

Transitional Guidance on the Biocidal Products Regulation

Transitional Guidance on Evaluation of Environmental Risk Mitigation Measures for Disinfectants Product Type 3 (Veterinary hygiene)

November 2014

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Transitional Guidance on Evaluation of Environmental RMM for Disinfectants Product Type 3

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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 veterinary hygiene purposes (Disinfectants PT 3: Veterinary 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This Transitional Draft Guidance will be reformatted when it is incorporated into the New Guidance Structure.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 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 for veterinary 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 3 disinfectants cover products used to disinfect the materials and surfaces associated with the housing or transportation of animals as well as products for the disinfection of footwear and animals' feet, non-medicinal teat dips, disinfection of milk extraction systems, hatcheries, and fish farms (see Emission Scenario Document (ESD) for PT 3, European Commission 2011). Consumer use of PT 3 disinfectants comprise products used for disinfecting the surroundings of pets or other non-medical products such as disinfecting soaps or other hygiene products with anti-microbial function.

The main emission route to the environment for PT 3 disinfectants is to manure/slurry, air and agricultural soil (from spreading of manure/slurry). Run-off as well as leaching processes after manure/slurry application to agricultural soil can also lead to exposure of biocides to surface water and groundwater, respectively. In general, across Europe, it is prohibited to discharge waste water containing slurry to the public (municipal) sewer, and hence liquid waste containing manure is either removed to a slurry or waste water collection tank and may be subsequently applied to agricultural soil or treated in a municipal on-farm sewage water treatment plant (STP). In contrast, PT 3 products applied for the disinfection of vehicles used for animal transport or from milking parlours outside the stable are mainly emitted to waste water treated in on-site STPs or in municipal STPs. Disinfectants from animals feet disinfection or from footwear disinfection might be discharged either to the slurry system or to the waste water. Disinfection with chemical agents is often accompanied by physical (e.g. thermal) treatment and the temperature of the treatment area has a decisive influence on the efficiency of the disinfection process (next to other factors such as the duration, the organic load, the pH, etc.).

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 ($PEC/PNEC > 1$), or non-target organisms 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 3 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 3 disinfectants are considered in this guidance document so far.

2. Risk mitigation measures for PT 3 disinfectants

Disinfectants used for veterinary hygiene purposes (PT 3) are an important tool to control animal pathogens in animal housing and transport, prevent animal diseases, increase production and improve the quality of animal products (ESD PT 3 European Commission 2011). Authorities have developed legal requirements on the application of approved disinfection measures to be applied in the case of outbreaks of certain animal/livestock diseases.

The use of disinfectants for professional uses should be integrated in good housekeeping principles as described e.g. in the BREF on “Rearing of Poultry and Pigs” (July 2003). This is not applicable for private use. Environmental aspects of manure and slurry are mainly discussed in the context of nutrients spread to fields. The principles of “Good Agricultural Practices” (GAP) should be followed when manure is used as organic fertilizer.

Several active substances may be rapidly degraded after release to manure. Degradation during the storage time of liquid manure may be considered as RMM if supported by available hard data. Other active substances or additives may be toxic and/or may cause long lasting effects.

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)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. The development of

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

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 proven by the applicant for authorisation of a biocidal product by submitting hard 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.

4.1.1 Category of Users

Disinfectants for veterinary hygiene purposes are mainly intended for professional use according to the ESD PT 3 (2011). Professional users such as farmers apply disinfectants in the course of their professional activities. Consumer use of PT 3 disinfectants comprise products used for hygiene purposes of pets.

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. The same applies to certain modes of applications such as fumigation.

Generally, to exclude consumer uses of PT 3 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 veterinary hygiene may specifically be designed for the disinfection of floor, walls and ceiling of stables and vehicles, container and cages for animal transport and animal housing, thus excluding other uses. Other disinfectants are used for the disinfection of animals' feet (especially hooves of dairy cows) or as non-medicinal teat dips. 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 3 disinfectants are usually applied by spraying, aerosol treatment (fogging, misting), foaming, fumigation, brushing, or dipping. For disinfection of footwear, workers walk over a mat soaked with a disinfectant or walk through a tub containing the disinfectant.

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.

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 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 pathways for PT 3 disinfectants are to manure/slurry, air and agricultural soil from spreading of manure/slurry) or to sewage water treatment plant (STP). Manure/slurry is usually stored for some months and might be anaerobically pre-treated before spreading to fields. The elimination of disinfectants during pre-treatment might be considered in the risk assessment if supported by available hard data.

Obligatory discharge of the wastewater from the disinfection of vehicles used for animal transport or from milking parlours 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%).⁵

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 taken⁶ 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

⁵ http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Water_statistics

⁶ 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.

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 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 cover the veterinary hygiene area. Some non-exclusive examples are:

- Strauch, D., Böhm, R. 2002. Reinigung und Desinfektion in der Nutztierhaltung und Veredelungswirtschaft. Enke-Verlag Stuttgart.
- Linton, A. H., Hugo, W. B., Russell, A. D. 1997. Disinfection in veterinary and farm animal practice. Blackwell Science Ltd.
- Caveney, L., Jones, B., Ellis, K. 2011. Veterinary Infection Prevention and Control. John Wiley & Sons, Chichester.
- Fraise, A. P., Lambert, P. A., Maillard, J. Y 2003. Russell, Hugo and Ayliffe's Principles and Practice of Disinfection, Preservation & Sterilization. Blackwell Publishers.
- Bodenschatz, W. 2012. Desinfektion - Rechtsvorschriften, Richtlinien des Robert Koch-Instituts: Desinfektion, Sterilisation, Reinigung, Schädlingsbekämpfung, Infektionsprävention. Loose page collection B. Behr's Verlag Hamburg.
- Böhm, R., Strauch, D. 1996. Desinfektion im Stall - weniger Krankheiten, mehr Leistung. Auswertungs- und Informationsdienst für Ernährung, Landwirtschaft und Forsten (ADI) Band 1163.
- European Association of Zoo and Wildlife Veterinarians (EAZWV) 2010. Transmissible Diseases Handbook (4th Ed.) Chapter VIII. Guidelines for cleaning and disinfection in zoological gardens. Infectious Diseases Working Group (IDWG).
<http://www.eaza.net/activities/Pages/Transmissible%20Diseases%20Handbook.aspx>

The Best Available Technique Reference Document (BREF) for intensive rearing of poultry and pigs (July 2003)⁷ states that regular cleaning and disinfection of the housing equipment and all the housing surfaces after removal of all the livestock is necessary but does not specifically refer to the selection and use of cleaning and disinfection agents. The main environmental impacts of farming result from the manure from the animals and poor land spreading management or techniques. Good housekeeping and improved farm, manure and nutrient management may also help reducing emissions from the use of disinfectants. In the revision of the BREF, initiated in 2009, it is envisaged to identify good agricultural practices for intensive rearing of poultry and pigs.

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

⁷ http://eippcb.jrc.es/reference/BREF/irpp_bref_0703.pdf

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.⁸

Appendix 1.

In this annex RMM for products used in the PT 3 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.

For products authorised for professional use only:

- Take care for general good housekeeping and good agricultural 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 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:

⁸ 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/>

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. | |
| Formulation | [<i>Preferably</i>] 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 | After use of [<i>e.g. teat dips, boot baths</i>] residues must be collected and disposed of separately. | RMM for avoiding emissions from certain applications where releases to manure or sewage treatment plant are not acceptable. The practicability of this RMM must be supported e.g. by recollection systems established by the supplier. |
| | To prevent the inhibition in functioning of an on-site wastewater treatment system and to protect aquatic organisms, possible residues containing the product must be discharged to [<i>the manure deposit or a municipal sewage treatment plant</i>]. | RMM referring to wastewater treatment requirements |
| | All waste water must be treated in an on-site or municipal wastewater treatment plant that incorporates both primary and secondary treatments. Onsite pre-treatment required by | Specify conditions and measures related to the onsite or municipal sewage treatment plant if appropriate (e.g. biological treatment, neutralization, minimum grade |

| Category | Specific RMM | Remarks |
|----------|---|---|
| | <p><i>[suitable techniques]</i> with a removal efficiency of <i>[expression of threshold or %]</i> before discharging into sewer.</p> <p>Neutralisation or inactivation <i>[is normally]</i> required before discharge into <i>[sewage system / into water treatment plants]</i>.</p> | <p>of elimination). To be justified with hard data and evaluated in the risk assessment.</p> |
| | <p>A storm water management plan is needed to ensure that the wastewater treatment plant is not overloaded with uncontaminated water.</p> | <p>Avoidance of a sewage treatment plant-bypass of contaminated water through storm water. Only practicable for Member states which have developed storm-water provisions.</p> |
| | <p>To protect surface water biological treatment operation needed before release of biodegradable disinfectants into surface water.</p> <p>The minimum grade of elimination in the sewage plant required is <i>[X %]</i></p> | <p>To be proven with hard data and evaluated in the risk assessment.</p> |
| | <p>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.</p> | <p>Prevention of direct discharge to surface water.</p> |
| | <p>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 surface water or to the sewer.</p> | <p>RMM for industry and other professional institutes where in practice the product is collected and disposed after use.</p> |
| | <p>To protect water living organisms, the product may not be authorised for uses in animal housings where emission to a sewage treatment plant or direct emission to surface water cannot be prevented.</p> | <p>RMM referring to application in animal houses (poultry houses) where during the cleaning procedure with high-pressure cleaning equipment a fraction of the applied biocidal product can be released to waste water that is discharged to a sewage treatment plant.</p> |
| | <p>Transfer of process wastes to manure storage containers required</p> | <p>Intermediate storage of wastewater containing disinfectants may also</p> |

| Category | Specific RMM | Remarks |
|----------|---|--|
| | | inactivate the active ingredients. Removal efficiency to be proven by hard data. |
| | <p>Ensure all waste water is collected and treated via a sewage treatment plant.</p> <p>If discharging to municipal sewage treatment plant, no onsite wastewater treatment required.</p> <p>If discharging to municipal sewage treatment plant, provide the required onsite wastewater removal efficiency of [... (%)].</p> | Obligatory connection of the sewer to a well-functioning municipal sewage treatment plant. |
| | Prevent adverse effects on municipal sewage treatment by limiting <i>[concentration in waste water to mg/l, load in waste water to ... kg/d]</i> . | 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 <i>[add name of active substance]</i> in the <i>[sewer system] [inlet of the sewage treatment plant]</i> exceeds the maximum allowable concentration of <i>[indicate limit concentration]</i> 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. |
| | Avoid peak loads through continuous discharge to the wastewater. | RMM for the protection of the activated sludge organisms to be proven by hard data. May be concluded in wastewater permits. Only practicable if enforcement is monitored by authorities. |
| | <p>Dry cleaning of containers and equipment and disposal via solid waste in order to minimize releases to water.</p> <p>Do not clean empty containers, but return them to the manufacturer or retailer.</p> | RMM referring to product design and recollection of packaging |
| | The discharge to small sewage treatment plant below [X] inhabitant equivalents is | RMM from the Bavarian state office for water management |

| Category | Specific RMM | Remarks |
|----------|--------------|---|
| | not allowed | on water protection after disinfection measures during the outbreak of the avian influenza. |

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 <i>[water living organisms, groundwater]</i> , 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 <i>[with connection to a sewage treatment plant]</i> . | RMM referring to the application area |
| | It is not permitted to apply this product on hard standing areas like asphalt, concrete <i>[and/or cobble stones, railways...]</i> 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, 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. |
| | Avoid spillage of concentrates to surface water or groundwater e.g. through the use of collection pans, that collect the liquids. | RMM from the Bavarian state office for water management on water protection after disinfection measures during the outbreak of the avian influenza. |

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 soil organisms and water living organisms, residues containing the product need to be removed to the manure deposit. | Prevention of direct emission to soil and water under the presumption that the risk via manure emission is acceptable |
| | To protect soil organisms and water living organisms, the <i>[foot bath]</i> should be located on a hard standing and residues containing the product need to be removed to the manure deposit. | Prevention of direct emission to soil and water under the presumption that the risk via manure emission is acceptable |
| | Before spreading slurry (manure) from treated animals it has to be stored for at least x day/months. | RMM only applicable if the storage time corresponds to that required for nutrient management according to good agricultural practice and some surveillance exist. |
| | To protect <i>[groundwater and soil organisms]</i> , 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 <i>[with connection to a sewage treatment plant]</i> . | RMM referring to the application area |
| | 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. |
| | Avoid spillage of concentrates to soil, or groundwater e.g. through the use of collection pans that collect the liquids. | RMM from the Bavarian state office for water management on water protection after disinfection measures during the outbreak of the avian influenza. |

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 [<i>fumigation operations</i>]. | |

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 [<i>bats</i>] and other protected animals in the [<i>gassed areas / spaces / structures / buildings</i>]. | RMM referring to the protection of specific non-target animals. |

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