Guidance on the Biocidal Products Regulation

Volume V, Guidance on Disinfection By-Products

DRAFT
Version 1.0
April 2016
LEGAL NOTICE

This document aims to assist users in complying with their obligations under the Biocidal Products Regulation (BPR). However, users are reminded that the text of the BPR is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.
# DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Version</th>
<th>Comment</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version 1.0</td>
<td>First edition</td>
<td>Xxxx 2017</td>
</tr>
</tbody>
</table>
PREFACE

This document describes the BPR obligations and how to fulfil them.

The application of halogen-containing biocides leads to the formation of disinfection by-products (DBPs). These DBPs have been shown to include hazardous substances that may pose a risk to human health or the environment. The Competent Authorities (CAs) and the Technical Meetings (TM) decided that a risk assessment of DBPs should be conducted as part of the authorisation of the halogenated biocidal products. The TM agreed that a harmonised approach to such a risk assessment should be found for all halogenated disinfectants at the stage of active substance approval (of the then BPD 98/8/EC, now Annex I inclusion for Biocidal Products Regulation (BPR)) instead of postponing it to the national authorisation stage.

From 2011 onwards NL has done work to develop such a harmonised approach for both the human health risk assessment and environmental risk assessment of DBPs. Several member states (MS) have participated in this process and given their input.

An initial document was presented at TMIV-2011. The main conclusion was that there were insufficient data available in the dossiers to assess the risks of DBPs following human exposure and environmental exposure. Where possible, identification of the DBPs formed and a qualitative assessment of those DBPs should be included in the Competent Authority Reports (CARs).

Regarding human health risk assessment, as decided at the CA and (former) TM-level, priority was given to PT2 (swimming-water) since this is considered as the most relevant from the point of human exposure to DBPs and its associated possible risk to health. The starting point of the human health risk assessment for DBPs was the decision by the CA-meeting to use existing national limits for individual (groups of) DBPs in swimming- and/or drinking-water. This was agreed to by TMII-2012 as being the appropriate first tier in the human health risk evaluation for DBPs. Based on that decision proposals for a pragmatic approach were developed. Prior to TM II-2012 these proposals were circulated among member states, a number of whom gave written input.

At the TM III-2012 formal agreement was obtained on the various points raised in these proposals. In a subsequent document NL outlined what could be the way forward as to the actual application of the method for the envisaged human health risk assessment.

Regarding environmental risk assessment, it was further agreed that discussion papers from the workshop on Ballast Water Treatment should be taken into account, together with the input from other MS and industry (IND). A revised document, first presented at TM1-2012, incorporated a more in-depth analysis of the relevance of (groups) of DBPs and further information required for the assessment. On special request of the European Commission (COM), the document investigated in particular whether the strategy and/or the conclusions of the EU Risk Assessment Report (EU-RAR) of sodiumhypochlorite under the former Existing Substances Regulation (793/93/EEC) could be taken over for biocide risk assessment. The document summarised the information on DBP-formation and risk assessment focusing on the following product types (PTs): PT2 (waste water treatment), PT11 (cooling water), and PT12 (pulp and paper) and was discussed again at TMII-2012. At TMIII-2012, NL presented a combined document including both the human and environmental risk assessment in order to

---

update the discussions and to integrate the various documents that had been presented at earlier TMs. The main problem identified at that stage was the lack of adequate monitoring data.

The document was then presented to the CA-meeting in December 2012 and March 2013 with a request to decide on the timelines and responsibilities for further action. No agreement was reached during those CA-meetings and the subject was put on hold.

After the Biocides Product Regulation (BPR, Regulation (EU) 528/2012) came into force and the biocides assessment had moved to the European Chemicals Agency (ECHA), an Ad Hoc Working Group for disinfectant by-products (ad hoc DBP WG) was established under the Biocides Product Committee (BPC) to re-activate the process and finalise the guidance. Under the mandate of this ad hoc DBP WG, NL organised a workshop, which was held on the 25th of June 2015 in Amsterdam. The goal of this workshop was to settle all outstanding issues and to allow finalising the description of the methods for the human health and environmental risk assessment of DBPs.

Based on the workshop discussions, the present document provides a strategy for the human health risk assessment of DBPs. The guidance with respect to environmental risk assessment is presented in a separate document. With this document the responsible parties for risk assessment of halogenated disinfectants can start the work on the evaluation of DBPs.
Table of Contents

1. PART 1 HUMAN HEALTH RISK ASSESSMENT OF DISINFECTION BY-PRODUCTS (DBPs)

2. PART 2 ENVIRONMENTAL RISK ASSESSMENT OF DISINFECTION BY-PRODUCTS (DBPs)

APPENDIX 1. SELECTION OF MARKER DBPS RELEVANT FOR HUMAN EXPOSURE IN SWIMMING-WATER TREATED WITH HALOGENATED DISINFECTANTS

APPENDIX 2. SELECTION OF WATER LIMITS FOR MARKER DBPS DEEMED RELEVANT FOR HUMAN EXPOSURE IN SWIMMING-WATER TREATED WITH HALOGENATED DISINFECTANTS

APPENDIX 3. METHODS FOR CHEMICAL ANALYSIS OF MARKER DBPS

APPENDIX 4. POTENTIAL RELEVANCE OF PTS REGARDING THE HUMAN HEALTH RISK ASSESSMENT OF DBPS IN THE CONTEXT OF BIOCIDES AUTHORISATION (WRITTEN COMMENTING ROUND)

REFERENCES

CONCLUSIONS AND RECOMMENDATIONS

Appendix 4. Potential relevance of Pts regarding the human health risk assessment of DBPs in the context of biocides authorisation (written commenting round)

Appendix 1. Selection of marker DBPs relevant for human exposure in swimming-water treated with halogenated disinfectants

Appendix 2. Selection of water limits for marker DBPs deemed relevant for human exposure in swimming-water treated with halogenated disinfectants

Appendix 3. Methods for chemical analysis of marker DBPs

1.1 Introduction

1.1.1 Regulatory context

1.1.2 A pragmatic approach to a complex issue

1.1.3 Scope of the document

1.2 HUMAN HEALTH RISK ASSESSMENT OF DBPS

1.2.1 General principles

1.2.2 Selection of marker DBPs

1.2.3 Selection of limits for marker DBPs

1.2.4 Marker DBP assessment

1.2.4.1 Introduction

1.2.4.2 Specific requirements

1.3 RELEVANCE OF OTHER PTS

1.4 CONCLUSIONS AND RECOMMENDATIONS

1.5 REFERENCES

APPENDIX 1. SELECTION OF MARKER DBPS RELEVANT FOR HUMAN EXPOSURE IN SWIMMING-WATER TREATED WITH HALOGENATED DISINFECTANTS

APPENDIX 2. SELECTION OF WATER LIMITS FOR MARKER DBPS DEEMED RELEVANT FOR HUMAN EXPOSURE IN SWIMMING-WATER TREATED WITH HALOGENATED DISINFECTANTS

APPENDIX 3. METHODS FOR CHEMICAL ANALYSIS OF MARKER DBPS

APPENDIX 4. POTENTIAL RELEVANCE OF PTS REGARDING THE HUMAN HEALTH RISK ASSESSMENT OF DBPS IN THE CONTEXT OF BIOCIDES AUTHORISATION (WRITTEN COMMENTING ROUND)

2.1 INTRODUCTION

2.1.1 Regulatory context

2.1.2 A complex issue

2.1.3 Scope of the document

ERROR! BOOKMARK NOT DEFINED.

or! Bookmark not defined.

or! Bookmark not defined.

or! Bookmark not defined.

or! Bookmark not defined.
2.2 GENERAL INFORMATION ON DBPS

2.2.1 Overview of reaction processes

2.2.2 Principal groups of DBPs

2.2.2.1 Trihalomethanes (THMs)

2.2.2.2 Halogenated acetic acids (HAAs)

2.2.2.3 Halogenated aldehydes

2.2.2.4 Halogenated acetonitriles

2.2.2.5 Halogenated amides

2.2.2.6 Halogenated ketones

2.2.2.7 Halogenated phenols

2.2.2.8 Bromate

2.2.2.9 Halogenated amines

2.3 ENVIRONMENTAL RISK ASSESSMENT OF DBPS

2.3.1 General principles

2.3.1.1 Initial worst case assessment

2.3.1.2 Group parameters

2.3.1.3 Addressing the unknown DBPs

2.3.1.4 Environmental risk assessment scheme

2.3.2 Use of existing information

2.3.3 Known DBPs to be included in the assessment
2.3.4 Exposure assessment

2.3.4.1 Relevant compartments

2.3.4.2 Exposure assessment strategies

2.3.5 Effects assessment

2.3.5.1 Derivation of PNECs

2.3.5.2 Group ecotoxicity assessment

2.3.5.3 Whole Effluent Testing (WET)

2.3.6 Mixture toxicity

2.3.7 Relevance of other PTs

2.4 CONCLUSIONS AND RECOMMENDATIONS

2.5 REFERENCES

APPENDIX 5. WHOLE EFFLUENT TESTING

APPENDIX 6. SUMMARY OF INFORMATION FROM THE EU-RAR ON NAOCL

A6.2.1 OCCURRENCE OF DBPS

A6.2.2 RISK ASSESSMENT IN THE EU-RAR

A6.2.3 Refined Risk Assessment

A6.3.1 OCCURRENCE OF DBPS

A6.3.2 RISK ASSESSMENT

A6.4.1 OCCURRENCE OF DBPS

A6.4.2 RISK ASSESSMENT
Figures

Table 1: DBPs to be included in the human risk assessment for PT2 swimming-pool uses
Table 2: DBP water limits to be used for 1st Tier evaluation for biocides
Table 3: DBP air limits to be used for 1st Tier evaluation for biocides
Table 4: Trihalomethanes (THMs)
Table 5: Bromate
Table 6: Chlorate & chlorite
Table 7: Haloacetic acids (HAAs)
Table 8: Haloacetic acids (HAAs) for swimming pools
Table 9: Halo-aldehydes (chloral hydrate and bromal hydrate)
Table 10: Haloacetonitriles
Table 11: Analytical methods
Table 12: Potential relevance of PTs regarding the human health risk assessment of DBPs in the context of biocides authorisation.
Table 13: DBPs that should be addressed in the environmental risk assessment of oxidative halogenated biocides. The relevant individual chlorinated and brominated forms are listed where applicable.
Table 14: Potential relevance of PTs regarding the environmental risk assessment of DBPs in the context of biocides authorisation.
Table 15: Classification scheme
Table 16: Summary of use scenarios from the EU-RAR with potential relevance for biocides authorisation.
Table 17: Measurement of by-products of hypochlorite application in cooling water of coastal power stations, summarising data from Jenner et al. 1997
Table 18: Formation of THMs upon chlorine treatment of cooling water at different sites.

Table from [9].

Table 19: Bromoform, chloroform, EOX and AOX in cooling water from different (industrial) locations. Translated copy from [9]
# List of Abbreviations

<table>
<thead>
<tr>
<th>Standard term / Abbreviation</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comment [SJ3]: CONSULTATION NOTE: ECHA Secretariat to complete during PEG consultation
1. Part 1 Human health risk assessment of disinfection by-products (DBPs)

1.1 Introduction

1.1.1 Regulatory context

The disinfection of water with oxidising biocides leads to the formation of by-products (DBPs). According to the Biocides Product Regulation (BPR), the effect of residues should be evaluated in the risk assessment (see e.g. Art. 9, 1b(iii)). According to the definition in Art. 3, 1h, residues include reaction products. A number of known (groups of) DBPs are biologically active, and some are (suspected) carcinogens or mutagens (e.g. chloroform, halogenated methanes, bromate). Moreover, most DBPs are more stable than the biocide itself. Therefore, a risk assessment of DBPs as part of the authorisation of biocidal products is necessary.

1.1.2 A pragmatic approach to a complex issue

The main problem for the risk assessment for DBPs is that the number of DBPs formed is very high. In drinking-water, which is the area where most of the research on the formation of DBPs has been carried out, more than 600 DBPs have currently been identified. At the same time, however, more than 50% of the total organic halogen (TOX) formed during disinfection of drinking-water remains unidentified (Pressman et al. 2010; DeBorde and Von Gunten 2008). For the human health risk assessment for DBPs priority was given to PT2 (swimming-water) since this is considered the most relevant from the point of view of degree of human exposure and possible health risk. During the past decade DBP formation in swimming-pools has increasingly been studied. In one major study in indoor swimming pools in Spain in which either chlorination or bromination was used for disinfection, more than 100 different DBPs were identified (Richardson et al. 2010). The type and amount of DBPs formed in swimming-pools depends on many variables, including the availability of organic matter, the presence of (in)organic nitrogen compounds and the salinity of the water. Operating conditions, such as concentration of the active substance, the number of visitors, characteristics of the receiving water (pH, TOC) and environmental circumstances such as temperature and radiation, all are of influence (Pickup 2010; Sun et al. 2009). Due to this complexity it is very hard to predict beforehand which compounds will be formed in a specific situation and at which concentrations. Attempts are made to develop models for that purpose by Singh et al. (2012) but these have not yet led to an applicable model. In this situation only a pragmatic approach to risk assessment is feasible, in which the existing scientific knowledge on the presence DBPs in swimming pools and on their toxicity is used in a simplified way. This approach therefore involves the selection of marker DBPs, as outlined in section 2.2. In the future updates of the approach will be needed. For this a frequency of every 5 years is proposed below. Any new scientific information on DBP formation in swimming-pools can then be taken into account.

In the risk assessment, the DBP-marker concentrations as measured after swimming-pool disinfection in a fully operative state-of-the-art swimming-pool are to be compared to existing risk limits as developed at the national level, i.e. swimming-pool or drinking-water limits that were derived based on toxicity data (section 2.1) as agreed by the CA and TM in 2012. In some cases where a potential risk is identified (exceedance of risk limit values), further risk assessment is possible by estimating human exposure to the DBP in question and comparing the result with available toxicity reference values for this DBP. This possible refinement is included in the description below.
1.1.3 Scope of the document

This document summarises background information and provides a strategy for the human health risk assessment of DBPs. It does not contain step-by-step instructions on how to perform the risk assessment, but defines the framework that applicants can use to build a dossier to demonstrate a safe use of the biocide under consideration.

According to the mandate of the ad hoc DBP WG, the starting-point of this document is the use of halogenated oxidative biocides for three product types (PTs) that are currently under discussion for active substance approval (PT2, 11 and 12). Proposed use in PT2 comprises disinfection of swimming-pools, and disinfection of waste water. PT11 involves disinfection of cooling water, and PT12 concerns paper production. PT2 (swimming-pool) is considered the most relevant for the human health risk assessment. PT2, 11 and 12 are all considered most relevant for the environmental risk assessment because of the extent of DBP-formation in combination with direct and indirect emissions to surface water. This is further discussed in a separate document for the human health risk assessment. Based on expert views, a tentative list is presented of other PTs for which the assessment of DBPs is considered relevant and some recommendations are made for future guidance development for these other PTs. The general principles of this guidance may also be useful for other groups of reactive biocides.

The strategy for the evaluation of DBPs that is proposed in this document is science-based. The implementation in the process of active substance and/or products authorisation is outside the scope of this document. As to procedural and/or legal issues it is recommended that applicants consult their respective Competent Authorities (CAs).

1.2 Human health risk assessment of DBPs

This section provides a general outline of the method (2.1). An important part of the approach is the identification of the relevant marker DBPs for human risk assessment for swimming-pools based on available scientific evidence (2.2). Consensus was reached on marker DBPs for specific groups of DBPs. For these marker DBPs existing limit values for water and air (for volatile compounds) were selected and agreed upon (2.3). In Appendix 2 the various drinking-water limits for individual DBPs are evaluated with regard to this question. In order to perform the actual risk assessment, an assessment of the exposure is needed. Data on exposure can be retrieved via public literature (existing substances) and by performing labscale or real life measurements (2.4) or by using anonymised existing measurements via specialised analytical labs.

1.2.1 General principles

The approach for the human-toxicological risk assessment for DBPs from halogenated oxidative biocides in PT02 as described here consists of simply comparing measured DBP concentration (exposure assessment) of selected DBPs to existing limits for swimming- and/or drinking-water for these DBPs. A list of existing limits is provided in section 2.3 (Table 2). This list reflects the consensus reached at the workshop held on the 25th of June 2015. As a general principle drinking-water limits are considered to be adequately protective for swimming-pools. For specific DBPs the question arises if the drinking-water limit may not be overprotective when used for swimming-pools. This is the case for DBPs for which dermal and inhalation exposure are low. Exposure in such cases is driven by the amount of ingested water during swimming. Because that ingested amount is lower than 2 litres per day as assumed in the derivation of drinking-water limits using the latter limits may be viewed as over protective. Where relevant this issue is addressed below. In principle the use of drinking-water limits should be viewed as a first tier approach which can be refined if needed with a more specific swimming-water limit. For some DBPs swimming-water limits are already available. These limits then take...
precedence over the drinking-water limits for that DBP. But, as agreed upon during the workshop of 25th June, only those swimming-water limits will be used for which the toxicological basis is known (see below).

Figure 1 provides a flow diagram of the proposed method, including the possible step of further risk assessment.

As indicated above, the method makes use of existing limits for swimming- and/or drinking-water. For applying the method, consensus values must be chosen from the various existing national or international swimming-water and drinking-water limits. In addition to that, the method requires information on concentrations of DBPs in swimming-pools during use of the biocide under evaluation. The step of comparing DBP concentrations with existing limit values for swimming-water or drinking-water may be seen as the 1st tier in the risk assessment. See Figure 1 for how this first step fits into the general scheme.

In the selection of the consensus limit value for swimming-/drinking-water, the toxicological basis for these values is an important point of consideration (critical toxic effect, NOAEL, allocation to drinking- or swimming-water). At the workshop of 25th June 2015 it was agreed to only use limit values for which the toxicological basis is known. It was agreed that where several limit values with a known toxicological basis are available the lowest value should be chosen.

The possible 2nd tier is relevant in case existing limits are exceeded. This is especially relevant when drinking-water limits are exceeded because these limits may in some cases be over protective for exposure via swimming-water. This 2nd tier can be based on the Tolerable Daily Intake (TDI) as toxicological limit and a reasonable worst case exposure calculation for swimming-pools. One option is to derive a special swimming-water limit in this 2nd tier that can be used instead of the the drinking-water limit. In appendix 2 this was for instance done for haloacetic acids because for these chemicals using a drinking-water limit most likely is over-protective. See Figure 1 for how the 2nd tier fits into the general scheme. Please note that an exposure assessment is needed for this 2nd tier, which requires additional attention.

TDIs that can be used for the 2nd tier can be selected from existing values as used by WHO in the derivation of its drinking-water guidelines (these guidelines represent by far the most extensive database as to DBPs and their toxicological evaluation). In case no value is available the feasibility of deriving an ad hoc-value based on available toxicity information should be considered. In general within the scheme, read-across is used to bridge the many data gaps known to exist at present for many DBPs. As a last resort the Threshold of Toxicological Concern (TTC) may be used to derive a tolerable intake level for use in the assessment.
Figure 1: Use of existing SWL and DWL for evaluating possible DBP human health risks

1. Is SWL available?
   - Yes: Concentration < SWL?
     - Yes: OK
     - No: Adjust use conditions.
   - No: Is DWL available?
2. Is DWL available?
   - Yes: Concentration < DWL?
     - Yes: OK
     - No: 2nd Tier risk assessment using reasonable worst case exposure and TDI Indicates risk?
       - Yes: Adjust use conditions.
       - No: OK
   - No: Evaluate toxicity data. Is read-across possible?
3. Is (provisional) toxicity limit (TDI) available or can it be derived?
   - Yes: OK
   - No: Evaluation not possible.

SWL = swimming water limit
DWL = drinking water limit
1.2.2 Selection of marker DBPs

The evaluation of halogenated disinfectants with regard to the question which DBPs could be used as markers in the human risk assessment for DBPs in PT2, is based on the published scientific literature on this subject. The choice of these markers inevitably is pragmatic because existing knowledge concerning the chemical identity of DBPs in swimming-pools and their concentrations is incomplete. A further limitation as to the choice of usable marker DBPs is the incomplete toxicity database for many individual DBPs. Of the large number of DBPs identified at the present moment toxicity data are available for a limited number only.

Based on the information on the presence of DBPs after using halogenated oxidative disinfectants in swimming-pools as published in scientific literature, markers were selected. The result is shown in Table 1. In Appendix 1 the choice of DBPs is described in more detail.

The DBPs as presented in Table 1 reflect the current published literature on occurrence of DBPs in swimming-pools. Most likely additional unpublished data exist, as in fact was confirmed at the workshop of the 25th of June 2015. Such additional data would be useful for further evaluation of the choice of markers. An important question is the degree to which the different groups of DBPs fluctuate relative to each other. If the different groups fluctuate in a correlated manner the number of DBPs to be evaluated could be further reduced (compared to Table 1). As of yet there is insufficient basis for such a reduction.

Table 1: DBPs to be included in the human risk assessment for PT2 swimming-pool uses

<table>
<thead>
<tr>
<th>Compounds</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trihalomethanes (THMs)</td>
<td>THMs are quantitatively the most important group of DBPs. Formation of either the chlorinated or brominated THMs will dominate depending on the source levels of active chlorine or active bromine present in the treated water.</td>
</tr>
<tr>
<td>Bromate</td>
<td>Formed after ozonation of water containing bromide. When bromide-containing water is disinfected by chlorination, formation of bromate also occurs. Use of brominated disinfectants is also expected to lead to increased bromate levels.</td>
</tr>
<tr>
<td>Chlorite and chlorate</td>
<td>Frequently found in swimming-water. Concentrations often in the mg/L range.</td>
</tr>
<tr>
<td>Haloacetic acids (HAAs)</td>
<td>HAAs are quantitatively 2nd most important group of DBPs. When bromide concentrations are low, mono-, di- and trichloroacetic acid are dominant, but brominated analogues (mono-, and dibromoacetic, bromochloroacetic acid) are present when bromide concentrations are higher. After use of brominated active ingredients brominated acetic acids are also expected to be present.</td>
</tr>
<tr>
<td>Haloaldehydes</td>
<td>Based on reviewed literature trihaloacetaldehydes (chloral hydrate and bromal hydrate) are relevant.</td>
</tr>
<tr>
<td>Haloacetonitriles</td>
<td>Dihaloacetonitriles are most important within this group based on reviewed literature. Dibromoacetonitrile formed in the presence of...</td>
</tr>
</tbody>
</table>
bromide.

Haloamines
Based on reviewed literature trichloramine is the most important DBP, especially for the air compartment in indoor swimming-pools.

1.2.3 Selection of limits for marker DBPs
Exposure to DBPs in swimming-pools occurs via the oral route (accidental water ingestion), via the skin and via inhalation. In deriving swimming-water limits for DBPs all of these exposure routes should be taken into account, i.e. the total calculated systemic exposure for a swimmer needs to be used. For the swimming-water limits as presented in Table 2 such a calculation of the total systemic exposure was done. A possible additional health effect, however, which is not covered by this calculation, is the potential route-specific local toxicity (irritation etc.) of the airways by DBPs. For these specific DBPs inhalation limits need to be selected.

1.2.3.1 Selection of swimming and drinking water limits for marker DBPs
As stated earlier in this document, the method requires a consensus list of existing swimming- and/or drinking-water limits for the selected marker DBPs. These limits can be used to assess the oral and dermal exposure route. Table 2 below provides a list of values. This table reflects the consensus as reached at the workshop of June 25, 2015. Only limits for which the toxicological basis was known were selected. Where more than one limit was available for which the toxicological basis was known the lowest value was chosen. During the workshop it was decided that limits (both SWL and DWLs) need to be reviewed every 5 years and earlier if needed.

In Appendix 2 the choice of water limits for the different marker DBPs is explained in more detail. Concerning the drinking-water limits, during the workshop of June 25, 2015, the question was raised whether these limits would not be underprotective in cases where exposure via swimming-water is high due to dermal and inhalation exposure. Conversely drinking-water limits may be overprotective in case the oral route is the only route in the swimming-pool situation (for non-volatile DBPs with low potency for dermal penetration). These points are discussed for individual marker DBPs in Appendix 2. For haloacetic acids this led to new swimming-water limits. These were derived because for these DBPs drinking-water limits are considered over-protective. See Appendix 2 for discussion. For chloral hydrate and bromal hydrate and for the relevant haloacetonitriles drinking-water limits were found to be adequately protective.²

---

² As explained in Appendix 2, inhalation exposure to these DBPs (chloral hydrate, bromal hydrate, haloacetonitriles) in swimming-pools is expected to be relatively low based on their Henry coefficients so using drinking-water limits for these DBPs may be considered a worst case approach. In case of exceedance of the drinking-water limits 2nd tier evaluation may be appropriate, including exploration of the possibility of deriving a swimming-water limit for these DBPs based on exposure calculations.
Table 2: DBP water limits to be used for 1st Tier evaluation for biocides

<table>
<thead>
<tr>
<th>Compound</th>
<th>Limit in [µg/L]</th>
<th>Origin of limit</th>
<th>Toxicological basis for limit (derivation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trichloromethane</td>
<td>3THMs: 50</td>
<td>Swimming-water limit The Netherlands</td>
<td>TDI for chloroform, cancer risk estimation for DBCM, based on exposure calculation oral+dermal+inhalation</td>
</tr>
<tr>
<td>(chloroform)</td>
<td>(chloroform</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>equivalents)³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tribromomethane</td>
<td>100</td>
<td>Swimming-water limit The Netherlands</td>
<td>Bromate is genotoxic carcinogen, value chosen based on extra cancer risk of $10^{-5}$ per lifetime as reference</td>
</tr>
<tr>
<td>(bromoform)</td>
<td></td>
<td></td>
<td>based oral exposure during swimming (dermal and inhalation considered negligible)</td>
</tr>
<tr>
<td>Bromodichloromethane</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dibromochloromethane</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bromate</td>
<td>100</td>
<td>Swimming-water limit The Netherlands</td>
<td>Bromate is genotoxic carcinogen, value chosen based on extra cancer risk of $10^{-5}$ per lifetime as reference</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>based oral exposure during swimming (dermal and inhalation considered negligible)</td>
</tr>
<tr>
<td>Chlorate &amp; chlorite</td>
<td>30000</td>
<td>Swimming-water limit Germany, Swimming-water limit The Netherlands</td>
<td>Based on TDI based on oxidative damage of blood cells as critical effect</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monochloroacetic acid</td>
<td>800</td>
<td>Swimming-water limit derived in the present document</td>
<td>Based on TDI as reported by WHO, 20% of TDI allocated to swimming-water</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dichloroacetic acid</td>
<td>1500</td>
<td>Swimming-water limit derived in the present document</td>
<td>Compound is genotoxic carcinogen, extra lifetime cancer risk level of $10^{-5}$ as reference</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trichloroacetic acid</td>
<td>8000</td>
<td>Swimming-water limit derived in the present document</td>
<td>Based on TDI as reported by WHO, 20% of TDI allocated to swimming-water</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monobromoacetic acid</td>
<td>800</td>
<td>Read across from monochloroacetic acid</td>
<td>Read across from monochloroacetic acid</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dibromoacetic acid</td>
<td>1000</td>
<td>Read across from dichloroacetic acid</td>
<td>Read across from dichloroacetic acid</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tribromoacetic acid</td>
<td>8000</td>
<td>Read across from trichloroacetic acid</td>
<td>Read across from trichloroacetic acid</td>
</tr>
<tr>
<td>Dibromochloroacetic acid</td>
<td>8000</td>
<td>Read across from trichloroacetic acid</td>
<td>Read across from trichloroacetic acid</td>
</tr>
</tbody>
</table>

³ Chloroform equivalents calculated by multiplying the concentration of the THM in question with the ratio of the molecular mass of chloroform divided by the molecular mass of the THM in question. For example, if 10 µg/L of DBCM is detected, the equivalent concentration as chloroform would be (mwt chloroform/mwt DBCM) x 10 µg/L = 5.7 µg/L.
### Compound Limit in [µg/L] Origin of limit Toxicological basis for limit (derivation)

<table>
<thead>
<tr>
<th>Compound</th>
<th>Limit in [µg/L]</th>
<th>Origin of limit</th>
<th>Toxicological basis for limit (derivation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloral hydrate</td>
<td>100</td>
<td>WHO drinking-water guideline</td>
<td>TDI based on liver effects, 80% of TDI allocated to drinking-water, drinking-water consumption 2 L per day</td>
</tr>
<tr>
<td>Bromal hydrate</td>
<td>100</td>
<td>Read across from chloral hydrate</td>
<td>Read across from chloral hydrate</td>
</tr>
<tr>
<td>Dichloroacetonitrile</td>
<td>20</td>
<td>WHO drinking-water guideline</td>
<td>TDI based on liver effects, 20% of TDI allocated to drinking-water, drinking-water consumption 2 L per day</td>
</tr>
<tr>
<td>Dibromoacetonitrile</td>
<td>70</td>
<td>WHO drinking-water guideline</td>
<td>TDI based on growth effects, 20% of TDI allocated to drinking-water</td>
</tr>
<tr>
<td>Bromochloroacetonitrile</td>
<td>20</td>
<td>Read across from dichloroacetonitrile</td>
<td>Read across from dichloroacetonitrile</td>
</tr>
</tbody>
</table>

To add to the usefulness of the guidance, for the selected marker DBPs the suitable methods for chemical analysis in swimming-pool water are given in appendix 3.

#### 1.2.3.2 Selection of air limits for inhalation exposure

Based on the literature on the subject, THMs and trichloramine are considered as the volatile DBPs for which this issue is potentially relevant.

For THMs, however, the potential for inducing local irritation in the airways is relatively low (US-EPA 2012, EU-RAR 2008) and at the concentrations as measured in swimming-pools of maximally around 200 µg/m³ (RIVM 2014) such effects are not likely. Thus, for THMs using the swimming-pool limit of 50 µg/L in the assessment may be considered to be protective also with regard to possible inhalation effects after release of the THMs to swimming-pool air.

Trichloramine is strongly irritating for airways and available literature clearly indicates this DBP to be associated with adverse respiratory effects in swimmers and pool attendants in indoor swimming-pools (see Appendix 1). By comparing measured air concentrations with an appropriate existing limit value in air the potential risk for local inhalation effects can be evaluated. In France a maximum of 500 µg/m³ has been in use from 1995 onwards (Hery et al. 1995) but ANSES and INRS now use a lower value of 300 µg/m³ (ANSES 2012). RIVM (2014) proposed using the 500 µg/m³ as maximum with a target value of 200 µg/m³. These values are all based on epidemiological surveys in which concentrations of trichloramine measured in swimming-pool air were correlated with respiratory health complaints among pool workers. Such surveys provide a rough indication only as to the exact concentration-effect relationship and consequently the air limits mentioned have relatively low reliability.

No data are available for tribromamine but by extension this DBP may also considered relevant for air.

---

Table 3: DBP air limits to be used for 1st Tier evaluation for biocides

<table>
<thead>
<tr>
<th>Compound</th>
<th>Limit in [µg/L]</th>
<th>Origin of limit</th>
<th>Toxicological basis for limit (derivation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trichloramine (air)</td>
<td>Maximum 300 µg/m³; Target value 200 µg/m³</td>
<td>ANSES (France), proposed Dutch air target value for indoor pools</td>
<td>Epidemiological surveys among pool workers</td>
</tr>
<tr>
<td>Tribromamine (air)</td>
<td>Maximum 300 µg/m³; target value 200 µg/m³</td>
<td>Read across from trichloramine</td>
<td>Read across from trichloramine</td>
</tr>
</tbody>
</table>

In principle exposure to non-volatile DBPs is possible via aerosol formation. It is noted that this route (aerosolization) probably is relatively unimportant in the overall exposure to DBPs in PT2. This issue can be addressed based on two studies in which aerosol formation during showering was examined. Xu and Weisel (2003) studied exposure through aerosol formation during showering with water contaminated with haloacetic acids and haloketones. For HAA water concentrations of 249-300 µg/L they calculated a daily exposure via aerosol during 10 minutes’ shower of less than 1 µg/day. Zhou et al. (2007) also studied aerosol formation during showering. They measured a total aerosol particle concentration inside a shower of 5-14 mg/m³. Using the latter range it can be calculated that a high concentration of 1000 µg/L DBP in water would lead to a total exposure concentration via aerosol of only 14 ng/m³. Note that of the total aerosol only part would be inhalable. This supports the idea that aerosol formation is a minor exposure route only for PT2.

1.2.4 Marker DBP assessment

1.2.4.1 Introduction

To perform risk assessment as described above, an assessment of marker levels is needed. Below aspects relevant for a representative assessment of the selected marker DBP’s are identified.

It is general knowledge that conditions influencing the formation of DBPs vary considerably in different swimming-pools. It is not possible to cover all these variables in the assessment. It is not feasible to require measurements for all conditions reflecting all potential variations of parameters. Further, it is acknowledged that not only the technical design of the swimming pool influences these parameters, but also the facility management applied by the swimming pool holder.

Relevant information on marker DBPs can be provided in three ways:

1. Much published and unpublished information on the formation of DBPs in swimming pools is available which can be used as basis for the exposure assessment. This information should be collected and reviewed by the applicant;
2. An initial assessment can be based on simulation and modelling;
3. Actual measurements should be performed in case no data are available or available data are of insufficient quality. A combination of these three approaches is preferable. It is primarily up to the applicant and the reviewing competent authority to assess what is needed in individual cases.
At the workshop, consensus was reached that, in the absence of sufficient data from literature, for active substance approval, measurements performed under defined conditions in minimally one “representative” pool are needed. The basic requirement for the DBP guidance is that it must generate information relevant for human health and which is sufficient for the evaluation of DBP formation risk in the vast majority of swimming pools within the EU, inclusive of pool size and type. At this time, full reliance in a dossier for the acceptance of a biocidal product on a model pool to provide relevant information related to practice on a set of key DBP’s, is not feasible. Note that extra care should be given to product authorisations for seawater swimming-pools because a different spread in marker DBPs will be present in these pools compared to fresh water swimming-pools.

Several oxidative halogenated disinfectants are already on the market. Therefore, measuring under actual use conditions should be possible. Applicants can approach specialised analytical labs for consultation. These labs have all the required information on measurements of DBPs under specified uses and conditions and are able to process the (anonymised) existing data for existing substances. These consultants are experts in translating the measurements to defined use conditions in representative swimming pools.

For new substances, not yet on the market, measuring under actual use conditions seems more difficult. For these substances, initial measurements can be performed by modelling and/or read across. The data that are generated by modelling will be subject to expert judgement by national authorities. Where needed a temporary authorisation for testing in practice (i.e. conducting measurements in at least one “representative” fully operational pool) can be opted for at the national authorisation level.

1.2.4.2 Specific requirements

- The information necessary for the assessment should be generated in tests in actual pools in which the swimming-water is shared by a number of swimmers;
- The pool must be operated with defined, standard equipment and have flow conditions that are generally applied and which are essential for maintaining pool water quality. It should exclude non-standard equipment which impacts on pool water quality, be it negative or positive;
- Measurements should take into account operational conditions which substantially increase the risk for DBP formation and which may exist in swimming pools, either temporarily or permanently, yet fall within operational limits that are considered acceptable practice, legally or otherwise;
- Measurements should exclude operational conditions which minimise the risk for formation of DBP’s, but would fall within operational limits that are considered acceptable, legally or otherwise;
- The evaluation period should be long enough and parameters must be measured sufficiently frequent to adequately reflect variability;
- Type of pool: selected marker DBP's should be measured in a competition pool, a recreational pool, and a toddler pool because experience shows levels are different in these types of pools. The question whether a separate assessment is necessary for salt water pools should be adressed on a case-by-case basis based

---

5 Indicational sizes (variation is possible): Competitive (length) 25-50 m x (width) 18-25 meter x (depth) 1.8-2.5 meter; Recreational pool: depth >0.5 m, other measures vary greatly; toddler pool: depth <0.5 m, other measures vary greatly.
on available information (relevance depends on the halogenated disinfectant used);

- Pool equipment and flow conditions: The relevant basic standard equipment in swimming-pools is sand filters or sand/activated coal combi filters. These are standardly complemented with a flocculation system and – more or less standardly - separate activated coal filters. In many countries, operational conditions for equipment are also specified or recommended (filter backflush velocity, duration, and frequency). Equipment for the in-situ formation of disinfectants mostly is considered standard. Pools must be equipped with controlled dosing systems for all chemicals to ensure operational stability, have a flow rate which meets the legally required maximum residence times in pools, and meets the limits for recommended disinfectant concentrations of swimming water throughout the pool. Additional equipment such as ozone and UV systems are not standard equipment and might positively or negatively affect the degree of marker DBP formation. To ensure the general relevance of the assessment it should be carried out only in pools equipped with this standard equipment;

- Operational conditions:
  - The directly controllable legal parameter limits for swimming-pools specified in most EU countries and which have an impact on the concentration of marker DBP’s in swimming-water include pH (7.3 ± 0.3-0.5, depending on member state), disinfectant concentration, and average fresh water supply per swimmer. They must be monitored because together with requirements for pool equipment as described above, they constitute good pool practices;
  - Chemical parameters for which the limits are also specified but which are not directly controllable are permanganate and in some countries urea also. The values of these parameters also have an impact on the concentration of marker DBP’s in swimming water: they represent the organic respectively the inorganic load brought by swimmers into the swimming-water and therefore must be monitored;
  - The realistic worst case-scenario for marker DBP formation will be realised when a minimum suppletion of fresh water per swimmer is combined with a maximum number of swimmers per day in the pool for a prolonged period. If the opposite conditions would be allowed (i.e. a very low level of pool use) the assessment would be of no value, as no legal limits exist for the minimum number of visitors in a pool per day, nor for the maximum fresh water supply per swimmer. Most EU countries specify a minimum suppletion water of 30L per swimmer. The maximum number of swimmers allowed is less uniform, but a value of around 50 swimmers per day per 100 m³ swimming water is quite common. These considerations should be important criteria for the selection of pools suitable for a representative marker DBP risk assessment.

- In general the frequency at which the recommended “good pool practice” parameters and the selected marker parameters should be analysed, depends on how fast their values changes. For example, parameters like disinfectant concentration and pH are commonly measured a few times per day, whereas parameters like chlorate and bromate change very slowly with good pool practice and are measured on a monthly basis only. Recommended frequencies for bromate, THMs and trichloramine are 2-4 times per year (limited fluctuation). Appropriate frequencies for other selected marker DBP’s like HAA’s will depend on what is found in practice, depending on the degree of fluctation. Some member states have recommended frequencies for all specified parameters (e.g.
Dutch Ministry of Infrastructure and the Environment (Pool Water Treatment 2015, under consultation);

- Samples for the analyses must be taken in the most unfavourable place in the pool. This place can be determined using a colour test according to CEN 15288/2. These, for example, are places which are the least refreshed by the circulating water and/or near or between two outlets (approximately 30 cm under the surface);

- The duration of the DBP concentration measurements must be four consecutive months at least. No test period should start within four months after major changes in the pool operation have taken place (i.e. new filter beds);

- Useful additional data for the applicant: To ensure that good pool practices have been followed throughout the test period, the analyses for the chemical parameters that are part of good pool practices, together with the easily measurable chloride and nitrate concentrations in swimming water, constitute a useful finger print for the applicant to monitor the extent to whether good pool practices were adhered to during the test period, and give insight in which operational parameters should be improved upon during the test period.

1.3 Relevance of other PTs

The present guidance is developed in view of the assessment of biocides in PT2, but the human health risk assessment of DBPs may be relevant for other PTs as well. To focus future work, the workshop participants were asked to indicate for which PTs a human health risk assessment of DBPs would be necessary. The results of the written consultation round are presented in Appendix 4. From this inventory, it appears that PTs 1, 3, 4 and 5 are considered most relevant from the perspective of human health risks of DBPs. Please note that this is a tentative list since only few responses were received. Also note that relevance in this context is related to potential DBP-formation as a direct result of the use of halogenated oxidising biocidal active substances in a particular PT. It is recognised that many processes operate on potable water. Potable water may contain DBPs due to prior disinfection, but these are not considered to be associated with the biocide itself. All water for human consumption is treated in line with Drinking Water Directive and Regulations. Comparative standards applied across EU.

During the breakout session for human health at the workshop in June 2015 priority levels were given to the different PTs at a further attempt of ranking the PTs for future guidance development. Highest priority was given to PT2, 4 and 5. Little priority to PT11 and 12 and a very diverse distribution was demonstrated for PT3. PT1 was given the label “no priority”. During the break out session it was pointed out that PT1 does have a direct exposure pattern for active chlorine use.

1.4 Conclusions and recommendations

This document provides a scientific and pragmatic strategy for the risk assessment of disinfection by-products (DBPs) in the context of biocides authorisation under European legislation.

The risk assessment is based on a set of known marker DBPs, using consensus health-based limit values and published, modelled or measured DBP concentrations under described conditions.

The known DBP-groups that should at least be included in the risk assessment are: trihalomethanes (THMs), halogenated acetic acids (HAAs), halogenated acetonitriles (HANs), bromate, haloaldehydes (chloral/bromal hydrate), and trihalogenated amines. In
principle all selected marker compounds listed in for these DBP-groups should be
directed in the risk assessment. Specific compounds may be excluded based on
argumentation, additional DBPs should be included if there are indications from e.g.
measurements or theoretical considerations that a particular active substance leads to
their formation.

Measurements of concentrations of DBPs after biocide use in swimming-pools are needed
to drive the risk assessment. Relevant concentration data may be gathered from
available literature. Where needed actual measurements should be performed.
Simulation studies or modelling can be used to derive realistic worst case formation
levels. The approach should be part of a robust argumentation and a full rationale should
be given in the case of extrapolating data from one situation to another. Most marker
DBPs that should be addressed in the risk assessment are relevant for several active
substances and/or applicants. It is recommended that industry parties coordinate
activities to refine the risk assessment of the known marker DBPs. Existing information
should be used where possible and the applicability to the present situation should be
demonstrated.

The present guidance focuses on PT2 for which human exposure was considered most
relevant in view of the extent of exposure to DBPs. Other PTs for which a DBP-
assessment may be needed are PT1, PT4 and PT5, followed by PT3, PT11 and PT12. It is
recommended to further investigate the applicability of the present guidance to these
PTs.

1.5 References

NOTE to the reader:
Reference list includes references used in the Appendices 1-4

Édition scientifique. http://nosobase.chu-
2015)
Cardador MJ, Gallego M (2011) Haloacetic acids in swimming pools: swimmer and
worker exposure. Environmental Science and Technology 45, 5783-5790.
unter besondere Berücksichtigung des elektrochemischen Aktivierungsverfahren zwecks
Verbesserung der Beckenswasserqualität. Dissertation im Fachbereich der Biologie –
DeBorde M, Von Gunten U (2008) Reactions of chlorine with inorganic and organic
compounds during water treatment - Kinetics and mechanisms: a critical review. Water
Research 42, 13-51.
DIN19643 zur Überwachung von Schwimmbeckenwasser. Wasser- und
Bädertechnik AB Archiv des Badewesens 03/2012 166.
Erdinger L, Kirsch F, Sonntag HG (1999) Chlorate as an inorganic disinfection by product
in swimming pools. Zentralblatt für Hygiene und Umweltmedizin 202, 61-75.
intended for human consumption. European Commission http://eur-
(Accessed August 2015)

(Accessed August 2015)

trichloramine (NCI3) levels and self-reported health symptoms in indoor swimming pool
workers: dose-response relationships. Journal of Exposure Science and Environmental
Epidemiology 23, 88 – 93

chloramines in the atmosphere of indoor swimming pools. Annals of Occupational


INRS (2015) Triklorame, kit de mesure de la trichloramine dans l'air.
August 2015)

Jacobs JH, Spaan S, Van Rooy GBGJ, Meliefste C, Zaat VAC, Rooyackers JM, Heederik D
(2007) Exposure to trichloramine and respiratory symptoms in indoor swimming pool

disinfection byproducts in natural watersheds. Journal of Environmental Monitoring, 14,
2990-2999.

Kaman A (2010) Occurrence and formation of disinfection by-products in indoor
swimming-pools water. Dissertation Graduate School Clemson University.

Krassner SW, Weinberg HS, Richardson SD, Pastor SJ (2006) Occurrence of a new
generation of disinfection byproducts. Environmental Science and Technology 40, 7175-
7185.

disinfection byproducts in indoor swimming pool waters treated with different disinfection

symptoms and bronchial responsiveness in lifeguards exposed to nitrogen trichloride in

Nordberg G.F., N.G. Lundstrom, B. Forsberg, A. Hagenbjork-Gustafsson, B.J. Lagerkvist,
Eriksson (2012) Lung function in volunteers before and after exposure to trichloramine in
indoor pool environments and asthma in a cohort of pool workers. BMJ Open 2:e000973

brominated compounds in seawater swimming pools treated with chlorine. Water
Research 46, 828-836.

occupational and public exposure to trichloramine in swiss indoor swimming pools: A

Pickup J (2010) Environmental safety of halogenated by-products from use of active

Pool Water Treatment bv, (2014), Kosteneffecten kwaliteitseisen (water en lucht) in de
voorgestelde herziening regelgeving Bhvbjz. Revision, August 21 2014.


http://www.edlc.co.uk/pdf/PWTAG%20CoP1.13v5_000.pdf


Appendix 1. Selection of marker DBPs relevant for human exposure in swimming-water treated with halogenated disinfectants

Trihalomethanes (THMs)

Based on the published literature on DBP formation, the trihalomethanes (THMs) is considered the most important group of DBPs both for drinking-water and for swimming-water. Of the total amount of halogenated substances in swimming-water, THMs represent about 20%, thus being the largest group of DBPs on a weight basis (Chrobok 2003). As to data on occurrence in swimming-pools THMs are by far the most data-rich group of DBPs. All four chlorinated/brominated THMs have been investigated toxicologically and national swimming-water limits are available. As the data reported by Richardson et al. (2010) clearly indicate, brominated and chlorinated DBPs are interchangeable in the sense that depending on the source levels of active chlorine or active bromine present in the treated water, formation of either the chlorinated or brominated THMs will dominate. Thus, based on existing information, THMs are a highly relevant group. Existing national THM limits for swimming-water or drinking-water apply to the sum of THMs expressed as chloroform equivalents.

Based on this THMs are selected as a marker for halogenated disinfectants for PT2. The sum concentration of all four THMs in the treated water under representative use conditions can be compared with existing THM swimming-water limits. For the appropriate existing swimming-water or drinking-water limits to be used for THMs, see section 4 of the main text.

Due to their high volatility and Henry coefficients THMs are present in air above swimming-pools. In a summary of the literature RIVM (2014) concludes that concentrations up to 100 µg/m³ occur in indoor swimming-pools with even higher concentrations in some cases up to around 200 µg/m³. As explained in section 5, the potency of THMs for inducing local toxicity in the respiratory tract is relatively limited based on current knowledge (mainly for chloroform) (US-EPA 2012, EU-RAR 2008). Thus at the THM concentrations found in air in indoor pools the risk for local effects on the respiratory tract most likely is low. Based on this priority for measuring THMs in air is judged as low.

Bromate

Bromate (BrO₃⁻) can be formed after ozonation of water containing bromide. When bromide-containing water is disinfected by chlorination, formation of bromate also occurs. Much of the bromate in such situations derives from the active chlorine disinfection feedstock formulation in which bromide is converted to bromate. In indoor swimming-pools in the Netherlands disinfected with chlorinated disinfectants bromate is often found (RIVM 2014). Use of brominated disinfectants also may lead to increased bromate levels in the swimming-pool water (US-EPA 2005).

Based on the known physico-chemical and biokinetic properties of bromate the dermal and inhalation routes are considered of minor importance for bromate. Expected levels of bromate in indoor swimming-pool air are low.

Thus, bromate is a relevant DBP for swimming-water. For selection of the appropriate existing swimming-water or drinking-water limits to be used for these chemicals, see section 4 of the main text.

Chlorite and chlorate

Depending on which halogenated disinfectant is used, concentrations of chlorite (ClO₂⁻) and chlorate (ClO₃⁻) may be increased in swimming-water. Elevated concentrations of
chlorate of up to 40 mg/L were found in German swimming-pools (n=33), traceable to increased levels in the stock solution of the halogenated disinfectant (Erdinger et al. 1999). Even higher levels of up to 140 mg/L are mentioned as found in the past in certain German pools (Dygutsch and Kramer 2012). These authors report that chlorite concentrations normally will be low only, because the further conversion into chlorate will occur under influence of the active chlorine present in the swimming-pool. Because of the influence of UV-light the levels of chlorate in outdoor pools can be higher than those in indoor pools.

Based on the known physico-chemical and biokinetic properties the dermal and inhalation routes are considered of minor importance for chlorate and chlorite. Expected levels of in indoor swimming-pool air are low.

Thus, chlorite and chlorate are selected as markers for halogenated disinfectants for PT2. For selection of the appropriate existing swimming-water or drinking-water limits to be used for these chemicals, see section 4 of the main text.

**Haloacetic acids (HAAs)**

As indicated by Krassner et al. (2006) the haloacetic acids (chlorinated, brominated) represent the second largest group within the whole DBP mixture. The presence of HAAs in swimming-water has been shown both indoors and outdoors (Cardador and Gallego 2011). These investigators found that of the chlorinated haloacetic acids, the levels of di- and trichloroacetic acids were higher than those for monoacetic acid. For bromoacetic acids in swimming-water, recent data for eight health-oriented swimming pools (thalassotherapy establishments) based on seawater (seawater contains increased levels of bromide) are available (Parinet et al. 2012). The pools were disinfected by chlorination. For nine HAAs (three chlorinated, three brominated, three mixed bromo/chloro) they report sum levels of median 419 μg/L with a maximum of 2233 μg/L. Of the individual HAAs, highest concentrations were present of monobromoacetic acid, dibromoacetic acid, tribromoacetic acid and dibromochloroacetic acid (Parinet et al. 2012).

Based on their known physico-chemical and biokinetic properties the dermal and inhalation routes are considered not relevant for the HAAs. Expected levels of HAAs in indoor swimming-pool air are low.

Based on the above, HAAs are selected as a marker for halogenated disinfectants for PT2. For selection of the appropriate existing swimming-water or drinking-water limits to be used for this group, see section 4 of the main text.

**Haloacetonitriles**

Haloacetonitriles constitute only 5% or less of the total DBPs after chlorination. Levels of haloacetonitriles in 23 chlorinated indoor swimming-pools in the USA ranged from 5 to 53 μg/L (mean 19 μg/L) (Kaman 2010). Dichloroacetonitrile was by far the dominant haloacetonitrile found. Levels of dibromoacetonitrile may be increased when seawater is used for swimming-pools with levels up to 49 μg/L having been reported (WHO 2006). This is due to presence of bromide in seawater. No information is available for the occurrence of haloacetonitriles in air in indoor swimming-pools. Expected air concentrations are low based on a Henry coefficient of 0.04 Pa.m$^3$/mol (HSDB 2012).

Based on this limited information dihaloacetonitriles are selected as relevant DBPs for halogenated disinfectants of PT2. For selection of the existing swimming-water or drinking-water limits to be used for this group, see section 4 of the main text.

**Haloaldehydes**

The only representative from this group for which there are substantial data is chloral hydrate (trichloroacetaldehyde). For bromal hydrate the only relevant piece of
information is the reporting by WHO (2006) of a level of 230 µg/L for a swimming-pool
prepared from seawater. For chloral hydrate concentrations of 5-34.9 µg/L were found in
86 swimming pools in Seoul, South-Korea (Lee et al. 2010). Chloral hydrate in drinking-
water is usually present at concentrations below 10 µg/L (WHO 2005). No information is
available for the occurrence of bromal or chloral hydrate in air in indoor swimming-pools.
Based on an estimated Henry coefficient of 0.0057 Pa.m²/mol (EPIWIN) for chloral
hydrate emission to air in swimming-pools, however, is expected to be low.
Based on this limited information the trihaloacetaldehydes (chloral hydrate and bromal
hydrate) are selected as potentially relevant DBPs for halogenated disinfectants of PT2.
For selection of the existing swimming-water or drinking-water limits to be used for this
Haloamines

Chlorine and bromine react readily with ammonia from urine to form chloramines and
bromamines respectively. In fact monochloramine is used for secondary disinfection of
drinking-water (longer-lasting water treatment as the water moves through pipes to
consumers) by adding ammonia downstream to water containing some residual active
chlorine. In swimming-water urine is a direct source for ammonia but further ammonia
can also be formed from urea present in urine. Thus after use of halogenated
disinfectants in swimming-pools formation of haloamines is to be expected in principle.
Of the three chloramines, monochloramine is the dominant one at the normal pH-range
(7-9) for drinking-water. When used as a disinfectant monochloramine is present at
concentrations of 0.5 to 2.5 mg/L. According to WHO (2011), di- and trichloramines are
formed in drinking-water only occasionally and cause taste and odour problem at lower
concentrations than does monochloramine.

In swimming-water the levels of chloramines (and bromamines) formed will depend on
the level of human contamination. In a study into formation of chloramines in swimming-
pools in a laboratory experiment, preferable formation of trichloramine over mono- and
dichloramine was found (Schmalz et al. 2011). Release of trichloramine to air took place
relatively slowly (mass transfer took 20 hours in rough-surface water). Mean levels of
mono-, di- and trichloramines in swimming-pool water of 290 µg/L (mono), 380 µg/L
(di) and <100 µg/L (tri) are reported for a chlorinated pool in Spain (Richardson et al.
2010). Measurements carried out in Germany and Switzerland and reported in 2009 and
2012 respectively, showed significantly lower levels of trichloroamine, i.e. clearly below
500 µg/L for almost all swimming-pools (Schmoll et al. 2009; Parrat et al. 2012). Levels
of trichloramine in air in chlorinated indoor swimming-pools in the Netherlands are in the
range of 130-1280 µg/m³ (Jacobs et al. 2007). Hery et al. (1995) and Massin et al.
(1998) reported similar levels for indoor swimming-pools in France but ANSES (2012)
reports a somewhat lower range for French indoor pools for the later period of 2007-
2009, i.e. 200-300 µg/m³.

As reported by research groups in France, the Netherlands and Switzerland, air
concentrations as measured in these countries are associated with adverse respiratory
effects, primarily in pool attendants but presumably also in pool consumers.
For bromamines no concentration data are available for swimming-pools. Their formation
in swimming pools after use of halogenated disinfectants seems plausible.
In conclusion only limited data are available on formation of the haloamine DBPs. The
few concentration measurements in disinfected water suggest mean levels up to several
hundred µg's per litre, mostly as mono- and dihaloamines. The literature indicates,
however, that trihaloamines are more problematic. Concentrations in air of trichloramine
have been associated with health complaints. A study by Schmalz et al. 2011 also
points to trichloramine as the most important chloroamine DBP for swimming-pools.
Whether tribromamine should be regarded as similar to trichloramine in regard to its occurrence and potential health effect, is uncertain (lack of relevant data).

In conclusion, based on available data evaluation for possible local toxic effects in the respiratory tract for trihaloamines is needed. For selection of the appropriate existing air limit value to be used for trihaloamines in air, see section 4.
Appendix 2. Selection of water limits for marker DBPs deemed relevant for human exposure in swimming-water treated with halogenated disinfectants

Trihalomethanes (THMs)

The following values are available:

Table 4: Trihalomethanes (THMs)

<table>
<thead>
<tr>
<th>Compound</th>
<th>Limit in [µg/L]</th>
<th>Origin of limit</th>
<th>Toxicological basis for limit (derivation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trichloromethane (chloroform)</td>
<td>ΣTHMs: 20 (chloroform equivalents)</td>
<td>Swimming-water limit Germany, FINA recommendation</td>
<td>Unknown, most likely based on technical feasibility</td>
</tr>
<tr>
<td>Tribromomethane (bromoform)</td>
<td>ΣTHMs: 50 (chloroform equivalents)</td>
<td>Swimming-water limit Netherlands</td>
<td>TDI for chloroform, cancer risk estimation for BDCM, based on exposure calculation oral + dermal + inhalation</td>
</tr>
<tr>
<td>Bromodichloromethane</td>
<td>Alternative value: ΣTHMs: 100⁶</td>
<td>EU drinking-water limit (EU 1998)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Dibromochloromethane</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Based on the requirement that the toxicological basis for the selected value must be known the Dutch swimming-water limit of 50 µg/L (sum-concentration expressed as chloroform-equivalents) is chosen for THMs. As indicated in the table, this limit was based on an exposure calculation that took into account all three routes of exposure: oral, inhalation and dermal. According to the result of the calculation inhalation is the dominant exposure route for THMs, covering more than 80% of total exposure (RIVM 2014).

Bromate

The following values are available:

Table 5: Bromate

<table>
<thead>
<tr>
<th>Compound</th>
<th>Limit in [µg/L]</th>
<th>Origin of limit</th>
<th>Toxicological basis for limit (derivation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bromate</td>
<td>2000</td>
<td>Swimming-water limit Germany</td>
<td>TDI (based on kidney toxicity) (100% allocation to swimming-water)</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>Swimming-water limit Netherlands</td>
<td>Bromate is genotoxic carcinogen, extra cancer risk level of 1.10⁻⁵ as</td>
</tr>
</tbody>
</table>

⁶ In directive 98/83/EC this value of 100 µg/L is indexed by Note 10: “Where possible, without compromising disinfection, Member States should strive for a lower value.”
Bromate has been widely recognized as a genotoxic carcinogen (for a summary see RIVM 2014). For genotoxic carcinogens quantitative cancer risk estimation is commonly carried out. Based on such a risk estimation the WHO and EU drinking-water limits of 10 µg/L were derived. The Dutch swimming-water limit of 100 µg/L was derived in a similar fashion, taking into account the expected exposure via swimming-water. The German swimming water limit of 2000 µg/L is based on a different assessment of the carcinogenic action by bromate. Based on the principle that swimming-pool limits take precedence over drinking-water limits and that the lowest value be chosen if more than one limit value is available, the Dutch limit of 100 µg/L is chosen for use in the present context.

**Chlorate & chlorite**

The following values are available:

**Table 6: Chlorate & chlorite**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Limit in [µg/L]</th>
<th>Origin of limit</th>
<th>Toxicological basis for limit (derivation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorate &amp; chlorite</td>
<td>700 (chlorate)</td>
<td>WHO drinking-water limit</td>
<td>TDI (based on thyroid effect) (80% allocation to drinking-water)</td>
</tr>
<tr>
<td></td>
<td>700 (chlorite)</td>
<td>WHO drinking-water limit</td>
<td>TDI (based on effect on brain weight, liver weight) (80% allocation to drinking-water)</td>
</tr>
<tr>
<td></td>
<td>30000 (Σchlorate/ chlorite)</td>
<td>Swimming-water limits Germany</td>
<td>Based on TDI based on oxidative damage of blood cells as critical effect</td>
</tr>
<tr>
<td></td>
<td>30000 (Σchlorate/ chlorite)</td>
<td>Swimming-water limit Netherlands</td>
<td>Based on TDI in combination with exposure calculation (oral exposure only)</td>
</tr>
</tbody>
</table>

Based on the principle that swimming-pool limits take precedence over drinking-water limits, the value of 30000 µg/L is chosen for use in the present context.
Haloacetic acids (HAAs)
The following values are available:

Table 7: Haloacetic acids (HAAs)

<table>
<thead>
<tr>
<th>Compound</th>
<th>Limit in [µg/L]</th>
<th>Origin of limit</th>
<th>Toxicological basis for limit (derivation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monochloroacetic acid</td>
<td>20</td>
<td>WHO drinking-water guideline</td>
<td>TDI based on spleen effect, 20% of TDI allocated to water</td>
</tr>
<tr>
<td>Dichloroacetic acid</td>
<td>50</td>
<td>Provisional</td>
<td>WHO drinking-water guideline</td>
</tr>
<tr>
<td>Trichloroacetic acid</td>
<td>200</td>
<td>WHO drinking-water guideline</td>
<td>TDI based on growth and liver effects, 20% of TDI allocated to drinking-water, drinking-water consumption 2 L per day</td>
</tr>
<tr>
<td>Monobromoacetic acid</td>
<td>20</td>
<td>Read across from monochloroacetic acid</td>
<td>Read across from monochloroacetic acid</td>
</tr>
<tr>
<td>Dibromoacetic acid</td>
<td>50</td>
<td>Provisional</td>
<td>Read across from dichloroacetic acid</td>
</tr>
<tr>
<td>Tribromoacetic acid</td>
<td>200</td>
<td>Read across from trichloroacetic acid</td>
<td>Read across from trichloroacetic acid</td>
</tr>
<tr>
<td>Dibromochloroacetic acid</td>
<td>200</td>
<td>Read across from trichloroacetic acid</td>
<td>Read across from trichloroacetic acid</td>
</tr>
</tbody>
</table>

The HAAs have low volatility and have a low potential for skin penetration. This is confirmed by the study by Cardador and Gallego (2011). In view of this using drinking-water limits for exposure via swimming-water is considered overprotective (given that the drinking-water limits assume a water ingestion of 2 L per day). Using the calculation as developed for bromate in RIVM (2014) a swimming-water limit for the HAAs can be estimated. The calculation makes use of the formula:

$$E_o = C_{\text{water}} \times \text{IVT} \times T \times 10^{-9} / \text{BW}$$

Where:

- $E_o$ is the oral exposure in mg/kg body weight/day (on the day of the visit to the swimming-pool)
- $C_{\text{water}}$ is the concentration in swimming-water
- $T$ is the time spent in the swimming-pool in minutes (30 min for babies, 180 min for adults, 180 min for athletic swimmers)
- IVT is the amount of ingested swimming-pool water in mg/minute (1000 mg/min for babies, 800 mg/min for adults, 400 mg/min for athletic swimmers)
BW is bodyweight in kg (6.2 kg for abies, 60 kg for adults and athletic swimmers).

Taking into account the number of visits to the swimming pool per year, the average long-term oral exposure can be calculated and compared to the long-term toxicological reference value. In RIVM (2014) this was done separately for different swimming-pool user groups (babies, adults, swimming-athletes). The values for T and IVT in the formula and the number of visits per year were derived from a study by Schets et al. (2011). Thus for babies the number of visits per year was put at 13, for adults at 65 and for athletic swimmers at 260. Using these frequencies the $E_o$ was calculated as a yearly average. Next, that $C_{water}$ was calculated at which the yearly average equaled 20% of the long-term toxicological reference value or, for genotoxic carcinogens, the $C_{water}$ at which the yearly average equaled the extra cancer risk level of 1 in 100,000.

Based on the results of the calculation, for HAAs limits for swimming-pools can be derived. These are shown in the table below.

**Table 8: Haloacetic acids (HAAs) for swimming pools**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Limit in [µg/L]</th>
<th>Origin of limit</th>
<th>Toxicological basis for limit (derivation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monochloroacetic acid</td>
<td>800</td>
<td>Swimming-water limit derived in the present document</td>
<td>Based on TDI as reported by WHO, 20% of TDI allocated to swimming-water</td>
</tr>
<tr>
<td>Dichloroacetic acid</td>
<td>1500</td>
<td>Swimming-water limit derived in the present document</td>
<td>Compound is genotoxic carcinogen, extra cancer risk level of $1.10^{-5}$ as reference</td>
</tr>
<tr>
<td>Trichloroacetic acid</td>
<td>8000</td>
<td>Swimming-water limit derived in the present document</td>
<td>Based on TDI as reported by WHO, 20% of TDI allocated to swimming-water</td>
</tr>
<tr>
<td>Monobromoacetic acid</td>
<td>800</td>
<td>Read across from monochloroacetic acid</td>
<td>Read across from monochloroacetic acid</td>
</tr>
<tr>
<td>Dibromoacetic acid</td>
<td>1000</td>
<td>Read across from dichloroacetic acid</td>
<td>Read across from dichloroacetic acid</td>
</tr>
<tr>
<td>Tribromoacetic acid</td>
<td>8000</td>
<td>Read across from trichloroacetic acid</td>
<td>Read across from trichloroacetic acid</td>
</tr>
<tr>
<td>Dibromochloroacetic acid</td>
<td>8000</td>
<td>Read across from trichloroacetic acid</td>
<td>Read across from trichloroacetic acid</td>
</tr>
</tbody>
</table>

**Halo-aldehydes (chloral hydrate and bromal hydrate)**

The following values are available:

**Table 9: Halo-aldehydes (chloral hydrate and bromal hydrate)**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Limit in [µg/L]</th>
<th>Origin of limit</th>
<th>Toxicological basis for limit (derivation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloral hydrate</td>
<td>100</td>
<td>WHO drinking-water guideline</td>
<td>TDI based on liver effects, 80% of TDI allocated to drinking-water, drinking-water consumption 2 L per day</td>
</tr>
</tbody>
</table>
Chloral hydrate has a low Henry coefficient (estimated value 0.00057 Pa.m$^3$/mol) and therefore inhalation exposure in swimming-pools is estimated to be low only. Dermal penetration is also considered limited only (Kp value of 0.0039 cm/h as measured in human skin in vitro versus 0.16—0.21 cm/h for THMs in the same test system) (Trabaris et al. 2012; Xu et al. 2002). In view of this, using drinking-water guidelines is considered adequately protective.

### Haloacetonitriles

The following values are available:

**Table 10: Haloacetonitriles**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Limit in [µg/L]</th>
<th>Origin of limit</th>
<th>Toxicological basis for limit (derivation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dichloroacetonitrile</td>
<td>20</td>
<td>WHO drinking-water guideline</td>
<td>TDI based on liver effects, 20% of TDI allocated to drinking-water, drinking-water consumption 2 L per day</td>
</tr>
<tr>
<td>Dibromoacetonitrile</td>
<td>70</td>
<td>WHO drinking-water guideline</td>
<td>TDI based on growth effects, 20% of TDI allocated to drinking-water</td>
</tr>
<tr>
<td>Bromochloroacetonitrile</td>
<td>20</td>
<td>Read across from dichloroacetonitrile</td>
<td>Read across from dichloroacetonitrile</td>
</tr>
</tbody>
</table>

For the different haloacetonitriles Trabaris et al. (2012) report Kp values for dermal penetration of 0.099–0.167 cm/h. This value was determined in human skin in vitro; in this system the Kp for THMs was between 0.16 and 0.21 cm/h. Based on this the dermal penetration of the haloacetonitriles is expected to comparable to that of the THMs. For dichloroacetonitrile and dibromoacetonitrile Henry coefficients of 0.379 and 0.041 Pa.m$^3$/mol have been reported (Jin et al. 2012) (compared to 370 Pa.m$^3$/mol for chloroform). Based on these values inhalation exposure for dihalonitriles is estimated to be low only. In view of this, using drinking-water guidelines is considered adequately protective.
### Appendix 3. Methods for chemical analysis of marker DBPs

#### Table 11: Analytical methods

<table>
<thead>
<tr>
<th>DBP</th>
<th>Analytical method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trihalomethanes (expressed as chloroform)</td>
<td>ISO 15680:2003</td>
</tr>
<tr>
<td>Bromate</td>
<td>ISO 15061:2001</td>
</tr>
<tr>
<td>Chlorate &amp; chlorite</td>
<td>ISO 10304-4:1999</td>
</tr>
<tr>
<td>Haloacetic acids</td>
<td>USEPA Method  552.3; USEPA Method 557</td>
</tr>
<tr>
<td>Chloral hydrate</td>
<td>USEPA Method 551.1</td>
</tr>
<tr>
<td>Bromal hydrate</td>
<td>USEPA Method 551.1</td>
</tr>
<tr>
<td>Haloacetonitriles</td>
<td>USEPA Method 551.1</td>
</tr>
</tbody>
</table>
Appendix 4. Potential relevance of PTs regarding the human health risk assessment of DBPs in the context of biocides authorisation (written commenting round).

Table 12: Potential relevance of PTs regarding the human health risk assessment of DBPs in the context of biocides authorisation.

<table>
<thead>
<tr>
<th>PT</th>
<th>Description of use area and products</th>
<th>Relevance for HH</th>
<th>Argumentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT 1: Human hygiene</td>
<td>Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.</td>
<td>Yes</td>
<td>NL: Not expected to consist of halogenated disinfection oxidising agents. (Although iodinated products may be used, the mode of action of these is different) SK: Not relevant for halogenated actives IND: Two uses supported: hand-wash and foot-wash. Consider hand-wash worst case for both HH. Organic molecules (e.g. fatty acids) on the skin could in principle react with chlorine in a hand-wash to produce DBP(s). Consideration of possible absorption of such DBP(s) would be needed. The calculation would require selection of relevant types of molecules known to be in sweat/secrections on skin e.g. fatty acids. Once the latter selection has been achieved, choose the nearest structurally representative DBP(s) from the list referred to in the ‘thought starter’ with (hopefully) a toxicity reference value available, then calculate maximum amount (mg) of each of these ‘potential’ DBP(s) based on application of chlorine hand-wash (max 0.02 w/v) and assumption that the available chlorine has a 1:1 molar conversion for each DBP (worst-case). Base the HH assessment on initial worst-case assumption of 100% absorption of each DBP (then 75% if fails at 100%). The calculations would assume no loss through evaporation of the DBPs from the skin, i.e. worst-case. Perhaps such evaporation could be used as a refinement if really needed.</td>
</tr>
<tr>
<td>PT</td>
<td>Description of use area and products</td>
<td>Relevance for HH</td>
<td>Argumentation</td>
</tr>
<tr>
<td>----</td>
<td>--------------------------------------</td>
<td>-----------------</td>
<td>---------------</td>
</tr>
<tr>
<td><strong>PT 2:</strong> Disinfectants and algaecides not intended for direct application to humans or animals</td>
<td>Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs.</td>
<td>Yes</td>
<td>Consideration of possible inhalation to any volatile DBP may need to be considered. Although expected to be negligible.</td>
</tr>
<tr>
<td>Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities.</td>
<td>Yes</td>
<td><strong>NL:</strong> see argumentation PT4 (e.g. cleaning in day care centre: exposure to DBPs in air and contact with cleaned surfaces – inhalation and dermal exposure).</td>
<td></td>
</tr>
<tr>
<td>Products used for disinfection of air, water not used for human or animal consumption, chemical</td>
<td>No</td>
<td><strong>NL:</strong> swimming pools already covered. Surface area less critical, but need to be addressed. Airconditioning systems also need to be addressed. <strong>IND:</strong> Clearly, the worst-case of exposure to DBPs is chlorinated swimming pools which would cover all uses in PT2. It may of course be necessary to do other specific DBP calculations in other use-patterns that the applicant is supporting, for example to cover hard surface disinfection, but only in the event swimming pools were to fail, in order to show a safe use within PT2. [Note: calculations for hard surface disinfection would be expected to show much lower dermal exposure than for PT1 hand-wash containing the same concentration of active chlorine. Only exposure via dermal route would be expected to be relevant for DBP resulting from active chlorine reacting with human secretions (?) on surfaces. Consideration of possible inhalation to any volatile DBP may need to be considered although expected to be negligible.</td>
<td></td>
</tr>
<tr>
<td>PT</td>
<td>Description of use area and products</td>
<td>Relevance for HH</td>
<td>Argumentation</td>
</tr>
<tr>
<td>----</td>
<td>--------------------------------------</td>
<td>-----------------</td>
<td>---------------</td>
</tr>
<tr>
<td></td>
<td>toilets, waste water, hospital waste and soil.</td>
<td>Yes</td>
<td>NL: already covered above</td>
</tr>
<tr>
<td></td>
<td>Products used as algaeicides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials.</td>
<td>Yes</td>
<td>NL: already covered above</td>
</tr>
<tr>
<td></td>
<td>Products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.</td>
<td>No</td>
<td>NL: halogenated actives not considered suitable for these scenario’s, as the quality of the products would be reduced.</td>
</tr>
<tr>
<td>PT 3: Veterinary hygiene</td>
<td>Products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with antimicrobial function.</td>
<td>Yes</td>
<td>NL: this PT is considered less relevant for consumer exposure. However, the scenario for disinfection of housing may be hazardous. Even though the operator (professional) can use protective measures, a safe re-entry period must be included in the labels to ensure consumer (bystander) exposure. SK: Uses potable water already containing DBP. Variable exposure to DBP depending on use. No release/exposure scenario is as extensive or chronic in comparison to exposure from DBP in potable water. IND: Use-patterns: teat dips, footbaths, animal house disinfection. Animal houses considered worst-case. Spraying of animal houses is considered to represent worst-</td>
</tr>
<tr>
<td>PT</td>
<td>Description of use area and products</td>
<td>Relevance for HH</td>
<td>Argumentation</td>
</tr>
<tr>
<td>----</td>
<td>--------------------------------------</td>
<td>-----------------</td>
<td>---------------</td>
</tr>
<tr>
<td></td>
<td>Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.</td>
<td>Yes</td>
<td>case, in terms of potential for dermal exposure due to splashing of DBPs formed when active chlorine solution contacts surfaces and potential for exposure to volatile DBP(s) in an enclosed place formed by contact with residual material left over after any water-washing. <strong>NOTE:</strong> The ESD for PT3 does state that disinfection takes place after ‘thorough cleaning’ so in actual fact, the amount of residual organic materials on walls and floors should be relatively low prior to exposure to active chlorine, and hence DBPs exposure would also be relatively low.</td>
</tr>
<tr>
<td>PT 4: Food and feed area</td>
<td>Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals.</td>
<td>Yes</td>
<td><strong>NL:</strong> DBPs can occur in foods that have come into contact with disinfected processing machines etc. or with packaging materials treated with biocides. In this context the active substance should also be addressed in the context of MRL setting (methodology still in progress). If DBPs are the primary source of residues, they should be considered in MRL setting. Exposure is expected to be limited to the oral route. <strong>SK:</strong> Primary source of DBP, potable water used for all other PT. Acts as baseline for DBP concentration. All water for human consumption treated in line with Drinking Water Directive and Regulations. Comparative standards applied across EU High daily exposure through drinking and bathing. All population.</td>
</tr>
</tbody>
</table>
### PT 5: Drinking water

<table>
<thead>
<tr>
<th>Description of use area and products</th>
<th>Relevance for HH</th>
<th>Argumentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Products used for the disinfection of drinking water for both humans and animals</td>
<td>Yes</td>
<td><strong>NL</strong>: Chemicals for use in drinking water is regulated on national level. In NL, biocides are allowed to be used in (contact with) drinking water, as long as the active substance is approved as a biocide (PT5, or PT4 for drinking water contact materials). No additional assessment will be performed for possible BPD’s. Only for THM’s (chloroform, bromoform, dibromochloromethane and bromodichloromethane) a restriction is set in the Drinkingwater Directive (98/83/EC). Tap water is used for all kinds of other purposes (drinking, cleaning, showering). <strong>SK</strong>: Primary source of DBP, potable water used for all other PT. Acts as baseline for DBP concentration. All</td>
</tr>
</tbody>
</table>
PT | Description of use area and products | Relevance for HH | Argumentation
---|---|---|---
| | | water for human consumption treated in line with Drinking Water Directive and Regulations. Comparative standards applied across EU High daily exposure through drinking and bathing. All population.
**IND:** For animal health, exposure to DBPs is not relevant because there will be negligible transfer of organic matter (i.e. saliva containing molecules that can react with active chlorine) from the animals’ mouths (or none in the case of chicken/turkey beaks) to the water, hence other animals drinking water in the same circulatory system on a farm, will be exposed to negligible amounts of any DBP."
For human and animal drinking water the organic matter present in the drinking water would be expected to be low and hence DBPs would be expected to be present at a negligible level

| PT6: Preservatives for products during storage | Products used for the preservation of manufactured products, other than foodstuffs, feedingstuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life. Products used as preservatives for the storage or use of rodenticide, insecticide or other baits. | No | **NL:** Not expected to include halogenated oxidising active substances.

<p>| PT7: Film preservatives | Products used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to | No | <strong>NL:</strong> Not expected to include halogenated oxidising active substances. |</p>
<table>
<thead>
<tr>
<th>PT</th>
<th>Description of use area and products</th>
<th>Relevance for HH</th>
<th>Argumentation</th>
</tr>
</thead>
</table>
| PT 8: Wood preservatives | Products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms, including insects. This product-type includes both preventive and curative products. | No               | **NL**: Not expected to include halogenated oxidising active substances.  
**SK**: Uses potable water already containing DBP for treatment process. |
| PT 9: Fibre, leather, rubber and polymerised materials preservatives | Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration. This product-type includes biocidal products which antagonise the settlement of micro-organisms on the surface of materials and therefore hamper or prevent the development of odour and/or offer other kinds of benefits. | No               | **NL**: Not expected to include halogenated oxidising active substances.  
**SK**: Uses potable water already containing DBP for manufacturing process. DBP generation not expected from use of materials and not in high concentration (leaching) |
| PT 10: Construction material preservatives | Products used for the preservation of masonry, composite materials, or other construction materials other than wood by the control of microbiological, and | No               | **NL**: Not expected to include halogenated oxidising active substances.  
**SK**: Uses potable water already containing DBP for manufacturing process. DBP generation not expected from use of materials and not in high concentration (leaching) |
<table>
<thead>
<tr>
<th>PT</th>
<th>Description of use area and products</th>
<th>Relevance for HH</th>
<th>Argumentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT 11: Preservatives for liquid-cooling and processing systems</td>
<td>Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels. Products used for the disinfection of drinking water or of water for swimming pools are not included in this product-type.</td>
<td>No</td>
<td><strong>NL:</strong> to discuss whether swimming at discharge point is hazardous or can be minimized by precautionary safety measures. Otherwise not directly relevant for human exposure. <strong>SK:</strong> Uses potable or surface water already containing DBP prior to preservative inclusion. Minimal exposure to general public from use.</td>
</tr>
<tr>
<td>PT 12: Slimicides</td>
<td>Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.</td>
<td>No</td>
<td><strong>NL:</strong> to discuss whether a significant amount of DBPs formed during the process are still present in paper and board when used as food packaging material and/or whether migration limits should be set. It is noted that the safety of DBPs is not assessed within the framework of FCM’s which are except for plastic FCM mainly regulated on national level. <strong>SK:</strong> Uses potable water already containing DBP prior to preservative inclusion. Minimal exposure to general public from use, would be exposure to residues in material made in process using water containing slimicide, e.g. paper.</td>
</tr>
<tr>
<td>PT 13: Working or cutting fluid preservatives</td>
<td>Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials.</td>
<td>No</td>
<td><strong>NL:</strong> Not expected to include halogenated oxidising active substances. <strong>SK:</strong> Uses potable water already containing DBP prior to preservative inclusion. Minimal exposure to general public from use, would be exposure to residues in material made in process using water containing preservative.</td>
</tr>
<tr>
<td>PT14-20 pest control</td>
<td></td>
<td>No</td>
<td><strong>NL:</strong> Not expected to be disinfectants and/or to include halogenated oxidising active substances.</td>
</tr>
<tr>
<td>PT</td>
<td>Description of use area and products</td>
<td>Relevance for HH</td>
<td>Argumentation</td>
</tr>
<tr>
<td>-------------</td>
<td>------------------------------------------------------------------------------------------------------</td>
<td>------------------</td>
<td>-------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>PT21: antifouling</td>
<td>Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.</td>
<td>No</td>
<td><strong>NL</strong>: Not expected to include halogenated oxidising active substances.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>SK</strong>: DBP present in seawater.</td>
</tr>
<tr>
<td>PT 22: Embalming and taxidermist fluids</td>
<td>Products used for the disinfection and preservation of human or animal corpses, or parts thereof.</td>
<td>No</td>
<td><strong>NL</strong>: Not expected to include halogenated oxidising active substances.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>SK</strong>: Uses potable water already containing DBP in treatment process. Exposure minimal from treated items as release to soil.</td>
</tr>
</tbody>
</table>
2. Part 2 Environmental risk assessment of disinfection by-products (DBPs)
