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**Thematic Strategy on Sustainable Use of Plant Protection Products  
– Prospects and Requirements for Transferring Proposals for Plant  
Protection Products to Biocides**

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16. Kurzfassung Die Thematische Strategie (TS) zur nachhaltigen Verwendung von Pestiziden berücksichtigt bisher nur Pflanzenschutzmittel. Für Biozide existiert keine harmonisierte Herangehensweise. Im Projekt wurden die Möglichkeiten und Erfordernisse zur Übertragbarkeit der Maßnahmen der Rahmenrichtlinie 2009/128/EG (RRL) zur nachhaltigen Verwendung von Pestiziden auf den Biozidbereich analysiert. Der Focus lag auf Holzschutzmitteln, Insektiziden und Antifoulingmitteln. Obwohl verschiedene Wirksubstanzen im Ablauf kommunaler Kläranlagen und im Oberflächenwasser nachgewiesen werden, fehlen verlässliche Daten zum Biozidverbrauch und den Verwendungsmustern, die als Grundlage für Monitoring-Programme herangezogen werden könnten. Die Berücksichtigung von Bioziden in der Verordnung (EG) Nr. 1185/2009 über Statistiken zu Pestiziden, die bisher nur Pflanzenschutzmittel umfasst, wird empfohlen. Diese Daten werden dringend für die Entwicklung geeigneter Indikatoren und die Festlegung von Zielen benötigt. Die nachhaltige Verwendung von Bioziden adressiert die drei Säulen soziale, umweltbezogene und wirtschaftliche Ziele. Eine systematische Analyse der Instrumente zur Verbesserung einer nachhaltigen Verwendung von Pestiziden, die in der TS und der RRL beschrieben sind, ergab, dass die Struktur auf den Biozidbereich übertragen werden kann. Dies betrifft z.B. die Aus- und Fortbildung, Anforderungen an den Verkauf, die Einführung von Sensibilisierungskampagnen, die Kontrolle der Anwendungsgeräte für Biozide, die Entwicklung von besten Techniken auf Basis der Prinzipien der integrierten Schädlingsbekämpfung und die Erhebung von Statistiken zum Biozidverbrauch. Einige biozidspezifische Besonderheiten müssen jedoch berücksichtigt werden: Anders als bei Pflanzenschutzmitteln werden einige Biozide bestimmungsgemäß in Wasserkörpern oder in Innenräumen eingesetzt. Für einige Produktarten sind die Emissionen während der Nutzungsphase (u.a. durch Auswaschung) weit bedeutender als während der Anwendungsphase. Die Entwicklung eines Aktionsrahmens zur nachhaltigen Verwendung von Bioziden auf Europäischer Ebene wird empfohlen. Zunächst sollte eine Problemanalyse durch Auswertung aller vorhandenen Daten vorgenommen und ein fundiertes Monitoringprogramm für Biozide erstellt werden. Dann sollten die Ziele und Instrumente einer nachhaltigen Verwendung von Bioziden definiert werden. Diese Maßnahmen könnten dann durch Auflage einer neuen TS für Biozide oder durch Änderung der bestehenden TS für Pestizide eingeführt werden. Bestimmte Maßnahmen könnten zunächst auf nationaler Ebene etabliert und in einem nationalen Aktionsplan integriert werden. Alle Maßnahmen zur nachhaltigen Verwendung von Bioziden sollten mit identifizierten nachteiligen Auswirkungen der Biozidanwendung begründet werden. Eine Priorisierung der zu berücksichtigenden Biozidanwendungen ist erforderlich. Später könnten die auf nationaler Ebene getroffenen Maßnahmen in eine generelle Strategie zur nachhaltigen Verwendung von Bioziden auf Europäischer Ebene münden.		
17. Schlagwörter Biozide, Biozid-Produkte-Richtlinie, nachhaltige Nutzung, Pestizide, Integriertes Schädlingsmanagement, Beste Techniken, Risikowahrnehmung		
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16. Abstract The Thematic Strategy on sustainable use of pesticides has so far been implemented only for plant protection products. For biocides there exists no harmonised approach. Within the project the possibilities and requirements for transferring measures of the Framework Directive 2009/128/EC on sustainable use of pesticides to the biocide area have been analysed, with specific focus on wood preservatives, insecticides, and antifouling agents. Several biocidal active substances are found in the outlets of sewage treatment plants and surface water, but reliable data on biocide consumption and use patterns, which could be used to adopt monitoring programmes, are generally missing. The inclusion of biocides into the scope of the Regulation (EC) No 1185/2009 concerning statistics on pesticides, which only covers plant protection products so far, is recommended. These data are urgently needed for the development of suitable indicators and the definition of the objectives. Sustainable use of biocides addresses the three pillars; social, environmental and economic. A systematic analysis of the instruments for improving sustainable use of pesticides described in Thematic Strategy and Directive 2009/128/EC indicated that the structure can be transferred to the biocide area. This concerns e.g. education and training, requirements for sales, the establishment of awareness programmes, control of the machinery for biocide application, the development of best practice standards based on integrated pest management principles, and the collection of statistics on biocide consumption. Some biocide specific characteristics need to be considered. Unlike plant protection products, the intended use of some biocides is to be directly applied in water bodies or indoors. For some product types, emissions during the service life of biocides (e.g. through leaching) are more relevant than during the application phase. The development of an action framework on sustainable use of biocides on European level is recommended. First, a problem analysis should be carried out by evaluating all available data and by establishing sound monitoring programmes for biocides. Then, the objectives and instruments of sustainable use of biocides should be defined. These measures could be implemented by establishing a new Thematic Strategy on biocides or by amending the existing one on pesticides. Certain measures that could be implemented first on a national level should be included in a national action plan. All measures on sustainable use should focus on identified impacts of biocide use. A prioritisation of biocide uses to be considered is required. Later on, existing national measures could be implemented in a general strategy on sustainable use at European level.		
17. Keywords biocides, Biocidal Products Directive, sustainable use, pesticides, integrated pest management, best practices, risk awareness		
18. Price	19.	20.

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## List of Abbreviations

BAT	Best Available Techniques
BBA	German Biological Research Centre for Agriculture and Forestry (now JKI)
BLAC	Federal/Federal State Working Committee Chemical Safety (Bund/Länder Arbeitsgemeinschaft Chemikaliensicherheit)
BPD	Biocidal Products Directive
BREF	Best Available Technique Reference Documents
CA	Competent Authority
CAR	Competent Authority Assessment Report
CEN	European Committee for Standardisation
CEPA	Confederation of European Pest Control Association
CEPE	European Committee for Paints and Inks
CIRCA	Communication & Information Resource Centre
CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment
DAR	Draft Assessment Report
EAP	Environment Action Programme
EC	European Communities or European Commission
EMA	European Medicines Agency (since December 2009 EMA)
ENTAM	European Network for Testing Agricultural Machines
EU	European Union
EP	European Parliament
EQS	Environmental Quality Standards
GP	Good Practice
GPPP	Good Plant Protection Practice
HACCP	Hazard Analysis and Critical Control Points
HAIR	Harmonised environmental Indicators for pesticide Risk
IPM	Integrated Pest Management
IPPC	Integrated Pollution Prevention and Control
IVA	Industrieverband Agrar e. V.
JKI	German Federal Research Centre for Cultivated Plants – Julius Kühn-Institut
MS	Member State
JRC	Joint Research

NAP	National Action Plan
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative and Toxic
PPE	Personal Protective Equipment
PPP	Plant Protection Products
PPPR	Plant Protection Products Regulation
PT	product type
REACH	Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Mitigation Measure
SPISE	Standardised procedure for the inspection of sprayers in Europe
VAT	Value Added Tax
VOC	Volatile Organic Compounds
vPvB	very persistent and very liable to bioaccumulate
WFD	Water Framework Directive
WHO	World Health Organisation



## **0 Introduction**

In June 2006, the “Thematic Strategy on Sustainable Use of Pesticides” was accepted by the European Commission. The implementation, through Framework Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides, aims at minimising hazards and risks to human health and the environment associated with the use of pesticides. In addition, the Directive promotes inter alia the use of an integrated pest management and alternative techniques such as non-chemical alternatives. Up to now the Pesticides Thematic Strategy and the corresponding directive focus on plant protection products. However, the possibility of extending the directive to biocides is retained.

While the Biocidal Product Directive and the national Chemicals law focus on the procedure for including active substances in the Annexes of the Directive and the national authorisation and mutual recognition of biocidal products, the use phase of biocidal products is not considered. Thus, for biocides there is a particular need of developing specific measures for their sustainable use.

The project aims at identifying possibilities and requirements to transfer the measures of the Thematic Strategy on Sustainable Use of Pesticides to the biocide area. Further it elaborates concrete proposals for three example product types (wood preservatives, insecticides and antifouling agents). The sustainable use of biocides covers measures for the protection of occupational and human health as well as measures for the protection of the environment. Although these can not always be seen as separate items, this project focuses on the environmental point of view. The results of the project will be brought into the upcoming development and harmonization processes on a strategy on sustainable use at EC level.

This report describes the final results of a systematic analysis of measures proposed within the Frame Directive 2009/128/EC on “Sustainable Use of Pesticides“ and its applicability for biocides. Annex I provides the results of a literature research on the occurrence of biocides in the environment. Annex II, III and IV document the case studies performed on the three product types PT 8 (wood preservatives), PT 18

(insecticides, acaricides and products to control other arthropods), and PT 21 (antifouling products).<sup>1</sup>

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<sup>1</sup> In this report PT 18 is referred to as insecticides but includes all other products for controlling arthropods

## **1 Objectives of sustainable use of biocides**

Biocides are intended to kill, to destroy or to deter living organisms. If such products are applied in the proximity of humans or if they are released into the environment, there is a high probability that they might cause damage to man and wildlife. Biocides share this capability with pesticides used as plant protection products. Concerning plant protection products, there is an overall consensus that their general benefits (protection of food production from pests) justify to a certain degree the overall risks arising from their use. Otherwise – without such a general benefit – risks from such pesticides would be unacceptable, at least to the environment. It seems to be legitimate that a similar discussion should be undertaken about the general attitude to biocides. Is there a general consensus about tolerable risks from biocides? Or should their risk be tolerated only in justified cases and certain situations?

### **1.1 Biocides in the environment**

Biocides are intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means (Article 2 (a) Directive 98/8/EC). Due to these inherent hazardous properties, biocides pose potential risks to human health and the environment. The discussion on the effects of biocides began with a focus on human health impacts. The scandal of health damages caused by wood preservatives in the 1970s and 1980s, as well as the discussion on pyrethroids used for textile finishing and for insect control in private households, were the reasons to regulate biocidal products. Consequently, active substances with a high risk, such as Pentachlorophenol or Lindane, were removed from the market. In the environmental area, the impacts of antifouling agents used for ship hull coating in particular have been discussed since the early 1980s. The extremely high ecotoxicity and endocrine effects of Tributyltin compounds, e.g. the so-called imposex effects on snails, resulted in a worldwide ban on these compounds.

Reliable data on biocide consumption and use patterns, which could serve as a first approximation for prioritising the most relevant active substances to be included in monitoring programmes or in a risk minimising strategy, are only available in a few European countries (e.g. the Nordic countries, and Switzerland). Rough estimates of the biocides market from several sources suggest that about 25% of the total

pesticides market can be attributed to biocides (Gartiser et al., 2007). Some consumption estimations, e.g. on disinfectants in hospitals, biocides in cooling water, disinfectants/bleaching agents/preservatives in household cleaning products, are available from several research projects funded by the German Environmental Agency (Kahle et al. 2009). There are only few data available on the overall emissions of biocides to the environment.

In Switzerland, out of 277 active biocidal substances, 22 have been pre-selected as candidate biocidal substances with relevance for surface water based on consumption and degradability data (Knechtenhofer et al., 2007).

With a few exceptions, such as Triclosan, organotin compounds or pesticides with multiple uses, biocides are seldom included in routine monitoring programmes. Notwithstanding, several studies from research projects clearly demonstrate that biocides are regularly found in environmental samples (see Annex I). Disinfectants and preservatives such as Triclosan and quaternary ammonium compounds, the fungicides Propiconazole and Tebuconazole, or the repellent Diethyltoluamide (DEET), have been detected in the effluent of sewage treatment plants (STPs). The fungicide Terbutryn and the herbicides Carbendazim and Diuron are found in surface water (e.g. Kahle et al. 2009).

The concentrations of the biocides Carbendazim, Diazinon, Diuron, IPBC, Irgarol 1051, Isoproturon, Mecoprop, and Terbutryn in the inlet and outlet of municipal STPs indicated that many biocides are not completely removed during wastewater treatment. Average elimination of the mentioned substances was usually found to be below 50%, except for Isoproturon (63%) and Terbutryn (72%) (Singer et al. 2010).

In urban environments, leaching from facade coatings has been identified as the main emission sources for these biocides. Similarly, the treatment of bitumen felts on flat roofs against rooting through plant roots seems to be a major emission source of the herbicide Mecoprop (Wittmer 2009). Some of the biocides found in surface water are also used for plant protection purposes, but obviously biocides contribute significantly to the overall emissions. Recently, emissions of Tolyfluanid have raised concern because the degradation product N, N-Dimethylsulfamide (DMS) is a precursor for the carcinogen N-Nitrosodimethylamine (NDMA), which is released during drinking water ozonisation (Schmidt et al., 2008). While the approval of Tolyfluanid for plant protection purposes has been withdrawn in Germany, the

substance is still used as biocidal preservative (PT 7, 8, 10) and as antifouling agent (PT 21). Annex I of this report contains the results of the literature search on biocides found in environmental media which has been carried out within this study.

## **1.2 Regulatory framework and objectives of sustainable use of pesticides**

Following the Sixth Environment Action Programme of the European Community 2002-2012 (6th EAP) in 2002, the development of seven Thematic Strategies for prioritised fields<sup>2</sup> is foreseen, among them pesticides. Thematic Strategies are instruments for achieving defined objectives in specific areas that follow a comprehensive strategic approach. They build on the existing regulatory framework and aim to integrate defined measures not only into the regulatory framework of this specific field but also into policies and legislation of other areas. The Thematic Strategies can be seen as key elements of the Commission's Better Regulation Strategy.

Directive 2009/128/EC on sustainable use of pesticides defines pesticides as plant protection products or biocidal products (Article 3 (10)). At present, this Directive applies to pesticides which are plant protection products. However, it is anticipated that the scope of this Directive will be extended to cover biocidal products (recital clause 2 of Directive 2009/128/EC).

The background for developing a thematic strategy on sustainable use of pesticides was that - although plant protection products (PPP) have been regulated for a long time - unwanted amounts of certain pesticides can still be found in environmental compartments (in particular soil and water). Also, residues exceeding regulatory limits still occur in agricultural products. For biocides, there exists an equivalent level of concern as for plant protection products, because both are intended to control harmful organisms: It was recognised that for PPP and for biocides there is a clear legislative gap concerning the use phase (figure 1).

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<sup>2</sup> These are: soil and the marine environment (in the priority area of biodiversity), air, pesticides and urban environment (in the priority area of environment, health and quality of life) and natural resources and waste recycling (in the priority area of natural resources and waste), <http://ec.europa.eu/environment/newprg/intro.htm>

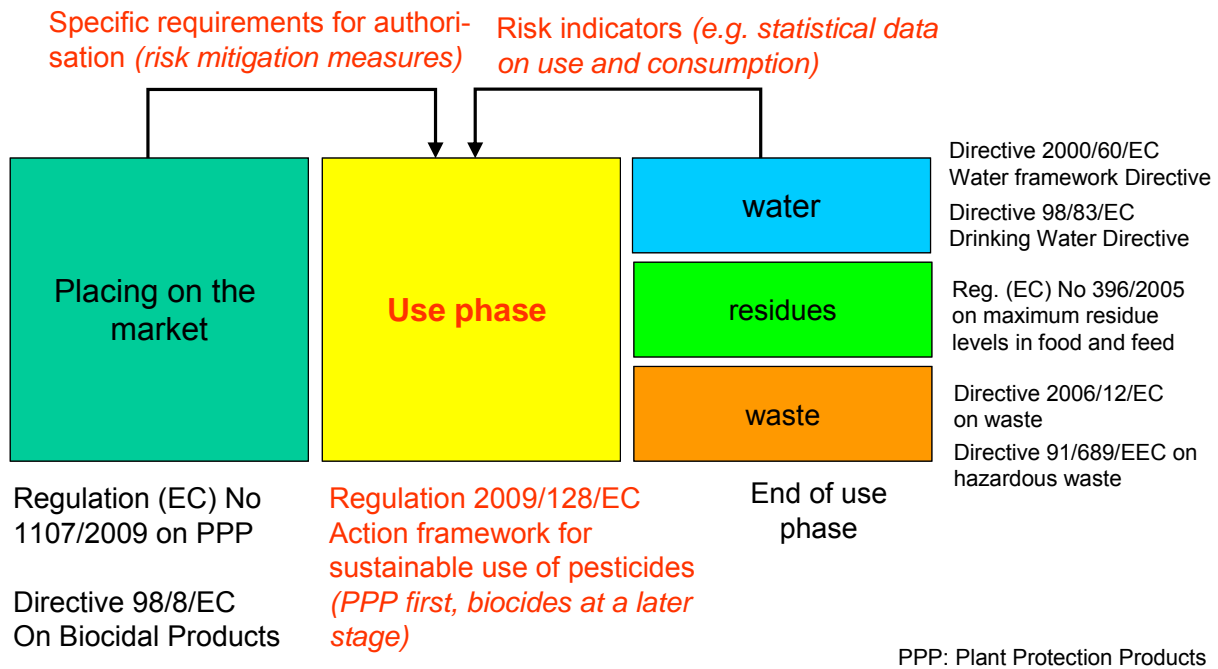


Figure 1: Position of the use phase within the life cycle of pesticides

Regulation (EC) No 1107/2009 and Directive 98/8/EC concerning the placing of plant protection products and biocidal products on the market only address the conditions for the manufacture and placing on the market of active substances used in PPP or in biocidal products (authorisation process). The end-of life stage of pesticides is considered e.g. in Regulation 396/2005/EC on maximum residue levels of pesticides in food/feed, the Water Framework Directive (WFD) 2000/60/EC, or the Drinking Water Directive 98/83/EC where maximum thresholds of pesticides (including their metabolites) are defined. Nevertheless residues exceeding the regulatory thresholds are still found in agricultural products and unwanted amounts are monitored in the environmental media, especially water and soil. These observations have led to the conclusion that rules reducing risks to human health and the environment from the use phase of pesticides are only insufficiently defined in the existing legislative framework. This gap should be closed by a Thematic Strategy on sustainable use of pesticides.

There are two mechanisms within existing legislation which have an influence on the use phase. First, conditions of use and risk mitigation measures (RMM) may be prescribed within product authorisation. Second, risk indicators which identify risks from the use of pesticides on human health and/or the environment may have an

influence on the use phase and on the approval requirements for products. Monitoring data on pesticides in environmental samples is one example of a risk indicator.

### **1.3 Definition of sustainable use of pesticides**

Definitions of sustainability often refer to the "three pillars" of social, environmental and economic sustainability. In theory these three pillars should be well balanced. Often, however, the main emphasis is on economic aspects, which is not considered as being sustainable. Thus social and environmental aspects need to be considered along with economic requirements. Neither for plant protection products nor for biocidal products is there a generally accepted definition of "sustainable use". In principle "sustainable use" goes beyond regulatory decision making for product authorisation and seeks additional opportunities for further risk reductions that can be achieved while ensuring effective action against harmful organisms. In the plant protection area, some regulatory experts refer to the definition of "integrated pest management" (IPM) which is considered as one appropriate tool in the context of "sustainable use of pesticides". Others consider that sustainable use goes further than IPM.

The three pillar model for sustainability seems appropriate for defining sustainable use of pesticides and biocides. The social dimension refers to human health, general hygiene conditions in workplaces and residential areas. The environmental dimension refers to the protection of water resources, soil, non-target organisms and biodiversity. The economic dimension refers to the protection of commodities, materials, livestock breeding, and industrial processes.

Article 3 (6) of Directive 2009/128/EC defines "integrated pest management" as *"careful consideration of all available plant protection methods and subsequent integration of appropriate measures that discourage the development of populations of harmful organisms and keep the use of plant protection products and other forms of intervention to levels that are economically and ecologically justified and reduce or minimise risks to human health and the environment. "Integrated pest management" emphasises the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms."* This definition refers to the need for *"careful consideration of all available methods"*, the *"integration of appropriate measures"* and incorporates the three pillars of sustainable development

*(“economically and ecologically justified;” “minimisation of risks human health and the environment”).* It is questionable whether the definition of IPM would be appropriate for describing sustainable use of those pesticides which are intended to control non-agricultural pests and other harmful organisms.

According to the OECD work on risk reduction of pesticides, the objective of “sustainable use” is risk reduction, especially aiming at a significant reduction of misuses, better compliance with existing regulations and use only at the “necessary minimum”. The necessary minimum can be described as pesticide use intensity where optimum efficacy is combined with the minimum quantity necessary. It depends on application parameters (pesticide selected, dosage, time, application equipment available), local conditions and using alternatively reliable non-chemical measures. IPM is mentioned as the key strategy for a sustainable use of pesticides, together with training and certification schemes for users, advisors and distributors (OECD 2009).

The FAO published a “Code Conduct on the Distribution and Use of Pesticides” which considers the life-cycle concept of pesticide management. It aims to address sound management of pesticides, focuses on risk reduction, protection of human and environmental health, and support for sustainable agricultural development by using pesticides in an effective manner and applying IPM strategies. However, a definition of sustainable use is not included (FAO 2002).

In the biocides area Article 3 (7) of Directive 98/8/EC on biocidal products requires that *„Member States shall prescribe that biocidal products are to be properly used. Proper use shall include compliance with conditions established pursuant to Article 5 and specified under the labelling provisions of this Directive. Proper use shall also involve the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary. Where biocidal products are used at work, use shall also be in accordance with the requirements of Directives for the protection of workers.”*

To summarise, there exists no harmonised definition of “sustainable use of pesticides” but it is clear that “sustainable use” is broader than “proper use” or “good and best practices”, and that “IPM” is an integral part of proper use. Sustainable use also includes social and economic (as well as environmental) objectives. Thus the benefits of the use of biocides on human health, material protection and monument



conservation have to be taken into account. In the context of such considerations, the need to apply biocides should be questioned. According to environmental authorities, the application of plant protection products in private areas can rarely be justified from an environmental point of view. The same is true if biocides are applied for reasons related to lifestyle. Consideration of pest control is only necessary in those cases where there is a real need to control so called harmful organisms; in all other cases biocides should not be applied.

Although no definition of sustainable use of biocides exists so far, this definition could implement the definition of proper use of Article 3 (7) of Directive 98/8/EC and the existing definition of IPM from Directive 2009/128/EC. One appropriate definition (to be discussed among stakeholders) proposed is: *“Sustainable use of biocides means a responsible use of biocidal products in a way that the objectives of hygiene, preservation and pest control can be achieved with the least possible adverse impacts to the environment and society (including human health) on a short-term and long-term timescale and promoting/encouraging the use of integrated control of harmful organisms, of preventive and alternative approaches or techniques such as non-chemical alternatives to biocides.”*

This working definition addresses the three pillars of social, environmental and economic sustainability. Directive 2009/128/EC describes several instruments for achieving the objectives of sustainable use such as training, sales of pesticides, information and awareness raising, requirements for pesticide application equipment and specific practices and uses such as IPM. The relationship of IPM (or Integrated control of harmful organisms), proper use and sustainable use of biocides might be illustrated as follows:

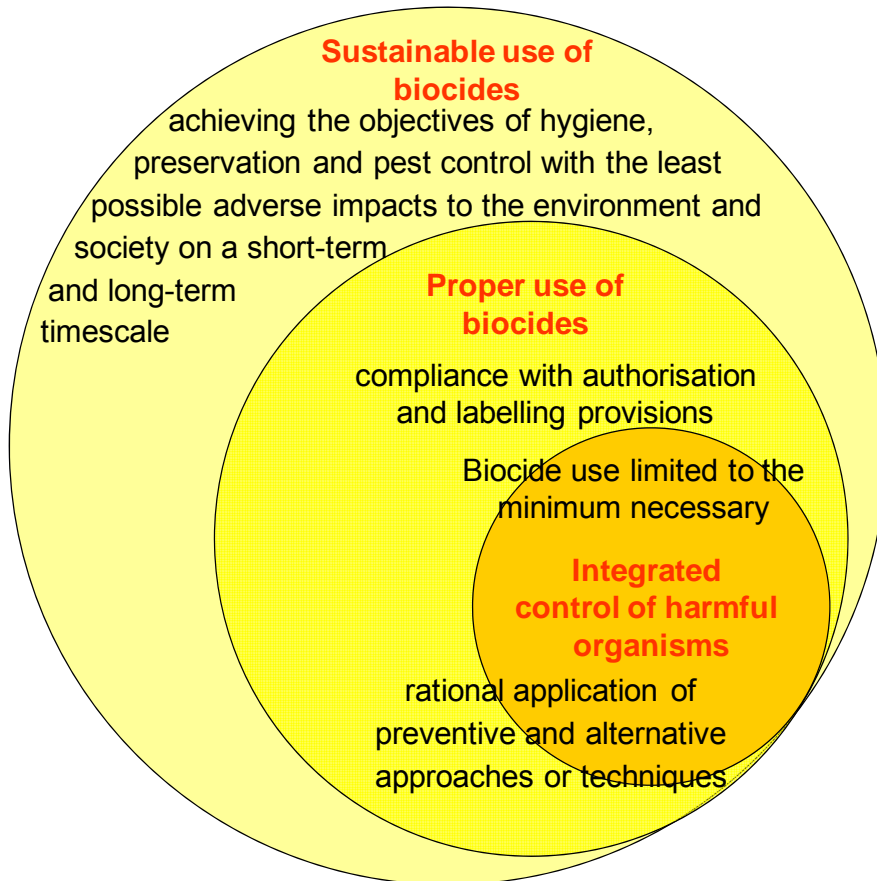


Figure 2: Relationship of IPM, proper use, and sustainable use of biocides

There is an overlap between integrated control of harmful organisms and “proper use” because the “minimum necessary” and the “consideration of non-biocidal measures” are included in both definitions. Sustainable use also includes further instruments within a general strategy for approaching the objectives of minimisation of risks, such as information to the public, training, awareness raising etc.

Nevertheless, before starting to analyse the three pillars of sustainability, there is a prerequisite which has to be addressed: the question whether individual application of biocides is sensible, needed and justified.

## 2 Legislative Background

### 2.1 Directive 2009/128/EC on Sustainable Use of Pesticides

In 2002, the European Parliament and the Council initiated a thematic strategy on the sustainable use of pesticides. In the Community, “Thematic Strategies” follow a holistic concept in addressing a specific topic by integration of the measures of the strategy in existing policies and new legislation. The thematic strategy complements the existing legislative framework by targeting the use phase of plant protection products. In 2006, the Commission presented a final draft of a “Thematic Strategy on the Sustainable Use of Pesticides” which was approved by the European Parliament on 13 January 2009.<sup>3</sup> In October 2009, Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides was adopted. The main issues of the Thematic Strategy and of Directive 2009/128/EC include:

- Establishment of National Action Plans (NAPs); within such National Action Plans Member States shall set their quantitative objectives, targets, measures and timetables to reduce risk and impacts of pesticide use on human health and the environment and to encourage the development and introduction of integrated pest management and of alternative approaches or techniques in order to reduce dependency on the use of pesticides (Directive 2009/128/EC, recital 5)
- Improvement of awareness and training of professional users and distributors including a certification systems to record such training (Directive 2009/128/EC, recital 8)
- Awareness raising of the general public (with particular attention to non-professional users), through campaigns and information passed on through retailers (Directive 2009/128/EC, recital 10)

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<sup>3</sup> COM(2006) 372 final Communication from the Commission concerning “A Thematic Strategy on the Sustainable Use of Pesticides” [http://eur-lex.europa.eu/LexUriServ/site/en/com/2006/com2006\\_0372en01.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/com/2006/com2006_0372en01.pdf) SEC (2006) 895 « TECHNICAL » ANNEX <http://register.consilium.europa.eu/pdf/en/06/st11/st11902-ad01.en06.pdf>

- Inspection of application equipment (Directive 2009/128/EC, recital 13)
- Prohibition of aerial spraying (should only be used by way of derogation where it offers clear advantages and also environmental benefits compared to other spraying methods) (Directive 2009/128/EC, recital 14).
- Enhanced protection of the aquatic environment and risk reduction e.g. by defining areas of strongly reduced or zero pesticide use (Directive 2009/128/EC, recital 15).
- Promotion of low pesticide-input farming, and Integrated Pest Management (IPM), and development of Integrated Pest Management standards. Member States shall describe in their National Action Plans how they ensure that the general IPM principles are implemented by all professional users by 1 January 2014 (Directive 2009/128/EC, recital 18, 19 and Article 13 (4)).
- Specific measures addressing appropriate handling of pesticides, including storage, diluting and mixing the pesticides and cleaning of pesticide application equipment after use, and recovery and disposal of tank mixtures, empty packaging and remnants of pesticides (Directive 2009/128/EC, recital 17)
- Exchange of information on the objectives and actions to the Commission and other Member States. The Commission should submit relevant reports accompanied, if necessary, by appropriate legislative proposals (Directive 2009/128/EC, recital 6).
- The National Action Plans shall include indicators to monitor the use of plant protection products containing active substances of particular concern, especially if alternatives are available (Directive 2009/128/EC, Article 4). In the Thematic Strategy the Improvement of monitoring of residues and environment as well as the establishment of exposure studies has also been suggested.
- In the Thematic Strategy the current situation with varying Value Added Tax (VAT) rates on Plant Protection Products, which puts farmers in various Member States in an unequal situation, has also been criticised. The application of normal VAT rate to pesticides, in order to reduce the incentive

for illegal cross border exchange of non-authorized products due to price differentials, has been suggested.

According to the Thematic Strategy, the progress in risk reduction should be measured through appropriate harmonised indicators, some of which have been developed under the HAIR project completed in 2007<sup>4</sup>.

In 2006, an impact assessment was carried out by the Commission services concerning the Thematic Strategy on the Sustainable Use of Pesticides<sup>5</sup>,<sup>6</sup>. The impact assessment led to the rejection of the two additional measures proposed as part of the Thematic Strategy “legally binding quantitative use reduction targets” and “setting up of taxes / levies at Community level”.

On 24 October 2007, the European Parliament (EP) published a resolution on the draft version of the Thematic Strategy on Sustainable Use of Pesticides.<sup>7</sup> This criticized the fact that the Thematic Strategy only covers plant protection products, which constitute only a part of pesticides. The EP called on the Commission forthwith to include pest control products (biocidal product types 14-19) as defined in Annex V to Directive 98/8/EC of the European Parliament and of the Council of 16th February 1998 concerning the placing of biocidal products on the market within the scope of the Thematic Strategy, as they pose similar risks to human health and the environment. Furthermore, the EP urged the Commission to extend the scope of the Thematic Strategy to include other biocides as soon as possible.

In the Framework Directive 2009/128/EC on Sustainable Use of Pesticides, it is anticipated that the scope of the Directive will be extended to cover biocidal products, without giving further details.

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<sup>4</sup> Harmonised environmental Indicators for pesticide Risk (HAIR)  
<http://www.rivm.nl/rvs/risbeoor/Modellen/HAIR.jsp>

<sup>5</sup> SEC(2006) 894, The Impact Assessment of 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 final  
[http://ec.europa.eu/governance/impact/docs/ia\\_2006/sec\\_2006\\_0894\\_en.pdf](http://ec.europa.eu/governance/impact/docs/ia_2006/sec_2006_0894_en.pdf)

<sup>6</sup> In parallel, a study has been elaborated by an external consultant (BiPRO) assessing economic impacts of the specific measures to be part of the Thematic Strategy on the Sustainable Use of Pesticides. BiPRO Beratungsgesellschaft für integrierte Problemlösungen. Assessing economic impacts of the specific measures to be part of the Thematic Strategy on the Sustainable Use of Pesticides REFERENCE: ENV.C.4/ETU/2003/0094R FINAL REPORT October 2004  
[http://ec.europa.eu/environment/ppps/pdf/bipro\\_ppp\\_final\\_report.pdf](http://ec.europa.eu/environment/ppps/pdf/bipro_ppp_final_report.pdf)

<sup>7</sup> P6\_TA-PROV(2007)0467 Thematic strategy on the sustainable use of pesticides, European Parliament resolution of 24 October 2007 on a Thematic Strategy on the Sustainable Use of Pesticides (2007/2006(INI))  
→ [http://chemicalwatch.com/downloads/pesticides\\_resolution.pdf](http://chemicalwatch.com/downloads/pesticides_resolution.pdf)

## 2.2 Regulation (EC) No 1107/2009 concerning plant protection products

In June 2011, Regulation (EC) No 1107/2009 which governs the placing on the market of plant protection products replaced the Directive 91/414/EEC. Inter alia the Regulation aimed to impose appropriate conditions supporting the objectives in accordance with Directive 2009/128/EC on sustainable use of pesticides (Recital 29 of Regulation (EC) No 1107/2009). In order to ensure a high level of protection of human and animal health and the environment, plant protection products should be used properly, in accordance with their authorisation, having regard to the principles of IPM and giving priority to non-chemical and natural alternatives wherever possible (recital 45). Article 31 describes the contents of authorisations which, in addition to a general description of the maximum dose, the period between applications and harvest the maximum number of applications, the restrictions with respect to the use area, user category and the distribution may also contain indications for proper use according to the principles of IPM. Article 55 prescribes that plant protection products shall be used properly. Proper use shall include the application of the principles of good plant protection practice and compliance with the authorisation conditions and labelling. Proper use shall also comply with the provisions of Directive 2009/128/EC and, in particular, with general principles of IPM.

Article 36 of the Regulation states *that “a Member State may refuse authorisation of the plant protection product in its territory if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question still poses an unacceptable risk to human or animal health or the environment.”*

Within the transition period, the active substances approved for use in plant protection products are listed in Annex I the Directive 91/414/EEC. The lists contain specific provisions concerning the authorisation, including appropriate RMM, similar to the provisions introduced in Annex I of the BPD. However, with a few exceptions, no specific provisions have been included. Most often the provisions refer only to “appropriate RMM”.<sup>8</sup>

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<sup>8</sup> Only few examples on RMM are given: Depuration of Thiabendazole after treatment with diatom earth or activated carbon; Spotwise application of Propiconazole; buffer zones to be considered while applying Chlorpyrifos, Chlorpyrifos-methyl, MCPA or MCPB; minimum holding periods for water in rice cultivation prior to discharge after the application of Azimsulfuron. For Methamidophos, Procymidone, Dinocap or Fenarimol judicious timing of the application and the selection of those formulations which minimise exposure of birds, mammals and appropriate distances to surface water bodies to protect water organisms are considered.

### **2.3 Directive on machinery for pesticide application**

Directive 2009/127/EC of 21 October 2009 on machinery for pesticide application has been accepted as an amendment to the Machinery Directive 2006/42/EC. To date, application equipment for biocidal products is not covered. However, since it is anticipated that the scope of Framework Directive 2009/128/EC will be extended to cover biocidal products, the extension of the scope of the environmental protection requirements to machinery for the application of biocidal products should be examined by the European Commission by 31 December 2012. It is evident that optimising the equipment for biocide application is one important tool for risk mitigation. Examples are the design of the equipment to enable safe filling and emptying and easy and thorough cleaning, but also to prevent leakage of biocides from the equipment. In addition, the efficiency of application influences exposure to the environment (vacuum pressure impregnation of wood preservatives may reduce leaching during the use phase, ultra low droplet size of insecticides may reduce overall amount of biocides applied).

### **2.4 Regulation (EC) No 1185/2009 concerning statistics on pesticides**

The Regulation (EC) No 1185/2009 concerning statistics on pesticides does not so far consider biocides but indicates that the scope may be expanded at a later stage so as to include biocides. The argument was that the *“effects of the Directive 98/8/EC will not become apparent until the first evaluation of active substances for use in biocidal products is finalised”* and that *“neither the Commission nor most Member States currently have sufficient knowledge or experience to propose further measures regarding biocides.”* However, it is *“anticipated that, taking into account the results of the evaluation of Directive 98/8/EC and on the basis of an impact assessment, the scope of this Regulation will be extended to cover biocidal products.”*

The previous draft versions of the Regulation on statistics in Article 3 imposed reporting obligations on suppliers of the products placed on the market and on professional users on records to be kept on the use of plant protection products.<sup>9</sup> These obligations have now been removed from the final version of Regulation (EC)

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<sup>9</sup> [http://www.insee.fr/ue2008/en/documents/COM-\(2006\)-778.pdf](http://www.insee.fr/ue2008/en/documents/COM-(2006)-778.pdf)

No 1185/2009 to Article 67 of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market.

Although, according to the Commission, tonnage data are considered as being confidential and the generation of such data as being costly<sup>10</sup>, any data that improve knowledge about production, use patterns, typical applications and consumption would be very useful for the risk assessment of biocides. Similar to the crop-specific data collection of plant protection products, PT specific data are required in the biocide area.

## **2.5 Biocidal Product Directive (98/8/EC)**

The Biocidal Product Directive (BPD) requires that biocidal products may only be authorised when they have no unacceptable effects on human or animal health and on the environment (Article 5). The BPD does not consider the use phase of biocides in detail. However, Article 5 (3-4) allows Competent Authorities to link the authorisation of a biocidal product to conditions relating to marketing and use that are necessary to protect the health of distributors, users, workers and consumers or animal health or the environment. Article 3 (7) requires Member States to prescribe that biocidal products are properly used. Proper use shall include compliance with conditions established pursuant to Article 5 and specified under the labelling provisions of this Directive. Proper use shall also involve the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary. Labelling requirements for biocidal products according to Article 20 of the BPD include the provision of information on identity, uses, mode of application, dosage, and precautionary measures (e.g. personal protective clothing and equipment) among other issues. While labelling requirements cover product related measures implemented after purchase, an important part of sustainable use is related to IPM strategies, which include preventive measures.

The proposal of the Commission for a biocides regulation replacing Directive 98/8/EC is currently being discussed among Member States (European Commission 2009).<sup>11</sup>

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<sup>10</sup> CA-Nov07-Doc.6.3: Note on the provision of information concerning tonnage of active substances/biocidal products placed on the market

<sup>11</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0267:FIN:EN:PDF>



In a report of the European Parliament on this proposal, several amendments have been suggested which refer to sustainable use: In Article 15 (5) a new subparagraph requires that *“Infestation with harmful organisms should be avoided by means of suitable deterrents to banish or repel such organisms. In addition, other precautionary steps should be taken, e.g. proper warehousing of goods, compliance with hygiene standards and immediate disposal of waste. Only if such measures have no effect should further steps be taken. Biocidal products that pose lower risks for humans, animals and the environment should always be used in preference to other products where those lower risk products provide an effective remedy in particular situations. Biocidal products that are intended to harm, kill or destroy animals that are capable of experiencing pain and distress should be used as a last resort.”*

Additionally it is suggested that within two years after adoption of the Regulation *“mandatory measures shall be established and implemented with a framework directive for Union action in order to achieve the sustainable professional use of biocidal products including the introduction of National Action Plans, integrated pest management, risk reduction measures and the promotion of alternatives.”<sup>12</sup>*

## **2.6 IPPC Directive**

Under Directive 2008/1/EC concerning integrated pollution prevention and control (IPPC-Directive) several best available techniques (BAT) Reference Documents (BREFs) have been developed for different sectors. In this context, BAT means the most effective and advanced stage in the development of activities and their methods of operation which are economically and technically suitable to prevent or reduce emissions to the environment. Although these BREFs have no legally binding status, they are often referred to by the relevant authorities when defining BAT and limit values for discharges and emissions. The following BREFs also cover the use of biocides in the respective sectors, directly or indirectly:

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<sup>12</sup> <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A7-2010-0239+0+DOC+PDF+V0//EN>

BREF	Date	PT
Intensive Rearing of Poultry and Pigs	07.2003	3, 18
Slaughterhouses and Animals By-products Industries	05.2005	4
Food, Drink and Milk Industries	08.2006	4
Surface Treatment using Organic Solvents	08.2007	8, 21
Textiles Industry	07.2003	9
Tanning of Hides and Skins	02.2003	9
Industrial Cooling Systems	12.2001	11
Pulp and Paper Industry	12.2001	12
Emissions from Storage (refers to storage of hazardous chemicals, including pesticides)	07.2006	-

In December 2007, the Commission adopted a proposal for amending the IPPC together with seven other Directives, among them the Solvents Emissions Directive, into a single comprehensive Directive on industrial emissions. The Solvents Emission Directive 1999/13/EC covers processes with the use of volatile organic compounds (VOC), such as coating of ships with antifouling agents or wood impregnation. Installations for the preservation of wood with a production capacity above 75 m<sup>3</sup> per day would in future be covered by IPPC (independent of whether or not organic solvents are used). However, considering biocides in BREF documents would require a shift in BREF development because (with a few exceptions), these do not relate to specific substances but focus on emission control as a whole.

## 2.7 EU Water Framework Directive (2000/60/EC)

According to the EU Water Framework Directive 2000/60/EC (WFD), proposals for emission control measures and environmental quality standards shall be elaborated for priority substances. Point source discharges into surface waters should be controlled by setting emission limit values and emission control standards based on BAT according to the IPPC Directive. A working group on priority substances has been established to work on the implementation of the priority substance related issues (selection of substances, monitoring, environmental quality standards (EQS) setting, source screening and emission controls).<sup>13</sup> In principle, the same instruments for reducing emissions are applied as for existing substances: the definition of EQS, the implementation of BAT and the monitoring of priority substances. Because only a

<sup>13</sup> <http://ec.europa.eu/environment/water/water-framework/objectives/pdf/strategy3.pdf>

few biocides have been so far considered in Annex X of the WFD on priority substances (Isoproturon, Diuron, Naphthalene), the ongoing process for including further priority substances into Annex X also influences the risk mitigation of biocides. Currently, several insecticides are being discussed as biocidal candidates for selection as priority substances (Permethrin, Cypermethrin, Deltamethrin, Dichlorvos, Diazinon) based on a study on monitoring-based prioritisation of further potential priority substances candidates (James et al. 2009). The inclusion of further biocidal active substances in monitoring programmes is a prerequisite for prioritising RMM from an environmental point of view.

## **2.8 Other regulatory areas**

Sustainable use is (partly) considered in several other regulatory areas. Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances (now implemented in Regulation (EC) No 1907/2006 (REACH)) refers to risk reduction measures for workers and/or the environment recommended by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE). The risk reduction options relate to point emissions from manufacturing and industrial use, the development and application of BAT as well as to the establishment of Environmental Quality Standards (EQS) and monitoring of substances. For some substances, such as Diphenylether octabromo derivatives, more detailed recommendations on data gaps and options regarding the restriction of marketing and use have been suggested (Recommendation 2002/755/EC).

Concerning 3,4-dichloroaniline, the recommendation states that the legislation for plant protection products (Directive 91/414/EEC) and for biocides (Directive 98/8/EC) is considered to give an adequate framework to limit the risks of the substance to the extent necessary. The release of 3,4-dichloroaniline from Diuron used as an herbicide on sealed surfaces should be considered in the risk assessment and misuse of Diuron should be prevented.

REACH defines “Risk Management Measures” as measures in the control strategy for a substance that reduce the emission of and exposure to a substance, thereby reducing the risk to human health or the environment. In the guidance document on information requirements and chemical safety assessment, Chapter R.13 states that the prevention and reduction of emissions of dangerous substances by process integrated measures are usually preferred over end-of-the pipe techniques. Good

housekeeping can address both occupational and environmental exposure and can be based on sector specific process recommendations or definition of BAT under the IPPC Directive. Basically two relevant types of risk management measures are distinguished for consumers:

- Product integrated risk management measures under the control of the supplier, such as the chemical composition and the functional design
- Consumer instruction/communication on safe use such as technical use instructions, instructions on protective clothing, instructions on storage and disposal

It is stated that consumer exposure assessment should also take into account reasonably foreseeable misuse. Exposure to the environment from misuse is not mentioned specifically in the guidance.

Sustainable use of chemicals is often attributed to “sustainable chemistry” or green chemistry. The addressees are companies producing chemicals or related products. There exists a European Technology Platform for Sustainable Chemistry which seeks to boost chemistry, biotechnology and chemical engineering research, development and innovation in Europe.<sup>14</sup>

Sustainable use of medicinal products often refers to the conservation and protection of medicinal plants in the context of their natural habitats, biodiversity and bio-piracy (Hamilton 2004). The term “sustainable pharmacy” is used for a new approach addressing environmental, economic and social aspects of pharmacy. One focus lies on environmental issues along the whole lifecycle of a pharmaceutical entity, including aspects of resources, energy input and waste e.g. during synthesis and production of an active pharmaceutical ingredient. Furthermore, degradability of the compounds themselves after their use and reduction of the environmental risk caused by pharmaceuticals is considered. Another issue is the contribution of people using pharmaceuticals (pharmacists, medical doctors and patients) to more efficient use of pharmaceuticals with a lower environmental burden and less risk for drinking water (Kümmerer et al. 2010). The European Medicines Agency (EMA) specifies in its revised EMA guidelines on environmental impact assessment for veterinary medicinal products that risk mitigation “*can be used to restrict the risk associated with a product to an acceptable level, or even to completely remove such a risk*” (EMA 2008). The EMA guideline for the environmental risk assessment of medicinal

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<sup>14</sup> <http://www.suschem.org/en/about>.

products for human use specifies that when the possibility of environmental risks cannot be excluded, precautionary and safety measures such as an indication of potential risks presented by the medicinal product for the environment on the product label with recommendations on product storage and disposal (EMEA 2006). While RMM can be considered in the authorisation procedure of related chemicals and/or products, the “sustainable use” approach consists of a broader strategy beyond regulatory decisions. The efficiency and practicability of RMM for biocidal products, with emphasis on wood preservatives and insecticides, have been evaluated by the consultant in research project FKZ 3709 65 402 on behalf of the German Federal Environment Agency (Gartiser et al. 2010).

### 3 Measures, tools and targets set up within Directive 2009/128/EC

#### 3.1 Measures for sustainable use of plant protection products - overview

Framework Directive 2009/128/EC for the sustainable use of pesticides specifies measures to reduce risks and impacts of pesticide use on human health and the environment and promotes the use of IPM and of alternative approaches or techniques such as non-chemical alternatives to pesticides. The measures proposed in Articles 5-14 of Framework Directive 2009/128/EC are summarised in Figure 3:



**Figure 3: Measures proposed for a sustainable use of PPP**

According to Article 4 of Directive 2009/128/EC, MS shall adopt National Action Plans (NAP) to set up quantitative objectives, targets, measures, and time tables to reduce risks and impacts of pesticide use. The NAPs shall address the different measures and shall include indicators to monitor the use of plant protection products. The objective of appropriate risk indicators is to measure the progress achieved in the reduction of risks and adverse impacts from pesticide use. Harmonised risk indicators

will be established at Community level but MS are also allowed to use their national indicators. Progress in the reduction of risks and the measures applied will be reported to the Commission.

The Thematic Strategy on Sustainable Use of Pesticides is accompanied by activities to gather reliable data and expert knowledge and to develop further guidance:

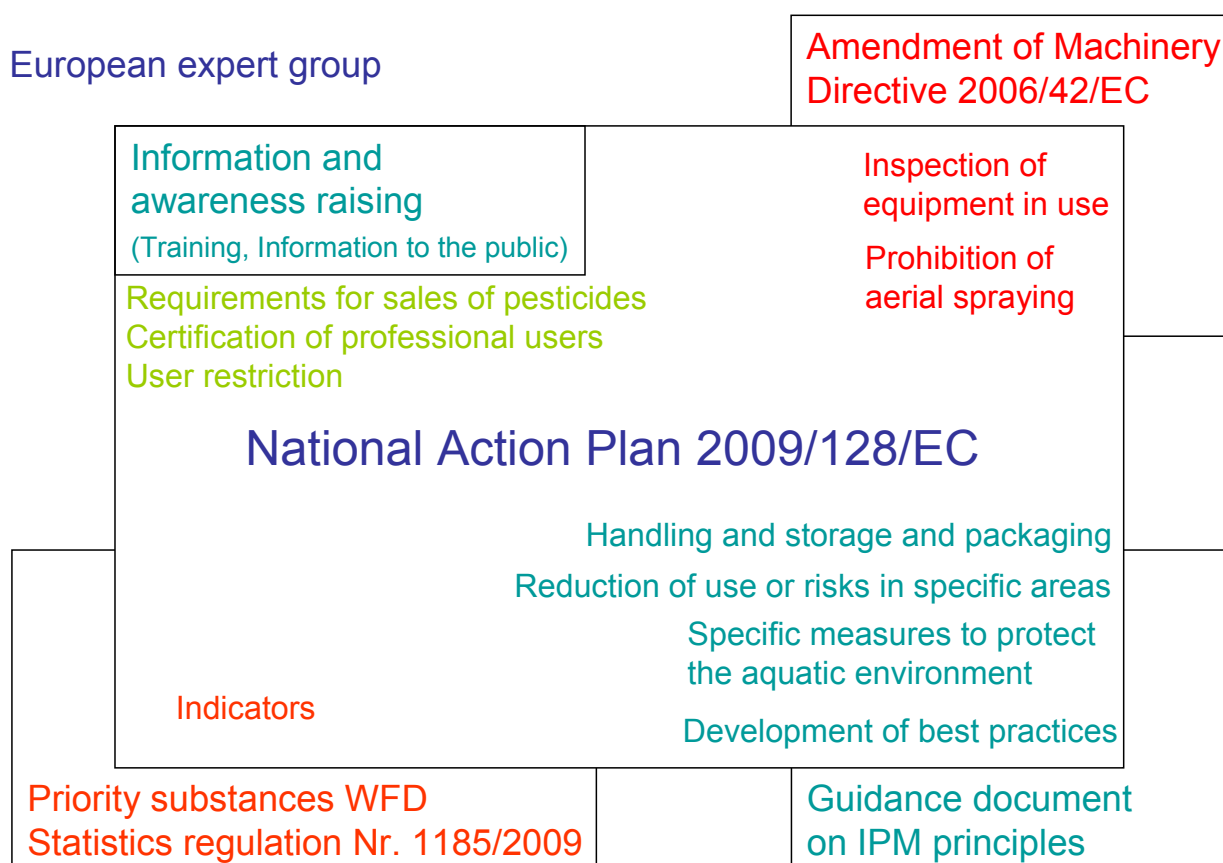
- An expert group has been established at EU level
- From 21 October 2009, Directive 2009/127/EC on machinery for pesticide application has been accepted as an amendment to the Machinery Directive 2006/42/EC. To date, application equipment for biocidal products is not covered but it is envisaged that this might be included at a later stage.
- Regulation (EC) No 1185/2009 concerning statistics on plant protection products COM (2006) 778 final) will improve data to be used as harmonised risk indicators and to follow the progress on sustainable use of pesticides (biocides are excluded so far).
- In October 2009 Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market has replaced Directive 91/414/EEC. It aims at harmonising the placing on the market of plant protection products<sup>15</sup>.
- A guidance document for establishing IPM principles have been drafted (European Commission 2009)<sup>16</sup>.
- Several research projects have been funded by the Commission for developing guidance and concepts on pesticide risk assessment and management.

The different instruments and measures and their relationship are shown in Figure 4.

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<sup>15</sup> COM(2006) 388 final, 2006/0136 (COD), Brussels, 12.7.2006  
[http://ec.europa.eu/food/plant/protection/evaluation/com2006\\_0388en01.pdf](http://ec.europa.eu/food/plant/protection/evaluation/com2006_0388en01.pdf)

<sup>16</sup> [http://ec.europa.eu/environment/ppps/pdf/draft\\_guidance\\_doc.pdf](http://ec.europa.eu/environment/ppps/pdf/draft_guidance_doc.pdf)



**Figure 4: Instruments and measures for sustainable use of pesticides**

Regulatory options, such as requirements for sales, certification of professional users and user restriction can be distinguished from technical options, such as the control of the equipment. In addition, the development of IPM principles and best practices (improving knowledge) is complemented by the distribution of that information to the public. Risk indicators serve to set and control the goals on risk reduction as defined in the National Action Plan and to select the most efficient measures.

### **3.2 Measures for sustainable use of plant protection products – description and discussion**

In the following sections the measures proposed in Framework Directive 2009/128/EC on the Sustainable Use of Pesticides are described and environmental issues are discussed in greater detail.



### 3.2.1 Training (Article 5)

According to Article 5 of Framework Directive 2009/128/EC on Sustainable Use of Pesticides, MS shall ensure that all professional users, distributors and advisers have access to appropriate training and shall establish certification systems providing evidence of attendance at training. All professional users, distributors and advisers should have access to appropriate training by bodies designated by the competent authorities. The Directive defines “professional users” in Article 3 as “any person who uses pesticides in the course of their professional activities, including operators, technicians, employers and self-employed people”. There is no distinction made between “professional” and “specialised professional” users.<sup>17</sup>

Training shall consist of both initial and additional training to acquire and update knowledge as appropriate. The training shall be designed to ensure that such users, distributors and advisers acquire sufficient knowledge regarding the subjects listed in Annex I of Directive 2009/128/EC, taking account of their different roles and responsibilities.

Member States shall establish certification systems which, as a minimum, provide evidence of sufficient knowledge of the subjects listed in Annex I acquired by professional users, distributors and advisers either by undergoing training or by other means. Certification systems shall include requirements and procedures for the granting, renewal and withdrawal of certificates. Annex I describes the minimum content of training measures. It comprises information about:

- All relevant legislation,
- The hazards and risks associated with pesticides,
- Integrated pest management strategies and techniques,
- Initiation to comparative assessments at user level,
- Measures to minimise risks to humans, non-target organisms and the environment,
- Risk-based approaches which take into account the local climate, soil and crop types,
- Procedures for preparing pesticide application equipment,
- Use of pesticide application equipment and its maintenance, and specific spraying techniques,
- Emergency action in case of accidental spillage and contamination,

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<sup>17</sup> Some Inclusion Directives for including active substances in Annex I of the BPD distinguish between “professional” and “specialised professional” users. “Professional use” can be regarded as any occupational application of biocides; “specialised professional use” refers to specific training or education required for the application of biocides.

- Special care in protection areas,
- Health monitoring and access facilities to report on any incidents,
- Record keeping on any use of pesticides.

### **3.2.2 Requirements for sales of pesticides (Article 6)**

According to Directive 2009/128/EC (9), sales of pesticides, including internet sales, are important elements in the distribution chain where specific advice on safety instructions for human health and the environment should be given to the end user. Recommendations should be given for non-professional users, in particular on safe handling and storage of pesticides as well as on disposal of the packaging.

Article 6 of Directive 2009/128/EC specifies that distributors selling pesticides classified as toxic or very toxic need at least one certified person in their employment, who shall be present and available at the place of sales to provide information to customers.

MS shall take the necessary measures to ensure that sales of pesticides not authorised for non-professional use shall be restricted to professional users holding a certificate. Distributors shall provide general information regarding the risks of pesticide use, in particular on hazards, exposure, proper storage, handling and application, as well as disposal.

Article 6 of Directive 2009/128/EC further requires Member States to ensure that certified distributors provide adequate information to customers on pesticide use, health and environmental risks and safety instructions. Micro distributors selling only products for non-professional use may be exempted, if they do not offer for sale pesticide formulations classified as toxic, very toxic, carcinogenic, mutagenic or toxic for reproduction. Sales of pesticides authorised for professional use should be restricted to certified persons.

### **3.2.3 Information and awareness-raising (Article 7)**

Article 7 of Directive 2009/128/EC requests Member States to inform the general public and to promote and facilitate information and awareness-raising programmes and the availability of accurate and balanced information relating to pesticides for the general public, in particular regarding the risks and the potential acute and chronic effects for human health, non-target organisms and the environment arising from

their use and the use of non-chemical alternatives. Additionally, systems for gathering information on acute and chronic poisoning incidents, as well as chronic poisoning, should be established. Further, the development of a guidance document on monitoring and surveying of the impacts of pesticide use on human health and the environment is envisaged.

### **3.2.4 Inspection of equipment in use (Article 8)**

Article 8 of Directive 2009/128/EC on sustainable use of pesticides requests Member States to ensure that pesticide application equipment in professional use shall be subject to inspections at regular intervals (3-5 years). MS shall establish certificate systems designed to allow the verification of inspections. By way of derogation and following risk assessment, handheld pesticide application equipment (e.g. knapsack sprayers) or application equipment that represents a very low scale of use may be exempted. These shall be listed in the National Action Plan. Where exemptions are granted from regular inspections, operators should be informed of the need to change the accessories regularly, and of the specific risks linked to that equipment. Additionally MS shall ensure that operators are trained for the proper use of that application equipment.

Annex II to Directive 2009/128/EC describes the requirements relating to the inspection of pesticide application equipment. The equipment must be in a condition so as to be filled and emptied safely, easily and completely; leakage of pesticides must be prevented; and easy and thorough cleaning must be guaranteed. Particular attention should be paid to the power transmission parts, the pump, the agitation devices for achieving an even concentration, the spray liquid tank (e.g. indicator of tank content, filling and emptying devices, filters, and mixers), measuring systems for measuring and adjusting pressure and/or flow rate, and pipes and hoses of the application equipment. The development of harmonised standards for pesticide application equipment is required.

These objectives have been introduced by Directive 2009/127/EC on machinery for pesticide application, amending Directive 2006/42/EC on machinery which provides rules on the placing on the market of pesticide application equipment. The scope of the Directive is limited to machinery for the application of pesticides that are plant protection products. However, since it is anticipated that the scope of the Framework

Directive on sustainable use of pesticides will be extended to cover also biocidal products, it should be examined by the Commission by 31 December 2012 on how the extension of the scope of the environmental protection requirements to machinery for the application of biocidal products could be realised (2009/127/EC, recital 3).

In Germany the manufacturer, distributor or importer of new types of plant protection equipment is requested to confirm that its design allows the proper use of the equipment (mandatory declaration procedure). The Federal Research Centre for Cultivated Plants (Julius Kühn-Institut, JKI) publishes the so called Plant Protection Equipment List, which lists plant protection equipment adhering to these requirements. In addition, equipment or parts thereof, e.g. nozzles, can be subjected to an inspection on a voluntary basis (voluntary approval/inspection procedure). The JKI has kept a register of "Loss reducing equipment" since 1993 which includes specific use conditions and determines "basic drift values" which are used in the risk assessment for non-target organisms. Drift reduction is considered as an important risk mitigation measure. The JKI also carries out inspections in compliance with procedures set out by the European Network for Testing Agricultural Machines, ENTAM. For sprayers, a Standardised Procedure for the Inspection of Sprayers in Europe (SPISE) was established in 2004.<sup>18</sup> According to experts from the JKI, the new requirements imposed by Directive 2009/128/EC on sustainable use of pesticides will have minor impacts for those MS that have established procedures for equipment control already (e.g. Germany, the Netherlands, Belgium), while others such as France, Spain, Italy, Hungary or Greece will have to inspect some 100.000 items of plant protection equipment in a relatively short time.<sup>19</sup>

### **3.2.5 Prohibition of aerial spraying (Article 9)**

Article 9 of Directive 2009/128/EC prohibits aerial spraying in general. In the context of the Directive, aerial spraying means application of pesticides from an aircraft (plane or helicopter). Exceptions can be made only if there are no viable alternatives available or aerial spraying is superior to land-based application of pesticides in terms of health and environmental effects. Pesticides applied need a specific approval for aerial spraying of crops. Particular requirements for these uses have to

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<sup>18</sup> <http://www.jki.bund.de>

<sup>19</sup> <http://www.bmelv.de/SharedDocs/Standardartikel/Landwirtschaft/Pflanze/Pflanzenschutz/JKI-Pflanzenschutzgeraete.html>

be established by Member States. The enterprise that is responsible for providing aerial spray applications shall be certified by a competent authority. The operator carrying out the aerial spraying must hold a certificate from Member States. If the area to be sprayed is in close proximity to areas open to the public, specific risk management measures must be taken to exclude or reduce any effects on the public. Aerial spraying is prohibited in close proximity to residential areas.

### **3.2.6 Information to the public (Article 10)**

Article 10 of Directive 2009/128/EC leaves it to the MS to include further provisions on informing persons who could be exposed to spray drift in their National Action Plans. This provision addresses the need to minimise exposure of bystanders potentially occurring through aerial applications, or those resulting from aerial sprayers or boom sprayers.

### **3.2.7 Specific measures to protect the aquatic environment and drinking water (Article 11)**

Article 11 of Directive 2009/128/EC requires MS to ensure that, when pesticides are used in the vicinity of water bodies, preference is given to products that are not classified as dangerous for the aquatic environment. Moreover, the most efficient application techniques should be used, for example low-drift application equipment.

MS shall ensure that appropriate buffer zones are established on fields adjacent to water courses. Here, pesticides must not be applied or stored. In particular, protective safeguard zones must be established for surface and groundwater used for the abstraction of drinking water.

Use of pesticides along transport routes, e.g. railway lines or on sealed or very permeable surfaces should be minimised or prevented.

Article 7 of the WFD (Directive 2000/60/EC) requires Member States to establish safeguard zones for water bodies used for drinking water production. In Germany, for drinking water protective areas, three distinct zones have been defined in order to protect ground water resources. In protection zone I (remedial zone), which includes a distance of at least 10 m around the pumping device, any kind of agricultural or other usages are forbidden. In protection zone II, which is defined as the “50-day-line” where most microorganisms are eliminated, any commercial and agricultural use

is not allowed, thus excluding the use of plant protection products. Protection zone III, which comprises the whole catchment area of the groundwater, serious endangering from application of liquid manure or sewage sludge, as well as from heavily degradable chemicals such as plant protection products and other pesticides, is not allowed (Zhu et al. 2008). Similarly, in the United Kingdom there are “groundwater source protection zones” which distinguish an inner protection zone (50 day travel time and as a minimum 50 m) and an outer protection zone (400 day travel time from a point below the water table).<sup>20</sup>

In Annex X of the WFD, priority substances have been identified for which a progressive reduction of emissions to water is intended. The list contains several plant protection products: Alachlor, Atrazine, Chlorfenvinphos Chlorpyrifos, Diuron, Endosulfan, Isoproturon, and Simazine. Most pesticides included in monitoring programmes belong to the chemical class of herbicides.

The German Federal Water Act from 2009 (§38 WHG) for the first time defines a legal framework for the management of the buffer zones of surface water (usually 5 m) for reducing diffuse entries of pollutants.

### **3.2.8 Reduction of pesticide use and risks in specific areas (Article 12)**

According to Article 12 of the Framework Directive 2009/128/EC the use of pesticides shall be prohibited or restricted to the minimum necessary:

- in areas used by the general public as public parks and gardens, sports and recreation grounds, school grounds and children's playgrounds, and in the close vicinity of healthcare facilities;
- protected areas, such as Natura 2000 sites<sup>21</sup> protected in accordance with Directive 79/409/EEC on the conservation of wild birds and 92/43/EEC on the conservation of natural habitats and of wild fauna and flora and in
- protected areas as defined in the Water Framework Directive 2000/60/EC.

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<sup>20</sup> <http://www.environment-agency.gov.uk/homeandleisure/37805.aspx>

<sup>21</sup> Under the title “Natura 2000 sites” a coherent European ecological network of special areas of conservation has been set up. This network is composed of sites hosting certain natural habitat types (defined in Annex I to Directive 92/43/EEC) and habitats of certain species (listed in Annex II to Directive 92/43/EEC). In addition, the Natura 2000 network includes special protection areas classified pursuant to Directive 79/409/EEC.

If the use of plant protection products cannot be avoided in these sensitive areas, use of biological control measures or low-risk pesticides should be considered prior to using pesticides. In addition, appropriate risk management measures should be applied.

The aquatic environment is a compartment that is particularly sensitive to pesticides. The Thematic Strategy addresses this issue by stressing that surface and ground waters should be protected from pollution by appropriate measures that reduce their exposure to spray drift, drain flow and/or run-off (see section 3.2.7).

The establishment of buffer and safeguard zones alone may not be sufficient to adequately protect the aquatic environment. Open land and laboratory studies in Mecklenburg-Western Pomerania in Germany documented that, despite a 20 m buffer zone, as laid down in the rules of good agricultural practice for pesticide use, relevant concentrations of the pesticides Isoproturon and Cypermethrin were found in the surface waters of agricultural landscapes. In addition, high concentrations were found in the spawn and larva of the fire-bellied toad. This is a species protected by Directive 92/43/EEC (MLUV Brandenburg, 2003; reported in PAN Germany 2008). It is therefore necessary to extend protection measures beyond the establishment of buffer and safeguard zones in order to protect the aquatic environment and endangered, particularly vulnerable species in very sensitive areas.

Despite the fact that, according to the Thematic Strategy, the use of pesticides shall be prohibited or restricted in very sensitive areas, the conservation of biodiversity is not explicitly mentioned as the subject of protection within the Thematic Strategy. However, Directive 92/43/EEC (a Directive that is referred to in the Thematic Strategy) states that its “aim is to contribute towards ensuring biodiversity through the conservation of natural habitats and of wild fauna and flora”. The proposal for a biocides regulation replacing the BPD introduces the “impact on biodiversity and the ecosystem” “as unacceptable effects”, which might cause the rejection of applications for authorisations.

The revised version of the German Programme for the Reduction of Chemical Plant Protection Products (BMVEL 2008) stresses that reducing the amount of pesticides in the environment and also subsequent risks will also serve nature conservation and biological diversity. For this reason, the National Action Plan on Sustainable Use of

Plant Protection Products has been incorporated as a fixed component in the National Biodiversity Strategy, reflecting the coherence between biodiversity and sustainable use of pesticides.

In the UK pesticide reduction programme, provisions are made to link relevant measures to those taken to preserve biodiversity. One expert group in the British reduction programme is concerned with the subject of biodiversity. One of the targets is to stop the decline in the bird population on agricultural land by 2010. Yearly inspections of bird populations are part of the reduction programme (PSD 2007).

However, as already mentioned above, the use of pesticides cannot always be avoided even in very sensitive areas, for example Natura 2000 sites. The risk associated with pest control must be weighed against the risks to the environment if the pest is not controlled. In practice, for example, if trees within the sensitive areas are infested by bark beetles, the potential damage caused by insects should be weighed against the potential damage to the ecosystem resulting from the application of plant protection products. If the pesticide application is considered to be unavoidable, appropriate risk management measures need to be established to protect the sensitive ecosystem in the conservation area.

### **3.2.9 Handling and storage of pesticides and treatment of their packaging and remnants (Article 13)**

Article 12 requests MS to adopt necessary measures to ensure that handling of pesticides will not endanger the health or safety of humans and the environment. This includes all activities before and after application of pesticides, handling of packaging and remnants after application and cleaning of equipment. The same measures are required for pesticides authorised and used by non-professional users, to avoid dangerous handling operations.

#### Handling and storage (including dilution and mixing)

The use of concentrates requires an additional mixing and loading stage during which spillage and leakage can easily occur. Use of water-soluble packaging has been proposed in several guidance documents for the safe use of Plant Protection Products (e.g. Scottish Executive 2004). These packages, made of e.g. polyvinyl



alcohol (PVA), reduce exposure through direct contact with the product during the mixing and loading stage and enable accurate dosing.

For amateur users, little data is available on storage and use of home pesticides (both plant protection products and biocides). In a UK study, the highest use of pesticides occurred in the garden, followed by homes, on pets and against head lice (the last mentioned are considered medicinal products). On average, 3.5 products per year were applied per household. Insecticides were the most common type of pesticide used in homes. Half of the pesticides were stored indoors, most commonly in kitchens; secondly in garages and sheds (Grey et al. 2006).

#### Cleaning of equipment and treatment of remaining mixtures after application

The cleaning of equipment after use and drainage of remaining mixtures from non-agricultural surfaces have been identified as the major cause of emissions to surface water. Thus, it is considered best practice to apply diluted liquids from cleaning processes directly on the areas previously treated. Direct or indirect discharge to sewers is prohibited (Anonymous 2005). For herbicides used as plant protection products, it is known from large-scale studies that about 2% of the total mass applied is ultimately lost to surface waters and that losses primarily occur during and immediately after the application. Spills during filling of spraying equipment, cleaning of the equipment and processing of spray waste on paved surfaces are examples of poor management practices. Careful pesticide handling is therefore a highly effective strategy for risk mitigation (Holvoet et al., 2007).

#### Treatment of packing and remnants

In Germany, since 1996 the agricultural pesticide industry and distributive trade has offered a German-wide recycling system for packaging used for its products by means of PAMIRA-System. Once a year, the 250 collection points are open for one to four days in which the farmer can return his used packaging. This packaging is checked with regard to its cleanliness and then registered and processed by efficient disposal companies. The processed plastic canisters are recycled to be used as a source of energy in cement plants or as raw material for the production of methanol. For the farmer, the return of packaging is free of charge. In 2008 in total 2262 t packaging material was recollected, corresponding to a rate of return of 60%

(<http://www.pamira.de/>). Similar voluntary collection schemes for crop protection packaging exist also in other Member States.

In France, ADIVALOR (Agriculteurs, Distributeurs, Industriels pour la VALORisation des déchets agricoles) collected about 3900 tonnes of packaging waste in 2006, which represents a recovery of more than 50% of empty containers produced (<http://www.adivalor.fr/docs/adivalor-english-presentation.pdf>).

### Non professional users

Considering non-professional users, MS shall take all necessary measures regarding pesticides to avoid dangerous handling operations, such as the use of pesticides of low toxicity, ready to use formulations and limits on sizes of containers or packaging.

### **3.2.10 Integrated Pest Management (Article 14)**

According to the Framework Directive 2009/128/EC, MS shall take all necessary measures to promote low pesticide-input pest management and to ensure that professional users of pesticides shift towards a more environmentally-friendly use of all available crop protection measures. To do so, MS shall establish or support the establishment of all necessary conditions for implementation of IPM and shall ensure that farmers have at their disposal systems, including training and tools for pest monitoring and decision making, as well as advisory services on IPM. Article 31 of Regulation (EC) No 1107/2009 on plant protection products prescribes that MS should consider indications for proper use according to the principles of IPM in their authorisations.

Article 14 of Directive 2009/128/EC defines "Integrated Pest Management" as "careful consideration of all available plant protection methods and subsequent integration of appropriate measures that discourage the development of populations of harmful organisms and keep the use of plant protection products and other forms of intervention to levels that are economically and ecologically justified and reduce or minimise risks to human health and the environment. IPM emphasises the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms".

Article 14 and Annex III of Directive 2009/128/EC describe the following general principles of IPM for prevention and/or suppression of harmful organisms:

- Crop rotation
- Use of adequate cultivation techniques
- Use of resistant/tolerant cultivars and standard/certified seed and planting material
- Use of balanced fertilisation, liming and irrigation/drainage practices
- Preventing the spreading of harmful organisms by hygiene measures (e.g. by regular cleansing of machinery and equipment)
- Protection and enhancement of important beneficial organisms

The Thematic Strategy requires Member States to promote low pesticide-input pest management, wherever possible giving priority to non-chemical methods, so that professional users will switch to practices and products with the lowest risk to health and environment. The measure shall be specified in the national action plans.

Additionally, Member States shall establish incentives to encourage professional users to implement crop or sector-specific guidelines for IPM on a voluntary basis. Public authorities and/or organisations representing particular professional users may draw up such guidelines.

The European Commission initiated a study in 2009 on the development of guidance for establishing IPM principles. Therein eight general principles have been identified (European Commission, 2009, see table 1).

The study evaluated existing definitions and approaches of general IPM principles and examples of crop specific IPM measures throughout Europe and North America. The concept of IPM is distinguished from Good Plant Protection Practice (GPPP) which has been implemented in several Member States. While GPPP can be seen as a basic strategy defining minimum requirements and strict compliance with legal regulations, the concept of IPM goes beyond this, attempting to minimize the use of pesticides in a holistic approach.

**Table 1: Integrated Pest Management (IPM) principles proposed for being implemented in the Thematic Strategy**

1	Measures for prevention and/or suppression of harmful organisms	Prevention of key pests, diseases and weeds by choice of appropriate resistant/tolerant cultivars, optimum crop rotation, adequate cultivation techniques, balanced fertilisation and irrigation practices; Protection and enhancement of important natural enemies.
2	Tools for monitoring	Monitoring of pests, diseases and weeds for determining whether and when to apply direct pest control measures; Scientifically sound warning, forecasting and early diagnosis systems to be used for decisions.
3	Threshold values as basis for decision-making	Robust and scientifically sound threshold values for decision making; considering differences in varietal susceptibility; spraying during certain weather conditions not recommended (i.e. wind velocity > 5 m/s, temperature > 25°C, relative humidity <50%).
4	Non-chemical methods to be preferred	Preventive (indirect) plant protection measures to be considered and applied before intervention with control (direct) measures; biological, biotechnical and physical methods to be preferred; weed to be achieved by non-chemical methods as far as possible.
5	Target-specificity and minimization of side effects	When direct plant protection methods have to be applied, priority given to measures which have the minimum impact on human health, non-target organisms and the environment; application of appropriate products; impact to be minimised by calculating dose for a given phenological crop stage.
6	Reduction of use to necessary levels	Application to be limited to the lowest possible area (e.g. band spraying, spot treatments); use of best application techniques to minimize drift and loss; purchase and use of spraying equipment producing the least drift and pesticide loss to be encouraged.
7	Application of anti-resistance strategies	Where risk of resistance is known and where repeated application of plant protection products in the crops is required, regional organisations to provide clear recommendations or mandatory requests for an anti-resistance strategy.
8	Records, monitoring, documentation and check of success	Documentation of the mode of application, the accurately calculation of the application, the official pre-harvest intervals and the safe disposal of obsolete pesticides.

Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market intends that applying general standards of IPM, as described in Directive 2009/128/EC on the sustainable use of pesticides, should be made mandatory from 2014 onwards. The development of IPM standards on pest and crop management and the use of low-risk plant protection products as well as of non-chemical methods are assigned the highest priority.

### 3.2.11 National Action Plans and indicators – national measures

According to Article 4 of the Thematic Strategy, MS shall adopt National Action Plans to set up their quantitative objectives, targets, measures and timetables to reduce risks and impacts of pesticide use on human health and the environment. MS shall also include indicators to monitor the use of PPP. Member States have to bring into force the laws, regulations and administrative provisions in order to comply with the Directive. By doing so, they have to define targets, measures, and indicators on their own. Examples are:

Prohibition of the use of some pesticides: The reduction of hazards and risks resulting from the use of pesticides by restriction of certain substances and information and enabling of workers to better protect themselves can be seen as an additional measure. For example, Denmark (DK) banned the most dangerous endocrine disruptors from being used in glasshouses; in addition, a website was published to inform in particular pregnant employers, employees and doctors about PPP ([www.gravidmedjob.dk](http://www.gravidmedjob.dk)). The Netherlands defines specific targets for reducing the risks for fresh water and drinking water by 95%.

Quantitative use reduction: Quantitative use reduction is not addressed in the Thematic Strategy but quantitative reduction targets can be defined at national level. For example, France (FR) aims at reducing the use of pesticides by 50% by 2018, by encouraging alternatives and a ban of 40 selected substances by 2010. Use reduction and risk reduction is also extended to the non-farming sector.

According to the German National Action Plan on sustainable use of PPP, it is aimed to reduce the risks resulting from the use of PPPs by 25 % by the year 2020. (BMVEL, 2009)

Taxes/levies on selected pesticides: Although the introduction of taxes for achieving quantitative use reduction target was not recommended in the impact assessment study prepared by the Commission in 2004 (Bipro study), it has been implemented for example in Denmark and Belgium. The taxes/levies are used for financing supporting measures and advisory service.

Training, awareness raising and control: Although “training and awareness raising” measures are already part of the Thematic Strategy, “control” is only foreseen in the

framework of control of equipment. Hence control can be seen as an additional national measure. In some MS, specific advisory services for farmers have been implemented (e.g. DK, Italy (I)). Additionally, support for farmers by different means is foreseen; e.g. Denmark and France provide regional forecasts and warning systems on pests and specific guidance for decision making. The strengthening and extension of independent advisory structures, e.g. advisor training and further education, quality assurance, certification and inclusion of private advisory services, is seen as an adequate measure in Germany. Also, knowledge transfer and other measures for the use of PPPs in non-agricultural areas and between different users, e.g. professional users, advisors and distributors have been identified as important measures at national level.

Research and development (R&D): Research and development is identified as a key task in reducing risks and impacts of pesticide use. Strengthening in the field of R&D was therefore implemented as a clear objective in NAPs in Denmark and France. For example, France laid the focus on research on systems with low pesticide use.

Indicators: European wide harmonised risk indicators which will be referred to in Annex IV shall be established, but MS may continue to use existing national indicators or adopt additional ones, by using statistical indicators, by identifying trends and priority items. The result of the evaluation shall be reported to the Commission and other MS.

The development of indicators is foreseen in the Thematic Strategy. Further, the development of specific indicators is another measure implemented at national level, as it is a precondition for any evaluation on national and regional level. For example DK and F developed treatment frequency indices. Another measure is to develop specific risk indicators, e.g. maximum residue limits for the assessment of health and environmental effects. Up to now several tools and sets of indicators exist; e.g. the environmental indicator tool SYNOPS<sup>22</sup> and statistical data received from the NEPTUN survey<sup>23</sup>, these are intended to be used as a basis for the further development of targets, indicators and evaluation. In France, monitoring of

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<sup>22</sup>

[http://www.jki.bund.de/nn\\_804620/DE/Home/pflanzen\\_\\_schuetzen/pfsmittel/risiken\\_\\_SYNOPS/risiken\\_\\_SYNOPS\\_\\_node.html](http://www.jki.bund.de/nn_804620/DE/Home/pflanzen__schuetzen/pfsmittel/risiken__SYNOPS/risiken__SYNOPS__node.html)

<sup>23</sup> [http://www.jki.bund.de/cln\\_044/nn\\_804440/DE/Home/koordinieren/neptun/neptun.html\\_\\_nnn=true](http://www.jki.bund.de/cln_044/nn_804440/DE/Home/koordinieren/neptun/neptun.html__nnn=true)

unexpected effects from the use of pesticides is also part of the NAP. In the UK there is a specific focus on pesticide used by amateurs. Further, a need for the development of more indicators, e.g. for the assessment of biodiversity, has also been identified.

## **4 Measures for sustainable use of biocides**

### **4.1 Existing approaches for sustainable use of biocides**

Some aspects concerning the use phase of biocidal products are already addressed in the authorisation process. According to Directive 98/8/EC (e.g. Annex VI, 62, 72) on the placing on the market of biocidal products, competent authorities may impose conditions on the use of the product or prescribe risk management measures. The risk management measures are, however, always relevant only for the specific biocidal product. Provisions on sustainable use would look at the risks arising from the use of all biocidal products. Measures aimed at ensuring the sustainable use of biocidal products would be applicable to a group of, or to all, biocidal products or for specific applications such as aerial spraying.

#### **4.1.1 Results of the COWI-study**

In 2008, the EU Commission contracted a study on the assessment of different options to address risks from the use phase of biocidal products. The final report, "Assessment of different options to address risks from the use phase of biocides", was published in March 2009 (COWI 2009).

The purpose of the study was to "help identify the appropriate measures and legal instruments that would allow ensuring a sustainable use of biocidal products". Five types of approaches (and their technical options) were identified to reduce the risk in the use phase of biocides:

- Reduce quantities to optimal levels (optimising the dosage, prevent growth of organisms, application of non-biocidal techniques, avoid using biocides where prevention is not essential)
- Reduce hazardousness (technical improvements, imported articles/ materials, use of less hazardous biocides for less demanding applications)
- Reduce releases and exposures by application (use of appropriate application techniques and equipment, use appropriate personal protection equipment)
- Reduce releases and exposures in the service life phase (reduce the release rate of biocides from products and articles, prevent inappropriate use of biocide treated materials/articles e.g. indoor use of preserved wood)



- Prevent development of resistance (change between different biocides, prevent using biocides at sub-lethal levels)

Among the measures to achieve the approaches, the following ones were analysed more in detail:

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

Considering the development of harmonised good practice (GP) reference documents, the establishment of Technical Working Groups comprising nominated experts from EU Member States, industry and environmental NGOs with the Joint Research Centre (JRC) as coordinating body was suggested, similar to the BAT Reference Documents (BREF) approach of the IPPC Directive. The German study on “Good practice of biocide use” was cited in detail as an example of the structure and the contents reference documents could include (Gartiser et al., 2005). These reference documents could be used as a basis for training of professional users by public organisations, industry or educational institutes. For some specific application areas, such as rodent control, guidance on best practice has been already developed (e.g. Central Science Laboratory, 2002).

In relation to the certification and inspection of application equipment, the German study on good practice for the use of biocides, which describes a number of equipment types for which certification procedures exist in Germany has again been cited. However, a Danish study on the impact of a control system for plant protection equipment concluded that the environmental and health impact will probably be very small and mostly an effect of phasing out old equipment (Dubgaard et al., 2007, cited in COWI, 2009).

Considering long term good practice and prevention, the COWI study concluded that measures such as IPM as used in the plant protection sector, including prevention, pest monitoring, use of thresholds (blanket restrictions), lowest use of chemicals and use of substitutes, are in principle also applicable for many biocidal applications.

The measures proposed in the COWI study mainly focus on professional users of biocides, while non-professional users are only indirectly affected (e.g. through use restrictions, sale restrictions, information/awareness raising campaigns).

Use restriction of biocides in sensitive areas on bodies of water has been identified as one option. Such restriction may be relevant for applications in very vulnerable environments. The COWI study gives the following examples of measures implemented in some Member States:

- Prohibition of the use of antifouling products in fresh water
- Some biocides may only be used indoors
- Restrict the use of some insecticides for the control of mosquitoes for use in cases 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 the environs of drinking water resources, public buildings (e.g. schools, kindergartens, etc.).

To date, according to the COWI study, 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.

#### **4.1.2 Evaluation of documents discussed at CA-meetings**

Several RMM for biocides are currently being discussed by Competent Authorities (CA).<sup>24</sup>

##### Spraying of wood preservatives

While few Member States completely forbid the spraying of wood preservatives by amateur users, most CA suggest that this should not be required as a general rule. They recommend that spraying by non-professional users should be prohibited if the exposure assessment results in unacceptable risks, with the need to use personal protective equipment (PPE).<sup>25</sup> The reason is that the use of PPE for reducing exposure and of ensuring the safe use of the product is not considered acceptable for non-professional users. The Technical Note for Guidance on human exposure includes a scenario of spraying for amateur users without assuming the use of PPE.<sup>26</sup>

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<sup>24</sup> It should be noted that the CA-meetings have an advisory status while decisions are taken by the Standing Committee on Biocidal Products.

<sup>25</sup> Spraying method of wood preservatives for amateur users. 26th CA meeting, CA-Sept07-Doc.5.3 – Final

<sup>26</sup> Use of Personal Protective Equipment. 27th CA meeting, CA-May08-Doc.6.2

### Use restrictions on rodenticides

It has also been proposed to restrict the user category of anticoagulant rodenticides to professionals, for resistance control and because many of them are classified as PBT substances. Nevertheless, there is no general restriction at the Community level. Because of the very sensitive nature of this issue, Member States should be allowed to decide on use categories, especially restrictions of use categories on their own.

However, restrictions on the area of use to that in and around buildings have been proposed as option for preventing primary and secondary poisoning. These provisions could be combined with the category of users and the product design. It may, for instance, be possible to restrict the outdoor use of a given anticoagulant to professionals only, whilst the amateur use of the same anticoagulant in a ready-to-use product may be restricted to indoor use.

Provisions on the composition of the product may also be useful to reduce the risk of primary and secondary poisoning. Among these is the indication of a maximum concentration allowed in biocidal products and the inclusion of a bittering agent in formulations to reduce the risk of accidental ingestion, by children in particular. Similarly, the inclusion of a blue dye renders the product unattractive to non-target animals like birds. In addition, in cases of accidental ingestion, the presence of a dye may help to confirm that there has been ingestion and thus facilitate antidote treatment.

Because the choice of the most appropriate RMM is closely linked to the design, pack size, area of use, category of users, conditions of use and composition of the final product, according to the Commission the choice of specific RMM should be deferred to the product authorisation stage when all the details of the products to be placed on the market are available. The objective of Annex I inclusion should thus be to identify general RMM, which can apply to all products, as well as specific risks/hazards to be addressed at the product authorisation stage.<sup>27</sup>

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<sup>27</sup> RISK MITIGATION MEASURES FOR ANTICOAGULANTS USED AS RODENTICIDES. CA-March07-Doc.6.3 final – revised after 25th CA meeting

From the discussions at the CA meetings, it is clear that, although some Member States suggested that RMM should be harmonised at EU level through specific provisions in the Annex I inclusions, others and the Commission deferred these to the (national) product authorisation level.

#### 4.1.3 Evaluation of (draft) Inclusion Directives and Assessment Reports

Suitable measures to reduce risks are quoted in the Inclusion Directives. To date, several active substances of product types 8, 14 and 18 have been included in Annex I of Directive 98/8/EC. The Inclusion Directives describe different RMM which shall be considered during the authorisation of biocidal products containing these particular active substances<sup>28</sup>. Although this study focuses on active substances used in PT 8 and PT 18, the RMM described for other product types so far have also been evaluated, because they might provide further information on risk mitigation for biocides. The specific provisions for product authorisations available so far are summarised in table 1.

**Table 2: Provisions for product authorisations from the Inclusion Directives**

	Risk mitigation measures	Examples
<b>A) Placing on the market</b>		
User restriction	<p>Restriction of the use of the fumigant sulfuryl fluoride to <b>trained professionals</b></p> <p>Use of aluminium phosphide releasing phosphine fumigant only by <b>specifically trained professionals</b> (in the form of ready-for-use products for PT18) while applying appropriate RMM (personal and respiratory protective equipment, use of applicators).</p> <p>Restriction to industrial operators.</p> <p>Restriction to professional use only as potential RMM. *)</p>	<p>Sulfuryl fluoride, PT 8, 18</p> <p>Aluminium phosphide, PT 14, 18</p> <p>Trimagnesium diphosphide. PT 18</p> <p>K-HDO, PT 8</p> <p>Bromadiolone, Chlorophacinone Coumatetralyl Difenacoum Difethialone Flocoumafen (all PT 14)</p>
Intended uses and area of	<b>Restriction of use</b> of K-HDO for the treatment of wood that may enter in direct contact with infants.	K-HDO, PT 8

<sup>28</sup> [http://ec.europa.eu/environment/biocides/annexi\\_and\\_ia.htm](http://ec.europa.eu/environment/biocides/annexi_and_ia.htm)  
<http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=bpd>

application /	<p>Restriction of the use class for certain wood preservatives: No <b>in-situ treatment of wood</b> outdoors *)</p> <p>Restriction of the use class for certain wood preservatives for wood that will be in continuous contact with water or weathering allowed. *)</p> <p>Restriction of in situ treatment of wooden structures near water, where direct losses to the aquatic compartment cannot be prevented, or for wood that will be in contact with surface water.</p> <p>No treatment of areas where other burrowing mammals than the target species are present.’</p> <p>Member States shall assess outdoor use of phosphine releasing compounds before such application is granted.</p>	<p>Boric acid Disodium octaborate Propiconazole Tebuconazole Thiabendazole Thiamethoxam Tolyfluanid (all PT 8) Boric acid Disodium octaborat Propiconazole Clothianidin Tebuconazole Thiabendazole Thiamethoxam Tolyfluanid (all PT 8) Thiacloprid, PT 8</p> <p>Aluminium phosphide, PT 14</p> <p>Magnesium phosphide, PT 18</p>
Package size	Minimisation of primary and secondary exposure of humans, non-target animals and the environment to rodenticides by setting an upper limit to the package.	Bromadiolone Chlorophacinone Coumatetralyl Difethialone Difenacoum (all PT 14)
Design of the biocidal product mode of application	<p>Some rodenticides shall not be used as <b>tracking powder</b>.</p> <p>Limitation of nominal concentration of the active substance in the products of some rodenticides and authorisation of ready-for-use products only.</p> <p>For amateur uses, only ready-to-use products shall be authorised.</p> <p>Some biocidal products (in this case rodenticides) shall contain an aversive agent and, where appropriate, a dye.</p>	<p>Bromadiolone Difenacoum Flocoumafen Difethialone (all PT 14) Alphachloralose &lt; 40 g/kg Bromadiolone &lt; 50 mg/kg Chlorophacinone &lt; 50 mg/kg Coumatetralyl &lt; 375 mg/kg Difenacoum &lt;75 mg/kg Difethialone &lt;25 mg/kg (all PT 14) Indoxacarb, PT 18 Bromadiolone, PT 14 Difenacoum, PT 14 Difethialone, PT 14</p> <p>Difethialone, PT 14 Difenacoum, PT 14</p>
<b>B) Application of biocidal products</b>		
Equipment	<p>Restriction K-HDO as wood preservative to industrial use in <b>fully automated and closed equipment</b>. *)</p> <p>Minimisation of primary and secondary exposure to rodenticides by obligation to use tamper resistant and secured bait boxes. *)</p>	<p>K-HDO, PT 8</p> <p>Alphachloralose Bromadiolone Chlorophacinone Coumatetralyl Difenacoum Difethialone Flocoumafen (all PT 14)</p>
Personal protective equipment	Use of appropriate <b>personal protective equipment</b> for reducing human exposure at industrial and/or professional use to certain wood preservatives.	Most wood preservatives

	Appropriate RMM for operators and bystanders exposed to the fumigants.	Sulfuryl fluoride, PT 8, 18
	Use of phosphine releasing fumigants only while using appropriate personal and respiratory protective equipment, use of applicators	Aluminium phosphide, PT 14, 18
Further RMM	Removal of all food items.	Sulfuryl difluoride, PT 18
	Minimisation of the potential exposure of humans, of non-target species and of the aquatic environment. Products shall not be placed in areas accessible to infants, children and companion animals.	Indoxacarb, PT 18
<b>C) Post application</b>		
Storage of treated wood	<b>Storage</b> of timber freshly treated with wood preservatives under shelter or on impermeable hard standing surfaces to prevent direct losses to soil or water.	IPBC Boric oxide Clothianidin Dichlofluanid Fenpropimorph Propinconazole Tebuconazole Thiabendazole Thiamethoxam Tolyfluanid (all PT 8)
Waiting period	After potential exposure to food, adherence to waiting periods which ensure MRLs set out in Regulation (EC) No 396/2005.	Aluminium phosphide, PT 18 Magnesium phosphide, PT 18
Disposal	<b>Collection</b> of any losses of wood preservatives for reuse or disposal.	Most wood preservatives
Drainage	Minimisation of the potential exposure of the aquatic environment by <ul style="list-style-type: none"> <li>• Products shall be positioned away from external drains.</li> <li>• Unused products shall be disposed of properly and not washed down the drain.</li> </ul>	Indoxacarb, PT 18
Wastewater treatment	Waste waters containing acrolein shall be monitored prior to discharge. Where necessary waste waters shall be held in suitable tanks or reservoirs or appropriately treated before discharge	Acrolein, PT 12
<b>D) Further regulatory options</b>		
Comparative risk assessment	Some rodenticides are subject to a comparative risk assessment due to their identified risks.	Bromadiolone Chlorophacinone Coumatetralyl Difenacoum Difethialone Flocoumafen (all PT 14) Acrolein, PT 12 Alphachloralose, PT 14 Aluminium phosphide, PT 14, 18 Boric acid, PT 8 Boric oxide, PT 8 Clothianidin, PT 8 Disodium octaborate, PT 8 Indoxacarb, PT 18 K-HDO, PT 8
Population exposed	Member States shall assess the populations that may be exposed to the product and the use or exposure scenarios that have not been addressed at the risk assessment	
Monitoring	Monitoring of sulfuryl fluoride concentrations in remote tropospheric air	Sulfuryl fluoride, PT 8, 18

\*) Condition may be modified according to the outcome of a risk assessment

While only a limited number of active substances has been included in Annex I of the BPD, far more draft Competent Authority Reports (CARs) are currently being discussed at the Community level. Parts of the reports (Doc I) are considered non-confidential and therefore available to the public.<sup>29</sup> Although most of these CARs are still not finalised and therefore might be subject to amendments, the RMM described there have been analysed in detail within another project (Gartiser et al. 2010).

## **4.2 Transferability of measures proposed for pesticides to biocides**

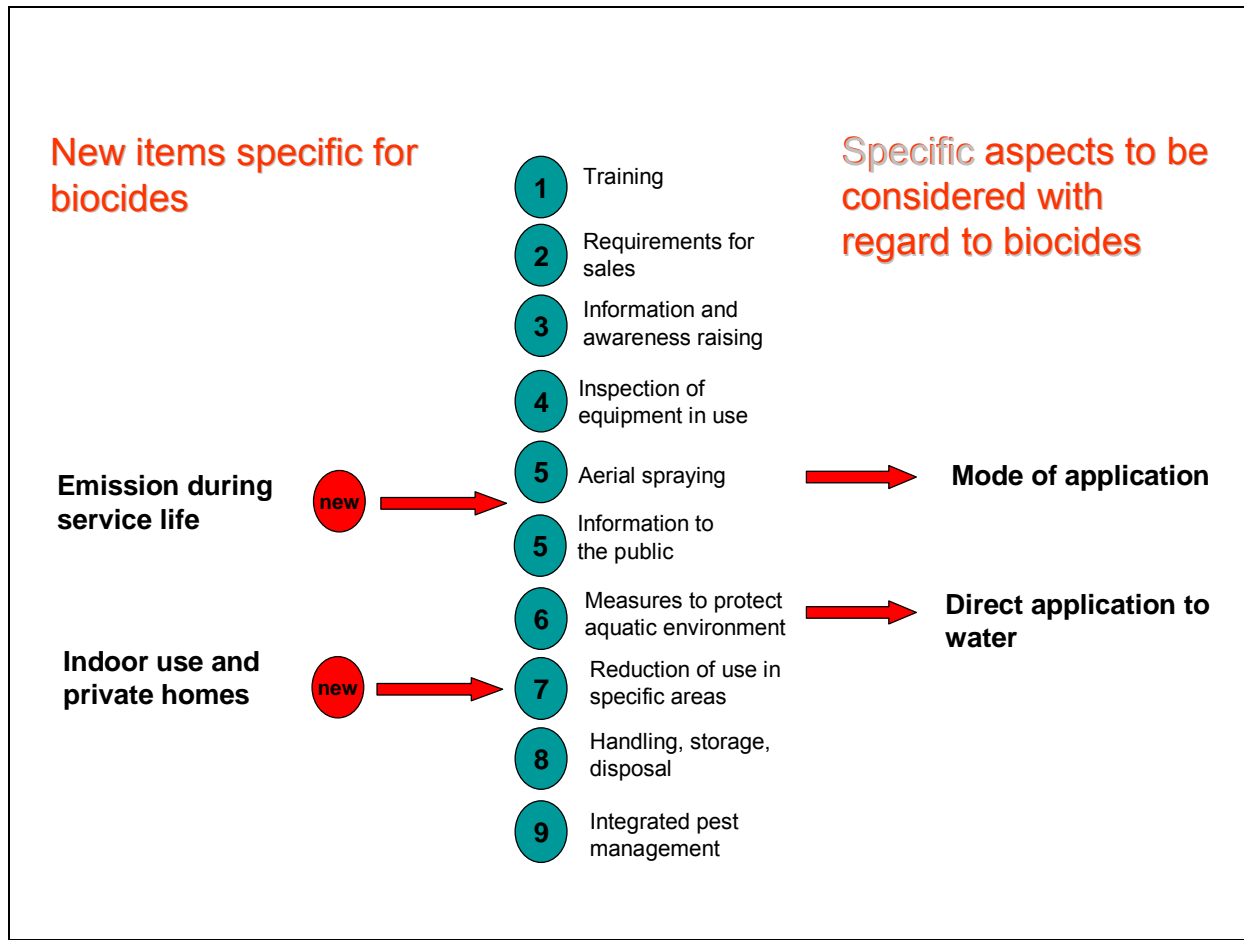
The analysis of transferability of measures proposed for pesticides to biocides follows a systematic approach, based on the general structure imposed by the corresponding articles of the Framework Directive 2009/128/EC on sustainable use of pesticides. This structure is partly extended or adapted according to the specific needs for the sustainable use of biocides. The objective of this approach is to have a common structure for the evaluation of general measures to be considered for all biocides. The same structure will also be used for deriving specific measures for certain product types and detailed measures for selected application scenarios in the case studies. Additionally, the analysis identifies which measures proposed for plant protection products are not transferable to the biocide sector.

### **4.2.1 Overview**

The following overview describes measures proposed in the “Thematic Strategy on the Sustainable Use of Pesticides” and their potential for transfer to the biocides area. The elements referred to in figure 5 are analysed more in detail in the corresponding subchapters.

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<sup>29</sup> [http://circa.europa.eu/Public/irc/env/bio\\_reports/library?l=/review\\_programme/ca\\_reports/pt18\\_insecticides&vm=detailed&sb=Title](http://circa.europa.eu/Public/irc/env/bio_reports/library?l=/review_programme/ca_reports/pt18_insecticides&vm=detailed&sb=Title)



**Figure 5: Elements of sustainable use of biocides (Overview)**

Most instruments implemented by Directive 2009/128/EC for Plant Protection Products also apply to the use of biocides.

Moreover, the form of the biocide (e.g. type of formulation) and the mode of application often determine human exposure and emission to the environment and should be considered. As biocides are often applied indoors in private homes or public facilities, the exposure of operators, bystanders and pets during the application needs to be considered with regard to a sustainable use of biocides.<sup>30</sup> Indoor use and private homes could thus be considered as “sensitive areas”. Another element specific for preservatives is the service life. It is known that leaching of wood

<sup>30</sup> This is proven e.g. by the fact that house dust still contains considerable amounts of very old biocides such as Chlorpyrifos, DDT, Hexachlorobenzene, Lindane, and Pentachlorophenol, which have been banned since years (Müssig-Zufika et al., 2008).



preservatives, masonry biocides or antifouling agents through leaching during the service life is of more relevance than during the application.

The transferability of these elements of the Thematic Strategy on pesticides to biocides is discussed more in detail below.

#### **4.2.2 Training (Article 5)**

The use of good practice reference documents and standards, in particular with respect to the training and certification of professional users, was identified as an essential measure for the sustainable use of biocides in the COWI study.

Training and/or certification of professional users could be envisaged as obligatory for certain PTs, including pest control (PT 14, 15, 18, 23) or disinfection in public facilities with relevance on human health (PT1-5).<sup>31</sup> For other PTs, like PT 8 and 21, the best practice application of biocides could be included in the curricula for training of professionals. For non-professionals, information campaigns to raise the awareness of the public are another means of preventing and/or reducing improper use of biocides. See also awareness programmes, Article 7.

Professional education and training for pest control workers (PT 14, 15, 18, 19, and 23) and for public health operators (PT1, 2, 5) already exists. For example, the curriculum for the training of pest controllers includes:<sup>32</sup>

Safety and occupational health, relevant laws, information sources, operational procedures, use and maintenance of equipment, handling and use of hazardous chemicals and pest control agents, RMM to avoid exposure of operators and bystanders, avoidance of environmental contamination, monitoring of pests, planning and realisation of pest control measures, consultancy of customers, quality assurance.

Many of these elements correspond to the items described in Annex I of Directive 2009/128/EC of sustainable use of pesticides. Training for pest controllers is a three-year program in Germany.

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<sup>31</sup> In some MS (e.g. Germany) biocidal products of PT 15, 17 and 23 may not be authorized by national law and are excluded from the mutual recognition procedure.

<sup>32</sup> [http://www.gesetze-im-internet.de/bundesrecht/sch\\_dlbekausbv/gesamt.pdf](http://www.gesetze-im-internet.de/bundesrecht/sch_dlbekausbv/gesamt.pdf)

In other biocidal application areas, professional associations and research institutes offer training measures for professional users. Some examples are:

- The Paper Technology Foundation (Papiertechnische Stiftung, PTS) offers research and consultancy for the paper industry and organises seminars, workshops and symposia in the fields of chemical and water management, surface technology etc.<sup>33</sup>
- The Association of the Lubricant Industry (Verband Schmierstoff-Industrie e.V., VSI,) has several working groups dealing with the use of cooling lubricants and publishes application guides for uses.<sup>34</sup>
- The German Association for Wood Research (Deutsche Gesellschaft für Holzforschung e.V.) publishes numerous guidance documents on best practices in wood protection and biocide application.<sup>35</sup>
- The German Pest Operator Association (Deutscher Schädlingbekämpfer-Verband e.V., DSV) offers training and education measures to their members and also develops technical standards for pest control (TRNS).<sup>36</sup>

The Confederation of European Pest Control Association (CEPA) published the Roma Protocol in April 2008, a commitment to professional standards for the European pest management industry. This envisages a certification system for companies or individuals, as well as the development of CEN (European Committee for Standardisation) standards describing criteria for the quality of services. Training and periodic updating in technical, commercial, administration and customer services issues is required to obtain and maintain an authorisation. The training includes lectures on biology and entomology, characteristics of general biocidal products, risk management, environmental impact assessment procedures, consumer awareness campaigns as well as operator safety measures (CEPA 2008). According to CEPA, some 38.000 persons are employed in about 6.800 European pest control companies. They have a total turnover of 1.501 million EUR. Rodent and insect controls are the largest segments, representing 78% of the turnover of all activities (CEPA 2003). In 1998 CEPA reached agreement with the European Commission to work on a training programme for the industry. The objective was to create a basic

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<sup>33</sup> <http://www.ptspaper.de>

<sup>34</sup> <http://www.vsi-schmierstoffe.de>

<sup>35</sup> <http://www.dgfh.de/>

<sup>36</sup> <http://www.dsvonline.de>

training tool in the form of a manual and a CD, which would help co-ordinate training across Europe.

According to CEN, the upcoming work proposal by CEPA will not address the issue of pest control itself, but the services offered and performed by pest controllers as well as the qualification needed and relevant curricula. In July 2010, a new project committee on “services of pest management companies” was adopted (CEN/TC 404). The first meeting of the project committee was scheduled for the 2<sup>nd</sup> of December 2010. The time frame for standard development is three years from the date of the acceptance of the proposal by the CEN Members. No draft working document is available to date.<sup>37</sup>

### Conclusions:

There are several ongoing national activities for education and training of professional users, established by professional associations and research institutes. It seems that guidance development on best practices as basis for training measures takes place only at national level. For this reason, it seems difficult to obtain an overview of the various activities in member states.

The only European activity known is that of CEPA for pest control services. A German technical standard of the pest control operator association is available. While education and training clearly need to be embedded in national (or local) engagement, there is clearly a lack of exchange of knowledge and expertises among Member States.

### **4.2.3 Requirements for sales (Article 6)**

The application of Article 6 of Directive 2009/128/EC on sustainable use of pesticides to the distribution of biocides through certified distributors, providing adequate information to customers, would be an effective instrument for improving sustainable use. The Directive stipulates that non-certified distributors or retailers may not sell biocidal products classified as toxic (T), very toxic (T+) or harmful (R40, R62, 63, 68) or oxidising (O) or extremely flammable (F+). These rules have already been

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<sup>37</sup> Personal communication of Ms Maitane OLABARRIA UZQUIANO, CEN - European Committee for Standardization from 08.11.2010

implemented into German law.<sup>38</sup> Self service sale of any plant protection product is prohibited in Germany, according to § 22 Abs. 1 of the plant protection law (Pflanzenschutzgesetz), irrespective of their classification. Therefore, plant protection products in supplying stores are shelved in locked cupboards and customers have to ask certified staff when purchasing pesticide products. To obtain relevant authorisation, sales people have to attend seminars (two days) and pass an exam.<sup>39</sup> These provisions could be extended to cover/include biocides for consumer use. In Germany these are sold in open shelves through self service or internet commerce. Some biocidal products, for example disinfectants for hands, surfaces or laundry (intended for human health purposes) could be distributed via pharmacies to the general public in order to obtain advice on the application of these products and on general hygiene requirements. Biocides for professional use are generally distributed via other supply chains where these provisions do not apply. Here often the suppliers' field staff advise their customers which biocidal product to apply. The qualifications of these distributors could also be certified, according to the requirements of Directive 2009/128/EC.

The German working group on chemical safety of the federal and federal states authorities published a guidance document on good practice for internet chemical commerce (BLAC 2009). This refers to legal requirements, such as indication of the hazardous properties of substances and mixtures which lead to a classification into risk-phrases (in future: hazard classes) according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Additionally, recommendations beyond the legal requirements are described. For example, it is recommended to publish the safety data sheets and product leaflets on the internet, as is already done by many companies. Customers should be asked to confirm their attention to safety measures before purchasing hazardous products. A reference on the package label to the web-site providing further information, such as safety data sheets, is useful. The website should inform customers that carcinogenic, mutagenic or reproductive toxic substances of categories 1 and 2 (in future 1a and 1b) must not be delivered to private users and that toxic and very toxic substances must only be sold to competent and experienced customers (private or commercial). A reference

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<sup>38</sup> ChemVerbotsV - Chemikalien-Verbotsverordnung vom 13. Juni 2003, last amendment 21.08.08

<sup>39</sup> Pflanzenschutz- Sachkundeverordnung vom 28. Juli 1987, last amendment on 7.5.2001 S. 885

of acceptable verification and/or certification schemes is recommended. The retailer must keep account of the recipients (BLAC 2009).

Article 6 of Directive 2009/128/EC also requires distributors selling pesticides to provide adequate information to customers as regards pesticide use, health and environmental risks and safety instructions both to professional and non-professional users. Essential information documents to be provided to professional customers are the safety data sheet and product leaflets. Private customers have to be informed adequately via the product label, in particular on hazards, exposure, proper storage, handling, application and safe disposal.

For rodenticides, the Inclusion Directives prescribe an upper limit to the package size as RMM in order to minimise primary and secondary exposure of humans, non-target animals and the environment. In Germany, the packaging size of wood preservatives for non-professionals has been limited to 750 ml, according to a voluntary agreement with industry.<sup>40</sup> In fact, lower amounts of wood preservatives supplied to consumers can be considered as a RMM to avoid extensive use indoors (see DIN 68 800-3).

#### Conclusion:

The requirements for sales of biocides could be adapted to those proposed for plant protection products as envisaged in Directive 2009/128/EC on sustainable use of pesticides. Some exemptions might apply for biocides where no risks have been identified. For example disinfectants used for drinking or swimming water treatment in the public health sector may be assumed to be applied by trained professional users. There also exist provisions for best practice of internet commerce but doubts remain whether these are followed.

#### **4.2.4 Information an awareness-raising (Article 7)**

Raising awareness of the general public (non-professional users), as well as of professional applicants, is essential for the proper use of biocides. Information about best practices, occupational health campaigns, promotion of so-called ecolabels, and the information system on biocides (web-based and print media based) are examples of suitable programmes to be established in NAPs.

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<sup>40</sup> [http://www.holzfragen.de/seiten/pop\\_biozide.html](http://www.holzfragen.de/seiten/pop_biozide.html)

The addressee of awareness programmes is the general public, to which accurate and balanced information relating to the risk of biocides arising from their use, their service life (e.g. treated articles) and the use of “low risk products” and non-chemical alternatives should be provided and promoted.

For both, private users and professionals, the product label and additionally application instruction documents are the primary information sources. Quality and completeness of label and instruction documents are therefore essential. The classification, packaging and labelling of biocidal products according to Article 20 of the BPD can be regarded as minimum requirements. However, a general limitation concerning the labelling of biocidal products is the limited space available for the labels on the packages of many ready to use products. Additionally, some suppliers misspend the limited space for multilingual instructions, the text being unreadable for many users. In interviews with pest controllers, it has been suggested that the product labels, application instructions and safety data sheets should be evaluated together with the authorisation or registration of the respective products.<sup>41,42</sup>

In addition to these minimum requirements already imposed by the Biocidal Product Directive, raising awareness of the general public (non-professional users) as well as of professional users is essential for proper use of biocides. The following programmes could be envisaged:

- Information gathering and documentation of best practices
- Occupational health campaigns by employer's insurance associations or authorities.
- Promotion of ecolabels with application of biocides
- Information system on biocides (web-based and print media based) and alternative measures

The quality of information is also dependent on the development of best practices or IPM tools (see 3.2.10).

The Framework Directive 2009/128/EC on sustainable use of pesticides requires MS to provide information about the health and environmental effects of pesticides and

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<sup>41</sup> Personal communication Dr. Harald Fänger Killgerm GmbH, Neuss, Germany.

<sup>42</sup> A draft label is part of the obligatory data package for product authorisation according to Article 8 of Directive 98/8/EC.

about non-chemical alternatives. In Germany a web-based information system (web portal combined with print media) has been established for the general public ([www.biozid-portal.de](http://www.biozid-portal.de)). The special portal developed and run by the Federal Environment Agency ([www.biozid.info](http://www.biozid.info)) is a part of the information system and aims to provide information to the general public about physical, chemical and other measures as alternatives for the use of biocidal products or for minimization of their use, the focus lying on the description of preventive measures.

#### Conclusion:

The requirement for MS to develop and establish awareness programmes is an important instrument for supporting sustainable use of biocides and should be considered in NAPs.

#### **4.2.5 Inspection of equipment in use (Article 8)**

For biocides, dosing apparatus' for the preparation of a disinfectant solution from concentrates can be distinguished from the equipment for application/distribution. Several national standards for equipment for biocide application have been identified in MS, including those for the application of biocides in PT 1-5, 8, and 18.

The draft amendment Directive on machinery for pesticide application of September 2008 included in its definition machinery for the application of both plant protection products and biocidal products for pest control, belonging to PT 14 through PT 19. However, the European Parliament voted against this in April 2009. This was done with the argument that the Framework Directive (now Directive 2009/128/EC) applies to plant protection products only and, therefore, its scope should be limited to plant protection products. In consequence, Directive 2009/127/EC on Machinery for Pesticide Application does not yet consider biocides. However, it is anticipated that the scope of Framework Directive 2009/128/EC will be extended to cover biocidal products. An extension of the scope of the environmental protection requirements to machinery for the application of biocidal products will likely be examined by the European Commission by 31 December 2012.

As Directive 2009/128/EC on sustainable use of pesticides allows derogation from the certification of application equipment for plant protection products for handheld pesticide application equipment or knapsack sprayers, or application equipment that

represent a very low scale of use, it is questionable whether all biocide application equipment would fall under a future Machinery Directive including biocidal products application equipment. However, the Thematic Strategy requires a risk assessment for applying the equipment being exempted. Manual pressure aerosol or trigger sprays which are used for both plant protection and biocidal purposes, primarily by consumers, have not been considered within the Machinery Directive so far. Thus no existing standards are known.<sup>43</sup> By contrast, several standards have been and are being developed for knapsack sprayers and compressed air sprayers (with compressor) which are also used in both sectors (Herbst et al. 2002). The following examples from ISO Technical Committee TC 23/SC 6 and CEN have been identified (taken from the ISO and CEN Websites)<sup>44</sup>:

- ISO 19932 part 1 and 2: 2006: Equipment for crop protection -- Knapsack sprayers -- Part 1: Requirements and test methods, Part 2: Performance limits
- EN 12761 part 1 and 2: 2001: Agricultural and forestry machinery - Sprayers and liquid fertilizer distributors - Environmental protection - Part 1: General, Part 2: Field crop sprayers
- EN ISO 28139:2009: Agricultural and forestry machinery - Knapsack combustion-engine-driven mistblowers - Safety requirements (ISO 28139:2009)

Other national and European Directives on product safety already apply to biocidal application equipment or packaging:

#### Aerosol dispensers Directive 75/324/EEC (amended by Directive 2008/47/EC)

Aerosol dispensers are non-reusable containers mainly made of metal containing a compressed gas with liquids, paste or powders allowing the contents to be ejected as solid or liquid particles. In the biocide sector their use is very common. Aerosol dispensers are used for the application of disinfectants (PT 1, 2, 3, 4), preservatives (8, 10), pest control agents (PT 18, 19) and others (PT 21). For metal aerosol dispensers the Directive limits the total volume of the container to 1000 mL. The safety provisions refer to general aspects like maximum pressure allowed, bursting under higher temperature, flammability of the content and labelling of the containers. Use related provisions like the size of the droplets are not considered

#### Dosing systems

National standards for dosing apparatus' exist for specific applications, for example in hospital hygiene as well as in the treatment of drinking and swimming water. However no international standards are available. As well as disinfectants, dosage systems are used in many other applications where biocide concentrates have to be diluted (especially in PT 11, 12, 13).

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<sup>43</sup> Personal communication Dr.-Ing. Heinz Ganzelmeier, Justus-Kühne-Institut, Germany from 07.09.2009

<sup>44</sup> <http://www.iso.org/iso/home.htm>; <http://www.cen.eu/cenorm/homepage.htm>



### High pressure cleaner

High pressure washers and steam cleaners are often used for the application of surface disinfectants. An international standard on safety requirements exists, but focuses primary on the electrical installation (EN 60335-2-79).

### Impregnating vessels for wood preservatives

Vessels for pressure treatment of wood using water-soluble impregnating agents or coal tar oil (creosote) fall under the Pressure Equipment Directive (97/23/EC) and the Machinery Directive 2006/42/EC. There are several impregnation efficiency standards of industrial or public associations, but no international standards on the construction of these vessels.

### Conclusion:

The availability of appropriate equipment for the application of biocides is an important instrument for the minimisation of exposure and targeted dosage of biocides and providing for secure and proper use. The Directive on Machinery 2006/42/EC should be amended to include machinery and equipment for the application of biocides. Initiatives for harmonisation and standardisation of the machinery for biocide application only exist in rudimentary form.

#### **4.2.6 Prohibition of certain modes of application (Adaptation of Article 9)**

The Framework Directive 2009/128/EC specifically quotes aerial spraying as a mode of application to be restricted. As aerial spraying of biocides is actually used to control mosquitoes and oak procession moths (see below), it is appropriate to consider a prohibition on aerial spraying of biocides.

In the biocide area, the physical form of the biocide and the mode of application are of major relevance. For example, spraying of insecticides indoors might cause higher exposure to humans and the environment than their application as bait. Therefore, this instrument should be amended to cover other modes of application of biocides.

### Prohibition of aerial spraying

In the present study, two scenarios have been identified where biocides are being applied on a large scale from helicopters.

These are the application of *Bacillus thuringiensis* toxins through helicopters in the Upper-Rhine area for mosquito control and the control of oak procession moths (*Thaumetopoea processionea*) in oak forests, the fine hairs of which can cause allergic reactions in sensitive individuals. In both cases, aerial spraying should only be allowed as a last resort by way of derogation, where it offers clear advantages compared to other application methods. According to proposals from the environmental authorities, it has to be considered whether possible risks to human health from certain pests could also be controlled by preventing people from entering infested areas. If this is possible, this option has to be selected. People could also be protected against mosquitoes by keeping them away from river banks, and sensitive individuals should avoid oaks as long as the hairy canker worms are around.

Large scale mosquito control or the control of oak processing moths by conventional insecticides might have considerable impacts on the environment and should be avoided from an ecological point of view. There are applications with lower environmental concern, such as the use of *Bacillus thuringiensis* toxins, which might be exempted from a general prohibition.

#### Prohibition of spray applications or fogging by non-professional users

The restriction of spraying application of wood preservatives to professional users has been rejected at the competent authority meetings (see 3.1.2).

In a German study on occupational exposure to insecticides, safe use of total release foggers (one-shot aerosol cartridges) by non-professionals has been questioned (Schneider et al. 2008). These products are also available to the general public (e.g. in pet shops and on-line orders in internet stores). Indoor foggers are used to apply biocides against infestations by fleas (from pets). They have residual efficacy (up to 6 months).

#### Other restrictions in the modes of application

The limitation of tracking powders as rodenticides is already considered in the inclusion directives of some rodenticides. Here, the use of tracking powder is restricted for some active substances. Other examples are the need for fumigants to be applied only by specifically trained professionals or the authorisation of only ready-for-use-products for non-professional uses.

### Conclusions:

There are biocidal modes of application which may result in considerable human and/or environmental exposures. These should be considered for use restriction measures. According to Directive 2009/128/EC on sustainable use of pesticides, aerial spraying should be prohibited in general. Derogations are possible if there are no alternatives available or if aerial spraying is likely to result in lower risks compared to other spraying methods. The pesticides used must be explicitly approved for aerial spraying. Relevant provisions can immediately be adjusted to include biocides.

Considering other modes of application, there is a close relationship to the user category (professional, non professional). Only for some rodenticides, insecticides and wood preservatives has the mode of application been restricted (no tracking powder but baits, fumigants restricted to certified professionals). This is already considered in several inclusion directives. To date, there are no proposals for certain modes of application to be restricted for a whole PT.

#### **4.2.7 Emission during service life (New Article)**

Instruments for reduction of environmental emissions during service life are not considered in Directive 2009/128/EC on sustainable use of pesticides, because here it cannot be distinguished from the application phase. However, for biocides used for preservation of materials (PT 6-10) and antifouling agents (PT 21), a considerable proportion of the total emissions take place during the service life, through leaching or the removal of coatings or treated articles. Therefore, in contrast to plant protection products, the service life of biocidal products should be considered in detail in addition to the use phase. Measures to be considered for risk reduction during the service life are the restriction of the use class of certain wood preservatives, requirements for the processing of treated articles or for the removal of biocide coatings.

#### **4.2.8 Information to the public (Article 10)**

Framework Directive 2009/128/EC in Article 10 specifically addresses provisions on informing persons who could be exposed to the spray drift (both aerial and boom sprayers). Few scenarios of large scale biocidal aerial applications have been identified. This measure may therefore be adapted as follows:

Considering information requirements to the general public, as biocides are often applied in the surroundings of human habitats, exposure of bystanders might be important. In contrast to plant protection products, the problem of residential bystander exposure to biocides also arises. This covers people exposed to the residues in the air and on surfaces in the house after biocide application. Additionally, biocides often are applied by non-professionals.

Therefore providing further information on safe use of biocides, preventive or non-chemical control measures to the general public would be a suitable instrument of sustainable use of biocides. This could be combined with programmes for awareness raising (see article 7).

The RMM guidance document for anticoagulant rodenticides already states that, when the product is being used in public areas, the areas treated must be marked during the treatment period. A notice explaining the risk of primary or secondary poisoning by the anticoagulant, as well as indicating the first aid measures to be taken in case of poisoning, must be made available alongside the bait.<sup>45</sup>

#### **4.2.9 Specific measures to protect the aquatic environment and drinking water (Article 11)**

The requirement of Directive 2009/128/EC, that preference should be given to products that are not dangerous for the aquatic environment when pesticides are used in the vicinity of water bodies, can immediately be transferred to the biocide sector. For example, Diflubenzuron (classified as dangerous for the environment) is the preferred active substance for oak processing moths instead of *Bacillus thuringiensis* (not dangerous for the environment), mostly for economical reasons (Anonymous, 2008).<sup>46</sup>

Directive 2006/118/EC on the protection of groundwater against pollution and deterioration defines Pollutant Quality Standards, among them thresholds for active substances in pesticides (plant protection products and biocides) and their relevant metabolites, degradation and reaction products: 0.1 µg/l (per single substance) and

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<sup>45</sup> <http://ec.europa.eu/environment/biocides/pdf/anticoagulants.pdf>

<sup>46</sup> Supply cost for the active substances Diflubenzuron is 5 EUR/ha and for *Bacillus thuringiensis* is 150 EUR/ha. However also other factors apply: For a successful BTI application moderate temperatures are required and it must not rain for 48 h. Additionally the survival rate of oak processing moths is higher when applying BTI (Anonymous 2008).

0.5 µg/l (total). In principle, the Water Framework Directive as well as the concept of drinking water protection zones refer to both plant protection products and biocides. The establishment of groundwater protection zones for drinking water exploitation is one example where the application of toxic substances, fertilizers, plant protection agents, etc., is restricted or forbidden in order to protect the quality of water resources.

Annex X of the Water Framework Directive 2000/60/EC (WFD) identifies priority substances for which a progressive reduction of emissions to water is intended. Among them are several biocides which a) are supported for Annex I inclusion (Isoproturon (PT 7, 9-12), Diuron (PT 7, 10), Naphthalene (PT 19); b) have been withdrawn from the review programme (Chlorpyrifos, Lindane); or c) have been identified for potential biocidal purposes but have not been notified (Endosulfan, Hexachlorocyclohexane, Pentachlorophenol, Simazine, Trichloromethane). The overlap with plant protection active substances is evident. These priority substances are included in monitoring programmes. Directive 2008/105/EC describes environmental quality standards (EQS) for these 33 priority substances / substance groups.

The process for including further priority substances in Annex X of the WFD is ongoing. Annex III of Directive 2008/105/EC indicates further substances that are subject to review for possible identification as priority substances. Among them are Dicofol, which has been identified but not notified, and “free cyanide”, which is released from the use of hydrogen cyanide (fumigant supported in the Review programme).

The Commission contracted a study on monitoring-based prioritisation of further potential priority substance candidates (James et al. 2009). From 316 substances selected as candidates for prioritisation, monitoring data were analysed and predicted no effect concentrations (PNEC values) in water, sediment and/or biota were derived. Priority was assigned according to risk ratios, i.e. PEC/PNEC. Forty-four organic substances have been selected for further evaluation. Among these are several substances which have been identified or notified as biocidal actives (see table 3)

**Table 3: Biocidal candidates for selection as priority substances**

Identified biocidal active substances	Notified active substances	
Malathion *, Dicofol, Phoxim, Pirimiphosmethyl *, Trichlorfon *, Fenthion, Chlorpyrifosmethyl, Methoxychlor, and Chloroacetic acid *	Permethrin *	PT 2, 3, 6, 8, 9, 18
	Cypermethrin	PT 8, 9, 18
	Deltamethrin *	PT 18
	Dichlorvos	PT 18
	Fenitrothion *	PT 18
	Diazinon *	PT 18

Those biocidal active substances which have only been identified as such, but are no longer being supported in the review programme for existing biocidal active substances, must not be marketed for biocidal use. There is, however, the possibility to reintroduce them as new active substances for evaluation. Some substances, marked with an asterisk (\*) have been identified as candidates for de-selection. These need further investigation, because only limited monitoring data were available.

In addition to this research project, the European Chemicals Bureau coordinates an advisory group to the European Commission which is developing a new concept for an optimised prioritisation strategy for future ranking. For substances for which monitoring data are not available at the required quality level, a modelling-based approach to assess potential exposure needs to be implemented. Information such as overall tonnage used, proportions of this tonnage going to particular uses and emissions from these uses may be used as input to a simple partitioning model (Lepper et al. 2008).

It is expected that, as a result of all these activities, about 10-20 priority substances will be selected for inclusion in Annex X of the WFD by January 2011.<sup>47</sup>

As a result of the literature review of this study (Annex I), existing lists of priority substances do not specifically consider biocides and monitoring of only these substances seems not to be appropriate for identification of deficiencies in the sustainable use of biocides. Those biocides included in these lists have mainly been banned and their occurrence in the environment is due to application in the past.

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<sup>47</sup> Personal communication Dr. Joachim Heidemeier, German Environmental Agency from 26.10.09

Conclusions:

The requirements of the Water Framework Directive, as well as the concept of drinking water protection zones, apply to both plant protection products and biocides. Additional measures might be envisaged where biocides are directly emitted to the environment, such as cooling water biocides (see 3.2.8). The identification of further priority substances and their monitoring in the environment is a prerequisite for setting environmental quality criteria (see Annex I).

**4.2.10 Reduction of use or risks in specific areas (Article 12)**

Similarly to plant protection products, the use of biocides should also be prohibited or restricted to the absolute minimum necessary in areas used by the general public or by sensitive populations, or in areas assigned to the conservation of wild birds, natural habitats and of wild fauna and flora. In this context, the aquatic environment and drinking water can also be regarded as sensitive areas (see Article 11). The following outdoor applications or uses have been identified in this regard:

- Wood preservatives used for fences or other construction facilities (e.g. cabins, jetties) in sensitive areas.
- Rodenticides used for open application outside of buildings. Here the protection of non-target organisms (pets and wildlife) is of major concern. Through suitable product design, like bait, environmental release of the active ingredient should be minimized.
- Cooling water biocides applied in cooling systems which discharge to water bodies within the sensitive area.
- Insecticides applied for mosquito control and against oak procession moths should be prohibited in sensitive areas (with exemptions after careful evaluation of all alternatives).
- Disinfectants and insecticides applied in stables which are released to manure storage systems may be prohibited in sensitive areas
- Antifouling agents are released during the application, use life and removal stages. Antifouling agents should only be applied if there is a really a need and should be prohibited, especially for private use, in case of an adverse risk/benefit ratio.
- Treatment of liquid manure with larvicides (insecticides) followed by manure application to soil as a fertiliser.

In addition, the disinfection of wastewater, bathing water, algacides for water pools and aquariums (PT 2), piscicides (PT 17, not allowed in most MS) may lead to emissions to water bodies. Biocides used for general disinfection (PT 2) and water

processing (PT 11, 12, 13) may also be emitted indirectly after passing through a municipal treatment plant. Surface water can be regarded as a sensitive area per se.

Many biocides are applied by private users in their homes (especially PT 1, 2, 18, 19). For biocides used indoors, the protection targets are humans and pets. Here also the problem of residential bystanders to biocides arises. Other biocides are applied in the surroundings of homes (PT 14). Therefore, private homes could be considered as a “sensitive area” from a human health view.<sup>48</sup>

### Conclusions:

There are biocidal applications which cause direct emissions to the environment. There are examples where biocidal uses in sensitive areas should be prohibited in general (e.g. private use of antifouling agents, wood preservatives, emission of cooling water biocides). An assessment of potential measures of sustainable use for some of the most relevant applications is part of the case studies (see Annex II - IV).

#### **4.2.11 Handling and storage of biocides and their packaging and remnants (Article 13)**

The general rules for storage and transport of chemicals as described in national guidelines such as TRGS 510 should be considered.<sup>49</sup>

Most aspects concerning the handling and storage of pesticides and their packaging and remnants also apply to biocides.

- Use of appropriate sizes of containers to minimize remnants. Oversizing of packages should be avoided
- Restriction of the use of concentrates in order to avoid exposure during the mixing and loading stages, where the risk of spillage and leakage is increased
- Restriction of the marketing of concentrates to professional users only. Marketing of ready-to-use products to non-professional users.
- Use of water soluble packaging for preparing working solutions while avoiding direct contact and enabling accurate dosing
- The establishment of a recycling system for packaging used for biocides

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<sup>48</sup> Directive 2009/128/EC defines sensitive areas as Natura 2000 sites or other places such as public parks and gardens, sports and recreation grounds, school grounds and children’s playgrounds, and in the close vicinity of healthcare facilities, where the risks from exposure to pesticides are high.

<sup>49</sup> TRGS 510 Storage of hazardous substances in non-stationary containers. October 2010  
<http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/TRGS-510.html>



In general, the packaging size and the quantity of the product should reflect its intended use. Oversized packages should be avoided, as they are likely to result in unused biocide residues. For the general public, the size of biocidal product packages should generally be smaller than for professional applicants. For example, in Germany, the packaging sizes of wood preservatives for use by non-professionals have been limited to 750 ml in a voluntarily negotiated agreement with the industry.<sup>50</sup>

The use of concentrates by non-professionals should be avoided in order to avoid exposure at the mixing and loading stage. Thus, the marketing of “ready-for-use” biocidal products should be given preference. The Inclusion Directives for most rodenticides limit the concentration in order to prevent (or at least reduce the risk of) poisoning of pets and other non-target organisms.

The use of water soluble packaging has been suggested for some biocide applications such as swimming pools, toilet tanks and recirculating water cooling systems<sup>51</sup>. There are a few biocidal products, especially wood preservatives, on the market which use water soluble packages. These systems allow preparation of working solutions from sealed concentrates.

In Germany, the responsibility of the supplier for the collection of packing and remnants of biocides is only applied to larger packages, such containers for antifouling agents or wood preservatives. Here, Directive 1999/13/EC on volatile organic compounds (solvents) has provided the legislative basis for these re-collection systems (workshop protocol “sustainable use of biocides”, Berlin, 25.2.2010).

For most biocidal products, residues should be collected by municipal collection systems for hazardous substances. The question of whether empty packages should be separately collected depends on the contamination of the packaging and the active substances used. For some applications, such as large barrels of wood

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<sup>50</sup> [http://www.holzfragen.de/seiten/pop\\_biozide.html](http://www.holzfragen.de/seiten/pop_biozide.html)

<sup>51</sup> <http://www.patentstorm.us/patents/5851406/description.html>

preservatives, the packages might be returned to the supplier, following the example of plant protection products.<sup>52</sup>

### Conclusions:

The disposal of product residues and packages by municipal collection systems for hazardous substances should be facilitated/promoted. For some applications, the packages might be returned to the supplier, following the example of plant protection products. Due to the broader range of possible applications of biocides compared to plant protection products it is, however, questionable whether suitable collection systems could be established.

#### **4.2.12 Integrated Pest Management (Article 14)**

Good practices in biocide application include the identification of a need (problem analysis, identification of pests and their threshold), the examination of potential measures to control pests and the consideration of preventive and/or non-biocidal measures. All these elements are part of IPM as applied in the plant protection area.

IPM is a decision making process which uses principles, practices and procedures applied to improve pest-control outcomes. While non-integrated pest control measures are primarily aimed at simply killing pests, the objective of IPM is also to eliminate the source of pest problems. In the WHO book on "Public health significance of urban pests" (Bonney et al. 2008) one chapter deals exclusively with IPM in general and specific principles are described for each pest. IPM principles were first developed to control agricultural pests but are increasingly used for general pest control. IPM integrates knowledge of pest biology, the environment and available technology including the use of biocides. The WHO book follows the definition of the US National Pest Management Association (NPMA, <http://www.pestworld.org/>) on IPM, in which five steps are specified:

1. Inspection (determine whether a current or potential pest exists at a specific location)

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<sup>52</sup> Since 1996 used packaging of plant protection products are collected and incinerated in cement kiln on an initiative of the German Crop Protection, Pest Control and Fertilizer Association (IVA, see <http://www.pamira.de/>).

2. Identification (accurate identification of pests and conditions that can support pests present at a specific site)
3. Establishment of threshold levels (establishing site-specific pest-population level that can be tolerated)
4. Employment of two or more appropriate control measures (design and implementation of an IPM programme necessary to suppress pest infestation while considering all practical, reasonable and effective control measures)
5. Evaluation of effectiveness (determination whether the IPM plan was implemented as designed and whether the objectives of the plan, pest reduction, were attained).

IPM considers pest biology and behaviour as well as the specifics of the environmental living conditions required by the pest. Table 4 shows the ways in which IPM differs from conventional pest control.

**Table 4: Differences between IPM and non-integrated pest control**

<b>Pest management programme components</b>	<b>Non-integrated pest control</b>	<b>IPM</b>
Programme strategy	Reactive	Preventive
Customer education	Minimal	Extensive
Potential liability	High	Low
Emphasis	Routine pesticide application	Pesticides used when exclusion, sanitation and other means are inadequate
Inspection and monitoring	Minimal	Extensive
Use of non-chemical controls	Minimal	Extensive
Positive identification of pests	Sometimes	Required
Use of pest thresholds	Minimal	Extensive
Outcome evaluation	Sometimes	Required

Source: WHO 2009

In addition to general IPM, principles the WHO (2009) presents several examples of IPM measures for specific pests.

**Example: IPM measures against cockroaches (summary):**

Cockroach infestations can result in serious contamination of food and have been shown to transfer disease pathogens. In addition, cockroaches can cause allergic reactions. Hence, cockroaches in dwellings and food processing areas need to be controlled. Originating from Africa, they are now cosmopolitan pests. Conventional treatment consists of the preventive and reactive application of insecticides with sprays and dust. Basic IPM programmes to control cockroaches were initiated in the 1980s. By applying IPM, the amount of insecticides can be reduced by 90 percent compared to conventional treatments. Removal of debris, harbourage sites and food sources is an element in integrated cockroach control programmes. The species should be identified and the location infested needs to be properly inspected. One main potential for reducing the amount of insecticides applied is to identify areas that do not need to be treated. Careful monitoring with cockroach traps using attractants or pheromones is used for determining the level of infestation. But traps alone do not effectively control cockroaches, particularly German cockroaches (*Blattella germanica*). Application of bait will result in reduction of cockroach numbers. Indeed the development of baits has revolutionized cockroach control, especially in the control of the German cockroach. Alternative strategies consist of non-chemical treatment by applying heat. Most household insect pests are extremely sensitive to high temperatures. At 52°C, a 30-minute exposure kills 100% of adult male German cockroaches. In field studies, it was possible to control German cockroaches by heating food handling areas in buildings to 46°C for 45 minutes.

Although IPM of biocides focuses on pest control of rodents and insects, the principles can also be applied to other biocide applications.

The COWI-study on the use phase of biocides refers to the study “Description of the appropriate use and good practice (GP) during the use and disposal of biocidal products”. Here, a uniform structure is proposed illustrating which items reference documents could include (Gartiser et al. 2005). Table 5 shows a comparison between elements of good practice and IPM.

**Table 5: Comparison of good practice and integrated pest management**

<b>Good Practice (German study)</b>	<b>Integrated pest management (NPMA)</b>
1. General principles and goals of the GP	
2. Description of the area of application	
3. Determination of the need for a biocides application (problem analysis, definition of the goal)	Inspection (determine whether a current or potential pest exists at a specific location) Establishment of threshold levels (establishing site-specific pest-population level that can be tolerated)
4. Examination of the measures and decision making	Identification (accurately identification of pests and conditions that can support pests present at a specific site)

<b>Good Practice (German study)</b>	<b>Integrated pest management (NPMA)</b>
5. Preventative, non-biocidal measures	Employment of two or more appropriate control measures (design and implementation of an IPM programme necessary to suppress pest infestation while considering all practical, reasonable and effective control 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 Applying risk management measures 6.5 Controlling of success 6.6 Waste disposal	Evaluation of effectiveness
7. Documentation	Determination whether the IPM plan was implemented as designed and whether the objective of the plan, pest reduction, was attained.
8. Storage and transport	

NPMA: US National Pest Management Association ()

The qualification of the user (education and training, professional certification) as well as the communication of hazards and risks was considered of decisive importance as a supporting measure for the realisation of and compliance with GP, but was not regarded as being part of the GP.<sup>53</sup> 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. Indeed, CEPA intends to develop common criteria by participating in the work of CEN (European Committee for Standardisation).

The GP-structure reflects several elements of IPM principles, such as the problem analysis and decision making process, the consideration of preventive and non-biocidal measures as well as the determination of success and documentation. The application of the biocidal product and related measures to protect users and the environment from exposure is not a main focus in the IPM strategy of the US National Pest Management Association.

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<sup>53</sup> However, qualification of users and communication are part of sustainable use of biocides.

The IPM principles proposed for sustainable use of pesticides include further provisions, namely the routine monitoring of harmful organisms, the preference for non-chemical methods, the application of anti-resistance strategies and the reduction of use to the minimum necessary (see 2.2.10).

One aim of the Thematic Strategy on pesticides is to establish expert groups to facilitate information exchange of best practices in the field of sustainable use of pesticides and IPM at a Community level (Article 18 of Directive 2009/128/EC). This could easily be adopted to cover biocides application.

#### Conclusions:

While some elements of IPM principles for plant protection, such as crop rotation, use of adequate cultivation techniques, use of resistant/tolerant cultivars and use of balanced fertilisation refer to good agricultural practice, most of the IPM-principles described above seem also to be applicable for biocides. Development and promotion of IPM guidance for pest control is considered one of the most promising instruments for the sustainable use of biocides.

#### **4.2.13 Indicators**

Data on the quantities of biocidal active substances and products produced or sold are not available. According to Annex II A, point 5.8 of the BPD, industry should provide data on the likely tonnage to be placed on the market. Although the evaluation of these data in the COWI study revealed very useful information about the biocide market, the figures are too aggregated to allow for an interpretation of use patterns. Regulation (EC) No 1185/2009 on statistics on plant protection products does not consider biocides, but indicates that the scope may be expanded at a later stage so as to include biocides.

Although, according to the Commission, tonnage data are considered as being confidential and the generation of such data as being costly, data on production, use pattern, typical applications and consumption would be very useful for assessing the risk associated with the use of biocides. Considering the progress of REACH and the Thematic Strategy of pesticides, there is a concern that biocides would be behind other chemical groups with respect to the availability of quantitative use data in the near future.

For substances for which no monitoring data are available, a modelling-based approach to assess potential exposure needs to be implemented for selecting priority substances in water policy. Information such as the overall tonnage used, the proportion of this tonnage going to particular uses and emissions from these uses may be utilized as input parameters (Lepper et al. 2008). The establishment of maximum residue levels (MRL) for residues of active substances in food or feed and their surveillance are further indicators on the sustainable use of biocides. It is expected that the development of MRLs will be relevant<sup>54</sup> for active substances used in PT 3, 4, 5, 18, 19 and 20.

#### Conclusion:

The inclusion of biocides into the scope of the Regulation on statistics on plant protection products is recommended, in order to obtain the data bases urgently needed for the development of suitable indicators. Other indicators already implemented at a national level (e.g. monitoring in environmental media, food, and feed, survey of poisoning cases) should be harmonised at EU level.

#### **4.2.14 Additional national measures**

In the following, possible additional measures are described. They are already implemented in certain MS. These measures are not directly addressed by the Thematic Strategy and therefore can be regarded as additional measures. The information is extracted from the COWI study, Annex 2 which summarises the replies of MS to the Commissions questionnaire on measures on the use phase of biocides. Further information was obtained through a short survey to the European Network for the Durable Exploitation of Crop Protection Strategies (ENDURE)<sup>55</sup> initiated by Dr. Hommel from the Julius Kühn-Institute.

#### Restriction of use, restriction of substances:

The restriction of use to certain user groups, e.g. professional users, is not explicitly mentioned in the Thematic Strategy as it is the subject of the authorisation process. Therefore, it is left open to MS to implement additional national restrictions.

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<sup>54</sup> Establishment of maximum residue levels for residues of active substances contained in biocidal products, CA-Sept09-Doc.3.4a

<sup>55</sup> [http://www.endure-network.eu/endure\\_publications](http://www.endure-network.eu/endure_publications)

Restrictions on the use of certain biocides with regard to specific areas is already part of Articles 11 and 12 and a general restriction for consumers to use very toxic, toxic, and CMR products Cat. 1 and 2 is found in several MS.

In several MS, among them e.g. Belgium, Hungary, the use of certain products is restricted to certified users as an additional risk reduction measure, especially for PT 14, PT 18, and PT 19. Lithuania also restricts the use of PT 2. France also restricts the use to professional users of products from PT 3 and PT 18 with regard to BSE and mosquito control. Slovenia also restricts the use of biocides from PT 5 if there are any risks for certain users. In Denmark, rodenticides are only authorised for professional use and there exist obligatory training/certification schemes for applicants.

On the contrary, Hungary for example only restricts the place of use (nature conservation areas) and specific products, but not complete PTs.

#### Taxes on sales of biocides:

In Denmark there is a biocide tax of 3% on most products and of 35% for insecticides (as for plant protection insecticides). So far, the tax only relates to the 6 PTs for which an authorisation system had been established before the BPD.

In Belgium, the Programme for the Reduction of Pesticides and Biocides (PRPB) is financed by general contributions from the chemical industry, through the fund for raw materials and products. The contribution is proportionate to the inherent risk of the product and its sales in Belgium. The inherent risk is determined on the basis of a score that is assigned to the various risk sentences on the product labels.<sup>56</sup>

#### Indicators and statistics:

Data collection is carried out in several MS but there is no harmonisation of the type of data to be collected. Information on biocides can cover data on manufacture, sales and use but also information on poisoning cases or the number of professional users, or specific areas where the use is restricted.

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<sup>56</sup> <http://www.health.belgium.be/eportal/Environment/Chemicalsubstances/PRPB/index.htm>



For example, in Finland retailers, distributors and producers have to provide data to the national authorities (STTV, SYKE) on biocidal products yearly. The data covers information on production, import/export and sales. Romania also collects data on import and export volumes, as well as on sales, general use, professional and non-professional use. Spain, Belgium Slovenia and Sweden collect data on sales of some active substances from specific product types (mainly PT 8, 14, 18) or with specific properties (toxic and very toxic, CMR) according to the COWI-study. As well as statistics on manufacture and sale of biocides, some MS (e.g. Hungary) also collect data on the number of certified professional users.

In Denmark the sales of both pesticides and biocides under the old authorisation system (PT 8, 12, 14, 18, 19, and algaecides) are reported in terms of active substances as well as of formulated products.<sup>57</sup>

In some MS, data on poisoning cases are collected but a harmonised method of collection is lacking. France suggested the harmonisation of poisoning control systems, for human as well as for animals and bio-monitoring to allow some exchange and comparison at EU level.

The COWI questionnaire also included questions regarding additional measures to reduce risks, where some MS gave their ideas.

France suggested working further on the mixing of biocidal products, on the cumulative use of biocidal products with or without the same active substance and on the management of resistance. Furthermore, the development of Emission Scenario Documents for “orphan” Product Types is mentioned as a measure to increase knowledge on uses and harmonisation.

Germany suggested to focus more on releases into the environment due to various types of use, e.g. as PPP, biocide, building material or release resulting from treated materials. The latter could also be subject to regulation.

Italy proposed to promote research and investigation activities on sanitary and environmental impacts of biocides. Further, a local control system and reporting of

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<sup>57</sup> [http://www.mst.dk/Virksomhed\\_og\\_myndighed/Bekaempelsesmidler/Pesticider/pesticidstatistik/Landbrug/](http://www.mst.dk/Virksomhed_og_myndighed/Bekaempelsesmidler/Pesticider/pesticidstatistik/Landbrug/)

uses should be mandatory. For assessing food chain contamination, studies and sampling of predators near treated zones are proposed.

The additional measures of a general quantitative use reduction and the introduction of taxes/levies as described for PPP are not mentioned in the questionnaires from any of the MS.

Conclusion:

The measures which are already included in the Thematic Strategy cover a broad range, but also leave room for additional national provisions.

## 5 Implementation of provisions for sustainable use of biocides

In an impact assessment concerning the revision of the BPD, a preliminary analysis of options to address sustainable use of biocides and the advantages and disadvantages of each option was carried out (Vernon et al., 2008). The following options were considered:

1. No action at present;
2. Include some biocides (pest control agents) in the Directive on Sustainable Use of Pesticides;
3. Include provisions on safe and sustainable use in the BPD; and
4. Create an independent framework on the safe and sustainable use of biocides.

The main advantages and disadvantages of the different options were described as follows:

No action at present	Include pest control biocides in the Directive on Sustainable Use of Pesticides	Include provisions on use in the BPD	Develop specific framework legislation on biocides
advantages			
No changes but some cost savings through no taking action.	Would strengthen the development of national plans for safe use of all pest control agents.	Would strengthen the development of national plans for safe use of all biocidal products.	All measures proposed can be discussed in detail with all stakeholders. Harmonisation of national action plans within Europe. Thematic strategy for the use of biocides could be linked with product-type overlapping. Development of use-specific, technical rules
Disadvantages			
Public pressure to establish rules for sustainable use might cause that individual member states develop own national actions which hinders harmonisation and mutual recognition.  Risks to human health and the environment during the phase are not adequately	No major changes but potentially some costs associated with training of professional users. Further discussion on the proposal on a pesticide Thematic Strategy would be required.  Differing mode of application and exposure of most biocides compared to	No major changes but potentially some costs associated with training of professional users. Experienced staff needed to develop measures on safe use for all biocidal products.  General statements on safe use may not be detailed enough.	Developing the framework takes time and effort. Long range process which delays measures becoming effective.  Specific measures on safe use at MS level might hinder mutual recognition of product authorisation. However, considering safe use of biocides,

addressed.	pesticides require different considerations  Development of the thematic strategy could be delayed.	Specific measures on safe use at MS level might hinder mutual recognition of product authorisation. However, considering safe use of biocides, trade issues are only of secondary nature in these circumstances.	trade issues are only of secondary nature in these circumstances.
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Source: Vernon et al. (2008)

This analysis was not developed further in the next stages of the project because the Commission initiated the COWI study (COWI 2009, see chapter 4.1.1).

At the Bonn workshop on the Revision of the BPD in April 2008, most participants objected to inclusion of pest control biocides within the Thematic Strategy for pesticides, because the differing mode of application and exposure of most biocides compared to pesticides would need different considerations. Producers, formulators, and regulatory consultants also confirmed that, even when the same active substances are used in both plant protection products and biocidal products, the mode of application, the formulation and exposure of respective products differ considerably. In addition, veterinary pharmaceuticals (directly applied to the skin of the animal) and biocides (used for the surroundings of the animals) usually have different formulations. There was a broad agreement that a better description of IPM and good practice standards are necessary at EU level. Some participants welcomed a new framework directive on the use phase; others considered the use phase to be covered already by Article 20 in the BPD (BMU 2008).

On 23 April 2008 the Commission organised an expert workshop on environmental and human health impacts of biocides.<sup>58</sup> The participants identified a need for more data on the quantities of biocidal products (e.g. sales, consumption, and use) so that general trends can be identified. Some participants considered that, before the impacts of the Biocides Directive are known through the implementation of the authorisation stage, it is premature to assess whether further actions on sustainable use might be necessary. Specific issues of concern identified were wildlife impacts, levels and impacts of anti-fouling agents in fresh water and anti-microbial resistance. In addition, there was concern about the lack of incentives for low risk products,

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<sup>58</sup> [http://ec.europa.eu/environment/biocides/sust\\_use.htm](http://ec.europa.eu/environment/biocides/sust_use.htm)

which are being lost from the market but could substitute those with higher risks. The promotion of low risk products could represent a part of the sustainable use strategy. It was noted that various training and/or certification schemes exist in many Member States for some product types and that there is a need for a minimum level of best practice harmonisation with regard to training requirements, at least for some PTs. There was a consensus that there is a need for a reporting obligation for Member States aimed at gathering data on the use of biocidal products.<sup>59</sup>

On 25 February 2010 a national workshop on sustainable use of biocides took place at the German Environmental Agency in Berlin with 30 participants from authorities, scientific institutes, NGOs and industry. Most experts agreed that provisions supporting the sustainable use of biocides would be useful. Here it became apparent that users of the biocidal products would prefer a separate Thematic Strategy for sustainable use of biocides, while the federal authorities favoured integration into the existing Thematic Strategy for pesticides. Some representatives of the federal states authorities suggested integrating aspects of sustainable use into the existing BPD (or future Regulation on biocidal products) without establishing a new framework directive (see 7.1).

Several RMM are currently being discussed by competent authorities (CAs). For example, the use of personal protective equipment (PPE) for reducing exposure and ensuring the safe use of the product are not considered acceptable for non-professional users.<sup>60</sup> While a few Member States completely forbid the spraying of wood preservatives by amateur users, most CAs suggest that spraying by non professional users should not be allowed if the exposure resulted in the need to use PPE.<sup>61</sup> It has also been proposed to restrict the use of anticoagulant rodenticides to professionals for resistance control, because many of them are classified as potential PBT/vPvB substances and have a high risk of primary and secondary poisoning for wildlife (birds and non-target mammals). However, at CA level this proposal was not accepted as an appropriate measure, considering the drawbacks for rodent control. In the inclusion Directives of these substances, the nominal concentration of the

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<sup>59</sup> [http://ec.europa.eu/environment/biocides/pdf/conclusions\\_workshop230408.pdf](http://ec.europa.eu/environment/biocides/pdf/conclusions_workshop230408.pdf)

<sup>60</sup> Use of Personal Protective Equipment. 27th CA meeting, CA-May08-Doc.6.2

<sup>61</sup> Spraying method of wood preservatives for amateur users. 26th CA meeting, CA-Sept07-Doc.5.3 – Final RISK MITIGATION MEASURES FOR ANTICOAGULANTS USED AS RODENTICIDES. CA-March07-Doc.6.3 final – revised after 25th CA meeting

active substance, the mode of application (no tracking powder, use of ready to use baits/ bait boxes etc.), and setting an upper limit to the package size have been described as suitable measures. Additionally, the restriction of products to specific areas (in and around buildings) and also restrictions of products to professionals or trained professionals only, should be considered in the framework of the national authorisation of rodenticidal biocidal products.

## **6 Summary of case studies on sustainable use of biocides**

Chapter 6 gives a short summary of the results of the case studies documented in detail in Annex II, III, and IV.

### **6.1 Wood preservatives**

Wood preservatives are used for both preventive and curative treatments of wood against insects or fungi. Preventive treatments are usually applied to wood at industrial treatment plants before the wood is put into service, whereas curative treatments are mostly applied to wood in-situ by professionals or amateurs. According to OECD (2003), in Germany about 95% of wood preservatives are applied in preventive treatment and about 5% in curative treatment. With regard to the mode of application, two principle different treatment techniques may be distinguished; namely deep penetrating and surface treatments. Deep penetrating treatments like vacuum-pressure or double vacuum are exclusively applied to wood in industrial treatment plants for preventive purposes. Surface treatments like spraying, dipping or brushing are applied both for preventive and curative purposes in all use sectors, i.e. industrial, professional and amateur users.

Emissions of wood preservatives and resulting exposure of the environment may occur during the application phase as well as during the storage and the service life of treated products. The route and degree of emission depend very much on the mode of application, the storage conditions of the treated wood and the use class. Whereas emissions to the environment are quite low for deep penetrating treatment techniques, surface treatments which are often performed in-situ (i.e. outdoors) may result in significant emissions. Leaching of wood preservatives during the storage of treated wood before use can be prevented efficiently by storing the treated wood in roof-covered and paved (= impermeable) areas. For most preserved wood, significant losses to the environment take place during the service life phase which can be very long (up to 50 years). With regard to the service life, five different use classes are distinguished which vary in terms of the exposure of the treated wood to the weather and the level of contact with ground or water.

Up to December 2010, 18 active substances of PT 8 have been included in Annex I or IA to Directive 98/8/EC. In the Inclusion Directives of these active substances,

different risk mitigation measures are described which shall be considered during the authorisation of biocidal products containing these active substances. The case study (see Annex II) shows that the measures proposed within Directive 2009/128/EC can in principle be transferred to biocides in order to promote the sustainable use of wood preservatives, but some adaptations are required. The service life stage has a specific importance both for human health and environmental risks. Indoor use of wood preservatives can be omitted by applying preventive constructional measures, such as covering the wood against insect infestations or open construction enabling visual control of the wood. As a general rule, habitable rooms with normal interior climate and protected from moisture do not need to be protected against wood fungi. Several RMM have been described in the Inclusion Directives and Assessment Reports / CARs for the active substances, among them restrictions to professional or industrial uses only, top coating for reducing leaching, storage of treated wood under cover and avoiding discharges to the sewer and surface water. To protect the aquatic (and the terrestrial) environment, the use of treated wood near water bodies or in protected areas could be restricted. There are training courses for the qualification and certification of professional users on a voluntary basis which could be made obligatory. Limitation of self-service systems (open shelves), including internet commerce, would be another option for improving advice on proper use given to consumers by qualified distributors. The equipment for industrial wood impregnation is partly subject to the Pressure Equipment Directive (97/23/EC) and the Machinery Directive 2006/42/EC, but a harmonisation of EU standards for all treatment processes (pressure and non-pressure treatment) is lacking. The development and harmonisation of Best Practice standards for wood impregnation would further support the sustainable use of wood preservatives.

Most wood preservatives will be authorised for specific use classes, depending on the subsequent situation of the wood (under cover, exposed to wetting, contact to soil etc.). The consequent labelling of treated wood, as envisaged in the current draft Biocides Regulation, is a prerequisite for preventing misuse, including the incineration of wood treated with wood preservatives.

## **6.2 Insecticides and products to control other arthropods**

PT 18 refers to insecticides, acaricides and products to control other arthropods, but is often named “insecticides” for practical reasons. The respective biocidal products



have a very wide use pattern and are used by specialised/trained professionals (e.g. pest controllers), professionals (e.g. farmers, cleaners), and consumers/private users. About 59 active substances are currently supported under the BPD, mainly pyrethroids. Many active substances among the organophosphates have been withdrawn, because of their risks, but a few (e.g. Dichlorvos) are available. Emissions to the environment mainly occur from cleaning and decontamination after indoor applications (mainly via sewage treatment plants), from releases of fumigants to the air, and from spreading of manure containing larvicides to soil. For mosquito control large scale aerial spraying/trickling is also performed, mainly with *Bacillus thuringiensis* toxins. The efficiency and proportionality of some indoor applications by consumers has been questioned and the promotion of risk awareness among consumers through public information campaigns is a promising tool. The possible development of resistance in the target organisms requires expert knowledge and training and certification of professional users is the most promising instrument supporting sustainable use. Similar to plant protection products, the application of IPM principles is a prerequisite and should be further developed by harmonisation of best practice standards. Numerous guidance documents on best practice describe appropriate use of insecticides and IPM principles. A European standard describing minimum requirements for professional pest control services is under development (CEPA activity).

Most instruments referred to in Directive 2009/128/EC on sustainable use of pesticides can be transferred to the biocidal insecticides, but some adaptations are required. In particular, indoor use of insecticides, which can be regarded as a “sensitive area” per se, needs special attention.

Several RMM for indoor use of insecticides have been proposed, such as their use in cracks and crevices or in concealed locations inaccessible to man and domestic animals to avoid secondary exposure. Other RMM concern the restriction of use in animal housings to those without a connection to the sewer system or direct release to surface water.

Self service purchase of insecticides from open shelves and through the internet could be restricted, especially for consumers, in the same way as it has already been implemented for plant protection products in Germany. Here, self-service purchase is prohibited, irrespective of the product’s classification.

### **6.3 Antifouling products**

The case study on antifouling products (see Annex IV)) showed that the majority of antifouling products - about 95% of global demand - is used for protecting ship hulls from unwanted growth and settlement of fouling organisms e.g. bacteria, algae, and crustaceans. Currently, 10 substances are included in the review programme for the evaluation of existing biocidal active substances. The ban on organotin compounds by the International Convention on the Control of Harmful Antifouling Systems on Ships, developed by the International Maritime Convention Organisation (IMO), will end the use of organotin based antifouling products globally. Currently, biocide free alternatives like low-friction and ultra-smooth surfaces (e.g. coatings with nanoparticles, silicone, polytetrafluoroethylene) that inhibit the attachment of fouling organisms are available but still under further development, because of drawbacks in their use and application.

Two pathways are relevant to emissions of antifouling biocides from ship hulls into the environment: the use phase during service life and operations during application, maintenance & repair. It is estimated that 1/3 – 2/3 of the applied paint is released to the water during service life as an intended function of the antifouling paint. Negative effects arising from the inherent substance properties can be partly addressed in the authorisation process, by demanding risk reduction measures and specific restrictions on defined user groups. For example, criteria for the leaching rate of a biocide, the efficiency of a product and the risk assessment of metabolites could be defined and evaluated during the authorization procedure. In the frame of a Thematic Strategy, the focus could be on the promotion of low-risk products and biocide free alternatives.

Compared to the service life stage the phase of application, maintenance & repair leads to lower emissions into the environment but could be influenced by measures proposed within the Framework Directive 2009/128/EC. The case study shows that in principle some of the measures proposed there can be transferred to antifouling products. The main issues covered in a Thematic Strategy could be: a mandatory training programme for professional users who are involved in the application of antifouling products and the further development and implementation of “Best Practice” approaches that are already partly available. Also, harmonised EU standards on technical-organisationally measures (e.g. automatic spraying

techniques, mixing) could be further developed. The scope of the Directive on Machinery 2006/42/EC to consider equipment for the application of pesticides could also be extended.

For non-professional users, awareness raising programmes seem most promising to contribute to sustainable use of biocides. Such programmes should inform about biocide free alternatives and, in case biocides cannot be avoided, which would be the less risky ones. In this context, a restriction for the sale of dangerous products through the internet or catalogues to amateurs could also be established.

Specific requirements e.g. hard ground, shrouding, waste water collection systems with filtering, waste equipment collection sites for marinas where application, maintenance & repair is allowed could be made mandatory within the framework of a Thematic Strategy. Also, the promotion of ecolabelled marinas could be supported to expand awareness.

To reduce emissions of antifouling biocides in sensitive areas e.g. lakes, coastal water bodies, the use of antifouling products could also be banned within the framework Directive.

The definition of harmonised indicators and the protection of non-target organisms from antifouling and their metabolites are other important issues that could be addressed by a Thematic Strategy.

## **7 Summary of national workshops**

### **7.1 Workshop on measures of sustainable use of biocides**

On February 25<sup>th</sup> 2010 a national workshop on sustainable use of biocides took place at the German Environmental Agency in Berlin. Around 30 national experts participated. The objective of the workshop was to reflect the results of the study so far, to adjust the focus of the remaining work and to define the focus of the second workshop.

Most participants agreed that provisions for supporting the sustainable use of biocides would be useful. Plant protection products and biocides often contain the same active substances. Therefore, the approach followed in the project, to analyse the transferability of the measures of Directive 2009/128/EC to the biocide area and to add biocide-specific aspects, was considered a promising strategy. Some of the authorities involved in the sustainable use of plant protection products (Julius Kühn Institute) noted that the clear objectives of the Thematic Strategy were defined before the adoption of the Directive 2009/128/EC. First, the impacts of plant protection agents were identified (residues in food, in water) that were not addressed in the authorisation procedure. Only afterwards were measures taken to achieve the goals. Therefore, the question arises which are the main problems in the biocide area. The other participants stated that the poor availability of data (including consumption and monitoring data on biocides) hinders a definition of the objectives. Moreover, the interpretation of the limited data is difficult because the active substances of many biocides are also used for other purposes, such as plant protection products. One objective of a sustainable use strategy for biocides could therefore consist of improving the data bases.

Representatives of the pest control industry questioned the use of the term "sustainability" in this context. It was reported that pest controllers, when asked "What do you understand by the sustainable use of biocides" referred to "application of persistent active substances" and "repeated treatment". It was therefore proposed to delete the term "sustainable" and speak only of "biocide use". The meaning of sustainability could be defined in a separate article. It was also discussed how the "minimum necessary" is to be defined. The Biocidal Products Directive requires in

Article 3 (7) that biocides should be properly used, whereby “the use of biocidal products is limited to the minimum necessary”. A quantifiable interpretation of this article is difficult because of the diversity of product types and use patterns. It should be taken into account that biocides are used for preventing infectious diseases or preserving materials and processes. Thus, one aspect of sustainable use is that sufficient active substances are available to counter the risk of resistance by frequent use and larger quantities of single biocides. It was discussed which aspects of sustainability could be considered in product authorisation, for example, in the form of RMM. Additionally, industry was worried about the impact of setting measures for sustainability after product authorisation such as use or sales restrictions.

With regard to the question of whether measures on sustainable use of biocides should be implemented by a specific directive on the sustainable use of biocides or should be included in existing policy, the following trends became apparent:

- Users of biocidal products preferred a separate Thematic Strategy for sustainable use of biocides. According to the users, national action plans for the sustainable use of plant protection products are not transferable to biocides, since there are too many differences from biocides. A flexible separate framework directive therefore seems appropriate to address sustainable use of biocides.
- The federal authorities (Bundesländer) favoured integration into the existing Thematic Strategy for pesticides. One advantage would be that any measures would be implemented faster than within a new Thematic Strategy. A specific timetable for including biocides into the existing Thematic Strategy should be included in the ongoing revision process of the Biocidal Products Directive.
- Some representatives of the federal states authorities suggested integrating aspects of sustainable use into the existing BPD (or future Regulation on biocidal products) without establishing a new framework directive.

There was agreement among participants that there is a need to prioritise measures and product types to be considered within a strategy on sustainable use of biocides. Here, the application forms (spray, bait), the application areas (indoor, outdoor) and the user category (professional, occupational, private) should be differentiated. The benefit of biocides on human health and material protection should by all means be considered when measures for sustainable use are discussed.

On the part of the chemical industry it was noted that Germany is quite well established when considering sustainable use of biocides, because there are already

several regulations. The focus now is to start the authorisation procedure for biocidal products, thus new requirements for sustainable use are not acceptable for medium-sized companies. Because there are few monitoring data available for biocides - in contrast to plant protection products – it is too early to define measures, because it is not clear where the main problems lie.

In contrast, the authorities argued that while the BPD only governs the authorisation of biocidal products, the Thematic Strategy on sustainable use of pesticides concerns to the applicants of biocides and not the chemical industry. Sustainable use of biocides does not focus on individual products but considers more fundamental aspects such as how to decide whether and which application should be carried out. This does not depend on the authorisation of biocidal products but refers to the decision making of users. In fact, with respect to sustainable use of biocides, Germany is well positioned in many areas. But this was also true for plant protection products before the adoption of the Directive 2009/128/EC on the sustainable use pesticides. Nevertheless, the framework Directive is seen as progress, because the EU dimension is also taken into account. The existing structures and arrangements for sustainable use of biocides could be included in a national action plan.

## **7.2 Workshop on objectives of sustainable use of biocides**

On February 2<sup>nd</sup> and 3<sup>rd</sup> 2011 a two-day-workshop was organised with different German authorities involved in the approval and surveillance of biocidal products. While the federal competent authorities are responsible for the authorisation process for active substances and biocidal products, market surveillance of biocidal products is carried out by the federal states (Bundesländer). The objectives of the workshop were to discuss open questions and the advantages/disadvantages of different options for implementing measures on the sustainable use of biocides. The workshop was aimed at supporting the development of a national position on sustainable use of biocides. In five sessions the identified impacts of biocides, the objectives of sustainable use, apparent conflicts in the protection goals, existing deficits in national legislation, and the different political options have been discussed.

According to the federal states, the surveillance of biocidal products on the market is difficult because there is little information on the application patterns of biocides. Surveillance of the proper use of biocides by private or non-trained professional

users is difficult or even impossible. Only for specialised/trained professional users such as pest controllers can some inspections be carried out by local authorities. For consumers, no enforcement possibilities exist.

During market surveillance there still arise difficulties with the attribution of the product type and the differentiation from plant protection or medicinal products (dual use). The German register of existing biocidal products is not supervised because no national authorisation of biocidal products was previously in place. A positive list of biocidal products would facilitate their surveillance. However, this will improve with the implementation of the BPD. It seems that some professional applicants prepare their own biocides for immediate use without intending an authorisation, arguing that these are not placed on the market. It was suggested that all these conflicting cases and the respective decisions of authorities should be collected and made available to the authorities. In future, the authorities involved in market surveillance demand to be better informed concerning the actual decisions at the EU level (e.g. the manual of decisions, up to date biocidal substance and product lists).

The main objectives of sustainable use of biocides are the protection of the environment, especially of water bodies and soil, the preservation of biodiversity, the minimisation of hazards to human health and the avoidance of resistance development. The primary objectives of sustainable use should be to reduce risks. A reduction of the amount of biocides consumed is not the best indicator for sustainable use but could easily be calculated. The Framework Directive encourages MS to set quantitative objectives in their NAP, among them the amount of biocides used.

Obviously there are conflicts between the objectives of sustainable use (e.g. infection control through application of biocides might affect the environment; biodiversity in rain forests is endangered when durable tropical wood replaces wood from temperate latitudes protected with wood preservatives). The question is how to define and indicate a conflict of the objectives and which criteria should be applied for its quantification. Should conflicts of objectives be referred to as single cases (regional scale) or should these also be addressed on a global scale?

A distinction between individual and social, as well as of subjective and objective conflicts between objectives is required. Which objectives should have a greater

emphasis? Has human health a greater importance than the environment and the environment a greater importance than costs?

A common approach to considering conflicts between the objectives in the biocide area is missing.

Biocides are often applied in the area of renewable raw materials such as wood and wool. A restriction for consumer use might cause consumers to use other materials for these purposes, such as plastic, concrete or aluminium, which might not be desirable in terms of sustainability. The labelling of materials treated with biocides, as foreseen in the future Biocides Regulation, is an important tool for consumers to have a sound basis for their purchasing decisions.

The issue of marketing statements which could encourage unnecessary use of biocides has also been discussed. As well as misleading labelling of biocidal products in respect of the risks to human health and the environment (which is not allowed according to Article 22 of the BPD), misleading statements on the reliability and proportionality of the applications proposed should also be considered. Article 62 of the draft Biocides Regulation will also prohibit misleading statements in respect of the efficacy of a biocidal product, but this only covers one part of reasonable use.

Preventive and alternative measures, such as constructional wood protection, may avoid conflicts between the objectives. Thus, alternatives should also be considered when weighting the objectives.

The main instruments for improving sustainable use mentioned at the workshop are improvement of education and training, advisory services and the quality of product information such as technical leaflets. Further on, the development of best practice documents for integrated pest control has been suggested. The risk awareness of the user is a very important issue. Sales restrictions via control of internet commerce and of self-service purchase of biocides have been referred to in this context. Low risk biocides as well as non-biocidal alternatives should be marketed with corresponding advertisement statements.

A general prohibition on consumer use of biocides was not considered appropriate but certain restrictions may be required. This should distinguish between reasonable and less reasonable applications of biocides. The need for and proportionality of



biocide use should be considered (e.g. home disinfectants only to be applied in the presence of persons susceptible to infections but not for general disinfection purposes). The US EPA and OECD require that any pesticide must have a proven benefit. If there is no benefit, the pesticide is not needed.

Sound advisory services for consumers offered by the distributors would be helpful. Further restrictions of self-service purchase of biocides, as are already in place for plant protection products, could be envisaged.

With reference to the minimisation of biocides in sensitive areas, some examples such as the restriction of antifouling agents at the Lake Constance show that these restrictions are enforceable if supported by society.

With respect to the different options for implementing measures on sustainable use of biocides, it became clear that no short term solutions are foreseeable at the European level. The different approaches followed by MS demonstrate that harmonisation is required. Some MS such as Belgium have considered biocides in their NAP for sustainable use of pesticides. There is a need to distinguish which measures can be implemented at European level and which should be implemented on a national scale. The first risk reduction plan for plant protection products in Germany was outlined before the European Directive came into force. A survey of the experience and strategies of how other MS include biocides in their NAP should be carried out.

A prioritisation of product types on which implementation of measures on sustainable use should be focused has also been suggested. Different measures will probably be required for each PT. Further on, the different information requirements of the user groups (professional, specialised professional, and consumer) should also be considered. The hazards of the substances should also be considered, in order to prevent over-regulation. Thus the focus should be on distinct (active) substances and applications. The acceptability of measures to society should also be kept in mind. To date, the limited information available concerning the use phase hinders providing a sound basis for prioritisation. Often hot spots are only causally identified when it is too late for preventive measures. The inclusion of biocides within the scope of Regulation (EC) No 1185/2009 concerning statistics on pesticides and / or national provisions for collecting data on sales and consumption of biocides are recom-

mended. This would also be the basis for establishing meaningful monitoring programs for biocides in environmental media. The development of monitoring programs is carried out by the German Federal Environment Agency but the implementation is done by the federal states. In the area of monitoring of pharmaceuticals in water bodies, co-operation between different authorities worked very well.

The authorities agreed that an action framework at the European level is required, even if this is a long term process. Considering the time frame required to implement the existing Directive on sustainable use of pesticides of about ten years, certain measures should be implemented earlier on a national level. All national measures should focus on identified impacts of biocide use and could then be included in the NAP. Later on, existing national measures could be implemented at a European level. It should be noted that any strategy for supporting sustainable use is not directly linked with the authorisation process but refers to additional measures for minimising exposure to biocides of humans and the environment during the use phase. A Framework Directive could also be established without defining a thematic strategy. First the objectives and instruments of sustainable use of biocides should be defined. In which regulatory framework these are implemented is of secondary concern.

The following next steps have been suggested by the authorities

- First, a problem analysis should be carried out. A systematic survey concerning the occurrence of biocides in different media (e.g. surface water, house dust) should be performed in order to collect any existing data. Because the monitoring and surveillance programs are carried out by the federal states, the data are widely distributed and there exists no detailed overview so far. Monitoring concepts and programs should be developed in order to identify the major impacts of biocides use and to identify the objectives of a thematic strategy for sustainable use of biocides and to define suitable indicators.
- Based on the results of the problem analysis, the objectives of a Thematic Strategy on sustainable use should be described.
- As a next step, definite proposals and modules for a Thematic Strategy, Framework Directive or a NAP should be elaborated for priority substances or biocides applications. The experience of other MS should be considered.
- The results shall be presented at a European level to experts. A European expert workshop on sustainable use of biocides is envisaged. The proposals and results shall support European activities concerning implementing measures for sustainable use of biocides.

## 8 Conclusions and recommendations

The Thematic Strategy on sustainable use of pesticides has so far been implemented only for plant protection products. No harmonised approach exists for minimising hazards and risks of biocides to human health and the environment during the use phase. In contrast to plant protection products, the use pattern of biocide is far more diverse, as reflected by the 23 different product types. The use of biocides in private homes is often more a response to lifestyle than to an objective need and the objectives may often be achieved by non-biocidal alternatives. Within the project the possibilities and requirements for transferring the measures of Framework Directive 2009/128/EC on sustainable use of pesticides to the biocide area have been analysed, with specific focus on wood preservatives, insecticides, and antifouling agents.

Several biocidal active substances, such as the fungicides Propiconazole, Tebuconazole, and Terbutryn as well as the herbicides Carbendazim and Diuron, are found in the outlet of STP and surface water and indicate that many biocides are not completely removed during wastewater treatment. Annex I of this report summarises the available literature data on the occurrence of biocides in the environment. Because reliable data on biocide consumption and use patterns are lacking, no prioritisation of the most relevant active substances to be included in monitoring programmes or in a risk minimising strategy is currently possible in Germany. Some MS provide statistics on biocides consumption and some monitoring programmes have been undertaken. These data could be evaluated first.

Sustainable use of biocides addresses the three pillars of social, environmental and economic sustainability. The social dimension refers to human health, general hygiene conditions in workplaces and residential areas. The environmental dimension refers to the protection of water resources, soil, non-target organisms and biodiversity. The economic dimension refers to the protection of commodities, materials, livestock breeding and industrial processes.

A systematic analysis of instruments for improving the sustainable use of pesticides described in Directive 2009/128/EC indicated that the structure of different instruments can be transferred to the biocide area, but some biocide specific adaptations

are required. Unlike plant protection products, the intended use of some biocides is to be directly applied to water bodies. This includes e.g. larvicides in stables and manure, insecticides used for mosquito control or cooling water biocides. Further, disinfectants or preservatives are mainly released to municipal STPs before entering surface water. The behaviour of the active ingredients in STPs is therefore of particular concern. The focus on indoor use of biocides also distinguishes these from plant protection products. Another aspect is that, for some PTs, emissions during the service life of biocides exceed emission during the application phase. This includes e.g. wood preservatives, film preservatives, masonry preservatives, or antifouling agents.

The instruments described in the Thematic Strategy could be transferred as follows:

Education and training is of decisive importance for the sustainable use of biocides. There are several ongoing national activities for professional users established by professional associations and research institutes. CEPA took the initiative for the standardisation of pest control services on a European level. In other sectors, such as the application of antifouling paints, experts expressed concern about the lack of training activities. While education and training clearly need to be embedded in national (or local) engagement, a lack of exchange of knowledge and expertise among Member States is apparent.

Restrictions on sales of biocides could be adapted from those proposed for plant protection products. Some exemptions might apply for specific biocides where no risks have been identified. There also exist provisions for best practice on internet commerce but doubts remain whether these are followed. The establishment of strict rules on internet commerce and their surveillance is recommended.

The development and establishment of awareness programmes is an important instrument for supporting sustainable use of biocides, especially for consumers. There are national activities such as the German biocide portal [www.biozid.info](http://www.biozid.info) which could be further developed and translated to other languages. Providing information on safe use of biocides, preventive or non-chemical control measures to the general public is a suitable instrument for improving sustainable use of biocides.

The availability of appropriate equipment for the application of biocides is an important tool for minimising exposure and for targeted dosage of biocides. Initiatives for harmonisation and standardisation of the machinery for biocide application only exist in rudimentary form. The Directive on Machinery 2006/42/EC should be amended to include machinery and equipment for the application of biocides.

While Directive 2009/128/EC specifically cites aerial spraying as a mode of application to be restricted, this is of minor importance in the biocide area. However, the physical form of the biocide and the mode of application are indeed of major relevance. For example, spraying of insecticides indoors might cause higher exposure to humans and the environments than application in the form of baits. Therefore, this instrument should be amended to cover other modes of application of biocides.

Directive 2009/128/EC does not consider instruments for reduction of environmental emissions during service life. However, for biocides used for preservation of materials (PT 6-10) and antifouling agents (PT 21), a considerable proportion of total emissions arise during service life, through leaching from treated materials or the removal of coatings. Therefore, in contrast to plant protection products, the service life of biocidal products should be considered in detail in addition to the use phase.

Another aspect of Directive 2009/128/EC concerns provisions on informing persons who could be exposed via spray drift. Because biocides are often applied in the surroundings of human habitats, exposure of bystanders might be important (e.g. during pest control). In contrast to plant protection products, the problem of residential bystander exposure to biocides also arises. These are people exposed to the residues in the air and on surfaces in homes after biocide application.

Among specific measures to protect the aquatic environment and drinking water, the requirements of the Water Framework Directive as well as the concept of drinking water protection zones apply to both plant protection products and biocides. Additionally, measures might be envisaged where biocides are directly emitted to the environment, such as cooling water biocides. The identification of further priority substances and their monitoring in the environment is a prerequisite for setting environmental quality criteria.

The reduction of biocide use in specific areas, such as Natura 2000 sites, may be required for few applications such as wood preservatives. Several outdoor applications of biocides have been identified (e.g. PTs 2, 8, 10, 11, 14, 18, 21), but the prevalent use for most PTs is indoors. For insecticides, a user restriction could be envisaged in public areas such as school grounds and children's playgrounds (e.g. only specialist professional users to be allowed to work in these areas).

For handling of biocides and plant protection products the same safety measures apply in principle; these are e.g. determined by the classification and labelling of the preparations. The disposal of biocides residues and packages by municipal collection systems for hazardous substances should be facilitated. For some applications, the packages might be returned to the supplier, following the example of plant protection products. Due to the broader range of possible applications of biocides compared to plant protection products, however, it is questionable whether suitable collection systems could be established. In contrast to plant protection products, the removal (e.g. of antifouling paints) or the disposal of treated articles such as impregnated wood also has to be taken into consideration. For example, the incineration of treated wood under non-controlled conditions has been questioned. The labelling of treated articles is a prerequisite for this and directly relates to the use phase of biocides. Labelling of treated articles is considered in the proposal for a biocides regulation replacing Directive 98/8/EC.

Best practices in biocide application include the identification of a need (problem analysis, identification of pests), the examination of potential measures to control pests and the consideration of preventive and/or non-biocidal measures. Most of these elements can also be related to the IPM principles developed for plant protection products and pest control agents. Development and promotion of IPM guidance for pest control is considered one of the most promising instruments for the sustainable use of biocides. For the biocide sectors, the IPM principles may be adopted according to the requirements of each PT. For example, the concept of Hazard Analysis and Critical Control Points (HACCP) is applied as a preventive approach to food safety and also includes the principles of IPM. Several BREFs cover sectors where biocides are routinely applied (e.g. the BREFs on the Food, Drink and Milk Industries, the Tanning of Hides and Skins, or the BREF on Cooling Systems).

The case studies on sustainable use of wood preservatives, insecticides, and antifouling revealed that the structure of different instruments described in the Thematic Strategy, after their amendment as described above, could also be applied not only at the level of a specific PT, but also at the level of a specific biocides application or when indicated at the active substance specific level.

To date, there are no suitable indicators available for describing progress in the sustainable use of biocides. The reason is that only limited data on sales and consumption of biocides, the use pattern, poisoning cases and monitoring data in environmental media exist. The inclusion of biocides into the scope of the Regulation (EC) No 1185/2009 concerning statistics on pesticides, which so far only covers plant protection products, is recommended. These data are urgently needed for the development of suitable indicators and the definition of the objectives of sustainable use. Some MS have already started developing indicators of sustainable use of biocides on national level and these approaches should preferably be harmonised at EU level.

In some MS further national measures have been implemented, especially the taxation of biocides according to the amount sold and to the intrinsic hazards.

In summary, an action framework on sustainable use of biocides on European level is recommended if it is designed in such a way that reduction of biocide use can be achieved. First, a problem analysis should be carried out by evaluating all available existing data and by establishing sound monitoring programmes for biocides. Then, the objectives and instruments of sustainable use of biocides should be defined. These measures could be implemented by establishing a new Thematic Strategy on biocides or by amending the existing one on pesticides. Because this is a long term process, certain measures should be implemented earlier at a national level. All national measures should focus on identified impacts of biocide use and should be included in a NAP. Later on, existing national measures could be integrated in a general strategy on sustainable use at European level.

## 9 References

Anonymous 2003. Biologische Bekämpfung der Schildzecke (*Ixodes ricinus* „Holzbock“) zur Verhinderung von FSME- und Borreliose-Erkrankungen. Stellungnahme des Sozialministeriums, Landtag von Baden-Württemberg Drucksache 13 / 2317, 31. 07. 2003 .

[http://www.landtag-bw.de/WP13/Drucksachen/2000/13\\_2317\\_d.pdf](http://www.landtag-bw.de/WP13/Drucksachen/2000/13_2317_d.pdf)

Anonymus 2008. Eichenprozessionsspinner (EPS) Bekämpfung per Hubschrauber. Der praktische Schädlingsbekämpfer H. 6, 2008, p.8-11

Anonymus. Grundsätze für die Durchführung der guten fachlichen Praxis im Pflanzenschutz vom 9. Februar 2005. Bundesanzeiger Nr. 58a vom 24. März 2005

Becker, N., Petric, D., Zgomba, M., Boase, C., Dahl, C., Lane, J., Kaiser, A., 2003 2003. Mosquitoes and their control. Kluwer Academic/ Plenum Publishers, 518 pages

BLAC 2009. Bund/Länder-Arbeitsgemeinschaft Chemikaliensicherheit Leitfaden Gute Internetpraxis für den Chemikalienhandel. September 2009

[http://www.blac.de/servlet/is/2146/ack\\_umk\\_internetb.pdf](http://www.blac.de/servlet/is/2146/ack_umk_internetb.pdf)

Boisvert, M., Boisvert, J. 2000. Effects of *Bacillus thuringiensis* var. *israelensis* on Target and Nontarget Organisms: a Review of Laboratory and Field Experiments. *Biocontrol Science and Technology* 10(5): 517–561

Bonnefoy, X., Kampen, H., Sweeney, K: 2008. Public Health Significance of Urban Pests. World Health Organization, Regional Office for Europe, Copenhagen <http://www.euro.who.int/document/e91435.pdf>

CEPA 2003. The pest control industry in Europe - a CEPA survey 2003, Brussels <http://www.cepa-europe.org/Media/publications/europeanpestindustry.pdf>

CEPA 2008. Roma Protocol A Commitment to Professional Standards for the European Pest Management Industry 3<sup>rd</sup> April 2008

<http://www.npta.org.uk/assets/documents/Roma%20Protocol%202008.pdf>:

COWI 2009. Assessment of different options to address risks from the use phase of biocides. Final report on behalf of the European Commission Environment Directorate-General, March 2009, Kongens Lyngby Denmark

[http://ec.europa.eu/environment/biocides/pdf/report\\_use.pdf](http://ec.europa.eu/environment/biocides/pdf/report_use.pdf)

EMA 2006. Guideline on the environmental risk assessment of medicinal products for human use. Committee for Medicinal Products for Human Use (CHMP). London, 01 June 2006

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/10/WC500003978.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500003978.pdf)

EMA 2008. Revised guideline on environmental impact assessment for veterinary medicinal products in support of the VICH Guidelines GL6 AND GL 38. Committee for medicinal products for veterinary use, Doc. Ref. EMEA/CVMP/ERA/418282/2005-Rev.1

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/10/WC500004386.pdf#](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004386.pdf#)



European Commission. 2009. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the placing on the market and use of biocidal products (Text with EEA relevance) {SEC(2009) 773} {SEC(2009) 774} COM(2009) 267 final, 2009/0076 (COD), 12.6.2009 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0267:FIN:EN:PDF>

European Commission. 2009. Development of guidance for establishing Integrated Pest Management (IPM) principles. Final Report 07.0307/2008/504015/ETU/B3 by BiPRO Beratungsgesellschaft für integrierte Problemlösungen, 24. April 2009 [http://ec.europa.eu/environment/ppps/pdf/final\\_report\\_ipm.pdf](http://ec.europa.eu/environment/ppps/pdf/final_report_ipm.pdf)

European Commission. 2009. Draft Guidance Document for establishing IPM principles Supplement to the Final Report 07.0307/2008/504015/ETU/B3, 23. April 2009 [http://ec.europa.eu/environment/ppps/pdf/draft\\_guidance\\_doc.pdf](http://ec.europa.eu/environment/ppps/pdf/draft_guidance_doc.pdf)

European Commission. 2004. Assessing economic impacts of the specific measures to be part of the Thematic Strategy on the Sustainable Use of Pesticides. Final Report ENV.C.4/ETU/2003/0094R by BiPRO Beratungsgesellschaft für integrierte Problemlösungen, October 2004

EUROPEAN PARLIAMENT 2010. REPORT on the proposal for a regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products. COM(2009)0267 – C7-0036/2009 – 2009/0076(COD), Session document A7-0239/2010, Committee on the Environment, Public Health and Food Safety, 1.9.2010 <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A7-2010-0239+0+DOC+PDF+V0//EN>

FAO 2002. International Code of Conduct on the Distribution and Use of Pesticides (Revised Version). Food and Agriculture Organization of the United Nations, Rome, 2002  
<http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Code/Download/code.pdf>

Federal Ministry of Consumer Protection Food and Agriculture (BMVEL). 2005. Programme for the Reduction of Chemical Plant Protection, [http://www.jki.bund.de/cln\\_045/nn\\_921038/DE/Home/koordinieren/reduktionsprogr/forumrcpdf.html](http://www.jki.bund.de/cln_045/nn_921038/DE/Home/koordinieren/reduktionsprogr/forumrcpdf.html)

Federal Ministry of Food, Agriculture and Consumer Protection (BMVEL). 2009. Expert Workshop on Implementation of the Directive of the European Parliament and of the Council Establishing a Framework for Community Action to Achieve a Sustainable Use of Pesticides (Framework Directive) on 23 to 25 June 2009 – Potsdam, Germany <http://nap.jki.bund.de/>

Gartiser, S., Hafner, Ch., Jäger, I., Reihlen, A., Ziesenitz, O., Schneider, K., Kalberlah, F., Oltmanns, J.: Description of the appropriate use and good practice during the use and disposal of biocidal products. Final report F 1929, Federal Institute for Occupational Safety and Health, December 2005 (in German)

Gartiser, S., Reuther, R., Reihlen, A., Luskow, H., Vernon, J., Zarogiannis, P. 2007. Study on Impact of the Implementation of Directive 98/8/EC concerning the Placing on the Market of Biocidal Products. Final Report for DG Environment, European Commission, October 10th 2007 <http://ec.europa.eu/environment/biocides/study.htm>

Gartiser, S., Jäger, I. Efficiency and practicability of risk mitigation measures for biocidal products - Wood preservatives and insecticides. Research Project FKZ 3709 65 402 Hydrotox GmbH Freiburg on behalf of the German Federal Environment Agency. 5th November 2010

Grey, C. N. B., Nieuwenhuijsen, M. J., Golding, J. 2006. Use and storage of domestic pesticides in the UK. *Science of The Total Environment* (368), issue 2-3, p. 465-470

Hamilton, A. C. 2004. Medicinal plants, conservation and livelihoods. *Biodiversity and Conservation* Volume 13 (8), p. 1477-1517

Herbst, A., Ganzelmeier, H. International Standards and their Impact on Pesticide. Application Aspects of Applied Biology 66, 2002 International Advances in Pesticide Application

[http://www.jki.bund.de/cln\\_044/nn\\_813794/SharedDocs/10\\_\\_FA/Publikationen/Pflanzenschutzgeraete/pubs/d2\\_\\_pdf,templateId=raw,property=publicationFile.pdf/d2\\_\\_pdf.pdf](http://www.jki.bund.de/cln_044/nn_813794/SharedDocs/10__FA/Publikationen/Pflanzenschutzgeraete/pubs/d2__pdf,templateId=raw,property=publicationFile.pdf/d2__pdf.pdf)

Hilbeck, A., Schmidt, J.E.U. 2006. Another View on Bt Proteins – How Specific are They and What Else Might They Do? *Biopestic. Int.* 2 (1): 1-50 (2006)  
<http://www.gmoera.umn.edu/public/publications/download/HilbeckSchmidt06.pdf>

Huemer, P. 2000. Auswirkungen von Kiefernprozessionsspinner-Bekämpfungsmaßnahmen mittels *Bacillus thuringiensis* auf die begleitende Lepidopterenfauna (Südtirol: Montiggler Wald). Landesabteilung Forstwirtschaft der Autonomen Provinz Bozen-Südtirol, Schriftenreihe für wissenschaftliche Studien:Nr.8/2000 Innsbruck [www.provinz.bz.it/forst/](http://www.provinz.bz.it/forst/)

James, A., Morin, A., Fribourg-Blanc, B. 2009. Implementation of requirements on Priority substances within the Context of the Water Framework Directive. Prioritisation process: Monitoring-based ranking. INERIS and International Office for Water, Contract N° 07010401/2008/508122/ADA/D2, September 2009

Knechtenhofer, L., Meier, I., Bürgi, D., Giger, W. 2007. Biozide als Mikroverunreinigungen in Abwasser und Gewässern - Teilprojekt 1: Priorisierung von bioziden Wirkstoffen. Studie im Auftrag des Bundesamt für Umwelt BAFU, Bern, ERZ Entsorgung + Recycling, Zürich.

<http://www.bafu.admin.ch/gewaesserschutz/03716/06387/>

Kümmerer, K., Hempel, M. (Ed.) 2010. *Green and Sustainable Pharmacy*, Springer, Berlin, 313 p.

Lepper, P., Daginnus, K., De Coen, W., Deviller, G., Netzeva, T., Pavan, M., Sobanska, M., Worth, A., Paya Perez, A., Eisenreich, S. 2008. Selection of Priority Substances in the context of the European Water Framework Directive. European Commission, Joint Research Centre, 21. May 2008

[http://ecb.jrc.ec.europa.eu/documents/QSAR/INFORMATION\\_SOURCES/PRESENTATIONS/Priority\\_setting\\_WFD.pdf](http://ecb.jrc.ec.europa.eu/documents/QSAR/INFORMATION_SOURCES/PRESENTATIONS/Priority_setting_WFD.pdf)

MLUV Brandenburg. 2003. Einfluss von Pestiziden auf Laich und Larven von Amphibien.

Müssig-Zufika, M., Becker, K., Conrad, A., Schulz, C., Seiffert, I., Seiwert, M., Lusansky, C., Pick-Fuß, H., Kolossa-Gehring, M. 2008. Kinder-Umwelt-Survey 2003/06 - KUS – Hausstaub Stoffgehalte im Hausstaub aus Haushalten mit Kindern in Deutschland. Umweltbundesamt, Forschungsbericht 202 62 219, Wabolu-Hefte 02/08. <http://www.umweltdaten.de/publikationen/fpdf-l/3356.pdf>

OECD. 2003. OECD Series on Emission Scenario Document, Number 2: Emission Scenario Documents for Wood Preservatives, Part 1 to 4.

OECD 2009. OECD Strategic approach in Pesticide Risk Reduction. ENVIRONMENT DIRECTORATE JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY, EN V/JM/MONO (2009)38, 23-Oct-2009  
<http://www.oecd.org/dataoecd/21/46/44033393.pdf>

Östman, Ö., Lundstrom, J. O., Persson, T. Z. 2008. Effects of mosquito larvae removal with *Bacillus thuringiensis israelensis* (Bti) on natural protozoan communities. *Hydrobiologia* (2008) 607:231–235  
<http://www.springerlink.com/content/c7441352h056514p/fulltext.pdf>

Pesticide Action Network Germany (PAN Germany).2008. For the Consideration of Biodiversity in Plant Protection Legislation, Hamburg 2008.

Pesticide Safety Directorate (PSD).2007. Strategy for Sustainable Use of Plant Protection Products. Biodiversity Action Plan. Version 4, November 2007:  
[http://www.pesticides.gov.uk/uploadedfiles/Web\\_Assets/Pesticides\\_Forum/Biodiversity\\_action\\_plan\\_Nov\\_07.pdf](http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/Pesticides_Forum/Biodiversity_action_plan_Nov_07.pdf)

SCENIHR. 2009. Assessment of the Antibiotic Resistance Effects of Biocides. Scientific Committee on Emerging and Newly Identified Health Risks, 19 January 2009  
[http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihhr/docs/scenihhr\\_o\\_021.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/docs/scenihhr_o_021.pdf)

Schmidt, C.K., Brauch, H.-J. 2008. N,N-Dimethylsufamide as Precursor for N-Nitrosodimethylamine (NDMA) Formation upon Ozonation and its Fate During Drinking Water Treatment *Environ. Sci. Techn.* 42, p. 6340-6346.

Scholl, E. 1995. Erarbeitung von Richtlinien für die integrierte Schädlingsbekämpfung im nichtagrarischem Bereich (außer Holzschädlinge). UBA-Forschungsbericht 126 06 011, Weltersbach, Juli 1995 [http://www.schadlingsbiologie.de/dGBorg/2007-03-01\\_UBATEXTE18-96\\_S1-451.pdf](http://www.schadlingsbiologie.de/dGBorg/2007-03-01_UBATEXTE18-96_S1-451.pdf)

Scottish Executive. 2004. Draft Code of Practice for the Safe Use of Plant Protection Products in Scotland. Scottish Executive and the Health and Safety Commission (HSC), Edinburgh, September, 2004  
<http://www.scotland.gov.uk/Resource/Doc/25725/0030018.pdf>

Singer, H., Jaus, S., Hanke, I., Lück, A., Hollender, J., Alder, A. C. 2010. Determination of biocides and pesticides by on-line solid phase extraction coupled with mass spectrometry and their behaviour in wastewater and surface water. *Environmental Pollution* 158, p. 3054-3064

Vernon, J., Tuffnell, N., Gartiser, S., Zamparutti, T., White, O., Pozo, E. 2008. Assessing the Impact of the Revision of Directive 98/8/EC concerning the Placing of Biocidal Products on the Market. Final report prepared for European Commission, Directorate General Environment, September 2008

[http://ec.europa.eu/environment/biocides/pdf/rev\\_ias\\_report.pdf](http://ec.europa.eu/environment/biocides/pdf/rev_ias_report.pdf)

WHO. 1999. Microbial Pest Control Agent BACILLUS THURINGIENSIS Environmental Health Criteria 217, Geneva

<http://www.who.int/ipcs/publications/ehc/en/EHC217.PDF>

ZHU, Y., BALKE, K.-D. Groundwater protection: What can we learn from Germany? J Zhejiang Univ Sci B 2008 9(3):227-231 227

<http://www.zju.edu.cn/jzus/2008/B0803/B080306.htm>