

Transitional Guidance on the Biocidal Products Regulation

Transitional Guidance on Evaluation of Environmental Risk Mitigation Measures for Disinfectants Product Type 1 (Human hygiene)

November 2014

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Transitional Guidance on Evaluation of Environmental RMM for Disinfectants Product Type 1

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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 human hygiene biocidal products (Disinfectants PT 1: Human hygiene)

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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This Transitional Draft Guidance will be reformatted when it is incorporated into the New Guidance Structure.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 on the market of biocidal products. 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 for human hygiene purposes 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 1 disinfectants cover products used for general human hygiene purposes with an anti-microbial claim. These biocidal products have to be distinguished from cosmetics or medical products with a therapeutic claim which not covered by the BPR and the former Biocide Directive (see Emission Scenario Document (ESD) for PT 1, European Commission 2004).

PT 1 biocides such as hand disinfectants or disinfectant soaps are mainly in the health service sectors, the food processing industry and other food handling areas or other workplaces as well as in private homes. The main emission route of "rinse-off" and "leave on" disinfectants is to sewage treatment plants (STP), either directly or after washing the clothes. Volatile substances such as ethanol antiseptics are mainly emitted to air. Impregnated and treated articles with a general disinfecting claim, such as "freshen-up" towels, may also be disposed of as waste, as product remnants and empty packages are.

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 1 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 recognition.

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 1 disinfectants are considered in this guidance document so far.

2. Risk mitigation measures for PT 1 disinfectants

Hand hygiene disinfectants and related products are an important tool in infection control by preventing the spread of pathogens. In healthcare facilities hand hygiene is considered one of the most effective measures for reducing healthcare associated infections. The use of disinfectants for professional uses should be integrated in a general hygiene strategy and best practices as described in numerous guidelines of hygienists. However, this is not applicable for private use.

The development of (cross-) resistance of microorganisms to disinfectants has been observed after both correct use and especially after misuse of disinfectants (e.g. cf. SCENIHR, 2009)¹. 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."² 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 or methods. The development of resistance may lead to the need 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.

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.

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

¹ SCENIHR. 2009. Assessment of the Antibiotic Resistance Effects of Biocides. 2009. p. 63

² BIOHYPO, 2013. Biocides and antibiotic resistance. http://cordis.europa.eu/result/brief/rcn/9974_en.html

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 for human hygiene purposes are mainly intended for professional use such as nurses, cleaning staff, employees in the food and feed area and other users which apply disinfectants in the course of their professional activities. PT 1 disinfectants are also marketed for consumer use. When focusing on consumer use of disinfectants, controversial opinions can be found with regards to the effectiveness of application by untrained consumers (e.g. cf. Josephson et al., 1997³; Scott et al., 1984⁴). 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. 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. Generally, to exclude consumer uses of PT 1 disinfectants intended for professional use, 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 for human hygiene are mainly applied to human skin and therefore have a relatively narrow area of use (public and private healthcare facilities, food industry and commerce, private homes etc.).

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

³ 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.

⁴ 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.

ingredients to substances that are not classified as substances of concern if this would reduce the over-all risk. From an environmental point of view the selection of biodegradable active substances such as alcohols and environmental sound additives should be preferred.

4.1.4 Formulation

PT 1 disinfectants are usually applied by spraying, washing or hand rubbing with ready-for-use products. In certain circumstances, accurate dosage may be supported by appropriate equipment.

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 package size also may help to reduce environmental exposure by avoiding the release/disposal of expired products. Product designs that support the application of disinfectants through accurate dosing should be preferred. Therefore, where appropriate, the placing on the market may 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 1 disinfectants is to sewage water treatment plant (STP) and to the air.

Considering the narrow application area, the application of ready-for-use products and the main emission route to STP there remain few options for specific RMM. These 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 taken⁵ 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.

⁵ 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.

4.1.8 Codes of Good Practices

The careful use of disinfectants is essential to minimise risks for human health and the environment. Frequent use of hand hygiene agents should be integrated in a general hand care concept.

For human hygiene disinfectants many good and best practice documents and training courses have been developed. Maintaining good hygiene practice and repeated training is a prerequisite for human hygiene disinfectants being effective. The hygienic design of the equipment supports minimising the amount of disinfectant. Several good and best practice documents cover the human hygiene area. Some non-exclusive examples are:

- WHO 2009. WHO Guidelines on Hand Hygiene in Health Care. World Health Organization whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf.
- Centres for Disease Control and Prevention 2002. Guideline for Hand Hygiene in Health-Care Settings - Recommendations of the Healthcare Infection Control Practices. Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force, Morbidity and Mortality Weekly Report (MMWR) 2002 (5), 56 pages. <http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>
- Fraise, A. P., Lambert, P. A., Maillard, J. Y 2003. Russell, Hugo and Ayliffe's Principles and Practice of Disinfection, Preservation & Sterilization, Blackwell Publishers.
- Kampf, G., Löffler, H., Gastmeier, P. 2009. Review: Hand Hygiene for the Prevention of Nosocomial Infections. Deutsches Ärzteblatt International 106(40), p. 649–655. <http://www.aerzteblatt.de/pdf.asp?id=66218>
- RKI. 2000. Empfehlungen Händehygiene - Mitteilung der Kommission für Krankenhaushygiene und Infektionsprävention am Robert Koch-Institut. Bundesgesundheitsbl. Gesundheitsforsch. – Gesundheitsschutz. 43, p. 230–233. http://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Kommission/Downloads/Haendehyg_Rili.pdf

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 uses of disinfectants.⁶

⁶ 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 appendix RMM for products used in the PT 1 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).
- Washing of the hands required before using disinfectants.
- For products authorised for professional use only.
- Take care for general good housekeeping and good hygiene practice.
- 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.

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 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. 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. Applications only by professional user with expert knowledge	
Treatment and/or disposal	To protect water living organisms and micro-organisms in the sewage treatment plant, it is not permitted discharge spills and residues containing the product to the sewer or surface water.	RMM for industry and other professional institutes where in practice the product is collected and disposed after use.

Possible RMM for unacceptable risks associated with the direct release to other environmental compartments

The exposure of the other compartments with disinfectants in PT 1 is indirect. If unacceptable risks are identified for surface water, groundwater, soil or air measures that are targeted at the compartment that releases the substance to the respective compartment (STP) should be used.

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