European Commission
Environment Directorate-General

Assessment of different options to address risks from the use phase of biocides

Final report

March 2009

COWI

COWI

COWI A/S

Parallelvej 2
DK-2800 Kongens Lyngby
Denmark

Tel +45 45 97 22 11
Fax +45 45 97 22 12
www.cowi.com

European Commission
Environment Directorate-General

Assessment of different options to address risks from the use phase of biocides

Final report

March 2009

Report no. 4
Date of issue 5 March 2009

Prepared JEK, CRL, SOM, AO, TVGU, LLES, RDI
Checked MSJ, SOM, CRL
Approved MSJ

Table of Contents

1 Summary and conclusions

This report constitutes the final report of the study providing an "Assessment of different options to address risks from the use phase of biocides". The study commenced in May 2008. It has been carried out by COWI AS.

Purpose and key questions

The purpose of the study has been to "help identify the appropriate measures and legal instruments that would allow ensuring a sustainable use of biocidal products" (according to the Terms of Reference for the study).

In delivering this, the study aimed to address the following key questions:

- What do we know about biocides in use in the European Union and how do we regulate the use?
- What do we know about the risks that biocides pose to the environment and to humans?
- What can we do to further control and/or reduce the risks associated with the use of biocides?
- How could we most appropriately introduce such mechanisms at the EU level?

Study delineation and method

The study was carried out over a 6 month period. Data and information on the use of biocides and on the risks are limited and difficult to identify. Still, in delivering the study, we have strived to obtain as much information as possible to supplement already existing sources and our own knowledge and experience. We have sought to get specific information from some EU Member States; we have consulted with JRC (Ispra), EUROSTAT and CEFIC; we have carefully studied and utilized the information from a questionnaire survey that the Commission undertook in 2008; and we have consulted the documents from the 2008 expert workshop. The study did not aim at specifically assessing the impacts of the identified measures.

In defining the use phase, we have differentiated between the application phase and the service life phase. Further, for all the Product Types (PT) we have distinguished between professional uses and non-professional uses. This has, in our views among other things, an importance for the relevance and feasibility of policy measures.

Third, biocides are by nature affecting living organisms, wherefore they are also used for specific and necessary purposes. We have in the study differentiated between their intended hazardous effects and their possible unintended effects, and in regard to the latter; between the exposure to humans and the exposure to the environment.

In assessing the risks posed by biocides, we have strived to provide an operational overview or categorisation using the above differentiations, and considering toxicity and exposure impacts. In view of the complexity; the limited calendar time and resources available for this study; and because the substance-by-substance risk assessment has almost become available since recent years as part of the review programme foreseen by article 16 of Directive 98/8/EC, the risk assessments carried out for this study are indicative and boil down to rather qualitative considerations about the magnitude and character of the possible risks of biocidal products to humans and the environment.

In assessing the measures, we have first looked into the possible options to reduce risks and secondly, we have identified a list of possible measures for all product types. We have screened this list with a view to, among other things, the feasibility and relevance of the identified measures. In this process, we have also taken inspiration from the replies to the questionnaire that the Commission circulated recently. Again, consideration has been given at this stage to the easily identifiable costs of those measures which needs to be refined with an actual impact assessment. Ultimately, we arrived at three possible measures that were considered to be:

- Efficient in the sense of being able to deliver risk reductions at an estimated reasonable costs and without invoking other equally or more hazardous impacts from the alternative approaches put into place
- Realistic in the sense of being a legal and political option that could materialize
- Feasible in the sense of having the potential, within certain Product Types, of applying to one or more of the technical approaches identified.
- Relevant in the sense of being an appropriate measure to address the exposures, toxicities and use, in other words risk patterns in question whereby the benefits in those cases are likely to be so significant that they justify action and related costs already identified.

Below, we first highlight our main conclusions from the study. This is followed by a listing of the main observations that derive from the study.

Biocides use in the EU

There is a considerable lack of knowledge about biocides in use in the EU. Information exists on individual active biocidal substances, but little is known about their production and use in the EU and its Member States.

The study undertook a brief survey of production/import figures available with the former ECB[1] in Ispra, Italy. This, and a study undertaken in Denmark on the biocides market, does provide some insights into the structure of biocides use in the EU. Still, however, these data are old, somewhat incomplete and derive only from these two sources - therefore, the conclusions arrived at should be interpreted with care and taken as indicative only.

That being said, the information indicates that for the EU as a whole, the largest use area is for disinfection purposes in private and public areas (PT2). Also, drinking water disinfection (PT5) is another important use area. This illustrates one of the presumably many geographical differences within the EU as regards use patterns. Another example is the fact that wood preservatives (PT8) are more important in the north, whereas masonry preservatives dominate (PT15) more in the south. Similarly, preservatives for liquid cooling and processing systems (PT11) accounts for a much higher relative share in the EU as a whole that in Denmark, probably reflecting climatic differences.

Risks from biocides in the use phase

The assessment of toxicity aspects and exposures has been done on a PT-by-PT basis in the annex accompanying this report. The results are summarized in this report, and the main conclusions on the need for risk reduction are summarized in the below table.[2]

Most of the PTs are used by professional users. Only one sub-type - PT2.1; private area disinfectants does (by definition) not have professional users. Also, significant (or potentially significant) exposure of non-professionals occur mainly in PT2 (2.1; private area disinfectants), PT7 (preservatives for paints), PT8 (preservatives for surface treatment of wood), PT10 (masonry preservatives), PT18 (insecticides) and PT21 (21.1; antifouling products for small vessels). In some countries PT14 (rodenticides) may also be relevant to consider for non-professional exposure.

It is felt that the PTs prioritized for the EU review of active substances under Directive 98/8/EC (PTs 8, 14 and 18) and for regulatory actions in some Member States (largely the same PTs) have also been considered - recognising though that the review process is ongoing - by the exercise described in this chapter to be likely to show the highest level of risk to humans and the environment. In addition to the mentioned three PTs, also PT2 is considered to present a significant aggregated risk.

[1] Now managed by the Consumer Product Safety and Quality unit at JRC, Ispra (It).

[2] Unfortunately, the lack of quantitative data on exposure (tonnages at EU and Member State level, monitoring data on emissions and occurrence in the environment etc.) as well as on hazard properties (toxicities and ecotoxicities) of the substances prevent a quantitative assessment of the overall risks. Therefore, it has only been possible to make a mainly qualitative description of the areas within each Product Type where impacts in the use phase of biocides are most likely to occur by identifying the main emission situations and exposure pathways.

Table 1 Overview, indication of significance of elements in the human and environmental risk assessment relating to the use phase of biocides (per PT) and overall assessment[1]. The specific exposure assessments do not include consideration of the overall tonnages.

Product-type	Tonnage (annual)	Human exposure, users	Human exposure, general	Env. exposure, direct	Env. exposure via WWTPs	Overall assessment of "risks"
Main Group 1: Disinfectants and general biocidal products						
1: Human hygiene biocidal products	XXX	XXX	-	-/X	XX	X
2: Private area and public health area biocidal products	XXX	XX	X	X	XXX	XX
3: Veterinary and hygiene biocidal products	XXX	XX	-	X	XX	X
4: Food and feed area disinfectants	XXX	XX	-	-	XXX	X/XX
5: Drinking water disinfectants	XXX	X	X	X	X	X
Main group 2: Preservatives						
6: In-can preservatives	XX	X	X	X	X	X
7: Film preservatives	XX	X	X	XX	X	X/XX
8: Wood preservatives	XXX	XX	X	XX/XXX	-	XX/XXX
9: Fibre, leather, rubber, and polymerised materials preservatives	XX	X	X	-	X	X
10: Masonry preservatives	XXX	XX	-	XX	-	XX
11: Preservatives for liquid cooling and processing systems	XXX	X	-	XX	XX	XX
12: Slimicides	XX	X	-	XX	XX	X/XX
13: Metalworking fluid preservatives	XX	XX	-	-	X	X
Main Group 3: Pest control						
14: Rodenticides	-	XX	X	XX	X	XX
15: Avicides	-	X	-	XX	-	-/X
16: Molluscicides	-	X	-	XXX	-	-/X
17: Piscicides	-	X	-	XXX	-	-/X
18: Insecticides and products to control other arthropods	XX	XXX	XX	XXX	-	XX/XXX
19: Repellents and attractants	XX	XX	X	XX	-	-/X
Main Group 4: Other biocidal products						
20: Preservatives for food and feedstock	X	X	X	-	-	-/X
21: Antifouling products	X	XX	X	XXX	-/X	XX
22: Embalming and taxidermist fluids	-	-	-	-	-	-
23: Control of other vertebrates	-	X	-/X	XX	-	-/X

1: XXX = major/high; XX = significant; X = moderate; - = minor/low.

Options and measures

When identifying possible options to reduce risks from the use of biocides, there are some important features to bear in mind. First, biocides do provide a necessary service, and the reduction in their use must not lead to significant repercussions on the quality of that necessary service to the Society. Second, alternative solutions may involve new or more problematic risks that require equivalent assessment before their validation as substitute. Consequently, when discussing a reduction in the use, the issue is one of dealing with the superfluous, thoughtless or misplaced use - which leads to unnecessary residuals and waste products and thereby to excess pollution and health problems.

The table below provides an overview of the identified possible options to reduce the risk, and the measures that can be put in place in pursuit of these options. Please note that some of the measures may be included under more than one of the options because they may be relevant to pursue more than one option.

Table 2 Options and measures by approach

Approach	Technical options	Measures
Reduce the quantities to optimal levels	Optimising the dosage	Restrict the application to certified users including applications of harmonised use conditions Certification of application equipment Promote development of application equipment Taxes/levies on selected biocides
	Prevent growth of organisms	Promotion of the development of materials and building techniques that prevent the growth of undesired organisms Promote substitute materials
	Application of non-biocidal techniques	Promote non-biocidal control, "Integrated Pest Management"
	Avoid using biocides where prevention is not essential	Sales restriction (e.g. no sale from open storage shelves) Taxes/levies on selected biocides Information/awareness raising campaigns
Reduce hazardousness	Technical improvements	The use of less hazardous biocides in biocidal product is already covered by the authorization procedures under the BPD
	Imported articles/ materials	Evaluation of substances and subsequent authorisation of biocidal products used in treated articles/materials Labelling requirements for biocides-treated articles/materials
	Use of less hazardous biocides for less demanding applications	Promotion of less hazardous biocides for less demanding applications Prohibition of the use of certain biocides in certain conditions or areas Information/awareness raising campaigns
Reduce the releases and exposures by application	Use of appropriate application techniques and equipment	Restrict the application of specific biocides to certified users Training programmes for professional users Certification of equipment; Promote development of improved application and protection equipment Awareness raising campaigns on the application of biocides, especially for private users Prohibit the use of aerial spraying

Approach	Technical options	Measures
	Use appropriate personal protection equipment	Restrict the application of specific biocides to certified users Training programmes for professional users Information/awareness raising campaigns on the application of biocides
Reduce the long-term releases and exposures during the service of biocide-containing materials and articles	Reduce the release rate of biocides from products and articles	Limit values for release rates of biocides from materials and articles (e.g. release rates of biocides from preserved wood)
	Prevent inappropriate use of biocide treated materials/articles e.g. indoor use of preserved wood	Awareness raising campaigns on the use of biocide treated products
Prevent the development of resistance	Change between different biocides	Training programmes for professional users
	Prevent using biocides at sub-lethal levels	- same as mentioned above

Measures in use in Member States

The Commission launched a questionnaire to Member States early in 2008, and 18 Member States replied to the questionnaire. Annexed to this report are the results of a detailed survey of the responses. Here it is worth noting that a number of the replies report on legislation that restricts the use to certified users. This goes in particular for PT14 and PT18 which are among the four PTs identified in this study also as posing potentially significant risks, but also PT19 and (to a smaller extent) PT2, PT4 and PT11. Other measures (in addition to those already mentioned here) that are mentioned by one or more Member State to be in use include[3]:

- Certification of application equipment
- Promotion of non-biocidal control
- Prohibition of the use of some PTs
- Restriction of the use of certain biocides under certain conditions

Relevant, realistic, feasible and efficient measures

Following the screening procedure described above under methodology, the following list of measures for further assessment was established:

- Training and certification of professional users. The Product Types with the highest score in the risk assessment relate to areas where professional users dominate. This measure is also already in place in quite a few of the Member States that replied to the questionnaire. Our observations point to the measure being relevant, realistic, feasible and possibly effective.

[3] It should be noted that in quite a few cases, the replies do not note for which PTs the regulation applies wherefore this type of information is excluded from this listing

- Certification and inspection of application equipment. This could be relevant for products with a high risk that inadequate application equipment results in over-dosage, high exposure or high releases to the environment. Several Member States report on requirements for specific application equipment albeit not being very detailed. However, it should be noted also that the dosage and application of the products are often much more dependent on the user of the equipment than on the equipment per se - as compared to plant protection products. Thus, there are some, but not as strong as above, indications of this measure for some PTs being relevant, realistic, feasible and possibly effective.

- Long term good practice and prevention, i.e. measures that by nature have a more long-termed perspective before they take (full) effect. This approach may resemble the Integrated Pest Management principles in place for Plant Protection Products and Member States in general do indicate - in their replies to the questionnaire - that similar principles could be applied on at least some biocidal PTs.

Training and certification of professional users - the concept

Training and/or certification schemes exist in many Member States such as training for wood preservatives, disinfectants, insecticides and rodenticides. The April 2008 workshop agreed on a need for a minimum level of good practice harmonization with regard to training requirements across the EU at least for the same PTs as those mentioned before, but less so regarding the certification requirements. From industry, there is an expressed interest in a harmonized certification system as set up by CEPA's (The Confederation of European Pest Control Associations representing around 80 percent of the market value for pest control industry) voluntary commitment of the Roma Protocol of April 2008.[4]

The measure on training and certification could consist of three separate elements that may be implemented at different levels for different product types:

- Harmonized Good Practice (GP) reference documents and standards that can serve as the basis for training schemes and as reference documents for authorization (a key use of the document) and as the basis for developing requirements and provisions. The development may take inspiration from the system that is in place to develop BAT Reference Documents in the context of the IPPC Directive. Separate documents would be needed for each PT and in some cases even at a more disaggregated level[5].

[4] to working for the development of a policy valid throughout Europe for certification of companies or individuals, along with criteria to enter and operate within the profession and to harmonise the use and implementation of standards across the European Pest Management Industry (CEPA 2008).

[5] A German study included the development of good practice (GP) reference documents for three product-types: PT 2 „Disinfectants in the private area and public health“, PT 8 „Wood preservatives“ and PT 14 „Rodenticides“) based on a uniform structure. In addition to illustrating the structure and contents of a GP reference document, the study concluded also that the qualifications of the user as well as the communication of risks is of decisive impor-

- Harmonized training schemes and requirements could involve mandatory training as regards professionals in the pest control industry and similar whereas a voluntary approach could apply to those where the use of biocides is a minor part of the activities. Training schemes would be based on the GP reference documents, and harmonization is predominantly relevant in connection with certification/authorization systems.

- Harmonized certification systems co-exist today in many Member States and in most cases so that the authorization systems concerns only the professional users providing the pest control as a service or as pest controllers in public areas. The biocides may still be used by non-professionals or professionals undertaking pest control in their own premises (e.g. farmers)[6]. Authorization provisions could include among other things provisions as regards education and documented training and require that pest control is to be undertaken in accordance with specified guidelines. Some systems only require authorization and training for the persons in charge of the pest control, whereas in others, professional competence should be demonstrated for every technician through examination and certification.

As regards relevant Product Types, a possible step-wise approach could start with those biocides that involve the risk of poisoning of children or other bypassers or involve very high risk for the operators. This relates to rodenticides (PT14), insecticides (PT18) and fumigants or gassing (within PT14, PT18 and PT23).

Other relevant Product Types (for which certification exist already in one or more Member States) include disinfectants for private area and public health areas (PT2[7]), food and feed area disinfectants (PT4), wood preservatives (PT8[8]), preservation for cooling systems (PT11 open systems only), avicides (PT15), molluscicides (PT16), piscicides (PT17) and repellents (PT19[9]). As regards disinfectants for swimming pools, masonry preservatives (PT10 for professional uses) and slimicides (PT12 in oil gas extraction), training and/or certification may also be relevant as there is a potential high risk of human and environmental exposure although the biocides are not used by dedicated pest control companies.

---

tance as adjunct measures for the realization of and compliance with the GP, but were not regarded as being part of the GP. Further, the study concluded that the GP reference document must involve references to legislation or other regulating documents such as DIN-standards or information sheets from professional associations, in which the basic information is given.

[6] Further, in some Member States certification is required for specific application techniques (in particularly the use of fumigants) or substances of a certain toxicity and not specific product-types.

[7] Possibly for some applications only

[8] Possibly for some applications only

[9] Possibly for some applications only

Training and certification of professional user - the impacts

As regards health and environmental impacts, there is little if no information to support an assessment of these effects. A very rough guesstimate would point in the direction of exposure reductions in the order of between 10%-50%. Experience from plant production equipment pointed to a reduction from "soft training" in the order of 10%. As regards biocides, it is likely that the gains can be higher as the determination of the optimal dosage is more difficult and hence this estimation of between 10% and 50%.

The health benefits from reducing the exposure to hazardous biocides are ultimately related to the number and severity of illnesses or adverse effects among both professional and non-professional users, and also among others exposed during the service life of the products or through secondary exposure. The actual benefit is however difficult to quantify. The available classification data for some of the biocidal sub-stances indicate that the key health effects of concern which could result from exposure to these biocides are acute intoxication or poisoning, sensitizing effects or effects related to exposure to substances causing chronic effects (CMR) from exposure to low doses.

The environmental benefits are expected to be reductions in acute as well as long-term hazards to aquatic organisms and the aquatic environment as well as reduced effects on microorganism in waste water treatment plants (WWTP), especially microorganisms responsible for the nitrification/denitrification processes for removal of nitrogen.On the average almost 3 out of 4 biocides can be assumed to be highly toxic to aquatic life and half of the substances in addition not easily biodegradable, and less emissions of these substances to the environment would therefore improve the environmental status, depending on the substances included in the scheme, the exact character of the scheme, etc.

Further, for the substances in PT14, PT15 and PT23, the benefit can be expected to be reduced poisoning of to non-target mammals, birds and other vertebrates in the terrestrial environment.

Costs of training and authorization will depend on the specifics of the biocide, the regulation and the scope of the training, and the way to integrate the biocides schemes in developing training schemes for plant protection products. Data from four Member States[10] point in the direction of some 2,500 EUR per attendant for a training course in order to obtain a certificate. In addition, there is the cost of lost production in the sense that those attending the course do not produce while attending. On the other side however, there are possible savings related to possible reduced future production losses (as a result of optimised behaviours) and/or possible efficiency gains as regards work processes etc. for users.

Another essential cost element is however the cost of setting up and operating the whole system. This is mentioned in some of the replies as an important area of concern and it relates to the authorization system; the drafting and updating

[10] Denmark, UK, Sweden and Netherlands. These are high-cost countries and the costs can be lower in other EU Member States.

of Good Practice reference documents; and enforcement issues. These are costs incurred by public authorities as well as by professional sector concerned.

Another important implementation aspect relate to the level of knowledge and expertise that is required in order to draft BPG documents and training material that is sufficiently targeted, relevant and pointing to the effective approaches. In this regard, inspiration can be sought from the German study's conclusions that the educational contents on biocidal products be anchored more clearly in the framework of already existing teaching plans. It was further pointed out that an operation-oriented description of the Good Practice would be more useful than a comprehensive general description..

Further studies recommended

In order to consolidate these first conclusions, the authors recommend the Commission to launch a study on the potential for reducing human and environmental exposures to biocides by introduction of training and certification of professional users of biocides for different PTs. For the present study available evaluations have been searched for in the MSs, and it would probably be necessary to collect basic data from a number of MS e.g. on the numbers of registered cases of poisoning (mainly relevant for PT14 and PT18) in countries with and without a certification system. Further some assessment, based on interviews of (or questionnaires to) professional users, may clarify the potential for reducing the exposures to biocides for other PTs.

Certification and inspection of application equipment - the concept

With inspiration from the lessons learned from plant protection products, and recognising that some Member States today do have either mandatory or voluntary systems already in place for that sector; certification of application equipment could be an appropriate measure as regards biocides control at the EU level, especially in cases where there is a high probability that inadequate application equipment result in over-dosage, high human exposure or high releases to the environment.

A system could include joint definitions; joint essential requirements for all new equipment and the establishment of necessary conditions for certification; for setting up a register of certified equipment and for the marketing of new application equipment. The system may be combined with a system for inspection/test of the equipment already in use.

Essential requirements to biocide application equipment within the scope of the Machinery Directive (e.g. dosing equipment) may be developed for amendment of the Directive.

Specific requirements - that could also apply on a voluntary basis - have to be defined in a compliance standard to be developed by standardization bodies. As the equipment is very diverse, an inventory should first be necessary in order to develop specific appropriate requirements to each type of equipment. A mandate could be elaborated through CEN, the European Committee for Standardization. As the equipment in use is apparently very diverse, setting conditions for all equipment and inspection will be quite extensive.

The study has identified the following application equipment as potentially relevant to consider: Disinfection agent-dosing apparatus (e.g. for disinfection in cooling systems.

Whereas a number of Member States have established compulsory control of some types of spraying equipment for plant protection products (Bipro 2004), no information has been available on equipment for application of biocides.

In the questionnaire response Germany mentions that especially in cases where the quantity that is to be applied is not easy to control and exposure is likely, it appears sensible to ensure the optimal concentration of active substance, the targeted and safe (low-risk) application as well as the control of the form (e.g. the optimal droplet size) by placing precise demands on the utilized equipment.

A certification of equipment may be relevant for equipment for injection of biocides or a continuous supply of biocides to a system: Drinking water disinfectants (PT 5), swimming pool disinfectants (PT 2, subgroup) or slimicides and other biocides used for oil extraction (PT 12, subtype).

It may further be relevant for equipment for spraying (including aerial spraying) of the biocides with a high risk of aerosol formation and uncontrolled releases to the environment. Such equipment may be used for disinfection in public areas (PT2), in veterinary hygiene (PT 3), in preserving/disinfection of masonry (PT 10) and by use of insecticides (PT18). Further, spraying of biocides as part of paint may be used for wood preservatives for surface treatment (PT 8) and antifouling products (PT 21). Equipment for fumigation and gassing may as well be covered by a certification system. Fumigation and gassing is mainly applied for control of rodenticides (PT 14), wood destructing insects (PT18) and other vertebrates (PT23). Tanks for pressure and vacuum preservation (PT8) may be covered as well.

Certification and inspection of application equipment - the impacts

As regards the health and environmental impacts, there is no information available to inform the quantitative analysis thereof. However, judging from the examples of experience with some plant protection equipment, and recognising that the gains in that field are likely to be significantly higher, a rough estimate could indicate reductions in the exposure of humans and environment to be in the order of 0-20% by use of new certified equipment compared to new equipment not certified (the reduction when comparing to old equipment would probably be significantly higher). A more detailed assessment of each type of equipment is necessary in order to estimate the potential with more certainty. The impact of a system for regular inspection of the equipment would probably be significantly lower.

The types of benefits of reduced exposure of human and the environment is at an overall level the same as described for training and certification of professional users above.

Judging from the expert workshop outcomes and from responses the questionnaire survey, it is a frequently observed position that introducing harmonised

inspection systems for equipment is likely to be difficult and costly, although it should be noted that there are responses also pointing in the opposite direction.

Further studies recommended

In order to consolidate these first conclusions, the authors recommend the Commission to launch a study including an inventory of equipment used for application of biocides for all PTs, and an assessment of the costs and the potential for improvement of the performance by applying best available techniques. The equipment description in a German assessment of Good Practice for the use of biocides may be used as a starting point for the inventory. Further, a working group (or more working groups) including experts with specialised expertise in the fields may be set up.

Long term good practice and prevention - the concept

Integrated pest management (IPM), as applied for plant protection is an integrated approach combining more measures among others prevention, pest monitoring, use of thresholds (blanket restrictions), lowest use of chemicals, and use of substitutes. Many of the IPM principles may be applicable for biocidal products as well and some of the principles would be an integrated part of the BPG documents and training schemes for certified users as described above.

Different from the use of plant protection products, biocides are used in urban environments and the biocides are applied on man-made surfaces and structures, or in food and feed production areas, or in hospitals. As a consequence the range of options for reducing the use of biocides by non-biocide prevention and control methods are much wider than for plant protection products, but the efficiency of the biocidal application is remaining central for many of the measures to be elaborated with a long term perspective as it concerns development of new materials and techniques.

An integrated approach to the reduction of the use and releases of biocides may (apart from measures addressed elsewhere) include: prevention of pests by improved hygiene; prevention of microbial growth by development of materials with surfaces that inherently impede the growth of microorganisms; monitoring of pests in order to help more efficient and timely targeting of the pests; use non-biocidal control techniques first; reduce the use of biocide-containing products by constructive solutions (e.g. large eaves preventing microbial growth on walls) and reduce the use of biocides in industrial processes by process changes and quality control (e.g. Hazard Analysis and Critical Control Points (HACCP) in food processing).

To pursue this, the following measures are of relevance: promotion of the development and use of non-biocidal techniques; promotion of the development and use of materials and surface coatings; promotion of the development and use of constructive solutions; development of pest monitoring systems; development of pest prevention techniques and non-biocidal techniques; and promotion of the development and use of alternative processing techniques, as well as voluntary quality control schemes.

In the responses to the questionnaire question regarding IPM the Member States in general consider that IPM principles could be applied on at the least

some product-types such as rodenticides (PT 14), insecticides (PT 18) and repellents and attractants (PT 19). Also, wood preservatives (PT 8) and antifouling products (PT 21) are mentioned by a few Member States as relevant product types. Measures like prevention by use of alternative materials or constructive solutions and promotion of non-biocidal control (other than prevention) may, however, in the long term be relevant for many PTs.

Long term good practice and prevention - the impacts

The reduction potential varies by product-types. It has not been possible to provide an assessment of the costs, which is to a high extent due to the long termed (and to some extent innovation driven) nature of this concept. For some product types development of new materials and techniques may result in a very significant reduction of the use of biocides. This concerns e.g. antifouling products and wood preservatives.

The types of benefits of reduced exposure of human and the environment is at an overall level the same as described for training and certification of professional users above.

Further studies recommended

Options for long term measures are different for all 23 PTs and at the moment the description of the options is too premature for a detailed assessment of cost and benefits of the measures. In order to inform the assessment of long term measures, the Commission may launch a more in-depth study of the actual options for reduction of the use of biocides for each PT. The study may include some more detailed investigations of the options for selected PTs as cases studies.

Assessment of legal instruments

An assessment was made of five legal instruments to implement the above mentioned three measures. The pros and cons of each instrument were identified in order to provide input for the decision-makers in the choice of the most appropriate legal instruments - or combinations hereof. The options considered are:

Option 1: No action

Option 2: Extension of the scope of the Pesticide Thematic Strategy and Framework Directive to *pest control* biocides at *this* stage

Option 3: Extension of the scope of the Pesticide Thematic Strategy and Framework Directive to *all types* of biocides at a *later* stage

Option 4: Incorporation of the use phase in the scope of the Biocide Directive 98/8/EC

Option 5: Development of a specific legislative instrument on the use of biocides

From a legal perspective, it is in general recommended to focus on improved legal simplicity and legal certainty. From this viewpoint, option 3 appears most appealing. *Legal simplicity* is achieved by combining both biocides and PPP in the same Directive. The legal basis for this is TEC Art. 175(1), which would

allow addressing both environmental and health related aspects arising from the use of biocides. Concerning *legal certainty*, the EU legislation on biocides products and PPP has until now been separated. Thus, in order to maintain the legal clarity, a combined Framework Directive should clearly address the individual needs and aspects related to biocides products and PPP, respectively. It is noted also that option 3 is foreseen by the Thematic Strategy and the proposed Framework Directive. Finally, as proposed by option 2, the combined Framework Directive could at an early stage include aspects of biocides products, where sufficient knowledge is available.

However, the three measures:

1 Training and certification of users
2 Certification and inspection of application equipment
3 Long term good practise and prevention

may be promoted effectively regardless of which of the above legal instruments is pursued. From a legal perspective, it is merely a matter of ensuring a clear formulation of the legislative act. Thus, the legal framework can already now set the frames and mechanisms for implementing such measures over time. The actual implementation requires further and continuously generated information on the actual use of biocides products. This applies in particular to the third of the measures.

2 Introduction

2.1 Study context

This report constitutes the final report of the study "Assessment of different options to address risks from the use phase of biocides". The study commenced with a kick-off meeting with DG-ENV on 3 June 2008 and the inception report was prepared during the month of June.

2.2 Study scope

Study purpose

The purpose of the study is to "to help identify the appropriate measures and legal instruments that would allow ensuring a sustainable use of biocidal projects" (according to the Terms of Reference).

Study scope

To this end, the study should provide necessary data on

- the risks posed by the use of biocides;
- the possible measures to reduce the risks;
- the environmental, social and economic impacts of the identified risk reduction measures.

In achieving this, the study should build on the results of preliminary consultations of stakeholders and competent authorities; information available from Member States and the outcome of an expert meeting held in April 2008.

Study tasks

The study essentially consists of three separate, but related, tasks, viz.:

1. Information gathering
2. Recommendations on measures to propose
3. Evaluation of the most appropriate action to take

2.3 Study methodology

Categories and typology

An important element of the study has consisted in the establishment of appropriate and manageable categories and typologies thereby providing a consistent way of addressing the search for information on quantities and volumes; and the descriptions of the risks.

First, it is important to consider the term use phase and how to define it. We propose to distinguish between an application phase and a service life phase,

and the below table goes more into detail with this understanding for the 23 Product-types (PT).

Table 2-1 Definitions of "application phase" and "service-life" for the 23 types of biocidal products under Directive 98/8/EC. The service life includes "disposal" in those cases where the use does not generate a collectable waste product but as a natural last step results in a direct discharge/emission e.g. cleaning product solutions being washed into the sewer after having exerted their action.

Product-type	Sub-type	Application phase	Service life
Main Group 1: Disinfectants and general biocidal products			
1: Human hygiene biocidal products	Skin and mouth disinfectants	The application of the product onto the skin or into the mouth incl. washing off excess product	The remaining period until the skin is washed or new mouth disinfectant is applied
2: Private area and public health area biocidal products	Disinfectants for private areas	The application of the product onto surfaces etc.	The remaining period until next disinfection takes place
	Disinfectants for public areas	The application of the product onto surfaces etc.	The remaining period until next disinfection takes place
	Disinfectants for medical equipment	The rinsing of the medical equipment in question	The period until new disinfection is required
	Disinfectants for laundries	The application of disinfectants at the laundry to clothes/fabric	The period until new disinfection of the clothes is required
	Disinfectants for air-conditioning systems	The filling of disinfectant liquid into the air-conditioning system	The operation of the air-conditioner until re-fill is required
	Disinfectants for chemical toilets	The filling of disinfectant liquid into the chemical toilet	The period from filling until the chemical toilet is emptied
	Disinfectants for swimming pools	The filling of disinfectant into the swimming pool dispenser system	The period from filling until re-fill is required (dispenser empty)
	Disinfectants for wastewater and hospital waste	The filling of disinfectant into the dispenser of the wastewater treatment system	The period from filling until re-fill is required (dispenser empty)
3: Veterinary hygiene biocidal products		The application of the product onto teats, udders, hoofs etc.	The period from application until new application is required
4: Food and feed area disinfectants		The rinsing of the production equipment or surface in question	The period until new disinfection is required
5: Drinking water disinfectants		The filling of the disinfectant into the dispenser/feeding system or directly into drinking water	The period from treatment until the water is consumed or discarded
Main Group 2: Preservatives			
6: In-can preservatives		Introduction of the preservative into the product prior to or concurrent with the filling of the can or other container	Strictly only the period until the can is empty, but here we include also the service life of the product as it still contains the preservative
7: Film preservatives	Film preservatives for paints	The application of the paint onto a surface	The service life of the paint i.e. until new application is required
	Film preservatives for plastics, sealant, fillers and other products	The application of the product onto surfaces, into joints etc.	The service life of the product i.e. until replacement

	Product-type	Sub-type	Application phase	Service life
8:	Wood preservatives	Vacuum and pressure preservatives	The industrial application of the biocide into the wood (including transport and storage)	The use of the treated wood until replacement/disposal
		Preservatives for surface treatment	The on-site coating of a wooden surface with preservative	The use of the treated wood until replacement/disposal
9:	Fibre leather, rubber, and polymerised materials preservatives	Preservatives for textiles, leather, rubber, paper and other polymeric materials	The application of the preservative onto or into the material (incl. manufacture of final product)	The consumers' use of the material until replacement/disposal
		Preservatives for insulating materials of organic fibres	The application of the preservative onto or into the material	The use of the insulating material until replacement
10:	Masonry preservatives		The application of the preservative onto the masonry surface	The period until new application on the same surface is required
11:	Preservatives for liquid cooling and processing systems		The filling of preservative into the cooling or processing system	The period until re-fill of the system is required
12:	Slimicides	Slimicides for wood and paper pulp	The introduction of the slimicide into the pulp	The period until the pulp has been turned into the final product
		Slimicides and other biocides used by oil extraction and fuel storage	The introduction of the slimicide into water-based drilling mud, tanks for fuel storage etc.	The period until new addition of slimicide into the product or container is required
13:	Metalworking fluid preservatives		The filling of biocide into metalworking fluid products or process equipment	The period until replacement of the liquid or re-filling with biocide is required
Main Group 3: Pest control				
14:	Rodenticides		The placing of the rodenticide at the location where control is required	The period until the required level of control is reached or new application of rodenticide is required
15:	Avicides		The placing of the avicide at the location where control is required	The period until the required level of control is reached or new application of avicide is required
16:	Molluscicides		The placing of the molluscicide at the location where control is required	The period until the required level of control is reached or new application of molluscicide is required
17:	Piscicides		The placing of the piscicide at the location where control is required	The period until the required level of control is reached or new application of piscicide is required
18:	Insecticides and products to control other arthropods		The application of insecticide at the location where control is required or onto the animal that requires treatment	The period until the required level of control is reached or new application of insecticide is required
19:	Repellents and attractants	Repellents and attractants for control of gnat and fleas	The placing of the product at the desired location including application on skin etc.	The period until the required level of control is reached or new application of repellent is required
		Repellents and attractants for control of game and birds	The placing of the product at the location where control is required	The period until the required level of control is reached or new application of repellent is required
Main Group 4: Other biocidal products				

	Product-type	Sub-type	Application phase	Service life
20:	Preservatives for food and feedstock		The application of the preservative onto the product or the processing system	The period from application until the food or feed is consumed
21:	Antifouling products	Antifouling paints for vessels < 25 m	Application of the antifouling paint on the hull of the vessel	The period from application until replacement of the paint is required
		Antifouling paints for vessels ≥ 25 m	Application of the antifouling paint on the hull of the vessel	The period from application until replacement of the paint is required
		Antifouling paints for other uses	Application of the antifouling paint onto the sub-sea structure (e.g. drilling platform, fish cage etc.)	The period from application until replacement of the paint is required
22:	Embalming and taxidermist fluids	Embalming fluids for humans	Injection of the embalming fluid into the corpse (or part hereof)	The period where the embalmed corpse stays intact
		Embalming and taxidermist fluids for animals.	The submergence of an animal in the embalming fluid or dry application of preservative	The period where the embalmed animal stays intact
23:	Control of other vertebrates		The placing of the biocide at the location where control of the "other vertebrate" is required	The period until the required level of control is reached or new application of biocide is required

Second, we also find it important to distinguish between PT that are used by professional users and those that are used by non-professional users. This has an important bearing on the applicability of the measures under consideration.

Third, as regards the risks posed by the different PTs, we have differentiated between the intended effects or hazardous properties of the biocides, and the unintended effects. By the latter term we mean those effects that occur as a result of the use, but which do not relate to the target purpose of the use.

Linking to measures

In order to link properly between this overview and the measures, we carry out an assessment of the options for risk reduction. In other words, what kind of response can possible measures aim to achieve: reductions as regards quantities; hazardousness; and/or releases and exposure (in application and in service life). Building upon that, and upon a typology of possible measures, we then assess the applicability by product-types of selected relevant measures.

Data and information

In elaborating this report, we have scrutinized very carefully the questionnaire responses that we were provided with from DG-ENV[11]. Furthermore, we have consulted with specific stakeholders whom we thought could maybe provide information, data or interesting view-points, and we have consulted reports and other material including the material from the expert consultation of April 2008. This report presents and builds upon what has come out of this exercise, and it also shows the substantial lack of knowledge as regards quantities of biocidal products used.

[11] Questionnaire to competent authorities in Member States, sent by the Commission in February 2008.

This lack of information is quite crucial as it is an important factor in providing robust quantitative assessments of risks and in providing assessments of the measures regarding their impacts (costs and benefits). Thus, these aspects are covered in semi-quantitative or qualitative terms supplemented with "expert judgments" wherever we find it justifiable.

2.4 Structure of this report

This report is structured as follows:

- Chapter 3 explains about the use of biocides in the EU building upon the available information as regards volumes.
- Chapter 4 assesses the risks from biocides in the use phase building upon the typologies and categorizations described above.
- Chapter 5 describes the options for risk reduction - i.e. the responses to possible legal stipulations.
- Chapter 6 looks into the possibly relevant measures to control the use of biocides in the EU.
- Chapter 7 considers different legal options for advancing further in this area.

3 Biocides in the EU

3.1 Active substances

Commission Regulation (EC) No 1451/2007 of 4 December 2007 "on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market" lists in Annex I the active biocidal substances having been "identified as available on the market before 14 May 2000". The list comprises a total of 964 active substances.

In Annex II of the same Regulation, the "active substances to be examined under the review programme" are listed. The list consists of substances notified by companies and some additional substances proposed for review by one or more Member States. 350 active substances are included on the list of which 330 are assigned to one or more specific use categories (Product-types, PT) while the last 20 are "sub-substances" which refer to one of the assigned substances.

For the majority of the substances, the applications for registration comprise use within more than one PT. The list of substances distributed on the 23 PTs contain in total 1528 entries implying that on the average each active substance appears in approximately 5 product-type categories. Generally speaking, the PTs representing disinfectants and preservatives contain the highest number of substances. A rough overview of the numbers of substances in each category is shown below.

Table 3-1 Approximate number of substances in the review programme for biocides per Product Type (PT).

	Number of substances per PT				
	150-199	100-149	50-99	10-49	< 10
Product Type (PT)	PT2	PT3 PT4 PT6 PT9 PT11 PT12 PT13	PT1 PT5 PT7 PT10 PT18	PT8 PT14 PT19 PT20 PT21 PT22	PT15 PT16 PT17 PT23

Chemically, the substances represent a wide range of groups from simple inorganic and organic molecules to highly complex compounds designed with specific biocidal properties, including a number of substances also registered as plant protection products (total of 16). Some natural substances, micro-organisms and a number of polymers are represented on the list.

Thus, it is not possible at an overall level to establish a typical chemical profile of biocidal active substances in the EU although, of course, a number of well-known groups of chemical substances such as sulfites/chlorites, quaternary ammonium compounds, benzothiazoles and -thiazolones, dithiocarbamates, coumarines, pyrethrins/pyrethroids and various strongly oxidising or otherwise very reactive substances are represented on the list.

3.2 Production, import and use of biocides

3.2.1 Quantitative information at Community level

Quantitative information about the production, import and use of biocidal products or active ingredients at Community level is very sparse. Therefore, as part of the present study, a brief survey of this type information submitted by companies within the notification procedure following the entry into force of the BPD was conducted. The survey took place at (the former) ECB in Ispra, Italy in July 2008.

As the quantitative information provided by the notifiers is confidential, a detailed presentation cannot be given in this report. However, some aggregated figures of annual production/import volumes are presented in Table 3-2.

It should be noted that the information provided by the companies for the notification is rather inhomogeneous and far from complete. In some cases, a total annual production/import volume has been reported but not distributed on PTs and in others specific volumes for the relevant PTs have been reported but not the total volume, or the sum of PT volumes and the total volume do not match (the latter may also include other industrial uses). Some companies have just indicated qualitatively the PTs where they believe the substances are used, and others have provided a mix of qualitative and quantitative information. In some cases, it is not quite clear whether the figures stated are active substance or product tonnages. The reference years also differ, but the vast majority of data are from the period 1998-2001 with the bulk being from 1999 and 2000. For the purpose of this survey the most recent production/import information was used (in a few cases with high year-to-year variability an average was used).

However, with these reservations is appears from a comparison with the number of substances registered for the review programme that at PT level quantitative production data (from 1998-2001) exist for more than 50 % of the substances (with a few exceptions). Hence, the tonnages presented in Table 3-2 are considered an absolute minimum estimate of the production volume of active biocidal substances in the EU. It is not known to what extent the produced biocidal substances have been exported outside the EU (i.e. not actually used in the

EU) and neither is the volume of import of biocides contained in imported materials and articles known.

Table 3-2 Annual production/import volume figures for active biocidal substances in Europe based on data provided by companies to the European Chemicals Bureau as part of the notification procedure.

PT	No. of substances per production tonnage group for each PT							Tot. no. with data	Total annual tonnage per PT	% of total tonnage
	≥10,000	1,000-9,999	100-999	10-99	1-9,9	<1	Only qual. info			
1	0	4	9	8	8	8	10	47	18,290	4.6
2	2	6	16	18	26	10	24	102	161,667	50.5
3	0	2	9	12	16	11	10	60	10,792	2.7
4	1	2	3	20	16	5	11	58	16,588	4.2
5	2	1	4	5	3	2	7	24	49,093	12.3
6	0	1	14	31	27	10	20	103	5,343	1.3
7	0	0	4	13	19	13	16	65	1,440	0.4
8	0	2	6	9	4	6	8	35	11,233	2.8
9	0	0	3	29	28	11	15	86	1,546	0.4
10	1	0	1	8	23	12	20	65	50,389	12.6
11	2	7	6	19	19	8	16	77	49,968	12.5
12	0	2	15	11	17	7	20	72	6,390	1.6
13	0	3	9	14	16	9	12	63	7,047	1.8
14	0	0	0	1	3	7	0	11	23,9	<0.1
15	0	0	0	0	2	1	0	3	1,05	<0.1
16	0	0	0	0	0	0	1	1	0	0
17	0	0	0	0	0	0	0	0	0	0
18	0	1	3	13	15	15	7	54	5,362	1.3
19	0	1	0	2	3	4	9	19	2,190	0.5
20	0	0	1	0	0	2	6	9	819	0.2
21	0	0	1	4	1	0	3	9	668	0.2
22	0	0	0	0	3	1	1	5	15,5	<0.1
23	0	0	0	0	0	1	0	1	0,59	<0.1
Tot.	8	32	104	217	249	143	216	969[1]	398,865	100

[1] Several substances occur in more than one PT.

Within the majority of PTs relatively few substances (<5) constitute significantly more than 50 % of the total production/import tonnage registered. For 11 of the PTs the most important substances account for more than 90 % of the total tonnage, while for another 4 PTs the share of the most produced substances is between 75-90 % of the total. Only for PTs 1, 6, 7, 9, 11 and 12 the share of the most produced substances is below 70 % (but still 50 %or more). No production is registered for PTs 16 and 17.

General disinfectants such as sodium hypochlorite, chlorine and hydrogen peroxide are the three substances with the highest production volumes of all substances, approximately 54 % of the total tonnage registered (almost 400,000 t).

An enquiry to EUROSTAT made as part of this study revealed that the overlap between active substances in PT18 (insecticides) and active substances in plant protection products (PPPs), as reported by the European Confederation of Pest Control associations (ECPA) to EUROSTAT, is limited (only 24 substances were both biocides and PPPs). However, for many of the few overlapping substances the tonnage produced/imported for biocidal uses constitutes a significant fraction of the total amount.

3.2.2 Quantitative information at Member State level

Only limited quantitative information on biocide production/consumption at Member State level has been obtained from the questionnaires. This is partly due to problems in collecting such data encountered in many MS where legislation and authorisation schemes for biocides are not yet implemented.

The Product Registers of the Nordic countries register to some extent the sales of biocides in the countries, and in order to find out whether the countries had any additional updated sales information available in the Nordic Product Registers and/or the SPIN database, the following were contacted: The Danish EPA (Pesticides and Gene Technology), the Danish National Working Environment Authority (the Product Register), the Swedish Chemicals Inspectorate and the Norwegian Pollution Control Authority. According to all contacted persons, no additional information was immediately available. The Norwegian Product Register has approximately 1000 biocidal products registered. Information about these products can easily be extracted. However, dividing the products into the different product types will require a formal enquiry and specifically allocated resources.

The German Federal Institute of Occupational Safety and Health, BAUA (www.baua.de) has in the response to the questionnaire from DG ENV reported aggregated sales tonnages for PTS 14, 18 and 19, i.e. the "Pest Control" product categories. The sales of biocides in PT14 was 3 t/y (2003), in PT18 35 t/y (2004) and in PT19 0.4 t/y (2000). It is not clear whether the tonnages are for the active substances or the formulated products.

The Ministry of Health (MoH) in Belgium has for the last couple of years registered sales data (tonnages) on all biocidal products. However, the detailed data are currently not publically available, and the process to decide on to what extent and how the data can be made accessible is still ongoing (Philippe Ruelle, MoH, pers.comm., January 2009). It has therefore not been possible to get access to and use the data for the purpose of this report.

3.2.2.1 Denmark

The only comprehensive assessment of the sales/consumption of biocides for all application areas in a Member State that has been available to the study team was undertaken in Denmark by initiative of the Danish EPA in 1999/2000 (Lassen et al. 2001). The objective of this study was to establish a comprehensive view of the consumption of biocidal products in Denmark and to develop models for assessments of human and environmental exposure to the biocides. The inventory was drawn up on the basis of information from the Danish Pesticide Statistics, the database of the Danish Product Register, trade organisations, private companies, Statistics Denmark and research institutions.

For a number of application areas, questionnaire surveys were conducted, either in cooperation with the trade organisations or by direct enquiries to private companies. The result of the inventory is shown in Table 3-3. For biocides in articles (e.g. in-can preservatives in paints) the consumption represents the total biocide content of traded articles including imported article. Please note that the consumption volumes represent the weight in terms of active substance.

Table 3-3 Consumption of biocides (active substance) with finished products in Denmark 1998/99[2]). The assessment only includes applications not covered by other EU regulation.

Product-type	Sub-type	Total consumption (tonnes/year)	% of total DK consumption
Main Group 1: Disinfectants and general biocidal products			
1: Human hygiene biocidal products	Skin and mouth disinfectants[3]	51 - 101	1.7
2: Private area and public health area biocidal products	Disinfectants for private areas	390 - 420	8.9
	Disinfectants for public areas	710 - 1,150	20
	Disinfectants for medical equipment	0.1 - 1	0.01
	Disinfectants for laundries	277	6.1
	Disinfectants for chemical toilets	3 - 15	0.2
	Disinfectants for swimming pools	500 - 1,000	16
	Disinfectants for wastewater and hospital waste	0	0
3: Veterinary hygiene biocidal products		82 - 79	2,0
4: Food and feed area disinfectants		530 - 620	13
5: Drinking water disinfectants		31 - 51	0.9

Product-type	Sub-type	Total consumption (tonnes/year)	% of total DK consumption
Main Group 2: Preservatives			
6: In-can preservatives	In-can preservatives for paints	29 - 118	1.6
	In-can preservatives for inks, fountain water, sealants and adhesives	1.2 - 3.7	0.05
	In-can preservatives for cleaning materials	24 - 180	2.2
	In-can preservatives for other products	10 - 100	1.2
7: Film preservatives	Film preservatives for paints	27 - 158	2
	Film preservatives for sealant, paper, plastics, fillers and other products	0.9 - 5.5	0.09
8: Wood preservatives	Vacuum and pressure preservatives	377 - 453	9.1
	Preservatives for surface treatment	16 - 21	0.4
9: Fibre leather, rubber, and polymerised materials preservatives	Preservatives for textiles, leather, rubber, paper and other polymeric materials	1.4 - 5.6	0.07
	Preservatives for insulating materials of organic fibres	48 - 137	2
10: Masonry preservatives		11 - 25	0.4
11: Preservatives for liquid cooling and processing systems		11 - 14	0.3
12: Slimicides	Slimicides for wood and paper pulp	33	0.7
	Slimicides and other biocides used by oil extraction and fuel storage	91	2
13: Metalworking fluid preservatives		10 - 13	0.3
Main Group 3: Pest control			
14: Rodenticides		4.1	0.09
15: Avicides		0	0
16: Molluscicides		0	0
17: Piscicides		0	0
18: Insecticides and products to control other arthropods		9.4	0.2
19: Repellents and attractants	For control of gnat and fleas	1.1	0.02
	For control of game and birds	2.6	0.06
Main Group 4: Other biocidal products			
20: Preservatives for food and feedstock		-[4]	-
21: Antifouling products	Antifouling paints for vessels < 25 m.	53	1.2
	Antifouling paints for vessels >= 25 m.	250-340	6.5
	Antifouling paints for other uses	5-10	0.2
22: Embalming and taxidermist fluids	Embalming fluids for humans	9-12	0.2
	Embalming and taxidermist fluids for ani-	3-6	0.1

Product-type	Sub-type	Total consumption (tonnes/year)	% of total DK consumption
	mals.		
23: Control of other vertebrates		3.9[1]	0.09
Total (rounded)		3,600-5,530	100

1) The 3.9 tonnes used for control of other vertebrates are also included in product-type 14 Rodenticides, as it is not clear how much of the total is used for other vertebrates (moles). In the total sum, the amount is only included once.
2) Only biocides not covered by other EU regulation are included. Application areas where the delineation is not clear are indicated by a *. All figures represent the consumption of active substances and are represented by the range within which the authors estimate the 'true' value can be found at an 80% certainty level.
3) Only skin disinfectants used in the health care sector and in antibacterial soap are included.
4) Preservatives for food and feedstock are in general covered by other regulation, but there are a few exemptions, for example preservatives in cheese rind. Within this project, there has not been made any attempt to assess the consumption of biocides for these exemptions.

3.3 Actions by Member States[12]

This section presents a broad regulatory overview of the actions taken by Member States based upon national regulation, guidelines and other restrictions and requirements. The section is linked to Chapter 7, where the EU legislation on biocide products and plant protection products is presented.

The 27 EU Member States are at different stages when it comes to regulating biocides. Knowledge about the different stages and regulations in the countries is valuable primarily for two following reasons. First, it provides an indication of the level of change that new regulation will require in the different countries. Hence, the countries that will have to make significant changes to comply with the new requirements are the countries that presumably will encounter the highest impacts from the changed regulation. Second, information about the legislation may give an indication of how existing regulation in this field is constructed and thus creates a basis for identifying best practices. This second part will be analysed further in chapters 5 and 6 that will further analyse which measures the different MS has implemented. It is, however, necessary first to map which countries that have legislation that goes further than implementing existing Community legislation.

The Commission has collected information regarding the current level of regulation of the use phase of biocides through a questionnaire sent by the Commission in February 2008 to competent authorities in the MS. Based on the information collected, the countries can be divided into four groups of countries. Countries that:

- have regulation or guidelines on the use phase of biocides;
- have no specific regulations or guidelines, but certain requirements restricting the use of biocidal products;

[12] As regards (possible) EU interventions and actions, this issue is further discussed in chapter 7.

- have neither regulation nor requirements concerning the use phase of biocides; and
- have not supplied information to the study.

It should be noted that the Consultant assumes that all Community legislation is implemented, hence only legislation supplementing the acquis is included here.

The categorisation of the countries, based on information supplied in the Commission disseminated questionnaire is seen in Table 3-4 below.

Table 3-4 Categorisation of Member States with regard to legislation on biocides, as indicated in the questionnaires.

	Existing regulation or guidance	No legislation or guidelines, but restrictions on the use phase	Neither regulation nor specific requirements to the use phase	No info*
Member States	Belgium Germany Estonia Spain Finland France Hungary Netherlands Romania Slovenia United Kingdom	Italy Lithuania Luxembourg Malta Slovakia Sweden	Cyprus	Austria Bulgaria Czech Republic Denmark Greece Ireland Latvia Poland Portugal
Total (27)	11	6	1	9

Note: Based on the Questionnaire to competent authorities in Member States, sent by the Commission in February 2008.

*These countries have not answered the Commission disseminated questionnaire: The level of regulation in these countries is therefore uncertain and not included in this overview of actions by the Member States.

In total, 18 Member States have answered the questionnaires, implying that information is lacking on the actions of nine MS. The further analysis is based on the information available to the Consultant through the questionnaire, and these nine countries are therefore not included.

Based on a review of the questionnaires it is clear that only Cyprus does not have any legislation or restrictions on the use phase of biocidal products. Consequently, at least 60 % of the MS - corresponding to 17 out of 27 - have some sort of restrictions on the use phase of biocides. In Table 3-5 the existing regulation of the use phase is listed for MS that have indicated that they have regulation or guidelines, and in Table 3-6 is listed MS with other kinds of specific restrictions applicable to the use phase of biocidal products.

Table 3-5 Overview of responses from Member States with regulation or guidelines on the use phase of biocides

Member State	Is there any existing legislation or guidance on the use phase of biocidal products?*
BE	The use is, in principle, regulated through the mode of application, frequency, advices, specifications, etc. of the authorisation acts.
DE	In the case of activities involving biocidal products, it is necessary to proceed properly and in accordance with good expert practice (§9, Section 11 of the Hazardous Substances Ordinance). A corresponding guideline is under consideration.
EE	In Estonia pest control is regulated according to Biocides Act § 43. "Organisation of pest control". Also it is established the regulation of the Minister of Social Affairs "The requirements for the pest control conducted by biocidal products".
SP	There are legal requirements for sale, storage and professional use activities.
FI	The use of biocides (i.e. those which has a national authorization scheme in place already) is not allowed without authorization. Instructions for use are part of the authorization decision.
FR	No mandatory specific provisions in the law, it remain on the general provisions on the Work Code.Opinions given by some health or environmental risk national agencies Some guidance : NFU 43500 standard (certification) on the good practices of use of plant protection products or biocidal products, for professional users CTB A+ certification on professional users of wood preservatives product PT08 (http://www.ctba.fr/1_le_group/metiers.php?rub=liste-certification#). This standard is applied by companies on a voluntary basis, and given by FCBA.
HU	3/1969. (V. 16.) EÜM rendelet 18/1998. (VI. 3.) Népjóléti Minisztérium rendelete 38/2003.(VII. 7.) ESzCsM-FVM-KvVm eü rendelet 8. Melléklete 362/2006. (XII. 28.) Korm. rendelet
NL	Dutch Law on Plant Protection Products and Biocides
RO	For use of insecticides and rodenticides: methodological guides issued by Ministry of Health
SL	[…]As basic guidelines we use OECD Guideline for the use of pesticides. Existing legislation for professional users: Rules on Correct Uses of Biocidal Products for Professional Users (OJ RS, No. 79/07). Used only for professional users who use BP as T+, T or CMR Group 1 or 2.
UK	The UK has an existing scheme in place that covers the use of **some** biocidal products. The Control of Pesticides Regulations 1986

*Question from section 4 of the Commission questionnaire. The responses are taken directly from the submitted replies of the MS

Table 3-6 Countries with specific requirements restricting use of biocides

Member State	Is there any existing legislation or guidance on the use phase of biocidal products?
IT	No. Only by contracts for disinfestations, the committent can monitor and control the biocides use (kind of products, way of distribution, etc.)
LT	No. Agreed labels and usage instructions are issued as an annexe to biocides authorisation certificates.
LU	No (Under the PPP legislation there is a system of authorized users/vendors)
MT	This guidance is being developed
SE	The use phase may be regulated by the use of specific provisions in the authorization.
SK	Provided no answer to the question. But according to the info supplied the use phase biocides, is touched upon in Act No355/2007 Coll. On the Public Health

*Question from section 4 of the questionnaire. The responses are taken directly from the submitted replies of the MS, with the exception of Slovakia

In annex 3, a short introduction to the legislation in each MS and the respective responses to the questions in the questionnaire are enclosed.

Measures applied by Member States are further described in chapters 5 and 6.

3.4 Summary and conclusions

Almost 1,000 active biocidal substances have been registered by the European Commission as having been available on the market in Europe before 2000. At the end of 2007 only about 350 substances were left on the list. These substances will be included in the EU review and evaluation process with the aim to determine whether they are acceptable for inclusion on Annex I, IA or IB to Directive 98/8/EC i.e. be permitted for use as biocides in the EU in the future.

Whereas the identities of the biocidal substances are known, little information exists about their production and use overall in the EU as well as in the individual Member States. No aggregated information at EU level has been gathered and therefore the outcome of the survey of 8-10 year old production/import figures undertaken at ECB in Ispra in July 2008 as part of this study are the only more detailed figures at Community level known to the authors. The total annual production/import tonnage for active biocidal substances registered was approximately 400,000 tonnes. An equivalent estimate for annual production/import of active ingredients in pesticides has not been found.

The figures are, however, not only somewhat retrospective, they are also incomplete as quantitative information existed only for slightly more than 50 % of the substances, the figures are on production and not use volume, and the amount of biocides in imported materials and articles is not known. Among the Member States only Denmark seems to have undertaken a thorough survey of the market (in 2000). A comparison between the distribution of active substance tonnage on product type categories at EU level (this study) and in Denmark is shown in Table 3-7.

The comparison illustrates that whereas there are certainly many similarities there are also a number of dissimilarities due to differences of geographic, climatic or societal nature that should be taken into account both in risk assessment and in the process of selecting suitable risk reduction measures. E.g. there is no doubt that by far the largest area of use of biocidal products in the EU Member States is for disinfection purposes in private and public areas (PT2) whereas the use of drinking water disinfectants (PT5) is very limited in Denmark but important at EU level as a whole. The reason being that Denmark almost exclusively uses untreated groundwater for drinking water while in large parts of Europe the use of chlorinated surface water is normal practice. The use of wood preservatives (PT8) is likely to be more important in the cool and humid northern Europe than in the south while the opposite is the case with regard to masonry preservatives (PT10). Also the more extensive use of preservatives for liquid cooling and processing systems (PT11) at EU level probably reflects the climatic differences and higher biological productivity in the warmer southern parts of Europe compared to the north. Finally, the use of antifouling agents (PT21) seems to be relatively much more important in Denmark than in the EU as a whole, maybe because of the relatively large importance of shipping and commercial fishery and the significant number of pleasure boats per inhabitant (easy access to the sea everywhere in Denmark).

In conclusion, the figures presented in this chapter give an indication of the volume and structure of the biocides market in Europe but the lack of quantitative sales/use information at Community as well as at Member State level does restrict the possibilities of assessing the overall magnitude and potential severity of risks associated with the use of this type of chemical products.

Still, the production/import figures in Table 3-2 and other data presented in this chapter do, in combination with information about hazard properties of the substances and typical release and exposure scenarios for humans and the environment, provide a basis for identifying the PTs and the use situations that from an overall point of view (i.e. at EU level) are the most critical and the most central to address when considering possible future Community level measures within the field of biocides and their use. The risk identification is the subject of the subsequent Chapter 4.

Table 3-7 Comparison of the relative distribution (%) of biocide tonnage on product types at EU level and in Denmark.

PT no.	Product Type name	EU distribution of annual production tonnage (%)	DK distribution of annual consumption tonnage (%)
1	Human hygiene biocidal products	4.6	1.7
2	Private area and public health area biocidal products	40.5	51.2
3	Veterinary and hygiene biocidal products	2.7	2.0
4	Food and feed area disinfectants	4.2	13
5	Drinking water disinfectants	12.3	0.9
6	In-can preservatives	1.3	5.1
7	Film preservatives	0.4	2.1
8	Wood preservatives	2.8	9.5
9	Fibre leather, rubber, and polymerised materials preservatives	0.4	2.1
10	Masonry preservatives	12.6	0.4
11	Preservatives for liquid cooling and processing systems	12.5	0.3
12	Slimicides	1.6	2.7
13	Metalworking fluid preservatives	1.8	0.3
14	Rodenticides	<0.1	0.1
15	Avicides	<0.1	0
16	Molluscicides	0	0
17	Piscicides	0	0
18	Insecticides and products to control other arthropods	1.3	0.2
19	Repellents and attractants	0.5	0.1
20	Preservatives for food and feedstock	0.2	0
21	Antifouling products	0.2	7.9
22	Embalming and taxidermist fluids	<0.1	0.3
23	Control of other vertebrates	<0.1	0.1

4 Risks from biocides in the use phase

In regulatory chemical management terminology, risk is defined as the likelihood of negative impacts on humans or the environment resulting from the exposure to a chemical. Hence, the assessment of risk has two main components that must be addressed, namely the hazard(s) inherently associated with the chemical in question (mainly toxicity/ecotoxicity) and the possible exposure of humans and/or the environment in terms of magnitude, frequency and duration.

If a chemical or a living biological organism used in a biocidal product has no hazardous properties there is in principle no risk associated with its use and, similarly, if no exposure occurs there is no risk either. However, in reality there will always be some uncertainty with regard to the hazard as we may not know about all the possible effects of a biocidal product (even a well described one), and with regard to exposure there will always be the risk that an accident or large spill can occur leading to human and/or environmental exposure even for a substance or a living organism with no exposure under normal conditions of manufacture, use and disposal.

The aim of this study is not to conduct a substance-by-substance risk assessment as this takes place as part of the review process under Directive 98/8/EC and therefore, the resources and time available have not allowed for a detailed survey of the humans and environmental hazard properties of the notified active substances.

In order to at least get a rough idea about the human and environmental toxicities of the substances and possible characteristics of these, e.g. within specific PTs, the list of chemical biocidal substances to be reviewed (Reg. 1451/2007, Annex II) was compared to the so-called "Annex I" list of dangerous substances (Directive 67/548/EEC) with EU's harmonised human and environmental classifications for approximately 3,300 entries covering close to 7000 substances. Unfortunately, no equivalent classification exists for living biological organisms[13].

[13] Directive 2000/54/EC on the protection of workers from risks related to biological agents does classify a substantial number of pathogenic bacteria, vira and parasites, using a simple group system (four groups). However, the system is not comparable to that used for chemicals and the biological agents covered by the directive are not intended for use as biocides.

However, it turned out that only 105 of the 350 substances for review under the BPD are classified on the Annex I list while for the remaining 245 substances no information (at overview level) on human and/or environmental toxicity is easily available. Details about human and environmental toxicity are given in Section 4.1 that also presents an overview of intended toxicities of the substances within each PT.

As the information/data on hazardous properties is scattered and far from complete the assessment of risk associated with the use phase of biocides to a large extent boils down to considerations about the magnitude and character of the possible exposure of humans and the environment. The exposure assessment is presented in Sections 4.2 (humans) and 4.3 (environment).

Some information about the magnitude of the EU production and import volumes of biocidal active substances was presented in Chapter 3 and will be used together with the rather qualitative assessments of hazards and exposures in this chapter. This is done in order to roughly conclude in Section 4.4 on the relevance of the different biocidal product types and their uses for further considerations about possible risk reduction initiatives and measures.

Originally, it was the intention to develop a simple ranking or indicator system for the evaluation of risks inspired by e.g. the former EURAM model or the present Belgian indicator system for screening level risk evaluation of pesticides and biocides. However, eventually it was realised that this was not a feasible approach at the level of aggregation used in this study (the two systems mentioned both operate at substance level) and also considering the complexity of biocide functions and use areas and the big gaps in quantitative information about the substances/products e.g. regarding toxicities (this information is only gradually being established through the review process under the BPD).

4.1 Hazardous properties of biocides

Products under the biocides directive are intended for controlling undesired effects of living organisms in a wide range of situations and under different conditions, as reflected in the number of product-types established under the directive (23 plus a number of sub-types giving a total of 41 product categories).

Consequently also the intended effects (toxicities) of the products target a range of organism groups, terrestrial as well as aquatic. Most of the product-types do, however, aim at controlling various micro-organisms such as bacteria, fungi and algae. An overview of the intended toxicities of biocidal product-types under Directive 98/8/EC is presented in Table 4-1 below.

Table 4-1 Overview of target groups of organisms i.e. the intended toxicities of biocidal products.

Product-type	Mammals and birds	Insects etc.	Fish	Other aquatic organisms	Micro-organisms[1]
Main Group 1: Disinfectants and general biocidal products					
1: Human hygiene biocidal products					x
2: Private area and public health area biocidal products					x
3: Veterinary and hygiene biocidal products					x
4: Food and feed area disinfectants					x
5: Drinking water disinfectants					x
Main Group 2: Preservatives					
6: In-can preservatives					x
7: Film preservatives					x
8: Wood preservatives		x			x
9: Fibre, leather, rubber, and polymerised materials preservatives					x
10: Masonry preservatives					x
11: Preservatives for liquid cooling and process-ing systems				x	x
12: Slimicides					x
13: Metalworking fluid preservatives					x
Main Group 3: Pest control					
14: Rodenticides	x				
15: Avicides	x				
16: Molluscicides				x[1]	
17: Piscicides			x		
18: Insecticides and products to control other arthropods		x			
19: Repellents and attractants	x	x			
Main Group 4: Other biocidal products					
20: Preservatives for food and feedstock		?			x
21: Antifouling products				x	x
22: Embalming and taxidermist fluids		x			x
23: Control of other vertebrates	x				

1 Bacteria, fungi and/or algae

2 Molluscicides used in crops and gardens for control of slugs/snails are plant protection products, not biocides.

4.1.1 Toxicity to humans

As mentioned in the introduction, the list of biocidal substances was compared to the harmonised hazard classifications listed on Annex I to Directive 67/548/EEC. With regard to human toxicity the number of substances classified in one of the main categories of concern was identified for each of the 23 PT's.

Main categories of concern are considered to be: substances that are:
- carcinogenic, mutagenic or toxic to reproduction (CMR substances)
- have acute lethal effects, non-lethal irreversible effects after a single exposure
- severe effects after repeated or prolonged exposure.

Other substances considered are corrosive substances, and substances that may cause skin or respiratory sensitization.

Of the 350 biocidal active substances, 105 appear on Annex I to Directive 67/548/EEC with harmonised hazard classifications. The remaining substances will have to be self-classified if required.Out of the 105 biocidal substances from Annex I, 36 are classified in the hazard categories very toxic" (Tx) and/or " toxic" (T) (16/29). Six of these substances are classified as "toxic" due to severe effects after repeated or prolonged exposure. 16 substances are classified in the hazard category "carcinogenic", "mutagenic" or "toxic for reproduction" in category 2 or 3 (4/12), 30 substances are classified as skin and/or respiratory sensitizers (29/2), 24 substances are classified as "corrosive" (C) with either the risk phrase R35 (causes severe burns) or R34 (causes burns) (4/20). The remaining active ingredients listed on Annex I are classified with regard to physical hazards or as harmful (Xn) or irritant (Xi).

As the criteria for classification in the Substance Directive does not cover all endpoints, the list of biocidal active ingredient has also been compared against the EU list of category 1 endocrine disrupters for which there is documentation of endocrine activity in at least one study with living organisms. This list comprises 194 substances. The list has been developed within the EU Strategy for Endocrine Disrupters and has been further refined to establish the priority list of substances for more detailed evaluation of their role in endocrine disruption. However, for the purpose of this study the more comprehensive list of all category 1 substances has been used, although it should be stressed that there is no conclusive evidence regarding the endocrine disrupting effect.

Seven substances on the list of biocidal substances are listed as category 1 endocrine disrupters and of these six are also listed on annex I with a classification based on other endpoints. Five are classified based on health effects endpoints included in Table 4-3.

For other endpoints not specifically addressed by the existing test guidelines and classification criteria, like e.g. aspects of neurotoxicity and immunotoxicity, it as not been possible to find easily accessible and agreed lists to check the biocidal substances against. Table 4-3 therefore only includes an overview for each of the 23 PT's of the number of biocidal substance which on Annex I are classified in one of the main hazard categories of concern as defined in the in-

troductory paragraphs in this section together with the category 1 endocrine disrupters.

Table 4-2 shows how the above-mentioned hazard categories are represented in the 23 different biocide product types for the 105 active biocidal ingredients classified on Annex I.

Table 4-2 Health classification in selected hazard categories for active biocidal ingredients on Annex I to Directive 67/548/EEC.

PT	No. of AI's in PT	Number of active ingredients listed on Annex I with the following classification:							Cat. 1 Endocrine disrupters
		CMR[1]	Tx[2]	T[3] (acute)	T[4] (chronic)	C[5]	R43[6]	R42[7]	
Main Group 1: Disinfectants and general biocidal products									
1	85	1	1	3	0	12	4	2	0
2	165	3	3	4	0	16	15	2	2
3	104	4	2	5	0	11	8	2	0
4	108	2	2	6	0	16	10	2	1
5	52	1	0	5	0	10	3	2	0
Main Group 2: Preservatives									
6	141	11	4	8	0	14	19	2	2
7	89	10	4	7	0	6	17	1	1
8	41	3	1	2	0	1	5	0	1
9	135	10	4	6	0	10	22	2	2
10	94	10	4	6	0	7	17	2	1
11	125	5	3	9	0	15	14	2	2
12	116	6	3	7	0	13	15	1	2
13	101	6	2	6	0	9	14	1	1
Main Group 3: Pest control									
14	14	0[8]	7	1	5	0	0	0	0
15	2	0	0	0	0	0	0	0	0
16	0								-
17	4	0	0	1	0	0	0	0	0
18	66	0	6	8	1	0	4	0	3
19	22	1	0	0	0	1	0	0	0
Main Group 4: Other biocidal products									
20	25	2	2	4	0	4	3	0	1
21	10	0	0	1	0	0	3	0	0
22	25	1	1	4	0	4	5	1	0
23	4	1	2	1	0	1	1	0	0

[1] C: Carcinogenic M: Mutagenic R: Toxic to reproduction; [2] T_x = Very Toxic. [3] T (Toxic acute) covers acute lethal effects; [4] T (Toxic, chronic) covers *non-lethal irreversible effects after a single exposure* and *severe effects after repeated exposure*; [5] C = Corrosive; [6] R43 = *May cause sensitization by skin contact*; [7] R42 = *May cause sensitization by inhalation*.
[8] Some rodenticides are known to have CMR properties but this is not yet included on Annex 1.

From the table it can be seen that most CMR classified substances are found in Main Group 2 (preservatives) where they are represented in the range of 4 to 11 % in the individual PT's. In Main Group 1 (disinfectants and general biocidal products) the CMR's are represented in the range of 1 to approximately 4 %. These two groups also represent the PT's where the highest production volumes of biocidal substances are seen. CMR's are found among the substances in three out of the four PT's in Main Group 4 in the range between 4 and 25 %. However, this group represents a much smaller production volume according to Table 3-2.

Substances which are acutely toxic are widely distributed in all product types in Main Group 1, 2 and 4 in ranges between 1 to 50 %. They are also found in rodenticides (PT14) and insecticides and products to control other arthropods (PT 18), which can be expected based on the intended toxicity. Substances causing severe effects from repeated or prolonged exposure are primarily found in rodenticides (PT 14) and represent approximately 36 % of the number of active ingredients. It should of course be stressed that the actual toxicity of the finished biocidal products also depends on the concentration of the hazardous ingredients in the products.

Corrosive substances are widely distributed in Main Group 1and 2 and also in Main Group 4 representing roughly between 2.5 to 25 % of the number of substances.

Substances which are sensitizing to skin are also widely represented in Main Group 1, 2 and 4 and in Main Group 3 only in PT 18 ranging from 5 to 30 %. Only two substances classified as respiratory sensitizers on Annex I are included in the list of biocides. They are represented in Main Group 1 and 2 in all products types except wood preservatives and constitute between 1 and 3.8 % of the number of substances.

Category 1 endocrine disruptors as defined in relation to the EU-Strategy for Endocrine Disruptors are primarily found in Main Group 1 and 2 ranging from 0.6 to 2.5 % in the individual PT's. PT 18 in Main Group 3 has the highest percentage of endocrine disrupting substances, namely 4.5 % and the one substance with potential ED effects in PT 20 constitute 4 % of the substances registered under this PT.

In Table 4-3 the key health classification categories of the five biocidal active substances with the highest production volumes within each product type are shown **in alphabetic order**. From this table it can be seen that CMR substances are represented in all main groups. PT's containing CMR substances include: PT 2, 7, 9, 10, 19 and 21. Acutely toxic substances in high volumes are primarily found in Main Group 1 and 2. Skin sensitizers are found in all Main Groups but primarily in Main Group 2 and 4. Only one substance causing respiratory sensitisation is found among the highest production volumes in PT 3 and PT 12.

Table 4-3 EU Substance Directive Annex I health classification of the presumably most important biocidal active substances within each PT in terms of annual production volume in the EU (per PT). The substances are listed alphabetically, not ranked.

PT	Most important substances in terms of production tonnage (1998-2001) per Product Type	Health classification from Annex I							Not on Annex I
		CMR[1]	Tx[2]	$T_{(acute)}$[3]	$T_{(chronic)}$[4]	C[5]	R43[6]	R42[7]	
Main Group 1: Disinfectants and general biocidal products									
1	Benzoic acid, pentapotassium bis(peroxymonosulphate)-bis(sulphate), sodium benzoate, sodium hypochlorite	0	0	0	0	1	0	0	3
2	Chlorine, ethylene oxide, hydrogen peroxide, sodium hypochlorite, symclosene, troclosene sodium	1	0	2	0	1	0	0	0
3	Chloroxylenol, cyanamide, formic acid, glutaral, hydrogen peroxide, sodium hypochlorite	0	0	2	0	4	2	1	1
4	Chlorine dioxide, hydrogen peroxide, L-(+)-lactic acid, peracetic acid, sodium hypochlorite	0	0	0	0	3	0	0	1
5	Biphenyl-2-ol, chlorine, chlorine dioxide, potassium permanganate, sodium hypochlorite	0	0	2	0	2	0	0	0
Main Group 2: Preservatives									
6	1,2-benzisothiazolone, bronopol, (ethylenedioxy)dimethanol, guazatine triacetate, isothiazolone mixture, L-(+)-lactic acid	0	0	0	0	0	1	0	4
7	Carbendazim, dichlofluanid, diuron, tolylfluanid, triclosan	2	0	1	0	0	2	0	0
8	Boric acid, copper oxide, didecylpolyoxethyl ammonium borate, disodium tetraborate, guazatine triacetate	0	0	0	0	0	0	0	5
9	(Benzothiazol-2-ylthio)methyl isocyanate, 2-chloroacet-amide, chlorocresol, diphenoxarsin-10-yl oxide, disodium tetraborate, ziram	1	2	1	0	0	4	0	2
10	2-chloroacetamide, 2-phenoxyethanol, pine extract	1	0	1	0	0	1	0	1
11	Chlorine, chlorine dioxide, hydrogen peroxide, silver zeolite A, sodium hypochorite, tetrakis(hydroxymethyl)-phosphonium sulphate	0	0	2	0	3	0	0	2

PT	Most important substances in terms of production tonnage (1998-2001) per Product Type	Health classification from Annex I							Not on Annex I
		CMR[1]	Tx[2]	T(acute)[3]	T(chronic)[4]	C[5]	R43[6]	R42[7]	
12	Bronopol, 2,2-dibromo-2-cyanoacetamide, hydrogen peroxide, glutaral, peracetic acid, sodium di-methyldithio-carbamate, sodium hy-pochlorite	0	0	1	0	4	1	1	2
13	Boric acid, disodium tetraborate, (hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol, trimethyl-1,3,5-triazine-1,3,5-triethanol	0	0	0	0	0	1	0	3
Main Group 3: Pest control									
14	Bromadiolone, chloralose, chlorophacinone, coumatetralyl	0	2	0	2	0	0	0	1
15	Chloralose	0	0	0	0	0	0	0	0
16	-	-	-	-	-	-	-	-	-
17	-	-	-	-	-	-	-	-	-
18	Cyanamide, dichlorvos, phenothrin, piperonylbutoxide, propoxur, pyrethrin and pyrethroids	0	1	1	0	0	2	0	3
19	Ethyl-N-acetyl-N-butyl-beta-alaninate, methyl neodecanamide, naphthalene	1	0	0	0	0	0	0	2
Main Group 4: Other biocidal products									
20	Chlorine dioxide	0	0	1	0	1	0	0	0
21	4,5-dichloro-2-octyl-2H-isothiazol-3-one, diuron, zineb	1	0	0	0	0	1	0	1
22	2-butanone peroxide, dodecylgua-nadine monohydrochloride, methyl-ene dithiocyanate	0	1	0	0	1	1	0	2
23	Trimagnesium phosphide	0	1	0	0	0	0	0	0

[1] C: Carcinogenic M: Mutagenic R: Toxic to reproduction; [2] T_x = Very Toxic. [3] T (Toxic acute) covers acute lethal effects; [4] T (Toxic, chronic) covers *non-lethal irreversible effects after a single exposure* and *severe effects after repeated exposure*; [5] C = Corrosive; [6] R43 = *May cause sensitization by skin contact*; [7] R42 = *May cause sensitization by inhalation*.

When taking into account the substances that have been reported in the highest amounts it appears that the use of substances with CMR effects are not pronounced in all PT's of Main Group 1 and 2. CMR substances are represented in PT 2, 7, 9 and 10. Skin sensitizers are represented in most PT's in Main Group 2.

An improved picture of the toxicities relevant for the various product types would require evaluation/classification of the substances that are not included in Annex I to the Substance Directive.

However, based on the existing classification information it may be concluded that both acute and chronic toxicity properties are present amongst the classified active biocidal substances, with CMR classified substances and sensitizing substances being of major concern. Based on the chemical structure, it is also likely to assume that a high proportion of the substances not listed on Annex I would have to be self classified.

4.1.2 Ecotoxicity

As for toxicity to humans, a screening identification of inherent environmental hazard properties of the active biocidal substances has been made based on the information available on Annex I to the so-called Substance Directive (Directive 67/548/EEC). To this moment, only very few environmental hazard classification categories have been developed and implemented at Community level and hence the hazard identification is restricted to potential acute or long term toxic (in reality only lethal) effects in the aquatic environment. In addition to this only less than one third of the biocidal active substances appear on the Annex I list with a classification.

Other environmental hazard properties and/or classifications are of course relevant for an environmental risk assessment (e.g. PBT/vPvB or endocrine disruption). However, the relevant information is, if existing, not easily available for a wide range of substances at one time and therefore considered to be out of the scope of this study as explained previously.

80 out of the 105 substances classified on Annex I to Directive 67/548/EEC have a classification for hazards to the (aquatic) environment. 24 substances are classified as "very toxic to aquatic organisms" (R50) and 51 as "very toxic to aquatic organisms" + "may cause long-term adverse effects in the aquatic environment" (R50-53) while 5 substances have a lower environmental classification. As many of the substances, not least the ones in main groups 1 and 2, are intended for controlling micro-organisms it is likely that in a number of cases the classification may be due to their toxicity to algae (a fact which does not exclude them from also being toxic to fish and other aquatic organisms).

This implies that one can roughly assume that on the average almost 3 out of 4 biocides will be highly toxic to aquatic life and that half of the substances in addition to high aquatic toxicity will be "not easily biodegradable". As biocides are designed to have a toxic effect on one or more groups of living organisms this result is not very surprising but it does give some support to the assumption that once a biocide enters the (aquatic) environment it most likely has a potential for causing adverse effects.

On a PT basis the average fraction of substances having an environmental hazard classification (among those with information on classification) is about 70 %. The average for Main Group 1, disinfectants, and main group 4, other biocidal products, is about 60 %, while it for Main Group 2, preservatives, is close to 80 % and for Main Group 3, pest control, is 95-100 % if PT19, repellents and attractants (which are not intended to kill organisms), is excluded.

In Table 4-4 the environmental classifications on Annex I of the Substance Directive of the most important substances within each PT (in terms of annual production/import tonnage) are presented. Although in many cases information about classification in missing it is still apparent that the most used substances in PT2, disinfectants, are generally very toxic to aquatic organisms and the same goes for PT5, drinking water disinfectants. Also the most used film preservatives are all very toxic to aquatic life (+ not easily biodegradable).

Table 4-4 Environmental classification (Annex I of Directive 67/548/EEC) of the presumably most important biocidal active substances within PT in terms of annual production volumes in the EU. The substances are listed alphabetically, not ranked.R50: very toxic to aquatic organisms; R50-53: as above + may cause long-term adverse effects in the aquatic environment; Lower: toxic or harmful to aquatic organisms.

PT	Most important substances in terms of production tonnage (1998-2001) per Product-type	Number of substances		
		Environmental classification (R50/R50-53/ lower)	No environmental classification	Not on Annex I
Main Group 1: Disinfectants and general biocidal products				
1	Benzoic acid, pentapotassium bis(peroxymonosulphate)-bis(sulphate), sodium benzoate, sodium hypochlorite	1/0/0	0	3
2	Chlorine, ethylene oxide, hydrogen peroxide, sodium hypochlorite, symclosene, troclosene sodium	2/2/0	2	0
3	Chloroxylenol, cyanamide, formic acid, glutaral, hydrogen peroxide, sodium hypochlorite	2/0/0	3	1
4	Chlorine dioxide, hydrogen peroxide, L-(+)-lactic acid, peracetic acid, sodium hypochlorite	3/0/0	1	1
5	Biphenyl-2-ol, chlorine, chlorine dioxide, potassium permanganate, sodium hypochlorite	4/1/0	0	0
Main Group 2: Preservatives				
6	1,2-benzothiazolone, bronopol, (ethylenedioxy)dimethanol, guazatine triacetate, isothiazolone mixture, L-(+)-lactic acid	2/0/0	0	4
7	Carbendazim, dichlofluanid, diuron, tolylfluanid, triclosan	0/5/0	0	0
8	Boric acid, copper oxide, didecylpolyoxethyl ammonium borate, disodium tetraborate, guazatine triacetate	0/0/0	0	5
9	(Benzothiazol-2-ylthio)methyl isocyanate, 2-chloroacetamide, chlorocresol, diphenoxarsin-10-yl oxide, disodium tetraborate, ziram	1/2/0	1	2
10	2-chloroacetamide, 2-phenoxyethanol, pine extract	0/0/0	2	1
11	Chlorine, chlorine dioxide, hydrogen peroxide, silver zeolite A, sodium hypochorite, tetrakis(hydroxymethyl)-phosphonium sulphate	3/0/0	1	2

PT	Most important substances in terms of production tonnage (1998-2001) per Product-type	Number of substances		
		Environmental classification (R50/R50-53/ lower)	No environ-mental classi-fication	Not on Annex I
12	Bronopol, 2,2-dibromo-2-cyanoacetamide, hydrogen perox-ide, glutaral, peracetic acid, sodium dimethyldithio-carbamate, sodium hypochlorite	4/0/0	1	2
13	Boric acid, disodium tetraborate, (hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol, trimethyl-1,3,5-triazine-1,3,5-triethanol	0/0/0	1	3
Main Group 3: Pest control				
14	Bromoadiolone, chloralose, chlorophacinone, coumatetralyl	0/1/1	1	1
15	Chloralose	0/0/0	1	0
16	-	-	-	-
17	-	-	-	-
18	Cyanamide, dichlorvos, phenothrin, piperonylbutoxide, pro-poxur, pyrethrin and pyrethroids	1/1/0	1	3
19	Ethyl-N-acetyl-N-butyl-beta-alaninate, methyl neodecana-mide, naphthalene	0/1/0	0	2
Main Group 4: Other biocidal products				
20	Chlorine dioxide	1/0/0	0	0
21	4,5-dichloro-2-octyl-2H-isothiazol-3-one, diuron, zineb	0/1/0	1	1
22	2-butenone peroxide, dodecylguanadine monohydrochlo-ride, methylene dithiocyanate	1/0/0	0	2
23	Trimagnesium phosphide	1/0/0	0	0

The overall conclusion regarding the ecotoxicological properties of biocides is that the majority of the active substances can be expected to be toxic or very toxic to aquatic life and that half of the substances additionally are not easily biodegradable. Not unexpectedly, the active substances in Main Group 3, Pest Control, show the highest degree of environmental toxicity (almost all substances when excluding PT19, attractants and repellents) but also a high fraction of the substances in Main Group 2, Preservatives, have an environmental classification.

Further, the substances in PT14, PT15 and PT23 can be expected to be (highly) toxic also to non-target mammals, birds and other vertebrates in the terrestrial environment.

Finally, it is concluded that the quantitatively most important substances cannot be expected to be less toxic to the (aquatic) environment than the average of biocidal substances.

4.2 Exposure of humans

As described in the Technical Notes for Guidance (TNsG) on Human Exposure to Biocidal products (TNsG 2008) the assessment of human exposure requires determination of the patterns of use, identification of the exposed population, establishing the pathways of exposure and quantification of potential chemical intake. In addition, it may be relevant to distinguish between primary and secondary exposure scenarios. Primary exposure is the exposure of the individual who actively uses the biocidal product while secondary exposure is the exposure that may occur after the actual use or application of the product. For professional users the TNsG on Human Exposure also recommends to distinguish between *intentional* and *incidental secondary* exposure, where intentional secondary exposure incurs during a worker's regular employment and incidental exposure relates to exposure not necessarily incurred during employment.

Professional users

Professional users (industrial users) are expected to handle biocidal products according to the conditions of use imposed by the authorisation of the products where relevant but also within the framework of the national worker protection legislation and have residual risk controlled through control measures, including the use of Personal Protective Equipment (PPE). They are also expected to have received additional training and information - also with regard to correct use of PPE - although this may not always be the case.

Non-professional users

Non-professional users (consumers) are not covered by specific legislation, they have no formal training and will usually not have access to controls or formal PPE. Non-professional users are not always expected to follow the instructions for use of the biocidal products. With regard to frequency and duration of use of and exposure to biocidal products, non-professional users are expected to have a lower frequency and duration of exposure compared to professional users.

Secondary exposure

Secondary exposure scenarios may be relevant for both professional and non-professional users. All Member States have been asked to provide information on the number of people involved in professional and non-professional use of biocides in their country and the amount of biocides or percentage of product types used by professionals and non-professionals. Only information received is that Hungary has 539 persons with authorisation for professional use. In Table 4-5 a qualitative overview of the involvement of and exposure of professional and non-professional users in the application phase and during the service life of the biocidal products is shown. The main group exposed is indicated by a bold "**x**". If information/knowledge is not available to rate the exposure to professionals compared to non-professionals, likely exposure in both groups is indicated by an "x". In addition, the risk of secondary exposure for both professionals and non-professionals is indicated in the last column with a "p" or "np" respectively.

Table 4-5 Overview of exposed professional and non-professional users during the application and service life phase of biocidal products and general possibilities for secondary exposure.

Product type	Sub-type	Application of biocidal product		Service life of article		Secondary exp.[1)]
		Prof	Non-prof	Prof	Non-prof	
MAIN GROUP 1: Disinfectants and general biocidal products						
1: Human hygiene biocidal products	Skin and mouth disinfectants	**x**	x	**x**	x	
2: Private area and public health area biocidal products	Disinfectants for private areas		**x**		**x**	np
	Disinfectants for public areas	**x**		**x**	x	p/np
	Disinfectants for medical equipment	**x**				
	Disinfectants for laundries	**x**				p
	Disinfectants for air-conditioning systems	**x**				p
	Disinfectants for chemical toilets	x	x			p/np
	Disinfectants for swimming pools	**x**	x			p/np
	Disinfectants for wastewater and hospital waste	**x**				
3: Veterinary and hygiene biocidal products		**x**	x	**x**	x	p
4: Food and feed area disinfectants		**x**				p/np
5: Drinking water disinfectants		**x**	x			np
MAIN GROUP 2: Preservatives						
6: In-can preservatives	In-can preservatives for paints and coatings, inks, washing and cleaning fluids, fluids used in paper, textile and leather production, and in-can preservatives for lubricants, fuels and other products, etc.	**x**		**x**	x	np
7: Film preservatives	Film preservatives for paints, sealant, paper, plastics, fillers and other products	**x**	x			np
8: Wood preservatives	Vacuum and pressure preservatives	**x**				p/np
	Preservatives for surface treatment	**x**	x			p/np
9: Fibre, leather, rubber, and polymerised materials preservatives	Preservatives for textiles, leather, rubber, paper and other polymeric materials	**x**		**x**		p/np
	Preservatives for insulating materials of organic fibres	**x**				
10: Masonry preservatives		**x**	x			p/np

Product type	Sub-type	Application of biocidal product		Service life of article		Secondary exp.[1]
		Prof	Non-prof	Prof	Non-prof	
11: Preservatives for liquid cooling and processing systems		**x**		(x)		p/np
12: Slimicides	Slimicides for wood and paper pulp	**x**		(x)		p/np
	Slimicides and other biocides used by oil extraction and fuel storage	**x**				
13: Metalworking fluid preservatives		**x**		(x)		p
MAIN GROUP 3: Pest control						
14: Rodenticides		**x**	x			p/np
15: Avicides		**x**				np
16: Molluscicides [2]		**x**				np
17: Piscicides		**x**		x		np
18: Insecticides and products to control other arthropods		**x**	x			p/np
19: Repellents and attractants	Repellents and attractants for control of gnat and fleas	x	x			p/np
	Repellents and attractants for control of game and birds	**x**	x			p/np
MAIN GROUP 4: Other biocidal products						
20: Preservatives for food and feedstock		**x**	(x)			p/np
21: Antifouling products	Antifouling paints for vessels < 25 m.	x	x			p/np
	Antifouling paints for vessels >= 25 m.	**x**				p
	Antifouling paints for other uses	**x**				p
22: Embalming and taxidermist fluids	Embalming fluids for humans	**x**				p
	Embalming and taxidermist fluids for animals.	**x**	x			p/np
23: Control of other vertebrates		**x**	(x)			p/np

[1] p: professionals np: non-professionals; [2] No substances notified

Professionals are mainly exposed during the application phase as their job will often be restricted to this phase. Non-professionals are more often exposed both during the application phase and during the service-life phase of the products as they are likely to use the products in or around their homes. For PT 1 (skin and mouth disinfectants) both professionals and non-professionals will have the highest exposure during the application phase.

Based on production volumes as shown in Table 3-2 the product types likely to result in the most extensive exposure are PT 1, 2, 4, 5, 10 and 11 which all exceed 10,000 tonnes per annum. PT 2 has the highest tonnage exceeding 160,000 tonnes per annum.

4.2.1 In the application phase

The TNsG on Human Exposure to Biocidal products (TNsG 2008) related the overall exposure to a series of tasks allocated to three distinct phases of use:

1. Mixing & loading	Include the tasks involved in delivery and handling of bulk ready-for-use and concentrate products, dilution of concentrates and/or the introduction of product to the application apparatus/system.
2. Application	Involves all uses of biocidal products, including application by hand, by hand-held tool, by dipping, by spraying, handling treated articles, and in machining. This phase of use can lead to the exposure of people who are present during the product application (secondary exposure).
3. Post-application	Includes exposure through separately cleaning and maintaining process equipment and tools. Secondary exposure is also included in the post-application phase.

The route of exposure will depend on the on e.g. the physical form of the product, the actual method of application and the available exposure controls. In the following Table 4-6 the possible routes of exposure in the application or use phase is shown for professional and non-professional users for the different product types.

For professional users the primary potential route of exposure during the application phase is for all PT's by dermal contact. Inhalation is an important potential route of exposure for biocides that are applied by spraying techniques, dusting or fogging or where aerosols are created during the handling and application of the product.

Ingestion is relevant for PT 1 (Skin and mouth disinfectants) and for PT 5 (drinking water disinfectants). Ingestion is also considered relevant for PT 18 (Insecticides and products to control other arthropods) primarily from unintentional ingestion. Inhalation from the gas phase of the biocidal substances is expected to be more limited as a high proportion of the substances have a relatively low vapour pressure.

Dermal contact is also considered the predominant route of exposure in relation to products used by non-professionals. However, as many products used in the home are applied as spray of powders or are applied in liquid form, inhalation of particularly aerosols is considered an important route of exposure. There are, however, also biocidal substances in some cleaning products, wood preservatives and other products used in the home, where inhalation of vapours may be more significant also in the application phase (e.g. PT 2, 6, 7, 8. 18, and 19).

Table 4-6 Exposure of professional and non-professional users to biocidal products in the application phase.

Product-type	Sub-type	Professional users			Non-professional users		
		inhal.	oral	dermal	inhal.	oral	dermal
MAIN GROUP 1: Disinfectants and general biocidal products							
1: Human hygiene biocidal products	Skin and mouth disinfectants		X	X		X	Xx
2: Private area and public health area biocidal products	Disinfectants for private areas	X		X	X	X	X
	Disinfectants for public areas	X		X			X
	Disinfectants for medical equipment	X		X			
	Disinfectants for laundries	X		X			
	Disinfectants for air-conditioning systems			X			
	Disinfectants for chemical toilets	X		X	X		X
	Disinfectants for swimming pools	X		X	X		X
	Disinfectants for wastewater and hospital waste	X		X			
3: Veterinary hygiene biocidal products		X		X	X		X
4: Food and feed area disinfectants		X		X			
5: Drinking water disinfectants		X	X	X			
MAIN GROUP 2: Preservatives							
6: In-can preservatives	In-can preservatives for paints and coatings, inks, washing and cleaning fluids, fluids used in paper, textile and leather production, and in-can preservatives for lubricants, fuels and other products, etc.	X		X			
7: Film preservatives	Film preservatives for paints, sealant, paper, plastics, fillers and other products			X			
8: Wood preservatives	Vacuum and pressure preservatives	X		X			
	Preservatives for surface treatment	X		X	X		X
9: Fibre, leather, rubber, and polymerised materials preservatives	Preservatives for textiles, leather, rubber, paper and other polymeric materials	X		X	X		X
	Preservatives for insulating materials of organic fibres	X		X			
10: Masonry preservatives		X		X	X		X

	Product-type	Sub-type	Professional users			Non-professional users		
			inhal.	oral	dermal	inhal.	oral	dermal
11:	Preservatives for liquid cooling and processing systems		X		X			
12:	Slimicides	Slimicides for wood and paper pulp			X			
		Slimicides and other biocides used by oil extraction and fuel storage			X			
13:	Metalworking fluid preservatives				X			
MAIN GROUP 3: Pest control								
14:	Rodenticides		X		X	X		X
15:	Avicides		X		X			
16:	Molluscicides				X			
17:	Piscicides				X			
18:	Insecticides and products to control other arthropods		X	X	X			
19:	Repellents and attractants	Repellents and attractants for control of gnat and fleas	X		X	X		X
		Repellents and attractants for control of game and birds	X		X	X		X
MAIN GROUP 4: Other biocidal products								
20:	Preservatives for food and feedstock				X			
21:	Antifouling products	Antifouling paints for vessels < 25 m			X			X
		Antifouling paints for vessels ≥ 25 m			X			
		Antifouling paints for other uses			X			
22:	Embalming and taxidermist fluids	Embalming fluids for humans	X		X			
		Embalming and taxidermist fluids for animals.	X		X	X		X
23:	Control of other vertebrates		X		X			X

4.2.2 In the service-life phase

An overview of exposure pathways of consumers/the general public during the post-application phase or service-life of biocidal products is shown in Table 4-7.

Table 4-7 Exposure of consumers/the general public to biocidal products during their service-life.

Product-type	Sub-type	Air, indoor	Air, outdoor	Food	Drinking water	Other inges-tion	Applied directly on skin	Bathing	Other skin contact
MAIN GROUP 1: Disinfectants and general biocidal products									
1: Human hygiene biocidal products	Skin and mouth disinfectants					X	X		X
2: Private area and public health area biocidal products	Disinfectants for private areas							X	X
	Disinfectants for public areas								X
	Disinfectants for medical equipment	X							
	Disinfectants for laundries	X							X
	Disinfectants for air-conditioning systems	X							X
	Disinfectants for chemical toilets	X							X
	Disinfectants for swimming pools	X	X					X	
	Disinfectants for wastewater and hospital waste								
3: Veterinary hygiene biocidal products		X					X		
4: Food and feed area disinfectants				X					
5: Drinking water disinfec-tants					X			X	
MAIN GROUP 2: Preservatives									
6: In-can preservatives	In-can preservatives for paints and coatings, inks, washing and cleaning flu-ids, fluids used in paper, textile and leather produc-tion, and in-can preserva-tives for lubricants, fuels and other products, etc.	X							X
7: Film preservatives	Film preservatives for paints, sealant, paper, plastics, fillers and other products	X							X
8: Wood preservatives	Vacuum and pressure pre-servatives								X
	Preservatives for surface treatment								X
9: Fibre, leather, rubber, and polymerised materials preservatives	Preservatives for textiles, leather, rubber, paper and other polymeric materials								X

	Product-type	Sub-type	Air, indoor	Air, outdoor	Food	Drinking water	Other inges-tion	Applied directly on skin	Bathing	Other skin contact
		Preservatives for insulating materials of organic fibres								X
10:	Masonry preservatives			X						X
11:	Preservatives for liquid cooling and processing systems									
12:	Slimicides	Slimicides for wood and paper pulp								X
		Slimicides and other biocides used by oil extraction and fuel storage								
13:	Metalworking fluid pre-servatives									X
MAIN GROUP 3: Pest control										
14:	Rodenticides						X			X
15:	Avicides						X			X
16:	Molluscicides									X
17:	Piscicides									X
18:	Insecticides and prod-ucts to control other arthropods			X						X
19:	Repellents and attrac-tants	Repellents and attractants for control of gnat and fleas								X
		Repellents and attractants for control of game and birds								X
MAIN GROUP 4: Other biocidal products										
20:	Preservatives for food and feedstock		X	X	X					X
21:	Antifouling products	Antifouling paints for vessels < 25 m								X
		Antifouling paints for vessels ≥ 25 m								
		Antifouling paints for other uses								X
22:	Embalming and taxi-dermist fluids	Embalming fluids for humans								
		Embalming and taxidermist fluids for animals.								X
23:	Control of other verte-brates		X	X						X

Exposure to the general public during the service-life of the products is mostly via indoor air or skin contact from direct application, bathing or contact with

treated surfaces. Exposure through ingestion is primarily relevant in relation to PT 1, 4, 5, 14, and 15.

Although many of the biocidal active ingredients as mentioned have a relatively low vapour pressure, some of these substances in biocidal cleaning products, wood preservatives and other products used in the home may be inhaled in small amounts over a longer period of time during the service-life and the total exposure may therefore be significant.

4.3 Exposure of the environment

According to the EU terminology for risk assessment of new and existing substances, and biocides (as described in EU's Technical Guidance Document on risk assessment of chemicals ("The TGD"), EU Commission, 2003), most of the biocidal products use categories (PTs) can be characterised as "wide dispersive use" (with some exceptions for certain sub-PTs) meaning that the majority of the biocide is released to the environment either in the application phase or during the service life of the biocidal product.

A few PTs can be characterised as "non-dispersive use" categories (PT4, food and feed disinfectants, PT13, metalworking fluids, PT20, preservatives for food and feedstock, and PT22, embalming and taxidermist fluids) implying that the application of products in these categories normally takes place under controlled conditions in rather confined areas and involving only trained people. PT9 (fibre, leather, rubber, and polymerised materials preservatives), or at least some parts of it, can probably be considered to be an "inclusion into or onto matrix" use category with limited exposure of the environment in the use phase.

The approximate minimum annual production/import volumes in the EU of biocidal active substances are presented product type-wise in Table 3-2. It appears that the production/import of substances for use as general disinfectants (Main Group 1) is by far the largest - almost two thirds of the total - and that PT2 alone makes up about 40 % of the total tonnages for all 23 PTs. Other PTs - especially 14, 15, 16, 17, 22 and 23 - are produced/imported in very low tonnages (< 25 t/y). This information will in Section 4.4 be combined with the more qualitative assessment of environmental exposure situations for each PT in this section to roughly conclude on the need for reduction of environmental risks.

4.3.1 In the application phase

For the majority of the biocidal product types (PTs), the main part of the releases to the environment is assessed to happen during the service life of the products and not in the application phase. This is particularly the case in case of application by professional users, which normally take place under more controlled conditions than the non-professional application i.e. with better collection and treatment of emissions, effluents and spills. Cleaning of application equipment (e.g. paint brushes) is considered a part of the application phase. Emissions to air are in many cases believed to be smaller in case of professional users who normally have better equipment and more routine in using it

than the non-professional users, and often perform the application under more confined and better controlled conditions.

An overview of the main routes of environmental exposure for the different PTs in the application phase including an indication of the relevant category of users (prof./non-prof.) is shown in Table 4-8.

Table 4-8 Qualitative assessment of exposure of the environment to biocidal products in the application phase (for professional and non-professional users, respectively).The exposure can take place directly to air, soil or (surface) water or indirectly, i.e. through a wastewater treatment plant (WWTP). Significant routes of exposure are marked with "x", minor exposure routes with "(x)". NR (not relevant) is used for PT uses where one of the user categories is not active (to any significant extent).

	Product type	Sub-type	Professional users				Non-professional users			
			Air	Soil	WWTP	Water	Air	Soil	WWTP	Water
Main Group 1: Disinfectants										
1:	Human hygiene biocidal products	Skin and mouth disinfectants			(x)				(x)	
2:	Private area and public health area biocidal products	Disinfectants for private areas	NR	NR	NR	NR	(x)		x	
		Disinfectants for public areas	(x)		x		NR	NR	NR	NR
		Disinfectants for medical equipment			(x)		NR	NR	NR	NR
		Disinfectants for laundries	(x)		x		NR	NR	NR	NR
		Disinfectants for air-conditioning systems	(x)		x?		NR	NR	NR	NR
		Disinfectants for chemical toilets	(x)				(x)			
		Disinfectants for swimming pools	x		x		(x)		(x)	
		Disinfectants for wastewater and hospital waste	(x)		x		NR	NR	NR	NR
3:	Veterinary and hygiene biocidal products			(x)	x	(x)		(x)	x	(x)
4:	Food and feed area disinfectants		(x)		x		NR	NR	NR	NR
5:	Drinking water disinfectants		x				(x)			
Main Group 2: Preservatives										
6:	In-can preservatives	In-can preservatives for paints	(x)		x		NR	NR	NR	NR
		In-can preservatives for inks, fountain water, sealants and adhesives	(x)		x		NR	NR	NR	NR
		In-can preservatives for	(x)		x		NR	NR	NR	NR

Product type	Sub-type	Professional users				Non-professional users			
		Air	Soil	WWTP	Water	Air	Soil	WWTP	Water
	washing and cleaning fluids								
	In-can preservatives in textile, leather and textile production	(x)		x		NR	NR	NR	NR
	In-can preservatives for other products					NR	NR	NR	NR
7: Film preservatives	Film preservatives for paints	x	x	x	x	x	x	x	x
	Film preservatives for plastics, sealant, fillers and other products	x		x		x		x	
8: Wood preservatives	Vacuum and pressure preservatives	x		x		NR	NR	NR	NR
	Preservatives for surface treatment	x	x	x	x	x	x	x	x
9: Fibre, leather, rubber, and polymerised materials preservatives	Preservatives for textiles, leather, rubber, paper and other polymeric materials	(x)		x		NR	NR	NR	NR
	Preservatives for insulating materials of organic fibres	(x)		(x)		NR	NR	NR	NR
10: Masonry preservatives		x	x	x	x	x	x	x	x
11: Preservatives for liquid cooling and processing systems		(x)		x	x	NR	NR	NR	NR
12: Slimicides	Slimicides for wood and paper pulp	(x)		x		NR	NR	NR	NR
	Slimicides and other biocides used by oil extraction and fuel storage	(x)		x	x	NR	NR	NR	NR
13: Metalworking fluid preservatives		(x)		x		NR	NR	NR	NR
Main Group 3: Pest control									
14: Rodenticides		x	x	x	x		x	x	x
15: Avicides			(x)	(x)	(x)	NR	NR	NR	NR
16: Molluscicides					x	NR	NR	NR	NR
17: Piscicides					x	NR	NR	NR	NR
18: Insecticides and products to control other arthropods		x	x	x	x	x	x	x	x
19: Repellents and attractants	Repellents and attractants for control of gnat and fleas	x		x		x		x	

Product type	Sub-type	Professional users				Non-professional users			
		Air	Soil	WWTP	Water	Air	Soil	WWTP	Water
	Repellents and attractants for control of game and birds	x	x			x	x		
Main Group 4: Other biocidal products									
20: Preservatives for food and feedstock		(x)		x				(x)	
21: Antifouling products	Antifouling paints for vessels < 25 m	x	(x)	x	(x)	x	x	(x)	x
	Antifouling paints for vessels ≥ 25 m	x	(x)	x	(x)	NR	NR	NR	NR
	Antifouling paints for other uses			x	(x)	NR	NR	NR	NR
22: Embalming and taxidermist fluids	Embalming fluids for humans	x		x		NR	NR	NR	NR
	Embalming and taxidermist fluids for animals.	x		x		x		x	
23: Control of other vertebrates		x	x	x	x	NR?	NR?	NR?	NR?

Apart from the PTs (or sub-PTs) where only one of the two user categories (prof. and non-prof.) are considered to be active to any significant extent, there are, as appears from the table, a number of PTs where the assessment of the typical environmental exposure associated with the application of the biocidal product differs between the two user categories.

For PT2, sub-group swimming pool disinfectants, it is assessed that the types of exposure are the same for professional and non-professional users but that the extent is more pronounced for the professional users who handle much bigger amounts at much larger facilities than the non-professional users, and more frequently than the latter. The same argument goes for PT5, drinking water disinfectants and for PT20, preservatives for food and feedstock.

For PT14, rodenticides, air is identified as a significant compartment for professional users but not for non-professional users. This is because certain products acting by evolution of toxic fumes are believed only to be applied by professionals.

For PT21, antifouling paints for vessels <25m, it is believed that in general application of such paints by professional users take place under more controlled conditions than when non-professionals carry out maintenance of their own yachts or boats. Therefore, the application by non-professionals is assessed to result in more direct exposure of soil and water but less exposure via WWTPs.

4.3.2 In the service-life phase

In many cases it will be difficult to establish a clear distinction between the service life part of the use phase and the disposal phase as "disposal" of the product is an integrated part of the service life and no actual waste that can be isolated and be disposed of is generated. This type of "waste disposal", which typically could be discharging the spent biocide into the drain (e.g. for disinfectants and other cleaning fluids) is therefore included in the assessment of exposure during the service life of biocides.

In Table 4-9 below, a qualitative assessment of the main pathways of environmental exposure to biocides is presented. Due to an enormous complexity of the biocidal products area with regard to functions and uses, and lack of quantitative data, it is not considered possible to make a quantitative or even semi-quantitative assessment of the exposure and risks to the environment at Community level without allocation of considerable resources to such a task. The assessment is therefore rather an indication of the main types of exposure and thereby the types of risks that typically can be expected from the use of various product types of biocides. This enables consideration of the types of technical risk reduction options and regulatory measures that can be relevant to consider in case the risk from a Community perspective is considered to be of concern.

Table 4-9 Qualitative assessment of exposure of the environment to biocidal products during their service life. Exposure in the disposal phase is indicated for the products where an actual waste product is generated at the end of the service life phase.
The "Environment directly" exposure comprise releases to air, soil, water and biota. Discharge of biocides with surface runoff from roads etc. in separate systems is conservatively considered a direct release to the environment (water) as most commonly such runoff is not treated prior to discharge. Significant routes of exposure are marked with "x", minor exposure routes with "(x)".

Product type	Sub-type	Main environmental exposure		
		Environment directly	Via WWTP	Via waste disposal
Main Group 1: Disinfectants				
1: Human hygiene biocidal products	Skin and mouth disinfectants		(x)	
2: Private area and public health area biocidal products	Disinfectants for private areas		x	
	Disinfectants for public areas		x	
	Disinfectants for medical equipment		x	
	Disinfectants for laundries		x	
	Disinfectants for air-conditioning systems	(x)	x	?
	Disinfectants for chemical toilets	(x)	x	

Product type	Sub-type	Main environmental exposure		
		Environment directly	Via WWTP	Via waste disposal
	Disinfectants for swimming pools	(x)	x	
	Disinfectants for wastewater and hospital waste		x	
3: Veterinary and hygiene biocidal products		x	x	
4: Food and feed area disinfectants			x	
5: Drinking water disinfectants			(x)	
Main Group 2: Preservatives				
6: In-can preservatives	In-can preservatives for paints	x	(x)	(x)
	In-can preservatives for inks, fountain water, sealants and adhesives		(x)	
	In-can preservatives for washing and cleaning fluids		x	
	In-can preservatives in textile, leather and textile production		x	(x)
	In-can preservatives for other products	?	x	?
7: Film preservatives	Film preservatives for paints	x	(x)	x
	Film preservatives for plastics, sealant, fillers and other products	x		x
8: Wood preservatives	Vacuum and pressure preservatives	x		x
	Preservatives for surface treatment	x		x
9: Fibre, leather, rubber, and polymerised materials preservatives	Preservatives for textiles, leather, rubber, paper and other polymeric materials		(x)	x
	Preservatives for insulating materials of organic fibres			x
10: Masonry preservatives		x		
11: Preservatives for liquid cooling and processing systems		x	x	?
12: Slimicides	Slimicides for wood and paper pulp		x	
	Slimicides and other biocides used by oil extraction and fuel storage	x	x	
13: Metalworking fluid preservatives			x	(x)
Main Group 3: Pest control				
14: Rodenticides		x	(x)	(x)
15: Avicides		x		(x)
16: Molluscicides		x		
17: Piscicides		x		

Product type	Sub-type	Main environmental exposure		
		Environment directly	Via WWTP	Via waste disposal
18: Insecticides and products to control other arthropods		x		
19: Repellents and attractants	Repellents and attractants for control of gnat and fleas	x	(x)	
	Repellents and attractants for control of game and birds	x		
Main Group 4: Other biocidal products				
20: Preservatives for food and feedstock				
21: Antifouling products	Antifouling paints for vessels < 25 m	x		(x)
	Antifouling paints for vessels ≥ 25 m	x		(x)
	Antifouling paints for other uses	x		
22: Embalming and taxidermist fluids	Embalming fluids for humans			(x)
	Embalming and taxidermist fluids for animals.			(x)
23: Control of other vertebrates		x		

4.4 Conclusions on the need for risk reduction

The risk to humans and/or the environment arising from the use of a specific biocidal substance and product is addressed in the risk assessment carried out as part of the EU review process of biocides. This substance-by-substance risk assessment is not the subject of this study.

However, the overall risk from the combined exposure to a variety of substances from the use of different types/categories of biocidal products is not considered in the review process (and is thereby not considered when substances are evaluated for inclusion on Annex I, IA or IB to Directive 98/8/EC) and requires a more holistic approach. Unfortunately, the lack of quantitative data on exposure (tonnages at EU and Member State level, monitoring data on emissions and occurrence in the environment etc.) as well as on hazard properties (toxicities and ecotoxicities) of the substances prevent a quantitative assessment of the overall risks. Therefore, it has only been possible to make a mainly qualitative description of the areas within each Product Type where impacts in the use phase of biocides are most likely to occur by identifying the main emission situations and exposure pathways.

It is noted that for the majority of PTs only consideration of professional users (application phase) is required as the products within these PTs are exclusively or almost exclusively used by professionals. Only one sub-type - PT2.1; private area disinfectants - does (by definition) not have professional users.

Significant or potentially significant exposure of non-professionals occur mainly in PT2 (2.1; private area disinfectants), PT7 (preservatives for paints), PT8 (preservatives for surface treatment of wood), PT10 (masonry preservatives), PT18 (insecticides) and PT21 (21.1; antifouling products for small vessels). In a number of countries PT14 (rodenticides) may also be relevant to consider for non-professional exposure.

Exposure of WWTPs is particularly important for disinfectants in PT1, PT2 and PT4 although also a number of the other PTs contribute to the load of biocides onto WWTPs by being partially discharged into the sewer system. As many of the active substances aim to control micro-organisms, biological WWTPs could be at risk (especially the nitrification/denitrification processes for removal of nitrogen are known to be sensitive).

Direct exposure of the environment in the use phase of biocides is considered to be most significant for PT7 (7.1; film preservatives for paints), PT8 (8.2 preservatives for surface treatment of wood), PT10 (masonry preservatives), PT18 (insecticides) and PT21 (antifouling products). Discharge of rain runoff from roads and other impervious surfaces is in this context considered a direct release to the environment (particularly relevant for PT7, PT8 and PT10, which of course all also have soil as a main receptor). Direct non-target exposure of biota is mainly relevant for PT14-19 and PT23).

The information needed for an overall rough assessment of relative risks associated with the different PTs and use situations include the data presented in Chapter 3 on annual production/import tonnages of biocidal active substances. This information, in combination with the assessment of degree of emission during use, gives an indication of the overall magnitude of exposure of humans and/or the environment.

The minimum annual production/import volumes in the EU of biocidal active substances was found to be about 400,000 tonnes at the time of notification (figures primarily from 2000-2001). Main Group 1, Substances for use as general disinfectants (PTs 1-5), is by far the largest group with almost two thirds of the total tonnage. PT2 alone makes up about 40 % of the total tonnages for all 23 PTs. Substances in some other PTs - especially PTs 14, 15, 16, 17, 22 and 23 - are produced/imported only in low tonnages (< 25 t/y per PT).

With regard to PT18 an enquiry to EUROSTAT as part of this study revealed limited overlap between PT18 substances and PPP active substances (pesticides). However, in the few cases of overlaps the tonnage for use as biocides constituted a significant fraction of the total tonnage.

A summary overview and assessment/prioritisation of human and environmental risks in the use phase of biocides forming the starting point of the subsequent identification and prioritisation of options for risk reduction is given in Table 4.10.

Ideally, an assessment of human and environmental toxicity should have been included in Table 4-10 as well but has been omitted because it, as described in

Section 4.2, in general turned out to be difficult to identify particular PTs with more toxic active substances than the others and also because the classification of the major part of the substances is not available.

Based on the available classification of substances, it can be concluded that among the substances with the highest production volumes few of the substances identified as being of major concern because of their classification (in particular CMR's and sensitizing substances) are represented in the product types with the highest total production volumes (PT 1, 2, 4, 5, 10, and 11). This regards PT 2 and 10 which each have one CMR substance included.

It is noted that the PTs having been prioritised for the EU review of active substances under Directive 98/8/EC (PTs 8, 14 and 18) and for regulatory actions in some Member States (largely the same PTs) have also been assessed by the exercise described in this chapter to present the highest aggregated/combined risk to humans and the environment. In addition to the mentioned three PTs, also PT2 is considered to present a significant aggregated risk.

Table 4-10 Overview, indication of significance of elements in the human and environmental risk assessment relating to the use phase of biocides (per PT) and overall assessment[1]. The specific exposure assessments do not include consideration of the overall tonnages.

Product-type	Tonnage (annual)	Human exposure, users	Human exposure, general	Env. exposure, direct	Env. exposure via WWTPs*	Overall assessment of "risks"
Main Group 1: Disinfectants and general biocidal products						
1: Human hygiene biocidal products	XXX	XXX	-	-/X	XX	X
2: Private area and public health area biocidal products	XXX	XX	X	X	XXX	XX
3: Veterinary and hygiene biocidal products	XXX	XX	-	X	XX	X
4: Food and feed area disinfectants	XXX	XX	-	-	XXX	X/XX
5: Drinking water disinfectants	XXX	X	X	X	X	X
Main group 2: Preservatives						
6: In-can preservatives	XX	X	X	X	X	X
7: Film preservatives	XX	X	X	XX	X	X/XX
8: Wood preservatives	XXX	XX	X	XX/XXX	-	XX/XXX
9: Fibre, leather, rubber, and polymerised materials preservatives	XX	X	X	-	X	X
10: Masonry preservatives	XXX	XX	-	XX	-	XX
11: Preservatives for liquid cooling and processing systems	XXX	X	-	XX	XX	XX
12: Slimicides	XX	X	-	XX	XX	X/XX
13: Metalworking fluid preservatives	XX	XX	-	-	X	X
Main Group 3: Pest control						
14: Rodenticides	-	XX	X	XX	X	XX
15: Avicides	-	X	-	XX	-	-/X
16: Molluscicides	-	X	-	XXX	-	-/X
17: Piscicides	-	X	-	XXX	-	-/X
18: Insecticides and products to control other arthropods	XX	XXX	XX	XXX	-	XX/XXX
19: Repellents and attractants	XX	XX	X	XX	-	-/X
Main Group 4: Other biocidal products						
20: Preservatives for food and feedstock	X	X	X	-	-	-/X
21: Antifouling products	X	XX	X	XXX	-/X	XX
22: Embalming and taxidermist fluids	-	-	-	-	-	-
23: Control of other vertebrates	-	X	-/X	XX	-	-/X

1: XXX = major/high; XX = significant; X = moderate; - = minor/low. WWTP = Waste water Treatment Plant.

5 Approaches, options and measures

5.1 Risks and benefits

The overall objective of measures in this context is to reduce the risks to human health and the environment from the use phase of biocides.

When considering a reduction in the risks to health and environment, the *benefits* accruing from the use of biocides should be kept in mind. The various biocides have different purposes which all serves human needs in terms of hygiene, disinfection, preservation, pest control, etc., as described in Chapter 4.

The reduction of risks from the use of biocides should thus not result in a reduction of or change in use of biocides, which would lead to new sorts of health and welfare problems. Alternative solutions to the present use of biocides may be even more problematic. If relevant biocides would become too complicated to use because of legal restriction or incomprehensible guidelines, increases may be seen in other - perhaps more damaging - kind of solutions.

The problem to be tackled is (only) the superfluous, thoughtless or misplaced use of biocides, which leads to unnecessary residuals and waste products and thereby to unacceptable environmental and health problems.

5.2 Overview of approaches

The objective - to reduce the risks to health and the environment from the use phase of biocidal products - can basically be met by five types of approaches:

- Reduce quantities to optimal levels
- Reduce hazardousness
- Reduce releases and exposures by application
- Reduce releases and exposures in the service life phase[14]
- Prevent development of resistance[15]

[14] I.e. releases from products and articles containing biocides.

[15] The latter approach is targeted at the future use of biocides and concerns development of resistance to biocides, thereby reducing the future need of higher quantities and more toxic biocides.

In this report, the word *approach* refers to the overall line of attack which can be divided into a number of options for reducing risks, whereas *options* refer to available technical way to reduce risks. *Measures* refer to the political action which may be taken in order to induce the technical changes to take place.

Below, the most relevant options and measures within the above mentioned five approaches are described in more detail.

Appendix 1 contains for each product-type an identification of options considered relevant for the product type in question.

The five types of approaches are described below and the most relevant options and measures identified.

5.3 Reduce quantities to optimal levels

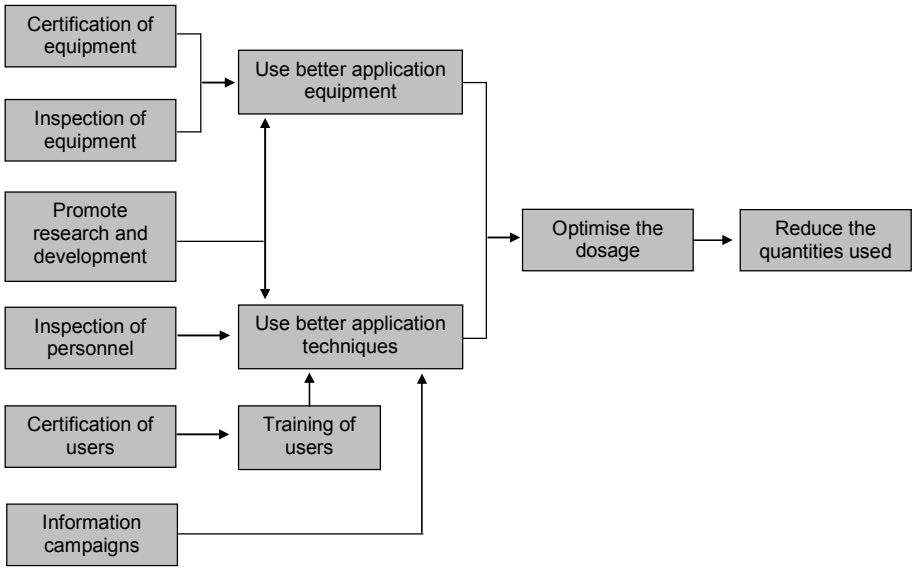
Reduction in the quantities of biocides used will - other things being equal - lead to a reduction in the exposure to humans and the environment. The consumption of biocides can be reduced, without compromise the need for pest prevention, by using the following options:

- Optimising the dosage (i.e. applying a dosage in accordance with the dosage defined by the authorisation of the substances)
- Prevent the growth of pests, thereby reducing the need for control
- Controlling the pest organisms by the application of non-biocidal techniques
- Avoid using biocides where prevention of pests is not exceeding a significant economic threshold that the damage caused by the pest is generating.

Optimise the dosage

In principle, the dosages applied are defined in the authorization of the substances, but in practice higher dosages may be applied due to inadequate applications techniques and applications equipment. Optimising dosage implies using only the amount of biocides needed for killing or inhibiting the organisms and applying biocides at the right time and place, and it can be obtained by using better application equipment and better application techniques. The most relevant *measures* in this respect are certification and inspection of equipment, promotion of research and development, inspection of personnel, certification of users and information campaigns. This is illustrated in the figure below.

Figure 5.1 Measures to optimise dosage



The use of better application equipment and better application techniques is particularly relevant for applications with high risk of over-dosage and a high risk of environmental and human exposure by the application.

Broad implementation of better applications techniques can be obtained by information campaigns and training of users. Although training may be undertaken at a voluntary basis, the most efficient training is obtained if the training is implemented as a part of a certification system where application of biocides is restricted to certified professional users.

For some applications of biocides, e.g. in can preservatives, it is relatively straight forward to specify the right dosages and follow the specification, and the risk of over-dosage is relatively small. Optimizing the dosage by application is in particular an issue for applications where biocides are applied on an area basis (e.g. masonry preservatives), are dispersed over a large area (e.g. rodenticides) or are continuously supplied (e.g. disinfectants for swimming pools).

Prevent the growth of organisms

The use of biocides may be reduced by use of materials and techniques that prevent the growth of undesired organisms. Different methods may be used which may resemble non-pesticides techniques applied as a part of the integrated pest management (IPM) approach applied in agriculture

The use of the biocides may be reduced by preventing the growth of the organism on surfaces by reducing the supply of nutrients or water or by using materials with surfaces that prevent the attachment of the organisms. This applies inter alia to masonry preservatives (constructive changes and changed building materials), film preservative (changes of surfaces e.g. by nanostructures) and antifouling products (changes of surfaces e.g. by nanostructures). For most ap-

plications extensive research is required for development of new types of surfaces.

The use of biocides in terms of preservatives for insulating materials may be reduced by using insulation materials than do not need biocides.

Rodent pests may be reduced by preventing their habitats and their movements in sewerage systems.

The main *measures* are research and development, information campaigns and the promotion of alternative methods.

Application of non-biocide techniques

Instead of using biocides for killing or removal of organisms, mechanical methods could be used. Examples are cleaning of masonry by high pressure cleaning instead of the use of masonry preservatives or increasing the frequency of cleaning of public areas and thereby reducing the need for disinfectants.

For control of rodents and other vertebrates non-biocide techniques includes the use of traps instead of the use of rodenticides, avicides, piscicides or biocides for control of other vertebrates.

As for the options mentioned above, the main measures are research and development, information campaigns and the promotion of other methods.

Only using biocides where and when necessary

Biocides are mainly applied where there is a need for control of undesired organisms causing significant economic damages. For some applications, however, the use of the biocides mainly has an aesthetic purpose or the biocides are applied for making life more pleasant. In these cases it may be considered to reduce the use to the most essential applications. Examples are some household applications of masonry preservatives (e.g. for terraces) or the control of ants in gardens. The quantities used for applications where prevention is not essential, is however considered to account for a very small part of the total use of biocides.

Possible measures may include information, awareness raising, taxes/levies. The latter would also be a driver for optimisation of dosages.

5.4 “Reduce hazardousness”

Technical improvements of biocides

Biocides are intended for killing or prohibiting the growth of organisms and are inevitably hazardous to the target organism. Technical improvement of biocides implies development of substances that are less hazardous to other organisms than the target organism, but still serve the function. Since biocides are intended to kill the target organism only at a certain place and time, such improvements may also imply the development of biocides that are easily degraded when they have served their function.

Reducing the toxicity and risk of the individual substances applied in the EU is already covered by the authorization procedures under the BPD. Stricter criteria for approval of biocides under the BPD would reduce the overall risk of the use of biocides, but an assessment of the need and feasibility of applying stricter criteria is beyond the boundary of the current study.

Imported articles/ materials

Articles/materials treated with biocides not authorised or even banned in the EU may be imported. Impacts of possible measures to manage articles or materials treated with biocides have recently been assessed for the European Commission (Milieu 2006).

Based on the results of the study and further consultation, the Commission has issued a proposal with the revision of the BPD bringing treated articles within the scope of the BDP.

Use of less hazardous biocides for less demanding applications

At the user level the hazardousness of applied biocides can be reduced by reserving more hazardous biocides for specific demanding applications and use less hazardous substances for less demanding applications.

According to the BPD the Member State shall impose, where appropriate, conditions or restrictions when giving authorisations and the Member State shall take the necessary measures to ensure that the applicant proposes a label, and, where relevant, the safety-data sheet, for the biocidal product which: specifies in particular the conditions or restrictions under which the biocidal product may or may not be used.

Additional measures may be promotion of less hazardous biocides for less demanding applications by information campaigns or the inclusion of biocides in the eco-label criteria (e.g. of disinfectants for private areas). However, at single-substance level the BPD already includes the procedures for preventing use of biocides in areas where the advantage of using the biocide do not commensurate with the hazardousness of the biocide.

5.5 Reduce releases and exposures by application

The spreading of biocides - and the environmental and human exposure - by application of the biocidal product is mainly a consequence of inappropriate application techniques and use of insufficient personal protection equipment.

The main options for reducing the releases are:

- Use of appropriate applications techniques and equipment;
- Reduce the use of certain application techniques e.g. spraying of wood preservatives;
- Prohibit the use of certain application techniques e.g. aerial spraying.

The relevant measures are more or less the same as described above for optimizing the dosage of used biocides:

- Restrict the application of specific biocides to certified users;
- Training programmes for professional users;
- Certification of equipment;
- Restrict specific application techniques in specific areas (e.g. spraying);
- Promote development of improved application and protection equipment;
- Awareness raising campaigns on the application of biocides;

The restriction of specific application techniques would typically be linked to a restriction to certified users or the control of application equipment and will not be assessed separately.

5.6 Reduce releases and exposures in service life

Products and articles containing biocides, e.g. preserved wood or plastic, may release biocides during their entire service life with the consequent exposure of humans and the environment. Measures targeted specifically for the service life phase could be aimed at preventing the releases, e.g. by a coating of the article. Other measures could be to ensure that articles are only used for the intended applications, e.g. prevent indoor use of preserved wood.

Measures targeted at the application phase - e.g. reduction of the load of biocides or the use of less hazardous biocides - would of course also have influence on reducing the risk during the service life phase.

5.7 Prevent resistance

Continuous use of the same biocides may result in development of resistance in targeted organisms.

The options for preventing the development of resistance are mainly:

- Switch different biocides at the appropriate frequency defined by the authorisation of all the biocidal products available for one given use.
- Prevent using biocides at sub-lethal levels.

Concerning the first, an example is to change the kind of biocide used in cooling systems every month in order to prevent local enrichment of resistant organisms.

Development of resistance is an issue relevant for all types of biocides. The prevention of resistance is covered by the authorisation procedures of the BPD. If the development of resistance to the active substance in the biocidal product is likely the Member State shall take steps to minimise the consequences of this resistance. This may involve modification of the conditions of authorisation or refusal of any authorisation or derogation for the use of otherwise banned products.

The main measure, in addition to the authorisation procedures, would be to ensure that the user has the necessary training so the biocides are used in accordance with the conditions or restrictions under which the biocidal product.

5.8 Overview of options and measures

For each approach a number of measures for implementing the options have been considered. Table 5.1 summarises the linkage between approaches, options and possible measures.

Table 5.1 Options and measures by approach

Approach	Technical options	Measures
Reduce the quantities to optimal levels	Optimising the dosage	Restrict the application to certified users including applications of harmonised use conditions Certification of application equipment Promote development of application equipment Taxes/levies on selected biocides
	Prevent growth of organisms	Promotion of the development of materials and building techniques that prevent the growth of undesired organisms Promote substitute materials
	Application of non-biocidal techniques	Promote non-biocidal control, "Integrated Pest Management"
	Avoid using biocides where prevention is not essential	Sales restriction (e.g. no sale from open storage shelves) Taxes/levies on selected biocides Information/awareness raising campaigns
Reduce hazardousness	Technical improvements	The use of less hazardous biocides in biocidal product is already covered by the authorization procedures under the BPD
	Imported articles/ materials	Evaluation of substances and subsequent authorisation of biocidal products used in treated articles/materials Labelling requirements for biocides-treated articles/materials
	Use of less hazardous biocides for less demanding applications	Promotion of less hazardous biocides for less demanding applications Prohibition of the use of certain biocides in certain conditions or areas Information/awareness raising campaigns

Approach	Technical options	Measures
Reduce the releases and exposures by application	Use of appropriate application techniques and equipment	Restrict the application of specific biocides to certified users Training programmes for professional users Certification of equipment; Promote development of improved application and protection equipment Awareness raising campaigns on the application of biocides, especially for private users Prohibit the use of aerial spraying.
	Use appropriate personal protection equipment	Restrict the application of specific biocides to certified users Training programmes for professional users Information/awareness raising campaigns on the application of biocides
Reduce the long-term releases and exposures during the service of biocide-containing materials and articles	Reduce the release rate of biocides from products and articles	Limit values for release rates of biocides from materials and articles (e.g. release rates of biocides from preserved wood)
	Prevent inappropriate use of biocide treated materials/articles e.g. indoor use of preserved wood	Awareness raising campaigns on the use of biocide treated products
Prevent the development of resistance	Change between different biocides	Training programmes for professional users
	Prevent using biocides at sub-lethal levels	- same as mentioned above

5.9 Measures in use in EU Member States

Based on the questionnaires and as described in Appendix 2, an overview has been made of measures presently implemented in the Member States. See the table below:

The table is based on the information provided by the MS in the questionnaire responses. Some MS make reference to existing legislation (see Annex 2). The table only includes information provided as answers to the questions formulated by the Commission in the disseminated questionnaire, and there may therefore be legislative measures not included in this table. Moreover, the information supplied by several MS is ambiguous. This is reflected and discussed in the Annex to this report presenting the answers from each of the MS that have answered the questionnaire.

Table 5.2 Measures applied in the Member States by product-type

Measure	Product-type	Member States
Restrict to certified users –mandatory	2	ES, LT
	4 and 11[1]	ES
	8	DE, SE
	14	BE, DE, HU, NL, RO, ES, SE, LT
	18	BE, DE HU[2], NL, RO, ES, SE[3], LT,
	19	BE[4], HU[2], DE, RO, SL, ES
	No information on PT supplied	EE, (MT[5]), SK
Restrict to certified users –voluntary	No information on PT supplied	FI, FR, IT, LU, SL, UK,
Certification of application equipment	2, 5	FR,
	No information on PT supplied[6]	DE, HU[2], RO[7], SK, ES[8]
Promote non-biocidal control, IPM	No information on PT supplied	(MT[5])
Information/information awareness campaigns	No information on PT supplied	FI, ES, SL
	18	BE
Prohibit the use of some product-types	15, 16, 17	DE
Restrict the use of certain biocides under certain conditions e.g. areas or species	21 (restrict in freshwater)	FI
	3 and 18	FR
	Restrictions not related to PT but other variables e.g. geography or user	BE, DE, HU[9], LT RO, SL, SK, SE, UK,
	Local competence - no information	ES
	5 and certain BPD biocidal products	SL
	PPE	SE

Notes: 1) In open cooling systems. 2) For professional users only. 3) Only use of insecticides mentioned in questionnaire. 4) For PT 19: Only restrictions for type A products (c, T, T+, cancer 1&2, mutagenic 1&2, reprotoxic 1&2). 5) Under development. 6) In the response to this question BE has indicated : "Needed for the certification of the user and for the storage place, PPE.." 7) Voluntary CE certification. 8) No legislation specific to biocides. 9) Additionally there is reference to specific products rather than PTs.

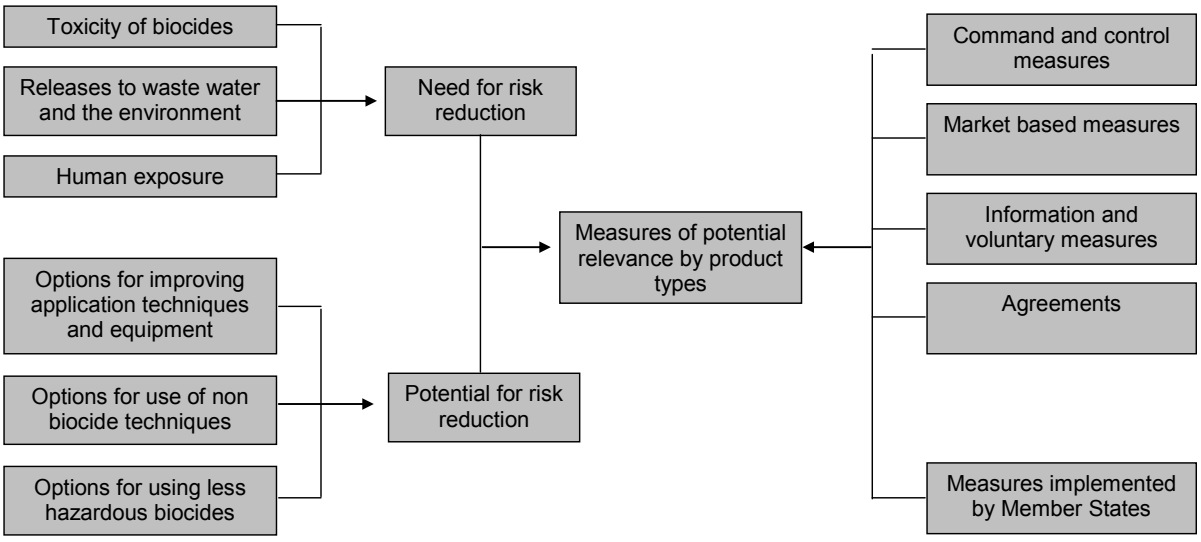
The main findings from the table are:

- 12 of 18 MS have requirements for use of biocides. 10 of these MS have PT specific requirements. Malta is in the process of developing guidelines.
- Six MS have voluntary training or certification procedures.
- Regulation concerning PT 14, 18 and 19 is most frequent and is in place in eight, eight and six MS respectively.

- Seven MS have restrictions on application equipment, whereof one MS has substance specific requirements.
- None of the MS included make use of tax measures, and IPM is currently not used to promote non-biocidal use. Malta is though in the process of developing IPM.
- 11 MS have restrictions on use, either related to substance or product group, or non-substance-specific restrictions e.g. on areas where use of biocides is restricted. In Spain restrictions is under local authority and there is no specific information about restrictions at federal level.
- A preference for lower risk products is specified for nine MS and in France, information is under development

5.10 Screening of measures

In order to select measures of potential relevance it is necessary to combine the results of the assessments in the previous chapters. The following schematic diagram illustrates the ideal selection procedure.



A consistent prioritization tool would involve the development of a ranking of the needs and potential for risk reduction by product-type, but the available data do not allow the development of such a consistent ranking system.

Instead, the measures for further assessment were selected by the use of "expert judgments". The gross list in Table 5-1 was used as a check list to make sure that all potential measures were considered. Then the quantitative and qualitative assessments done in the previous chapters were taken into consideration together with a number of rough screening criteria selected in liaison with the Commission, according to which the measures should be: Feasible, relevant,

efficient and realistic. On this basis it was assessed which measures should be eliminated from the list, and which measures should be kept for further assessment. This process resulted in the following list of measures to be considered for further assessment:

- Training and certification of professional users
- Information/awareness raising campaigns
- Certification of application equipment
- Restrict the use of certain biocides in certain conditions or areas
- Prohibit aerial spraying
- Taxes/levies on selected biocides
- Restrict the use of non-approved biocides in articles
- Promote long-term good practice

From this list a further screening was made, based on the description for each product-type of the application, the risk of human and environmental exposure by the application and the options for risk reduction in Annex 1. The relevance of the different measures is of course for some product-types not unambiguous and may be discussed further.

Training and certification of professional users

Product types with the highest score in the overall assessment of the risk relating to the use phase of biocides in Table [4.10] are areas where the application of the biocides is done by professionals. In many Member States the use of the biocides is restrict to certified users in order to minimise the risk of human and environmental exposure by the application. Certification systems are today mainly applied for biocides for pest control, but training and certification may be applicable for more product types. The measure is selected for further assessment.

Information /awareness raising campaigns

Information/awareness raising campaigns may be considered for product-types mainly applied by non-professional users. The questionnaires to Member States do not specifically include questions regarding information awareness campaigns, but many Member States have probably undertaken campaigns addressing one or more product-types. Information campaigns may address application of the biocides, promote use of low toxicity products and promote non-biocide techniques. Because of the use of biocides vary widely across the EU, Member States are in the best position to identify the information needs. In line with the principle of subsidiarity information campaigns at Community level will not be assessed further.

Certification of application equipment

Certification of application equipment may be relevant for applications where there is a high risk, that inadequate application equipment results in overdosage, high human exposure or high releases to the environment. Several Member States report that specific application equipment is required, but do not provide detailed information on product-types, indicating that certification of equipment would be feasible at least for some product-types.

A certification system for equipment may be linked to a system for certification of the users, requiring that the certified users apply certain equipment and techniques, but may also be implemented at the product level only. Whereas for

plant protection products a major part of the products are applied with large machinery, where it is essential that the equipment optimises the dosage and spreading of the pesticides, for biocides the dosage and spreading of the products is much more dependent on the user of the equipment.

In the questionnaire response Germany mentions that especially in cases where the quantity that is to be applied is not easy to control and exposure is likely, it appears sensible to ensure the optimal concentration of active substance, the targeted and safe (low-risk) application as well as the control of the form (e.g. the optimal droplet size) by placing precise demands on the utilized equipment.

Restrict the use of certain biocides in certain conditions or areas

Certain biocides may be restricted to certain conditions or areas. Such restriction may be relevant for applications in very vulnerable environments and for some biocides where the use of the biocides is restricted to the use for particularly demanding applications.

Examples of such measures implemented in some Member States include (see Table 5.2:

- Prohibition of the use of antifouling products in fresh water;
- Some biocides may be used indoors only;
- Restrict the use of some insecticides for the control of mosquitoes for use in case of epidemic of disease;
- Restrict the use of biocides in designated nature and landscape conservation areas or water protection zones;
- Restrict the use of biocides in environs of drinking water resources, public buildings (e.g. schools, kinder garden, etc.).

At Community level the restriction to certain conditions of the use of biocides is covered by the authorization procedures under the BPD. Member State shall impose, where appropriate, conditions or restrictions when giving authorisations and the Member State shall take the necessary measures to ensure that the applicant proposes a label, and, where relevant, the safety-data sheet, which specifies in particular the conditions or restrictions under which the biocidal product may or may not be used. Restriction of the general use of biocides in designated areas is not considered appropriate at Community level and the measure is not included in the assessment.

Prohibit aerial spraying

In order to prevent releases from aerial spraying the application method may be prohibited. The method seems only to be applied for substances within PT 18. It may be considered to prohibit the use of aerial spraying in line with Article 9 of the Proposal for a directive for establishing a framework for Community action to achieve a sustainable use of pesticides (COM(2006) 373 final) that obliges Member States to prohibit aerial spraying but allows for derogations.

Taxes/levies on selected biocides

Taxation may be considered as a measure for reducing the quantities of biocides used and promote the use of less hazardous biocides.

Taxation may in principle be applicable for all product-types, and for the non-professional applications taxation may be one of the main measures for pre-

venting over-dosage, preventing use of biocides for non-essential applications and promotion of non-biocide techniques. According to the questionnaire responses none of the Member States applies taxation for reducing the use of biocides. The market for biocides is highly differentiated, and it is likely to be very complicated to implement a harmonised taxation in EU. The measure is therefore not included in the assessment.

Restrict the use of non-approved biocides in articles

The options for establishing a procedure for evaluation and approval of substances used in treated articles, labelling requirements and registering of biocides in imported articles has been assessed elsewhere and is not included in the present assessment. In addition, it is also one of the issues identified by the Commission for the revision of the Biocides Directive.

Promote long-term good practice

Promotion of long-term good practice may include an integrated approach combining more measures among others the use of non-biocide pest control techniques, reducing the need of biocides by promotion of development of new materials and development of good practice manuals. The approach may resemble the Integrated Pest Management (IPM) principles applied for plant protection products. In the responses to the questionnaire the Member States in general consider that the IPM principles could be applied on at the least some product-types and the measure will be included in the further assessment.

Results of the screening

The screening thus results in the following list of the most feasible and relevant Community level measures for further assessment:

- Training and certification of professional users;
- Certification and inspection of application equipment;
- Long term good practice and prevention.

Prohibition of aerial spraying may be considered both feasible and relevant, but has not been assessed further as the study has not aimed at assessing very specific measures relevant for one PT only.

6 Assessment of relevant measures

In this chapter each of the three selected measures will be assessed with respect to health impacts, environmental impacts and socio-economic impacts related to implementation of the measure. As described in Chapter 5 the three selected measures are:

- Training and certification of professional users
- Certification and inspection of application equipment
- Long term good practice and prevention

In order to carry out the assessment of the measure, each section on a measure is introduced by a "design" of the measure, which outlines the elements of the measure and practical and implementation considerations.

6.1 Training and certification of professional users

6.1.1 Introduction

Today various training and/or certification schemes exist in many Member States such as training for wood preservatives, disinfectants, insecticides, rodenticides. In the workshop in April 2008 there was a consensus that there is a need for a minimum level of good practice harmonisation with regard to training requirements across the EU at least for some PTs (e.g. wood preservatives, disinfectants, rodenticides, insecticides), less so regarding the certification requirements.

Also from industry side there is expressed interest in a harmonised certification system. The Confederation of European Pest Control Associations (CEPA) that represent around 80 percent of the market value for pest control industry; commit voluntarily themselves in the Roma protocol of April 2008 to working for the development of a policy valid throughout Europe for certification of companies or individuals, along with criteria to enter and operate within the profession and to harmonise the use and implementation of standards across the European Pest Management Industry (CEPA 2008).

6.1.2 Design of the measure

The aim of the certification systems is to ensure that the persons using the biocides have adequate training, and use adequate application equipment and personal protection equipment. The certification systems may be supplemented with a system for inspection of application procedures by certified users.

The measure is assumed to consist of three separate elements that may be implemented at different levels for different product types:

- Harmonised Good Practice (GP) reference documents and standards
- Harmonised training schemes and requirements
- Harmonised certification system.

GP reference documents and standards

Harmonised good practice (GP) reference documents may serve as a basis for training schemes (and training curricula), as reference documents for the authorisation of biocides and as basis for the development of certification systems requirements and be provision. The use of the term Good Practice instead of Best Practice reflects the fact that it for this area would often be difficult to measure what is the best practice.

GP reference documents may by developed for all product-types and are not necessarily linked to the development of obligatory training or certification.

The reference documents may be developed by Technical Working Groups (TWGs) comprising nominated experts from EU Member States, industry and environmental NGOs with the Joint research Centre as coordinating body. A similar system exists for the BAT Reference Documents (BREF) developed in the framework of the IPPC directive and coordinated by the European IPPC Bureau.

An essential use of the GP reference documents (independent of any further measures) is as reference documents for the authorization of biocides. By the authorization specific application procedures for the biocides can be stipulated with reference to specific procedures described in the reference documents.

Specific GP reference documents should be developed for each product-type and for very heterogeneous product types, even more than one reference document may be needed.

A German study included the development of good practice (GP) reference documents for three product-types: PT 2 „Disinfectants in the private area and public health“, PT 8 „Wood preservatives“ and PT 14 „Rodenticides“) based on a uniform structure. The structure may illustrate what the reference documents could include:

1. General principles and goals of the GP
2. Description of the area of application
3. Determination of the need of a biocides application (problem analysis, definition of the goal)

4. Examination of the measures and decision making
5. Preventative, non-biocidal measures
6. Proper use of biocidal products:
   - 6.1 Selection of low-risk products
   - 6.2 Minimising the amount of biocide used
   - 6.3 Licensing of equipment
   - 6.4 Measures for risk management
   - 6.5 Controlling of success
   - 6.6 Waste disposal
7. Documentation
8. Storage and transport

The qualification of the user (education, schooling and training, professional certification) as well as the communication of risks was considered of decisive importance as adjunct measures for the realisation of and compliance with the GP, but were not regarded as being part of the GP.

The study concluded that the GP reference document cannot do without references to legislation or other regulating documents such as DIN-standards or information sheets from professional associations, in which the basic information is given.

Whereas the GP reference documents are aimed at informing the professional users and the authorities, it may be relevant also to develop common criteria concerning the quality of services provided by the pest control industry.

CEPA works currently for the development of common criteria through participating in the work of CEN (European Committee for Standardisation).

A harmonised system for GP reference documents should as minimum define:

- The organisation for development and publication of GP reference documents;
- Which product-types to be covered by the reference documents;
- A unified structure of the GP reference documents.
- A specification of the use of the reference document.

Training schemes

Training schemes may be developed for obligatory training (in conjunction with a certification system) and for voluntary training of professional users.

Where the obligatory training would most likely address the professionals in the pest control industry and public organisations, the latter may address professionals having application of biocides as a minor part of their activities.

The training schemes should be based on the BPG documents.

It seems to be difficult to justify harmonised training schemes for voluntary training and training schemes will consequently be discussed only in connection with certification/authorisations systems.

Certification system

Certification/authorisation systems for professional users exist today in many Member States for a number of application areas.

In a few instances the use of the biocides for a certain product-type is restricted to authorized professional users (e.g. use of rodenticides in Denmark). In most Members States the authorization systems concerns only the professional users providing the pest control as a service or as public pest controllers, while the biocides may still be used by non-professionals or professionals undertaking pest control in their own premises (e.g. farmers). In some Member States certification is required for specific application techniques (in particularly the use of fumigants) or substances of a certain toxicity and not specific product-types.

For certification systems, the legislation may stipulate that the service may only be provided by certified users, while the certification is issued on the basis of documented training by e.g. a national pest control association.

For authorisation systems the authorization may more typically be issued by the recognised public authority.

In order to obtain an authorization specific provision in the authorization may include:

- A registering in a register of economic activities (for providing pest control as a service),
- Some basic education;
- Some work experience in pest control;
- Documented specific training (examination certificate).

The legislation would typically stipulate that the pest control should be undertaken in accordance with some guidelines to be followed by the authorized person.

Training may be provided by public organisations, industry organisations or educational organisations. The cost of training and an authorisation fee would typically be paid by the applicant.

In some systems, authorization and training is only required for the persons in charge of the pest control, whereas in others professional competence should be demonstrated for every technician through examination and certification.

A harmonised system for authorisation should define:

- The product-types and application techniques to be covered by the certification/authorisation system;
- The users covered by the system (eventually by product-type);
- Conditions for obtaining the certificate/authorisation (experience, training, etc.);
- Reference to GP reference documents.

These issues will be discussed further in the following section.

6.1.3 Relevant product types

The development of GP reference documents is in principle relevant for all product-types with the highest priority for product-types for which a certification system is developed (if any).

Restriction of the use of biocides to certified users may in particularly be considered for product-types where:

- the toxicity of the biocides is relatively high, and
- there is a high risk of environmental or human exposure by inadequate application techniques.

As shown in Table 6-1 restriction of the use to certified users is implemented in many Member States for uses of biocides within Main Group 3: Pest Control; and in particularly for rodenticides (PT 14), insecticides (PT18, probably for certain professional applications only) and repellents (PT 19, probably for some applications only). Similarly certifications systems may also be relevant for avicides (PT 15), molluscicides (PT 16) and piscicides (PT 17) and the absence of certification systems for these product-types may simply reflect that these product-types are not used in many countries.

Other product-types, for which certification systems exist in some Member States, include disinfectants for private area and public health areas (PT2, probably some areas only), food and feed areas disinfectants (PT 4), wood preservatives (PT 8, probably some uses only), preservation for cooling systems (PT 11, open systems only) and control of other vertebrates (PT 23) (fumigation).

These product-types are more or less the same as the product-types applied by companies in the pest control industry (see Table 6-1).

It is considered that these products-types are those for which obligatory certification and training of professional users would be most obvious and have highest priority.

For other product-types the biocides are applied by professionals but most often not by dedicated pest control companies. As indicated in Table 6-1 it is considered, on the basis of high risk of human and environmental exposure (see chapter 4), that training and/or certification systems may also be relevant for other product-types including disinfectants for swimming pools (PT2, disinfectants for swimming pools), masonry preservatives (PT 10, for professional use) and slimicides (PT 12, use in oil extraction).

For two of the product-types, disinfectants for medical equipment (PT 2, subtype) and embalming fluids for humans (PT 22, subtype) the application is in practice restricted to professionals, that must be expected to have the necessary training.

A number of the product-types are also applied by non-professional users in private areas (see Table 6-1). For those users the information in the GP reference documents would still be relevant and guidelines for private users may be developed on the basis of the reference documents by local or national authorities. It may also be considered to restrict some applications to professional certified users (e.g. in Denmark rodenticides and fumigants are not to be applied by non-professionals) but this options has not been assessed here.

For some applications there is a particular high risk of exposure of other persons than the user to substances that may be highly toxic. A particular concern is the risk of poisoning of children or other by-passers or operations with very high risk for the operators. This concerns rodenticides (PT14) and insecticides (PT18) and the use of fumigants or gassing (some applications of PT14, PT18 and PT23). In case of a stepwise approach gradually including more PTs in a certification system, these applications may be assigned first priority.

Table 6-1 Product-types for which obligatory training and certification may in particular be relevant

Product-type	Sub-type	Implemented in Member States (based on questionnaire) *1	Applied by pest control companies	Non-professional use
Main Group 1: Disinfectants and general biocidal products				
2: Private area and public health area biocidal products	Disinfectants for public areas	ES, LT	Partly	
	Disinfectants for swimming pools			Non-public swimming pools
3: Veterinary hygiene biocidal products			Partly	Private stables
4: Food and feed area disinfectants		ES	Partly	Private areas
5: Drinking water disinfectants				Small consumption of specific substances
Main Group 2: Preservatives				
8: Wood preservatives	Vacuum and pressure preservatives	DE, SE	Yes	
10: Masonry preservatives				Private areas
11: Preservatives for liquid cooling and processing systems		ES (open systems)		
12: Slimicides	Slimicides for wood and paper pulp			
	Slimicides and other biocides used by oil extraction and fuel storage			
Main Group 3: Pest control				

	Product-type	Sub-type	Implemented in Member States (based on questionnaire) *1	Applied by pest control companies	Non-professional use
14:	Rodenticides		BE, DE, HU, NL, RO, ES, SE, LT	Yes	Control of mice in private areas
15:	Avicides			Yes	
16:	Molluscicides			Yes	
17:	Piscicides			Yes	
18:	Insecticides and products to control other arthropods		BE, DE HU2, NL, RO, ES, SE, LT,	Yes	Private areas
19:	Repellents and attractants	Repellents and attractants for control of gnat and fleas	BE, HU, DE, RO, SL, ES	Partly	Repelling of mosquitoes in private areas
		Repellents and attractants for control of game, birds and other vertebrates		Partly	Repelling of pets in private areas
21:	Antifouling products	Antifouling paints for vessels >= 25 m.		Partly	
		Antifouling paints for other uses			?
22:	Embalming and taxidermist fluids	Embalming fluids for humans			
		Embalming and taxidermist fluids for animals.			Small consumption of taxidermist's biocides
23:	Control of other vertebrates		(probably some certification requirements related to fumigation and gassing)	Yes	

*1 Based on information in questionnaire and probably not comprehensive.

6.1.4 Health and environmental impacts

The benefits of a training and certification measure could be expected to be reduction in health problems or deterioration and environmental damage caused by unintended emissions, spill, accidental contact with biocides, etc. by optimising the dosage, optimise the application techniques, and promote non-biocide control of the organisms.

The product types, for which these measures are relevant, are all among the applications with high scoring in the overall assessment of potential human and environmental risk summarised in Table 4-10.

Potential for improvement

For estimating the potential reduction in releases by implementation of the measures it is necessary to have an indication of the potential for improvement of the application techniques.

It has not been possible to indentify any evaluation of the health and environmental impacts of the implementation of obligatory certification and training system for biocide application equipment in Member States.

For plant protection equipment BIPRO (2004) assume on the basis of expert interviews that a "soft training" will bring a plant protection product use reduction to an extent of about 10% compared to the untrained user. The main reason is that the training will guide users to follow more exactly the recommendations of the PPP producer and the equipment producer and avoid unintentional higher dosages.

For biocides the determination of optimal dosage is for most applications more difficult than for plant protection products. For the plant protection products optimal dosages e.g. in terms of dosage per hectare can more easily be followed than dosage for e.g. application of insecticides by use of spraying. So the risk of over-dosage and unnecessary releases of the substances are considered to be higher for many biocides applications than for PPP.

The potential reduction in the exposure of humans and the environment by these measures may likely be in the range of 10-50%, but a more detailed assessment of each type product-type is necessary in order to estimate the potential with more certainty.

The type of size of the benefits would depend on the PT's and specific products to be included in the scheme.

Human health benefits

In general terms humans are (as described in Chapter 4, Table 4-6) exposed to biocides primarily by inhalation and skin contact. The health benefits from reducing the exposure to hazardous biocides are ultimately related to the number and severity of illnesses or adverse effects among both professional and non-professional users, and also among others exposed during the service life of the products or through secondary exposure. The actual benefit is however difficult to quantify. The available classification data for some of the biocidal substances indicate that the key health effects of concern which could result from exposure to these biocides are acute intoxication or poisoning, sensitizing effects or effects related to exposure to substances causing chronic effects (CMR) from exposure to low doses.

Active substances which cause chronic effects from long term exposure to low doses and sensitizing substances are a major concern in both public health and in relation to occupational safety due to their irreversible nature. Benefits from reducing the exposure to biocides include the reduction of the potential contribution to cocktail effects from exposure to certain biocidal substances in combination with other substances and thereby the general load of chemical exposure in the society. This is relevant for professional users as well as non-professional users. Although there is limited information available about endo-

crine disrupting effects from biocides in general, this is an area where potential cocktail effects need more attention. Biocidal substances that end up in the indoor climate during the application and service life of the products are likely to have an impact on also the more vulnerable groups like children and immunocompromised persons. This is e.g. relevant for PT2, PT6 and PT18.The PT's most likely to be included as a first step in a training and certification scheme are as mentioned above PT2, PT8, PT14 and PT 18. The health implications of these product types include, as shown in Table 4-2, especially:

- For PT 14 and 18 the substances are mainly classified due to their acute toxicity to humans and the benefits of the measure could be expressed in reduced instances of poisoning.

- Substances within PT2 and PT8 (and other PTs potentially addressed by the measure) are classified due to a wider range of effects including CMR effects and sensitization. These effects are characterized by being induced by chronic exposure to low levels of many different substances and health benefits of the reduced exposure to specific biocides are very difficult to quantify.

Environmental benefits

To this moment, the environmental hazard identification is more or less restricted to potential acute or long term toxic effects in the aquatic environment (chapter 4 for more details). Other environmental hazard properties are of course relevant for an environmental risk assessment e.g. PBT/vPvB or endocrine disruption, but the relevant information is not easily available for a wide range of substances.

One can roughly assume that on the average almost 3 out of 4 biocides will be highly toxic to aquatic life and that half of the substances in addition to high aquatic toxicity will be "not easily biodegradable". The proposed measure may reduce such effects on aquatic organisms (e.g. exposed by direct releases to surface waster) and probably also on microorganisms in the soil. The effects on the microorganisms may change the ecosystem structure in soil and the aquatic environments, but data indicating the extent of such changes due to the use of biocides (and the possible benefits of reducing the exposure) has not been available.

Biocides released to waste water treatment plants (WWTP) may effect the microorganisms of the WWTPs, especially the nitrification/denitrification processes for removal of nitrogen, making the WWTPs less efficient. Exposure of WWTPs is particularly important for disinfectants in PT1, PT2 and PT4 although also a number of the other PTs contribute to the load of biocides onto WWTPs by being partially discharged into the sewer system. It has, however, not been possible to quantify the possible benefits of better functioning WWTPs as result of reduced releases of biocides to the sewer system .

Further, the substances in PT14, PT15 and PT23 can be expected to be highly toxic also to non-target mammals, birds and other vertebrates in the terrestrial environment. The economic benefits of reducing the risks of lethal effects on mammals, birds and other vertebrates, is not easy to estimate.

6.1.5 Economic impacts

Economic impacts

The primary economic impacts[16] would be the costs of establishing and operating the training and certification scheme. Cost elements include:

- Costs of development of training requirements
- Cost of development and maintaining GP documents
- Administrative costs of maintaining certification system
- Costs of inspection and other enforcement
- Costs of obtaining and maintaining certificate
- Costs of training courses
- Time consumption costs of participating in training and inspection
- Production costs related to training

Theoretically there may be effects for competitiveness and prices, but it is assessed that these will be negligible.

It is important to only count costs once. For instance, a training course paid by the user/business in a full-cost arrangement is a cost to the user/business, but not to administration, since the costs in this case are covered by training course fees.

In assessing the costs of training and certification we have based the assessment on the MS responses to the questionnaires. Information is however scarce, since not all MS have answered the questionnaires and the responses which were received did not contain very much information on this issue.

Training courses

The total costs of introducing the measure will depend on how many product types will be included, as described in the previous section and with reference to Table 4-10, and the ambitions of the training. In order to give some illustration of the potential costs, MS responses to questionnaires combined with follow-up e-mail correspondence have been used to find examples of the magnitude of the costs of training and certifications for some MS. These are presented below.

Sweden

The Swedish legal system with respect to biocides has been in force since 1975. The figures from Sweden are based on the "Swedish model" concerning the use of biocidal pesticides for professionals[17].

[16] As economic impacts are - in line with the approach used in the EU Impacts Assessment Guidelines (March 2006 update) - considered impacts in terms of changes in costs and prices, such as increased costs for firms and public authorities. If the public authorities are involved in the establishment of the training and certification scheme, the associated costs should correctly be regarded as *implementation costs* (Section 9.9 in the Annexes to EU Impacts Assessment Guidelines). However, since the allocation of costs between firms and public authorities are presently not known, this distinction is not made here. The *benefits* of the scheme in terms of environment and health improvements are described in the previous section.

The biocides are classified according to different user categories when they are approved, and it is legally demanded to follow the stipulated field of use according to the label. Relevant user levels are:

- User category 1: Professional use requiring licence
- User category 2: Other professional users
- User category 3: Retail market (non-professional users)

User categories 1 and 2 are thus professional users and user category 3 are users at the retail market. Products which according to a risk evaluation done by the registration authority are regarded unsuitable for the consumer market will not be approved for the retail market (user category 3).

Whereas professional users in category 1 are well defined, there is no specified licensing or legal system indicating who is to be regarded as "professional" according to user category 2. Products for professional use (user category 1 and 2) are differentiated in three categories:

A/ May be used by professional users in category 2.

B/ May be used only by professional users in category 1 with special licensing of the individual pest controller. The user sub-category "1 So" covers pests such as insects and rodents and user sub-category "1 AV" covers other uses like the use of antifouling and wood preservatives.

C/ The same as B/ but with an extra licensing, e.g. for toxic fumigants. User category 1 SoX, covers "Extra toxic" biocides - normally fumigants.

The licensing for user category 1 and product categories B and C is thus mandatory. The Swedish authorities issue the personal licensing of each pest controller after a four days training. The licence is to be renewed every 5 years and cost about 1.500 Euro per person.

As indicated above, the licence for professional users are required for the use of rodenticides (PT14), wood preservatives (PT8) and insecticides (PT18), where training is part of a specific provision in the authorization. The licensing is described in a separate statute published by the Swedish National Board of Health and Welfare and this authority issues the personal licensing of each pest controller.

The Netherlands

In the Netherlands, the Dutch Institute EVM (Certificeringsinstituut Plaagdierpreventie) is responsible for pest control courses. These concern PT 14. The training course has a cost of 2500 Euro for a 10 day course and deals with law,

[17] This section builds on the Swedish response to Commission questionnaire and *The Swedish 'Model' concerning the use of Biocidal Pesticides for Professional Use*. Swedish response to the Commission questionnaires.

biology of pests, practice, use of equipment, etc. The courses are normally overviewed by the Ministry of the Environment[18].

UK

UK indicates in the questionnaire that the costs of setting up a training and certification scheme are very difficult to predict, but it is expected to be "very costly". An estimate of 500 Euro per day is given for an individual to attend a training/certification event in the UK.

Denmark

In Denmark control of rats can only be undertaken by an authorized person or a person working under the responsibility of an authorized person. A course for obtaining rodent authorisation (PT 14) takes 4 days, including accommodation and consumption, and costs 1.300 Euro. This does not include salary for the attendant. There are no requirements for update of the course[19].

Clearly, the price of training courses will differ between Member Status because of differences in local conditions such as wages.

Time costs

Time consumption costs[20] of participating in training courses also constitute a cost of the measure. Time costs will likewise differ between Member States. The hourly labour costs for *all branches*[21] in 2005 were 18.50 Euro for EU27, but with very large variations within the EU: From 1.61 Euro/hour for Bulgaria and 31.40 Euro/hour for Luxembourg. The labour costs for *services*[22] were 19.81 Euro/hour, with similar variations from 1.52 - 33.64 Euro/hour. Another indication of the large differences is that EU15 hourly wage costs for services were 24.34, whereas the similar figure for new Member States, EU10[23], was 6.08 Euro.

The costs of time consumption will therefore be highly dependent on the Member States which they concern. As an example, an estimate of the costs of time consumption for a four days course in Sweden would amount to approximately 920 Euro[24], whereas the similar costs of time consumption in Poland would amount to 170 Euro[25].

An overview of the certification/training costs and hourly labour costs are presented below.

---

[18] Telephone conversation with Nico Vonk, The Dutch Institute EVM (Certificeringsinstituut Plaagdierpreventie) October 24, 2008.

[19] http://www.blst.dk/Rottebekaempelse/kommuner/Autorisationskursus+i+rottebekæmpelse/04080400.htm.

[20] Data based on European Commission > Eurostat home page > Data navigation tree (http://epp.eurostat.ec.europa.eu/). See also The European pest control industry - Statistics 2003 at http://www.cepa-europe.org/Media/publica-tions/europeanpestindustry.pdf

[21] NACE branches c to o. All branches except agriculture, fishing, private households with employed persons.

[22] NACE branches g to k: Services (excluding public administration).

[23] CZ, EE, CY, LV, LT, HU, MT, PL, SI, SK.

[24] 4 days of 7.4 hours at 31 Euro per hour. (http://epp.eurostat.ec.europa.eu/)

[25] 4 days of 7.4 hours at 5.75 Euro per hour. (http://epp.eurostat.ec.europa.eu/)

Box 1 Examples of Member State data related to costs of training and certification

Country	Days	Cost of training course[1] (Euro)	Product type (PT)	Labour costs per hour[2] (Euro)
Sweden	4	1500	PT 8 - Wood preservatives PT 14 - Rodenticides PT 18 - Insecticides	31/h
The NL	10	2500	PT 14- Rodenticides	27/h
United Kingdom	N/A	500[1] (per day)	N/A	24/h
Denmark	4	1300	PT 14- Rodenticides	33/h

1) MS questionnaires and e-mail/ telephone communication with MS contact persons and contact person from The Danish Environmental Agency. 2) Eurostat (http://epp.eurostat.ec.europa.eu/). NACE branches g to k: Services (excluding public administration).
3) Rough estimate indicated in the questionnaire.

The examples from these four countries show costs per day of training courses, excluding labour costs, of:

Sweden: 375 Euro/day
The Netherlands: 250 Euro/day
United Kingdom: 500 Euro/day
Denmark: 325 Euro/day

The above mentioned costs give an indication of the size of the costs of a training course. The figures can on the other hand not be used for comparison of costs between the Member States, since the contents of the courses differ with respect to the PTs included and number of days, and may differ with respect to a number of other dimensions as well.

As indicated above labour costs show very large variations across the EU. Since the costs of training courses are highly dependent on wages, the costs per day of training courses must be expected to be much lower in e.g. EU 10 (new Member States).

For the above mentioned countries the costs of training courses and time consumption for the indicated lengths and content of the training courses would amount to:

Sweden: 1.500 Euro + 920 Euro = 2.420 Euro (4 days)
UK (example): 2.000 Euro + 710 Euro = 2.710 Euro (4 days)
Denmark: 1.300 Euro + 980 Euro = 2.280 Euro (4 days)
The Netherlands: 2.500 Euro + 2.000 Euro = 2.000 Euro (10 days)

Thus, for Sweden for example the total costs of the training course are 1.500 Euro as indicated in the box above, and the costs of time consumption are 31 Euro per hour * 7.4 hours * 4 days = approx 920 Euro. In total 2.420 Euro.

Thus, a rough estimate of the costs for a four days training course in northern Member States could be around 2.500 Euro. The costs will depend on inter alia the wage level in the individual Member State.

Other costs

To the mentioned figures should be added production costs, i.e. the costs of the lost production while the employee attends the course. It is not possible to give a general estimate of these costs from very different kinds of productions.

In the figures are also not included costs for administration. These costs could be related to e.g. establish and run a certifications system and costs of developing and maintaining training requirements and GP documents. A total of six Member States have mentioned the administrative costs as an economic issue to be regarded as an impact of this measure. Belgium, France, Lithuania and Slovenia mention the costs of administration and the development of such a scheme and the enforcement of authorities and users as an impact of this measure, whereas Cyprus specifically indicates that this measure will require two full time officers in the Department of Agriculture, responsible for the evaluation of the biocides and the market control. The Health and Safety Executive, CA for Biocides in the United Kingdom underlines that such a scheme would be very costly, representing an increased cost to the industry.

A central part of the German assessment[26] mentioned earlier was the drawing up of a Good Practice document for 20 biocidal product types (PT). The legal basis and information sheets of the German statutory accident insurance funds, professional associations, and additional organisations were systematically collected and evaluated with regard to the appropriate use, suitable work safety measures, the licensing of equipment, training, and existing regulations describing the 'state of the art' techniques. Thereby for the first time an overview was created over the complex and very different areas of application for 20 biocidal product types. These were intended to be used as the starting point for creating German GP-documents. Although it is mentioned that they only represent preliminary working papers, make no claim of completeness, they may serve as starting point also of an EU process of developing GD documents by providing an efficient framework for professional information exchange in dialog with experts. In this way the costs of developing GP documents could be reduced.

Marginal costs

When assessing the marginal, i.e. extra costs, of developing a training scheme for biocide users, it should be taken into account, whether the Member State in question already has established a training scheme. If such a scheme fulfils the requirements of an EU wide training scheme, there would be no extra costs, or if the system could be adapted to the EU wide system, the additional costs may be less, than for Member States with no training scheme at all.

Cost parameters

As indicated above, costs would depend on the following:

- Does the Member State already have a training scheme for biocides?
- How many PTs should be included in the training scheme?

[26] From an attachment to the German questionnaire response: *Description of the appropriate use and good practice during the use and disposal of biocidal products.*

- The length of the training course (may depend on number of PTs)
- Should the courses be repeated e.g. every 5 year?
- The wage level in the Member State

Perspectives

In order to put the training cost figures into perspective, it would be interesting to know the potential number of people apt for training courses in the EU. The European Confederation of Pest Control Associations (CEPA), founded in 1974, is the only organisation representing the pest control sector throughout Europe to the institutions of the European Union[27]. One of its main aims is to harmonise regulations concerning the use and the application of biocide products. In total, more than 38.000 persons are employed in the pest control industry. Separate figures for persons working with the use phase of biocides are however not available.

As mentioned above, the PTs for which Sweden, The Netherlands and Denmark have set up training schemes concerns PT 8 (wood preservatives, PT 14 (rodenticides) and PT 18 (insecticides). Measured in terms of yearly turnover for the industry[28] these three PTs represent the most important market segments: Rodent control (587 millions of Euros), insect control (585 millions of Euros) and wood protection (126 millions of Euros), which together represented 87 % of the total biocides market in terms of turnover in 2003.[29]

The German assessment[30] identified ca. 35 occupations requiring special perennial profession training which could have something to do with biocides. This includes the various trades from the foods area, morticians, boat builders, professional employees for bathing operations, specialists for water supply technology, building cleaning services, refrigeration and cooling system builders, retail sales personnel, house painters and varnishers, paper makers, pest controllers, textile confectionists, etc. In addition, ca. 15 occupations requiring in-service training were identified, which could involve the use of restorers, pest controllers and disinfectors.

It was assessed, that existing trades and specialised occupations would form a good basis for a uniform determination of the instructional contents with regard to the use of biocides. In some of the educational curricula were found detailed instructions for the use of biocides (e.g., in the course for building cleaners), while in others less weight is given to knowledge of the use of biocides (e.g., professional training in the hotel industry). The work revealed that the application patterns can be so different even within one product type, that an opera-

[27] http://www.cepa-europe.org/Content/whatiscepa/2/index.html

[28] The European pest control industry - Statistics 2003: http://www.cepa-europe.org/Media/publications/europeanpestindustry.pdf.

[29] Compared to the distribution of biocide tonnage, it can be seen from Table 3-7, that these product types only represent a relatively smaller amount of the total biocide tonnage in EU.

[30] From an attachment to the German questionnaire response: *Description of the appropriate use and good practice during the use and disposal of biocidal products.*

tion-oriented description of the Good Practice is more useful than a comprehensive general description.

Certain important occupations, such as disinfectors or pest controllers, could not be assigned to a single PT, but involved several PTs. It was found striking, that there was no trade occupation requiring special perennial profession training for disinfectors and also no federal-level uniform regulation of the respective training.

It was recommended, that the educational contents on biocidal products be anchored more clearly in the framework of already existing teaching plans.

Cost savings

A training and certification scheme would educate professional users and encourage them to use more adequate application equipment, more precise dosages, etc. A training and certification scheme is therefore likely to result in improved effectiveness in the professional use of biocides, which would in turn provide cost savings in fields business as well as public sector using biocides.

6.1.6 Implementation and enforcement issues

In the responses to the questionnaire the Member States have depicted the major potential difficulties and advantages which they foresee of a Commission encouraged scheme for training and certification of users.

Advantages

Most of the advantages concern the protection of health and the environment, as described earlier. Other advantages mentioned are less risk of resistance developing and safer handling of hazardous substances.

Main difficulties

Some of the main difficulties pointed out are:

- The development of training schemes and GP reference documents require high knowledge of the specificities of each biocidal use, and a high knowledge of the current practices.
- Various training schemes and GP reference documents are required for different product types.
- The lack of resources (human and financial) for development of training schemes and GP reference documents and for organising training.
- High costs for enforcement authorities and users.
- Ensuring that all those subject to such a requirement actually do participate in the training. Lack of interest in case of voluntary training system and difficulties in defining the professional user.

Quotes from Member States responses from questionnaires[31]:

Variability of biocides in use

- Due to many PTs and types of uses the users are difficult to reach.
- To define what is a "professional user".
- It is necessary for various training schemes to be devised: For hygiene experts in food processing companies, fumigation in pest control, the protection of stock, the transportation of goods, safe handling of wood preservatives, etc.
- The risk that arises from the variety of the product types and active substances is wide and it's difficult to develop one general scheme for all areas.
- Different kinds of users and products (e.g. formulations).
- Too many different areas involved with biocides to have one training scheme, there is a lack of knowledge and experience with the industry, lack of money, lack of resources – trainers, examiners, and assessors. Increased costs to industry

Lack of knowledge and resources

- To develop such scheme requires a high knowledge of the specificities of each biocidal use and of the current practices. Need to have a prioritization.
- Difficulties expected in transitional period between national and the EU qualification schemes
- Need to rise institutional capacity

Voluntary training

- Difficulties: lack of interest in case of voluntary training system.
- Ensuring that all those subject to such a requirement actually do participate in the training. Lack of interest in case of voluntary training system.
- Major difficulties will be the identification of the amateur users of biocides, the lack of staff to develop the training tools

The main difficulties pointed out concern the large number and specificities of products even within the same product types, which is anticipated to make it a very complicated task to develop a common training scheme. Besides representing an increased cost to the industry, there is a reservation was regarding the many different areas, which are involved with biocides to have one training

[31] Member States' responses to questionnaires.

scheme, a lack of economic resources and a lack of knowledge and experience within the industry, lack of trainers, examiners, and assessors for a common training scheme to be realistic.

Possible approaches

In this regard, the German approach may be of interest. Thus, as described above the German assessment recommended, that the educational contents on biocidal products be anchored more clearly in the framework of already existing teaching plans. It was further pointed out that that an operation-oriented description of the GP would be more useful than a comprehensive one.

The response from Luxembourg suggests a similar approach. It welcomes a harmonized training scheme, which would also take into account already existing qualifications (obtained by (academic) education; experience), as long as this training could be offered in cooperation with competent bodies in neighbouring Member States. Luxembourg further suggests that training for products limited upon authorisation to 'professional' and 'industrial' users could, at least partially, be provided by industry. This could be considered an integral part of the product package, and would allow a quick way to react to situations arising from new or extended uses or new findings concerning the use.

These approaches could be combined with a stepwise approach gradually including more PTs in a certification scheme.

Sweden and The Netherlands responded that they do not see any major difficulties with a Commission encouraged scheme, and Estonia even mentions that it would be "very helpful for all Member States if the Commission will encourage the development of such kind of unified training scheme".

Enforcement

Only two Member States have touched directly upon the issue of enforcement. Malta mentions that judging from their experience the major problem would be that of ensuring that all those subject to such a requirement actually do participate in the training. Lithuania mentions big costs for enforcement authorities and users. Costs of enforcement will depend on the set-up of the training scheme. For instance, if the training scheme is build into already existing training scheme, the costs may be relatively small. On the other hand, for Member States without many of such systems or without the necessary support of the general legal enforcement system, the enforcement costs would be larger.

Issues to approach

Thus, the measure implies establishing an administrative framework for and development of Good Practice (GP) reference documents and standards, training schemes and requirements and a harmonised certification system. A stepwise approach is recommended, starting with biocides which are regarded most problematic such as PT14, PT18 and PT23 and biocides where training and certification schemes are already established in some countries (namely P8, P14 and P18).

It should be considered to require a five years renewal for the training scheme, as in Sweden, and as far as possible to integrate training and GP reference documents in already existing schemes, as suggested in Germany.

It could further be considered how to handle that some biocides are used more widely in some Member States than in others, in order not to introduce unnecessary administration.

6.1.7 Conclusions

The impacts of a training and certification system would comprise costs as well as benefits. On the one hand it will provide benefits in terms of reduction in health hazards and environmental damage caused by excess use of biocides, and on the other hand there will be costs of establishing and running the system. It is assumed that the measure would not reduce the use of biocides to levels below levels necessary for acceptable reduction of the damage from the target organisms (such as rats, insects, etc.)[32].

The benefits of the scheme is expected to be reductions in health problems or deterioration and environmental damage caused by diffuse releases, spill, accidental contact with biocides, etc. The type of and size of the benefits would depend on the specific products to be included in the scheme.

The health benefits from reducing the exposure to hazardous biocides are ultimately related to the number and severity of illnesses or adverse effects among both professional and non-professional users, and also among others exposed during the service life of the products or through secondary exposure. The actual benefit is however difficult to quantify. The available classification data for some of the biocidal substances indicate that the key health effects of concern, which could result from exposure to these biocides, are acute intoxication or poisoning, sensitizing effects or effects related to exposure to substances causing chronic effects (CMR) from exposure to low doses.

The environmental benefits are expected to be reductions in acute as well as long-term hazards to aquatic organisms and the aquatic environment as well as reduced effects on microorganism in waste water treatment plants (WWTP), especially microorganisms responsible for the nitrification/denitrification processes for removal of nitrogen. On the average, almost 3 out of 4 biocides can be assumed to be highly toxic to aquatic life and half of the substances in addition are not easily biodegradable, and less emissions of these substances to the environment would therefore improve the environmental status, depending on the substances included in the scheme, the exact character of the scheme, etc.

Further, for the substances in PT14, PT15 and PT23, the benefit can be expected to be reduced poisoning of to non-target mammals, birds and other vertebrates in the terrestrial environment.

The costs of establishing and running training courses have been estimated on the basis of data provided by the Member States. The costs for a four days

[32] *If* a measure would reduce the use of biocides below this level, the costs to society of increased illness, damage, loss of production, etc. caused by the biological organisms in question should be included in the cost-benefit assessment.

training course were estimated to be in the order of magnitude of 2.500 Euros, including time consumption costs, for Member States with high average wages. Lower costs could be expected in Member States with lower average wages.

A training and certification scheme would educate professional users and encourage them to use more adequate application equipment, more precise dosages, etc. A training and certification scheme is therefore likely to result in improved effectiveness in the professional use of biocides, which would in turn provide cost savings in fields business as well as public sector using biocides.

In order to consolidate these first conclusions, the author recommend the Commission to launch a study on the potential for reducing human and environmental exposures to biocides by introduction of training and certification of professional users of biocides for different PTs. For the present study available evaluations have been searched for in the MSs, and it would probably be necessary to collect basic data from a number of MS e.g. on the numbers of registered cases of poisoning (mainly relevant for PT14 and PT18) in countries with and without a certification system. Further some assessment, based on interviews of (or questionnaires to) professional users, may clarify the potential for reducing the exposures to biocides for other PTs.

6.2 Certification and inspection of application equipment

6.2.1 Introduction

For plant protection products it has for long time been recognised that improvement of the quality and efficacy of pesticide application equipment is necessary to enable pesticide users to optimise the effectiveness of the treatments whilst minimising any adverse impact on human health and the environment. A proposal on essential requirements for the protection of the environment to be satisfied by new pesticide application equipment to be placed on the market has been introduced by the Commission for implementation of parts of the Thematic Strategy on the Sustainable Use of Pesticides. Further, regular and compulsory inspection of application equipment, based on harmonised standards, has been introduced in a proposal for a directive establishing a framework for Community action to achieve a sustainable use of pesticides[33].

Some Member States have today either mandatory or voluntary systems for certification of equipment for application of biocides. Examples are equipment for spraying or dispersing of biocides or bait boxes for pest control. Certification of application equipment may be a relevant measure for applications where there is a high probability that inadequate application equipment result in overdosage, high human exposure or high releases to the environment.

[33] Brussels, 12.7.2006. COM(2006) 373 final. 2006/0132 (COD). Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a framework for Community action to achieve a sustainable use of pesticides.

The options for development of a harmonised system for certification of equipment for application of biocides will be addressed in the following section.

6.2.2 Design of measure

A harmonised system for certification of new application equipment may include:

- Development of essential requirements for new application equipment;
- Definition of the product-types and application equipment to be covered by a certification system;
- Development of specific requirements for certification of new application equipment
- Setting conditions for obtaining the certificate and define registration system for the certified equipment;
- Setting conditions for keeping a register of certified equipment and information exchange between Member States;
- Setting conditions for marketing of new application equipment.

The system may be combined with a system for inspection/test of the equipment already in use including:

- Setting conditions to be met by equipment in use;
- Definition of a system for obligatory testing/inspection of equipment.

Development of essential requirements for new application equipment

The Machinery Directive 98/37/EC sets out the essential health and safety requirements that machinery placed on the Community market has to meet. Environmental protection requirements are not currently covered by the Machinery Directive but included in a new proposal for amending the directive to more specifically addressing new pesticide application equipment to be placed on the market. (COM(2008) 535 final[34]). The Directive specifies different types of machinery that must meet all the essential health and safety requirements and the new proposal propose to include machinery for pesticide application in the list. It would be relevant to include machinery for biocide application as well. Further, the new proposal propose a new section setting essential requirements to new machinery for pesticide application (COM(2008) 535 final). It would be relevant similarly to develop essential requirements to biocide application equipment for amendment of the Machinery Directive.

The essential requirements would apply to equipment within the scope of the Machinery Directive. The Directive excludes equipment for which the only power source is directly applied manual effort. The requirements would e.g. apply to dosing apparatus and equipment for vacuum- and pressure preserva-

[34] Brussels, 5.9.2008. COM(2008) 535 final. 2008/0172 (COD). Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on machinery for pesticide application, amending Directive 2006/42/EC of 17 May 2006 on machinery (presented by the Commission)

tion of wood, but would not apply to e.g. handheld sprayers without power supply.

Definition of the product-types and application equipment

Product types for which this a certification system would be relevant will be discussed further in the next section.

A German assessment of Good Practice for the use of biocides (Gartiser et al. 2005) describes a number of equipment types for which procedures for the determination of the functional performance of equipment (partly as certification procedures) exist in Germany. Combined with information from other Member States the following equipment, for which some norms exist, have been identified:

- Disinfection agent-dosing apparatus (e.g. for disinfection in hospitals);
- Spraying equipment for disinfection (e.g. in veterinary hygiene);
- Dosing equipment for the treatment of drinking water (e.g. dosing of chloral dioxide or ozone);
- Spraying equipment for the application of pest control agents;
- Bait boxes for pest control;
- Equipment for gassing/fumigation of insects and other pests;
- Equipment for vacuum- and pressure preservation of wood.

Other equipment for which a system for certification of the equipment may be relevant (and may exist in some Member States) is:

- Dosing equipment for biocides in swimming pools;
- Dosing equipment for cooling systems;
- Spraying equipment for application of masonry preservatives;
- Equipment for aerial spraying (e.g. for mosquito control);
- Spraying equipment for application of wood preservatives and anti-fouling products.

Development of essential requirements and standards

Essential requirements to construction features and functional performance of the equipment have to be defined in a compliance standard to be developed by standardization bodies. As the equipment is very diverse, an inventory should first be necessary in order to develop specific appropriate requirements to each type of equipment. The requirements may cover functional performances like droplet sizes and dosing and specification of equipment parts like nozzles, manometers, valves, fittings, etc.

Dosing equipment may in some Member States be covered by national standards/norms, but at European level no standards exist for the technical performance of the equipment.

A mandate could be elaborated through CEN, the European Committee for Standardization, by working groups with the representation of concerned interests: Industry, authorities and civil society.

It should be noted that the standards may be developed on a voluntary basis and not necessarily linked to an obligatory certification system.

As part of the impact assessment of specific measures to be part of the Thematic Strategy on the Sustainable Use of Pesticides (Bipro 2004) different options for development of a mandatory certification system have been assessed. The conclusion of the assessment was that introducing a mandatory certification system for new pesticide application equipment at Community level, rather than at Member State level, is the only option that is able to attain the desired objectives of protection of the environment and human health. This is probably also true for biocide application equipment.

Define legal provisions

Beside the development of compliance standards, legal provisions may be developed defining:

- Legal provisions for marketing of new application equipment;
- Conditions for obtaining the certificate i.e. information requirements for companies marketing the equipment;
- System for registering of certified equipment;
- Requirements to the users for test of equipment;

A certification system for equipment may be linked to a system for certification of the users (as discussed in section 6.1), requiring that the certified users apply certain equipment and techniques.

Inspection of marketed equipment

The point inspection of marketed new equipment would usually be an integrated part of the enforcement of a marketing restriction.

Testing/inspection of equipment in use

For the test/inspection of the user's maintenance and use of the equipment, the objectives of the control should be established and the conditions to be met by the equipment specified (linked to standards for new equipment).

The systems would imply a system for regular (e.g. every third year) test of the equipment for compliance with the specified conditions.

A number of Member States have established a compulsory control of some types of spraying equipment for plant protection products (Bipro 2004), but no information on regular control of equipment for application of biocides in Member States has been obtained.

As the used equipment is very diverse, setting conditions for all equipment and inspection will be quite extensive. It may be considered that inspection of equipment covers fewer product-types than a certification system.

In response to the question regarding inspection of equipment in the questionnaire, several Member States mention that the it would be difficult and costly to develop an inspection system and in the expert workshop minutes it is noted that harmonised inspection requirements are probably not suitable for most of PTs due to the nature of the application equipment.

6.2.3 Relevant product-types

Certification (and eventually inspection) of application equipment may be relevant for applications where there is a high risk that inadequate application equipment result in over-dosage, high human exposure or high releases to the environment.

In the questionnaire response Germany mentions that especially in cases where the quantity that is to be applied is not easy to control and exposure is likely, it appears sensible to ensure the optimal concentration of active substance, the targeted and safe (low-risk) application as well as the control of the form (e.g. the optimal droplet size) by placing precise demands on the utilized equipment.

A certification of equipment may be relevant for equipment for injection of biocides or a continuous supply of biocides to a system: Drinking water disinfectants (PT 5), swimming pool disinfectants (PT 2, subgroup) or slimicides and other biocides used by oil extraction (PT 12, subtype).

It may further be relevant for equipment for spraying of the biocides with a high risk of aerosol formation and uncontrolled releases to the environment. Such equipment may be used for disinfection in public areas (PT2), in veterinary hygiene (PT 3), in preserving/disinfection of masonry (PT 10) and by use of insecticides (PT18). Further, spraying of biocides as part of paint may be used for wood preservatives for surface treatment (PT 8) and antifouling products (PT 21).

Equipment for fumigation and gassing may as well be covered by a certification system. Fumigation and gassing is mainly applied for control of rodenticides (PT 14), wood destructing insects (PT18) and other vertebrates (PT23).

Tanks for pressure and vacuum preservation (PT8) may be covered as well.

Table 6-2 Product-types for which certification/inspection of application may in particular be relevant

Product-type	Sub-type	Type of relevant equipment	Certification/ guidelines existing in some Member States[1]	Non-professional use
Main Group 1: Disinfectants and general biocidal products				
2: Private area and public health area biocidal products	Disinfectants for public areas	Sprayers	x	
	Disinfectants for swimming pools	Dosing apparatus	x	
3: Veterinary hygiene biocidal products		Sprayers	x	Private stables
5: Drinking water disinfectants		Dosing apparatus	x	Non-public swimming pools
Main Group 2: Preservatives				
8: Wood preservatives	Vacuum and pressure preservatives	Tanks	x	
	Preservatives for surface treatment	Sprayers		Private areas
10: Masonry preservatives		Sprayers		Private areas
11 Preservatives for liquid cooling and processing systems		Dosing apparatus		
12: Slimicides	Slimicides and other biocides used by oil extraction and fuel storage	Dosing apparatus		
Main Group 3: Pest control				
14: Rodenticides		Sprayers, fumigations/gassing	x	Private areas
18: Insecticides and products to control other arthropods		Sprayers, fumigations/gassing/aerial spraying	x	
Main Group 4: Other biocidal products				
21: Antifouling products	Antifouling paints for vessels < 25 m.	Sprayers		
	Antifouling paints for vessels >= 25 m.	Sprayers		Pleasure boats
	Antifouling paints for other uses	Sprayers		Nets?
23: Control of other vertebrates		Fumigations/gassing	x	Private areas

Note 1: Based on questionnaire and submitted information from Member States but the question has not been addressed specifically. Either standards or guidelines. Several MSs indicate that some certification systems exist but do not indicate PTs.

6.2.4 Potential health and environmental impact

The product types, for which these measures are relevant, are among the applications with high scoring in the overall assessment of potential human and environmental risk summarised in Table 4-10.

The certification and test/inspection of equipment may result is decreased releases of biocides by optimising the dosage and by optimising the targeting of the biocides. A reduction may mainly be expected for application in which the dispersion of the substance is variable and not easily controlled by the user and at the same time a relevant exposure is probable. For estimating the potential reduction in releases by implementation of the measures it is necessary to have an indication of the potential for improvement of the equipment. Further, for estimating the potential impact of inspection of equipment in use it will be necessary to have an indication of the potential for improvement in the maintenance of the equipment.

It has not been possible to identify any evaluations of the health and environmental impacts of the implementation of a certification or inspection system for biocide application equipment in Member States. Neither, no data are available indicating the level of reduction of the use of biocides by use of certified equipment.

Potential for improvement

For plant protection equipment BIPRO (2004) assume that new certified sprayers will reduce overuse and losses to the environment due to a higher efficiency and will consume approximately 5% less plant protection products compared to new but not certified sprayers. The reduction when comparing new certified equipment to old equipment would probably be significantly higher. For the comparison of controlled versus non-controlled sprayers (in use) the reduction is assumed to be in the range of 5 - 10%.

A recent Danish assessment of the impact of a control system for plant protection equipment concludes that the environmental and health effect probably will be very small and mostly an effect of phasing out old equipment (Dubgaard et al. 2007).

The reduction figures cited above are assumed for large tractor-operated sprayers, where the dosing to a large extent is controlled by the equipment. For handheld sprayers (most relevant for application of biocides) the dosing and dispersion of the biocides is to a large extent controlled by the person who use the equipment, and it is questionable whether the same reduction can be obtained for this kind of equipment. It is probably of more importance that the user has the necessary training and is applying the equipment correctly.

For dosing apparatus (e.g. for swimming pools and water works), the correct dosage is controlled by the apparatus that should be able to apply a constant dosage. An impact of a certification system would depend on the potential for optimisation of the actual equipment, which has not been assessed.

Based on the experience with plant protection products the potential reduction in exposure of humans and environment by implementation of a certification systems is most likely in the range of 0-20%, but a more detailed assessment of each type of equipment is necessary in order to estimate the potential with more certainty. The impact of a system for regular inspection of the equipment would probably be significantly lower.

The type of size of the benefits would depend on the PT's and specific products to be included in the scheme.

Human health benefits

In general terms humans are (as described in Chapter 4, Table 4-6), exposed to biocides primarily by inhalation and skin contact. The health benefits from reducing the exposure to hazardous biocides are ultimately related to the number and severity of illnesses or adverse effects among both professional and non-professional users, and also among others exposed during the service life of the products or through secondary exposure. The actual benefit is however difficult to quantify. The available classification data for some of the biocidal substances indicate that the key health effects of concern which could result from exposure to these biocides are acute intoxication or poisoning, sensitizing effects or effects related to exposure to substances causing chronic effects (CMR) from exposure to low doses.

Active substances which cause chronic effects from long term exposure to low doses and sensitizing substances are a major concern in both public health and in relation to occupational safety due to their irreversible nature. Benefits from reducing the exposure to biocides include the reduction of the potential contribution to cocktail effects from exposure to certain biocidal substances in combination with other substances and thereby the general load of chemical exposure in the society. This is relevant for professional users as well as non-professional users. Although there is limited information available about endocrine disrupting effects from biocides in general, this is an area where potential cocktail effects need more attention. Biocidal substances that end up in the indoor climate during the application and service life of the products are likely to have an impact on also the more vulnerable groups like children and immunocompromise persons. This is e.g. relevant for PT2, PT6 and PT18. For PT 14 and 18 the substances are mainly classified due to their acute toxity to humans and the benefits of the measure could be expressed in reduced instances of poisoning. Substances within PT2 and PT8 (and other PTs potentially addressed by the measure) are classified due to a wider range of effects including CMR effects and sensitization. These effects are characterized by being induced by chronic exposure to low levels of many different substances and health benefits of the reduced exposure to specific biocides are very difficult to quantify.

As shown in Table 6.2 equipment for application of biocides, primarily sprayers, equipment for fumigation/gassing and dosing apparatus, are used for a wide range of PTs.

Environmental benefits

To this moment, the environmental hazard identification is more or less restricted to potential acute or long term toxic effects in the aquatic environment (chapter 4 for more details). Other environmental hazard properties are of

course relevant for an environmental risk assessment e.g. PBT/vPvB or endocrine disruption, but the relevant information is not easily available for a wide range of substances.

One can roughly assume that on the average almost 3 out of 4 biocides will be highly toxic to aquatic life and that half of the substances in addition to high aquatic toxicity will be "not easily biodegradable". The proposed measure may reduce such effects on aquatic organisms (e.g. exposed by direct releases to surface waster) and probably also on microorganisms in the soil. The effects on the microorganisms may change the ecosystem structure in soil and the aquatic environments, but data indicating the extent of such changes due to the use of biocides (and the possible benefits of reducing the exposure) has not been available.

Biocides released to waste water treatment plants (WWTP) may effect the microorganisms of the WWTPs, especially the nitrification/denitrification processes for removal of nitrogen, making the WWTPs less efficient. Exposure of WWTPs is particularly important for disinfectants in PT1, PT2 and PT4 although also a number of the other PTs contribute to the load of biocides onto WWTPs by being partially discharged into the sewer system. It has, however, not been possible to quantify the possible benefits of better functioning WWTPs as result of reduced releases of biocides to the sewer system .

Further, the substances in PT14, PT15 and PT23 can be expected to be highly toxic also to non-target mammals, birds and other vertebrates in the terrestrial environment. The economic benefits of reducing the risks of lethal effects on mammals, birds and other vertebrates, is not easy to estimate.

6.2.5 Costs and economic impacts

Product specific costs

As described above, certification and inspection of application equipment will most appropriately be relevant for a selected number of product types or subtypes, i.e. within around half of the product types: PT 2, 3, 5, 8, 10, 12, 14, 18, 21, 23 (re. section 6.2.3).

For the different application equipment specific standards should be developed as well as requirements for and follow up on certification, registration and inspection, as described in section 6.2.2. Since standards and certification systems have been developed for some equipment in some Member States it would be cost-efficient to make these a starting point for establishing the measure.

The main costs of the measure could be expected to consist of:

- Costs of development of essential requirements to the equipment (standards)
- Costs of research and development of new equipment types
- Costs of issuing certificates and maintaining a certification system
- Cost of keeping a register of equipment
- Costs of inspection and other enforcement
- Costs of time for users

Different cost expectations

In the questionnaire to the Member States the question regarding inspection of certified application equipment is phrased as 'an inspection system for *certain* application equipment'. Still, some Member States expects the costs of such a system to be 'very high' (Malta), 'extensive' (UK) or 'big costs for enforcement authorities and users' (Lithuania). Yet, other Member States do not expect major problems: 'No problems foreseen' (The Netherlands) and 'We don't see any major problems' (Sweden). No specific cost estimates were provided in the responses to the questionnaires.

Cost indications

When assessing the costs of the measure one should distinguish between the costs of certification and the costs inspection. Since cost indications were not provided in the responses to the questionnaire, instead some indications of magnitude could be obtained from comparison with certification and inspection of application equipment for plant protection products.

A German PPP example

An example is a study of the German certification systems for sprayers used for plant protection[35]. A voluntary testing system for application equipment was established more than 50 years ago, but in 1992 the voluntary field sprayer inspection became mandatory. The organisation and monitoring of the inspection is a task of the state authorities. The costs for the sprayer inspection are indicated in the German study. After shift from a voluntary system to a mandatory system costs increased, because new testing equipment was required, and it then amounted to 125-175 $ per machine (100-140 Euro per machine, 2001 reporting).

Whereas these costs could not be used as an indication of the costs of mandatory inspection of biocide application equipment, they may nevertheless show the magnitude of the costs for one specific mandatory inspection, by which rough comparisons could be made with respect to the type and challenges faced by the biocide inspection as compared to the plant protection sprayer. This should be done on an individual basis for the application equipment in question.

A voluntary testing system for new types of application equipment was also described[36]. An equipment approval will be given for 5 years. Testing includes a comprehensive testing of technical parameters and includes testing under practical conditions over a whole growing season on a farm. An expert group is established, meeting twice a year, which agrees on standards and testing procedures.

A Danish example

Similarly, a Danish report[37] has looked into the costs of obligatory inspection of sprayers for agricultural purposes. In the study it is estimated, that mandatory inspection of sprayers with a five years interval will amount to a yearly cost of

[35] *German certification systems for new sprayers and those already in use* from"II Simpósio Internacional de Tecnologia de Aplicação de Agrotóxicos" reunirá de 17 a 20 de julho de 2001.

[36] German certification systems for new sprayers and those already in use from"II Simpósio Internacional de Tecnologia de Aplicação de Agrotóxicos" reunirá de 17 a 20 de julho de 2001.

[37] Dubgaard (2007).

3.9 million Euros for Denmark, using available Danish estimates from a random check carried out. However, the report refers to German and Belgian experiences, which indicate that the yearly costs could be reduced to around 1 million Euros. Included in the total costs should also be time consumption of the farmers, which was calculated to in the order of 0.5 - 0.6 million Euros.

This is thus an example of calculating total national costs. It shows for this case, that the costs of farmers' time used for inspection amounts to 10-15 % of other inspection costs, when using the Danish estimates, and around 50-60 % of other costs when building on the German and Belgian estimates.

Other costs, which was mentioned but not assessed in the study, were costs for registration system, administration of authorisation system and establishment of appraisal shops. It was further mentioned, that accelerated scrapping of old sprayers would reduce the costs of mandatory inspection.

6.2.6 Implementation aspects

German biocide application equipment

In the German questionnaire response[38] some consideration are made concerning the use of biocide application equipment for different uses of biocidal products, for example for dosing and application. Through the determination of the appropriate dose, the application of unnecessary amounts of biocides and the related risks for health and the environment can be avoided. In various areas equipment for the application of biocidal products is examined in Germany with regard to construction features and functional performance, and if found acceptable, is certified. Respective regulations were evaluated in order to determine whether comparable stipulations would be reasonable for equipment for biocide uses.

Procedures for the determination of the functional performance of equipment (partly as certification procedures) exist for:

- Disinfection agent-dosing apparatus
- Spraying equipment for disinfection in veterinary hygiene (PT 3)
- Applied substances and procedures for the treatment of drinking water
- Equipment for the application of pest control agents
- Plant protection equipment

For the area of the application of wood preservatives (PT8) the German Society for Wood Research publishes several work sheets for the safe use of impregnating systems (including requirements for the apparatus itself). However, there are no obligatory procedures for inspecting equipment for either preventative or combative wood treatment. There is also a lack of such tests for equipment for the application of antifouling agents (PA 21).

From the German response to questionnaire, Annex 1:

[38] From an attachment to the German questionnaire response: *Description of the appropriate use and good practice during the use and disposal of biocidal products.*

Most often, the aspect of the dosing of the active substance and the protection of human health against un-allowed exposure are considered in *plant protection*. Considerations as to how to use plant protection equipment are part of the education of specialised professional users - according to the Plant protection professionals-ordinance and the GP in plant protection. Plant protection equipment (with the exception of small equipment) may only be imported, sold or used, if through its use „no detrimental effects arise for the health of humans and animals and for the groundwater“. This must be declared to the responsible authority by the manufacturer.

To what extent binding regulations for equipment for *biocide* dosing and application lead to an improvement of safety during their use must be answered separately for each and every type of product and use. Under conditions of use, in which the concentration of the substance is variable and not easily controlled by the user and at the same time a relevant exposure is probable, the use of certified equipment appears to be a worthwhile objective.

As mentioned earlier in connection with the measure of training the German assessment also states, that "the application patterns can be so different even within one product type, that an operation-oriented description of the GP is more useful than a comprehensive one. Additional instruments for a proper usage of biocidal products and adherence to GP, especially *the licensing of equipment*, waste disposal, training and risk communication, were described, and it t turned out, that the development of GP for the use of biocidal products is possible with the participation of practitioners and experts".

6.2.7 Conclusions

The impacts of a certification and inspection system would comprise costs as well as benefits. On the one hand it will provide benefits in terms of reduction in health hazards and environmental damage caused by excess use of biocides, and on the other hand there will be costs of establishing and running the system as well as the potential costs of more expensive equipment.

The benefits of the scheme is expected to be reductions in health problems or deterioration and environmental damage caused by diffuse releases, spill, accidental contact with biocides, etc. The type of and size of the benefits would depend on the specific products to be included in the scheme.

The health benefits from reducing the exposure to hazardous biocides are ultimately related to the number and severity of illnesses or adverse effects among both professional and non-professional users, and also among others exposed during the service life of the products or through secondary exposure. The actual benefit is however difficult to quantify. The available classification data for some of the biocidal substances indicate that the key health effects of concern, which could result from exposure to these biocides, are acute intoxication or poisoning, sensitizing effects or effects related to exposure to substances causing chronic effects (CMR) from exposure to low doses.

The environmental benefits are expected to be reductions in acute as well as long-term hazards to aquatic organisms and the aquatic environment as well as reduced effects on microorganism in waste water treatment plants (WWTP), especially microorganisms responsible for the nitrification/denitrification processes for removal of nitrogen. On the average, almost 3 out of 4 biocides can be assumed to be highly toxic to aquatic life and half of the substances in addition are not easily biodegradable, and fewer emissions of these substances to the environment would therefore improve the environmental status, depending on the substances included in the scheme, the exact character of the scheme, etc.

Further, for the substances in PT14, PT15 and PT23, the benefit can be expected to be reduced poisoning of to non-target mammals, birds and other vertebrates in the terrestrial environment.

No quantitative cost estimates were provided from the Member States for this measure, and the qualitative assessments of costs diverged from 'very high' (Malta) and extensive' (The UK) to 'no problems' or 'no major problems' (The Netherlands and Sweden).

For comparison, a Danish study assessed the costs of obligatory inspection of sprayers for agricultural purposes in Denmark to 3.9 million Euros, with a lower estimate based on German and Belgian experiences of 1 million Euros, both including time costs. Further studies will be needed in order to estimate a similar figure at EU level.

In order to consolidate these first conclusions, the authors recommend the Commission to launch a study including an inventory of equipment used for application of biocides for all PTs, and an assessment of the costs and the potential for improvement of the performance by applying best available techniques. The equipment description in the German assessment of Good Practice for the use of biocides (Gartiser et al. 2005) may be used as a starting point for the inventory. In order to inform the assessment, a working group (or more working groups) including experts with specialised expertise in the fields may be set up.

6.3 Long term good practice and prevention

6.3.1 Introduction

Integrated pest management (IPM), as applied in the plant protection products context, is an integrated approach combining more measures among others prevention, pest monitoring, use of thresholds (blanket restrictions), lowest use of chemicals, and use of substitutes.

Many of the IMP principles may be applicable for biocidal products as well and some of the principles, e.g. lowest use of chemicals and use of substitutes, would be an integrated part of the GP reference documents and training schemes for certified users as described in section 6.1.

Different from the use of plant protection products, biocides are used in urban environments and the biocides are applied on man-made surfaces and structures. As a consequence the range of options for reducing the use of biocides by non-biocide prevention and control methods are much wider than for plant protection products, but many of the measures have a long term perspective as it concerns development of new materials and techniques.

A recent German study on IPM principles for use of biocidal products introduce the term "Urban IPM" which "… *is defined as a flexible network of changes allowing a common-sense approach to the shaping of the habitats of humans and those of other organisms."* (Scholl 1995). Although the study has a more philosophical approach than applied here, it emphasises that a long term perspective concerns the shaping of the living conditions of the humans and the organisms.

6.3.2 Design of measure

An integrated approach to the reduction of the use and releases of biocides may (apart from measures addressed elsewhere) include:

- Prevention of pests by improved hygiene. Examples are the improved hygiene in public areas reducing the need for disinfectants or improved hygiene in the households reducing the need for rodent control.

- Use non-biocidal control techniques. Examples are use of high pressure cleaners for cleaning of masonry or use of traps for pest control. Other examples are the use of ultraviolet light or filters in cleaning of water.

- Monitoring of pests in order to assist more efficient targeting of the pests.

- Prevention of microbial growth by development of materials with surfaces that inherently impede the growth of microorganisms. Examples are development of surfaces with nanostructures that prevent fouling on ship hulls and development of tiles with surfaces that prevent growth of algae.

- Reduce the use of biocide-containing products by constructive solutions. Examples are constructive solutions where pressure preserved wood can be replaced with non preserved wood or construction of storage facilities for food and feed in a way that reduce the need for pest control. Another example is the construction of large eaves preventing microbial growth on walls.

- Reduce the use of biocides in industrial processes by process changes and quality control. Example is process changes in paper and pulp production preventing the use of slimicides and Hazard Analysis and Critical Control Points (HACCP) in food processing.

Measures includes (apart from measures described elsewhere):

- Promotion of the development and use of non-biocidal technique;
- Promotion of the development and use of materials and surface coatings;
- Promotion of the development and use of constructive techniques;
- Development of pest monitoring systems;
- Development of information system for prevention and non-biocidal techniques;
- Promotion of the development and use of alternative process techniques.

6.3.3 Relevant product types

In the responses to the questionnaire question regarding IPM the Member States in general consider that IPM principles could be applied on at the least some product-types. Many MSs mention the applicability of an IPM approach for rodenticides (PT 14), insecticides (PT 18) and repellents and attractants (PT 19) and a fewer MSs mention wood preservatives (PT 8) and antifouling products (PT 21).

As noted in the minutes of the expert workshop it seems difficult to apply blanket restrictions (use of thresholds) for optimizing the dosage. In this regard, biocides are different from plant protection products.

Table 6-3 indicates the product-types for which promotion of non-biocidal prevention and control is considered relevant.

6.3.4 Potential health and environmental impact

The product-types for which these measures are relevant are all among the applications with high scoring in the overall assessment of potential human and environmental risk summarised in Table 4-10.

The promotion of long term good practice and prevention may result is decreased releases of biocides primarily by a decrease in the quantities of biocides used while still keeping an acceptable level of control.

Potential for improvements

The reduction potential varies by product-types. It has not been possible to indentify any evaluation of the health and environmental impacts of the implementation of the concerned prevention measures, but as the measures to some extent imply the development of new materials and techniques, experience would not exist.

For some product-types development of new materials and techniques may result in a very significant reduction of the use of biocides. This concerns antifouling products and wood preservatives.

Table 6-3 Product-types for which promotion of long term good practice and prevention may in particular be relevant

Product-type	Sub-type	Areas pointed at for IPM by Member States *1	Prevention by use of alternative materials or constructive solutions	Promote non-biocidal control (other than prevention)
Main Group 1: Disinfectants and general biocidal products				
1: Human hygiene biocidal products	Skin disinfectants			x
2: Private area and public health area biocidal products	Disinfectants for private areas		x	x
	Disinfectants for public areas		x	x
	Disinfectants for swimming pools			x
	Disinfectants for wastewater and hospital waste			x
3: Veterinary hygiene biocidal products			x	
5: Drinking water disinfectants				x
Main Group 2: Preservatives				
7: Film preservatives			x	
8: Wood preservatives			x	
9: Fibre leather, rubber, and polymerised materials preservatives			x	x
10: Masonry preservatives			x	x
12: Slimicides	Slimicides for wood and paper pulp			?
	Slimicides and other biocides used by oil extraction and fuel storage			?
Main Group 3: Pest control				
14: Rodenticides		x	x	x
15: Avicides			x	x
16: Molluscicides				x
17: Piscicides				x
18: Insecticides and products to control other arthropods		x	x	x
19: Repellents and attractants	Repellents and attractants for control of gnat and fleas	x	x	x
	Repellents and attractants for control of game, birds and other vertebrates	x	x	x
Main Group 4: Other biocidal products				

	Product-type	Sub-type	Areas pointed at for IPM by Member States *1	Prevention by use of alternative materials or constructive solutions	Promote non-biocidal control (other than prevention)
20:	Preservatives for food and feedstock			x	x
21:	Antifouling products		x	x	
22:	Embalming and taxidermist fluids	Embalming fluids for humans			
		Embalming and taxidermist fluids for animals.			
23:	Control of other vertebrates				x

*1 Based on questionnaire response

With the development of fouling-resistant surfaces and cleaning techniques, potentially the use of antifouling products for pleasure boats may be totally phased out, but the materials and techniques developed so far have not been satisfactory. As antifouling product for pleasure boats may result in significant exposure of non-professional users and the aquatic environment (see section 4.4) a reduction of the use of the products for this application would have a significant positive impact on both human health and the aquatic environment. The use of antifouling products for larger vessels may potentially also be reduced significantly by development of alternative materials and techniques, but the time perspective for the development may be longer. For larger fast-sailing vessels biocide-free silicone-based antifouling products are now marketed. Beside the antifouling effect the silicone-based products also result in lower energy consumption.

Reduction in the use of preserved wood would have a significant positive impact on non-professional users and the soil environment (see section 4.4). Preserved wood is mainly used in environments where the wood is exposed to soil and rain and the use may be reduced by constructive solutions where the degradation of the wood is prevented or the wood is (partly) replaced by other materials.

Long-term measures with regard to control of rodents concerns monitoring, better construction of sewer systems, improved waste handling, etc. No information has been identified evaluating the potential for reduction in the use of biocides by prevention, but the potential may be significant.

Apparently there may be a potential for reducing the quantities of biocides by long-term measures, but a more detailed assessment would be required for estimating the expected reduction in the use of biocides.

The human health and environmental benefits

The type of size of the benefits would depend on the PT's and specific products to be included in the scheme. The types of benefits as consequence of reduced exposure would in general be the same as described in sections 6.1.4 and reference is made to the description there.

6.3.5 Economic impacts

Member States' viewpoints

In the responses to the questionnaire a number of Member States have answered questions related to the possible transposition of Integrated Pest Management (IPM) principles to biocides.

As described above, all of the responding Member States indicate that they support this idea, at least for selected PT. Some of the Member States find that all the listed categories should be included in a possible IPM guideline for biocides: Prevention, general hygiene, pest monitoring, use of threshold, lowest use of chemicals and use of substitutes (e.g. mechanical), whereas others are more specific.

Some Member States expect IPM for biocides to be difficult to implement due to the large variations in products and the multiple users groups, instructors and authorities (Finland, France, Italy, Slovenia, UK), whereas others see no major problems (Sweden, The Netherlands). Some Member States highlights the lack of staff or resources as the major problem (Cyprus, Malta, Slovakia) and some Member States points out that legal tools or binding regulations would be necessary (Estonia, Italy).

Germany has investigated the issue of IPM and has attached a number of annexes in their questionnaire response. Germany finds that IPM guidelines would only be feasible for minimization of the use of biocides, since only few alternatives are presently available for biocides.

The advantages foreseen are not surprisingly reductions of risks and improvements of human health and the environment plus facilitation of a harmonized IPM approach in the EU.

There are no specific indications of costs in the Member States' responses, which is probably due to the lack of experiences in this field and the diffuse character of the issue, making it difficult for Member States to make qualified estimates.

Nevertheless, in order to qualify the discussion, the German research and investigations are of interest. A presentation will therefore be given of these experiences.

German investigations

The following annexes to the German response to the questionnaire are of main interest for the issue of IPM for biocides:

- Description of the appropriate use and good practice during the use and disposal of biocidal products (Annex I)

- Feasibility Study on the Support of the Information Requirement in Compliance with §22 ChemG on Alternative Measures for the Minimization of the Use of Biocides (Annex II)[39]

- Feasibility Study for a new Eco Label according to DIN EN ISO 14024 for selected Product Types, part 3: Biocide-free Antifouling Products (Annex III)

- Elaboration of guidelines for integrated pest control in the non-agricultural area (apart from wood preservatives. (Annex V).

The German Chemical Act

The German Chemical Act requires the competent authority for biocides to make information on "physical, chemical and other measures as alternatives for the use of biocidal products or for minimization of their use available to the general public".

This is thus an example of a Member State which has already implemented legislation on an important ingredient of IPM for biocides, namely information on alternatives to biocides and measures for use reduction.

According to the German response to the questionnaire, only a few alternatives exist in the area of biocides.

Information system for IPM biocides

In order to support the legal information requirement a feasibility study was carried out (Annex II). The aim of the study was to compile the very broadly dispersed knowledge and provide the basis for a future information system. A systematic compilation of biocide-free alternatives in the various branches/product categories as well as an overview of state-of-the-art for integrated measures for minimizing the use of biocides was completed. Besides biocide free physical, biological or chemical alternatives, the information focus should thus be placed on the description of preventive measures.

As regards the information system a solution with a web portal and print media was found most suitable. It was found that *despite* the very heterogeneous application areas of biocides and the different user groups, the available information could be gathered in a consolidated structure. For some applications an internet solution would though not be sufficient, but should be supplemented with other initiatives. Target groups and information content should be determined for each application area of biocides in close cooperation with the stakeholders.

Implementation of the results is currently under discussion in Germany.

Costs of information system

As part of the project the required capacity and the costs for the establishment of a German information system, including working up the data, as well as setting up, updating and operating the information system, was estimated. The

[39] Commissioned by Federal Environmental Agency, Berlin, Germany in co-operation with Stefan Gartiser et al. Germany. April 2004 – October 2005.

project is envisaged to include upstart and three consecutive phases and amounts to:

Man hour costs:
Upstart: 70.000 Euro
Phase 1: 156.000 Euro
Phase 2: 156.000 Euro
Phase 3: Not estimated

A further 1.100 Euro per month is foreseen for software licences and 2.000 Euro per *month* for travel costs, and other costs of 6.000 Euro per *year*.

In order to use these costs estimates for further elaboration, it is recommended to investigate the background documents and set-up in more detail. The purpose of this presentation of the results is merely to present some indicative illustration of costs related to developing an EU IPM guideline.

According to the German response to the questionnaire, the feasibility study could serve as a good basis for the elaboration of product/branch-related guidelines for IPM or for determining more precisely use according to good expert practice.

Eco-labelling for antifouling products

Also in Germany, a research project on development of new labels in the area related to antifouling products was conducted (Annex III)[40]. This feasibility study aimed to examine whether appropriate and valuable certification criteria could be proposed for use in the control of biocide-free antifouling systems. The study focused on both the review of suitable methods of testing fouling resistance as well as the exclusion of dangerous compounds, the objective being a market focussed more towards effective and environmentally friendly products. The market for antifouling systems consists of both private and commercial ship owners as well as governmental authorities and Navies.

Both the growing concerns about the adverse effects of current antifouling biocides on humans and wildlife, and the advent of the EU Biocidal Products Directive, have instigated multiple research and development activities directed towards more environmentally friendly and biocide-free antifouling products. Research and development activities for biocide-free antifouling systems were briefly reviewed with the inclusion of some biocide-free antifouling products available on the market at the present time.

The proposal to create an eco label for biocide-free antifouling products was not met with general approval by the paint industry in total. The European and the German Paint Maker Association expressed multiple objections, while in contrast, some smaller enterprises openly support the creation of such an eco label.

[40] Feasibility Study for a new Eco Label according to DIN EN ISO 14024 for selected Product Types, part 3: Biocide-free Antifouling Products. Germany.

Despite minor difficulties associated with the definition of efficacy limits on fouling resistance rates and the question of how many products will meet the criteria for the exclusion of dangerous compounds, the creation of an eco label for biocide-free antifouling systems is still in progress. The creation of an eco label may facilitate the entry of new technologies to the market.

It is commented, that to date, however, no company has registered its interest in such an eco-label, but that the topic may be taken up again at any time if interest is expressed.

IPM guidelines

This German study[41] defines urban IPM as a flexible network of changes allowing a common-sense approach to the shaping of the habitats of humans and those of other organisms and looks for intelligent combination activities and lifelong learning processes. It is the first time that such an integrated approach has been available in the German language.

The *first*, general part of the report is an inventory of existing methods and means, followed by a discussion of the status quo and recommendations for improvement. This part concludes with a step by step action plan. The *second* part contains a condensed presentation of urban IPM methods, followed by minimal-risk pesticide handling: modes of action; resistance and repellence; active ingredients, formulations, products and application techniques, personal protection and spill prevention; and a cross reference list for active ingredients, formulations, products, and applications. The *third* part gives the pest profiles and management strategies for selected problems: ants, damp, fleas, mice, mites, cloth moths, mosquitoes, rats, cockroaches, mold, ticks.

Consumers are the main target group. Some major sections are aimed at the pest controllers, while other parts address legislators, administrators, the Biological faculties of universities, pesticide manufacturers etc.

Research project on alternatives

Germany is further planning a 2008 research project entitled: *Thematic Strategy for Sustainable Use of Pesticides - possibilities and preconditions for transfer to biocides*. The rationale is, that an important building block in the development of IPM is the promotion of low-risk or non-biocidal alternatives. The assignment of eco-labels and the development of new environmentally friendly agents and processes is an important instrument here in creating an incentive for the marketing and use of environmentally friendly products.

6.3.6 Conclusions

The practical implications of this measure are not well defined at the moment, and no specific quantitative or qualitative costs estimates are provided by the Member States. They differ quite a lot in their expectations for a possible IPM system. Thus, some Member States expect IPM for biocides to be difficult to implement due to the large variations in products and the multiple users groups,

[41] Elaboration of Guidelines for Integrated Pest Control in the non-Agricultural Areas (except wood pests).

instructors and authorities (Finland, France, Italy, Slovenia, UK), whereas others see no major problems (Sweden, The Netherlands).

Germany has a legal obligation to inform the general public about ways to minimise the use of biocides, including alternatives to the use of biocides. In a German feasibility study it was concluded that despite the heterogeneous character of the different uses of biocides, a German information system on biocides could be established in a consolidated structure with costs in the order of 70,000 Euros for the upstart and 156,000 Euros for the first two phases. Further studies will be needed in order to estimate a similar figure at EU level.

The reduction potential will vary by product-types. It has not been possible to provide an assessment of the costs which is to a high extent due to the long termed (and to some extent innovation driven) nature of this concept. For some product-types development of new materials and techniques may result in a very significant reduction of the use of biocides. This concerns e.g. antifouling products and wood preservatives.

The type of size of the benefits would depend on the PT's and specific products to be included in the scheme. The types of benefits as consequence of reduced exposure would in general be the same as described in sections 6.1.4 and reference is made to the description there.

In the responses to the questionnaire question regarding IPM the Member States in general consider that IPM principles could be applied on at the least some product-types such as rodenticides (PT 14), insecticides (PT 18) and repellants and attractants (PT 19). Also, wood preservatives (PT 8) and antifouling products (PT 21) are mentioned by a few Member States as relevant product types.

Measures like prevention by use of alternative materials or constructive solutions and promotion of non-biocidal control (other than prevention) may, however, in the long term be relevant for many PTs.

Options for long term measures are different for all 23 PTs and at the moment the description of the options is too premature for a detailed assessment of cost and benefits of the measures. In order to inform the assessment of long term measures, the Commission may want to launch a more in-depth study of the actual options for reduction of the use of biocides for each PT. The study may include some more detailed investigations of the options for selected PTs as cases studies.

7 Assessment of legal Instruments

This chapter assesses the appropriate legal instruments to implement the measures identified in the previous chapter.

It is not the purpose to single-out the "right" legal instrument. Rather, the purpose is to present specific pros and cons, which together will provide input for the decision-makers to decide upon the most appropriate legal instruments - or a combination hereof - among the following five options:

Option 1: No action

Option 2: Extension of the scope of the Pesticide Thematic Strategy and Framework Directive to *pest control* biocides at *this* stage

Option 3: Extension of the scope of the Pesticide Thematic Strategy and Framework Directive to *all types* of biocides at a *later* stage

Option 4: Incorporation of the use phase in the scope of the Biocide Directive 98/8/EC

Option 5: Development of a specific legislative instrument on the use of biocides

7.1 Legislation/regulation at Community level

The Commission has prioritised the legislative process regarding sustainable use of plant protection products and this process is presently well on its way, whereas the corresponding legislative process regarding biocides is still pending. Nevertheless, in July 2006 the Commission adopted a new Thematic Strategy aiming at improving the way pesticides are used in the EU[42]. The strategy complements the existing EU legislation (providing the framework and specific requirements to marketing; Directive 91/414/EEC), since its focus is on the *use phase* of pesticides. The 2006 strategy, which was accompanied by a proposal for a Framework Directive[43], only deals with plant protection products, but it

[42] A Thematic Strategy on the Sustainable Use of pesticides, COM(2006)372 Final.

[43] Proposal for Directive of the European Parliament and of the Council Establishing a framework for Community action to achieve a sustainable use of pesticides COM(2006) 373 Final.

foresees a possible extension of its scope to partially or fully also include products presently being regulated under the Biocides Directive (98/8/EC).

The current key legal documents on the regulation of biocides are the Biocide Directive (98/8/EC), and the Plant Protection Product Directive (91/414/EEC). These are briefly introduced below.

The Biocide Directive (98/8/EC)

Directive 98/8/EC of the European Parliament and of the Council aims "at the authorisation and the placing on the market for use of biocidal products within the Member States; the mutual recognition of authorisations within the Community;" as well as "the establishment at Community level of a positive list of active substances which may be used in biocidal products". Hence it has a different focus than this study which focuses on the use phase. The directive is anyhow relevant for this study, and it provides a set of definitions of key notions and is as such an important foundation for further work on biocides regulation.

The directive provides a list of 23 product-types that are regulated by the Directive. These product-types are also referred to in national legislation.

The main objective of Directive 98/8/EC concerns the harmonisation of the marketing of biocides within the EU and thus, addresses primarily an early stage in the life-cycle of biocides. This objective follows from the Directive itself and from the legal mandate of the Directive, which is based upon the EC Treaty (TEC) Art. 95 (former TEC Art. 100A).

The objective and legal basis does not eliminate regulation related to "the use" of biocides - for instance, addressing use by means of the authorisation procedures, by differentiating between professional and non-professional users etc. However, addressing the use phase under Directive 98/8/EC creates two problems:

First, the overall purpose of the Directive concerns the fulfilment of the Internal Marked. Thus, the regulation of the use phase must not compromise this overall purpose. This means that use-related aspects, such as health and environmental concerns, risk becoming secondary where it might conflict with the interests in harmonising the marketing of biocides within the EU.

Second, the TEC art. 95 require full harmonisation of the Directive among the Member States. More stringent national provisions on environmental and health related aspects are only possible if the criteria in TEC Art. 95 (4-8) are fulfilled.

These aspects shall be seen in the context of the proposed Framework Directive on the sustainable use of pesticides. The objectives of the Framework Directive are broader as its follows a horizontal and cross-cutting approach as recommended in the Thematic Strategy (COM 2006 372, p.7). Further, the proposed Framework Directive states in the Context of the Proposal (COM(2006)373 p. 5):

"One of the shortcomings of the legal framework is that the actual use phase…..is not sufficient addressed. Because of their scope, the existing legal instruments will not be able, even when revised, to achieve all the objectives outlined in the 6EAP. Therefore, the measures in the Thematic Strategy - and in particular in this Draft Directive - attempts to fill this gap"

Accordingly, the Framework Directive is based upon TEC Art. 175 - addressing overall environmental and health objectives. By this scope, the Member States have the possibility of applying more stringent national protective measures according to TEC Art. 176.

The proposed Framework Directive concerns the use of plant protection products. However, the same discussion applies to biocides as addressed in the Thematic Strategy and in the proposal for the Framework Directive[44].

The Directive 98/8/EC is currently under revision. It is expected that a new proposal will be presented in 2009[45].

The Plant Protection Product Directive (91/414/EEC)

Council Directive 91/414/EEC states that active substances cannot be used in plant protection products unless they are included in a positive EU list. An EU programme of evaluation to create this list is underway. Most of the active substances under evaluation are pesticides but some - such as growth regulators, pheromones etc - are not. All plant protection uses are covered; not just those in agriculture. Pesticides used in other areas, for example as veterinary drugs or as biocides, are covered by other legislation. Once a substance is included in the positive list Member States may authorise the use of products containing them. The Directive concerns the authorization, placing on the market, use and control within the Community of plant protection products in commercial form and the placing on the market and control within the Community of active substances intended for a use specified in Article 2 (1).

The Directive 91/414 is currently being revised[46].

The Thematic Strategy (COM(2006)372 Final)

The Thematic Strategy addresses the sustainable use of pesticides (including both plant protection products and biocides). As referred above, the Thematic Strategy states that the scope of the existing legal instruments does not sufficiently address the use phase (p. 4). The Strategy aims at addressing this deficiency in order to create a coherent and consistent overall policy framework (p.4) and to develop a horizontal and cross-cutting approach well beyond the relatively limited scope of these specific legal instruments (p.7).

[44] The Directive 91/414 is based upon TEC Art. 37 (former TEC art. 43) fulfilling the harmonisation of the agricultural market.

[45] A "mini-revision" has already been made based on amendments proposed in October 2008; Proposal for a Directive amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods, COM(2008)618 Final.

[46] Proposal for a Regulation concerning the placing of plant protection products on the market, 12 July 2006 COM (2006) 388 Final.

Based upon the Strategy the Commission has launched a proposal for a framework Directive on the sustainable use of pesticides. The Directive concerns plant protection products only, as the experiences on biocide product still is too limited. The Strategy and the proposal suggest including biocide products at a late stage, if similar measures were considered necessary for biocides.

7.2 Option 1: No action

Pro

- The Member States (MS) continue to develop own regimes on the use of biocides - in line with the Subsidiarity Principle.
- Allows for more knowledge generation - and knowledge sharing at European level. This improves the level and quality of information available on biocides - useful for later EU legislation.
- The Biocide Directive 98/8/EC and the proposed Framework Directive on the sustainable use of pesticides will further stimulate the awareness and knowledge generation in the field of use of biocidal products. Hence, a "spill-over" effect could lead to improved European legislation on the sustained use of biocidal products.

Con

- Today, great variations in the regulation on the use of biocides in the EU.
- Need for improved regulation in some Member States for the safeguarding of the health and the environment.
- Legal initiatives already established in the related field of use of PPP. In order to ensure consistency and legal clarity, similar legal initiatives are needed for the use of biocidal products.

Discussion

The Thematic Strategy clearly addresses the need for improved regulation concerning the full life-cycles of pesticides, including biocidal products. However, as the experiences on the use of biocidal products are limited the Thematic Strategy also proposes to include such regulation at a later stage awaiting further knowledge on the use of biocidal products.

"No activity" does not necessarily mean "no regulation indefinitely". If applying option 1, we suggest adopting an action plan for the on-going assessment of the use of biocidal product and the need for specific legal instruments, where relevant.

"No activity" in order to gather more knowledge and in order to stimulate more awareness among users applies appropriately to our proposed measure: *"Long term good practice and prevention"*. Such experiences will provide useful input for future legal regulation on such good practise.

7.3 Option 2: Extension of the scope of the Pesticide Thematic Strategy and Framework Directive to Pest Control biocides at this stage[47]

Pro

- Could enhance and fast-track the implementation of regulating the most hazardous biocide products.
- The legal basis of the Pesticide Framework Directive is TEC Art. 175(1). This could also include the environmental and health related aspects arising from pest control biocides.
- Provides more time for information and knowledge gathering for later EU legislation on non-pest biocidal products (if, this option (2) is used together with a later adoption of options (3-5) below for non-pest biocides products).

Con

- Could unintended prolong the legislative process as more stakeholders (industry, consumer groups, etc.) shall be involved.
- Hence, could delay the adoption and implementation of the proposed Framework Directive, which in itself would be a disadvantage for the regulation of the use of PPP.
- Lack of legal clarity: The later regulation of non-pest biocide products by Options 3-5, results in two or more separate set of EU legislation on biocide products. This could jeopardise the transparency and the principles related to the efforts of more simplified EU legislation.

Discussion

This option would allow for a "fast-track" approach by including some of the most hazardous biocidal products already now - provided that the information on the use of such biocidal products is sufficiently available at this early stage.

However, in sustaining the efforts on simplifying EU legislation such an approach shall be carefully addressed in order to avoid fragmentised regulation on biocidal products when later, eventually a new framework directive on biocidal products would be adopted (following Option 5).

The same approach could be applied for any other aspect related to the use of biocidal products, where sufficient information is available.

[47] This option corresponds to an early remark by the European Parliament based upon the first reading of the Thematic Strategy and the Framework Directive ToR Annex, p. 2. This section can be read alone or as part of the following Option 3.

7.4 Option 3: Extension of the scope of the Pesticide Thematic Strategy and Framework Directive to all types of biocides at a later stage

Pro

- The legal basis of the Framework Directive is TEC Art. 175(1). This could also include the environmental and health related aspects arising from biocide products.
- The later stages allows for more time to gather information and knowledge on biocidal products for EU legislation.
- Legal clarity: It would appear as a simplified approach to combine PPP and biocides regulation in one framework directive.
- Rational and cost effective approach in combining efforts.
- Foreseen by the Thematic Strategy and the proposed Framework Directive.

Con

- By combining the regulations on - and thus, interests related to - both PPP and biocides, we risk prolonging the legislative process as more stakeholders (industry, consumer groups, etc.) shall be involved.
- Hence, this "combined" approach could delay the adoption and implementation of a combined Directive on PPP and biocides as continuing separate legislation on biocidal products and PPP might result in faster implementation (!)

Discussion

This approach is already foreseen in the Thematic Strategy and the proposed Framework Directive. The Strategy and the Directive clearly state the advantages of such an approach.

Until now the EU legislation on biocidal products and PPP has been separate. Thus, in order to maintain the legal clarity a combined Framework Directive should clearly address the individual needs and aspects related to biocide products and PPP, respectively.

Following from option 2, the combined Framework Directive can perhaps at an earlier stage include aspects of biocide products, where sufficient knowledge is available.

The Framework Directive could address the regulation of biocidal products at an early stage- and even before sufficient information is generated. It follows from the concept of a Framework Directive that the Directive itself sets the frame for achieving sound and overall management of the use of pesticides. Thus, the Framework Directive could in its text already now outline the mechanisms for stimulating the information flow on biocidal products preparing for later adoption of EU legislation under the outline of the Framework Directive itself. Such an approach would be useful for all the three measures as identified in the previous chapter.

7.5 Option 4: Incorporation of the use phase in the scope of the Biocide Directive 98/8/EC

Pro

- Simplified approach: Having only one combined Directive on the placing on the marked and the use of biocidal products.
- The Directive 98/8/EC already addresses the use of biocides in the context of placing the biocidal products on the market.
- Apply aspects of the use of biocide products where it is directly linked to the purpose of placing the biocidal products on the market.
- "Fast-track" approach as the Directive is under revision and specific aspects related to the use-phase could be regulated already now, where sufficient relevant information on the use is available.

Con

- The objective of Directive 98/8/EC concerns the marketing of biocide products fulfilling the harmonisation of the Internal Market (based upon TEC Art. 95).
- TEC Art. 95 does not sufficiently address the full life-cycle of biocides, including the use-phase of biocidal products, including health and environmental related aspects.
- The proposed Framework Directive applies TEC art. 175 as legal mandate ensuring environmental and health related objectives for the use-phase.
- Deviation from the Thematic Strategy, which recommends a horizontal and cross-cutting regulatory approach based upon a Framework Directive.
- If followed, the EU legislation on PPP and on biocidal products follows two different approaches, which would jeopardise the legal clarity of the EU legalisation.

Discussion

As presented above in section 7.2, the regulatory scope of the Directive 98/8/EC does not easily include the use of biocides. The objective of Directive 98/8/EC concerns primarily the marketing of biocidal products as part of harmonising the internal market. This follows directly from the legal bases, being TEC Art. 95.

As presented in the pros, use-related aspects could be included under the current scope where it is directly linked to the purpose of placing the biocide products on the market the regulation. However, such an inclusion must not compromise this overall purpose. This means that use-related aspects, such as health and environmental concerns, risk becoming secondary where it might conflict with the interests in harmonising the marketing of biocides within the EU.

To compare, the proposed Framework Directive applies TEC art. 175 as legal mandate ensuring environmental and health related objectives for the use-phase

Besides the legal basis of the Directives, another significant difference between the Directive 98/8/EC and the proposed Framework Directive concern the different regulatory approaches

The Directive 98/8/EC applies a traditional vertical regulatory approach by setting firm product and process norms for the Member States to follow. The legal basis of TEC 95 (former TEC Art. 100a) indicates the objective of the Directive pursuing the harmonisation of the Internal Market. This also indicates a narrow margin for the Member States in deviating from the set norms, as earlier described.

The proposed Pesticide Thematic Strategy and Framework Directive are based on a horizontal, cross-cutting and holistic approach aimed at integrating the Member States further into the regulatory process. The development of National Action Plans comprising national measures and actions illustrates the approach. Also, the legal basis of TEC Art. 175 and the related Art. 176 allow for wider possibilities for the Member States in applying national norms.

This horizontal regulatory approach is also applied in the Water Framework Directive 2000/60/EC.

7.6 Option 5: Development of a specific legislative instrument on the use of biocides

Pro

- Legal certainty: A framework directive on the use of biocide products will accompany the related Pesticide Thematic Strategy and Framework Directive.
- Applying a framework directive will utilise the latest regulatory approach.

Con

- Time and resource consuming
- Legal uncertainty in continuing the EU differentiated approach concerning PPP and biocides, which is not easily understood. Reform in combining the two approaches into one legislative regime would be welcomed.

Discussion

Such an approach would be similar to the regulatory approach applied by the PPP.

This option would also continue the applied two-string approach in regulating PPP and biocide products separately. It continues a regulatory trend, which have existed for almost two decades and thus, would be easily understood. However, as argued under Option 3 time is perhaps right for combining the legislation for all pesticides within one framework directive as part of the ongoing attempts of the EU Commission in simplifying EU legislation..

7.7 Conclusion

The measures that were proposed in the previous chapters:

1. Training and certification of users
2. Certification and inspection of application equipment
3. Long term good practise and prevention

can be promoted effectively regardless of the legal instruments outlined above. From a legal perspective, it is merely a matter of clear formulation of the legislative act although as indicated above, some legal options are more appropriate than others.

Hence, the choice of the most appropriate action to take is determined by legal aspects, policy choices and the most effective phasing-in of measures

For the legal aspects, we recommend focusing upon improved legal certainty and simplicity

As mentioned, the identified measures can all be effectively promoted by the legal instruments mentioned. Thus, the legal framework can already now set the frames and mechanisms for implementing such measures over time. The actual implementation requires further and continuing information generation on the actual use of biocide products. This is especially true for the third measure.

8 Literature and consulted sources

BIPRO (2004): *Assessing economic impacts of the specific measures to be part of the Thematic Strategy on the Sustainable Use of Pesticides*. BIPRO for the European Commission, Brussels.

CEPA (2008): *Roma protocol.* CEPA, the European Pest Management Industry Association. Rome, 3rd April 2008.

Dubgaard, A., K. S. Andersen and J.E. Ørum. (2007): *Konsekvensanalyse af regelmæssig og obligatorisk kontrol af sprøjteudstyr* [Assessment of regular and obligatory control of spraying equipment]. Institute of Food and Resource Economics, University of Copenhagen.

European Commission (1998): *Directive 98/8/EC of the European Parliament and of the council of 16 February 1998 concerning the placing of biocidal products on the market*. Official Journal of the European Communities 24.4.98.

European Commission (2006a): *A Thematic Strategy on the Sustainable Use of Pesticides.* Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions. COM(2006) 373 final.

European Commission (2006b): *A Thematic Strategy on the Sustainable Use of Pesticides*. *Technical Annex.* Commission staff working document accompanying the Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions. Commission of the European Communities. COM(2006) 372 final.

European Commission (2006c): *The Impact Assessment of the Thematic Strategy on the Sustainable Use of Pesticides*. Commission Staff Working Paper Accompanying the Proposal for a Directive of the European Parliament and of the Council establishing a framework for Community action to achieve a sustainable use of pesticides. COM(2006) 373.

Lassen, C., S. Skårup, S.H. Mikkelsen, J. Kjølholt, P.J. Nielsen and L. Samsøe-Petersen (2001): *Inventory of biocides used in Denmark.* Environmental Project No. 585. Danish EPA, Copenhagen.

Milieu (2006): *Study on impacts of possible measures to manage articles or materials treated with biocides – in particular when imported.* Milieu Environmental Law & Policy and DTC for the European Commission.

Scholl, E. (1995): *Erarbeitung von Richtlinien für die integrierte Schädlingsbekämpfung im nichtagrarischen Bereich (außer Holzschädlinge).* Forschungsbericht 126 06 011, Umweltbundesamt, Berlin.

TNsG. (2008): *Human Exposure to Biocidal Products. Technical Notes for Guidance.* Document endorsed at the 25th meeting of representatives of Members States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (19-21 June 2007). January 2008.

Further, Annex 1 contains a more elaborate list of literature consulted to elaborate that annex.

List of institutions/persons consulted

- The Danish EPA, Pesticides and Gene Technology Division (Jørgen Larsen) 21.8.2008
- The Danish National Working Environment Authority, the Product Register (Poul Erik Andersen) 21.8.2008
- The Swedish Chemicals Inspectorate (Helena Casabona, Mary Lakovidou), 21.8.2008 + 27.08.2008
- The Norwegian Pollution Control Authority (Christian Dons), 27.08.2008
- CEFIC (Michael Freemantle and Raf Bruyndoncx), telephone and mail communication in July 2008 + telephone conference on 22.08.2008.
- Consumer Product Safety and Quality ("European Chemicals Bureau"), Joint Research Centre, Ispra, Italy (Erik van de Plassche), 14-15.07.2008 + 27.08.200
- National focal points and other contact persons in Belgium, Netherlands, Sweden and Germany.