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Efficacy requirements for drinking water disinfectants - survey and proposal

Requirements according to Biocidal Products Regulation in relation to disinfection practices in the Nordic countries

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Towards suitable and sufficient efficacy requirements for drinking water disinfectants used in the Nordic countries – survey and proposal

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Terms and and definitions

Available chlorine	Measure of oxidizing capacity expressed in terms of the equivalent amount of elemental chlorine. E.g. the concentration of hypochlorite may be expressed as available chlorine by determining the electrochemical equivalent amount of Cl2 to that compound.
BPR	Biocidal Products Regulation (EU) 528/2012
CFU	Colony forming unit
CT	Disinfectant concentration × duration of disinfection step. Measure of disinfection treatment efficacy
DOC	Dissolved organic carbon
Efficacy guidance	Guidance on the Biocidal Products Regulation, Volume II Efficacy - Assessment and Evaluation (Parts B+C), Version 3.0 April 2018
Free available chlorine	Chlorine dissolved in water as HOCl and OCl-
Large water supply zone (WSZ)	Supply of drinking water exceeding 1 000 m³ a day as an average or serving more than 5 000 persons
Microbial barrier analysis	Estimation of reductions in microbial concentration caused by different steps in water treatment process and comparing the combined reduction with expected maximum levels of microbes in raw water
Primary disinfection	The first (i.e., primary) disinfectant used in a treatment system, with the primary objective of the disinfectant being to achieve the necessary microbial inactivation.
PT	Product type. Water disinfectants belong to PT 5 according to BPR.
Secondary disinfection	The second disinfectant used in a treatment system, with the primary objective of the disinfectant being to maintain the disinfection residual through the distribution system [1].
TOC	Total organic carbon
Water supply zone (WSZ)	Geographically defined area within which water intended for human consumption comes from one or more sources and within which water quality may be considered as being approximately uniform.

1. Introduction

Drinking water disinfectants used in large water treatment plants and in associated water distribution systems are regulated by the Biocidal Products Regulation EU) 528/2012. They differ from other disinfectants in four relevant aspects: 1) disinfection is conducted by professionals in carefully controlled and relatively constant conditions; 2) substantial amount of research and monitoring data describing efficacy of the established active substances is available; 3) the biocidal products do not generally contain co-formulants and 4) disinfection efficacy, disinfectant quality and disinfection by-products are all regulated also by other regulations in addition to BPR. For instance, microbial quality of drinking water is monitored as required by Council Directive 98/83/EC of 3 November 1998 (Drinking Water Directive).

The special features of drinking water disinfectants should be considered when setting the efficacy requirements in relation to the BPR. Currently, the efficacy requirements for biocidal products, including drinking water disinfectants, are defined in the Guidance on the Biocidal Products Regulation, Volume II Efficacy - Assessment and Evaluation (Parts B+C). Author's opinion is that not all the requirements in the current guidance version 3.0 (April 2018) are suitable for drinking water disinfectants as they are used in drinking water plants in the Nordic countries. Use concentrations required to fulfil the current criteria may cause chemical safety concerns and deteriorate sensory quality of water. Sufficient microbiological safety of drinking water can be achieved with lower use concentrations. The document presents reasoning behind these views and suggests modifications for the next version of the guidance.

2. Disinfection at the drinking water suppliers and their water distribution systems in the Nordic countries

According to the Drinking Water Directive, large water supply zones are individual supplies of water exceeding 1000 m^3 a day as an average or serving more than 5000 persons. This report focuses on large zones because they cover the majority of the population and there is information readily available about them. Microbiological monitoring results of large water supply zones are reported by the European Commission [2].

Table 1. Large water supply zones in Finland and Sweden in 2013 [2, 3] and Norway 2018 [4]

	FI	SE	NO
Number	153	186	165
Coverage of total population	80%	83%	73%

Water treatment plants in Denmark and Iceland use predominantly ground water which is not chemically disinfected. Therefore, the situation in these countries is not discussed further in this document.

The most commonly used chemical drinking water disinfectant in Finland, Norway and Sweden is active chlorine (Table 2). Chlorine dioxide is used of fewer plants, primarily in Sweden. Ozone is by even fewer, mainly by some large plants in Finland. Of all water delivered by Finnish drinking water plants, 33% is disinfected by ozone [5]. Chloramine is used in all three countries as a secondary disinfectant, predominantly by large plants delivering water to wide distribution networks. E.g. in Finland, 50% of the drinking water produced by water treatment plants is treated additionally with chloramine [5].

In addition to chemical disinfectants listed in Table 2, UV-irradiation is commonly used to disinfect drinking water in the Nordic countries but it is not a biocide and therefore outside the scope of this document.

Table 2. Chemical disinfectants used continuously in plants delivering drinking water to large supply zones in the Nordic countries.

Disinfectant	Percentage of water plants utilizing		
	NO[1] (n=106)	SE[2] (n=80)	FI (n=153) [5]
Hypochlorite or chlorine gas	53%	43%	48%
Chlorine dioxide	0	8.8%	0.7%
Ozone	0	0	3.9%
Chloramine	4.0%	14%	9.8%
No chemical disinfection	45%	41%	38%

[1] Data representing the year 2018 from the Norwegian Food Control Authority. Figures were received from the Norwegian Institute of Public Health on March 2020
[2] Unpublished data received from Mats Engdahl, The Swedish Water & Wastewater Association on March 2020, Information was available from 80 plants delivering drinking water to 4.9 million people (49% of the population).

More than 40% of large water supply zones' drinking water originates from surface water in Finland [2] and Sweden [3]. The specific feature of surface waters in the Nordic countries is a high concentration of humic acids which are decomposed to carcinogenic substances as a result of chemical disinfection. Therefore at least in Finland, raw surface water is typically processed to reduce DOC levels before adding disinfectant [6]. This results in relatively low levels of DOC already at the primary disinfection step.

Disinfection practices applied in Finland, Sweden and Norway can be considered successful: all the test results (n = 6055) from large water supply zones in 2011-2013 in Finland complied with microbiological parametric values (*E. coli* and enterococci) of the Drinking water directive [2]. In Sweden, ≥99.93 % samples complied [3] and in Norway 99.85% samples compiled in 2014 [7]. [1]

3. Efficacy requirements for water disinfectants in the Guidance on the BPR

The current requirements are listed in the Guidance on the Biocidal Products Regulation, Volume II Efficacy - Assessment and Evaluation (Parts B+C), Version 3.0 April 2018, referred as efficacy guidance in this report. The drinking water disinfectant uses are divided into five categories in the guidance. The most relevant category for the purposes of this report is "disinfection at the drinking water suppliers and their water distribution systems". This use has been further divided into primary and secondary disinfection. Primary disinfection takes place at the water treatment plant "prior to distribution into the communal piping system". Secondary disinfectants are "added by drinking water suppliers to previously-treated water already in the public distribution network to ensure that an adequate disinfectant residual is maintained throughout the distribution network."

There are two types of treatments which can be regarded as secondary disinfection, depending on the definition of the term. One is dosing of disinfectant to water already in the distribution network, e.g. in water

[1] The parametric values defined in the Drinking water directive reflect bactericidal efficacy only. The minimum requirements in the BPR efficacy guidance cover also virucidal efficacy. A substantial amount of monitoring data describing virucidal efficacy of the current practices in the Nordic countries is currently not available because such monitoring is not required in the drinking water directive.

towers. Chlorine dioxide is used for this purpose in the Nordic countries. This type of treatment aims to reduce the number of viable micro-organisms in water and not only to prevent growth. The second type of treatment that can be regarded as secondary disinfection is generation of monochloramine from active chlorine and ammonium added to water at the water treatment plant. It is not totally clear whether this use will fall in the category of secondary disinfectants as defined in the efficacy guidance because monochloramine is dosed before water is pumped to public distribution network. Furthermore, the purpose of the treatment is not to reduce the number of viable microorganisms in water (disinfection) but rather to prevent their growth in the network. For the purpose of this report, however, it is assumed that requirements set for secondary disinfectants are applicable also to monochloramine generated at the water treatment plant after primary disinfection. This treatment is considered as secondary disinfection in other sources [1, 8]. There are no alternative requirements set specifically for this type of use in the efficacy guidance.

Efficacy against viruses and bacteria needs to be shown for both primary and secondary disinfectants. Both type of disinfectants should pass suspension tests which are modified versions of EN 1276 (bacteria) and EN 14476 (viruses) and a simulated use test. The preferred simulated use test for primary disinfectants is the UBA test "Quantitative determination of the efficacy of drinking water disinfectants" [9]. However, also "alternative methods will be considered and are acceptable provided they are scientifically justified and will be evaluated by the CA on a case-by-case basis". For secondary disinfection, "a simulated-use test is required with relevant use conditions with respect to temperature, soiling and contact time." This can be interpreted that the preferred method is the UBA method, possibly modified with respect to temperature, soiling and contact time. Alternative methods are allowed too, as they are for primary disinfectants.

The guidance states that acceptance criteria for the simulated use test for both primary and secondary disinfectants should be those specified in the UBA method.

The most problematic requirement is passing the suspension tests EN 1276 and EN 14476 at relevant use concentration. Although this is the basic requirement, the guidance opens for a possibility to pass only the simulated use test: "If the simulated use test passed but the suspension test did not pass, the applicant needs to justify why the concentration used in the simulated use test should be considered as the effective dose."

4. Comparison between efficacy requirements in the Guidance and the current practices in the Nordic countries

Commonly used disinfectants and their use concentrations in the Nordic countries are compared to EFF guidance requirements in Table 3. Table indicates that the applied use concentrations are unlikely to pass the required phase 2 step 1 tests. Similar level of efficacy should be expected in primary disinfection as required by the UBA test [15]. Monochloramine used as secondary disinfectant to prevent bacterial proliferation in the distribution network is unlikely to pass even the requirements set in the simulated use test. The contradiction between the current use concentrations and the requirements of EFF guidance needs to be solved.

Table 3. Commonly used disinfectants and their use concentrations in the Nordic drinking water treatment plants and comparison to efficacy requirements in the BPR efficacy guidance [10].

Disinfectant	Ct value mg/min/L E. coli log 2 reduction, 5 °C, no added interfering compounds [8]	Use concentration mg/L	Log 2 (10 min) and log 4 (25 min) reduction in the simulated use test (bacteria and viruses) at typical use concentration	Log 5 reduction in the modified EN 1276 test [10] at the use concentration	Log 4 reduction in the modified EN 14476 test [10] at the use concentration
Active chlorine (from hypochlorite or chlorine gas, pH 6-7)	0.034-0.05	0.3-1.6 [6, 5, 11]	Yes [9]	No [12]	No [12]
Chlorine dioxide (pH 6-7)	0.4-0.75	0.4[a]	Yes [9]	ND	ND
Ozone (pH 6-7)	0.02	0.4-0.7 [13, 5]	Probably[b]	ND	Possibly[b]
Monochloramine (pH 8– 9)	95-180	0.03 - 0.5 [14, 5]	No[b,c]	No[b,c]	ND

[a] Maximum dosing allowed to treat drinking water in Germany [15]. Use concentrations in the Nordic countries were not available

[b] Suggested by Table 3.1 in [16] and Table 0-2 in [17]

[c] According to Ct value (first column), even 2 log reduction of *E. coli* would require longer than 150 min contact time at use concentration 0.5 mg/L

Equations for calculation of disinfection efficacy of chlorine compounds and ozone are presented in [1, 17, 8, 16].

The conditions required in the efficacy studies are compared to the practices in Nordic water treatment plants in Tables 4 and 5. The contact time and interfering substances required for the simulated use test can be considered to be in line with the Nordic practices in primary but not in secondary disinfection. The level of DOC required in EN 1276 and EN 14476 tests is higher than the level that is typical in the Nordic water treatment plants.

Table 4. Contact time required in efficacy tests

	Primary disinfection	Secondary disinfection
EFF guidance requirements	max 30[a] min for the suspension tests 10 and 25 min for the simulated use test [9]	max 30[a] min for the suspension tests “relevant use conditions” for a simulated use test;
Current practice in the Nordic water treatments plants	Probably in line with the requirements in the EFF guidance	30 min not relevant for monochloramine used to maintain microbiological quality rather than to disinfect. It may be relevant for disinfectants dosed to distribution network after water has left a treatment plant.

[a] max contact time in EN 1276 and EN 14476 tests according to the EFF guidance

Table 5. Interfering substances in the efficacy tests

	Primary disinfection	Secondary disinfection
EFF guidance requirements	15 mg/L DOC in EN 1276 and EN 14476; 2 mg/L DOC in the simulated use test[1]	“relevant use conditions”
Nordic raw water	3 mg/L TOC [13]	2 mg/L TOC [18]

[1] See footnote 4 in Appendix 4 of the EFF guidance

In addition to the conditions above, the efficacy guidance requires that efficacy needs to be shown at 15 °C but not necessary at a lower temperature. Disinfection efficacy is typically lower at lower temperatures. Testing at 15 °C only does not ensure efficacy in the Nordic countries where raw water is often 4 °C and can be down to 0.5 °C in rivers and brooks [16].

5. Suggested modifications to the BPR efficacy guidance

As indicated above, the efficacy requirements for the water disinfectants are stricter in the efficacy guidance than the current requirements in the Nordic water treatment plants. To meet the requirements of the guidance, the use concentrations would need to be increased. Higher concentrations would generate problems, such as more disinfection by-products and decreased sensory quality of water. The current drinking water legislation limits the use of disinfectants and so does the article 17 (5) of the BPR: ”the use of biocidal products is limited to the minimum necessary”. Therefore, use concentrations should not be increased. Instead, the efficacy guidance requirements should be modified to be in concordance with the current practices, which according to microbiological monitoring, produce high quality drinking water. Below, we list suggestions to modify the section 5.4.5.2 “Disinfection at the drinking water suppliers and their water distribution systems” in the April 2018 version of the efficacy guidance.

1. Passing the modified EN 1276 or EN 14476 test should not be required

- The log reduction requirements for primary disinfection are generally lower than log 5 reduction of bacteria (EN 1276) and log 4 reduction of viruses (EN 14476).[2] This is partly because raw water cannot be expected to contain such a high concentrations of microbes and partly because microbes may be removed also by other processing steps such coagulation, filtration and UV disinfection [16].
- Apparently, sodium hypochlorite cannot pass these tests at use concentration (typically <1 ppm active chlorine). Sodium hypochlorite is the most important water disinfectant in Europe and its use concentrations cannot be significantly increased. Non-authorization of sodium hypochlorite due to failure to pass the EN tests at use concentration is not a viable option. If sodium hypochlorite cannot pass the tests, and non-authorization cannot result from this, it would be logical not to require these tests for any drinking water disinfectant.
- DOC 15 mg/L should not be a basic requirement for primary disinfectants. Water in Finland, Sweden and Norway is often processed prior to disinfection to reduce DOC levels below 15 mg/L. Water treatment plant managers know the DOC level of their raw water and are able to choose the disinfectant type and concentration accordingly.
- The initial bacterial load (>7 log CFU/ml in EN 1276) and associated growth medium added to the test suspension increases DOC in the test suspension significantly higher than 15 mg/ml (DOC required in the test) and results in unrealistically high total DOC.
- According to the OECD guidance document [19] for testing pool and spa water, "the test volume should have the capacity to act as a sufficient reservoir to maintain the recommended concentration of active(s) when the volume of test inoculum is added. The inoculum volume and its solutes should not overwhelm the test system such that the recommended concentration of the test disinfectant is substantially altered. A ratio of 199:1 as described in AOAC 965.13 is satisfactory in most cases where the disinfectant demand of the system has been measured and accounted for."
    - In EN 1276, the ratio of disinfectant dilution volume to the volume of inoculum and interfering substance is only 4:1. Furthermore, inoculum density is at least ten times higher than that normally used in test recommended in the guidance document [19]. Thus, it can be expected that inoculum volume and its solutes overwhelm the test system.
- According to the simulated use test [9], "only DOC that occurs naturally in water should be used (as artificial DOC does not show valid results)"

2. Use instructions should allow use concentration lower than that passing the simulated use test

- According to BPR and drinking water directive the use of disinfectant should be limited to the minimum necessary without compromising the disinfection. The minimum necessary concentration may be lower than that passing the UBA test. The desired level of reduction of microbes in chemical disinfection is determined by microbiological quality of raw water and other processing steps, such as UV-disinfection and filtration/coagulation, that reduce the number of microbes. The concentration of disinfectant should be set according to process-specific microbial reduction goals in chemical disinfection, not according to concentration that passes the UBA test.

[2] It should be noted that the April 2018 guidance version gives possibility not to pass the EN 1276 or EN 14476: "If the simulated use test passed but the suspension test did not pass, the applicant needs to justify why the concentration used in the simulated use test should be considered as the effective dose." At the time of writing, it is unclear how the quoted sentence is interpreted among the competent authorities.

- According to the simulated use test [9], “In practical applications, dosing may deviate from the concentration determined to be sufficiently effective by this test, depending on indication, application conditions and legal regulations. Determining the adequate doses for different water matrices and application scenarios are a separate (next) step not addressed here”
- We propose to add a sentence ”Lower concentrations may be used depending on the national legislation, quality of water that is disinfected and the water treatment process” to the instructions for use.

3. Acceptance criteria of the preferred simulated use test (UBA test) should not be applied for chloramines

    - Chloramines are widely used as secondary disinfectants by drinking water treatment plants in Finland, Norway and Sweden. Chloramines cannot generate >4 log reduction of test bacteria at concentrations currently used. This means that these concentrations cannot be authorized according to any efficacy criteria set in the current PT 5 efficacy guidance.
    - Chloramines are used to keep up the quality of disinfected water in the distribution system rather than for actual disinfection. Therefore, the requirement to generate 4 log reduction is unsuitable for chloramines.
    - We suggest including a drinking water microbiological quality maintenance use to PT 5 and set the efficacy requirements accordingly. Efficacy tests should show inhibition of growth rather than large reductions in levels of viable bacteria.
    - Demonstration of virucidal efficacy should not be required for chloramines because pathogenic viruses cannot multiply in distribution network. If viruses are present in raw water, they should be inactivated or removed during the water treatment process before dosing of chloramine.
    - According to [8], chapter 3.4.1 “the practice of residual disinfection has become controversial, with some opponents arguing that if biological stability is achieved and the system is well maintained, the disinfectant is unnecessary”. This discussion is outside the scope of this document but regardless of the outcome, it is clear that the current efficacy requirements for secondary disinfectants are not in line with the objectives set for the treatment in the Nordic countries.

4. Monitoring data for ozone, chlorine, chlorine dioxide and monochloramine should be considered instead of testing

    - Abundance of monitoring and research data demonstrating bactericidal efficacy of these compounds is available. A limited number of additional tests that can be expected are insignificant contribution to the body of evidence.
    - Practical guidelines defining efficacious application rates are available from trusted sources, e.g. [1, 17, 8, 16].
    - Drinking water disinfectants used at water treatment plants do not normally contain co-formulants that could affect efficacy. Therefore, read across of test results is less problematic than typically for other types of biocidal products.
    - Limited requirements were also set for hypochlorous acid/hypochlorite used for swimming pool disinfection (section 5.4.2.6.2 in the efficacy guidance). This approach is included in the OECD guidance document 170 for demonstrating efficacy of pool and spa disinfectants in laboratory and field testing. The document implies that traditional

disinfectants based on bromine or chlorine do not need to be tested because their efficacy is well established. The traditional drinking water disinfectants could be treated similarly. Monitoring data could be used instead of laboratory tests.

5. Concerning disinfectants other than the established ones (ozone and the typical chlorine compounds): passing the tests specified in the current efficacy guidance should not be considered sufficient demonstration of efficacy for drinking water disinfectants used at water treatment plants. At least, dependency of efficacy on water parameters (temperature, pH) should be elucidated, possibly using literature data. Efficacy should be shown also below 15 °C.

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References

[1] "EPA guidance manual - Alternative Disinfectants and Oxidants," United States Environmental Protection Agency, 1999.

[2] "Overview of the drinking water quality in Finland- Results of the reporting 2011 - 2013 under the Drinking Water Directive 98/83/EC," European Topic Centre; Inland, coastal, marine waters.

[3] "Overview of the drinking water quality in Sweden - Results of the reporting 2011 - 2013 under the Drinking Water Directive 98/83/EC," European Topic Centre; Inland, coastal, marine waters.

[4] S. Hyllestad, T. Lyngstad, C. Nordheim and K. Janak, "Rapportering av data for vannforsyningssystemer i Norge for 2018," Folkehelseinstituttet, Oslo, 2019.

[5] Liikanen, R. (Finnish Water Utilities Association), "Unpublished data," 2019.

[6] T. Vartiainen, "Desinfiointi varmistaa talousveden mikrobiologisen puhtauden," *Vesitalous,* vol. 48, no. 5, pp. 4-6, 2007.

[7] "MatsVreg-Rutineanalyser - Levert vann - 2014; Mattilsynets skjematjenester MATS - extracted 20.5 2015," Norwegian Institute of Public Health.

[8] M. LeChevallier and A. Kwok-Keung, "Water treatment and pathogen control - process efficiency in achieving safe drinking water," World Health Organization, 2004.

[9] "Quantitative determination of the efficacy of drinking water disinfectants," Umwelt Bundesamt, 2013.

[10] "Guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C)," European Chemicals Agency, Helsinki, 2018.

[11] Anna Mehl, Norwegian Food Safety Authority, *Unpublished data,* 2020.

[12] von Rége, H. Pure Sodium Hypochlorite Biocidal Product Group, e-mail 14th February 2020.

[13] J. Castrén, "Optimization of the disinfection efficiency of ozonation in drinking water treatment (in Finnish)," Tampere University of Technology, Tampere, 2013.

[14] J. Lamminpohja, "Chloramination in Water Treatment (In Finnish)," Metropolia University of Aplied Sciences, 2017.

[15] Umweltbundesamt, "Bekanntmachung der Liste der Aufbereitungsstoffe und Desinfektionsverfahren gemäß § 11 der Trinkwasserverordnun – 17. Änderung –," Bundesanzeiger, 2012.

[16] H. Odegaard, S. Osterhus and B.-M. Pott, "Microbial barrier analysis (MBA) – a guideline," Norwegian Water BA, Hamar, 2014.

[17] "Guidance manual for compliance with the filtration and disinfection requirements for public water systems using surface water sources," U.S Environmental Protection Agency, 1990.

[18] M. Keinänen-Toivola, M. H. Ahonen and T. Kaunisto, “Talousveden laatu Suomessa vuosina 1984-2006,” Vesi-Instituutti/Prizztech Oy, 2007.

[19] “Guidance document for demonstrating efficacy of pool and spa disinfectants in laboratory and field testing,” OECD, 2012.