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TRANSITIONAL GUIDANCE

Transitional Guidance on the Biocidal Products Regulation

Transitional Guidance on Evaluation of Environmental Risk Mitigation Measures for Disinfectants Product Type 2 (Disinfectants and algaecides not intended for direct application to humans or animals)

November 2014

TRANSITIONAL GUIDANCE

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Transitional Guidance on Evaluation of Environmental RMM for Disinfectants Product Type 2

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European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

PREFACE

This Transitional Guidance is to be applied to applications for product authorisation submitted under the Biocidal Product Regulation (EU) No 528/2012 (the BPR). This document describes the BPR obligations and how to fulfil them.

A “Transitional Guidance” is a document that has been initiated under the “old” Biocidal Products Directive 98/8/EC and because it has been finalised before the relevant new BPR guidance document has been fully developed, it is being made available as a Transitional Guidance document until such time as the relevant new document is ready for publication.

This Transitional Guidance document has been through a Public Consultation organised by the Commission and this document is now finalised and waiting for inclusion into Volume IV Environment Part C Evaluation of the new BPR guidance structure: there will be no further consultation on these documents and they will be added by a corrigendum when the relevant Volume is available.

Environmental risk mitigation measures for disinfectants used in the private and public health area and other biocidal products (Disinfectants PT 2: Disinfectants and algaecides not intended for direct application to humans or animals)

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NOTE to the reader:

This Transitional Draft Guidance will be reformatted when it is incorporated into the New Guidance Structure. When this is completed, the finalised version will be uploaded onto the website of ECHA. No consultation will be made to do this.

1. General introduction

The aim of this set of Guidance documents is to gather and to harmonise possible risk mitigation measures (RMM) for disinfectants (product type (PT) 1-5). The target group are all stakeholders working on authorisations of disinfectants in the biocidal sector (e.g. applicants, consultants, Competent Authorities). Several disinfectants are currently under evaluation within the review programme established by the Biocidal Products Regulation (EU) No 528/2012 (BPR) concerning the placing of biocidal products on the market. These products represent a large amount of all biocidal products used in Europe. To facilitate the work of the applicants and the Competent Authorities (CA) during the product authorisation and mutual recognition, the Guidance documents present a set of possible RMM that can be used for all authorisations in Europe and thus simplify mutual recognitions while ensuring a similar level of environmental protection.

This Guidance document describes RMM for disinfectants used in the private and public health area (PT 2) to be considered during the authorisation of biocidal products as well as the evaluation of active substances, especially if an environmental risk is identified. The PT 2 disinfectants cover very diverse application areas and are therefore divided in the following subgroups (see Emission Scenario Documents for PT 2 and its supplement, European Commission 2002, 2011).

Sub PT	Private area and public health area disinfectants and other biocidal products*
2.1	Swimming pools
2.2	Sanitary sector
2.3	Horticulture
2.4	Tiles and surfaces
	Medical sector
2.5	Disinfection of rooms, furniture and objects Disinfection of instruments
2.6	Laundry disinfectants
2.7	Hospital waste disinfectants
2.8	Disinfection of air conditioning systems
	Disinfection in industrial and institutional areas
2.9	Disinfectants for sewage and wastewater
2.10	Soil and other disinfectants
2.11	Disinfection of chemical toilets

* There does not exist an official attribution of sub-PT numbers but these are introduced here for a better structuring.

The COWI study concluded that the largest use area is for disinfection purposes in private and public health areas (PT 2) where about 50% of the overall tonnage from all biocidal actives is consumed.[1]

The main emission route for PT 2 disinfectants are municipal sewage treatment plants (STP) and surface water as well as sediments (either through direct discharges e.g. of swimming water or from the outflow of STPs). For some disinfection application such as non-contained disinfection processes or fumigation, there is some potential for direct emission to the air and soil.

Some of the active substances and/or other ingredients of the biocidal products are classified as harmful, toxic or very toxic to aquatic life and/or may cause long lasting effects according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances (CLP Regulation). Some substances could pose an unacceptable risk when released to the environment. If the risk assessment for disinfectant products results in an unacceptable environmental risk to aquatic or soil organisms, or to biological STP (PEC/PNEC > 1) according to the applicable guidelines these biocidal products may only be authorised if the risk can be reduced to an acceptable level by RMM (conditional authorisation).

In a study on behalf of the German Federal Environment Agency the existing environmental RMM for disinfectants (PT 1-5) proposed by different stakeholders were compiled and combined to a set of different RMM that the authorities can choose from during the product authorisation process, depending on identified risks. The different RMM for PT 2 are compiled in the annex of this document. Considering the progress of the review programme for existing active substances, this paper outlines a common approach for products authorisations and mutual recognitions.

It should be noted, that there are RMM which refer to the product designers and formulators and others which refer to the user of a biocidal product. The efficiency and practicability of any RMM to be quantitatively considered must be evaluated in the risk assessment by authorities. In this respect, the possibility of enforcement and control of a RMM should be considered. Any RMM referring to the user of a biocidal product must be clearly indicated on the label.

⚠ Only environmental risks from the use of PT 2 disinfectants are considered in this guidance document so far.

2. Risk mitigation measures for PT 2 disinfectants

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. This is not applicable for private use.

Several active substances may be rapidly degraded by chemical-physical processes during application or biodegraded in STP. Other active substances may be toxic and/or may cause long lasting effects. STPs are important intermediate compartments for PT 2 disinfectants and need to be protected from substances inhibitory to the activated sludge organisms.

In addition, disinfectants may also be directly discharged to surface water depending on the capacity of the on-site wastewater (pre)treatment plant and/or the connection to a sewer discharging to municipal STPs. Another source for direct discharges is the storm

[1] http://ec.europa.eu/environment/biocides/pdf/report_use.pdf

water overflow of STPs. 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. In the STP the concentration might decline through chemical reactions e.g. with proteins.

Further on, some oxidative disinfectants may react to disinfection by-products (DBP) with inorganic or organic matter present in water. Many DBPs are harmful and may pose a risk to the environment and/or form persistent organic compounds and adsorbable organic halogens (AOX) which also raises environmental concerns. A background document on the assessment of DBP is being developed by CAs where it is proposed inter alia to carry out PEC/PNEC-assessments of DBP based on monitoring data from the biocide uses subjected to authorisation. The results of these risks assessments should be taken into account when considering RMM for the respective products.

The development of (cross-) resistance of microorganisms to disinfectants has been observed both after correct use and especially after misuse of disinfectants (e.g. cf. SCENIHR, 2009)[2]. A recent EU research project (BIOHYPO: Confronting the clinical relevance of biocide induced antibiotic resistance) “found no significant correlation between reduced susceptibility of pathogens to biocides and antibiotic resistance except in the case of chlorhexidine and benzalkonium chloride. However, partners fear that this may change in the future.”[3] Resistance development may be prevented or reduced by the avoidance of application faults and of sublethal concentrations of the active substances as well as by the use of alternative substances or methods. The development of resistance may lead to the use of higher concentrations or an increased frequency of use and thus to higher emissions. The development of cross-resistance of microorganisms to antibiotics following use and misuse of disinfectants is controversially discussed among hygienists.

Treated articles with a primary biocidal function are biocidal products and are covered by the BPR and must be authorised as biocidal products while the efficiency of the claim must be proven by sound data. RMM for these treated articles mainly cover the use phase and the disposal of the products.

RMM can refer to different addressees such as the industrial formulator, the supplier and distributor, the user of disinfectants, and authorities involved in the surveillance of good practices.

In this guidance document RMM are divided in general and specific RMM.

3. General RMM

General RMM, for example general precautionary advice, best available techniques, good housekeeping, applying hygiene management systems, should be applied to all products, independent from the results of the risk assessment, if applicable and exemplify a way to reduce the use of disinfectants to the minimum necessary as requested in Article 17(5) of the BPR. This use shall also involve the rational application of a combination of physical, biological, chemical or other measures as appropriate. They describe reasonable conditions of use and reflect common sense. The intention is to avoid misapplication of disinfectants. However, general RMM cannot be used in the environmental exposure assessment in quantitative terms, because the effect on the emissions and the compliance cannot be proven.

[2] SCENIHR. 2009. Assessment of the Antibiotic Resistance Effects of Biocides. 2009. p. 63

[3] BIOHYPO, 2013. Biocides and antibiotic resistance. http://cordis.europa.eu/result/brief/rcn/9974_en.html

4. Specific RMM

Specific RMM result from the risk assessment and are suitable for a quantitative reduction of the exposure through modification of the respective emission scenarios. Note that RMM for users have to be clearly communicated with the label or product leaflets. Specific RMM are designed to reduce an identified environmental risk (PEC/PNEC > 1) to an acceptable level. The efficiency and practicability of specific RMM has to be proven by the applicant for authorisation of a biocidal product by submitting sound data or studies. Some RMM might also be appropriate if the risk quotient shows a level of concern (e.g. PEC/PNEC > 0.1). This may for example be the case if a substance is used in different PT simultaneously. Specific RMM should be considered in the revision of Emission Scenario Documents (ESDs) as far as possible in order to harmonise the approach. If they represent the way the product is commonly applied, the efficiency of the RMM could be quantified.

4.1 Categorisation of specific RMM

Specific RMM can be attributed to different categories described below. The precise RMM for each category and specific unacceptable risks can be found in Appendix 1 of this document. It should be noted that some RMM, whose main focus is on human health, nonetheless indirectly lead to lower exposure to the environment (e.g. because specific uses or user categories are excluded). These are also included in the document.

4.1.1 Category of Users

Disinfectants of PT 2 are intended for private, professional and industrial use. While industrial users would apply disinfectants at industrial sites, e.g. in the production of packaging materials, pharmaceuticals or cosmetics as well as in biotechnology, professional use includes professional users other than manufacturers (e.g. drinking water disinfection in water supply companies). This differentiation has already been included in the Technical Notes for Guidance on Data Requirements (p. 35).

For certain disinfection activities and/or the use of biocidal products, which are very toxic, toxic or which may cause long lasting effects the use may be restricted to specifically trained and certified professional users. The same applies to certain modes of applications such as fumigation.

When focusing on consumer use of PT 2 disinfectants, controversial opinions can be found with regards to the effectiveness of application by untrained consumers (e.g. cf. Josephson et al., 1997[4]; Scott et al., 1984[5]). Therefore with respect to RMM only short and simple instructions are likely to be implemented by the user. Thus, emphasis should be on product integrated RMM under the control of the supplier (chemical composition and design, packaging, etc.). The product label should communicate all instructions on safe use, storage and disposal to consumers. These instructions are mainly attributed to general RMM which cannot be quantitatively assessed.

The restriction of the use of the products to certain user groups is a possible RMM if unacceptable risks are identified during the risk assessment of the products and could be mitigated by the restriction of a user category. Generally, to exclude unauthorised uses

[4] Josephson, K. L., Rubino, J. R. and Pepper, I. L. 1997. Characterization and quantification of bacterial pathogens and indicator organisms in household kitchens with and without the use of a disinfectant cleaner. Journal of Applied Microbiology. 83, 1997, pp. 737-750.

[5] Scott, Elisabeth, Bloomfield, Sally F. and Barlow, C. G. 1984. Evaluation of disinfectants in the domestic environment under 'in use' conditions. The Journal of Hygiene. 92, 04 1984, Vol. 2, pp. 193-203.

of PT 2 disinfectants a measure could be taken for these disinfectants not to be offered on open shelves or by internet commerce through self-service.

4.1.2 Area of use

Disinfectants used in the private and public health area usually are specifically designed for the disinfection of surfaces, instruments, air condition systems, laundries, swimming water etc., thus excluding other uses. 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. Specific provisions on the area of use could be combined with other provisions, in particular with those on the category of users and on the product design.

The area of use may also contribute to reduce the formation of DBP through the use of some oxidative disinfectants, e. g. by avoiding areas where the inorganic or organic precursors of such DBP are known and present.

The practicability of RMM concerning the area of use depends on the unambiguous description of allowed uses. Because the intended uses determine the emission scenarios to be assessed, these RMM may be considered in quantitative terms.

4.1.3 Composition

The composition of a disinfectant product is under the control of the formulator and immediately has an influence on potential risks to the environment. All products with ingredients that are classified as substances of concern should be evaluated for possible risks. The discussion of the classification of substances of concern is still ongoing. On a voluntary basis the formulators of the products could consider the substitution of these ingredients to substances that are not classified as substances of concern if this would reduce the over-all risk. The possible formation of DBPs should also be considered.

4.1.4 Formulation

PT 2 disinfectants are usually applied by spraying, foaming, soaking, brushing or direct addition to water. Often the working solutions are made up from concentrates via automatic dosing pumps. In certain circumstances, the formulation of the product may help to reduce the risk for the environment through accurate dosage and avoidance of spillages.

The possible formation of DBPs should also be considered when evaluating the formulation.

Product integrated RMM such as those which determine the formulation may be quantitatively considered in the exposure assessment.

4.1.5 Packaging and pack size

The packaging of the product also plays a role and can be used to reduce environmental exposure by avoidance of over dosage. Product designs supporting the application of disinfectants through accurate dosing e.g. via dosing pumps should be preferred. Therefore, where appropriate, the placing on the market should be restricted to certain specific product design.

Product integrated RMM may be optimized by product developers and discussed with authorities. They could be considered in the exposure assessment in quantitative terms if appropriate. It is recommended to develop an overview of CE marked labelled devices. At present it is not clear in what extent specific devices would lower the use and thus emission of the biocidal product to a safe level for the environment. It would be helpful if more information would become available for environmental risk assessment.

4.1.6 Treatment and/or disposal

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 the active substance are RMM for reducing acute toxicity to activated sludge.

Obligatory discharge of the 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%).[6] 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.

These RMM may only be considered in quantitative terms in the exposure assessment if they are implemented in routine practice by the user and if some surveillance is carried out by authorities.

4.1.7 Labelling

Article 69 (1) of the Biocidal Products Regulation (EU) No 528/2012 stipulates that biocidal products shall be labelled in accordance with the SPC, and with Directive 1999/45/EC relating to the classification, packaging and labelling of dangerous preparations, and where applicable Regulation (EC) No 1272/2008. This includes precautionary statements. However the requirements of these legislations may not allow a sufficient description of possible specific risks which may arise during the use of disinfectants and be detected during the risk assessment. Therefore, additionally standard phrases should allow a sufficient description of the special risks and of the safety precautions to be taken[7] where risks have been identified. Thus, in addition to the elements already listed in Article 69(2), product labels or the packaging of disinfectants should show the safety precautions for the protection of humans, animals or the environment. These safety precautions should always be carried on the label of the products or on an accompanying leaflet together with the other directions for use and disposal of the product. Reference only to an internet source is not sufficient.

4.1.8 Codes of Good Practices

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 disinfectant. Several good and best practice documents as well as technical standards cover the PT 2.[8] 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).

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[6] http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Water_statistics

[7] This is by analogy to what has been done in the PPP area where standard phrases for special risks and safety precautions for plant-protection products have been established.

[8] A more detailed analysis of available best practice documents has been elaborated in 2010 within a study on behalf of the European Commission. http://ec.europa.eu/environment/biocides/sust_use.htm

- 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.
- 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.
- 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

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 5 (4/1997 – 9/2000). 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/

Laundry disinfectants

- BS EN 14065 (12/2010). Laundry Processed Textiles – Biocontamination control system.
- RKI-Guideline on accepted disinfectants and disinfection processes (RKI 2007).

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 (Chemietoiletten) (Disposal of the content of mobile toilets with sanitary additives (chemical toilets). Deutsche Vereinigung für Wasserwirtschaft, Abwasser und Abfall e. V (DWA).
- DVWK-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.

National legislations on wastewater discharges often provide requirements which have an impact on the selection of PT 2 disinfectants. For example, the German Wastewater Ordinance defines limit values of the AOX concentration and thus restricts the use of

organically bonded halogen compounds or halogen-releasing substances.[9] The technical standards for swimming water procession DIN 19643 parts 1 to 5 describe minimum and maximum treatment levels. The formation of Trihalomethane compounds resulting from chlorination is limited to of 0.02 mg/l. The formation of DBP could partly be managed by avoidance and/or removal of the inorganic or organic precursors.

The hygienic requirements in laundries and its quality assurance have been described in the (voluntary) Risk Analysis and Biocontamination Control concept (RABC) according to EN 14065.

In addition to product labelling and instructions for use, several good and best practice documents should be made available to the user.

RMM referring to codes of good practice may only be considered in quantitative terms in the exposure assessment if these good practices are well established in professional use of disinfectants and if some surveillance by authorities is carried out. The practicability of these RMM is not under the control of the authorisation process for disinfectants. RMM regarding good practices do not apply for consumer use of disinfectants.[10]

[9] For example the AOX load at the point of discharge for hospital and residential home laundries, 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).

[10] This is in compliance to the risk management measure discussed under REACH where many RMM communicated to consumer are not applicable for quantitative considerations, due to unknown compliance. http://www.cefic.org/Industry-support/Implementing-reach/Libraries/

Appendix 1.

In this annex RMM for products used in the PT 2 are proposed.

General RMM

The named general RMM should be applied to all products, if suitable, to ensure a proper and safe use of biocidal products throughout the life cycle when their use is needed. Words written in *italic font* in brackets should be adapted respectively for each application of the biocidal product. They are only placeholders and illustrate proposals. Depending on the application of the disinfectant the sentences can be chosen and/or modified. Some are only suitable for professional users. These are listed in the end of the list. The Precautionary Statements of the CLP Directive and the label requirements according to Article 69(2) of the BPR are not repeated here but have to be followed.

- Only apply consumer disinfectants if there is a high risk of the transmission of pathogenic germs (e.g. infectious diseases of relatives).
- Pre cleaning of surfaces required before using disinfectants. Rinse the used cleaning agent and remove the redundant water.

For products authorised for professional use only:

- Take care for general good hygiene and housekeeping.
- Before deciding to use disinfectants it should be examined whether disinfection in fact is required. Restrict the extent and frequency of disinfection measures to the minimum necessary and substitute chemical disinfection by thermal or other methods where possible.

Specific RMM

The following specific RMM can be chosen based on identified unacceptable risks during the risk assessment. The RMM are assigned to tables related to the first environmental compartment whereto the substance is released. In most of the cases for disinfectants this is the STP. These RMM can also have an effect on possible unacceptable risks in the following compartments (e.g. a measure that lowers the concentration in the influent of the STP can also lower the concentration in the receiving surface water after the STP). RMM suitable for other cases where the substance is directly released to other compartments are arranged in tables as well related to these receiving compartments below. Some specific RMM might be too difficult to be followed by non-professional users. Thus, emphasis for these products should be on product integrated RMM under the control of the supplier (chemical composition and design, packaging, etc.).

Words written in *italic font* in brackets should be adapted respectively for each application of the biocidal product. They are only placeholders and illustrate proposals. The list is not exhaustive and should be continued during the product authorization process.

How to use the table:

Example 1: Risk in the STP

If during the risk assessment for a disinfectant a risk is identified for the STP the risk assessor can use a RMM from Table 1 (Possible RMM for unacceptable risks associated with the direct release to the STP). These RMM describe possible ways to mitigate risks.

Not all RMM are suitable for each case, the decision on what RMM to choose and how to modify it has to be made case-by-case.

Example 2: Risk in surface water

A risk in surface water can result from a direct or an indirect exposure. If the risk is due to an indirect exposure through the STP the risk assessor could use a RMM from Table 1 (Possible RMM for unacceptable risks associated with the direct release to the STP) to mitigate the risk. If the risk is due to a direct exposure the risk assessor could use a RMM from Table 2 (Possible RMM for unacceptable risks associated with the direct release to surface water). Again, the choice of the RMM has to be based on the application of the product and should be feasible.

Table 1: Possible RMM for unacceptable risks associated with the direct release to the STP

Category	Specific RMM	Remarks
Category of users	Only professional uses are allowed.	
Area of use	To protect *[water living organisms / micro-organisms in a sewage treatment plant]* cleaning and disinfection *[of …]* should be carried in automatic systems.	RMM for instrument disinfectants
Packaging and pack size	The size of the package placed on the market should be proportionate to the duration of the treatment and appropriate to the pattern of use of particular user groups.	Minimisation of the overall load through accurate dosage and avoidance of accidents and disposal of active substances. This should be part of the negotiations between applicant and evaluators.
	Provide in small packages *[add the maximum package size]* only.	RMM directed to the formulator, small packages may help reducing consumption and disposal.
Formulation	[*Preferably*] use automatic dosage equipment instead of manual mixing and loading.	Accurate dosage helps avoiding misapplication and reducing the volume of the working solution and of the amount used and discharged
Treatment and/or disposal	All waste water must be processed in an industrial or municipal sewage treatment plant that incorporates both primary and secondary treatments. Onsite pre-treatment required by [*suitable techniques]* with a removal efficiency *of [expression of threshold or %]* before discharging into sewer. Neutralization or inactivation *[is*	Specify conditions and measures related to the onsite or municipal sewage treatment plant if appropriate (e.g. biological treatment, neutralization, minimum grade of elimination). To be justified with sound data and evaluated in the risk assessment.

Category	Specific RMM	Remarks
	normally] required before discharge into *[sewage system / into water treatment plants].*	
	A storm water management plan is needed to ensure that the sewage treatment plant is not overloaded with uncontaminated water.	Avoidance of a sewage treatment plant-bypass of contaminated water through storm water. Only practicable for Member states which have developed storm-water provisions.
	To protect surface water biological treatment operation needed before release of biodegradable disinfectants into surface water. The minimum grade of elimination in the sewage treatment plant required is *[x %]*.	To be proven with sound data and evaluated in the risk assessment.
	To prevent the inhibition in functioning of an on-site sewage treatment system and to protect aquatic organisms, possible residues containing the product must be discharged to a municipal sewage treatment plant.	RMM referring to wastewater treatment requirements
	To protect micro-organisms in the sewage treatment plant, it is not permitted to discharge spills and residues containing the product to sewer.	RMM for industry and other professional institutes where in practice the product is collected and disposed after use.
	To protect water living organisms, residues containing the product should be discharged to the sewer connected to the sewage treatment plant. For disinfection of surfaces >2000 m^2, the sewer connection of that facilities must be preceded by a sediment grease separation tank conform EN 1825-1 and 2.	Removal efficiency to be proven by sound data.
	Ensure process wastes are transferred to storage containers. A retention period of the disinfectant working solution of x days leads to considerably less contaminated wastewater compared to working solutions which are changed every day.	Intermediate storage of wastewater until the disinfection agents are inactivated. Removal efficiency to be proven by sound data.

Category	Specific RMM	Remarks
	Limit release rate to waste water to [*X*] kg/day.	Minimization of amount used through recycling of cleaning solution. RMM to be considered in wastewater permits and inspected by authorities. Only practicable if enforcement can be monitored.
	To protect water living organisms only use in CIP-treatment when recirculation of the cleaning solution for minimizing releases to wastewater is applied.	
	Ensure all waste water is collected and treated via a sewage treatment plant. If discharging to municipal sewage treatment plant, no onsite wastewater treatment required. If discharging to municipal sewage treatment plant, provide the required onsite wastewater removal efficiency of *[… (%)]*.	Obligatory connection of the sewer to a well-functioning municipal sewage treatment plant.
	Ensure that sludge from treatment operation is not spread to soil in agriculture, horticulture and grassland.	RMM for industrial on-site wastewater treatment plants only practicable if enforcement is supervised by authorities. Does not apply if the sludge is burnt.
	Prevent adverse effects on municipal sewage treatment by limiting *[concentration in waste water to ….. mg/l / load in waste water to … kg/d].*	Risk based evaluation of the maximum amount allowed to be used. RMM to be derived from the risk assessment only practicable if enforcement is monitored by authorities.
	If the concentration of *[add name of active substance]* in the *[sewer system, inlet of the sewage treatment plant]* exceeds the maximum allowable concentration of *[indicate limit concentration]* collect the disinfectant and dispose them as hazardous waste.	Risk based decision of the disposal of working solutions. RMM to be derived from the risk assessment only practicable if enforcement is monitored by authorities.
	If concentrations of *[add name of active substance]* in the sewer system exceed maximum allowable concentration of *[indicate limit concentration]* neutralize *[e.g. glutaraldehyde with glycine, chlorine with sodium bisulfite].*	Treatment of the working solutions. RMM to be proven by sound data, generation of disinfection by-products to be evaluated.
	Avoid peak loads through continuous discharge to the wastewater.	RMM for the protection of the activated sludge organisms to be proven by sound data. May

Category	Specific RMM	Remarks
		be concluded in wastewater permits. Only practicable if enforcement is monitored by authorities.
	Dry cleaning of containers and equipment and disposal via solid waste in order to minimize releases to water. Do not clean empty containers, but return them to the manufacturer or retailer.	RMM referring to product design and recollection of packaging
	In order to achieve efficacy and to minimize the formation of disinfection by-products (DBP) remove total organic carbon (TOC) and other precursor compounds prior to adding the disinfectant.	To be applied where halogenated oxidizing biocides are used.
	The waste water must not contain chlorination chemicals (if used to prepare the process water) above 1 mg/l free chlorine in the influent to the washing machine.	RMM for avoiding DBP in laundries (German Wastewater Ordinance, Appendix 55).
	Collect the content of chemical toilets in storage tanks and transfer it to sewage treatment plants. Ensure that only 2 m^3 per day of mobile toilet content are discharged into a sewage treatment plant designed for [*X*] inhabitant equivalents.	RMM for avoiding discharges of sanitizers used in chemical toilets to the environment and avoiding peak loads in sewage treatment plant (ATV-M-270).
	Before releasing disinfectants from chemical toilets to sewage treatment plants maintain a storage time of *[x d]*.	RMM for ensuring the inactivation of sanitizers to be confirmed by sound data.
	Reduce residual concentrations of *[indicate the oxidative disinfectant]* by *[indicate the technique, e.g. filtration, addition of reducing agents]* before discharging the wastewater to surface water.	RMM for disinfection of municipal wastewater

Table 2: Possible RMM for unacceptable risks associated with the direct release to surface water

Category	Specific RMM	Remarks
Category of users	Only professional uses are allowed.	
Treatment and/or disposal	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 sewage treatment plant.	Prevention of direct discharge to surface water.
	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 discharged to the sewer *[with connection to a sewage treatment plant]*.	RMM referring to the application area
	It is not permitted to apply this product on hard standing areas like asphalt, concrete [*and/or cobble stones, 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.)	RMM referring to the application area
	To protect water living organisms, application of this product is restricted to indoor areas or areas under roof with a hard standing, where drain away to soil or surface water can be prevented.	RMM where local treatment outdoors may occur, but emission to water must be prevented and considered possible in practice.
	To protect water living organisms, do not apply this product near water drainage systems.	RMM where local treatment outdoors may occur and emission to water must be prevented.
	To protect water living organisms, it is not permitted to discharge spills and residues containing the product to surface water.	RMM for industry and other professional institutes where in practice the product is collected and disposed after use.

Table 3: Possible RMM for unacceptable risks associated with the direct release to soil

Category	Specific RMM	Remarks
Category of users	Only professional uses are allowed.	
Treatment and/or disposal	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 discharged to the sewer *[with connection to a sewage treatment plant]*.	RMM referring to the application area
	To protect soil living organisms, application of this product is restricted to indoor areas or areas under roof with a hard standing, where drain away to soil or surface water can be prevented.	RMM where local treatment outdoors may occur, but emission to soil must be prevented and considered possible in practice.

Table 4: Possible RMM for unacceptable risks associated with the direct release to groundwater

The exposure of groundwater with disinfectants is indirect. If unacceptable risks are identified for the groundwater, measures that are targeted at the compartment that releases the substance to the groundwater (e.g. soil) should be used.

Table 5: Possible RMM for unacceptable risks associated with the direct release to air

Category	Specific RMM	Remarks
Category of users	Only professional uses are allowed.	
	Application only by professional user with certificate of competence for [*fumigation operations*].	

Table 6: Possible RMM for unacceptable risks associated with the direct release to non-target organisms

Category	Specific RMM	Remarks
Category of users	Only professional uses are allowed.	
Treatment and/or disposal	Take the necessary precautions to prevent exposure of [*bats*] and other protected animals in the [*gassed areas / spaces / structures / buildings*].	RMM referring to the protection of specific non-target animals.

EUROPEAN CHEMICALS AGENCY
ANNANKATU 18, P.O. BOX 400,
FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU