

Reduction of environmental risks from the use of biocides: Environmental sound use of disinfectants, masonry preservatives and rodenticides

Annex II: Case study on PT 2: Disinfectants in the private and public health area

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private and public health area

by



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List of Abbreviations

AOX	Adsorbable Organic Halogens
BAT	Best Available Techniques
BPR	Biocidal Products Regulation
BREF	Best Available Technique Reference Documents
DBP	Disinfection by-Products
DWA	Deutsche Vereinigung für Wasserwirtschaft, Abwasser und Abfall e.V. (German Association for Water, Wastewater and Waste)
ECHA	European Chemicals Agency
ESD	Emission Scenario Document
FIOSH	German Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, BAuA)
HACCP	Hazard Analysis and Critical Control Points (Regulation (EC) No 852/2004)
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
STP	Sewage treatment plant
THM	Trihalomethanes
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

1 Introduction

Disinfectants used in the private and public health area are an important tool for maintaining hygiene conditions and for infection control by preventing the growth of microbiological pathogens. The use of disinfectants for professional uses is usually integrated in a general concept or management system for good hygiene practice according to European and national legislation. The application of best practices cannot be assumed for private uses. Public concerns have been raised about risks and benefits of disinfectants in private homes, and it has been argued that untrained consumer use of disinfectants is often ineffective against microbes (Zamparutti et al. 2010). The German Federal Institute for Risk Assessment states that as a rule cleaning agents are sufficient for maintaining hygienic conditions in private homes. The use of disinfectants is only required to protect ill or weak patients, if this is demanded by a doctor (BfR 2014).

2 Active Substances and target organisms

Disinfectants of PT 2 are used to control microbiological pathogens of different organism groups (bacteria, viruses, fungi). The definition of PT 2 from Annex V of the Biocidal Product Regulation (BPR) refers to “disinfectants and algacides not intended for direct application to humans and animals”. It is distinguished between products used for the disinfection of surfaces, materials, equipment and furniture, swimming pools, bathing, aquariums, air conditioning systems, walls and floors in private-, public-, and industrial areas, besides products used for disinfection of air, chemical toilets, waste water, hospital waste, and soil. Algacides used for water treatment of swimming pools, aquariums and for remedial treatment of construction materials are also attributed to PT 2, as well as products incorporated in articles or materials (textiles, tissues, masks, paints) with the purpose of producing treated articles with disinfecting properties.

Efficacy testing is done according to CEN standards while using model organisms such as the bacteria *Staphylococcus aureus*, *Enterococcus faecium*, *Pseudomonas aeruginosa*, *Proteus mirabilis*, and the fungi *Candida albicans* and *Aspergillus niger*. Sporocidal activity is tested against *Bacillus subtilis* and *Bacillus cereus*.

In May 2010 from all 270 active substances included in the review programme, in total 87 were supported for PT 2. The COWI study concluded that the contribution of disinfectants in the private and public health area (PT 2) to the overall consumption of biocides of about 400,000 t is 50.5% (COWI 2009).

Table 1: Active substances of PT 2 evaluated in the Review Programme

Substance group	Substances (examples)
Non-oxidative	
Alcohols	Ethanol; Propan-1-ol; Propan-2-ol; 2-Phenoxyethanol; Biphenyl-2-ol
Aldehydes	Formaldehyde; Glutaraldehyde; Glyoxal; Cinnamaldehyd
Phenols	Chlorocresol; Sodium p-chloro-m-cresolate; 5-Chloro-2-(4-chlorophenoxy)phenol
Quaternary ammonium compounds	QAC, benzyl-C12-14-alkyldimethyl, chlorides; benzyl-C12-16-alkyldimethyl, chlorides; Didecyldimethylammonium chloride
Organic acids	Glycolic acid; Nonanoic acid; Salicylic acid
Amines	Amines, C10-16-alkyldimethyl, N-oxides; Amines, n-C10-16-alkyltrimethylene with chloroacetic acid; N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine
Guanidines	Poly(hexamethylenebiguanide); Poly(hexamethyldiamine guanidinium; Oligo(2-(2-ethoxy)ethoxyethylguanidinium chloride
Metals	Silver; Silver chloride; Silver-Zinc-Zeolite; Silver zeolite A; Copper; Copper sulphate; Pyrrhione zinc
Gases	Ethylenoxide; Formaldehyde
Others	Bronopol; Pyridine-2-thiol 1-oxide, sodium salt; Monolinuron, 2,2-dibromo-2-cyanoacetamide; Mixture 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-

Substance group	Substances (examples)
	2H-isothiazol-3-one
Oxidative	
Chlorine based	Chlorine; Sodium hypochlorite; Chlorodioxide; 1,3,5-Trichlorisocyanuric acid; Tosylchloramide sodium; Trichlorisocyanuric acid
Bromine based	Sodium bromide (precursor); 1-Bromo-3-chloro-5,5-dimethylhydantoin (BCDMH)
Oxygen based	Hydrogen peroxide; Peracetic acid; 2-Butanone peroxide; Peroxyoctanoic acid; Pentapotassium bis(peroxymonosulphate) bis(sulphate)

Up to August 2014, only 3 active substances of PT 2 (Copper sulphate pentahydrate, Nonanoic acid and Hydrochloric acid) have been approved under the EU Biocidal Products Regulation 528/2012 (BPR), according to the progress of the review program.

Disinfectants used in laundries or cleaning products such as perorganic acids, inorganic peroxides, or Sodium hypochlorite have both a disinfecting and bleaching effect and may not be indicated as biocidal products if the biocidal effect is not intended (see Annex V of BPR).

3 User groups and mode of application

Disinfectants used in the public health area cover biocidal products specifically designed for professional uses such as the disinfection of instruments. Disinfectants for air conditioning systems are exclusively applied by professional users. Especially surface disinfectants, laundry disinfectants, and swimming pool disinfectants are used by both professionals and consumers. Professional users often receive basic knowledge about disinfectants within their professional training. Other professional user might have specific expert knowledge and hold a certificate such as hygienists or disinfectors. Consumers have no special knowledge concerning the use of disinfectants.

The area of use will mainly be derived from the intended uses indicated by the applicant which have to be supported by efficacy testing but may be restricted when risks are identified. PT 2 disinfectants are usually applied by mopping, wiping, brushing, spraying, foaming, or fogging (e.g. surface disinfection), automatic dosage valves (e.g. sterilizers, washer-disinfectors, swimming water, laundries), or tipping (e.g. to the storage tank of chemical toilets). Often the working solutions are made up from concentrates via automatic dosing pumps.

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 study 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 found to be washing and cleaning products where the intended effect is not always primarily biocidal but rather bleaching or cleaning. For surface disinfection (including 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 homes 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 (BfR 2014; Zamparutti et al. 2010). According to the Guideline for Disinfection and Sterilization in Healthcare Facilities the public health benefits of using disinfectants in homes are unknown. However, it is recognised, that many sites in the home, e.g. kitchen and bathroom are microbially contaminated. Some hygienists refer to the increasing number of people who are in need of care at home such as immune deficient patients. For these 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 at applications for which the risks have been established.

According to the Dutch Hygiene Code for private households, regular cleaning is usually adequate for the effective removal of dirt and risk-bearing microorganisms. Unnecessary use of disinfectants could lead to harmful microorganisms adapting to these agents, which would then require the use of higher dosages of other agents. There are occasionally forms of microbiological contamination where their removal by regular cleaning is inadequate to prevent their spreading. 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 disinfection, thorough cleaning should take place, as the presence of organic material may have a negative influence on the efficiency of the disinfectant (Anonymous 1999).

Possible measures to enhance a more sustainable use of disinfectants for consumer uses range from awareness raising measures, the prohibition of misleading advertisements, and the education of salespersons until the prohibition of products with identified risks or non-proven benefits.

4 Possible emission routes and available ESD

4.1 Emission scenario documents

Several Emission Scenario Documents (ESDs) have been published by the European Chemicals Agency (ECHA) which provides an overview on the most relevant uses of disinfectants.¹

¹ <http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents>

Table 2: Overview of emission scenarios for disinfectants of PT2

PT	Title	Reference ²	Main emission pathways
2	Private area and public health area disinfectants and other biocidal products		
	Swimming pools	RIVM report 601450 009, 2002	Surface water or STP
	Sanitary sector	EUBES 1 (RIVM report 601450 008, 2001)	STP → Surface water
		RIVM report 601450 009, 2002	
	Horticulture	RIVM report 601450 009, 2002	Soil
	Tiles and surfaces	RIVM report 601450 009, 2002	STP
	Medical sector		
	Disinfection of rooms, furniture and objects	EUBES 1 (RIVM report 601450 008, 2001)	STP
		RIVM report 601450 009, 2002	
	Disinfection of instruments	EUBES 1 (RIVM report 601450 008, 2001)	STP
		RIVM report 601450 009, 2001	
	laundry disinfectants	EUBES 1 (RIVM report 601450 008, 2001)	STP
		RIVM report 601450 009, 2002	
	hospital waste disinfectants	ESD for PT 2 (EC, 2011)	Incineration
		EUBES 1 (RIVM report 601450 008)	
	Disinfection of air conditioning systems	RIVM report 601450 009, 2002	Air, STP
		ESD for PT 2 (EC, 2011)	
		RIVM report 601450 009, 2002	
	Disinfection in <i>industrial and institutional</i> areas	ESD for PT 2 (EC, 2011)	STP
		RIVM report 601450 009, 2002	
	Disinfectants for sewage and wastewater	RIVM report 601450 009, 2002	Surface water
	Soil and other disinfectants	RIVM report 601450 009, 2002	Soil
	Disinfection of chemical toilets	ESD for PT 2 (EC, 2011)	STP
		RIVM report 601450 009, 2002	

Disinfectants of PT 2 cover very diverse application areas. The main emission pathway is to the sewer system. For some disinfection applications 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.

Private area 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 into 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.

Disinfectants specifically intended for the use with medical devices (e.g. endoscopes) are covered by the Medicinal Products Directive. Nowadays most instruments made up of metals are disinfected by steam.

² Van der Poel et al. (2001), van der Poel et al. (2002), EC (2011)

Thermo-labile instruments such as endoscopes are often disinfected by aldehydes or peroxides. Prior to steam disinfection, the instruments are mechanically and chemically cleaned (DWA-M 775 2010).

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 filters 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 waters) in compliance with wastewater discharge guidelines.^{3 4}

Laundry disinfectants

In laundries the hygienic requirements for textiles must be fulfilled. Usually thermal disinfection at temperatures of 65 °C for 10 minutes or 71 °C for 3 minutes is considered sufficient for the disinfection of heat-stable linen. Clothing consisting of man-made fibres may be damaged or distorted if subjected to heat and are normally washed at 40 °C and dried at 60 °C. For chemical disinfection, often Chlorine-releasing agents are added to the penultimate rinse at a concentration of 125-150 ppm of available Chlorine (Fraise et al. 2004). To avoid the formation of disinfection by-products, often perorganic acids or inorganic peroxides are used as alternatives. All oxidizing disinfectants have both a disinfecting and bleaching effect. Quaternary ammonium compounds such as Benzyl-C12-16-alkyldimethyl chlorides are also used for disinfection of laundries, both in private and professional machines.

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 to the collecting pan or to the circulating water. The application can be continuous or intermittent (Zamparutti et al. 2010).

Disinfection of sewage and wastewater

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, EC 2011).

The technical rule ATV-M 205 (1998) describes the disinfection principles of biologically treated wastewater. It is described, that biological treatment of municipal wastewater already reduces bacteria and viruses by about 95% -99%. Thus, only disinfection of biologically treated municipal wastewater is reasonable. Dis-

³ ÖWAV-Merkblatt. Private, Hallen- und Freischwimmbäder. Ableitung von Spül-, Reinigungs- und Beckenwasser. (April 2008)

⁴ http://www.lfu.bayern.de/wasser/merkblattsammlung/teil4_oberirdische_gewaesser/doc/nr_458.pdf

infection is only carried out for achieving the required quality for bathing surface water following the Directive 2006/7/EC or Article 7 of the Water Framework Directive 2000/60/EG concerning surface water used for the abstraction of drinking water. Routine chemical disinfection of treated wastewater from the outflow of STP using Chlorine is not considered acceptable (only in case of emergency). Diffuse sources from agriculture and storm water discharges not treated in STP might contribute to a large extent to the microbiologic pollution of surface water. In certain situations raw wastewater from quarantine wards, considered as highly contagious, must be disinfected preferably with thermic processes (ATV-M 205 1998). 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 waters. 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, hence 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 ESD for PT 2 (EC, 2011) concerning chemical toilets, refers to the ATV-M-270 standard on the disposal of the content of mobile toilets with sanitary additives. It states that only 2 m³ 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.

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 to agricultural soils in horticulture or greenhouses. The application to children playgrounds has been supposed. In the past fumigants such as Methyl bromide have been used for that purpose (van der Poel et al. 2002). The inactivation 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 concentrations 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.

4.2 Emission during application / treatment phase

Ready for use surface disinfectants on alcohol basis, usually applied by spraying or wiping, mainly evaporate into the air and do not reach wastewater. The inactivation of disinfectants by organic matter or more specifically of QAC by anionic surfactants or of aldehydes by proteins etc. requires that cleaning of the objects before applying disinfectants is essential.

4.3 Emission during service life

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 and are also covered by PT 2. The BPR

(Article 58) requires that treated articles must only be placed on the market if all active substances present are approved in accordance with the Regulation. Furthermore, treated articles should be appropriately labelled. A treated article that has a primary biocidal function shall be considered a biocidal product and must be authorised. Article 3 of the BPR authorises the Commission to decide, by means of implementation acts, whether a substance is a nanomaterial, a biocidal product, a treated article or none of them.

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 nanoparticulate) revealed that the environmental risk for the aquatic compartment and for sewage treatment plants is limited, 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, and Triclocarbon. Five textiles contained Triclosan, but none of 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, 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 (KEMI 2011).

4.4 Emission during restore end-of life stage

The main emission pathway of PT 2 disinfectants is to the sewer with the exception of alcohols and aldehydes used for surface disinfection from which a major part evaporates. The DWA (Deutsche Vereinigung für Wasserwirtschaft, Abwasser und Abfall e. V.) publishes technical guidelines for different wastewater sectors, e.g. the technical rule, DWA-M 775 (2010) „Wastewater from hospitals and other medical facilities”, which describes requirements for the discharge of disinfectants. Residues from working solutions of disinfectants usually discharge to the sewer and enter STP while concentrates must be collected and disposed as hazardous waste. The used working solutions with up to 2% of aldehydes may be discharged to the sewer (DWA-M 775, 2010). The recollection of containers containing concentrate residues of disinfectants may be one option to reduce emissions to the environment, by avoiding influx to these emission pathways.

5 Stakeholder survey

A questionnaire on the application and use phase of disinfectants for consumers and public health (PT 2) has been drafted in order to obtain the view of stakeholders on the practicability and efficiency of potential measures. After discussing the questionnaire with experts from the German Federal Environment Agency it was distributed to around 50 stakeholders (professional and industrial associations, users, formulators, authorities, consultants and others). The feedback rate was disappointing, but the quality and information content of the answers was good. In total 13 responses have been received, which belong to the following stakeholder groups:

- Formulators of disinfectants: 2
- User of disinfectants 5 (Hospital experts for occupational health and ecology)
- Authorities 3 (occupational accident insurances)
- Industrial Associations 2 (IHO and IKW of German chemical industry)

- Others (research institute) 1 (Institute involved in textiles and laundry research)

With respect to the understanding of stakeholders on a sustainable use of disinfectants, they provided several proposals on definitions of sustainable use which are summarized in table 3:

Table 3: Proposals for a definition of sustainable use provided by stakeholders⁵

Definitions
Obtain the best disinfection efficiency with the lowest amount of the active substance while avoiding residues. Use of ultimate biodegradable ingredients. <i>Hospital expert in charge of ecology and occupational health.</i>
Define clear indication limits for disinfection measures (no unnecessary disinfection): Only to be applied with proven or very likely useful effects.
Good information to the user to ensure proper application of disinfectants by the internal hospital hygiene department and by providing good information material of the manufacturer or supplier (SDB, operating instructions, informative sheet, efficacy reports, etc.).
Ensure the correct dosage by technical means (avoiding over-and under-dosing) as automatic mixing, dosing, etc.
Use of readily biodegradable ingredients, additives (aldehydes, alcohols, amines). No use of QAC, chlorine phenols, guanidines, heavy metal ions, APEO surfactants, EDTA ...)
No use of chlorine-based active substances that are AOX-formers.
No use of potentially corrosive agents, which could damage the construction or commodities to be disinfected (by oxidation, strong acid or bases).
No use of products, which pollute the air (except for alcoholic disinfectants), no use of inhaled allergens, such as Glutaraldehyde.
No products with unnecessary additives (fragrance, perfume oils).
If possible, substitute manual disinfection by (chemo-thermic) automats.
No use of questionable packing materials (PVC), use of container size proportional to the usage rate expected. Don't produce large amounts of small packaging waste nor dispose expired big containers.
<i>University hospital expert in charge of ecology and occupational health.</i>
Avoidance of ingredients with low biodegradability. Reduction of disinfection measures to the minimum necessary, lower preventive disinfection frequencies. Use of renewable raw materials.
<i>University hospital expert.</i>
Only intended the use of disinfectants in areas with proven efficacy where necessary.
<i>Hospital expert in charge of ecology.</i>
Sustainable development combines economic progress with social justice and the protection of the natural environment. Sustainability is not specifically defined, and often only one side is considered. Sustainable use of disinfectants: Reduction of the risks to human health and the environment. Reduction of risks associated with pathogens implies advantages and disadvantages. For example, benefit for human health and disadvantages to the environment which might also result in disadvantages to human health.
<i>Hospital expert in charge of ecology.</i>
Sustainability means economic progress combined with social justice and the protection of the natural environment. Reduction of risks to human health and the environment. There might be conflicting objectives: The benefit of risk reduction through reduction of pathogens might involve disadvantages for the environment and the occupational health.
<i>Hospital expert in charge of occupational health and ecology.</i>
Complete biodegradability of active substances and its degradation products in STPs. No human health risks for users through volatility or allergenic potential of ingredients.
<i>Hospital expert in charge of occupational health and ecology.</i>
Use as much disinfectants, as necessary, but as little as possible. Application of the legally-normative standard (quality and testing requirements for proper textile laundries, hygiene requirements of health service facilities, guidance of the Commission for Hospital Hygiene and Infection Prevention).
<i>Expert from a scientific textile institute also involved in laundries.</i>

⁵ In the questionnaire distributed to the stakeholders the original questions was "What do you understand on a sustainable use of biocides".

Definitions

Sustainable use means that disinfectants are targeted applied to solve very specific hygienic problems in households in compliance with the instruction of the manufacturer. The application area for this hygienic measure and the group of people affected are crucial: for example persons, who are immunocompromised due to illness or medication, should apply specific hygiene measures. All three pillars of sustainability (social, environmental and economic) should be considered in the assessment of a sustainable use.

Expert from an industrial association of the chemical industry.

Targeted use of disinfectants while considering the general requirements.

Formulator of disinfectants

The risk / disadvantages should be in reasonable proportion to the benefits. Besides trees and rivers, also humans / patients / staff are part of the ecological system.

Formulator of disinfectants

Proper use of the appropriate products to achieve optimum results.

Expert from an industrial association of the chemical industry.

Use of disinfectants which in the long term are ecologically and economically reasonable without negative impacts.

Expert from the institution for statutory accident insurance and prevention in the public health area.

Positive effects on humans, animals and the environment. Application of appropriate methods and products. Combination of construction design and chemistry avoids using "hard" chemicals.

Expert from the institution for statutory accident insurance and prevention involved air conditioning systems.

Ensure the lowest possible health impacts to the user combined with low environmental risks. Application of disinfectants only where hygienically required.

Expert from the institution for statutory accident insurance and prevention in the public health area.

Most stakeholders refer to the three pillar concept where the economic (protection of commodities and construction works), social (human health) and environmental protection are of equivalent importance. This is not in line with the definition used in this project that considers the environment as the guard rail for further development. Some stakeholders also gave very important hints on environmental impacts through specific uses such as, the discharge of conditioned swimming pool water after the winter period, where huge amounts of QAC may be released to surface waters.

Stakeholders were asked to indicate the selection criteria for active substances and quite uniformly answered, that disinfectants are selected according the following criteria (in order of priority):

1. Specific effectiveness on organisms to be inactivated
2. Human health risks, e.g. through sensitising effects
3. Purchase cost
4. Behaviour in the sewage treatment plants (degradation and adsorption)
5. Ecotoxic effects (classification in R50/53, R51/53, R52/53, H400, H410-413)
6. Ready degradability of the active substances
7. Effort for storage and disposal of residues
8. Local waste water regulations, e.g. concerning the AOX

The main selection criteria for disinfectants are efficacy, human health aspects and purchase costs; elements of environmental behaviour and effects have been attributed far lower importance.

The stakeholders were also asked to indicate their expectation about the practicability and efficiency of measures proposed to reduce environmental impacts. These measures included aspects such as further training and education, requirements for sales and control mechanisms, information and awareness raising, surveillance of applications, and measures to reduce emissions during the use phase.

Table 4: Evaluation of measures to reduce environmental impacts of PT 2 disinfectants (examples)

<p>PT 2</p> <p>■ high ■ mean ■ low ■ none</p>	<p>PT 2</p> <p>■ high ■ mean ■ low ■ none</p>	<p>PT 2</p> <p>■ high ■ mean ■ low ■ none</p>
Prohibition of certain products and applications for nonprofessional users	Certification of professional users, distributors and consultants within further education and training	Development of hygienic plans, disinfection plans and work instructions adjusted to the needs of disinfection measures
<p>PT 2</p> <p>■ high ■ mean ■ low ■ none</p>	<p>PT 2</p> <p>■ high ■ mean ■ low ■ none</p>	<p>PT 2</p> <p>■ high ■ mean ■ low ■ none</p>
Quality Assurance and Control	Consideration of disinfectants concerning purchase selection and use during audits of the occupational health assurances	Promotion of web-based information platform

A qualitative evaluation of measures, to which a high efficiency has been attributed, resulted in the following order of priority:

Table 5: Evaluation of measures to reduce environmental impacts of PT 2 disinfectants (examples)

Order	Measures
1	Prohibition of certain products and applications for nonprofessional users (consumer).
2	Development of hygienic plans, disinfection plans and work instructions adjusted to the needs of disinfection measures.
3	Advice to clients by manufacturers (including safety data sheets, technical leaflets, instructions for use). Renunciation of daily routine disinfection of floors in public health areas Replacement of air conditioners with rotary spray through humidifiers.
4	Certification of professional users, distributors and consultants within further education and training. Knowledge transfer on a sustainable use of disinfectants during education and training, e.g. for nursing or cleaning staff. Providing information on "best practices" and safe use. Optimization of disinfection by previous cleaning. Quality Assurance and Control.
5	Replacement of poorly biodegradable / eliminable disinfectants (in sewage treatment plants) by rapidly degradable active ingredients and additives. Avoidance of peak loads through discharge of concentrated solutions.
6	Instruction of co-workers from contractors for in-house cleaning, proof qualification of contractors. Restrictions on the marketing. Development of technical standards and guidelines for the cleaning of instruments and equipment. Mandatory testing and control of biocide treated materials. Replacement of air conditioner circulation spray humidifiers by steam humidifiers.
7	Product sales only permitted by trained employees. Regulation of product sales via internet. Promotion of web-based information platforms. Development of standards and guidelines for private users, when disinfection measures are required and how they should be used. Replacement of disinfection measures by thermal and thermochemical processes. Limitation of the container size for consumer users to minimize residual amounts. Collection and disposal of residual amounts.
8	Regulation of the sales of products through retail trade to the general public, e.g. through the sale of household disinfectants in pharmacies. Development of a classification system for environmental sound disinfectants. Routine examination of bacterial load in the relevant areas. Establishment of collection systems for residues by the manufacturer / distributor. Consideration of disinfectants concerning purchase selection and use during audits of the occupational health assurances. Integration of environmental criteria into new or existing eco-labels and/or quality labels.

Further suggestions submitted by stakeholders were:

- The thermic disinfection of the bedpan (or bed pans) used for toileting of bedridden patients has been mentioned as one example for the possible replacement of chemical disinfectants by thermal processes and regular cleaning. Manual disinfection should be substituted by (chemo)thermic automats where possible.
- Avoid unnecessary disinfection measures. Replace routine surface disinfection to a large extent by cleaning methods.
- Better emptying of canisters by lancets and recollection of canisters by suppliers in hospitals would reduce the residues discharged to wastewater. By decanting residues into new canisters the total amount used would be reduced. This is not applied owing to hygienic reasons but may be performed for cleaning agents (not for disinfectants).
- The prohibition of any misleading advertisement statements could reduce consumer use of disinfectants. The US EPA approach, where any hygienic statement must be proven with efficacy testing is mentioned as a good example.
- Ensure the correct dosage by technical means (avoiding over- and under-dosing) as automatic mixing and dosing.
- Professional users should receive additional advice from the assigned waste manager or the work safety representative.
- Appropriate decision criteria for health care disinfectants are: Use of readily biodegradable ingredient additives. Minimisation of QAC, phenols, guanidines, and heavy metal ions, APEO surfactants, EDTA as well as of Chlorine-based active substances that are AOX-formers. No use of potentially corrosive agents, which could damage the construction or commodities to be disinfected (by oxidation, strong acid or bases). No use of products, which pollute the air (except for alcoholic disinfectants). No use of inhalative allergens, such as Glutaraldehyde. No products containing unnecessary additives (fragrance, perfume oils).
- Packing materials of PVC should be avoided and container sizes should be proportional to the usage rate (don't produce large amounts of small packaging waste nor dispose expired big containers).
- Observed misuses of disinfectants in hospitals are: Mixing of different disinfectants or disinfectants with cleaning agents (e.g. QAV and anionic detergents). Insufficient hand disinfection. Interchange of disinfectants and cleaning agents in disinfection machines. Unnecessary cleaning of toilets and coffee cups with active oxygen disinfectants. Cleaning of flower vases with aldehyde disinfectants or QAC. Improper use of surface disinfectants in washing machines caused breakdown of the machine. Confusion of products, too low contact time applied, insufficient dosage, and usage of wrong products, application in the wrong area are further aspects of misuses.
- Discharge of QAC, used for the preservation of out-of-service swimming pools during winter, might cause, when released from outdoor pools after overwintering. There are products on the market with > 10% QAC from which 1 liter is added to 15 m³ of water.⁶

⁶ e.g. N,N-Dimethyl-2-hydroxypropylammoniumchloridpolymer in concentrations up to 12%)

- According to a German occupational insurance association, responsible for public health care facilities, up to now the evaluation of disinfectants has been carried out under the aspects efficacy, human health and economy. Environmental concerns have not been considered so far, but are considered as important issue. The need for a coordinated approach is emphasized.

6 Elements of sustainable use

6.1 Risk mitigation measures

Within a project on behalf of the German Environment Agency risk mitigation measures (RMM) proposed by producers, industrial/professional users, and authorities were analysed with focus on environmental risks of disinfectants. In this context a RMM guidance document has been developed which is discussed among competent authorities (Gartiser and Jäger 2013). It is distinguished between general RMM and specific RMM. General RMM refer to the application of best practices, good housekeeping etc. and may support a sustainable use of disinfectants. Specific RMM are derived from the environmental risk assessment and may be quantified and considered in the risk assessment by changing the input parameters. These are applied during product authorisation for specific products based on the results of the risk assessment. However, a quantification of the efficiency and practicability of specific RMM and an evaluation of the possibility of enforcement are required, in order to be quantitatively considered in regulatory decisions.

The project revealed that 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. Biological treatment in municipal or on-site STP is the most common RMM for the protection of surface waters. 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 (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 use conditions should be considered in the assessment of all biocidal products with oxidising active substances.

The benefits of consumer use of PT 2 disinfectants are controversially discussed among hygienists who argue that untrained consumers 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 be quantitatively considered in the risk assessment.

Many RMM related to disinfectants focus on human health aspects. Some disinfectants, especially aldehydes, may cause allergic contact dermatitis and are classified as skin sensitisers (R43). Therefore substitution of aldehydes is one major objective in occupational health strategies and may cause increasing use of other active ingredients with lower biodegradability.

6.2 Training/Education

Training and education only applies to professional users. For consumers only measures for awareness raising are appropriate. According to the legal rules on accident prevention from the occupational insurance associations, any disinfection measures in German health care facilities must only be performed by persons,

who have completed training in health care professions or have been instructed and are supervised by professional qualified persons such as hospital hygienists, doctors or hygiene medical specialists.⁷ The disinfection measures must follow a hygiene management plan. If routine surface disinfection is carried out by contractors, at least the supervisor must be competent. For some uses specific expert knowledge may be required. For example, the application of Ethylene oxide and Formaldehyde in automatic gas sterilizers in healthcare facilities requires permission, and the user must hold a certificate recognized by authorities. Basic training for Ethylene oxide and/ or Formaldehyde sterilization processes is provided within a two and a half day course followed by an examination of the acquired competence.⁸

Medical doctors may receive a five year training to become a medical specialist for hospital hygiene, while assigned doctors for hospital hygiene participate in distinct training courses.⁹

Hospital nurses may receive further training to become a nurse specialist for hygiene. In Germany, the education is organised according to the Guideline on hospital hygiene and infection prevention. The duration is at least one year (full time) or two years (extra-occupational courses).¹⁰ People from different professions may participate in further training courses of about three weeks to become an officially recognized disinfectant¹¹.

The occupation as building cleaner in Germany requires a three year education and qualifies apprentices to work in the area of facility management of hospitals and other health care facilities. This also includes the performance of surface disinfection measures.¹²

The expert employees for swimming bath operations receive a three year education which enables them to control water processing and quality, including the performance of disinfection measures.¹³

Cooling plant builders in Germany receive a 3 ½ year education in construction and maintenance of air-conditioning systems. The requirements on hygiene standards for air conditioning systems are described in the VDI 6022 technical standards (mostly bilingual version). They refer to technical rules and mainly describe requirements for the design, filter systems and maintenance of air conditioning systems. VDI 6022 part 4 describes the qualification of personnel for hygiene controls, hygiene inspections, and assessment of indoor-air quality. VDI 6022 part 4.1 explains the hygiene training measures required for all persons which maintain air conditioning systems. There are two categories on hygiene training: Category "A" is required for more demanding hygiene tasks on air-conditioning systems and hygiene inspections, while category "B" is developed for routine services and repairs as well as for simple inspections. The training time is 7 hours for category „B“ and 17 hours for category „A“ and is subsequently completed with a written test. The profes-

⁷ GUV-R 206 GUV-Regel Desinfektionsarbeiten im Gesundheitsdienst. Bundesverband der Unfallkassen, Oktober 1999
http://www.unfallkasse-nrw.de/fileadmin/server/download/Regeln_und_Schriften/Regeln/R_206.pdf

⁸ TRGS 513 Tätigkeiten an Sterilisatoren mit Ethylenoxid und Formaldehyd (Oktober 2011)

⁹ http://de.wikipedia.org/wiki/Hygienebeauftragter_Arzt

¹⁰ RKI. 1997. Richtlinie für Krankenhaushygiene und Infektionsprävention.. Kommission für Krankenhaushygiene und Infektionsprävention http://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Kommission/Downloads/Altanl_Rili.pdf

¹¹ <http://www.rettungsdienstlehrinstitut.de/ausbildung-zum-staatlich-anerkannten-desinfektor.html>

¹² http://www.gesetze-im-internet.de/bundesrecht/gebreinigausbv_1999/gesamt.pdf

¹³ http://www.gesetze-im-internet.de/bundesrecht/b_derfangausbv/gesamt.pdf

sional association on thermal environment of buildings which is a member of the European Ventilation Industry Association, is engaged with the maintenance of air-conditioning systems.¹⁴ The German professional association on air and water hygiene¹⁵ offers one week training courses which may be concluded with a certificate as a ventilation and air conditioning quality manager according to VDI 6022.¹⁶

6.3 Requirements for sales of biocides

Some biocidal products, for example disinfectants for hands, surfaces or laundry (intended for human health purposes) could be distributed via pharmacies to the general public in order to obtain advice on the application of these products and on general hygiene requirements. Biocides for professional use are generally distributed via other supply chains where these provisions do not apply. Here, often the suppliers' field staff advises their customers which biocidal product to apply. The qualifications of these distributors could also be certified, according to the requirements of Directive 2009/128/EC.

Stakeholders from NGOs, authorities and user associations complained about the occurrence of misleading advertising claims. As an example, the electrochemical on-site production of Chlorine under non-controlled conditions was mentioned. Towel rails treated with silver and nanoparticles were referred to as another example of unnecessary applications. It was suggested to develop a publicly accessible guide on misleading advertising claims.

Article 58 of the BPR applies to treated articles that are not biocidal products and requires that the label of treated articles refer to all active substances and where substantiated, the biocidal property attributed to the treated article. According to Annex II, dealing with information requirements for active substance efficacy, data to support the label claims on biocidal products and treated articles, should be submitted. Labels should not be misleading with respect to the risks of the products to human health, animal health or the environment or its efficacy. In any case, the terms 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or similar indications (Article 72 BPR) should not be mentioned..

The US EPA restricts the label claims for treated articles for avoiding non-proven advertising statements. The following example of an acceptable label statement is given: *"Antimicrobial properties are built-in to inhibit the growth of bacteria that may affect this product. The antimicrobial properties do not protect users or others against bacteria, viruses, germs, or other disease organisms. Always clean and wash this product thoroughly before and after each use. Furthermore, the preservative claim and qualifying statement on the product packaging (type, size color) must be given no greater prominence than other described product features. Articles or products that claim to be effective in controlling microorganisms such as E. coli, S.aureus, Salmonella sp. or Streptococcus sp. must be registered as a pesticide. These articles or products make a public health claim that goes beyond the preservation of the treated article itself. EPA requires the submission of chemical data in support of the public health labelling claims and patterns of use of the product."*¹⁷

Annex A of the BS EN 14885 on the application of "European Standards for chemical disinfectants and antiseptics" requires that the terms antibacterial, antiviral, antifungal and antimicrobial should not be regarded as

¹⁴ Fachverband Gebäude-Klima e.V., <http://www.fgk.de/>

¹⁵ Deutscher Fachverband für Luft- und Wasserhygiene e.V. (DFLW), www.dflw.info

¹⁶ <http://www.vdi.eu/engineering/vdi-standards/>

¹⁷ <http://www.epa.gov/pesticides/factsheets/treatart.htm>

scientific terms because they are not linked with requirements for efficacy. The term sanitizer should not be used, because it is not defined.¹⁸

The Vienna Environmental Ombudsman (Umweltanwaltschaft Wien) established a working group “EcoPurchasing Vienna” and provides a data base on commercially available disinfectants. The city of Vienna as an employer of 30,000 people requires, that all disinfection measures in public health services such as nursing, as well as in schools and kindergartens should be performed with environmental sound and occupational safe disinfectants with prove efficacy. The Viennese Database for Disinfectants (WIDES Database) is the main tool to achieve these objectives and is also available in English.¹⁹

6.4 Awareness programmes and information

There exist several activities concerning awareness rising of user of biocides including disinfectants.

A web-based information system for the general public developed and run by the German Federal Environment Agency, provides information to the general public about physical, chemical and other measures as alternatives for the use of biocidal products, or for minimization of their use. The focus lies on the description of preventive measures (www.biozid.info). The web-portal is continuously extended.

The Pesticide Action Network (PAN) Germany, distributes “tips for maintaining hygiene in private homes without much chemicals” which include links to information centres for consumers.^{20, 21}

The A.I.S.E.²², representing the soaps, detergents and maintenance products, initiated the, “Read the label” campaign and provides information for industrial and institutional users of detergents and cleaning products. The aim is that the user follows the instructions provided by industry according to the Classification, Labeling & Packaging Regulation (CLP).²³

Stakeholders from industry also suggested that a combination of apps or bar codes could be used to provide more detailed use instructions alongside with the accompanying labels, in order to avoid overloading of labels with information.

The university hospital of Bonn, under the auspices of the WHO, initiated a campaign “Hygiene tips for kids”, where children, teachers and parents receive basic hygiene. Routine hand hygiene with detergents plays a major role in this concept, the use of disinfectants is only recommended after medical advice (Gebel et al. 2008).²⁴

The German Commission for Hospital Hygiene and Infectious Disease elaborated a guideline on hygienic requirements for medical care of immunosuppressed patients. This is directed to professional persons in

¹⁸ BS EN 14885 (11/2006) Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics.

¹⁹ <http://www.wien.gv.at/english/environment/protection/oekokauf/disinfectants/index.html>

²⁰ http://www.pan-germany.org/download/biozide/hygiene_gewusst_wie.pdf

²¹ <http://www.verbraucherzentrale.de>

²² International Association for Soaps, Detergents and Maintenance Products, <http://uk.cleanright.eu/>, <http://www.aise.eu>

²³ <http://www.aise.eu/library/publications.aspx>

²⁴ <http://www.hygiene-tipps-fuer-kids.de/>

charge of medical care such as doctors or nurses, but also refers to family members which care for their relatives (KRINKO 2010). Here, disinfection measures are included as part of a general strategy of hygiene maintenance and this guideline could serve as an example when the use of disinfectants is recommended and how they should be applied.

The US Department of Health and Human Services established a program on healthy housing. The healthy housing reference refers to disinfectants as source of volatile organic compounds.²⁵ The National Healthy Homes Training Center and Network, founded by the U.S. Centers for Disease Control and Prevention, aim to provide training for public health and housing practitioners in the assessment and treatment of housing-related health hazards. This also provides a forum for the exchange of practical guidance about healthy housing strategies among federal, state, tribal, and local agency staff.

The German Industrial Association for Personal Hygiene and Detergents (Industrieverband für Körperpflege- und Waschmittel, IKW) promotes a Germany-wide initiative for sustainable action in washing, dishwashing and cleaning for consumer uses. A web-page provides information, tips, actions and recommendations for sustainable laundry, maintenance and cleaning.²⁶ Here, it is stated that the use of disinfectants or “antibacterial” cleaners for the removal of normal dirt in kitchen, bathroom and toilets normally is not necessary. According to the IKW, sustainability in the context of washing and cleaning agents not only covers the efficient use of environmentally compatible and sustainable cleaning and hygiene products. Regular cleaning and maintenance of the equipment extends the proper functioning of these commodities and maintains its value. The time required for the application should be considered as a significant further aspect of sustainability in the social life.²⁷

6.5 Equipment for biocide application

Product designs supporting the application of disinfectants through accurate dosing, e.g. via dosing pumps, should be preferred.

The Technical Committee CEN/TC 102, “Sterilizers for medical purposes”, develops standardizations for the design and testing of sterilizers, washer-disinfectors and their associated accessories. There is a close cooperation with ISO/TC 198, “Sterilization of health care products”. For the sterilisation of washers such as disinfectant bedpans, the technical standards of ISO 15883, part 1-7, is applied. Usually thermal disinfection of bedpans requires a temperature of 80°C with a holding time of approximately 10 minutes.²⁸ There exist numerous standards on hygiene requirements during the processing of medicinal products. ISO 17664 describes the information, to be provided by the manufacturer, for the processing of resterilisable medical devices. ISO 11135 deals with requirements for the development, validation and routine control of a sterilisation process with Ethylene oxide. The recommendation of the German Commission for Hospital Hygiene and Infectious Disease Prevention gives an overview about relevant national guidelines and standards (KRINKO 2012).

²⁵ <http://www.cdc.gov/nceh/publications/books/housing/housing.htm>

²⁶ <http://www.forum-waschen.de/>, www.ikw.org/

²⁷ http://www.forum-waschen.de/tl_files/content/pdf-info-texte-veroeffentl/Leitfaden-Sauberkeit-im-Haushalt-Teil1+2.pdf

²⁸ MERKBLATT Anforderungen für den Betrieb von Steckbeckenspülmaschinen LUGV Brandenburg, Abteilung Gesundheit, Referat G4 – 27.08.2010

The equipment is one decisive factor for the control of *Legionella* bacteria in water systems, responsible for a severe form of pneumonia (Legionnaires' disease). Proliferation of the bacteria is prevented by avoiding water temperatures between 20 °C and 45 °C, avoiding water stagnation which can encourage the growth of biofilms and avoiding the use of materials which harbour bacteria and / or provide nutrients for microbial growth. Additionally, exposure to water droplets and aerosol should be reduced by controlling the release of water sprays, e.g. for humidifiers and water misting systems or showers.^{29,30}

The construction of air conditioning equipment requires adequate access for regular cleaning. Improving the cleaning ability of the heat exchanger, the condensate tubes and the washers is one objective of optimised construction. In general, washers are considered as poor filters and should not be solely relied on to clean the air (Jones 2001).

Swimming pools

The CEN Technical Committee CEN/TC 402 is in charge of standardization, in the field of domestic swimming pools, spas and other types of pools and their related materials, equipment and accessories, used for domestic/private purposes. In Europe, about 3.7 million privately owned swimming pools exist. The CEN/TC 402 Working Group 2 deals with pool water circulation, filtration and treatment. Several standards are under development.³¹

Under CEN/TC 164 "Water supply" several standards, describing quality requirements of chemicals used for the treatment of swimming pool water, have been elaborated such as EN 15072: "Sodium dichloroisocyanurate, anhydrous", EN 15073 "Sodium dichloroisocyanurate, dehydrate", EN 15796 "Calcium hypochlorite", EN 15363 "Chlorine" and EN 15077 "Sodium hypochlorite".

In 2012, the Technical Report CEN/TR 16355, "Recommendations for prevention of *Legionella* growth in installations inside buildings conveying water for human consumption", has been published. It provides basic information about the conditions for *Legionella* growth in drinking water installations and gives recommendations for preventing the growth of *Legionella* in these installations. Although drinking water disinfectants are attributed to PT 5, the same principles also apply to swimming water treatment installations. Further standards such as DIN EN 16401 refer to chemicals used for the treatment of swimming pool water (Sodium chloride used for electrochlorinator systems).

DIN EN 12740 and DIN EN 12461 contain guidance for handling, inactivating and testing of waste in laboratory and large-scale processes and production sites within the biotechnology.³²

Aside from the design of the equipment for biocide application, also the hygiene design of machinery to be cleaned or disinfected is an important instrument to maintain its function. BS EN ISO 14159 developed by ISO/TC 199, "Safety of machinery", describes hygienic requirements on machinery such as the construction

²⁹ <http://www.nchh.org/Training/National-Healthy-Homes-Training-Center.aspx>

³⁰ Legionella and legionnaires' disease: European policies and good practices. European Agency for Safety and Health at Work <http://www.osha.europa.eu/en/publications/factsheets/100>

³¹ <http://www.cen.eu> prEN 16582 part 1-3 and prEN 16713 part 1-3 Domestic swimming pools.

³² BS EN 12740 (11/1999) Biotechnology. Laboratories for research, development and analysis. Guidance for biotechnology laboratory operations, BS EN 12461 (7/1998) Biotechnology. Large-scale process and production. Guidance for the handling, inactivating and testing of waste.

principles, the choice of materials, the consideration of uses and users, as well as directions for use and maintenance.³³

The standard BS EN ISO 14159 (6/2008), “Safety of machinery - Hygiene requirements for the design of machinery”, applies to all types of machines and associated equipment, used in applications, where hygiene risks to the consumer of the product can occur (e.g. food processing, pharmaceutical products, cosmetic products). It requires that materials should be suitable for their intended use and that surfaces need to be durable, cleanable and capable of being disinfected. The materials should be resistant to cracking, erosion, corrosion and abrasion and should prevent penetration of unwanted matter under intended use. The design must ensure that relevant areas are readily accessible for cleaning and inspection and the demountable parts need to be readily removable. Alternatively, the machinery may be designed to be cleaned in places. Dead spaces shall be avoided. Verification of compliance with hygiene requirements is undertaken by examination of the functional specifications and the fabricated machine; and/or by undertaking of specific practical tests (if available). The standard also specifies requirements on an instruction handbook and instructions for use.

6.6 Further measures to reduce emissions during application

The disinfection of water with oxidising biocides, leads to the inevitable formation of disinfection by-products (DBPs) because part of the biocides react with organic and inorganic water ingredients. During evaluation of active substances, DBP are not specifically addressed, but it is recommended to consider the formation of DBP in product authorisation.³⁴ Measures to reduce the formation of DBPs include the removal of precursors, such as organic matter, through water pre-treatment (e.g. filtration) and/or shifting to other disinfection systems such as UV or Ozone. DBPs might also be removed by air stripping, activated carbon, UV light and advanced oxidation.

6.7 Measures to reduce emission during service life

Emissions from treated articles may be controlled by testing the leaching behaviour under the conditions of use, and allowing only limited amounts to be released to the environment.

6.8 Measures to reduce emission during restore and end-of life stage

The main emission pathway for PT 2 disinfectants is via the sewer system, either to an on-site STP or to a municipal STP. Avoidance of peak loads discharged to biological treatment plants, or neutralisation of active substances are measures for reducing acute toxicity to activated sludge.

Obligatory discharge of wastewater to a well-functioning municipal STP might be considered as a RMM. Note, that the proportion of the population, connected to urban wastewater treatment within Europe, shows considerable differences (between ca. 30% and 95%). If no STP is existent in a community, it can be expected that direct releases of wastewater from the food and feed area, including disinfectants to surface water is very likely.

³³ BS EN ISO 14159 (6/2009) Safety of machinery - Hygiene requirements for the design of machinery

³⁴ 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.

Gas sterilizers using Ethylen oxide deactivate the active substance after use by catalytic or thermic oxidation, or through washing the gas with an acid water scrubber system where it reacts to Ethylene glycol (DWA-M 775 2010, US-EPA 1997). Formaldehyde sterilizer discharge Formaldehyde in concentrations below 0.5 g/L to the sewer which is assumed as being acceptable because no impact on SPT is expected after dilution with other wastewater streams (DWA-M 775 2010). The discharge of Formaldehyde dilutions below 2%, from disinfection measures or from pathologies, is considered acceptable. Even concentrations between 2% and 10% might be acceptable for STPs, if released steadily while avoiding peak loads. However, the safe level for Formaldehyde in the air of the sewage conduit might be exceeded. Formaldehyde solutions above 10% should generally be considered as hazardous waste (DWA-M 775 2010).

6.9 Specific measure to protect the aquatic/terrestrial environment

No specific measures to protect the environment from the release of disinfectants, such as on-site treatment techniques, have been identified so far. The selection of environmental sound active substances and ingredients, as well as the avoidance of direct emissions to surface waters and of peak loads to STP, seem to be the most appropriate measures.

6.10 Reduction of biocide use in sensitive areas

The application of PT 2 disinfectants mainly occurs indoors and STP is the main receiving compartment. Thus, sensitive areas may only be affected in few exceptional cases, such as disinfection of soils. Direct discharges of disinfected swimming pool water to surface water might cause impacts on sensitive areas and may therefore be restricted. Emptying the content of chemical toilets from caravans to sensitive environments might potentially occur but is generally forbidden. Considering other sensitive areas as defined in Directive 2007/128/EC, where public places such as healthcare facilities are included, stakeholders questioned whether biocides should be prohibited completely, because the application of disinfectants may be legally demanded in those areas. On the other hand, it was complained that there is few guidelines for the application of disinfectants in "sensitive" areas, such as kindergartens or private homes with sick people.

6.11 Handling and storage of biocides and their packaging and remnants

The general rules for storage and transport of chemicals as described in national guidelines such as TRGS 510 should be considered.³⁵ Most aspects concerning the handling and storage of pesticides and their packaging and remnants also apply to biocides. This refers to appropriate container sizes to minimize remnants, the restriction of the use of concentrates to professional users only, and the establishment of a recycling system for packaging used for biocides. The disposal of product residues and packages by municipal collection systems for hazardous substances should be promoted. For some applications, the packages might be returned to the supplier, following the example of plant protection products.

³⁵ TRGS 510 Storage of hazardous substances in non-stationary containers. <http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/pdf/TRGS-510.pdf>

6.12 Integrated best practice approaches

The application of best hygiene practices should also consider options for alternative or biocide-free measures. This includes the application of cleaning agents such as detergents instead of biocides where possible, and/or the application of physical disinfection methods. In this case the environmental soundness of alternative ingredients should also be evaluated. The method of life cycle assessment could be applied to compare different options for selected disinfection areas. For example, a life cycle assessment of different processes for washing microbiologically contaminated hospital and home care laundry revealed, that chemical disinfection at 40°C had a lower potential environmental impact than thermal (90 °C) or chemo-thermal 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 chemo-thermal processes, was considerably lower than that of the chemical process (Eberle et al. 2007). This demonstrates that other aspects of environmental impacts should also be considered.

6.13 Existing guidance documents on best practices and standards

The careful use of disinfectants is essential to minimise risks for human health and the environment. In many application areas for disinfectants, good and best practice documents and training courses have been developed by authorities and professional associations. Maintaining good hygiene practice and good housekeeping is a prerequisite for disinfectants being effective. Hygienic design of the equipment and the facility helps minimising the amount of disinfectants. Several good and best practice documents as well as technical standards cover the PT 2. Some non-exclusive examples are:

Hospitals and healthcare facilities

- 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.
- TRGS 525 (5/1998) Umgang mit Gefahrstoffen in Einrichtungen zur humanmedizinischen Versorgung. (Hazardous substances in health care facilities)
- 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), Bundesgesundheitsblatt – Gesundheitsforsch., - Gesundheitsschutz 47, p. 51–61
- RKI 2007. Liste der vom Robert Koch-Institut geprüften und anerkannten Desinfektionsmittel und – Verfahren, Stand vom 31.8.2013 (16. Ausgabe) Bundesgesundheitsblatt – Gesundheitsforsch. - Gesundheitsschutz 56, p. 1706–1728
- 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
- Recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) <http://www.dgkh.de/english-information/>

Disinfectants in consumer products

- 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

Swimming pools

- DIN 19643 part 1 to 4 (11/2012). Aufbereitung von Schwimm- und Badebeckenwasser (Treatment of water of swimming pools and baths)
- WHO 2006. Guidelines for safe recreational water environments, VOL. 2 Swimming pools and similar environments. http://www.who.int/water_sanitation_health/bathing/en/
- BGR/GUV-R 108 Betrieb von Bädern. Berufsgenossenschaftliche Regel, Stand Juni 2011 https://www.bgw-online.de/DE/Medien-Service/Medien-Center/Medientypen/bgw_vorschriften-regeln/BGR-GUV-R-108-Betrieb-von-Baedern.html

Laundry disinfectants

- BS EN 14065 (12/2010). Laundry Processed Textiles – Biocontamination control system
- RKI-Guideline on accepted disinfectants and disinfection processes (RKI 2013).³⁶

Air conditioning systems

- VDI 6022 pat 1, 3, 4, 6 (7/2011 – 8/2012). Ventilation and indoor-air quality - Hygiene requirements for ventilation and air-conditioning systems and units.
- DIN 1946-4 Ventilation and air conditioning: part 4: VAC systems in buildings and rooms used in the health care sector (12/2008), Part 7: Ventilation systems in laboratories (7/2009).

Wastewater discharge and chemical toilets

- ATV-M-270 (5/1997). Entsorgung von Inhalten mobiler Toiletten mit Sanitärzusätzen (Chemie-toiletten) (Disposal of the content of mobile toilets with sanitary additives (chemical toilets). Deutsche Vereinigung für Wasserwirtschaft, Abwasser und Abfall e. V (DWA)
- DWA-M 775 (12/2010): Abwasser aus Krankenhäusern und anderen medizinischen Einrichtungen. (Waste water from hospitals and other medical facilities.) Deutsche Vereinigung für Wasserwirtschaft, Abwasser und Abfall e.V. (DWA)
- BS EN 12255-14 (1/2004). Wastewater treatment plants. Disinfection.

7 Indicators

In the stakeholder survey, supported by a questionnaire, the following potential indicators for observing the progress obtained in sustainable use of biocides have been indicated in the order of priority:

1. Collection of consumption data for specific product types
2. Occurrence of allergens against cleaning agents and disinfectants
3. Biocide specific monitoring of effluents from sewage treatment plants
4. Biocide specific surveillance of ground and drinking water (e.g. number of values exceeding 0.1 µg/L)

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http://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Desinfektionsmittel/Desinfektionsmittellist/Desinfektionsmittelliste_node.html

5. Occurrence of nosocomial infection (acquired in hospitals), multi-resistant microbes, and specific pathogens (Salmonella, Legionella, Rotavirus, Norovirus etc.)
6. Indication of poisoning cases
7. Inquiry of the waste amounts (product remains)
8. Biocide specific monitoring of surface waters
9. Exposure measurements on workplaces during the use of disinfectants
10. Surveillance of biocide residues in medicinal products
11. Inquiry on the proportion of consumer uses of disinfectants
12. Survey among professionals / consumer users
13. Survey about the number of (certified, trained) professional users
14. Survey about the number of certified salespersons of disinfectants
15. Survey about the number of certified consultants for disinfectant applications
16. Survey about the number of advanced training events and participants
17. Inquiry of the recycling quote of packages and remains
18. Survey about the resource allocations for research and development spent for risk reduction (e.g. for technical solutions)
19. Hit rates on specific information web portals (e.g. www.biozid.info)

The stakeholder did not refer to further suitable indicators but made some suggestions on a local level, such as that the amount of disinfectants purchased (e.g. in a hospital) could be compared with the expected amount resulting from the intended uses. The success of disinfection measures could be (and is) monitored by microbiological control samples of target objects. For laundry disinfectants, the number of companies with established quality management systems according to the Risk Analysis and Biocontamination Control concept (RABC), as described in EN 14065 has been suggested a potential indicator.³⁷ There are certification systems for laundries which fulfil this standard.³⁸ Collection consumption data on disinfectants has been considered the most important indicators besides monitoring data in environmental media. From industrial associations, also the decrease of infection cases with multi-resistant *Staphylococcus aureus* (MRSA), Norovirus, and Verotoxin-producing *Escherichia coli* (Enterohämorrhagische *E. coli*, EHEC) or data on infection incidences in private homes has been suggested as a suitable indicator. A formulator suggested that any use of disinfectants should be accompanied by a document where the selection criteria and objectives are described. Thus the absence of these documents within surveillance of market or application areas could serve as an indicator.

³⁷ BS EN 14065 (12/2010). Laundry Processed Textiles – Biocontamination control system

³⁸ RAL-GZ 992/1 and RAL-GZ 992/2, <http://www.waeschereien.de>

8 Recommendations and package of measures based on the questionnaire

The prohibition of any misleading advertisement statements could reduce consumer use of disinfectants. The US EPA approach that any hygienic statement must be proven with efficacy testing is mentioned as a good example. The new BPR requires that biocidal claims of treated articles must be proven with efficacy statements. The following measures received the highest acceptance of at least 50% of all stakeholders who attributed high or medium efficiency to these measures. For each category the measures are listed by their order of priority.

Category "Further training and education"

- Development of hygienic plans, disinfection plans and work instructions adjusted to the needs of disinfection measures.
- Advice to clients by manufacturers (including safety data sheets, technical leaflets, instructions for use).
- Instruction of co-workers from contractors for in-house cleaning, proof qualification of contractors.

Category: "Requirements for sales and control mechanism"

- Knowledge transfer on a sustainable use of disinfectants during education and training, e.g. of nursing- or cleaning staff.
- Prohibition of certain products and applications for nonprofessional users (consumer).
- Certification of professional users, distributors and consultants within further education and training.
- Restrictions on marketing.
- Development of a classification system for environmental sound disinfectants.
- Regulation of sales of products through retail trade to the general public, e.g. through the sale of household disinfectants in pharmacies.

Category "Information and awareness raising"

- Providing information on "best practices" and safe use.

Category "Surveillance of applications"

- Renunciation of daily routine disinfection of floors in public health areas
- Replacement of air conditioners with rotary spray through humidifier.
- Optimization of disinfection by previous cleaning.
- Quality Assurance and Control.
- Replacement of poorly biodegradable / eliminable disinfectants (in sewage treatment plants) by rapidly degradable active ingredients and additives.
- Mandatory testing and control of biocide treated materials.
- Development of technical standards and guidelines for the cleaning of instruments and equipment.
- Development of standards and guidelines for private users, when disinfection measures are required and how they should be used.

- Replacement of disinfection measures by thermal and thermochemical processes.
- Replacement of air conditioners with circulation spray humidifiers by steam humidifiers.

Category “Measures to reduce emissions during the use phase”

- Limitation of the container size for consumer users to minimize residual amounts.

The most effective measure belongs to the requirements for sales and control mechanism and suggests restriction of certain disinfectants for consumer use. The measures attributed to training and education, also received high acceptance. This includes the development of management tools such as hygienic plans and the advice of manufacturers to their clients. Up to now stakeholders did not identify substantial measures to reduce emissions during the use phase.

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