: none"> Rodenticides [22] ◊ products used according to the Federal Communicable Diseases Act 		APP*	<ul style="list-style-type: none"> Federal Communicable Diseases Act (FCDA) § 10c; National legislation on plant products. 	<ul style="list-style-type: none"> BgVV/BMG: responsible for toxicology and listing of products UBA/BMU: responsible for ecotoxicology and efficacy testing 	under preparation
	<ul style="list-style-type: none"> ◊ other products for the control of mice, rats, other rodents Avicides [23] Piscicides [24] Molluscicides [28] 	NONE	NONE			
	<ul style="list-style-type: none"> Insecticides, acaricides and products to control other arthropods [26 & 27] ◊ Products used according to the Federal Communicable Diseases Act § 10c 		APP*	<p>Use category 26:</p> <ul style="list-style-type: none"> Federal Communicable Diseases Act § 10c; National legislation on plant products. <p>Use category 27:</p> <ul style="list-style-type: none"> Federal Communicable Diseases Act § 10c; and, partly Medicines Act (for skin application) [27] 	<ul style="list-style-type: none"> BgVV/BMG: responsible for toxicology and listing of products UBA/BMU: responsible for ecotoxicology and efficacy testing 	under preparation
	◊ other products used to control other arthropods	NONE	NONE			
	<ul style="list-style-type: 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 preparation
	◊ 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 requirements exist?
		active ingredient	end-use biocide			
(iv) Other biocidal products	<ul style="list-style-type: none"> • 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 (recommandation).
- ∞ DGV-list of disinfectants for food industrial which were tested on efficacy concerning to the guidelines of the DVG (recommandation).
- * 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 requirements 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					
(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 requirements 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 brackets.

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data requirements 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	<ol style="list-style-type: none"> 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 <i>Responsibilities:</i> 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	<ol style="list-style-type: none"> 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 <i>Responsibilities:</i> 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	<ol style="list-style-type: none"> 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 	<ul style="list-style-type: none"> • Ministry of Agriculture and Reg. Development National Inst. for Agricultural Quality Control State Control Inst. for Veterinary Biologicals, Drugs and Feeds <i>Responsibilities:</i> 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 requirements 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	<p>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</p> <p>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</p> <ul style="list-style-type: none"> and also decrees 2 and 3 	<ul style="list-style-type: none"> Ministry of Health (cont.) National Inst. of Food Hugiene and Nutrition <p><i>Responsibilities:</i> efficacy assessment, health and environmental risk assessment</p>	Yes
Water disinfectants and sanitizers	Drinking water disinfectants for use in human or animal drinking water [6], swimming pools [18], hot baths [19].		APP	<p>11. Ordinance 3/1971 (VII 17) of the Minister of Health concerning public health rules applicable to substances used in drinking water supply systems</p> <p>12. Ordinance 28/1978 (V26) of the Council of Ministers amending certain legislation regarding pollutant discharge fines.</p> <ul style="list-style-type: none"> and also decrees 2 and 3 	<p>Ministry of Health Medical Officer's Office National Publ. Health Center National Inst. of Public Health</p> <p><i>Responsibilities:</i> approval, efficacy assessment, health and environmental risk assessment</p>	Yes
(ii) Preservatives/microbiocides	For use on/in cosmetic products	APP		<p>13. Decree 7/1994 (IV 20) of the Minister of Welfare on the health requirements to be fulfilled for the marketing of cosmetics</p> <ul style="list-style-type: none"> and also decrees 2 and 3 	<p>Ministry of Health Medical Officer's Office National Publ. Health Center National Inst. of Food Hygiene and Nutrition</p> <p><i>Responsibilities:</i> approval, control functions</p>	Yes

TABLE 1: HUNGARY (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data requirements exist?
		active ingredient	end-use biocide			
(iv) Wood preservatives and structural treatments	For use on/in: <ul style="list-style-type: none"> remedial, joinery [13] preventive treatments [14] 	APP	APP	decrees 2 and 3	<ul style="list-style-type: none"> Sopron University of Forestry <i>Responsibilities:</i> approval, efficacy assessment Ministry of Health Medical Officer's Office National Publ. Health Center National Inst. of Chemical Safety <i>Responsibilities:</i> coordination, health and environmental risk assessment 	Yes
(vii) Products for use in vertebrate and invertebrate pest control	<ul style="list-style-type: none"> Rodenticides [22] Repellents [25] <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> and also decrees 2, 3 and 15 	Ministry of Health Medical Officer's Office National Center of Epidemiology Dept. of Vector Control <i>Responsibilities:</i> 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 requirements 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.		APP	Pesticides Act	<p>The ministries of:</p> <ul style="list-style-type: none"> • 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. <p>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.</p>	Yes
	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-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 requirements exist?
		active ingredient	end-use biocide			
(vii) Products for use in vertebrate and invertebrate pest control	H.1 Household products applied outdoors.		APP	Pesticides Act	Ministeries of: <ul style="list-style-type: none"> • Agriculture • Health Water protection (social affairs) • Environment (Administration Board for pesticide approval) 	Yes
	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.					

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 requirements 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 decision-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 decision-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 decision-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 requirements 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 decision-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 decision-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 requirements 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 requirements 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 <i>Comissão de Avaliação Toxicológica de Produtos Fitofarmacêuticos</i>	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 brackets.
- 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 requirements 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 Pesticides (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 requirements exist?
		active ingredient	end-use biocide			
(ii) Preservatives/ Microbiocides (cont.)	<ul style="list-style-type: none"> Fiber, <i>leather</i>, rubber and <i>polymrerized material preservatives</i> [9b, 9c]. <i>Mansonry preservatives</i> [9d] 	APP	APP	Ordinance on Pesticides (SFS 1985:836)	KemI	Yes ^g
	<ul style="list-style-type: none"> Slimicides [8b, 8c] 	APP	APP	Ordinance on Pesticides (SFS 1985:836)	KemI	Yes ^s
	<ul style="list-style-type: none"> Metalworking-fluid preservatives [9k] 	NONE	NONE	Exempted from the Ordinance on Pesticides (SFS 1985:836)	KemI	No
(iii) Pest Control Products	<ul style="list-style-type: none"> Rodenticides [22] 	APP	APP	Ordinance on Pesticides (SFS 1985:836)	KemI	Yes ^s
	<ul style="list-style-type: none"> <i>Avicides</i> [23] Molluscicides [28] <i>Piscicides</i> [24] Insecticides, acaricides and products to control other arthropods [26, 27] 	APP	APP	Ordinance on Pesticides (SFS 1985:836)	KemI	Yes ^g
	<ul style="list-style-type: none"> Repellents and attractants [25] 	APP	APP	Ordinance on Pesticides (SFS 1985:836)	KemI	Yes ^s
(iv) Other biocidal products	<ul style="list-style-type: none"> 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
	<ul style="list-style-type: none"> Antifouling products [12] 	APP	APP	Ordinance on Pesticides (SFS 1985:836)	National Chemicals Inspectorate (KemI)	Yes ^s
	<ul style="list-style-type: none"> Structural Pesticides [14] 	APP	APP	Ordinance on Pesticides (SFS 1985:836)	KemI	Yes ^s
	<ul style="list-style-type: none"> 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 requirements 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Ordinance relating to environmentally hazardous substances • Federal law on trade in toxic substances 	<ul style="list-style-type: none"> • 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 requirements 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		APP	COPR*	Pesticides Safety Directorate (PSD)	Yes
	23. Avicides					
	25. Repellents and attractants		APP	COPR*	<ul style="list-style-type: none"> • Pesticides Safety Directorate (PSD) • Health and Safety Executive (HSE) 	Yes
	26. Insecticides (indoor/outdoor)		APP	COPR*	Health and Safety Executive (HSE)	Yes
	27. Insecticides/acaricides used on: humans, clothes, pets					
	28. Molluscicides					
	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 Independent 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 requirements exist?
		active ingredient	end-use biocide			
Agricultural premises and equipment [i-5a]	<p>For use in</p> <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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]	<p>For use in:</p> <ul style="list-style-type: none"> food/feed processing plants (e.g., dairy, egg, meat, poultry, fish/seafood etc.) eating establishments (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	<ul style="list-style-type: none"> 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]	<p>Premises is defined to include: ceilings, doors, doorknobs, fixtures, floors, light switches, stairs, wall, windows, and woodwork. The following areas are treated:</p> <ul style="list-style-type: none"> 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 requirements exist?
		active ingredient	end-use biocide			
Commercial, institutional and industrial premises and equipment (cont.)	<ul style="list-style-type: none"> • 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]	<p>For use in:</p> <ul style="list-style-type: none"> • residential (e.g., homes, apartments, mobile homes, shelters, etc.); • public areas (e.g., public areas, public buildings, or public rooms). 			<ul style="list-style-type: none"> • FIFRA • FFDCA 	EPA/OPP	Yes under FIFRA
Medical premises and equipment [i - 1a, b]	<p>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 <u>man and animal</u>. 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.)</p>	APP	APP	<ul style="list-style-type: none"> • FIFRA • FFDCA (certain sterilants) 	<ul style="list-style-type: none"> • EPA/OPP • Food and Drug Administration of Health and Human Services (FDA) 	Yes under FIFRA
Human drinking water systems [i-6a]	<p>Sites under this use category include public water systems, individual water systems, emergency water systems, and water purifier systems.</p>	APP	APP	<ul style="list-style-type: none"> • FIFRA • FFDCA • Safe Drinking Water Act (it sets allowable ceilings for contaminants in drinking water) 	<ul style="list-style-type: none"> • 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 requirements 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	<ul style="list-style-type: none"> • FIFRA • FFDCA 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • FIFRA • Clean Water Act (CWA) 	<ul style="list-style-type: none"> • 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 regulation		No

TABLE 1: USA (cont.)

Broad grouping	Product types/use categories	Product notification or approval required?		Relevant laws	Responsible agency(s)/ministry(s)	Data requirements 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	<ul style="list-style-type: none"> FIFRA Organotin Antifouling Paint Control Act (1988) (OAPCA) <p>It regulates the level of organotin in antifouling paints and prohibits the sale, distribution or use of paints with release rates greater than $m4 \text{ micrograms/cm}^2$ on boats less than 25 m in length.</p>	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Federal Insecticide, Fungicide and Rodenticide (FIFRA) Federal Food, Drug and Cosmetic Act (FFDCA) 	<ul style="list-style-type: none"> 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 requirements 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 requirements exist? ^v
		active ingredient	end-use biocide			
(i) Disinfectants and general biocidal products	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 requirements exist? ♥
		active ingredient	end-use biocide			
(iii) Pest control	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.