Umweltforschungsplan
des Bundesministeriums für Umwelt,
Naturschutz und Reaktorsicherheit

Förderkennzeichen (UFOPLAN) FKZ 3710 67 406

Efficiency and practicability of risk mitigation measures for biocidal products with focus on disinfectants

Final report

Dr. Stefan Gartiser (project direction)
Ismene Jäger

Hydrotox GmbH, Freiburg

ON BEHALF OF THE FEDERAL ENVIRONMENT AGENCY

Freiburg, 19th November 2012

Berichts-Kennblatt

1. Berichtsnummer	2.	3. IV 1.2 Biozide

4. Titel des Berichts
Effizienz und Praxisnähe von Risikominderungsmaßnahmen für Biozidprodukte mit Schwerpunkt auf Desinfektionsmitteln“

5. Autor(en), Name(n), Vorname(n) Dr. Stefan Gartiser (Projektleitung) Ismene Jäger	8. Abschlussdatum 19.11.2012
	9. Veröffentlichungsdatum
6. Durchführende Institution (Name, Anschrift) Hydrotox GmbH, D-79111 Freiburg, Bötzinger Str. 29	10. UFOPLAN-Nr. FKZ 3710 67 406
	11. Seitenzahl 69
7. Fördernde Institution (Name, Anschrift) Umweltbundesamt, Postfach 14 06, 06813 Dessau-Roßlau	12. Literaturangaben 88
	13. Tabellen und Diagramme 16
	14. Abbildungen 3

15. Zusätzliche Angaben

16. Kurzfassung

Ziel des Forschungsvorhaben war es, geeignete Lösungsansätze zur Vermeidung/Reduzierung identifizierter Risiken aufzuzeigen und Risikominderungsmaßnahmen (RMM) zusammenzustellen, die für eine EU-weit harmonisierte Bewertung von Biozidprodukten benötigt werden. Hierzu wurden die von Herstellern, Verwendern und Bewertungsbehörden vorgeschlagenen RMM zusammengestellt und bewertet, wobei der Fokus auf Umweltrisiken lag. In diesem Zusammenhang wurden Produktart-spezifische “Guidance Dokumente“ erarbeitet, die von den zuständigen Behörden auf EU-Ebene diskutiert werden.

Viele Desinfektionsmittelwirkstoffe werden während des Gebrauchs inaktiviert oder sind leicht biologisch abbaubar. Eine Neutralisation/Inaktivierung der Wirksubstanzen wird manchmal als RMM durchgeführt, insbesondere bei starken Säuren, Basen oder oxidierenden Mitteln. Die meisten Desinfektionsmittel sind so bestimmt, in kommunalen Kläranlagen inaktiviert zu werden. Desinfektionsmittel für die Tierhygiene (PA 3) und den Lebens- und Futtermittelbereich (PA 4) werden z.T. auch in Abwasserbehandlungsanlagen vor Ort behandelt. Viele Desinfektionsmittel enthalten Detergentien oder andere Begleitstoffe, von denen eine höhere Umweltbelastung ausgehen kann, als von den eigentlichen Wirkstoffen. Die Bildung von Desinfektionsmittel-Nebenprodukten sollte unter den Einsatzbedingungen aller Biozidprodukte mit oxidierenden Wirkstoffen bewertet werden.

Bei der Auswahl von RMM sollten realitätsnahe Optionen, die den besten Techniken und Praktiken entsprechen, berücksichtigt werden. Gegebenenfalls ist eine Erfolgskontrolle durch die Behörden erforderlich. Es wird zwischen allgemeinen RMM und speziellen RMM unterschieden. Allgemeine RMM beziehen sich auf die Anwendung bester Praktiken, eine gute Betriebsführung etc. Spezifische RMM werden über die Umweltrisikobewertung abgeleitet. Eine quantitative Bewertung der Effektivität und Praktikabilität spezifischer RMM und die Möglichkeit ihrer Durchsetzung sind für eine quantitative Berücksichtigung im Rahmen der Risikobewertung erforderlich. .

17. Schlagwörter
Biozide, Biozid-Produkte-Richtlinie, Desinfektionsmittel, Risikominderung
Beste Techniken, Risikowahrnehmung

18. Preis	19.	20.

Report Cover Sheet

1. Report No.	2.	3. IV 1.2 Biocides

4. Report Title

Efficiency and practicability of risk mitigation measures for biocidal products with focus on disinfectants

5. Author(s), Family Name(s), First Name(s)
Dr. Stefan Gartiser (project direction)
Ismene Jäger

6. Performing Organisation (Name, Address)

Hydrotox GmbH, D-79111 Freiburg, Bötzinger Str. 29

7. Funding Agency (Name, Address)
Umweltbundesamt (Federal Environmental Agency)
Postfach 14 06, 06813 Dessau-Roßlau

8. Report Date
19.11.2012

9. Publication Date

10. UFOPLAN-Ref. No.
FKZ 3710 67 406

11. No. of Pages
69

12. No. of Reference
88

13. No. of Tables, Diagrams
16

14. No. of Figures
3

15. Supplementary Notes

16. Abstract

The aim of the project was to identify appropriate solutions for avoidance or reduction of identified risks of disinfectants and to compile risk mitigation measures (RMM) required for an EU-wide harmonised assessment of biocidal products. To this end, RMM proposed by producers, industrial/professional users, and authorities have been collected and analysed with focus on the mitigation of environmental risks. In this context, product type specific RMM guidance documents have been developed and were discussed among competent authorities.

Many disinfectant active substances are inactivated during use or are readily biodegradable. Neutralization of the active substance(s) is a RMM sometimes applied for strong acids/bases or oxidising agents. Most disinfectants are designed to be inactivated in municipal sewage treatment plants. Disinfectants for veterinary hygiene (PT 3) and in the food industry may also be treated in on-site STPs (PT 4).

Many disinfectants also contain detergents and other ingredients that may be of higher environmental concern than the active substances themselves. The formation of disinfection by-products under the use conditions should be considered in the assessment of all biocidal products with oxidising active substances.

The selection of RMM should consider realistic options which reflect best techniques/practices and may require some surveillance by authorities. It is distinguished between general RMM and specific RMM. General RMM refer to the application of best practices, good housekeeping etc. Specific RMM are derived from the environmental risk assessment. A quantification of the efficiency and practicability of specific RMM and an evaluation of the possibility of enforcement of RMM are required, in order to be quantitatively considered in the risk assessment.

17. Keywords
biocides, Biocidal Products Directive, disinfectants,
best practices, risk awareness

18. Price	19.	20.

Contents

The draft guidance documents on environmental risk mitigation measures for

- human hygiene biocidal products (PT 1)
- disinfectants used in the private and public health area and other biocidal products (PT 2)
- veterinary hygiene purposes (PT 3)
- food and feed area disinfectants (PT 4)
- drinking water disinfectants (PT 5)

are currently being discussed among Competent Authorities. The drafts may be requested at the German Environment Agency, e-mail: einvernehmensstellebiozidg@uba.de.

List of Figures

List of tables

List of Abbreviations

AOX	Adsorbable Organic Halogens
BAT	Best Available Techniques
BMU	German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit)
BPD	Biocidal Products Directive
BPR	Biocidal Products Regulation
BREF	Best Available Technique Reference Documents
CA	Competent Authority
CAR	Competent Authority Report
CEFIC	Conseil Européen de l'Industrie Chimique
CIP	Cleaning in Place
CIRCA	Communication & Information Resource Centre
CLP	Regulation (EC) on Classification, Labelling and Packaging of Substances and Mixtures No 1272/2008
CMR	Carcinogenic, Mutagenic, or toxic for Reproduction
CSR	Chemical Safety Report (REACH)
CVMP	Committee for Medicinal Products for Veterinary Use
DAR	Draft Assessment Report
DBP	Disinfection by-Products
DEFRA	Department for Environment, Food and Rural Affairs (UK)
DU	Downstream user (REACH)
DWA	Deutsche Vereinigung für Wasserwirtschaft, Abwasser und Abfall e.V. (German Association for Water, Wastewater and Waste)
ECHA	European Chemicals Agency
ESComPhrases	Standard Phrases for Exposure Scenarios *(CEFIC)*
eSDS	extended Safety Data Sheet (REACH)
DLG	Deutsche Landwirtschafts-Gesellschaft (German Agricultural Society)
DOC	Dissolved Organic Carbon
ESD	Emission Scenario Document
eSDS	Extended Safety Data Sheet
ESIS	European chemical Substances Information System
EU	European Union

EuPhraC	European Phrase Catalogue
FAO	Food and Agriculture Organization of the United Nations
FIOSH	German Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, BAuA)
GP	Good Practice
HACCP	Hazard Analysis and Critical Control Points (Regulation (EC) No 852/2004)
MS	Member State
OCs	operational conditions (of use) (REACH)
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
PT	Product Type
QAC	Quaternary Ammonium Compounds
RABC	Risk Analysis and Biocontamination Control (EN 14065)
REACH	Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk mitigation measure
RMS	Rapporteur Member State
SDS	Safety Data Sheet
SP	Safety precautions (*Annex V Directive 91/414/EEC)*
SpERCs	Specific Environmental Release Categories *(CEFIC)*
STP	Sewage treatment plant
SVHC	Substance of very high concern
THM	Trihalomethanes
TOC	Total organic carbon
TNsG	Technical Notes for Guidance
TRGS	Technische Regeln für Gefahrstoffe (Technical Rules for Hazardous Substances)
UBA	Federal Environment Agency (Germany)
UK	United Kingdom

WHO	World Health Organisation

0 Introduction

In assessing the impact of biocides to the environment, specific measures to reduce a possible risk to the environmental compartments may be required. First experiences in the evaluation of active substances showed that the rapporteur member states (RMS) have followed different approaches of risk mitigation measures (RMM) for a given risk to the environment. The absence of a coordinated approach to RMM during the assessment of active substances raises the concern that the discussion of the problem is postponed to the phase of the national product authorisation. Due to the short deadlines foreseen for mutual recognition of product authorisations this is a critical point because at this stage a harmonisation of RMM is difficult to realise.

Within a preceding research project, sponsored by the German Federal Environment Agency (FKZ 3709 65 402), the RMM proposed by authorities, industry, and associations were systematically analysed in terms of efficiency and practicability on the example of wood preservatives (PT 8) und insecticides (PT 18) (Gartiser et al. 2011).[1] In the follow-up project, the potential of risk mitigation has been studied on the example of product types (PT) 1 to 5 ("disinfectants and general biocidal products"). The aim of this research project is to identify appropriate solutions for avoidance/reduction of identified risks of disinfectants and to compile RMM required for an EU-wide harmonised assessment of biocidal products. To this end, RMM proposed by producers, industrial/professional users, and authorities have been collected and analysed.

Although these measures have often been developed in terms of occupational health and safety and as these can hardly be separated from proposals to minimise environmental risks, this project focuses on the mitigation of environmental risks.

With respect to risk mitigation preferably the entire lifecycle of a biocidal product should be considered. This means the life cycle steps from the formulation, the placing on the market until the application, the use phase, and the final disposal. However, the main emphasis was put on the use phase of biocides.

The project duration was from November 2010 until October 2012. The working plan was updated in line with the results of an European workshop on RMM for biocide use, held in February 2011 at the German Federal Environment Agency in Dessau, became available. The actualised project objectives are the development of product-type specific "guidance documents", with precise proposals for RMM for each PT. One result of the RMM-workshop was that a standardisation of RMM-phrases is meaningful. The description of general and specific RMM-phrases is required as a complement to the demands of the CLP-regulation. As a result a set of guidance documents with concrete proposals has been drafted which are being discussed by Competent Authorities.

[1] http://www.uba.de/uba-info-medien-e/4053.html

1 Data sources

1.1 Emission scenario documents

Several Emission Scenario Documents (ESDs) have been published by the European Commission which provide an overview on the most relevant uses of disinfectants.[2]

Table 1: Overview of emission scenarios for disinfectants

PT	Title	Reference
1	**Human hygiene biocidal products**	EUBEES 2 (Royal Haskoning, 2004)
2	**Private area and public health area disinfectants and other biocidal products**	RIVM report 60145008 (2001)
	Swimming pools	RIVM report 601450 009, 2002
	Sanitary sector	EUBEES 1 (RIVM report 601450 008, 2001) RIVM report 601450 009, 2002
	Horticulture	RIVM report 601450 009, 2002
	Tiles and surfaces	RIVM report 601450 009, 2002
	Medical sector	
	Disinfection of rooms, furniture and objects	EUBEES 1 (RIVM report 601450 008, 2001)
	Disinfection of instruments	RIVM report 601450 009, 2002 EUBEES 1 (RIVM report 601450 008, 2001) RIVM report 601450 009, 2001
	laundry disinfectants	EUBEES 1 (RIVM report 601450 008, 2001) RIVM report 601450 009, 2002
	hospital waste disinfectants	Supplement to the ESD for PT 2 (SCC, 2011) EUBEES 1 (RIVM report 601450 008) RIVM report 601450 009, 2002
	disinfection of air conditioning systems	Supplement to the ESD for PT 2 (SCC, 2011) RIVM report 601450 009, 2002
	Disinfection in *industrial and institutional* areas	Supplement to the ESD for PT 2 (SCC, 2011)
	Disinfectants for sewage and wastewater	RIVM report 601450 009, 2002
	Soil and other disinfectants	RIVM report 601450 009, 2002
	Disinfection of chemical toilets	Supplement to the ESD for PT 2 (SCC, 2011)
3	Veterinary hygiene biocidal products:	
	Disinfection of animal housing	ESD for PT 3 (SCC, 2011)
	Vehicles used for animal transport	ESD for PT 3 (SCC, 2011)
	Disinfection of footwear and animals' feet	ESD for PT 3 (SCC, 2011)
	Non-medicinal teat dips	ESD for PT 3 (SCC, 2011)
	Disinfection of milk extraction systems	RIVM report 601450 009, 2002
	Disinfection of hatcheries	ESD for PT 3 (SCC 2011)
	Disinfection of fish farms	No separate scenario available
4	Food and feed area disinfectants	
	Food, drink and milk industries	ESD for PT 4 (SCC, 2011)
	Large catering kitchens, canteens, slaughterhouses and butcheries	ESD for PT 4 (SCC, 2011)
	Disinfection of milking parlour systems	ESD for PT 4 (SCC, 2011)
5	Drinking water disinfectants	EUBEES 2 (UBA report, 2003)

Further guidance has been provided at a workshop on environmental risk assessment for PT 1-6 held in Arona, Italy in 2008.[3]

[2] http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/emission-scenario-documents

For the main uses of disinfectants ESDs are available. The ESDs do not include RMM which may be considered during the authorisation of biocidal products, but they provide useful background information on the main emission routes and related literature (see chapter 2).

1.2 Evaluation of (Draft) Assessment Reports

In the Inclusion Directives, which approve active substances for Annex I listing and their use in biocidal products, suitable measures to reduce risks are described. Only active substances of PT 8, 12, 14, 18, and 19 have been included in Annex I of Directive 98/8/EC so far.[4] The only active substance included into Annex I of the BPD for PT 1-5 until June 2012 is Hydrochloric acid (PT 2).[5] Thus, only one Inclusion Directives, describing risk mitigation measures to be considered during the authorisation of disinfectants (PT 1-5) are available so far (CIRCA visited 28.6.12). However several (Draft) Competent Authority Reports (CARs) for disinfectants are currently being discussed (Table 2).[6]

Table 2: (Draft) Competent Authority Reports for active substances of PT 1-5

	PT 1	PT 2	PT 3	PT 4	PT 5
Benzoic acid			X	X	
Bromoacetic acid				X	
Calcium hypochlorite		X	X	X	X
Chlorine		X			X
Decanoic acid				X	
Didecylmethylpoly(oxyethyl)ammonium Propionate		X		X	
Hydrochloric acid		X			
Iodine, PVP-iodine	X		X		
Magnesium-monoperoxyphthalate-Hexahydrate		X			
Nonanoic acid		X			
Octanoic acid				X	
Perestane		X			
Sodium hypochlorite	X	X	X	X	X

Source: EC Communication & Information Resource Centre Administrator https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp

A preliminary summary of these CARs with respect to RMM is shown in Table 3. Here, the conclusions of the Competent Authorities are documented without being critically assessed by the consultant.

[3] http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/emission-scenario-documents

[4] http://tcsweb3.jrc.it/esis/ and http://ec.europa.eu/environment/biocides/annexi_and_ia.htm visited 28.6.12

[5] See http://esis.jrc.ec.europa.eu/index.php?PGM=bpd and Inclusion Directive 2012/16/EU.

[6] http://circa.europa.eu/Public/irc/env/bio_reports/library?l=/review_programme/ca_reports

Table 3: Preliminary analysis of CARs for active substances of PT 1-5

Active substance (RMS)	CAS	Uses, identified risks, specific provisions, RMM
Benzoic acid PT 3, 4 (Germany)	65-85-0	Used for surface treatment in animal premises. No environmental risks identified. In consequence no environmental RMM required.
Bromoacetic acid PT 4 (Spain)	79-08-3	Used exclusively in breweries for cleaning in place (CIP). Readily biodegradable. RMM to be proposed by the applicant should reduce the concentration in the effluent in the STP to reach a yield PEC/PNEC <1. Therefore, control of the concentration in effluent, of releases to water should be applied. Annotation during the Review process from the German MS: Proposed RMM: Concentration of a.s. in the effluent of the STP should be smaller as xy mg/L. This trigger value should not exceed and could be controlled with monitoring data from the effluent of a STP. Only for disinfectant in food and feed area, especially in breweries. Only for professional users.
Decanoic acid PT 4 (Austria)	334-48-5	Used as CIP disinfectant in food, drink and milk industries, STP considered as main receiving compartment. Slight risk to aquatic organisms identified, which is considered acceptable because a degradation during or after application (before release to the sewer system) is not considered, but expected and no degradation in surface water was considered though it is ready biodegradable. Further dilution in a river is also not considered. No specific provisions and RMM for the environment proposed.
Perestane PT 2 (Hungary)	84781-03-8	Used as private area and public health area disinfectants and other biocidal products. Professional use for CIP in pharmaceutical and cosmetic industry as well as for the disinfection of medical equipment (endoscopes). No concern for the environment in surface waters or sediment. Consequently, RMM are not necessary.
Didecylmethyl-poly(oxyethyl) ammonium Propionate PT 2, 4 (Italy)	94667-33-1	Used for private and public health areas, medical equipment, chemical toilets with preventive efficacy against bacteria and fungi (PT 2) and as surface disinfectant in food and feed area (PT 4). As regards the environmental risk assessment, for some usage scenarios a risk can be identified for the aquatic and the terrestrial compartments. Anyway, the PEC values have been derived for a worst case scenario only considering default values. Therefore, the PEC/PNEC ratios can be regarded as an overestimate and a more realistic worst case could be obtained by applying refinement values. No specific provisions and RMM for the environment. May be used in hard surface and instrument disinfection and chemical toilet disinfection by professional and non professional users.
Magnesium-monoperoxyphthalate-Hexahydrate PT 2 (Poland)	84665-66-7	Used as a broad-spectrum microbiocide for the disinfection of surfaces, inanimate objects and materials and equipment in private and public health areas. No risk to aquatic and terrestrial compartment expected in the biocidal products investigated (hard surface disinfectant in health care areas). In consequence no environmental RMM proposed. Non powder formulation; generation of dust should be avoided, e.g. by the use of formulations as coated granulates in dosed sachet to avoid/reduce the emissions to the air. Only for use as aqueous solution; -indoor use only;-professional uses only.
Nonanoic acid (Pelargonic acid) PT 2(Austria)	112-05-0	Used for reduction of suspended and other algae in garden ponds not intended for swimming. Outdoor use as algaecide in garden ponds. Hence the active substance will not pass through a wastewater treatment plant. Acceptable risk to aquatic

Active substance (RMS)	CAS	Uses, identified risks, specific provisions, RMM
		and sediment dwelling organisms, even in a very worst case estimation. In consequence no elements to be taken into account by member state (MS) when authorising products. No RMM for the environment proposed.
Calcium hypochlorite PT 2-5 (Italy)	7778-54-3	Bactericide, fungicide or virucide, also inactivates prions. For professional, industrial and private uses. Highly reactive compound, reacts rapidly with organic matter in the sewer, STP, surface water and soil. Kinetic model shows that hypochlorite is eliminated during transport in the sewer within the first minutes. No specific elements should be taken into account at product authorisation level. No RMM for the environment proposed.
Chlorine PT 2, 5 (Italy)	7782-50-5	Used for disinfection of swimming pools, public pools, sewage/ waste water, and drinking water Chlorine is a highly reactive compound, which reacts rapidly in the atmosphere, in soil, and in the sewer with organic matter. Acceptable risk in all relevant product types (PT 2 and PT 5) (PEC/PNEC < 1). No specific elements to be taken into account at product authorisation level. No RMM for the environment proposed.
Hydrochloric acid PT 2 (Latvia)	7647-01-0	For use as private area and public health area disinfectants and other biocidal products (disinfection of air, surfaces, materials, equipment and furniture) as well as products used as algaecides. Amateurs use only indoors, no direct exposure of the outdoor environment. Not classified as harmful for the environment. No environmental emissions are expected upon use of the product and thus no risks to the environment have been identified. No RMM for the environment proposed.
Iodine PVP-iodine PT 1, 3 (Sweden)	7553-56-2 25655-41-8	Representative biocidal product contains an iodophor, i.e. iodine complexed with Polyvinylpyrrolidone. Used as liquid hand disinfectant (PT 1) and manual non-medical teat disinfection and surface disinfection in animal houses (PT 3). It is likely that the magnitude of the natural occurrence of iodine species in the environment renders for example the formation of methyl iodide from biocidal use of iodine to be insignificant. Risks identified for surface water, soil and groundwater. However, the calculated PECs are well within the natural background levels and iodine is an essential element to both animals and plants. Thus the standard assessment factors applied may be considered as overly conservative. The actual risks should be considered to be acceptable. No environmental RMM proposed. Only to be used by professionals.
Octanoic acid (Austria)	124-07-2	Use as disinfectant for CIP treatment, STP is considered as the main receiving compartment. A slight risk to aquatic organisms was identified, however, it is considered acceptable because degradation during or after application (before release to the sewer system) is not considered, but expected and because no degradation in surface water was considered though it is ready biodegradable. Further on dilution in a river is also not considered. No environmental RMM proposed.
Sodium hypochlorite PT 1-5 (Italy)	7681-52-9	Used for disinfection of skin and textiles during washing process (PT 1), for disinfection of surfaces in industrial, public and health care and domestic areas, for treatment of sewage / waste water including municipal waste water and public and private swimming pools (PT 2), for disinfection of animal houses and transport facilities (PT 3), for surface disinfection in food and feed industry by spraying and wiping (PT 4), and for disinfection of drinking water (PT 5). In water, in the sewer and during sewage treatment, the concentration is calculated to drop down to "zero" within a few minutes after release into the sewer. In soil, free active chlorine reacts rapidly with organic matter.

Active substance (RMS)	CAS	Uses, identified risks, specific provisions, RMM
		The ultimate fate of hypochlorite in soil is its reduction to chloride. Acceptable risks identified (PEC/PNEC <1). No specific elements should be taken into account at product authorisation level. No RMM for the environment proposed.

From the CARs available so far the following conclusions can be drawn:

- For most active substances no concern for the environment has been identified for the uses considered (without taking into account possible aggregated exposure) and in consequence no specific elements are to be taken into account at product authorisation level.
- For some active substances a slight risk has been identified which has been considered as being acceptable because the worst case scenarios applied were regarded as overestimate of risks.
- For active substances for which the risk quotient is close to 1 only unspecific requirements have been established (e.g. CIP treatment with Bromoacetic acid). It is mentioned that the "applicant should propose RMM that reduce the concentration in the effluent to the STP thus that the PEC/PNEC is below 1. This has to be a controlled by monitoring."
- Disinfectant-by-products resulting e.g. from chlorine, bromine and iodine releasing compounds are not considered in the risk assessment.
- Some RMM such as "only for professional uses" or "only for use in closed automats" are described in the "elements to be taken into account by Member States when authorising products" (e.g. Perestane).

1.3 Research projects of the Commission

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".

The COWI study concluded that for Europe the largest use area for biocides are disinfectants in private and public health areas (PT 2) where about 50% of the overall tonnage from all biocidal actives is consumed. These data have been provided to the European Chemicals Bureau by companies for the notification of active substances. Similar figures are found in a Danish study on consumption of biocides (Lassen et al. 2001). Generally disinfectants such as sodium hypochlorite, chlorine and hydrogen peroxide are the three substances with the highest production volumes of all substances, approximately 54% of the total tonnage registered (almost 400,000 t) (COWI 2009). In May 2010 from all 270 active substances included in the review programme the following numbers were supported in PT 1-5 (Table 4):

Table 4: Active substances supported for PT 1-5

						PT – active substance combinations	
PT	1	2	3	4	5	PT 1-5	total PT 1-23
Number of active substances per PT [1)]	38	87	55	56	21	257	716
Consumption [% of all active substances] [2)]	4.6	50.5	2.7	4.2	12.3	74.3	100 (399,000 t)

Sources: [1)] European Commission, May 2010

[2)] COWI (2009)

In 2010, the Commission contracted a study "Towards the development and dissemination of best practice on sustainable use of biocidal products". The objective of this study is to identify the existing best practices for all 23 PT that have been developed by the competent authorities of MS or industry in order to ensure a sustainable use of biocidal products. Furthermore, the study examines the ways how the concept of best practices could be best adapted and used at the EU level. The information aims supporting the Commission in deciding what role the best practices shall play in any future policy on the sustainable use of biocidal products. About 300 best practice documents to be applied for PT 1-5 have been identified in this study, of which 37 may be considered as standards (Zamparutti et al. 2010).

1.4 Research projects of competent authorities

The German Competent Authorities initiated several research projects related to the implementation of the Biocidal Product Directive (ULIDAT data source, http://doku.uba.de/). Also the German Federal Institute for Occupational Safety and Health (FIOSH) realised several research projects concerning 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 RMM (Gartiser et al 2000, Hahn et al. 2005, Bleck et al. 2008, Schneider et al. 2008, Gartiser 2011). The results of the research projects have been summarised in chapter 3. In another research project on occupational exposure and safe use of biocides, disinfectants of PT 2 to PT 5 have been identified as biocidal products placed on the market mainly as concentrates (Müller and Bleck 2008). For consumers mainly ready to use products are marketed. Best available techniques and best practice examples were documented and presented as guidance sheets. For example, the installation of automatic dosage equipment is preferred, manual mixing and loading increases the potential of human exposure and mal-dosage. Automatic dosage equipment might also lead to reduced emissions to the environment. As a rule, the concentrate should be added to the water and not contrawise, in order to avoid non-controllable exothermic reactions. One advantage of automatic dosage is that the concentrates were only handled when containers were changed. For these scenarios ways of optimization were identified especially with regard to the positioning of the containers and the techniques of loading. Environmental impact concerning the discharge of working solutions or concentrates to wastewater was not analysed within that project (Müller et al. 2008).

Within the project on environmentally compatible cooling water treatment chemicals also cooling water biocides have been analysed which are attributed to PT 11 (Gartiser et al. 2002). This PT has not been included in the study. However, many of the active substances are also

used in other water treatment processes such as swimming water treatment. Among the oxidative biocides chlorine or chlorine bleach (sodium hypochlorite) are applied, next to hypobromous acid which in contrast to chlorine is still effective at pH 9. In open recirculation cooling systems also organic chlorine and bromine release agents such as 1-bromo-3-chloro-5,5-dimethylhydantoin (BCDMH) and non-oxidative biocides such as 5-chlorine-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one, quaternary ammonium compounds (QAC, e.g. Alkyldimethylbenzylammonium chloride), and Dibromonitrilopropionamide (DBNPA) are applied. Especially after direct discharge of cooling water to surface water the biocidal effects must be eliminated in a relatively short time. This calls for a rapid hydrolysis and/or biological degradability of the biocides. For indirect emissions via municipal sewage treatment plants it has to be proven that the biological wastewater treatment is not inhibited and that the biocides are retained in the treatment plant. Preferably, the biocides should be biologically degraded. While elimination through adsorption on the activated sludge (e.g. QAC) protects the receiving water, this merely shifts the problem, when the collected sludge is spread on the land for agricultural or forestry use. Different approaches for evaluating the hazard potential from cooling water chemicals and the selection of appropriate active ingredients have been described in the BREF on cooling systems, among the concept of water risk classes (hazard based approach), benchmarking concept (immission based approach, ranking of risk quotients PEC/PNEC) (Gartiser et al. 2002). The updated version of the ESD on cooling water biocides currently being discussed will include an annex with proposals on adopted (site specific) dilution factors to be used in the risk assessment depending on the river flows.[7] As an inverse interpretation, a RMM could describe that these biocides uses are only allowed if the river flow guarantees that certain dilution factor is met. The example of cooling water biocides shows that elements of the risk assessment can be used to select appropriate active substances depending on the local conditions. This approach could also be used for the selection of disinfectants, especially for those with industrial use (PT 4).

1.5 Prioritisation of active substances to be considered

For most application areas of disinfectants these end up in municipal STP. Part of volatile disinfectants, e.g. for hands and surfaces, also evaporates to the air. Veterinary disinfectants for animal hygiene in stables are mainly discharged to manure, which is spread to soil. From some applications such as swimming water processing direct releases to surface water may occur.[8] Similar to cleaning agents many disinfectants are designed to be treated in municipal STP. Direct releases of municipal wastewater to surface water may occur in situations with storm water overflow (bypass to surface water). Considering these exposure scenarios, biodegradability of disinfectants is of major importance next to acute toxicity to sewage sludge or aquatic organisms. Thus for a first screening the classification of active substances may be of interest. Eickmann et al. (2007, 2011) analysed publicly accessible information on 673 biocidal products used to disinfect surfaces, skin, hands, instruments, and laundry in the public health

[7] Personal communication Peter Okkermann CTGB - Board for the Authorisation of Plant Protection Products and Biocides, the Netherlands from 13.6.12

[8] Further applications attributed to PT 2 include algaecides or soil disinfectants although little information about these uses is given in the ESDs.

area. Among them the authors identified 162 ingredients of which 52 contributed more than 90 % of all ingredients indicated.[9] From these 52 ingredients those which have been classified in environmental risk phrases are referred to in Table 5.

Table 5: Ingredients in disinfectants for the public health area

	CAS number	Risk phrases
Biocidal active substances		
Glutaraldehyde	111-30-8	R50
Chlorocresol (4-chloro-3-methylphenol)	59-50-7	R50
QAV, benzylcoco alkyldimethyl, chlorides	61789-71-7	R50
Peracetic acid	79-21-0	R50
Biphenyl-2-ol	90-43-7	R50
Sodium hypochlorite	7681-52-9	R50
N-Dodecylpropan-1,3-diamin	5538-95-4	R50
Didecyldimethylammoniumchloride	*7173-51-5*	*R50*
Formaldehyde	*50-00-0*	*R51*
N-(3-Aminopropyl)-N-dodecyl-propan-1,3-diamin	*2372-82-9*	*R50*
Benzyl-C12-18-alkyldimethylammoniumchloride	*68391-01-5*	*R50*
Mecetroniumetilsulfat	*3006-10-8*	*R52/53*
Non-biocidal ingredients		
Tetrasodium EDTA dehydrate	64-02-8	R52/53
Sodium nitrite	7632-00-0	R50

Biocidal active substances *marked in cursive* have not been classified in R50-53 in the Table of Eickmann (2011), but should be according to SDS from product evaluation.

From the evaluation of Eickmann et al (2011) it becomes evident that in this application area relatively few active substances fulfil the criteria for classification as "hazardous to the aquatic environment" and that other ingredients of biocidal products than active substances might also be of high concern with respect to environmental risks and must therefore not been disregarded. According to Eickmann et al. (2007) sodium nitrite is mainly used as ingredient for the instrument disinfectants.[10] Biocidal products containing sodium nitrite have been identified but these contain also other active ingredients.[11]

The consideration of exposure routes and of the behaviour of micro-pollutants in STP has been successfully used for pre-selecting chemicals with potential relevance for surface water to be included in monitoring programmes. In Switzerland, in total 22 biocidal substances with relevance for surface water have been pre-selected within the BIOMIK project, based on consumption and degradability data (Bürgi et al. 2007).

[9] For 19.4% of all ingredients no detailed analyses were possible due to unspecific indication of their identity.

[10] Sodium nitrite has been identified as biocidal active substance, but has not been supported in the Review-Program for the evaluation of old active substances

[11] http://www.pliwa.de/downloads/produktinformation/pi_pliwa_roto-pren_de.pdf

Following a similar prioritisation approach, the Dutch RIVM has selected twelve substances as indicators of the presence of biocides in surface water, among them five disinfectants (Bakker 2010). Currently, a monitoring concept for biocides is being elaborated in Germany. A first survey considered institutions that operate monitoring programs as well as working groups at universities, and a literature search on biocide monitoring. For the prioritization of biocides to be included in monitoring a concept was elaborated and substantiated that covers the entry pathways, emissions, and ecotoxicological effects, as well as the distribution and the fate of the compounds in environmental compartments (Rüdel and Knopf 2012). The cornerstones of the concept are elaborated within a follow up project (FKZ: 3712 67 403). In this project active substances that are relevant for different environmental compartments will be identified.

Table 6 compares the priority active substances identified in the different studies, which are supported as disinfectants. It should be noted that readily biodegradable actives have been removed from the prioritisation lists in the Dutch and the German studies, but not in the Swiss study.

Table 6: Disinfectants with relevance for surface water

Name	CAS	CH	NL	D	PT
Boric acid	10043-35-3	X			1-3
1,2-benzisothiazol-3(2H)-one	2634-33-5		X		2
Chlorhexidine gluconate	18472-51-0		X		1-4
Glutaral	111-30-8	X			1-5
2-octyl-2H-isothiazol-3-one	26530-20-1	X	X		4
Triclosan	3380-34-5	X		X	1-3
Methyl-Triclosan (transformation product of triclosan)	4640-01-1			X	
Formaldehyde	50-00-0	X			1-5
Bronopol	52-51-7	X	X		1-4
Dimethyloldimethyl hydantoin	6440-58-0	X			2
Poly(hexamethylenebiguanide)	91403-50-8		X		1-4
Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides	68391-01-5	X			1-5
Didecylmethylpoly(oxethyl) Ammonium Propionate	94667-33-1			X	2-4
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9			X	1-4

Sources: Bürgi et al. (2007), Bakker (2010), Rüdel and Knopf (2012).

Götz et al. (2010) proposed a simple exposure based methodology for pre-selecting micro-pollutants according to their potential to occur in the water phase of surface waters.

In another project in which a concept for the cumulative environmental exposure assessment of biocides has been elaborated, a similar approach has been suggested to pre-select the need for cumulative assessments: Substances which have a high potential to be a surface water contaminant would require higher attention with regard to cumulative exposure (Groß et al.

2010). Total consumption of the active substances is one of the most important input parameters.[12]

1.6 Identification of industrial and professional associations

There exist numerous industrial and professional associations in Germany and Europe which are involved in the hygiene and disinfection areas. Many of them have been contacted within the context of the study on best practice on sustainable use of biocidal products (Zamparutti et al. 2010). Together with the final report an excel file is has been submitted with the download links to the most relevant documents, which can be sorted by PT.[13] In total 183 documents cover PT 1-5.

Table 7 presents the national and international associations with relevance to the use of disinfectants which have been contacted at least twice within the study.

[12] „There is an ongoing discussion on the definition of "cumulative" or "aggregate" exposure, see Biocides: BIP 6.7 - Scoping document for the drafting of guidance for cumulative and synergistic effects" (CA-Sept12-Doc.5.1.a). The term formally used was "cumulative exposure", but might be replaced by the term "aggregate exposure".

[13] http://ec.europa.eu/environment/biocides/pdf/Matrix%20of%20all%20ossible%20BP%20documents.xls

Table 7: National and international associations consulted

National associations	Internet address
Deutsche Gesellschaft für Hygiene und Mikrobiologie (DGHM)	http://www.dghm.org
Verbund für angewandte Hygiene e.V. (VAH)	http://www.vah-online.de
Vereinigung der Hygienefachkräfte Deutschland (VHD)	http://www.die-vhd.de
Bundesverband der Hygieneinspektoren e.V.	http://www.bundesverband-hygieneinspektoren.de
Deutsche Veterinärmedizinische Gesellschaft (DVG)	http://www.dvg.net
Bund für Lebensmittelrecht und Lebensmittelkunde e.V. (BLL)	http://www.bll.de
Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF)	http://leitlinien.net
Bundesfachverband Öffentliche Bäder e. V.	http://www.baederportal.com
Bundesverband der Energie- und Wasserwirtschaft (BDEW) Bundesverband der deutschen Gas- und Wasserwirtschaft (BGW)	http://www.bdew.de
Deutsche Vereinigung für Wasserwirtschaft, Abwasser und Abfall e. V. (DWA)	http://www.dwa.de
Deutsche Vereinigung des Gas- und Wasserfaches e.V. (DVGW)	http://www.dvgw.de
Industrieverband Körperpflege- und Waschmittel e. V. (IKW)	http://www.ikw.org
Gütegemeinschaft sachgemäße Wäschepflege e.V.	http://www.waeschereien.de
Kuratorium für Technik und Bauwesen in der Landwirtschaft e.V. (KTBL)	http:/www.ktbl.de
Industrieverband Hygiene und Oberflächenschutz (IHO)	http://www.iho.de
Verband der Hersteller von Textilhilfsmitteln, Gerbstoffen und Waschrohstoffen (TEGEWA)	http://www.tegewa.de
Zentralverband der Deutschen Geflügelwirtschaft e.V.	http://www.zdg-online.de/
Zentralverband der Deutschen Schweineproduktion e.V. (ZDS)	http://www.zds-bonn.de
European and international associations	
International Scientific Forum on Home Hygiene (IFH)	http://www.ifh-homehygiene.org
European Water Association	http://www.ewaonline.de
Euro Chlor	http://www.eurochlor.org
Comité Européen des Agents de Surface et de leurs Intermédiaires Organiques (CESIO)	http://www.cefic.org
European Federation for Cosmetic Ingredients (EFfCI)	http://www.effci.org
US Environmental Protection Agency (EPA)	http://www.epa.gov
Association Internationale de la Savonnerie, de la détergence et des produits 'Entretien (AISE)	http://www.aise.eu
Institute of Occupational Safety and Health (IOSH)	http://www.iosh.co.uk
International Water Association (IWA)	http://www.iwahq.org
European Union of National Associations of Water Suppliers and Waste Water Services	http://eureau.org
International Federation of Environmental Health (IFEH)	http://www.ifeh.org
International Network of Safety and Health Practitioner	http://www.inshpo.org
World Health Organisation (WHO)	http://www.who.int
European Chemical Industry Council (CEFIC)	http://www.cefic.be
European Working Group for *Legionella* Infections	http://www.ewgli.org
European Society of Clinical Microbiology and Infectious Diseases	http://www.escmid.org
Human and Environmental Risk Assessment on ingredients of household cleaning products (HERA)	http://www.heraproject.com

The response of the associations was hesitant. However, some websites provide useful information which is evaluated in chapter 2.

1.7 Market analyses for disinfectants

Many suppliers of disinfectants make product leaflets and safety data sheets (SDS) available on their websites. Some suppliers also sent product data on CD. In Table 8 the websites which have been analysed are documented.

Table 8: Analysis of websites of disinfectant suppliers

Company	Website	Product types
Anti-Germ Deutschland GmbH	http://www.anti-germ.de (only German)	PT 2-4
Asiral Industrie-reiniger GmbH	http://www.asiral.de (German and English)	PT 1-4 (prof. use)
B. Braun Melsungen AG	http://www.bbraun.de (only German)	PT 1, 2 (prof. use)
Bode Chemie GmbH & Co.	http://www.bode-chemie.de (German and English)	PT 1, 2 (prof. use)
Calvatis GmbH	http://www.calvatis.com (German and English)	PT 3, 4 (prof. use)
Chemoform	http://www.chemoform.de (German and English)	PT 2 swimming water treatment (prof. and private use)
Dr. Schumacher GmbH	http://www.schumacher-online.com (German and English)	PT 1, 2 (prof. and private use)
Dr. Weigert	http://www.drweigert.de (German and English)	PT 2, 4 (prof. use)
Dürr Dental GmbH + Co. KG Bereich Orochemie	http://www.duerrdental.de (German and English)	PT 1,2 (prof. use)
Etol-Werk	http://www.etol.de (only German)	PT 2, 4 (prof. use)
EWABO Chemikalien GmbH & Co. KG	http://www.ewabo.de (German and English)	PT 3 (prof. use)
Fresenius AG	http://www.fmc-ag.de (German and English)	PT 2 (prof. and private use)
Ecolab Deutschland GmbH	http://www.ecolab.com (German and English)	PT 1-4 (prof. and private use)
FINK TEC GmbH	http://www.finkgruppe.de (German and English)	PT 4 (prof. use)
InterHygiene GmbH	http://www.interhygiene.de (German and English)	PT 1, 3 (prof. use)
Kesla Pharma Wolfen GmbH	http://www.kesla.de (only German)	PT 2-4 (prof. use)
Laboratorium Dr. Deppe	http://www.dr-deppe.de (only German)	PT 1, 2 (prof. use)
Lysoform, Dr. Hans Rosemann Gmbh	http://www.lysoform.de (only German)	PT 1, 2 (prof. use)
Kesla Chemie	http://www.kesla.de (only German)	PT 1 – 4 (prof. use)
Schülke & Mayr GmbH	http://www.schuelke.com (German and English)	PT 1, 2, 4 (prof. and private use)
Stockmeier Chemie GmbH & Co. KG	http://www.stockmeier-chemie.com (German and English)	PT 2, 3 (prof. unse)
Späne GmbH	http://www.spaene.com (German and English)	PT 3-5
Brauns-Heitmann GmbH & Co. KG	http://www.brauns-heitmann.de (only German)	PT 1, 2 (only consumer)
Unilever Deutschland GmbH	http://www.unilever.de (only German)	PT 2 (only consumer)

Company	Website	Product types
Dr.Krauss & Dr.Beckmann KG	http://www.dr-beckmann.de (German and English)	PT 2 (only consumer)
Colgate-Palmolive AG	http://www.colgate.ch http://www.danklorix.de (only German)	PT 2 (only consumer)
FLOREAL Haagen GmbH	http://www.floreal.de (only German	PT 2
AZUR GmbH & Co. Schwimmanlagen KG	www.azurpool.de (only German)	PT 2 (prof. and private use)
Reckitt Benckiser Deutschland GmbH	http://www.rb.com http://www.sagrotan.de (only German)	PT 1, 2 (only Consumer)
Sanitized AG	http://www.sanitized.com (German and English)	PT 2 (mainly consumer)

More than 1000 documents (product leaflets, SDS, use instructions etc.) for several 100 products have been downloaded and analysed. The data sources focus on German producers, but are assumed to be representative for the European market because most companies are present in a number of Member States. The overlaps of some uses/products with other regulatory areas (notable medicinal products, cleaning products and cosmetics) should be considered. For example Sodium hypochlorite (1-10%) is marketed for bleaching purposes and hygiene maintenance without classification as disinfectant. The product leaflets of some consumer products did not indicate the active ingredients.

The ingredients of disinfectants identified in the product survey which are classified in environmental risk phrases are summarised in Table 9.

Table 9: Ingredients in disinfectants for PT 1-5 (market research) [14]

	CAS number	Risk phrases
Biocidal active substances		
Aminoalkylglycine (Amines, n-C10-16-alkyltrimethylenedi-, reaction products with chloroacetic acid)	139734-65-9	R50
Benzyl-C12-18-alkyldimethylammoniumchloride	68391-01-5	R50
Biphenyl-2-ol	90-43-7	R50
Chlorocresol (4-chloro-3-methylphenol)	59-50-7	R50
Clorophene	120-32-1	R50/53
Dialkylmethyloxyethylammoniumpropionate	94667-33-1	R50/53
Dichloro-1,3,5-trianinetrione, sodium salt (Troclosene sodium)	2893-78-9	R50/53
Didecyldimethylammoniumchloride	7173-51-5	R50
Formaldehyde	50-00-0	R51
Glutaraldehyde	111-30-8	R50
QAV, benzylcoco alkyldimethyl, chlorides	61789-71-7	R50
Quaternary ammonium compounds, benzyl-C12-14-alkyldimethyl, chlorides	85409-22-9	R50
Mecetroniumetilsulfat	3006-10-8	R52/53
Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-on	55965-84-9	R50/53
N-(3-Aminopropyl)-N-dodecyl-propan-1,3-diamin	2372-82-9	R50
N-Dodecylpropan-1,3-diamin	5538-95-4	R50
Peracetic acid	79-21-0	R50
Pentapotassium bis(peroxymonosulphate) bis(sulphate)	70693-62-8	R52
Polyhexamethylenbiguanide	27083-27-8	R50/53
Sodium hypochlorite	7681-52-9	R50
Non-biocidal ingredients		
Sodium nitrite	7632-00-0	R50
Nonylphenol	37205-87-1	R51/53
Nonylphenolethoxylat	9016-45-9	R52/53
Sulphamidic acid	226-218-8	R52/53
Tetrasodium EDTA dehydrate	64-02-8	R52/53
Attribution dubious		
Alkylpropylendiamin-1,5-bis-guanidinium-acetat	98246-84-5	R50
Amines, C12-18-alkyldimethyl, N-oxides,	68955-55-5	R50
Cocopropylenediamin-guanidiniumdiacetate	85681-60-3	R50
Dichloroisocyanurate sodium	81918-50-5	R50/53
N,N-Didecyl-N-methyl-poly(oxyethyl)ammoniumpropionat	107879-22-1	R50
Quaternary ammonium compounds, C12-14-alkyl[(ethylphenyl)methyl]dimethyl, chlorides	85409-23-0	R50

[14] Because many of these substances still have no Annex I inclusion the risk phrases are preliminary and might be revised during the evaluation process.

A considerable overlap to the disinfection list of Eickmann et al. (2011) for the public health area is obvious. Non-biocidal ingredients such as Nonylphenol and Nonylphenolethoxylat must not be disregarded.[15] The attribution of some ingredients with disinfection like chemical structure remains dubious. This might be explained with their uncertain assignment as an active substance or with the use of active substances not allowed for biocidal use any more.

The evaluation of product documents showed that few RMM are recommended. Mainly general RMM are addressed, such as detailed dosage recommendations or the area of application which rather describe the conditions of use. In addition, a lot of equipment supporting safer application is described, such as dosing pumps, pump spray heads, foam spray nozzles, discharge taps, dosing bottles, hand sprayers, measuring beakers, pumping stations etc. Other RMM refer to specific product designs such as ready-to-use products (e.g. wipes or granulate in sachets) which also permit simple and reliable dosing. General recommendations refer to the need of cleaning surfaces before using disinfectants agents, as otherwise their effect may be reduced.

Disinfectants used for veterinary hygiene sometimes indicate that these have no negative effects on biogas plants/fermentation plants. In the reverse meaning, for products which inhibit anaerobic digestion, as standard RMM phrase could say "*Do not use where manure is anaerobically treated*".

Another RMM for instrument disinfectants says "With a standing time of 7 days, it contaminates the waste water considerably less than solutions that have to be changed every day." However, without further data about the active substances compared and their total loads this statement could not be evaluated.

Other environmental RMM from SDS refer to accidental releases like "*prevent product from reaching sewage system, holes and cellars*" or "*absorb spillages with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust* Some RMM refer to the disposal of the product such as "*must not be disposed of together with household garbage*", "*do not allow the product to reach sewage system*", "*do not allow the product to enter drainage system, surface or ground water*" or "*must be specially treated according to existing regulations*" or "*disposal of packaging according to existing regulations*."

In consequence such standard phrases could be considered as general RMM.

[15] It should be noted that under REACH Nolylphenol and Nonylphenol ethoxylate in domestic and industrial cleaning agents are restricted to < 0.1% according to Commission Regulation (EC) No 552/2009

2 Chemistry and efficacy of disinfectants

2.1 Efficacy of and resistance to disinfectants

The efficacy of disinfectants is influenced by many factors and mainly depends on the concentration of the active substance, the contact time, fouling conditions, and the temperature. Other factors are the effects of auxiliary ingredients, the presence of organic matter, the pH, the mechanically energy applied, etc. In general, biocides have a broader spectrum of activity than antibiotics. While antibiotics tend to have specific intracellular targets, biocides may have multiple targets. Especially chemical reactive disinfectants such as all chlorine and oxygen releasing active substances have generalised multiple targets such as the membrane-bound and intracellular enzymes. The widespread use of antiseptic and disinfectant products has caused concern on the development of microbial resistance, in particular cross-resistance to antibiotics (McDonnell et al. 1999, Gilbert et al. 2003).

The inactivation of disinfectants by organic matter or more specifically of QAC by anionic surfactants or of aldehydes by proteins etc. is known. Therefore, cleaning of the objects before applying disinfectants is essential. The mechanisms of the antibacterial action of disinfectants are summarised in several reviews. For example alcohols exhibit rapid broad-spectrum antimicrobial activity through denaturation of proteins but are not sporicidal. Aldehydes act via cross-linking of amino groups in proteins, RNA, and DNA. Oxidising agents such as halogens and peroxygens e. g. oxidise thiol groups of proteins while surface-active agents such as QAC predominantly act at the cytoplasmic (inner) membrane in bacteria or the plasma membrane in yeasts and phenols produce generalized membrane damages. Triclosan is membrane-active, but has also blocks lipid biosynthesis by specifically inhibiting an enzyme (enoyl-ACP reductase and homologes) (McDonnell et al. 1999).

Resistance to disinfectants can be intrinsic (efficacy of the disinfectant to certain microorganisms) or acquired by mutation or gene transfer. Common mechanisms of resistance development include the biofilm formation by excreting extracellular polymeric substances, increasing cellular impermeability, active transport of biocides through efflux pumps, and mutations at the target site (Russell 2003). Other experts distinguish between adaptation as a temporary lack of susceptibility to biocides e.g. caused by nutrients and resistance which is genetically determined. The main preventive measure against the development of resistance is the avoidance of application faults and of sublethal concentrations of the active substances. The transfer of resistance often occurs through extrachromosomal plasmids. Routine change of disinfectants is not considered necessary but it is also not wrong (Diehl et al. 2000). Russel (2004) analysed the lessons from the past with reduced susceptibility of microorganisms to disinfectants. He concluded that, although the long term use of disinfectants has apparently not resulted in the development of highly resistant strains as expected, there remain concerns and thus it is essential that antiseptics and disinfectants are employed only when necessary in order to minimize the possibility of bacterial resistance arising.

An assessment of the antibiotic resistance effects of biocides has been carried out by the “Scientific Committee on Emerging and Newly Identified Health Risks”. This study concluded that some resistance mechanisms are common to both biocides and antibiotics. In particular, the use of Triclosan, Chlorhexidine, and QAC was linked to the development of resistance to antibiotics. To address these concerns an urgent need is identified for quantitative data on

exposure to biocides, standards and methods to evaluate the ability to induce/select for resistance, and environmental studies on resistance and cross-resistance to antibiotics following use and misuse of biocides (SCENIHR 2009). A Dutch literature research in resistance and biocides concluded, that inappropriate use of biocides with a too short exposure time or an insufficient dose results in the spread of less sensitive organisms. professionals. The use of biocides in households and for personal hygiene should be minimized since it cannot be ruled out that this practice encourages antibiotic resistance (Schets et al. 2012).

Other authors state that it is generally accepted, the main cause of resistance to antibiotics is the widespread inappropriate use of antibiotics in medicine, animal husbandry, and veterinary practice. While in laboratory in-vitro studies it has been demonstrated that sub-effective exposure of microorganisms to biocides may induce chances in their susceptibility to antibiotics, according to the authors this effect has not been observed in clinical practice (Gilbert et al. 2003).

For some applications such as drinking water disinfectants the development of resistance is mainly discussed in the context of factors such as corrosion, dead-end pipes, organic matter, and biofilm development, all supporting the attachment of microorganisms to surfaces and preventing their susceptibility to disinfectants. While the inherent resistance (susceptibility) of microorganisms and specific pathogens to drinking water disinfectants has broadly been analysed, the development of acquired resistance of microorganisms through the use of drinking water disinfectants has received far less attention. Some publications suggest that the same mechanisms of resistance development occur. In the study of Shrivastava et al. (2004) it was supposed that suboptimal chlorine treatment of water could select multidrug-resistant bacteria (*Pseudomonas aeruginosa*). The study of Xi et al. (2009) concluded, that water treatment might increase the antibiotic resistance of surviving bacteria and water distribution systems and may serve as an important reservoir for the spread of antibiotic resistance to opportunistic pathogens.

2.2 Neutralisation and Inactivation

After treatment, it may be essential that the activity of the antimicrobial compound is nullified. This may be achieved by means of a neutralizing agent (inactivator, neutralizer), which inactivates the antimicrobial agent. Active chlorine and iodine may be neutralised with Sodium thiosulphate, QACs and Chlorhexidine by Lecithin and Tween (Fraise et al. 2004). Product leaflets for Hydrogen chloride, which is used for disinfection of drinking water equipment, require neutralisation of the acid by Sodium hydroxides or Calciumhydroxid. In water treatment the inactivation of Chlorine concentration exceeding the limit values by e.g. Sodium bisulfite is partly practiced. Whether further inactivation of disinfectants before discharge to the STP is carried out in practice is not known but in principle this offers a RMM.

2.3 Biodegradability and behaviour in sewage treatment plants

One main exposure route of many disinfectants is through municipal sewage treatment plants (STP). For prioritising active substances for which RMM may be required the behaviour of ingredients of biocidal products in STP is of mayor importance. Substances which are readily biodegradable can be considered to be effectively biodegraded in biological STPs and thus normally do not pose a risk to the environment, if emitted to a biological STP below concentrations inhibiting activated sludge. However, representatives from authorities state, that

biodegradability cannot be the only trigger for prioritising the risk to the environment of biocidal active substances. For example, the use of Decanoic acid for disinfection purposes in food industry resulted in a slight risk for surface water due to the huge amount consumed. The stormwater overflow of STP is one source for direct releases to surface water.[16]

According to the draft CAR available so far most organic active substances used in disinfectants are readily biodegradable while inorganic disinfectants such as sodium hypochlorite are rapidly inactivated through other mechanisms.

While biological wastewater treatment could be considered as a RMM for disinfectants it should be noted that the ratio of the population connected to wastewater collection and treatment systems varies considerably within Europe. The percentage of the population connected to wastewater treatment depends on the economic structure of the country, its topography, and the population density. A few countries have a connection share of more than 90% (Austria, Germany, Luxembourg, Netherlands, Spain, UK) or more than 80% (Estonia, Ireland, Greece, France, Finland, Sweden). On the other hand, in other member states such as Bulgaria, Malta, Cyprus and Romania the infrastructure is less developed and the connection share is below 50%.[17] If wastewater treatment in STPs is considered as a RMM for certain applications of disinfectants the uses of these biocidal products should be limited to areas connected to STPs.

2.4 Disinfection by-products

The disinfection of water with oxidising biocides leads to the inevitable formation of disinfection by-products (DBPs) because part of the biocides reacts with organic and inorganic water ingredients. Mutagenicity of disinfection by-products (DBP) has attained much attention because mutagenicity is an indicator for potential carcinogenic risks on human health by drinking water consumption. While the focus has laid on halogen-containing biocides such as chlorinated and brominated disinfectants it is know that also other oxygen releasing disinfectants such as Ozone or peroxides produce harmful DBP. In the reviews of Amy et al. (2000) and Weinberg et al. (2002) it is stated that more than 500 DBPs have been reported in the literature for the major disinfectants currently used (Chlorine, Ozone, Chlorine dioxide, Chloramines). The CARs do not specifically address the matter of DBP although its importance has been emphasized worldwide by authorities and scientists. The main focus concerning DBPs is human exposure through drinking water or swimming water although environmental concerns have also been addressed (e.g. formation of persistent organohalogens by reaction of natural organic matter with chlorine, formation of AOX). Next to chlorine and chlorine releasing compounds also peroxides such as Hydrogen peroxide or Ozone may cause mutagenic disinfection-by-products (e.g. the Bromate anion or N-Nitrosodimethylamine). The use of Chlorine dioxide as disinfectant is accompanied with the formation of Chlorite and Chlorate. Authorities state that although health risks caused by DBPs may be small (and need to

[16] The ECHA Guidance Doc. Chapter R.16 indicates that for a standard regional scale environment it is assumed that 80% of the wastewater is treated in a biological STP and the remaining 20% released directly into surface waters e.g. through stormwater overflows.

[17] http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=env_watq4&lang=en

be compared with the risk of a disease outbreak through pathogens), these should be taken seriously because of the large population exposed (US EPA 1999). Also anthropogenic compounds contribute to DBPs. For example the degradation products of the fungicide Tolylfluanide, several pharmaceuticals and personal care products, are precursors of carcinogenic N-nitrosodimethylamine (NDMA) (Schmidt et al. 2008, Shena et al. 2011).

The German Environment Agency has delivered comments on DBP to several draft CARs. According to environmental authorities one obstacle in considering DBP in the risk assessment of biocides is that only metabolites which contribute to more than 10% of the total amount used are considered as being relevant for the risk assessment irrespective of their properties. Further on, DBP consist of a mixture of different compounds that differs according to the type of substrate the disinfectants are added to, and according to the conditions. The occurrence of DBPs often is difficult to distinguish from other contaminants from non biocidal uses.[18]

Knowledge about the formation of DBPs might be used for process optimisation and risk mitigation. For example, it is reported, that advanced oxidation processes including a combination of Ozone/UV or Ozone/Hydrogen peroxide as oxidising agent result in higher elimination efficiency on total organic carbon (TOC), AOX and the AOX formation potential compared to ozonation (Glauner 2005). A combination of ozonation with membrane filtration resulted in a reduction of up to 50% of the dissolved organic carbon (DOC) and in the formation of partially oxidized compounds from natural organic matter. In consequence, these were less reactive with chlorine which resulted in a reduction of trihalomethanes (THM) and haloacetic acids by up to 80% and 65%, respectively (Karnik et al. 2005).

In Switzerland the project “Micropollutants in the aquatic environment” (MicroPoll) has been carried out. The focus was on urban drainage and persistent substances which may pass the STP and may have adverse effects on aquatic life. Within this context also measures at the STP (e.g. Ozone or activated carbon treatment) which can eliminate a broad range of micropollutants have been assessed. The overall objective of the Swiss waste water treatment strategy is load reduction and water quality improvement (FOEN 2009, Abegglen et al. 2009). Meanwhile it is also recognised that there exist numerous naturally occurring organohalogen compounds which are produced both biogenic and abiotic (Gribble 2010).

The literature on DBPs is uncountable. For example in the data base Science Direct more than 17,000 hints on DBPs are indicated (including formation, occurrence and control, analytics, reaction with anthropogenic micro-pollutants, and human health). Thus, the analysis of the importance of DBPs focuses on review papers.

The main concern of DBP is on human health. A preliminary environmental risk assessment of selected DBP has been carried out by Pickup (2010). While for trihalomethans as DBP of chlorination the risk quotients for surface water were below 0.1 in some sectors the risk quotients for haloacetic acids were above 1 and thus indicated a risk. The respective scenarios were emptying of swimming pool, sewage disinfection, and cooling water. In contrast, no risk was identified for routine operation of swimming pools.

[18] Personal communication Peter Okkermann CTGB - Board for the Authorisation of Plant Protection Products and Biocides, the Netherlands from 13.6.12

Avoidance or removal of DBP precursors such as TOC and bromide are considered essential for minimisation of DBP. Several models have been developed to predict the formation of DBPs from the use of a particular disinfectant and the factors that control the appearance and formation of these DBPs allowing appropriate control strategies to be developed. To assist small water supply systems in minimizing DBP formation, there is a need to develop simple, easily operated treatment systems for the removal of natural organic matter from source waters (Amy et al. 2000).

The Directive 98/83/EC on the quality of water intended for human consumption requires Member States to take all measures necessary to ensure that any contamination from disinfection by-products is kept as low as possible without compromising the disinfection. The maximum concentration of Trihalomethane DBPs in drinking water is 100 µg/l (total) and that of Bromate is 10 µg/l, but Member States are asked to stive for lower values, where possible without compromising the disinfection.

In wastewater regulation often the AOX concentration resulting from the unspecific reaction of chlorine releasing active substances with organic matter is limited (see chapter 3). For drinking water and swimming water the following quality criteria with regard to DBP have been derived:

Table 10: Limitation of Disinfection-by-products in drinking and swimming water

	Drinking water [1)]	**Swimming water** [2)]
Bromate	0.01 mg/L	
1,2 Dichloromethane	0.003 mg/L	
Trihalogenmethanes (Trichloromethane, Bromodichloromethane, Dibromochloromethane, Tribromomethane)	0.01 mg/L	0.02 mg/L
Trichloroethan and Trichloroethen	0.01 mg/L	
Bound chlorine (includes also derivates of ammoniac such as Monochloramine and Dichloramine)		0.2 mg/L (determined as difference between total chlorine and active chlorine)
Chlorite	0.2 mg/L [3)]	0.1 mg/L (only when Chlorine-chlorodioxide is applied)

[1)] German Drinking water Ordinance 2001

[2)] Schwimm- und Badebeckenwasserkommission des Umweltbundesamtes (2006)

[3)] DIN 2001-2 (April 2004). Trinkwasserversorgung aus Kleinanlagen und nicht ortsfesten Anlagen - Teil 2: Nicht ortsfeste Anlagen.

In principle, quality criteria concerning the formation of DBP during the application of certain oxidative disinfectants and their monitoring could be considered as RMM for some sectors such as drinking water, swimming water or laundry water.

The consideration of DBPs is currently being discussed by the CAs at the Technical Meetings. A background document has been prepared by the Dutch CA where it is suggested to establish a DBP working group and to evaluate DBPs following a semi-quantitative PEC/PNEC approach. First, a monitoring programme should be established for identifying DBP and determining their typical concentration after application of oxidative disinfectants in the relevant product types. Depending on the outcome of the PEC/PNEC comparisons a refined assessment should be

performed using the information from bioassays within a whole effluent assessment approach.[19]

[19] Assessment of disinfection by-products (DBP) - Background document for TM prepared by NL, with contributions from SE and DE, and comments from FR and IND - Main discussion points for TM II/12.

3 Product type specific survey of RMM

3.1 Disinfectants for human hygiene (PT 1)

The products used for human hygiene purposes with an anti-microbial claim are considered biocidal products, while cosmetic products and products specifically intended for medicinal purposes are not covered by the BPD. Examples for PT 1 products include hand disinfectants, disinfectant, antiseptic, antibacterial or antimicrobial soaps or cleaning gels/ solutions, fresh-up towels with a general disinfecting claim, or disinfectant mouth solution (without therapeutic claims). The main emission pathway for detergent like disinfectants are STP, but a distinction between 'leave-on' and 'rinse-off' products could be made as well as a recognition of the fraction to air for volatile products. Only general RMM such as "dilute with plenty of water" or "do not allow entering sewers/ surface or ground water" have been proposed in technical leaflets of the corresponding biocidal products.

3.2 Private and public health area and other biocidal products (PT 2)

Disinfectants of PT 2 cover very diverse application areas. The main emission pathway is to the sewer system. Further applications attributed to PT 2 include algaecides or soil disinfectants although little information about these uses is given in the ESDs. For some disinfection application such as non-contained disinfection processes, fumigation or soil disinfection there is some potential for direct emission to the air, soil, and to solid waste.

Hospitals and healthcare facilities

Disinfectants for private and public health areas include disinfectants for surfaces (rooms, furniture, objects, lavatories), instruments, or laundries. Surface disinfectants either are rinsed off with water after disinfection (rinse-off products) or left for drying (non-rinse off or leave-on products). The main emission pathway in industrial, institutional, health care and private home areas is to the sewer system. Usually the release to waste water is by default 100%. Depending on the chemical properties of the active substances evaporation to the air might also be a major pathway e.g. for aldehydes and alcohols. The concentration might decline through chemical reactions e.g. with proteins.

The technical rule for hazardous substances TRGS 525 "Hazardous substances in health care facilities" describes some principles concerning the use of disinfectants:

- Before deciding to use disinfectants it should be examined whether disinfection in fact is required (refers to a sustainable use of disinfectants).
- The choice of a disinfectant depends on the spectrum of the pathogens expected and the medical and technical workplace safety. Environmental concerns should be considered.
- It is first necessary to examine whether the use of disinfectants can totally or partially be substituted by thermal processes. If this is not possible, it should be examined whether hazards can be reduced by process change (e.g. automation, no application with aerosol formation potential such as spraying).
- When selecting disinfectants and procedures and considering the hygienic requirements those with the lowest health risks to workers should be selected.

Some professional medical associations such as the DGHM (Deutsche Gesellschaft für Hygiene und Mikrobiologie) and the VAH (Verbund für angewandte Hygiene e.V.) focus on efficacy testing and certification of disinfectants. The VAH-list of disinfectants is an inventory of all disinfectant products with valid VAH certificates, showing their active ingredients, contact times and use concentrations. It is used as a reference for quality assurance in prophylactic disinfection in Germany.

Within a project for the German Federal Environment Agency on environmentally sound disinfectants in hospital wastewater the input of disinfectants has been balanced from consumption data of hospitals and the characteristics of the main disinfectants were described. Without considering alcohols (which mostly are used for hand disinfection and evaporate) the input of active substances was 4.4 g/(bed*day), corresponding to a wastewater concentration of around 9 mg/l. The input from large kitchens and laundries must not be ignored, as they contribute up to 99% of total loads of chlorine or peroxides, and up to 28% of total load of QAC. Considering ecotoxicity, the maximum wastewater concentrations of 11 active ingredients exceeded the 50% effect level in different ecotoxicity tests. Main sources for ecotoxicity were QAC and alkylaminederivates used for instrument disinfection and chlorine-releasing and peroxide compounds used in the laundries. In spite of the ecotoxicity observed, hospital wastewater is well treatable in biological sewage plants. The ecotoxic and genotoxic effects observed in the Zahn-Wellens-Test were completely eliminated after a treatment process. Considering unfavourable conditions (smaller treatment plants, high loads in a short time), a disturbance of the purification process due to disinfectants cannot be excluded. The criteria most important for the selection of disinfectants for practical applications are the admission in disinfectant lists, the effectiveness and the protection of users. The environmental behaviour is only considered at a lower rank. It is recommended to consider the environmental behaviour as an additional criterion for the selection of disinfectants more than is done currently (Gartiser et al. 2000, 2001).

Within the AWMF (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften) the Working Group on Hospital & Practice Hygiene has developed numerous guidelines on hygiene requirements and the application of disinfectants in different hospital areas. Here, several requirements for hygiene efficacy indirectly also affect exposure to the environment. For example cleaning and disinfection of flexible endoscopes should be carried out in automatic systems. Manual processing of endoscopes is not considered feasible.[20] Surface disinfection should be carried out with the wet-mop technique. Moistening of surfaces alone is not considered sufficient. Only small areas should be treated by spraying of (most often alcohol based) disinfectants because of aerosol formation. Exact dosage of disinfectants is essential for assuring their efficacy. Central dosage apparatus systems are not recommended because these may contaminate.[21]

In the Netherlands wet cleaning and disinfection in hospitals is mainly limited to areas where patients can be exposed (e.g. operation chambers, bathrooms). Cleaning of materials and especially floors is preferably carried out by the use of a dry system with little or no moisture.

[20] AWMF-Leitlinien-Register Nr. 029/008: Hygienemaßnahmen bei der Endoskopie

[21] AWMF-Leitlinien-Register Nr. 029/030: Hygienische Anforderungen an Hausreinigung und Flächendesinfektion

After treatment the floor is dry and immediately can be used. Dry cleaning is insufficient in case of more attached dirt. In those cases wet cleaning is chosen (Anonymous 2009 a, b).

In the U.S.A. a "Guideline for Disinfection and Sterilization in Healthcare Facilities" has been published which indicates that in some states limit concentrations of certain chemical germicides (e.g. Glutaraldehyde, Formaldehyde, and some phenols) from disposal through the sewer system exist. If health-care facilities exceed the maximum allowable concentration of a chemical they can switch to alternative products, can collect the disinfectant and dispose them as hazardous waste, or they can use small-scale treatment methods (e.g. neutralize glutaraldehyde with glycine, addition of sodium bisulfite to oxidative disinfectants) (Rutala et al. 2008).

Routine use of disinfectants for hospital floors and other noncritical surfaces is controversially discussed among hygienists while there is an agreement that targeted surface disinfection is indispensable in hospitals (RKI 2004; Dettenkofer et al. 2007; Rutala et al. 2008). An uncritical use of biocides, especially in low concentrations, may lead to the development of resistance. Special situations require special actions for disinfection and cleaning, e.g. when treating infected or severely immunocompromised patients or patients colonised with multi-resistant pathogens. Targeted disinfection of surfaces which are frequently touched is an established component of infection control activities to prevent the spread of nosocomial (multi-resistant) pathogens, but of lesser importance than proper hand hygiene (Dettenkofer et al. 2007). Other hygienists indicate that while cleaning of hospital floors with soap and water was less effective than the use of disinfectants a few hours after floor disinfection, the bacterial count was nearly back to the pre-treatment level. However, detergents become contaminated and investigators have shown that mop water becomes increasingly dirty during cleaning and becomes contaminated if soap and water is used rather than a disinfectant (Rutala et al. 2008).

The German Robert Koch Institute (RKI) has developed a guidance document where several risk areas for infection are defined. Surfaces near patients or with frequent contact to hands and skin should be disinfected while cleaning is considered sufficient e.g. for floors in areas with low infection risk. Occupational exposure to disinfectants and the sensitising effects of some aldehydes such as Formaldehyde or Glutaraldehyde is highlighted and substitution of these products is recommended. Used working dilutions of disinfectants usually are discharged to STP while the concentrates must be disposed as hazardous waste. When selecting disinfectants their behaviour in STP and their biodegradability should be considered (RKI 2004).

Disinfectants used in consumer products

Within a research project for the German Federal Environment Agency on possible health effects of consumer exposure to biocides a market research has been carried out that has shown that only a limited number of active substances are used in most of the products. The main application areas of biocidal substances were in washing and cleaning products, whereas the intended effect is not always primarily biocidal but possibly bleaching or cleaning. For surface disinfection (inclusive removal of moulds and films) mainly Sodium hypochlorite (NaOCl), alcohols, QAC and Hydrogen peroxide are used. For laundry disinfection and cleaning of clothes Hydrogen peroxide, NaOCl and QAC are used. In machine dishwashing Dichloroisocyanurates and Trichloroisocyanuric acid are applied. For water purification in private swimming pools mainly Dichloroisocyanurates, Trichloroisocyanuric acid, Sodium hypochlorite and Hydrogen peroxide are used. In addition, liquid washing and cleaning

products contain preservatives such as Isothiazolinones, Benzoic acid, 2-phenoxyethanol, Chloroacetamide, Bronopol and Triclosan, QAC, Glutardialdehyde and Formaldehyde or formaldehyde releasers (Hahn et al. 2005, 2010).

Public concerns have been raised that the use of antimicrobials in the home can promote development of antibiotic-resistant bacteria. In Germany, the benefit and usefulness of surface disinfectants in private homes is questioned by authorities. Thus, biocides should not be used by consumers except in specific cases (e.g. a doctor's order), to avoid the risk of enhancing microbial resistance. It is argued that untrained consumer use of disinfectants is often ineffective against microbes (BfR 2005; Zamparutti et al. 2009). According to the Guideline for Disinfection and Sterilization in Healthcare Facilities the public health benefits of using disinfectants in the home are unknown. However, it is recognised, that many sites in the home kitchen and bathroom are microbially contaminated. Some hygienists refer to the increasing number of people which are in need of care at home. The "targeted hygiene concept" - which means identifying situations and areas where risk exists for transmission of pathogens – is considered a reasonable way to identify when disinfection might be appropriate (Rutala et al. 2008, IVNA and IFH 2003).

A review paper of Gilbert et al. (2003) concluded that the incorporation of antibacterial agents in personal products has had little or no impact on the patterns of microbial susceptibility observed in the environment, but there remain associated risks. The use of such products should therefore be associated with a clear demonstration of the added value and hygienic products should be targeted to applications for which the risks have been established.

According to the Dutch Hygiene Code for the private households regular cleaning is usually adequate for the effective removal of dirt and risk-bearing micro-organisms. Unnecessary use of disinfectants could lead to harmful micro-organisms adapting to these agents, which would then require the use of higher dosages of other agents. There are occasionally forms of microbiological contamination whereby the removal of these micro-organisms by regular cleaning methods are inadequate to prevent the contamination from spreading and undesirable risks. In these cases the application of chemical or thermal disinfection might be required for medical considerations. For all cleaning and disinfection products, the concentration, application time and correct procedure affect the agent's efficiency. Disinfectants should only be applied to the area of application indicated on the product packaging, in compliance with the instructions and the correct application time. Prior to disinfecting, thorough cleaning should take place, as the presence of organic material may have a negative influence on the efficiency of the disinfectant (Anonymous 1999).

Water distribution and use as drinking and swimming water

The ESD for disinfectants used for swimming pools considers that the swimming water is discharged to STP (van der Poel et al. 2002). Generally surplus water from public pools should be discharged to the sewer system connected to STP. However, direct discharge of pool water to surface water or infiltration through soil filter to the groundwater or discharge via the storm water sewer may be allowed if the active chlorine concentration is below 0.01 mg/L and the

water fulfils other requirements (e.g. no unacceptable temperature increase of surface water). [22] [23]

The control of DBP resulting from swimming water processing includes the selection of source waters without DBP precursors, the removal of such precursors by pre-treatment, and disinfection systems that use less chlorine by combining it with UV or Ozone. Further on, the application of good bather hygienic practices such as pre-swim showering and filtering techniques reduce the occurrence or precursors. Some volatile DBP such as chloroform and nitrogen trichloride (a chloramine) produced in the pool water (depending upon the disinfection system used) may also be managed to some extent through good ventilation (WHO 2006).

The Bundesfachverband Öffentliche Bäder e. V. publishes several guidelines concerning the use of disinfectants in the swimming pool area. Surface disinfection of stainless steel should not be carried out with active chlorine based disinfectants such as sodium hypochlorite because of possible corrosion. For disinfection of swimming water reference is given to DIN 19643 part 1 to 5.[24] These standards, for which English translations exist, describe minimum levels of treatment, i.e. biocide concentrations (Chlorine, Sodium hypochlorite, Calcium hypochlorite, and Ozone), which are effective as well as maximum levels that are considered “safe” for swimmers. Different process combinations for swimming water treatment through precipitation, filtration, chlorination, and ozonation are described. A maximum concentration of Trihalomethane compounds resulting from chlorination of 0.02 mg/l is allowed. Dosage and controlling of disinfectants and technical optimization of the processes are major objectives of these standards which therefore help minimizing the amount of biocides required. For the control of *Legionella* contamination in hot water distribution systems thermal disinfection and regular monitoring is recommended.

The DVGW (Deutsche Vereinigung des Gas- und Wasserfaches e.V.) publishes technical rules for drinking water disinfection, including dosage of disinfectants, maintenance of the dosage system, distribution of drinking water, material to be used for pipes and valves, decontamination of the distribution network, storage of disinfectants, automatic control techniques etc. All these rules correspond to best practices which optimize the amount of disinfectants required.

Laundry disinfectants

In laundries the hygienic requirements for textiles must be fulfilled. Often perorganic acids or inorganic peroxides are used which have both a disinfecting and bleaching effect. For laundries quality assurance systems such as the Risk Analysis and Biocontamination Control

[22] ÖWAV-Merkblatt. Private, Hallen- und Freischwimmbecken. Ableitung von Spül-, Reinigungs- und Beckenwasser. (April 2008)

[23] http://www.lfu.bayern.de/wasser/merkblattsammlung/teil4_oberirdische_gewaesser/doc/nr_458.pdf

[24] DIN 19643 part 1 to 5 (4/1997 – 9/2000). Aufbereitung von Schwimm- und Badebeckenwasser (Treatment of water of swimming pools and baths)

concept (RABC) has been elaborated within EN 14065.[25] There exist certification systems for laundries which fulfill this standard.[26] With respect to the disinfection process reference is given to the RKI-Guideline on accepted disinfectants and disinfection processes (RKI 2007). The disinfection of the textiles can be achieved by thermal processes (15 minutes at 85°C or 10 minutes at 90°C) without disinfectants or by chemo-thermal processes at 60°C-70°C with disinfectants (mainly with Peracetic acid, Sodium perborate, Sodium peroxide, Sodium hypochlorite, aldehydes, QAC). A life cycle assessment of different laundry processes for washing microbiologically contaminated hospital and care home laundry revealed that chemical disinfection at 40°C had a lower potential environmental impact than thermal (90 °C) or chemothermal treatment (70°C) based on energy and water consumption, the global warming and acidification potential. In contrast, the aquatic eco-toxicity of the thermal- and chemothermal processes were considerably lower than the chemical process (Eberle et al. 2007). This demonstrates that other aspects of environmental impacts should also be considered.

In Germany, wastewater discharges originating from the washing of dirty textiles, carpets, mats and non-woven fabrics in plants and public institutions is regulated in the wastewater ordinance (Appendix 55).[27] With respect to biocides the following requirements are given:

The waste water must not contain

- biocides from the finishing of washed items in standing baths
- organic chlorine and chlorine-releasing compounds or chlorine from the use of detergents and washing adjuvants, where these are not used in the clear rinsing zone or the clear rinsing bath when washing hospital and residential home laundry as well as working clothes for the meat and fish-processing industry.
- chlorination chemicals (if used to prepare the process water) above 1 mg/l free chlorine in the influent to the washing machine.

The last two requirements aim on limiting the generation of AOX. In consequence the maximum AOX load at the point of discharge for hospital and residential home laundry, according to Annex 55 of the German wastewater ordinance, is limited to 18 g/t and that for working clothes from the meat and fish-processing industry to 40 g/t (before mixing with other waste water). The specific load levels refer to the washing capacity (dry weight of the laundry).

Air conditioning systems

Disinfectants added to air conditioning systems should prevent contamination of the cooling liquid and the air condition system with bacteria, inter alia to control *Legionella* species. They may be released to the indoor air when the cooling water is vaporised and / or released to the sewer system by blow down water. Biocides are mainly applied for the disinfection of the circulating cooling water and of the moistened operating parts. The biocides are either applied

[25] BS EN 14065 (12/2010). Laundry Processed Textiles – Biocontamination control system.

[26] RAL-GZ 992/1 and RAL-GZ 992/2, http://www.waeschereien.de

[27] http://www.bmu.de/files/pdfs/allgemein/application/pdf/wastewater_ordinance.pdf

to the collecting pan or to the circulating water. The application can be continuous or intermittent (Zamparutti et al. 2010). In Germany the requirements on hygiene standards for air conditioning systems are described in VDI 6022 part 1-3 (bilingual version) and in DIN1946.[28] The technical rules and standards mainly describe requirements for the design, filter systems and maintenance of air conditioning systems. With reference to disinfectants it is mentioned that only products or methods are used whose effectiveness has been proven under practical conditions and that no health-endangering substances must be released to the air in the case of steam or spray humidifier. Environmental concerns are not considered.

Wastewater discharge and disinfection

Disinfection of wastewater effluents from STP is also covered by PT 2. Here exclusively oxidising disinfectants (mainly Ozone, sometimes chlorine) and ultraviolet radiation are applied whose reaction products directly enter surface water. With respect to hospital waste autoclaving of clinical material is the main disinfection technique. Chemical disinfection may occasionally be used in the disposal of clinical material or during bacterial contamination episodes. The potential for any release of biocides into the environment from disposal of hospital waste is considered minimal as disinfected waste is packed and incinerated (ESD for PT 2, SCC 2011).

Sanitary additives containing biocides added to chemical toilets for disinfection purposes, and for the reduction of odour, are completely released to the influent of STP. The fraction released may be reduced if data are available justifying that disintegration occurs. Considering an appropriate storage time of disinfectants in chemical toilets might therefore be a RMM for these products.[29]

The DWA (Deutsche Vereinigung für Wasserwirtschaft, Abwasser und Abfall e. V.) publishes technical guidelines for different wastewater sector, among them the technical rule DWA-M 775 „Wastewater from hospitals and other medical facilities", which describes requirement for the discharge of disinfectants.[30] For minimization the formation of adsorbable organic halogens (AOX) active chlorine compounds are not recommended. Dishwashers in large scale kitchens, disinfection machines and washing machines preferably should be run chemo-thermal with alkaline cleaning agents. However, it is also recognized that there exist conflicting environmental protection goals such was energy saving. If for this reason the machines run at lower temperatures preferably oxygen releasing compounds should be used.

[28] VDI guideline: VDI 6022 Technical rule Ventilation and indoor-air quality: part 1: Hygiene requirements for ventilation and air-conditioning systems and units (VDI Ventilation Code of Practice) (2011-07), part 3: Assessment of indoor-air quality (2011-07), draft part 4: Qualification of personnel for hygiene checkings, hygiene inspections, and assessment of indoor-air quality (2011-07). DIN 1946-4 Ventilation and air conditioning: part 4: VAC systems in buildings and rooms used in the health care sector (2008 12), Part 7: Ventilation systems in laboratories (2009-07).

[29] The ESD for chemical toilettes states that the release of disinfectant to STP is by default 100% but can be reduced if data are available justifying such a reduction e.g. by disintegration (SCC 2011).

[30] DWA-M 775 (12/2010): Abwasser aus Krankenhäusern und anderen medizinischen Einrichtungen. (Waste water from hospitals and other medical facilities).

While disinfectant concentrates should be disposed as hazardous the working solutions may be discharged to municipal STP provided that peak loads are avoided.

The technical rule ATV-M 205 describes the disinfection principles of biological treated wastewater.[31] The best experience exists with UV radiation, followed by ozonation. Chlorination – although being effective -should only be applied in emergency situations because of the formation of DBP such as Chlorophenoles, THM and AOX. The use of Chlorine dioxide instead of chlorine gas reduced the level of these DBP but others such as Chlorites and Chlorates might be generated. Residual concentrations of the disinfectants must be removed (e.g. by filtration or by addition of reducing agents) before the wastewater is discharged to surface water. The European Standard EN 12255-14 (2003) "Wastewater treatment plants – disinfection" describes the requirements for the disinfection of effluents from wastewater treatment plants.

In chemical toilets, urine and faeces are collected in tanks and sanitary additives containing biocides are added for disinfection and reduction of odour. Normally the sewage of chemical toilets is transferred to a municipal STP via tank vehicles. The draft supplement ESD for PT 2 concerning chemical toilets refers to the ATV-M-270 standard, which states only 2 m^3 per day of mobile toilet content are allowed to be discharged into a standard STP designed for 10.000 inhabitant equivalents. Through continuous discharge to the wastewater peak loads should be avoided.[32]

Further applications of PT 2

Further applications attributed to PT 2 include algaecides or soil disinfectants although little information about these uses is given in the ESDs. Annex V of the BPR refers algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials and soil disinfectants to PT 2. Also products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties are now covered by PT 2.

Soil disinfection may be applied for agricultural soil in horticulture or greenhouses. The application for children playgrounds has been supposed. In the past fumigants such as Methyl bromide have been used for this purpose (van der Poel et al. 2002). The inactivation of the of the zoonotic pathogen Coxiella burnetii which causes the Q-fever in contaminated soil by formic acid, cream of lime, sodium hydroxide and formalin, all applied in concentration of several volume per cents, has been studied by Dörner (2011). There exist also alternative procedures with heat (Wasiak 2009). It appears that soil disinfection is occasionally applied in the cases of serious outbreaks of diseases.

[31] ATV-M 205 (7/1997) Desinfektion von biologisch gereinigtem Abwasser (Disinfection of biologically treated wastewater (DWA).

[32] ATV-M 270 (5/1997). Entsorgung von Inhalten mobiler Toiletten mit Sanitärzusätzen (Chemietoiletten) (Disposal of the content of mobile toilets with sanitary additives (chemical toilets). Deutsche Vereinigung für Wasserwirtschaft, Abwasser und Abfall e. V (DWA)

The BPR (Article 58) requires that treated articles must only be placed on the market if all active substances contained are approved in accordance with the Regulation. Further on, treated articles should be appropriately labeled. A treated article that has a primary biocidal function shall be considered a biocidal product and must be authorised. For treated articles others than the ones treated with wood preservatives (PT 8) or antifouling agents (PT 21) sound emission scenarios are hardly available. In contrast, for efficacy testing of the antimicrobial activity or treated articles several standards are available (OECD 2007). The Milieu study on impacts of possible measures to manage treated articles provides background about the application of treated articles (Zamparutti et al. 2006). Considering certain active substances such as silver there is an overlap with the discussion on nanomaterials. A literature study on silver exposure to the environment (soluble, in suspension, and nanoparticular) resulted that the environmental risk for the aquatic compartment and for sewage treatment plants is small, but cannot be totally excluded, while for soil and sediment there is an indication for environmental risks (Hund-Rinke et al. 2008). In a study for the Danish EPA 17 treated textiles were analysed for the antibacterial compounds Triclosan, Dichlorophen, Kathon, Hexachlorophen, amd Triclocarbon. Five textiles contained Triclosan, but none the other target substances could be detected (Rastogi et al. 2003). An internet survey of treated articles in consumer products has been carried out by the Swedish Chemicals Agency. The following uses of treated articles have been identified: textiles, building products, kitchen ware, bathroom accessories, cleaning supplies, and office supplies, and child care articles. Only in a few cases information about the active substances used was found (KEMI 2012). In another study the leaking behaviour of silver from treated textiles during washing processes has been analysed. After ten washes 10-98 % of the silver had been washed out of the textiles. But half of the silver had already been washed out after three washes in several textiles (KEWI 2011).

3.3 Veterinary hygiene biocidal products (PT 3)

Disinfection of animal housings and disinfectants for veterinary hygiene such as non-medicinal teat dips, footwear and animals' feet mainly are released to manure/slurry, air and soil (from spreading of manure/slurry). Agricultural run-off to surface water after manure/slurry application to soil can also lead to environmental exposure of biocides. In general, across Europe, it is prohibited to discharge waste water containing slurry to the public (municipal) sewer, and hence liquid waste containing manure is either removed to a slurry or waste water collection tank and may be subsequently applied to land, treated in an on-farm STP or transported to a municipal STP. In principle, the biodegradation in manure and slurry could be considered in the emission estimation. A methodology has been provided in the ESD for PT 18. In contrast, disinfectants used for vehicles for animal transport and disinfectants for hatcheries may also enter sewers to sewage treatment plants.

Regulation (EC) No 1/2005 on the protection of animals during transport requires Member States to ensure that transporters clean and disinfected transport vehicles immediately after use using disinfectants officially authorised by the competent authorities. In Germany the DVG (Deutsche Veterinärmedizinische Gesellschaft) lists disinfectants with proven efficacy used in livestock breeding. The quality label of the DLG (Deutsche Landwirtschafts-Gesellschaft) for disinfectants in stables considers efficacy with and without contamination with proteins as well

as material and animal compatibility, but not environmental behaviour. Similar lists of approved disinfectants for animal disease prevention and control exist in other Member States (e.g. Defra, UK).[33]

Several basic chemicals such as hydrated lime (Calcium dihydroxide), Calcium oxide (quicklime), and Calcium magnesium oxide (dolomitic lime) are applied for veterinary hygiene purposes and are referred to in disinfection guidelines in the case of animal disease outbreaks (Anonymous 2007, EuLA 2009). The application of 2% Sodium hydroxide is considered a suitable surface and equipment disinfectant which may be used in outbreaks of the classical swine fever virus or the avian influenza (Smith 2006, Strauch and Böhm 2002, FAO 2007) although Sodium hydroxide is not supported as a biocidal product nor has been included in the Annex I of the Biocidal Products Regulation on active substances for which a simplified authorisation procedure has been accepted. The EU-Eco-regulation on organic production and labeling of organic products it its implementation refers to allowed products for cleaning and disinfection, among them Calcium oxide, Calcium hydroxide, and Sodium carbonate (Annex VII of Regulation (EC) No 889/2008). Several national guidelines from authorities describing suitable disinfection measures to be applied in the case of outbreaks of animal diseases refer to these basic chemicals.[34]

Disinfectants used for livestock breeding mainly are released to manure. For some processes such as pig breeding a minimum storage time of 8 weeks for liquid manure is required by the German pig breeding hygiene ordinance.[35]

Discharges of manure from stables to municipal STP are not allowed in most European countries (see ESD PT 3). However, on-site pretreatment of manure before spreading to the agricultural fields is sometimes performed. The observance of the principles of “Good Agricultural Practices” (GAP) concerning the use of organic fertilizer such as manure is regulated in several national laws (e.g. in the German Düngeverordnung). The technical rule ATV-M 702 developed by the DWA and the KTBL (Kuratorium für Technik und Bauwesen in der Landwirtschaft e.V.), which is under revision, requires wastewater from cleaning processes from animal breeding to be discharged to the liquid manure system.[36]

The BREF Rearing of Poultry and Pigs (July 2003) mainly describes good housekeeping and careful cleaning and disinfecting of the facilities. Environmental aspects are mainly discussed in the context of nutrients spread on field with manure. Applying good agricultural practice principles in animal housing and landspreading of manure, on-farm treatment of pig and or

[33] http://disinfectants.defra.gov.ukI

[34] BMU Richtlinie über Mittel und Verfahren für die Durchführung der Desinfektion bei anzeigepflichtigen Tierseuchen, February 2007
http://www.bmelv.de/SharedDocs/Downloads/Landwirtschaft/Tier/Tiergesundheit/Tierseuchen/Infektionsrichtlinie.html

[35] Verordnung über hygienische Anforderungen beim Halten von Schweinen, Schweinehaltungshygieneverordnung (SchHaltHygV) from 7. Juni 1999

[36] ATV-M 702 - Wirtschaftsdünger, Abfälle und Abwässer aus landwirtschaftlichen Betrieben (August 1995)

poultry manure are examples of BAT. The choice of disinfectants and their environmental impacts are not discussed. The BREF on slaughterhouses and animals by-products industries (May 2005) includes a chapter with recommendations to avoid and reduce the use of cleaning and disinfection agents containing active chlorine in order to reduce emissions of disinfection by-products (organic halogens, chlorinated hydrocarbons) to water. Sodium hypochlorite is the most commonly used disinfectant in this area next to Chlorine dioxide, Hydrogen peroxide, Peracetic acid, Formaldehyde and QAC.

The Bavarian state office for water management developed a guidance document on water protection after disinfection measures during the outbreak of the avian influenza: In water protective areas only disinfectants based on organic peracids or on inorganic peroxides are allowed. Spillage of concentrates to soil, surface water or groundwater must be avoided, e.g. through collection pans. The used working solutions should be discharged to municipal STP or to the liquid manure tank or should be collected and transported to STP via tank trucks. The discharge to small STP below 50 inhabitant equivalents is not allowed (Anonymous 2007).

Because the main part of disinfectants used for veterinary hygiene as well as of veterinary medicinal products end up in manure/slurry, which after some storage time is spread on fields, RMM derived for reducing environmental exposure to veterinary pharmaceuticals may also be applied for disinfectants. In a research project on RMM for human and veterinary medicinal products the following examples have been proposed (Liebig et al. 2011):

Special precautions for the disposal

- Ensure that any unused product or waste materials do not contaminate the environment.

Special precautions for the use in aquacultures

- Prior to use of the product a discharge consent is required from the relevant authority
- Use only if the flow rate of untreated waters allows for an x-fold dilution of the volume of treated water before discharge into surface waters. Where the appropriate dilution of treated water cannot be achieved use holding tanks or ponds, discharge lagoons and biofilters to clean treated water.

Special precautions for the use in intensively reared animals

- Before spreading slurry (manure) from treated animals it has to be stored for at least x day/months.[37]
- When spreading slurry (manure) onto arable land the maximum nitrogen spreading limit must not exceed x kg N ha^{-1} yr^{-1}.[38]

Special precautions for the use in intensively reared and pasture animals

- Dirty water must only be spread with a maximum spreading rate of x L (< 50000 L ha^{-1}) onto arable land or pastures.[39]

Obviously the quantitative RMM are derived from the exposure part of the risk assessment and are aimed to reduce the PEC through modification of the input parameters of the emission scenarios. These RMM may also reduce environmental exposure to disinfectants especially for those disinfectants which are eliminated during the storage of manure/slurry.

3.4 Disinfectants used in food and feed areas (PT 4)

Disinfection in the food and feed area includes the disinfection of the equipment, containers, surfaces or the pipework associated with the production, transport, storage or consumption of food, feed or drink. Dishwashing products intended to have a biocidal effect and disinfecting detergents intended for surfaces where food or feed is produced, placed, stored or offered for consumption are attributed to PT 4 and also cover consumer uses while disinfecting detergents intended non-kitchen surfaces are attributed to PT 2, according to the Manual of Decisions.[40]

Disinfectants are usually applied by spraying, foaming, soaking or brushing. Disinfection of pipes is performed by cleaning in places where the disinfectants are added to the circulating water (CIP).[41] The complete plant or pipeline circuits are cleaned and disinfected almost without manual interaction of the operator. The solutions (detergent and disinfectants) are automatically dosed and partially recovered (Stanga 2010).

---

[37] This RMM applies only if data on degradation of biocides in manure/slurry are available. A testing protocol has been developed by Kreuzig et al. (2010).

[38] RMM derived from the exposure assessment which uses an average EU nitrogen spreading limit of 170 kg N ha^{-1} yr^{-1}. Practicability depends on the available area under cultivation.

[39] The RMM is derived from the exposure assessment for dairy cattle teat dips or sprays (PECsoil) according to the EMEA guideline which uses a default maximum spreading rate of dirty water of 50000 L ha^{-1} (EMA 2008). Any RMM followed by lower spreading rates than the default value would cause lower emissions. The practicability of this RMM is questioned, if no surveillance is implemented and if the available area under cultivation is insufficient.

[40] https://circabc.europa.eu/sd/d/fa19127f-39e2-4ab2-9676-77b9a8a06c65/MoD_21_12_11.pdf

[41] CIP can be performed as lost cleaning (solution is only used once and then poured into the sewage) or as stacked cleaning (solution is stored after use in a container until re-use, the concentration of the disinfectant is adjusted automatically) (ESD PT 4).

Regulation (EC) No 852/2004 on the hygiene of foodstuffs requires that food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles (Hazard Analysis and Critical Control Points). Disinfectants are one important (but by far not the only one) tool to be included in a HACCP concept. There exist numerous guidelines and technical standards about food hygiene and hygiene management such as the "Codex Alimentarius" collection of internationally adopted food standards of the WHO/FAO (1999), standard family EN ISO 22000 on food safety management systems (a derivative of ISO 9000) and technical books (e.g. Stanga 2010). Several European standards deal with the hygienic design and the certification of the machinery and equipment for food production and processing.[42]

The main fraction of the residues is released to the sewer system. Due to the high load of organic substance the wastewater from the food, drink and milk industry is usually pre-treated before release to the environment (e.g. fat precipitator, pH adjustment). Usually the main fraction of the residues is released to the sewer system. Biological treatment might be carried out in on-site STP (after which the wastewater is directly released to surface water) or in municipal off-site STP.

The DVG lists disinfectants used in the food industry area with proven efficacy. The DLG quality label for disinfectants in creameries considers efficacy with and without contamination with proteins as well as material compatibility, but not environmental behaviour. Other associations such as the VHD (Vereinigung der Hygienefachkräfte Deutschland) provide check lists and best practices for hygiene management and application instructions. The BLL (Bund für Lebensmittelrecht und Lebensmittelkunde e.V.) provides national guidance documents from different sectors of the food industry for hygiene management plans according to Directive 93/43/EEC and Regulation (EC) No 852/2004 on the hygiene of foodstuffs.

According to a guidance document of the Bavarian state office for water management on wastewater discharge in rural areas the selection of disinfectants used specially in the processing of wine and milk as well as used in the context of slaughtering should be selected according to their environmental safety (Anonymous 2004).

The DLG guideline on hygiene techniques and management for cleaning and disinfection of stables recommends a 6 step process: primary cleaning (emptying feeding troughs and preparing all equipment for cleaning), soaking (several hours with and without detergents), cleaning (preferably with high-pressure cleaner top-down), flushing with water, drying, and disinfecting. The last disinfection step might be thermal or chemical and follows intensive cleaning ("mud cannot be disinfected"). The active substances recommended in the DLG list of approved disinfectants belong to aldehydes, chlorine and oxygen releasing products, phenols or QAC, acids or alkalis (von der Lage 2010).

Wastewater from cleaning of milking installation may be discharged to municipal STP according to ATV-M 702. Discharge to liquid manure is also possible (Anonymous 2005).

The BREF on food, drink and milk industries (August 2006) states that "the selection and use of cleaning and disinfection agents must ensure effective hygiene control but with due

[42] e.g. EN 1672-2 (9/2009) Food processing machinery - basic concepts - Part 2: hygiene requirements.

consideration of environmental implications. When the use of cleaning agents is essential, it is necessary to check first that they can achieve an adequate level of hygiene and then to assess their potential environmental impact." Referring to wastewater treatment it is stated that "cleaning and disinfection agents may represent a problem if they are poorly degradable".

The BREF also refers to operational optimising of the CIP systems by recirculating cleaning solutions for minimising the quantity of the cleaning and disinfection agents used. Only when the water and solutions are contaminated there is the need to recharge them and losses will occur. Measuring the particulate content of the cleaning solution (e.g. turbidity) offers one option for deciding when there is the need to dispose the solution. Thus, a standard RMM phrase could read as "To protect water-living organisms only use in CIP-treatment when recirculating of the cleaning solution for minimising releases to wastewater is applied". According to the BREF it is BAT to avoid the use of halogenated oxidising biocides, except where the alternatives are not effective.

Although the 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. Thus, the processes described as BAT might be considered as RMM and in consequence are (or could be) used in the exposure assessment for the environment.

According to the ESD for PT 4 cleaning through physical means (scrubbing, pressure spraying, steaming) is always necessary before disinfection. In order to ensure that food is not contaminated by biocides, all disinfected equipment is rinsed with water after application.

The German Wastewater Ordinance indicates in Appendix 4 "Processing of oilseeds, and refining of cooking fats and oils" that wastewater from cleansing and disinfection processes may contain only surfactants that attain an 80 percent degree of DOC elimination after 28 days. Appendix 20 refers to wastewater from processing of animal carcasses and animal products. Here, the maximum AOX concentration of 0.1 mg/l is deemed to be met if the cleaning agents and disinfectants do not contain any organically bonded halogen compounds or halogen-releasing substances. Also in Appendix 25 on leather production as a general requirement it is stated that the AOX pollution of the waste water should be kept as low as possible via the selection and use of appropriate cleaning agents and disinfectants.[43]

In a research project of the German Federal Institute for Occupational Safety and Health (BAuA) on occupational exposure from the use of biocidal products the application of disinfectants in food and feed producing enterprises has been analysed (BAuA F 2034, completed in December 2010). The main focus of the project was on the development of analytical methods for determining human exposure to peracetic acid and hydrogen peroxide.

3.5 Drinking water disinfectants (PT 5)

The main types of disinfection processes include primary disinfection (main purpose is to kill the vast majority of microorganisms), residual disinfection (maintenance of a anti-microbial potential in the distribution system), and stand-by disinfection (high dosage-application to clean up a contaminated system or when taking a new system into use). Most of the disinfectants

[43] http://www.bmu.de/files/pdfs/allgemein/application/pdf/wastewater_ordinance.pdf

applied have an oxidizing property and are not stable. The main receiving "compartment" for drinking water disinfectants will be the sewer-system and the municipal sewage treatment plant (STP). Special smaller case applications include the use of silver salts in mobile set- ups, like the conservation of water tanks on ships. The ESD for PT 5 refers to numerous potential harmful by-products of water disinfections which may be controlled by minimizing DOC content and other precursor compounds prior to adding the disinfectant.

In Germany only disinfectants with approved efficacy are included in the "list of treatment substances and disinfection processes as per § 11 of German Drinking water Ordinance" (TrinkwV 2001) which is maintained at the Federal Environment Agency.[44]

Among the approved disinfectants are chlorine, Calcium hypochlorite, Chlorine dioxide, Sodium hypochlorite, and Ozone (next to UV radiation). Reference is given to the DVGW guidelines for dosage of disinfectants as well as the minimum/maximum dosage and the DBP to be considered. Silver and Silver chloride (addition 0.1 mg/l) is only allowed in exceptional cases for the preservation of drinking water. In emergency situations other Sodium Dichloroisocyanurate or Dichloroisocyanuric acid sodium salt dehydrate may be allowed for a short period.

DIN 2001-1 describes standards for small drinking water facilities with less than 1000 m^3 abstraction per year. Disinfection should preferably be carried out with UV radiation. Another option is automatic addition of electrolytically produced chlorine or hypochlorite.[45]

DIN 2001-2 applies for mobile small drinking water facilities used in land, air and water vehicles and temporary used facilities. Only disinfectants approved for drinking water processing by the German Federal Environment Agency are allowed (mainly Chlorine, Hypochlorite, Chlordioxide, UV radiation). Silver salts may only be added in exceptional cases for the preservation of water in storage tanks. Preservation with silver salts does not replace the disinfection step. Further advice refers to the amount of rinsing fresh water through the pipes and tubes after stagnation periods. As a rule at least the 2-3 fold of the volume of the pipes and tubes should be discharged before the drinking water is used.[46]

The WHO publishes guidelines for drinking water processing with chemical fact sheets for the different disinfectants and individual hazardous chemicals present in drinking water.[47]

It is recognized that all chlorine releasing chemical disinfectants produce inorganic or organic DBPs such as THM, Haloacetic acid, Haloketones, Haloacetonitriles, as a result of chlorination of naturally occurring organic precursors such as humic substances. Monochloramine produces lower THM concentrations than Chlorine but produces other DBPs, including Cyanogen

[44] http://www.umweltbundesamt.de/wasser/themen/downloads/trinkwasser/trink11.pdf

[45] DIN 2001-1 (May 2007). Trinkwasserversorgung aus Kleinanlagen und nicht ortsfesten Anlagen - Teil 1: Kleinanlagen - Leitsätze für Anforderungen an Trinkwasser, Planung, Bau, Betrieb und Instandhaltung der Anlagen

[46] DIN 2001-2 (April 2009). Trinkwasserversorgung aus Kleinanlagen und nicht ortsfesten Anlagen - Teil 2: Nicht ortsfeste Anlagen - Leitsätze für Anforderungen an Trinkwasser, Planung, Bau, Betrieb und Instandhaltung der Anlagen

[47] http://www.who.int/water_sanitation_health/dwq/chemicals/en/index.html

chloride. The oxidation of Bromide (e.g. through Ozone) produce Hypohalous acids, which react to form brominated THMs. A range of other DBPs, including aldehydes and carboxylic acids, may also be formed.

The following process control measures for minimizing the formation of disinfection by-products are suggested by the WHO:

- changing the process conditions (pH adjustment, removal of precursor compounds prior to application)
- using a different chemical disinfectant with a lower propensity to produce DBP with the source water;
- using non-chemical disinfection (e.g. UV irradiation);
- removing DBPs prior to distribution (e.g. air stripping, activated carbon, UV light, advanced oxidation).

However, according to the WHO any attempt to control DBP concentrations should not compromise the efficiency of disinfection. A suitable residual level of disinfectant should be maintained throughout the distribution system (WHO 2011).

3.6 Categorisation of RMM

From the analyses it becomes clear that there are different elements of risk mitigation to be taken account which refer to different addressees (formulator, user, authorities) and areas (area of use, on-site treatment, municipal STP, environmental compartment). Elements of best practice should be taken into account and all DBP resulting from the use of oxidative disinfectants should be evaluated. One example for a possible categorization of RMM is given in Figure 1.

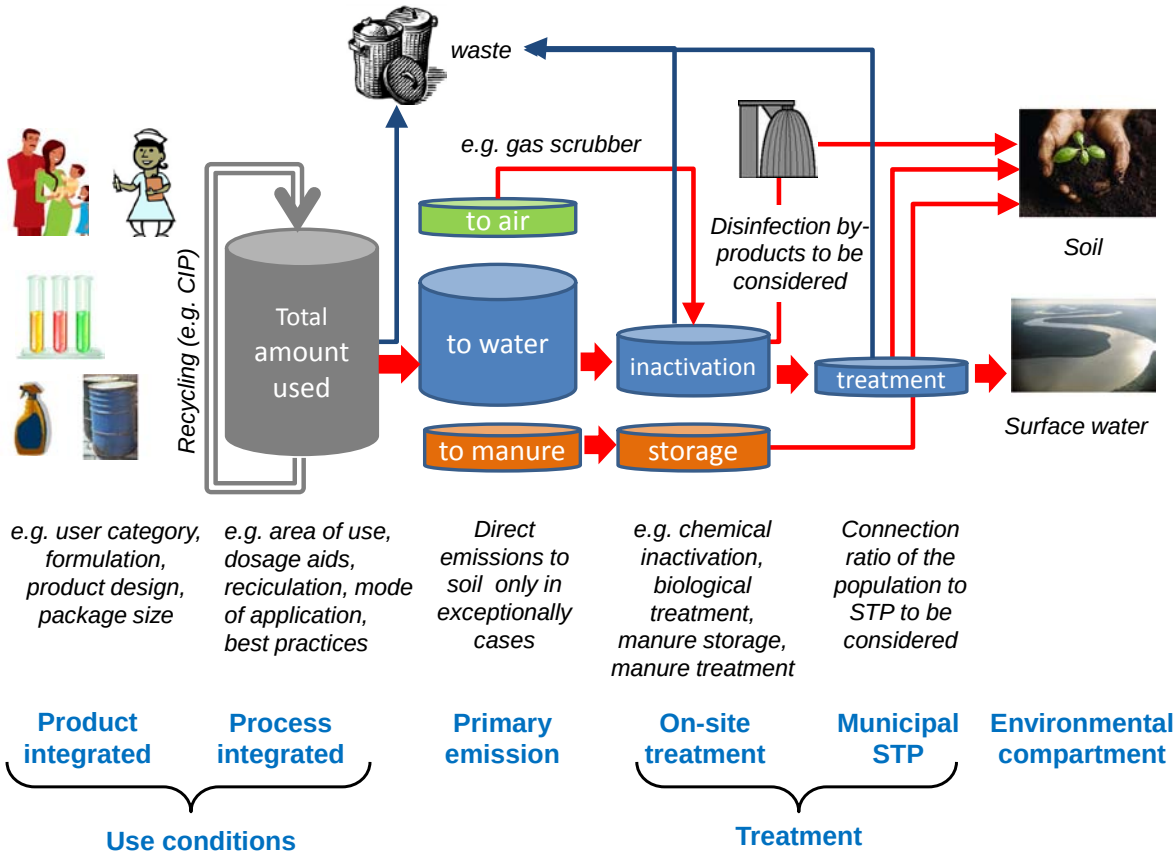


Figure 1: Categorisation of RMM for disinfectants

It should be noted that not all elements of RMM from Figure 1 are attributable to each PT. For example the release of disinfectants to manure followed by storage or biologically treatment in biogas plants is limited to (part of) disinfectants for hygiene in stables (PT 3). There are only a few examples of potential direct emissions of disinfectants to soil (e.g. soil disinfection). The terms and understanding differs from that implemented under REACH, as outlined in chapter 4.2.2 where the conditions of use are distinguished as operational conditions and risk management measures.

4 Standardisation of risk mitigation measures

4.1 Objective

The objective of standardising risk mitigation measures and corresponding RMM phrases is to harmonise the existing approaches for the assessment of biocidal active substances and products and to facilitate mutual recognition of product authorisations. On 23 and 24 February 2011 a European workshop on “Efficiency and practicability of risk mitigation measures (RMM) for biocidal products” was held at the German Federal Environment Agency (Gartiser et al. 2011). One result of the workshop was that it should be distinguished between basic or general RMM (e.g. BAT, IPM) that could lead to a sustainable use of biocidal products and specific RMM (e.g. top-coat on wood preservatives) to be included in risk assessment. RMM should be harmonised as far as possible on a European level in order to facilitate the European market

and mutual recognition of authorisations although some flexibility is also required for reflecting the national situation. The harmonisation of RMM could be supported by establishing standard RMM phrases. However, some RMM phrases require a more detailed specification. A survey of existing RMM would be useful.

4.2 Existing approaches for harmonisation of RMM phrases

4.2.1 CLP-Regulation

The Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures replaces the Dangerous Substances Directive 67/548/EEC and the Dangerous Preparations Directive 1999/45/EC. The former risk phrases (R-phrases) have been exchanged by hazard statements (H-numbers) which are listed in Annex III of the CLP-Regulation, the former safety phrases (S-phrases) have been substituted by precautionary statements (P-numbers) described in Annex IV of the CLP-Regulation. These phrases should be considered as harmonised and must not be reworded if used for labelling of biocidal products or as RMM phrases in product authorisation. Concerning environmental issues there are the following hazard and precautionary statements:

Table 11: Precautionary statements of the CLP-Directive

Hazard Statement		Precautionary Statement	
H400	very toxic to aquatic life	P 273 P391 P501	avoid release to the environment Collect spillage dispose of contents/container to …
H410	very toxic to aquatic life with long lasting effects		
H411	toxic to aquatic life with long lasting effects		
H412	harmful to aquatic life with long lasting effects	P 273 P501	avoid release to the environment dispose of contents/container to …
H413	may cause long lasting harmful effects to aquatic life		
EUH059	hazardous to the Ozone Layer		

From Table 11 it is evident that the precautionary statements P273 and P 501 apply to all hazard statements, while P391 only applies to the classification as very toxic or toxic.

There exist further general precautionary statements which can be considered as RMM for the protection of both human health and of environment such as

- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P103 Read label before use.
- P234 Keep only in original container.

Other precautionary statements which relate to the protection of humans may indirectly cause releases to the environment:

- P271 Use only outdoors or in a well-ventilated area.
- P363 Wash contaminated clothing before reuse.

4.2.2 REACH

REACH regulates the manufacture, import and use of substances on the EU market. Although active substance in biocides are exempted from most REACH provisions, other substances, which are used as co-formulants and are not subject to a detailed assessment in the context of the product authorisation, fall under REACH [48]. Hence, the identification of conditions of safe use under REACH for substances used in biocides could be relevant and helpful in the context of the product authorisation.

REACH requires the development of exposure scenarios as part of the chemical safety assessment for any substance, which fulfils the criteria as hazardous according to the CLP-regulation.[49]

The relevant exposure scenarios are to be integrated into safety data sheets (SDS) which makes them extended SDS (eSDS). Exposure scenarios describe the operational conditions and risk management measures under which a substance can be used safely in a specific use. These conditions are derived during the chemical safety assessment, which includes an exposure assessment and risk characterisation for each identified use of a substance. The exposure scenario attached to an SDS should clearly describe how the substance should be handled, stored and disposed of as well as which exposure controls are to be adopted.

The ECHA guidance on information requirements and chemical safety assessment ("ECHA IR/CSA guidance") describes in Part G how to extend the SDS with exposure scenarios. Further, it contains information on how the exposure scenario information should be communicated and implemented within the supply chain, i.e. formulators are to take information in exposure scenarios into account in developing their SDS for the formulation (ECHA 2008a).

The eSDS are supposed to cover risk management measures and operational conditions related to workers, environment and consumers.[50]

Thus the eSDS is expected to become an important source of information also for environmental managers at production sites and product safety managers. Chapter G.4.3 of the ECHA IR/CSA refers to standard phrases for risk management measures in the extended SDS. It is stated that "the use of standard phrases can simplify the description of risk management measures and operational conditions of use in the exposure scenarios and the main body text of the SDS. To allow for flexibility to cover the majority of different measures and recommendations, a modular system with standard phrases would be appropriate. The phrases could either describe discrete measures in a single, more elaborated phrase and/or address more complex information by combining different short phrases."

---

[48] REACH Article 15(2) specifies that active substances in biocide products are to be regarded as registered. A potential overlap exists for substances of concern which should be assessed according to the biocides regulation and would also have to be registered under REACH.

[49] For substances registered in amounts below 10 t/a per manufacturer / importer, no chemical safety assessment is required and hence no exposure scenarios have to be developed.

[50] In REACH guidance the abbreviation RMM is used for "risk management measure". In this report RMM is used for "risk mitigation measure."

The ECHA IR/CSA guidance, Part G differentiates between two sets of exposure-determining parameters: operational conditions (of use) ("OCs") and risk management measures. OCs include the type of the process (e.g. dipping, spraying), the type of activities, uses of instruments, or other processing conditions (e.g. temperature, pressure), which can occur during the production or the use of a substance (as such, or in a preparation) and which can have an effect on the exposure of humans and/or environment. Risk management measures include all actions, use of equipment, or parameters introduced with the goal to prevent, to control or to reduce the exposure of humans and/or environment. Both OCs and risk management measures describe the "conditions of use". The use of standard phrases as text modules is considered essential for the elaboration of (extended) SDSs (ECHA 2008a).

Currently described risk management measures related to the environment usually refer to spill management and prevention of harm to the sewage treatment micro-organisms. Standard phrases on waste water and waste air treatment techniques are usually not available in the existing phrase catalogues of substance manufacturers (ECHA 2008a).

In addition to standard phrases, also more specific risk management measure information such as the efficiency of a measure (e.g. percentage of emission reduction) may be needed (ECHA 2008a, ECHA 2008b, Cefic and VCI e.V. 2009).

ECHA attributes the responsibility for developing standard phrases suitable to communicate operational conditions and risk management measures within REACH to industry. The first examples of standard phrases were developed for the Standard Phrases Catalogue by the Federation of German Industries (Bundesverband der Deutschen Industrie e.V., BDI)[51] . CEFIC had established a task force which developed the "Risk management measure library" to support the requirements of the ECHA IR/CSA guidance.[52] The CEFIC risk management measure library also contains some default and maximum achievable risk mitigation efficiencies (Cefic 2010).[53] In the library several data references are given for environmental RMM:

[51] http://reach.bdi.info/378.htm

[52] http://www.cefic.org/Industry-support/Implementing-reach/Libraries/. The RMM library was established during a REACH implementation project (RIP 3.2). The library was not updated or changed since 2007.

[53] The RMM efficiency mainly refers to technical treatment techniques, e.g. for adsorption technology in water media a RMM efficiency factor of 0.1 and for aerobic biological treatment for degradable compounds a RMM efficiency factor of 0.76 is assumed.

Table 12: Data sources for RMM options under REACH

BAT Reference documents for IPPC	The BREF include a catalogue of emission reduction or other environmentally beneficial techniques that are considered to be most relevant in the determination of BAT.[54]
OECD and EU emission scenario documents (ESDs)	Some ESDs list specific emission reduction measures and partly incorporated them into the level of emission factors. However, it is frequently not possible to distinguish the different exposure-determining parameters.
Emission estimation tool for manufacturers, importers, and downstream users within the REACH-system (OECD "matrix project"). UBA/RIVM project	Includes integrated measures to reduce releases from processes or to pretreat discharges on-site. Partly, efficacy in reducing emissions is quantified or integrated in the emission model, partly, there is only qualitative information. Most information is based on the OECD and EU emission scenario documents.

The consideration of RMM for biocidal products in the BREFs and ESDs of the corresponding sectors provides one option for describing best practices and realistic exposure assessments.

The "European Standard Phrases Catalogue for Establishing EU Safety Data Sheets" (EuPhraC) has been established by the former BDI working group "Standard Phrases" and is now being revised by the EU-wide „Working Group EuPhraC.[55] The EuPhraC includes phrases on operational conditions and risk management measures with the majority relating to general advice on the handling of substances. In addition, it describes situations and environmental compartments into which emissions occur. Risk management measures are frequently worded as "condition to avoid", whereas under REACH a positive description of what to implement is required. Hence, in a narrower understanding of risk management measures as defined in the ECHA guidance, only few of the standard phrases currently included in the EuPhraC can be regarded as actually addressing risk management measures.[56] New standard phrases may be proposed by anyone and are evaluated by the working group and potentially integrated the EuPhraC.[57]

The EuPhraC catalogue includes e.g. the hazard statements of the CLP-Regulation. If the standards phrases with respect to the environment from the EuPhra catalogue are structured according to the different life cycle stages to be covered as suggested in a previous project on RMM of biocides (Gartiser et al. 2011) the following examples can be distinguished:

[54] However, these measures are usually described for the „traditional pollutants", such as heavy metals or SOx and dust. Substance specific efficiencies or applicabilities are normally not provided in the BREFs.

[55] http://reach.bdi.info/380.htm

[56] Personal communication Antonia Reihlen, Oekopol GmbH from 10.9.12

[57] Personal communication Dirk Henckels, Qualisys GmbH, Langenfeld, Germany from 21.7.2011

A) Placing on the market[58]

User restriction

- Professional application, industrial use, workers (industrial/professional)
- Risk management measures, professional (e.g. soil/water, air)[59]
- Consumer application

Intended uses and area of application

- Observe consumer instruction/communication on safe use.

Package size

- Provide in small packages only!

Design of the biocidal product mode of application

- Conditions and measures at level of article production process to prevent release during service life

B) Application of biocidal products[60]

Mixing and loading

- Mixing and filling processes, by machines.
- Transfer materials directly to mixing vessels.
- Minimise residue by optimised weighing, charging and mixing of the substances used.
- Use only automated, enclosed, separately ventilated process steps (e.g. mechanical mixing, application, spraying, curing or other thermal process, grinding or other abrasive process).

Equipment

- Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil.

Further Risk Management options

- Keep good industrial hygiene.
- Do not allow contact with soil, surface or ground water.

---

[58] In the REACH system the options for restricting the product use to certain user groups or forms belong to the specification of the "intended use" or the "use advised against" rather than to the risk management measures. However, factually emission and exposures may be reduced by these specifications.

[59] May be interpreted as risk management measures for the environment resulting from the restriction to professional uses.

[60]. The below phrases all relate to the operational conditions of a chemical if strictly interpreting the definition of OCs and risk management measures as defined in the ECHA guidance on information requirements and chemical safety assessment, as they aim at increasing processing efficiency as well as emission reduction.

- Technical conditions and measures at process level (source) to prevent release.
- Organizational measures to prevent/limit release from site.

C) Post application

Storage

- Use appropriate container to avoid environmental contamination.

Disposal

- Clean the tool immediately after use with: xxx.
- Dispose of sludge.
- Recover sludge.
- Conditions and measures related to disposal of articles at end of service life.
- Conditions and measures related to recovery of articles at the end of service life.

Drainage

- Avoid release to the environment. Refer to special instructions / SDS.
- Do not allow uncontrolled discharge of product into the environment.
- Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.
- Flow rate of receiving surface water (m^3/d):

Wastewater treatment

- Product may/should not be released into water without pre-treatment (biological sewage plant).
- Conditions and measures related to municipal sewage treatment plant.
- Size of municipal sewage system / treatment plant (m^3/d).
- Capacity of receiving environment: xxx
- Water flow in sewage/river:
- Sludge treatment technique.
- Measures to limit air emissions.

D) Further regulatory options

- Environment factors not influenced by risk management[61]
- Other given operational conditions affecting environmental exposure.
- Environmental hazards cannot be excluded by inappropriate handling or disposal.

Most of these standard phrases describe the intended uses, the operational conditions, or the capacity of the receiving environment and thus, under REACH, are not considered risk management measures. The phrases which relate to the environmental risk either describe a legal situation (restrictions, prohibitions of release) or qualify which compartment is most at risk from a substance. Examples of standard phrases are:

- Discharge to aquatic environment is restricted (= legal situation).
- As no environmental hazard was identified no environmental-related exposure assessment and risk characterization was performed (=legal situation of registrant).
- Risk from environmental exposure is driven by freshwater (=compartment at risk).
- Risk from exposure via the aquatic environment is driven by effluent discharge to freshwater (=compartment at risk).
- Prevent environmental discharge consistent with regulatory requirements (=legal situation connected with a “don’t”).
- Discharge to aquatic environment is restricted by law and industry prohibits release (=legal situation).
- Other operational conditions of use affecting environmental exposure (=operational condition).
- Dispose of waste in accordance with environmental legislation (=legal situation).

The EuPhrac is integrated into the communication standard ESCom.XML developed by industry that aims to facilitate the IT-communication of SDS/ES. The ESCom Guidance refers to the following technical measures at process level (source) to prevent release to the environment, which are actually referring to risk management measures in the sense of REACH:

- physico-chemical elimination.
- biological elimination.
- Contain and treat vapours from stripping operations.

[61] The flow rate of receiving surface water is mentioned as one environment factor not influenced by the risk management. This refers to an environmental condition that the registrant may assume in his chemical safety assessment and then has to communicate with the ES/SDS in order to allow the user to check if he implements the conditions in the exposure scenario (personal communication Antonia Reihlen, Oekopol from 10.9.12). With respect to biocides the reverse interpretation would be to restrict the area of use to those who discharge to a river with a minimum flow rate of the receiving water of x m^3/s. However, the practicability of such a condition is questioned by the consultants.

- Incinerate, absorb, or adsorb vapours stripped from solution whenever necessary.

With respect to Operational Conditions for consumers the following examples with (direct or indirect) relevance for the environment have been referred to in the ESCom Guidance:

- Amount per use.
- Concentration after dilution for use maximum [%]: xxx
- Automated task.
- Exposure duration.
- Spray duration.
- Use frequency.
- Delivery in small amounts is recommended.
- Delivery in viscous solutions is recommended.
- Ensure that splashes and spills are avoided by product design.

No phrases concerning risk management measures were identified.

In addition to the above, the sector organisations under the umbrella of CEFIC develop so called Specific Environmental Release Categories (SpERCs). SpERCs are a set of information on the operational conditions, potentially including risk management measures, which describe how a substance is used in a specific application. Each SpERC includes so called “release factors” which specify the percentage of a substance input into a process which is released to the different environmental compartments (water, air, soil). Risk Management Measures may also be described in a SpERC and, in the ideal case, is specified with an efficiency of emission reduction.

Again, the background is that REACH uses exposure scenarios for establishing and communicating conditions of safe use of substances in the supply chain. SpERCs can support the development and communication of these exposure scenarios for the environment, as they provide standardised information on the conditions of use. All SpERCs include a description of the respective use, the number of emission days and whether or not a municipal sewage treatment plant is assumed to exist and the release factors specifying the share of the substance input emitted from the process to air, water and soil.

While the Environmental Release Categories (ERC) defined in the ECHA IR/CSA guidance are used as a starting point for emission estimates under worst case conditions the SpERCs describe the good practices and may consider the application of risk management measures. The SpERCs are developed by industry sector groups and trade associations and are published as fact sheets, which partly also refer to risk management measures (default efficiency values in % removal).

The CEFIC guidance document on SpERCs provides some standard phrases to express the requirements towards onsite risk management measures to reduce or limit discharges, air emissions and releases to soil. However, the decision on which types of risk management measures are appropriate to achieve the required emission reduction should be taken by the registrant as part of his chemicals safety assessment. It depends on the process and the type of substance he registers. Examples of phrases are:

- Treat onsite wastewater (prior to receiving water discharge) to provide the required removal efficiency of x (%).
- If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of x (%).
- If discharging to domestic sewage treatment plant, no onsite wastewater treatment required.
- Treat air emissions to provide a typical removal efficiency of (%).

SpERCs are generic descriptions of a "realistic-worst case point source" or "average diffuse emission sources" and may specify some local parameters such as the maximum use amount of a substance or the minimum flow rate of a sewage treatment plant received the discharge. Examples of phrases are:

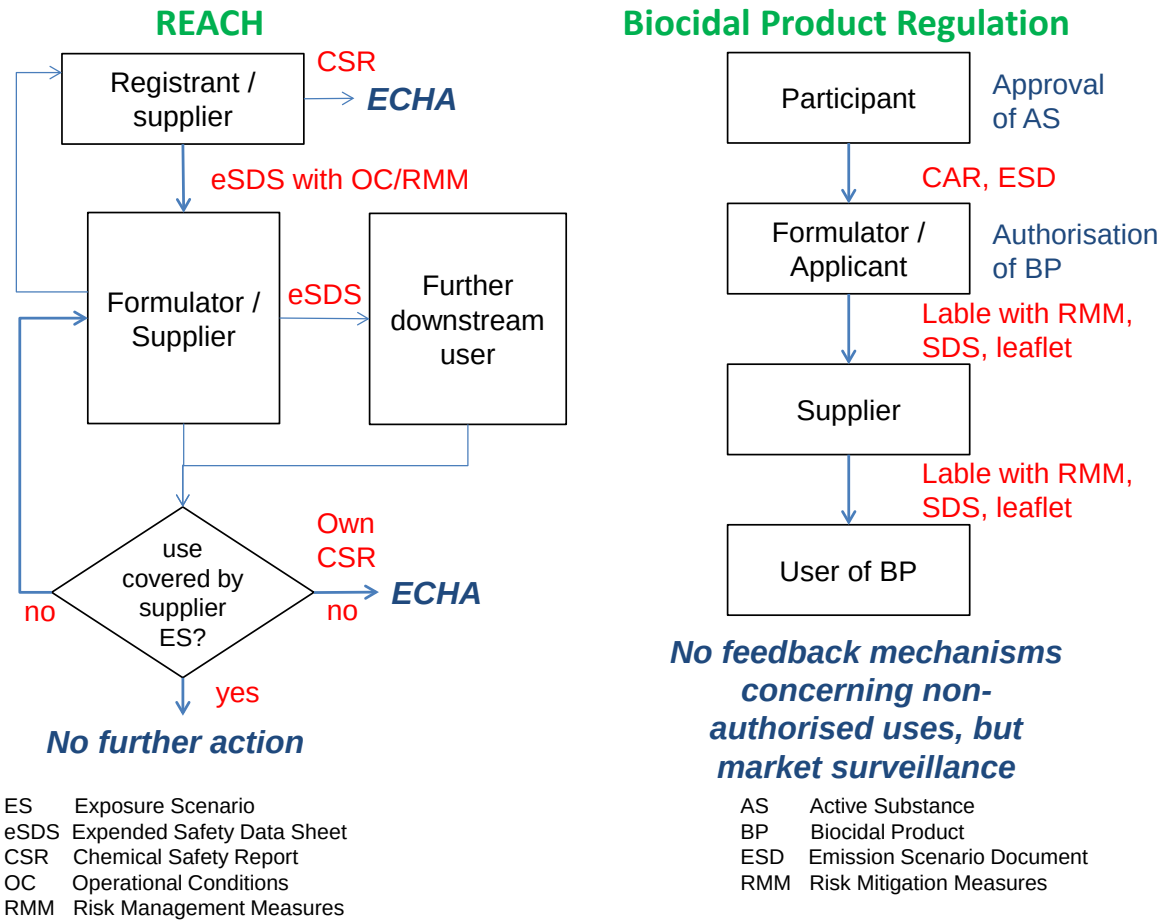
- Maximum allowable site tonnage (MSafe) based on release following total wastewater treatment removal is x (kg/d)
- Assumed domestic sewage treatment plant flow is x m3/d) (the SpERC default value is 2000 m^3/d).

If with SpERC- based emission estimates a possible risk is identified a refinement of the assessment is needed. Here, higher tier environmental exposure estimation options are applied, such as model calculations, the consideration of the local freshwater dilution factor, or comparison of measured environmental concentrations (CEFIC 2010).

An analysis of the process of different industrial associations for developing and documenting SpERCs has been carried out by Lüskow et al. (2011). One result of the project was that the stakeholders (industry, authorities, registrants, downstream user) differ in their expectation, understanding, and application of SpERCs. Furthermore it was found out that the differentiation between operational conditions and obligatory and optional risk management measures is not very clear in the SpERCs, leading to confusion with regard to the applicability of the release factors.

There is one important difference between RMM applied under REACH and product authorisation schemes such as the BPR and the Plant Protection Products regulation. Under REACH risk management measures necessary to ensure the safe use of a substance as such or in mixtures are communicated in the supply chain to the downstream user. The downstream user has the obligation to check whether or not his use of the substance is accordance with the conditions in the exposure scenario. This may result in a duty to communicate to the supplier or to ECHA if the operational conditions and/or risk management measures in the exposure scenarios or safety data sheets do not describe the particular use conditions (REACH Article 34 and 37). In this case, the supplier may refine the eSDS or the downstream user may perform an own assessment which proves that his use does not cause any risks (downstream user chemical safety report - DU CSR) and submit to ECHA a notification that he did so.

In the biocide sector RMM may be required as prerequisite for a biocidal product to be authorised, but there does not exist a formalised feedback mechanism from the user to the supplier (see Figure 2).



ES Exposure Scenario
eSDS Expended Safety Data Sheet
CSR Chemical Safety Report
OC Operational Conditions
RMM Risk Management Measures

AS Active Substance
BP Biocidal Product
ESD Emission Scenario Document
RMM Risk Mitigation Measures

Figure 2: Application of RMM under REACH and under the BPR

The main difference between REACH and the BPR is, that under the BPR specific uses must be authorised which offers the opportunity to implement RMM by restricting the category of user, the use areas, and specific product specifications, which under REACH would be assigned as operational conditions.

4.2.3 IPPC Directive

Under Directive 2008/1/EC concerning integrated pollution prevention and control (IPPC-Directive) several Best Available Techniques Reference Documents (BREFs) have been developed for sectors where disinfectants are applied:

Table 13: BREF documents under the IPPC Directive

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

The evaluation of the BREFs is summarised in the respective product type sub-chapters of Chapter 3.

4.2.4 Safety precautions concerning plant protection products

On 14 June 2011, Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market repealed and replaced Directive 91/414/EEC.

ANNEX V of Directive 91/414/EC describing standard phrases for safety precautions for the protection of humans or the environment will be included in Regulation (EC) No 1107/2009.

The following additional standard phrases for the environment are defined to supplement the phrases provided for by Directive 1999/45/EC:

Table 14: Standard phrases for safety precautions under the PPP Regulation

	Standard phrase referring to the environment (SPe)	**Assignment of standard phrases**
SPe 1	To protect groundwater/soil organisms do not apply this or any other product containing *(identify active substance or class of substances, as appropriate)* more than *(time period or frequency to be specified)*	The phrase shall be assigned to PPP for which an evaluation shows for one or more of the labelled uses that RMM[62] are necessary to avoid accumulation in soil, effects on earthworms or other soil-dwelling organisms or soil microflora and/or contamination of groundwater.
SPe 2	To protect groundwater/effects on aquatic organisms do not apply to (*soil type or situation to be specified)* soils.	The phrase may be assigned as a RMM to avoid any potential contamination of groundwater or surface water under vulnerable conditions (e.g. associated to soil type, topography or for drained soils), if an evaluation shows for one or more of the labelled uses that RMM are necessary to avoid unacceptable effects.
SPe 3	To protect aquatic organisms/non-target plants/non-target arthropods/ insects respect an unsprayed buffer zone of (distance to be specified) to non-agricultural land/surface water bodies.	The phrase shall be assigned to protect non-target plants, non-target arthropods and/or aquatic organisms, if an evaluation shows for one or more of the labelled uses that RMM are necessary to avoid unacceptable effects.
SPe 4	To protect aquatic organisms/non-target plants do not apply on impermeable surfaces such as asphalt, concrete, cobblestones, railway tracks and other situations with a high risk of run-off.	Depending on the use pattern of the plant protection product, Member States may assign the phrase to mitigate the risk of run-off in order to protect aquatic organisms or non-target plants.
SPe 5	To protect birds/wild mammals the product must be entirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows.	The phrase shall be assigned to plant-protection products, such as granules or pellets, which must be incorporated to protect birds or wild mammals.
SPe 6	To protect birds/wild mammals remove spillages.	The phrase shall be assigned to plant protection products, such as granules or pellets, to avoid uptake by birds or wild mammals. It is recommended for all solid formulations, which are used undiluted.

[62] Regulation (EC) No 1107/2009 refers to "Risk Mitigation Measures" (RMM) as the BPD does.

	Standard phrase referring to the environment (SPe)	Assignment of standard phrases
SPe 7	Do not apply during bird breeding period.	The phrase shall be assigned when an evaluation according to the uniform principles shows that for one or more of the labelled uses such a mitigation measure is necessary.
SPe 8	Dangerous to bees/To protect bees and pollinating insects do not apply to crop plants when in flower/Do not use where bees are actively foraging/Remove or cover beehives during application and for (state time) after treatment/Do not apply when flowering weeds are present/Remove weeds before flowering/Do not apply before (state time).	The phrase shall be assigned to plant protection products for which an evaluation shows for one or more of the labelled uses that RMM must be applied to protect bees or other pollinating insects. Depending on the use pattern of the plant protection product, and other relevant national regulatory provisions, Member States may select the appropriate phrasing to mitigate the risk to bees and other pollinating insects and their brood.

Further standard phrases for safety precautions for good agricultural practice have been established which mainly refer to rodent control (resistance strategy, secure deposit of the baits, marking the treatment area, removal of dead rodents).

The standard phrases mainly refer to situations typical for PPP and not for disinfectants. However, the composition of standard phrases (protection goal, specific quantifiable instructions for use, indication when to assign the standard phrase) could be also adopted for biocides. The standard phrases SPe 3 and SPe 4 referring to the protection of surface water through prevention of direct releases might have their correspondent disinfectant use (e.g. surface disinfection in the surroundings of swimming pools or in livestock building not connected to STPs).

4.2.5 National RMM-phrases for biocidal products

The Netherlands

In the Netherlands, the Board for the Authorisation of Plant Protection Products and Biocides (CTGB) also is responsible for non-agricultural pesticides which have been subjected in national authorisation schemes since 1962. RMM are derived from the risk assessment (if a risk is identified for specific use), in combination with agreed RMM proposed by applicants. The authorisation decision includes so called “Legal Instructions for Use” (LIU) which have to be put on the product label can be found on the pesticides databank at the CTGB website[63, 64, 65] (LIUs are in Dutch, but the evaluation reports are in English). LIUs consist in a general section with a

[63] Evaluation Manual for the Authorisation of plant protection products and biocides, NL part, chapter 7, General introduction □http://www.ctgb.nl/ > application > Evaluation manual > Biocides

[64] A excel list of the existing LIU has been provided by Dr.. P. C. Okkerman (CTGB). The list is not publicly available but is mainly an internal document to standardise mitigation measures. It is still growing and therefore changes on a regular basis.

[65] http://www.ctgb.nl/ > Pesticides and active substances > Pesticides database > Biocidal product-types

description of the authorised use including RMM and a more specific section with a higher level of detail (concentration to be used, frequency of treatment ...). The LIU represent a compromise between the efficacy of the biocide and the acceptable risks on human health and the environment. The LIU is helpful for the standardisation of the authorisation process because it facilitates the identification and agreement on measures and standardises their communication preventing misunderstandings and enabling quick recognition of instructions. A similar system on EU level would be helpful. The feasibility and practicability of conditions and measures specified by the LIU is checked with inspection agencies and experts in the field. Elements of the LIU include information about the efficacy (target species, dosage, time, frequency...), consumer information (site of application – safety requirements, restrictions), applicant instructions (protection measures), resistance management, and regulations/restrictions with regard to the environment. In practice, according to the Dutch authorities, legal compliance with the LIU can only be enforced with respect to professional users to some extent while for consumers and private persons this cannot be realised (Gartiser et al. 2011). Some examples of environment related RMM in LIUs are shown in Table 15.

Table 15: Environment-related RMM included in the Legal Instructions for Use (LIU) of biocides by the Dutch authorities

Emission via STP to water (indoor application)	To protect water-living organisms, this product may only be applied if spills and residues containing the product are discharged to the sewer connected to the STP. To protect water-living organisms, prevent that residues containing the product enter the sewer and apply the following safety measures: "..." To protect water-living organisms and micro-organisms in the STP, it is not permitted to discharge spills and residues containing the product to the sewer or surface water. To protect soil organisms and water-living organisms, residues containing the product need to be removed to the manure deposit. To protect water-living organisms, residues containing the product should be discharged to the sewer connected to the STP. For disinfection of surfaces >2000 m^2, the sewer connection of that facility must be preceded by a sediment grease separation tank conforming with EN 1825-1 and 2.
Direct emission to surface water (indoor application, emission from drift)	To protect water-living organisms [and soil organisms] prevent contamination of surface water [and soil] (due to drift or run off of the product or residues containing the product).
Direct emission to soil and water (outdoor application)	To protect [water-living organisms, groundwater and soil organisms], application of this product is restricted to areas with a hard standing. Spills and residues containing the product need to be removed to the sewer [with connection to a STP] [or manure deposit]. It is not permitted to apply this product on hard standing areas like asphalt, concrete and cobble stones [and railways] or other places that result in a quick drain away to soil or surface water. (Spills and residues containing the product need to be removed as chemical waste).
Risk for birds and mammals	To protect birds, pets and mammals, spills and residues containing the product need to be removed as chemical waste.

The environmental RMM do not refer to certain product types, but differentiate emission routes such as direct (e.g. outdoor use) or indirect emission (e.g. indoor use) to sewer, water or soil or potentially exposed animals (birds and mammals) where the risk assessment without these measures indicates an unacceptable risk.

A general principle for RMM on labels of products for professional use is that they must be enforceable. If this is not possible then the specific use is restricted (e.g. indoor use only) or

removed from the label (e.g. use for the disinfection of stables for broilers is not permitted). RMM on labels of products for non-professional use are only recommendations. If these RMM are difficult to achieve, then these specific types of use must be removed from the label or the product cannot be authorised. A future goal is to separate products for professional and non-professional use and provide them with separate labels. As a general principle the reason for RMM (e.g. where the risks are and what should be protected) should clearly be indicated. According to the Dutch CA the RMM should not repeat the LIU which are already included on the label, derived from the classification and labelling requirements but should go further.

United Kingdom

The UK CA developed guidelines for precautionary phrases which distinguish between amateur, professional, and industrial users.[66]

Here the safety-phrases of the Dangerous Substances Directive as well as additional phrases are referred to with focus on surface biocides (e.g. wood preservatives), insecticides, repellents, rodenticides, antifouling products, algicides, and vertebrate repellents. Disinfectants are not specifically addressed. In principle, the guidance helps the application of requirements for classification and labelling. Examples are:

If the product carries the classification of N: Dangerous for the environment (R50, R50/53, R51 or R51/53), add: “Do not empty into drains” (S29)

If the product is applied outdoors and carries R50 / R51 / R52 and /or R53, add: “Do not contaminate ground, waterbodies or watercourses with chemicals or used container”.

Germany

The German Federal Environment Agency and the Federal Institute for Occupational Safety and Health (BAuA) elaborated so called “Encoded standard instruction phrases in the biocides procedure”. These formulation proposals can be referred to by the applicants for the design of a label with additional details according article 20 (3) of the BPD. The list includes the S-phrases of the Dangerous Substances Directive as well as the P-numbers of the CLP-Regulation. Further on, several Sh, Sg, Sj, and Sk numbers, which refer to Article 20 on classification, packaging and labelling of biocidal products of the BPD[67] are indicated, such as

- Sk1 Only for professional users.
- Sk2 Application only by persons with certificate of competence for fumigation operations.
- Sk3 Application only by persons with expert knowledge (e.g. qualified pest control personnel).
- Sh1 Do not dispose of with household and commercial waste.

[66] UK Guidelines for precautionary phrases (April 2009). The 78 pages document has been provided by the German Federal Environment Agency. The current status is not known.

[67] Article 20 (3) of the BPD requires that the label must show clearly and indelibly the information, indicated in phrases a to m.

- Sh2 Avoid direct release of undiluted product into the sewage system or the environment.
- Sh3 Only pass on empty containers/packaging for recycling.
- Sg1 Read the attached instructions before use.
- Sj13 Keep available binding agents (e.g. oil binders) to take up liquids which would pollute water.
- Sj14 In case of contamination of soil or water bodies notify the competent authorities.

Further numbers specifically refer to the safe use of wood preservatives and rodenticides.

5 Elaboration of guidance documents

The RMM guidance documents developed within the project were aimed to support the harmonisation of RMM on a European level in order to facilitate the European market and mutual recognition of biocidal product authorisations.

The only agreed guidance document on RMM for biocides elaborated at EU level refers to the use of rodenticides. Based on the structure of that document a proposal for further guidance documents was developed which describe concrete RMM for the use of disinfectants.

The guidance documents on RMM for disinfectants developed within this project provide a first proposal to be discussed among CA. Another objective of the guidance documents is to provide a set of standard RMM-phrases and a clear specification concerning the application of RMM in the risk assessment. Existing RMM-phrases are included in the annexes of the guidance documents but some flexibility should be provided for reflecting the national situations and different use patterns.

5.1 Analysis of the RMM guidance document for rodenticides

Anticoagulants were chosen as subject for the first RMM guidance document because especially the 2nd generation anticoagulants are highly toxic, non-selective, and classified as PBT. In addition, resistance to some of these substances has been reported. According to the Commission the choice of specific risk mitigations measures is closely linked to the design, the package, the area of use, the category of users, the conditions of use, and the composition of the product. Thus, specific RMM are deferred to the product authorisation stage. In the specific provisions of the Annex I inclusion only general RMM, which can apply to all products, are described.

Table 16: Evaluation of the guidance document on RMM for anticoagulants

	RMM proposed in the guidance document	Interpretation of the objectives
Category of users	Restriction to professional uses if other RMM do not adequately limit the risks.	Avoidance of resistance development
Area of use	Use in and around buildings or indoor use only. Outdoor use by professionals only. Amateur use only indoors with ready-to-use products.	Prevention of primary and secondary poisoning of non-target organisms
Composition	Products should not contain more than X % of the active substance (exemption for professionals). Products shall contain an aversive agent and a dye. Products shall not contain aromas/ flavours attractive to humans.	Reduce the risk of primary and secondary poisoning
Formulation	Non-dusting formulation. Ready-to-use products.	Reduce the risk for the operator
Packaging	Product design that make baits less accessible to birds, domestic animals and children.	Reduce the risk of exposure and increase of operator safety

	RMM proposed in the guidance document	Interpretation of the objectives
Pack size	Larger pack sizes restricted to professionals, small pack sizes for amateur users.	Proportionate pack size to the duration of the treatment
Codes of Good Practices	Careful management of anticoagulant rodenticides by application of several good practice documents and training courses available to professional users.	Minimise exposure to non-target species whilst maximising impact in target rodents.
Labelling	Standard phrases such as: Baits must be securely deposited in a way so as to minimise the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away. Search for and remove dead rodents at frequent intervals during treatment (unless used in sewers), at least as often as when baits are checked and/or replenished. Dispose of dead rodents in accordance with local requirements. Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits. Remove all baits after treatment and dispose of them in accordance with local requirements. Keep out of the reach of children. When the product is being used in public areas, the areas treated must be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.	Description of the special risks and the safety precautions

Defining RMM for anticoagulants is special because for substances fulfilling the PBT and vPvB criteria, the exposure and risk characterisation has the objective to minimise emissions from identified uses and subsequent exposures of humans and the environment (Chapter R.11 of the ECHA IR/CSA guidance, May 2008). Hence, no safe level exists and the measures are not derived based on the assumption that they ensure safe use. In contrast to PBT substances, the risk characterisation according to the PEC/PNEC concept refers to the risk quotient as a trigger value (PEC/PNEC > 1) which defines the level of risk.

The analyses of the RMM document for anticoagulants indicate that next to specific RMM such as the “area of use” or “instructions for the formulation of rodenticides” also general RMM are considered. Especially the reference to codes of good practices is directed to the use phase and compliance with these general RMM by the user is difficult to control, even for professional users. In order to motivate user to act and make risk management as easy as possible, one objective of the guidance document is to indicate further information sources on guidance for safe use.

5.2 Use of standard phrases in the guidance document

The standard phrases established in European legislation or proposed by industrial associations or authorities refer to both general as well as specific RMM. The main focus of the specific RMM phrases is on wood preservatives, rodenticides, and insecticides (PT 8, 14, 18).

Specific RMM for disinfectants are scarce. Several working groups elaborate lists of standard phrases and it may be useful to co-operate with them and use the already existing phrases for the guidance documents as far as applicable and by including further specific RMM phrases for disinfectants into the existing lists.

It is suggested to assign the problematic emission route (STP, water, soil, air, wildlife), the user group (industrial, professional, non-professional), and the respective life cycle category to each of the RMM. The life cycle stage include the formulation or product design[68], the use, the service life (e.g. for treated articles) and waste (treatment / disposal). If reasonable, the specific RMM should be composed like standard phrases from the PPP area. That means that the protection goal is mentioned (e.g. “in order to protect surface water ...”), that specific quantifiable instructions for use are indicated (“removal efficiency of wastewater treatment > x%”) and that guidance is given, when to assign the standard phrase (“the phrase may be assigned as a RMM if an evaluation shows that...”). If the description of the protection goals or of the RMM requires too extended texts some deviations from the ideal standard phrase may be required for practical reasons.

5.3 Trigger value for RMM

It should be distinguished between general RMM and specific RMM. General RMM reflect the application of best practices, BAT, good housekeeping, general hygiene requirements, precautionary and preventive measures. It is suggested that these are triggered by the hazards of the ingredients (biocidal active substance and additives) or by the classification of the biocidal products. Especially the classification as “(very) toxic or harmful to aquatic life” and “with long lasting effects” could lead to an assignment of general RMM, similar and in addition to the precautionary statements of the CLP Regulation. Some general RMM could also be considered in the context of sustainable use of biocides.[69]

Specific RMM have to be adopted where the risk assessment indicated a risk for the environment. In this case these RMM are a prerequisite for the authorisation of biocidal products. Thus, specific RMM should be risk based and derived from the risk assessment. Nevertheless there may be exemptions which reflect national requirements. A quantification of the efficiency of RMM is required in order to be considered in the calculation of risk quotients (see Figure 3).

[68] The manufacture of active substances is not covered by the BPD or the BPR.

[69] Directive 2009/128/EC on sustainable use of pesticides only covers plant protection products so far but it already states that similar provisions could also be adopted for biocides.

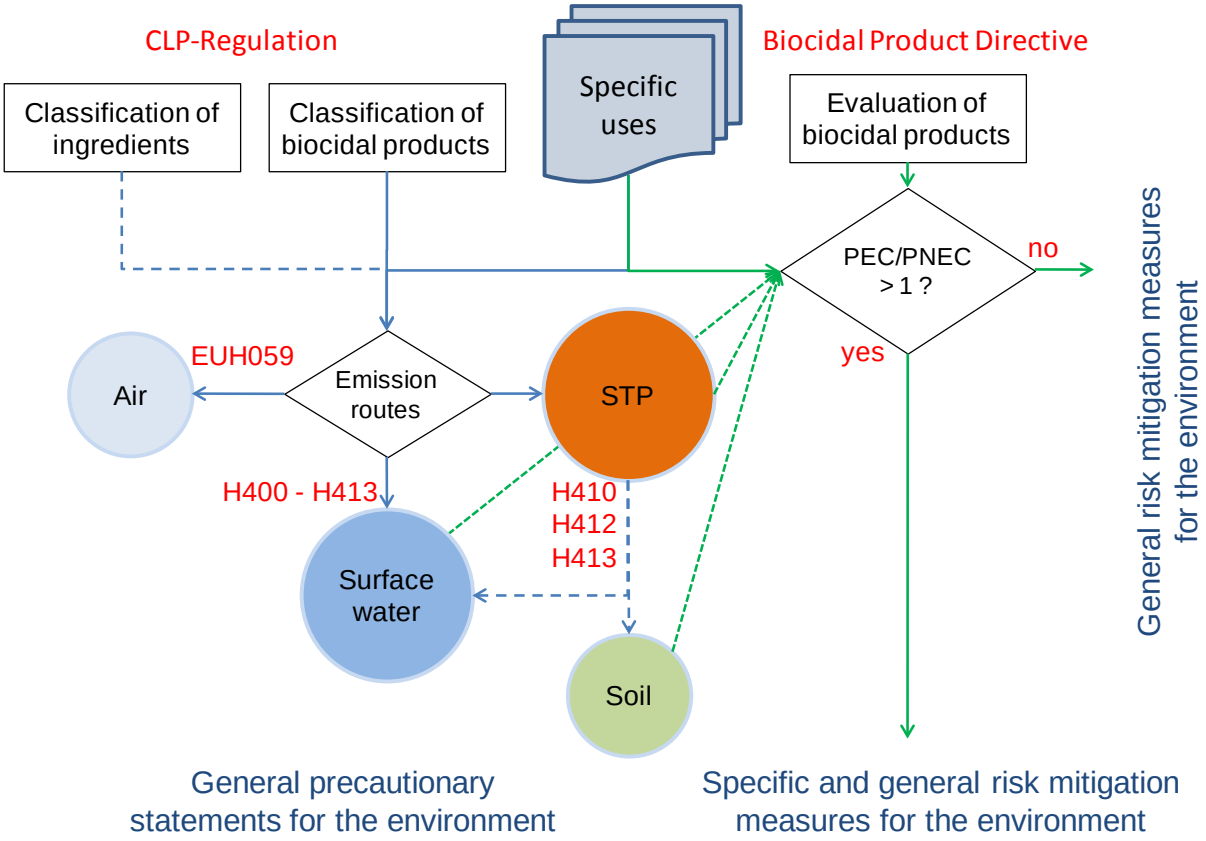


Figure 3: Assignment of general and specific RMM

In Figure 3 the blue lines represent the information resulting from the classification of the ingredients and biocidal products while the green lines represent the results of the risk assessment of a specific biocidal product.

The environmental compartment predominantly affected should be considered when deriving RMM. STPs are an important intermediate compartment for many disinfectants and thus it should be distinguished between direct emissions to surface water and discharges to STP. Substances which are very toxic to aquatic life without long lasting effects (H400) are probably eliminated effectively during wastewater treatment, except if they are toxic to activated sludge organisms. However, they may exhibit acute effects when directly released to surface water. Substances with long lasting effects (H410 to H413) might not be quantitatively removed in STP or might be spread with sewage sludge to soil.

Referring to specific RMM it remains the question when to apply them. While risk quotients (PEC/PNEC) > 1 clearly indicate a risk, some researchers also assume that a PEC/PNEC of > 0.1 still indicates a residual probability that adverse effects can occur.[70] Article 17 of the BPR describes criteria for low-risk biocidal products. Again, "low-risk" is defined where the risk quotient for any given environmental compartment is lower than 0.1. The same conclusion can

[70] Dr David Aston, Arch Timber Protection, UK; The Regulator's view about alternative approaches to PEC/ PNEC comparisons in environmental risk assessment; http://www.bfafh.de/inst4/43/ppt/3regulat.pdf

be found in the TNsG on Annex I inclusion (2002) stating that “an active substance shows effects of concern if PEC/PNEC ratio is lower than 1 but higher than 0.1 (the result of the risk assessment indicates a residual probability that adverse effects can occur). In the context of cumulative environmental exposure of biocides and mixture toxicity also a trigger value of PEC/PNEC = 0.1 has been proposed as an indicator to carry out a deeper evaluation (Groß et al. 2010). Thus, it is necessary to allow some flexibility in adopting specific RMM which minimise the risk without restricting the access to the market also in cases, where the risk quotient is between e.g. 0.1 and 1. If the risk quotient for one single use exceeds 0.1, for example, a cumulative exposure assessment could be carried out or RMM may be suggested to further reduce the risk following the precautionary principle. However, if the PEC/PNEC is below 1 the authorisation of the product will be granted if all other provisions are fulfilled as well.

In the study on RMM for veterinary medicinal products it was supposed that available RMM should also be applied where if the risk quotient PEC/PNEC is < 1 considering other legislative principles such as the prohibition of the deterioration of water quality prescribed in the Water Framework Directive (Liebig et al. 2011). Also the Committee for Medicinal Products for Veterinary Use recognises that “zero risk” does not exist and therefore potential RMM should be considered (CVMP 2009).

5.4 Structure of the guidance documents

There has been a discussion with CAs whether one RMM guidance document covering all disinfectants (PT 1-5) should be elaborated or one guidance for each PT.

From Annex V of the BPD and Chapter 3 of this report it becomes evident, that PT 1-5 are very diverse. They include:

- skin disinfectants (PT 1),
- products used for the disinfection of surfaces, materials, equipment, air conditioning systems, and swimming water treatment in private, public and industrial areas (PT 2),
- products used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported (PT 3),
- products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food and feed (PT 4) and
- drinking water disinfectants (PT 5).

Especially PT 2, referring to “other biocidal products” in the private and public health area can be regarded as a reservoir for all possible application areas.

Obviously, the limited number of specific RMM identified most often cover several PTs, on the other hand some RMM, such as those with respect to CIP (PT 4) or manure storage (PT 3) cover only one PT. The general introduction to the use areas and the corresponding ESDs as well as the references to the best practice documents were better described in PT specific guidance. Furthermore, specific guidance documents, in which all information that is not applicable or required is deleted, seemed better readable. Therefore, it has been decided by the project advisor from the German UBA to draft one guidance document for each PT while accepting that some repetition is inevitable.

It was suggested that all RMM guidance documents should follow a uniform structure covering the following items:

- Background and description of the product type
- Introduction on general and specific RMM
- Category of users
- Area of use
- Composition
- Formulation
- Packaging and pack size
- Treatment and/or disposal
- Codes of Good Practices
- Annex with general and specific standard phrases on RMM for the product type

This structure also reflects the composition of the RMM guidance documents for anticoagulants. It was further suggested that general RMM, triggered by the classification of the active substances and/or product should be distinguished from specific RMM, triggered by the outcome of the risk assessment.

6 Recommendation and outlook

The following conclusions and recommendations are given:

- Many oxidising active substances are inactivated during use. Other active substances, such as alcohols or aldehydes, are readily biodegradable. For most substances evaluated so far no concerns for the environment have been identified. However, only few active substances of PT 1-5 have been evaluated yet and the assessment cumulative exposure is often missing.
- Neutralization of the active substance(s) before discharge to the sewer or surface water is a RMM sometimes applied, especially for strong acids/bases or oxidising agents.
- Most disinfectants are designed to be inactivated in municipal biological sewage treatment plants. Disinfectants for veterinary hygiene (PT 3) and in the food industry may also be treated in on-site STPs (PT 4). Further treatment techniques next to neutralisation are rarely applied.
- Biological treatment in municipal or on-site STP is the most common RMM for the protection of surface water.
- Many disinfectants also contain detergents and other ingredients that may be of higher environmental concern than the active substances themselves. Therefore these additives should be specifically considered in the risk assessment during product authorisation.
- The formation of DBPs almost exclusively has been considered in the context of drinking and swimming water treatment so far. It mainly depends on the presence of organic matter and other precursors of DPB. The formation of DBP under the use conditions should be considered in the assessment of all biocidal products with oxidising active substances.
- Under REACH risk management standard phrases are being developed which will be included in the extended SDS together with the exposure scenarios and operational conditions. Although part of the standard phrases might be adopted for biocides the difference between REACH and the BPD should be kept in mind: Under REACH RMM are communicated in the supply chain to the downstream user, who has the duty to inform the supplier if they are inappropriate. In the biocide sector RMM may be required as prerequisite for a biocidal product to be authorised, but there does not exist a formalised feedback mechanisms from the user to the supplier.
- The selection of RMM should consider realistic options which reflect best practices and require some surveillance by authorities. However, only few data on efficiency of a certain RMM are available. The quantification of the efficiency of RMM requires sound risk assessment by modification of the input parameters.
- Surveillance and enforcement of RMM are critical points.
- In the guidance documents it is distinguished between general RMM and specific RMM. General RMM reflect the application of best practices, best available techniques, good housekeeping, and general hygiene requirements. These contribute to a sustainable use of disinfectants. Specific RMM are risk based and thus derived from the environmental risk assessment. They will be prerequisite for the authorisation of biocidal products with

identified unacceptable risks for environmental compartments or biota. A quantification of the efficiency, practicability of specific RMM and an evaluation of the possibility of enforcement of RMM are required, in order to be considered in the calculation of risk quotients.

- Some RMM might also be appropriate if the risk quotient shows a level of concern (e.g. PEC/PNEC > 0.1) and/or cumulative environmental exposure resulting from the use of different biocidal products with the same active substance (from the same PT or different PTs) is expected.
- RMM on labels of products for non-professional use should only be considered as recommendations. If these RMM are too complex and difficult to achieve, these specific uses should not be authorized if the RMM are needed to lower a PEC/PNEC ratio below 1.
- The benefits of consumer use of PT 2 disinfectants is controversially discussed among hygienists who argue that untrained consumer often do not apply disinfectants effectively. Only general RMM for consumer uses of disinfectants have been identified which can only be regarded as recommendations. For consumer products only product integrated RMM under the control of the supplier (chemical composition and design) may quantitatively be considered in the risk assessment.
- Little information about emissions and no emission scenarios from treated articles attributed to PT 2 are available. Those RMM proposed for treated articles mainly cover the end of use part of the life cycle. This will be a future field of research.

7 References

Abegglen, C., Escher, B., Hollender, J., Koepke, S., Ort, C., Peter, A., Siegrist, H., von Gunten, U., Zimmermann, S., Koch, M., Niederhauser, P., Schärer, M., Braun, C., Gälli, R., Junghans, M., Brocker, S., Moser, R., Rensch, D. 2009. Ozonung von gereinigtem Abwasser Schlussbericht Pilotversuch Regensdorf. Studie der Eawag im Auftrag des Bundesamts für Umwelt BAFU und des AWEL Amt für Abfall, Wasser, Energie und Luft des Kantons Zürich, Dübendorf, 16. Juni 2009 http://www.bafu.admin.ch/gewaesserschutz/03716/03720/04348/index.html?lang=de

Amy, G., Bull, R., Craun, G. F., Pegram, R. A., Siddiqui, M., 2000. Disinfectants and disinfectant by-products. United Nations Environment Programme, International Labour Organisation, World Health Organization, International Programme on Chemical Safety. Environmental Health Criteria 216, 1–499. whqlibdoc.who.int/ehc/WHO_EHC_216.pdf

Anonymous 1999. Hygiene Code for the private household based on the Dutch situation. Netherlands Nutrition Centre http://www.nutricion.org/publicaciones/pdf/hygiene_codehouses.pdf

Anonymous 2000. Abwasser aus Schwimm- und Heilbädern. Bayerisches Landesamt für Wasserwirtschaft Merkblatt Nr. 4.5/2-31 from 1.8.2000 http://www.lfu.bayern.de/wasser/merkblattsammlung/teil4_oberirdische_gewaesser/doc/nr_458.pdf

Anonymous 2004. Hinweise zur Abwasserentsorgung bei landwirtschaftlichen Einzelanwesen. Bayerisches Landesamt für Wasserwirtschaft Merkblatt Nr. 4.2/3 from 01.10.2004 http://www.lfu.bayern.de/wasser/merkblattsammlung/teil4_oberirdische_gewaesser/doc/nr_423.pdf

Anonymous 2005. Beseitigung von Abwasser aus Milchkammern im ländlichen Raum. Bayerisches Landesamt für Wasserwirtschaft Merkblatt Nr. 4.5/10 from 25.07.2005 http://www.lfu.bayern.de/wasser/merkblattsammlung/teil4_oberirdische_gewaesser/doc/nr_4510.pdf

Anonymous 2006. Hygieneanforderungen an Bäder und deren Überwachung - Empfehlung des Umweltbundesamtes nach Anhörung der Schwimm- und Badebeckenwasserkommission des Bundesministeriums für Gesundheit beim Umweltbundesamt. Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz 49, p. 926–937 http://www.umweltbundesamt.de/wasser/themen/downloads/badebeckenwasser/49_s_926-937_hygieneanforderungen_an_baeder.pdf

Anonymous 2007. Gewässerschutz bei der Anwendung von chemischen Desinfektionsmitteln im Rahmen der Vogelgrippe-Abwehr. Bayerisches Landesamt für Wasserwirtschaft Merkblatt Nr. 4.5/17 from 19.03.2007 http://www.lfu.bayern.de/wasser/merkblattsammlung/teil4_oberirdische_gewaesser/doc/nr_4517.pdf

Anonymous 2009a. Ziekenhuizen Beleid reiniging desinfectie en sterilisatie. Werkgroep Infectiepreventie. July 2004, revised version July 2009. http://www.rivm.nl/dsresource?objectid=rivmp:46365&type=org&disposition=inline

Anonymous 2009b. Reiniging en desinfectie van ruimten, meubilair en voorwerpen. Werkgroep Infectiepreventie, June 2000, revised version June 2009 http://www.rivm.nl/dsresource?objectid=rivmp:46703&type=org&disposition=inline

Bakker, J. 2010. Biociden in oppervlaktewater voor drinkwaterproductie. RIVM Briefrapport 601712007/2010 http://www.rivm.nl/bibliotheek/rapporten/601712007.pdf

BfR 2005. Verbrauchertipps zu Lebensmittelhygiene, Reinigung und Desinfektion. Bundesinstitut für Risikobewertung http://www.bfr.bund.de/de/publikation/merkblaetter_fuer_verbraucher-512.html

Bürgi, D., Knechtenhofer, L., Meier, I., Giger, W. PROJEKT BIOMIK Biozide als Mikroverunreinigungen in Abwasser und Gewässern - Teilprojekt 1: Priorisierung von bioziden Wirkstoffe. Zürich, 21. Juli 2007 http://www.bafu.admin.ch/gewaesserschutz/03716/06387/index.html?lang=de

Cefic and VCI e.V. 2009. REACH Practical Guide on Exposure Assessment and Communication in the Supply Chains Part 1 – 3. May 2009 http://www.cefic.org/Documents/IndustrySupport/Doc-1-Part-1-to-3-Practical-Guidance-Final.pdf

CEFIC 2010. Guidance Specific Environmental Release Categories (SpERCs) - Chemical Safety Assessments, Supply Chain Communication and Downstream User Compliance. Cefic SpERC Core Team Revision 1, July 2010 http://www.cefic.org/Documents/IndustrySupport/REACH%20Implementation/SPERC%20Guidance%20100707%20FINAL.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

CVMP. 2009. Recommendation on the evaluation of the benefit-risk balance of veterinary medicinal. products. Committee for Medicinal Products for Veterinary Use EMEA/CVMP/248499/2007

Diehl, K.-H. et al. 2000. Do microorganisms develop resistance to antimicrobial biocides? Expert judgement by the DGK Microbiology and Hygiene Expert Group. IFSCC magazine 3 (2)

Dörner, J. 2011. Wirksamkeitsprüfung chemischer Verfahren zur Desinfektion von Coxiella burnetii in kontaminierten Bodenmatrizes. (Efficacy testing of chemical disinfection of Coxiella burnetii in contaminated soil). Dissertation Fachbereich Veterinärmedizin der Justus-Liebig-Universität Gießen http://geb.uni-giessen.de/geb/volltexte/2011/8280/pdf/DoernerJulia_2011_07_05_.pdf

Eberle, U., Lange, A., Dewaele, J., Schowanek, D. 2007. LCA Study and Environmental Benefits for Low Temperature Disinfection Process in Commercial Laundry Int J LCA 12 (2), p. 127 - 138

ECHA 2008a. Guidance on information requirements and chemical safety assessment Part G: Extending the SDS. Guidance for the implementation of REACH, version 1.1, May 2008 http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_g_en.pdf?vers=20_08_08

ECHA. 2008b. 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

EMA. 2008. Revised guideline on environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 and GL38. European Medicines Agency EMEA/CVMP/ERA/418282/2005-Rev.1. http://www.emea.europa.eu/pdfs/vet/era/41828205enfin.pdf

Eickmann, U., Türk, J., Knauff-Eickmann, R., Kefenbaum, K., Seitz M. 2007. Desinfektionsmittel im Gesundheitsdienst - Informationen für eine Gefährdungsbeurteilung. Gefahrstoffe Reinhaltung der Luft 67 (1/2), 17-25 http://www.dguv.de/ifa/de/pub/grl/pdf/2007_004.pdf

Eickmann, U.; Knauff-Eickmann, R.; Seitz, M.: Desinfektionsmittel im Gesundheitsdienst. 2011. Gefahrstoffe – Reinhalt. Luft 71 (9), S. 393-396 (see also Anhang 2 Arbeitsschutzrelevante Stoffinformationen zu den 63 häufigsten Inhaltsstoffen in den untersuchten Desinfektionsmitteln http://www.technikwissen.de/libary/common/X015Anhang-2.pdf).

EuLA. 2009. Practical Guidelines on the use of lime for the prevention and control of avian influenza, foot and mouth disease and other infectious diseases. Version 3, European Lime Association January 2009 http://www.eula.eu/publications/brochures/#c1284

European Commission. 2010 (draft). Supplement to the Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products. Supplement to the methodology for risk evaluation of biocides Technical Notes for Guidance

European Commission. 2010 (draft). Supplement to the Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products. Supplement to the methodology for risk evaluation of biocides Technical Notes for Guidance

European Commission. 2010 (draft). Supplement to the Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas. Supplement to the methodology for risk evaluation of biocides Technical Notes for Guidance

FAO/WHO (1999): The Codex Alimentarius – Recommended international code of practice – General principles of food hygiene. http://www.fao.org/docrep/005/Y1579E/y1579e02.htm

FAO 2007 Avian Influenza Fact Sheet - Disinfection. http://www.fao.org/eims/secretariat/empres/eims_search/img/pdf.gif

FOEN. 2009. Micropollutants in the aquatic environment - Assessment and reduction of the pollutant load due to municipal waste water. Federal Office for the Environment FOEN, Bern, 2009

Fraise, A., Lambert, P. A., Maillard, J. Y. (Ed.) 2004. Russell, Hugo & Ayliffe's Principles and practice of disinfection, preservation and sterilization. Wiley-Blackwell, 4th edition.

Gartiser, S., Stiene, G. 2000. Umweltverträgliche Desinfektionsmittel im Krankenhausabwasser. Forschungsbericht Nr. 297 27 526 des Bundesministeriums für Umwelt, Naturschutz und Reaktorsicherheit im Auftrag des Umweltbundesamtes, UBA-FB 000012, 1/00

Gartiser, S., Urich, E. 2002. Einsatz umweltverträglicher Chemikalien in der Kühlwasserkonditionierung. Abschlussbericht F+E-Vorhaben FKZ 200 24 233 im Auftrag des Umweltbundesamtes, Februar 2002, UBA-Texte 70/02 (English translation available at http://www.hydrotox.de/english/fr-forschung.html)

Gartiser, S., Stiene, G., Hartmann, A., Zipperle, J. 2001. Einsatz von Desinfektionsmitteln im Krankenhausbereich - Ursache für ökotoxische und gentoxische Effekte im Krankenhausabwasser? Vom Wasser Bd. 96 (2001), 71-88

Gartiser, S., Jäger, I. 2011. Efficiency and practicability of risk mitigation measures for biocidal products - Wood preservatives and insecticides. Final report FKZ 3709 65 402 on behalf of the German Environment Agency, UBA-Texte Nr. 01/2011, UBA-FBNr: 001446/E, 21 December 2010 http://www.uba.de/uba-info-medien-e/4053.html

Gartiser, S., Jäger, I. 2011. Workshop report: Efficiency and practicability of risk mitigation measures (RMM) for biocidal products -Wood preservatives and insecticides on 23. and 24. February 2011 at the German Federal Environment Agency

Gilbert, P., McBain, A. J. 2003. Potential Impact of Increased Use of Biocides in Consumer Products on Prevalence of Antibiotic Resistance. Clin. Microbiol. Rev. 16(2), p. 189 -208 http://cmr.highwire.org/content/16/2/189.full.pdf+html

Glauner, T., Kunz, F., Zwiener, C., Frimmel, F. H.: Elimination of swimming pool water disinfection by-products with advanced oxidation processes (AOPs). Acta hydrochim. hydrobiol. 33, 585-594 (2005)

Götz, C.W.; Stamm, C.; Fenner, K.; Singer, H.; Schärer, M.; Hollender, J.; Targeting aquatic microcontaminants for monitoring: exposure categorization and application to the Swiss situation; Environmental Science and Pollution Research 17(2), 2010, 341-54

Gribble, G.W. 2010. Naturally Occurring Organohalogen Compounds – A Comprehensive Update. Progress in the Chemistry of Organic Natural Products, Vol. 91, Springer-Verlag, Wien

Groß, R., Gartiser, S. 2010. Elaboration of a concept for the cumulative environmental exposure assessment of biocides. Final report research project FKZ 360 04 030, Freiburg, 21 December 2010 (unpublished)

Hahn, S., Gartiser, S., Schneider, K, Mangelsdorf, I., Melching-Kollmuß, S., Bitsch, A., Oltmanns, J., Hassauer, M., Schuhmacher-Wolz, U., Voss, J.-U., Jäger, I.: Gesundheitsrisiken durch biozidhaltige Produkte und Gegenstände des täglichen Be-darfs. Abschlussbericht Aktionsprogramm „Umwelt und Gesundheit“, Förderkennzei-chen (UFOPLAN) 204 61 218/05 im Auftrag des Umweltbundesamtes, November 2005

Hahn, S.; Schneider, K.; Gartiser, S.; Heger, W.; Mangelsdorf, I.; 2010. Consumer exposure to biocides – identification of relevant sources and evaluation of possible health effects; Environmental Health 2010, 9:7; http://www.ehjournal.net/content/9/1/7

Herrmann, M., Wagner, B. O. 2003 Emission scenario document on drinking water disinfectants. German Environment Agency (final version August 2003) http://ecb.jrc.ec.europa.eu/documents/Biocides/EMISSION_SCENARIO_DOCUMENTS/ESD_PER_PRODUCT_TYPE/PT_05/PT_5_Drinking_water_disinfectants.pdf

Hund-Rinke, K., Marscheider-Weidemann, F., Kemper, M. 2008. Beurteilung der Gesamtumweltexposition von Silberionen aus Biozid-Produkten. UBA-Texte Nr. 43/2008 http://www.umweltdaten.de/publikationen/fpdf-l/3673.pdf

IVNA and IFH 2003. Home Hygiene: Prevention of infection in the home: A training resource for carers and their trainers. Community Infection Control Nurses Network and International Scientific Forum on Home Hygiene, last revision 2011 http://www.ifh-homehygiene.org/integratedcrd.nsf/571fd4bd2ff8f2118025750700031676/9aaaeb306bb3c50c80257522004b4fdc?OpenDocument

Karnik, B. S., Davies, S. H., Baumann, M. J., Masten, S.J.: The effects of combined ozonation and filtration on disinfection by-product formation. Water Research 39 (13) 2005, 2839-2850

KEMI 2011. Antibacterial substances leaking out with the washing water - Analyses of silver, triclosan and triclocarban in textiles before and after washing. Kemikalieinspektionen PM4/11 http://www.kemi.se/Documents/Publikationer/Trycksaker/PM/PM1_12_Antibact_eng.pdf

KEMI 2012. Biocide treated articles –an Internet survey. Kemikalieinspektionen PM2/12 http://www.kemi.se/Documents/Publikationer/Trycksaker/PM/PM2_12_Biocide_treated_articles.pdf

Kreuzig, R., Schlag, P., Teigeler, J., Hartmann, C., Cvetkovi, B. 2010. Technical Protocol: Transformation of Biocides in Liquid Manures. Texte Nr. 38/2010 http://www.uba.de/uba-info-medien-e/3994.html

Lassen, C., S. Skårup, S.H. Mikkelsen, J. Kjølholt, P.J. Nielsen and L. Samsøe-Petersen. 2001. Inventory of biocides used in Denmark. Environmental Project No.585. Danish EPA, Copenhagen. http://www2.mst.dk/Udgiv/publications/2001/87-7944-383-4/pdf/87-7944-384-2.pdf

Liebig, M., Floeter, C., HAHN, T., Wenzel. A., Knacker, T. 2011.Entwicklung von wirksamen Maßnahmen zur Verringerung des Umweltrisikos von Tier- und Humanarzneimitteln. Final report FKZ 3709 65 403 on behalf of the German Federal Environment Agency

Lüskow, H., Wirth, O., Reihlen, A., Jepsen, D. 2011. Standardisation of Emission Factors for the Exposure Assessment under REACH. UBA-Texte 12/2011 http://www.umweltdaten.de/publikationen/fpdf-l/4085.pdf

McDonnell, G., Russell, A. D. 1999. Antiseptics and Disinfectants: Activity, Action, and Resistance Clinical Microbiology Reviews 12 (1), p. 147–179

Merkblatt DVWK-M 775: Abwasser aus Krankenhäusern und anderen medizinischen Einrichtungen. DVWK-Regelwerk, Deutsche Vereinigung für Wasserwirtschaft, Abwasser und Abfall e.V. (DWA), Hennef, Dezember 2010, ISBN 978-3-941897-62-5 (69 pages)

Müller, A., Bleck, D. 2008. Arbeitsplatzbelastungen bei der Verwendung von bioziden Produkten Teil 2: Sicherer Umgang mit Konzentraten. BAuA Research Project F 1703, Dortmund/Berlin/Dresden www.baua.de/de/Publikationen/Fachbeitraege/F1703.pdf

OECD 2007. Analysis and assessment of current protocols to develop harmonised test methods and relevant performance standards for efficacy testing of treated articles / treated materials. ENV/JM/MONO(2007)4 http://www.oecd.org/chemicalsafety/agriculturalpesticidesandbiocides/

Pickup, J. 2010. Environmental safety of halogenated by-products from use of active chlorine. Euro Chlor Science Dossier 15, May 2010, www.eurochlor.org

Rastogi, S. C., Krongaard, T., Jensen, G. H. 2003. Antibacterial compounds in clothing articles. Survey of Chemical Substances in Consumer Products. Danish Environmental Protection Agency, Survey no. 24 2003 http://www.mst.dk/-NR/-rdonlyres/-E91ACBF2-E364-4D13-9DC7-5C153320D3DD/-0/-24.pdf

Rüdel, H., Knopf, B. Vorbereitung eines Monitoring-Konzepts für Biozide in der Umwelt. Report FKZ 360 04 036 on behalf oft he German Environment Agency. Fraunhofer Institut für Molekularbiologie und Angewandte Oekologie (IME) Schmallenberg, 6.02.2012

RKI 2004. Anforderungen an die Hygiene bei der Reinigung und Desinfektion von Flächen - Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention beim Robert Koch-Institut (RKI), Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz 47, p. 51–61 http://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Kommission/Downloads/Flaeche_Rili.pdf

RKI 2007. Liste der vom Robert Koch-Institut geprüften und anerkannten Desinfektionsmittel und –verfahren Stand vom 31.5.2007 (15. Ausgabe) Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz 50, p. 1335–1356 http://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Desinfektionsmittel/Desinfektionsmittelliste.pdf

Russell, A. D. 2003. Similarities and differences in the responses of microorganisms to biocides. Journal of Antimicrobial Chemotherapy 52, p. 750–763

Russell, A. D. 2004. Bacterial adaptation and resistance to antiseptics, disinfectants and preservatives is not a new phenomenon. Journal of Hospital Infection 57, p. 97–104

Rutala, W. A., Weber, D. J. 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities. Healthcare Infection Control Practices Advisory Committee (HICPAC) http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf

SCENIHR. 2009. Assessment of the Antibiotic Resistance Effects of Biocides.Scientific Committee on Emerging and Newly Identified Health Risks, 19 January 2009 http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_021.pdf

Schets, F. M. , Blaak, H., Braks, M., de Bruijn, A. C. P., Haenen, A., Luttik, R., van de Ven, B., de Roda Husman, A. M. 2012. Biociden en resistentie. RIVM Rapport 601712009/2012

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

Shena, R., Andrews, S.: Demonstration of 20 pharmaceuticals and personal care products (PPCPs) as nitrosamine precursors during chloramine disinfection. Water Research 45 (2) 2011, 944-952

Shrivastava R et al. 2004. Suboptimal chlorine treatment of drinking water leads to selection of multidrug-resistant Pseudomonas aeruginosa. Ecotoxicol Environ Saf. 58(2):277-283

Smith, M. 2006. Cleaning and Disinfecting to Prevent a Foreign Animal Disease Outbreak. Poultry Industry Council, Factsheet 157 adapted from a presentation by Maurice Smith www.poultryindustrycouncil.ca

Stanga, M. (2010): Sanitation - Cleaning and Disinfection in the Food Industry. Wiley-VCH, Weinheim

Strauch, D., Böhm, R,.2002. Reinigung und Desinfektion in der Nutztierhaltung und Veredelungswirtschaft. Enke-Verlag Stuttgart. 336 pages.

TRGS 525. Umgang mit Gefahrstoffen in Einrichtungen zur humanmedizinischen Versorgung. Technische Regeln für Gefahrstoffe (May 1998)

US EPA 1999. Alternative Disinfectants and Oxidants Guidance Manual. United States EPA Environmental Protection Agency. EPA 815-R-99-014, April 1999

Van der Aa, E., Balk, F. 2004. Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product type 1). Haskoning Nederland on behalf of the European Commission DG ENV / RIVM http://ecb.jrc.ec.europa.eu/documents/Biocides/EMISSION_SCENARIO_DOCUMENTS/ESD_PER_PRODUCT_TYPE/PT_01/PT_1_Human_Hygiene.pdf

Van der Poel, P., Bakker, J. 2001. Emission scenarios for all 23 product types of the Biocidal Products Directive (EU Directive 98/8/EC). RIVM report 601450009 http://www.rivm.nl/bibliotheek/rapporten/601450009.pdf

Van der Poel, P. 2001. Emission scenarios Document for product type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector) - Supplement to the methodology for risk evaluation of biocides. RIVM report 601450008, Bilthoven

http://ecb.jrc.ec.europa.eu/documents/Biocides/EMISSION_SCENARIO_DOCUMENTS/ESD_PER_PRODUCT_TYPE/PT_02/PT_2_Private_area_and_public_health_area_disinfectants.pdf

Van der Poel, P., Bakker, J. 2002. Emission scenarios for all 23 product types of the Biocidal product Directive(EU Directive 98/8/EC). Emission Scenario Document for Biocides, RIVM report 601450009 www.rivm.nl/bibliotheek/rapporten/601450009.pdf

Von der Lage, A., Beckert, I., Niemann, F. 2010. Hygienetechnik und Managementhinweise zur Reinigung und Desinfektion von Stallanlagen. Ausschuss für Technik in der tierischen Produktion, dlg-merkblatt 364, September 2010 http://www.dlg.org/merkblaetter.html

Wasiak, K. 2009. Untersuchungen zur Inaktivierung von ausgewählten Krankheitserregern und Indikatororganismen im Boden bei der Anwendung von thermischen Verfahren und Kalk. Dissertation Fachbereich Veterinärmedizin der Justus-Liebig-Universität Gießen http://geb.uni-giessen.de/geb/volltexte/2009/7065/pdf/WasiakKrzysztof_2009_04_30.pdf

Weinberg, H. S., Krasner, S. W., Richardson, S. D., Thruston, A. D., 2002. The Occurrence of Disinfection By-Products (DBPs) of Health Concern in Drinking Water: Results of a Nationwide DBP Occurrence Study. EPA/600/R-02/068 http://www.epa.gov/athens/publications/reports/EPA_600_R02_068.pdf

WHO 2011. Guidelines for Drinking-water Quality - 4th Edition. World Health Organisation, WA 675, Geneva, Switzerland http://whqlibdoc.who.int/publications/2011/9789241548151_eng.pdf

WHO 2006. Guidelines for safe recreational water environments, VOL. 2 Swimming pools and similar environments. World Health Organisation http://www.who.int/water_sanitation_health/bathing/en/

Xi, C., Zhang, Y., Marrs, C. F., Ye, W., Simon, C., Foxman, B., Nriagu, J. 2009. Prevalence of antibiotic resistance in drinking water treatment and distribution Systems. Applied and environmental microbiology, 75 (17), p. 5714–5718

Zamparutti, T., Goldenman, G., van der Burgt, N., Vernon, J., Tuffnell, N., Gartiser, S. Study towards the Development and Dissemination of Best Practice on Sustainable Use of Biocidal Products. Final Report, 3 October 2010 http://ec.europa.eu/environment/biocides/sust_use.htm

Zamparutti, T. et al. 2006. Study on impacts of possible measures to manage articles or materials treated with biocides – in particular when imported. Submitted by Milieu Ltd. (Belgium) and the Danish Toxicology Centre, Study Contract No 07-0402/2005/414388/MAR/B4 https://circabc.europa.eu/w/browse/6355ec78-211e-44bb-b42f-b6b4b51477e3