

Guidance on the Biocidal Products Regulation

Volume V, Guidance on Disinfection By-Products

DRAFT

Version 1.0
October 2016



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Guidance on the BPR: Guidance on Disinfection By-Products

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1 **DOCUMENT HISTORY**

Version	Comment	Date
Version 1.0	First edition	Xxxx 2016

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1 PREFACE

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

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

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

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

21 Regarding **human health risk assessment**, as decided at the CA and (former) TM-
22 level, priority was given to PT2 (swimming-water) since this is considered as the most
23 relevant from the point of human exposure to DBPs and its associated possible risk to
24 health. The starting point of the human health risk assessment for DBPs was the decision
25 by the CA-meeting to use existing national limits for individual (groups of) DBPs in
26 swimming- and/or drinking-water. This was agreed to by TMII-2012 as being the
27 appropriate first tier in the human health risk evaluation for DBPs. Based on that
28 decision proposals for a pragmatic approach were developed. Prior to TM II-2012 these
29 proposals were circulated among member states, a number of whom gave written input.
30 At the TM III-2012 formal agreement was obtained on the various points raised in these
31 proposals. In a subsequent document NL outlined what could be the way forward as to
32 the actual application of the method for the envisaged human health risk assessment.

33 Regarding **environmental risk assessment**, it was further agreed that discussion
34 papers from the workshop on Ballast Water Treatment should be taken into account,
35 together with the input from other MS and industry (IND). A revised document, first
36 presented at TMI-2012, incorporated a more in-depth analysis of the relevance of
37 (groups) of DBPs and further information required for the assessment. On special
38 request of the European Commission (COM), the document investigated in particular
39 whether the strategy and/or the conclusions of the EU Risk Assessment Report (EU-RAR)
40 of sodium hypochlorite under the former Existing Substances Regulation (793/93/EEC)¹
41 could be taken over for biocide risk assessment. The document summarised the
42 information on DBP-formation and risk assessment focusing on the following product
43 types (PTs): PT2 (waste water treatment), PT11 (cooling water), and PT12 (pulp and
44 paper) and was discussed again at TMII-2012. At TMIII-2012, NL presented a combined

¹ EC. 2007. European Union Risk Assessment Report SODIUM HYPOCHLORITE, CAS No: 7681-52-9, EINECS No: 231-668-3, Final report, November 2007. Rapporteur Member State Italy, http://esis.jrc.ec.europa.eu/doc/existing-chemicals/risk_assessment/REPORT/sodiumhypochloritereport045.pdf.

1 document including both the human and environmental risk assessment in order to
2 update the discussions and to integrate the various documents that had been presented
3 at earlier TMs. The main problem identified at that stage was the lack of adequate
4 monitoring data.

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

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

16 Based on the workshop discussions, the present document provides a strategy for the
17 human health risk assessment and the environmental risk assessment of DBPs. With this
18 document the responsible parties for risk assessment of halogenated disinfectants can
19 start the work on the evaluation of DBPs.

20

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5 pathways mentioned in the text below. Bold arrows represent the major

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9 Figure 3: Breakpoint curve showing the processes that occur when water is chlorinated

10 (copied from <http://water.me.vccs.edu/concepts/chlorchemistry.html>)

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14 ammonia (figure copied from <http://www.lenntech.com/>)

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8	(industrial) locations. Translated copy from [9]	
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1 List of Abbreviations

Standard term / Abbreviation	Explanation
AOX	Absorbable organic halogen
ANSES	French CA
BAT	"Biologischer Arbeitsstoff-Toleranz-Wert": biological tolerance value for occupational exposures
BPC	Biocides Product Committee
BPR	Biocides Product Regulation
CA	Competent Authority
CAR	Competent authority assessment report
CEN	Comité Européen de Normalisation - European Committee for Standardization
COM	European Commission
DBA	Dibromoacetic acid
DBP	Disinfection by-products
DBP-WG	Disinfection by-products Working group
DCA	Dichloroacetic acid
DOC	Dissolved oxygen concentration
DOX	Dissolved organic halogen
DWL	drinking water limit
EC _x	Effective Concentration at x%
EC ₁₀	Effective Concentration at 10%
EC ₅₀	Effective Concentration at 50%
ECHA	European Chemicals Agency
EOX	Extractable organic halogen
EPIWIN	A modelling tool
EU	Europe
EU-RAR	European Risk assessment report
EUSES	The European Union System for the Evaluation of Substances
HAA	Halogenated acetic acids
HAN	Halogenated acetonitriles

Standard term / Abbreviation	Explanation
IND	industry
ISO	International Organization for Standardization
LC _x	Lethal concentration at x%
LC ₅₀	Lethal concentration at 50%
MBA	monobromoacetic acid
MCA	monochloroacetic acid
MS	Member States
NL	Netherlands
NOAEL	No observed adverse effect level
NOEC	No observed effect concentration
OSPAR	OSPAR Commission - Oslo Paris Convention (for the Protection of the Marine Environment of the North-East Atlantic)
PEC	predicted concentrations
PNEC	predicted no effect concentration
PT	Product type
QSAR	Quantitative Structure-Activity Relationships
RIVM	Dutch Competent Authority
RSS	Raw settled sewage
SE-EPA	Swedish Environmental Protection Agency
SPME	Solid phase micro extraction
SSD-approach	Species specific data approach
STP	Sewage treatment plant
SWL	swimming water limit
TCA	trichloroacetic acid
TBA	tribromoacetic acid
TDI	Tolerable Daily Intake
THM	Trihalomethane
TM	Technical meetings
TOC	Total organic carbon
TOX	Absorbable organic halogen

Standard term / Abbreviation	Explanation
TTC	Threshold of Toxicological Concern
TU	Toxic Units
TU _a	Toxic Units for acute toxicity
TU _c	Toxic Units for chronic toxicity
US-EPA	US Environmental Protection Agency
UV	Ultra-violet
WET	Whole effluent testing
WHO	World Health Organisation
XAD	A highly absorbent resin

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2

1 **1. Part 1 Human health risk assessment of disinfection by-products (DBPs)**

3 **1.1 Introduction**

4 **1.1.1 Regulatory context**

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

13 **1.1.2 A pragmatic approach to a complex issue**

14 The main problem for the risk assessment for DBPs is that the number of DBPs formed is
15 very high. In drinking-water, which is the area where most of the research on the
16 formation of DBPs has been carried out, more than 600 DBPs have currently been
17 identified. At the same time, however, more than 50% of the total organic halogen
18 (TOX) formed during disinfection of drinking-water remains unidentified (Pressman et al.
19 2010; DeBorde and Von Gunten 2008). For the human health risk assessment for DBPs
20 priority was given to PT2 (swimming-water) since this is considered the most relevant
21 from the point of view of degree of human exposure and possible health risk. During the
22 past decade DBP formation in swimming-pools has increasingly been studied. In one
23 major study in indoor swimming pools in Spain in which either chlorination or
24 bromination was used for disinfection, more than 100 different DBPs were identified
25 (Richardson et al. 2010). The type and amount of DBPs formed in swimming-pools
26 depends on many variables, including the availability of organic matter, the presence of
27 (in)organic nitrogen compounds and the salinity of the water. Operating conditions, such
28 as concentration of the active substance, the number of visitors, characteristics of the
29 receiving water (pH, TOC) and environmental circumstances such as temperature and
30 radiation, all are of influence (Pickup 2010; Sun et al. 2009). Due to this complexity it is
31 very hard to predict beforehand which compounds will be formed in a specific situation
32 and at which concentrations. Attempts are made to develop models for that purpose by
33 Singh et al. (2012) but these have not yet led to an applicable model. In this situation
34 only a pragmatic approach to risk assessment is feasible, in which the existing scientific
35 knowledge on the presence DBPs in swimming pools and on their toxicity is used in a
36 simplified way. This approach therefore involves the selection of marker DBPs, as
37 outlined in section 2.2. In the future updates of the approach will be needed. For this a
38 frequency of every 5 years is proposed below. Any new scientific information on DBP
39 formation in swimming-pools can then be taken into account.

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

1 1.1.3 Scope of the document

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

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

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

23 1.2 Human health risk assessment of DBPs

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

34 1.2.1 General principles

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

1 water limits for that DBP. But, as agreed upon during the workshop of 25th June, only
2 those swimming-water limits will be used for which the toxicological basis is known (see
3 below)Figure 1 provides a flow diagram of the proposed method, including the possible
4 step of further risk assessment.

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

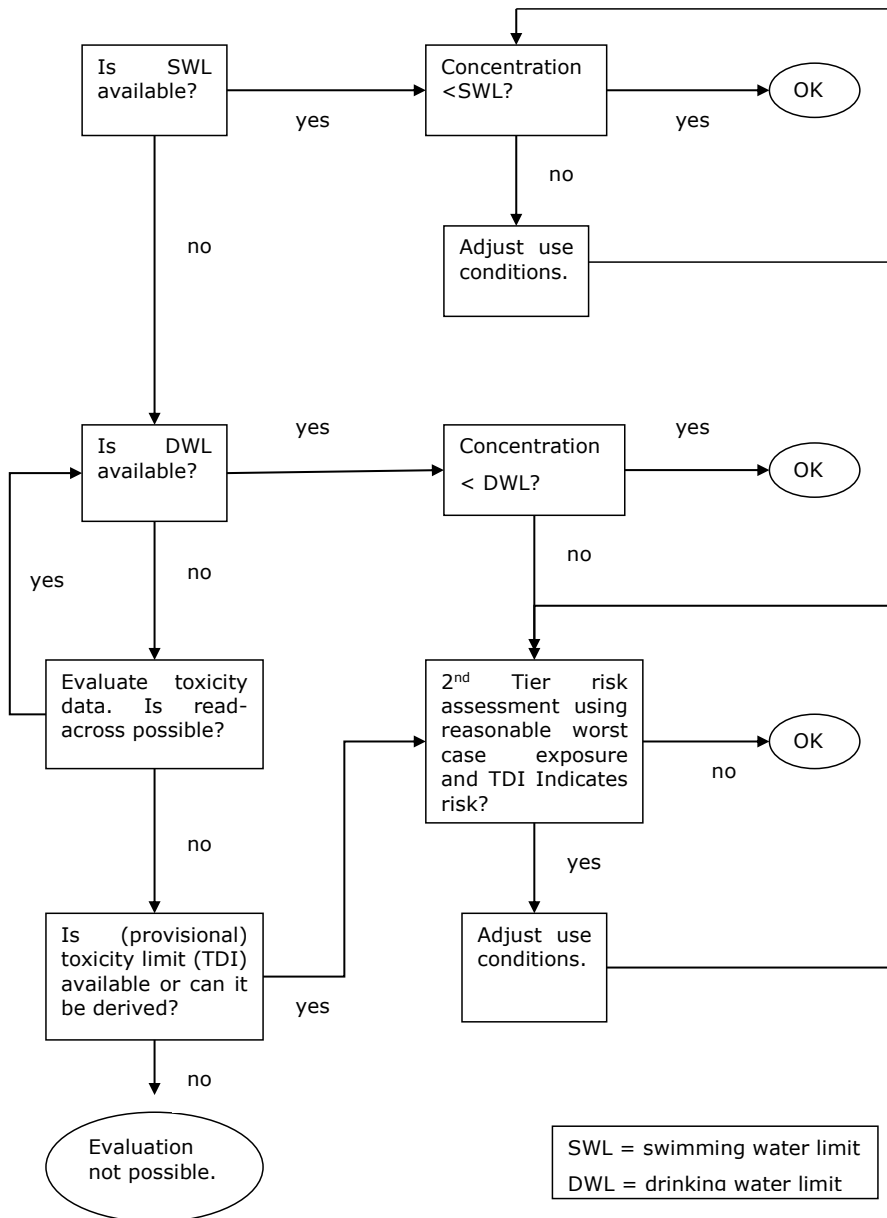
13 In the selection of the consensus limit value for swimming-/drinking-water, the
14 toxicological basis for these values is an important point of consideration (critical toxic
15 effect, NOAEL, allocation to drinking- or swimming-water). At the workshop of 25th June
16 2015 it was agreed to only use limit values for which the toxicological basis is known. It
17 was agreed that where several limit values with a known toxicological basis are available
18 the lowest value should be chosen.

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

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

37

1 Figure 1: Use of existing SWL and DWL for evaluating possible DBP human health risks



1 1.2.2 Selection of marker DBPs

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

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

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

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

Compounds	Notes
Trihalomethanes (THMs)	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.
Bromate	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.
Chlorite and chlorate	Frequently found in swimming-water. Concentrations often in the mg/L range.
Haloacetic acids (HAAs)	HAAs are quantitatively 2 nd 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.
Haloaldehydes	Based on reviewed literature trihaloacetaldehydes (chloral hydrate and bromal hydrate) are relevant.
Haloacetonitriles	Dihaloacetonitriles are most important within this group based on reviewed literature. Dibromoacetonitrile formed in the presence of

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

1

2 **1.2.3 Selection of limits for marker DBPs**

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

11 **1.2.3.1 Selection of swimming and drinking water limits for marker DBPs**

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

19 In Appendix 2 the choice of water limits for the different marker DBPs is explained in
20 more detail.

21 Concerning the drinking-water limits, during the workshop of June 25, 2015, the
22 question was raised whether these limits would not be underprotective in cases where
23 exposure via swimming-water is high due to dermal and inhalation exposure. Conversely
24 drinking-water limits may be overprotective in case the oral route is the only route in the
25 swimming-pool situation (for non-volatile DBPs with low potency for dermal penetration).
26 These points are discussed for individual marker DBPs in Appendix 2. For haloacetic
27 acids this led to new swimming-water limits. These were derived because for these DBPs
28 drinking-water limits are considered over-protective. See Appendix 2 for discussion. For
29 chloral hydrate and bromal hydrate and for the relevant haloacetonitriles drinking-water
30 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.

1 **Table 2: DBP water limits to be used for 1st Tier evaluation for biocides**

Compound	Limit in [µg/L]	Origin of limit	Toxicological basis for limit (derivation)
Trichloromethane (chloroform)	ΣTHMs: 50 ³ (chloroform equivalents) ⁴	Swimming-water limit The Netherlands	TDI for chloroform, cancer risk estimation for BDCM, based on exposure calculation oral+dermal+inhalation
Tribromomethane (bromoform)			
Bromodichloromethane			
Dibromochloromethane			
Bromate	100	Swimming-water limit The Netherlands	Bromate is genotoxic carcinogen, value chosen based on extra cancer risk of 10 ⁻⁵ per lifetime as reference based oral exposure during swimming (dermal and inhalation considered negligible)
Chlorate & chlorite	Σchlorate/ chlorite: 30000	Swimming-water limit Germany Swimming-water limit The Netherlands	Based on TDI based on oxidative damage of blood cells as critical effect
Monochloroacetic acid	800	Swimming-water limit derived in the present document	Based on TDI as reported by WHO, 20% of TDI allocated to swimming-water
Dichloroacetic acid	1500	Swimming-water limit derived in the present document	Compound is genotoxic carcinogen, extra lifetime cancer risk level of 10 ⁻⁵ as reference
Trichloroacetic acid	8000	Swimming-water limit derived in the present document	Based on TDI as reported by WHO, 20% of TDI allocated to swimming-water
Monobromoacetic acid	800	Read across from monochloroacetic acid	Read across from monochloroacetic acid
Dibromoacetic acid	1000	Read across from	Read across from dichloroacetic acid

³ The derivation of the Dutch swimming-pool limit of 50 µg/litre [for THM] was based on exposure calculations. Chronic exposure for swimmers was estimated for a proposed THM-level of 50 µg/litre in swimming-pool water. The guidance value (in Table 2) is for swimming-pools and is not seen to be in conflict with the official EU drinking-water limit, although the potential problem of exceeding TLV values is recognized. Such problems should be addressed at a National level until relevant CA evaluations and discussions of product authorisations can be considered.

⁴ 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)
		dichloroacetic acid	
Tribromoacetic acid	8000	Read across from trichloroacetic acid	Read across from trichloroacetic acid
Dibromochloroacetic acid	8000	Read across from trichloroacetic acid	Read across from trichloroacetic acid
Chloral hydrate	100	WHO drinking-water guideline	TDI based on liver effects, 80% of TDI allocated to drinking-water, drinking-water consumption 2 L per day
Bromal hydrate	100	Read across from chloral hydrate	Read across from chloral hydrate
Dichloroacetonitrile	20	WHO drinking-water guideline	TDI based on liver effects, 20% of TDI allocated to drinking-water, drinking-water consumption 2 L per day
Dibromoacetonitrile	70	WHO drinking-water guideline	TDI based on growth effects, 20% of TDI allocated to drinking-water
Bromochloroacetonitrile	20	Read across from dichloroacetonitrile	Read across from dichloroacetonitrile

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

3 1.2.3.2 Selection of air limits for inhalation exposure

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

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

12 Trichloramine is strongly irritating for airways and available literature clearly indicates
13 this DBP to be associated with adverse respiratory effects in swimmers and pool
14 attendants in indoor swimming-pools (see Appendix 1). By comparing measured air
15 concentrations with an appropriate existing limit value in air the potential risk for local
16 inhalation effects can be evaluated. In France a maximum of 500 µg/m³ has been in use
17 from 1995 onwards (Hery et al. 1995) but ANSES and INRS now use a lower value of
18 300 µg/m³ (ANSES 2012). RIVM (2014) proposed using the 500 µg/m³ as maximum with
19 a target value of 200 µg/m³. These values are all based on epidemiological surveys⁵ in
20 which concentrations of trichloramine measured in swimming-pool air were correlated

⁵ References: Hery et al. (1995), Jacobs et al. (2007), Parrat et al. (2012), Nordberg et al. (2012), Fantuzzi et al. (2013)

1 with respiratory health complaints among pool workers. Such surveys provide a rough
 2 indication only as to the exact concentration-effect relationship and consequently the air
 3 limits mentioned have relatively low reliability.

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

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

Compound	Limit in [µg/L]	Origin of limit	Toxicological basis for limit (derivation)
Trichloramine (air)	Maximum 300 µg/m ³ ; Target value 200 µg/m ³	ANSES (France), proposed Dutch air target value for indoor pools	Epidemiological surveys among pool workers
Tribromamine (air)	Maximum 300 µg/m ³ ; target value 200 µg/m ³	Read across from trichloramine	Read across from trichloramine

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

20 **1.2.4 Marker DBP assessment**

21 1.2.4.1 Introduction

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

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

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

- 32 1. Much published and unpublished information on the formation of DBPs in
 33 swimming pools is available which can be used as basis for the exposure
 34 assessment. This information should be collected and reviewed by the applicant;
- 35 2. An initial assessment can be based on simulation and modelling;

1 3. Actual measurements should be performed in case no data are available or
2 available data are of insufficient quality. A combination of these three approaches
3 is preferable. It is primarily up to the applicant and the reviewing competent
4 authority to assess what is needed in individual cases.

5 At the workshop, consensus was reached that, in the absence of sufficient data from
6 literature, for active substance approval, measurements performed under defined
7 conditions in minimally one "representative" pool are needed. The basic requirement for
8 the DBP guidance is that it must generate information relevant for human health and
9 which is sufficient for the evaluation of DBP formation risk in the vast majority of
10 swimming pools within the EU, inclusive of pool size and type. At this time, full reliance
11 in a dossier for the acceptance of a biocidal product on a model pool to provide relevant
12 information related to practice on a set of key DBP's, is not feasible. Note that extra care
13 should be given to product authorisations for seawater swimming-pools because a
14 different spread in marker DBPs will be present in these pools compared to fresh water
15 swimming-pools.

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

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

29 1.2.4.2 Specific requirements

- 30 • The information necessary for the assessment should be generated in tests in
31 actual pools in which the swimming-water is shared by a number of swimmers;
- 32 • The pool must be operated with defined, standard equipment and have flow
33 conditions that are generally applied and which are essential for maintaining pool
34 water quality. It should exclude non-standard equipment which impacts on pool
35 water quality, be it negative or positive;
- 36 • Measurements should take into account operational conditions which substantially
37 increase the risk for DBP formation and which may exist in swimming pools,
38 either temporarily or permanently, yet fall within operational limits that are
39 considered acceptable practice, legally or otherwise;
- 40 • Measurements should exclude operational conditions which minimise the risk for
41 formation of DBP's, but would fall within operational limits that are considered
42 acceptable, legally or otherwise;
- 43 • The evaluation period should be long enough and parameters must be measured
44 sufficiently frequent to adequately reflect variability;

- 1 • Type of pool: selected marker DBP's should be measured in a competition pool⁶, a
2 recreational pool, and a toddler pool because experience shows levels are
3 different in these types of pools. The question whether a separate assessment is
4 necessary for salt water pools should be addressed on a case-by-case basis based
5 on available information (relevance depends on the halogenated disinfectant
6 used);
- 7 • Pool equipment and flow conditions: The relevant basic standard equipment in
8 swimming-pools is sand filters or sand/activated coal combi filters. These are
9 standardly complemented with a flocculation system and – more or less
10 standardly - separate activated coal filters. In many countries, operational
11 conditions for filtration equipment are also specified or recommended (filter
12 backflush velocity, duration, and frequency). Equipment for the in-situ formation
13 of disinfectants mostly is considered standard. Pools must be equipped with
14 controlled dosing systems for all chemicals to ensure operational stability, have a
15 flow rate which meets the legally required maximum residence times in pools,
16 and meets the limits for pH and recommended disinfectant concentrations of
17 swimming water throughout the pool. Additional equipment such as ozone and
18 UV systems are not standard equipment and might positively or negatively affect
19 the degree of marker DBP formation. To ensure the general relevance of the
20 assessment it should be carried out only in pools equipped with this standard
21 equipment;
- 22 • Operational conditions:
- 23 ○ The directly controllable legal parameter limits for swimming-pools specified
24 in most EU countries and which have an impact on the concentration of
25 marker DBP's in swimming-water include pH ($7.3 \pm 0.3-0.5$, depending on
26 member state), disinfectant concentration, and average fresh water supply
27 per swimmer. They must be monitored because together with requirements
28 for pool equipment as described above, they constitute good pool practices;
- 29 ○ Chemical parameters for which the limits are also specified but which are not
30 directly controllable are permanganate and in some countries urea also. The
31 values of these parameters also have an impact on the concentration of
32 marker DBP's in swimming water: they represent the organic respectively the
33 inorganic load brought by swimmers into the swimming-water and therefore
34 must be monitored;
- 35 ○ The realistic worst case-scenario for marker DBP formation will be realised
36 when a minimum suppletion of fresh water per swimmer is combined with a
37 maximum number of swimmers per day in the pool for a prolonged period. If
38 the opposite conditions would be allowed (i.e. a very low level of pool use)
39 the assessment would be of no value, as no legal limits exist for the minimum
40 number of visitors in a pool per day, nor for the maximum fresh water supply
41 per swimmer. Most EU countries specify a minimum suppletion water of 30L
42 per swimmer. The maximum number of swimmers allowed is less uniform,
43 but a value of around 50 swimmers per day per 100 m³ swimming water is
44 quite common. These considerations should be important criteria for the
45 selection of pools suitable for a representative marker DBP risk assessment.
- 46 • In general the frequency at which the recommended "good pool practice"
47 parameters and the selected marker parameters should be analysed, depends on

⁶ 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.

1 how fast their values changes. For example, parameters like disinfectant
2 concentration and pH are commonly measured a few times per day, whereas
3 parameters like chlorate and bromate change very slowly with good pool practice
4 and commonly are measured on a monthly basis only. Recommended frequencies
5 for bromate, THMs and trichloramine are 2-4 times per year (limited fluctuation).
6 Appropriate frequencies for other selected marker DBP's like HAA's will depend
7 on what is found in practice, depending on the degree of fluctation. Some
8 member states have recommended frequencies for all specified parameters (e.g.
9 Dutch Ministry of Infrastructure and the Environment (Pool Water Treatment
10 2015, under consultation);

- 11 • Samples for the analyses must be taken in the most unfavourable place in the
12 pool. This place can be determined using a colour test according to CEN 15288/2.
13 These, for example, are places which are the least refreshed by the circulating
14 water and/or near or between two outlets (approximately 30 cm under the
15 surface);
- 16 • The duration of the DBP concentration measurements must be four consecutive
17 months at least. No test period should start within four months after major
18 changes in the pool operation have taken place (i.e. new filter beds);
- 19 • Useful additional data for the applicant: To ensure that good pool practices have
20 been followed throughout the test period, the analyses for the chemical
21 parameters that are part of good pool practices, together with the easily
22 measurable chloride and nitrate concentrations in swimming water, constitute a
23 useful finger print for the applicant to monitor the extent to whether good pool
24 practices were adhered to during the test period, and give insight in which
25 operational parameters should be improved upon during the test period.

26 1.3 Relevance of other PTs

27 The present guidance is developed in view of the assessment of biocides in PT2, but the
28 human health risk assessment of DBPs may be relevant for other PTs as well. To focus
29 future work, the workshop participants were asked to indicate for which PTs a human
30 health risk assessment of DBPs would be necessary. The results of the written
31 consultation round are presented in Appendix 4. From this inventory, it appears that PTs
32 1, 3, 4 and 5 are considered most relevant from the perspective of human health risks
33 of DBPs. Please note that this is a tentative list since only few responses were received.
34 Also note that relevance in this context is related to potential DBP-formation as a direct
35 result of the use of halogenated oxidising biocidal active substances in a particular PT. It
36 is recognised that many processes operate on potable water. Potable water may contain
37 DBPs due to prior disinfection, but these are not considered to be associated with the
38 biocide itself. All water for human consumption is treated in line with Drinking Water
39 Directive and Regulations. Comparative standards applied across EU.

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

46 This guidance could be used as a starting-point for other PTs. However, other PTs will
47 have different starting materials, pH, temperature etc. and this will affect which DBPs
48 are formed. Depending on the PT, the selection of the marker DBPs could be very
49 different from those now selected for swimming-water. Therefore, for the other PTs
50 future development of an adapted guidance is needed to ensure a harmonised

1 approach across the EU.

2 **1.4 Conclusions and recommendations**

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

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

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

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

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

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NOTE to the reader:

Reference list includes references used in the Appendices 1-4

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1 **Appendix 1. Selection of marker DBPs relevant for** 2 **human exposure in swimming-water treated with** 3 **halogenated disinfectants**

4 **Trihalomethanes (THMs)**

5 Based on the published literature on DBP formation, the trihalomethanes (THMs) is
6 considered the most important group of DBPs both for drinking-water and for swimming-
7 water. Of the total amount of halogenated substances in swimming-water, THMs
8 represent about 20%, thus being the largest group of DBPs on a weight basis (Chrobok
9 2003). As to data on occurrence in swimming-pools THMs are by far the most data-rich
10 group of DBPs. All four chlorinated/brominated THMs have been investigated
11 toxicologically and national swimming-water limits are available. As the data reported by
12 Richardson et al. (2010) clearly indicate, brominated and chlorinated DBPs are
13 interchangeable in the sense that depending on the source levels of active chlorine or
14 active bromine present in the treated water, formation of either the chlorinated or
15 brominated THMs will dominate. Thus, based on existing information, THMs are a highly
16 relevant group. Existing national THM limits for swimming-water or drinking-water apply
17 to the sum of THMs expressed as chloroform equivalents.

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

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

32 **Bromate**

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

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

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

46 **Chlorite and chlorate**

47 Depending on which halogenated disinfectant is used, concentrations of chlorite (ClO₂⁻)
48 and chlorate (ClO₃⁻) may be increased in swimming-water. Elevated concentrations of

1 chlorate of up to 40 mg/L were found in German swimming-pools (n=33), traceable to
2 increased levels in the stock solution of the halogenated disinfectant (Erdinger et al.
3 1999). Even higher levels of up to 140 mg/L are mentioned as found in the past in
4 certain German pools (Dygutsch and Kramer 2012). These authors report that chlorite
5 concentrations normally will be low only, because the further conversion into chlorate
6 will occur under influence of the active chlorine present in the swimming-pool. Because
7 of the influence of UV-light the levels of chlorate in outdoor pools can be higher than
8 those in indoor pools.

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

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

15 **Haloacetic acids (HAAs)**

16 As indicated by Krassner et al. (2006) the haloacetic acids (chlorinated, brominated)
17 represent the second largest group within the whole DBP mixture. The presence of HAAs
18 in swimming-water has been shown both indoors and outdoors (Cardador and Gallego
19 2011). These investigators found that of the chlorinated haloacetic acids, the levels of di-
20 and trichloroacetic acids were higher than those for monoacetic acid. For bromoacetic
21 acids in swimming-water, recent data for eight health-oriented swimming pools
22 (thalassotherapy establishments) based on seawater (seawater contains increased levels
23 of bromide) are available (Parinet et al. 2012). The pools were disinfected by
24 chlorination. For nine HAAs (three chlorinated, three brominated, three mixed
25 bromo/chloro) they report sum levels of median 419 µg/L with a maximum of 2233 µg/L.
26 Of the individual HAAs, highest concentrations were present of monobromoacetic acid,
27 dibromoacetic acid, tribromoacetic acid and dibromochloroacetic acid (Parinet et al.
28 2012).

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

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

35 **Haloacetonitriles**

36 Haloacetonitriles constitute only 5% or less of the total DBPs after chlorination. Levels of
37 haloacetonitriles in 23 chlorinated indoor swimming-pools in the USA ranged from 5 to
38 53 µg/L (mean 19 µg/L) (Kaman 2010). Dichloroacetonitrile was by far the dominant
39 haloacetonitrile found. Levels of dibromoacetonitrile may be increased when seawater is
40 used for swimming-pools with levels up to 49 µg/L having been reported (WHO 2006).
41 This is due to presence of bromide in seawater. No information is available for the
42 occurrence of haloacetonitriles in air in indoor swimming-pools. Expected air
43 concentrations are low based on a Henry coefficient of 0.04 Pa.m³/mol (HSDB 2012).

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

47 **Haloaldehydes**

48 The only representative from this group for which there are substantial data is chloral
49 hydrate (trichloroacetaldehyde). For bromal hydrate the only relevant piece of

1 information is the reporting by WHO (2006) of a level of 230 µg/L for a swimming-pool
2 prepared from seawater. For chloral hydrate concentrations of 5-34.9 µg/L were found in
3 86 swimming pools in Seoul, South-Korea (Lee et al. 2010). Chloral hydrate in drinking-
4 water is usually present at concentrations below 10 µg/L (WHO 2005). No information is
5 available for the occurrence of bromal or chloral hydrate in air in indoor swimming-pools.
6 Based on an estimated Henry coefficient of 0.0057 Pa.m³/mol (EPIWIN) for chloral
7 hydrate emission to air in swimming-pools, however, is expected to be low.

8 Based on this limited information the trihaloacetaldehydes (chloral hydrate and bromal
9 hydrate) are selected as potentially relevant DBPs for halogenated disinfectants of PT2.
10 For selection of the existing swimming-water or drinking-water limits to be used for this
11 group, see section 4. No evaluation for possible local toxic effects in the respiratory tract
12 is needed for this group of DBPs.

13 **Haloamines**

14 Chlorine and bromine react readily with ammonia from urine to form chloramines and
15 bromamines respectively. In fact monochloramine is used for secondary disinfection of
16 drinking-water (longer-lasting water treatment as the water moves through pipes to
17 consumers) by adding ammonia downstream to water containing some residual active
18 chlorine. In swimming-water urine is a direct source for ammonia but further ammonia
19 can also be formed from urea present in urine. Thus after use of halogenated
20 disinfectants in swimming-pools formation of haloamines is to be expected in principle.

21 Of the three chloramines, monochloramine is the dominant one at the normal pH-range
22 (7-9) for drinking-water. When used as a disinfectant monochloramine is present at
23 concentrations of 0.5 to 2.5 mg/L. According to WHO (2011), di- and trichloramines are
24 formed in drinking-water only occasionally and cause taste and odour problem at lower
25 concentrations than does monochloramine.

26 In swimming-water the levels of chloramines (and bromamines) formed will depend on
27 the level of human contamination. In a study into formation of chloramines in swimming-
28 pools in a laboratory experiment, preferable formation of trichloramine over mono- and
29 dichloramine was found (Schmalz et al. 2011). Release of trichloramine to air took place
30 relatively slowly (mass transfer took 20 hours in rough-surface water). Mean levels of
31 mono-, di- and trichloramines in swimming-pool water of 290 µg/L (mono), 380 µg/L
32 (di) and <100 µg/L (tri) are reported for a chlorinated pool in Spain (Richardson et al.
33 2010). Measurements carried out in Germany and Switzerland and reported in 2009 and
34 2012 respectively, showed significantly lower levels of trichloroamine, i.e. clearly below
35 500 µg/L for almost all swimming-pools (Schmoll et al. 2009; Parrat et al. 2012). Levels
36 of trichloramine in air in chlorinated indoor swimming-pools in the Netherlands are in the
37 range of 130-1280 µg/m³ (Jacobs et al. 2007). Hery et al. (1995) and Massin et al.
38 (1998) reported similar levels for indoor swimming-pools in France but ANSES (2012)
39 reports a somewhat lower range for French indoor pools for the later period of 2007-
40 2009, i.e. 200-300 µg/m³.

41 As reported by research groups in France, the Netherlands and Switzerland, air
42 concentrations as measured in these countries are associated with adverse respiratory
43 effects, primarily in pool attendants but presumably also in pool consumers.

44 For bromamines no concentration data are available for swimming-pools. Their formation
45 in swimming pools after use of halogenated disinfectants seems plausible.

46 In conclusion only limited data are available on formation of the haloamine DBPs. The
47 few concentration measurements in disinfected water suggest mean levels up to several
48 hundred µg's per litre, mostly as mono- and dihaloamines. The literature indicates,
49 however, that trihaloamines are more problematic. Concentrations in air of trichloramine
50 have been associated with health complaints. A study by Schmalz et al. 2011) also
51 points to trichloramine as the most important chloroamine DBP for swimming-pools.

- 1 Whether tribromamine should be regarded as similar to trichloramine in regard to its
- 2 occurrence and potential health effect, is uncertain (lack of relevant data).
- 3 In conclusion, based on available data evaluation for possible local toxic effects in the
- 4 respiratory tract for trihaloamines is needed. For selection of the appropriate existing air
- 5 limit value to be used for trihaloamines in air, see section 4.
- 6

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)

Compound	Limit in [µg/L]	Origin of limit	Toxicological basis for limit (derivation)
Trichloromethane (chloroform)	ΣTHMs: 20 (chloroform equivalents)	Swimming-water limit Germany, FINA recommendation	Unknown, most likely based on technical feasibility
Tribromomethane (bromoform)	ΣTHMs: 50 (chloroform equivalents)	Swimming-water limit Netherlands	TDI for chloroform, cancer risk estimation for BDCM, based on exposure calculation oral + dermal + inhalation
Bromodichloromethane			
Dibromochloromethane	Alternative value: ΣTHMs: 100 ⁷	EU drinking-water limit (Council Directive 98/83/EC)	Unknown

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

Compound	Limit in [µg/L]	Origin of limit	Toxicological basis for limit (derivation)
Bromate	2000	Swimming-water limit Germany	TDI (based on kidney toxicity) (100% allocation to swimming-water)
	100	Swimming-water limit Netherlands	Bromate is genotoxic carcinogen, extra cancer risk level of $1 \cdot 10^{-5}$ as

⁷ In Council 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."

Compound	Limit in [µg/L]	Origin of limit	Toxicological basis for limit (derivation)
	10	EU drinking water limit, national drinking-water limit WHO drinking-water limit	reference, based on exposure calculation (oral only, dermal and inhalation considered negligible) Bromate is genotoxic carcinogen, value chosen based on technical feasibility, value associated with upper bound cancer risk of $5 \cdot 10^{-5}$ according to WHO based on drinking-water consumption 2 L per day

1 Bromate has been widely recognized as a genotoxic carcinogen (for a summary see
 2 RIVM 2014). For genotoxic carcinogens quantitative cancer risk estimation is commonly
 3 carried out. Based on such a risk estimation the WHO and EU drinking-water limits of 10
 4 µg/L were derived. The Dutch swimming-water limit of 100 µg/L was derived in a similar
 5 fashion, taking into account the expected exposure via swimming-water. The German
 6 swimming water limit of 2000 µg/L is based on a different assessment of the
 7 carcinogenic action by bromate. Based on the principle that swimming-pool limits take
 8 precedence over drinking-water limits and that the lowest value be chosen if more than
 9 one limit value is available, the Dutch limit of 100 µg/L is chosen for use in the present
 10 context.

11 **Chlorate & chlorite**

12 The following values are available:

13 **Table 6: Chlorate & chlorite**

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

14 Based on the principle that swimming-pool limits take precedence over drinking-water
 15 limits, the value of 30000 µg/L is chosen for use in the present context.

1 **Haloacetic acids (HAAs)**

2 The following values are available:

3 **Table 7: Haloacetic acids (HAAs)**

Compound	Limit in [µg/L]	Origin of limit	Toxicological basis for limit (derivation)
Monochloroacetic acid	20	WHO drinking-water guideline	TDI based on spleen effect, 20% of TDI allocated to water
Dichloroacetic acid	50 (provisional)	WHO drinking-water guideline	Compound is genotoxic carcinogen, value chosen based on technical feasibility, value associated with upper bound cancer risk of 1.25×10^{-5}
Trichloroacetic acid	200	WHO drinking-water guideline	TDI based on growth and liver effects, 20% of TDI allocated to drinking-water, drinking-water consumption 2 L per day
Monobromoacetic acid	20	Read across from monochloroacetic acid	Read across from monochloroacetic acid
Dibromoacetic acid	50 (provisional)	Read across from dichloroacetic acid	Read across from dichloroacetic acid
Tribromoacetic acid	200	Read across from trichloroacetic acid	Read across from trichloroacetic acid
Dibromochloroacetic acid	200	Read across from trichloroacetic acid	Read across from trichloroacetic acid

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

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

11 Where:

12 E_o is the oral exposure in mg/kg body weight/day (on the day of the visit to the
13 swimming-pool)

14 C_{water} is the concentration in swimming-water

15 T is the time spent in the swimming-pool in minutes (30 min for babies, 180 min
16 for adults, 180 min for athletic swimmers)

17 IVT is the amount of ingested swimming-pool water in mg/minute (1000 mg/min
18 for babies, 800 mg/min for adults, 400 mg/min for athletic swimmers)

1 BW is bodyweight in kg (6.2 kg for babies, 60 kg for adults and athletic swimmers)
 2 Taking into account the number of visits to the swimming pool per year the average
 3 long-term oral exposure can be calculated and compared to the long-term toxicological
 4 reference value. In RIVM (2014) this was done separately for different swimming-pool
 5 user groups (babies, adults, swimming-athletes). The values for T and IVT the formula
 6 and the number of visits per year were derived from a study by Schets et al. (2011).
 7 Thus for babies the number of visits per year was put at 13, for adults at 65 and for
 8 athletic swimmers at 260. Using these frequencies the E_o was calculated as a yearly
 9 average. Next, that C_{water} was calculated at which the yearly average equaled 20% of the
 10 longterm toxicological reference value or, for genotoxic carcinogens, the C_{water} at which
 11 the yearly average equaled the extra cancer risk level of 1 in 100,000.
 12 Based on the results of the calculation, for HAAs limits for swimming-pools can be
 13 derived. These are shown in the table below.

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

Compound	Limit in [µg/L]	Origin of limit	Toxicological basis for limit (derivation)
Monochloroacetic acid	800	Swimming-water limit derived in the present document	Based on TDI as reported by WHO, 20% of TDI allocated to swimming-water
Dichloroacetic acid	1500	Swimming-water limit derived in the present document	Compound is genotoxic carcinogen, extra cancer risk level of $1 \cdot 10^{-5}$ as reference
Trichloroacetic acid	8000	Swimming-water limit derived in the present document	Based on TDI as reported by WHO, 20% of TDI allocated to swimming-water
Monobromoacetic acid	800	Read across from monochloroacetic acid	Read across from monochloroacetic acid
Dibromoacetic acid	1000	Read across from dichloroacetic acid	Read across from dichloroacetic acid
Tribromoacetic acid	8000	Read across from trichloroacetic acid	Read across from trichloroacetic acid
Dibromochloroacetic acid	8000	Read across from trichloroacetic acid	Read across from trichloroacetic acid

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

16 The following values are available:

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

Compound	Limit in [µg/L]	Origin of limit	Toxicological basis for limit (derivation)
Chloral hydrate	100	WHO drinking-water guideline	TDI based on liver effects, 80% of TDI allocated to drinking-water, drinking-water consumption 2 L per day

Compound	Limit in [$\mu\text{g/L}$]	Origin of limit	Toxicological basis for limit (derivation)
Bromal hydrate	100	Read across from chloral hydrate	Read across from chloral hydrate

1 Chloral hydrate has a low Henry coefficient (estimated value $0.00057 \text{ Pa}\cdot\text{m}^3/\text{mol}$) and
 2 therefore inhalation exposure in swimming-pools is estimated to be low only. Dermal
 3 penetration is also considered limited only (Kp value of 0.0039 cm/h as measured in
 4 human skin in vitro versus $0.16\text{--}0.21 \text{ cm/h}$ for THMs in the same test system) (Trabaris
 5 et al. 2012; Xu et al. 2002). In view of this, using drinking-water guidelines is
 6 considered adequately protective.

7 Haloacetonitriles

8 The following values are available:

9 **Table 10: Haloacetonitriles**

Compound	Limit in [$\mu\text{g/L}$]	Origin of limit	Toxicological basis for limit (derivation)
Dichloroacetonitrile	20	WHO drinking-water guideline	TDI based on liver effects, 20% of TDI allocated to drinking-water, drinking-water consumption 2 L per day
Dibromoacetonitrile	70	WHO drinking-water guideline	TDI based on growth effects, 20% of TDI allocated to drinking-water
Bromochloroacetonitrile	20	Read across from dichloroacetonitrile	Read across from dichloroacetonitrile

10 For the different haloacetonitriles Trabaris et al. (2012) report Kp values for dermal
 11 penetration of $0.099\text{--}0.167 \text{ cm/h}$. This value was determined in human skin in vitro; in
 12 this system the Kp for THMs was between 0.16 and 0.21 cm/h . Based on this the dermal
 13 penetration of the haloacetonitriles is expected to be comparable to that of the THMs. For
 14 dichloroacetonitrile and dibromoacetonitrile Henry coefficients of 0.379 and 0.041
 15 $\text{Pa}\cdot\text{m}^3/\text{mol}$ have been reported (Jin et al. 2012) (compared to $370 \text{ Pa}\cdot\text{m}^3/\text{mol}$ for
 16 chloroform). Based on these values inhalation exposure for dihalonitriles is estimated to
 17 be low only. In view of this, using drinking-water guidelines is considered adequately
 18 protective.

19

1 **Appendix 3. Methods for chemical analysis of marker**
2 **DBPs**

3 **Table 11: Analytical methods**

DBP	Analytical method
Trihalomethanes (expressed as chloroform)	ISO 15680:2003
Bromate	ISO 15061:2001
Chlorate & chlorite	ISO 10304-4:1999
Haloacetic acids	USEPA Method 552.3; USEPA Method 557
Chloral hydrate	USEPA Method 551.1
Bromal hydrate	USEPA Method 551.1
Haloacetonitriles	USEPA Method 551.1
Trihaloamines	Hery et al. (1995), INRS (2015)(also VITO 2015)

4

5

1 **Appendix 4. Potential relevance of PTs regarding the**
 2 **human health risk assessment of DBPs in the context of**
 3 **biocides authorisation (written commenting round).**

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

PT	Description of use area and products	Relevance for HH	Argumentation
PT 1: Human hygiene	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.	Yes	<p>NL: Not expected to consist of halogenated disinfection oxidising agents. (Although iodinated products may be used, the mode of action of these is different)</p> <p>SK: Not relevant for halogenated actives</p> <p>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.</p> <p>The calculation would require selection of relevant types of molecules known to be in sweat/secretions 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.</p>

PT	Description of use area and products	Relevance for HH	Argumentation
PT 2: Disinfectants and algaecides not intended for direct application to humans or animals	Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs.	Yes	<p>Consideration of possible inhalation to any volatile DBP may need to be considered. Although expected to be negligible.</p> <p>NL: see argumentation PT4 (e.g. cleaning in day care centre: exposure to DBPs in air and contact with cleaned surfaces –inhalation and dermal exposure).</p>
	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.	Yes	<p>NL: swimming pools already covered. Surface area less critical, but need to be addressed. Airconditioning systems also need to be addressed.</p> <p>IND: 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.</p> <p>[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.</p> <p>Consideration of possible inhalation to any volatile DBP may need to be considered although expected to be negligible.</p>
	Products used for disinfection of air, water not used for human or animal consumption, chemical	No	NL: use in airconditioners should be considered, other scenarios not relevant

PT	Description of use area and products	Relevance for HH	Argumentation
	toilets, waste water, hospital waste and soil.		
	Products used as algacides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials.	Yes	NL: already covered above
	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.	No	NL: halogenated actives not considered suitable for these scenario's, as the quality of the products would be reduced.
			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.
PT 3: Veterinary hygiene	Products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function.	Yes	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. Spraying and fogging scenarios, incidental contact directly after application. Egg washing, footbaths. Potential for food/feed residues. IND: Use-patterns: teat dips, footbaths, animal house disinfection. Animal houses considered worst-case. Spraying of animal houses is considered to represent worst-

PT	Description of use area and products	Relevance for HH	Argumentation
			<p>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.</p> <p>NOTE: 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.</p>
	<p>Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.</p>	<p>Yes</p>	
<p>PT 4: Food and feed area</p>	<p>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.</p>	<p>Yes</p>	<p>NL: 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.</p> <p>SK: 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.</p>

PT	Description of use area and products	Relevance for HH	Argumentation
			<p>IND: Use-patterns are CIP and hard surface disinfection. Hard surface disinfection probably worst-case, since actual hand contact of possible DBPs formed is more likely than from CIP. Possible, but likely negligible inhalation exposure due to formation of volatile DBPs. Can be considered and dismissed with a generic air concentration calculation perhaps, to show extremely low concentrations of DBPs in air are likely from this type of use-pattern. Although potentially CIP could present an oral exposure risk, there is the intention for a 'water-rinse' instruction after use of any active chlorine solution, before any food product is passed through treated lines. Therefore, no DBP will go into food/drink from CIP processes. So, oral exposure to DBPs should be negligible.</p>
	<p>Products used to impregnate materials which may enter into contact with food.</p>	<p>No</p>	<p>Not expected to include halogenated oxidising active substances.</p>
<p>PT 5: Drinking water</p>	<p>Products used for the disinfection of drinking water for both humans and animals</p>	<p>Yes</p>	<p>NL: 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). SK: Primary source of DBP, potable water used for all other PT. Acts as baseline for DBP concentration. All</p>

PT	Description of use area and products	Relevance for HH	Argumentation
			<p>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</p>
<p>PT6: Preservatives for products during storage</p>	<p>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.</p>	<p>No</p>	<p>NL: Not expected to include halogenated oxidising active substances.</p>
<p>PT7: Film preservatives</p>	<p>Products used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to</p>	<p>No</p>	<p>NL: Not expected to include halogenated oxidising active substances.</p>

PT	Description of use area and products	Relevance for HH	Argumentation
	protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.		
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	<p>NL: Not expected to include halogenated oxidising active substances.</p> <p>SK: Uses potable water already containing DBP for treatment process.</p>
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	<p>NL: Not expected to include halogenated oxidising active substances.</p> <p>SK: Uses potable water already containing DBP for manufacturing process. DBP generation not expected from use of materials and not in high concentration (leaching)</p>
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	<p>NL: Not expected to include halogenated oxidising active substances.</p> <p>SK: Uses potable water already containing DBP for manufacturing process. DBP generation not expected from use of materials and not in high concentration (leaching)</p>

PT	Description of use area and products	Relevance for HH	Argumentation
	algal attack.		
PT 11: Preservatives for liquid-cooling and processing systems	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.	No	NL: to discuss whether swimming at discharge point is hazardous or can be minimized by precautionary safety measures. Otherwise not directly relevant for human exposure. SK: Uses potable or surface water already containing DBP prior to preservative inclusion. Minimal exposure to general public from use.
PT 12: Slimeicides	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.	No	NL: 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. SK: 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 slimeicide, e.g. paper.
PT 13: Working or cutting fluid preservatives	Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials.	No	NL: Not expected to include halogenated oxidising active substances. SK: 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.
PT14-20 pest control		No	NL: Not expected to be disinfectants and/or to include halogenated oxidising active substances.

PT	Description of use area and products	Relevance for HH	Argumentation
PT21: antifouling	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.	No	<p>NL: Not expected to include halogenated oxidising active substances.</p> <p>SK: DBP present in seawater.</p>
PT 22: Embalming and taxidermist fluids	Products used for the disinfection and preservation of human or animal corpses, or parts thereof.	No	<p>NL: Not expected to include halogenated oxidising active substances.</p> <p>SK: Uses potable water already containing DBP in treatment process. Exposure minimal from treated items as release to soil.</p>

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1 **2. Part 2 Environmental risk assessment of disinfection**
2 **by-products (DBPs)**
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Commented [SJ3]: **CONSULTATION NOTE:** Part 2 removed for the consultation on Part 1.

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