

TEXTE

01/2011

Efficiency and practicability of risk mitigation measures for biocidal products

Wood preservatives and insecticides

ENVIRONMENTAL RESEARCH OF THE
FEDERAL MINISTRY OF THE ENVIRONMENT,
NATURE CONSERVATION AND NUCLEAR SAFETY

Project No. (FKZ) 3709 65 402
Report No. (UBA-FB) 001446/E

**Efficiency and practicability of risk
mitigation measures for biocidal products**
Wood preservatives and insecticides

by

Stefan Gartiser (project direction)
Ismene Jäger

Hydrotox GmbH, Labor für Ökotoxikologie
und Gewässerschutz, Freiburg

On behalf of the Federal Environment Agency (Germany)

UMWELTBUNDESAMT

This publication is only available online. It can be downloaded from
<http://www.uba.de/uba-info-medien-e/4053.html>.

The contents of this publication do not necessarily
reflect the official opinions.

ISSN 1862-4804

Publisher: Federal Environment Agency (Umweltbundesamt)
P.O.B. 14 06
06813 Dessau-Roßlau
Germany
Phone: +49-340-2103-0
Fax: +49-340-2103 2285
Email: info@umweltbundesamt.de
Internet: <http://www.umweltbundesamt.de>
<http://fuer-mensch-und-umwelt.de/>

Edited by: Section IV 1.2 Biocides
Dr. Jürgen Fischer

Dessau-Roßlau, January 2011

Report Cover Sheet

1. Report No. UBA-FB 001446/E	2.	3. IV 1.2 Biocides
4. Report Title Efficiency and practicability of risk mitigation measures for biocidal products - Wood preservatives and insecticides		
5. Autor(s), Family Name(s), First Name(s) Gartiser, Stefan (project direction) Jäger, Ismene		8. Report Date 5.11.2010
6. Performing Organisation (Name, Address) Hydrotox GmbH Labor für Ökotoxikologie und Gewässerschutz 79111 Freiburg, Bötzingen Str. 29		9. Publication Date January 2011
		10. UFOPLAN-Ref. No. FKZ 3709 65 402
		11. No. of Pages 143
		12. No. of Reference 51
7. Funding Agency (Name, Address) Umweltbundesamt (Federal Environmental Agency) Postfach 14 06, 06813 Dessau-Roßlau		13. No. of Tables, Diagrams 7
		14. No. of Figures 5
		15. Supplementary Notes
16. Abstract In assessing the impact of biocides on the environment, specific risk mitigation measures (RMM) may be required to reduce the risks for the environment. RMM can be considered to be instruments of risk management. The practicability of RMM proposed by authorities, industry and users of biocides have been assessed with particular emphasis on wood preservatives and insecticides. The RMM proposed in Competent Authority Reports and considered in the Inclusion Directives are based on the intended uses and the representative biocidal product and might not cover all applications. Product labels, safety data sheets and technical leaflets often provide useful additional information. Good and best practice documents are important supporting tools for RMM to be implemented. Product integrated RMM implemented during product development, design and distribution are immediately practicable while those which refer to the user of biocidal products mainly depend on the communication of risks, risk awareness, education, specific training and of the availability information. The label recommendations on proper application of the biocidal product are an important tool for risk communication. Not all RMM proposed can be addressed during authorisation but have to be tackled in other regulatory areas, e.g. the development of BAT or other best practices. Thus, apart from RMM being addressed in regulatory decisions, a broader strategy of sustainable use of biocides is required in order to increase the practicability of RMM. Little information is available on the quantitative efficiency of RMM which hinders their consideration in the risk assessment. More specific RMM may be included in the authorisations of biocidal products when full information on the formulation and the conditions of use are available		
17. Keywords Risk mitigation measures, risk management, biocides, Biocidal Products Directive, sustainable use, best practices, risk awareness		
18. Price	19.	20.

Berichts-Kennblatt

1. Berichtsnummer UBA-FB 001446/E	2.	3. IV 1.2 Biozide
4. Titel des Berichts Effizienz und Praxisnähe von Risikominderungsmaßnahmen für Biozidprodukte		
5. Autor(en), Name(n), Vorname(n) Gartiser, Stefan (Projektleitung) Jäger, Ismene	8. Abschlußdatum 5.11.2010	9. Veröffentlichungsdatum Januar 2011
6. Durchführende Institution (Name, Anschrift) Hydrotox GmbH Labor für Ökotoxikologie und Gewässerschutz 79111 Freiburg, Bötzingen Str. 29	10. UFOPLAN-Nr. FKZ 3709 65 402	11. Seitenzahl 143
	12. Literaturangaben 51	13. Tabellen und Diagramme 7
	14. Abbildungen 5	
7. Fördernde Institution (Name, Anschrift) Umweltbundesamt, Postfach 14 06, D-06813 Dessau		
15. Zusätzliche Angaben		
16. Kurzfassung Bei der Bewertung der Umweltauswirkungen von Bioziden können spezifische Risikominderungsmaßnahmen (RMM) vorgeschrieben werden, um Risiken für die Umwelt zu reduzieren. RMM werden als Instrument des Risikomanagements angesehen. Die Praktikabilität der von Behörden, Industrie und Anwendern von Bioziden vorgeschlagenen RMM wurde bewertet, mit speziellem Augenmerk auf Holzschutzmittel und Insektizide. Die in den „Competent Authority Reports“ und Aufnahmeleitlinien berücksichtigten RMM beruhen auf den beabsichtigten Verwendungen und dem repräsentativen Biozidprodukt, decken jedoch möglicherweise nicht alle Anwendungen ab. Die Produktlabel, Sicherheitsdatenblätter und technischen Merkblätter enthalten oftmals wertvolle zusätzliche Informationen. Dokumente zur Beschreibung guter und bester Techniken sind wichtige Instrumente zur Unterstützung der Umsetzung von RMM. Produktintegrierte RMM, die bei der Produktentwicklung, dem Produktdesign und den Vertriebswegen ansetzen, sind unmittelbar praktikabel, während RMM, die sich an die Anwender richten, im Wesentlichen von der Risikokommunikation und Risikowahrnehmung sowie von Ausbildung und Trainingsmaßnahmen abhängig sind. Die Anwendungsempfehlungen der Produktlabel zur ordnungsgemäßen Anwendung von Biozidprodukten sind wichtige Instrumente zur Kommunikation von Risiken. Nicht alle der vorgeschlagenen RMM können im Rahmen des Zulassungsverfahrens eingebunden werden. Diese müssen in anderen Rechtsbereichen, wie z.B. der Entwicklung von BVT oder anderen „beste Praktiken“, adressiert werden. Daher ist, um die Praktikabilität der RMM zu erhöhen, neben RMM im Rahmen von Zulassungsentscheidungen eine breitere Strategie zur nachhaltigen Verwendung von Biozidprodukten erforderlich. Bezüglich der Effizienz von RMM liegen nur wenige quantitative Informationen vor, was deren Berücksichtigung bei der Risikobewertung erschwert. Im Rahmen der Zulassung von Biozidprodukten, wenn alle Informationen zur Formulierung und den Anwendungsbedingungen verfügbar sind, können spezifischere RMM mit der Zulassung verknüpft werden.		
17. Schlagwörter Risikominderung, Risikomanagement, Biozide, Biozid-Produkte-Richtlinie, nachhaltige Nutzung, Beste Praktiken, Risikowahrnehmung		
18. Preis	19.	20.

Contents

1	Introduction.....	7
2	Legislative background	9
2.1	Definition and boundary of risk mitigation	9
2.2	Biocidal Product Directive.....	11
2.3	Plant protection products.....	16
2.4	Directive on machinery for pesticide application.....	16
2.5	Existing chemical substances.....	17
2.6	REACH.....	18
2.7	Medicinal products.....	20
2.8	IPPC Directive	22
2.9	Water Framework Directive 2000/60/EC	23
3	Data sources on risk mitigation measures	25
3.1	European Commission	25
3.2	Research projects and literature.....	26
3.3	Good and best practice documents of associations and authorities	26
3.4	Biocidal product registers	27
3.5	Analysis of leaflets of biocidal products.....	28
4	Results of the literature research.....	30
4.1	Introduction.....	30
4.2	Efficiency of risk mitigation measures for plant protection products	32
4.3	OECD Pesticide Risk Reduction Steering Group	34
4.4	FAO/WHO	36
4.5	REACH.....	36
4.6	Medicinal products.....	37

5	Provisions on risk mitigation measures for biocides	39
5.1	Guidance documents discussed at CA-meetings	39
5.2	Evaluation of (draft) Inclusion Directives	41
5.3	Results of the COWI-study	44
6	Risk mitigation measures for PT 8 and 18 biocides	48
6.1	Competent Authority reports on biocidal active substances	48
6.1.1	Wood preservatives (PT 8)	48
6.1.2	Insecticides (PT 18)	51
6.1.3	Substances of (very) high concern	54
6.1.4	Conclusion	57
6.2	Good and best practice documents	58
6.2.1	Wood preservatives	58
6.2.2	Insecticides	65
6.2.3	Conclusion	69
6.3	Product labels, safety data sheets and technical leaflets	69
6.3.1	Product labels and safety data sheets	69
6.3.2	Technical leaflets of wood preservatives	73
6.3.3	Technical leaflets of Insecticides	74
6.3.4	Conclusion	76
6.4	Other aspects of risk management	77
6.4.1	Regulatory instruments	78
6.4.2	Upgrading of other regulations	80
6.4.3	Guidance development	81
6.4.4	Information and awareness-raising	82
6.4.5	Emission during service life	82
6.5	Addressees of risk mitigation measures	82
7	Efficiency and practicability of risk mitigation measures	85
7.1	Introduction	85
7.2	User group	85
7.3	Wood preservatives	86

7.3.1	Placing on the market.....	86
7.3.2	Application of biocidal products	90
7.3.3	Post application	93
7.4	Insecticides.....	96
7.4.1	Placing on the market.....	96
7.4.2	Application of biocidal products	97
7.4.3	Post application	100
7.5	Further regulatory options	103
7.5.1	Sustainable use of biocides.....	103
7.5.2	Comparative risk assessment.....	104
7.5.3	Socio-economic benefit analysis	105
7.5.4	Reference to national conditions	105
7.6	Efficiency of risk mitigation measures.....	106
8	Conclusions and recommendation.....	108
8.1	Introduction.....	108
8.2	Provisions of the Biocidal Products Directive	108
8.3	Risk mitigation in other regulatory areas	110
8.4	Elements for risk mitigation	111
8.5	Recommendations.....	115
9	References	117

Annex 1: Provisions for product authorisations from the PT 8 CARs

Annex 2: Provisions for product authorisations from the PT 18 CARs

Annex 3: RMM proposed in PT 8 product leaflets

Annex 4: RMM proposed in PT 18 product leaflets

List of Tables

Table 1:	Risk mitigation measures on biocidal use with emphasis on human health.....	14
Table 2:	Web-sites of suppliers of PT 8 and 18 biocidal products	29
Table 3:	Provisions for product authorisations from the Inclusion Directives.....	42
Table 4:	Risk mitigation measures on biocides identified in the COWI-study	46
Table 5:	Provisions for product authorisations from the PT 8 CARs.....	49
Table 6:	Provisions for product authorisations from the PT 18 CARs.....	52
Table 7:	Examples of labels according to Article 20 BPD.....	70

List of Figures

Figure 1:	Steps in environmental risk management.....	9
Figure 2:	Data sources and analysis	25
Figure 3:	Instruments for sustainable use of pesticides.....	78
Figure 4:	Addressees of Risk mitigation measures.....	83
Figure 5:	Elements of risk mitigation and risk management	111

List of Abbreviations

BAT	Best Available Techniques
BAuA	German Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin)
BBA	German Biological Research Centre for Agriculture and Forestry (now JKI)
BPD	Biocidal Products Directive
BMELV	Federal Ministry for Food, Agriculture and Consumer Protection (Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz)
BREF	Best Available Technique Reference Documents
BTI	Bacillus thuringiensis subsp. israelensis
CA	Competent Authority
CAR	Competent Authority Report
CEN	European Committee for Standardisation
CEPA	Confederation of European Pest Control Associations
CEPE	European Council of producers and importers of paints, printing inks and artists' colours
CIRCA	Communication & Information Resource Centre
CMR	Carcinogenic, Mutagenic, or toxic for Reproduction
CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment
DAR	Draft Assessment Report
DEFRA	Department for Environment, Food and Rural Affairs (UK)
DGfH	German Association for Wood Research (Deutsche Gesellschaft für Holzforschung e.V.)
DIBt	Deutsches Institut für Bautechnik
EC	European Communities or European Commission
EMA	European Medicines Agency
EP	European Parliament
EQS	Environmental Quality standards
ERA	Environmental Risk Assessment
ESD	Emission Scenario Document
ESIS	European chemical Substances Information System
EU	European Union
GP	Good Practice
GPPP	Good Plant Protection Practice

IPM	Integrated Pest Management
IPPC	Integrated Pollution Prevention and Control
JKI	German Federal Research Centre for Cultivated Plants (Julius Kühn-Institut)
MRLs	Maximum Residue Levels (on food and feed)
MS	Member State
MSDS	Material Safety Data Sheets
NAP	National Action Plan
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative and Toxic
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
POP	Persistent organic pollutant
PPE	Personal Protection 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
RMS	Rapporteur Member State
RRSG	OECD Pesticide Risk Reduction Steering Group
SETAC	Society of Environmental Toxicology and Chemistry
STP	Sewage treatment plant
SVHC	Substances of Very High Concern
TNsG	Technical Notes for Guidance
TRGS	Technische Regeln für Gefahrstoffe (Technical Rules for Hazardous Substances)
UBA	Federal Environment Agency (Germany)
ULIDAT	Environmental Literature Database of the UBA (Umweltliteraturdatenbank)
VMP	Veterinary Medicinal Products
vPvB	Very Persistent and Very Bioaccumulative
WFD	Water Framework Directive 2000/60/EC
WHO	World Health Organisation
WHOPES	The WHO Pesticide Evaluation Scheme

1 Introduction

In assessing the impact of biocides on the environment, specific measures to reduce risks to the environment may be required. Initial experience in the evaluation of active substances showed that the rapporteur member states have followed different paths to risk mitigation for a given risk to human health and / or the environment. For the environmental area, a coordinated approach to risk mitigation measures is missing. This raises the concern that discussion of the problem will be postponed to the national product authorisation phase and the mutual recognition of biocidal products. However, at this stage a harmonization of possible risk mitigation measures is difficult to achieve due to the short deadlines.

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 of Directive 98/8/EC). When an unacceptable risk has been determined during the risk assessment, it may be possible to reduce the risk to acceptable levels by imposing “risk mitigation measures” (RMM). Thus, RMM can be regarded as instruments of the risk management process. The term “risk reduction measure” is often also used as synonym for RMM. However, a clear definition of the different terms is lacking.

The objective of the research project is to contribute to compiling RMM required for an EU-wide harmonized assessment of biocidal products and to identify appropriate solutions to prevent / reduce the identified risks. This has been illustrated using the examples of the product types (PT) wood preservatives (PT 8) and insecticides (PT 18). To this end, RMM proposed by producers, users and authorities have been collected and critically evaluated in terms of practicability and efficiency. Although these measures have often been developed in terms of occupational health and safety, they cannot be separated from proposals to minimize environmental risks. This project mainly considers environmental risks, ideally during the entire lifecycle of a biocidal product. This means the succession from the formulation, the placing on the market until the application, the use phase, service life, and the final disposal. The main emphasis has been put on the use phase/service life of biocides and on articles treated with biocides.

The work plan consisted of five tasks. First, a systematic internet search and review of the literature on risk mitigation measures of biocides was performed while also considering other chemicals legislation. Second, the (draft) Competent Authority Assessment Reports (CARs) of existing biocidal active substances published so far have been evaluated. Third, existing proposals for risk mitigation measures during the application and use of biocidal products have been analysed. Fourth, the actual risk mitigation measures proposed by industry for wood preservatives and insecticides on the market which are relevant for the environment have been analysed. For this, existing information available for the various user groups, such as operating instructions, manuals, technical leaflets, safety data sheets and product labels have been evaluated. Fifth, the proposed risk mitigation measures have been assessed for their suitability and practicability in the forthcoming product authorisation.

The focus of the project is on RMM that could be required within regulatory decisions on both active substances and biocidal products. Among these are the restriction of users (e.g. only professionals or specialised professionals), obligatory education and certification of professional users, certification and inspection of equipment, specification of the mode of application and so on. These regulatory options should be distinguished from other risk management or risk reduction measures which address general information to the public, training and awareness raising, integrated pest management, data collection on use and consumption of the active substances and requirements for sales. These are addressed in the project on “sustainable use of biocides” sponsored by the German Federal Environment Agency (FKZ 3708 63 400).

2 Legislative background

2.1 Definition and boundary of risk mitigation

In chemical risk assessment, a risk is defined by the hazardousness of a chemical and the exposure to it of humans and/or the environment. Hazard is determined by the potential of a particular substance to cause harmful effects. A risk assessment consists of a systematic approach where an effects assessment (dose-response analysis) of chemicals is combined with an exposure assessment covering all uses and life stages of the substance. Environmental risks are often expressed as risk quotients (PEC/PNEC) of the different environmental compartments. If the risk characterisation concludes that there is a potential risk, the process moves on to risk management where the acceptability of this risk is analysed. In chemical risk assessment and related regulatory areas chemicals and products may not be allowed to be marketed for applications for which an unacceptable risk has been identified. In the risk management process risk mitigation measures can also involve both modifying the hazardousness of the chemical used (substitution of the chemical by less hazardous ones) or by reducing the likelihood and/or the extent of exposure (figure 1).

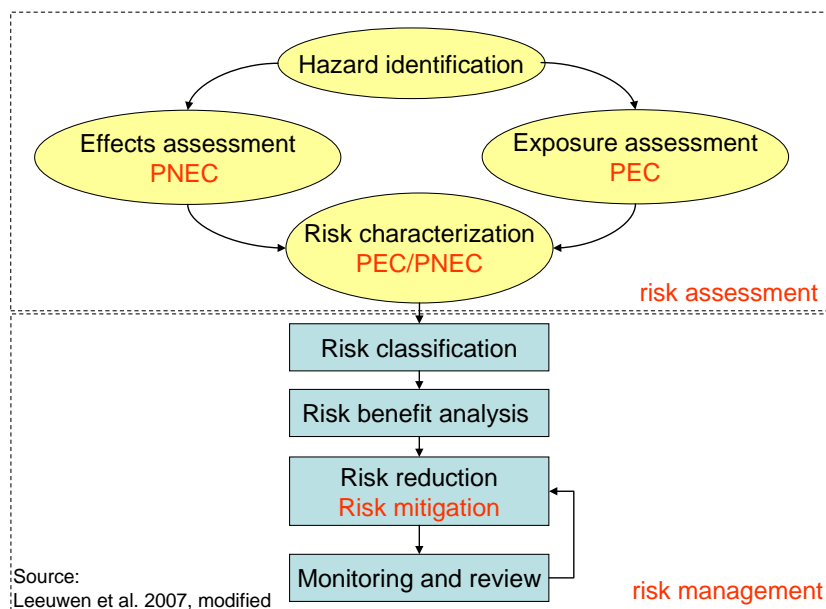


Figure 1: Steps in environmental risk management

Risk management is about taking measures based on risk assessments and considerations of a legal, political, social economic and engineering nature. It is mainly a political process, although science is involved in the decision making (Leeuwen et al. 2007). In the ESD on wood preservatives (part 4) “risk management techniques” are defined as techniques that reduce risk through market controls, emission reduction techniques and label recommendations, controlling the product quantity or concentration or form, restricting the sectors for use, specifying control measures and PPE, etc. (OECD 2000).

In some cases, where no substitutes are available, a risk/benefit analysis may be performed. This is especially the case where substances of (very) high concern (carcinogens, mutagens, toxic to reproduction, PBT), to which exposure should be prevented, are involved.

Although there is no generally accepted definition of “risk mitigation”, one could describe it as a *“systematic reduction in the extent of exposure to a risk and/or the likelihood of its occurrence”*. Risk mitigation is also used as a synonym for “risk reduction”.¹

In the context of this project, “risk mitigation” is attributed to regulatory decisions. This means that the authorisation of a biocidal product might be subject to certain RMM. In so far as the risks have been identified during the assessment of the active substances and/or their representative biocidal products, certain RMM can be described in the inclusion directives.

Definition of risk mitigation measures (RMM)

There still does not exist a clear definition of “*risk mitigation measures*” across the different fields of chemical risk assessment. In the TNsG on biocidal product evaluation “risk” is defined as *“the possibility that a harmful event arising from exposure to a chemical or physical agent may occur under specific conditions”*. While the TNsG refer to “*risk management measures*” or “*risk reduction measures*”, in Annex I of Directive 98/8/EC the term “risk mitigation measures” is used (see chapter 2.2). Also, Regulation (EC) No 1107/2009 refers to “*risk mitigation*”

¹ <http://www.businessdictionary.com>

measures” for specific conditions of use of plant protection products. In contrast, in the context of REACH the phrase “*risk management measures*” is used (see chapters 2.3 and 2.6).

In this report the terms “*risk mitigation measures*” and “*risk reduction measures*” are used as synonyms and considered as part of the risk management process where specific provisions and restrictions for products to be authorised are decided. “*Risk management measures*” include further aspects such as non approval of authorisations or risk-benefit analysis. The term “*risk management measures*” is also used in Directive 2009/128/EC on sustainable use of pesticides which also describes instruments for beyond regulatory decisions (see below).

It should be noted that, in the plant protection area, a broader strategy on the minimization of risks to human health and the environment through the use of pesticides has been adopted in Directive 2009/128/EC on sustainable use of pesticides. This also covers many aspects beyond regulatory decisions, such as the promotion of integrated pest management and of alternative non-chemical techniques, the improvement of awareness of the general public through information campaigns and of training of professional users/distributors. The detailed measures are described in National Action Plans (NAPs). To date, Directive 2009/128/EC has focused on plant protection products. However, the possibility of extending it to biocides is kept open. The transferability of proposals elaborated for plant protection products to the biocides area is analysed in another research project (FKZ 3708 63 400, see 6.4).

2.2 Biocidal Product Directive

According to Article 5 of the Biocidal Product Directive 98/8/EC (BPD), Member States shall authorise a biocidal product only if it has no unacceptable effect on the environment itself, or as a result of its residues, with particular regard to its fate and

distribution in the environment (surface water, groundwater, drinking water, soil and air) and its impact on non-target organisms².

The common core data set for active substances in Annex IIA describes under section VIII the following measures necessary to protect humans, animals and the environment:

- Recommended methods and precautions concerning handling, use, storage, transport or fire
- In case of fire, nature of reaction products, combustion gases, etc.
- Emergency measures in case of an accident
- Possibility of destruction or decontamination following release in or on the following: (a) air (b) water, including drinking water (c) soil
- Procedures for waste management of the active substance for industry or professional users
- Possibility of reuse or recycling
- Possibility of neutralisation of effects
- Conditions for controlled discharge including leachate qualities on disposal
- Conditions for controlled incineration
- Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms

Annex VI of the BPD describes the common principles for the evaluation of dossiers for biocidal products. The points to be considered in decision making are highlighted:

56	In making a decision concerning authorisation, the Member State shall arrive at one of the following conclusions for each product type and for each area of use of the biocidal product for which application has been made: 1. the biocidal product cannot be authorised; 2. the biocidal product can be authorised subject to specific conditions/restrictions ; 3. more data is required before a decision on authorisation can be made.
63	In the decision-making process the Member State shall take into consideration the following: <ul style="list-style-type: none"> • the results of the risk assessment, in particular the relationship between exposure and effect, • the nature and severity of the effect, • the risk management which can be applied, • the field of use of the biocidal product,

² Article 16 of the proposal of the Commission for a Regulation concerning the placing on the market and use of biocidal products (COM(2009)267) also considers the impact on biodiversity and the ecosystem.
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0267:FIN:EN:PDF>

	<ul style="list-style-type: none"> • the efficacy of the biocidal product, • the physical properties of the biocidal product, • the benefits of using the biocidal product.
80	For any given environmental compartment if the PEC/PNEC ratio is equal to or less than 1 the risk characterisation shall be that no further information and/or testing are necessary. If the PEC/PNEC ratio is greater than 1 the Member State shall judge, on the basis of the size of that ratio and on other relevant factors, if further information and/or testing are required to clarify the concern or if risk reduction measures are necessary or if the product cannot be given an authorisation at all.

The Technical notes for guidance (TNsG) for the inclusion of active substances in Annexes I, IA and IB state in section 1 that specific risk reduction measures should be considered if necessary for the risk management of the active substance. Additionally, if an active substance fails the preliminary risk assessment, it may be possible for the exposure scenario to be modified in a limited way to take account of risk management tools. The principles of comparative risk assessment are roughly described as a procedure to determine whether there is an alternative active substance for the same purpose with less risk. However, no principles and options for risk mitigation measures at the active substance level are described.

The TNsG on Product Evaluation (update from February 2008) in section 5.3.2 describe the following conditions or restrictions of use with respect to the environment:

“In some instances a route of likely exposure may be prevented, or the exposure reduced, by the use of appropriate control/preventative measures. Examples include use of proofing to prevent wildlife from entering areas where the biocide is being applied. The risk assessment should determine the measures necessary to protect humans, animals and the general environment during both the proposed normal use of the biocidal product and in a realistic worst case situation. The proposed instructions for use of the biocidal product, including procedures for cleaning application equipment, must be such that the likelihood of accidental contamination of the environment is minimised. The Competent Authority shall also take the necessary measures to ensure that the applicant proposes packaging and, where appropriate, the procedures for destruction or decontamination of the biocidal product and its packaging or any other relevant material associated with the biocidal product, which conforms to the relevant regulatory provisions.”

The provisions on conditions on use are not very specific and do not describe a set of options of risk mitigation measures.

In contrast, the RMM for physico-chemical properties are referred to in detail. In particular, RMM on explosivity, oxidising properties, flammability, storage stability and compatibility and reactivity with other products are described with the objective to avoid accidents. Measures to ensure human health are also more fully elaborated (table 1).

Table 1: Risk mitigation measures on biocidal use with emphasis on human health

	For professionals	For non-professionals
Acute toxicity	engineering controls; Use of personal protective equipment	Child resistant closures
Irritation and Corrosivity	Engineering controls; Use of personal protective equipment	Closed transfer systems for diluting concentrates; Ready-for-use formulations
Sensitisation	Engineering controls; Use of personal protective equipment; Improved packaging, e.g. the use of water soluble packaging	Transfer systems for diluting concentrates
Repeated dose toxicity; Genotoxicity; Carcinogenicity; Reproductive toxicity	Engineering controls; Use of personal protective equipment; A warning not to use the product in situations where bystander exposure could be continuous	Mutagens, carcinogens or toxic to reproduction (Cat.1+2) or danger of serious damage to health on prolonged exposure cannot be authorised; For use by non-professionals Authorisation for occasional use only; Reduction in pack size

It is stated that a requirement to wear personal protective equipment as the only means of reducing the risk from a product to an acceptable level would exclude the possibility of authorisation for use by the general public.

The TNsG on Product Evaluation in sections 4.4.1 and 5.1.1 mentions the following risk management options for human health and the environment:

- limiting the concentration of the active substance in the product;
- changing the formulation type (e.g. adding a dust suppressant);
- changing the form of packaging (e.g. enclosing the product);
- labelling (e.g. restrictions on the method of use);

- limiting the container size;
- restriction of category of user, e.g. to professional use only;
- restriction of application methods, e.g. enclosed instead of open processes, brushing instead of spraying;
- restriction in the field of use, e.g. indoor use only;
- modification of formulation, e.g. ready-for-use rather than concentrate, replacement of substances of concern with less dangerous ones, etc.;
- modification of packaging, labelling and measures for the protection of people and/or the environment, e.g. reduced pack size or use of automated transfer systems;
- adjustment of dose or application rate to suit particular circumstances;
- if exposure can be by more than one route simultaneously, then total exposure should be determined.

Obviously, some of these options have implication for both human health and on the exposure to the environment.

On 12 June 2009, the European Commission adopted a proposal for a Regulation concerning the placing on the market and use of biocidal products, which is currently being discussed by Member States and the European Parliament. This Regulation will replace the existing BPD. Among the most significant innovations, articles treated with biocidal products are intended to be included under the scope of the Regulation (Chapter X of the Commission's proposal). According to the proposal all treated articles or materials will be labelled. Labelling shall include the name of all active substances, the biocidal property attributed to the treated articles or materials, the authorisation number of all biocidal products used and any hazard statement or precautionary statement set out in the authorisation for the biocidal product. Where necessary because of the size or the function of the treated article or material, the labelling shall be printed on the packaging, on the instructions for use or on the warranty of the treated article or material. These requirements will have a significant influence on reducing emissions during the service life of materials treated with biocides such as treated wood. Compliance with the application area (use class) attributed to wood preservatives can only be followed if the treated wood is labelled accordingly.

2.3 Plant protection products

Directive 91/414/EEC (from June 2011 on replaced by Regulation (EC) No 1107/2009) governs the placing on the market of plant protection products.³ Article 11 of the Directive states, that “*where a Member State has valid reasons to consider that a product ... constitutes a risk to human or animal health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory*”. Annex I lists the active substances authorised for use in plant protection products and 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”.⁴

2.4 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).

³ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1991L0414:20070201:EN:PDF>

⁴ 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.

2.5 Existing chemical substances

The Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances concerned provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. This Regulation has now been implemented into Regulation (EC) No 1907/2006 (REACH). REACH Article 14 sets out requirements concerning the chemical safety report and the duty to apply and recommend risk reduction measures. Article 37 refers to downstream user chemical safety assessments and the duty to identify, apply and recommend risk reduction measures, without going into details. For a number of existing substances, the Commission has published recommendations of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on risk reduction measures for workers and/or the environment.

Commission recommendation	Existing substances
2008/98/EC	Piperazine; Cyclohexane; Methylenediphenyl, diisocyanate; But-2-yne-1,4-diol; Methyloxirane; Aniline; 2-Ethylhexylacrylate; 1,4-Dichlorobenzene; 3,5-dinitro-2,6-dimethyl-4-tert-butylacetophenone; Di-(2-ethylhexyl)phthalate; Phenol; 5-tert-butyl-2,4,6-trinitro-m-xylene
2002/755/EC	diphenyl ether, octabromo derivative
2008/447/EC	benzyl butyl phthalate (BBP), 2-furaldehyde (furfural), perboric acid, sodium salt
2001/194/EC	diphenylether/pentabromo derivative and cumene
2008/454/EC	sodium chromate, sodium dichromate and 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (tetrabromobisphenol A)
2006/283/EC	Dibutylphthalate; 3,4-Dichloroaniline; Di-'isodecyl'phthalate; 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich; Di-isononyl phthalate; 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich; Ethylenediaminetetraacetate; Methyl acetate; Monochloroacetic acid; n-Pentane; Tetrasodiummethylenediaminetetraacetate

Without going into details, the following risk reduction options have been mentioned in the context of one or more of these existing substances:

- Member States should lay down conditions, emission limit values or equivalent parameters or technical measures in order for the installations concerned to operate according to the best available techniques taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions.
- Member States should carefully monitor the implementation of Best Available Techniques (BAT) and report any important developments to the Commission in the framework of the exchange of information on BAT.
- Local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

- For the river basins where emissions ... may cause a risk, Member State should establish Environmental Quality Standards (EQS) and the national pollution reduction measures to achieve those EQS should be included in the river basin management plans in line with the provisions of Directive 2000/60/EC (Water Framework Directive).

The risk reduction options relate to point emissions from manufacturing and industrial use BAT as well as the establishment of EQS and monitoring.

For some substances, such as diphenylether octabromo derivative, more detailed recommendations on data gaps and options regarding the restriction of marketing and use have been suggested (Recommendation 2002/755/EC).

Interestingly, for diphenylether/pentabromo derivatives, the recommendation states that *“Whereas the risk assessment and risk reduction strategy only identified the production and use of the substance in polyurethane foams, all other uses resulting in emissions, discharges and losses to the environment would be unacceptable.”* (Recommendation 2001/194/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) are 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 a herbicide on sealed surfaces should be considered in the risk assessment and misuse of diuron should be prevented.

2.6 REACH

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.⁵ In the guidance document on information requirements and chemical safety assessment, Chapter R.13, the following principles on risk management measures and operational conditions are described:⁶ Concerning exposure to the environment it is stated 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

⁵ In REACH guidances the abbreviation RMM is used for “risk management measure”. In this report RMM is used for “risk mitigation measure”

⁶ http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r13_en.pdf?vers=20_08_08

can address both occupational and environmental exposure and can be based on sector specific process recommendations or definition of BAT under the IPPC Directive. The REACH Guidance R.13 describes several factors influencing exposure of humans and emissions to the environment.

- The physical form of a product is important for the exposure potential of the substance. Solid substances or preparations may be supplied as fine light powders which imply high dustiness. Liquids may form aerosols or splashes when processed with mechanical energy. The vapour pressure and water solubility are important parameters which determine the main emission routes.
- The product specifications, i.e. concentration/percentage of the substance in a preparation or article, may be directly linked to the exposure of humans and the environment
- Operational conditions such as the duration and frequency of an application, the amount applied, potential containments of the process and/or the capacity of the surrounding environment (indoor/outdoor) directly influence the extent of exposure. It is stated that ventilation is difficult to control by consumers. When indicated on the label that the product should be used 'in well ventilated areas' or 'outdoor', this does not mean that a certain (high) ventilation rate is assured.

Considering user information as risk management measures, the guidance R.13 states that complex instructions are not suitable to ensure control of risk at the consumer level. Only short and simple instructions are likely to be implemented by a significant proportion of consumers. Thus, emphasis should be on measures that are integrated to the design of the product and how it is subsequently used.

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.

According to REACH, substances in articles need to be considered as part of the life-cycle of a substance. During the service life of articles, substances can be released into the environment dependent on the total quantity of the substance incorporated

into the article and the fraction of this that will be released, taking account of the duration of article use, the surface area to volume ratio, accelerated wear and tear or factors enhancing emissions (including weathering or erosion-intense use).

The Guidance R.13 also refers to risk management measures effectiveness, which is defined as the percentage reduction in exposure concentration or emission (release) produced by application of the risk management measure. This requires a quantification of the effects that the different risk management measures may have on the risk determining factors.

Chapter R.11 of the REACH Guidance document (May 2008) concerns the PBT assessment of chemicals. For substances fulfilling the PBT and vPvB criteria, the exposure and risk characterisation has the objective to minimise emissions from manufacture or identified uses and subsequent exposures of humans and the environment. The need or potential to (further) minimise emissions may be recognised at any point in the development of the Exposure Scenario. In this case, the appropriate risk management measures or operational conditions should be included in the risk management framework and their effectiveness be assessed.

2.7 Medicinal products

Veterinary medicinal products

Requirements for assessment of environmental safety for veterinary medicinal Products (VMP) were introduced into the legislation by Directive 92/18/EEC. This states that potential harmful effects which the use of the product may cause to the environment should be analysed and precautionary measures which may be necessary to reduce such risks should be identified. The environmental assessment should be carried out in two phases. In the first phase the extent of environmental exposure is estimated and in the second phase the fate and effects of the active residue are assessed. The revised EMEA guidelines on environmental impact assessment for veterinary medicinal products specify the following RMM:⁷

“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. In principle, the applicant

⁷ <http://www.emea.europa.eu/pdfs/vet/era/41828205enfin.pdf>

should propose RMM and, if appropriate, the efficacy of such measures should be substantiated by data in the dossier.”

To be effective, such a risk mitigation measure should meet the following criteria: It should

- Mitigate exposure of the VMP to the environment
- Be in line with agricultural practice
- Be in agreement with the legislation of the EU and its Member States
- Be possible to demonstrate the effect of the proposed risk mitigation measure by evaluating the exposure assessment with the proposed risk mitigation measure included

In accordance with Directive 2001/82/EC on Veterinary Medicinal Products (as amended) this risk has to be weighed against the favourable aspects of a marketing authorisation. Examples of possible RMM are

- The product should not be allowed to enter surface waters as it has harmful effects on aquatic organisms
- Do not allow treated animals to swim in watercourses until at least x hours/days after administration
- The product should not come into water courses as this may be dangerous for fish and other aquatic organisms
- The long-term effects on the population dynamics of dung beetles have not been investigated. Therefore, it is advisable not to treat animals on the same pasture every season
- Data on the degradation of the active residue in manure may be submitted. If the active residue is rapidly and completely degraded in manure then the assessment may be ended after Phase I (exposure assessment)

Human medicinal products

The EMEA guideline for the environmental risk assessment of medicinal products for human use came into effect on 1 December 2006.⁸ In accordance with Article 8(3) of Directive 2001/83/EC an Environmental Risk Assessment (ERA) shall accompany an application for a marketing authorisation for a medicinal product for human use and is required for all new marketing authorisation applications. Phase I consists in a pre-screening of the exposure based on consumption data and the log K_{ow}. A PEC_{surface water} value of 0.01 µg/L has been defined as a limit value. Phase II consists of an initial prediction of risk by a base set aquatic toxicology and fate assessment (Tier A)

and a compartment-specific refinement of risks by an extended data set on emission, fate and effects (Tier B). When the possibility of environmental risks cannot be excluded, precautionary and safety measures may consist of:

- An indication of potential risks presented by the medicinal product for the environment
- Product labelling, Summary Product Characteristics (SPC), Package Leaflet for patient use
- Product storage and disposal

Labelling should generally aim at minimising the quantity discharged into the environment by appropriate mitigation measures. Appropriate disposal of unused pharmaceuticals, e.g. when shelf life has expired, is considered important to reduce environmental exposure. In order to enhance environmental protection, it is therefore recommended that package leaflets should include the following general statement: *“Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.”*

2.8 IPPC Directive

Under Directive 2008/1/EC concerning integrated pollution prevention and control (IPPC-Directive) several Best Reference Documents (BREFs) on BAT 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 often are 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:

⁸ <http://www.emea.europa.eu/pdfs/human/swp/444700en.pdf>

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 (<i>refers to storage of hazardous chemicals, including pesticides</i>)	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. Installations for the preservation of wood with a production capacity above 75 m³ per day would in future be covered by IPPC (independent of whether or not organic solvents are used).

The UK Department for Environment, Food and Rural Affairs (DEFRA, 2008) carried out an impact assessment of the revised IPPC Directive. This stated that, to date, only 9% of wood preservation industry installations in the UK use more than 25 tonnes of solvent per year and are therefore covered by current Solvents Emissions Directive. The reason is that most of the installations use water-based preservation agents. If the 75m³/day capacity as proposed in the revised IPPC Directive was applied, then more than 50% (250 installations) in the UK would fall under the scope of the IPPC Directive.

2.9 Water Framework Directive 2000/60/EC

According to the 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 best available techniques 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, EQS setting, source

screening and emission controls).⁹ In principle, the same instruments for reducing emissions are applied as for existing substances (see 2.5): the definition of EQS, the implementation of BAT and the monitoring of priority substances. Because only a few biocides have so far been 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 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.

⁹ <http://ec.europa.eu/environment/water/water-framework/objectives/pdf/strategy3.pdf>

3 Data sources on risk mitigation measures

Within the project, available technical documents from authorities (TNsG, guidance documents) as well as the Inclusion Directives submitted so far and available (draft) Competent Authority Reports (CARs) have been evaluated. Additionally RMM proposed by producers, industrial/professional users, and authorities in other documents were collected and analysed (Figure 2). All data were critically evaluated in terms of practicability and efficiency with the main emphasis on the use phase of biocides and on treated materials such as wood treated with wood preservatives.

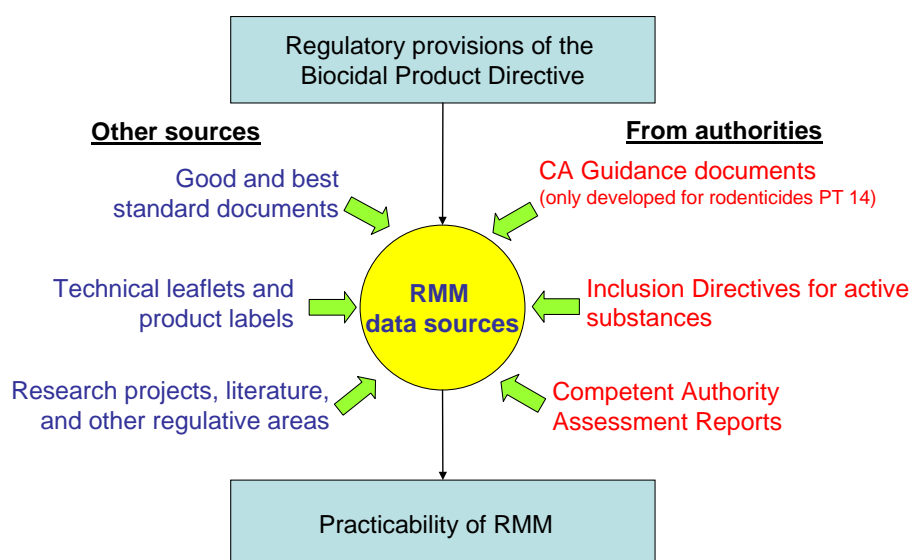


Figure 2: Data sources and analysis

3.1 European Commission

The European Commission provides detailed information about the BPD, the Plant Protection Products Directive, and the Regulation (EC) No 726/2004 on Medicinal Products for Human and Veterinary use. The Competent Authorities Assessment Reports (CARs) of active substances included in Annex I or IA of the BPD are available from the European chemical Substances Information System (ESIS)¹⁰. Drafts of the CARs are available on the CIRCA-Website of the Commission.¹¹

¹⁰ <http://ecb.jrc.ec.europa.eu/esis/>

¹¹ http://circa.europa.eu/Public/irc/env/bio_reports/library?l=/review_programme/ca_reports/pt18_insecticides&vm=detailed&sb=Title

Additionally, the contractor has had direct access to discussion documents and meeting protocols from the Competent Authorities provided by the CIRCA Interest Group on Biocides. These documents are available to Competent Authorities and observers, indicating a substantial interest in keeping informed.

3.2 Research projects and literature

The German Competent Authorities initiated several research projects related to the implementation of the BPD (ULIDAT data source, <http://doku.uba.de/>). The consultant is carrying out a “study on prospects and requirements for transferring proposals for the thematic strategy on sustainable use of pesticides to the biocides area” (Gartiser et al. 2009). The German Federal Institute for Occupational Safety and Health (BAuA) has initiated several research projects about occupational exposure to biocides (e.g. wood preservatives, insecticides, antifouling agents) which also provide useful information about the mode of application, best practices and options for risk mitigation measures (Bleck et al. 2008, Schneider et al. 2008, Hebisch et al. 2009).

A literature research was carried out using the data sources Science Direct, Medline, and ULIDAT, and the SETAC Journals “Environmental Toxicology and Chemistry” and “Integrated Environmental Assessment and Management” covering the period from 2000 till 2009.

3.3 Good and best practice documents of associations and authorities

Information provided by industrial or professional associations is mainly directed at providing guidance on good or best practices on decision making, biocides application, service life (only wood protection) and disposal of biocidal products, remnants, packages and treated wood. Part of the information available has been gathered in the context of a “Study towards the Development and Dissemination of Best Practice on Sustainable Use of Biocidal Products” carried out by a consortium with participation of the consultants of Hydrotox on behalf of the European Commission.¹² Here, European and/or national standards, guidelines of authorities and professional associations and guidance from international organisation describe best practices. Additionally, around 16 German associations involved in the

¹² Contract number 070307/2009/546211/ETU/D4

application of wood preservatives and insecticides were asked to provide further information on risk mitigation.

3.4 Biocidal product registers

There was also an attempt to evaluate existing national certificates of accepted biocidal products. While some national registers of biocidal products are openly available, the assessment reports or certificates are generally considered confidential.

Member State	Website
Belgium Federal Public Service (FPS) Health, Food Chain Safety and Environment	https://portal.health.fgov.be → Milieu → Chemische Stoffen → Biociden
Danish Environmental Protection Agency	http://www.mst.dk/English/PesticidesAndGeneTechnology/Biocides/Authorized_biocidal_products/
Dutch Board of Authorisation of Pesticides (CTB)	http://www.ctb-wageningen.nl/
German BAuA	https://www.biozid-meldeverordnung.de/offen/index.php
German Deutsches Institut für Bautechnik (DIBt)	Letter of approval available from some suppliers
United Kingdom Health and Safety Executive	http://news.hse.gov.uk/category/biocides/
Spanish Ministerio de Sanidad y Política Social	http://www.msps.es/ciudadanos/saludAmbLaboral/prodQuimicos/sustPreparatorias/biocidas/frmRegistroPlaguicidas.jsp
Swedish Chemical Agency KEMI	http://apps.kemi.se/bkmregoff/default.cfm

The Belgian register of biocidal products is linked to the respective certificates. The Danish register contains the product label of authorised products. The Belgian register also gives some information on risk mitigation following the classification and labelling (risk and safety phrases) of the product, including the instructions of application. The other registers provide basic information such as the product name, the intended uses, the active substances, and their concentration. Wood preservatives approved by the German Deutsches Institut für Bautechnik (DIBt) for construction purposes receive a written approval notification which can be downloaded by some suppliers. Here reference is given to the corresponding DIN 68800-3 (preventive treatment) or DIN 68800-4 (curative treatment) (see chapter 6.3.2). For veterinary pharmaceuticals in Germany the “Lila Liste” also describes several insecticides used for surrounding surfaces of animal husbandry facilities (<http://eurovet.com>). These are considered to be biocidal products while those applied directly to animals are pharmaceuticals. The product leaflets describe some general RMM, such as avoidance of contact with water bodies. To summarise, the

product registers analysed do not provide further useful information on risk mitigation in addition to the product leaflets.

3.5 Analysis of leaflets of biocidal products

The RMM relevant for the environment of wood preservatives and insecticides on the market was analysed. For this, formulators, manufacturers, and users were asked to provide operating instructions, manuals, technical leaflets, safety data sheets and product labels. The aim was to evaluate existing information available for the various user groups. As in 2009 on the product authorisation started, in particular biocidal products, for which applications for authorisation has been or will be applied, were intended to be included in the analysis. However, only few biocidal products have been authorised under the BPD so far and therefore most information was derived from the internet where this information is not delivered.

The study therefore followed the subsequent steps:

1. Collection of addresses from formulators and distributors of PT 8 and PT 18 products
2. Internet research on web-sites of formulators and distributors
3. Targeted inquiry of formulators
4. Evaluation of data

The collection of addresses from formulators was based on the member list of the German pest control association¹³ and the list of wood preservatives approved for use in construction timber.¹⁴ On 19th February the consultant visited the European exhibition for pest control EUROCIDO® in which several suppliers of biocidal products (mainly PT 18) participated. A considerable amount of information is available from the web-sites of formulators and distributors of biocidal products. The obligation under Article 20 of the BPD concerning the classification, packaging and labelling of biocidal products has improved available data on the identity and concentration of active substances as well as the dose rate, use instructions, and - where applicable – use restrictions and information on any specific danger to the

¹³ Deutscher Schädlingbekämpferverband e.V.“ (DSV); www.dsvonline.de

¹⁴ Holzschutzmittelverzeichnis Deutsches Institut für Bautechnik (DIBt), German Institute for Building Technology, <http://www.dibt.de/>

environment. The internet research focussed on companies from Germany and the United Kingdom, but most companies are also active in other European Member States.

Around 20 formulators of PT 8 and 18 biocidal products were asked for further information. Three companies (Killgerm GmbH, DE Neuss, Frowein GmbH&Co.KG, DE Albstadt, and Dyrup DK-Søborg) provided detailed product leaflets on electronic media, others (e.g. Remmers Baustofftechnik, DE Lönning) provided printed information. The Killgerm CD provides a data base of around 500 technical product leaflets and safety data sheets. The data were collected and evaluated between March and June 2010.

Table 2 gives an overview of web-sites which provide useful information.

Table 2: Web-sites of suppliers of PT 8 and 18 biocidal products

PT 8 Wood preservatives		PT 18 Insecticides	
Biokil Crown Limited	www.biokilcrown.co.uk (English)	Acotec GmbH&Co KG	www.acotec-online.de (only German)
Dyrup GmbH	http://dyrup.dk (Danish, German, French)	Bayer Crop Science GmbH / Bayer Environmental Science	www.pestcontrol-expert.com www.bayercropscience.de (multilingual)
Kwizda Agro GmbH	www.kwizda-agro.at (German, English)	Biokil Crown Limited	www.biokilcrown.co.uk (English)
Obermeier GmbH & Co. KG	http://www.koraholzschutz.de (German, English)	Detia Garda GmbH	http://www.detia-degesch.de/ (English, Spanish, German)
PIGROL Farben GmbH	http://www.pigrol.de (only German)	Fakolith GmbH	www.fakolith.com
		Frowein GmbH&Co KG	www.frowein808.de (English, German)
Remmers (UK) Limited	http://www.remmers.co.uk (German, English)	Frunol delicia	www.frunol-delicia.de (English, German)
Rentokill Pest Control	www.de.rentokil.com/de/ (German, English)	hentschke + sawatzki CHEMISCHE FABRIK GMBH	http://www.hentschke-sawatzki.de (only German)
RUETGERS Organics GmbH	http://www.ruetgers-organics.de (German, English)	Kwizda Agro GmbH	www.kwizda-agro.at (only German)
Synthesa Chemie Gesellschaft m.b.H.	http://www.synthesa.at (only German)	PPS GmbH	www.pps-vertrieb.de (German, English, French)
Dr. Wolman GmbH	http://www.wolman.de (English, German)	Raiffeisen GmbH&Co KG	http://www.raiffeisen.com/sdb/index_html (only German)
Wykamol Group	www.wykamol.com (English)	Rentokill Pest Control	www.de.rentokil.com/de/ (English, German)
		Reinelt&Temp	http://www.rtk-online.de/perme.htm (only German)

4 Results of the literature research

4.1 Introduction

A literature survey on “risk mitigation measures” in distinct data bases revealed 126 hints in the Medline database and 166 hints in the Science Direct data base. Often these publications address safe operation of industrial or engineering processes. This includes the avoidance of system breakdown or accidental releases, which is outside the scope chemical risk assessment. Risk mitigation strategies for pharmaceuticals and plant protection products are described in some of these publications. For plant production products integrated pest management, control of spray drift and run-off are discussed in more detail while for pharmaceuticals improvement of the waste management of obsolete packages as well as good agriculture practice and manure control for veterinary drugs is emphasized (Reichenberger et al. 2007, Vischetti et al., 2008, Montforts et al. 2004).

In the toxicological literature, e.g. Leeuwen et al. (2007) stated that the options for risk reduction of chemicals range from minor adaptations to the production process or the intended use of the chemical to a complete ban on the production or use of a chemical. The decision basis should be a risk-benefit analysis, this is a balance sheet of the respective risks and benefits of a proposed risk-reducing intervention as compared to the baseline, i.e. the situation of not imposing risk reduction. In addition to the result of the risk assessment, other aspects of risk reduction should be considered such as

- Technical feasibility: Are the measures technically feasible?
- Social and economic factors: e.g. what are the costs, do the measures affect employment?
- What are the legislative/political factors?
- Are there implications on ethical / cultural values?

The authors distinguish between risk reduction measures and risk management.

Categories of risk management measures are:

- Product/substance related measures
- Limitation of the marketing of a substance/product
- Limitation of the use of a substance/product
- Instructions/information/warnings

- Technical measures
- Organizational measures
- Personal protection measures

Examples of risk reduction measures are:

Substance flow measures	recycling of waste substitution of substances in products quality of raw materials and products
Process optimization	good housekeeping process-internal recycling substitution of processing aids process optimization
End-of-pipe treatment	waste-water treatment gas-flow treatment waste destruction and disposal

A study by the German Environmental Agency on sustainable and precautionary risk assessment and risk management of chemicals describes new strategies on risk management based on the precautionary principle and the substitution principle (Ahlers et al., 2001). Some of the aspects discussed in this report have been considered in REACH. It is stated that sustainability is intimately related to the precautionary principle and that the precautionary principle involves three components: (I) eliminating concrete environmental hazards ("danger prevention"), (II) avoiding or reducing risks to the environment in advance ("risk prevention"), and (III) acting to shape our environment in the future, in particular to protect and improve the fundamental basis for life ("care for the future"). The report focuses on risk assessment strategies, the consideration of specific intrinsic properties of chemical substances such as PBT or CMR or endocrine disrupting substances, the importance of applying BAT for reduction of emissions and so on. Biocides are only marginally considered.

Granular pesticides (insecticides and nematicides) applied outdoors pose a specific hazard for birds because of the potential for birds to ingest the granules. Birds clearly select grit and granules for ingestion based on the characteristics of the particles. Each granular formulation represents a unique combination of granule characteristics (e.g., granule type, colour, and size). Thus, testing granular formulations would provide information regarding the risk it poses to birds (Stafford et al, 1999).

4.2 Efficiency of risk mitigation measures for plant protection products

The EU has funded several projects on risk mitigation strategies for plant protection products. In the FOOTPRINT-project (Functional Tools for Pesticide Risk Assessment and Management) one deliverable focused on the “state-of-the-art” of mitigation strategies and their effectiveness (Reichenberger et al. 2006, 2007). Grassed buffer strips located at the lower edges of fields are mentioned as an efficient RMM. Constructed wetlands mitigate inputs of plant protection products via runoff/erosion and drift into surface waters. Subsurface drains are an effective mitigation measure for runoff losses of plant protection products from slowly permeable soils. For the drainage and leaching pathways, the only feasible mitigation measures are application rate reduction, product substitution and shifting the application date to a less sensitive time. Several measures, such as no-spray buffers, windbreaks and drift reducing nozzles are being applied to reduce spray drift. Point-source inputs can be mitigated by increasing the awareness of farmers with regard to handling and application of plant protection products and encouraging them to implement loss-reducing measures of “best management practice” (Reichenberger et al. 2007). There are some quantitative data on efficiency of RMM. For example, point-sources of plant protection products mainly consist of runoff from hard surfaces and may contribute to more than 90 % of the total load of plant protection products in surface water. The effect of conservation tillage (no-till, chisel ploughing, and ridge till) on the runoff of plant protection products to surface waters was quantified. All three investigated conservation tillage systems (no-till, chisel ploughing, and ridge till) reduced herbicide runoff losses on average by 70%, 69% and 42% respectively (Reichenberger et al. 2006).

Some of the measures proposed in the FOOTPRINT-project correspond more or less to sustainable use of plant protection products but are difficult to transfer to the authorisation stage of biocidal products. Technical approaches to reduce spray drift would affect both plant protection and biocidal products. Some of these proposals could be included in best practice documents which could be harmonised across Europe. The identification of the main emission sources and pathways is one prerequisite for any quantitative evaluation of the efficiency of RMM. Quantitative data on the efficacy of RMM are derived from case studies and mainly based on monitoring data. For the biocide sector few such data are available.

Other projects deal with emission control of priority pollutants in the context of the implementation of the Water Framework Directive. Within the EU funded project on Source Control of Priority Substances in Europe (SOCOPSE), material flow analyses for selected priority pollutants have been conducted and available and emerging measures and management options have been evaluated (<http://www.socopse.se>). For selected substances, emission reduction strategy reports have been elaborated (Genty 2009). Among the substances the herbicide Isoproturon, which is mainly used as plant protection product for cereals, has been evaluated. The use of Isoproturon as biocide (PT 6, 7, 9-13) has not been identified in this report. Instead, the report indicates that it is only used in agriculture (Ducos 2009). The evaluation of appropriate RMM started with the identification of the main emission sources and modelling of the fate of Isoproturon. Among the source control options under control of the users (farmers), the limitation of surface runoff, the control of point source pollution and the implementation of other good farming practices have been mentioned. Several mitigation measures to reduce isoproturon pollution have been identified:

Reduction of runoff	Reducing application rate/frequency, shifting application date (earlier or later), banning application along the edge of rivers/fields, planting vegetated buffer strips (grassed waterway, hedge, riparian zone...), implementing constructed wetlands, applying conservation tillage, covering the ground (cover crops, mulching), and controlling sprayers regularly → efficiency "variable", "unknown" or 80-100%
Control of farm point-source pollution	Training and information campaigns, best pesticide handling practices, sharing equipment or spraying by contractors, no pesticide application on farmyard. → efficiency "variable", 60-100%
Other good farming practices	Respecting manufacturer's specifications and avoiding spraying when soils are cohesive; Applying pesticides in good weather conditions with consideration of climatic conditions; Renewing and maintaining equipment (sprayer, nozzles); Storing equipment under cover; Storing, transporting and disposing containers safely; Keeping records (treatments, storage, maintenance, disposal, assessments); Maximising the opportunities for non-pesticide control (crop rotation, cultivation and establishment method, crop monitoring, suitably managed set-aside, opportunities with other uncropped land); Assessing the risks of pesticide contamination in all situations → efficiency "unknown" till up to 100%
End-of-pipe options	Applying BAT and advanced wastewater treatment techniques by adsorption on granular activated carbon filters, and/or oxidation by ozone → efficiency 80-100%

Interestingly, an efficiency of 60% - 80% reduction in emissions has been attributed to “training and information campaigns”. Substitution of Isoproturon (a Cat. 3 carcinogen) is also mentioned as a RMM. It should be noted that many of these RMM and the respective rough estimates on efficiency are drawn from an imission point of view which would be difficult to transfer to the authorisation of biocidal products. In another project, funded by the German Environment Agency, the emission situation of priority substances in Germany was analysed and national options for the progressive reduction of discharges, emissions and losses were identified and described (Hillenbrand et al. 2007). Again, most options cover a more general strategy for emission reduction not applicable for product authorisation.

To summarise, no reliable data on the efficiency of RMM for biocides are available. Data on quantities of biocidal active substances and products produced or sold, as well as a quantitative description on the main emission sources, are missing and few monitoring data on biocides in environmental media exist. All these data are required as a basis for describing quantitative efficiency levels of specific RMM for biocides.

4.3 OECD Pesticide Risk Reduction Steering Group

The OECD Pesticide Risk Reduction Steering Group (RRSG) has developed a strategic approach to the development and implementation of risk reduction options, policies and practices (OECD 2009a). Four key elements on risk reduction have been identified:

- high standards in legally based registration and placing on the market of active substances and products,
- a package of mandatory and voluntary provisions and requirements for proper use of pesticides,
- promotion of alternative methods such as non-chemical plant protection measures, wherever possible, and
- control and monitoring through implementation of risk indicators to describe the progress of risk reduction programmes.

Sustainable use of pesticides is also considered to contribute to further risk reduction, especially by aiming at a significant reduction of misuse, better compliance with existing regulations and use of only 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 alternative reliable non-chemical measures. Sustainable use of biocides is analysed in detail within a parallel project sponsored by the German environmental agency by the same consultant (FKZ 3708 63 400).

The OECD RRSg also published a survey on different approaches to the collection and use of agricultural pesticides sales and use data (OECD 2009b). In 19 of 20 OECD countries that responded to the survey, data collection is mandatory. Data sources include pesticide manufacturing companies, pesticide manufacturers' associations, retailers, wholesalers, importers and exporters, and farmer/grower organisations. The data collected consisted of the crop and area treated, the product (or formulation) and amount used, the average product (or active ingredient) rates of application (kg/ha), the biological control methods used (if any), the timing of application and the average number of applications per year.

Another highlight of OECD's work consists of an analysis of common approaches towards spray drift reduction in OECD countries (OECD 2009c). A range of possible approaches that use and combine habitat protection considerations (buffer zones), technical aspects (drift reduction equipment, drift deposition modelling), regulatory aspects (label restrictions) and non-legislative activities (education & training programmes, including best practices) are described. These policies also take account of the fact that spray drift occurs under both non-controllable (e.g. wind speed and directions, temperature, humidity, crop structure) and controllable conditions (e.g. field practice, non-spray zones, nozzle type, spray pressure).

In principle, the risk management of plant protection products and biocides are within the scope of the work of OECD's environment, health and safety division. However, risk management of biocides has not been considered so far.

Some examples of RMM proposed for plant protection agents are the definition of a mandatory distance to water bodies, the use of drift reducing nozzles, the consideration of the application conditions (especially wind speed), or the planting of drift-reducing vegetation (Schulz et al. 2009).

4.4 FAO/WHO

The FAO published a “Code of 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.¹⁵ The FAO also provides Guidelines on the management of public health pesticides. The guidelines address major aspects of the management of public health pesticides including legislative control, administrative arrangements, product registration, procurement, storage and transport, distribution, application, maintenance and disposal, monitoring and surveillance, management of insecticide resistance, and quality control.¹⁶ Further guidelines refer to organization and operation of training schemes and certification procedures for operators of pesticide application equipment¹⁷ and on insecticides for indoor residual spraying.¹⁸

4.5 REACH

In a German project the obligations of producers, importers, and users of industrial chemicals concerning the minimization of risks of industrial chemicals implied by REACH-Regulation have been analysed (Führ et al. 2005). Here, the requirements of several regulatory areas (industrial plants, equipment, waste, water, occupational health) on risk minimization have been described. One consequence of REACH will be that the responsibility for risk evaluation and developing risk minimisation strategies for the use of chemicals will be shifted towards producers and importers as well as to downstream-users, such as formulators and applicators. If the legislature decides to introduce self-responsibility into a policy field, the central question is how the stakeholder will react to unspecified obligations. One conclusion of the study was that extensive communication and information processes along the supply chain are of crucial importance for reducing risks. It can be helpful to organize the exchange between producers, formulators and downstream-users up to the final consumer in order to change the perspectives of individual stakeholders (Führ et al. 2007).

¹⁵ <http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Code/Download/code.pdf>

¹⁶ http://whqlibdoc.who.int/hq/2003/WHO_CDS_WHOPES_2003.7.pdf

¹⁷ <http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/Training01.pdf>

4.6 Medicinal products

Montfort et al. (2004) made a critical analysis of risk mitigation proposals for medicinal products. They state that, as precautionary measures are not a mandatory requirement, there is no obligation to consumers to follow to these measures. Although precautions will have their intended effects in a certain number of instances, the reasonable worst case situation remains the one where the precautions are not followed. In that sense, the precautions are merely recommendations.

The package leaflets of many products containing parasiticides for pasture animals carry a precaution that warns that treated animals should not enter surface water at or after treatment. Apparently, the aquatic environment is at risk when treated animals have access to surface water, since residues of parasiticides are excreted with dung for days after treatment. Another example concerns precautionary measures on animal drinking water treatment with drugs, where it is stated that manure from treated pigs should be stored for 3 months prior to spreading and spreading onto land. Manure storage is a potentially important instrument for limiting exposure of the environment to veterinary drugs (as well as to certain insecticides). This is also considered in a concept paper on the fate of veterinary medicinal products in manure.¹⁹ Other package leaflets warn that a minimum distance of 10 m to bordering surface waters should be observed during the application of slurry from treated animals onto agricultural fields (Montfort et al. 2004).

RMM have also been addressed within the EU funded project “Environmental Risk Assessment of Veterinary Medicines in Slurry” (ERAVMIS). The results of the project indicate that risk reduction can be achieved by instructing the user to use the product in such a way that emission of the product to the environment is further limited. All risk management options that target the *modus operandi* at the farm are outside the scope of the registration and belong to the arena of environmental policy making. The environmental risk assessment is performed taking into account Good Agricultural Practice codes of conduct (Montforts et al. 2003).

It should be noted that there have been also several attempts to develop end-of pipe RMM for removing pharmaceuticals from municipal wastewater by advanced

¹⁸ http://whqlibdoc.who.int/hq/2001/WHO_CDS_WHOPES_2001.3.pdf

¹⁹ <http://www.emea.europa.eu/pdfs/vet/era/1004309en.pdf>

treatment such as ozonisation or activated charcoal (e.g. EU POSEIDON project “Assessment of Technologies for the Removal of Pharmaceuticals and Personal Care Products in Sewage and Drinking Water Facilities to Improve the Indirect Potable Water Reuse”).

5 Provisions on risk mitigation measures for biocides

5.1 Guidance documents discussed at CA-meetings

Several RMM for biocides are currently being discussed by Competent Authorities (CA). Although this study focuses on PT 8 and PT 18 biocidal active substances, all guidance documents referring to RMM have been evaluated in order to identify further aspects of risk mitigation.

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 not be allowed if the exposure assessment indicates unacceptable risks with the need to use personal protective equipment (PPE).²⁰ The reason is that the use of PPE for reducing exposure and 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.²¹

Similarly, in relation to the use of substances with irritant, corrosive or sensitising properties by non-professional users, it has been stated that consumers will not normally use PPE unless it is convincingly recommended by the manufacturer and provided with the product. However, the decision on the use or not of PPE is mostly important for the product authorisation stage.²²

Use restriction on rodenticides

In order to prevent the development of resistances against anticoagulant rodenticides and because many of them are classified as PBT substances, it has also been proposed to restrict the user category to professional users. However, at CA level this proposal was not accepted as an appropriate measure, considering the drawbacks for rodent control, especially in regions with low human population densities.

²⁰ Spraying method of wood preservatives for amateur users. 26th CA meeting, CA-Sept07-Doc.5.3 – Final

²¹ Use of Personal Protective Equipment. 27th CA meeting, CA-May08-Doc.6.2

²² Use of substances with irritant, corrosive or sensitising properties by non-professional users, CA-Nov07-Doc.6.5

Restrictions on the area of use have been proposed as an option for preventing primary and secondary poisoning. The restriction of rodenticide use to confined spaces such as in and around buildings or indoor use has been proposed as a possible RMM for rodenticides. These provisions could be combined with limitations on the category of users and on 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 are the indication of a maximum concentration of an active ingredient allowed in biocidal products and the inclusion of bittering agents in formulations for reducing the risk of accidental ingestion, in particular by children. Similarly, the inclusion of a blue dye renders the product unattractive to non-target animals like birds. In cases of accidental ingestion, the presence of a dye may also 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, package size, area of use, category of users, conditions of use and composition of the final product, according to the Commission the choice of specific risk mitigations measures should be deferred to product authorisation stage when all the details of the products to be placed on the market are available. The objective of the 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 product authorisation.²³

According to 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.

In an Annex of the CAR for the rodenticide chlorophacinone, referring to environmental risks for primary and secondary poisoning in birds and mammals, it is stated *that “the only way for confirming the effectiveness of the mitigation measures*

²³ RISK MITIGATION MEASURES FOR ANTICOAGULANTS USED AS RODENTICIDES. CA-March07-Doc.6.3 final – revised after 33th CA meeting, <http://ec.europa.eu/environment/biocides/pdf/anticoagulants.pdf>

is a higher tier assessment reflecting the magnitude and likelihood of the remaining expected environmental consequences” (Suárez et al. 2008).

Manual of Technical Agreements

The Manual of Technical Agreements of the Biocides Technical Meeting (MOTA) intends to provide the agreements of the Technical Meetings (TMs) in a concise format. In version 3 from 24 February 2010, two questions on risk mitigation and restrictions have been answered:

- Should application by spraying be allowed for non-professionals, as this may result in high exposure levels? → Spraying by non-professionals can be allowed if no PPE is required.
- If a substance is classified as CMR, is it possible to allow the use for general public? → Not possible as the BPD Article 5 (2) clearly indicates that CMR substances cannot be authorised for marketing or for use to the general public (but only for professional uses under consideration of appropriate RMM).

The problem of the risk characterisation of non-threshold carcinogens has been discussed in detail in technical meetings. Some MS considered the concept of “negligible exposure” to be a key issue in the assessment of such substances. However, these substances should only be used in very exceptional cases where socio-economic or public health reasons support their use. These cases will be subjected to comparative assessment to look for substitutes. Other MS suggested that non-threshold carcinogens should not be included in Annex I at all because there is no safe level.²⁴

5.2 Evaluation of (draft) Inclusion Directives

Several active substances of product types PT 8, 12, 14 and 18 have been included in Annex I of Directive 98/8/EC so far (data base is from April 2010). The respective Inclusion Directives describe specific provisions on different RMM which shall be considered during the authorisation of biocidal products containing these active

²⁴ http://ecb.jrc.ec.europa.eu/DOCUMENTS/Biocides/MINUTES_TECHNICAL_MEETING/2008_TMIII08_open_session.pdf

substances²⁵. Although this study focuses on PT 8 and PT 18 biocidal active substances, the RMM described for other product types so far have also been evaluated, because they might provide further information on risk mitigation of biocides. Specific provisions for product authorisations available so far are summarised in table 3.

Table 3: Provisions for product authorisations from the Inclusion Directives

		Examples
A) Placing on the market		
User restriction	<p>Restriction of the use of the fumigant sulfuryl fluoride to trained professionals</p> <p>Use of aluminium phosphide releasing phosphine fumigant only by specifically trained professionals (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 application /	<p>Restriction of use of K-HDO for the treatment of wood that may enter in direct contact with infants.</p> <p>Restriction of the use class for certain wood preservatives: No in-situ treatment of wood 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>K-HDO, PT 8</p> <p>Boric acid</p> <p>Disodium octaborat</p> <p>Propiconazole</p> <p>Tebuconazole</p> <p>Thiabendazole</p> <p>Thiamethoxam</p> <p>Tolyfluanid (all PT 8)</p> <p>Boric acid</p> <p>Disodium octaborat</p> <p>Propiconazole</p> <p>Clothianidin</p> <p>Tebuconazole</p> <p>Thiabendazole</p> <p>Thiamethoxam</p> <p>Tolyfluanid (all PT 8)</p> <p>Thiacloprid, PT 8</p> <p>Aluminium phosphide, PT 14</p> <p>Magnesium phosphide, PT 18</p>

²⁵ http://ec.europa.eu/environment/biocides/annexi_and_ia.htm
<http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=bpd>

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	Some rodenticides shall not be used as tracking powder .	Bromadiolone Difenacoum Flocoumafen Difethialone (all PT 14)
	Limitation of nominal concentration of the active substance in the products of some rodenticides and authorisation of ready-for-use products only.	Alphachloralose < 40 g/kg Bromadiolone < 50 mg/kg Chlorophacinone < 50 mg/kg Coumatetralyl < 375 mg/kg Difenacoum < 75 mg/kg Difethialone < 25 mg/kg (all PT 14)
	For amateur uses, only ready-to-use products shall be authorised.	Indoxacarb, PT 18 Bromadiolone, PT 14 Difenacoum, PT 14 Difethialone, PT 14
	Some biocidal products (in this case rodenticides) shall contain an aversive agent and, where appropriate, a dye.	Difethialone, PT 14 Difenacoum, PT 14
B) Application of biocidal products		
Equipment	Restriction K-HDO as wood preservative to industrial use in fully automated and closed equipment . *) Minimisation of primary and secondary exposure to rodenticides by obligation to use tamper resistant and secured bait boxes. *)	K-HDO, PT 8 Alphachloralose Bromadiolone Chlorophacinone Coumatetralyl Difenacoum Difethialone Flocoumafen (all PT 14)
Personal protective equipment	Use of appropriate personal protective equipment for reducing human exposure at industrial and/or professional use to certain wood preservatives.	Most wood preservatives
	Appropriate RMM for operators and bystanders exposed on the fumigants.	Sulfuryl fluoride, PT 8, 18
	Use of phosphine realising fumigants only while applying 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 by Products shall not be placed in areas accessible to infants, children and companion animals.	Indoxacarb, PT 18
C) Post application		
Storage of treated wood	Storage of timber freshly treated with wood preservatives under shelter or on impermeable hardstanding to prevent direct losses to soil or water.	IPBC Boric oxide Clothianidin Dichlofluanid Fenpropimorph Propinconazole Tebuconazole Thiabendazole Thiamethoxam Tolylfluanid (all PT 8)

Waiting period	After potential exposure to food adherence of waiting periods which ensure MRLs set out in Regulation (EC) No 396/2005.	Aluminium phosphide, PT 18 Magnesium phosphide, PT 18
Disposal	Collection 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"> • Products shall be positioned away from external drains. • Unused products shall be disposed of properly and not washed down the drain. 	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
D) Further regulatory options		
Comparative risk assessment	Some rodenticides are subject to a comparative risk assessment due to their risks identified.	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

5.3 Results of the COWI-study

In 2008, the EU Commission contracted a study (conducted by the consultant COWI) 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". In Annex II the replies of Competent Authorities to a questionnaire on national measures on sustainable use

of biocides are summarised. The results concerning use restriction, data on sales and certification of professional users and the equipment are shown in table 4.²⁶

²⁶ Data on sales are not seen as an instrument on RMM but may be required for an exposure assessment (especially for cumulative exposure) which could imply the need of RMM as a result of the risk assessment. Additionally, data on sales are potential indicators for sustainable use.

Table 4: Risk mitigation measures on biocides identified in the COWI-study

	Data on the sales of active substances	Certification of professionals	Certification of the equipment	Use and user restrictions
Belgium	data are collected annually	Mandatory for PT 14, 18, 19, but information remains unclear	Part of the certification of use and storage	Only within the authorisation acts
Estonia	none	Must be registered in the register of economic activities and must hold a certificate of professional qualifications		PT 21 in fresh water prohibited; maximum leaching value for Cu from pleasure boats
Finland	once a year	Ambiguous information submitted		Antifouling in fresh water is forbidden; maximum Cu leaching of PT 21 from pleasure boats
France		Voluntary standards for training and certification according to a NFU 43500 standard, certification on CTB A+ for PT 8	Mandatory for disinfection of places and equipment for potable water disinfection.	Restrictions for use of PT 3 and PT 18 regards to BSE and mosquito control
Germany	none	Mandatory for professional pest controllers; For fumigation proof of expert knowledge (Hazardous Substances Ordinance Annex III, No. 5.3 and Technical Rule 512) Voluntary certification for PT 8.	For disinfestations or decontamination ordered by the authorities in accordance with §18 of the Infection Protection Act: Only agents and equipment from a positive list may be used. Moreover the "Guidelines for the voluntary checking and control of equipment" provides for voluntary inspections	Pest control with very toxic, toxic or hazard substances is regulated by Technical Rule 523 and fumigation by Technical Rule 512
Hungary	none	For PT 14, 18 and 19 certification is mandatory	Mandatory for certain application equipment e.g. on placing out	In nature conservation areas
Lithuania		Training and certification for PT 2, 14 and 18	Very toxic, toxic, CMR of category 1 and 2 only to be used by authorised professional users only	
Netherlands		Training and certification required for PT 14 and 18		
Romania	yes	Training and certification for PT 14, 18, 19	Voluntary CE certification for application of equipment	Use of toxic or very toxic only allowed for professionals
Italy		voluntary	In some cases (e.g. fumigants, rodenticides) there is a mandatory equipment to use	

	Data on the sales of active substances	Certification of professionals	Certification of the equipment	Use and user restrictions
Malta		Training for professional user is required		
Slovak Republic		Mandatory qualification scheme PT 1 and 3		Restricted in "environs of drinking water resources and public building"
Slovenia	Collected each year from producers, retailers and professional users of T, T+ and CMR 1 and 2 Group	Voluntary qualification schemes within Chamber of Commerce; Association of DDD organizations mainly for PT1-5, 14, 18-19	none	Uses where the product toxic or very toxic, or carcinogenic, mutagenic, toxic for reproduction category 1 and 2 "shall not be put on the market for general use
Spain	Movement register book for toxic and very toxic for sale, storage and use activities; data on insecticides, disinfectants and rodenticides from customs authorities and the National Association of pest control agencies.	Toxic and very toxic products require special qualification. Training and certification is required for professional users of PT 2, 4, 14, 18 and 19 as well as for PT11	Requirements related with pressurized and electrical devices; some voluntary certifications for pesticides application equipments	
Sweden		Concerning the use of certain substances of PT 14, PT 8, PT18; Training is part of a specific provision in the authorization		PPE is only allowed used by professionals
UK		Voluntary qualification requirements for usage of some substances in PTs 8, 14, and 18		May be restricted e.g. on indoor/outdoor use or restrictions concerning non-professional users

Table 4 shows that in some member states data on sales and on consumption of biocides are routinely collected. For some PTs user restrictions and certification of professional user and the equipment are mandatory. However, the data provided by CAs and evaluated within the COWI study according the authors is not consistent (COWI 2009). (Indeed it is known that e.g. Sweden collects data on consumption of biocides but this is not referred to in the report).

6 Risk mitigation measures for PT 8 and 18 biocides

6.1 Competent Authority reports on biocidal active substances

Although only a limited number of active substances has been included in Annex I of the BPD, far more draft CARs are currently being discussed at the Community level. Part of the assessment report (Doc I) is considered non-confidential and therefore available to the public.²⁷ Although these CARs are still not finalised and therefore might be subject to amendments, the RMM described have been analysed in detail. Because of the possibility that the confidential parts of the assessment reports (Doc II) might include further descriptions of RMM, the sponsor made available a number of Doc II documents after providing a confidentiality agreement.

6.1.1 Wood preservatives (PT 8)

The RMM proposed in (draft) CARs have been categorised by the different life cycle steps and are summarized in table 5. Annex 1 provides a more detailed basis of this analysis. There are user restrictions to trained professionals or industrial operators. Restrictions of the area of application (use class, wood in contact to children, food or feedstuffs, near water bodies, groundwater protection areas, in-situ application) have also been proposed. While the usefulness of a fixative should be proven by leaching studies, there is no requirement to indicate a proper fixation duration before the treated wood is handled or marketed. Some wood preservatives should only be used in industrial facilities (dipping and/or vacuum pressure) and there are requirements that the area should not be connected to sewage treatment plants (STPs) and that all losses (including from cleaning of the equipment) should be collected and reused or disposed. The need for compliance with “good working practice” is mentioned and the development and harmonisation of a Code of Good Practice (for spray applications) has been proposed. Storage of treated wood on bare soil is not allowed but the level of protection proposed for preventing emissions during storage is different (concrete, impermeable hard standing surfaces, collection of leachates, under roof). Only a few CARs address options for waste water treatment of the leachates (mainly for boron containing preservatives). Top coating has been

²⁷ http://circa.europa.eu/Public/irc/env/bio_reports/library?l=/review_programme/ca_reports/pt18_insecticides&vm=detailed&sb=Title

suggested as a RMM for use classes 3 and 4, but its long-term effectiveness has also been questioned by some CAs because obligatory top coating cannot be controlled and/or because the topcoat could be damaged by weathering or processing (see chapter 7.3). Regarding the disposal of treated wood, some CARs refer to incineration and national legislation. For wood treated with certain actives use by the general public has been questioned, because it does not allow a sufficient control of the waste management. Several regulatory options such as comparative assessments of PBT substances, an assessment of populations exposed, or the need for further risk assessments have been proposed.

Table 5: Provisions for product authorisations from the PT 8 CARs

		Examples
A) Placing on the market		
User restriction	Restriction of the use to trained (and licensed) professionals Restriction to industrial operators Recommended only for professional use	Sulfuryl fluoride Hydrogen cyanide K-HDO Dazomet *)
Area of application	Restriction of wood in direct contact with infants. Only for use classes 1 and 2 (indoor) No in-situ treatment of wood outdoors Restriction of use with continuous contact with water or weathering Restriction of in situ treatment near water or for wood that will be in contact with surface water. Likelihood of use in hazard class 3 to be considered by MS Prohibition for use in groundwater protection areas. Only preventive or only curative treatment	K-HDO Chlorfenapyr *) Chlorfenapyr *) Boric acid Boric acid Propiconazole Thiacloprid Dichlofluanid Thiacloprid Tolylfluanid No example found
Package size		No example found
Design of the biocidal product mode of application	Proper fixative formulation to reduce leaching Reassessment of emission behaviour via experimental leaching tests	4,5-Dichloro-2-octyl-2H-isothiazol-3-one (DCOIT) *) Clothianidin *)
B) Application of biocidal products		
Mixing and loading	Concentrate of the substance only handled under closed conditions Mixing and loading should be automated in a closed system and automated spraying/flow-coating fully enclosed.	Didecyldimethylammonium chloride *) 4,5-Dichloro-2-octyl-2H-isothiazol-3-one *)
Equipment	Use limited to (double vacuum) vacuum pressure treatment (in fully automated and closed equipment). No surface drains to STP. Losses to be collected and disposed. Tanks, containers and the technical apparatus must not be cleaned Only dipping by automated/mechanical means, not manually Principles of good working practice should be applied	Copper (II) hydroxide *) K-HDO Dichlofluanid Thiacloprid

Personal protective equipment	Use of appropriate personal protective equipment for reducing human exposure at industrial and/or professional use to certain wood preservatives. Use of self-contained breathing apparatus and gas-tight chemical clothing	Most wood preservatives Hydrogen cyanide *)
Further RMM Fumigation	Protective zone around the fumigated structure, re-entry only when gas concentrations are $\leq 3 \text{ mg/m}^3$. Assure that it is not raining (no high air humidity) in the final phase of ventilation. Soil to be mechanically protected during the in-situ treatment	Hydrogen cyanide *) Propiconazole
C) Post application		
Storage of treated wood	Keep the treated timber on storage places covered by roofs Impermeable hard standing area, recover all losses for recycling or appropriate disposal. <i>This is in fact standard practice and an established legal requirement for facilities processing metal-based wood preservatives.</i> Reduction of emissions to soil with impermeable coating e.g. concrete and, when relevant, a protective roof Collecting rain water from the storage area	Fenpropimorph Copper (II) hydroxide *) Flufenoxuron *) Tebuconazole
Waiting period	Time for fixation required	No example found
Contact to food, feed or children	Wood products must not come in contact with food or feedstuffs. Use restriction to construction timber which is not accessible to children	DCOIT *) Bifenthrin *)
Top coating	Leaching to be diminished by emission reducing measures such as the application of a topcoat Wood in use class 3 / installed over small ponds / near water bodies should be protected with a topcoat When PEC/PNEC is > 1 timber to be protected with a topcoat. Uncertainty to long-term effectiveness of top coating as a RMM	Copper (II) hydroxide *) Bifenthrin *) Flufenoxuron *) Tebuconazole Tolylfluanid
Disposal of the biocidal product	During wood pre-treatment no emissions to surface water allowed. Waste recycling or incineration Collection of any losses of wood preservatives for reuse or disposal	Bifenthrin *) Most wood preservatives
Water treatment	Ozone often used in combination with carbon filtering or sand filtering which reduces the level of N-nitrosodimethylamine (NDMA). However, the practicability and acceptability of these methods by waterworks remain uncertain.	Tolylfluanid
Wastewater treatment	High levels of borates can be captured precipitation with lime Treatments with boron specific ion exchange resins and activated carbon are also possible. Contaminated soil can be leached with water or acid to reduce boron levels. Feasible waste treatment options have to be proven when recycling to the impregnation tank is not practicable	Boric acid, Boric oxide, Disodium tetraborate Clothianidin, Fenpropimorph
Disposal of treated wood	The end life cycle of products should be managed according to in force regulation The use by the general public does not allow a sufficient control of the waste management No risk during incineration under controlled conditions from active substance but potentially from other substances. Local authorities should be consulted, tonnage quantities of products are not considered appropriate for landfills.	Bifenthrin *) Flufenoxuron *) Bifenthrin *) (potential PBT substance) DCOIT *) Boric acid Boric oxide

D) Further regulatory options		
Comparative risk assessment	PBT substances → candidate for comparative assessment.	Bifenthrin *)
Population exposed	Toxic for reproduction category 2 MS shall assess the populations exposed to the product MS should pay attention to possible occurrence of resistance. MS experts should develop and harmonise a code of good practice for spray applications The Applicant will have to provide updates on the thiacloprid resistance in moths. The need for a risk assessment for bats should be determined at a national level National authorities should address any specific national conditions and/or undertake regional assessments	Boric acid Boric acid Clothianidin Bifenthrin *) Clothianidin *) Thiacloprid Cu (II) CO ₃ – Cu (II) OH (1:1) *)
Monitoring	Monitoring of sulfuryl fluoride concentrations in remote tropospheric air by applicant Regular monitoring of exposed workers/operators	Sulfuryl fluoride Hydrogen Cyanide

*) Only draft CARs analysed, conclusions might be revised after discussion at technical meetings

6.1.2 Insecticides (PT 18)

The RMM proposed in (draft) CARs are summarized in table 6. Annex 2 provides a more detailed basis of this analysis. Many RMM, such as the use of personal protective equipment, focus on human health aspects, where exposure to the environment is only indirectly affected. Other RMM, such as crack and crevice treatment, aim at reducing exposure to the environment, while human health might also be affected through avoidance of decontamination. There are user restrictions to (specifically) trained professionals and on the area of application (e.g. not for animal housing with drains to STP or surface water, only indoor use, only crack and crevice treatment, no use on surfaces liable to be cleaned, no application on textiles). For certain actives the mode of application is also prescribed (not allowed for aerial spraying, only for ready-for use bait cartridges for bait stations, not to be scattered on surfaces). After the application, compliance with the waiting periods for ensuring MRLs, the cleaning procedure (not wet, only dry cleaning, washing water to be disposed), the disposal of treated wasp nests and the application of resistance management principles are addressed. Further regulatory options refer to non-inclusion of PBT substances, the assessment of the population exposed, the monitoring of workers/operators and of the appearance of resistance. Often it is reported that further data should be provided by the applicant if these apply for other uses.

Table 6: Provisions for product authorisations from the PT 18 CARs

		Examples
A) Placing on the market		
User restriction	Restriction of the use to (specifically) trained professionals Restriction to professional use	Sulfuryl fluoride Aluminium phosphide Diflubenzuron *)
Intended uses and area of application /	Not to be applied in animal housings with drainage to STP	Imidacloprid *)
	Only for uses in animal housings without exposure to a STP or direct emission to surface water. Only for crack and crevice treatment indoors and for spot application outdoors Only to be applied indoors Areas liable to submersion or likely to be routinely cleaned are excluded. Do not apply during cooking Risk for surface water and sediment identified → need of all uses to be carefully examined Use outdoors only against wasp and wild bee nests where losses to drains can be prevented. Prevent foraging bees gaining access to the treated. Protection from secondary poisoning to insectivorous vertebrates in stables. No direct applications to soil are permitted. Do not spray bed linen or clothing MS shall assess outdoor use Aerial application not allowed (no data submitted) Application to drinking water reservoirs or water intended for human consumption and to food crops not allowed Products shall be authorized only for the identified safe use following the land application.	Clothianidin *) Deltamethrin *) Bendiocarb *) Thiamethoxam *) Fipronil *) lambda-cyhalothrin *) Bendiocarb *) Thiamethoxam *) Bendiocarb *) Magnesium phosphide BTI H-14 Strain SA3 *) BTI H-14 Strain SA3 *) BTI H-14 Strain AM65-52 *) Triflumuron
Package size		No example found
Design of the biocidal product mode of application	The biocidal product shall contain an aversive agent For amateur uses, only ready-to-use products	Spinosad *) Indoxacarb
B) Application of biocidal products		
Mixing and loading	Supplied as a powder or with water soluble sachets	Bendiocarb
Equipment		No example found
Mode of application	Only for ready-for-use bait cartridge for bait stations	Diflubenzuron *)
Personal protective equipment	Wear self contained breathing apparatus and gas-tight chemical clothing, re-entry to treated structures and when air concentrations is below 3 mg/m ³ Personal and respiratory protective equipment, use of applicators Products for non-professional user should be sold together with appropriate gloves Coverall, respiratory mask, goggles and gloves and the washing of hands and exposed skin after use; remove soiled clothing immediately	Hydrogen cyanide *) Aluminium phosphide Clothianidin *) Silicon dioxide *) Bendiocarb *)

	Good general ventilation, wear clean, long-sleeved, body-covering clothing; prevent prolonged contact	Spinosad *)
Further RMM	Removal of all food items. Unprotected persons and animals should be kept away from treated areas until dry Should be applied out of reach of children Do not handle treated fabrics until they are dry and air thoroughly before use.	Sulfuryl difluoride Bendiocarb *) Spinosad *) Bendiocarb *)
Fumigation	A protective zone around the fumigated structure Fumigation and following ventilation only when it is not raining, there is no high air humidity	Hydrogen cyanide *)
Poisoning of non target organisms	No application by scattering because of risk of direct poisoning of birds and mammals	Spinosad *)
C) Post application		
Waiting period	Ensure waiting periods for MRLs in food	Aluminium phosphide
Decontamination	Only dry cleaning of the treated surfaces and disposable clothes for the applicator to be applied.	Thiamethoxam *)
Disposal	After treatment bee nests should be removed and properly disposed. Container and washings must be disposed of safely. Paint brush and hand held sprayer are washed out with water; the washings to be disposed onto waste ground.	Bendiocarb *) Spinosad *)
Drainage	Products positioned away from external drains and unused products shall be disposed properly. Do not wash into sewer	Indoxacarb Spinosad *)
Management of resistance	For extended period of control use to be alternated with products with different modes of action (other active substances).	Bendiocarb *) Spinosad *)
D) Further regulatory options		
Non-inclusion in Annex I	No safe use of PBT/vPvB substance Proposed uses of Bifenthrin in insecticidal products do not fulfil the safety requirements It is proposed not to include Bifenthrin in Annex I	Flufenoxuron *) Bifenthrin *)
Comparative risk assessment	No areas of concern for choosing carbon dioxide as a candidate for comparative assessment.	Carbon dioxide
Data package	Only the professional use (as a gel) evaluated (no test about the elimination of the a.s. in STP available) → further data required when necessary. Not all potential uses evaluated → MS shall assess those risks not representatively addressed so far.	Diflubenzuron *) Imidacloprid *) Fipronil *) Pyriproxyfen *)
Population exposed	MS shall assess the populations exposed	Aluminium phosphide Indoxacarb
Monitoring	Monitoring in remote tropospheric air Monitoring of exposed workers/operators Levels of effectiveness and possible evidence of resistance should be monitored	Sulfuryl fluoride Hydrogen Cyanide *) Bendiocarb *)

*) Only draft CARs analysed, conclusions might be revised after discussion at technical meetings

6.1.3 Substances of (very) high concern

6.1.3.1 Chromium fixative

Chromium has been extensively used as a fixative agent in wood protection, especially in combination with copper and arsenic wood preservatives (copper chrome arsenate, CCA). During this process the carcinogenic chromium (VI) is turned into chromium (III). The chromium compounds chromium tri-oxide and sodium dichromate have been notified as biocidal active substances for PT 8 but were not supported in the Review Programme later on. There was a discussion on chromium and its efficacy as a wood preservative active substance in the EU. While chromium(VI) compounds are considered carcinogenic to humans (Group 1), metallic chromium and chromium(III) compounds to date are not classifiable as to their carcinogenicity (Group 3).²⁸ If chromium was considered as an active substance it could no longer be used at all in formulated biocidal products, because it would most likely fail an Annex I inclusion.

Industry refers to the use of chromium as a fixative below its effective concentration as wood preservative.²⁹ This is an example where the substance of concern is not the active substance but the fixative agent.

The Competent Authorities concluded that chromium-containing wood preservatives meeting the following requirements on their composition and use shall be allowed to remain on the market:³⁰

Requirements regarding the composition of the products:

- No form other than chromic acid (chromium trioxide, a chromium(III) compound) should be allowed in the product. Other chromium compounds, such as potassium dichromate or sodium dichromate should not be allowed, as no data have been provided to demonstrate that these compounds have no, or only a negligible, biocidal activity.
- In salts containing chromate, the active substance must be a copper compound, such as copper (II) oxide or copper hydroxide. Other copper

²⁸ WORLD HEALTH ORGANIZATION (1997) Chromium, Nickel and Welding Summary of Data Reported and Evaluation. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 49

²⁹ Guidance document agreed between the Commission services and the competent authorities of Member States on the role of chromium in wood preservation ENV.B.4/KB D(2005), Brussels, 4.07.2005 http://ec.europa.eu/environment/biocides/pdf/nfg_cr_040705.pdf

³⁰ CA-Sept07-Doc.9.3: Proposal for a way forward on chromium Draft

compounds such as copper sulphate or copper hydroxide carbonate shall not be allowed.

- Boric acid may be added to the chromium/copper salts described above to increase the biocidal activity of the product against certain target organisms.
- Water serves as the solvent for these components. The mass ratio of chromium trioxide to copper (II) oxide must not exceed a ratio of 3 to 1 in salts containing chromate. In those circumstances, it has been demonstrated that the biocidal activity of the chromium compound on the respective target organisms is negligible.

Requirements regarding the use of the products:

- Only for use class 4.
- To be applied only via vacuum pressure impregnation.
- Treated wood to undergo appropriate heat treatment to allow fixation and full reduction of Cr (VI).
- The maximum amount of CrO₃ containing wood preservatives to be used per cubic meter of wood shall be defined and limited at product authorisation in order to restrict the amount of Chromium (VI) applied.

This example demonstrates that non-active compounds also require specific attention during the risk assessment and risk mitigation of biocidal products.

6.1.3.2 Creosote

Creosote is considered to be a non-threshold carcinogen and is classified as carcinogen category 1B in accordance with Regulation (EC) No 1272/2008 (REACH). The substance, which is a mixture of hundreds of compounds, also contains constituents that are persistent, bioaccumulative and toxic (PBT). However, in a stakeholder consultation on 30 April 2008 most stakeholders considered the use of creosote to be vital for railway sleepers and for poles in electricity transmission and telecommunications networks, and that a phasing out of creosote would have major practical and economic disadvantages. Therefore in the draft inclusion Directive it has been suggested that creosote should be included in Annex I for five years only and should be made subject to a comparative risk assessment.³¹

According to REACH Annex XVII (No 31) creosote may not be used inside buildings, in toys, in playgrounds, in parks, gardens, and outdoor recreational and leisure facilities, in the manufacture of garden furniture, for containers intended for growing

³¹ CA-May10-Doc.3.4 Draft DIRECTIVE to include creosote as an active substance in Annex I

purposes and for packaging. Creosote shall not be sold to consumers and may be placed on the market only in packaging of a capacity equal to or greater than 20 litres (probably to avoid widely dispersed uses of from small packages).

According to the draft Inclusion Directive, creosote must not be applied to wood permanently exposed to salt water, to wood in contact with the ground or fresh water and thus permanently exposed to wetting. Appropriate RMM must be taken to protect workers, including down-stream users, from exposure during treatment and handling of treated wood. For protecting the soil and aquatic compartments, in particular, labels and/or safety data sheets of products authorised shall indicate that freshly treated timber must be stored under shelter after treatment and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for re-use or disposal.

However, the discussion on creosote is continuing and no decision has been taken so far by authorities. In any case, the application of creosote should be restricted because any emissions to the environment are considered as problematic because of the PBT properties and carcinogenicity of creosote.

6.1.3.3 Substitution

The substitution of very dangerous active substances such as carcinogenic or (potential) PBT or vPvB substances would be one option for improving sustainable use. The evaluation of risks during the Review Programme on existing biocidal active substances has already led to the removal of many priority substances from the market. Flufenoxuron is an example which probably will not be included in Annex I of the BPD due to its PBT/vPvB properties, according to the suggestions of the Rapporteur Member State (draft CAR report on Flufenoxuron). Depending on the progress of the Review Programme, further PBT substances or candidates for comparative risk assessment might be identified. For some insecticides not supported in the Review Programme, namely Malathion and Temephos (both being organophosphates), some Member States applied for essential use applications. However, essential use exemptions are only valid for single Member States during the transition period ending in 2010.

According to the existing BPD, only active substances for which risks have been identified are subject to a comparative assessment. There is no comparison of biocidal active substances with better properties than others, except pointing out those with low risks in Annex IA.³² During the decision making for the method to be applied for pest control, more hazardous active substances could be substituted by less hazardous ones on case by case basis. However, operators need instruments and background information as a decision tool.

6.1.4 Conclusion

Clearly the RMM proposed depend on the intended uses supported for the active substance and the data provided with the dossier.

The results of the risk characterisation are sometimes based on a worst case approach while assuming 100% leaching of wood preservatives or no elimination of insecticides in municipal STP because no data supporting lower leaching rates or biodegradation in STP have been submitted. If the environmental risk is not considered safe in this worst case approach, and no higher tier assessment is carried out, the area of application of wood preservatives and insecticides might be limited to indoor uses (wood preservative use classes 1 and 2, only crack and crevice treatment with insecticides indoors). The representative biocidal products included in the dossier also determine the intended uses and the concentration at which the biocide should be applied. Although the BPD has advanced the removal of substances of (very) high concern from the market, there remain some substances (active or fixative) whose risks and benefits remain controversial in Member States discussions.

³² The Commission's proposal for a biocide regulation replacing 98/8/EC modifies the rules on comparative assessment. Biocidal products containing an active substance that is a candidate for substitution shall not be authorised if there exists another authorised biocidal product or a non-chemical control or prevention method for the uses specified with significantly lower risk for human or animal health or the environment (Article 21).

6.2 Good and best practice documents

6.2.1 Wood preservatives

National standards and codes of practice

In Germany, the technical standard DIN 68800 (Protection of timber, Part 1-5) regulates the appropriate and safe use of wood preservatives:

- DIN 68800-1: General specifications
- DIN 68800-2: Preventive constructional measures in buildings
- DIN 68800-3: Preventive chemical protection
- DIN 68800-4: Measures for the eradication of fungi and insects

The standards, currently under revision, distinguish between habitable rooms (e.g. living rooms, bedrooms) where people spend a considerable part of their time and non habitable rooms (e.g. cellar, garage). The choice of durable wood species with less than 10% sapwood or glued wood panels is mentioned as a non-biocidal preventive measure. The standard describes several technical aspects for wood impregnation independent of wood species and moisture content, the type of formulation of wood preservatives (water based, solvent based), the technical process (dipping, vacuum impregnation) and the intended use class. Preferably the wood should be treated after the last mechanical processing e.g. by sawing or planning. For use classes 1 and 2 wood moisture below 20% should be maintained or achieved within 6 months after its installation.

In DIN 68800-3 it is mentioned that spraying of wood preservatives should not be allowed outside of stationary plants. For subsequent in-situ treatments, brushing is preferred.

After impregnation with non weather-resistant wood preservatives of use class 1 and 2, wood should be protected from rain during storage, transport and processing. Wood protected with weather-resistant wood preservatives should be protected from rain on site until the surface is dried and the fixation completed.

For the user, treated wood should be labelled with accompanying documents indicating the wood preservative and the amount used, the intended use classes, the penetration depth, the identification of the impregnation plant and the amount/time of treatment and whether cracks appearing after impregnation have been treated.

According to DIN 68800-3, installed wood must be labelled if it has been treated with wood preservatives.

Wood intended for use class 3.2 (not covered, not in contact with the ground, subject to frequent wetting, e.g. for gardening or landscaping) should preferably be treated by vacuum pressure impregnation.

Considering curative treatment against insects, DIN 68800-4 distinguishes between living infestations and extinct infestations (which need not be treated). In habitable rooms or storage rooms for food and feed no extended application of curative wood preservatives is allowed, unless the surfaces in habitable rooms are covered airtight. An extended application is defined by a ratio of the area treated to the room volume of $> 0.2 \text{ m}^2/\text{m}^3$. Fungal decay is usually combated by eliminating the cause of moisture and by replacing the infested wood. Only where infestations with dry rot (*Serpula lacrymans*) occur, might it be necessary to treat infected walls and adjacent wood.

In addition, several Technical Rules for Hazardous Substances (TRGS) exist, both for preventive treatments (TRGS 551 and 618) and curative treatments of wood (TRGS 512 and 523). For example, TRGS 523 sets out special protective measures to be taken in connection with pest control activities (including curative treatments with wood preservatives) using highly toxic, toxic and health hazardous substances and preparations.

The German Holz- und Bautenschutzverband e.V. offers a seminar / training course for the qualification of professional users. Successful participation in this course, which is concluded with an obligatory examination, is certified by an expert knowledge certificate for wood preservation („Sachkundenachweis für Holzschutz am Bau“). The certificate confirms the qualification required in DIN 68800, part 4 and indicates that the holder has up-to-date scientific and technical expert knowledge on the preparation, guidance, execution and testing of wood preservation measures.³³

The „Bundesausschuss Farbe und Sachwertschutz“ provides several items of guidance for painters and varnishers. Guidance document No. 18 “Coating of timber and derived timber products outdoors” is often referred to in product leaflets.³⁴ The

³³ Ausbildungsbeirat Holzschutz am Bau (Hrg.). Handbuch zur Sachkundebildung Holzschutz am Bau Fragen und Antworten. 3. Auflage Stand Februar 2009

³⁴ Merkblatt 18: Beschichtungen auf Holz und Holzwerkstoffen im Außenbereich (Stand: März 2006)
<http://www.farbe-bfs.de/>

guidance applies to wood not used for construction purposes. Reference is given to DIN 68800-3. The different timber products, the preparation of surfaces, different application techniques as well as maintenance of wood conservation are described in detail.

The German Association for Wood Research (DGfH) published several Codes of Practice for best practices in wood protection and biocide application (vacuum pressure impregnation, non-pressure impregnation, aromatic based wood preservatives, and water based wood preservatives) which were mainly developed in the 1990s. However, the association halted its activity for economic reasons and the future status of the guidance documents is unclear. They are currently not publicly available. In Germany many product leaflets refer to these standards (see chapter 6.3.2).

Some suppliers of wood preservatives provide further guidance on the preparation of timber prior to treatment:

- Timber packs must be of the correct moisture content in order to allow sufficient penetration into the wood fibre. Below 28% moisture content is the recommendation.
- Timber must be debarked and, as far as possible, free from sawdust and debris. Plastic wrapping should be removed. Packs that have been very tightly banded should have the bands cut prior to treatment to allow free passage of the fluid into the packs.
- All possible working of the timber should be performed prior to treatment
- If timber shows signs of incipient attack from fungus or insects it should not be treated. A small amount of blue-stain is not critical.
- Where possible, space the packs with laths in order to allow free passage of the fluid and to aid the drying process afterwards (PTG High Pressure Treated Timber User Guide)³⁵.

Occupational insurance associations also provide useful information on safe use of wood preservatives. Here, principles of the assessment of workplace and environmental safety are described and reference to further guidance is given. For dipping tanks the following technical safety measures are indicated: use of pumps for dosing the concentrate, use of water pipes which do not end in the working solution for filling, mixing through up and down movement of wood packages and not through compressed air. Freshly impregnated wood must be held by the fork lift truck above

³⁵ <http://www.ptgtreatments.co.uk/pdfs/PTG%20HighPressureTreatedTimberUserGuide09.PDF>

the dipping tank as long as liquid drips down. Afterwards the treated wood must be protected from weathering until the fixation time is completed. Special attention is given to the use of chromate as fixation agent (may not be used in dipping tanks) and solvent based wood preservatives (also because of the risk of fire and explosion) (Holz-Berufsgenossenschaft 2009).

In Germany, the Federal Ministry for Food, Agriculture and Consumer Protection (BMELV) published a “Practical Guide for Consumers on wood preservatives” in order to provide amateur (consumer) users with information on the safe use of wood preservatives and contact points for further advice.³⁶

Furthermore, a web-based information system for biocides (web portal combined with print media) is being established for the general public and will be available under www.biozid.info. This portal, developed and run by the Federal Environment Agency, aims to inform the general public about physical, chemical and other measures as alternatives to the use of biocidal products or for minimization of their use, with a focus on the description of preventive measures.

In the USA, the state of Michigan offers an extensive manual/guide for commercial applicators in Category 7B “wood destroying pests”.³⁷

BAT for the Wood Preservation Sector

The BREF for the sector “Surface Treatment Using Organic Solvents” deals with industrial processes for wood preservation using organic solvent-based preservatives. The BREF contains a number of practices considered to be BAT and which could be applied to the wood impregnation sector. However, there exist only a small number of plants using organic solvent-based preservatives to which the BREF can be applied to (DEFRA 2008). The BREF mentions the following BAT criteria for the reduction of emissions to soil and water from wood impregnation:

- Drain surplus biocide system in contained areas for both water- and solvent based systems. The collected biocides can either be re-used or disposed of as hazardous waste
- Take preventive measures (e.g. good housekeeping measures concerning the evacuation of the treated wood from the application area)

³⁶ http://www.bmelv.de/cln_137/cae/servlet/contentblob/382182/publicationFile/21812/VerbraucherleitfadenHolzschutzmittel.pdf

³⁷ Randall et al. 2000. Management of wood destroying pests – a guide for commercial applicators category 7B, Extension Bulletin E-2047, Michigan State University
<http://www.pested.msu.edu/Resources/bulletins/E2047.html>

- Install a rework system that returns the dripped agent to the storage vessel and/or have an impermeable floor so the risk of soil contamination and possible (ground)water pollution can be avoided
- When impregnation takes place under pressure the vessel is usually put under vacuum as a final stage of the procedure. Afterwards the wood produces less drip down
- A fixation process can be performed or otherwise the wood can be stored inside;
- In order to reduce the environmental effects of the use of creosote it is advisable to use a type of creosote with a limited PAH-content
- Process wastewater containing chemical preservatives should be contained as part of a closed loop application system;
- Effluents that may contain wood preservative chemicals require an additional level of treatment, such as detoxification (using ultraviolet oxidation) and precipitation or stabilisation of heavy metals, depending on the nature of contamination;
- Storage tanks and components should meet international standards for structural design integrity and operational performance;
- Chemical storage and treatment sites and tanks should be situated in containment areas, for example, a covered, walled, concrete area beneath which there is an impermeable membrane. Any spills into this area should drain into a tank/sump located in a contained area from which leaks can be detected;
- Level gauges, alarms, and cut-off systems on storage tanks should be installed to decrease the risk of overfilling;
- Tankers delivering bulk shipments of treatment chemicals should employ spill prevention measures;
- A contained and impermeable post treatment dripping zone should be located within the total containment area. Residue from dripping timber should be collected for reuse
- Treatment chemicals that can be heat-cured onto wood should be adopted to prevent leaching properties. The curing machine should be located within the containment area
- Treated wood that is cured may be stored in the open. If not cured, wood should be covered and storm water should be collected and treated.

The wood preservation industry has established a “Code of Practice for Timber Treatment Installations” which has been endorsed by the Environment Agency (2003) and currently forms the basis of how the operator and the regulator can demonstrate BAT:

- Bunding of timber treatment plant and wood-preservative storage tanks: The plant associated loading and unloading area and preservative storage tank should be located within a bund. The bund should be impervious and resistant to chemicals that it contains. The bund should be covered in an enclosed area to avoid the collection of rainwater. Provisions should be made for the secure

and contained storage of packaging that contains wood preservatives such as 200 litre drums or intermediate bulk containers (IBCs). Bunding should have an adequate capacity to contain a spillage (110% of the total quantity of each). Regular inspections of the bunding should be carried out.

- Post treatment containment and conditioning areas: Treated wood must be held until surfaces are dry and within a bunded area. The dripping area should be contained and impermeable and timber should be transferred from plant to post treatment area within a total containment zone.
- Storage of conditioned timber: Bulk dry treated timber should be stored under cover on an impermeable surface.
- Waste management: Wastes associated with wood preservation processes (i.e. redundant preservative solution, sawdust used to soak up spills, redundant preservative containers, contaminated rainwater from bunds etc), are usually classified as hazardous and should be dealt with as according to Hazardous Waste Regulations.
- Bulk delivery of chemicals: Containment of any potential spill from the tanker, delivery and/or handling vehicle, taking the discharge system into account. Tankers should discharge chemicals within a contained area close to the bunded storage area.
- Plant maintenance: A planned written scheme of maintenance and examination should be followed. This should cover all protective devices, pressure valves and pipework that could give rise to pollution in the event of failure.

The Code of Practice states that the implementation of a formal and documented Management System would greatly enhance the safe and efficient operation of a timber-treatment facility and could also be used to save money through reducing waste and raw materials and as a tool to prevent pollution.

Concerning the handling of treated wood, the formulators of wood preservatives have developed their own guidance e.g. on high pressure treated timber.³⁸ Here, the following useful recommendations for the use phase³⁹ of treated wood are given:

- Do not burn preserved wood.
- Wear a dust mask and goggles when cutting or sanding wood.
- Wear gloves when working with wood.
- Some preservative may migrate from the treated wood into soil/water or may dislodge from the treated wood surface upon contact with skin. Wash exposed skin areas thoroughly.
- All sawdust and construction debris should be cleaned up and disposed of after construction.

³⁸ <http://www.ptgtreatments.co.uk/pdfs/PTG%20HighPressureTreatedTimberUserGuide09.PDF>

³⁹ In this context "use phase" refers to both the application of a biocidal product as on its service life.

- Wash work clothes separately from other household clothing before re-use.
- Preserved wood should not be used where it may come into direct contact or indirect contact with drinking water, except for uses involving incidental contact such as fresh water docks and bridges.
- Do not use preserved wood under circumstances where the preservative may become a component of food, animal feed, or beehives.
- Do not use preserved wood for mulch.
- Only preserved wood that is visibly clean and free of surface residue should be used.
- Do not use preserved wood in direct contact with aluminium.
- If wood is to be used in an interior application and becomes wet during construction, it should be allowed to dry before being covered or enclosed.
- Disposal Recommendations: Preserved wood may be disposed of in landfills or burned in commercial or industrial incinerators or boilers in accordance with National and Regional regulations.
- If you wish to apply a paint, stain, clear water repellent or other finish to your preservative treated wood, we recommend following the manufacturers instructions and label of the finishing product. Before you start, we recommend you apply the finishing product to a small test area before finishing the entire project to ensure it provides the intended result before proceeding.
- Certain metal products (inc fasteners, hardware and flashing) may corrode when in direct contact with wood treated with copper based preservatives. To prevent premature corrosion and failure it is important to follow the recommendations of the manufacturer for all metal products.
- Mould growth can and does occur on the surface of many products, including treated or untreated wood, during prolonged surface exposure to excessive moisture conditions. To remove mould from treated wood surfaces, wood should be allowed to dry. Typically, mild soap and water can be used to remove surface mould.

Information on how to handle treated wood during the use phase is mainly missing in product leaflets and most “best practice” documents on impregnation.

The disposal of wood preservation waste (residues) fall under the Hazardous Waste Directive 2000/532/EC. The following waste codes have been defined:

- 03 02 01 Non-halogenated organic wood preservatives
- 03 02 02 Organochlorinated wood preservatives
- 03 02 03 Organometallic wood preservatives
- 03 02 04 Inorganic wood preservatives

However, in some product leaflets also the following waste codes have been referred:

- 08 01 11 Waste paint and varnish containing organic solvents or other dangerous substances

- 08 01 19 Aqueous suspensions containing paint or varnish containing organic solvents or other dangerous substances

6.2.2 Insecticides

The best practice for insecticide use can be described by Integrated Pest Management standards. There exist several (national and international) guidance documents concerning pest control and including IPM principles:

- WHO 2008 Public Health Significance of Urban Pests (Bonnefoy et al 2008)
- Handbuch für den Schädlingbekämpfer (Bodenschatz 2009)
- The British Pest Management Manual (Meyer et al. 2007)
- Malis Handbook of Pest Control (Malis et al. 2004)
- Complete Guide to Pest Control with and without Chemicals (Ware 2005)
- Pesticide Applicator Core Training Manual - Certification, Recertification and Registered Technician Training - Part A: Required reading for: Private pesticide applicators, Commercial pesticide applicators, Registered technicians (Stachecki 2002)
- Healthy Hospitals - Controlling Pests Without Harmful Pesticides (Owens 2003)
- Health and Safety Agency for Northern Ireland (1995). The safe use of pesticides for non-agricultural purposes. Approved Code of Practice
- TRNS Teil 1 (14.07.2005). Technische Regeln und Normen der Schädlingbekämpfung Gesundheits- und Vorratsschutz (G+V) sowie Materialschutz im Gesundheits- und Vorratsschutz (M/G+V). The German Pest Operator Association (Deutscher Schädlingbekämpfer-Verband e.V., DSV)

The Confederation of European Pest Control Associations (CEPA) has started an initiative for standardisation pest controlling services under CEN.

For specific applications, such as Mosquito control, further specific guidance exists:

- The European Mosquito Control Association (EMCA, <http://www.emca.asso.fr/>) organise European Mosquito Control Workshops and publishes the European Mosquito Bulletin which is online available (<http://e-m-b.org/>)
- Becker et al. (2003). Mosquitoes and their control. Kluwer Academic Publishers

The WHO Pesticide Evaluation Scheme (WHOPES) publishes numerous guidance documents on pest control organization, operation, and training as well as on application equipment and efficacy testing (<http://www.who.int/whopes/resources/en/>). The focus is clearly on vector control, primarily for tropical diseases.

Environmental aspects are indirectly addressed e.g. by the choice of the active substance. However, the transferability of these documents to European condition is questionable, because, for example, organochlorines like DDT or organophosphates like Chlorpyrifos are recommended for malaria control while these actives are no longer allowed for biocidal purposes in Europe.

Most of the documents refer to all aspects of pest control, including preventive measures, non-biocidal alternatives and integrated pest management. The knowledge of the biology of pest organisms, the optimization of the pest control agents used, the modes of their application, the application equipment, and training of operators are of major interest. Environmental aspects are indirectly addressed and focus on rules on cleaning of the equipment, storage, transport, and disposal of (obsolete) products.

Additionally, some technical rules and standards should be considered. The Technical Rules for Hazardous Substances (TRGS) 512 "Fumigations" describe the personal protection equipment to be used when applying fumigants. For hydrogen cyanide and phosphine releasing compounds (aluminium phosphide, magnesium phosphide) air-purifying filters may be used, for sulfuryl fluoride atmosphere-supplying respirators are required which are independent from the air surrounding the user. Operators must prove their competence and certification by their successful participation at training courses.

In Germany the technical rule TRGS 523 on pest control applies to pest control applications with very toxic, toxic and health hazardous substances and preparations. Preventive pest control methods are not considered. Pest control operators must hold a register of all pest control products with their classification, amount and area to be used. These data are only provided to the authorities on request. The TRGS requires that the equipment for application of pest control agents, such as spraying or fogging equipment, may only be used according to the operating instructions of the supplier and must be checked for functional and safety efficiency at least once a year. The minimum personal protective equipment required for different application methods is described in a matrix (pouring, sprinkling, dusting, coating, spraying, high pressure spraying, atomizing). The spray and the bait shall be prepared in the open air, if possible. Otherwise, proper ventilation shall be ensured. The solutions to be used shall not be prepared in residential buildings, in kitchens or storage rooms for food or

feed. Only the quantity necessary for the intended pest control activity shall be prepared. Residual quantities shall be avoided. The equipment used shall be cleaned when the work has been completed and the residues of the solutions prepared or the rinsing fluids shall not be allowed to enter any bodies of water. Any waste arising shall be disposed of in compliance with the provisions governing the disposal of waste, in particular, with due regard to the Ordinance for the Definition of Wastes. Contaminated packaging materials shall be collected separately and directly disposed of according to local hazardous waste collection schemes. After pest control measures, access to treated areas must be approved by the operator after considering measures such as continuous aeration, removal of bait residues or cleaning/decontamination. Any waste arising shall be disposed of in compliance with the provisions of the waste legislations. TRGS 523 describes general rules for storage of pest control agents, which should not endanger human health and/or the environment. Any misuse should be avoided by suitable precautionary measures. For storage of more than 50 kg of pest control agents classified as toxic or very toxic additional, TRGS 514 applies. It describes further requirements for the construction of stock facilities such as protection from floodwater, housebreaking, fire-protection etc. as well as requirements for floor surfaces,, which must retain liquids and must be impermeable and not connected to sewers. In addition, TRGS 523 prescribes requirements concerning the information and documentation of measures. For example, pest control activities in public facilities, particularly schools, day-care centres, or hospitals, must be notified to the Competent Authority 14 days prior to their implementation.

For insecticides used in animal housing and manure storage systems, the drainage has a decisive influence on emissions to STP and/or surface water. Therefore, as a RMM, use in animal housings may be not allowed where exposure to a STP or direct emission to surface water cannot be prevented. Insecticides are closely related to veterinary medicinal products for which RMM have been / are being developed. On farms, the pests encountered are flies (e.g. house fly *Musca domestica*) or bloodsucking flies, lice, mites (acaricides), louse flies, fleas, and cattle grubs. Poultry is especially susceptible to bloodsucking parasites. Housings for pigs, fat stock and calves have wet manure storage exclusively; breeding of poultry leads to dry manure storage. Effluents from liquid manure (slurry) and the cleaning water from milking systems or stable cleaning usually enter wet storage tanks (liquid waste, slurry).

Direct release of these effluents to the sewer is not allowed in most member states. Insecticides applied as a larvicide to manure storage systems end up completely in the manure. In Germany, liquid manure and all ingredients from cleaning/disinfection as well as veterinary medicinal products must not be discharged to sewers connected to STPs but must be collected in storage tanks and treated on-site (e.g. anaerobic treatment) or spread as fertilizer on agriculture fields (ATV-M 702 1995, Bayerisches Landesamt für Wasserwirtschaft 2004). This is considered good agricultural practice. Local exceptions may exist where the cleaning water from milk production is discharged to the sewer together with domestic wastewater. For manure treatment, good housekeeping and compliance with national rules for manure and slurry spreading activities (e.g. German Fertilizer Ordinance, Düngeverordnung from 2006) has a decisive influence on leaching of insecticides to water bodies. The main objective is to limit nitrogen input to soils and water bodies. Directive 91/676/EEC limits the amount of manure applied to soil to 170 kg N per hectare. Environmental problems associated with manure also include the content of veterinary drugs, disinfectants and insecticides used for animal housing. An IPPC BREF document on Intensive Rearing of Poultry and Pig is available (European Commission 2003). Manure treatment (e.g. anaerobic digestion) prior to or instead of land spreading is considered as conditional BAT but the majority of farms in the EU manage manure by land spreading. The BREF describes some situations when disinfectants should be applied. One example is that the housing should be fully cleaned and disinfected after delivering broilers to the slaughterhouse. General biocides such as insecticides are not considered in detail.

While general principals on IPM rules can be described, such as the need for monitoring, it seems that sound IPM measures have to be developed for specific pests. This is comparable to IPM in the agricultural sector which considers specific crops.

Applying IPM principles is a promising tool for improving the sustainable use of insecticides. The promotion of initiatives on IPM (e.g. by CEPA), the request to include IPM principles in development of standards and the establishment of an EU expert group developing common standards would be options to support IPM development.

6.2.3 Conclusion

Good and best practice documents are a very important tool for achieving a harmonised understanding of when and how to apply biocides, which RMM should be implemented to reduce risks and how to control compliance with best practice.

In the case of wood preservatives, the best practice documents tend to focus on BAT and inclusion of impregnation facilities for water based wood preservatives under the IPPC would be an effective instrument for improving these processes and related activities (e.g. storage of treated wood). Existing national standards and codes of practice could be used as a starting point for harmonisation.

In the case of insecticides, best practice documents mainly have a diffuse character. There is much information available from different sources and the implementation of the principles of integrated pest management seems to be the most promising instrument for reducing the apparent risks.

6.3 Product labels, safety data sheets and technical leaflets

More than 1500 product labels, technical leaflets and/or safety data sheets from PT 8 and 18 products have been screened for useful information concerning risk mitigation measures proposed by industry. The information consisted of basic instructions as required in Article 20 of the BPD on classification, packaging and labelling of biocidal products and Article 21 of the BPD concerning the preparation of safety data sheets. Additionally, more detailed instructions and recommendations were provided with the technical product leaflets. Sometimes these also refer to further guidance documents or standards to be considered.

6.3.1 Product labels and safety data sheets

The requirements concerning the classification, packaging and labelling of biocidal products are specified in Article 20 of the BPD. The following information has to be provided to operators together with the biocidal products:

Article 20 of the directive 98/8/EC

The label must show clearly and indelibly the following:

- (a) the **identity** of every active substance and its concentration in metric units;
- (b) the **authorisation number** allocated to the biocidal product by the Competent Authority;
- (c) the **type of preparation** (e.g. liquid concentrates, granules, powders, solids, etc.);
- (d) the **uses** for which the biocidal product is **authorised** (e.g. wood preservation, disinfection,

surface biocide, anti-fouling, etc.);
(e) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the authorisation;
(f) particulars of likely direct or indirect adverse side effects and any directions for first aid ;
(g) if accompanied by a leaflet, the sentence 'Read attached instructions before use';
(h) directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging;
(i) the formulation batch number or designation and the expiry date relevant to normal conditions of storage;
(j) more detailed information about application <ul style="list-style-type: none"> - the period of time needed for the biocidal effect, - the interval to be observed between applications of the biocidal product - or between application and the next use of the product treated, - or the next access by man or animals to the area where the biocidal product has been used, - including particulars concerning decontamination means and measures and - duration of necessary ventilation of treated areas; - particulars for adequate cleaning of equipment; - particulars concerning precautionary measures during use, - storage and transport like e.g. - personal protective clothing and equipment, - measures for protection against fire, - covering of furniture, - removal of food and feeding stuff and - directions to prevent animals from being exposed and where applicable:
(k) the categories of users to which the biocidal product is restricted;
(l) information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water ;
(m) for microbiological biocidal product <p>labelling requirements according to Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work.</p>

This information is given in the labels and technical leaflets in more or less detail. Some examples are given in table 7.

Table 7: Examples of labels according to Article 20 BPD

	PT 8 wood preservative	PT 18 insecticides
Type of preparation	Clear, liquid primer formulated with a fungicide - ready-to-use wood preservative which should not be diluted.	Insecticidal gel bait for the control of cockroach nymphs and adults
Uses	Used for preventive protection against blue stain on all wood in outdoor areas without ground contact. It is used for impregnating and priming soft and hard wood, especially dimensionally stable building elements such as windows, exterior doors, roller blinds and as a primer for renovation coats.	A wettable powder recommended for the control of cockroaches, ants, fleas, flies, adult mosquitoes, stored product pests, bed bugs, carpet pests, wasps, bees, silverfish and other bristle tails, ground beetles, earwigs, crickets, booklice, spiders, woodlice, centipedes, millipedes, ticks and thrips. For Use in: Domestic Premises: Private housing
Directions of use	The product can be brushed, dipped or flow coated; spraying only in closed facilities. The substrate must be free of grease, wax, dirt and dust. Remove coatings that form a film, e.g. thick-layered stains, varnishes and paints. Cover	Apply directly to the insects present on the fabric of warehouses, granaries, mills, bakeries and similar situations, or insects on the surfaces of bags and cases containing stored food products. Special attention should be paid to cracks and crevices and other insect harbourages.

	bituminous and plastic materials and tie plants out of the way. The moisture content of the wood may not exceed 15%.	Or more precisely e.g. for ants: Where possible dig out nests. Sprinkle powder freely along any runs and around nests. Where ants are invading premises apply liberally to points of access, e.g. doorsteps, window frames, airbricks etc. Re-treat as necessary
Adverse side effects	Only to be used according to directions and only in the approved application areas. Misuse may harm health and the environment. Do not use on wood that could come in direct contact with food or animal feed. This preservative and leftover product should not be allowed to reach aquatic environments, the ground or the sewer system. Avoid open fire and light. After application, the wood has increased combustibility until the solvents have evaporated. Do not use on beehives or on the inside of greenhouses. Harmful for aquatic organisms – may have a long-term harmful effect in aquatic environments. Harmful: may cause lung damage if swallowed. Repeated contact may cause skin to dry out and crack.	Keep away from food, drink and animal feeding stuffs. Keep out of the reach of children. In case of accident or if you feel unwell seek medical advice immediately (show the label where possible). Avoid inhalation of spray and contact with skin and eyes
First aid	Immediately remove any clothing soiled by the product. In case of irregular breathing or respiratory arrest, provide artificial respiration. After inhalation: take affected persons into the open air and position comfortably. Seek medical treatment in case of complaints. After skin contact: wash immediately with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor. After eye contact: rinse opened eye for several minutes under running water. Then consult doctor. After swallowing: do not induce vomiting; call for medical help immediately. Keep the person affected quiet.	Move to fresh air. Keep patient warm and at rest. If symptoms persist, call a physician. In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. In case of contact with skin wash off immediately with soap and plenty of water. If symptoms persist, call a physician
Application	For effectiveness against blue stain, 160 - 200 ml/m ² are required. Apply two coats of the material with a brush. Close opened containers tightly after use and use the remains as soon as possible. After drying (at least 24 hours), stains, varnishes or paint can be applied. These coatings should be applied within four weeks. may be delayed on highly absorbent wood and in damp and cold weather. After treatment clean brush, dipping basin, flow-coating facilities immediately with thinner xyz.	For the control of flying insects, close all doors and windows and direct spray upwards into the centre of the room with a slow sweeping motion, 5-10 seconds in an average room (30 m ³). Vacate room and keep door closed for 15 minutes. Ventilate before re-entry.” “Apply directly as spots or thin ribbons to surfaces in identified target areas. It should be placed out of sight and where light intensity is low. Avoid excessively dusty, damp or greasy locations is particularly valuable in sensitive areas where the use of conventional insecticide formulations is restricted e.g. in the vicinity of electric and electronic equipment, mechanical plants etc.” “Wear suitable protective clothing, gloves and eye/face protection. Do not

		breathe dust. Otherwise wear respiratory protective equipment and eye protection (see HSE Guidance Booklet HS(G) 53: "The Selection, Use and Maintenance of Respiratory Protective Equipment – A Practical Guide)
Disposal	Dispose of larger quantities of leftover product in the original container in compliance with valid regulations. Completely empty containers may be recycled. Refuse Code No.: 03 02 02 (organo-chlorinated wood preservative)	In accordance with current regulations and, if necessary, after consultation with the site operator and/or with the responsible authority, the product may be taken to a waste disposal site or incineration plant. Advice may be obtained from the local waste regulation authority.

According to Article 21 of the BPD, safety-data sheets shall be prepared for biocidal products classified as dangerous and in accordance with Article 10 of Directive 88/379/EEC and for active substances used exclusively in biocidal products.

Safety data sheets have a strictly prescribed structure and aspects related to risk mitigation measures can easily be identified:

Requirements of safety data sheets	Risk mitigation measures
1. Identification of the substance /preparation and of the company/undertaking	Substance Information
2. Hazards identification	Human Health and Environment
3. Composition/information on ingredients	Substance Information
4. First aid measures	Human Health
5. Fire-fighting measures	Human Health and Environment
6. Accidental release measures	Human Health and Environment
7. Handling and storage	Human Health and Environment
8. Exposure controls/personal protection	Human Health
9. Physical and chemical properties	Substance Information
10. Stability and reactivity	Human Health
11. Toxicological information	Human Health
12. Ecological information	Environment
13. Disposal considerations	Environment
14. Transport information	Environment
15. Regulatory information	Human Health and Environment
16. Other information	Depending on Product

The measures are described very generally. For wood preservatives the following exemplary general safety phrases have been assigned:

Keep out of reach of children. When using do not eat or drink. Avoid contact with eyes and skin. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Take off immediately all contaminated clothing. After skin contact washes with plenty of soap and water. Wear suitable protective clothing, gloves and eye/face protection. Do not mix with strong acids or alkalis. Use appropriate containment to avoid environmental contamination. If swallowed, do not induce vomiting: seek medical advice immediately and show container, label or this safety data sheet. Avoid breathing vapours. Absorb spillage in suitable inert material. Sweep or shovel -up spillage and remove to a safe container. Wear impervious gloves, goggles and overalls when cleaning up the spillage. Do not allow to enter watercourses. Dispose of according to local regulations.

Similarly for insecticides the following safety phrases are often assigned:

Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment. Avoid contact with spilled product or contaminated surfaces. Use personal protective equipment. Remove all sources of ignition. Do not allow to get into surface water, drains and ground water. If spillage enters drains leading to sewage works inform local water company immediately. Ensure aerosol container is empty before disposal. Dispose of empty and cleaned packaging safely.

The safety data sheets are therefore very useful to gain a quick overview about the hazard of a product but more information is needed to use it safely.

6.3.2 Technical leaflets of wood preservatives

The evaluation of technical leaflets for wood preservatives indicated useful additional information on how to apply the products. Most recommendations refer to technical aspects of how to use the products (use classes, pre-treatment of wood surfaces, mode of application, working temperature, amount of preservative required, dry time, number of coatings, compatibility with other coatings, waiting time before grinding/overcoating etc.). Further, several risk mitigation measures have been proposed which are documented in Annex 3 in a structured way. To summarise, the following main RMM have been described:

Area of application: Often national requirements are referred to. For example large scale use in habitable or adjoining rooms is not allowed according to DIN and ÖNORM technical standards unless the rooms are protected from the treated wood by barriers. Additionally, ensuring dust-tight covering of treated wood in habitable and comparable rooms has been recommended as a RMM. Also, more background information is given that wood preservatives should only be applied where necessary, e.g. for load-bearing and reinforcing wood building elements. Detailed instructions on the mode of application are provided.

Preparation of the wood surface before application: The mechanical pre-treatment of wood, such as cleaning the wood from debris, the required moisture of the wood to be treated or instructions for removal of thermal insulation before curative treatment are described in detail. It is noted that the preserved wood should not be cut or otherwise reworked as this will expose unpreserved wood. Any surface exposed by drilling or cutting must be re-treated. Some technical leaflets on wood preservatives also indicate that damaged old coatings should be removed completely by sanding and replaced by new wood preservative coating.

General principles for maintaining dip tanks: Cover the dipping tank when not in use, make sure to avoid moisture and/or contamination ingress; use a “grate” above the bottom of the tank so that any debris is collected below etc.

Storage of treated wood: While the time needed for completing the fixation of wood preservative is indicated, often only general advice is given that the impregnated wood must be protected from weathering when stored. Precise description of the preferred method (covered, under roof) is often missing.

Post-application: Some leaflets suggest that the wood surface should be protected by two or three coatings and recommend sanding of the surface before the application of the subsequent coating. However, risks from the inhalation of saw dust or sanding dust from treated wood are inadequately addressed. The only advice is to wear a dust mask and to carry out these operations outdoors whenever possible. While several product leaflets refer to the possibility that the treated wood could be coated after drying and checking the adhesion of the new coating, top coating as a risk mitigation measure has not been identified in product leaflets.

Disposal of treated wood: It is noted that treated wood should not be burned in open fires or in stoves, or fireplaces, because of the release of toxic substances. Treated wood may be disposed of by complying with local landfill rules or burned in industrial incinerators in accordance with existing regulations.

Further information sources: Many product leaflets refer to further information provided by the Deutsche Gesellschaft für Holzforschung e.V. (DGfH), the DIN 68 800-3 and DIN 68 800-4 on wood preservation and other technical guidance and “Codes of Practice” from industrial association such as Deutsche Bauchemie e.V. Reference is also made to the UK HSE Guidance Note “Remedial Timber Treatment in Buildings”.⁴⁰ Wood preservatives approved by the German Deutsches Institut für Bautechnik (DIBt) for technical construction products receive a written approval notification which can be downloaded by some suppliers. Here reference is given to the corresponding DIN 68800-3 (preventive treatment) or DIN 68800-4 (curative treatment) and as a prerequisite only professional use by trained operators is allowed. The limitation of large-scale use in habitable areas (defined as a ratio of 0.2 m²/m³ of the treated surface to the room volume) is mentioned. The mode of application, the use classes for which the product is designed, the amount required for impregnation and the fixation time are specified. Other specifications refer to the duties of documentation and external control of the production site.

6.3.3 Technical leaflets of Insecticides

The information provided with the technical product leaflets is, as a rule, more specific than that on the label. Measures are illustrated to inform users about the intrinsic properties of the substances. Information on, for example, user restrictions, intended uses, areas and mode of application, special product designs, resistance manage-

⁴⁰ HSE ‘Remedial Timber Treatment in Buildings A Guide to Good Practice and the Safe Use of Wood Preservatives’ priced at £4.00 (ISBN 0-11-885-9870) http://www.pesticides.gov.uk/safe_use.asp?id=870

ment, specific equipment, poisoning of non target organisms, decontamination and disposal are presented. In particular, information is given about the mode of application, including detailed instructions. If new methods are described, such as water soluble sachets or special professional monitoring traps, the information is more detailed. Further risk management measures are described in several leaflets, like measures to avoid pests, sealing and eliminating of hiding places and hints to find these hiding places. Risk mitigation measures concerning the protection of non target organisms are often very general, e.g. “avoid all contact with plant life” or “prevent access to bait by birds and non target animals”. Advice about decontamination measures could only be found in a very few leaflets.

Generally it was noticed that the leaflets differ significantly in the level of detail and practical advice. In Annex 4 different risk mitigation measures which were described in the technical leaflets are summarised. They can be used as examples to define a **profile of requirements** for the application of biocides. From the review of the technical leaflets, some areas of information requirements have been identified which go beyond the requirements of Article 20 of Directive 98/8/EC:

Preventive measures: Different information to avoid or at least minimise insect attacks is presented in some of the evaluated sheets. The maintenance of rooms e.g., regular cleaning measures, the control of goods, ideal storing conditions for food, sealing and elimination of hiding places for insects is a very important requisite for pests to be avoided. But the knowledge that modern building techniques create a lot of “biotopes” e.g. in built-in furniture, insulating wall panels, suspended ceilings and installation slots is also necessary. Special measures such as polyurethane foam with a natural flavouring to deter insects from trespassing are also described.

Early detection/early warning systems: Different early detection/early warning systems are introduced, such as pheromone or adhesive traps e.g. for cockroaches or moths. Evaluation of which and how many insects are present before performing any pest control measures, helps to avoid unnecessary action. Regular inspections of rooms to recognise the vermin early enough are necessary. The proper placement of baits and traps leads to more effective results. During the application of baits, other food must be removed from these rooms.

Preparation: Before the application of biocides it may be recommended to clean the room and to uncover all hiding places of the insecticides. It is useful to close windows, doors and all other openings. Shake the biocide container if necessary to obtain a homogeneous concentration. The expiry date of the concentrate and of the diluted material must be known.

Training/equipment: In many of the product information sheets the application of the product is already well presented. In addition, the use of proper equipment is necessary to guarantee the success of the measure. Some producers describe the equipment in detail, e.g. the use of different spray nozzles. It is important to give accurate advice on this point. These RMM could be supplemented by obligatory training events for professional users.

Post application: After the application, according to Article 20, it is also necessary to consider the proper (waiting) time e.g. until the biocide has dried, until the room can be ventilated, or until the room can be re-entered. **In addition** the success of the measure (eradication principle) must be determined to decide whether pest control has to be repeated.

Decontamination: Although decontamination measures are already part of Article 20 (j) they are only described by a very few producers. To avoid unnecessary exposure to residues and at the worst secondary poisoning through chronic exposure, instructions about decontamination procedures are very relevant and should be obligatory.

Resistance management: This is also a very important point to be considered because otherwise a larger amount and eventually more toxic biocides will have to be used for pest control. Some producers describe the use of different applications like gel and spray and/or products with different active ingredients to minimise resistance development in insects. Others describe the intervals at which biocides can be used to avoid resistance development.

6.3.4 Conclusion

Compared to the product labels and safety data sheets, more detailed guidance is given in technical leaflets which can be used as more precise RMM. The evaluation of technical leaflets indicated useful additional information on how to apply the products. The different companies apparently have developed their own strategies on how to communicate risks and risk mitigation measures to the user of biocidal products. This means that product leaflets for different products from one formulator are similar. The information requirements described in Article 20 of the BPD are included, but in many cases only very briefly and/or very generally (ensure ventilation, use of appropriate PPE, no release to soil and water...).

Additional measures have been identified where mitigation of risks is possible. For example prevention to avoid insect attacks, early warning systems, proper preparation of rooms and materials, post application measures, decontamination of treated areas and materials (which, however, might result in releases to the

environment), resistance management and training to use e.g. the proper equipment are risk mitigation measures which could be found by example in some technical leaflets. These measures appear to be very important to reduce the risks associated with applying biocides.

In accordance with REACH guidance R.13, it is accepted that the communication of risks depends not only on the information provided by the label or technical leaflets but also on the presentation of the information. Especially for consumers, complex instructions are not suitable to ensure control of risk. Only short and simple instructions are likely to be implemented by a significant proportion of consumers.

Technical leaflets on wood preservatives often highlight further information sources, such as national standards or codes of practice from authorities or professional associations. For insecticides, few references to guidance documents are given and these mainly address respiratory protection equipment. However, some formulators provided further information on pests on their websites. The development of user specific and pest targeted guidance documents and their harmonisation on a European level would be one option to improve compliance with RMM. In Germany a web-based information system (web portal combined with print media) is being established for the general public and will be available under www.biozid.info. This portal, developed and operated by the Federal Environment Agency, aims to inform the general public about physical, chemical and other measures as alternatives to the use of biocidal products or for minimization of their use, the focus lying on the description of preventive measures.

6.4 Other aspects of risk management

In the context of the project, the term “risk mitigation” is used to refer to regulatory decisions as part of the risk management process. That means that the approval of active substances or the authorisation of a biocidal product might be subject to certain risk mitigation measures. A broader strategy on the minimisation of risks has been adopted through Directive 2009/128/EC on sustainable use of pesticides (which only refers to plant protection products so far). Here, also, many aspects beyond regulatory decisions are covered (Figure 3).

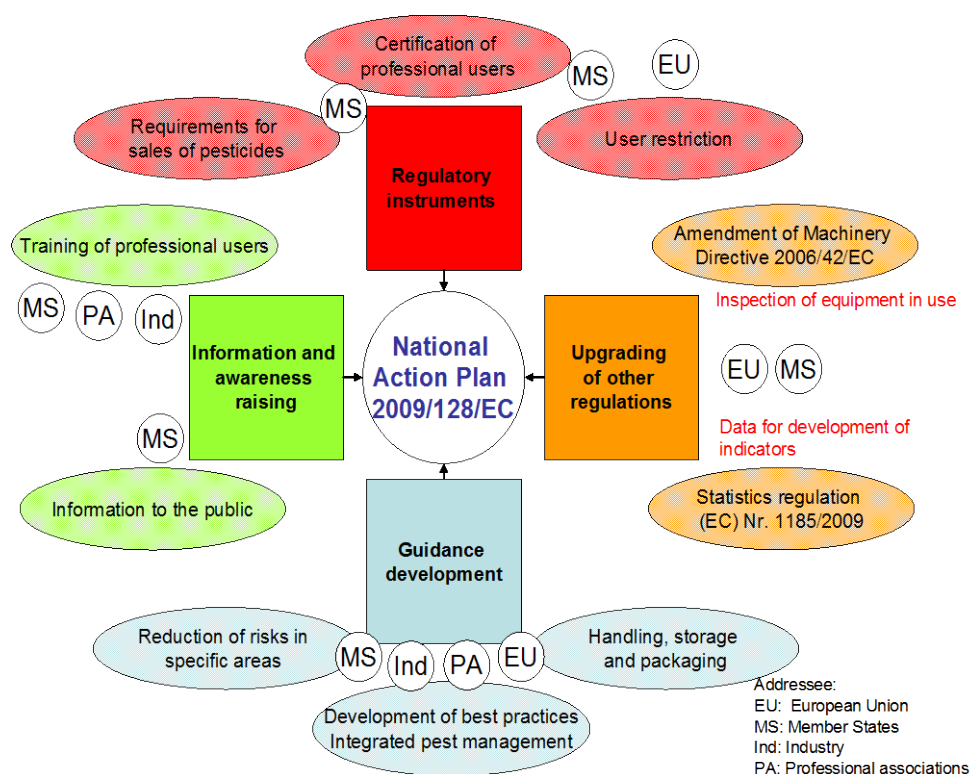


Figure 3: Instruments for sustainable use of pesticides

The transferability of proposals on sustainable use of pesticides developed for plant protection products to the biocides area is analysed in another research project (FKZ 3708 63 400). In this chapter only the main aspects of sustainable use of biocides are briefly described.

6.4.1 Regulatory instruments

Training of professional users, distributors and advisers:

According to Article 5 of 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 certificate systems providing evidence of attendance to training.

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 considered 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). For other PTs like PT 8 and 21 the best

practice application of biocides could be included in professional education. For non-professionals, information campaigns on awareness-raising could prevent or reduce improper use of biocides.

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 at the national level only. Because of this, is difficult to obtain a realistic overview about different activities at member states level.

Requirements for sales of biocides:

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. For non-professional users recommendations should be given, 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 person in their employment, who has a certificate, and who shall be present and available at the place of sale to provide information to customers. Article 6 of Directive 2009/128/EC further requires Member States to ensure that certified distributors provide adequate information to customers with regard to pesticide use, health and environmental risks and safety instructions.

The distribution of biocides through certified distributors which provide adequate information to customers would be an effective instrument for improving sustainable use. Directive 2009/128/EC requires that non-certified distributors or retailers should not sell biocidal products classified as toxic (T), very toxic (T+), harmful (R40, R62, 63, 68), oxidising (O), or extremely flammable (F+). These rules are already established in German chemical law. Additionally, self service sale of all plant protection products in Germany is prohibited according to § 22 Abs. 1 of the plant protection law (Pflanzenschutzgesetz), irrespective of their classification. Therefore plant protection products in supply stores are shut away in separate cupboards and customers have to ask certified staff to purchase these products. For their certification, sales people have to participate in seminars which usually take two days

and end with an examination. These provisions could immediately be extended to consumer biocides which to date are sold on open shelves through self service or internet commerce.

6.4.2 Upgrading of other regulations

Inspection of equipment in use:

Article 8 of Directive 2009/128/EC 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 a risk assessment, handheld pesticide application equipment, knapsack sprayers or application equipment that represents a very low scale of use may be exempted. For biocide applications, dosage apparatus for the preparation of a disinfectant solution from concentrates can be distinguished from the equipment for application. Several national minimum standards for equipment for biocide application have been identified, including PT 1-5, 8, and 18. The Directive on machinery 2006/42/EC should also be amended to include machineries and equipment for the application of biocides where required. Initiatives for harmonisation and standardisation of the machinery for biocide application exist only in rudimentary form.

Improvement of use and monitoring data:

According to Article 4 of Directive 2009/128/EC, MS shall adopt National Action Plans (NAP) to set 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 plant protection products. Sound data on the quantities of biocidal active substances and products produced or sold are lacking. Also, few monitoring data on biocidal active substances in environmental media exist to date. The inclusion of biocides into the scope of the statistic regulation (EC) No. 1185/2009 is recommended. The environmental monitoring of biocides should be extended in order to be useful as a risk indicator for the use of biocides. Thus a systematic survey for the prioritisation of biocides to be included in monitoring programmes should be performed, depending on the consumption of active substances, the use pattern (considering main emission routes), the contribution of other emission sources (e.g. plant protection products) and the environmental behaviour and fate properties (biodegradation, adsorption, metabolites).

6.4.3 Guidance development

Integrated Pest Management:

Directive 2009/128/EC requires that MS shall take all necessary measures to promote low pesticide-input farming 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 integrated pest management 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 integrated pest management.

Article 14 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".

Reduction of use or risks in specific areas:

Article 12 of Directive 2009/128/EC requires that pesticides shall be prohibited or restricted to the minimum necessary in areas used by the general public, in protected areas such as Natura 2000 sites and in protected areas as defined in the Water Framework Directive 2000/60/EC. Similar to plant protection products, the use of biocides could also be prohibited or restricted these areas. Examples might be outdoor applications of wood preservatives in sensitive areas, restrictions of rodenticides outside buildings. In contrast to plant protection products, some biocidal products are intentionally applied directly to water or soil (cooling water biocides, insecticides for mosquito control, termite treatment, antifouling agents, and treatment of liquid manure with larvicides). Also, the disinfection of wastewater, bathing water, algacide for water pools and aquariums (PT 2), piscicides (PT 17, not allowed in most MS) may result in 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 a municipal treatment plant. Surface water can be regarded as sensitive area per se.

6.4.4 Information and awareness-raising

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. Information about best practices, occupational health campaigns, the promotion of ecolabels, and information systems on biocides (web-based and print media based) are examples of suitable programmes to be established in national action plans (NAP). For both private users and professionals, the product label and additional 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 a minimum requirement. In Germany, a web-based information system (web portal combined with print media) is being established for the general public and will be available under www.biozid.info.

6.4.5 Emission during service life

Measures for reduction of environmental emissions during the service life are not considered in Directive 2009/128/EC on sustainable use of pesticides, because here it cannot be separated from the application phase. However, for biocides used for preservation of materials (PT 6-10) and antifouling purposes (PT 21) a considerable part of the total emission takes 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 (e.g. of preserved wood) of biocidal products should be considered in detail in addition to the use phase (application). Measures to be considered for risk reduction during the service life include restrictions on the use class of certain wood preservatives, requirements for the processing of treated articles or for the removal of biocide coatings.

6.5 Addressees of risk mitigation measures

The overall evaluation of risk mitigation measures proposed in different sources indicates that the addressees of these measures are those responsible for product development, marketing, and application of biocidal products (Figure 4). The product

labels, safety data sheets, and technical leaflets are the main media for appropriate use of biocidal products and communication of risks. In addition to user and use restrictions imposed by authorities or recommended by producers, the development of specific guidance on best practices and standards is the way to achieve harmonisation of RMM. Depending on the use area, these guidance documents could consist of BREFs, “Codes of practice” from authorities and industry, ISO standards or public organisations.

For product development, the mode of application (e.g. dipping, vacuum pressure of wood preservatives) or the formulation of ready to use products or baits for insecticides are examples of RMM attributed to the formulator. For these, the user of the product has no freedom to decide how to apply the product. Thus, the formulator has the responsibility for compliance with best practice. For product application, instructions concerning the decontamination of areas, ventilation of treated areas after application of insecticides, storage of treated timber or the use of top coating to prevent leaching are examples of specific RMM.

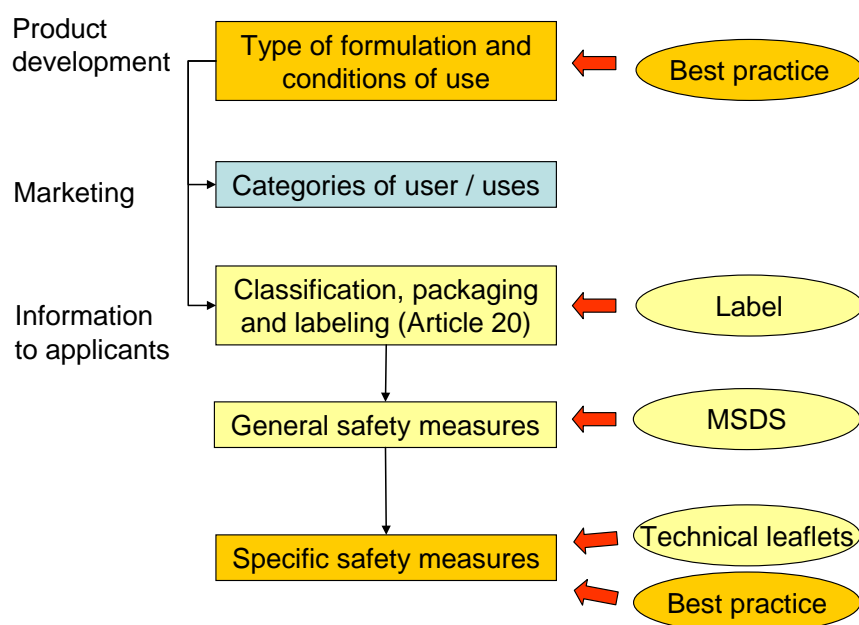


Figure 4: Addressees of Risk mitigation measures

Specific safety measures are considered to have the highest potential for the implementation of RMM. This information is provided in technical leaflets and “best

practice” documents e.g. for integrated pest management. While several “best practice” documents have been developed at the national level, few documents exist which have been adopted and harmonised on a European level (see chapter 6.2).

7 Efficiency and practicability of risk mitigation measures

7.1 Introduction

In this chapter the efficiency and practicability of risk mitigation measures proposed or imposed by formulators and authorities are analysed. As described in chapter 6.5, it can be expected that compliance with any RMM during product development is higher than compliance with RMM which relate to the applicators of biocidal products. A ready-for-use product will not be diluted; the danger of misapplication of baits integrated into boxes is lower than for granules. It can be expected that wood preservatives designed for dipping or vacuum pressure will mainly be applied in these facilities. The distribution chain for biocidal products is mainly determined by the suppliers, in so far as some control over internet commerce exists. Thus the danger that private users might purchase biocidal products designed for professionals is rather low. On the other hand, use restrictions to “specifically trained” professional users are difficult to control if no certification system exists.

In contrast, compliance with RMM directed to the user of biocidal products mainly depends on the communication of risks, risk awareness, education, specific training and the availability of approved “best practices” which are broadly recognised by experts. The following examples of RMM are discussed more in detail with respect to their practicability. In chapter 7.6 some conclusions concerning the quantitative efficiency of RMM are discussed.

7.2 User group

The user group has a decisive influence on the selection of appropriate RMM. For consumers, it is recognised that wearing personal protective equipment (PPE) as the only means of reducing the risk from a product to an acceptable level cannot be used as an RMM (TNsG on Product Evaluation). However, if the PPE are provided together with the product, this might be considered as a suitable RMM.⁴¹ Similarly, it is stated in the REACH guidance R.13 that ventilation is difficult to control by consumers. When the label indicates that the product should be used ‘in well ventilated areas’ or ‘outdoors’, this does not mean that a certain (high) ventilation rate

⁴¹ Use of substances with irritant, corrosive or sensitising properties by non-professional users, CA-Nov07-Doc.6.5

is assured. Thus there is a distinction between RMM applicable to professional users and those applicable to consumers. As the term “professional use” is no guarantee that the professional user has received some training on how to apply biocidal products, there is also the potential of misapplication by professional users. Some product leaflets indicate that the relevant biocidal products should only be used by “professional specialists” or “experts from authorised companies” or by “certified experts”.

Compliance with these suggestions can only be controlled if some sale restrictions or training and certification procedures for operators have been established for certain biocidal applications. These items are addressed in Directive 2009/128/EC on sustainable use of pesticides. Article 6 of Directive 2009/128/EC requires that non-certified distributors or retailers should not sell biocidal products classified as toxic (T), very toxic (T+) or harmful (R40, R62, 63, 68) or oxidising (O) or extremely flammable (F+). According to Article 5 of Directive 2009/128/EC, Member States shall ensure that all professional users, distributors and advisers have access to appropriate training and shall establish certificate systems providing evidence of attendance to training.

To conclude, the definition of the user group has a decisive potential for risk mitigation provided that biocidal products intended for professional use are not made available for purchase to consumers. Training of professional user is a prerequisite for safe use of biocidal products.

7.3 Wood preservatives

7.3.1 Placing on the market

7.3.1.1 Use classes

The restriction of the use classes according to ISO 21887⁴² is one main risk mitigation measure. The CARs suggest that no emissions to the environment are expected from treated wood in use class 1 (under cover, fully protected from the weather and not exposed to wetting) and 2 (under cover, fully protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting). The

⁴² ISO 21887 (2007): Durability of wood and wood-based products -- Use classes

product leaflets also often give reference to the use classes and the area of use. Often some general remarks are included such as “Only to be applied for load-bearing and reinforcing wood building elements” or “Do only apply where the protection of the wood is required”.

The German register of wood preservatives with DIBt approval (Holzschutzmittelverzeichnis) includes further restrictions on the areas in which certain wood preservatives should not be applied. The following standard phrases have been described as risk mitigation measures concerning the area of application:

E2 *“Should not be used in large-areas for treated wood intended for habitable rooms or adjoining rooms unless the treated wood is covered by barriers against these rooms”*

E3 *“Should not be used in large-areas for treated wood intended for habitable rooms or adjoining rooms unless it can be proven that this is inevitable because of structural requirements”*

E4 *“Should not be used for treated wood intended for habitable rooms or adjoining rooms unless the treated wood is covered.”*

The definition of large-area treatment in residential rooms is provided in DIN 6800-4 and refers exclusively to curative treatment of wood. If the ratio of the area treated with wood preservatives to the volume of the rooms is above 0.2, the treatment is considered as being large-area.

The distinction between habitable and non-habitable rooms for wood in use classes 1 and 2 is not considered in ISO 21887.

Correct labelling of treated wood is a prerequisite for compliance with the use class. In the distribution chain this is the responsibility of the wood preserving industry and of the supplier of treated wood. Some good and best practice documents consider labelling of treated wood (see chapter 6.2). Several associations in the wood preserving industry have established their own quality label (e.g. Gütezeichen RAL-GZ 411). Labelling of treated articles is addressed in Article 47 of the proposal for a Regulation concerning the placing on the market and use of biocidal products. Here the following information is required: active substances used, biocidal property

attributed, authorisation number of all biocidal products, hazard/precautionary statement set out in the authorisation.

In conclusion, the attribution of use classes will be part of the authorisation of biocidal products. The distinction of the application area in habitable rooms and subsidiary rooms is the subject of some controversy. There is no guarantee that an attic floor used as storage place will not be upgraded later on for habitat purposes. Training and risk awareness of the user as well as the labelling of impregnated wood are prerequisites for the avoidance of misapplication and thus for the RMM “use class” to become effective.

7.3.1.2 Package

In the (draft) CAR reports and product leaflets the package size is not mentioned as a potential RMM. In Germany, the packaging size of wood preservatives for non-professionals has been limited to 750 ml according to a voluntary agreement is expected with industry.⁴³ 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). For industrial treatment, some suppliers provide water soluble wood preservatives in water-soluble sachets which facilitates exact dosing and avoids direct contact of operators with the biocide. According to REACH Annex XVII (No 31), creosote may only be placed on the market in packaging of a capacity equal to or greater than 20 litres, probably to avoid wide dispersed use from small packages.

In conclusion, any provisions on the package size in the authorisation of biocidal products would become effective immediately, provided that the user can only purchase products intended for their respective user group. (If, for example, wood preservatives for consumer use have a limited package size, exhibiting biocidal products for professional use on the same shelf should be avoided.) In addition to regulatory options, the support of suppliers and traders is also essential for this RMM to become effective.

⁴³ http://www.holzfragen.de/seiten/pop_biozide.html

7.3.1.3 Industrial application

Several guidance documents address the design and operation of industrial impregnation of wood. The BREF on Treatment using Organic Solvents covers one part of the wood impregnation industry and water soluble wood preservatives might be considered in a future Directive on industrial emissions. 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 exist several impregnation efficiency standards from industrial or public associations but no international standards on the construction of these vessels. The draft CARs refer to some principles of the design of the equipment such as

- Industrial application facilities should not be connected to a local STP.
- Freshly treated timber must be stored under cover after treatment to prevent direct losses to soil.
- The tanks, containers and the technical apparatuses for the production of Cu-HDO must not be cleaned, except in an automated process where rinsing water will be collected and reused in the production process.

If the Directive 2009/127/EC on machinery for pesticide application (an amendment to the Machinery Directive 2006/42/EC) were extended to cover biocides, wood preservatives would probably be among those PTs which would be considered as a priority. 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. Surveillance of the equipment is part of routine control of industrial facilities by local authorities.

In conclusion, technical provisions exist for avoiding emissions of wood preservatives to the environment from the impregnation and storage of wood which are referred as being “best practice”. As supporting measures for these RMM, the inclusion of (water based) wood preservation under the IPPC directive and an upgrading of the Machinery Directive could be considered.

7.3.1.4 Formulation containing a fixative

Leaching of wood preservatives may occur particularly in wood impregnation plants where the treated wood is stored in open storage areas exposed to rainwater. Leaching rates for wood preservatives have been determined by Schoknecht et al. (2002, 2004). Only a few CARs mention that the formulation of wood preservatives must include a proper fixative to reduce leaching of treated wood. This should be accompanied by robust leaching studies on the formulation and the application systems that will be used to ensure safe use of treated materials. Product leaflets in general are more exact in indicating the minimum storage or fixation time required for fixation (usually from 1 hour to 7 days) and give advice on protecting the treated wood from weathering. The use of chromium fixatives is an example where non-biocidal ingredients might cause the highest concern (see 6.1.3.1).

In conclusion, the minimisation of leaching of wood preservatives through fixatives will be considered during the authorisation of biocidal products. In the evaluation of active substance, “dummy” products without fixative have often been evaluated as reference products. The effectiveness of fixatives should be proven through leaching tests which also determine the minimum storage or fixation time required. The German Environmental Agency funded a research project to determine the minimum fixation time for wood preservatives. The time necessary to reach a fixation level of 95% depended on temperature and active substances and was usually between 2 and 14 days. High air humidity prolonged the fixation time up to 58 days (Schoknecht et al., 2003).

7.3.2 Application of biocidal products

7.3.2.1 Personal Protective equipment

In some CARs suitable cotton coveralls, protective gloves and footwear are also recommended for amateur users for painting and brush applications. Other CARs mention that acceptable human health risks require the application of the basic principles of good practice and using appropriate and obligatory PPE, in particular for the dipping process. Product leaflets in general give rather unspecific recommendations on PPE, such as “use appropriate PPE”, “wear suitable protective clothing (coveralls) and synthetic rubber PVC gloves” or “during spray applications some respiratory protection will normally be required”. Other refer to further guidance

such as the UK HSE Guidance Booklet HS(G)53: “Respiratory protective equipment - a practical guide for users”. Sometimes the safety data sheets are more precise in describing appropriate PPE.

In conclusion, the use of personal protective equipment could be an effective RMM for professional users, mainly relating to human health aspects. However, training and risk awareness of users are prerequisites for the proper use of personal protective equipment.

7.3.2.2 In situ application

In some CARs it is suggested that soil in the vicinity of the object to be treated in-situ should be mechanically protected during the treatment (e.g. with a tarpaulin or plastic sheeting) and that, subsequently, appropriate waste management should be applied. In product leaflets in-situ treatment is mainly mentioned in the context of curative treatment. Here recommendations such as “removal of thermal insulation” and “covering of plants and water tanks before application” are given. Both recommendations are difficult to control and require some risk awareness by users. It can be anticipated that in-situ treatment is particularly liable to malpractice.

In conclusion, RMM proposed for in-situ application are difficult to control and depend on training and risk awareness by applicants as well as on proper labelling of the biocidal products. In-situ application of preventive wood preservatives outdoors (fence scenario) often requires repeated coatings and the emissions depend e.g. on the weather conditions.

7.3.2.3 Top coating

In the CARs top coating has very often been mentioned as a risk mitigation measure for wood preservatives used in wood class 3, although this measure has not been described in any of the inclusion directives so far. In fact, this risk mitigation measure is controversial amongst Competent Authorities. Some CA suggest, that before accepting these measures, there should be scientific evidence (through testing) showing that such a coating will prevent the wood preservative from leaching through the coating, also in the long term. This evidence should be presented for preventive as well as curative treatments of the wood. Also, evidence should be provided that the proposed risk reduction measure is feasible for the practical use of the product in

combination with a coating. The consumer/user/purchaser should be aware that the wood is treated with a product making it obligatory that the wood has to be coated before use. The coating should not be damaged or processed further, and the risk mitigation measure should be assessed for its feasibility. Other CAs consider top coating as appropriate only if the wooden structure does not significantly change its dimensions due to swelling and shrinking processes during permanent weathering (formation of cracks in the coating). Selecting other application methods than dipping might be an option. As a rule, changes in wood dimensions will inevitable occur if permanently exposed to weathering. Furthermore, a top coating will not persist for a long time span (3-5 years) limiting the effectiveness of prevention of losses of biocides to the environment. Consequently, the assessment of a given wood preservative should include experimental data on any risk mitigations proposed e.g. top coating, to base the risk characterisation on solid grounds. In another CAR it is stated that top coating decreased the leaching from treated wood substantially but not sufficiently. Uncertainty about the use of top coating as one of the risk mitigation measures is related to the fact that a long-term effectiveness of top coating is not decisively proven, although in the early stages, i.e. during the first two years, leaching has been shown to decrease drastically compared to leaching with only a primer. The RMS also is of the opinion that the top coating requirement is difficult to enforce. It could be possible to order mandatory top coating when wood is treated industrially, but for in situ brushing it can be difficult to control. According to the applicant and some Member States, this would not be a problem, because the requirement for top coating can be given in the instructions for use and labels of the primer products, which has evidently been done for some primers already.

In product leaflets the possibility that the treated wood could be coated with other materials after drying and checking the adhesion of the new coating is often mentioned. However, no requirements for top coating as a RMM have been identified.

To summarise, the effectiveness of top coating as a RMM has been questioned because a top coat on construction timber will be only appropriate if the wooden structure does not significantly change its dimensions, which will inevitable occur if permanently exposed to weathering. Furthermore, a top coating may not persist for a longer time span (3-5 years) without maintenance, limiting the effectiveness of

prevention of losses of biocides to the environment (Fischer 2008)⁴⁴. For industrial application, a longer time span (e.g. 10-15 years) might be achievable. Control and periodic maintenance of top coatings have a decisive influence on the effective time span of top coatings.

7.3.3 Post application

7.3.3.1 Storage of treated wood

While for some wood preservatives it is required that treated timber in storage areas should be covered by roofs, other CARs suggest only that storage on bare soil should not be allowed. The emissions from treated wood to soil should be substantially reduced by covering the storage area with a protective roof or covering the soil with an impermeable coating e.g. concrete. Leachates should be collected and treated appropriately (e.g. incineration). The best way to ensure sufficient protection of the environment would be to keep the treated timber in storage areas covered by roofs. As this measure is not a standard practice at industrial sites, according to the RMS, further options should be considered. Alternatively, storage of pre-treated timber should be carried out on areas of impermeable hard standing. This measure will not be sufficiently protective to surface water during storage of timber treated by dipping. In order to protect surface water, the leachate run-off must be collected and recycled into the impregnation process. In addition, feasible waste treatment options have to be proven when recycling to the impregnation tank is not practicable. In product leaflets, storage of treated timber is mentioned in the context of the fixation time until which impregnated wood must be stored under a roof or covered. Because the wood preservative can easily be leached after impregnation the operator must consider measures to avoid emissions to soil, ground water, surface water and sewers and protect impregnated wood from weathering. Some guidance documents from authorities and industry also indicate that storage of treated timber should be under cover on an impermeable surface.

In summary, the storage of impregnated wood under cover until completion of the fixation time, or until the installation of impregnated wood where non fixating wood preservatives are used, has a very important influence on emissions to the

⁴⁴ Fischer, J., Environmental risk assessment of wood preservatives – review program and product authorisation Cost Action E37 Final Conference in Bordeaux 2008 <http://bfafh.de/inst4/45/pdf/11fische.pdf>

environment. There are technical provisions which are referred to as “best practice”. RMM for storage of treated wood could best be integrated into best practice developed for the industrial sector, e.g. in appropriate BREFs under the IPPC directive. The development of “best practices” is an integral element of the Directive on sustainable use of pesticide (which only covers plant protection products so far).

7.3.3.2 Contact to food or feedstuffs

Some CARs mention that wood products treated with biocides must not come in contact with food or feedstuffs. Sometimes it is argued that this RMM should be considered because neither analytical methods nor toxicological risk assessment of contamination in food and feedstuffs have been carried out. In the OECD Emission Scenario Documents (ESD) contact with food is only referred to from a human health point of view as indirect exposure of humans via the environment by exposure through food, drinking water and breathing air. No scenarios have been described where wood in contact to food or feed should be treated with wood preservatives. The only example where this could be relevant is storerooms where processed plants such as flour in mills might come into contact with treated wood. It could be considered whether contact of treated wood with food and feed should generally be prohibited. This RMM is often referred to in product leaflets: “Do not apply to surfaces on which food is prepared or for wood intended to come into direct contact with food or feed”. The German register of wood preservatives with DIBt approval (Holzschutzmittelverzeichnis) includes the following standard phrase as a risk mitigation measure: E1 *“Should not be used for treated wood intended to come into contact with food or feed”*.

In summary, compliance with this RMM depends on appropriate labelling of the impregnated wood as well as on the risk awareness of the applicator.

7.3.3.3 Wood accessible to children

Only a few CARs referred to non-acceptable risks from exposure of children playing on preserved wood. However, secondary exposure to wood preservatives for infants in contact with treated wood (chewing wood or dermal contact) is routinely assessed in the CARs. The German register of wood preservatives with DIBt approval (Holzschutzmittelverzeichnis) includes the following standard phrase as a risk

mitigation measure: E7 *“Should not be used for treated wood intended for playgrounds or other purposes with periodical contact to human skin.”* Contact with treated wood by children has not specifically been considered in the product leaflets analysed. The RMM proposed could easily be integrated in existing standards for designing playgrounds or toys such as DIN EN 1176-1:2008 “Playground equipment and surfacing - Part 1: General safety requirements and test methods”.

In conclusion, proper labelling of treated articles as well as training and risk awareness of users are prerequisites for this RMM to be effective. There is also the option to consider restrictions on wood preservatives for playgrounds or toys in relevant technical standards.

7.3.3.4 Disposal of biocidal products and of treated wood

Some CARs give indications of how to dispose of treated wood. Most often reference is given to incineration under controlled conditions. Sometimes the need to assess other ingredients of a formulation concerning their risk during the final life-cycle stage is addressed. According to some CARs, it is most unlikely that the active substance from treated wood will result in an environmental risk during incineration under controlled conditions; however, other active substances in a formulation may result in an environmental risk during incineration of treated wood. Therefore, special focus on this life-cycle stage has been deferred to the Member State assessment at the product authorisation stage. Most often the CARs suggest that the end life cycle of products containing wood preservatives should be managed according to regulations in force. In product leaflets the disposal of the biocidal products and their packages is mainly considered. Often the code number of the European waste list is indicated. Empty packages might be delivered for recycling; residues of the product must be collected at suitable collection point.

Only few product leaflets give advice concerning impregnated wood; that it should not be burned in open fires or in stoves, fireplaces or residential boilers because toxic substances may be produced as part of the smoke and ash. Treated wood may be disposed of by complying with local landfill rules or burned in commercial or industrial incinerators or boilers in accordance existing regulations.

The handling and storage of pesticides and their packaging and wastes are considered in Article 13 of Directive 2009/128/EC, which so far only covers plant protection products. Emissions during the service life are not considered in the existing legislation. While the disposal of wood preservatives could be included in a general strategy on sustainable use of biocides, the disposal of treated wood requires further attention. There are national laws on the reuse and disposal of used wood (in Germany the Altholzverordnung⁴⁵) which could be harmonised at a European level. Again, compliance with this RMM depends on correct labelling of treated wood as well as on education and risk awareness of the user.

In conclusion, the proper disposal of impregnated wood must be supported by further measures such as the establishment of collection points for treated wood. Risk awareness amongst the general public is a prerequisite for avoiding malpractice. Technical standards for optimisation of the disposal of treated wood e.g. by incineration under controlled conditions, might be considered.

7.4 Insecticides

7.4.1 Placing on the market

In some CARs there is a distinction between professional users and (specifically) trained professionals. These user restrictions are also found in product leaflets. Other products for amateur use are specifically labelled. This implies that some insecticides must only be used by certified professionals and some marketing restrictions (no electronic commerce, no self-service from open shelves) would be required. The marketing of ready-to-use products is a suitable tool to reduce risks where emissions to the environment or human exposure from mixing and loading might occur, especially for amateur uses. There are, however, also ready-to-use-products which may pose risks. In a German study on occupational exposure to insecticides, the safe use of total release foggers (one-shot aerosol cartridges) by non-professionals has questioned (Schneider et al. 2008). These products are also available to the general public (e.g. in pet shops and through on-line orders to internet stores). Indoor foggers are applied against fleas associated with the infestation of pets and have residual efficiency (up to 6 months). Although the main concern related to foggers is impacts

⁴⁵ <http://www.gesetze-im-internet.de/bundesrecht/altholzvg/gesamt.pdf>

on human health, exposure to the environment following cleaning/decontamination of surfaces may be also of importance.

The mode of application can be dictated by the form of the biocidal product, which is determined during the production. For example, some insecticides may only be applied by bait cartridges, thus excluding e.g. application by spraying. For some insecticides application by scattering on surfaces has not been considered as safe because of the risk of direct poisoning of birds and mammals. Overdosing might be avoided by the application of insecticide lacquer. The use of micro-encapsulated water based insecticides is a promising instrument for minimizing the amount used. There are, however, also CARs which do not exclude modes of application which have not been assessed, but suggest that these should be analysed if necessary. One example is an insecticide for which only professional application as a gel has been claimed by industry. It is questionable whether risks resulting from modes of application other than those which were the basis for the inclusion of an active substance into Annex I can be assessed in a harmonised way during product authorisation.

In conclusion, the product design has a decisive influence on exposure of humans and the environment. Any optimisation of the biocidal product in terms of form, concentration and mode of application would support its proper use, especially for “ready for use” products.

7.4.2 Application of biocidal products

7.4.2.1 Design of the package and equipment

Different designs for various applications are presented in the product leaflets. These designs sometimes support RMM and the safe(r) use of the biocidal products. E.g. integrated monitoring/control boxes, insecticide lacquer to avoid overdosing, micro-encapsulated water based products, water soluble sachets (see below), equipment such as special spray nozzles, dosage help and proportioner devices, re-usable canisters and, last but not least, even completely physical mechanisms which do not use biocides at all. An applicator friendly design is a promising tool to reduce risks because it helps to avoid the incorrect use.

Any optimization of the package and equipment can be regarded as product integrated RMM, which is considered to be highly practicable because the scope for wrong (technical) application of the biocidal products by operators/consumers is reduced.

7.4.2.2 Area of application

Often, no outdoor application of insecticides is recommended as RMM. Additionally, only indoor application in closed compartments is referred to as RMM. Restrictions on the area of application of insecticides are difficult to control. Product authorisations might imply that the product must not be used in animal housings with an outlet to the sewer system in order to avoid emissions to a STP or to surface water. Instead, the liquids should be collected together with liquid manure. Other RMM impose restrictions on other uses than crack and crevice treatment in domestic houses in order to avoid any emissions to the environment through the cleaning step. Although the intended areas of application are described in the product leaflets, compliance with the instructions is a prerequisite for safe use and cannot be guaranteed.

In conclusion, RMM referring to the application area play an important role in emission control but their practicability is questionable. Restrictions on the area of application of insecticides are difficult to control after the products have been sold. Requirements to prevent sales of insecticides to consumers or unqualified professionals would be one option for an appropriate risk management. Further supporting measures such as dissemination of information or promotion of risk awareness or surveillance by authorities are required.

7.4.2.3 Prearrangement and mode of application

The mode of application is described properly and in detail in the product leaflets. Compliance with safe use will be easier to ensure for ready for use products than for products that require mixing and loading. However the instructions in product leaflets are sometimes not very clear e.g. “cover damageable surfaces” (how?) or “should be applied to all areas where insect pests are found” (how to be sure?). In addition, as in other cases, it is not possible to control whether a stated mode of application is followed in practice.

In conclusion, the label recommendations concerning the preparation of the target area and the proper application of the biocidal product are an important tool for risk communication but often require education and training.

7.4.2.4 Mixing and loading

In Germany, technical rule TRGS 523 on pest control with hazardous substances requires that the working solutions or baits should preferably be prepared outdoors from the concentrates. This principle, which is aimed at human health protection, might cause environmental exposure, if spillage of biocides occurs or if residues are emitted to rain runoff.

In specially designed products which are sold in sealed water soluble sachets, a measured quantity of insecticide concentrate is already available. Therefore no exposure is expected during mixing and no measuring is necessary and there will be no residues as in conventional concentrate bottles

In conclusion, the mixing and loading step is one point where emissions to the environment could occur. Any dosage aid which ensures that the proper concentration is maintained with the minimum quantity needed reduces potential emissions to the environment. There may, however, be conflict between human health and environmental protection goals.

7.4.2.5 Personal Protective equipment

The TNSG on Product Evaluation state that the need for personal protective equipment as the only means of reducing the risk from a product to an acceptable level would exclude the possibility of authorisation for use by the general public. Nevertheless, some CARs suggest that products intended for non-professional users should be sold together with appropriate gloves.

The use of personal protective equipment as a RMM focuses on human health. Emissions to the environment are only indirectly affected, e.g. by subsequent washing of coveralls. The practicability of this RMM depends on the risk awareness, education and training of the operators.

7.4.2.6 Ventilation

Some CARs recommend respiratory protection for professional user or good general ventilation. In product leaflets ventilation advice is only given very generally, e.g. “Ventilate before re-entry” or “adequate ventilation is necessary”. For consumers, ventilation is difficult to control. When the label indicates that the product should be used ‘in well ventilated areas’ or ‘outdoors’, this does not mean that a particular (high) ventilation rate is assured (REACH Guidance R.13).

RMMs concerning ventilation after application of insecticide primarily have a human health objective. The environment is also affected indirectly when closure of the area treated or the waiting period for the deposition of the insecticide on surfaces is not considered. For fumigants (especially for those soluble in water), the weather conditions should be taken into account before ventilation because of wash out phenomena.

7.4.3 Post application

7.4.3.1 Decontamination

The cleaning (or decontamination) of surfaces after application of insecticides has been identified as an important entry pathway for emissions to surface water. Therefore it has been suggested that only crack and crevice treatment or only dry cleaning of the treated surfaces should be allowed. Another emission route is the “decontamination” after application of textiles such as protective clothes by washing and the release of contaminants to the wastewater. The use of disposable clothes for the applicator has accordingly been suggested as RMM. On the other hand, the removal of insecticide residues from surfaces might be required to reduce long-term exposure of occupants (Winter et al. 1999, 2000). In Germany, the technical rule TRGS 523 requires that, after pest control measures, access to treated areas must be approved by the operator after considering measures such as continuous aeration, removal of bait residues or cleaning. The equipment used shall be cleaned when the work has been completed. The residues of the solutions prepared etc. or the rinsing fluids shall not be allowed to enter any bodies of water. Compliance with authorised uses like crack and crevice treatments is difficult to control when the form of the biocidal product enables other modes of application. Again, compliance with the instructions of the product leaflet is a prerequisite for safe use.

In the technical leaflets of the biocidal products analysed, cleaning measures are very rarely described. Sometimes decontamination measures are recommended but must be requested from the company. Sometimes it is suggested to clean areas such as clothing, seating, furniture, where contact with the skin is expected frequently, with alkaline cleaning agents.

To summarise, the cleaning of treated surfaces is an important emission pathway for insecticides to sewage and surface water. Avoidance of wet cleaning as a RMM might lead to conflict between human health and environmental protection goals. The practicability of these RMM depends on risk awareness and education.

7.4.3.2 Disconnection of stables and manure systems from STPs

For insecticides used in animal housing and manure storage systems it has been proposed that no uses may be authorised where exposure to a STP or direct emission to surface water cannot be prevented. Stables which are not connected to public sewers or open drainage would comply with this RMM. Instead, the liquid manure and all its ingredients (disinfectants, insecticides, and veterinary medicinal products) is collected and used as a fertiliser on agricultural fields. In most member states this is considered to be good agricultural practice. There might, however, be exceptions, especially when considering wastewater from milk production facilities. Therefore, a product label excluding all uses where emissions to the sewer might occur seems to be an appropriate RMM. Whether the farmers respect these requirements in practice again depends on risk awareness and education.

7.4.3.3 Waiting period and re-entry to treated area

A minimum waiting period has to be defined after application of some active substances to ensure that pests are effectively treated. For fumigants, the waiting periods for exposed food must be followed in order to ensure compliance with the MRLs set out in Regulation (EC) No 396/2005. Here again the main concern is for human health, but the environment is also indirectly affected (increase of emissions to the surrounding air when ventilation is initiated before the droplets have settled down to surfaces, secondary poisoning of animals etc.) It has also been suggested that bee nests should be removed after treatment; and disposed of in a controlled

manner. All these measures are already part of the principles of integrated pest management.

7.4.3.4 Management of resistance

In some CARs and product leaflets there are indications of the need for management strategies for resistance where an extended period of control is required. The monitoring of resistance and the alteration of treatments using products with different modes of action have been proposed as measures to avoid the development of resistance. Both are difficult to control in the context of product authorisation, but are part of the principles of integrated pest management.

Some product leaflets provide information on resistance management. The use of a product with a different active ingredient and if necessary a different method of control (such as a bait if a spray was used before) is recommended if more frequent treatments are required. Other companies describe a new class of insecticides, the neonicotinoids, where use as a gel can help to avoid resistance. However, these suppliers recommend that this new insecticide should be one component of an integrated pest management program. RMM concerning the management of resistance are difficult to consider within product authorisation but require a broader strategy within integrated pest management. Indirectly, the occurrence of resistance also has implications for the environment, because wrong application or overdosing of a biocidal product causing resistance in the target organisms requires further treatment.

7.4.3.5 Disposal

The disposal of residues of active ingredients, rinsing water and empty containers is addressed in the product leaflets as well as in all SDS. The measures include “disposal according to current regulations”, “do not allow remaining product residues and empty containers to get into surface water, drains and ground water”, and “to ensure that containers are not reused, they should be pierced before disposal”. In a few cases re-usable canisters are delivered. These measures, except the last mentioned, cannot be controlled and compliance can not be guaranteed. Accompanying instruments such as the establishment of collection systems for

obsolete products or packages might be required in order for RMM referring to disposal to become effective.

7.4.3.6 Further RMM

Some producers/suppliers also provide background information with their product leaflets on preventive measures to avoid pests, on sealing and elimination of hiding places, regular cleaning measures, control of goods, ideal storing conditions etc. This information is in many cases not very detailed but nevertheless helps to support the minimisation of biocide application.

In principle, all initiatives by industry to provide further background information on preventive measures and integrated pest management are positive and support the objectives of sustainable use of biocides.

7.5 Further regulatory options

7.5.1 Sustainable use of biocides

The analysis of RMM for wood preservatives and insecticides demonstrates that many RMM are not effective alone but require a broader general strategy, similar to the thematic strategy for sustainable use of pesticides. Risk awareness amongst the general public is a prerequisite for avoiding malpractice. Provisions for the development and distribution of information on technical standards and best practices, including preventive measures and integrated pest management, would also improve proper use. Label recommendations are an important tool for risk communication but often require education and training. Risk awareness campaigns would support decision making before the biocidal product is purchased. Preventive measures and integrated pest management also support the objectives of sustainable use of biocides. An extension of the Machinery Directive could be envisaged to cover certain biocides application equipment. All these measures could be included in a general strategy on sustainable use of biocides.

7.5.2 Comparative risk assessment

Several active substances for wood preservation have been recommended for comparative assessment in the corresponding (draft) CARs. Several boron containing wood preservatives, such as boric acid, shall not be authorized for use class 3 and 4a if a comparative assessment finds that there is a sufficient number of active substances for same use purposes with significantly lower risk and without unacceptable effects. The PBT substances Bifenthrin and Flufenoxuron are also subject to a comparative risk assessment. While this risk management measure is part of the approval of active substances and the authorisation of biocidal products, one should bear in mind that the choice of suitable products with lower risks is an integrated part of safety assessments in the work-place. Substitution of hazardous chemicals in products and processes is an important management instrument for the reduction of chemical related risks. As the discussion on chromium as a fixative agent shows, this also is true for the risks from other ingredients of a formulation.

With respect to insecticides, there are examples where the risk assessment led to the proposal not to include an active substance into Annex I of the BPD. For other actives for which only the professional use in a ready-for-use bait cartridge has been evaluated, it has been suggested that products giving rise to exposure of humans or the environment will require a more extensive data package. Often it is stated in the CARs that not all potential uses have been evaluated at the Community level. Therefore Member States should assess those risks to the compartments and populations that have not been representatively addressed. This is considered a weak point for product authorisation, because product authorisations take place at a national level and the risk assessment for completely different user groups or modes of application might lead to different regulatory decisions which could constrain mutual recognition of product authorisations. The regulatory options refer to risk assessment and/or the authorisation process and can be regarded as part of the risk management process. The results of the (comparative) risk assessments should be considered for authorisations of biocidal products; they are not RMM as such but have to be considered part of the risk management process.

7.5.3 Socio-economic benefit analysis

According to the TNsG, substances of very high concern such as categories 1 or 2 carcinogenicity substances or PBT or vPvB substances are not acceptable where exposure is likely to occur. (The BPD is less precise in this context.) This would exclude creosote from being included into Annex I of the BPD. Annex XVII (31) of Regulation (EC) No 1907/2006 (REACH) also describes certain restrictions concerning the use of creosote. Consequently, the Swedish CA recommended in their CAR for creosote not to include it in Annex I. However, they refer again to the TNGs where it is also stated that: *“The benefits of products containing the active substance should be considered. Especially in cases where there are concerns about the acceptability of the risks, the need for and benefits of biocidal products containing the substance should be considered carefully and weighed against the acceptable level of risk.”*

The CA suggested that the withdrawal of creosote could have substantial impact on European infrastructure and socio-economics, in particular since creosote treated wood is used in the electrical and telephone supply industries and for railways across much of the European Union. It therefore recommended that a comprehensive analysis of the benefits of the use of creosote at a European level should be carried out.

In principle, there is no safe exposure level for non-threshold carcinogens and it would be a political decision to accept a certain risk level in combination with a risk communication approach with regard to the exposed population.⁴⁶

Socio-economic benefit analysis is part of the risk management process but is not a RMM as defined in this study (see chapter 2.1)

7.5.4 Reference to national conditions

In some CARs the authorities referred to specific national conditions and/or to regional assessments to be considered during the authorisation of biocidal products.

⁴⁶ http://ecb.jrc.ec.europa.eu/documents/Biocides/MINUTES_TECHNICAL_MEETING/2008_TMIII08_open_session.pdf

Also, in the context with the collection and elimination of wastes, the CARs often suggest complying with the regulations of the Member State authorising the individual product. General statements concerning the *“need to address any specific national conditions and/or to undertake regional assessments”* have also been included in some CARs, because only local environmental risk assessments have been carried out so far.

Referring to national legislation is one option for considering further RMM for specific risks but might cause differences in national product authorisation and therefore run counter to harmonisation and mutual recognitions of authorisations.

7.6 Efficiency of risk mitigation measures

A quantitative assessment of the efficiency of specific RMM would be required for regulatory decisions. Here, the question is whether the risk identified can be reduced to acceptable levels. REACH refers to RMM effectiveness, which is defined as the percentage reduction in exposure concentration or emission (release) produced by application of the risk management measure. This requires a quantification of the effects the different RMMs may have on the risk determining factors (Guidance R.13). Considering the environment, one option would be to include the effectiveness of specific RMM into the respective ESDs. In the existing ESDs, however, quantitative data on the efficiency of RMM are missing. Instead, only qualitative statements are presented, if any.⁴⁷ There are RMM which are highly dependent on the active substance to be considered. For example, the efficiency of the biological STP depends on the biodegradability of the substance, which may differ between 0-100%. Considering adsorption to activated sludge as an important elimination factor, the efficiency of the STP depends on the disposal of the sewage sludge (landfill, incineration, or soil conditioner) and thus on the local conditions. Some approaches to quantify the efficiency of RMM have been undertaken in the context of the authorization of plant protection products (see chapter 4.2). The identification of the

⁴⁷ For example, the ESD part 1 on wood preservatives states that providing that climatic conditions allow it, "natural" fixation by storing the impregnated wood for 4 to 12 weeks (average: 6-8) gives the best fixation results, in terms of reduction of leaching during use. Similarly, the ESD on insecticides and products to control other arthropods for household and professional uses recommends that in order to maximize the powders effects, the product should be kept on the treated areas (minimizing therefore the air stream and the cleaning events). The consequences of this RMM for minimising exposure to the environment are not mentioned or even quantified.

main emission sources and pathways is a prerequisite for the quantitative evaluation of the efficiency of RMM. For the biocide sector these data are rarely available.

8 Conclusions and recommendation

8.1 Introduction

The Biocidal Products 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. In assessing the impact of biocides, specific measures to reduce risks to the environment may be required. As far as the risks have been identified during the risk assessment of the active substances and/or their representative biocidal products, certain risk mitigation measures (RMM) have been described in the specific provisions of the inclusion directives for the active substances. In the Assessment Reports of the Competent Authorities some further RMM have been proposed but generally the RMM in the CARs resemble those in the inclusion Directives. More specific RMM may be included in the authorisations of biocidal products when all information of the formulation and the conditions of use are available. Product authorisation under the BPD, however, has only recently started and thus little information is available so far on where and how RMM are being considered in practice. For the environmental area, a harmonization of possible RMM is lacking. The objective of the research project was to compile risk mitigation measures proposed by authorities, industry and applicators with special emphasis on wood preservatives (PT 8) and insecticides (PT 18). The results are intended to contribute to an EU-wide harmonized assessment of biocidal products with emphasis on risk mitigation.

Risk mitigation can be defined as a systematic reduction in the extent of exposure to a risk and/or the likelihood of its occurrence. Risk mitigation is also used as a synonym for “risk reduction”. Both are part of risk management. In the context of the project, “risk mitigation” is part of regulatory decisions. That means that the authorisation of a biocidal product might be subject to certain risk mitigation measures in order to reduce risks to acceptable levels.

8.2 Provisions of the Biocidal Products Directive

According to the Commission, the choice of specific risk mitigation measures 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 the Annex I inclusion should

thus be to identify general risk mitigation measures, which can be applied to all products, as well as specific risks/hazards to be addressed at product authorisation. Some Member States are concerned that, by postponing the discussion on suitable RMM to the product authorization stage, it might be difficult to harmonise RMM. This also might affect the mutual recognition procedure of biocidal products.

From the assessment of publicly available documents in the context of the implementation of the Biocidal Product Directive (BPD) the following conclusions can be drawn:

- The TNsG on Product Evaluation do not give detailed guidance on how and when to consider RMM in product authorisation.
- Not all RMM proposed can be addressed in the authorisation step but have to be tackled in other regulatory areas, e.g. the development of BAT or other best practices. These RMM are part of a more general approach to risk management. Many of these RMM elements are considered in Directive 2009/128/EC on sustainable use of pesticides, which only covers plant protection products so far (e.g. development of integrated pest management and best practices, certification of distributors and professional applicants, training, availability of information). While these RMM certainly help to reduce emissions of biocides to the environment, their efficiency is difficult to consider during product authorisation.
- In the Inclusion Directives use and user restrictions specifically apply for actives classified as carcinogen, toxic for reproduction, or PBT (persistent, bioaccumulative and toxic) as well as for fumigants (because these require wearing personal protective equipment and specific training).
- During the evaluation of biocidal active substances the rapporteur member states have followed different approaches to RMM which reflect national circumstances.
- In the draft CARs most RMM refer to the formulated (representative) biocidal products. The RMM proposed are derived from the results of the (environmental) risk assessment. Often the user category is defined as RMM (e.g. exclusion of consumer use for substances of high concern). The user category certainly has a decisive influence on the extent of emissions to the environment (through reduction of the overall amount or better compliance with best practice). Considering the exposure assessment, RMM often refer to product integrated measures (e.g. ready for use products) or on the area of use (e.g. indoor, outdoor).
- Often the RMM described are difficult to control or are controversial among Competent Authorities (e.g. crack and crevices treatment of insecticides, top coating of wood preservatives). Thus, harmonisation of the appraisal of the practicability of different RMM is required.
- It remains unclear what consequences RMM which have been decided for the approval of an active substance will have at the product authorisation level (e.g. whether a use class restriction of a wood preservative might be expanded to outdoor use, when the applicant provides further leaching data).

- For some RMM (e.g. for storage of treated wood) there is agreement among Competent Authorities but different RMM levels (e.g. covered, under roof) are proposed. Reference is given to “best practice” or “good housekeeping”.

8.3 Risk mitigation in other regulatory areas

Similarly to Annex I of the BPD, Directive 91/414/EEC concerning plant protection products, which will be replaced by Regulation (EC) No 1107/2009 from June 2011 on, describes several RMM for the active substances, such as spotwise application, buffer zones to be considered, minimum holding periods in rice cultivation, timing of the application and the selection of those formulations which minimise exposure of birds and mammals and appropriate distances to surface water bodies.

Recommendations on risk reduction measures for workers and/or the environment have been established within Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances (now implemented into REACH). Here, Member States are required to define emission limit values, Environmental Quality Standards (EQS), or technical measures for operating installations according to the best available techniques (BAT). Local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected. Member States should carefully monitor the implementation of BAT. The focus of these provisions is directly linked with the Water Framework Directive 2000/60/EC and the IPPC Directive 2008/1/EC concerning the integrated pollution prevention and control.

REACH (EC Regulation No. 1907/2006) defines “Risk Management Measures” as measures in the control strategy for a substance that reduce the emission and exposure to a substance, thereby reducing the risk to human health or the environment. The guidance document Chapter R.13 distinguishes between “product integrated risk management measures” under the control of the supplier and “instructions/communication on safe use” for users in addition to “principles on operational risk management measures” such as prevention and reduction of emissions by process integrated measures, end-of-the pipe techniques, good housekeeping, or BAT.

Concerning Directive 2001/82/EC on veterinary medicinal products, the corresponding EMEA guidelines on environmental impact assessment specify RMM

which focus on good agricultural practice (manure storage and spreading) while Directive 2001/83/EC on medicinal products for human use and the corresponding EMEA guideline focus on product storage and disposal (disposal via wastewater or household waste).

8.4 Elements for risk mitigation

The focus of the project is, as mentioned before, on RMM which could be implemented during the authorisation of biocidal products. However, not all RMM proposed can be addressed in the authorisation step but have to be tackled in other regulatory areas, e.g. the development of BAT or other best practices. Compliance with RMM often depends on information being available and on awareness of risks. Thus training, communication of risks and spreading of information are essential for achieving the objectives. Figure 5 summarises the different aspects of risk mitigation / risk management and risk gives some examples.

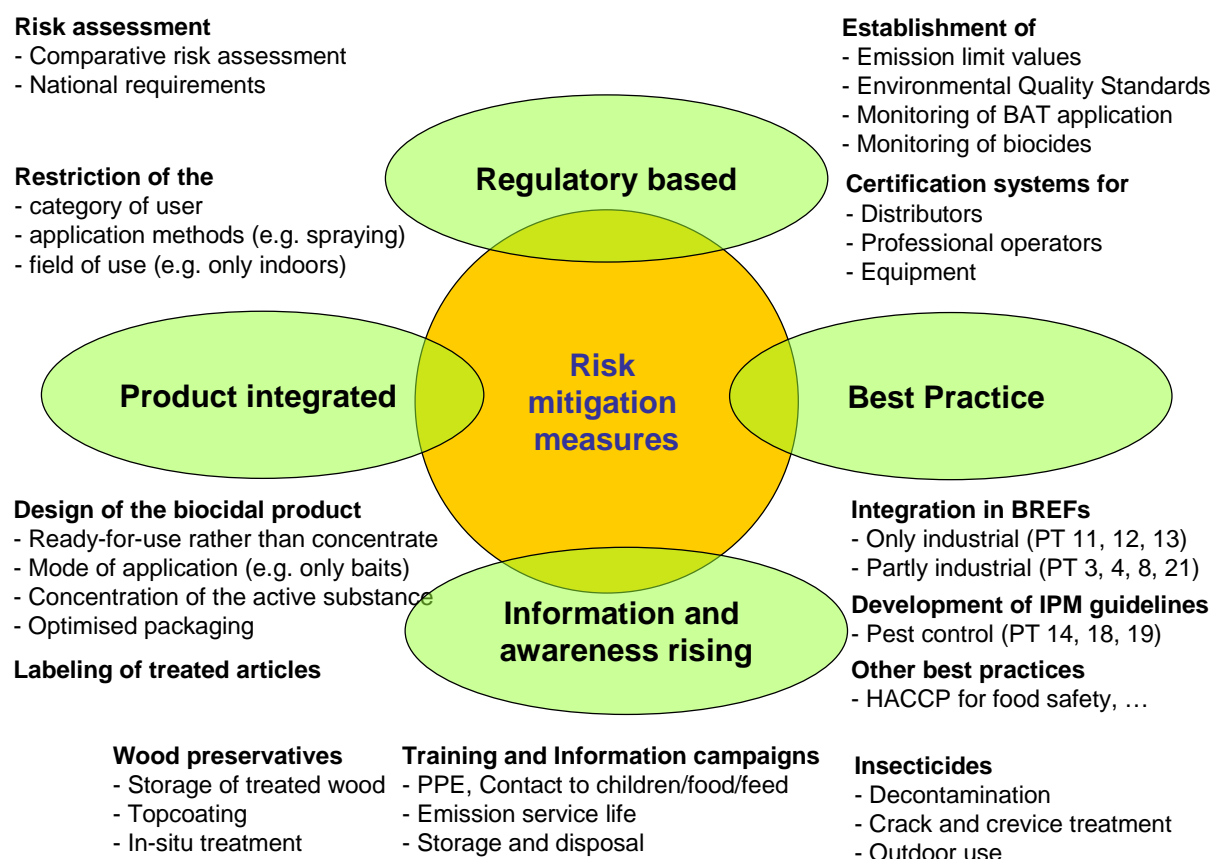


Figure 5: Elements of risk mitigation and risk management

The efficiency and practicability of RMM proposed or imposed by authorities and formulators depends on the addressees: It can be expected that compliance with any RMM implemented during product development will be higher than those RMM which refer to the applicators of biocidal products. Compliance with RMM directed to the users of biocidal products mainly depends on the communication of risks, risk awareness, education, specific training and the availability of approved “best practices” which are broadly recognised by experts.

Regulatory based RMM

Several RMM proposed by authorities have an immediate consequence for the authorisation of biocidal products. Some rodenticides and wood preservatives are subject to a comparative risk assessment due to the risks identified. This relates to substances of (very) high concern (potential PBT or vPvB, toxic for reproduction, carcinogenic). Examples are boron compound acids (reprotoxic), many anticoagulant rodenticides as well as the wood preservatives Bifenthrin and Flufenoxuron (PBT). The wood preservative creosote, due to its carcinogenic and PBT properties as well as observed emissions of creosote to the environment due to applications exposed to weathering, would not normally be included in Annex I. However, according to the TNGs, the benefits of products containing the active substance should also be considered. Therefore the Competent Authority recommended that a comprehensive analysis of the benefits from the use of creosote on a European level should be carried out within a socio-economic analysis. Currently, some of these issues are discussed in the context of the revision of the BPD.

Other RMM refer to emission control measures such as the establishment of emission limit values, environmental quality standards, monitoring of compliance with BAT which is in line with Regulation (EEC) No 793/93 on existing substances (now implemented into REACH) and directly linked to the Water Framework Directive and the IPPC Directive.

Further RMM which might be imposed by authorities concern either product development or the qualification and certification of applicants. The former will be considered during the development, production and marketing of biocidal products where the user category (private, professional, specialised professional), the area of use or the mode of application is defined. The latter concerns further regulatory

options which have been implemented partly on a national scale, such as the certification of distributors and professional applicators and the inspection of equipment in use. These instruments could be part of a more general approach for improving sustainable use of biocides. For plant protection products these, instruments are covered by Directive 2009/128/EC on sustainable use of pesticides.

Authorities are also involved in the development of BAT guidance such as the BREF documents under the IPPC Directive. However, considering biocides in BREF document 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.

Product integrated RMM

Product integrated RMMs are under the control of the supplier but authorities have a decisive influence on the product design via the authorisation process. Examples of product integrated RMM are the chemical composition and physical form of a product and its functional design. Ready to use products prevent exposure and emissions during mixing and loading. The mode of application (e.g. insecticide application as gel bait instead of spraying, impregnation of wood via vacuum pressure instead of dipping) has a decisive influence on environmental exposure (both during application and service life). Also, operational conditions such as the duration and frequency of an application and the amount applied directly influence the extent of emissions to the environment. Information on how to apply a biocidal product correctly and which RMM have to be considered is communicated through product labels, safety data sheets and technical leaflets. The evaluation of technical leaflets indicated that different companies have developed their own strategies on how to communicate risks and risk mitigation measures to the user of biocidal products. While the technical leaflets and safety data sheets have to be submitted with application for authorisations of biocidal products, the influence of authorities on the quality of these documents is limited.

The Commission's proposal for a Regulation concerning biocidal products currently being discussed among Member States will include articles treated with biocidal products under its scope. Labelling of treated articles or materials will be required. Indeed, these requirements will be a prerequisite for reducing emissions during the

service life of materials treated with biocides, such as treated wood. Compliance with the application area (use class) specified for wood preservatives can only be followed if the treated wood is labelled accordingly.

Implementation of RMM in “best practice” guidelines

Good and best practice documents are a very important tool for achieving a harmonised understanding of when and how to apply biocides, which risk mitigation measures should be implemented to reduce risks and how to control compliance with best practice. Here other aspects such as preventive measures or non-biocidal alternatives are also discussed.

Several BAT Reference Documents (BREFs) have been developed for different sectors. Although these BREFs have no legally binding status, local authorities often refer to them when defining BAT and limit values for discharges and emissions. Some BREFs cover industrial processes where biocides are applied (e.g. cooling systems, tanning of hides and skins, pulp and paper industry, textiles industry, surface treatment using organic solvents), others are part of the food industry where disinfectants are used (rearing of poultry and pigs, slaughterhouses and animals by-products, food, drink and milk industries). With a few exceptions, the safe use of biocides is only marginally addressed in these BREFs. The consideration of biocidal application (and its alternatives) in existing and new BREFs under IPPC would be an effective instrument for improving these processes and related activities. In the case of insecticides, best practice documents focus on integrated pest management, but only few harmonised best practice documents are available. Much information is available from different sources and the implementation of the principles of integrated pest management seems to be the most promising instrument for reducing potential risks. The development of best practices and integrated pest management measures are also addressed in Directive 2009/128/EC on sustainable use of pesticides (which so far only covers plant protection products).

Information and awareness rising

Many RMM proposed by authorities and industry are communicated to the user of biocidal products via product labels or leaflets or via best practice documents. They are in most cases difficult to control. Whether the users of biocidal products (both

consumer and professional) comply with specific RMM is mainly dependent on the information available and on the awareness of risks. For example, it could be questioned whether the user always follows the instructions to use protective clothing or on storage and disposal. Compliance with restrictions of the use of treated articles such as impregnated wood (e.g. only indoors, no contact to children, food and feed) depends on the user's risk awareness. At this stage, persons who did not apply the biocidal product nor read the product label or leaflet use treated articles. It cannot be guaranteed that the area of use for which the biocidal product has been authorised (e.g. use class of wood preservatives) is considered. Therefore, an extension of the labelling requirements to treated articles, as foreseen in the revision of BPD, is necessary.

The Directive on sustainable use of pesticides (which so far only covers plant protection products) requires Member States to promote and facilitate information and awareness-raising programmes and the availability of accurate and balanced information relating to pesticides for the general public. Information about best practices, occupational health campaigns, the promotion of ecolabels and information system on biocides (web-based and print media based) are examples of suitable programmes to be established in national action plans.

The promotion of ongoing national activities for education and training of professional users established by professional associations and research institutes, as well as information systems for the general public, are important instruments for improving the sustainable use of biocides. In Germany, a web portal on alternative measures of biocidal uses is being established and is available under www.biozid.info.

8.5 Recommendations

The following recommendations are given:

- The elaboration of harmonised guidance documents on suitable RMM for each product type (so far only prepared for anticoagulant rodenticides). This includes general information about the practicability and quantitative efficiency of specific RMM.
- The development of a guidance document to specify the information requirements of Article 20 of the BPD: Which RMM can be described more

generally, which should be described at a higher level of detail? Which additional information sources should be provided or referred to? Further on the product label must consider the requirements of the inclusion Directives of the respective active substance. Guidance would help industry to decide which information should be included in labels, safety data sheets, and product leaflets.

- Consideration of labelling requirements for treated articles as foreseen in the draft Biocide Regulation.
- Inclusion of provisions on sustainable use and risk mitigation of biocidal product use into the corresponding BREF documents, especially those for industrial processes. More detailed consideration of biocidal use in the development and updating of BREF documents describing BAT for those sectors covered by the IPPC Directive.
- The development of guidance documents to support Member States to promote and facilitate information and awareness-raising programmes and the availability of accurate and balanced information relating to biocides for the general public.
- Elaboration of provisions for including biocides under the scope of Directive 2009/128/EC on sustainable use of pesticides or establishing a separate framework on sustainable use of biocides.
- Data on quantities of biocidal active substances and products produced or sold are required as a basis for determining the potential strategies to ensure the optimum efficacy with the minimum quantity necessary. The inclusion of biocides into the scope of the statistics regulation (EC) No. 1185/2009 is recommended.
- As few monitoring data on biocidal active substances in environmental media exist so far, environmental monitoring of biocides should be extended in order to provide a risk indicator for the use of biocides. Monitoring data are also required to describe the quantitative efficiency levels of specific RMM.

9 References

ATV-M 702 1995. Wirtschaftsdünger, Abfälle und Abwässer aus landwirtschaftlichen Betrieben. Abwassertechnische Vereinigung in Zusammenarbeit mit dem Kuratorium für Technik und Bauwesen in der Landwirtschaft e.V. (KTBL), August 1995

Ahlers, J., Beulshausen, T., Bigalke, T., Eggers, H.-H., Gies, A., Greiner, P., Henseling, K.-O., Mehlhorn, B., Merkel, H., Paulini, I. Steinhäuser, K., Stolzenberg, H.-C., Vormann, K., Wiandt, S. 2001. Sustainable and Precautionary Risk Assessment and Risk Management of Chemicals Part I: New Strategies for the Ecological Risk Assessment and Risk Management of Substances. UBA-Texte 30/01.

Bayerisches Landesamt für Wasserwirtschaft 2004. Hinweise zur Abwasserentsorgung bei landwirtschaftlichen Einzelanwesen. Referat 31/35, Merkblatt Nr. 4.2/3 Stand: 01.10.2004

http://www.lfu.bayern.de/wasser/fachinformationen/merkblattsammlung/teil4_oberirdische_gewaesser/doc/nr_423.pdf

Hinweise zur Abwasserentsorgung bei landwirtschaftlichen Einzelanwesen

Becker et al. (2003). Mosquitoes and their control. Kluwer Academic Publishers

Bleck, D., Müller, A. 2008. Arbeitsplatzbelastungen bei der Verwendung von bioziden Produkten - Teil 5. Expositionsszenarien und Arbeitsschutzmaßnahmen bei der Anwendung von Antifouling-Produkten. BAuA Projektnummer: F 2136, 142 Seiten Dortmund/Berlin/Dresden.

http://www.baua.de/nn_11598/de/Publikationen/Fachbeitraege/F2136.html

Bodenschatz, W. (ed.) 2009. Handbuch für den Schädlingsbekämpfer, loose-leaf-collectionleaflet, Gustav Fischer Verlag, Stuttgart

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

COWI A/S. 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 January 2009, Kongens Lyngby Denmark (CA-Feb09-Doc.5.3.1) http://ec.europa.eu/environment/biocides/pdf/report_use.pdf

DEFRA 2008. Phase 2 of the Impact Assessment of Proposals for a Revised IPPC Directive Part 7: Preservation of Wood and Wood Products Final report, London, June 2008

http://randd.defra.gov.uk/Document.aspx?Document=EP01014_7375_FRP.pdf

Ducos, G. 2009. Emission Reduction Strategy Report. Source Control of Priority Substances in Europe (SOCOPSE), Work Package 3 – D.3.3 <http://www.socopse.se>

ECHA. 2008. Guidance on information requirements and chemical safety assessment Chapter R.13: Risk management measures and operational conditions. European Chemicals Agency, version 1.1, May 2008
http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r13_en.pdf?vers=20_08_08

Environmental Agency, UK (2003). Timber Treatment Installations 2003 - Code of Practice for Safe Design and Operation http://www.environment-agency.gov.uk/static/documents/Business/timber_code_2003.pdf

Forster, R., Streloke, M. 2001. Workshop on Risk Assessment and Risk Mitigation Measures in the Context of the Authorization of Plant Protection Products (WORMM) 27.-29. September 1999. Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft Berlin-Dahlem Heft 383
<http://pub.jki.bund.de/index.php/MittBBA/article/viewFile/736/671>

Führ, M., Krieger, N., Bizer, K., Merenyi, S., Cichorowski, G., Kleihauer, S., Ahrens, A., Heitmann, K., Hackmack, U. 2006. Risikominderung für Industriechemikalien nach REACH - Anforderungen an eine Arbeitshilfe für Hersteller, Importeure und Stoffanwender. Forschungsbericht 20467462/04, UBA Texte 05/06
<http://www.umweltdaten.de/publikationen/fpdf-l/3010.pdf>

Führ, M., Bizer, K. (2007). REACH as a paradigm shift in chemical policy e responsive regulation and behavioural models. Journal of Cleaner Production 15 (4), pp 327-334 http://www.reach-helpdesk.info/fileadmin/Dokumente/Zeitschriften/article1276_mf.pdf

Gartiser, D., Groß, R., Luskow, H. 2009. Thematic Strategy on Sustainable Use of Plant Protection Products – Prospects and Requirements for Transferring Proposals for Plant Protection Products to Biocides FKZ 3708 63 400, Task 2 and 3 Measures for sustainable use of pesticides and their applicability for biocides (draft November 2009)

Genty, A. 2009. An Inventory and Assessment of Options for Reducing Emissions: Isoproturon Work. Source Control of Priority Substances in Europe (SOCOPSE) Package 3 – D.3.1 <http://www.socopse.se>

Health and Safety Agency for Northern Ireland (1995). The safe use of pesticides for non-agricultural purposes. Approved Code of Practice.
http://www.hseni.gov.uk/pesticides_safe_use.pdf

Hebisch, R., Holthenrich, D., Karmann, J., Riechert, F., Berger, M., Kersten, N., 2009. Arbeitsplatzbelastungen bei der Verwendung von bioziden Produkten Teil 4: Holzschutzmittel. BAuA Projektnummer: F 1809, 60 Seiten, Dortmund/Berlin/Dresden
<http://www.baua.de/cae/servlet/contentblob/668730/publicationFile/47148/F1809.pdf>

Hillenbrand, T., Marscheider-Weidemann, F., Strauch, M., Heitmann, K., Schaffrin, D. 2007. Emissions reduction for priority and priority hazardous substances of the Water Framework Directive. Research Report 203 21 280, UBA-Texte 28/07
<http://www.umweltdaten.de/publikationen/fpdf-l/3311.pdf>

Holz-Berufsgenossenschaft (2009) Holzschutzmittel Handhabung und sicheres Arbeiten. BGI 736, Ausgabe 11/2009 http://www.holz-bg.de/download/BGI_736.pdf

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

Leeuwen, C..J., Vermeire, T.G. (eds.) 2007. Risk Assessment of Chemicals - An Introduction. 2nd edition. Springer, Dordrecht, NL

Mallis, A., Moreland, D., Hedges, S. A. (Ed). 2004. Malis Handbook of Pest Control. Ninth edition <http://www.mallishandbook.com>

McKinlay, R., Planta, J. A., Bella, J. N. B., Voulvoulis, N. 2008. Calculating human exposure to endocrine disrupting pesticides via agricultural and non-agricultural exposure routes. Science of The Total Environment, 3498 (1-3), p. 1-12

Meyer, A., Allan, E., Madge, O 2009. The British Pest management Manual. Loose-leaf-collection, British Pest Control Association

Montforts, M., Blackwell, P., Boxall, A., Halling-Sørensen, B., Hermansen, S., Ingerslev, F., Jacobsen, A.-M., Kay, P., Laak, T., Moltmann, J., Schmitt, H., Søeborg, T., Tarazona, J., Tolls, J., Verschoor, A. 2003. Environmental Risk Assessment of Veterinary Medicines in Slurry (ERAVMIS), EU contract number EVK1-CT-1999-00003, RIVM report 601450018/2003
<http://rivm.openrepository.com/rivm/bitstream/10029/8996/1/601450018.pdf>

Montforts, M. H., van Rijswijk, H. F., de Haes, H. A. 2004. Legal constraints in EU product labelling to mitigate the environmental risk of veterinary medicines at use. Regul Toxicol Pharmacol. 40 (3): p. 327-335

OECD 2000. OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 2: Emission Scenario Document for Wood Preservatives PART4
<http://www.oecd.org/dataoecd/60/8/2502780.pdf>

OECD. 2009a. OECD STRATEGIC APPROACH IN PESTICIDE RISK REDUCTION. ENV/JM/MONO(2009)38 23-Oct-2009
<http://www.oecd.org/dataoecd/21/46/44033393.pdf>

OECD 2009b. OECD SURVEY ON COUNTRIES' APPROACHES TO THE COLLECTION AND USE OF AGRICULTURAL PESTICIDE SALES AND USAGE DATA: SURVEY RESULTS. ENV/JM/MONO(2009)37
<http://www.oecd.org/dataoecd/21/5/44033366.pdf>

OECD 2009c. REPORT OF THE SEMINAR ON PESTICIDE RISK REDUCTION THROUGH SPRAY DRIFT REDUCTION STRATEGIES AS PART OF NATIONAL RISK MANAGEMENT
[http://www.ois.oecd.org/olis/2009doc.nsf/LinkTo/NT00006B7A/\\$FILE/JT03272744.PDF](http://www.ois.oecd.org/olis/2009doc.nsf/LinkTo/NT00006B7A/$FILE/JT03272744.PDF)

Owens, K. 2003. Healthy Hospitals - Controlling Pests Without Harmful Pesticides. Beyond Pesticides Washington DC
http://www.beyondpesticides.org/hospitals/Healthy_Hospitals_Report.pdf

Reichenberger, S., Bach, M., Skitschak, A., Frede, H.-G. 2006. State-of-the-art review on mitigation strategies and their effectiveness. Report DL#7 of the FP6 EU-funded FOOTPRINT project www.eu-footprint.org, 76 p.

Reichenberger, S., Bach, M., Skitschak, A., Frede, H.-G. 2007. Mitigation strategies to reduce pesticide inputs into ground- and surface water and their effectiveness - A review. *Science of The Total Environment*, 384 (1-3), p. 1-35

Schoknecht, U., Horn, W., Jann, O., Wegner, R. 2002. Biozidemissionen aus Materialien. UBA-Bericht, Förderkennzeichen 299 67 410, Berlin

Schoknecht, U., Mathies, H., Wegner, R., Bornkessel, C. 2003. Gutachten über die Entwicklung eines Prüfverfahrens zur Ermittlung von Mindestfixierzeiten von Holzschutzmitteln. Abschlussbericht FKZ 360 04 011, UBA-Texte 83/03
<http://www.umweltdaten.de/publikationen/fpdf-l/2547.pdf>

Schoknecht, U., Wegner, R., Melcher, E., Seidel, B., Kussatz, C., Maletzki, D. 2004. The influence of test parameters on the emission of biocides from preservative treated wood in leaching tests. UBA-Bericht, Förderkennzeichen 203 67 441. Berlin.

Schneider, Kl., Olthmanns, J., Gartiser, S. 2008. Arbeitsplatzbelastungen bei der Verwendung von bioziden Produkten Teil 3: Expositionsszenarien und Arbeitsschutzmaßnahmen bei der Anwendung von Molluskiziden, Insektiziden, Repellentien und Lockmitteln. Endbericht F 1922 im Auftrag der Bundesanstalt für Arbeitsschutz und Arbeitsmedizin.
http://www.baua.de/nn_5846/de/Publikationen/Fachbeitraege/F1922.html

Schulz, R., Stehle, S., Elsaesser, D., Matezki, S., Müller, A., Neumann, M., Ohliger, R., Wogram, J., Zenker, R. 2009. Geodata-Based Probabilistic Risk Assessment and Management of Pesticides in Germany: A Conceptual Framework. *Integrated Environmental Assessment and Management* 5 (1), p. 69–79

Stachecki, J. (Ed) 2002. Pesticide Applicator Core Training Manual - Certification, Recertification and Registered Technician Training - Part A: Required reading for: Private pesticide applicators, Commercial pesticide applicators, Registered technicians <http://www.pested.msu.edu/Resources/bulletins/E2195.html>

Stafford, T. R., Best, L. B. 1999. Bird response to grit and pesticide granule characteristics – Implications for risk assessment and risk reduction. *Environmental Toxicology and Chemistry*, Vol. 18, No. 4, pp. 722–733

Suárez, E., Fernández, C., Pro, J., Ramos, C., Unamuno, V., Ortiz, J., Haro, A., Tarazona, J.V. 2008. Assessing the environmental risk for primary and secondary poisoning in birds and mammals of the rodenticide chlorophacinone. Annex to the CAR of chlorophacinone. Division of Ecotoxicology and Environmental Risk Assessment. Department of the Environment, INIA, September, 2008
http://www.inia.es/gcontrec/pub/Annex_chlorophacinone_environmental_risk_assessment_1220614981640.pdf

TNsG Principles and Practical Procedures for the inclusion of active substances in Annexes I, IA and IB April 2002 ECB, February 2008

TRGS 512 Fumigations. Technical Rules for Hazardous Substances, November 2008

<http://www.baua.de/cae/servlet/contentblob/666012/publicationFile/51348/TRGS-512.pdf>

TRGS 523 Pest control using highly toxic, toxic and health hazardous substances and preparations. Technical Rules for Hazardous Substances, November 2003

<http://www.baua.de/cae/servlet/contentblob/666012/publicationFile/51348/TRGS-512.pdf>

Vischetti, C., Cardinali, A., Monaci, E., Nicelli, M., Ferrari, F., Trevisan, M., Capri, E. 2008. Measures to reduce pesticide spray drift in a small aquatic ecosystem in vineyard estate. *Sci. Total Environ.* 389 (2-3), p. 497-502

Ware, G. W. 2005. Complete Guide to Pest Control with and without chemicals. 4th edition. MeisterPro Information Resources

WHO 2006. Pesticides and their application for the control of vectors and pests of public health importance Sixth edition. Department of Control of Neglected Tropical Diseases WHO Pesticide evaluation scheme (WHOPES) http://whqlibdoc.who.int/hq/2006/WHO_CDS_NTD_WHOPES_GCDPP_2006.1_eng.pdf

Winter, G., Hoffmann, G. 2000. Zur Dekontamination von insektizidbelasteten Flächen nach Entwesungen in Innenräumen. *Bundesgesundheitsblatt – Gesundheitsforschung – Gesundheitsschutz*, Vol. 43 (9), p. 698-714

Winter, G., Sonneck, R. 1999. Decontamination of insecticides from various surfaces. Proceedings of the 3rd international Conference on Urban Pests, Prague, Czech Republic, 19 - 22 July <http://www.icup.org.uk/reports%5CICUP430.pdf>

Annex 1: Provisions for product authorisations from the PT 8 CARs

		Examples
A) Placing on the market		
User restriction	<p>Restriction of the use of the fumigant sulfuryl fluoride to trained professionals</p> <p>Only for professional, trained <u>and licensed</u> users (fumigators).</p> <p>Restriction to industrial operators</p> <p>Only industrial applications have been evaluated → other uses, e.g. application by brushing should be carefully evaluated to ensure safe use</p> <p>Only industrial dipping technique, industrial vacuum pressure and residential brushing and injecting in use class 1 to 3 allowed; spraying excluded</p> <p>Restriction to professional use only</p> <p>Recommended only for professional use</p>	<p>Sulfuryl fluoride</p> <p>Hydrogen cyanide *)</p> <p>K-HDO</p> <p>Didecyldimethylammonium chloride *)</p> <p>4,5-Dichloro-2-octyl-2H-isothiazol-3-one *)</p> <p>Bifenthrin *)</p> <p>Copper (II) carbonate *)</p> <p>Copper (II) oxide *)</p> <p>Didecyldimethylammonium chloride *)</p> <p>Fenoxycarb *)</p> <p>Dazomet *)</p>
Area of application	<p>Restriction of use of K-HDO for the treatment of wood that may enter in direct contact with infants.</p> <p>Treated wood in service only for use classes 1 and 2 Only indoor uses allowed, i.e. professional indoor spraying, brushing and injection and amateur brushing</p> <p>Restriction of the use class for certain wood preservatives: No in-situ treatment of wood outdoors</p> <p>Wood products must not be used for in situ applications by brush. Give label instructions in order to prevent application to timber where direct losses to water and soil are possible</p> <p>Restriction of the use class for certain wood preservatives for wood that will be in continuous contact with water or weathering</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>The likelihood of Hazard Class 3 timbers being used to construct structures near to water (as there is a potential risk to the aquatic environment) should be considered as part of each Member State's product authorisation process</p> <p>Prohibition for use of treated wood in groundwater protection areas However, regional or European wide prohibition does not seem feasible. The concept of groundwater protection area</p>	<p>K-HDO</p> <p>Chlorfenapyr *)</p> <p>Boric acid</p> <p>Disodium octaborat</p> <p>Propiconazole</p> <p>Tebuconazole</p> <p>Thiabendazole</p> <p>Thiamethoxam</p> <p>Tolylfluand</p> <p>Coco</p> <p>Alkyltrimethylammonium chloride</p> <p>Boric acid</p> <p>Disodium octaborat</p> <p>Propiconazole</p> <p>Clothianidin</p> <p>Tebuconazole</p> <p>Thiabendazole</p> <p>Thiamethoxam</p> <p>Tolylfluand</p> <p>Thiacloprid</p> <p>Dichlofluand</p> <p>Propiconazole</p> <p>Thiacloprid</p> <p>Tolylfluand</p>

	<p>does not exist in all European countries or it is not similar in different MS. Users of biocidal products or treated timber do not necessarily know if the place is situated on such an area. Therefore, this type of prohibition is impossible to enforce.</p> <p>Dermal exposure of children playing on preserved wood not considered safe when the wood is treated by dipping.</p> <p>Only preventive or only curative treatment</p>	<p>Chlorfenapyr *)</p> <p>No example found</p>
Package size		No example found
Design of the biocidal product mode of application	<p>Formulation must include a proper fixative formulation to reduce leaching from treated wood. Robust leaching studies with the formulation and the application systems should be conducted to ensure safe use of treated materials.</p> <p>When assessing ready for use products containing the active substance together with fixatives and additives it is important to reassess the emission behaviour via experimental leaching tests.</p>	<p>4,5-Dichloro-2-octyl-2H-isothiazol-3-one (DCOIT) *)</p> <p>Clothianidin *)</p>
B) Application of biocidal products		
Mixing and loading	<p>Concentrate of the substance only handled under closed conditions</p> <p>Mixing and loading should be automated in a closed system and automated spraying/flow-coating fully enclosed.</p>	<p>Didecyldimethylammonium chloride *)</p> <p>4,5-Dichloro-2-octyl-2H-isothiazol-3-one *)</p>
Equipment	<p>Use limited to vacuum pressure treatment. The notifier has specified: "It is standard practice in industrial timber treatment not to generate any liquid wastes. Treatment facilities are closed systems where only one specific product is continuously employed. Consumed treatment solutions are filled up to the required volume. Product containers (in Germany TÜV certified) are completely emptied and returned to the manufacturer of the wood preservative for refilling. Waste can therefore only be generated upon closedown of the facility or changeover to another product. Both events are to be avoided from an economic viewpoint. Therefore they do not occur on a regular basis and are therefore not relevant for risk assessment Every 3–4 years, it is required to remove splinters from the bottom of the treatment vessels. Splinters are removed by a sieve and disposed of as controlled waste in certified containers (with a record of proper waste management) according to the appropriate key of the European Waste List 2001/118/EC."</p> <p>Therefore, the RMS proposes the following restriction: <i>"only to be used at timber treatment installations with no surface drains connection to STP in the contained area of the plant". This will ensure that all treatment product will be re-cycled within the facility or collected and disposed of according to local authority regulations and minimise the release to the environment.</i></p> <p>All copper-containing wood preservatives should only be used in double vacuum pressure timber treatment facilities with no drains connection to storm drains or to STPs. The losses should be collected and disposed of according to the national authority regulations.</p> <p>Restriction K-HDO as wood preservative to industrial use in fully automated and closed equipment.</p> <p>The tanks, containers and the technical apparatuses for the production of Cu-HDO must not be cleaned, except in an automated process where rinsing water will be collected and reused in the production process.</p>	<p>Copper (II) hydroxide *)</p> <p>Copper (II) carbonate – Copper (II) hydroxide (1:1) *)</p> <p>K-HDO</p>

	<p>Application only by dipping/immersion process and vacuum pressure by professional users</p> <p>Only dipping by automated/mechanical means and not manually should be allowed</p> <p>Principles of good working practice should be applied and label instructions and recommendations respected. Application processes must be carried out within a contained area on impermeable hard standing, with bunding to prevent run-off and with a recovery system in place (e.g. sump).</p>	<p>Didecyldimethylammonium chloride *)</p> <p>Dichlofluanid</p> <p>Thiacloprid</p>
Personal protective equipment	<p>Use of appropriate personal protective equipment for reducing human exposure at industrial and/or professional use to certain wood preservatives.</p> <p>Operators/fumigators must wear self contained breathing apparatus and gas-tight chemical clothing when working with cylinders during introduction of gas, on initial re-entry to treated structures and when air concentrations exceed 3 mg/m³</p>	<p>Most wood preservatives</p> <p>Hydrogen cyanide *)</p>
Further RMM Fumigation	<p>A protective zone around the fumigated structure shall be set in such a way as to prevent a contact of bystanders with the gas during fumigation and during ventilation. Re-entry into treated structures/areas without the use of SCBA is allowed only when gas concentrations are $\leq 3 \text{ mg/m}^3$</p> <p>Indirectly exposure of aquatic environment by precipitation or by descending fog → fumigation and following ventilation should thus be carried out only under favourable temperature and dissipation conditions ($> 10^\circ\text{C}$, assure that it is not raining especially in the final phase of ventilation and that there is not a high air humidity or temperature inversion which would deteriorate conditions for dispersion of ventilated hydrogen cyanide.</p> <p>Soil in the vicinity of the object to be treated in-situ has to be mechanically protected during the treatment (e.g. with a tarpaulin or plastic sheeting) and subsequent waste management has to be sorted out in an appropriate way.</p>	<p>Hydrogen cyanide *)</p> <p>Propiconazole</p>
C) Post application		
Storage of treated wood	<p>Keep the treated timber on storage places covered by roofs</p> <p>Storage of pre-treated timber to areas of impermeable hard standing so as to prevent direct exposure of the soil compartment and allow the recovery of the losses for recycling or appropriate disposal. Give label instructions in order to prevent application to timber were direct losses to soil are possible.</p> <p>As regards the storage area, the notifier specified that <i>“Furthermore, the assumption of unsealed soil is not considered relevant in the context of the risk assessment. Any facility processing metal-based wood preservatives must be assumed to be equipped with sealed storage areas as a default risk mitigation measure (Tier 2 assessment). This is in fact standard practice and an established legal requirement for facilities processing metal-based wood preservatives. The leachate is collected and recycled into the process, whereas emissions to soil and adjacent surface waters are effectively prevented by these technical measures.”</i></p> <p>Therefore, the RMS proposed the following statement: <i>“The timber treated on an industrial site must be stored on hard standing to prevent direct losses to soil and all effluents should</i></p>	<p>Fenpropimorph</p> <p>Coco Alkyltrimethylammonium Chloride *)</p> <p>Copper (II) hydroxide *)</p>

	<p><i>be collected and disposed of according to local authority regulations to minimise the release to the aquatic environment."</i></p> <p>The emissions from treated wood to soil should be substantially reduced by covering the storage area with impermeable coating e.g. concrete and, when relevant, a protective roof</p> <p>Best way: keep the treated timber on storage places covered by roofs. Alternatively storage of pre-treated timber should be carried out on areas of hard standing exhibiting impermeable grounds while collecting and recycling leachates into the impregnation process.</p> <p>Storage of timber freshly treated with wood preservatives under shelter or on impermeable hardstanding to prevent direct losses to soil or water.</p> <p>Storage of treated wood either undercover with a recovery system in place (e.g. sump) or on impermeable hard standing and banded to prevent run-off with a recovery system in place (e.g. sump). These measures are considered a reasonable requirement for all industrial wood treatment sites to prevent unnecessary contamination of the environment and are common to best available practice (BAP) throughout much of the existing industry in many MS</p> <p>Storage of industrial treated timber to hard standing (preventing the direct losses to soil) and collecting rain water from the storage area. This is currently considered good practice in many member states</p>	<p>Flufenoxuron *)</p> <p>Clothianidin</p> <p>IPBC, Boric oxide , Clothianidin, Dichlofluanid, Fenpropimorph, Propinconazole, Tebuconazole, Thiabendazole, Thiamethoxam, Tolylfluanid Thiacloprid</p> <p>Tebuconazole</p>
Waiting period	Time for fixation required	No example found
Contact to food, feed or children	<p>Wood products must not come in contact with food or feedstuffs (<i>Neither analytical methods nor toxicological risk assessment of contamination in food and feedstuffs has been carried out</i>)</p> <p>Impregnated wood must not come into direct contact with food or feedstuffs</p> <p>Use restriction to construction timber which is not accessible to children</p> <p>Dermal exposure of children playing on preserved wood not considered safe when the wood is treated by dipping</p>	<p>Coco Alkyltrimethyl- ammonium Chloride *) DCOIT *) Didecylmethylpoly(oxyethyl)ammoniu m Propionat *)e 4,5-Dichloro-2- octyl-2H-isothiazol- 3-one *) Bifenthrin *)</p> <p>Chlorfenapy *)r</p>
Topcoating	<p>Treatment only acceptable if emissions during service life (leaching) can be diminished by emission reducing measures (for instance the application of a topcoat to the treated wood).</p> <p>Wood installed over small ponds should be protected with a topcoat to avoid leaching into water.</p> <p>Wood in use class 3 to be restricted to wood not over or near water bodies unless wood installed over small ponds are protected with a topcoat to avoid leaching.</p> <p>Where emissions to water are possible and products (wooden structures) show a PEC/PNEC ratio higher than 1 (case of noise barrier), treated timber has to be protected with a topcoat.</p>	<p>Copper (II) hydroxide *)</p> <p>Bifenthrin *) Flufenoxuron *) Fenpropimorph</p> <p>Tebuconazole Thiamethoxam</p>

	<p>Top coating decreased the leaching of tolylfluanid from treated wood substantially but not enough. Uncertainty to the use of top coating as one of the risk mitigation measures is related to the fact that a long-term effectiveness of top coating is not finally proved.</p> <p>Additional treatment with a propiconazole-free coating or fixative may be considered to reduce the leaching from treated wood in wood Hazard Class 3.</p>	<p>Tolyflfluanid</p> <p>Propiconazole</p>
Disposal of the biocidal product	<p>During wood pre-treatment no emissions to surface water allowed. Waste recycling or incineration</p> <p>Collection of any losses of wood preservatives for reuse or disposal</p>	<p>Bifenthrin *)</p> <p>Most wood preservatives</p>
Drainage		
Water treatment	<p>Water purification measures: According to the applicant ozone is used for purification of water often in combination with other steps in water treatment. These steps, e.g. activated carbon filtering or sand filtering following ozonation, can lead into direct reduction of the level of N-nitrosodimethylamine (NDMA) in water in optimal conditions. However, the practicality and acceptability of these methods by waterworks remain uncertain. It should be borne in mind that Biocidal Products Directive regulates only placing on the market of biocides. Risk mitigation should therefore consist of measures directly linked to use of biocidal products. Consequently, it is beyond the administrative branch and the competence of the BPD authorities to regulate practices or techniques in waterworks.</p>	Tolyflfluanid
Wastewater treatment	<p>Removal at low concentrations is unnecessary. Where water containing high levels of borates can be captured precipitation with lime can be used to reduce boron levels to the 100 ppm range. Treatments with boron specific ion exchange resins and activated carbon are also possible. Contaminated soil can be leached with water or acid to reduce boron levels.</p> <p>Feasible waste treatment options have to be proven when recycling to the impregnation tank is not practicable</p>	<p>Boric acid, Boric oxide, Disodium tetraborate, Disodium octaborate tetrahydrate</p> <p>Clothianidin, Fenpropimorph</p>
Disposal of treated wood	<p>The end life cycle of products should be managed according to in force regulation</p> <p>The use by the general public does not allow a sufficient control of the waste management</p> <p>It is most unlikely that the active substance from treated wood will result in an environmental risk during incineration under controlled conditions; however, other active substance in a formulation may result in an environmental risk during incineration of treated wood. Therefore special focus on this life-cycle stage has been deferred to the Member State assessment at the product authorisation stage.</p> <p>No special disposal treatment is required, but local authorities should be consulted about any specific local requirements. Tonnage quantities of products are not considered appropriate for landfills. Such products should, if possible, be used for an appropriate application.</p>	<p>Bifenthrin *)</p> <p>Flufenoxuron *)</p> <p>Bifenthrin (PBT substance) *)</p> <p>Flufenoxuron (PBT substance) *)</p> <p>DCOIT *)</p> <p>Boric acid, Boric oxide, Disodium tetraborate, Disodium octaborate</p>

D) Further regulatory options		
Comparative risk assessment	PBT substances → candidate for comparative assessment. Toxic for reproduction category 2	Bifenthrin *) Flufenoxuron *) Boric acid, Boric oxide, Disodium tetraborate, Disodium octaborate tetrahydrate Boric acid, Boric oxide, Clothianidin, Disodium octaborate, K-HDO Bifenthrin *) Flufenoxuron *) Clothianidin *)
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 MS should pay attention to possible occurrence of resistance. MS experts should develop and harmonise a code of good practice for spray applications since for these processes potential exposure is always high Thiacloprid resistance may be a problem in moths. The Operator will have to provide regular updates on the status of thiacloprid resistance in the target species The need for a risk assessment for bats should be determined at a national level For the use covered by "Water jetty", "Noise barrier", "Sheet piling", "House", "Fence" and "Transmission pole" scenarios, there is a need for national authorities to address any specific national conditions and/or undertake regional assessments for the authorisation of copper-containing wood preservatives biocidal products.	Thiacloprid Thiacloprid Copper (II) carbonate – Copper (II) hydroxide (1:1) *)
Monitoring	Monitoring of sulfuryl fluoride concentrations in remote tropospheric air by applicant Regular monitoring of exposed workers/operators using sensitive TSH blood level test should be performed.	Sulfuryl fluoride Hydrogen Cyanide

*) Only draft CARs analysed, conclusions might be revised after discussion at technical meetings

Annex 2: Provisions for product authorisations from the PT 18 CARs

		Examples
A) Placing on the market		
User restriction	<p>Restriction of the use of the fumigant sulfuryl fluoride to trained professionals</p> <p>Use of aluminium phosphide releasing phosphine fumigant only by specifically trained professionals (in the form of ready-for-use products for PT18) while applying appropriate risk mitigation measures (personal and respiratory protective equipment, use of applicators).</p> <p>Shall be authorised for specialised professional users only</p> <p>Restriction to professional use</p>	<p>Sulfuryl fluoride</p> <p>Aluminium phosphide</p> <p>Trimagnesium diphosphide</p> <p>Triflumuron *)</p> <p>Diflubenzuron *)</p> <p>Spinosad *)</p> <p>Thiamethoxam *)</p>
Intended uses and area of application /	Products may not be authorised for uses other than crack and crevice treatment in domestic houses and in hospital indoors and for spot application outdoors	Deltamethrin *)
	<p>Only to be applied indoors</p> <p>When performing indoor treatments, the operator must place the product in cracks and crevices or in concealed locations inaccessible to man and domestic animals, in order to minimize the possibility of secondary exposure.</p> <p>Areas liable to submersion or likely to be routinely cleaned are excluded. Do not apply during cooking activities.</p> <p>In rooms where regular wet cleaning are envisaged crack and crevice treatments only.</p> <p>When performing professional treatments indoors, the operator must apply the powder in confined and poorly accessible areas, in order to minimize the possibility of exposure to the general population, to pets and to the environment.</p> <p>Risk was identified for the surface water and sediment compartments → All intended areas of use need to be carefully examined with regard to risks for terrestrial and aquatic ecosystems</p> <p>Use outdoors shall be restricted to the treatment of wasp and wild bee nests where losses to drains can be prevented. Prevent foraging bees gaining access to the treated bees' nests preferably by removing the combs or blocking nest entrance.</p> <p>No direct applications to soil are permitted.</p> <p>Do not spray bed linen or other materials which come into direct contact with occupants of the bed. Do not apply to clothing and bedding</p> <p>Member States shall assess outdoor use of phosphine releasing compounds before such application is granted.</p> <p>Risk of secondary poisoning to insectivorous vertebrates in stables → RMM to protect those areas with elevated ecological value. Farmers have to be informed accordingly.</p>	<p>Thiamethoxam *)</p> <p>Fipronil *)</p> <p>Bendiocarb *)</p> <p>Silicon dioxide *)</p> <p>lambda-cyhalothrin *)</p> <p>Bendiocarb *)</p> <p>Bendiocarb *)</p> <p>Magnesium phosphide</p> <p>Thiamethoxam *)</p>

	<p>The aerial application is not allowed, since no adequate data were submitted about the possible impact on general population.</p> <p>Aerial spraying by planes, helicopters or others flying vehicles not authorized to minimize the possible risk of sensitization and respiratory distress in humans; this is due to the lack of knowledge on the environmental fate in the aerial compartment following (repeated) treatment (tractor-mounted or hand-held sprayer allowed).</p> <p>Application to drinking water reservoirs or water intended for direct human consumption directly or indirectly, and to food crops, processed foods or surfaces likely to be used to store, process or present food, is not allowed to minimize the general population exposure.</p> <p>Products may not be authorized for uses in animal housings where exposure to a STP or direct emission to surface water cannot be prevented (no test about the elimination in STP available → worst case estimate)</p> <p>Must not be applied in animal housings with an influent to sewer system or a direct release to surface water (due to missing data on elimination in STP)</p> <p>Risks identified for the direct application of to surface water and application in animal housings via run-off of treated manure and via STP → shall be included in Annex I in professional products without specific provisions (at least one of the proposed uses does not lead to an unacceptable risks)</p> <p>Risk for several scenarios where exposure to sediment and terrestrial environment occurred → Products shall be authorized only for the identified safe use following the land application.</p>	<p>BTI H-14 Strain SA3 *)</p> <p>BTI H-14 Strain AM65-52 *)</p> <p>BTI H-14 Strain SA3 *)</p> <p>BTI H-14 Strain AM65-52 *)</p> <p>Clothianidin *)</p> <p>Imidacloprid *)</p> <p>Pyriproxyfen *)</p> <p>Triflumuron</p>
Package size		No example found
Design of the biocidal product mode of application	<p>The biocidal product shall contain an aversive agent</p> <p>For amateur uses, only ready-to-use products shall be authorised.</p>	<p>Spinosad *)</p> <p>Indoxacarb</p>
B) Application of biocidal products		
Mixing and loading	Supplied as a powder or with water soluble sachets that is diluted in water by the professional operator	Bendiocarb
Equipment		No example found
Mode of application	<p>Only for ready-for-use bait cartridge for bait stations. MS should be able to authorise ready-for-use trapping devices for non-professionals if the risks of the intended use are deemed comparable to the professional ones</p> <p>Only professional application as a gel has been claimed. Therefore, some additional risk assessment should be required if necessary</p>	<p>Diflubenzuron *)</p> <p>Fipronil *)</p>
Personal protective equipment	Operators/fumigators must wear self contained breathing apparatus and gas-tight chemical clothing when working with cylinders during introduction of gas, on initial re-entry to treated structures and when air concentrations exceed 3 mg/m ³	Hydrogen cyanide *)

	<p>Appropriate risk mitigation measures for operators and bystanders exposed on the fumigants.</p> <p>Use of phosphine realising fumigants only while applying appropriate personal and respiratory protective equipment, use of applicators</p> <p>When performing treatments, operators must wear appropriate protective gloves (representative product was a ready to use gel)</p> <p>Products intended for non-professional user should be sold together with appropriate gloves</p> <p>Coverall, respiratory mask, goggles and gloves and the washing of hands and exposed skin after use</p> <p>Good general ventilation, no respiratory protection, wear clean, long-sleeved, body-covering clothing; prevent prolonged contact (e.g. Nitrile, Neoprene, Polyvinyl chloride gloves).</p>	<p>Sulfuryl fluoride</p> <p>Aluminium phosphide</p> <p>Fipronil</p> <p>Clothianidin *)</p> <p>Silicon dioxide *)</p> <p>Spinosad *)</p>
Further RMM	<p>Removal of all food items.</p> <p>When using, do not eat, drink or smoke, remove soiled clothing immediately, Clean hands and face at work intervals and after work, work in an adequately ventilated room, do not breathe spray, wash any contamination from skin or eyes immediately, avoid excessive contamination of coveralls and launder regularly, do not contaminate foodstuffs, eating utensils or food contact surfaces, wear suitable protective clothing, gloves and eye/face protection.</p> <p>PPE for workers: Respiratory protection which offers a 10-fold protection factor, chemical resistant gloves, chemical resistant goggles, impermeable coveralls</p> <p>Unprotected persons and animals should be kept away from treated areas until dry</p> <p>Should be applied out of reach of children</p> <p>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.</p> <p>Do not handle treated fabrics (textiles except clothing and bedding) until they are dry and air thoroughly before use.</p>	<p>Sulfuryl difluoride</p> <p>Bendiocarb *)</p> <p>Bendiocarb *)</p> <p>Spinosad *)</p> <p>Indoxacarb</p> <p>Bendiocarb *)</p>
Fumigation	<p>A protective zone around the fumigated structure shall be set in such a way as to prevent a contact of bystanders with the gas during fumigation and during ventilation. Re-entry into treated structures/areas without the use of self-contained breathing apparatus is allowed only when gas concentrations are $\leq 3 \text{ mg/m}^3$</p> <p>Indirectly exposure of aquatic environment by precipitation or by descending fog → fumigation and following ventilation should thus be carried out only under favourable temperature and dissipation conditions ($> 10^\circ\text{C}$, assure that it is not raining especially in the final phase of ventilation and that there is not a high air humidity or temperature inversion which would deteriorate conditions for dispersion of ventilated hydrogen cyanide.</p>	<p>Hydrogen cyanide *)</p>

Poisoning of non target organisms	Application by scattering on surfaces cannot be considered as safe because of risk of direct poisoning of birds and mammals, unless precautionary measures are taken.	Spinosad *)
C) Post application		
Waiting period	After potential exposure to food adherence of waiting periods which ensure MRLs set out in Regulation (EC) No 396/2005. Recommendations shall be made that the treatment remains undisturbed for a minimum period (to be defined by the pest being treated against) to ensure that newly hatched offspring are exposed.	Aluminium phosphide Magnesium phosphide Bendiocarb *)
Decontamination	Only dry cleaning of the treated surfaces and disposable clothes for the applicator to be applied. In case water is used for cleaning, water emission to water bodies should be avoided.	Thiamethoxam *)
Disposal	After treatment bee nests should be removed, if possible, and disposed of in a controlled manner (i.e. Pesticide Waste Disposal Scheme)". Container and washings must be disposed of safely and in accordance with applicable regulations. The preferred options are to send to licensed reclaimer or to permitted incinerators. Paint brush and hand held sprayers are washed out with water; the washings are disposed of by pouring them onto waste ground where any remaining residues will degrade quickly on the soil. Empty packaging and used bait granules should be disposed off with normal household refuse.	Bendiocarb *) Spinosad *)
Drainage	Minimisation of the potential exposure of the aquatic environment by <ul style="list-style-type: none"> • Products shall be positioned away from external drains. • Unused products shall be disposed of properly and not washed down the drain. Do not wash into sewers and do not contaminate ponds, waterways or ditches with chemical or used container.	Indoxacarb Spinosad *)
Management of resistance	Where an extended period of control is required, treatments should be alternated with products with different modes of action. A resistance management strategy is proposed that is based on the use of two modifiers, the frequency of use and the rotation with other active substances Intensive use over a few months may lead to an increased tolerance of <i>Musca domestica</i> , or even to select resistant strains.	Bendiocarb *) Spinosad *) Triflumuron *)
D) Further regulatory options		
Non-inclusion in Annex I	Flufenoxuron as PBT/vPvB substance used against cockroaches and fleas is not considered to be safe for the environment and should can not be included in Annex I Proposed uses of Bifenthrin in insecticidal products do not fulfil the safety requirements It is proposed not to include Bifenthrin in Annex I	Flufenoxuron *) Bifenthrin *)

Comparative risk assessment	No areas of concern have currently been identified which would justify choosing carbon dioxide as a candidate for comparative assessment.	Carbon dioxide
Data package	<p>Only the professional use of diflubenzuron in a ready-for-use bait cartridge for bait stations has been evaluated at Community level. Products causing exposure to humans or the environment will require a more extensive data package.</p> <p>No test about the elimination of the a.s. in STP available → no elimination in STP considered → Risk for surface water and sediment from the use of imidacloprid in poultry stables with a wastewater discharge to STP identified</p> <p>Only professional application of the product as a gel has been claimed. Therefore, some additional risk assessment and efficacy tests should be required if necessary.</p> <p>Not all potential uses have been evaluated at the Community level. It is therefore appropriate that Member States assess those risks to the compartments and populations that have not been representatively addressed.</p>	<p>Diflubenzuron *)</p> <p>Imidacloprid *)</p> <p>Fipronil *)</p> <p>Pyriproxyfen *)</p>
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	<p>Aluminium phosphide</p> <p>Indoxacarb</p> <p>Thiamethoxam *)</p>
Monitoring	<p>Monitoring of sulfuryl fluoride concentrations in remote tropospheric air</p> <p>Regular monitoring of exposed workers/operators using sensitive TSH blood level test should be performed.</p> <p>Levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and the proximity of untreated refuse can contribute to the risk of re-infestation. In cases where label rates are correctly applied, but fail to give the expected level of control, and resistance is demonstrated, use of any product containing the same class of chemistry should cease.</p>	<p>Sulfuryl fluoride</p> <p>Hydrogen Cyanide *)</p> <p>Bendiocarb *)</p>

*) Only draft CARs analysed, conclusions might be revised after discussion at technical meetings

Annex 3: RMM proposed in PT 8 product leaflets

A) Placing on the market	
User restriction	<p>Curative preservative can only be applied by professional companies by brush, borehole impregnation or spraying in closed rooms</p> <p>For use only as a wood preservative (professional use only).</p> <p>For professional preservation specialists</p> <p>May only be used by experts from companies authorised for curative wood protection treatment</p>
Area of application	<p>Contains biocides for preventive protection of wood construction purposes against wood destroying fungi and insects. Only to be used where the protection of the wood is required.</p> <p>Do only apply where the protection of the wood is required</p> <p>Only to be applied where curative treatment is required</p> <p>Do not apply for wood intended for use in large-areas of habitable rooms or adjoining rooms unless the treated wood is covered against these rooms. ”</p> <p>Do not apply for wood intended for use in large-areas of habitable rooms or adjoining rooms unless it can be proven that this is inevitable because of structural requirements.</p> <p>Large area use is defined when a value of 0.2 m²/m³ (ratio of the treated surface to room volume) is exceeded in cubic spaces.</p> <p>Only to be applied for load-bearing and reinforcing wood building elements. Do not use on large areas in living spaces or areas where people gather unless the treated wood elements are covered dust tight on these sides. Do not use on large areas in other interior spaces unless unavoidable for technical reasons.</p> <p>Only for dipping in stationary facilities. Not to be used by coating, spraying or for vacuum pressure impregnation. Only apply for wood which moisture is below 50 %.</p> <p>Treated wood should not be used where it may come into direct or indirect contact with drinking water</p> <p>Not convenient for beehives</p> <p>Do not use treated wood for construction of those portions of beehives which may come into contact with honey</p> <p>Do not use on beehives or on the inside of greenhouses</p> <p>Do not use on beehives, green houses or saunas</p> <p>Do not apply indoors</p> <p>Certain metal products (including fasteners, hardware and flashing) may corrode when in direct contact with wood treated with copper based preservatives. To prevent premature corrosion and failure it is important to follow the recommendations of the manufacturer for all metal products. Do not use preserved wood in direct contact with aluminium.</p> <p>Only use on paved areas or on impermeable surfaces where spills of wood preservatives can be collected or bound e.g. with sawdust and disposed under controlled conditions</p> <p>Not to be applied on unpaved surfaces</p> <p>Not for wood to be used in sauna facilities</p> <p>Do not apply wood preservatives in dry interior rooms because there wood impregnation is not necessary in general. Exceptions are windows or load-bearing construction wood</p> <p>Do only apply where the protection of the wood is required</p> <p>Only to be applied where curative treatment is required</p>

Design of the biocidal product	Wood preservatives supplied in water-soluble sachets
B) Application of biocidal products	
Preparation	<p>Remove or cover all foodstuffs before application as well as fish tanks / bowls. Do not use on beehives or beekeeping equipment or apply to surfaces on which food is prepared.</p> <p>All sawdust and construction debris should be cleaned up and disposed of after construction</p> <p>Timber should be dry (water content less than 28%) de-barked and free of surface contamination before dipping.</p> <p>Remove thermal insulation in roof spaces and do not reinstate until the timbers are dry. Cover fitted insulation (lagging on pipes) with polythene and cover water storage tanks with heavy grade polythene to be left in-situ after treatment. Remove or cover all foodstuffs before application as well as fish tanks / bowls.</p> <p>Ensure that all timbers to be treated are adequately exposed and cleaned (vacuum cleaning preferred). Any paint or varnish finishes or any sapwood severely damaged edges of timbers ("frass") should be removed prior to treatment</p> <p>Before curative treatment with borehole impregnation remove insulation or bulk below the floor and build them in again only after drying. Insure that wood preservative does not run uncontrolled into the bulk.</p>
	For in-situ treatment outdoors tie back all plants and do not wet them
Information of bystander	Where applicable, notify occupants of adjoining properties before treatments commence.
Mixing and loading	<p>Wear suitable protective clothing (coveralls), synthetic rubber/PVC gloves when using, plus eye protection when diluting. Once made, ensure drums of diluted solution are properly labelled during use and in storage.</p> <p>Wood preservatives supplied in water-soluble sachets for preparing dilutions</p> <p>The electrolyte content of the water added for dilution might increase corrosivity of the dipping solution and should be assessed for suitability.</p>
Equipment for preventive impregnation	<p><u>General care for dip tanks:</u></p> <p>Cover the dipping tank when not being used to avoid moisture and/or contamination ingress. Timber must be free of sawdust etc prior to dipping. Ensure that the tank has not been contaminated as this can lead to settlement/ separation. It is advisable to use a "grate" above the bottom of the tank so that any debris is collected below. Clean and empty out the tank regularly - at least every 12 months or as required. The above advice is crucial in order to avoid possible sludging, crystallisation, flocculation and longer drying out times.</p> <p>Cover dipping tank after use</p> <p>Cover immersion tank with a floating cap. At longer hold-up periods decant wood preservatives into tightly closing containers and label them accordingly.</p> <p>Immersion tanks should preferably be made from stainless steel or other material protected against corrosion</p> <p>Timber should be dry and should be totally immersed in the solution for as long as possible (10 minutes recommended) to allow thorough penetration. Panels must be allowed to drain and dry before exposure to weathering.</p>
Mode of application	<p>Do not apply via spraying by hand</p> <p>Spraying only in closed facilities</p> <p>Do not apply by spraying considering environmental protection reasons</p> <p>Do not apply by spraying in private use because of uncontrolled breathing and contamination of the environment. Spraying only allowed in stationary facilities by professionals</p>

	<p>Spraying only in closed rooms by authorised companies when other application system are not feasible</p> <p>Application by brushing, rolling or spraying (also airless) - consider the instructions of airless spraying equipment</p> <p>Can be applied by brush, spray or used in dipping tanks.</p> <p>Application by brushing, dipping, flooding. Spraying only in closed facilities.</p>
Curative treatment against insects	<p>Insert injection syringe into boring holes and press the spray head. Remove excessive material with a clean cloth. After 78 h seal boring holes with wax lute for minimizing releases of the active substance. Put treated articles and furniture only after 7 days at the earliest into residential areas. Assure ventilation.</p>
Personal protective equipment	<p>Use of appropriate personal protective equipment for reducing human exposure at industrial and/or professional use to certain wood preservatives.</p> <p>Wear suitable protective clothing (coveralls) and synthetic rubber PVC gloves when using</p> <p>During dipping wear use respiratory protection equipment, safety gloves and goggles</p> <p>Do not breathe spray mist. Otherwise wear respiratory protective equipment and eye protection (See HSE Guidance Booklet HS(G)53: "Respiratory protective equipment - a practical guide for users")</p> <p>During spray applications some respiratory protection will normally be required.</p>
Further RMM	<p>Ensure adequate ventilation during and after treatment</p> <p>Ventilate treated areas thoroughly after application</p> <p>Provide adequate ventilation following treatments and maintain as long as possible after re-occupation</p>
Re-treatment	<p>Once existing dry rot (<i>Serpula lacrymans</i>) in walls has been killed by initial application (1-7 days) this should be removed by brushing or power hosing followed by a second application of the biocide</p>
Cleaning of the equipment	<p>Clean tools immediately after use with a thinner and dispose of the remains from cleaning properly.</p> <p>Residues from oily and nitro-containing products as well as soaked cloths and filter residues must be stored in sealed metal container outside of the building after use.</p> <p>Non-compliance might cause self-ignition.</p>
C) Post application	
Storage of treated wood	<p>To become effective the impregnated wood must be stored for 2 days, at temperatures $\leq 5^{\circ}\text{C}$ for at least 7 days protected from direct weathering.</p> <p>Fixation above 0°C after dripping terminated after 1 h. Store freshly impregnated wood protected from rain on paved surfaces.</p> <p>Wood preservative salts may be initially leached out in small amounts through rain despite their good fixation. This might result in a contamination of subjacent surfaces. This should be prevented by precautionary measures.</p> <p>Only treated wood that is visibly clean and free of surface residue should be used where contact is likely.</p> <p>Treated wood should not be used where it may come into direct or indirect contact with drinking water</p> <p>Store treated wood after impregnation protected from rain under roof or covered until the fixation is completed</p> <p>After impregnation the wood preservative can easily be leached. The operator must consider measures to avoid emissions to soil, ground water, surface water and sewers. Impregnated wood must be protected from weathering during storage</p> <p>Rapid fixation after drying. Prevent eathering during storage time of at least 2 days or 7 days at $< 5^{\circ}\text{C}$.</p>
Waiting period	<p>Preservative may be released after impregnation. For the fixation a time of around 1 h is required, independent of temperature (above zero)</p> <p>Treated timber should always be allowed to dry sufficiently before it is despatched. In general a period of not less than 24 hours should elapse. This is typically a minimum</p>

	<p>requirement and timber packs should be touch dry with no free fluid in the packs at all. It should be remembered that timber will also swell to some extent during treatment and should be allowed to dry at a natural rate until it has reached its pre-treatment moisture content.</p> <p>Unprotected persons and animals should be kept away from treated areas for 48 h or until surfaces are dry</p> <p>After curative treatment, when timbers are dry, re-occupation can normally take place 1 to 2 hours after treatments. Floor coverings should not be laid for at least 48 hours (or longer for certain sensitive floor materials, e.g. foambacked carpet etc.) In all cases, use lining papers to protect coverings from direct contact with timbers.</p>
Processing	<p>Preserved wood should not be cut or otherwise reworked as this will expose unpreserved wood. Any surface exposed by drilling or cutting must be re-treated with an approved cut end preservative. Failure to re-treat may reduce the effectiveness of the preservative treatment. Rip-sawing, thicknessing and planing are not permitted unless the timber is subsequently re-preserved to the original specification. If cutting cannot be avoided, then precautions should be taken to keep airborne dust levels below the Workplace Exposure Limit for Wood Dust. In particular, avoid inhalation of dust when using high speed cross-cut saws or mechanical sanders.</p> <p>Avoid frequent or prolonged inhalation of sawdust from wood, treated or untreated. When sawing, sanding, and machining wood, wear a dust mask. Whenever possible, these operations should be performed outdoors to avoid indoor accumulations or airborne sawdust.</p> <p>Grind only if absolutely required after painting, do not breath abrasive dust</p> <p>Cover treated masonry in habitable rooms by plaster or other materials</p>
Contact to food, feed	<p>Wood products must not come in contact with food or feedstuffs</p> <p>Do not apply on surfaces on which food is prepared</p> <p>Avoid all contact with plant life</p> <p>Do not apply for wood intended to come in direct contact with food or feed</p>
Protected animals	<p>All bats are protected. Before treating any structure used by bats consult authorities.</p>
Topcoating and covering from dust	<p>While several product leaflets refer to the possibility that the treated wood could be coated over with other coating materials after drying and checking the adhesion of the new coating, top coating as a risk mitigation measure has not been identified in product leaflets</p> <p>Cover treated wood in habitable and comparable rooms dust-tight</p>
Disposal of the biocidal product	<p>The code number of the European list of waste is 03 02 01</p> <p>Empty packages might be delivered for recycling, residues of the product must be collected at suitable gathering points (code number of the European list of waste 03 02 02)</p>
	<p>Do not dispose with household garbage but deliver to hazardous waste incineration or to pollutants collection points</p> <p>This preservative and leftover product should not be allowed to reach aquatic environments, the ground or the sewer system</p> <p>Dispose of larger quantities of leftover product in the original container in compliance with valid regulations. Completely empty containers may be recycled.</p> <p>Do not reuse empty containers. Empty containers can be sent for disposal or recycling</p>
Drainage	<p>The product and its working solutions must not be released to soil and into the sewer.</p> <p>Do not spill residues to the sink/sewer</p> <p>Must not end-up in water bodies, soil or the sewer. Do not apply in the proximity of water bodies.</p> <p>Do not contaminate water courses or ground.</p> <p>Because preservatives or sawdust may accumulate on clothes, they should be laundered before reuse. Wash work clothes separately from other household clothing.</p>

Plant and process safety	<p>For vacuum pressure treatment the facility must be operated in accordance with the requirements imposed by authorities and accident prevention & insurance associations according to applicable law, the authorisation procedure, or occupational health rules.</p> <p>Under unfavourable conditions (e.g. soft water, wood ingredients) foam formation in the facility cannot be excluded.</p>
Disposal of treated wood	<p>Treated wood should not be burned in open fires or in stoves, fireplaces or residential boilers because toxic substances may be produced as part of the smoke and ashes. Treated wood may be disposed of by complying with local landfill rules or burned in commercial or industrial incinerators or boilers when done in accordance existing regulations.</p>
Reference to further guidance	<p>The „Merkblatt für den sicheren Betrieb von Kesseldruckanlagen mit wasserlöslichen Holzschutzmitteln“ of the Deutsche Gesellschaft für Holzforschung e.V. (DGfH) should be considered.</p> <p>The „Merkblatt sicheren Betrieb von Nichtdruckanlagen mit wasserlöslichen Holzschutzmitteln“ of the Deutsche Gesellschaft für Holzforschung e.V. (DGfH) should be considered.</p> <p>The "Merkblatt für den Umgang mit Holzschutzmitteln" des Industrieverbandes Bauchemie und Holzschutzmittel e.V. provides further information</p> <p>DIN 68 800-3 (1990-04) should be considered during application.</p> <p>Beschichtungen auf Holz und Holzwerkstoffen im Außenbereich (Stand: März 2006) Technischen Richtlinien für Maler- und Lackiererarbeiten Nr.18. (BFS-Merkblätter of the Bundesausschuss Farbe und Sachwertschutz)</p> <p>The "Code of Practice for Handling Wood Preservatives" issued by the industrial association, Deutsche Bauchemie e.V., provides comprehensive information</p> <p>The provisions in DIN 68 800-4: 1992-11-"Wood Preservation; Control measures against fungi and in-sects that damage wood" apply for control measures with this wood preservative</p> <p>For general guidance consult the HSE Guidance consult the HSE Guidance Note "Remedial Timber Treatment in Buildings" (HSE Books, ISBN 0-11-885987-0)</p> <p>For use of masonry biocides as for the control of dry rot consider the BWPDA Code of Practice for Remedial Timber Treatments</p> <p>Where damp conditions are likely to persist, timbers should be treated by industrial pre-treatment as detailed in BS 5589: 1989 Code of practice for preservation of timber.</p>

Annex 4: RMM proposed in PT 18 product leaflets

A) Placing on the market	
User restriction	<p>For use only by professional operators</p> <p>For Amateur use</p> <p>Use only by certified experts according to the Ordinance on Hazardous Substances</p>
Intended uses and area of application /	<p>For indoor use only</p> <p>Do not use on filter beds at sewage treatment works</p> <p>Can be used in buildings including domiciles, apartment buildings, hotels, restaurants, hospitals, food factories, store houses, vessels and aircrafts</p> <p>For use only as an insecticide</p> <p>Do not use in living quarters</p> <p>Not large scale use in sensitive areas like sickrooms, kinder garden, schools, living quarters, bureaus etc. allowed. Spray directly all hiding places and the direct surrounding areas</p> <p>Use in technical areas, depots, basements etc.</p> <p>Especially applicable in sensitive areas like kinder gardens, schools, pet shops, zoological gardens, food companies, electronic rooms</p>
Design of the biocidal product mode of application	<p>WSS (water soluble sachet). WSS insecticidal treatment is based on the novel water internal microemulsion technology in which all organic solvent components are removed from the formulation</p> <p>Professional monitoring trap with water resistant synthetic material. Long durability by fungicidal finish</p> <p>Product is not a formulated pesticide. It consists of an attractive adhesive matrix on a white PET/Cardboard/PET backing layer.</p> <p>The monitoring box can be used for integrated monitoring/control of insecta and mice activity</p> <p>Detailed description of the application of an insecticide lacquer to avoid overdosing</p> <p>A new micro-encapsulated water-based product. The formulation is especially effective on difficult surfaces</p> <p>The ultra-low-volume technique can be used most efficiently due to the extremely small aerosol droplets</p> <p>A completely physical mechanism which desiccates the insects</p> <p>A gel-bait which can be easily applied and is active in small quantities.</p> <p>A special robust polyurethane foam with a natural flavour to deter insects from trespassing.</p> <p>A ready to use lacquer spray to be used for selective spraying of barriers with the direction not to use it as a space spray</p> <p>Re-useable canister. Send back for refilling</p> <p>One or more special spray nozzles are included and described in detail in the product leaflet for the proper use.</p> <p>Possibility of automatic fumigation.</p> <p>A red dye included in the gel to see clearly where gel has already been applied and is still present.</p> <p>Micro-emulsion, water-based, more efficient due to effective dispersion of the active ingredient.</p> <p>Pigs lick residues of the biocide containing cyanamide (larvicide) which therefore should be removed with water from the floor. A blue colour indicator is used to detect residues of the biocidal product</p>
B) Preparation and application of biocidal products	
Mixing and loading	<p>Sealed water soluble sachets contain a measured quantity of insecticide concentrate. Therefore no exposure is expected and no measuring is necessary and there will be no residues like in conventional concentrate bottles.</p>

Resistance Management	<p>Space sprays containing pyrethrins or pyrethroids must not be used more than once a week against house flies in intensive or controlled environment animal houses as they could cause control failure due to resistance. If more frequent treatments are required use a product with a different active ingredient and if necessary a different method of control (such as a bait).</p> <p>The active component belongs to a new class of insecticides, the neonicotinoids with a different mode of action to other classes of insecticide such as pyrethroids and organophosphates. The use pattern as a gel ensures that the majority of the public hygiene is not treated thereby reducing the likelihood of contacting a sub lethal deposit. Nevertheless, to minimise the chances of either behavioural or active ingredient resistance developing in the future, it is advisable to avoid using it exclusively and continuously as the sole agent for cockroach control. It should be used as one component of an integrated pest management program which features gel formulations with different food bases, and products from alternative chemical classes with different application methods, such as residual sprays.</p> <p>Some producers describe to use different applications like gel and spray and/or products with different active ingredients to minimise resistance of insects.</p>
Equipment	<p>Profi-aerosol spray</p> <p>Special dispensers can be programmed with a timer to use the products during the maximum activity of the insects</p> <p>Dosage help and proportioner device</p> <p>Use of special apparatus like cartridge guns</p>
Preparation and application	<p>For the control of flying insects, close all doors and windows and direct spray upwards into the centre of the room with a slow sweeping motion, 5-10 seconds in an average room (30 m³). Vacate room and keep door closed for 15 minutes. Ventilate before re-entry.</p> <p>Cover damageable surfaces. Do not spray in or around electronic equipment. To avoid flammable air vapour mixtures adequate ventilation is necessary</p> <p>Should be applied to all areas where insect pests are found, particularly hiding places and runways. Exposed areas and cracks and crevices should be treated with the spray and the powder should be applied to inaccessible areas such as service ducts, roof voids and around electrical equipment where spraying is undesirable. Where access is particularly restricted, such as behind wall or bath panelling, drill a small hole, blow in the powder and reseal.</p> <p>Cut or tear open one end of the paper sachet. Remove but do not open the soluble sachet. Do not touch the water soluble sachet with wet hands or wet gloves. Add the required number of soluble sachets to the water.</p> <p>Cartridges are designed for the controlled placement of an insecticidal bait</p> <p>Do not use in rooms with more than 35° C. Do not fumigate without being present (no automatic fumigation)</p> <p>Ready to use cold and hot fumigation products for the use for flying and crawling insects</p> <p>Do not spray insecticides on or around bait gels or place it on recently treated surfaces, as this may discourage cockroaches from feeding on it.</p>
Personal protective equipment	<p>Personal protective equipment is described in the labels, technical leaflets and safety data sheets</p>
Further RMM	<p>Many producers provide background information with their product leaflets also on preventive measures to avoid pests.</p> <p>Sealing and elimination of hiding places, regular cleaning measures, control of goods, ideal storing conditions.</p> <p>Modern building technique creates a lot of "biotopes" e.g. in built-in furniture, insulating wall panels, suspended ceilings, installation slots</p> <p>It is helpful to evaluate before performing any pest control measure which and how many insects are present. Suitable tools for this are pheromone and adhesive traps.</p>

Poisoning of non target organisms	<p>Cover all water storage tanks before application</p> <p>Avoid all contact with plant life</p> <p>Remove or cover fish tanks and bowls before application. Cut aeration</p> <p>Seal areas to be treated as effectively as possible. Close doors and windows block fireplaces and exclude draughts. Clear people, plants and animals including fish from the area to be treated. Do not apply smoke in the presence of plants. Ventilate treated areas thoroughly after treatment Do not disturb bats or their roosts.</p> <p>Prevent access to bait by children, birds and non-target animals (particularly dogs, cats and pigs).</p> <p>When treating wild bee nests action should be taken to prevent foraging bees gaining access to treated nests preferably by removing the combs or blocking nest entrances.</p>
C) Post application	
Waiting period	<p>The waiting time is mentioned in many different product information sheets depending on the active ingredient and application.</p> <p>Hydrogen cyanide fumigant is high solubility in water. Thus wash out with rain during ventilation must be avoided</p>
Decontamination	<p>Cleaning measures are described very rarely in product information sheets. In very few cases cleaning procedures are presented very detailed for different surface materials. In other also very few cases suitable decontamination measures are recommended but must be asked at the company. Sometimes it is suggested to clean areas, clothing, seating furniture where contact with the skin is expected frequently, with alkaline cleaning agents.</p>
Disposal	<p>Do not contaminate water, food or feed by storage or disposal. Excess product and rinse water has to be disposed according to local regulations for disposal. A small quantity will likely remain in the container; this container should be triple rinsed and the rinse water should be treated as waste.</p> <p>To ensure that containers are not reused, they should be pierced before disposal.</p> <p>Do not allow remaining product residues and empty containers to get into surface water, drains and ground water.</p> <p>Disposal of residues of active ingredients, rinsing water, empty containers etc. in accordance with current regulations</p> <p>Everything like apparatus and containers which were in contact with the product has to be cleaned thoroughly.</p>
Reference to further guidance	<p>Do not breathe dust. Otherwise wear respiratory protective equipment and eye protection (see HSE Guidance Booklet HS(G) 53: "The Selection, Use and Maintenance of Respiratory Protective Equipment – A Practical Guide).</p> <p>Guidance on cleaning of grain stores can be obtained from the 'The grain storage guide' published by the Home-Grown Cereals Authority (HGCA)</p>