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EUROPEAN CHEMICALS AGENCY

TRANSITIONAL GUIDANCE

Transitional Guidance on the Biocidal Products Regulation

Transitional Guidance on Evaluation of Environmental Risk Mitigation Measures for Disinfectants Product Type 5 (Drinking water)

November 2014

TRANSITIONAL GUIDANCE

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Transitional Guidance on Evaluation of Environmental RMM for Disinfectants Product Type 5

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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 drinking water disinfectants (Disinfectants PT 5:Drinking water)

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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This Transitional Draft Guidance will be reformatted when it is incorporated into the New Guidance Structure.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 drinking water disinfectants to be considered during the authorisation of biocidal products as well as the evaluation of active substances, especially if an environmental risk is identified. PT 5 disinfectants cover products used by professional users as well as by consumers within their outdoor activities. Drinking water disinfectants must comply with specific national and European quality standards set up for water intended for human consumption. The main types of disinfection processes are primary disinfection (main purpose is to kill the majority of microorganisms), residual disinfection (maintenance of an anti-microbial potential in the distribution system), and stand-by disinfection (high dosage-application to clean up a contaminated system or when taking a new system into use). Most of the disinfectants applied have an oxidizing property and are not stable. Non-oxidative biocides such as silver salts or copper/silver ionisation are used (Emission Scenario Document (ESD) for PT 5, European Commission 2003).

The Drinking water Directive 98/83/EC requires Member States to ensure that, where disinfection forms part of the preparation or distribution of water intended for human consumption, the efficiency of the disinfection treatment applied is verified. Thus, also before the implementation of BPR most Member States have implemented approval schemes for drinking water disinfectants. There are relatively few active substances applied, among them chlorine, chlorine dioxide, sodium hypochlorite, and hydrogen peroxide. Also silver salts, dichloroisocyanurates, potassium permanganate, and iodine are applied.

In contaminated distribution equipment also shock treatments with higher dosages of disinfectants (e.g. 10 fold of standard concentration) are required to clean the pipes. In this case any wastewater generated should be evaluated and treated, as appropriate, e.g. by inactivation of chlorine with sodium thiosulfate

The main emission route of drinking water disinfectants is to the sewer system and municipal sewage treatment plants (STP).

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 5 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 5 disinfectants are considered in this guidance document so far.

2. Risk mitigation measures for PT 5 disinfectants

Drinking water disinfectants are an important tool for maintaining the hygienic quality of water intended for human consumption. The use of disinfectants should always be integrated in a general water safety plan which includes all steps of water supply from the protection of the catchment area to the distribution system. Drinking water processing consists in physical-chemical removal processes (e.g. coagulation, sedimentation, precipitation, filtration) combined with chemical disinfection, if required.

Drinking water disinfectants generated in-situ (ozone, chlorine from electrolytic processes, ultra-violet radiation) were not covered by the former Biocidal Product Directive (BPD) but will be assessed under the new BPR, including possible risks from the precursor(s).

Most active substances have oxidation properties and are rapidly eliminated during application. It is common practice, to reduce the residual chlorine level to a specific concentration before the water enters the distribution system by addition of sulfur dioxide or sulfite compounds (dechlorination). During application a part of the oxidative active substances reacts 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 raise environmental concerns. Directive 98/83/EC on the quality of water intended for human consumption, requires Member States to take all measures necessary to ensure that any contamination from disinfection by-products is kept as low as possible without compromising the disinfection. The maximum concentration of Trihalomethane DBPs in drinking water is 100 µg/l (total) and that of Bromate is 10 µg/l, but Member States are asked to strive for lower values, where possible without compromising the disinfection. A background document on the assessment of DBP is being developed by CAs where it is inter alia proposed 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.

There are several proposals for efficacy testing of drinking water disinfectants[1]. While the inherent resistance (susceptibility) of microorganisms and specific pathogens to drinking water disinfectants has broadly been analysed, the development of acquired resistance of microorganisms through the use of drinking water disinfectants has received far less attention. Some publications suggest that the same mechanisms of

[1] http://www.umweltbundesamt.de/wasser-e/themen/downloads/trinkwasser/drinking_water_disinfectants.pdf

resistance development occur.[2] Resistance development is mainly discussed in the context of factors such as corrosion, dead-end pipes, organic matter, and biofilm development all supporting the attachment of microorganisms to surfaces and preventing their susceptibility to disinfectants.

Resistance development may be prevented or reduced by the avoidance of application faults and of sub lethal concentrations of the active substances as well as by the use of alternative substances.

RMM can refer to different addresses 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.

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 the Appendix I 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.

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

4.1.1 Category of Users

Drinking water disinfectants are mainly applied by specifically trained professional users such as drinking water operators. On a smaller scale privately owned treatment plants for outlying settlements exist next to mobile drinking water tanks from outdoor activities.

The benefits of consumer use of PT 5 disinfectants should carefully be compared with the feasibility of non-chemical treatment techniques. With respect to RMM for consumer uses of disinfectants 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). 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.

To exclude non-professional (consumer) uses of PT 5 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

Drinking water disinfectants are mainly applied in public or industrial drinking water abstraction plants but there exist also (very) small water supplies from private owners. Additionally mobile disinfection devices exist for the outdoor sector. The water source often determines the quality of the water. Groundwater sources generally are of superior quality to surface water from rivers and reservoirs and require less treatment. The area of use and the choice of the water source 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

In most cases the biocidal product is identical to the active substance or its precursor. The possible formation of DBPs should also be considered.

4.1.4 Formulation

PT 5 disinfectants are mainly applied by automatic dosing pumps. In certain circumstances the disinfectant is manually added to a water tank, especially within outdoor activities. Accurate dosage is one factor to prevent risk for the environment and avoid spillages. The possible formation of DBPs should also be considered when evaluating the formulation. Product integrated RMM 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 and disposal of unused product. 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 5 disinfectants is via the sewer system. The removal of precursor of DBP and disinfection concentrations exceeding the limit values by technical treatment and the removal of DBP before the water enters to the distribution system are possible options for RMM. 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[3] 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. Maintaining good water processing practices is a prerequisite for disinfectants being effective. The 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 processing of drinking water and minimisation of the formation of DBPs. Some non-exclusive examples are:

- White, G. C. 2010. White's handbook of chlorination and alternative disinfectants. 5th Edition, Black & Veatch Corporation, John Wiley & Sons, Hoboken, New Jersey.
- Niessner, R., Höll, K. 2010. Wasser Nutzung im Kreislauf: Hygiene, Analyse und Bewertung. 9th edition, De Gruyter, Berlin.
- Dammers, N. 2011. Towards a Guidance Document for the implementation of a Risk Assessment for small water supplies in the European Union - Overview of best practices. Study of the Water cycle Research Institute on behalf of DG ENV European Commission, November 2011.
- WHO 2011. Guidelines for Drinking-water Quality - 4th Edition. World Health Organisation, WA 675, Geneva, Switzerland. http://whqlibdoc.who.int/publications/2011/9789241548151_eng.pdf
- Le Chevallier, M. W., Au, K. K. 2004. Water Treatment and Pathogen Control: Process Efficiency in Achieving Safe Drinking Water. World Health Organization,

[3] 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.

IWA Publishing, London.
http://www.who.int/entity/water_sanitation_health/dwq/en/watreatpath.pdf

- WHO, OECD. 2003. Assessing microbial safety of drinking water - Improving approaches and methods. IWA-publishing, London.
http://www.who.int/water_sanitation_health/dwq/9241546301full.pdf
- Weinberg, H. S., Krasner, S. W., Richardson, S. D., Thruston, A. D., 2002. The Occurrence of Disinfection By-Products (DBPs) of Health Concern in Drinking Water: Results of a Nationwide DBP Occurrence Study. EPA/600/R-02/068.
http://www.epa.gov/athens/publications/reports/EPA_600_R02_068.pdf
- US EPA 1999. Alternative Disinfectants and Oxidants Guidance Manual. United States EPA Environmental Protection Agency. EPA 815-R-99-014, April 1999.
- Borchers, U. 2012. Die Trinkwasserverordnung 2011: Erläuterungen- Änderungen – Rechtstexte. Beuth-Verlag Berlin.

The drinking water guideline of the WHO and supporting documents as well as the drinking water guideline of the European Commission are supplemented by national guidelines and lists of approved drinking water disinfectants.[4] The formation of DBP could partly be managed by avoidance and/or removal of the inorganic or organic precursors.

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.[5]

[4] e.g. in Germany: http://www.gesetze-im-internet.de/bundesrecht/trinkwv_2001/gesamt.pdf http://www.umweltbundesamt.de/wasser/themen/downloads/trinkwasser/trink11.pdf or in the United Kingdom: http://dwi.defra.gov.uk/drinking-water-products/approved-products/soslistcurrent.pdf.

[5] 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 5 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. 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.

- Take care for general good hygiene and good water processing practice.
- Examine whether the use of disinfectants can totally or partially be substituted by other (e.g. microfiltration) processes.

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 as relating to the 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.	
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 the unused product. This should be part of the negotiations between applicant and evaluators.
	Provide in small packages 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	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. chlorine with sodium dioxide or sodium bisulfite].*	Removal of oxidative disinfectants exceeding the limit values to be proven by sound data. Generation of disinfection by-products and neutralization by-products to be evaluated.

Category	Specific RMM	Remarks
	A wastewater permit must be available before rinsed solutions from shock treatment of the equipment are discharged to *[surface water / sewage treatment plants].*	RMM in case of decontamination of the equipment.
	After shock treatments with *[e.g. chlorine, potassium dichloroisocyanurate, hydrogen peroxide]* collect the rinsed solutions and inactivate them with *[e.g. sodium thiosulfate].*	RMM in case of decontamination of the equipment.
	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.	RMM for reducing the formation of DBP by pre-treatment of the water source.
	Monitor disinfection by-products *[e.g. bromate, 1,2 dichloromethane, trihalogenmethanes, bound chlorine, monochloramine, dichloramine, chlorite]* and ensure that the limit values *[indicate limit values]* are maintained.	Maintaining quality criteria for DBP in drinking water.
	Remove disinfection by-products prior to distribution of drinking water *[e.g. by air stripping, activated carbon, UV light, advanced oxidation].*	RMM proposed by WHO guidelines for drinking water quality.

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	A wastewater permit must be available before rinsed solutions from shock treatment of the equipment are discharged to *[surface water / sewage treatment plants].*	RMM in case of decontamination of the equipment.

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.	

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.	

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.	

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