World Health Organization
REGIONAL OFFICE FOR Europe

Drinking Water Parameter Cooperation Project

Support to the revision of Annex I Council Directive 98/83/EC on the Quality of Water Intended for Human Consumption (Drinking Water Directive)

R e c o m m e n d a t i o n s

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Disclaimer

This document has been produced with the financial assistance of the European Union. The views expressed herein can in no way be taken to reflect the official opinion of the European Union.

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Acronyms and abbreviations

ADI	Acceptable daily intake
B(a)P	Benzo(a)pyrene
BTEX	Benzene, toluene, ethylbenzene and xylene
DALY	Disability adjusted life years
DBP	Disinfection by-product
CFU	Colony forming unit
DVGW	German Technical and Scientific Association for Gas and Water [Deutscher Verein des Gas- und Wasserfaches]
EC	European Commission
EDC	Endocrine disrupting compound
EFSA	European Food Safety Authority
ELISA	Enzyme-linked immunosorbent assay
EU	European Union
E. coli	*Escherichia coli*
GC	Gas chromatography
GV	Guideline value
HAA	Haloacetic acid
HPC	Heterotrophic plate counts
HPLC	High-performance liquid chromatography
ICP	Inductively coupled plasma
IPCS	International Programme on Chemical Safety
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LLE	Liquid-liquid-extraction
LOAEL	Lowest-observed adverse effect level
LOQ	Limit of quantification
LRV	Log removal value
MS	Mass spectrometry
MTBE	Methyl *tert*-butyl ether
NDMA	N-nitrosodimethylamine
NOAEL	No-observed adverse effect level
NTU	Nephelometric turbidity unit
PAH	Polycyclic aromatic hydrocarbon
PCR	Polymerase chain reaction
PFC	Perfluorinated chemicals

PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctanesulfonic acid
PFU	Plaque forming unit
pH	Hydrogen ion concentration
PTWI	Provisional tolerable daily intake
PV	Parametric value
PVC	Polyvinyl chloride
REACH	Registration, evaluation, authorisation and restriction of chemicals
SPE	Solid phase extraction
TCU	True colour unit
TDI	Tolerable daily intake
THM	Trihalomethane
TOC	Total organic carbon
USA	United States of America
US EPA	United States Environmental Protection Agency
UV	Ultraviolet
WHO	World Health Organization
WFD	Water Framework Directive
WSP	Water safety plan

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Summary statement

In the past two decades, Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (Drinking Water Directive) has been instrumental in protecting consumer's health from the possible negative impacts of consumption of contaminated drinking-water. This is demonstrated, *inter alia*, by the latest synthesis report on the quality of drinking-water in the European Union (EU) which confirms high compliance figures between 98.85% and 100.00% for chemical and microbiological parameters covered by Directive Annex I Parts A and B.

While focusing on compliance with essential water quality parameters is an important means for measuring the effectiveness of the Directive in protecting public health, it should be noted that despite high compliance figures outbreaks of infectious waterborne disease remain a common occurrence in the EU. This is mainly due to the fact that such compliance monitoring does not recognize the limited amount of water that can be sampled with highly variable pathogen numbers and that results are usually delivered after exposure has occurred. Such outbreaks cause a serious health burden and may undermine the confidence of EU citizens in the safety of their water supply.

With this in mind, it should be recognized that compliance monitoring of faecal indicator bacteria provides insufficient safeguards to public health and that additional requirements are needed in order to protect EU citizens against exposure to enteric pathogens via drinking-water, particularly viruses and protozoan parasites, as well as opportunistic pathogens that may proliferate in drinking-water systems, particularly *Legionella*.

The second edition of the World Health Organization (WHO) Guidelines for drinking-water quality of 1993 forms the basis for Directive 98/83/EC, specifically with respect to the parametric standards set in Annex I to the Directive which, according to Recital 16, are generally based on the WHO Guidelines.

To address the shortcomings resulting from overemphasis on microbiological compliance monitoring, WHO considered the need for a new approach to assuring drinking-water safety that would be proactive in preventing risks to health. From this emerged the WHO Framework for safe drinking-water, which provides a conceptual basis to manage public health risks from water supplies, as laid down in the third and fourth editions of the WHO Guidelines.

The water safety plan (WSP) approach is a core pillar of the WHO Framework. It provides the most effective means of consistently ensuring the safety of a drinking-water supply through the use of a comprehensive risk assessment and risk management approach that encompasses all steps in water supply from catchment to consumer. For each supply, WSPs lead to the development of a supply-specific profile of chemical and microbiological hazards of local concern, including the events and routes by which those hazards can enter the supply. Such profiles form the basis for effective management, operation and monitoring of water supplies.

With the revision of Annex II to the Directive in October 2015, the European Commission (EC) has taken an important step towards adopting risk-based principles, specifically by requiring in Annex II Part C approved risk assessments as a basis for granting deviations from the list of parameters subject to verification monitoring and default sampling frequencies. Although the introduction of such risk-based monitoring programmes, at the time, was optional, it provided an important impetus for focussing attention and limited resources to hazards of local concern.

This report recommends a number of steps which aim at further improving the level of health protection of European citizens by means of amending the Directive.

The recommended amendments, in their entirety, primarily aim at strengthening a "risk-based lens" in accordance with the WHO Framework for safe drinking-water, and specifically the core requirements of the WSP approach. In synopsis, we recommend:

1. Stipulating periodic catchment appraisals and investigative monitoring of source water quality as part of hazard analysis and risk assessment. Such provisions would be complementary to the requirements of the Water Framework Directive (in conjunction with the Groundwater Directive and Environmental Quality Standards Directive) but then look beyond ecological and chemical status of water bodies and emphasize on health-related aspects of source water protection. Catchment appraisal and investigative source water monitoring are instrumental in systematically identifying, naturally occurring and anthropogenic, microbiological and chemical hazards of local concern, including hazardous events that may threaten source water quality. The outcomes of the assessment would allow regulators and water suppliers to focus attention and resources on locally relevant health risks, direct water treatment needs, support effective catchment protection measures and guide the establishment of risk-based verification monitoring programmes in accordance with the provisions of Annex II Part C of the Directive. Details of these proposals are provided in Chapters 3 and 8.
2. Introducing generic and specific requirements for operational monitoring. Vigilant routine operational monitoring helps to ensure the effectiveness of control measures which is particularly important for maintaining microbiological safety at all times. Operational monitoring is a key requirement of the WSP approach and, if vigilantly undertaken, provides an important additional measure of safety in drinking-water supply. To support provisions on operational monitoring, it is further recommended to re-structure Annex I Part C such that it emphasizes essential parameters for operational monitoring (see also point 6 below). Details of these proposals are provided in Chapters 5 and 16.
3. Refining requirements for assessing and effectively controlling potential health risks from enteric pathogens in drinking-water, specifically for viral and protozoal pathogens, will be an important step in enhancing public health protection. It is specifically proposed to amend the requirements for microbiological verification monitoring in Annex I Part A to include indicators for viral and protozoal

contamination (i.e. in addition to bacterial faecal indicator bacteria), in conjunction with introducing a general requirement for validating the efficacy of existing treatment barriers on the basis of the outcomes of catchment appraisal and investigative monitoring of faecal contamination in source waters (see also point 1 above). Details of these proposals are provided in Chapters 6 and 8, as well as in the corresponding microbiological fact sheets in Appendix 3.

4. Introducing specific requirements for prevention and control of *Legionella* proliferation in warm drinking-water installations in priority buildings. *Legionella* causes a significant health burden in the EU and the highest health burden of all waterborne pathogens. Thereby, addressing *Legionella* in the Directive would present a significant step in protecting the health of EU citizens. We specifically recommend including requirements for risk-based evaluation of drinking-water installations in priority buildings, operational monitoring of temperature (see also point 2 above), verification monitoring of *Legionella* in Annex I Part A with a trigger value which is intended to prompt risk-based responses. Details of these proposals are provided in Chapters 6 and 7, as well as in the corresponding *Legionella* fact sheet in Appendix 3.

5. Amending the list of chemical parameters covered by Annex I Part B, specifically by

    a. Adding six new parameters or parameter groups on the basis of their widespread occurrence, proving their relevance throughout the EU (see Recital 12), and of their respective health concern. Their inclusion would clearly (i) in the case of chlorate, chlorite and haloacetic acids, provide a broader and more robust basis for assessing and controlling disinfection breakdown and by-products in drinking-water; (ii) in the case of microcystin-LR and uranium, address commonly encountered naturally occurring contaminants of source waters; and (iii) in the case of perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) provide focus on a group of industrially-derived substances which occurs widely, shows high persistence in the (water) environment and is of health and public concern. Adding those parameters to Annex I Part B responds to reported occurrence and related concerns expressed by Member States since the adoption of the current Directive. Details of these proposals are provided in Chapter 14 and the corresponding chemical fact sheets in Appendix 6.

    b. Considering removal of five parameters or parameter groups, namely benzene, cyanide, 1,2-dichloroethane, mercury and polycyclic aromatic hydrocarbons (PAHs), on the basis of their physico-chemical characteristics and likely low occurrence in drinking-water. Details of these proposals are provided in Chapter 12.

        The removal of those parameters would not lower the level of health protection but would acknowledge their limited significance in drinking-water throughout the EU context (see also Recital 12) and also avoid diverting attention and resources in terms of verification monitoring.

If any of these substances were to be identified under hazard analysis and risk assessment as of local concern, they would become subject to verification monitoring in accordance with Article 7 (6) in conjunction with Annex II Part C.

c. Updating parametric values for three parameters, namely antimony, boron and selenium, in accordance with the latest available health-based guideline values as published in the first addendum to the fourth edition of the WHO Guidelines. All three values are suggested to be relaxed in comparison to the parametric values in the current Directive. Details of these proposals are provided in Chapter 14 and the corresponding chemical fact sheets in Appendix 6.

   Relaxing the parametric values for these three threshold chemicals would not lower health protection; the newly suggested values reflect new toxicological data and consequent reduction in uncertainty. The proposed values ensure that water intended for human consumption can be consumed safely on a life-long basis, and thus continue to represent a high level of health protection (see also Recital 13).

   It is of note that if the EC wishes to maintain more stringent values, this is a matter of policy choice. In making such choices, however, careful consideration needs to be given to the impact on cost and whether there is sufficient benefit to health to justify increased costs, including consideration of running and renewal costs in meeting the existing limit values. The basis of such decisions should always be made transparent to avoid misunderstanding of the implications of exceeding a standard.

Under consideration of the proposals summarized under points a.–c. above, the amended Annex I Part B provides the list of essential chemical parameters subject to verification monitoring in accordance with Article 5 and in conjunction with Annex II.

The adoption of requirements for catchment appraisal and investigative source water monitoring in the Directive (see point 1 above) provides effective means for systematically identifying chemical hazards of local concern, which may not be covered by Annex I Part B. Such additional substances should continue to be dealt with under the provisions of Article 7 (6) in conjunction with Annex II Part C, which appear to remain effective instruments to protect health.

6. Restructuring in Annex I Part B according to primary source and route to drinking-water to aid clarity and transparency for consumers, water suppliers and regulators and to support decisions on risk-based control and verification monitoring options. Likewise, restructuring of current Annex I Part C seems also appropriate in order to clearly distinguish between those (indicator) parameters which concern the acceptability of consumers and those which are essential for operational monitoring purposes (see also point 2 above). Details of these proposals are provided in Chapters 15 and 16.

1. Introduction

Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption, the Drinking Water Directive (in this document: "the Directive"), was published about 20 years ago. In accordance with Article 11 of the Directive, "*at least every five years the Commission shall review Annex I in the light of scientific and technical progress and shall make proposals for amendments, where necessary*". Recital 16 of the Directive further acknowledges that "*the standards in Annex I are generally based on the World Health Organization's Guidelines for Drinking-water Quality*".

The parametric values of the parameters covered in Annex I were primarily based on the second edition of the World Health Organization (WHO) Guidelines for Drinking-water Quality (in this document: "the Guidelines") (WHO, 1993). There were a number of differences between the Directive and the Guidelines in line with the recommendation of WHO that the Guidelines should be adapted to local or regional conditions.

Since the publication of the Directive there have been two further editions of the Guidelines with a number of changes to WHO guideline values (GVs) in the light of new scientific evidence. The latest, fourth edition of the Guidelines was published in 2011; WHO undertakes regular updates on a rolling basis, and the first addendum to the fourth edition of the Guidelines was published in early 2017 (WHO, 2017a).

In December 2015, the European Commission (EC) and the WHO Regional Office for Europe concluded the "Drinking Water Parameter Cooperation Project". The objective of the project was to provide policy-relevant advice to enable informed, science-based decision making for the potential revision of Annex I of the Directive, specifically to

- Review and evaluate the latest scientific evidence-base as basis for proposing a revised list of parameters with respective health-based values for those currently covered in Annex I;
- Provide a rationale for potential inclusion of new parameters and/or for potential removal of parameters from Annex I;
- Develop parameter fact sheets with a condensed summary of the evidence base, including information relevant to establishing monitoring and control programmes; and
- Review different approaches to and importance of considering mixtures in drinking-water.

This report summarizes the findings and recommendations pursuant to the above objectives. The report is structured in four parts:

- *Part A: General considerations* sets the scene and introduces the building blocks of a risk-based approach to drinking-water quality management which provides the overall framework for this report.

- *Part B: Microbiological aspects* addresses the role of indicator organisms currently covered in Annex I Part A and Part C and provides a rationale for the inclusion of new risk-based provisions in the Directive related to the prevention of *Legionella* and enteric pathogens in drinking-water systems, in accordance with the recommendations of the WHO Guidelines.
- *Part C: Chemical aspects* covers general considerations related to WHO guideline value development, including considerations related to chemical mixtures in drinking-water. It provides a rationale for parameters which are proposed to be dropped from Annex I Part B and those (emerging) contaminants which are proposed to be included in the Directive. It confirms or proposes new health-based parametric values based on the latest available scientific evidence, in accordance with the first addendum to the fourth edition of the WHO Guidelines. Finally, it proposes a grouping of parameters to support their management and control in a risk-based management context.
- *Part D: Indicator parameters* emphasizes the role and importance of indicators for maintaining acceptability of drinking-water to consumers and operational monitoring and controlling of treatment, disinfection and distribution processes. It concludes with a proposal for a revised coverage and structure of the parameters covered in Annex I Part C.

To inform the development of recommendations laid down in this report, we invited European Union (EU) Member States[1] and stakeholders, through official letters sent on 19 May and 13 June 2016 by the EC, to submit data on the occurrence of 20 selected drinking-water contaminants. We received data from 19 Member States and various stakeholders, such as water supply utilities. An overview of the data received and an aggregated summary of the data is shown in Appendix 1. Some of these data are referred to in various sections of this report.

Draft versions of this report have been presented and discussed with Member States and stakeholders in the course of the project. EC and WHO co-organized a large stakeholder consultation (Brussels, 23 September 2016) at which we presented the underlying rationale and preliminary findings of the project, including possible proposals for the revision of Annex I of the Directive; a summary report of the stakeholder consultation is provided in Appendix 2. In addition to the feedback received during the stakeholder consultation, we invited all Member States and stakeholders to submit written feedback on the draft background papers presented at the consultation. We received responses from eleven Member States and seven stakeholders. All relevant feedback was considered during the preparation of the report.

[1] For the purpose of this report, we use the term “Member State” to refer to EU Member States, unless otherwise stated.

In the preparation of this report, we also considered the feedback from and outcomes of further consultations at which we presented the status of work. We specifically consulted with the following groups:

- European Federation of National Associations of Water Services (Lausanne, 2 February 2017) to discuss, among others, the implications of a risk-based approach on management and regulation of microbiological risks in drinking-water, as well as significance and possible coverage of chemical parameters addressed by the Directive;
- EC informal expert group under the Directive (Brussels, 27 March 2017) to discuss role and possible coverage of chemical and indicator parameters in the Directive; and
- Chemical working group of the WHO Guidelines committee (Berlin, 29 March 2017) to discuss approaches to chemical mixtures in drinking-water and the (draft) concept paper that was developed in the course of this project.

Part A: General considerations

2. Risk-based approach

KEY MESSAGES

- The water safety plan (WSP) approach is a core pillar of the WHO Framework for safe drinking-water. WSPs provide the most effective means of consistently ensuring the safety of a drinking-water supply through the use of a comprehensive risk assessment and risk management approach that encompasses all steps in water supply from catchment to consumer.
- The WSP process leads to the development of supply-specific profiles which identify chemical and microbiological hazards of local relevance and concern, including the events and routes by which those hazards can enter the supply.
- Risk-based verification monitoring for chemical hazards is informed by WSPs and allows regulators and water suppliers to focus on the actual risks for a particular supply.
- Vigilant operational monitoring is essential to assure microbiological safety at all times.

Since the publication of the second edition of the Guidelines (WHO, 1993), WHO considered the need for a new approach to assuring drinking-water safety that would be proactive rather than reactive, aimed at preventing risks to health instead of just responding to the occurrence of problems. From this emerged the WHO Framework for safe drinking-water (Figure 1) which provides a conceptual basis to manage public health risks in water supply. Water safety plans (WSPs) are a core pillar of this Framework, as laid down in the third and fourth editions of the WHO Guidelines (WHO, 2004a; 2017a).

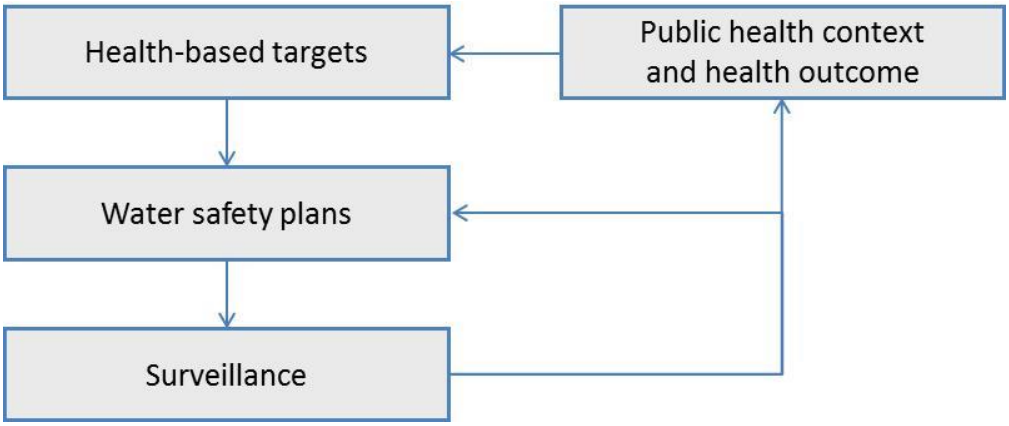

Figure 1. WHO Guidelines framework for safe drinking-water

WSPs are considered as the most effective means of consistently ensuring the safety of a drinking-water supply. The WSP approach presents a preventative risk assessment and management framework which aims at systematically identifying, assessing and managing risks to water supply. WSPs address potential health risks derived from microbial, chemical

and physical hazards that may manifest throughout all steps of the water supply chain. There has been significant momentum and increasing policy recognition of the WSP approach in the WHO European Region. An increasing number of countries have either revised, or plan to revise, their drinking-water regulations to require WSP implementation.

In the WHO Framework for safe drinking-water, WSPs are guided by health-based targets for safe drinking-water supply systems which should be set by high-level health authorities and take into account the overall public health situation and contribution of drinking-water to disease. Health-based targets can be health outcome targets or water quality targets, treatment performance targets or specified technology targets. A system of independent surveillance verifies that the WSP is operating properly.

Essential requirements of the WSP approach are:

- To identify hazards in a supply and assess the risks associated with exposure to those hazards at each supply stage ranging from source water catchment, water abstraction, treatment, storage, distribution to the point of use;
- To establish effective measures to control the risks identified. The selection of control measures should be guided by the multi-barrier approach. Control measures (or barriers or mitigation steps) can start in the catchment with catchment controls continue through the various stages of treatment barriers, of which there are usually several, and include maintaining the high quality drinking-water as it flows through distribution and storage systems, including the plumbing systems in buildings;
- To establish management and operational monitoring procedures to ensure that the chosen control measures operate at their optimum at all times;
- To establish procedures for verification monitoring (in addition to those used in operational monitoring) to determine whether the performance of the drinking-water supply is in compliance with the water quality standards. (Note that verification monitoring may be undertaken by the supplier, surveillance agencies or a combination of the two.)

Further details of the WSP approach and its core requirements are laid down in the WHO Guidelines (WHO, 2017a) and supporting technical guidance, such as the *Water safety plan manual: step-by-step risk management for drinking-water suppliers* (WHO, 2009a) and the *Water safety plan: a field guide to improving drinking-water safety in small communities* (WHO Regional Office for Europe, 2014).

The WSP process leads to the development of supply-specific profiles which identify chemical and microbiological hazards of local relevance and concern, including the events and routes by which those hazards can enter the supply. These profiles allow the water supply operator to identify appropriate management interventions and control measures to minimize the risks of the hazard reaching the consumer in numbers or concentrations that are likely to cause adverse effects, including rejection of aesthetically unacceptable water.

WHO recognized that measuring long lists of chemical parameters in verification monitoring, whether or not they were present, not only diverts attention away from preventing or

reducing the potential for hazards to reach consumers, but was also potentially confusing in terms of demonstrating safety to consumers. It is also not effective as monitoring that targets the hazards identified to be locally the most relevant, is better at making sure that the most important hazards in a supply are being controlled adequately.

In terms of the Directive, the development of local hazard profiles and risk assessments supports regulators to direct analytical resources where they are most needed, rather than following a check list approach in verification monitoring in which all parameters are effectively given equal weight. WHO has termed this approach “risk-based monitoring”, which is now enshrined in Annex II Part C of the Directive.

Risk-based monitoring provides a means of ensuring the best use of resources in focusing on the most pressing problems in any supply for all Member States. One of the significant benefits to come from adopting WSPs is that knowledge of chemical hazards provides much of the evidence for selecting and prioritizing parameters for risk-based monitoring. This also includes targeted sampling by reducing the frequency of monitoring of those substances that were shown not to be present but also by focusing on the most appropriate point to optimize sampling. However, reduced monitoring for microbial parameters is not possible because of the nature of microbiological risks and the fact that microbial parameters are indicators of the presence of a wider range of pathogens (see Chapter 8).

Annex II Part C of the Directive clearly stipulates a risk-based monitoring approach. On the basis of approved risk assessments, it sets criteria for the possible exclusion of parameters listed in Annex I from verification monitoring, possible expansion of the list of parameters covered by Annex I to become subject to verification monitoring in accordance with Article 7 (6) and/or possible reduction of monitoring frequencies stipulated by Annex II Part B.

To further strengthen and enhance a risk-based approach, however, we propose to consider additional provisions in the Directive, specifically:

- To stipulate periodic catchment appraisals and investigative monitoring of source water quality as key pillars of hazard analysis and risk assessment in order to systematically identify natural and anthropogenic catchment hazards of local concern – see Chapter 3 for further detail;
- To strengthen consideration of microbiological and chemical hazards that may develop from domestic plumbing in buildings – see Chapters 4, 6 and 7 for more detail;
- To introduce requirements for operational monitoring – see Chapters 5 and 16 for more detail;
- To refine requirements for assessing and managing risks from enteric pathogens in drinking-water – see Chapters 6 and 8 for more detail.

3. Catchment appraisals and source water quality monitoring

KEY MESSAGES

- Source water protection is a key element in a multi-barrier approach to provide safe drinking-water.
- Catchment appraisal is integral part of the WSP approach.
- Periodic catchment appraisals ensure that water suppliers understand the catchment and sources of hazards and hazardous events that may threaten source water quality.
- Catchment appraisals allow for the appropriate selection of water sources, inform the configuration of water treatment, the design of risk-based source water monitoring activities and support identification of effective catchment protection measures with other stakeholders.
- Investigative monitoring of source water quality, based on the outcomes of the catchment appraisal, is an important element of a risk-based approach to determine contamination levels, trends and variations in occurrence of the hazards of local concern.
- We recommend including generic requirements in the Directive for periodic catchment appraisals and periodic investigative source water quality monitoring.

Water sources used for drinking-water supply include groundwater and surface water, such as rivers, lakes and reservoirs, and seawater. Hazards in source waters include pathogenic microorganisms or chemicals from domestic, agricultural, commercial or natural sources.

Source water protection is a key element in a multi-barrier approach to provide safe drinking-water. Understanding the catchment characteristics and source water quality, including its variations, is vital to support the identification, assessment and prioritization of the risks, and the development of management strategies for their control. Where source water quality is sufficiently well protected, water sources are secured for water supply – now and in the future. Well protected water resources may also require less (additional) treatment efforts, and the provision of safe drinking-water may be achieved with greater reliability. This is particularly relevant in resource limited settings, such as small water supplies in rural areas, where there may be a lack of effective and reliable water treatment.

Catchment appraisal is a vital and integral element in a risk-based approach. The core elements of identification and assessment of catchment-derived hazards and risks in drinking-water are comprehensively described in *Protecting groundwater for health: managing the quality of drinking-water sources* (WHO, 2006a) and *Protecting surface water for health: identifying, assessing and managing drinking-water quality risks in surface-water catchments* (WHO, 2016a).

Catchment appraisal serves various purposes:

- A thorough understanding of catchment characteristics and source-water quality, including its trends and variations, allows for the careful selection and protection of water sources for water supply. This is the first and most important element in safe water supply.
- A good understanding of the contamination sources and pathways in the catchment and the vulnerability of source-water to water quality deterioration due to weather events, human activity, accidental discharges or other events, are key to design appropriate water treatment. Short-term variations are of particular importance to the microbial source water quality, and monitoring programs for microbiological indicators need to be suited to track and understand the (sources of) faecal contamination of source water.

Catchment appraisal is a building block that fulfils the rationale of the recent amendment of Annex II of the Directive where "*results of monitoring (…) should be used to determine the potential risk for drinking water before and after treatment*". Catchment appraisal is essential to the design of risk-based monitoring programs to focus on those parameters and moments/events of primary concern in a given catchment.

The outcomes of catchment appraisal should guide the scope of investigative monitoring of chemical and microbiological parameters in source water to determine contamination levels, trends and variations in occurrence of hazards (i.e. considering those hazards that might be present in the catchment in addition to the parameters listed in the Directive). The outcomes of the catchment appraisal will specifically inform the selection of locally relevant parameters (both naturally occurring and of anthropogenic origin) subject to investigative monitoring, as opposed to pre-defined monitoring requirements of substances that may not be present in the local context. For instance, catchment appraisal would investigate and map the use of chemicals in the catchment area (e.g. pesticides) and thus provide the basis for the design of an efficient investigative monitoring program to plan new and evaluate existing catchment control measures and trends in source-water quality.

Catchment appraisal and investigative source water monitoring ensure that the individual drinking-water supplier knows the composition of their specific source water and understands the hazards and hazardous events that may threaten drinking-water safety. This is key information "downstream" to target the water treatment, but certainly also "upstream" to foster effective catchment protection with/by the other stakeholders.

Managing risks to public health that arise from drinking-water is often seen as the primary duty of the water supplier. However, most catchments are used by various stakeholders, including for purposes that may contaminate the source water used for drinking-water. In such cases, close collaboration is required between the water suppliers and stakeholders who can take action, as well as with environment/catchment authorities responsible for surveillance of activities in the catchment, to achieve regulatory arrangements that ensure safe water supply is given the appropriate priority.

Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (Water

Framework Directive; WFD) aims to achieve a holistic way to efficiently protect water bodies in the EU, including those that serve as source for drinking-water supply. While this is a useful basis for providing safe drinking-water, the focus of the WFD and its "daughter" Directive 2006/118/EC on the protection of groundwater against pollution and deterioration (Groundwater Directive), however, is on good ecological and chemical status, but does not cover microbiological quality, which is essential for maintaining safe drinking-water supply. Although WFD Article 7 regulates the protection of water bodies used for drinking-water supply, and gives monitoring requirements for these waters, the priority substances list for surface waters does not necessarily reflect locally relevant priorities in a given water supply. Equally, this applies to groundwater quality standards as per Annex I and the minimum list of groundwater pollutants as per Annex II of the Groundwater Directive. Therefore, the Directive needs an approach complementary to the WFD Article 7 and the Groundwater Directive.

We therefore recommend including generic requirements in the Directive which stipulate:

- Periodic catchment appraisals to identify chemical and microbiological source water hazards of local concern, including catchment appraisals in response to known changes of human activity in the catchment area and/or in response to source-related drinking-water quality incidents;
- Periodic investigative source water monitoring based on the outcomes of the catchment appraisal, taking into consideration and capitalizing on existing monitoring programmes in the context of the WFD, Groundwater Directive and Directive 2013/39/EU of the European Parliament and the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy (Environmental Quality Standards Directive).

Such requirements are essential for the individual drinking-water supplier and relevant local authorities to trigger understanding of specific source-water related hazards to human health, to design effective, health-risk-based catchment protection measures, to set treatment performance targets and inform the configuration of water treatment and to design risk-based operational monitoring programmes.

In the context of strengthening the assessment and control of risks from enteric pathogens in drinking-water, specific requirements for catchment appraisal and microbial source water quality monitoring are proposed in Chapter 8, including a proposal for consideration of new parameters (i.e. somatic coliphages).

4. Water safety in buildings

KEY MESSAGES

- It is essential that those buildings in which a significant number of vulnerable members of the population are likely to be present should be given priority for risk assessment and management. Those areas in which there is a high risk of the presence of lead in drinking-water should also be made a priority for management.
- It is important that appropriate monitoring requirements for *Legionella* and toxic metals, particularly lead, should be established by Member States to identify where the greatest risks lie and to facilitate the introduction of management procedures where they are of greatest need.
- An approval system that ensures only suitable materials are used in contact with drinking-water is strongly recommended.
- In many, if not most, jurisdictions in the EU, buildings are not under the control of the water supplier. Thereby we recommend including a requirement in the Directive for those responsible for managing water quality in buildings.

The WHO Guidelines refer to the need for managing the water supply system from source to the consumer's tap. Likewise, the Directive considers the quality of water at the tap, including that from hot water systems. Article 1 of the Directive defines water intended for human consumption as "*all water either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes*" and Article 6 stipulates that the point of compliance is "*in the case of water supplied from a distribution network, at the point, within premises or an establishment, at which it emerges from the taps that are normally used for human consumption*".

The chemical and microbiological quality of water can and does change between the point the water enters the building and the consumer's tap. Therefore, the systematic management of water in buildings is a vital part of maintaining drinking-water safety.

With respect to microbiological hazards, there is the potential for regrowth of microorganisms with *Legionella* and other opportunistic pathogens, such as *Pseudomonas aeruginosa,* of concern to health. *Legionella* is a problem as a consequence of inhalation of droplets carrying the organisms, leading to serious lung infections, and *Pseudomonas aeruginosa* is a potential problem for vulnerable persons, particularly in hospitals or other institutions via contact with or inhalation of water (droplets) where it can cause a range of serious infections that can be difficult to treat because of their resistance to antibiotics.

Systematic system assessment for the potential to support the growth of potentially pathogenic bacteria and testing for the presence of *Legionella* should become a key requirement in the Directive for safely managing water systems in buildings accessed by the public, particularly those in which vulnerable populations are likely to be present (e.g.

hospitals and other healthcare facilities, nursing homes) and others in which members of the public will be present for extended periods and potentially exposed to aerosols (e.g. hotels, saunas and sports centres). Further details on the health significance of *Legionella* and concrete proposals for consideration of *Legionella* prevention in the Directive are provided in Chapter 7.

Another high risk circumstance that can lead to the introduction of pathogens is that of inadvertent cross connections made between unsafe water, such as wastewater or greywater, and drinking-water systems. Therefore, appropriate codes of practice ensuring reliable separation of systems and training of plumbers should also be part of managing water quality in buildings.

The materials used in pipework and fittings necessary for plumbing in buildings and in the connections to the mains supply are also important in terms maintaining the quality of drinking-water at the consumer's tap. Both metallic and non-metallic fittings may cause chemical contamination of the drinking-water and consumer acceptability (i.e. odour and taste) problems; furthermore, organic materials may also be conducive to the growth of biofilms harbouring *Legionella*. It is therefore recommended in the WHO Guidelines that approval systems should be established to ensure that only approved materials and fittings in contact with drinking-water that do not cause levels of contamination that would be of concern are used in water supply and in buildings. While there are several Member States which operate approval systems and cooperate closely there is, at the moment, no EU-wide scheme.

Metal corrosion resulting in contamination of drinking-water is a recognized phenomenon that has been known for many decades. The current Directive addresses a number of metals in Annex I Part B that can dissolve in water from service connections, pipework and fittings in buildings (e.g. cadmium, copper, lead, nickel). There are many existing plumbing systems which contain metals that give rise to concentrations of concern for health, particularly lead. Because the concentrations vary significantly dependent on the materials in contact with water, the water quality and the period over which the water has been in contact with the metals, the protocols for taking samples need to recognize this variation. Generally protocols will need to reflect a reasonable worst case situation (i.e. to give the greatest chance of demonstrating whether a problem exists) to identify the presence of metals at elevated concentrations and the need for appropriate management and corrective action, which may include corrosion control and pipe or fittings replacement. In the Directive context, we recommend stipulating harmonized protocols for the sampling of plumbing systems in buildings. Such protocols support the production of comparable water quality results across Member States and provide a reliable framework for informing management and corrective action in buildings.

The plumbing system of buildings is the final stage in managing risks from source to tap. Although managing water quality in buildings can be complicated due to differing legal responsibilities and jurisdictions, it cannot be ignored. The effective management of risks in buildings is an essential step in providing consumers with safe drinking-water at the tap. To

further strengthen management of water safety in buildings, we recommend that the Directive:

- Includes a generic provision to ensure that Member States establish a requirement to manage water quality in buildings and who has responsibility for managing the water quality in buildings;
- Introduces specific requirements for the prevention and control of *Legionella* in buildings – for further details see Chapter 7;
- Continues ongoing efforts towards introducing an EU-wide approval scheme for materials in contact with drinking-water; and
- Stipulates harmonized protocols for sampling of plumbing systems in buildings. A number of Member States have existing protocols for sampling of metals from plumbing systems and identifying problem areas and problem buildings (e.g. German Environment Agency, 2004); these should provide the basis for a harmonised protocol.

WHO has made available guidance for risk-based management of water quality in building in the documents *Water safety in buildings* (WHO, 2011a) and *Legionella and the prevention of legionellosis* (WHO, 2007a).

5. Operational monitoring

KEY MESSAGES

- Vigilant operational monitoring is complementary to verification (or compliance) monitoring and essential for maintaining the safety of a drinking-water supply.
- The value of operational monitoring is the (rapid) insight in operational performance and water quality problems, allowing (rapid, pre-planned) corrective action.
- Operational monitoring entails both a set of simple and rapid (on line) water quality tests and visual observations/inspections. The latter are particularly useful in small-scale systems.
- We recommend placing a generic requirement in the Directive for operational monitoring programmes, as well as specific requirements for essential operational monitoring parameters.

As outlined in Chapter 2, the WSP approach requires two complementary types of monitoring – operational monitoring and verification monitoring.

The purpose of verification monitoring – frequently also referred to as compliance monitoring and/or end-product testing – is to confirm at the point of compliance whether the drinking-water is meeting the established water quality standards. In the Directive's context, minimum requirements for verification monitoring are set by Article 5 in terms of parameter coverage and parametric values (as per Annex I) and by Article 7 in terms of appropriate monitoring programmes (as per Annex II).

Operational monitoring is complementary to verification monitoring. Operational monitoring is the ongoing, planned set of activities to demonstrate that the control measures in a water supply system continue to work effectively (as planned) to prevent hazards from reaching the water consumer. In the WHO Guidelines, operational monitoring is placed at the heart of the Framework for safe drinking-water. This is in line with Annex II of the Directive, that specifies in Part A Number 1 (a) that monitoring programmes are to "*verify that the measures in place to control risks to human health throughout the water supply chain from the catchment area through abstraction, treatment and storage to distribution are working effectively and that water at the point of compliance is wholesome and clean*".

Operational monitoring enables timely detection of operational or water quality problems, so that action can be taken prior to the supply of unsafe drinking-water. Timely detection of problems is particularly relevant for microbiological safety. A breach of the control measures leading to a contamination of water with pathogens causes acute health risks. Safeguarding drinking-water against the risks of pathogens requires continuous vigilance. Therefore, frequent to continuous monitoring of the efficacy of control measures against pathogen risks is essential.

Operational monitoring entails both

- Simple and rapid (online) water quality tests (such as turbidity, chlorine residual); and
- Visual observation (such as inspections of well-head integrity or the follow-up of hygiene protocols during mains repairs). Routine visual observations/inspections are effective to identify many important hazards and/or causes of failure. They are particularly important and useful in small-scale systems where the frequency of verification testing is typically low and reliance on analytical results alone is especially inappropriate.

Tests and observations should be selected that are specific to the local water supply system and the control measures in place, and the hazards of local concern. The frequency of testing/observing may vary widely, from continuous monitoring of water quality parameters (such as turbidity) to quarterly inspections of observable infrastructure and catchment features, and should be appropriate to the risk associated with possible failure of the control measures. The value of operational monitoring is in the simplicity and ability to give (rapid) insight in operational performance and water quality problems, allowing (rapid) correction to restore control.

It is important and good practice to predefine the operational window and critical limits (limits that trigger corrective action) for each of the parameters in operational monitoring. Corrective actions are aimed to bring the control measure, and water supply system as a whole, back into proper operation. Wherever possible, corrective actions should be predefined and planned to ensure that they can be put in place quickly.

Any events that lead to local change in conditions (such as heavy rainfall, snowmelt), in river flow or visible water quality conditions (such as heavy turbidity, algae blooms) should trigger increased vigilance, including on operational monitoring and possibly tuning of the control measures to the event conditions. If these events are known to occur in the water supply system, the response to such events should also be pre-planned.

Operational monitoring can be conducted in all relevant steps of the water supply system, from catchment to consumer. Examples of operational monitoring parameters are:

- For catchment and source waters: turbidity, ultraviolet (UV) absorbency, algal growth, river flow, colour, conductivity, local meteorological events and integrity of protective (e.g. fences) or abstraction infrastructures (e.g. well seals);
- For treatment: flow, chemical dosage, disinfectant concentration and contact time, UV intensity, hydrogen ion concentration (pH), light absorbency, membrane integrity, turbidity and colour;
- For piped distribution systems: chlorine residual, integrity of reservoirs, hygiene protocols for repair works, pressure and turbidity;
- For buildings: hot water and cold water temperature; and
- For non-piped systems: turbidity, colour, cleanliness of collection containers and integrity of protective or abstraction infrastructures.

Vigilant operational monitoring is essential for maintaining the safety of a drinking-water supply. To further strengthen risk-based management and operation in the context of the Directive, we recommend:

- Placing a generic requirement in the Directive stipulating the establishment of appropriate operational monitoring programmes for each drinking-water supply system. Such programmes should be supply system specific, taking into account the outcomes of the local hazard analysis and risk assessment, and intended to confirm the effectiveness of all control measures in abstraction, treatment, distribution and storage; and
- Including specific requirements for essential operational monitoring parameters, specifically (i) turbidity at appropriate points in the water supply system, including for filtration processes; (ii) temperature of hot water in buildings; and (iii) appropriate parameters to monitor the performance of disinfection processes (e.g. chlorination, UV light, ozonation), if applied. Chapters 7, 8 and 16 provide more background on these essential parameters, as well as concrete proposals for the possible incorporation in Annex I Part C of the Directive

Part B: Microbiological aspects

6. Microbial safety of drinking-water in the Directive and the WHO Guidelines

KEY MESSAGES

- The way the Directive has operationalized the general obligation of Article 4 for the assessment of microbial safety of drinking-water by point-of-compliance testing for faecal indicator bacteria and heterotrophic plate counts provides insufficient safeguards to public health.
- Additional requirements are needed to protect EU citizens against enteric pathogens, particularly viruses and protozoan parasites, and opportunistic pathogens that may proliferate in the drinking-water network or plumbing systems, particularly Legionella.
- The occurrence of outbreaks of legionellosis and intestinal illness via drinking-water systems causes a serious health burden and may undermine the confidence of EU citizens in the safety of their water supply.

6.1 General obligation

A straightforward comparison of the microbiological parameters in Annex I of the Directive with the WHO Guidelines does not do justice to the paradigm change in assessing the microbiological safety of drinking-water introduced since the third and fourth edition of the Guidelines. Therefore, this chapter aims to give a brief overview of the rationale for a new, risk-based paradigm as the backbone of the Guidelines with an emphasis on microbiological safety.

The general principle in the WHO Guidelines is: *"Safe drinking-water, as defined by the Guidelines, does not represent any significant risk to health over a lifetime of consumption, including different sensitivities that may occur between life stages."*

This is essentially the same principle as stated in the general obligation of Article 4 of the Directive: *"(…) Member States shall take the measures necessary to ensure that water intended for human consumption is wholesome and clean. For the purposes of the minimum requirements of this Directive, water intended for human consumption shall be wholesome and clean if it (…) is free from any micro-organisms and parasites and from any substances which, in numbers or concentrations, constitute a potential danger to human health."*

It could be argued that reference to the "potential danger" in the Directive is stricter than the "significant risk" referred to in the WHO Guidelines. However, it is important to consider how this general principle is translated into practical requirements.

6.2 Role and limitations of indicators in controlling enteric pathogens

The Directive's general obligation of Article 4 is translated into minimum water quality requirements for microbiological parameters set out in Annex I Part A. These parameters are

E. coli and enterococci. The minimum water quality requirement is defined as their absence in 100 mL of water.

The rationale for selecting *E. coli* and enterococci is their role in the evaluation of the safety of drinking-water with regard to enteric pathogens (i.e. pathogenic micro-organisms that infect the intestinal tract). Such pathogens are spread via excreta (and for some: urine) of humans and, for several of these pathogens, also via excreta of warm-blooded animals. Contamination of drinking-water with excreta containing these pathogens can cause illness when the water is consumed. Contamination with excreta is still the most significant and frequently occurring health risk through drinking-water exposure.

E. coli and enterococci are present in high numbers in the intestinal tract of all healthy people. The rationale for setting minimum quality requirements for these two parameters is their indicator function: both parameters – if present in water – indicate (a recent) contamination with human or (warm-blooded) animal excreta in water.

The indicator concept was developed already more than 100 years ago: Schardinger proposed in 1892 that, since *E. coli* (then called *Bacterium coli*) was a characteristic component of the faecal flora, its presence in water could be taken as *"an indication of the presence of faecal pollution and therefore of the potential presence of enteric pathogens"* (Schardinger, 1892).

There is a wide range of bacterial, viral, protozoal and helminth pathogens that may be present in excreta and for which there is evidence that they can occur in drinking-water and cause waterborne disease (i.e. bacteria such as *Campylobacter, Salmonella, Shigella,* enterohemorrhagic *E. coli;* viruses such as norovirus, enterovirus, adenovirus, rotavirus, hepatitis A and E virus; parasitic protozoa such as *Cryptosporidium* and *Giardia;* helminths such as *Ascaris*). Cost and complexity in pathogen testing would make an approach aiming at assaying water for all possible enteric pathogens unrealistic and very expensive. As the common source of all of these pathogens is faecal pollution, faecal indicator bacteria such as *E. coli* and enterococci are used world-wide to indicate whether drinking-water is contaminated with human or animal excreta. Their presence indicates that enteric pathogens may be present; hence the drinking-water is unsafe. In the current Directive, these two parameters are used to cover the assessment of drinking-water safety for the whole suite of enteric pathogens. This approach of capturing all health-risks associated with enteric pathogens by two indicator parameters is markedly different from health-associated chemical parameters, where a more individual parameter approach is used.

E. coli and to a lesser extent enterococci, are undoubtedly the most commonly used microbial parameters for testing drinking-water quality in the EU and world-wide. Their use has led to significant improvement in the safety of drinking-water in the EU and world-wide. They have been adopted already in the first edition of the WHO Guidelines, in the Directive and virtually in all national drinking-water quality standards globally. One of the main reasons for their success was and is the ease (and low cost) of the assay.

The use of these microbial indicators, however, has serious shortcomings. These have been summarized as "*too little and too late*" (OECD and WHO, 2003).

"Too late": The gap between a contamination incident and detection by E. coli monitoring

A major shortcoming for public health protection is that monitoring the microbial safety of drinking-water is reactive, in the sense that any incident or breakdown in the water supply system can occur many hours and sometimes days before it is detected by monitoring of any of the microbial indicator parameters. The water has been consumed before the microbial test results are reported. This is related to the nature of the microbial testing which currently requires at least a day to produce a result. It is also related to the monitoring strategy which frequently focuses on finished drinking-water as it leaves the treatment works and in the distribution system, rather than on source water to identify peak events in time to take appropriate response measures. Also, the sampling frequencies typically stipulated for compliance monitoring in distribution networks suggest that contamination events in the distribution network have a low probability of being detected, let alone that timely corrective actions can be taken. Water utilities are expected to be in control of the water quality they supply and demonstrate due diligence. The use of *E. coli* and enterococci for end-product or compliance monitoring with methods that produce results slowly (i.e. within days) is not sufficient. Illustrative is the observation that many waterborne outbreaks are first "detected" by consumer complaints about water quality changes; see overview of outbreaks in France (Therre et al., 2008) and for instance the large outbreaks through municipal water supplies in Finland in 2007 (Miettinen et al., 2012) and in Belgium in 2010 (Braeye et al., 2015).

"Too little": Limited indication of enteric viruses and protozoa

The use of *E. coli* and enterococci as bacterial indicators of faecal pollution has proved successful in preventing the spread of waterborne bacterial pathogens of faecal origin, such as cholera and typhoid.

However, they are less suitable for preventing the spread of viruses and parasitic protozoa. Already since the 1960s it has been recognized that enteric viruses, such as hepatitis A, enteroviruses, noroviruses, rotaviruses, can be transmitted through drinking-water. Virus contamination of water also originates from pollution with human excreta but the nature of viruses is very different from that of bacteria. They are much smaller than bacteria (i.e. 20–80 nm in comparison to 0.5–2.0 µm) and therefore less likely to be removed during filtration or soil passage. Also, their resistance to disinfection is typically higher than bacteria, ranging from high resistance of hepatitis A virus to chlorination to the very high resistance of adenovirus to UV irradiation. The occurrence of outbreaks of viral illnesses associated with drinking-water which was in compliance with *E. coli* standards indicates that *E. coli* is an inadequate parameter to assess the virological safety of treated drinking-water (Maunula et al., 2005).

Since the 1990s, a further challenge was identified with the drinking-waterborne outbreaks of intestinal illness due to parasitic protozoa, mainly *Giardia* and *Cryptosporidium*. As with viruses, large waterborne outbreaks have occurred, also in the EU, without any indication from *E. coli* testing that water quality was compromised (see early *Cryptosporidium*

outbreaks in England and Wales (Badenoch, 1990), large *Cryptosporidium* outbreaks in Sweden (Widerström et al., 2014) and Ireland (Pelly et al., 2007). *Giardia* and particularly *Cryptosporidium* are far more robust in the environment, and survive much longer in water and resist chemical disinfection far better than the indicator bacteria.

Several Member States and non-EU countries have responded to this shortcoming by explicitly targeting *Cryptosporidium,* or both protozoa and viruses, in their national drinking-water regulation. They updated their drinking-water regulation or national recommendations with respect to the adoption of the WSP approach and/or management strategies for specific (groups of) pathogens. Several examples are given in Table 1.

Table 1. Examples of drinking-water regulations and guidelines with additional control strategies for microbial safety

Country	**Regulation**	**Additional requirements**	**Reference**
Australia	Australian drinking water guidelines	Preventive risk management approach	Australian National Health and Research Council (2016)
Canada	Guidelines for Canadian drinking water quality	Enteric viruses, enteric protozoa (*Giardia, Cryptosporidium*) Treatment performance	Government of Canada (2017)
France	Order on the surveillance of Legionella in domestic hot water production, storage and distribution installations	*Legionella pneumophila*	Government of France (2017)
Germany	Drinking water ordinance	Legionella, hazard analysis	Government of Germany (2017)
	Recommendations by the German Environment Agency	Risk assessment of enteric viruses and protozoa	German Environment Agency (2014)
Netherlands	Drinking water decree	Risk assessment of enteric bacteria, viruses, protozoa, *Legionella*	Government of the Netherlands (2011)
New Zealand	Drinking water standards for New Zealand	*Cryptosporidium* monitoring *Cryptosporidium*, bacteria and virus treatment performance	Ministry of Health New Zealand (2008)
United Kingdom: England and Wales	Water supply (water quality) regulations 2001	*Cryptosporidium* risk assessment (no longer in force)	England and Wales (2001)
	Water supply (water quality) regulations 2016	Risk assessment, drinking-water safety plans	England and Wales (2016)
United Kingdom: Scotland	Public water supplies (Scotland) regulations 2014	*Cryptosporidium* risk assessment	Scotland (2014)
United States of America (USA)	Surface water treatment rules	Bacteria, *Giardia*, viruses, *Legionella* Treatment performance	US EPA (1989)
	Long term 2 enhanced surface water treatment rule	*Cryptosporidium* Treatment performance	US EPA (2006a)

Generally speaking these regulations and recommendations are not simply an extension of the list of water quality standards and monitoring requirements, but focus much more on risk assessment and risk management of all the relevant elements of the water supply system and whether they are capable of producing and delivering microbially safe drinking-water.

6.3 Legionella in drinking-water systems

Unlike the enteric pathogens, opportunistic pathogens are not from faecal origin but naturally occur and grow in (specific) water environments. They include *Legionella pneumophila*, *Pseudomonas aeruginosa,* non-tuberculous mycobacteria and others. They can be present in drinking-water and have been associated with illness through drinking-water.

Legionellosis is a serious form of pneumonia that is caused by inhalation of water droplets (aerosols) from warm water systems in which *Legionella* can multiply. Legionellosis is, unlike gastro-intestinal infections that are spread via food and from person to person, almost exclusively associated with (aerosols originating from) water systems, including warm drinking-water systems in buildings, but also cooling towers, fountains etc. The reported incidence in the EU is 11.4 per million Europeans, which amounts to about 6,000 cases per year with a fatality rate of 10% (ECDC, 2014), while the rate of the milder and usually self-limiting “Pontiac Fever” (causing flu-like symptoms for a few days) is estimated to be at least 10-fold higher, thus causing a considerable disease burden (Brodhun & Buchholz, 2011). The reported incidence of legionellosis (i.e. the severe pneumonia caused by *Legionella*) varies significantly between Member States from 0.1 to 40 per million. Due to under-diagnosis and under-reporting, the true incidence may be considerably higher than what is reported.

Because legionellosis is generally a severe disease, the costs associated with legionellosis are substantial. For the USA, with an estimated 13,000 hospitalizations due to legionellosis, the direct healthcare costs amount to 434 million US$ per annum (Collier et al., 2012). A study on legionellosis among pneumonia cases in Germany indicated that *Legionella* was a leading cause of community-acquired pneumonia in Germany (von Baum et al., 2008). While around 900 legionellosis cases are reported through the infectious disease reporting system, von Baum et al. estimate 15,000–30,000 community-acquired cases of legionellosis annually in Germany. More than 80% of all legionellosis cases are caused by *L. pneumophila* serogroup 1.

Legionella and the other opportunistic pathogens are a particular control challenge and require multi-stakeholder involvement (water supplier and building owner) for adequate control. *Legionella* has been found throughout the water distribution system: from the mains supply to the consumer’s showerhead. It has been found in the plumbing system of many types of buildings, including hospitals, hotels and homes. *Legionella* resides in the biofilm and appears to proliferate inside amoebae that feed on the biofilm. Control of proliferation of *Legionella* in water networks and plumbing systems require adequate control of microbial growth in these systems, particularly control of conditions that favour

proliferation of *Legionella* (such as elevated temperatures). Adequate control of *Legionella* and other opportunistic pathogens requires control of the water treatment (removal of nutrients for biofilm growth), distribution network (materials, residence time, possibly disinfection residual) and in-house plumbing system (temperature, materials). The main points for control of proliferation of *Legionella* lie within the buildings' plumbing systems. Similarly, control of *P. aeruginosa* requires proper design and operation of health care water systems.

The parameter for the general bacteriological quality of drinking-water in the Directive (i.e. colony counts at 22°C) is not directly related to *Legionella* or other opportunistic pathogens, and meeting the parametric value for colony counts is not sufficiently protective against *Legionella* and other opportunistic pathogens (for further details see Section 7.5). So, the current Directive does not offer adequate protection against *Legionella* or other opportunistic pathogens that may grow in drinking-water systems.

Several Member States have implemented codes for *Legionella* control and prevention as part of their occupational safety regulations, under Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (Sas, 2011). The Directive requires the employer to develop a risk assessment scheme, thus reducing the exposure of their employees to biological agents such as *Legionella.* This implies that many public buildings fall under this regulation. The protection focuses on the employees however, and (vulnerable) occupants, such as elderly or hospital patients, are not taken into account. Several Member States have specific standards or guidelines for risk assessment and risk management of *Legionella* in building plumbing systems, mostly focused on warm water systems (and other water systems, such as cooling towers). Some Member States (e.g. Germany, Netherlands) have embedded *Legionella* control by risk assessment and monitoring of warm water systems in the national drinking-water legislation (see also Table 1). However, in the wake of better insulation of buildings to mitigate energy demand for heating or cooling, insufficiently insulated cold water systems can become warmer. Cold water systems that get too warm are increasingly being recognised as a further relevant source of *Legionella*.

6.4 Other microbial risks

6.4.1 Pseudomonas aeruginosa

Pseudomonas aeruginosa is a potential problem in hospitals or other institutions via skin or wound contact with or inhalation of water (droplets) where it can cause a range of serious infections in persons with a predisposing factor, such as burn wounds or persons with cystic fibrosis or immunocompromised persons. These are progressive, serious infections that become more difficult to treat because of the development of antibiotic resistance. *P. aeruginosa* infections have been linked to water systems in healthcare settings, such as sinks and baths, warm water systems and showers. While *P. aeruginosa* has been shown to cause waterborne infections in health-care settings, there is little evidence that normal uses of drinking-water are a source of such infections in the general population. It is therefore not

recommended to include *P. aeruginosa* as parameter for drinking-water monitoring in the Directive. A few Member States have dedicated requirements for control of *P. aeruginosa* in hospitals (e.g. United Kingdom, Germany) (German Environment Agency, 2017; DoH, 2017). We recommend monitoring the trend of *P. aeruginosa* infections and the association to (hospital) water installations and evaluate this again during the next revision of the Directive.

6.4.2 Antibiotic resistance

The discharge of antibiotic resistant bacteria and the ability of resistance genes to transfer to other bacteria in the environment are increasingly recognized as important public health issues (Berendonk et al., 2015). In general, the current Directive and recommendations in this report to control health risks from enteric bacteria via drinking-water will also ensure very high removal and inactivation of antibiotic resistant bacteria. Adequate control of enteric bacteria therefore also implies that drinking-water is adequately controlled against antibiotic resistant bacteria. Elements where adequate control is uncertain are:

- The risk of transfer of antibiotic resistance genes, particularly the carbapenem, vancomycin and fluoroquinolone resistance genes, to bacteria that are adapted to life in water treatment or distribution networks. This might lead to the presence of relevant antibiotic resistance genes in drinking-water. However, whether and to what extent this occurs in practice and under what conditions this can or cannot occur is insufficiently researched and understood to currently recommend specific control measures for antibiotic resistance genes in drinking-water.
- Occurrence and growth of antibiotic resistant bacteria in drinking-water distribution networks and plumbing installations. There have been reports of antibiotic resistant *P. aeruginosa* (see Section 6.4.1) and antibiotic resistant coliforms in water installations in hospitals. If recurrent presence of coliforms is detected in hospitals during the verification monitoring for coliforms (see Chapter 7), it is advisable to check for the presence of antibiotic resistance genes in these bacteria and notify the hospital and health agency if these resistant bacteria are found.

The European One Health Action Plan against Antimicrobial Resistance (EC, 2017) has stipulated that stronger evidence is needed about the role of the environment in the transmission of antibiotic resistance. In line with this Action Plan, we recommend research to capture trends in the occurrence of antibiotic resistant bacteria and resistance genes and the association to drinking-water supply and (hospital) water installations. The European Action Plan identifies the watch list under the WFD as a vehicle for monitoring the presence of antimicrobials in the environment. We support this from the perspective of provision of safe drinking-water. We also recommend incorporating relevant antimicrobial resistant bacteria in the WFD watch list and evaluating the evidence again during the next revision of the Directive.

6.5 Current parameters are insufficient to ensure microbial drinking-water safety

The shortcomings of the current parameters in the Directive addressed above have a very important implication: they imply that end-product (compliance) testing of drinking-water for faecal indicator bacteria and colony counts provides insufficient safeguards to public health. With the current state of knowledge about microbial safety of drinking-water, the view that the general obligation of Article 4 of the Directive is fulfilled with focusing on compliance testing requirements for *E. coli*, enterococci and colony counts can no longer be maintained.

The Directive offers insufficient protection against enteric pathogens, particularly viruses and protozoan parasites, and opportunistic pathogens that may grow in the drinking-water distribution network and plumbing systems in buildings. Legionellosis is almost exclusively waterborne and the health burden and cost in the EU is significant and largely preventable. The occurrence of outbreaks of legionellosis and intestinal illness via drinking-water systems may undermine the confidence of EU citizens in the safety of their water supply.

7. Provisions for prevention and control of Legionella

KEY MESSAGES

- We recommend including a requirement to assess the risk of *Legionella* proliferation in warm drinking-water installations in priority buildings.
- We recommend including a requirement for operational monitoring of temperature to confirm effective operation of control measures that should prevent *Legionella* proliferation.
- We recommend including a requirement for verification monitoring of *Legionella* with a trigger value which is intended to prompt corrective action to prevent further *Legionella* proliferation.
- We recommend a risk-based response to an exceedance of the trigger value, requiring more strict and rapid corrective actions when higher *Legionella* concentrations are found.
- Options to make the requirements more risk-based and control costs are discussed.

7.1 Legionella under the Directive

The current Directive does not offer adequate protection against *Legionella* in public water systems; the current parameters in the Directive do not cover the control of *Legionella*. *Legionella* is transmitted through inhalation of aerosols and not by ingestion (human consumption); however, as indicated in Chapter 4, water intended for other domestic purposes (such a showering) also falls under the scope of the Directive.

Environmental investigation around the legionellosis cases in Europe shows that cooling towers most frequently contain *Legionella* and that *Legionella* strains match the strains isolated from the case. *Legionella* also proliferates in warm water systems. It has been isolated from water installations in domestic premises; for example, in a study of sporadic cases of legionellosis in the United Kingdom, legionellae were isolated from approximately 15% of the homes of infected patients but from only about 5% of homes tested as controls (Coward et al., 1999). The contribution of (warm) water systems in buildings and homes to the incidence of legionellosis in Europe is difficult to quantify. It is likely, however, that part of the sporadic legionellosis is associated with *Legionella* from warm water plumbing and clusters of legionellosis cases have been linked to plumbing systems.

We recommend incorporating provisions for *Legionella* control in the Directive, based on the following rationale:

- *Legionella* causes a significant health burden in the EU;
- *Legionella* causes the highest health burden of all waterborne pathogens;
- *Legionella* is, *inter alia*, transmitted via (warm) water systems in buildings;

- Adequate control of (warm) drinking-water systems prevent occurrence of legionellosis via these systems;
- Adequate control of *Legionella* in (warm) drinking-water systems in buildings requires multi-stakeholder involvement, including building owners, employers and water utilities;
- In the case of legionellosis outbreaks via (warm) water systems, demonstration of due diligence of each of the stakeholders is required.

The Directive should include requirements for an assessment of risk and adequate control, including operational monitoring and verification monitoring, as indicated in the WHO Guidelines and the WHO document *Legionella and the prevention of legionellosis* (WHO, 2007a). The fact sheet on *Legionella* Appendix 3 provides summary information on the parameter.

7.2 Scope

Legionella control measures and monitoring should primarily focus on warm water systems in public buildings that house vulnerable populations, and systems with showers or other features that produce aerosols – with the caveat that cold water systems should be operated at less than 20-25°C and where this is not possible (e.g. in warm climates), it is recommended to include them in risk assessments. Member States that have already embedded risk assessment and monitoring of *Legionella* in their water regulation have made different choices in terms of public buildings covered by the legislation.

After a *Legionella* outbreak via a whirlpool at an exhibition, the response in the Netherlands was to assess the *Legionella* risk in all public buildings. A crude cost-benefit analysis, however, indicated that this leads to unreasonably high costs for *Legionella* control in water systems, as compared to other investments in infectious disease prevention (de Hollander & Hanemaaijer, 2003). Also, the evaluation of the risks associated with different building types pointed towards most benefits from focus on specific buildings (Versteegh et al., 2007). As a result, the legislation was focused on priority buildings only, such as healthcare facilities, hotels, refugee facilities, prisons, gas stations with shower facilities, pools and harbour facilities. The French guideline applies to a similar selection of public buildings (Government of France, 2017). In Germany, the drinking-water legislation applies to all public and commercially used buildings above a defined size threshold for the warm water system, including apartment buildings (Government of Germany, 2017), as it was recognized that plumbing systems in such buildings may contain *Legionella*, particularly after prolonged periods of non-use of facilities. In Member States where *Legionella* is embedded in the health and safety regulations, the scope of the legislation includes all buildings where work is carried out and aerosolization of water takes place, such as buildings with (wet) cooling towers, warm or cold water systems and pools. The owners of such buildings/water systems are responsible that the health and safety of employees but also others such as visitors or the public (HSE, 2013).

Although legionellosis may be acquired through drinking-water installations in all types of buildings, outbreaks of legionellosis through drinking-water installations have primarily been reported from larger buildings, such as hospitals, other healthcare facilities, hotels and other types of tourist accommodation (ECDC, 2016). Healthcare facilities also host people that are most at risk for legionellosis. Therefore, we recommend following the advice of the European Centre for Disease Prevention and Control (ECDC, 2016) to focus on drinking-water installations in priority buildings: hospitals, long-term healthcare settings, hotels and other tourist accommodation sites and other larger buildings where sizable populations at higher risk are exposed. Section 7.4 discusses further options for risk-based definition of the scope of the Directive for *Legionella* control.

7.3 Risk assessment, control and monitoring

Infection with *Legionella* requires both proliferation and exposure. Exposure occurs via aerosols, and proliferation does occur in warm drinking-water systems, particularly in large, complex systems with stagnation zones and temperatures above 25˚C and below 55˚C. Since *Legionella* can grow in association with amoebae, and these in turn proliferate on biofilms, it is also important to control biofilm formation to reduce the potential for *Legionella* to grow. We recommend the following elements in the Directive:

- Evaluation of drinking-water installations in priority buildings for the presence of hazardous conditions that could support the growth of Legionella;
- Evaluation of whether control measures are adequate to control growth of *Legionella*;
- Operational monitoring of control measures, such as temperature and (when applied) disinfectant residual;
- Monitoring of drinking-water installations in priority buildings for the presence of *Legionella*.

7.3.1 Hazardous conditions and system assessment

The first step in the risk assessment is to characterize the drinking-water installation and to evaluate for the presence of hazardous conditions. Factors that can lead to proliferation of or exposure to *Legionella* in drinking-water distribution networks and in building plumbing systems include (adapted from WHO, 2007a):

- Distribution system problems, such as stagnation, dead zones and low flow rate;
- Construction materials that contribute to microbial growth and biofilm formation, particularly hemp (i.e. in shower hoses) and natural rubber (i.e. in O-rings);
- Inefficient or ineffective disinfection, particularly when biofilms and amoeba are present to protect *Legionella* from disinfectants;
- Water temperatures of 25–55°C even in small areas of the system;
- Presence of biofilms (and amoeba); and

- Aerosol production (i.e. showerheads, nebulizers, toilet flushing etc.)

It is important to investigate whether the combination of factors present in the system is likely to lead to the proliferation of legionellae. These factors are strongly interrelated, with temperature being a key factor.

7.3.2 Control measures

The second step in the risk assessment is to evaluate whether risks of *Legionella* growth are adequately controlled. Effective control requires considering multiple interventions, in line with the WSP approach. Systems will need to be assessed individually, with particular attention to system sites and appendages where aerosol formation may occur. Essential control measures are:

- Keep water temperature of cold water systems <25˚C (and if possible <20˚C) and of warm water systems >55°C (even in small areas of the system). For circulating warm water systems, this implies that the temperature of the water leaving the heater should be 60˚C or higher. For non-circulating warm water systems, the piping to connect the heater to the tap should be as short as possible; and
- Design and operate distribution networks and plumbing systems to limit stagnation, including removal of dead zones.

Supportive control measures are:

- Use disinfecting agents that are more effective for control of *Legionella* in biofilms, such as monochloramine;
- Use construction materials that do not promote microbial growth;
- For source waters with high natural organic matter, ensure sufficient removal of nutrients to produce water with no or very limited growth of microbes (biostability); several treatment processes have been shown to produce biostable water; and
- Reduce presence of biofilms (and amoeba) through removal of nutrients, regular cleaning and disinfection.

7.3.3 Operational monitoring

Operational monitoring is used to determine whether the control measures are effectively functioning. Some control measures have to be embedded in the system design and operational monitoring would be through site inspection to verify that systems are constructed with the appropriate materials and designed to reduce stagnation. Other control measures are more prone to variation and need to be monitored regularly (ideally continuously) to determine that they are functioning properly.

The key operational monitoring parameter, which is recommended to be included in the Directive, is temperature in drinking-water systems in buildings, focusing on point-of-use of warm water to monitor that it is >55˚C, but also including points in the cold water system

that could reach temperatures >25˚C (Table 2). The suggested minimum values are intended to be triggers for corrective action to prevent increase of *Legionella*.

Other operational monitoring options for Member States or operators to consider include:

- Water temperature of warm water leaving the heater and returning to the heater;
- Disinfectant residual (when applied); and
- Quality of the drinking-water feeding the domestic system in the building, such as turbidity (when disinfection is applied) and nutrient content.

Table 2. Suggested parameter for operational monitoring of *Legionella* control in Annex I Part C

Parameter	Role in risk-based approach	Priority for inclusion	Monitoring requirement	Value	Monitoring site	Remarks
Temperature	Confirmation of effective operations of control measures preventing *Legionella* proliferation	High	Yes	Yes Water at point of use (warm water tap, shower head): >55˚C[1]	Warm water system	New parameter Values are intended to be triggers for corrective action to prevent *Legionella* proliferation
				<25°C	Cold water system	

[1] This applies to the temperature of the warm water system before mixing with cold water.

7.3.4 Verification monitoring

Verification monitoring is used to verify that the chosen suite of control measures effectively control or prevent the risk of *Legionella* proliferation. This would imply inclusion of *Legionella* as a parameter in the Directive and setting a respective monitoring requirement.

The German and Dutch legislation on *Legionella* in drinking-water and French guidelines require monitoring in public buildings (i.e. hospitals and other healthcare institutions, nursing homes, prisons, hotels etc.) with a frequency of once (Germany) or twice (Netherlands) per year. The water quality target is set to 100/L (Netherlands) to 1000/L (France, Germany).

We recommend including *Legionella* as a parametric value in Annex I Part A of the Directive (Table 3). A value of 1000/L seems appropriate to indicate that conditions for *Legionella* proliferation are present in the warm water system and require management attention to *Legionella* control. This is not a health-based value but a screening value to trigger action to prevent further proliferation of *Legionella* and the associated health risk. Suggested sampling site is water at the point of use, specifically at points of aerosolization, such as a showerheads or warm water taps. Enumeration of Legionella should be according to

standardized culture methods (i.e. EN ISO 11731:2017) and the sampling protocol should aim to sample the water from the warm water plumbing system directly (and not flush the system before sampling), as this water is most prone to harbour *Legionella*.

Table 3. Suggested parameter for verification monitoring of *Legionella* control in Annex I Part A

Parameter	**Role in risk-based approach**	**Priority for inclusion**	**Monitoring requirement**	**Value and frequency[1]**	**Monitoring site**	**Remarks**
Legionella	Verification of adequate control of *Legionella*	High	Yes, culture method	Value: <1000/L Frequency: Small systems (<10 m^3/d): 1 site per year Medium-sized systems (10-60 m^3/d): 10 sites per year Large systems (>60 m^3/d): 1 site per 5 m^3 (or part thereof) per year	Consumer's tap: Monitoring should focus on sites where there is aerosolization (showerheads, warm water taps) and thus the highest risk of *Legionella* occurrence	New parameter Value is intended to be a trigger for corrective action to prevent further *Legionella* proliferation

[1] The risk assessment may point to conditions where *Legionella* growth is more likely to occur and should guide the monitoring to these conditions.

Verification monitoring is intended to be an indicator for *Legionella* proliferation and inappropriate management. The parameter value is not set as a health target but as a "trigger value" initiating remedial action and (re-)investigation of the system. A risk-based approach for corrective action upon exceedance of the trigger value can be linked to the level of exceedance. We recommend including a risk-based response scheme (which is based on the rule W 551 of the German Technical and Scientific Association for Gas and Water (DVGW)) linked to verification monitoring of *Legionella* in Annex I of the Directive (Table 4). The WHO document on *Legionella and the prevention of legionellosis* (WHO, 2007a) provides more comprehensive information.

Table 4. Risk-based responses in *Legionella* control for inclusion in Annex I of the Directive

***Legionella* concentration (CFU/L)**	**Assessment**	**Corrective action**	**Next step**
≤1000	Tier 1: Adequate control of *Legionella*	None	Resample after one year
>1000-10000	Tier 2: *Legionella* present in low concentration	Resample within two weeks: If still >1000-10000/L: sanitize/disinfect the warm water system within one week If >10000/L: move to appropriate category If ≤1000/L: resample within three months	Resample within two weeks to determine if *Legionella* is ≤1000/L
>10000-100000	Tier 3: *Legionella* present in high concentration	Resample immediately and conduct further risk assessment of drinking-water installation: If still >10000-100000/L: sanitize/disinfect the warm water system immediately, take measures to prevent recurrence based on risk assessment If >100000/L: move to appropriate category	Resample within one week after sanitizing/ disinfection to determine if *Legionella* is ≤1000/L Check if control measures are implemented
>100000	Tier 4: *Legionella* present in very high concentration	Resample immediately and conduct further risk assessment of drinking-water installation: If still >100000/L: disinfect the warm water system and restrict use (i.e. ban showering) immediately, take control measures to prevent recurrence based on risk assessment If ≤100000/L: move to appropriate category	Resample within two weeks to determine if *Legionella* is ≤1000/L Check if control measures are implemented

7.4 Addressing *Legionella* in the Directive

In conclusion, we recommend to:

- Set the scope on priority buildings (as indicated in Section 7.2), with water systems with any point of use accessible to the public and capable of producing aerosols (i.e. showers, hot tubs or jets);
- Include a general description of priority buildings in the Directive. The general description should include hospitals, healthcare institutions, buildings with a lodging facility (e.g. hotels, pensions, group accommodation), penal institutions, bathing facilities (i.e. swimming pools) and campgrounds. The general description could include a statement that Member States should focus on larger buildings with more users potentially exposed to these aerosols;

- Include a requirement for an evaluation of drinking-water installations in priority buildings for the presence of hazardous conditions that could support the growth of *Legionella*, and whether control measures are adequate to control growth of *Legionella*.
- Include a requirement for operational monitoring of temperature in Annex I Part C as suggested in Table 2.
- Include a requirement for verification monitoring of *Legionella* in Annex I Part A as suggested in Table 3.
- Include a requirement for response in case of exceedance of the trigger value of the verification monitoring as suggested in Table 4.

Alternatives

We recognize that introduction of a risk assessment, operational and verification monitoring for drinking-water systems in buildings is associated with significant costs. A cost estimate of the introduction of *Legionella* legislation for priority buildings in the Netherlands showed the actual costs depend largely on the size and complexity of the water installation. For small, simple systems the costs were estimated at around 50 Euro per year and for large, complex systems (such as in large hospitals) at around 20,000 Euro per year. The total cost in the Netherlands was estimated at 23 million Euro per year for 10,000 installations (Government of the Netherlands, 2004). About half of the costs were associated with the risk assessment and the other half with the verification monitoring. The costs are primarily determined by:

- Warm water systems and types of buildings that are covered by the new requirements;
- Requirements for assessment and monitoring;
- Methods used for assessment and monitoring; and
- Requirements for corrective actions if the trigger value is exceeded.

Several alternatives exist (and may be combined) to make the requirements even more risk-based and thereby also limit the costs of these new requirements. These alternatives and their pros and cons are briefly highlighted here.

Option 1. Limit the initial requirements to *Legionella* verification monitoring according to Table 3 and operational monitoring Table 2, and require risk assessment only to warm water systems that exceed the proposed trigger value (such as done in the German drinking-water regulation). Pro: This alternative will inflict *Legionella* control in warm water systems that have demonstrable presence of *Legionella*. Con: Infrequent *Legionella* monitoring is not a 'catch-all' and may miss moments in which *Legionella* is present, including in cold water systems (run at too high a temperature), given a false sense of safety.

***Option 2*.** Focus verification monitoring on *L. pneumophila* instead of *Legionella* spp. This is the approach taken by France, for example (Government of France, 2017). *L. pneumophila* is the most significant causative agent of legionellosis in Europe. Non-*pneumophila* species

(e.g. *L. anisa, L. bozemanii, L. longbeachae, L. dumoffi, L. micdadei*) account for ≤5% of the culture-confirmed cases of legionnaire disease in the EU (ECDC, 2016). In 4.8% of legionnaire disease cases detected by extended diagnostic testing of pneumonia cases in Germany non-*pneumophila* species were implicated (von Baum & Lück, 2011). At the same time, warm drinking-water systems may frequently contain non-*pneumophila* species. A focus on *L. pneumophila* monitoring (for which methods are available; Veenendaal, 2017) means that corrective actions are only triggered for warm drinking-water systems where *L. pneumophila* is present, which represent the water systems associated with the highest burden of disease. Focusing the Directive on *L. pneumophila* has additional advantages:

- Inclusion of *L. pneumophila* as parameter in the Directive leaves the option for Member States to include *Legionella spp*. in their national drinking-water regulation, while inclusion of *Legionella spp*. in the Directive does not leave the option for Member States to focus on *L. pneumophila* (as France has done recently).
- When a microbiological parameter is defined taxonomically, the parameter is much less prone to ambiguous results. This also allows for the development of alternative methods, as the endpoint is defined, while in the case of *Legionella spp*. the endpoint is defined by the culture method. Note that this has also been the rationale for changing from faecal coliforms to *E. coli* in the previous revision of the Directive.

An intermediate option could be to conduct the verification monitoring with a method for *Legionella* spp. (EN ISO 11731) and when this shows the presence of *Legionella* spp. in a building to require resampling for *Legionella* spp. and *L. pneumophila.* If *L. pneumophila* is not present, the corrective actions could be moved to the next-lower tier.

A cost-benefit analysis of the different alternatives is beyond the scope of this report. Therefore, our basic recommendation is to include *Legionella* control following the abovementioned recommendations.

7.5 The role of heterotrophic plate counts in Legionella control and regrowth in distribution and plumbing systems

The method for heterotrophic plate counts (HPC) was first described in 1883 by Robert Koch, initially as an indicator of water treatment performance, but this was abandoned after the introduction of specific faecal indicator bacteria (see Section 6.2). Currently, HPC is primarily used as parameter to indicate the occurrence of “regrowth” in piped distribution systems (i.e. growth of microorganisms in the distribution network, in biofilms or sediments on the pipe walls). Regrowth occurs generally in all drinking-water systems. This is normal but elevated levels of growth may give rise to aesthetical water quality issues (i.e. brown water, presence of invertebrates), technical issues (i.e. corrosion of pipe materials) and increase the risk that opportunistic pathogens can grow in the biofilms or in association with amoeba that graze on biofilms. Control of regrowth is therefore relevant to prevent such health, aesthetic and technical issues. In the Directive, HPC is used for this purpose, and also the WHO Guidelines refer to HPC for this purpose. HPC is referred to in the Directive as colony counts.

Heterotrophs can broadly be defined as micro-organisms that require organic carbon for growth and the HPC are the colony counts on simple, culture-based test on growth medium with organic carbon. Elevated HPC in samples from the drinking-water at the consumer's tap indicate the presence of conditions in the distribution system that may cause regrowth, such as stagnation of water in the network of plumbing, loss of disinfectant residual, elevated temperatures, materials that leach organic carbon, presence of sediments/biofilm.

The concept of using colony counts at both 22˚C and 37˚C came from the idea that colony counts at 37˚C (body temperature) would be more indicative of ingress of faecal contamination and of regrowth of bacteria that may have a health significance. However, there is no evidence from epidemiological studies that HPC at 22˚C or 37˚C have a relation with health risk. Also, there is no direct association between HPC and presence/numbers of opportunistic pathogens such as *Legionella.* Sudden increase of HPC may be associated with faecal contamination, but presence of the specific faecal indicator parameters *E.coli* and enterococci is needed as true indicator of faecal contamination. Hence, the colony counts at 37˚C have no added value and are 'conceptually misleading' as they have no association with health risk.

Therefore, we recommend to keep the HPC 22˚C in Annex I Part C of the Directive as indicator of (undesirable levels of) regrowth and maintain the requirement "no abnormal change" (see Table 5). For smaller water supplies, the sampling frequency becomes too low to be able to detect abnormal change and the requirement is not meaningful. For these cases, we recommend to include a parameter value of 100/mL (i.e. based on the previous Directive and WHO (2003a)).

Table 5. Suggested parameters for verification monitoring of regrowth control in Annex I Part C

Parameter	Role in risk-based approach	Priority for inclusion	Monitoring requirement	Value	Monitoring site	Remarks
HPC 22˚C	Verification of adequate control of regrowth	High	Yes	Yes No abnormal change[1]	Finished water and consumer's tap Increase between finished water and consumer's tap indicates regrowth	Existing parameter

[1] If the sampling frequency is too low to detect what is "no abnormal change", the HPC value should be below 100/mL.

Further information on HPC can be found in the WHO document *Heterotrophic plate counts and drinking-water safety: the significance of HPCs for water quality and human health* (WHO, 2003a), as well as in the fact sheet in Appendix 3.

In recent years, several studies have looked into alternative parameters to indicate regrowth (potential) in the distribution network. These studies include alternative, low-carbon culture

media. It was recognized that the culture media used for HPC are not particularly representative of the low carbon environment in drinking-water distribution systems and HPC represent only a small fraction of the total bacteria present in drinking-water (Siebel et al., 2008; van der Wielen & van der Kooij, 2010). Alternative media such as R2A have been studied extensively and produce higher counts than the prescribed HPC medium. Other parameters that have been suggested are ATP (adenosine tri-phosphate) and total cell count, by microscopy or flow cytometry (Berney et al., 2008). ATP is a compound that is part of the energy metabolism of micro-organisms (and all other life) and the concentration reflects the amount of microbial activity in water. Total (microbial) cell count is a measure that aims to capture all microbial cells that are present in water, and is independent of the capacity to grow on culture media. The counts obtained with these methods are generally orders of magnitude higher than colony counts at 22˚C. Total flow cytometry cell counts have recently been incorporated in the Swiss drinking-water guidelines. In evaluating ATP and total cell counts as alternative/addition to the HPC (now 134 years old!), there is merit in their representation of the total activity or cell counts in the distribution network.

However, there is also debate about their sensitivity in detecting regrowth issues (van der Wielen et al., 2016) and the methods are not found to be widely disseminated throughout the water laboratory infrastructure in Member States. They are therefore not recommended for inclusion in the Directive at this time, but the developments in research and dissemination do deserve reconsideration at the next revision.

8. Provisions for prevention and control of enteric pathogens

KEY MESSAGES

- Adequate control of enteric pathogens requires a multiple barrier approach from catchment to consumer.
- For groundwater supplies, the vulnerability depends on the level of protection of the aquifer and abstraction and the vicinity of faecal contamination sources. A risk-based, tiered approach for periodic catchment appraisal and investigative source water monitoring is recommended.
- For surface water supplies and contaminated groundwater supplies, treatment needs to be an adequate barrier against enteric bacteria, viruses and parasitic protozoa. We recommend that the Directive defines treatment performance targets for these pathogens, based on the level of faecal contamination of the source water. This level of faecal contamination is determined by periodic catchment appraisal and investigative source water monitoring for *E. coli*.
- We recommend uptake of requirements for operational monitoring of important treatment processes in the Directive. Turbidity is recommended for operational monitoring to confirm adequate performance of filtration processes, and effective disinfectant dose is recommended to confirm the adequacy of disinfection processes.
- We recommend incorporating requirements for verification monitoring of water leaving the treatment works, specifically incorporating somatic coliphages as new parameter, changing the parameter "*Clostridium perfringens* including spores" to "*Clostridium perfringens* spores" and assigning this new role to *E. coli,* coliforms and intestinal enterococci.

8.1 Further enhancing control of enteric pathogens under the Directive

As concluded Chapter 6, the requirements in the current Directive for microbial water quality testing for faecal indicator bacteria and colony counts at the point of compliance provide insufficient safeguards to ensure safe drinking-water. The WHO Guidelines' risk-based approach towards assessing and managing microbial risks in drinking-water (Chapter 2) can fill this gap in the Directive. As stated in Chapter 2, effective management of drinking-water safety with regards to enteric pathogens requires a comprehensive understanding of the system from catchment to consumer and to identify hazards and risks to the safety of the drinking-water delivered through this system and to evaluate whether the control measures (ranging from catchment protection measures, engineered treatment processes to hygiene and design protocols for maintenance of networks and plumbing systems) are able to control these risks to such an extent that drinking-water can be regarded as safe.

For enteric pathogens the key control strategy is the multi-barrier approach: to install sufficient barriers in the water supply system from catchment-to-consumer to ensure drinking-water at the tap is safe (Figure 2):

1. Prevent enteric pathogens to enter source water (catchment protection);
2. Remove or inactivate enteric pathogens by water treatment processes to levels that do not represent any significant risk to health; and
3. Protect the drinking-water in the distribution network, including the plumbing system against ingress.

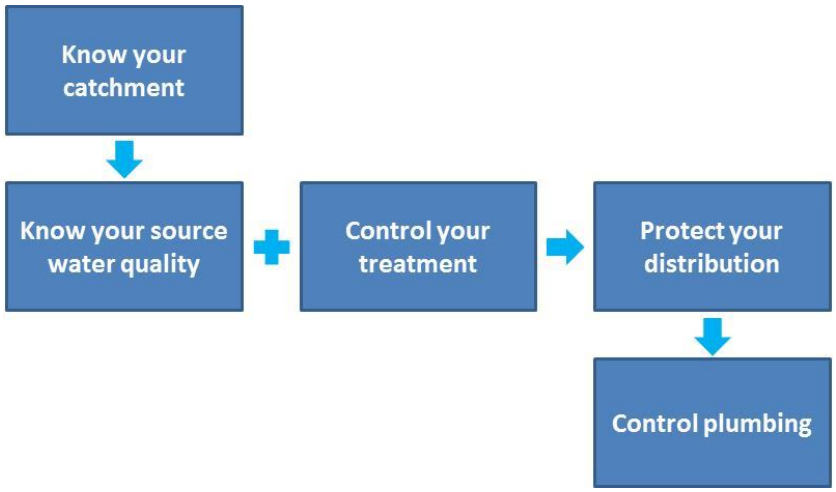

Figure 2. Drinking-water safety management from catchment to consumer: multi-barrier approach

To further implement the risk-based approach for microbial safety in the Directive, we recommend introducing requirements for the following elements:

- Periodic catchment appraisal of the presence of faecal contamination sources and pathways towards source water, and of the control measures that (could further) reduce the level of faecal contamination of the source water (see also Chapter 3);
- Periodic investigative monitoring of the level of faecal contamination of source water, based on the outcomes of the catchment appraisal, to determine the level of faecal contamination of source water, especially under peak event conditions (see also Chapter 3);
- Treatment performance targets for the required log removal values for enteric bacteria, viruses and protozoa, based on the results of the catchment appraisal and source water monitoring;
- Operational monitoring of the most significant barriers to enteric pathogens in water treatment:
  - Turbidity to monitor the performance of filtration processes (assigning a new role and parameter value for turbidity as parameter in Annex I Part C);

- Appropriate parameters to monitor the performance of disinfection processes (e.g. chlorination, UV light, ozonation), if applied, in Annex I Part C;

- Verification monitoring in finished drinking-water (i.e. water after abstraction and, if applied, treatment, before it enters the distribution network):
  - *E. coli*, coliforms (in specific cases) and intestinal enterococci to verify that the water supply system ensures sufficient elimination of enteric bacteria (by assigning this role to these Directive parameters);
  - Somatic coliphages (new parameter) to verify that the water supply system ensures sufficient elimination of enteric viruses; and
  - *Clostridium perfringens* spores to verify that the water supply system ensures sufficient elimination of *Cryptosporidium* and *Giardia* (by specifying this role to this Directive parameter).

This is an integrated "package" that needs to be implemented fully to be effective. The general rationale for each of the individual elements of the "package" is explained in the following Sections 8.2-8.4. Specific recommendations for uptake in the Directive are presented at the end of each thematic section – i.e. in Section 8.2.1.4 on catchment appraisal and investigative source water monitoring for groundwater supplies, in Section 8.2.2.4 on catchment appraisal and investigative source water monitoring for surface water supplies, in Section 8.3.7 on verification of treatment performance and Section 8.4.4 on verification of distribution system integrity.

8.2 Catchment appraisal and investigative source water monitoring

As described in Chapter 3, catchment appraisal and risk-based, investigative monitoring of source water are key elements of the multiple-barrier approach to ensure safe drinking-water. They ensure that water suppliers understand the catchment and sources of hazards and hazardous events that may threaten source water quality and allow for the appropriate selection of water sources, inform the configuration of water treatment, the design of risk-based source water monitoring activities and support identification of effective catchment protection measures with other stakeholders. In the following, the general outline of catchment appraisals in Chapter 3 is translated to specific recommendations for catchment inspection and risk-based source water monitoring for faecal contamination.

For the first barrier – protection of the catchment and of the abstraction site against faecal contamination – a distinction is made between water supplies that use groundwater or surface water as source. Groundwater from well-confined and highly protected aquifers are free from faecal contamination and enteric pathogens and do not need treatment for pathogen removal; protection of the catchment and abstraction is the key element in ensuring safe drinking-water. Surface water, as well as unprotected groundwater, is prone to contamination from human, livestock and wildlife sources. For these supplies, protection of the catchment and abstraction remains crucial, but treatment is necessary to reduce pathogens to levels that are so low that the treated drinking-water does not represent any

significant risk to health. For the other steps in the multi-barrier approach (i.e. sufficient treatment and protection of drinking-water during distribution), the description in Sections 8.3 and 8.4 applies to all types of supplies.

8.2.1 Groundwater supplies

For groundwater supplies, we recommend to include a requirement for catchment appraisal in the Directive, following a tiered, risk-based approach that requires increased vigilance with increased vulnerability of the groundwater supply.

The first important step in providing safe drinking-water is the selection of the best available source water. The most protected source waters will be the easiest and the cheapest to transform into safe drinking-water. In general, groundwater is better protected than surface water. Groundwater from deep aquifers is protected from pathogen contamination by the covering soil layers: rain water or other water (such as from surface water infiltration, irrigation, sewer leakage etc.) that percolates through the soil can harbour pathogens but these are effectively removed by attachment to soil particles, die-off and biological processes. Pathogen die-off during the extended time of travel from the surface through the ground to the point of abstraction in low permeability aquifers is an important factor in reducing microbial risk. Deep groundwater from confined or semi-confined aquifers is therefore a preferred source for drinking-water production, where available. Shallower groundwater sources or groundwater that can be influenced by surface water will be more vulnerable to faecal contamination. Fine-textured soils (clay, silt) retain pathogens better than light-textured soils (sand). Soil types with a very coarse texture (fractured rock, sand and limestone, gravel) or cracks provide a relatively poor barrier against microbial contamination. Here, contact between pathogens and soil particles is less intense, leading to a lower attachment rate and greater penetration of the pathogens into the soil.

Protection of the catchment and abstraction against enteric pathogens requires understanding of the catchment hydrology/hydrogeology, sources of pathogen contamination in the catchment and pathways by which these sources could contaminate the groundwater in order to:

- Select the most appropriate site for drinking-water abstraction or well placement;
- Select appropriate catchment protection measures (as far as they can be realistically implemented);
- Predict and prepare for the occurrence of hazardous/peak contamination events;
- Design a risk-based monitoring program.

Groundwater supplies in the EU have been source of outbreaks of bacterial, viral and protozoan pathogens (Willocks et al., 1998; Hänninen et al., 2003; Gallay et al., 2006; Kvitsand & Fiksdal, 2010; Guzman-Herrador et al., 2015; Kuhn et al., 2017). Enteric viruses are a particular challenge for groundwater supplies, since their small size allows them to penetrate soils much better than bacteria. They also survive longer in groundwater and soil than bacteria. Hence, the current (bacterial) parameters in the Directive provide insufficient

information about the level of protection of groundwater supplies against enteric viruses. We therefore recommend introducing a new parameter for this purpose: somatic coliphages. Somatic coliphages share many properties with human enteric viruses, notably composition, morphology, structure and environmental fate and transport. As a result, somatic coliphages are useful models to assess the behaviour of enteric viruses in groundwater supplies.

8.2.1.1 Catchment appraisal – sanitary survey of the catchment and abstraction area

A sanitary inspection of the catchment area evaluates the level of protection of the aquifer (i.e. depth, soil type, presence of protective soil layers and unsaturated zone etc.) and the presence of sources of microbial (and chemical) hazards in the catchment area that may contaminate the groundwater (i.e. manure storage, livestock, sewers, septic tanks, infiltrating streams, infiltration wells etc.). Catchment appraisal can also identify if certain climatological (i.e. heavy rainfall, snow melt), environmental (i.e. high animal loads) or man-made conditions (i.e. agricultural practices, tourism) could give rise to peak contamination events of the source water. Further guidance on catchment appraisal and sanitary inspection can be found, for example, in the WHO document *Protecting groundwater for health* (WHO, 2006a).

For water supply systems using groundwater as a source, the catchment appraisal could be implemented as a tiered assessment of the level of catchment protection using the combination of sanitary inspection and monitoring (Figure 3).

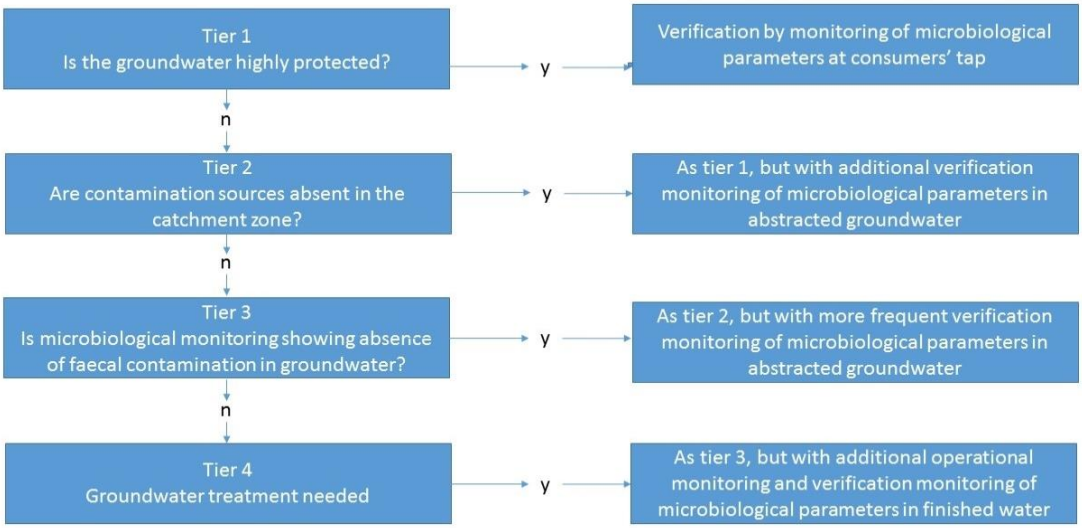

Figure 3. Risk assessment and risk-based monitoring of groundwater supplies

Tier 1: Evaluate the level of protection of the aquifer and the abstraction infrastructure and processes using a sanitary inspection. If this tier indicates that the groundwater supply is highly protected and not vulnerable to contamination, the verification monitoring that the groundwater supply is free from faecal contamination can be combined with the verification

monitoring of the other parts of the supply (distribution). The sampling site for verification monitoring is the consumers' tap.

Tier 2: If tier 1 indicates the groundwater supply or spring is vulnerable to contamination, evaluate the presence of contamination sources in the catchment. When tier 2 indicates contamination sources are absent, the groundwater supply is vulnerable, but unthreatened. Investigative monitoring should verify that groundwater is free from faecal contamination. The sampling site for investigative monitoring is the abstracted groundwater or spring water. Also, the sanitary inspection should be repeated at least every five years to ensure that contamination sources continue to be absent.

Tier 3: If tier 2 indicates contamination sources are present, the supply is vulnerable and threatened. Verify that groundwater is free from faecal contamination by frequent investigative monitoring. The sampling site for investigative monitoring is the abstracted groundwater or spring water.

Tier 4: If the sanitary inspection and/or monitoring results indicate that faecal contamination of the groundwater is likely to occur, even if that is infrequent, additional treatment of the groundwater is necessary to eliminate enteric pathogens. Investigative monitoring of the abstracted groundwater should indicate if and to what extend the groundwater is contaminated. Verification monitoring should include the treatment (for more detail, see Section 8.2.2 on surface water supplies). The efficacy of the treatment to eliminate enteric pathogens should be monitored with operational monitoring (for more detail, see Section 8.2.2 on surface water supplies).

8.2.1.2 Risk-based, investigative monitoring

The risk-based, investigative monitoring of groundwater supplies and springs is guided by the catchment appraisal as per Section 8.2.1.1). Monitoring of *E. coli,* coliforms and somatic coliphages in the abstracted water is recommended to verify the groundwater supply is not contaminated. Since viruses are less effectively removed by soil passage than bacteria, also coliphages should be monitored in the abstracted groundwater to determine the risk of virus contamination. The catchment appraisal may have identified possible hazardous events; these should be used to guide monitoring, so that at least part of the samples is taken during hazardous events. On-line monitoring of turbidity of the abstracted groundwater may help to identify moments/events that cause groundwater contamination and can serve as basis for risk-based monitoring of *E. coli* and somatic coliphages (i.e. through sampling during turbidity spikes).

8.2.1.3 Periodic review

Periodic review of the catchment appraisal is necessary to ensure that it is still accurate. New contamination risks may emerge from local developments. The frequency of review of the catchment appraisal could be every five years, with the precondition that the water supplier needs to stay aware of developments in the catchment that could affect the risk of

contamination of the groundwater supply and evaluate if these call for earlier review of the appraisal.

The basic periodicity of the investigative monitoring can be linked to the catchment appraisal (every five years). As long as the investigative monitoring indicates the groundwater supply is under control, the basic periodicity can be maintained. Whenever the results of the investigative monitoring indicate that the groundwater supply is contaminated, the periodicity needs to be increased to yearly. To return to the basic periodicity requires at least three consecutive years of investigative monitoring showing the groundwater supply is not contaminated.

8.2.1.4 Recommendations for the Directive

The specific recommendations are to include a requirement for:

- Periodic catchment appraisal to evaluate the level of protection of the groundwater supply and the presence of faecal contamination sources in the catchment that may contaminate the abstracted groundwater;
- Periodic risk-based, investigative monitoring of abstracted groundwater with the parameters *E. coli*, coliforms and somatic coliphages (for more detail, see fact sheets in Appendix 3). Suggested parameters and parameter values for investigative monitoring are given in Table 6 and the sites of sampling and compliance and the minimum number of samples are given in Table 7. The number of samples depends on the size of the water supply, as determined by the daily production or distribution capacity of the supply. The catchment appraisal also identifies potential hazardous events and the conditions under which they occur. This is used to target (part of) the monitoring efforts.

Table 6. Risk-based, investigative monitoring of groundwater supplies: suggested parameters and values

Parameter	**Role**	**Value**	**Remarks**	**Method**
E. coli	To verify integrity and hygiene of groundwater and abstraction for enteric bacteria	0 CFU/100 mL	New parameter role	EN ISO 9308-1 or 9308-2
Coliforms	To verify integrity and hygiene of groundwater and abstraction for enteric bacteria	0 CFU/100 mL	New parameter role	EN ISO 9308-1 or 9308-2
Somatic coliphages	To verify integrity and hygiene of groundwater and abstraction for enteric viruses	0 PFU/100 mL	New parameter	EN ISO 10705-2

Table 7. Risk-based, investigative monitoring of groundwater supplies: sampling sites and frequencies

Volume (m^3) of water distributed or produced each day within a supply zone		**Tier 1:** Highly protected	**Tier 2:** Vulnerable, no contamination sources in catchment[1]	**Tier 3:** Vulnerable, contamination sources in catchment[1]	**Tier 4:** Vulnerable, contamination sources in catchment[1] and (occasional) faecal contamination of abstracted groundwater
			Sampling site: Abstracted groundwater	**Sampling site:** Abstracted groundwater	**Sampling sites:** Groundwater and finished water
			Minimum number of samples in an investigation year		
≤ 100		No additional samples of finished or groundwater Verification monitoring is embedded in the verification monitoring at the consumers' tap	5[a]	10[a]	10[a]
> 100	≤ 1 000		5[a]	10[a]	10[a]
> 1 000	≤ 10 000		10[a]	50[b]	50[b]
>10 000	≤ 100 000		50[b]	365	365
>100 000			365	365	365

[1] The catchment is defined as the zone around the groundwater abstraction or spring where a faecal contamination would take at least 100 days in the soil (aquifer and unsaturated zone) before it reaches the abstraction point; [a] all samples are to be taken during times when the risk of hazardous events is high; [b] at least 10 samples are to be taken during times when the risk of hazardous events is high.

8.2.2 Surface water supplies

Surface water[2] is generally contaminated with enteric pathogens, the level depending on the presence of sewage discharges, combined sewer overflows, septic tank seepage, input from shipping, manure discharges and run-off from agricultural lands and abundance of wildlife, particularly waterfowl. In pristine surface waters the level of contamination is usually low, while in urban rivers the contamination levels may become very high. Protection of the catchment and the abstraction are still very important elements of the multi-barrier approach.

Catchment appraisal ensures that the water supplier understands the faecal contamination sources, pathways and events and the level of contamination of a specific source water at the intake (including potential peak contamination events). Understanding the level of faecal contamination of source water is needed to determine the required level of pathogen removal by water treatment, to ensure the finished drinking-water does not represent any significant risk to health. The level of faecal contamination of source water is impacted by control measures in the catchment area; the more effective the controls in the catchment, the lower the level of faecal contamination and vulnerability of the source water to peak events, and the lower the required level of pathogen removal.

[2] Also groundwater that is under the influence of faecal contamination from surface water (or other sources) needs treatment to produce safe drinking-water. In the following text "surface water" includes groundwater that is under the influence of faecal contamination by surface water (i.e. tier 4 of groundwater supplies).

8.2.2.1 Catchment appraisal – sanitary survey of the catchment area

The catchment appraisal of surface water supplies starts with a sanitary survey of the catchment area to assess the presence, vicinity and abundance of the different contamination sources, as well as the vulnerability of the source water at the intake to peak contamination events as a result of heavy rainfall, snowmelt, flooding or other events. The catchment appraisal should result in an understanding and characterization of the pathogen sources arising from people and livestock in the catchment, their (relative) intensity, proximity and pathways by which they can reach the intake, with emphasis on conditions that could lead to peak contamination levels. The survey should also evaluate the presence of barriers, such as water storage in reservoirs, buffer zones, flood water diversion that may reduce the pathogen load to the intake. Comprehensive guidance on the elements of a sanitary inspection of surface water supplies can be found in the WHO document *Protecting surface water for health* (WHO, 2016a).

8.2.2.2 Risk-based, investigative monitoring

Monitoring of source water for *E. coli* complements the sanitary survey and generates understanding of the level of faecal contamination of the surface water at the intake point (Tables 8 and 9). Risk-based monitoring means that the hazardous events identified in the sanitary survey should guide the monitoring towards contamination events or periods that may occur in the catchment and reach the water intake point. Heavy rainfall and snowmelt are well-known triggers of peak contamination events. On-line monitoring of turbidity may be helpful in guiding the *E. coli* monitoring to peak events. On the other hand, low flows of rivers and streams (usually in summer) may mean that discharges of domestic wastewater are less or even undiluted.

Table 8. Risk-based, investigative monitoring of surface water supplies: suggested parameters and values

Parameter	Role	Value	Remarks
E. coli	To establish level of faecal contamination of source water	See Table 10	New parameter role

Table 9. Risk-based, investigative monitoring of surface water supplies: sampling sites and frequencies

Volume (m^3) of water distributed or produced each day within a supply zone		Sampling site is source water at the intake
		Minimum number of samples in an investigation year
≤ 100		10[a]
> 100	≤ 1 000	10[a]
> 1 000	≤ 10 000	50[b]
>10 000	≤ 100 000	365[c]
>100 000		365[c]

[a] All samples are to be taken during times when the risk of hazardous events is high; [b] at least 10 samples are to be taken during times when the risk of hazardous events is high; [c] near real time monitoring of faecal contamination may also serve this purpose.

8.2.2.3 Periodic review

Periodic review of the catchment appraisal is necessary to ensure that it is still accurate. New contamination risks may emerge from local and/or upstream developments. The frequency of review of the catchment appraisal could be every five years, with the precondition that the water supplier needs to stay aware of developments in the catchment area that could affect the risk of contamination of the source water and evaluate if these call for earlier review of the appraisal. The periodicity of the investigative monitoring can be linked to the catchment appraisal (every five years).

8.2.2.4 Recommendations for the Directive

The specific recommendations are to include a requirement for:

- Periodic catchment appraisal to evaluate the presence of faecal contamination sources in the catchment area and the pathways that may lead to (peak) contamination of the specific source water; and
- Periodic risk-based, investigative monitoring of source water with the parameter *E. coli* (existing parameter in the Directive, but with a new role assigned), following the proposals in Tables 8 and 9.

8.3 Treatment

8.3.1 Determining required treatment performance

Water treatment should be able to consistently treat the surface water to drinking-water that is safe. Safe drinking-water is defined in the WHO Guidelines as meeting a disease-burden target of 10^{-6} disability adjusted life years (DALY). This target is translated to concentrations of reference pathogens in drinking-water that correspond to this safety level (see Appendix 4). Treatment performance targets can be set based on the difference between the concentration of reference pathogens in the source water and the

concentration in drinking-water that corresponds to the 10^{-6} DALY target (see Appendix 4). The key implication of this approach is that it provides a defensible, health-based metric for the level of treatment that is required to produce safe drinking-water.

In order to set the treatment performance targets, information on the level of faecal contamination of the source water is needed. One approach would be to establish the concentration of reference pathogens in source waters by investigative monitoring of specific (reference) pathogens. Such pathogen monitoring programs for *Cryptosporidium* are part of the drinking-water legislations in the USA, New Zealand and Canada (see Table 1 for references). *Cryptosporidium, Campylobacter,* enterovirus monitoring is currently part of the Dutch drinking-water legislation; the United Kingdom requires *Cryptosporidium* monitoring in source water of at-risk water supplies (see Table 1 for references). The advantage of pathogen monitoring is the site-specific assessment of pathogen concentrations; thus providing the best evidence-base for establishing treatment performance targets. However, a major disadvantage is the high cost and limited availability of specialized pathogen testing laboratories for waterborne pathogens throughout the EU.

A more feasible alternative is to establish the level of faecal contamination based on the catchment appraisal complemented with investigative monitoring of *E. coli* in source water and to infer treatment performance targets from the established level of faecal contamination of the source water, and the available evidence on the corresponding concentrations of reference pathogens. This does not inflict high costs and does not require specialized laboratories. The disadvantage is the uncertainty about the precision of the estimated pathogen concentration. A number of studies have indicated that the estimation of enteric pathogen concentrations based on the concentration of *E. coli* or other faecal indicators is uncertain and may vary between different sites (Payment & Locas, 2011; Wu et al., 2011; Lalancette et al., 2014). The United States Environmental Protection Agency (US EPA) decided to incorporate *Cryptosporidium* monitoring to deduce treatment performance targets and to allow *E. coli* monitoring only to guide treatment performance in pristine waters (US EPA, 2006b). Also other drinking-water regulations require pathogen testing (New Zealand, Canada). Nevertheless, the approach to infer pathogen concentrations from the results of the sanitary survey and *E. coli* monitoring has been used in France for the (*Cryptosporidium*) risk assessment of 1700 water supplies and validated by subsequent *Cryptosporidium* monitoring, and allowed setting priorities for risk management (WHO, 2016b). It is also embedded in the Quebec regulations for drinking-water (Government of Quebec, 2017) and the recent draft Australian drinking-water guidelines (NHMRC, 2016).

The approach to infer treatment performance targets from an established level of faecal contamination (as per Section 8.3.2) is recommended for adoption in the Directive, since this is generally applicable, is feasible throughout the EU for both large and small supplies and requires the least resources. Pathogen monitoring is not recommended as default, but utilities or Member States should be able to use the option of pathogen monitoring as a more precise evidence-base for defining treatment performance targets.

8.3.2 Source water classification

The results of the catchment appraisal and investigative *E. coli* monitoring according to Tables 8 and 9 are combined to classify the source water according to the level of faecal contamination (Table 10). The characteristics evaluated in the catchment appraisal and the results of the *E. coli* monitoring may not match for specific source waters. In these cases, the result leading to the most contaminated source water category prevails. The *E. coli* ranges are updated from on the second edition of the Guidelines (WHO, 1993), the recent draft Australian guidelines (Government of Australia, 2016) and the Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States (repealed by the WFD).

Table 10. Classification of source water of surface water supplies

Characteristics (sanitary survey)	***E. coli* level (90%) (CFU/100 mL)**	**Source water category**
The watershed lies in an area without human settlements and activities like agriculture. Wildlife may be present but not in high densities.	< 2	Very pristine
The watershed lies in an area with little or dispersed human settlement and small scale agricultural activities. No direct input of human or livestock wastes is present.	2-20	Pristine
The watershed lies in an area with villages and extensive agricultural activities (animal-based or food crops using manure or waste water sludge for fertilization) are undertaken. Human faecal wastes are collected and treated before discharged into the watershed. The intake of water for production of drinking water is not under the direct influence of wastewater discharges.	20-200	Moderately contaminated
Small cities, villages and agricultural (animal-based or food crops using manure for fertilization, feedlots) areas are present in the watershed. Wastewater is collected and treated before discharge in the watershed. Sewer overflows and agricultural run-off enter the watershed, but the water intake is not directly under the influence of these discharges.	200-2000	Contaminated
Many and large urbanized areas and intensive agriculture (feedlots, large manure-storage facilities, intensive fertilization with manure) are present in the watershed. Wastewater is generally collected and treated before discharge into the watershed, but significant untreated discharges may occur frequently.	2000-20000	Heavily contaminated
Many and large urbanized areas and intensive agriculture (feedlots, large manure-storage facilities, intensive fertilization with manure) are present in the watershed. Wastewater is generally collected but not or marginally treated before discharge into the watershed, heavily impacted by sewer overflows and manure discharges.	>20000	Grossly contaminated

Understanding the relative significance of pathogen sources and pathways is essential to evaluate the protection level of the surface water zones designated for public water supply under the WFD. It may trigger catchment protection measures to eliminate the most

significant sources and pathways, such as riparian strips, diversion of contaminated run-off from reservoirs, eliminating combined sewer overflows adjacent to intake points for drinking water supply.

8.3.3 Treatment performance targets

The results of the classification of source waters according to the level of faecal contamination in Table 10 can be translated to treatment performance targets (Table 11), using the available information on the concentration of enteric pathogens in source waters in the EU (Appendix 4).

As indicated, the translation of the categorization of source waters based on *E. coli* monitoring data and sanitary surveys to enteric pathogen concentrations and treatment performance targets is uncertain and errs on the safe side. It is advised to give the opportunity to Member States to opt for pathogen monitoring as a more site-specific and precise basis for the definition of treatment performance targets. To support this, Appendix 4 includes a table of treatment performance targets based on measured concentrations of reference pathogens.

Table 11. Suggested treatment performance targets for the different source water categories and enteric pathogens

Source water category	**Treatment performance target (in log_{10})**		
	Enteric protozoa	Enteric bacteria	Enteric viruses
Very pristine	2	4	2
Pristine	3	5	3
Moderately contaminated	4	6	4
Contaminated	5	7	5
Heavily contaminated	6	8	6
Grossly contaminated	Not suitable as source for drinking-water supply; if no alternative sources are available, very extensive treatment barriers are needed.		

Assessing whether a specific water treatment system is capable of meeting these treatment performance targets can be based on the default log removal values for treatment processes provided in Appendix 4.

8.3.4 Control of enteric pathogens by treatment

The treatment needs to be able to consistently remove/inactivate enteric bacteria, viruses and protozoan parasites. The performance targets set the requirements for the treatment. A key principle here is the application of multiple treatment barriers. Some pathogens are more resistant to specific treatment processes than others. *Cryptosporidium* is very resistant to chlorination, much more than enteric viruses. Viruses are much smaller than *Cryptosporidium* and less readily removed by filtration processes. Disinfection processes (i.e.

chlorination, ozone, UV) need clean water for maximum efficiency, so perform better and more reliable when preceded by treatment processes that remove suspended solids and dissolved (organic) matter.

It is therefore recommended to include a requirement in the Directive for (at least) two treatment processes that remove or inactivate enteric pathogens for source waters that do not classify as very pristine. Ideally this combination should be a combination of physical removal (filtration-type processes) and disinfection (with chemical agents or UV).

The performance of water treatment processes (defined here as log removal of enteric bacteria, viruses and protozoan parasites) is site specific. It depends on the design of the process, the way the process is operated and controlled and the conditions in which the process has to operate. A well-designed coagulation process that is operated under strict control of coagulant dosing related to feed water quality and produces water with a consistently low turbidity will remove enteric pathogens better and more consistently than a similar system that is less well-controlled and where effluent turbidity shows turbidity spikes. Similarly, a UV system of which design and operational control are certified according to ÖNORM 5873 (2001) or DVGW W 294 (2006), and is operated under these specifications to consistently provide a UV fluence of 40 mJ/cm^2, will inactivate enteric pathogens better and more consistently than a UV system that is less well designed and controlled.

Other drinking-water regulations (i.e. in Australia, Canada, New Zealand and USA) assign performance credits for the different types of treatment processes, and define the operational conditions and operational monitoring requirements and limits that need to be met to be able to assign these performance credits. An example is given in Appendix 4. Given the regulatory history and environment of the Directive, we recommend not to embed such detailed guidance, but rather to state general principles in the Directive. General principles are:

- Focus on those treatment processes with a substantial impact on enteric pathogens;
- Determine the required contribution of each of these treatment processes to the overall performance (how many bacteria, virus and protozoan parasite log removal credits are needed for each treatment process);
- Evaluate if the treatment processes are capable of providing this contribution, given their feed water quality (variations), design, operation and control, and include hazardous events/failures that may compromise the performance of the treatment process in this evaluation;
- Define appropriate operational monitoring (i.e. parameters, frequency, critical limits) to confirm that the treatment process and overall treatment is performing as planned (see also Section 8.3.5);
- Monitor if the treatment processes are performing within the critical limits; and

- Pre-plan timely corrective actions to bring the (overall) treatment performance back under control for the situation that the operational monitoring is (moving) beyond the critical limits.

8.3.5 Operational monitoring

Operational monitoring is particularly relevant for microbiological safety. Safeguarding drinking-water against the risks from micro-organisms, where a contamination event poses acute health risks, requires continuous vigilance. Frequent to continuous monitoring of the efficacy of barriers against pathogen risks is essential.

The current Directive does have a clear link to operational monitoring for microbial safety, by stating in Article 7 that "*… Member States shall take all measures necessary to ensure that, where disinfection forms part of the preparation or distribution of water intended for human consumption, the efficiency of the disinfection treatment applied is verified …*" but does not incorporate this explicitly in the water quality parameters/values and does not explicitly refer to operational monitoring. Most Member States rely on the microbiological monitoring requirements in the Directive to fulfil this requirement, but as discussed above, these parameters are not well suited for this. The nature of the current methods for microbiological monitoring (lab-based, long time-to-result) makes them unsuitable for operational monitoring. Other parameters are much more suitable for operational monitoring and can be used to frequently or continuously monitor to verify that the control measures are working effectively. Examples are:

- Monitoring of disinfectant dose and disinfectant residual in combination with contact time (flow) to monitor the efficacy of chemical disinfection;
- Monitoring of UV transmission, UV irradiance and contact time (flow) to monitor the efficacy of UV disinfection (in combination with validation of UV reactor design and operation according to ÖNORM 5873 or DVGW W 294, for example);
- Continuous monitoring of turbidity in the effluent of (individual) filters to monitor removal efficiency of (coagulation and) filtration processes.

Several Member States have embedded additional operational monitoring requirements in technical specifications of good practice. Even though operational monitoring is system-specific, general recommendations can be given for operational monitoring of filtration processes and disinfection processes. One parameter in the Directive should be assigned an important role in operational monitoring of filtration systems: turbidity is a well-established parameter to monitor the performance of filtration processes. It can be monitored readily and on-line in the effluent of (individual) filters and indicate whether the filtration process performs as expected. The more intense the operational monitoring (grab samples combined filter effluent versus on line sensors in individual filter effluents) the higher the level of removal that can be assigned to the filtration process. It is therefore recommended that post-filtration turbidity monitoring be included as an additional role for the turbidity monitoring required under the Directive (Table 12).

Table 12. Suggested parameters for operational monitoring of filtration processes

Parameter	Role in risk-based approach	Priority for inclusion	Monitoring requirement	Value	Monitoring site	Frequency
Turbidity	Operational monitoring of efficacy of physical removal by filtration processes[1]	High	Yes	<0.3 NTU (95%) and not >0.5 NTU for 15 consecutive minutes	Post-filtration	Daily or online
Effective disinfectant dose[2]	Operational monitoring of efficacy of disinfection processes	High	Yes	Effective dose is sufficient to achieve planned removal efficiency	Disinfection process	Daily or online

[1] For membrane filtration processes other parameters may be better suited for operational monitoring of integrity of the membrane treatment process; [2] chemical disinfection: disinfectant residual, flow, temperature, pH; translate to dose recognizing (variable) disinfectant decay in receiving water and residence time distribution in contact chamber(s). UV disinfection: monitor UV irradiance in reactor, UV transmission of water, flow; translate to dose recognizing UV absorption in water and residence time distribution in UV reactor.

For disinfection processes, the effective disinfectant dose is the key parameter to determine the efficacy of the disinfection process. In this context, dose is not the amount of disinfectant dosed to the water, but the concentration of disinfectant over the contact time, recognizing the decay of the disinfectant concentration in the receiving water as well as the residence time distribution.

8.3.6 Verification monitoring

Verification monitoring is used to verify, independently of the operational monitoring, that the water treatment related control measures effectively control the risk of enteric pathogens. The parameters in the current Directive that can serve as independent verification that the treatment performance target is met for enteric bacteria are *E. coli* and enterococci, when monitored in treated water. It is recommended to assign this role explicitly to these parameters. It is also recommended to complement these parameters with parameters to verify treatment performance against enteric viruses and protozoan pathogens. Somatic coliphages can serve this purpose for enteric viruses and spores of *C. perfringens* for enteric parasitic protozoa. Table 13 summarizes the suggested parameters and values, and Table 14 the suggested risk-based monitoring frequencies.

More comprehensive information can be found in WHO document *Water treatment and pathogen control: process efficiency in achieving safe drinking-water* (WHO, 2004b) and the *Water safety plan manual* (WHO, 2009a).

Table 13. Risk-based verification monitoring of surface water supplies: suggested parameters and values

Parameter	Role in risk-based approach	Priority for inclusion	Monitoring requirement	Quality requirement	Monitoring site	Remarks
E. coli[1]	Verification of treatment control for enteric bacterial pathogens[4]	High	Yes	Yes (0/100ml)	Post-treatment	New parameter role
Enterococci[2]	Verification of treatment control for enteric bacterial pathogens[4]	Medium[2]	Yes	Yes (0/100ml)	Post-treatment	New parameter role
Clostridium perfringens spores[3]	Verification of treatment control for disinfection-resistant pathogens such as *Cryptosporidium*	High	Yes	Yes (0/100ml)	Post-treatment	New parameter role
Somatic coliphages	Verification of treatment control for enteric viruses	High	Yes	Yes (0/100ml)	Post-treatment	New parameter

[1] This is the (implicit) place of *E. coli* monitoring in the current Directive; [2] parameter is complementary to *E. coli;* [3] the current wording in Annex I Part C "*Clostridium perfringens,* including spores" should be changed to "*Clostridium perfringens* spores".

Table 14. Risk-based verification monitoring of surface water supplies: sampling sites and frequencies

Volume (m^3) of water distributed or produced each day within a supply zone		Sampling site is finished water
		Minimum number of samples per year
≤ 100		10[a]
> 100	≤ 1 000	10[a]
> 1 000	≤ 10 000	50[b]
>10 000	≤ 100 000	365
>100 000		365

[a] All samples are to be taken during times when the risk of treatment breakthrough of enteric pathogens is high; [b] at least 10 samples are to be taken during times when the risk of treatment breakthrough of enteric pathogens is high.

8.3.7 Recommendations for the Directive

Specific recommendations are to include requirements for:

- Classifying the source water according to faecal contamination level by combining the results of the catchment appraisal and investigative monitoring (Table 10). The characteristics evaluated in the catchment appraisal and the results of the *E. coli* monitoring may not match for specific source waters. In these cases, the result leading to the most contaminated source water category prevails;

- Setting targets for adequate removal of enteric bacteria, viruses and protozoa, based on the source water classification (Table 11) and require that water suppliers evaluate whether their water treatment system is capable of achieving these performance targets;
- Operational monitoring of filtration processes using turbidity and for disinfection processes using effective disinfectant dose (Table 12) to ensure treatment is capable of consistently removing enteric pathogens (see also Chapter 16);
- As per Tables 13 and 14, verification monitoring in finished drinking-water of:
  - *E. coli* and intestinal enterococci (existing parameters in the Directive, but with an assigned new role) for verification of removal of enteric bacteria;
  - Somatic coliphages (new parameter) for verification of removal of enteric viruses; and
  - *Clostridium perfringens* spores (existing parameter, but updated) for verification of enteric protozoa.

8.4 Distribution

In the past two decades, concerns were raised in North America and Europe over illness associated with distribution system contaminations as a result of cross connections, pressure transients and maintenance works (Payment et al., 1991; 1997; Craun & Calderon, 2001; Karim et al., 2003; Hunter et al., 2005; Nygard et al., 2007; Besner et al., 2011; LeChevallier et al., 2011). In the Nordic countries, 18-20% of the outbreaks through drinking-water between 1975 and 1991 were associated with cross connections, both in community and private supplies (Stenström, 1994). In the European project MICRORISK, outbreaks through public water supplies in Europe between 1990 and 2004 were reviewed and subjected to a fault tree analysis (Risebro et al., 2007). Eighty-six outbreaks were reported, with a total of 72 546 cases of which 341 were hospitalised and 1 died. In 33% of these outbreaks, contamination during distribution was the dominant cause of the outbreak. Incidents and maintenance work are associated with an increased risk of enteric illness (Säve-Söderbergh et al., 2017). This indicates further vigilance is needed in the protection of the distribution network against ingress of faecal contamination.

8.4.1 Risk assessment

Good practices in construction, operation and maintenance of distribution networks are of paramount importance in protecting the water quality, both with and without a disinfectant residual, in the network. The basic control measures against ingress of enteric pathogens in the distribution network and plumbing systems are:

- *Physical integrity* prevents ingress in places or times where the hydraulic pressure is low or absent. Physical integrity is particularly important in places such as reservoirs that are not pressurized.

- *Hydraulic integrity*. Continuous maintenance (including back-up power supply) of sufficiently high pressure in the network to prevent contaminants entering the network is required.
- *Presence of a disinfectant residual* to inactivate enteric pathogens that may enter the network during failure or absence of hydraulic and physical integrity.
- *Protection against backflow*. Use of break tanks before larger user-installations (industries, hospitals) and the use of backflow preventers in the water meters of house connections.
- *Strict hygiene during construction and maintenance*. Training and supervision of maintenance staff is essential.
- *Approval system* for materials and valves and hydrants to ensure use of materials that are resilient and long-lasting.

The risk assessment systematically evaluates the system's potential vulnerability to external hazards. Examples of information that would normally be used for this evaluation are:

- Presence of sources of enteric pathogens in the vicinity of drinking-water distribution network: urban areas, livestock husbandry, manure storage, wildlife etc.;
- Presence of geohydrological (flooding, infiltration etc.) or weather (heavy rainfall) conditions that could transport enteric pathogens from the sources (in)to the network;
- Low pressure events/areas, and intermittent supply;
- Pipe/fitting material, age and condition of pipes and reservoirs;
- Cross-connections, proximity to sewers and high-hazard facilities, and the relative depth of water supply pipes and sewers;
- Areas with high leakage, illegal connections, household or farm storage systems or where the quality of construction is uncertain;
- Large buildings, such as hospitals.

At each step, the objective is to identify how contamination could arise from enteric pathogens, by considering the events that could lead to the presence of contamination. A sanitary inspection is a systematic investigation of the distribution system to identify vulnerable points and evaluate if control measures are in place. Examples of sanitary inspections are:

- Physical inspections of new connections to evaluate protection against backflow;
- Site inspection during repairs;
- Document inspection of repairs;
- Site inspection of infrastructure (above ground): fences, locks, hatches etc.;
- Site inspection of reservoirs during maintenance;

- Checking location and operation of valves;
- Evaluate leakage rate in different areas;
- Check certification of materials;
- Inspection of the condition of pipe materials after repairs;
- Evaluate mains breaks.

Hygiene protocols should be in place for repairs, construction and other works on the distribution network as these may pose a high risk of contamination. The sanitary inspection should also inspect strict adherence to these protocols.

8.4.2 Operational monitoring

As with treatment, operational monitoring is particularly relevant for microbiological safety in distribution. Safeguarding drinking-water against the risks of microorganisms, where a contamination event causes health risks acutely, requires continuous vigilance, particularly in the distribution network as no or a limited barrier is present to protect the consumer once contamination occurs. Frequent to continuous monitoring of the efficacy of barriers against pathogen risks is essential. Parameters that can be used for frequent to continuous monitoring that provide evidence that control measures are in place and effective are pressure monitoring (indicating if hydraulic and structural integrity is compromised) and monitoring of disinfectant residual (where applied; indicating potential ingress of contaminants). Other online sensors may also provide information on the potential contamination of the distributed water.

More comprehensive information can be found in WHO document *Safe piped water: managing microbial water quality in piped distribution systems* (WHO, 2004c) and *Water safety in distribution systems* (WHO, 2014).

8.4.3 Verification monitoring

For protection against enteric pathogens, verification is based on the analysis of faecal indicator microorganisms, with the organism of choice being *E.coli.* It provides conclusive evidence of recent faecal pollution and should not be present in drinking-water. Tables 15 and 16 suggest the frame for monitoring of the distribution system.

If *E. coli* is detected at the consumers' tap, the first actions are to resample the same premises to confirm the continued presence of faecal contamination, and to inspect if there are conditions that could have caused a faecal contamination, such as low/no pressure events, 'upstream' repairs, leaks, cross-connections etc. Incidental detection of *E. coli* in samples at consumers' taps should always be regarded as indication of faecal contamination of the water in the network, but given the sensitivity of the analysis, false-positive results may occasionally occur, due to sampling or lab errors. Hence resampling is needed to confirm the contamination. When resampling, it should be recognized that at the time of resampling (usually at least one day after the first sample was taken), the water in the

network will have been used or transported downstream. It is therefore recommended to follow an exceedance up with investigative sampling and resample at more locations than the 'positive' premises and to take the knowledge of the hydraulics of the distribution network near the 'positive' sampling site into account when selecting sampling sites for resampling. If the inspection indicated one or more potential conditions that may have caused a faecal contamination, it is recommended to include samples in the investigative sampling that could help determine the source and the spread in case a contamination has occurred. Source tracking is important to stop any contamination entering the network and understanding the spread is important to understand where and how to take effective corrective measures.

Table 15. Suggested parameters for verification monitoring of distribution systems

Parameter	Role in risk-based approach	Priority for inclusion	Monitoring requirement	Value	Monitoring site	Remarks
E. coli[1]	Verification of integrity of distribution network against ingress of faecal contamination	High	Yes	Yes (0/100ml)	Consumers' tap	Existing parameter role
Coliforms[2]	Verification of integrity of distribution network against ingress of contamination	Medium	Yes	Yes (0/100ml)	Consumers' tap	Existing parameter role

[1] This is the place of *E. coli* monitoring in the current Directive; [2] parameter is complementary to *E. coli.*

Table 16. Risk-based verification monitoring in distribution: sampling sites and frequencies

Volume (m^3) of water distributed or produced each day within a supply zone		Sampling site is consumer's tap
		Minimum number of samples per year
≤ 100		>0
> 100	≤ 1 000	4
> 1 000	≤ 10 000	4 + 3 for each 1000m^3/d and part thereof of the total volume
>10 000	≤ 100 000	
>100 000		

8.4.4 Recommendations for the Directive

Specific recommendations are:

- To maintain the current values and frequencies for monitoring of *E. coli* and coliforms at the consumer's tap (as per Tables 15 and 16); and
- To maintain the current level of protection of the distributed drinking-water, but specify this role for these parameters more explicitly.

Part C: Chemical aspects

9. Parametric values in the Directive and guideline values in the WHO Guidelines

KEY MESSAGES

- The parametric values in the current Directive are broadly based on the second edition of the WHO Guidelines from 1993.
- Differences between current WHO guideline values and the parametric values in the Directive have several reasons – science-based and policy choices.
- The WHO Guidelines have been updated and there are changes in guideline values based on new data.

A comparison of the parameters included in Annex I Part B of the Directive with the Guidelines shows that 17 of the parameters have either different parametric values or are characterized differently between the Directive and the WHO Guidelines. A number of these differences are minor and reflect rounding to whole numbers, where appropriate. For a number of other substances that may be carcinogenic the guideline values have a tenfold lower value in the Directive to reflect the EC's policy decision to regard a risk of 10^{-6} as acceptable in contrast to the WHO benchmark risk of 10^{-5} (see further details in Chapter 10). In other cases differences are based on practical decisions agreed by stakeholders and the EC. Finally, there are also differences because of updates in the WHO Guidelines since the publication of the Directive in 1998. The differences are summarized in Table 17.

Table 17. Parametric values for chemical parameters in Annex I Part B of the Directive and WHO guideline values

Parameter	Directive PV	WHO GV	Date WHO review	Comments
Acrylamide	0.1 μg/L	0.5 μg/L	2011	Based on cancer risk extrapolation Difference due to assumed capability of achieving lower values in Europe
Antimony	5 μg/L	20 μg/L	2003	Threshold chemical WHO GV updated based on new scientific data that reduced uncertainty
Arsenic	10 μg/L	10 μg/L	2011	Based on cancer risk extrapolation (approximately 10^{-5}); for the Directive, the EU accepts a higher level of risk than 10^{-6} due to treatment performance WHO GV is designated provisional on the basis of treatment performance and analytical achievability
Benzene	1 μg/L	10 μg/L	1993	Based on cancer risk extrapolation Difference in acceptable level of risk (EC: 10^{-6}; WHO: 10^{-5})
Benzo(a)pyrene (B(a)P)	0.01 μg/L	0.7 μg/L	1993	Based on cancer risk extrapolation EU retained WHO GV from first edition of Guidelines for precaution; WHO GV is based on 10^{-5} risk using an unusual risk model
Boron	1 mg/L	2.4 mg/L	2009	Threshold chemical WHO GV updated with new scientific data; WHO also uses an allocation factor of 40% instead of 10% for the Directive
Bromate	10 μg/L	10 μg/L	2005	Based on cancer risk extrapolation; non-linear dose response relationship, so GV is conservative WHO GV designated provisional because of limitations in available analytical and treatment methods Under revision by WHO
Cadmium	5 μg/L	3 μg/L	2011	Threshold chemical Difference due to rounding

Parameter	Directive PV	WHO GV	Date WHO review	Comments
Chromium	50 μg/L	50 μg/L	1993	Based on cancer risk extrapolation; non-linear dose response relationship WHO GV designated provisional due to uncertainties in the toxicological data; WHO GV relates to total chromium Under revision by WHO
Copper	2 mg/L	2 mg/L	2004	Threshold chemical WHO GV is an acute value
Cyanide	50 μg/L	GV withdrawn	2009	Threshold chemical WHO GV withdrawn because primarily found due to accidental spills; acute and chronic health-based values are available
1,2-Dichloroethane	3 μg/L	30 μg/L	2003	Based on cancer risk extrapolation Difference in acceptable level of risk (EC: 10^{-6}; WHO: 10^{-5})
Epichlorohydrin	0.1 μg/L	0.4 μg/L	1993	Threshold chemical WHO GV designated provisional due to uncertainties surrounding the toxicity Difference due to assumed capability of achieving lower value in Europe
Fluoride	1.5 mg/L	1.5 mg/L	2004	Threshold chemical
Lead	10 μg/L	10 μg/L	2011	Previously threshold chemical, now based on the as low as reasonably practicable principle WHO GV designated provisional because the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has withdrawn the provisional tolerable weekly intake (PTWI) on grounds that there is no discernible threshold
Mercury	1 μg/L	6 μg/L	2004	Threshold chemical WHO GV updated based on new scientific data; WHO GV relates to inorganic mercury

Parameter	Directive PV	WHO GV	Date WHO review	Comments
Nickel	20 μg/L	70 μg/L	2004	Threshold chemical WHO GV updated based on new scientific data in humans Under revision by WHO
Nitrate	50 mg/L	50 mg/L	2011	Threshold chemical
Nitrite	0.5 mg/L at tap 0.1 mg/L at works post treatment	3 mg/L	2011	Threshold chemical PV based on precautionary approach combined with practical achievability
Pesticides	0.1 μg/L	Individual GVs and health-based values	-	Policy decision to cover each individual pesticide and relevant metabolites; this relates to toxicologically relevant metabolites, i.e. those retaining pesticidal activity and/or which retain significant toxicity to mammals WHO proposes individual health-based values
Heptachlor and heptachlor epoxide	0.03 μg/L	GV withdrawn	2004	WHO GV withdrawn because no findings of occurrence in drinking-water; original GV was based on 1% of the tolerable daily intake (TDI) but levels in food have significantly reduced Could be covered by the 0.1 μg/L rule for pesticides
Aldrin and dieldrin	0.03 μg/L	0.03 μg/L	1993	Based on a 1% allocation of the TDI to drinking-water; exposure from food and other sources has significantly reduced Could be covered by the 0.1 μg/L rule for pesticides
Pesticides total	0.5 μg/L	As for pesticides	-	Policy decision as above
Polycyclic aromatic hydrocarbons (PAHs): – Benzo(b)fluoranthene – Benzo(k)fluoranthene – Benzo(ghi)perylene – Indeno(1,2,3-cd)pyrene	0.1 μg/L	No GV	-	PV is based on pre-1984 Guidelines and is not health-based but on maximum concentrations seen in surface water at a time when treatment was less effective WHO GV was withdrawn in 1984 because it was not possible to set a health-based value for most PAHs and B(a)P was considered to be most important; this was reviewed and confirmed in 1998

Parameter	Directive PV	WHO GV	Date WHO review	Comments
Selenium	10 μg/L	40 μg/L	2011	Threshold chemical WHO GV updated based on new data on occurrence and assessment of the quality of epidemiological studies WHO GV is designated provisional because of the uncertainties inherent in the scientific database
Tetra- and trichloroethene	10 μg/L	40 μg/L 20 μg/L	1993	Threshold chemicals PV based on precautionary approach (political decision) WHO GV for trichloroethene designated provisional on basis of uncertainties in toxicological and epidemiological data Under revision by WHO
Trihalomethanes (THMs) total: – Bromoform – Bromodichloromethane – Chloroform – Dibromochloromethane	100 μg/L	 100 μg/L 60 μg/L 300 μg/L 100 μg/L	 1993 1993 1998 1993	Threshold chemicals except bromodichloromethane based on cancer risk extrapolation PV based on practical approach to reduce chlorination by-products
Vinyl chloride	0.5 μg/L	0.3 μg/L	2004	Based on cancer risk extrapolation WHO GV was updated in 2004

10. General considerations in WHO guideline value derivation

KEY MESSAGES

- Both WHO and EC take a conservative or precautionary approach to deriving Guideline values and parametric values.
- WHO guideline values are based on long-term exposure. Short-term exceedances do not normally represent a discernible increase in the risk to the health of consumers.
- Mixtures of chemicals are considered by WHO and in the Directive.
- WHO recommends that regulators should adapt the Guidelines' recommendations to their particular circumstances and needs.
- WHO states that "safe drinking-water", as defined by the Guidelines, does not represent any significant risk to health over a lifetime of consumption, including different sensitivities that may occur between life stages".
- If the EU wishes to adopt more stringent values this is a matter of policy but they should always consider the impact on cost and whether there is sufficient benefit to health to justify increased costs. The basis of such decisions should always be made transparent to avoid misunderstanding of the implications of exceeding a standard.

10.1 Guideline values for substances which may be carcinogenic and the acceptable level of risk

The values determined for substances that are considered to be carcinogenic are mostly established by the application of mathematical models to toxicological data primarily in laboratory rodents, usually the linearized multistage model. This approach is described in the Guidelines as follows: "*The guideline values for carcinogenic substances have been computed from hypothetical mathematical models that cannot be verified experimentally. These models do not usually take into account a number of biologically important considerations, such as pharmacokinetics, DNA repair or protection by the immune system. They also assume the validity of a linear extrapolation of very high dose exposures in test animals to very low dose exposures in humans. As a consequence, the models used are conservative (i.e. err on the side of caution). The guideline values derived using these models should be interpreted differently from TDI-based values because of the lack of precision of the models. At best, these values must be regarded as rough estimates of cancer risk. Moderate short-term exposure to levels exceeding the guideline value for carcinogens does not significantly affect the risk*."

In the WHO Guidelines, the guideline value is the concentration in drinking-water associated with an upper-bound excess lifetime cancer risk of 10^{-5} (one additional case of cancer per 100,000 population exposed to two litres of water per day, containing the contaminant at that concentration, for 70 years. However, the resulting guideline value is the upper 95%

confidence interval on the calculation and the actual risk is almost certainly much lower than this and may be zero. WHO considered that this essentially means that the risk at a level of 10^{-5} can be considered negligible. It is also theoretical and cannot be considered to be the actual number of additional cancer cases that will occur.

Taking a more precautionary approach by choosing a risk value of 10^{-6} as acceptable may not provide any greater health protection but it will frequently increase the cost of achieving the stated concentration. In making a policy choice about the acceptable level of risk it is therefore important to consider whether the minimal benefits that will be achieved justify maintaining an acceptable risk level of 10^{-6} as general policy rather than considering each substance according to its circumstances. However, final policy choices on the acceptable level of risk are the responsibility of the EC and Member States.

10.2 Guideline values for threshold chemicals

In the case of so called “threshold chemicals” which are based on the no observed effect level or benchmark dose in animal studies, but occasionally on human epidemiology, uncertainty factors are applied to the no-observed adverse effect level (NOAEL) or occasionally lowest-observed adverse effect level (LOAEL) with an additional uncertainty factor applied, to derive an acceptable daily intake (ADI) or TDI. These uncertainty factors can be as great as 1000.

The TDI is an estimate of the amount of a substance in food and drinking-water, expressed on a body weight basis (milligram of the substance per kilogram of body weight), that can be ingested over a lifetime without appreciable health risk. A proportion of the TDI is allocated to drinking-water to allow for exposure from other sources (including food) and this also frequently errs on the side of caution. For such chemicals the guideline value is expected to be associated with no risk of adverse effects.

In the current Directive the parametric value for a number of substances that are considered to be threshold substances have been set at precautionary levels based primarily on political considerations. While such approaches are possible, they are the responsibility of the EC and Member States. It is important, if such decisions are taken, that the basis of the values is clear and transparent to avoid confusion regarding the implications for health of exceeding the value.

10.3 Food and environmental quality aspects

WHO emphasizes the need to consider the overall exposure to contaminants when considering standards and allocating resources to controlling contaminants. In developing drinking-water guideline values for “threshold” chemicals, WHO takes into account the potential and, where there are suitable data, actual exposure from food, typically by allocating a certain fraction of overall exposure to drinking-water.

The development of standards for drinking-water and food has significant similarities; however, there are also significant differences. The approach to developing safe levels (TDI or ADI) for a contaminant is basically very similar. The standards for food are mostly

developed to provide a benchmark for preventing contaminants reaching food in significant quantities that will result in the ADI or TDI being exceeded through the diet (e.g. pesticide maximum residue levels) and migration limits for food packaging materials. For other environmental contaminants, there are levels above which the product should not be sold (e.g. metals in shellfish), but this is based on individual products of which there are many.

However, the variety of food is large in comparison with drinking-water, which is essentially a single product, and the monitoring and enforcement of standards is very different and less specific. In addition, the interpretation of food standards is different to that of drinking-water standards in the EU, with food standards being considered on an average exposure basis and drinking-water standards as absolute maxima in individual samples. Thereby the approach to chemical contaminants remains much more stringent for drinking-water than food. This difference means that the practical impact of standards on water supply is greater than on food, particularly since drinking-water is often from a single source that cannot be easily changed.

While food legislation is generally targeted at preventing contamination and avoiding the consumption of contaminated produce, legislation on contaminants in water bodies, which may or may not be sources of drinking-water, is primarily aimed at protecting aquatic life. The development of standards for chemical pollutants in surface waters under the WFD follows guidance aimed at protecting the most sensitive "receptor", whether that be aquatic organisms, wildlife vulnerable to secondary poisoning, or humans consuming fish/shellfish or drinking-water (EC, 2011). It should be noted, however, that the protection of aquatic life is based on different approaches because the exposure is different and there are major differences in the toxic mechanisms in mammals and aquatic organisms. The protection of aquatic or terrestrial ecosystems is based on protecting population stability, while in mammalian toxicology the protection of humans from chemical contaminants in food and drinking-water aims at protecting the individual. The WFD approach of protecting aquatic ecosystems in a way that also protects human health relies on the prevention of water contamination, including by improving sewage/wastewater treatment and developing management procedures to minimize diffuse pollution. The Member States' river basin management plans, which identify pressures and measures at catchment level, are an important tool in achieving this objective.

10.4 Long-term versus short-term exposure

For the great majority of chemicals, the WHO Guidelines are based on long-term exposure. This means that short-term exceedances of the guideline or standard value do not normally represent a discernible increase in the risk to the health of consumers. This is true for both threshold chemicals and those for which values have been derived using low-dose risk extrapolation. It is, therefore, important that consumer confidence in the water supply is not unnecessarily undermined when there are short-term exceedances of the guideline or standard values. The EC may consider providing guidance as to how to interpret exceedances of the parametric values (short and longer-term). This could be assisted by

developing short-term values for parameters for use in the event of an exceedance or incident.

10.5 Considering mixtures in drinking-water

Chemical constituents and contaminants rarely, if ever, occur alone in water sources. There are invariably a number of chemicals present. They may be naturally occurring in drinking-water sources, they may be present as a consequence of human activity or they may be present as a consequence of drinking-water treatment or materials used in distributing drinking-water to consumers, including in buildings. These chemicals may be present in varying, but mostly very low, concentrations.

Chemicals present together may interact resulting in either an increase in toxicity (synergism or addition) or a decrease in toxicity (antagonism). However, there may be no interaction, in which case the substances present may be considered to act independently. Where interaction resulting in synergism or antagonism is possible, to be realized this generally requires a sufficiently high concentration of one or more components to interfere with the biochemical or physiological processes in which the chemicals in the mixture are involved.

WHO has considered mixtures in drinking-water (WHO, 2017b) in a review that has undergone external international peer review. The conclusions of this and other reviews is that the scientific evidence supports dose addition or no interaction as the most likely situations, particularly at the low doses normally encountered in drinking-water.

However, the Directive already addresses mixtures with several parameters for various reasons. These include nitrate and nitrite which have a similar mechanism of action and are addressed by the formula nitrate/50 + nitrite/3 ≤ 1, as also recommended by the WHO Guidelines and which reflects an additive toxicity. THMs are grouped effectively as a means of reducing the overall exposure to chlorination by-products, while the addition of haloacetic acids (HAAs) would reinforce this approach. WHO recommends that for pesticides with a similar mode of action, an additive approach should be used. This has been addressed through a more precautionary approach in the Directive with the value for any individual pesticide of 0.1 µg/L and for total pesticides of 0.5 µ/L irrespective mode of action. Another example from the Directive is the combined value of 10 µg/L for tri- and tetrachloroethene to reflect possible addition where they occur together, although WHO proposes individual values. Such approaches are fairly pragmatic but address the need to provide appropriate regulatory guidance while retaining a system which is practical.

In the future there may be a need to consider other groups of chemicals. The review of the different approaches to and importance of considering mixtures in drinking-water in the EU context, which is presented in Appendix 5, provides a basis for identifying a useful way forward.

10.6 Adaptation of guideline values to national circumstances

The WHO Guidelines do encourage Member States not to merely copy guideline values into national standards but to take consideration of their particular circumstances. This usually

means that if the costs or practicality of meeting a guideline value are too great, for most chemicals a higher value can then be accepted without compromising health. If regulators decide to choose a lower value than the guideline value it is important that this is made clear and duly justified so that in the case of an exceedance authorities understand the basis of the standard. In setting national standards it is also important to consider the impact of standards on affordability. Increased costs of water will impact on poorer families or communities to a disproportionate extent. These populations are already at greater risk of a number of health problems and WHO has a stated policy about the need to maintain the affordability of water, particularly for the poorest in society (WHO, 2017a).

11. Prioritization of parameters in the context of a risk-based approach

KEY MESSAGES

- WHO recommends that chemical parameters for inclusion in the Directive should be prioritized to avoid reducing the impact of standards with largely redundant parameters. They should be either of particular health significance and should occur across the Member States at significant concentrations.
- The concept of local hazard analysis and risk assessment is a key part of the WSP approach and may identify additional substances that are of local concern. Their control and monitoring should be dealt with locally in accordance with Annex II of the Directive.
- The requirement in the Directive that no substance should be present at concentrations which constitute a potential danger to health should be emphasized, including substances not explicitly listed in Annex I.

Since the publication of the second edition of the WHO Guidelines, which was the basis for the parameters in the current Directive, there has been a change in approach by WHO, reflected since the third edition of the Guidelines published in 2004. The focus shifted from over reliance on end-product monitoring of a long list of possible chemical contaminants to a more proactive approach to preventing contamination or to ameliorating potential risks before consumers are exposed. This approach is encapsulated in the WHO Framework for safe drinking-water which is underpinned by the introduction of the WSP approach (see also Chapter 2).

In this context, WHO has encouraged Member States to adopt a more selective approach to the choice of chemical parameters that are included in national, or in the case of the EU, supra-national standards. Such selectivity helps to focus attention on what is actually important and reduce the possibility that a long list of parameters, subject to routine monitoring, will distract attention from the main issues relating to health and acceptability. In addition, a long list of parameters has been interpreted by some consumers as an indication that their drinking-water is seriously polluted when this is not the case and so has the opposite effect to that intended.

In accordance with the risk-based approach encompassed in WSPs, the change encourages a more targeted approach to controlling and monitoring contaminants. This is based on an analysis of hazards of local concern throughout the supply from source to the point of delivery to the consumer and an assessment of the risk from those hazards in relation to exposure and the potential for exceedance of health-based guideline values or standards as adopted by a particular Member State.

The EC has already started to introduce this approach by adopting risk-based monitoring for physico-chemical contaminants through the modification to Annex II of the Directive in October 2015. It is, therefore, essential to consider the priorities for the contaminants to be

included in Annex I of the Directive and to assess which of the parametric values for those contaminants should be changed in line with new scientific evidence and revisions of the WHO Guidelines.

Only a very small number of chemicals have been shown to cause adverse health effects in humans through drinking-water exposure, while others are known to cause adverse effects in laboratory animals. For these, the potential risks to human health can only be estimated by extrapolation. However, experimental studies are carried out at much higher doses than those encountered in the environment from drinking-water, food or other sources and there is usually significant caution included in such extrapolations (see Section 10.1 for further details).

While there are many possible contaminants in water sources that have the potential to reach drinking-water, most of these are of no significance. Substances that are known to cause adverse health effects in humans as a consequence of exposure through drinking-water are arsenic, fluoride, lead and nitrate/nitrite, i.e. there is clear evidence in humans for effects through exposure in drinking-water. There is limited evidence in humans that the unintentional by-products of disinfection of drinking-water using chlorine may pose a low risk to exposed individuals but it still remains uncertain whether the associations seen in epidemiological studies are causal. There have been suggestions that soluble manganese salts may also impact health but at present this remains to be confirmed. It is important to remember that for all substances considered, the overall weight of evidence is the key factor in determining cause and effect.

Occasionally there will be contaminants present that are of interest in a small number of specific circumstances and it may not be appropriate to include these in standards that relate to all Member States. Article 4 of the Directive does incorporate a clause which requires Member States to ensure that they do not supply water that contains any microorganisms or chemicals in numbers or concentrations that constitute a potential danger to public health. It is, therefore, appropriate for Member States on encountering contamination that is not widespread across the EU to set national standards for such contaminants based on either the WHO Guidelines or on an alternative appropriate source of guidance that will provide a basis for consistency across Member States. This is an important step in direct implementation of the Directive and it is important that Member States identify an appropriate national authority that can carry out this function. It is important that the principle of not allowing water sources or drinking-water quality to degrade is maintained and made clear and this is an overarching principle for the protection of water. Inclusion or exclusion of a parameter from the list of parameters in Annex I Part B does not change this.

Some substances are primarily encountered as a consequence of spills (e.g. cyanide) that are not predictable. Routine monitoring for such substances is not a reliable way of protecting against such accidents, and will dilute resources. Safe levels can be obtained from a number of authorities, including the WHO Guidelines.

When a substance is encountered that is not listed in Annex I then the latest edition of the WHO Guidelines can be consulted as a first source of advice. When a standard in Annex I is exceeded, the Guidelines also provide an important source of information as to the public health significance of the concentrations encountered. Typically an excursion above a guideline value does not constitute a risk to health and in some cases WHO has established short term exposure values.

In composing a list of contaminants to be covered by Annex I Part B to the Directive, the combination of presence, concentration and potential for health impacts is the basis for selecting and prioritizing substances. It is important that care is taken not to dilute the value of the most important parameters by including long lists of substances that are of limited or no significance for drinking-water quality. The substances considered for inclusion in Annex I were chosen because information was available on likely widespread occurrence at significant concentrations and the potential for health effects. Substances raised by Member States because of local problems were considered in the context of impact across Europe. The outcomes of the selection process are further discussed in Chapters 12-14 which provide a rationale for the possible removal of parameters currently covered in Annex I Part B and recommendations for inclusion of new parameters.

It is of note that the existing parameters in the Directive have gone through a selection process. There are data on the existing parameters in the Directive, which were taken from the second edition of the WHO Guidelines following wide consultation with Member States and other interested parties/organizations. This process was followed in the preparation for proposals in 2007 and has been followed here building on the information used in the previous evaluations. This includes international interest and activity beyond Europe. While it was not possible to follow a systematic approach that would effectively start from the beginning, the selection of substances and groups of substances reflects concerns from around the world but also Europe. Consultation with Member States and other stakeholders (see Chapter 1 and Appendix 2) has provided feedback on the relevance to Member States of the parameters to be considered. The available health data was then considered to determine whether it was appropriate to include these parameters in the Directive.

The ranges of concentrations for those substances under consideration for removal, inclusion or change were obtained from the data provided by Member States and water suppliers (see Chapter 1 and summary of data obtained in Appendix 1). For some substances, not already included in the Directive, the number of Member States or water suppliers able to provide data was quite small. The ranges along with median (or sometimes mean) concentrations were used to check whether the highest values were outliers due to incidents or unusual circumstances. Data were received from 18 Member States but the details of reporting were not consistent between the Member States but a more detailed data collection and analysis was not possible within the timeframe and remit of the project. There is a need for a more systematic collection and evaluation of quantitative occurrence data outside of the need to consider compliance. However, the data provided a very valuable insight into the occurrence of these substances and the levels at which they are found in drinking-water. The data are referred to in the chemicals fact sheets in Appendix 6.

12. Rationale for removing parameters from Annex I Part B

KEY MESSAGES

- It is recommended to remove five parameters from Annex I Part B (i.e. benzene, cyanide, 1,2-dichloroethane, mercury and PAHs), given their characteristics and likely low occurrence in drinking-water and source waters.
- If any of the aforementioned substances, or other substance considered by the WHO Guidelines, are identified as of concern as a result of local hazard analysis and risk assessment, then guidance can be sought from the WHO Guidelines. Therefore, the Directive could make explicit reference to the WHO Guidelines as a point of reference in such circumstances.

It is recommended that several parameters should be removed from Annex I Part B. These are benzene, cyanide, 1,2-dichloroethane, mercury and PAHs. The reasoning for each is presented in the following sections.

Should any of these substances be identified under local hazard analysis and risk assessment, then guidance can be sought from the WHO Guidelines. In addition, the requirement of Article 5 of the Directive that no substance should be present in a concentration that could constitute a potential danger to human health remains and is strongly supported by WHO. It is, therefore, probable that also other substances will be identified through local hazard analysis and risk assessment stipulated by Annex II for which advice as to their significance will be required and on which the WHO Guidelines do provide an important point of reference.

12.1 Benzene

Benzene is only encountered in drinking-water very rarely and even when encountered it is below the precautionary parametric value. According to the EU synthesis report on drinking-water quality for the period 2011-2013, the reported compliance rate was 99.99%. However, the data indicate that the reported occurrence includes pollution incidents. According to data requested from Member States in 2016, the highest maximum concentration reported was 300 µg/L, which is well above the reported taste threshold in drinking-water, but the highest median value was 0.5 µg/L.

Benzene is readily degraded in the environment and although it is of significance for air pollution from hydrocarbon sources, particularly gasoline, it is generally not significant for drinking-water. It is one of the BTEX-group of substances (benzene, toluene, ethylbenzene and xylene) and these can be found when petroleum products, particularly diesel, are spilt, but benzene is not a good marker for the others. These substances are primarily a problem for drinking-water in incidents because of their very low taste and odour threshold. If localized concerns are identified in hazard analysis and risk assessment, usually associated

with other BTEX compounds, the WHO Guidelines provide a suitable source of guidance, including the WHO background document on benzene in drinking-water (WHO, 2003b).

12.2 Cyanide

Cyanide is rarely found in drinking-water at significant concentrations. According to the EU synthesis report on drinking-water quality for the period 2011-2013, the reported compliance rate was 100%. When it does occur, this is primarily because of spills related to certain mining and industrial activities. According to data requested from Member States in 2016, the highest maximum concentration reported was 94 µg/L but the highest median value was 10 µg/L.

WHO has re-evaluated the guideline value proposed in 1993. Incorporation into national standards for drinking-water and routine monitoring are not a practical or reliable means of detecting or preventing such spills. In the event of a spill or other discharge, the WHO Guidelines provide a suitable source of advice, including the WHO background document on cyanide in drinking-water (WHO, 2009c).

12.3 1,2-Dichloroethane

1,2-Dichloroethane is an intermediate in the manufacture of vinyl chloride. It is rarely encountered in drinking-water at significant concentrations. According to the EU synthesis report on drinking-water quality for the period 2011-2013, the reported compliance rate was 100%. The data indicate that its occurrence is very rare. It has occasionally been seen to exceed the parametric value of 3 µg/L but this appears to be primarily due to acute pollution incidents. According to data requested from Member States in 2016, the highest maximum concentration reported was 40 µg/L but the highest median value was only 0.5 µg/L. If localized concerns are identified in hazard analysis and risk assessment, the WHO Guidelines provide a suitable source of guidance, including the WHO background document on 1,2-dichloroethane in drinking-water (WHO, 2003c). With the increased implementation of the Groundwater Directive and Environmental Quality Standards Directive, however, 1,2-dichloroethane should not be found.

12.4 Mercury

Mercury is only of concern for drinking-water in the water soluble inorganic form as opposed to the more toxic organic form (e.g. methyl mercury), which is of extremely low water solubility. Concern about mercury is largely related to the organic forms which accumulate in food. It is rarely encountered in drinking-water in the EU and where it has occurred it is extremely localized. According to the EU synthesis report on drinking-water quality for the period 2011-2013, the reported compliance rate was 99.98%. According to data requested from Member States in 2016, the highest maximum concentration reported was 20 µg/L but the highest median value was only 0.1 µg/L.

The WHO guideline value for inorganic mercury was revised in the fourth edition of the Guidelines based on a revised assessment by the International Programme on Chemical

Safety (IPCS). Subsequently, JECFA proposed a provisional tolerable intake of 4 µg/kg body weight which would justify a higher guideline value for inorganic mercury in drinking-water. It is therefore considered appropriate to remove mercury from Annex I. If localized concerns are identified in hazard analysis and risk assessment, the WHO Guidelines provide a suitable source of guidance, including the WHO background document on mercury in drinking-water (WHO, 2005).

12.5 Polycyclic aromatic hydrocarbons

PAHs arise in drinking-water as a consequence of old coal tar linings on cast-iron mains. This practice ceased several decades ago and so the problem is gradually decreasing. The PAHs mentioned in the directive are benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(ghi)perylene and indeno(1,2,3-cd)pyrene, which have a group parametric value of 0.1 µg/L. An additional PAH, which is included separately, is B(a)P with a parametric value of 0.01 µg/L. All of these substances are of low water solubility and their presence is associated with particulate matter from the breakdown of the old linings. Coal tar linings do remain an issue for management of distribution systems and the presence of coal tar linings is an important part of identifying possible hazards in hazard analysis and risk assessment that is part of the WSP approach. WHO has not proposed a health-based value or guideline value for PAH other than B(a)P. If localized concerns are identified in hazard analysis and risk assessment, the WHO Guidelines provide a suitable source of guidance, including the WHO background document on PAH in drinking-water (WHO, 2003d).

The current Directive parametric value is based on a pre-guidelines value (pre-1984) in the old WHO international standards that was not based on health but on the premise that six named PAHs, including B(a)P and fluoranthene, were greater than 0.11 µg/L in only 1% of source waters and much lower in drinking-water except if coal-tar linings were present in distribution. It was noted that two thirds of all PAHs in surface waters were bound to particulate matter (WHO, 1984). Our analysis of the data available suggests that the presence of these PAHs and B(a)P are significantly correlated. It was therefore considered that the value of retaining PAHs in Annex I was extremely limited since it is proposed that B(a)P is retained. According to the EU synthesis report on drinking-water quality for the period 2011-2013, the reported compliance rate for PAHs was 99.95% but the data indicate that exceedances must include incidents of sediment disturbance in distribution. According to data requested from Member States in 2016, the highest maximum concentration reported was 9.9 µg/L, which would certainly associated with taste and odour problems and discoloration by particles. WSPs should include procedures for managing distribution systems that would minimise the risk of disturbing sediments resulting in aesthetically unacceptable water.

13. Parameters that were considered but not proposed for inclusion in Annex I Part B

KEY MESSAGES

- Several emerging contaminants and groups of contaminants were considered but not recommended for inclusion in Annex I Part B because the data show that concern for health is highly unlikely. Contaminants considered were: asbestos, glass fibres, nanoparticles, chlorophenols, N-nitrosodimethylamine, thallium, calcium/ magnesium, personal care products, pharmaceuticals and endocrine disrupting compounds (EDCs).

Since 1993, the second edition of the Guidelines and 1998, the adoption of the Directive, there has been a significant amount of research on contaminants, both natural and anthropogenic, that may reach drinking-water. The advent of advanced analytical techniques that allow the detection of increasingly small amounts of substances in both untreated and treated water has resulted in awareness of a wide range of possible contaminants in source waters, although not all of these are found in drinking-water. Many of these substances are not new in terms of their presence in the environment and so the better description is substances of emerging concern or of emerging interest. Most of these contaminants are found primarily in surface water that receives sewage effluent because they arise from human use. Some others are found largely in groundwater and come from past human activities, while others arise during drinking-water treatment or are naturally occurring in either groundwater or surface water.

For the purpose of this report, WHO had identified a number of substances or groups of substances for possible inclusion in Annex I Part B, others were suggested by Member States and/or the EC for consideration. We considered all proposed substances, including emerging contaminants, and recommend a number of these for inclusion in Annex I Part B (see Chapter 14). Others were considered but not found to be appropriate for inclusion at this time. These are addressed in the following sections. It was not in the mandate of this project to consider all possible contaminants, whether or not there was evidence of occurrence at significant concentrations in drinking-water in the EU (see also Chapter 11).

13.1 Asbestos

Asbestos is a fibrous material that has a complex inorganic chemical structure. The primary route to drinking-water is from old asbestos-cement pipes that were widely used up to the 1980s, since when the health and safety aspects of handling such pipes and the reliability and performance have resulted in them not being used today. Source waters in areas rich in asbestos minerals may also be a source but clearly this is limited to specific regions. While asbestos fibres certainly do get into drinking-water, analysis is actually through enumeration of fibres using electron microscopy and is not a routine procedure. WHO has carried out a detailed assessment of the potential health effects of asbestos fibres in drinking-water and

the weight of evidence does not support the contention that they are of concern for health. In view of the overall evidence it is not considered necessary to include asbestos fibres in Annex I to the Directive. However, asbestos-cement pipes should no longer be used and they should no longer be approved for use for drinking-water. This also indicates that a programme for removal of existing asbestos-cement pipes is not necessary, as those pipes deteriorate and require gradual replacement with other materials.

Further information on asbestos in drinking-water can be found in the respective WHO background document (WHO, 2003e).

13.2 Glass fibres

Glass fibres may reach drinking-water from the use of glass reinforced plastic materials in contact with drinking-water. However, there is little evidence as to whether significant numbers of glass fibres, or more probably glass microfibers, do reach drinking-water and there is no evidence to support the contention that such fibres ingested in drinking-water would be a hazard to health. It is not, therefore, considered appropriate to include glass fibres in Annex I to the Directive.

13.3 Nanoparticles

Nanoparticles come in a variety of forms and types. Nanomaterials and coatings are increasingly used. While there are very few data to show that they reach drinking-water, there is some evidence that they would be removed in treatment (FERA, 2011). However, there are no appropriate means of measuring them or setting drinking-water standards at this time, but it would be appropriate to ensure that any proposals to include them in materials for use in contact with drinking-water should be assessed under a European approval scheme for materials and chemicals in contact with drinking-water to ensure that they are used safely.

13.4 Chlorophenols

Chlorophenols occur in drinking-water from the reaction between chlorine and naturally occurring and anthropogenic phenol. They are a particular problem because of their low taste and odour threshold in drinking-water and would be captured by acceptability requirements at concentrations well below any of concern for health (i.e. taste thresholds vary from 0.1–2.0 µg/L). Where they do occur it is usually very intermittently and so routine monitoring is not a reliable means of identifying their presence. It is, therefore, not considered appropriate to include them in Annex I to the Directive. Further information on chlorophenols in drinking-water can be found in the respective WHO background document (WHO, 2003f).

13.5 N-Nitrosodimethylamine

N-Nitrosodimethylamine (NDMA) can be formed in drinking-water treatment as a by-product of chloramination and chlorination at low concentrations. It is also a contaminant of

certain pesticides and can occur from several industrial processes. It is a known carcinogen in many species of animal including mammals and it is genotoxic. While there is limited evidence that it causes cancer in humans, it would be reasonable to expect that it does. WHO has carried out a risk assessment and proposed a guideline value of 0.1 µg/L. Studies of occurrence in the United Kingdom and elsewhere indicate that concentrations do not normally exceed one tenth of this and that occurrence is intermittent. Where concentrations did exceed 0.01 µg/L, this was due to a coagulant used in water treatment whilst that particular coagulant is no longer used. In view of the above information and the fact that drinking-water is a very minor source of NDMA exposure, it is not considered appropriate to include NDMA in Annex I to the Directive. If there are localized circumstances identified in hazard analysis and risk assessment, further information on NDMA in drinking-water can be found in the respective WHO background document (WHO, 2008).

13.6 Thallium

Thallium is a toxic heavy metal that is very rarely encountered in drinking-water sources or drinking-water (i.e. there is only one reported case of significant contamination in one Member State). It occasionally occurs particularly associated with some forms of metal mining activity but is so rarely encountered as to be inappropriate to include in Annex I to the Directive. However, it would be identified during a catchment appraisal and, if identified, should be considered for local control and monitoring.

13.7 Calcium and magnesium

Calcium and magnesium are naturally present in most waters at varying concentrations and are key components of hardness. Calcium and magnesium are essential elements for humans. There is no evidence for adverse effects. It has been suggested as to whether there should be a minimum concentration considered acceptable for drinking-water. While there is some evidence for the beneficial effects on the cardiovascular system, particularly for magnesium, there remains considerable controversy as to the extent of that benefit and the justification for including a minimum concentration for drinking-water.

WHO has recommended, however, that where water is produced by reverse osmosis or thermal desalination, and there is a need to condition the water to reduce corrosivity to metal components and cement mortar construction materials and improve taste acceptability, that where possible the water should be re-mineralized with calcium and magnesium salts.

Hardness causes scaling but this is also dependent on other physicochemical factors. However, scaling is generally more prevalent as hardness increases. The minerals that cause hardness are the major component of the minerals naturally found in drinking-water (including calcium and magnesium) and also influence the taste. It is considered that the minerals causing hardness may be of benefit to health while there is no credible evidence that it can cause adverse health effects. Some Member States practice central softening but

this is different to reverse osmosis or other desalination techniques, which effectively remove all of the minerals.

It is recommended that the Directive includes a recommendation that where drinking-water is derived from desalination or any reverse osmosis treatment that demineralizes the water, then Member States should, if possible, add calcium and magnesium salts to condition the water to reduce corrosion and improve taste (see also Chapter 16).

Further information on calcium and magnesium can be found in respective WHO publications (WHO, 2006b; 2009b; 2011b) and the WHO background document on hardness in drinking-water (WHO, 2011c).

13.8 Personal care products

Personal care products are a wide group of products and the substances used in them also constitute a wide grouping. Many of these substances are not designed to have any inherent biological activity and include substances present in toiletries, make-up, domestic cleaning and air freshening products, along with sunscreens and insect repellents. Antibacterial substances such as triclosan and chlorophene are also widely used in these products. Their route to water is largely through treated sewage discharges but the database on occurrence is even less extensive than for pharmaceuticals. The WSP approach would suggest that improved sewage treatment would be the most effective way forward for the managed water cycle supported by other regulatory activities aimed at the production and marketing of these products (Fawell & Ong, 2012).

Currently there appear to be insufficient data to carry out a meaningful assessment of personal care products in drinking-water but so far nothing has emerged from the literature that would suggest an urgent need for assessment of particular substances or groups of substances, although they remain a potential issue that requires further investigation; thus it is considered inappropriate to include any personal care products in Annex I to the Directive.

13.9 Pharmaceuticals

Pharmaceuticals are a diverse group of substances of which there are many thousands and numbers increase all the time. Pharmaceuticals include both prescribed and over-the-counter preparations that do not require prescriptions. They include those that are taken internally and those used externally in the form of creams, ointments and medicated shampoos and illicit recreational drugs are sometimes included in the category.

With the advent of advanced analytical techniques a number of pharmaceutical residues have been identified at extremely low concentrations, primarily in surface waters impacted by treated sewage effluent. Some of these have also been found in drinking-water at trace concentrations orders of magnitude below any concentration of clinical significance. The primary source of these pharmaceuticals is treated and untreated sewage effluent. There is also a probability that some pharmaceuticals used in animal health may reach water sources as a consequence of the release of slurry from intensive animal rearing facilities but data are limited and this is probably a relatively minor input compared with treated sewage effluent.

It is difficult to generalize which pharmaceuticals will be present in different countries due to differing use patterns and concentrations will vary according to circumstances and flows. As the population increases and, perhaps more significantly, the proportion of older people increases, the quantities of pharmaceuticals consumed will increase over time.

One problem in assessing the extent of contamination of source and drinking-water is the paucity of systematic analytical studies that have been carried out to a high quality, with appropriate quality assurance procedures. This also limits the conclusions that can be drawn regarding the effectiveness of different wastewater treatment processes during normal operation across the EU.

Several studies have been carried out in Europe and the USA to examine the risks from pharmaceuticals in drinking-water. The weight of evidence from these studies is that it is very unlikely that pharmaceuticals in drinking-water pose a threat to human health at the low concentrations found; this also includes mixtures of substances with similar mechanisms of action. WHO also convened an expert committee to consider all of the data and this group came to a similar conclusion. The WHO expert group concluded that concentrations in surface waters are typically less than 0.1 µg/L and in drinking-water typically less than 0.05 µg/L, with most present at much lower concentrations. The expert group further concluded: "*Analysis of the available data indicate that there is a significant margin of safety or margin of exposure between the consumption of very low concentrations of pharmaceuticals in drinking water and the minimum therapeutic doses, which suggests a very low risk to human health. Based on this, development of formal guideline values for pharmaceuticals in the WHO Guidelines for Drinking-water Quality is not considered to be necessary*. *Concerns over pharmaceuticals in drinking water should not divert water suppliers and regulators from other priorities for drinking-water and health, most notably microbial hazards, such as bacterial and viral pathogens, and chemical hazards, such as naturally occurring arsenic and fluoride*."

In terms of the WSP approach there are several actions that would be appropriate focusing on mitigating the quantities entering water sources. Reducing inputs of pharmaceuticals is the most sustainable long-term solution and that can be achieved in various ways. Improving wastewater treatment is deemed to be an appropriate way of reducing pharmaceutical residues in the environment, although this is a long-term solution. Disposal of unused pharmaceuticals is not the major source in sewage but according to studies in the USA preventing such disposal to sewer may reduce inputs by up to 10% although a study in Germany suggests reduction potential by up to 40%. Optimization of sewage treatment will also help to reduce inputs to source water and optimization of drinking-water treatment will reduce intake via drinking-water. In the long-term, "green chemistry" is being used to develop products that are more readily degraded in biological treatment of sewage.

Although the issue of pharmaceutical residues cannot be ignored, it is considered inappropriate to include any pharmaceuticals in Annex I to the Directive at this time. Further information can be found in the WHO publication on pharmaceuticals in drinking-water (WHO, 2012).

13.10 Endocrine disrupting compounds

Endocrine disrupting compounds (EDCs) are a mixed group of chemicals of varying structure that have the capability to interfere with endocrine mediated physiological and biochemical processes in the body. The most widely studied in relation to drinking-water are those that possess oestrogenic or oestrogen mimicking activity. EDCs consist of a wide range of natural and synthetic hormones; some other substances of industrial origin may be present but show much lower oestrogenic activity than the natural and synthetic hormones. Some are subject to control policies, such as alkyl phenols, which are breakdown products from alkyl phenol ethoxylates used in the past as building blocks for detergents but now no longer permitted, although there may be existing stocks still being used. Industrial substances are of significantly lower potency than the natural hormones. Other substances that also possess some endocrine disrupting activity are potentially more soluble in water but are of even lower potency compared to hormones (e.g. bisphenol A and F and some phthalates).

EDCs are primarily an issue for surface water. They are known to be present in many rivers that are impacted by effluent from municipal and industrial wastewater treatment. Some may be used in the manufacture of materials that may be used in contact with drinking-water and these should be prevented by appropriate product approval. However, in the absence of a European-wide approval system it is uncertain how many Member States follow appropriate approval schemes.

Concern was first raised due to effects seen in fish in waters impacted by sewage effluent in which a condition called inter-sex was observed in males. The incidence of the condition decreased rapidly with distance from the discharge. Subsequently the condition was shown to be primarily due to natural and synthetic hormones such as oestrone, oestradiol and ethinyl oestradiol.

Currently there is no evidence for risks to health from drinking-water, which is a minor source of exposure, and such risks are unlikely; WHO does not propose guideline values for EDCs. A study of rivers in the United Kingdom heavily impacted by treated sewage effluent using a highly sensitive *in vivo* bioassay showed that no estrogenic activity remained at the intakes of treatment works abstracting water from those rivers and this was confirmed by chemical analysis (Fawell et al., 2001). A large study funded by the EC, which examined a wide range of potential EDCs in raw water and at various stages through drinking-water treatment to final water concluded that "*even if the highest concentration of an individual EDC reported for drinking water is considered for the assessment of effects on humans, based on the current knowledge, endocrine effects via the consumption of drinking water are very unlikely*." The study also concluded: "*The raw water of waterworks, especially surface waters, frequently contains EDCs. However, common drinking water treatment technology (e.g. bank filtration, coagulation, ozonation, granular activated carbon) should be very effective in removing EDCs. That is underlined by the results of the case study, the literature and by novel results from the EU research project POSEIDON*" (Wenzel et al., 2003). However, there has been public concern fuelled to an extent by inaccurate media reporting of the topic around the observation of inter-sex in male fish mentioned above.

Many of the substances are relatively insoluble in water and are partly removed by adsorption to solids in the sewage treatment works and to sediment and particles in receiving waters, where further degradation can occur. The primary means of control in surface waters would be by improving sewage and industrial effluent treatment. They are removed in drinking-water treatment where there is coagulation and filtration or granular activated carbon and also with bank infiltration. There are no generic analytical methods because the group is so diverse. Bioassays have been used for comparative purposes. Under the WSP approach the steps would be to prevent or reduce contamination reaching water sources and secondly to ensure that water treatment barriers are effective. Monitoring of the hormones under the WFD (i.e. as part of the surface water watch list) is ongoing to inform future management of the risks from such substances in the environment.

Routine monitoring for the full range of EDCs would currently be difficult, expensive and not effective at preventing contamination of drinking-water. It is therefore not recommended to include provisions for EDCs in Annex I Part B. If Member States, however, wish to provide reassurance to consumers regarding oestrogenic and other EDCs in drinking-water, it would be possible to use precautionary, arbitrary benchmark values which are close to the proposed environmental quality standards, or possible future environmental quality standards, for the protection of aquatic life. Aquatic life is much more sensitive to the effects of oestrogenic EDCs than mammals, including humans. The following three representative EDCs and benchmark values could be considered:

- 17-Beta-oestradiol: 0.001 µg/L;
- Nonyl phenol: 0.3 µg/L; and
- Bisphenol A: 0.1 µg/L.

These three substances were chosen as benchmarks because they are known to be present in surface water sources impacted by treated sewage effluent and other discharges. Oestradiol is a natural human oestrogen that is excreted in urine and nonyl phenol is a building block of alkylphenol ethoxylates used in surfactants, although these are now forbidden in the EU. Both substances have been causally related to intersex in fish in wastewater impacted rivers. Bisphenol A is widely used in the manufacture of some plastics and epoxy resins. It has had a high political and media profile as an EDC in Europe. The three substances also represent differing chemical structures. The values are below those that would be of interest for human health, for example the TDI for bisphenol A is 4 µg/kg of body weight.

The purpose of such benchmark values is to determine if the (surface water) source is impacted by treated sewage effluent or other effluents known to contain oestrogenic EDCs. If any of the three substances is detected above the precautionary benchmark value, then these values can be used to verify the efficacy of treatment since all of these EDCs are of low water solubility.

If they were not found at these low concentrations at the intake then there would be no need to go further; if they were found, then measurements would be taken post-treatment

to show that removal in treatment is adequate. If they are found in final water above the precautionary benchmark values there would be a need to optimise or improve treatment.

14. Parameters recommended for inclusion in Annex I Part B

KEY MESSAGES

- It is recommended to retain 20 chemical parameters/groups of parameters which are currently included in Annex I Part B, i.e. all parameters except those five parameters suggested for removal, as discussed in Chapter 12).
- It is suggested to change three parametric values to reflect latest WHO guideline values: antimony, boron and selenium.
- It is recommended to include six new parameters/groups of parameters in Annex I Part B: chlorite, chlorate, HAAs, microcystin-LR, perfluorooctanoic acid (PFOA)/ perfluorooctanesulfonic acid (PFOS) and uranium.
- Several WHO guideline values continue to be under evaluation: bromate, chromium, nickel, PFOA/PFOS and tetrachloroethene/trichloroethene. The updated or new guideline values will be made available as soon as the second addendum to the fourth edition of the WHO Guidelines becomes available.

A number of additional substances were considered for inclusion in Annex I to the Directive. These reflect increased knowledge gained since 1998 on occurrence in drinking-water and on the potential for impacts on health of consumers. The selection was based on a combination of factors, including knowledge on occurrence in the EU at concentrations close to or exceeding health-based values determined by WHO or other authorities, including the European Food Safety Authority (EFSA), the availability of data on toxicity and health effects, and availability of international peer reviewed assessments. Evidence on occurrence is not generally systematic but comes from reports from Member States (see Chapter 1 and Appendix 1) and academic publications. The proposals were discussed with Member States and other stakeholders to further ensure that those substances chosen were the most significant in requiring guidance.

Tables 18 and 19 list the substances that are recommended for inclusion in Annex I Part B, including their suggested parametric value and a short rationale for their inclusion. Table 18 lists the recommended parameters/groups of parameters that are already included in the current Annex I Part B. Table 19 lists the parameters/groups of parameters that are new recommendations. These cover substances of potential significance from the three groups: naturally occurring, anthropogenic origin and derived from treatment/disinfection processes. The following sections provide a more detailed rationale for the inclusion of newly proposed parameters. Note that detailed technical fact sheets for all substances listed in Tables 18 and 19 are included in Appendix 6.

It should be further noted that the WHO process for revision or development of guideline values for a small number of parameters, which was a part of this project, is still continuing although the guideline values were discussed at a meeting of the Expert Committee on the

Guidelines for Drinking-water Quality in March 2017. This process has been fast-tracked but WHO's rigorous review process requires a number of steps, including international expert peer review. These guideline values will be made available as soon as possible in the second addendum to the fourth edition of the WHO Guidelines. The current reference point is the first addendum of the fourth edition of the Guidelines published in 2017 (WHO, 2017a).

14.1 Haloacetic acids in the context of controlling disinfection by-products

Various drinking-water treatment processes can give rise to unwanted by-products. These are primarily associated with oxidative processes, especially disinfection by chlorine but some can also occur as a consequence of the action of ozone and UV disinfection and the use of chloramines as a residual disinfectant. Most by-products are formed from the reaction of the disinfectant with organic and inorganic precursors in the raw water. These precursors are dominated by naturally occurring organic substances such as humic and fulvic acids from the breakdown of plants and soil microorganisms.

Chlorination is the best studied of these processes because that was the first in which by-products were identified. There are many different chlorination by-products that have been identified, often in trace concentrations and the numbers found have increased with the development of analytical techniques for trace organic substances in water.

While the evidence for adverse health effects being caused by chlorination by-products is not definitive, there is an association between some chlorination by-products and bladder cancer in non-smokers. In balancing the risks and benefits of chlorination it is reasonable to minimize the overall quantity of chlorination by-products to a level that is still consistent with adequate disinfection.

The two groups present in the greatest quantity are the THMs and HAAs. While it may be possible to set standards for a large number of individual substances, this does not provide a practical solution to limiting the overall quantity of by-products. The primary approach to controlling chlorination by-products is to remove the precursor substances in drinking-water treatment and therefore act as a treatment performance indicator.

In the Directive context, THMs have been used as a surrogate for by-products; a respective parametric value is included in Annex I Part B. However, THMs are not a good surrogate for all the by-products (e.g. HAAs that are formed under more acidic conditions), so it is considered more appropriate to include the two groups of substances in Annex I Part B to provide two indicators to cover the wider range of disinfection by-products (DBPs) that may be formed.

The suggested value for HAAs of 80 µg/L for the sum of nine representative substances (i.e. mono-, di- and trichloroacetic acid, mono- and dibromoacetic acid, bromochloroacetic acid, bromodichloroacetic acid, dibromochloroacetic acid and tribromoacetic acid) is based on practical achievability. This approach represents a sensible way of reducing the levels of chlorination by-products in drinking-water and technical developments may enable lower concentrations to be achieved in the future. According to data requested from Member

States in 2016, very few data were available on concentrations of HAAs but the highest value reported was 112 µg/L.

Further information can be found in the corresponding fact sheet in Appendix 6.

14.2 Chlorate and chlorite

Drinking-water disinfection with chlorine remains an important barrier to pathogens in many parts of the EU and around the world. The most common means of adding free chlorine is by adding sodium hypochlorite. This has largely replaced gaseous chlorine because of the safety issues in handling and storing gaseous chlorine. Chlorine dioxide is also used for drinking-water disinfection. Chlorite is a breakdown product, whose level depends on the dose of chlorine dioxide. Chlorine dioxide is used in several Member States and its use may increase in the future.

Chlorate is a breakdown product formed in hypochlorite; it is exacerbated if the hypochlorite is not fresh and properly stored. It is also a by-product of chlorine dioxide disinfection along with chlorite; however, if chlorine dioxide is used as a pre-treatment before ozone then the chlorite formed from the chlorine dioxide is converted to chlorate after ozone. It can occur at significant concentrations approaching, and even exceeding, the health-based guideline value and so is of importance in drinking-water.

Chlorate should be controlled by managing concentrations in hypochlorite used for chlorination, i.e. managing the manufacture, storage and use of hypochlorite. Existing standards control the concentration of chlorate in hypochlorite supplied but water suppliers need to give due consideration to storage and use. Limited data provided by drinking-water suppliers indicates that with large and well-resourced suppliers, concentrations rarely exceed 0.3 mg/L but there are few data from warmer climates and more resource-limited circumstances. However, there is evidence that the WHO guideline value of 0.7 mg/L can be exceeded in some circumstances, even in larger drinking-water supplies. According to data requested from Member States in 2016, the highest maximum concentration reported was 1.6 mg/L but the highest median value was 0.4 mg/L.

EFSA was requested to examine the risks to health of chlorate in food and developed a TDI of 3 µg/kg body weight. EFSA also found data that indicated that chlorate levels in food were sufficient to exceed the TDI for some population groups. The conclusion was that the source of chlorate in food was drinking-water chlorinated with hypochlorite used in food processing, as well as chlorination processes in the food industry to protect against pathogen contamination (EFSA, 2015).

WHO revised chlorate for the first addendum to the fourth edition of the Guidelines. The WHO expert group considered, *inter alia*, the EFSA evaluation and concluded that the TDI approach was excessively conservative. JECFA evaluated chlorate and derived a health-based value of 0.01 mg/kg of body weight, about three times greater than the EFSA value, which would give a drinking-water value of 0.24 mg/L but WHO retained the existing guideline value of 0.7 mg/L, which is significantly above the value that would be determined using the EFSA TDI because the rat is considered to be considerably more sensitive than man to these

effects. A very low drinking-water value derived from the EFSA TDI, however, would threaten the use of chlorination by hypochlorite. The expert group concluded that although it is appropriate to seek keeping chlorate levels as low as reasonably practical, the guideline value would be retained and designated provisional. WHO used an allocation of 80% of the TDI to drinking-water which would be acceptable if the main source of chlorate in food was drinking-water, however, that now remains uncertain. There are potential interferences in the analysis of chlorate and it was considered that the levels of chlorate in food should be investigated in a specialist study to confirm the levels in different foods and the way in which chlorate reaches those foods.

WHO has a world-wide remit and considers that the adequate disinfection of drinking-water must never be compromised in meeting guideline values for DBPs and disinfection breakdown products. The concern that chlorate exposure through food is too high needs further investigation and WHO still retains the current guideline value. The fact that the data from water suppliers, although limited, indicates that with large and well-resourced suppliers concentrations rarely exceed 0.3 mg/L, suggests that a lower value may be achievable in the EU – for example 0.35 mg/L, approximately half of the WHO guideline value measured as an annual average with a maximum of 0.7 mg/L. This would reduce exposure through both food and drinking-water, while potentially allowing for variation in concentrations and maintaining disinfection. However, it would be important to consider the possible impact in warmer climates, including the impact of increased periods of hot weather on small resource limited supplies and on other Member States than those from which the data was provided.

It is also important that Member States take steps to ensure that sodium hypochlorite used in both drinking-water and food processes is stored in such a way as to minimize the concentration of chlorate. WHO does not regard the guideline value as a value to work up to and if it is reasonable to meet lower values then this would be appropriate.

Chlorine dioxide is used for drinking-water disinfection in some Member States but it is much less common than sodium hypochlorite, although it should be noted that chlorine dioxide use may also be used in buildings for Legionella control. Chlorine dioxide breaks down to chlorite and lower concentrations of chlorate. WHO has proposed a guideline value for chlorite of 0.7 mg/L, the same as for chlorate. Control is by controlling the dose of chlorine dioxide. However, it should be noted that if chlorine dioxide is followed by an oxidative process such as ozonation, this can result in the oxidation of chlorite to chlorate with resulting high concentrations of chlorate.

Further information can be found in the corresponding fact sheets in Appendix 6.

14.3 Perfluorinated substances

Perfluorinated chemicals (PFCs) are a group of substances that were used in the manufacture of a wide range of products, including non-stick and dirt resistant coatings and wetting agents in fire-fighting foams. These substances are unusual in that they are

persistent, water soluble and lipophobic; thus they are mobile, can reach groundwater and are very difficult to treat.

Perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) are the most common substances and are found, often at significant concentrations, in groundwater primarily as a consequence of point sources, such as discharges from factories which used or manufactured perfluorinated compounds and from heavy use of particular fire-fighting foams at airports or other oil-based fires. Perfluorinated firefighting foams appear to have been discontinued and new practice foams have also been introduced so much of the existing pollution of groundwater, and surface waters fed by contaminated groundwater, relates to historical pollution. However, other uses are also a source of pollution. There is evidence that discharges from industry and sewage effluents are still occurring in some places in the EU. Some of this may be residual material in domestic and industrial settings and some is residual material in the ground from firefighting foams but there is clearly a need to prevent further discharges where at all possible. There is evidence that industry has developed similar substances that are much less persistent but these would presumably require to be submitted to the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulations. In response to the data requested from Member States in 2016, only limited data were provided because there is no formal requirement for systematic monitoring. The highest maximum concentration reported for PFOS was 8 µg/L while the highest median value was 0.005 µg/L. Similarly the highest maximum value reported for PFOA was nearly 12 µg/L and the highest median value was 0.1 µg/L.

PFOS is now prohibited in the EU under Directive 2006/122/EC that came into force in June 2008. Both PFOS and PFOA have been phased out by major manufacturers. As a consequence Member States should no longer be using new materials that are sources of these substances so inputs should immediately decrease. However, there will be a historical legacy associated with these substances.

While the evidence for health effects of these substances on humans is limited there is clear evidence for effects on the stomach, liver and thyroid in laboratory animals. There is concern over the levels of these substances found in the bodies of consumers and although drinking-water is not the only source, it is important to ensure that exposure through drinking-water is controlled. PFOS and PFOA are usually the major contaminants but there is a significant range of other perfluorinated substances but the data on toxicity are much more limited at present and only few TDI's have been established. Currently it is difficult to propose a health-based value for the mixture of perfluorinated compounds but PFOS and PFOA are usually the dominant substances where there are elevated concentrations from firefighting foams and related sources.

Therefore it is recommended to include health-based parametric values for PFOS and PFOA in Annex I Part B which also would provide useful targets for water managers designing treatment, based on the TDI's developed by EFSA (2008). If both substances are present then it would be possible to use the formula of the sum of the concentration of each divided by the respective standard being equal to or less than 1. Should the EC be minded to introduce a precautionary value to cover all perfluorinated substances then it should be

remembered that removal is difficult and costly and would be a significant burden on municipal water supplies.

Introducing health-based parametric values for PFOS and PFOA would raise awareness, since other perfluoroalkyl derivatives from the breakdown of the parent coatings and fire-fighting foams are not present separately from PFOS and PFOA. Actions to treat water to remove PFOS and PFOA would appear to also be suitable for removing the additional compounds. WHO is aware that new PFCs are under development but these should be prevented from reaching the environment under other legislation for controlling such ingredients and breakdown products.

Further information can be found in the corresponding fact sheet in Appendix 6.

14.4 Microcystin in the context of controlling cyanobacterial toxins

Cyanobacteria, or blue-green algae, form explosive growths or blooms in still or slow flowing water bodies. Some of these blooms produce toxins which are chemical contaminants of natural biological origin. The most common toxins are thought to be microcystins, a group of molecules of which the most frequently encountered and the most toxic is considered to be microcystin-LR. Microcystins are highly toxic to the liver and show signs of being tumour promotors. The WHO guideline value and most standards around the world are based on a study in mice and are intended to prevent liver damage with long-term exposure.

They are released from blooms of cyanobacteria and are, therefore, only present intermittently in slow flowing or still surface waters. High levels of microcystins are found in the cells of microcystin-producing cyanobacteria and are released when the cells are disrupted. Concentrations in raw water are very low except when blooms are present. However, there are other toxins that can be released by such blooms, such as cylindrospermopsin.

According to data reported by Member States in 2016, concentrations in drinking-water ranged from zero to a maximum of 1.6 µg/L, although the number of samples was very small. Concern regarding microcystin-LR has been expressed by several Member States where drinking-water sources are affected by cyanobacterial blooms and the toxin has been identified at high concentrations in the blooms. Concentrations in untreated source water can reach hundreds if not thousands of micrograms per litre close to blooms.

Both microcystins and cylindrospermopsin have been identified in drinking-water sources in Europe, while other cyanobacterial toxins, such as the neurotoxins saxitoxin and anatoxin-a, have been included in some cyanotoxin surveys but so far have rarely been found in Europe. In this context, the impact of climate change on cyanobacterial occurrence, bloom formation and the formation of specific toxins in Europe remain uncertain. In addition to toxins, cyanobacteria can produce substances that cause unacceptable tastes for consumers at very low concentrations (e.g. geosmin and 2-methyl isoborneol).

Analysis is relatively complex, although there are enzyme-linked immunosorbent assay (ELISA) methods that do provide an indication of concentrations. Still, routine monitoring for

microcystin in drinking-water is not the best way of managing the problem of toxins, which will only be present intermittently in source water during algal blooms. However, it is recommended that a parametric value for microcystin-LR be included in Annex I Part B at the WHO guideline value of 1 µg/L which was established in 2003 and reaffirmed in 2017. The value provides a standard for ensuring that treatment capability is adequate to prevent significant levels reaching consumers if blooms cannot be adequately managed in source waters. It also provides a suitable benchmark for assessing when concentrations in drinking-water require further evaluation. The guideline value is intended as a value protective of health over an extended period but the presence of microcystin-LR in water sources and, potentially, drinking-water will usually be short-term.

Further information can be found in the corresponding fact sheet in Appendix 6.

14.5 Uranium

Uranium is found in some groundwaters across Europe, often at high concentrations, as a result of leaching from natural deposits but can also be released in mill tailings from uranium mining and processing and from the use of some phosphate fertilizers that contain uranium as a contaminant.

Uranium in drinking-water is primarily an issue for smaller supplies with limited resources. According to data requested from Member States in 2016, the highest maximum value reported was 160 µg/L with the highest median value of 18 µg/L. However, this does represent a relatively limited number of supplies. There is a clear need for guidance for Member States as more incidences of natural uranium contamination are identified, and public reassurance on the safety of uranium-containing drinking-water is appropriate. It is therefore recommended that a parametric value for uranium is included in Annex I Part B at the WHO guideline value of 30 µg/L which was assessed in 2011. This value is based on human data and on a TDI derived from the lower 95% confidence limit on the 95th percentile of exposure distribution from an epidemiological study from Finland, supported by other epidemiological studies. This value underwent international peer review and is considered to be conservative by the WHO expert group.

Further information can be found in the corresponding fact sheet in Appendix 6.

While the WHO guideline value would be based on toxicity, it would also provide significant protection against radioactivity from natural uranium, which is an alpha particle emitter, and would not exceed the screening value for alpha particles assuming natural uranium was the only radionuclide present.

Radioactivity in drinking-water in the EU is controlled by Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption. The standards are based on an indicative dose of 0.10 mSv, which is the same value as that in the WHO Guidelines and represents a very low level of risk that is not expected to give rise to any detectable adverse effects. This is monitored by screening for gross alpha and gross beta particles with screening values of 0.1 Bq/L for gross alpha (WHO: 0.5 Bq/L) and 1.0 Bq/L for

gross beta. If these screening values are not exceeded the indicative dose will not be exceeded. If they are exceeded then there is a requirement to carry out more detailed analysis to identify the radionuclides present (e.g. natural uranium, uranium-238) to determine whether the dose is still below the indicative dose as the different radionuclides also differ in the radiation dose they deliver. Natural uranium is 95% uranium-238 and delivers a very low radiation dose.

Table 18. Parameters proposed to be retained in Annex I Part B and recommended parametric values

Parameter	PV	Rationale
Acrylamide	0.1 µg/L	Acrylamide is a contaminant in polyacrylamide which is widely used as an important coagulant aid in treatment. It is of concern for health because of its carcinogenic properties. It is found widely in food where it is formed during the cooking process. The value was determined from a linear extrapolation of carcinogenic risk in laboratory animals but it is recognized that it is appropriate to try to achieve a level as low as reasonably practical because of high exposure from food. It is recommended to retain the current PV on the basis of achievability in the EU context because of the importance of good coagulation in controlling pathogens and DBPs. It is controlled through specification of the maximum residue of acrylamide monomer in polyacrylamide and the dose of polyacrylamide in water treatment. While there are REACH controls on grout used in the environment there are no specified controls on polyacrylamide coagulant aids. An analytical method has now been developed for measuring acrylamide in drinking-water.
Antimony	20 µg/L	Antimony is a known inhalation carcinogen but the form of antimony in drinking-water is not carcinogenic. WHO based their guideline value on decreased body weight in rats. Antimony is a contaminant in metal alloys widely used in metals and fittings used in contact with drinking-water. It is present in existing systems but will vary according to what is used in buildings. It may occur in groundwater but no specific data relating to the EU. The parameter shows a high compliance rate which needs to be maintained. It is recommended to adopt the WHO GV as revised PV. The WHO GV was updated in 2003 based on new scientific data that reduced uncertainty.
Arsenic	10 µg/L	Arsenic is a widespread but often localized naturally occurring groundwater contaminant. Issue for many small supplies. It is one of the few substances known to cause adverse health effects through drinking-water, including carcinogenicity. Requirement to achieve level as low as reasonably practical. It is recommended to retain the current PV. WHO has retained the GV after revaluation of new scientific data in 2010.
B(a)P	0.01 µg/L	B(a)P is widely found in old coal-tar linings on cast-iron pipes. Only found associated with particles as very low solubility. It has a low taste and odour threshold. Important marker for other PAHs in coal-tar linings that are deteriorating. B(a)P is a known carcinogen by contact with extended exposure. The WHO guideline value was developed to ensure a minimal risk of carcinogenicity, particularly as exposure in drinking-water is infrequent while carcinogenicity depends on long-term semi-continuous contact exposure. The current PV was proposed as GV in the first edition of the WHO Guidelines. In view of the low taste and odour thresholds, it is recommended to retain the current PV.

Parameter	PV	Rationale
Boron	2.4 mg/L	Boron is widespread at low concentrations but high in areas with boron rich rocks and particularly in seawater. Important for Member States dependent on desalinated water or where there is significant saline intrusion. Boron has been shown to cause reproductive effects in laboratory animals. It is recommended to adopt the WHO GV as new PV. The WHO GV was updated in the fourth edition of the Guidelines using the new data to determine a conservative value.
Bromate	10 µg/L Under review by WHO	Bromate is formed in water treatment with ozone from bromide in source water. It can be a significant contaminant in sodium hypochlorite when it is manufactured by electrolysis using brine that does not come from low bromide salt deposits. It is widely found in drinking-water at concentrations close to the PV and difficult to control if bromide concentrations increase (e.g. in periods of low river flows when the concentration of bromide is increased). WHO is assessing the data on bromate and preparing a revised GV. Bromate is carcinogenic in laboratory rodents but new toxicological data demonstrate that the current WHO GV not only is a safe value but highly precautionary as the dose response is non-linear. It is recommended that the PV is the health-based GV currently being developed by WHO. *If the revised GV is not adopted by WHO in time for the revision of the Directive, we recommend to retain the current PV.* It is recommended that compliance is determined on the basis of an annual average value.
Cadmium	5 µg/L	Cadmium is widespread in metal alloys as a contaminant and in old galvanized iron pipes. May occur in source water as a pollutant. Cadmium is known to cause kidney toxicity. It is recommended to retain the current PV because the WHO GV is not significantly different.
Chromium	50 µg/L Under review by WHO	Chromium is locally found naturally in groundwater and is an industrial source water pollutant present as chromium III or chromium VI. The valency state can change in treatment, i.e. oxidative treatments will result in a higher proportion of chromium VI. Chromium VI is the form which is more toxic. Chromium VI is carcinogenic in humans by inhalation of welding fume but although there is some evidence for carcinogenicity in laboratory animals by the oral route there is clear evidence that the dose-response is non-linear. The value for total chromium is based on chromium VI. WHO is assessing the data on chromium VI and preparing a revised GV. It is recommended that the PV be the GV currently being developed by WHO. *If the revised GV is not adopted by WHO in time for the revision of the Directive, we recommend to retain the current PV.*
Copper	2 mg/L	Copper is widespread as a consequence of copper plumbing with intermittently very high levels that can cause acute gastric irritation, which is a concentration effect. It also causes problems with staining sanitary ware and at high concentrations with taste. It is recommended to retain the current PV. The WHO GV was updated for the third edition of the Guidelines,

Parameter	PV	Rationale
Epichlorohydrin	0.1 µg/L	Epichlorohydrin is from polyamine coagulant aids used in water treatment where it is the residual monomer in the polymer. Epichlorohydrin is carcinogenic in laboratory animals but is a contact carcinogen. While it cannot be measured in drinking-water there is a need for a standard to ensure that, in the absence of a European approval system for materials in contact with drinking-water, levels in polyamine coagulant aids and so exposure of consumers is properly controlled. It is recommended to retain the current PV which is marginally below the WHO GV, and on the basis of achievability in the EU context.
Fluoride	1.5 mg/L	Fluoride is one of the few substances known to cause health effects through drinking-water in the form of dental and skeletal fluorosis. It can be locally present at high levels naturally in groundwater. Some Member States add fluoride for prevention of dental caries. It is recommended to retain the current PV. It is recommended that Member States should ensure that for fluoride added for the prevention of dental caries, the average concentration should not be greater than 1.0 mg/L to ensure that the PV is not exceeded.
Lead	10 µg/L	Lead is one of few substances known to cause health impacts through drinking-water, affecting learning in children and increased blood pressure in adults. Widespread occurrence from lead plumbing in buildings and lead service connections, but also from alloys and lead solder, which should no longer be used or installed. It is recommended to retain the current PV. The WHO GV is not a health-based value because JECFA has withdrawn the PTWI on grounds that there is no discernible threshold. Therefore, concentrations should be as low as reasonably practical. It is recommended that consideration should be given to requiring Member States to submit and institute action plans for removal of existing lead plumbing within five years following the adoption of the Directive with the objective of meeting a target value of 5 µg/L after a suitable period, taking into account the difficulties of achieving lead pipe removal.
Nickel	20 µg/L Under review by WHO	Nickel occurs in source water, naturally and from pollution, and from chromium plated taps. In the case of the latter it is rapidly flushed. Occurrence may increase with pressure on groundwater resources. High levels of ingested nickel can cause an allergic reaction in those sensitised to nickel. WHO is assessing the data on nickel and preparing a revised GV. Although the probable GV will be lower, the current Directive PV seems to be achievable in the EU.
Nitrate	50 mg/L	Nitrate is a widespread pollutant as a consequence of agricultural activity and disposal of wastewater. Groundwater levels are still increasing in many places. Nitrate can cause methaemoglobinaemia in bottle-fed infants. Nitrite also causes methaemoglobinaemia but is more potent. It is recommended to retain the current PV. After review, WHO has retained its original GV. Needs to be considered together with nitrite: the concentration of nitrate/50 + the concentration of nitrite/3 ≤ 1 (retained from current Directive as per Note 5 to Annex I Part B).

Parameter	PV	Rationale
Nitrite	0.5 mg/L at tap if chloraminated 0.1 mg/L at works post treatment	Nitrite occurs in source waters from pollution and in distribution when chloramination is used. It is similar to nitrate in its ability to cause methaemoglobinaemia in bottle-fed infants but is about ten times more potent. It is recommended that the current PV is retained in view of the fact that these values appear to be readily achievable in the EU. Needs to be considered together with nitrate: the concentration of nitrate/50 + the concentration of nitrite/3 ≤ 1 (retained from current Directive as per Note 5 to Annex I Part B).
Pesticides	N/A	Not covered by WHO. The WHO Guidelines propose individual health-based values. It is an EU policy decision to cover each individual pesticide and relevant metabolites. It is recommended that separate values for aldrin/dieldrin and heptachlor/heptachlor epoxide be removed and picked up in the general PV.
Selenium	40 µg/L	Selenium occurs naturally, localized in groundwater across the EU. At high intakes selenium can cause adverse effects on the gastro-intestinal tract, teeth, skin and nails, including hair loss. It is recommended to adopt the WHO GV as revised PV. WHO GV updated based on new data on occurrence and assessment of the quality of epidemiological studies.
Tetrachloroethene and trichloroethene	10 µg/L Under review by WHO	Tetra- and trichloroethene are found in groundwater as a consequence of historical pollution, usually related to poor handling and disposal of solvents in industrial settings. Not found in surface water due to volatilization. WHO is assessing the data on tetra- and trichloroethene and preparing revised GVs. It is recommended that the PVs be the GVs currently being developed by WHO. *If the revised GVs are not adopted by WHO in time for the revision of the Directive, we recommend to retain the current PV.*
THMs	100 µg/L	THMs are chlorination by-products and, along with HAAs, are used as indicators of the wider level of DBPs in drinking-water. They never occur on their own but always with a wide range of other by-products. The PV is based on a practical approach to reduce chlorination by-products. It should continue to cover the sum of bromoform, bromodichloromethane, chloroform and dibromochloromethane. The concentration should be maintained as low as reasonably practicable by removing natural precursor organics from source water. The requirement to minimise DBPs should be retained.

Parameter	PV	Rationale
Vinyl chloride	0.5 μg/L	Vinyl chloride is found as residual monomer in older and poor quality polyvinyl chloride (PVC) pipes. It may rarely be found in groundwater from breakdown of other chlorinated hydrocarbons. It is carcinogenic to humans by inhalation in industrially exposed populations. Monitoring and control are currently through product specification and it is controlled to a maximum residue of 0.1% in PVC through REACH. Still, it is useful to have a PV in case of vinyl chloride being identified in groundwater. It is important that there is a European-wide approval for PVC pipes to ensure that the residual vinyl chloride monomer is kept as low as possible in the manufacturing process and in any imported pipes. It is recommended to retain the current PV which is marginally above the WHO GV, and on the basis of achievability in the EU context.

Table 19. Parameters proposed to be included in Annex I Part B and recommended parametric values

Parameter	PV	Rationale
Chlorate	0.7 mg/L	Chlorate is a by-product formed in hypochlorite solution used in chlorination that is not fresh and properly stored. It is also a minor by-product of chlorine dioxide disinfection along with chlorite. Concern has been raised by EFSA about exposure levels from food and drinking-water in Europe. Chlorate affects uptake of iodine in mammals and so can adversely impact thyroid hormones. It is recommended to adopt the WHO GV as PV which has been assessed in 2016 in preparing the first addendum to the fourth edition of the WHO Guidelines. It may be considered feasible to set a lower value of approximately 0.35 mg/L measured as an average annual value and a maximum value of 0.7 mg/L, if evidence shows that this is readily achievable in drinking-water while retaining adequate disinfection, which should never be compromised in meeting the PV.
Chlorite	0.7 mg/L	Chlorite is a breakdown product from chlorine dioxide used for drinking-water disinfection. Chlorite can have an adverse effect on red blood cells. It is recommended to adopt the WHO GV as PV which has been assessed in 2016. It is recommended that compliance is determined on the basis of an annual average value.
HAAs	80 µg/L	HAAs are by-products formed from the reaction of chlorine on natural organic matter. Along with THMs, HAAs are important used as indicators of the wider level of DBPs in drinking-water and in controlling by-products as formed from different organics. The recommended PV is not health-based but supports a practical approach to reduce chlorination by-products. The proposed PV should cover the sum of the following nine representative substances: mono-, di- and trichloroacetic acid, mono- and dibromoacetic acid, bromochloroacetic acid, bromodichloroacetic acid, dibromochloroaetic acid and tribromoacetic acid. Concentrations should be maintained as low as reasonably practicable by removing natural precursor organics from source water. A requirement to minimise DBPs should be included.
Microcystin-LR	1 µg/L	Microcystins are a group of naturally occurring toxins potent liver toxins. They are released from blooms of cyanobacteria and are only present intermittently in slow flowing or still surface waters. The most frequently encountered and the most toxic microcystin is considered to be microcystin-LR. It is recommended to adopt the WHO GV as PV which has been assessed in 2003. The GV provides a standard for ensuring that treatment processes are adequate to prevent significant levels reaching consumers if blooms cannot be adequately managed in source waters. It also provides a measure to reassure consumers that levels in drinking-water are safe if a bloom occurs.

Parameter	PV	Rationale
PFOA PFOS	4.0 µg/L 0.4 µg/L Under review by WHO	PFOA and PFOS are the most common perfluorinated compounds. The occurrence is localized but widespread in groundwater and some surface water sources. Both substances are persistent in groundwater and found frequently at concentrations exceeding health-based standards, primarily as a consequence of discharges or the past use of firefighting foams based on perfluorinated surfactants. While there are frequently a wider range of perfluorinated substances present at low concentrations it is difficult at this time to develop a standard due to limited toxicity data. They are known to cause liver damage in laboratory animals along with a range of other biochemical changes. It is recommended that the PVs are the GVs currently being developed by WHO. Based on the TDI for PFOS of 0.15 µg/kg body weight developed by EFSA, for a 60 kg adult and allowing 10% of the TDI from water gives a GV of 0.4 µg/L, and for PFOA a GV of 4.0 µg/L. These GVs are subject to final confirmation by WHO. Where both are present at the same time the formula PFOS concentration/0.4 µg/L + PFOA concentration/4.0 µg/L ≤ 1.0 should apply.
Uranium	30 µg/L	Uranium primarily occurs naturally in groundwater where it is localized but widespread. It is a particular issue for small supplies. Uranium has been shown to cause kidney toxicity but the WHO GV is based on human data. It is recommended to adopt the WHO GV as PV which has been assessed in 2011 The WHO GV would provide significant protection against radioactivity from natural uranium and would not exceed the screening value for alpha particles if only uranium-238 was present.

15. Options for the structure of chemical parameters of Annex I of the Directive

KEY MESSAGE

- It is recommended that the parameters in Annex I Part B should be organized according to source and route to drinking-water to aid clarity and transparency, and to aid decisions on risk-based monitoring and management.

Currently, the chemicals covered in Annex I Part B of the Directive are divided into two groups: chemical parameters and indicator parameters. Member States must introduce the chemical parameters into legislation and define parametric values, which are a maximum acceptable concentration. For indicator parameters there is much greater flexibility in the way they are introduced, the parametric values and the way in which they are interpreted.

The sources of and ways in which parameter groups are controlled and monitored vary. There are advantages in separating the parameters into different groups relating to the source and the way in which they are controlled and monitored. For parameters covered by Annex I Part B, Table 20 proposes five categories of parameters, including options for control and verification monitoring.

We recommend including such grouping in Annex I to the Directive. This makes the source of the contaminant and the actions required in verification monitoring and control much clearer and transparent, not only for regulators from Member States to identify appropriate actions associated with risk-based monitoring, but also to politicians and the general public. Such grouping could be particularly beneficial for aiding in the assessment of hazards in small supplies for which there may be only limited resources and expertise available. There are arguments for and against some of the groupings – for example, distribution and plumbing could be combined but the advantage of keeping them separate is that plumbing is largely under the control of the building owner and the approach to sampling and control are rather different.

A key part of the control of contaminants in drinking-water is the approval of materials used in contact with drinking-water and product specifications for treatment chemicals. This is an essential component of assuring drinking-water safety and is an important part of the proactive preventative approach that is at the heart of WSPs. The WHO Guidelines advocate such schemes and there is a clear requirement for a scheme that is available to all Member States to serve as an important supporting component of the Directive. Such a scheme, properly applied, is a much better means of protecting public health from chemicals associated with materials used in contact with drinking-water than trying to proactively regulate concentrations in drinking-water by means of a drinking-water standard. For plumbing materials or other materials in contact with drinking-water that are already widely present in the system a standard can be helpful but rather as an indicator that a problem exists or as a marker of the need for future improvement. For lead, which is of greatest

concern, it is recommended that the EC requires Member States to establish programmes for removal of existing lead, as well as mitigating lead contamination by corrosion control. In addition it is essential that no lead solder is used in drinking-water systems and that copper alloy fittings are also low lead.

Table 20. Proposed grouping of parameters covered in Annex I Part B, including control and monitoring options

Group by primary source	Parameter	Control options	Monitoring options	Comments on verification monitoring
Source water: naturally occurring	Arsenic	Source selection/ management, source blending and/or drinking-water treatment	At works in final water	Monitoring if local hazard analysis and risk assessment suggests that the substance is present in source water
	Boron			
	Chromium[1]			
	Fluoride[2]			
	Selenium			
	Uranium			
	Microcystin-LR			Monitoring in supplies using still or slow flowing surface water during cyanobacterial blooms
Source water: anthropogenic origin	Chromium[1]	Pollution control, source blending and/or drinking-water treatment	At works in final water	Monitoring if local hazard analysis and risk assessment suggests that the substance is present in source water
	Nitrate/nitrite[3]			
	Pesticides			
	PFOS and PFOA			
	Tetra- and trichloroethene			Monitoring if local hazard analysis and risk assessment suggests that the substance is present in groundwater (no monitoring in supplies using surface water)
Treatment	Acrylamide	Product specification/ approval (by regulations and manufacturers) Process control (by water supplier)	By product verification At works in final water	Monitoring if polyacrylamide coagulant aids are used in treatment by water quality analysis in final water and/or by ensuring that the polyacrylamide used is approved as low monomer content and the dose is controlled so that the PV is not exceeded
	Chlorate			Monitoring if sodium hypochlorite solutions are used for chlorination by water quality analysis in final water and/or before addition to drinking-water to account for changes in concentration during storage

Group by primary source	Parameter	Control options	Monitoring options	Comments on verification monitoring
	Chlorite			Monitoring in final water if chlorine dioxide is used in treatment
	Epichlorohydrin			Monitoring if polyamine flocculants are used in treatment by ensuring that the flocculant used is approved to be of low epichlorohydrin content and the dose is controlled so that the PV is not exceeded
	Bromate	Process control	At works in final water	Monitoring if ozonation is used in treatment and if sodium hypochlorite solutions manufactured by electrolysis used for chlorination
	Fluoride (added)[2]			Monitoring if fluoride is added
	HAAs		At tap	Monitoring if chlorination is used in treatment
	THMs			Monitoring if chlorination is used in treatment
Distribution	Antimony[4]	Material selection, distribution management and/or product specification/ approval	In distribution or at tap	Monitoring if local hazard analysis and risk assessment suggests that metal alloys are used in distribution and there is evidence for elevated antimony
	B(a)P			Monitoring if local hazard analysis and risk assessment suggests that there are indications of particle/sediment disturbances
	Cadmium[4]			Monitoring if local hazard analysis and risk assessment suggests that old galvanized pipes and contaminated metal alloys are used in distribution and there is evidence for elevated cadmium
	Nitrite[3]			Monitoring if local hazard analysis and risk assessment suggests presence of ammonia and/or chloramination is used
	Vinyl chloride		By product verification	Monitoring of the quality of existing PVC pipes if local hazard analysis and risk assessment suggests that PVC pipes are used in distribution

Group by primary source	Parameter	Control options	Monitoring options	Comments on verification monitoring
Internal plumbing in buildings	Antimony[4]	Product specification/approval and/or corrosion control	At tap by tailored, representative sampling protocols to demonstrate worst case concentrations	Monitoring if local hazard analysis and risk assessment suggests that metal alloys are used in plumbing and there is evidence for elevated antimony
	Cadmium[4]			Monitoring if local hazard analysis and risk assessment suggests that old galvanized pipes and contaminated metal alloys are used in plumbing and there is evidence for elevated cadmium
	Copper			Monitoring if local hazard analysis and risk assessment suggests that copper pipes, valves and fittings are used in plumbing and there is evidence for elevated copper
	Lead			Monitoring if local hazard analysis and risk assessment suggests that lead pipes and/or service connections are still in use
	Nickel			Monitoring if local hazard analysis and risk assessment suggests that chromium-plated taps are used in plumbing

[1] Chromium is included in the groups “source water: naturally occurring” and “source water: anthropogenic origin”; [2] Fluoride is included in the groups “source water: naturally occurring” and “treatment”; [3] Nitrite is included in the groups “source water: anthropogenic origin” and “distribution”; [4] Antimony and cadmium are included in the groups “distribution” and “internal plumbing in buildings”.

Part D: Indicator parameters

16. Indicator parameters for operational monitoring and consumer acceptability

KEY MESSAGES

- Some indicator parameters are important for ensuring acceptability of drinking-water to consumers.
- Some indicator parameters are important for operational monitoring of treatment, disinfection and distribution processes to ensure optimized operation at all times.
- Some indicator parameters are important for benchmarking the efficacy of treatment.
- It is recommended to group indicator parameters according to their primary function.
- It is recommended to remove oxidizability as an indicator parameter.
- It is recommended to strengthen the role of turbidity monitoring.

The parameters in Annex I Part C are designated as "indicator parameters". It should be noted that these parameters are not of direct health significance (except possibly manganese). The set of indicator parameters currently covered in Annex I Part C serves different functions

- Some indicator parameters are important for ensuring acceptability of drinking-water to consumers; and
- Some indicator parameters are important for operational monitoring of treatment and distribution processes to ensure optimized operation at all times.

Table 21 provides an overview of the microbiological and physico-chemical indicator parameters which are currently covered in Annex I Part C to the Directive, including more details on their main sources, indicator functions, consumer acceptability and possible health considerations.

Many of the physico-chemical indicator parameters are covered under "acceptability aspects" in the WHO Guidelines and no formal guideline values are proposed because acceptability varies significantly in different societies and even in different parts of a country depending on what people are used to. In some cases health-based values are given in the WHO Guidelines as a reference point to indicate what actions might be necessary if acceptability issues do occur.

It should be noted that constituents causing acceptability problems have no direct health effects. However, water that is highly turbid, very coloured or has objectionable taste or odour may be regarded by consumers as unsafe and rejected. In extreme cases, consumers may avoid aesthetically unacceptable but otherwise safe drinking-water in favour of more pleasant but potentially unsafe sources. Therefore, water that is unacceptable to consumers poses an indirect health concern. Equally, water that is aesthetically unacceptable to

consumers is likely to both undermine confidence in the water supply and also, in developed countries such as are found in the EU, drive consumers to more expensive sources of more palatable water, such as bottled water.

Other parameters currently covered in Annex I Part C are more closely associated with ensuring that control measures in drinking-water treatment and disinfection are operating effectively or relate to operational issues such as corrosion control of distribution and plumbing materials, although some of these also have an acceptability dimension. An additional role is to provide advice on actions that should be taken in special circumstances to reduce corrosion and increase acceptability of waters derived using reverse osmosis treatment (e.g. desalination).

With respect to ***microbiological parameters*** which are currently covered in Annex I Part C (i.e. *C. perfringens*, colony count at 22°C and coliform bacteria) it is recommended to maintain those in the Directive but change their roles and (partially) parametric values to align with a risk-based approach for the effective control of enteric pathogens in drinking-water. Detailed recommendations are described in the overview tables in Chapter 8, specifically in Section 8.2.1.4 on investigative source water monitoring for groundwater supplies, in Section 8.2.2.4 on investigative source water monitoring for surface water supplies, in Section 8.3.7 on verification monitoring of treatment performance and Section 8.4.4 on verification monitoring for distribution systems. The fact sheets for *C. perfringens*, colony count at 22°C and coliform bacteria in Appendix 3 provide additional guidance.

With respect to ***physico-chemical parameters***, it is recommended that the current set of indicators is largely retained with the exception of the following parameter which is suggested to be removed:

- *Oxidizability.* Whereas the parameter provides a measure of organic matter in drinking-water, it is largely superseded by the measurement of total organic carbon (TOC) which is more easily measured and is more useful.

It is further recommended that the following parameters are added as indicator parameters:

- *Temperature in buildings*. The background and rationale for inclusion of this parameter is discussed in Section 7.3.3. Temperature is suggested for operational monitoring (see also Table 2) to confirm effective operations of control measures preventing *Legionella* proliferation in plumbing systems of priority buildings.
- *Calcium and magnesium.* The background and rationale for inclusion is discussed in Section 13.7. It is proposed not to include a parametric value but a requirement that for water produced in desalination or by using reverse osmosis remineralization using calcium and magnesium salts should be used if possible.

It is further recommended to make amendments to the following parameters:

- *Aluminium.* All works should be able to meet 200 µg/L but well-run large water treatment facilities should be meeting less than 100 µg/L. The latter should be

reflected in the requirements to keep aluminium levels as low as reasonable achievable.

- *Turbidity.* It is important to increase clarity on the different functions of turbidity. Currently the parameter primarily focuses on acceptability to consumers ("acceptable to consumers and no abnormal change") but a footnote indicates that Member States should strive for <1 NTU if treating surface water. The important role of turbidity in controlling filtration performance and ensuring efficacy of disinfection should be made much clearer and also the requirement that turbidity should be as low as reasonably achievable.

  To improve control of enteric pathogens in drinking-water, it is therefore proposed to strengthen monitoring requirements for turbidity, as follows:

  – Introduce requirements for operational monitoring as a measure of the efficacy of physical removal by filtration processes in accordance with Section 8.3. These requirements should stipulate a parametric value of <0.3 NTU (95%), preferably measured at the outlet of each filter, and not >0.5 NTU for 15 consecutive minutes (see also Table 12). These values should be achievable by well-run supplies under normal circumstances. The requirement should be complemented by a footnote that turbidity levels should be kept as low as reasonably achievable.

  – Introduce a specific operational monitoring requirement for small water supplies with a parametric value of <1.0 NTU because small water supplies where there is limited or no treatment may not be able to achieve above suggested low levels of turbidity.

  – Introduce a parametric value of <4 NTU at tap, a value at which turbidity is not visible in final water and thus no negative impacts on consumer acceptability is expected.

There are questions regarding possible adverse health effects of *manganese* from drinking-water. Data on the potential health-effects of manganese remain uncertain, particularly relating to the form of manganese that may be of concern, and it is difficult to determine a suitable health-based value at this time. It is the soluble form of manganese that is of concern and there is a need for more research on the form of manganese under differing circumstances (e.g. anaerobic groundwater). Due to the uncertainties it is recommended to retain manganese as indicator parameter this time; the current parametric value should be protective.

Based on the above considerations Table 22 shows the final composition of physico-chemical indicator parameters recommended for inclusion as Annex I Part C in the Directive. In order to highlight and increase clarity of the respective functions of different indicator parameters, it is specifically recommended to introduce the following three parameter groups (as shown in Table 22):

- *Essential operational monitoring.* This group comprises of three parameters (i.e. turbidity, effective disinfectant dose and temperature of water in buildings) which are critical in monitoring the effectiveness of processes related to the control of enteric pathogens and *Legionella* proliferation in buildings. It is recommended that the Directive requires water suppliers/building owners to undertake such operational monitoring at appropriate frequencies – at minimum on a daily basis, but preferably by continuous/online monitoring – and to prepare management procedures for corrective actions if the operational monitoring indicates a breach of appropriate operational limits. As discussed in Chapters 2 and 5, vigilant operational monitoring is an essential building block of the WSP approach and vital for ensuring optimized operation at all times and thus maintaining the safety of a drinking-water supply.
- *Indicators for treatment and distribution*. This group comprises of six (further) technical parameters which are important for controlling and monitoring specific treatment, disinfection and distribution processes. They may be used by water suppliers for the purpose of operational monitoring where relevant. While it is recommended that the Directive continues stipulating their monitoring against suggested parametric values (see Table 22), it should be noted that their monitoring and legal status would be similar to the present indicator parameters where an exceedance does not mean a breach of the Directive.
- *Consumer acceptability*. This group comprises of ten parameters which are important for ensuring acceptability of drinking-water to consumers. All parameters and parametric values are already included in the current Directive. It is recommended that the Directive continues stipulating their monitoring against the suggested parametric values (see Table 22). The point of compliance for these parameters should be the consumer's tap.

Table 21. Parametric values for indicator parameters currently covered in Annex I Part C

Parameter	PV	Date of WHO review	Main source/pathways in drinking-water	Comments
Microbiological indicator parameters				
C. perfringens (including spores)	0/100 mL	-	Faeces of humans and warm-blooded animals	This parameter does not need to be measured unless the water originates from or is influenced by surface water. A detailed description of the indicator value and significance in drinking-water of *C. perfringens* is provided in the fact sheet in Appendix 3.
Colony count 22°C	No abnormal change	-	Heterotrophic microorganisms which include members of the natural microbial flora of water environments and organisms in pollution sources	A detailed description of the indicator value and significance in drinking-water of colony counts at 22°C is provided in the fact sheet in Appendix 3.
Coliform bacteria	0/100 mL	-	Occur in both sewage and natural waters; some of these bacteria are excreted in the faeces of humans and animals, but many coliforms are heterotrophic and able to multiply in water and soil environments	A detailed description of the indicator value and significance in drinking-water of coliform bacteria is provided in the fact sheet in Appendix 3.

Parameter	PV	Date of WHO review	Main source/pathways in drinking-water	Comments
Physico-chemical indicator parameters				
Aluminium	200 µg/L	2010	Primarily from use as coagulant in water treatment; it is also naturally occurring in some raw waters	No WHO health-based GV established. Aluminium is primarily a problem for acceptability if aluminium floc is deposited in distribution and then when disturbed can cause discolouration and turbidity. Although aluminium in drinking-water was associated with an increased incidence of Alzheimer's Disease in some epidemiological studies, the weight of evidence does not support this contention. A health-based value of 900 µg/L could be derived from the 2007 JECFA evaluation with a proposed PTWI of 1 mg/kg of body weight, assuming a 20% allocation of the PTWI to water and assuming that all aluminium was bioavailable. This value, however, exceeds practicable levels based on optimization of the coagulation process in drinking-water plants using aluminium-based coagulants.
Ammonium	0.5 mg/L	1993	Primarily from raw water originating from metabolic processes and from run-off from animal rearing; also used to produce chloramines for residual disinfection	No WHO health-based GV established. Occurs in drinking-water at concentrations well below those of health concern. The need to control relates to its ability to compromise efficiency of disinfection with chlorine and possibly formation of nitrogenous by-products, and other operational problems. The threshold odour concentration of ammonia at alkaline pH is approximately 1.5 mg/L, and a taste threshold of 35 mg/L has been proposed for the ammonium cation.
Chloride	250 mg/L	1993	Primarily found in raw water from industrial discharges, surface run off of salt for de-icing, treated wastewater and also saline intrusion into groundwater and surface water.	No WHO health-based GV established. Not of health concern at levels found in drinking-water. It is primarily a problem for taste but can also exacerbate corrosion of metal pipes and fittings. High concentrations of chloride give a salty taste to water and beverages. Taste thresholds for the chloride anion depend on the associated cation and are in the range of 200–300 mg/L for sodium, potassium and calcium chloride. Concentrations in excess of 250 mg/L are increasingly likely to be detected by taste, but some consumers may become accustomed to low levels of chloride-induced taste. Chloride can be a useful operational indicator of change.

Parameter	PV	Date of WHO review	Main source/pathways in drinking-water	Comments
Colour	Acceptable to consumers and no abnormal change	1993	Naturally occurring in raw water from organic matter (humic and fulvic acids); presence of iron and other metals, either as natural impurities or as corrosion products	No WHO health-based GV established. Most people can detect colour above 15 TCU. Levels of colour below 15 TCU are often acceptable to consumers. High colour from natural organic carbon (e.g. humics) could also indicate a high propensity to produce by-products from disinfection processes. Water that is aesthetically unacceptable can lead to the use of water from sources that are aesthetically more acceptable, but potentially less safe. Colour is an important operational water quality parameter to indicate unexpected change.
Conductivity	2,500 µS cm^{-1} at 20°C	-	Measure of total dissolved inorganic solids in water	No WHO health-based GV established. Conductivity is not specifically mentioned in the WHO Guidelines. High conductivity is sometimes associated with more aggressive waters. The value in the Directive was developed to reflect what is both achievable and acceptable to consumers. Conductivity is an important operational water quality parameter to indicate change.
pH	≥ 6.5 and ≤ 9.5	1993	Measure of hydrogen ion concentration in water	No WHO health-based GV established. Although pH usually has no direct impact on consumers, it is an important operational water quality parameter. It impacts corrosion at low pH and chlorination efficiency at high pH levels. The range of the PV reflects acceptable range for both chlorination and reducing corrosion.
Iron	200 µg/L	1993	Naturally occurring in the ferrous form in anaerobic surface (lakes and reservoirs) and groundwater; also from use as coagulant in treatment and as corrosion deposits in cast iron water mains	No WHO health-based GV established. Iron is not of health concern at levels causing acceptability problems in drinking-water. There is usually no noticeable taste at iron concentrations below 300 µg/L, although turbidity and colour may develop. At levels above 300 µg/L, iron stains laundry and plumbing fixtures. The Guidelines propose a health-based value of 2000 µg/L which is higher than the acceptability threshold. When iron is oxidized to the ferric form it is deposited as brown ferric oxides. This may lead to the accumulation of deposits in the distribution system and can cause severe episodes of discolouration when deposits on pipe walls are disturbed. There are issues with some acid groundwaters where oxidation can be delayed and consumers exposed to soluble ferrous salts which are much more bioavailable.

Parameter	PV	Date of WHO review	Main source/pathways in drinking-water	Comments
Manganese	50 µg/L	2011	Naturally occurring in some surface and acid or anaerobic groundwater	No WHO health-based GV established but this is under review. Manganese is not of health concern at levels causing acceptability problems in drinking-water. The WHO Guidelines propose a health-based value of 400 µg/L which is higher than the acceptability threshold. At levels exceeding 100 µg/L, manganese in water supplies causes an undesirable taste in beverages and stains sanitary ware and laundry. The PV of 50 µg/L reflects discolouration. The presence of manganese in drinking-water may lead to the accumulation of deposits in the distribution system. There are questions regarding possible adverse health effects of manganese from drinking-water but there is much uncertainty, particularly relating to the form of manganese that may be of concern but the PV should be protective.
Odour	Acceptable to consumers and no abnormal change	-	From various raw water constituents and domestic installations	No WHO health-based GV established. The odour of drinking-water should be acceptable to the consumer. What is “acceptable” will vary among consumers and what they are used to. Water that is aesthetically unacceptable can lead to the use of water from sources that are aesthetically more acceptable, but potentially less safe.
Oxidisability	5.0 mg/L O2	-	Measure of organic matter in water	No health-based GV established. This parameter does not need to be monitored where TOC is monitored. It is an old parameter and is generally considered to be of less value than TOC.
Sulphate	250 mg/L	2003	Naturally occurring in raw water and from industrial discharges	No WHO health-based GV established. Not of health concern at levels found in drinking-water. Sulphate has an effect on taste. Taste impairment varies with the nature of the associated cation; taste thresholds have been found to range from 250 mg/L for sodium sulphate to 1000 mg/L for calcium sulphate. May affect gastro-intestinal gut motility at concentrations in excess of 500 mg/L in naïve individuals but this is not considered to be an adverse health effect.

Parameter	PV	Date of WHO review	Main source/pathways in drinking-water	Comments
Sodium	200 mg/L	1993	Naturally occurring in raw water	No WHO health-based GV established. Not of health concern at levels found in drinking-water. The PV is well below that which could affect blood pressure. There may be concerns for bottle-fed infants at high levels but the reduction in sodium levels in infant formulae has significantly reduced the risk of hypernatraemia. Sodium impacts taste; along with chloride sodium is a potential indicator of salination. The taste threshold concentration of sodium in water depends on the associated anion and the temperature of the solution. At room temperature, the average taste threshold for sodium is about 200 mg/L. Drinking-water is unlikely to be a significant source of sodium intake.
Taste	Acceptable to consumers and no abnormal change	-	From various raw water constituents and domestic installations	No WHO health-based GV established. The taste of drinking-water should be acceptable to the consumer. What is “acceptable” to consumers will vary according to different tastes and consumers do become used to tastes associated with inorganic constituents such as hardness or the lack of hardness. Water that is aesthetically unacceptable can lead to the use of water from sources that are aesthetically more acceptable, but potentially less safe.
TOC	No abnormal change	-	Naturally occurring in raw water and from discharges	No WHO health-based GV established. TOC is an Indicator of organic matter, particularly in raw water. TOC is a useful operational water quality parameter to indicate change.
Turbidity	Acceptable to consumers and no abnormal change <1.0 NTU post treatment for surface water sources	2015	Caused by suspended particles or colloidal matter (inorganic or organic)	No WHO health-based GV established. Turbidity is an important operational water quality parameter to indicate change in water quality as well as in coagulation filtration efficiency. Turbidity can also interfere with the efficiency of disinfection. To ensure effectiveness of disinfection and parasite removal, well-run large supplies should be able to achieve < 0.3 NTU under normal circumstances. Small water supplies, where there is limited or no treatment, may not be able to achieve such low levels of turbidity. Turbidity can have negative impact on consumer acceptability of water as a result of visible cloudiness. Turbidity is not visible in final water at < 4 NTU.

Table 22. Physico-chemical indicator parameters, parametric values and parameter groupings recommended for inclusion in Annex I Part C

Parameter group	**Parameter**	**PV**	**Function**	**Comments**
Essential operational monitoring	Turbidity	<0.3 NTU (95%) and not >0.5 NTU for 15 consecutive minutes <1 NTU (small supplies)	To maintain coagulation/filtration efficacy Point of compliance is water leaving the filters, preferably measured at the outlet of each filter	*New parameter role and parametric values (see also parameter group consumer acceptability)* Turbidity levels should be kept as low as reasonably achievable. Turbidity is also an important parameter in source water monitoring in identifying peak/contamination events (see Chapter 8.2for details).
	Effective disinfectant dose	Effective dose is sufficient to achieve planned removal efficiency	To maintain disinfection efficiency (see Article 7(1) of the Directive) Point of compliance is water leaving the disinfection process	*New parameter for supplies where disinfection is applied* Operational monitoring of effective disinfectant dose requires monitoring of several parameters: Chemical disinfection: monitor disinfectant residual, flow, temperature and pH value. Translate to dose recognizing (variable) disinfectant decay in receiving water and residence time distribution in contact chamber(s). UV disinfection: monitor UV irradiance in reactor, UV transmission of water, flow. Translate to dose recognizing UV absorption in water and residence time distribution in UV reactor.
	Temperature of water in buildings	Warm water system: >55˚C Cold water system: <25˚C	Confirmation of effective operations of control measures preventing *Legionella* proliferation Points of compliance are the showerhead (warm water) and the consumer's tap (cold water)	*New parameter* Should be measured only in priority buildings, as specified by the Directive (see Section 7.4).

Parameter group	Parameter	PV	Function	Comments
Indicators for treatment and distribution	Aluminium	100 µg/L 200 µg/L (small supplies)	To measure efficiency of coagulation and filtration	*New complementary parametric value* Aluminium only to be measured when aluminium salts are used for coagulation.
	Ammonium	0.5 mg/L	To maintain disinfection efficiency	Ammonium reacts with free chlorine to form chloramines; less efficient for primary disinfection.
	Calcium and magnesium	-	To reduce corrosion and improve taste in desalinated water	*New parameter* Addition of calcium and magnesium salts should be considered as a means of conditioning and mineralizing desalinated and other reverse osmosis treated water.
	Conductivity	2,500 µS cm^{-1} at 20°C	To indicate taste and scaling problems	*Complementary parameter role (see also parameter group consumer acceptability)* Conductivity can be a useful operational water quality parameter to indicate change.
	pH	≥ 6.5 and ≤ 9.5	To maintain efficacy of treatment and disinfection processes and manage corrosion in distribution	
	TOC	No abnormal change	To indicate possible contamination or changed organic content	TOC can be a useful operational water quality parameter to indicate change.

Parameter group	Parameter	PV	Function	Comments
Consumer acceptability	Chloride	250 mg/L	To indicate taste problems	Chloride can be a useful operational water quality parameter to indicate change.
	Colour	Acceptable to consumers and no abnormal change	To indicate appearance problems and possible contamination	Colour can be a useful operational water quality parameter to indicate change.
	Conductivity	2,500 µS cm^{-1} at 20°C	To indicate taste and scaling problems	Conductivity can be a useful operational water quality parameter to indicate change.
	Iron	200 µg/L	To indicate discolouration	The presence of iron in drinking-water may lead to the accumulation of deposits in the distribution system and cause episodes of discolouration.
	Manganese	50 µg/L	To indicate discolouration	The presence of iron in drinking-water may lead to the accumulation of deposits in the distribution system and cause episodes of discolouration.
	Odour	Acceptable to consumers and no abnormal change	To indicate acceptability problems and possible contamination	Odour and taste can be closely linked, particularly for more volatile contaminants. Together these can indicate operational problems, e.g. high chlorine or chloramine residual or hydrogen sulphide, or contamination.
	Sulphate	250 mg/L	To indicate taste problems	
	Sodium	200 mg/L	To indicate taste problems	
	Taste	Acceptable to consumers and no abnormal change	To indicate acceptability problems and possible contamination	See odour above.
	Turbidity	4 NTU (at tap)	To indicate particulate matter and ingress	*New parameter role and parametric value (see also parameter group essential operational monitoring)* Turbidity levels should be kept as low as reasonably achievable and always be acceptable to consumers.

References

Australian National Health and Research Council (2011). National water quality management strategy: Australian drinking water guidelines 6: version 3.3 updated November 2016. Available at: https://www.nhmrc.gov.au/_files_nhmrc/file/publications/nhmrc_adwg_6_version_3.3_2.pdf (accessed on 27 July 2017).

Badenoch J (1990). Cryptosporidium in water supplies. Report of the Group of Experts. Department of the Environment, Department of Health. London: HMSO; 230pp.

Beer KD, Gargano JW, Roberts VA et al. (2015). Surveillance for waterborne disease outbreaks associated with drinking water — United States, 2011–2012. MMWR Morb Mortal Wkly Rep 64(31):842–8.

Berendonk TU, Manaia CM, Merlin C, Fatta-Kassinos D, Cytryn E, Walsh F, Bürgmann H, Sørum H, Norström M, Pons MN, Kreuzinger N, Huovinen P, Stefani S, Schwartz T, Kisand V, Baquero F, Martinez JL (2015). Tackling antibiotic resistance: the environmental framework. Nat Rev Microbiol 13(5):310-317.

Berney M, Vital M, Hülshoff I, Weilenmann HU, Egli T, Hammes F (2008). Rapid, cultivation-independent assessment of microbial viability in drinking water. Water Res 42(14):4010-4018.

Besner MC, Prevost M, Regli S (2011). Assessing the public health risk of microbial intrusion events in distribution systems: conceptual model, available data and challenges. Water Research 45:961-979.

BMUB, BMEL (2017). Nitrate report 2016. Berlin: Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety and Federal Ministry of Food and Agriculture.

Braeye T, De Schrijver K, Wollants E, van Ranst M, Verhaegen J. (2015). A large community outbreak of gastroenteritis associated with consumption of drinking water contaminated by river water, Belgium, 2010. Epidemiology and Infection 143(4):711-719.

Brodhun B, Buchholz U (2011). Epidemiologie der Legionärskrankheit in Deutschland. Bundesgesundheitsbl 54:680–687.

Collier S, Stockman L, Hicks L, Garrison L, Zhou F, Beach M (2012). Direct healthcare costs of selected diseases primarily or partially transmitted by water. Epidemiology and Infection 140(11): 2003-2013.

Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013L0051 (accessed on 29 July 2017).

Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States. Available at: http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:31975L0440 (accessed on 30 June 2017).

Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31998L0083 (accessed on 30 June 2017).

Coward S et al. (1999). The risks of Legionella in water systems in homes, Part 1. Building research establishment client report number CR361/98R. Final report prepared for the Building Regulations Division. London: Department of Environment, Transport and the Regions.

Craun GF, Calderon RL (2001). Waterborne disease outbreaks caused by distribution system deficiencies. Journal of the American Water Works Association 93(9):64–75.

De Hollander G, Hanemaaijer A (2003). Nuchter omgaan met risico's. RIVM rapport 251701047/2003. Bilthoven: National Institute of Public Health and the Environment.

Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32000L0054 (accessed on 30 June 2017).

Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32000L0060 (accessed on 30 June 2017).

Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:02006L0118-20140711 (accessed on 25 July 2017).

Directive 2006/122/EC of the European Parliament and of the Council of 12 December 2006 amending for the 30th time Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (perfluorooctane sulfonates). Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006L0122 (accessed on 29 July 2017).

Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy. Available at: http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32013L0039 (accessed on 25 July 2017).

DoH (2017). Health technical Memorandum 04-01: Safe water in healthcare premises. Part C: Pseudomonas aeruginosa – advice for augmented care units. London: Department of Health. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/524884/DH_HTM_0401_PART_C_acc.pdf (accessed on 6 August 2017).

DVGW (2004). W 551: Trinkwassererwärmungs- und Trinkwasserleitungsanlagen: Technische Maßnahmen zur Verminderung des Legionellenwachstums: Planung, Errichtung, Betrieb und Sanierung von Trinkwasser-Installationen. Bonn: Deutscher Verein des Gas- und Wasserfaches.

DVGW (2006). W 294-1: UV-Geräte zur Desinfektion in der Wasserversorgung - Teil 1: Anforderungen an die Beschaffenheit, Funktion und Betrieb. Bonn: Deutscher Verein des Gas- und Wasserfaches.

EC (2011). Common implementation strategy for the Water Framework Directive (2000/60/EC). Guidance document no. 27: Technical guidance for deriving environmental quality standards. Brussels: European Commission. Available at: https://circabc.europa.eu/w/browse/0cc3581b-5f65-4b6f-91c6-433a1e947838 (accessed on 5 August 2017).

EC (2016). Synthesis report on the quality of drinking water in the Union examining Member States' reports for the 2011-2013 period, foreseen under Article 13(5) of Directive 98/83/EC. Brussels: European Commission. Available at: http://ec.europa.eu/environment/water/water-drink/pdf/reports/EN.pdf (accessed on 30 June 2017).

EC (2017). A European one health action plan against antimicrobial resistance (AMR). Brussels: European Commission. Available at: https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf (accessed on 6 August 2017).

ECDC (2014). Legionnaires' disease in Europe, 2012. Stockholm: European Centre for Disease Prevention and Control. Available at: https://ecdc.europa.eu/en/publications-data/legionnaires-disease-europe-2012 (accessed on 28 June 2017).

ECDC (2016). Legionnaires' disease in Europe, 2014. Stockholm: European Centre for Disease Prevention and Control.

EFSA (2008). Perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts. Scientific Opinion of the Panel on Contaminants in the Food Chain. EFSA Journal 653: 1-131.

EFSA (2014). Scientific Opinion: Risks for public health related to the presence of chromium in food and drinking-water. EFSA Panel on Contamination in the Food Chain. Parma: European Food Safety Authority. EFSA Journal 12(3): 3595.

EFSA (2015). Scientific opinion: Risks for public health related to the presence of chlorate in food. EFSA Panel on Contamination in the Food Chain. Parma: European Food Safety Authority. EFSA Journal 13(6): 4135.

England and Wales (2001). The water supply (water quality) regulations 2001: No. 3911. Available at: http://www.legislation.gov.uk/wsi/2001/3911/contents/made (accessed on 6 August 2017).

England and Wales (2016). The water supply (water quality) regulations 2016: No. 614. Available at: http://www.legislation.gov.uk/uksi/2016/614/contents/made (accessed on 6 August 2017).

Fawell JK, Ong CN (2012). Emerging contaminants and the implications for drinking water. Int J Water Res Dev 28(2):247-263.

Fawell JK, Sheahan D, James HA, Hurst M, Scott S (2001). Assessment of oestrogens and oestrogenic activity in raw and treated water in Severn Trent Water. Water Research 35(5):1240-1244.

FERA (2011). Review of the risks posed to drinking water by man-made nanoparticles. Report DWI 70/2/246 by the Food and Environment Research Agency for the Drinking Water Inspectorate. Available at: http://dwi.defra.gov.uk/research/completed-research/reports/DWI70_2_246.pdf (accessed on 28 June 2017).

Gallay A, De Valk H, Cournot M, Ladeuil B, Hemery C, Castor C, Bon F, Mégraud F, Le Cann P, Desenclos J C (2006). A large multi-pathogen waterborne community outbreak linked to faecal contamination of a groundwater system, France, 2000. Clinical Microbiology and Infection 12:561–570.

German Environment Agency (2004). Beurteilung der Trinkwasserqualität hinsichtlich der Parameter Blei, Kupfer und Nickel: Empfehlung des Umweltbundesamtes nach Anhörung der Trinkwasserkommission des Bundesministeriums für Gesundheit und Soziale Sicherung. Bundesgesundheitsbl - Gesundheitsforsch -Gesundheitsschutz 47:296–300. Available at: https://www.umweltbundesamt.de/sites/default/files/medien/374/dokumente/tw_qualitaet_pb_cu_ni.pdf (accessed on 9 September 2017).

German Environment Agency (2014). Vorgehen zur quantitativen Risikobewertung mikrobiologischer Befunde im Rohwasser sowie Konsequenzen für den Schutz des Einzugsgebietes und für die Wasseraufbereitung: Empfehlung des Umweltbundesamtes nach Anhörung der Trinkwasserkommission. Bundesgesundheitsbl 57:1224–1230. Available at: https://www.umweltbundesamt.de/sites/default/files/medien/374/dokumente/empfehlung_vorgehen_zur_quantitativen_risikobewertung_bundesgesundheitsbl_2014_57_1224-1230.pdf (accessed on 6 August 2017).

German Environment Agency (2017). Empfehlung zu erforderlichen Untersuchungen auf Pseudomonas aeruginosa, zur Risikoeinschätzung und zu Maßnahmen beim Nachweis im Trinkwasser: Empfehlung des Umweltbundesamtes nach Anhörung der Trinkwasserkommission.

Available at: http://www.umweltbundesamt.de/sites/default/files/medien/374/dokumente/empfehlung_zur_risikoeinschaetzung_pseudomonaden.pdf (accessed on 6 August 2017).

Government of Canada (2017). Guidelines for Canadian drinking water quality – summary table. Available at: https://www.canada.ca/en/health-canada/services/environmental-workplace-health/reports-publications/water-quality/guidelines-canadian-drinking-water-quality-summary-table-health-canada-2012.html (accessed on 27 July 2017).

Government of France (2017). Arrêté du 1er février 2010 relatif à la surveillance des légionelles dans les installations de production, de stockage et de distribution d'eau chaude sanitaire. Version consolidée au 27 juillet 2017. Available at: https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000021795143&dateTexte=20170727 (accessed on 27 July 2017).

Government of Germany (2017). Trinkwasserverordnung in der Fassung der Bekanntmachung vom 10. März 2016 (BGBl. I S. 459), die durch Artikel 2 des Gesetzes vom 17. Juli 2017 (BGBl. I S. 2615) geändert worden ist. Available at: https://www.gesetze-im-internet.de/bundesrecht/trinkwv_2001/gesamt.pdf; and in English at: http://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/E/Englische_Dateien/Drinking_Water_Ordinance.pdf (accessed on 27 July 2017).

Government of the Netherlands (2004). Besluit van 26 oktober 2004 tot wijziging van het Waterleidingbesluit en het Besluit hygiëne en veiligheid badinrichtingen en zwemgelegenheden (preventie van legionella in leidingwater). Nota van toelichting. Staatsblad van het Koninkrijk der Nederlanden 2004:576.

Government of the Netherlands (2011). Besluit van 23 mei 2011, houdende bepalingen inzake de productie en distributie van drinkwater en de organisatie van de openbare drinkwatervoorziening (Drinkwaterbesluit) Available at: http://wetten.overheid.nl/BWBR0030111/2015-11-28 (accessed on 6 August 2017).

Government of Quebec (2017). Regulation respecting the quality of drinking water. Available at: http://legisquebec.gouv.qc.ca/en/ShowDoc/cr/Q-2,%20r.%2040 (accessed on 6 August 2017).

Guzman-Herrador B, Carlander A, Ethelberg S, Freiesleben de Blasio B, Kuusi M, Lund V, Löfdahl M, MacDonald E, Nichols G, Schönning C, Sudre B, Trönnberg L, Vold L, Semenza JC, Nygård K (2015). Waterborne outbreaks in the Nordic countries, 1998 to 2012. Euro Surveill 20(24):21160.

Hänninen ML, Haajanen H, Pummi T, Wermundsen K, Katila ML, Sarkkinen H, Miettinen I, Rautelin H (2003). Detection and typing of Campylobacter jejuni and Campylobacter coli and analysis of indicator organisms in three waterborne outbreaks in Finland. Appl Environ Microbiol 69(3):1391-1396.

Hunter PR, Chalmers RM, Hughes S, Syed Q (2005). Self-reported diarrhea in a control group: strong association with reporting of low-pressure events in tap water. Clinical Infectious Diseases 40(4):32-34.

HSE (2013). Legionnaires' disease: The control of legionella bacteria in water systems: Approved code of practice and guidance. London: Health and Safety Executive. Available at: http://www.hse.gov.uk/pubns/books/l8.htm (accessed on 6 August 2017).

Japanese Ministry of Health, Labour and Welfare (2015). Water quality. Available at: http://www.mhlw.go.jp/english/policy/health/water_supply/4.html (accessed on 29 June 2017).

Karim MR, Abbaszadegan M, LeChevallier M (2003). Potential for pathogen intrusion during pressure transients. Journal of the American Water Works Association 95(5):134-146.

Kuhn KG, Falkenhorst G, Emborg HD, Ceper T, Torpdahl M, Krogfelt KA, Ethelberg S, Mølbak K (2017). Epidemiological and serological investigation of a waterborne Campylobacter jejuni outbreak in a Danish town. Epidemiol Infect 145(4):701-709.

Kvitsand HML, Fiksdal L (2010). Waterborne disease in Norway: emphasizing outbreaks in groundwater systems. Water Sci Technol 61(3):563-571.

Lalancette C, Papineau I, Payment P, Dorner S, Servais P, Barbeau B, DiGiovanni GD, Prévost M (2014). Changes in Escherichia coli to Cryptosporidium ratios for various fecal pollution sources and drinking water intakes. Water Res 55:150-161.

LeChevallier MW, Xu M, Yang J, Teunis P, Fleming KK (2011). Managing distribution system low transient pressures for water quality. Denver: Water Research Foundation.

Linos A, Petralias A, Christophi CA, Christoforidou E, Kouroutou P, Stoltidis M, Veloudaki A, Tzala E, Makris KC, Karagas MR (2011). Oral ingestion of hexavalent chromium through drinking water and cancer mortality in an industrial area of Greece – an ecological study. Environmental Health 10:50.

Miettinen IT, Lepistö O, Pitkänen T, Kuusi M, Maunula L, Laine J et al. (2012). A waterborne outbreak caused by a severe faecal contamination of distribution network: Nokia case. In: Kay D, Fricker C (eds.): The significance of faecal indicators in water: a global perspective. London: Royal Society of Chemistry Publishing; p. 34-7.

Ministry of Health New Zealand (2008). Drinking-water standards for New Zealand 2005, revised 2008. Wellington: Ministry of Health New Zealand. Available at: http://www.health.govt.nz/publication/drinking-water-standards-new-zealand-2005-revised-2008 (accessed on 6 August 2017).

NHMRC (2016). Australian Drinking Water Guidelines: Draft framework on microbial health based targets. National Health and Medical Research Council. Available at: https://consultations.nhmrc.gov.au/public_consultations/adwg-microbial (accessed on 6 August 2017).

NRW (2012). Vom Programm “Reine Ruhr” zur Strategie einer nachhaltigen Verbesserung der Gewässer- und Trinkwasserqualität in Nordrhein-Westfalen [From the program “Clean Ruhr” to a strategy for sustainable improvement of source water and drinking water quality]. Düsseldorf: Ministry for Climate Protection, Environment, Agriculture, Nature and Consumer Protection, Düsseldorf, North Rhine-Westphalia.

Nygard K, Wahl E, Krogh T, Tveit OA, Bohleng E, Tverdal A, Aavitsland P (2007). Breaks and maintenance work in the water distribution systems and gastrointestinal illness: a cohort study. International Journal of Epidemiology 36(4):873-880.

OECD, WHO (2003). Assessing microbial safety of drinking water: improving approaches and methods. Organisation for Economic Co-operation and Development, World Health Organization. London: IWA Publishing. Available at: http://www.who.int/water_sanitation_health/publications/9241546301/en (accessed on 29 June 2017).

ÖNORM M 5873-1 (2001). Anlagen zur Desinfektion von Wasser mittels Ultraviolett-Strahlen - Anforderungen und Prüfung - Anlagen mit Quecksilberdampf-Niederdruckstrahlern.

Payment P, Locas A (2011). Pathogens in water: value and limits of correlation with microbial indicators. Ground Water 49(1):4-11.

Payment P, Richardson L, Siemiatycki J, Dewar R, Edwardes M, Franco E (1991). A randomized trial to evaluate the risk of gastrointestinal disease due to consumption of drinking water meeting current microbiological standards. American Journal of Public Health 81(6):703-708.

Payment P, Siemiatycki J, Richardson L, Renaud G, Franco E, Prevost M (1997). A prospective epidemiological study of gastrointestinal health effects due to the consumption of drinking water. International Journal of Environmental Health Research 7(1):5-31.

Pelly H, Cormican M, O'Donovan D, Chalmers R, Hanahoe B, Cloughley R, McKeown P, Corbett-Feeney G (2007). A large outbreak of cryptosporidiosis in western Ireland linked to public water supply: a preliminary report. Euro Surveill 12(18):3187.

Risebro HL, Doria MF, Andersson Y, Medema G, Osborn K, Schlosser O, Hunter PR (2007). Fault tree analysis of the causes of waterborne outbreaks. Journal of Water and Health 5:1-18.

Sas K (ed) (2011). Legionella and legionnaires' disease: a policy overview. Luxembourg: European Agency for Safety and Health at Work. Available at: https://osha.europa.eu/en/tools-and-publications/publications/literature_reviews/legionella-policy-overview.pdf/view (accessed on 6 August 2017).

Säve-Söderbergh M, Bylunda J, Malm A, Simonssona M, Toljander J (2017). Gastrointestinal illness linked to incidents in drinking water distribution networks in Sweden. Water Res 122:503-511.

Sazakli E, Villanueva CM, Kogevinas M, Maltezis K, Mouzaki A, Leotsinidis M (2014). Chromium in drinking water: association with biomarkers of exposure and effect. Int. J. Environ Res. Public Health 11: 10125-145.

Schardinger F (1892). Über das Vorkommen Gährung erregender Spaltpilze im Trinkwasser und ihre Bedeutung für die hygienische Beurteilung desselben. Wien Klin Wachr 5:403-405, 421-423.

Scotland (2014). The public water supplies (Scotland) regulations 2014: No. 364. Available at: http://www.legislation.gov.uk/ssi/2014/364/contents/made (accessed on 6 August 2017).

Siebel E, Wang Y, Egli T, Hammes F (2008). Correlations between total cell concentration, total adenosine tri-phosphate concentration and heterotrophic plate counts during microbial monitoring of drinking water. Drinking Water Engineering & Science 1:1-6.

Stenström TA (1994). A review of waterborne outbreaks of gastroenteritis in Scandinavia. In: Water & Public Health. Golding AMB, Noah N, Stanwell-Smith R (eds). Smith-Goron, London, p.137-143.

Therre H, de Valk H, Vaillant V, Beaudeau P, Mouly D. (2008). Assessment of waterborne outbreaks investigated in France since 1998 and key recommendations: summary report. Saint-Maurice: French Institute for Public Health Surveillance.

US EPA (1989). Surface water treatment rule. United States Environmental Protection Agency Available at: https://www.epa.gov/dwreginfo/surface-water-treatment-rules (accessed on 6 August 2017).

US EPA (2006a). Long term 2 enhanced surface water treatment rule. United States Environmental Protection Agency. Available at: https://www.gpo.gov/fdsys/pkg/FR-2006-01-05/pdf/06-4.pdf (accessed on 6 August 2017).

US EPA (2006b). Source water monitoring guidance manual for public water systems for the final Long Term 2 Enhanced Surface Water Treatment Rule. United States Environmental Protection Agency: Office of Water (4601M) EPA 815-R06-005. Available at: https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=2000CZCJ.txt (accessed on 6 August 2017).

US EPA (2017). National primary drinking water regulations table. United States Environmental Protection Agency. Available at: https://www.epa.gov/ground-water-and-drinking-water/table-regulated-drinking-water-contaminants (accessed on 29 June 2017).

van der Wielen PW, van der Kooij D (2010). Effect of water composition, distance and season on the adenosine triphosphate concentration in unchlorinated drinking water in the Netherlands. Water Res 44(17):4860-4867.

van der Wielen PW, Bakker G, Atsma A, Lut M, Roeselers G, de Graaf B (2016). A survey of indicator parameters to monitor regrowth in unchlorinated drinking water. Environ Sci: Water Res Technol 2:683-692.

Veenendaal HR, Brouwer-Hanzens A, van der Kooij D (2017). Incubation of premise plumbing water samples on buffered charcoal yeast extract agar at elevated temperature and pH selects for Legionella pneumophila. Water Research 123:439-447.

Versteegh JFM, Brandsema PS, van der Aa NFGM, Dik HHJ, de Groot GM (2007). Evaluatie legionellapreventie Waterleidingwet. RIVM rapport 703719020/2007. Bilthoven: National Institute of Public Health and the Environment.

von Baum H, Ewig S, Marre R, Suttorp N, Gonschior S, Welte T, Lück C; Competence Network for Community Acquired Pneumonia Study Group (2008). Community-acquired Legionella pneumonia: new insights from the German competence network for community acquired pneumonia. Clin Infect Dis 46(9):1356-64.

von Baum H, Lück C (2011). Community-acquired Legionella pneumonia : data from the CAPNETZ study. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 54(6):688-692.

Wenzel A, Muller J, and Ternes T (2003). Study on endocrine disrupters in drinking water. Final Report to the European Commission: ENV.D.1/ETU/2000/0083.

WHO (1984). Guidelines for drinking-water quality: Volume 2: health criteria and other supporting information. Geneva: World Health Organization. Available at: http://apps.who.int/iris/bitstream/10665/252073/1/9241541695-eng.pdf?ua=1 (accessed on 28 July 2017).

WHO (1993). Guidelines for drinking-water quality: second edition. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/publications/gdwq2v1/en/ (accessed on 30 June 2017).

WHO (2003a). Heterotrophic plate counts and drinking-water safety: the significance of HPCs for water quality and the human health. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/publications/hpc/en/ (accessed on 29 June 2017).

WHO (2003b). Benzene in drinking-water: background document for development of WHO guidelines for drinking-water quality. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/benzene/en/ (accessed on 29 June 2017).

WHO (2003c). 1,2-Dichlorethane in drinking-water: background document for development of WHO guidelines for drinking-water quality. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/12dichloroethane/en/ (accessed on 29 June 2017).

WHO (2003d). Polynuclear aromatic hydrocarbons in drinking-water: background document for development of WHO guidelines for drinking-water quality. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/polyaromahydrocarbons/en/ (accessed on 29 June 2017).

WHO (2003e). Asbestos in drinking-water: background document for development of WHO guidelines for drinking-water quality. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/asbestos/en/ (accessed on 29 June 2017).

WHO (2003f). Chlorophenols in drinking-water: background document for development of WHO guidelines for drinking-water quality. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/chlorophenols/en/ (accessed on 29 June 2017).

WHO (2004a). Guidelines for drinking-water quality: third Edition. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/publications/gdwq3/en/ (accessed on 29 June 2017).

WHO (2004b). Water treatment and pathogen control: process efficiency in achieving safe drinking water. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/publications/9241562552/en/ (accessed on 29 June 2017).

WHO (2004c). Safe piped water: managing microbial water quality in piped distribution systems. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/publications/safe-piped-water/en/ (accessed on 29 June 2017).

WHO (2005). Mercury in drinking-water: background document for development of WHO guidelines for drinking-water quality. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/mercury/en/ (accessed on 29 June 2017).

WHO (2006a). Protecting groundwater for health: managing the quality of drinking-water sources. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/publications/protecting_groundwater/en/ (accessed on 29 June 2017).

WHO (2006b). Meeting of experts on the possible protective effect of hard water against cardiovascular disease (Washington, 27–28 April 2006). Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/gdwqrevision/cardiofullreport.pdf (accessed on 29 June 2017).

WHO (2007a). Legionella and the prevention of legionellosis. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/publications/legionella/en/ (accessed on 29 June 2017).

WHO (2007b). Evaluation of certain food additives and contaminants. Sixty-eighth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series 947. Geneva: World Health Organization. Available at: http://apps.who.int/iris/bitstream/10665/43870/1/9789241209472_eng.pdf (accessed on 3 August 2017).

WHO (2008). N-Nitrosodimethylamine in drinking-water: background document for development of WHO guidelines for drinking-water quality. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/ndma/en/ (accessed on 29 June 2017).

WHO (2009a). Water safety plan manual: step-by-step risk management for drinking-water suppliers. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/publications/publication_9789241562638/en (accessed on 29 June 2017).

WHO (2009b). Calcium and magnesium in drinking-water: public health significance. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/publications/publication_9789241563550/en (accessed on 29 June 2017).

WHO (2009c). Cyanide in drinking-water: background document for development of WHO guidelines for drinking-water quality. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/cyanide/en/ (accessed on 29 June 2017).

WHO (2011a). Water safety in buildings. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/publications/2011/9789241548106/en/ (accessed on 29 June 2017).

WHO (2011b). Safe drinking-water from desalination. Geneva: World Health Organization. Available at: http://apps.who.int/iris/bitstream/10665/70621/1/WHO_HSE_WSH_11.03_eng.pdf?ua=1 (accessed on 29 June 2017).

WHO (2011c). Hardness in drinking-water: background document for development of WHO guidelines for drinking-water quality. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/hardness/en/ (accessed on 29 June 2017).

WHO (2012). Pharmaceuticals in drinking-water. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/publications/pharmaceuticals-in-drinking-water/en/ (accessed on 29 June 2017).

WHO (2014). Water safety in distribution systems. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/publications/water-safety-in-distribution-system/en/ (accessed on 29 June 2017).

WHO (2016a). Protecting surface water for health: identifying, assessing and managing drinking-water quality risks in surface-water catchments. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/publications/pswh/en/ (accessed on 29 June 2017).

WHO (2016b). Quantitative microbial risk assessment: application for water safety management. Geneva: World Health Organization. Available at: http://apps.who.int/iris/bitstream/10665/246195/1/9789241565370-eng.pdf?ua=1 (accessed on 6 August 2017).

WHO (2017a). Guidelines for drinking-water quality: fourth edition incorporating the first addendum. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/publications/drinking-water-quality-guidelines-4-including-1st-addendum/en (accessed on 29 June 2017).

WHO (2017b). Chemical mixtures in source water and drinking-water. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/publications/chemical-mixtures-in-water/en/ (accessed on 29 June 2017).

WHO Regional Office for Europe (2014). Water safety plan: a field guide to improving drinking-water safety in small communities. Copenhagen: WHO Regional Office for Europe. Available at: http://www.euro.who.int/en/health-topics/environment-and-health/water-and-sanitation/publications/2014/water-safety-plan-a-field-guide-to-improving-drinking-water-safety-in-small-communities (accessed on 29 June 2017).

Widerström M, Schönning C, Lilja M, Lebbad M, Ljung T, Allestam G et al. (2014). Large outbreak of Cryptosporidium hominis infection transmitted through the public water supply, Sweden. Emerg Infect Dis 20(4):581-9.

Willocks L, Crampin A, Milne L, Seng C, Susman M, Gair R, Moulsdale M, Shafi S, Wall R, Wiggins R, Lightfoot N (1998). A large outbreak of cryptosporidiosis associated with a public water supply from a deep chalk borehole. Communicable disease and public health 1(4):239-243.

Wu J, Rees P, Dorner S (2011). Variability of E. coli density and sources in an urban watershed. J Water Health 9(1):94-106.

Appendix 1:
Summary of occurrence data

To inform the development of recommendations laid down in this report, we Member States and stakeholders, through official letters sent on 19 May and 13 June 2016 by the EC, to submit data on the occurrence of 20 selected drinking-water contaminants. We received data from 19 Member States and various stakeholders, such as water supply utilities.

An overview of the data received and an aggregated summary of the data is shown in the following. The full suite of data received has been provided to the EC under separate coverage.

Table A.1. Overview of occurrence data received from Member States and stakeholders

Parameter / Country/utility	Antimony	Benzene	B(a)P	Boron	Chlorate	Chlorite	Chlorophenols	Cyanide	1,2-Dichloroethane	HAAs	Mercury	Microcystin	NDMA	PFOS	PFOA	PAHs	Selenium	Tetra- and trichloroethene	Thallium	Uranium
Responses obtained from Member States																				
Austria	+	+	+	+	+	+	+	+	+	-	+	-	+	-	-	+	+	+	-	+
Belgium (3 regions)	3	3	3	3	3	2	-	3	3	-	3	1	-	1	1	3	3	3	-	2
Cyprus	+	+	+	+	-	-	-	+	+	-	+	-	-	-	-	+	+	+	-	-
Czech Republic	+	+	+	+	+	+	-	+	+	+	+	+	-	-	-	+	+	+	-	-
Denmark	+	+	+	+	-	-	+	+	+	-	+	-	-	+	+	+	+	+	-	-
Estonia	+	+	+	+	-	-	-	+	+	-	+	-	-	-	-	+	+	+	-	-
France	+	+	+	+	-	+	-	+	+	-	+	+	+	+	+	+	+	+	-	-
Germany (4 federal states)	4	4	4	4	1	3	1	3	4	-	4	-	-	-	-	4	4	4	1	3
Hungary	+	+	+	+	+	+	-	+	+	-	+	-	-	-	-	+	+	+	-	-
Italy	+	+	+	+	-	+	-	+	+	-	+	+	-	+	+	+	+	+	1	+
Lithuania	+	+	+	+	-	-	-	+	+	-	+	-	-	-	-	+	+	+	-	-
Malta	+	+	+	+	-	+	+	+	+	-	+	-	-	-	-	+	+	+	-	-
Netherlands	+	+	+	+	+	+	+	+	+	+	+	-	+	+	+	+	+	+	+	+
Portugal	+	+	+	+	-	-	-	+	+	-	+	-	-	-	-	+	+	+	-	-
Romania	+	+	+	+	-	-	-	+	+	-	+	-	-	-	-	+	+	+	-	-
Slovakia	+	+	+	+	-	+	+	+	+	-	+	-	-	-	-	+	+	+	-	-
Slovenia	+	+	+	+	+	+	-	+	+	-	+	-	-	-	-	+	+	+	-	-
Spain	+	+	+	+	+	+	+	+	+	+	+	+	+	-	-	+	+	+	+	-
United Kingdom (3 regions)	2	2	2	2	1	-	2	2	2	2	2	1	-	-	-	2	2	2	-	-
Responses obtained from water utilities																				
Finland (2 utilities)	2	2	2	2	-	-	-	2	2	-	2	-	-	1	1	2	2	2	-	-
France (3 utilities)	2	3	2	3	1	1	-	3	3	2	3	2	2	-	-	2	3	3	1	-
Germany (14 utilities)	14	14	14	7	-	1	-	14	14	-	14	-	4	14	14	14	14	14	1	13
Italy (8 utilities)	8	8	8	8	5	8	-	8	8	-	8	1	-	3	3	8	8	8	-	2
Sweden	1	1	+	+	+	+	+	+	+	-	+	-	-	+	+	+	+	+	+	+

Table A.2. Descriptive statistical values for occurrence data reported by Member States

Parameters	Number of samples reported by countries	Reported maxima above PV/GV (%)	Reported arithmetic means above PV/GV (%)[a]	Reported medians above PV/GV (%)[a]	Compliance rate as reported by EC for 2011-2013 (%)
Parameters covered by Annex I Part B with established PV					
Antimony	316095	56	0	0	99.94
B(a)P	268233	81	22	0	99.96
Benzene	259175	31	11	0	99.99
Boron	325916	69	20	0	99.85
Cyanide	236486	20	0	0	100.00
1,2-Dichloroethane	275191	27	0	0	100.00
Mercury	270819	50	11	0	99.98
PAH	260070	63	33	0	99.95
Selenium	290194	56	0	0	99.83
Tetra- and trichloroethene	365345	25	0	0	99.84
Additional parameters with or without WHO GV					
Chlorate	8724	25	0	(0)	N/A
Chlorite	37246	40	0	(0)	N/A
Chlorophenols	10917	No GV	No GV	No GV	N/A
HAAs	13589	No GV	No GV	No GV	N/A
Microcystin	15558	60	0	0	N/A
NDMA	417	0	(0)	(0)	N/A
PFOA	2411	No GV	No GV	No GV	N/A
PFOS	2400	No GV	No GV	No GV	N/A
Thallium	2482	No GV	No GV	No GV	N/A
Uranium	27289	80	(0)	(0)	N/A

[a] The number of reported arithmetic means and medians was generally low. Statistical values for parameters with reported figures available for less than three countries are omitted for analysis but included in brackets.

Appendix 2:
Feedback from Member States and stakeholders

Draft versions of this report have been presented and discussed with Member States and stakeholders in the course of the project. EC and WHO co-organized a large stakeholder consultation (Brussels, 23 September 2016) at which we presented the underlying rationale and preliminary findings of the project, including possible proposals for the revision of Annex I of the Directive; a summary report of the stakeholder consultation is provided in this Appendix.

In addition to the feedback received during the consultation, we invited all Member States and stakeholders to submit written feedback on the draft background papers presented at the stakeholder consultation. We received responses from eleven Member States and seven stakeholders. An annotated log of the feedback has been provided to the EC under separate coverage. All relevant feedback was considered during the preparation of the report.

Summary report of stakeholder consultation

Brussels, 23 September 2016

Background and objective

In the framework of a grant agreement, the WHO Regional Office for Europe advises the EC on the scientific evidence base underpinning the possible revision of Annex I of the Drinking Water Directive, specifically with respect to parameter coverage and health-based guideline values of chemical and microbiological agents in drinking-water. For this purpose, two draft background papers were prepared by WHO, i.e. one on chemical and physical parameters and one on approaches to managing microbiological risks in drinking-water.

The objective of the stakeholder consultation was to present the concepts and approaches of two draft background papers to Member State regulators and other stakeholder groups (i.e. water industry, consumer associations, academia) and seek their feedback and advice to serve as critical input to the further development of WHO advice on the revision of the Directive.

The consultation was jointly organized by the EC and the WHO Regional Office for Europe and held on 23 September 2016 at the Centre de Conférences Alberte Borchette in Brussels. The meeting was attended by more than 50 participants from Member States and stakeholder organizations (excluding WHO and EC staff).

Meeting proceedings

In preparation of the meeting, delegates were provided with the two aforementioned working documents.

The meeting was organized in two sessions, i.e. one on microbiological parameters and one on chemical parameters. At the outset of the respective sessions, WHO experts introduced the key concepts, underlying evidence and preliminary recommendations covered by the background papers. This was then followed by a moderated discussion in which delegates of Member States and other stakeholders provided feedback and advice. The discussion was guided, but not limited to, the following prompting questions:

Microbiological aspects:

- Risk assessment is key to ensuring safe water supply. Is the proposed sanitary-survey-based risk assessment approach feasible and adequate in the EU context?
- Operational monitoring is a core element of the WSP approach. Is there a need to translate the general requirement of Article 7.1 into more explicit requirements for operational monitoring in the DWD?
- Should the DWD focus on *Legionella pneumophila* or *Legionella* species?
- Is there added value in monitoring enterococci and/or total coliforms in addition to *E. coli*?

- Should the role of microbial parameters be specified to take into account different requirements for operational and verification monitoring?

Chemical aspects:

- Based on the data received, is it appropriate to remove the parameters that fall into the "low priority for inclusion" category?
- Should existing DWD standards be updated in the light of new data used to update WHO guideline values where this is indicated?
- Which new parameters should be included based on what is proposed but remembering that standards will be needed?
- Should the parameters in the DWD be grouped to take into account different requirements for monitoring and control?

Summary of main discussion points

Feedback on draft background document on microbiological parameters

- Participants were generally supportive to the proposed inclusion of a risk-based approach to assessing and controlling **risks from enteric pathogens** in drinking-water, including new monitoring requirements for coliphages, as presented in the draft background document. Several delegates emphasized, however, that such an approach presents a "shift in culture" in managing microbiological risks for many water suppliers across the EU. Therefore, it was suggested that, when introducing such requirements in the Directive, it is vital to keep them "simple" in order to allow enforcement across all settings and avoid overstraining of water suppliers with limited resources (e.g. small systems).
- Several participants supported the proposal of putting stronger emphasis in the Directive on monitoring of **source water quality** in drinking-water catchments, in conjunction with regular catchment appraisals. These were essential steps in developing an understanding of possible (upstream) faecal sources, loads of enteric pathogens in source water, treatment needs and eventual risks to human health. In this regard, several participants stressed the close linkages to controlling wastewater discharges in drinking-water catchments and the need for harmonizing respective Directives. Delegates also highlighted that monitoring of source water under influence of surface water is relevant to both chemicals and microorganisms, and that a holistic monitoring approach was required.
- A number of participants strongly supported the proposal of explicitly including requirements for **operational monitoring** in the Directive, preferably in the main body of text. Operational monitoring is an integral part of risk-based management and essential for maintaining the safety of a drinking-water supply. Operational monitoring is to confirm operational performance of control measures and allow for rapid corrective action. The discussion revealed the significant value of online

monitoring of turbidity and disinfectant residual, for example. The Directive should clearly reinforce the importance of operational monitoring and also clearly specify the responsibilities for such monitoring (i.e. water suppliers).

- The proposal of explicitly addressing ***Legionella*** in the Directive was echoed positively by a number of participants. Several Member State delegates confirmed the relevance of *Legionella* in their countries. Legionellosis is waterborne and represents a significant disease burden across the EU. This provided a strong rationale for inclusion of *Legionella*-related requirements in the Directive. Few delegates, however, expressed concerns as to whether *Legionella* should be regulated under the jurisdiction of the Drinking Water Directive. In response, other participants pointed to the objective of the Directive to provide safe drinking-water at the consumer's tap. This includes warm water systems and all domestic water uses (including showering). An explicit focus on appropriately managing drinking-water systems in buildings was needed to ensure design and maintenance of plumbing systems which are preventive of *Legionella* growth.

  It was further highlighted that monitoring of *Legionella* should be primarily focused on high risk public buildings hosting vulnerable population groups. Overall, there is a need for more background research about, *inter alia*, outbreak conditions and potential pathways in order to further investigate the role of drinking-water in *Legionella* transmission. Special emphasis should also be given to cold water systems which could be a future problem considering the effects of climate change and increasing insulation of buildings.

  Further discussion is needed as to whether to specify requirements for *Legionella pneumophila* or for *Legionella* species. Whereas *L. pneumophila* is known to cause the vast majority of legionellosis, several delegates preferred inclusion of *Legionella* species as this parameter may indicate more reliably problems with *Legionella* growth in domestic installations and thus trigger necessary.

- There was limited discussion on whether to maintain **enterococci and/or coliform bacteria** as parameters in the Directive. There were no strong statements in support to removing either parameter. The value of coliform bacteria as an useful indicator for investigating distribution system integrity was highlighted.

Feedback on draft background document on chemical parameters

- Several Member State delegates expressed disagreement with the proposal to **removing a limited number of chemical parameters** which are currently covered by Annex I Part B. In the draft background document, such parameters were preliminarily categorized "low priority for inclusion" on the grounds of very low likelihood of occurrence in drinking-water, generally low exposure through drinking-water and high compliance figures across the EU.

  Several reasons were brought forward to support this position. Concern was expressed that if certain parameters were removed from Annex I, there was no point

of reference (parametric value) anymore to assess and guide responses to water quality incidents with the substance in question. It was further highlighted that removing certain parameters might send wrong signals to policy makers and cause problems to leveraging further steps of ensuring drinking-water quality (e.g. in cleaning up historical pollution of contaminated sites and/or previous uses). Also the public may be concerned about removing parameters, i.e. perceiving such a step as leading to less health protection.

Some delegates argued that the removal of parameters from Annex I was not necessary for the purpose of reducing monitoring efforts and costs. The risk-based approach stipulated by (revised) Annex II already allows for making choices in reducing of parameter coverage and frequencies, based on the outcomes of local risk assessments. Other participants highlighted that the interaction of chemical parameters is not well understood and there are no models to assess the effects of chemical mixtures. Thus, removing parameters from the Annex I may lead to an underestimation of risks. Delegates also stresses that the removal of parameters may also lead to a loss of laboratory capacities.

Some delegates proposed that a core set of parameters should be established, which is subject to obligatory monitoring, irrespectively of the outcomes of the risk assessment. This core set may be expanded by parameters of local relevance (as per risk assessment). Another option discussed was to establish a separate/additional list of parameters and parametric values which serves as a point of reference in case of spills or otherwise occurrence in drinking-water at elevated levels which, however, is not subject to obligatory monitoring; the WHO Guidelines for Drinking-water Quality may also serve as such a point of reference.

- For several substances of emerging concern, the draft background paper made a preliminary proposal for the **possible inclusion of new parameters** in Annex I of the Directive. There was general agreement on the suggested range of parameters under consideration. It was emphasized, however, that the selection should also be guided by public perception (e.g. on pharmaceuticals of EDCs), and not exclusively on health-based criteria.

  It was further noted that decisions on removal and/or inclusion of parameters in the Directive shouldn't be exclusively guided by compliance in drinking-water but also informed by data on occurrence of substances in raw waters. In this context the EC should also consider occurrence data obtained under the WFD and the Directive on Environmental Quality Standards.

  Individual delegates proposed considering calcium and magnesium in order to define minimum mineralization levels, as well as non-relevant pesticide metabolites.

- The concept of **grouping chemical parameters** (by the categories suggested in the draft background document) was supported by the majority of meeting participants. Grouping of parameters in Annex I by primary source and control and monitoring options would significantly foster transparency and understanding of local authorities

and the public with respect to the origin of parameters, meaning and implications of possible exceedances of parametric values and possible means of control and monitoring. Thus, the grouping helps to avoid misunderstandings in assessing possible exceedances and inappropriate responses. Moreover, the grouping is also helpful in addressing public perception issues and risk communication vis-à-vis the public (e.g. in relation to naturally occurring substances in water).

Conclusions and follow up action

- WHO and EC thanked all meeting participants for their active engagement and valuable feedback and reflections on the preliminary proposals and considerations presented in the two background documents.
- WHO will consider all feedback in the further development of its recommendations to the EC. WHO reminded meeting participants, however, about its mandate in the context of WHO/EC cooperation project. It is to provide evidence-based advice to the EC on water quality parameters and parametric values covered by Annex I of the Directive and on further strengthening a risk-based approach in the Directive. With this in mind, not all comments can be picked up by WHO but would need to be addressed by the EC in making policy choices for the Directive.
- WHO and EC invited meeting participants to provide additional written comments within two weeks after the meeting.
- Updates on the project progress will be provided at forthcoming meetings of the EC Drinking Water Directive Expert Group.

Appendix 3:
Microbiological fact sheets

The fact sheets cover the following microbiological parameters which are suggested to be retained and/or included in Annex I of the Directive:

The fact sheets are largely based on the microbial fact sheets in the fourth edition of the WHO Guidelines and the OECD/WHO background document *Assessing microbial safety of drinking-water: improving approaches and methods* (OECD & WHO, 2003), complemented with information from the scientific literature (references provided in the fact sheets).

Clostridium perfringens spores

General description

Clostridium spp. are gram-positive, anaerobic, sulphite-reducing bacilli. They produce spores that are exceptionally resistant to unfavourable conditions in water environments, including UV irradiation, temperature and pH extremes, and disinfection processes, such as chlorination. The characteristic species of the genus, *C. perfringens*, is a member of the normal intestinal flora of 13–35% of humans and other warm-blooded animals. Other species are not exclusively of faecal origin. Like *E. coli*, *C. perfringens* does not multiply in most water environments and is a highly specific indicator of faecal pollution.

Source and occurrence

C. perfringens and its spores are virtually always present in sewage. The organism does not multiply in most water environments. *C. perfringens* is present more often and in higher numbers in the faeces of some animals, such as dogs, than in the faeces of humans and less often in the faeces of many other warm-blooded animals. The numbers excreted in faeces are normally substantially lower than those of *E. coli*.

Indicator value

In view of the exceptional resistance of *C. perfringens* spores to disinfection processes and other unfavourable environmental conditions, they have been proposed as an indicator of protozoa in treated drinking-water supplies. In addition, *C. perfringens* can serve as an indicator of faecal pollution that took place previously and hence can indicate sources liable to intermittent contamination. The evidence that *Clostridium* is a reliable indicator for enteric viruses is limited and inconsistent, largely based on one study of reductions by drinking-water treatment. Results should be treated with some caution, as the exceptionally long survival times of its spores are likely to far exceed those of enteric pathogens. *C. perfringens* spores are smaller than protozoan (oo)cysts and may be useful indicators of the effectiveness of filtration processes.

Significance in drinking-water

The presence of *C. perfringens* spores in finished water after treatment is an indication that the filtration processes are not adequately removing enteric protozoa. Detection in finished water immediately after treatment should lead to investigation of filtration plant performance.

Analysis

Spores of *C. perfringens* are usually detected by membrane filtration techniques (as per EN ISO 14189). The sample is pasteurized prior to membrane filtration to inactivate vegetative cells. Membranes are incubated on selective media under strict anaerobic conditions. These detection techniques are not as simple and inexpensive as those for other indicators, such as *E. coli* and intestinal enterococci.

Selected bibliography

Araujo M et al. (2001). Evaluation of fluorogenic TSC agar for recovering Clostridium perfringens in groundwater samples. Water Science and Technology 43:201–204.

Ashbolt NJ, Grabow WOK, Snozzi M (2001). Indicators of microbial water quality. In: Fewtrell L, Bartram J (eds). Water quality—guidelines, standards and health: assessment of risk and risk management for water-related infectious disease. London: IWA Publishing, pp. 289–315.

Nieminski EC, Bellamy WD, Moss LR (2000). Using surrogates to improve plant performance. Journal of the American Water Works Association 92(3):67–78.

Payment P, Franco E (1993). Clostridium perfringens and somatic coliphages as indicators of the efficiency of drinking-water treatment for viruses and protozoan cysts. Applied and Environmental Microbiology 59:2418–2424.

Coliform bacteria

General description

Total coliform bacteria include a wide range of aerobic and facultative anaerobic, gram-negative, non-spore-forming bacilli capable of growing in the presence of relatively high concentrations of bile salts with the fermentation of lactose and production of acid or aldehyde within 24 hours at 35–37°C. *E. coli* and thermotolerant coliforms are a subset of the total coliform group that can ferment lactose at higher temperatures. As part of lactose fermentation, total coliforms produce the enzyme f3-galactosidase. Traditionally, coliform bacteria were regarded as belonging to the genera *Escherichia*, *Citrobacter*, *Klebsiella* and *Enterobacter*, but the group is more heterogeneous and includes a wider range of genera, such as *Serratia* and *Hafnia*. The total coliform group includes both faecal and environmental species.

Source and occurrence

Total coliform bacteria (excluding *E. coli*) occur in both sewage and natural waters. Some of these bacteria are excreted in the faeces of humans and animals, but many coliforms are heterotrophic and able to multiply in water and soil environments. Total coliforms can also survive and grow in water distribution systems, particularly in the presence of biofilms.

Indicator value

Total coliforms include organisms that can survive and grow in water. Hence, they are not useful as an indicator of faecal pathogens, but they can be used to assess the cleanliness and integrity of distribution systems and the potential presence of biofilms. However, there are better indicators for these purposes. It has been proposed that total coliforms could be used as a disinfection indicator. However, the test for total coliforms is far slower and less reliable than direct measurement of disinfectant residual. In addition, total coliforms are far more sensitive to disinfection than are enteric viruses and protozoa. HPC measurements detect a wider range of microorganisms and are generally considered a better indicator of distribution system integrity and cleanliness.

Significance in drinking-water

Total coliforms are less suitable as indicator organisms. They have been regarded as indicator for faecal contamination, but because they can survive and multiply in plant material, soil, sediments in water reservoirs, they are not a conclusive indication of faecal contamination. They can indicate the intrusion of soil into drinking-water reservoirs, which does indicate loss of integrity. And they have been detected as first signal of faecal contamination of water supply, but confirmation by detection of *E. coli* and/or intestinal enterococci is needed to be sure of a faecal origin of the contamination. They have also been used as model organisms for treatment efficacy, but also here this is hampered by their potential to grow under certain conditions in the water systems. *E. coli* and enterococci serve as more conclusive indicators for faecal contamination and also to assess treatment efficacy, so there is no need for coliforms as parameter. The presence of total coliforms in distribution systems and stored water supplies can reveal growth and possible biofilm

formation or contamination through ingress of foreign material, including soil or plants. Growth and biofilm formation are monitored more adequately with colony counts and ingress of foreign material, without the presence of *E. coli* or enterococci is unlikely to be associated with a health risk, so also here, the role of the coliforms as parameter is of little added value.

Methods

Total coliforms are generally measured in 100 mL samples of water. A variety of relatively simple procedures are available based on the production of acid from lactose (as per EN ISO 9308-1) or the production of the enzyme β-galactosidase (as per EN ISO 9308-2). The procedures include membrane filtration followed by incubation of the membranes on selective media at 35–37°C and counting of colonies after 24 hours. Alternative methods include most probable number procedures using tubes or microtitre plates and presence/absence tests. Field test kits are available.

Selected bibliography

Ashbolt NJ, Grabow WOK, Snozzi M (2001). Indicators of microbial water quality. In: Fewtrell L, Bartram J (eds.) Water quality—guidelines, standards and health: assessment of risk and risk management for water-related infectious disease. London: IWA Publishing, pp. 289–315.

Grabow WOK (1996). Waterborne diseases: update on water quality assessment and control. Water SA 22:193–202.

Sueiro RA et al. (2001). Evaluation of Coli-ID and MUG Plus media for recovering Escherichia coli and other coliform bacteria from groundwater samples. Water Science and Technology 43:213–216.

Colony counts or heterotrophic plate counts at 22˚C

General description

Colony counts or HPC measurement detects a wide spectrum of heterotrophic microorganisms, including bacteria and fungi, based on the ability of the organisms to grow on rich growth media, without inhibitory or selective agents, over a specified incubation period and at a defined temperature. The spectrum of organisms detected by HPC testing includes organisms sensitive to disinfection processes, such as coliform bacteria, organisms resistant to disinfection, such as spore formers and organisms that rapidly proliferate in treated water in the absence of residual disinfectants. The tests detect only a small proportion of the microorganisms that are present in water. The population recovered will differ according to the method and conditions applied. Although standard methods have been developed, there is no single universal HPC measurement. A range of media is available; incubation temperatures used vary from 20°C to 37°C and incubation periods range from a few hours to 7 days or more.

Source and occurrence

Heterotrophic microorganisms include both members of the natural (typically non-hazardous) microbial flora of water environments and organisms present in a range of pollution sources. They occur in large numbers in raw water sources. The actual organisms detected by HPC tests vary widely between locations and between consecutive samples. Some drinking-water treatment processes, such as coagulation and sedimentation, reduce the number of HPC organisms in water. However, the organisms proliferate in other treatment processes, such as biologically active carbon and sand filtration. Numbers of HPC organisms are reduced significantly by disinfection practices, such as chlorination, ozonation and UV light irradiation. However, in practice, none of the disinfection processes sterilizes water; under suitable conditions, such as the absence of disinfectant residuals, HPC organisms can grow rapidly. HPC organisms can grow in water and on surfaces in contact with water as biofilms. The principal determinants of growth or “regrowth” are temperature, availability of nutrients, including assimilable organic carbon, lack of disinfectant residual and stagnation.

Indicator value

The test has little value as an indicator of pathogen presence. HPC measurement can be used in assessing the cleanliness and integrity of distribution systems and the occurrence of regrowth and presence of biofilms in distribution networks and plumbing systems.

Significance in drinking-water

After disinfection, numbers would be expected to be low; for most uses of HPC test results, however, actual numbers are of less value than changes in numbers at particular locations. In distribution systems, increasing numbers can indicate deterioration in cleanliness, possibly stagnation and the potential development of biofilms. HPC can include potentially “opportunistic” pathogens such as *Acinetobacter*, *Aeromonas*, *Flavobacterium*, *Klebsiella*, *Moraxella*, *Serratia*, *Pseudomonas* and *Xanthomonas*. However, there is no evidence of an

association of any of these organisms with gastrointestinal infection through ingestion of drinking-water in the general population.

Methods

No sophisticated laboratory facilities or highly trained staff are required. Results on simple aerobically incubated agar plates are available within hours to days, depending on the characteristics of the procedure used. The EN ISO method for this parameter is EN ISO 6222.

Selected bibliography

Ashbolt NJ, Grabow WOK, Snozzi M (2001). Indicators of microbial water quality. In: Fewtrell L, Bartram J (eds.) Water quality—guidelines, standards and health: assessment of risk and risk management for water-related infectious disease. London: IWA Publishing, pp. 289–315.

Bartram J et al. (eds.) (2003) Heterotrophic plate counts and drinking-water safety: the significance of HPCs for water quality and human health. London: IWA Publishing.

Enterococci

General description

Intestinal enterococci are a subgroup of the larger group of organisms defined as faecal streptococci, comprising species of the genus *Streptococcus*. These bacteria are gram-positive and relatively tolerant of sodium chloride and alkaline pH levels. They are facultative anaerobic and occur singly, in pairs or as short chains. Faecal streptococci, including intestinal enterococci, all give a positive reaction with Lancefield's Group D antisera and have been isolated from the faeces of warm-blooded animals. The subgroup intestinal enterococci consists of the species *Enterococcus faecalis*, *E. faecium*, *E. durans* and *E. hirae*. This group was separated from the rest of the faecal streptococci because they are relatively specific for faecal pollution. However, some intestinal enterococci isolated from water may occasionally also originate from other habitats, including soil, in the absence of faecal pollution.

Source and occurrence

Intestinal enterococci are typically excreted in the faeces of humans and other warm-blooded animals. Some members of the group have also been detected in soil in the absence of faecal contamination. Intestinal enterococci are present in large numbers in sewage and water environments polluted by sewage or wastes from humans and animals.

Indicator value

The intestinal enterococci group can be used as an indicator of faecal pollution. Most species do not multiply in water environments. The numbers of intestinal enterococci in human faeces are generally about an order of magnitude lower than those of *E. coli*. Important advantages of this group are that they tend to survive longer in water environments than *E. coli* (or thermotolerant coliforms), are more resistant to drying and are more resistant to chlorination. Intestinal enterococci have been used in testing of raw water as an indicator of faecal pathogens that survive longer than *E. coli* and in drinking-water to augment testing for *E. coli*. In addition, they have been used to test water quality after repairs to distribution systems or after new mains have been laid.

Significance in drinking-water

The presence of intestinal enterococci provides evidence of recent faecal contamination, and detection should lead to consideration of further action, which could include further sampling and investigation of potential sources such as inadequate treatment or breaches in distribution system integrity.

Methods

Enterococci are detectable by simple, inexpensive cultural methods that require basic bacteriology laboratory facilities. Commonly used methods include membrane filtration with incubation of membranes on selective media and counting of colonies after incubation at 35–37°C for 48 hours (as per EN ISO 7899-2). Other methods include a most probable

number technique use the ability of intestinal enterococci to hydrolyse 4-methyl-umbelliferyl-β-D-glucoside at 41°C.

Selected bibliography

Ashbolt NJ, Grabow WOK, Snozzi M (2001). Indicators of microbial water quality. In: Fewtrell L, Bartram J (eds.) Water quality—guidelines, standards and health: assessment of risk and risk management for water-related infectious disease. London: IWA Publishing, pp. 289–315.

Grabow WOK (1996). Waterborne diseases: update on water quality assessment and control. Water SA 22:193–202.

Junco TT et al. (2001). Identification and antibiotic resistance of faecal enterococci isolated from water samples. International Journal of Hygiene and Environmental Health 203:363–368.

Pinto B et al. (1999). Characterization of “faecal streptococci” as indicators of faecal pollution and distribution in the environment. Letters in Applied Microbiology 29:258–263.

Escherichia coli

General description

E. coli is the most widely used indicator of faecal pollution and is in use already since the late 19th century. It is a bacterium that is present in very high numbers (up to 10^9 per gram) in human and (warm-blooded) animal faeces. *E. coli* is a natural and essential part of the bacterial flora in the gut of humans and animals. Most *E. coli* strains are non-pathogenic and reside harmlessly in the colon. However, certain serotypes (such as O157:H7) do play a role in intestinal and extra-intestinal diseases, such as urinary tract infections, and have been involved in drinking-waterborne outbreaks

Source and occurrence

E. coli are typically excreted in the faeces of humans and other warm-blooded animals. It is found in sewage, treated effluents, and all natural waters and soils subject to recent faecal contamination, whether from humans, wild (warm-blooded) animals, or livestock activity. *E. coli* is rarely found in water in the absence of faecal pollution, although there is some evidence for growth in some environments, such as tropical soils. Water temperatures and nutrient conditions present in drinking-water distribution systems are highly unlikely to support the growth of these organisms.

Indicator value

E. coli is considered the most suitable indicator of faecal contamination. In most circumstances, populations of thermotolerant coliforms are composed pre-dominantly of *E. coli*; as a result, this group is regarded as a less reliable but acceptable indicator of faecal pollution. *E. coli* (or, alternatively, thermotolerant coliforms) is the first organism of choice in monitoring programs for verification, including surveillance of drinking-water quality. These organisms are also used as disinfection indicators, but testing is far slower and less reliable than direct measurement of disinfectant residual. In addition, *E. coli* is far more sensitive to disinfection than are enteric viruses and protozoa.

Significance in drinking-water

The presence of *E. coli* (or, alternatively, thermotolerant coliforms) provides evidence of recent faecal contamination, and detection should lead to consideration of further action, which could include further sampling and investigation of potential sources such as inadequate treatment or breaches in distribution system integrity.

Methods

E. coli are measured using culture methods. The principle of these methods has been in use for water quality monitoring for over 100 years. The methods are relatively simple and cheap and well-established throughout the EU. The standard methods EN ISO 9308-1 and 9308-2 are the culture methods specified in the Directive that are both appropriate. These methods require at least 18 hours producing a result. Others culture methods have been approved or are in the process of approval as alternative method. The use of molecular methods, such as real-time quantitative polymerase chain reaction (PCR), allows for a very

rapid and specific detection of *E. coli*. Short time-to-result is very beneficial for adequate protection of the health of the drinking-water consumers. Field test kits are available.

Guideline value derivation

The guideline value is absence in 100 ml of drinking-water. This guideline value has been unchanged since the first edition of the Directive and the WHO Guidelines, and actually since the beginning of bacteriological water quality examinations. The origin of the guideline value is not completely clear. The early water microbiologists (at the end of the 19th century) were already analysing drinking-water sources for the presence of bacteria, including for the presence of *Bacterium coli* (later renamed as *Escherichia coli*) as an indicator of contamination of the water with human faecal material, and hence the potential presence of pathogens (at that time the bacterial pathogens that cause typhoid or cholera).

The guideline value of 0/100 mL seems to be based on practical considerations (100 mL was a convenient volume to use in bacterial water testing), and on the observation that water derived from deep wells and springs, which was protected from contamination by excreta, consistently contained 0/100 mL, while shallow well water and surface water contained more than 0/100 mL (Savage, 1906). It is intriguing to consider that the main water quality parameter to protect the health of the EU citizens has no direct health basis. A few studies in the EU (France, United Kingdom) have looked at the health risk associated with non-compliance with the Directive for *E. coli* (and enterococci) (Ferley et al., 1986; Zmirou et al., 1987; Risebro et al., 2012). These studies focused on small water supplies, since these are notorious for non-compliance and serve around 10% of the EU population (Hulsmann, 2011). The studies indicate that people (particularly children) that consume non-compliant water have a higher (up to 6 times) rate of diarrhoeal illness than people that consume compliant water. This association was particularly observed when water was non-compliant for both *E. coli* and enterococci.

Selected bibliography

Ashbolt NJ, Grabow WOK, Snozzi M (2001). Indicators of microbial water quality. In: Fewtrell L, Bartram J (eds.) Water quality—guidelines, standards and health: assessment of risk and risk management for water-related infectious disease. London: IWA Publishing, pp. 289–315.

Ferley JP, Zmirou D, Collin JF, Charrel M (1986). [Longitudinal study of the risks related to the consumption of water not conforming to bacteriological norms]. Rev Epidemiol Sante Publique 34(2):89-99. French.

George I et al. (2001). Use of rapid enzymatic assays to study the distribution of faecal coliforms in the Seine river (France). Water Science and Technology 43:77–80.

Grabow WOK (1996). Waterborne diseases: update on water quality assessment and control. Water SA 22:193–202.

Hulsmann A (2011). The quality of drinking water in the European Union 2005-2007. Synthesis report on the quality of drinking water in the Member States of the European Union in the period 2005-2007 Directive 98/83/EC. Available at: https://circabc.europa.eu/sd/a/b580866d-8eb7-4937-9a97-d3d3485d046e/2005-2007%20SynthesisReport.pdf (accessed on 6 August 2017).

Risebro HL, Breton L, Aird H, Hooper A, Hunter PR (2012). Contaminated small drinking water supplies and risk of infectious intestinal disease: a prospective cohort study. PLoS One 7(8):e42762.

Savage WG (1906). The bacteriological examination of water supplies. Lewis HK, London.

Sueiro RA et al. (2001). Evaluation of Coli-ID and MUG Plus media for recovering Escherichia coli and other coliform bacteria from groundwater samples. Water Science and Technology 43:213–216.

Zmirou D, Ferley JP, Collin JF, Charrel M, Berlin J (1987). A follow-up study of gastro-intestinal diseases related to bacteriologically substandard drinking water. American Journal of Public Health 77(5):582-584.

Legionella

General description

The genus *Legionella*, a member of the family Legionellaceae, has at least 50 species comprising 70 distinct serogroups. *Legionellae* are gram-negative, rod-shaped, non-spore-forming bacteria that require L-cysteine for growth and primary isolation. *Legionella* spp. (i.e. all members of the genus *Legionella*) are heterotrophic bacteria found in a wide range of water environments and can proliferate at temperatures above 25°C.

Human health effects

Although several *Legionella* spp. are considered potentially pathogenic for humans, *L. pneumophila* is the major waterborne pathogen responsible for legionellosis, of which two clinical forms are known: Legionnaires' disease and Pontiac fever. The former is a pneumonic illness with an incubation period of 3–6 days. Host factors influence the likelihood of illness: males are more frequently affected than females, and most cases occur in the 40- to 70-year age group. Risk factors include smoking, alcohol abuse, cancer, diabetes, chronic respiratory or kidney disease and immunosuppression, as in transplant recipients. Pontiac fever is a milder, self-limiting disease with a high attack rate and an onset (5 hours to 3 days) and symptoms similar to those of influenza: fever, headache, nausea, vomiting, aching muscles and coughing. Studies of seroprevalence of antibodies indicate that many infections are asymptomatic.

Source and occurrence

Legionella spp. are members of the natural flora of many freshwater environments, such as rivers, streams and impoundments, where they occur in relatively low numbers. However, they thrive in certain human-made water environments, such as water cooling devices (cooling towers and evaporative condensers) associated with air-conditioning systems, hot water distribution systems and spas, which provide suitable temperatures (25–50°C) and conditions for their multiplication. Devices that support multiplication of *Legionella* have been associated with outbreaks of Legionnaires' disease. *Legionella* survive and grow in biofilms and sediments and are more easily detected from swab samples than from flowing water. *Legionella* can be ingested by trophozoites of certain amoebae such as Acanthamoeba, Hartmanella and Naegleria, which play an important role in their persistence and proliferation in water environments.

Routes of exposure

The most common route of infection is the inhalation of aerosols containing the bacteria. Such aerosols can be generated by contaminated cooling towers, warm water showers, humidifiers and spas. Aspiration has also been identified as a route of infection in some cases associated with contaminated water, food and ice. There is no evidence of person-to-person transmission.

Significance in drinking-water

Legionella spp. are common waterborne organisms, and devices such as cooling towers, hot water systems and spas that utilize mains water have been associated with outbreaks of infection. Owing to the prevalence of *Legionella*, the potential for ingress into drinking-water systems should be considered as a possibility, and control measures should be employed to reduce the likelihood of survival and multiplication. Disinfection strategies designed to minimize biofilm growth and temperature control can minimize the potential risk from *Legionella* spp.

The organisms are sensitive to disinfection. Monochloramine has been shown to be particularly effective, probably due to its stability and greater effectiveness against biofilms. Water temperature is an important element of control strategies. Wherever possible, water temperatures should be kept outside the range of 25–50°C and preferably 20–50°C to prevent the growth of the organism. In hot water systems, temperatures leaving heaters should be above 60°C, and temperatures above 50°C should be maintained throughout associated pipework. However, maintaining temperatures of hot water above 50°C may represent a scalding risk in young children, the elderly and other vulnerable groups. Where temperatures in hot or cold water distribution systems cannot be maintained outside the range of 25–50°C, greater attention to disinfection and strategies aimed at limiting development of biofilms are required. Accumulation of sludge, scale, rust, algae or slime deposits in water distribution systems supports the growth of *Legionella* spp., as does stagnant water. Systems that are kept clean and flowing are less likely to support excess growth of *Legionella* spp. Care should also be taken to select plumbing materials that do not support microbial growth and the development of biofilms.

Legionella spp. represent a particular concern in devices such as cooling towers and hot water systems in large buildings. Specific risk assessments and control measures for *Legionella* spp. should be implemented for these buildings. *Legionella* are not detected by HPC techniques, and *E. coli* (or, alternatively, thermotolerant coliforms) is not a suitable indicator for the presence/absence of this organism.

Methods

For *Legionella* in (warm) drinking-water, the EN ISO 11731 is the basic method. This method detects *L. pneumophila* but also other *Legionella* species that can grow on the specified medium. Identification of *L. pneumophila* can be conducted with simple and cheap commercially available serological tests, i.e. systems like Malditof, PCR and others. Recently, an adaptation of the ISO growth conditions was shown to make the method highly specific for *L. pneumophila* (Veenendaal et al., 2017).

Selected bibliography

Bartram J et al. (eds) (2007). Legionella and the prevention of legionellosis. Geneva: World Health Organization.

Codony F et al. (2002). Factors promoting colonization by legionellae in residential water distribution systems: an environmental case-control survey. European Journal of Clinical Microbiology and Infectious Diseases 21:717–721.

Emmerson AM (2001). Emerging waterborne infections in health-care settings. Emerging Infectious Diseases 7:272–276.

Rusin PA et al. (1997). Risk assessment of opportunistic bacterial pathogens in drinking-water. Reviews of Environmental Contamination and Toxicology 152:57–83.

Veenendaal HR, Brouwer-Hanzens A, van der Kooij D (2017). Incubation of premise plumbing water samples on buffered charcoal yeast extract agar at elevated temperature and pH selects for Legionella pneumophila. Water Research 123:439-447.

Somatic coliphages

General description

Bacteriophages (phages) are viruses that use only bacteria as hosts for replication. Coliphages use *E. coli* and closely related species as hosts and hence can be released by these bacterial hosts into the faeces of humans and other warm-blooded animals. Somatic coliphages initiate infection by attaching to receptors permanently located on the cell wall of hosts. They replicate more frequently in the gastrointestinal tract of warm-blooded animals but can also replicate in water environments. Somatic coliphages consist of a wide range of phages (members of the phage families Myoviridae, Siphoviridae, Podoviridae and Microviridae) with a spectrum of morphological types.

Source and occurrence

Coliphages are excreted by humans and animals in relatively low numbers. Somatic coliphages have been found to generally outnumber cytopathogenic human viruses in water environments by a factor of about 500, although these ratios vary considerably. Sewage contains somatic coliphages in numbers of the order of 10^6–10^8 per litre; in one study, slaughterhouse wastewater was found to contain somatic coliphages in numbers up to 10^{10} per litre. There are indications that they may multiply in sewage, and somatic coliphages may multiply in natural water environments using saprophytic hosts. Somatic phages have been detected in numbers up to 10^5 per litre in lake and river water.

Indicator value

Phages share many properties with human viruses, notably composition, morphology, structure and mode of replication. As a result, coliphages are useful models or surrogates to assess the behaviour of enteric viruses in water environments, groundwater protection and the sensitivity to treatment and disinfection processes. In this regard, they are superior to faecal bacteria and could be considered for inclusion in verification and surveillance monitoring where source waters are known or suspected to be affected by human faecal waste. However, there is no direct correlation between numbers of coliphages and numbers of enteric viruses. In addition, coliphages cannot be absolutely relied upon as an indicator for enteric viruses. This has been confirmed by the isolation of enteric viruses from treated and disinfected drinking-water supplies that yielded negative results in conventional tests for coliphages.

Significance in drinking-water

The presence of coliphages in drinking-water indicates shortcomings in groundwater protection or treatment and disinfection processes designed to remove enteric viruses. F-RNA coliphages provide a more specific indicator for enteric viruses than *E. coli*. Detection in abstracted groundwater or finished water immediately after treatment should lead to investigation of groundwater protection or treatment performance respectively.

Methods

Somatic coliphages are detectable by relatively simple and inexpensive plaque assays, which yield results within 24 hours. The recommended method is EN ISO 10705:2. Plaque assays using large petri dishes have been designed for the quantitative enumeration of plaques in 100 mL samples, and presence/absence tests have been developed for volumes of water of 500 mL or more. Alternatively, simple concentration methods are available (Méndez et al., 2004; Helmi et al., 2011).

Selected bibliography

Ashbolt NJ, Grabow WOK, Snozzi M (2001). Indicators of microbial water quality. In: Fewtrell L, Bartram J (eds). Water quality—guidelines, standards and health: assessment of risk and risk management for water-related infectious disease. London: IWA Publishing, pp. 289–315.

Grabow WOK (2001). Bacteriophages: update on application as models for viruses in water. Water SA 27:251–268.

Helmi K, Jacob P, Charni-Ben-Tabassi N, Delabre K, Arnal C. (2011). Comparison of two filtration-elution procedures to improve the standard methods ISO 10705-1 & 2 for bacteriophage detection in groundwater, surface water and finished water samples. Lett Appl Microbiol 53(3):329-35.

Méndez J, Audicana A, Isern A, Llaneza J, Moreno B, Tarancón ML, Jofre J, Lucena F. (2004). Standardised evaluation of the performance of a simple membrane filtration-elution method to concentrate bacteriophages from drinking water. J Virol Methods 117(1):19-25.

Mooijman KA et al. (2001). Optimisation of the ISO-method on enumeration of somatic coliphages (draft ISO 10705-2). Water Science and Technology 43:205–208.

Schaper M et al. (2002). Distribution of genotypes of F-specific RNA bacteriophages in human and non-human sources of faecal pollution in South Africa and Spain. Journal of Applied Microbiology 92:657–667.

Storey MV, Ashbolt NJ (2001). Persistence of two model enteric viruses (B40-8 and MS-2 bacteriophages) in water distribution pipe biofilms. Water Science and Technology 43:133– 138.

Appendix 4:

Supporting information on the control of enteric pathogens

Health-based treatment performance targets

Setting microbial performance targets for water treatment require information on the quality of the source water and the level of safety required in treated water. The WHO Guidelines define the required level of safety of drinking-water: the general requirement "not represent a significant risk" is translated into a health target: a DALY of $<10^{-6}$ per person per year. DALY is a metric for the burden of disease in a population (i.e. based on the years of life lost by disease and the years of life lived with a disability, weighed for the severity of the disability). DALYs are used extensively in setting priorities in public health policy at WHO or national levels. A more detailed explanation of DALY's and health-based target setting can be found in the WHO Guidelines and supporting documents.

DALYs are not a practical metric in water supply, so the WHO Guidelines translate the DALY-target to performance targets for the water supply system. The 10^{-6} DALY per person per year corresponds to a certain (very low) concentration of pathogens in drinking-water. This is calculated from the disease burden (in DALY) per case for illness due to specific enteric pathogens, the dose-response of these pathogens and the volume of drinking-water consumed. The Guidelines and supporting documents have described the DALY per case and dose response for the reference pathogens *Cryptosporidium, Campylobacter* and rotavirus and have computed corresponding concentrations in drinking-water of 1.3×10^{-5}/L, 1.1×10^{-4}/L and 1.1×10^{-5}/L respectively, using a consumption volume of 1 litre per person per day. When the concentration of these pathogens in source water is 1 per litre, for example, the treatment performance targets can be determined by the difference in concentration in source water and required concentration in treated drinking-water: for *Cryptosporidium* the difference between 1/L in source water and 1.3×10^{-5}/L in drinking-water that corresponds with 4.9 log (or 99.987%) removal, for *Campylobacter* 4.0 log (or 99.99%) removal and for rotavirus 5.0 log (99.999%) removal.

The recent draft Australian drinking-water guidelines have used this same approach to compute the concentration of *Cryptosporidium, Campylobacter* and norovirus in drinking-water that correspond to this 10^{-6} DALY per person per year, but with a consumption of 2 litre per person per day and with updated information on DALY per cases from Australia, that for *Campylobacter* now included the potential for secondary symptoms of irritable bowel syndrome (Gibney et al., 2014). The Australian pathogen concentrations in drinking-water that correspond to 10^{-6} DALY are: *Cryptosporidium* 5.0×10^{-6}/L, *Campylobacter* 1.0×10^{-5}/L and norovirus 9.4×10^{-6}/L. At a pathogen concentration of 1 per litre in source water, this would lead to the following required removals: *Cryptosporidium* 5.3 log (or 99.995%) removal, *Campylobacter* 5.0 log (or 99.999%) removal and norovirus 5.0 log (99.999%) removal. Compared to the WHO Guidelines, these draft Australian guidelines result in higher performance targets for *Cryptosporidium* (5.3 instead of 4.9) and *Campylobacter* (5.0 instead of 4.0) and similar ones for viruses. As indicated, the Australian draft guideline values incorporate more serious, secondary symptoms in the DALYs per case than the WHO Guidelines. These secondary symptoms also occur in these infections in EU Member States.

Hence, we recommend using the Australian guidelines as they are more conservative and correspond with somewhat higher treatment performance targets.

Table A.3 shows calculated treatment performance targets based on a range of concentrations of reference pathogen concentrations in source water. The range of *Cryptosporidium* concentrations in Table A.3 is similar to the range normally detected in source waters of 10 EU drinking-water supplies (*Cryptosporidium* 0.005–1.9/L; *Campylobacter* <1–1700/L; entero- and norovirus 0.015–330/L (Microrisk, 2006).

The treatment performance target shown in Table A.3 for *Cryptosporidium* are also similar to those calculated by US EPA (2010), where concentrations of 0.075–3 oocysts per litre imply a treatment performance target of 3–5.5 log to achieve safe drinking-water. For viruses, US EPA requires 4 log.

Table A.3. Examples of treatment performance targets depending on reference pathogen concentrations in source water

Average concentration in source water (number/L)	**Treatment performance target (log-removal) to achieve 10^{-6} DALY per person and year**		
	Cryptosporidium	*Campylobacter*	Norovirus
0.001	2.3	2.0	2.0
0.01	3.3	3.0	3.0
0.1	4.3	4.0	4.0
1	5.3	5.0	5.0
10	6.3	6.0	6.0
100	7.3	7.0	7.0
1000	8.3	8.0	8.0

The use of pathogen monitoring data (i.e. that would allow derivation of treatment performance targets following table A.3) is suggested as optional for Member States (see Chapter 8). The approach recommended for uptake in the Directive is to derive treatment performance targets from the combination of catchment appraisal and source water monitoring of *E. coli* (see Chapter 8). To translate the data on *E. coli* monitoring to treatment performance targets, European data on the concentration versus enteric pathogens (*Campylobacter, Cryptosporidium* and enterovirus) relative to the concentration of *E. coli* in fresh waters are used (see Table A.4).

The *E. coli* to pathogen ratios are derived from studies in EU fresh waters where *E. coli* and pathogen concentrations were quantified simultaneously. For *Cryptosporidium* this is based on 921 data from one European and six national studies in >19 rivers, lakes, reservoirs and streams from five Member States with study sites impacted by domestic wastewater and agricultural run-off (RIWA, 2001; Microrisk, 2006; Carmena et al., 2007; Schets et al., 2008; Mons et al., 2009; Agence de l'Eau Seine Normandie, 2010; Kistemann et al., 2012); for Campylobacter this is based on 745 data from five studies using culture methods in six

rivers/streams from four Member States with study sites impacted by domestic wastewater and agricultural run-off (Obiri-Danso & Jones, 1999; van Lieverloo et al., 2007; Rechenburg & Kistenmann, 2009; Agence de l'Eau Seine Normandie, 2010; Rodriguez & Araujo, 2012); for culturable enterovirus this is based on 432 data from one European and four national studies using culture methods in 15 freshwater rivers and lakes from five MS with study sites impacted by domestic wastewater (Havelaar et al., 1993; Microrisk, 2006; RIWA, 2001; Agence de l'Eau Seine Normandie, 2010). Culturable enterovirus was selected over norovirus. Norovirus is more frequently associated with outbreaks, but, as norovirus data from environmental waters are collected with quantitative PCR and this may significantly overestimate the presence of infectious viruses.

Table A.4. Treatment performance targets depending on *E. coli* concentrations in source water

Source water category *E. coli* concentration (90%) CFU/100 ml	**Treatment performance target (in log_{10})**		
	Cryptosporidium	*Campylobacter*	Enteroviruses
<2	2	4	2
2-20	3	5	3
20-200	4	6	4
200-2000	5	7	5
2000-20000	6	8	6
>20000	Not suitable as source for drinking-water supply; if no alternative sources are available, very extensive treatment barriers are needed.		

Log removal values

This appendix contains default log removal value (LRV) credits for a range of commonly used water treatment processes. These default values have been derived from published international data in the process of developing the Australian drinking-water guidelines (Government of Australia, 2016) and are also valid for the EU context. The water treatment processes for which default LRV credits are provided are:

- Direct filtration with coagulation and flocculation;
- Conventional media filtration coagulation, flocculation and sedimentation;
- Membrane filtration;
- UV light disinfection; and
- Chlorine, chloramine, chlorine dioxide and ozone disinfection.

As well as detailing the default LRV credits, associated operational targets and critical limits are provided for each water treatment process. The default LRV credits can only be claimed if it can be demonstrated that operational targets and critical limits are being met.

If a water supplier wants to use a water treatment process which is not detailed in the tables below, or would like to claim LRV credits that are greater than default values provided below, then they should go through a validation process.

The maximum default LRV credits provided for any single process is 4 log10, in order to prevent an over dependence on a single barrier. This is consistent with the concept of multiple barriers to contamination.

Published data

Media filtration and disinfection are the most common forms of drinking-water treatment and the capability of these processes to remove and inactivate waterborne pathogens has been well documented. LRV credits for these processes have been published in international drinking-water guidelines produced by the US EPA (2003; 2005; 2006), Health Canada (2011; 2012a; 2012b) and the New Zealand Ministry of Health (2008).

LRV credits for media filtration are shown in Table A.5, together with operational targets and critical limits. The operational targets and critical limits are based on US EPA (2003; 2005; 2006), which have been updated to align with contemporary good practice in Australia (WSAA, 2015).

A key element of good practice water treatment operation is monitoring the performance of individual filters. For those water suppliers who currently monitor combined filter performance, LRV credits for combined filtrate turbidity are provided in Table A.5. For water supplies where there is no online turbidity measurement, there is no online continuous monitoring of a critical control point barrier to pathogens. This weakness should be

remedied, and in the meantime, the upper bound of grab sample data can be used to provide an interim measure of turbidity.

Table A.5. Pathogen removal by filtration (media and membrane)

Treatment process	LRV credit			Turbidity targets
	Protozoa	Bacteria	Viruses	
Direct filtration[1]	2.5	1.0	1.0	Individual filtrate turbidity ≤0.3 NTU for 95% of the month and not >0.5 NTU for 15 consecutive minutes *Combined filtrate turbidity ≤0.3 NTU for 95% of the month and not >0.5 NTU for 15 consecutive minutes.*
	3.0	1.0	1.0	Individual filtrate turbidity ≤0.2 NTU for 95% of the month and not >0.5 NTU for 15 consecutive minutes *Combined filtrate turbidity ≤0.15 NTU for 95% of the month and not >0.5 NTU for 15 consecutive minutes.*
	3.5	1.0	1.0	Individual filtrate turbidity ≤0.15 NTU for 95% of month and not >0.3 NTU for ≥15 consecutive minutes
Conventional filtration[2] and dissolved air flotation followed by media filtration	3.0	2.0	2.0	Individual filtrate turbidity ≤0.3 NTU for 95% of the month and not >0.5 NTU for 15 consecutive minutes *Combined filtrate turbidity ≤0.3 NTU for 95% of the month and not >0.5 NTU for 15 consecutive minutes*
	3.5	2.0	2.0	Individual filtrate turbidity ≤0.2 NTU for 95% of the month and not >0.5 NTU for 15 consecutive minutes *Combined filtrate turbidity ≤0.15 NTU for 95% of the month and not >0.5 NTU for 15 consecutive minutes*
	4.0	2.0	2.0	Individual filtrate turbidity ≤0.15 NTU for 95% of month and not >0.3 NTU for ≥ 15 consecutive minutes
Slow sand filtration	3.0	2.0	2.0	Filtrate turbidity ≤1.0 NTU for 95% of the month and not >5.0 NTU for 15 consecutive minutes
Micro-filtration	3.0	3.0	1.0	Individual filter turbidity ≤0.1 NTU for 95% of month and not >0.15 NTU for ≥15 consecutive minutes Membrane integrity test to manufacturer's specification for the required LRV credit and/or certified to a recognised standard
Ultra-filtration	3.0	3.0	2.5	Individual filter turbidity ≤0.1 NTU for 95% of month and not >0.15 NTU for ≥15 consecutive minutes Membrane integrity test to manufacturer's specification for the required LRV credit and/or certified to a recognised standard

[1] Direct filtration incorporates coagulation and flocculation without sedimentation followed by filtration; [2] conventional filtration incorporates coagulation, flocculation and sedimentation followed by filtration.

Table A.6 shows published LRV credits for various disinfectants. Similarly to the LRV credits shown for media filtration, most of the data is taken from the US EPA (1999a; 1999b; 2006), LeChevallier and Au (2004) and Hijnen et al. (2006). These values have also been adopted in drinking-water guidelines published by Health Canada (2011; 2012a) and the New Zealand Ministry of Health (2008). The exceptions are the LRV credits for viruses achievable by chlorination and chloramination, which are based on Australian investigations (Keegan et al., 2012).

In the case of the inactivation of protozoa and viruses, the standard approach is to identify reference pathogens that are relatively resistant to the method of disinfection. The identified LRV credits can then be applied to all pathogenic waterborne protozoa or viruses, as appropriate. The provision of data for the inactivation of *Giardia* by chlorine and chloramine, even though it is less resistant than *Cryptosporidium*, is provided because of the significance of this organism in causing gastro-intestinal disease.

Table A.6. Pathogen inactivation by disinfection

Disinfectant	**LRV**			**C.t values**
	Protozoa	**Bacteria**	**Viruses**	
Chlorination	2			C.t for *Giardia* at 10ºC, pH 6-9 = 1230 mg.min/L
		2		C.t for *E.Coli* at 10-15ºC, pH 6-10 = <1mg.min/L
				Inactivation of coxsackievirus B5 at 10°C, pH 7, turbidity 0-2NTU:
			1	C.t = 3 mg.min/L
			2	C.t = 4 mg.min/L
			3	C.t = 5 mg.min/L
			4	C.t = 6 mg.min/L
Chloramination	2			C.t for *Giardia* at 10˚C, pH 6-9 = 1230 mg.min/L
		2		C.t for *E.coli* at 15˚C, pH 9 = 64 mg.min/L
				C.t for adenovirus at 10˚C, pH 7, turbidity 0-2 NTU:
			1	C.t = 969 mg.min/L
			2	C.t = 1688 mg.min/L
			3	C.t = 2392 mg.min/L
			4	C.t = 3082 mg.min/L
UV light				Inactivation of *Cryptosporidium*:
	1			Dose = 2.5 mJ/cm^2
	2			Dose = 5.8 mJ/cm^2
	3			Dose = 12.0 mJ/cm^2
	4			Dose = 22.0 mJ/cm^2
		2		Dose for inactivation of *E.coli* = 9 mJ.cm^2
				Inactivation of adenovirus:
			1	Dose = 58 mJ/cm^2
			2	Dose = 100 mJ/cm^2
			3	Dose = 143 mJ/cm^2
			4	Dose = 186 mJ/cm^2

Disinfectant	LRV			C.t values
	Protozoa	Bacteria	Viruses	
Ozone				Inactivation of *Cryptosporidium* at 10°C:
	1			C.t = 9.9 mg.min/L
	2			C.t = 20 mg.min/L
	3			C.t = 30 mg.min/L
		2		C.t for inactivation of *E.coli* = 0.02 mg.min/L
				Inactivation at 10°C:
			2	C.t = 0.5 mg.min/L
			3	C.t = 0.8 mg.min/L
			4	C.t = 1.0 mg.min/L
Chlorine dioxide				Inactivation of *Cryptosporidium* at 10°C:
	1			C.t = 277 mg.min/L
	2			C.t = 553 mg.min/L
	3			C.t = 830 mg.min/L
		2		C.t for inactivation of *E. coli* = 0.4–0.75 mg.min/L
				Inactivation at 10°C, pH 6-9:
			2	C.t = 4.2 mg.min/L
			3	C.t = 12.8 mg.min/L
			4	C.t = 25.1 mg.min/L

References

Agence de l'eau Seine Normandie (2010). Campagne de mesures pour une meilleure connaissance des risques microbiologiques emergents pour la ressource en eau dans l'agglomeration Parisienne. Rapport Marché n°0898004 / affaire n° 08-038-01.

Carmena D, Aguinagalde X, Zigorraga C, Fernandez-Crespo JC, Ocio JA (2007). Presence of Giardia cysts and Cryptosporidium oocysts in drinking water supplies in northern Spain. Journal of Applied Microbiology 102:619-629.

Gibney KB, O'Toole J, Sinclair M, Leder K (2014). Disease burden of selected gastrointestinal pathogens in Australia. International Journal of Infectious Diseases 28:176-185.

Havelaar AH, van Olphen M, Drost YC (1993). F-specific RNA bacteriophages are adequate model organisms for enteric viruses in fresh water. Appl Environ Microbiol 59(9):2956-2962.

Health Canada (2011). Guidelines for Canadian Drinking Water Quality: Guideline technical document: Enteric protozoa: Giardia and Cryptosporidium. Ontario: Water Quality and Health Bureau, Healthy Environments and Consumer Safety Branch, Health Canada.

Health Canada (2012a) Guidelines for Canadian Drinking Water Quality: Guideline technical document: Enteric viruses. Ontario: Water Quality and Health Bureau, Healthy Environments and Consumer Safety Branch, Health Canada.

Health Canada (2012b). Guidelines for Canadian Drinking Water Quality: Guideline technical document: Turbidity. Ontario: Water Quality and Health Bureau, Healthy Environments and Consumer Safety Branch, Health Canada.

Hijnen WAM, Beerendonk EF, Medema GJ (2006). Inactivation credit of UV radiation for viruses, bacteria and protozoan (oo)cysts in water: A review. Water Research 40:3-22.

Keegan A, Wati S, Robinson B (2012). Chlor(am)ine disinfection of human pathogenic viruses in recycled waters. Smart Water Fund Project SWF62M-2114, Smart Water Fund, Melbourne.

Kistemann T, Rind E, Koch C, Claßen T, Lengen C, Exner M, Rechenburg A (2102). Effect of sewage treatment plants and diffuse pollution on the occurrence of protozoal parasites in the course of a small river. Int J Hyg Environ Health 215(6):577-583.

LeChevallier MW, Au K-K (2004). Water treatment and pathogen control. Geneva: World Health Organization.

Microrisk (2006). Microbiological risk assessment: a scientific basis for managing drinking water safety from source to tap. EU FP5 project EVK1-CT2002-00123. Available at: https://www.kwrwater.nl/wp-content/uploads/2016/09/MICRORISK-FINAL-REPORT-Quantitative-microbial-risk-assessment-in-the-Water-Safety-Plan.pdf (accessed on 6 August 2017).

Mons C, Dumètre A, Gosselin S, Galliot C, Moulin L (2009). Monitoring of Cryptosporidium and Giardia river contamination in Paris area. Water Res 43(1):211-217.

New Zealand Ministry of Health (2008). Drinking-water Standards for New Zealand 2005 (Revised 2008), Wellington.

Obiri-Danso K, Jones K (1999). Distribution and seasonality of microbial indicators and thermophilic campylobacters in two freshwater bathing sites on the River Lune in northwest England. J Appl Microbiol 87(6):822-832.

Rechenburg A, Kistemann T (2009). Sewage effluent as a source of Campylobacter sp. in a surface water catchment. Int J Environ Health Res. 19(4):239-49.

RIWA (2001). Cryptosporidium and Giardia: occurrence in sewage, manure, surface water used as swimming- and drinking water. Rotterdam: RIWA.

Rodríguez S, Araujo R (2010). Occurrence of thermotolerant Campylobacter species in surface waters of a Mediterranean area and in its prevailing pollution sources. J Appl Microbiol 109(3):1027-1034.

Schets FM, van Wijnen JH, Schijven JF, Schoon H, de Roda Husman AM (2008). Monitoring of waterborne pathogens in surface waters in Amsterdam, The Netherlands, and the potential health risk associated with exposure to Cryptosporidium and Giardia in these waters. Applied and Environmental Microbiology 74(7):2069–2078.

US EPA (1999a). LT1ESTWR Disinfection profiling and benchmarking: Technical guidance manual. Washington DC: United States Environmental Protection Agency.

US EPA (1999b). Alternative disinfectants and oxidants guidance manual. Washington DC: United States Environmental Protection Agency.

US EPA (2003). LT1ESWTR Disinfection profiling and benchmarking: Technical guidance manual. Washington DC: United States Environmental Protection Agency.

US EPA (2005). Membrane filtration guidance manual. Washington DC: United States Environmental Protection Agency.

US EPA (2006). National primary drinking water regulations: Long term 2 enhanced surface water treatment rule. Final rule. Washington DC: United States Environmental Protection Agency.

US EPA (2010). Long term 2 enhanced surface water treatment rule toolbox guidance manual. Washington DC: United States Environmental Protection Agency.

van Lieverloo JH, Blokker EJ, Medema G (2007). Quantitative microbial risk assessment of distributed drinking water using faecal indicator incidence and concentrations. J Water Health 5 Suppl 1:131-149.

WSAA(2015). Drinking water source assessment and treatment requirements: Manual for the application of health-based treatment targets. Adelaide: Water Services Association of Australia.

Appendix 5:

Discussion paper on chemical mixtures in drinking-water

A review of the different approaches to and importance of considering mixtures in drinking-water in the EU

Introduction

Chemical constituents and contaminants rarely, if ever, occur in water sources alone. There are invariably a number of chemicals present. They may be naturally occurring in drinking-water sources, they may be present as a consequence of human activity or they may be present as a consequence of drinking-water treatment or materials used in distributing drinking-water to consumers, including in buildings. These chemicals may be present in varying, but mostly very low, concentrations.

This naturally raises the question of whether substances should be considered individually or together for risk assessment and management but also for regulatory purposes. It is important when considering individual and groups of chemicals to be aware of what the final objective is. For example, is the purpose to determine whether a group of chemicals need to be controlled or managed, how urgently that needs to be addressed and where the best point for intervention is? Equally, the purpose may be to develop standards for limiting exposure (e.g. for drinking-water), in which case it is important to consider how and where the standard will be measured and applied.

Chemicals present together may interact resulting in either an increase in toxicity (synergism or addition) or a decrease in toxicity (antagonism). However, there may be no interaction in which case the substances present may be considered to act independently. Where interaction resulting in synergism or antagonism is possible, to be realized this generally requires a sufficiently high concentration of one or more components to interfere with the biochemical or physiological processes in which the various chemicals are involved. While there are no clear examples from drinking-water, an example would be the use of piperonyl butoxide as a synergist for pyrethrins in insecticide sprays where the synergist, piperonyl butoxide blocks the pathway by which the pyrethrins are detoxified in the insect.

Some groups of related chemicals are already considered in setting drinking-water guidelines and standards, particularly where they are almost invariably present together and they have similar structures or mechanisms of toxicity. However, human exposure to chemicals through drinking-water can be short or long-term, intermittent or continuous while the concentrations of individual components may also vary significantly with time. A recent review by WHO (2017) on chemical mixtures in source and drinking-water in its assessment of combined exposure to chemicals from drinking-water points out that "*such considerations will be important in the decision as to whether a risk assessment of chemical mixtures is necessary, or whether regulatory action based on such a risk assessment is required. In terms of delivering workable regulatory frameworks it will not be practical to consider each water supply as an individual risk assessment or to take into account all of the substances that could be present*."

The aforementioned review on chemical mixtures in source and drinking-water (WHO, 2017) is associated with the WHO Guidelines for Drinking-water Quality and this paper is based to

a great extent on that document. The WHO review is, in turn, based on a framework for assessing the toxicity of mixtures produced by IPCS (WHO, 2009).

Existing approaches

Currently most groups of substances in the environment and at environmental concentrations are considered on the basis of additivity (dose addition). The WHO Guidelines already consider some groups of substances that occur together in varying combinations and concentrations. The first to be addressed based on toxicity were **nitrate and nitrite**. The formula developed by WHO, which reflects an additive approach, was adopted in the current Directive. The mechanism of action is the same, although nitrate first requires reduction to nitrite in the body and is less potent.

WHO also provides advice on **THMs** using a similar formula and assuming dose addition, although this is not actually widely used in developing national regulations for DBPs. This is because THMs are one group of substances in a much larger mixture even though they tend to be present in the highest concentration. An additional complication is that the mixture is not necessarily consistent across different water supplies, for example if there is high natural bromide in the water then the proportion of brominated THMs is increased and probably other brominated substances. Although there is no conclusive evidence of adverse effects in consumers there remains suggestive evidence of a small risk relating to bladder cancer. Listing large numbers of different substances is not very helpful or productive in reducing the total load of chlorine DBPs but total THMs and total HAAs do provide a means of encouraging the reduction in the natural precursor compounds by drinking-water treatment, which will reduce the total load of DBPs by intervening at their source and will also provide a number of other benefits in terms of drinking-water quality. This is the approach adopted by countries in North America and is, in part, adopted by the EU.

WHO also suggests that **pesticides** with a similar mechanism of toxicity should be considered for risk assessment by using an additive formula similar to that used for nitrate and nitrite (e.g. atrazine and simazine). This has been dealt with in the EU by a policy decision for a standard of 0.1 µg/L for any individual pesticide and relevant metabolite and a value of 0.5 µg/L for total pesticides. It must, however, be recognized that this is not based on health and it is important that there is general understanding, otherwise an exceedance of the standard can lead to confusion and unnecessary concern amongst citizens.

Other groups of substances, which are considered together in the Directive are **tri- and tetrachloroethene**, which are sometimes found in groundwater but usually not together. The 10 µg/L standard in the Directive is based on comments from a previous EC advisory committee and covers either of the substances individually or as a combination of the two, effectively assuming that both substances have the same mechanism and level of toxicity.

A further group is **PAHs** in which four named PAH are given a group standard of 0.1 µg/L. This is a value that, in part, derives from an early WHO value of 0.2 µg/L for a group of six PAH (dropped in the first edition of the WHO Guidelines due to lack of health rationale), which included the four substances named in the PAH parameter in the Directive plus two

others, one of which was B(a)P, and which is included in the Directive as a separate parameter.

An additional group considered by WHO, or rather series of groups, are **petroleum products**, and which may be an issue in the event of an incident in which there is pollution with a source of petroleum hydrocarbons. WHO has not developed guideline values but has provided health-based values for different fractions of hydrocarbons associated with petroleum products based on the most toxic of the components as a marker substance and surrogate for the group. This tends to reflect the way in which the different fractions behave in the environment and is conservative, not least because the most soluble fractions also cause significant odour and taste in water at concentrations below those of concern for health.

In considering whether it is appropriate to regulate substances as a group it is important to also consider the context and the benefits of additional complexity in the regulatory process. In looking at the range of circumstances and huge number of combinations of chemicals to which it is possible for humans to be exposed, the EC Scientific Committee on Health and Environmental Risks (SCHER) has recommended an initial filter to prioritize the risk assessment of chemical mixtures of potential concern (EU, 2012):

1. Human and/or environmental exposure at significant levels;
2. Chemicals that are produced and/or marketed as multi-constituent substances or commercial 'mixtures' with several components and/or active ingredients and/or substances of concern;
3. Potential serious adverse effects of one or more chemicals at the likely exposure levels;
4. Likelihood of frequent or large scale exposure of the human population or the environment;
5. Persistence of chemicals in the body and/or in the environment;
6. Known information of potential interaction at levels of human and environmental exposure;
7. Predictive information that chemicals act similarly; and
8. Particular attention should be paid to chemical mixtures for which one or more components are assumed to have no threshold for its effects.

However, these considerations are also intended to address such issues as commercial mixtures, which are less likely to be of relevance to drinking-water because when commercial mixtures enter the environment they are often dispersed and changed. For examining drinking-water, the list of criteria would be shorter, for example point 2 would not be relevant, and the number of occasions when there is a clear need for and benefit from such risk assessments leading to regulation is also likely to be limited. It is important to balance the benefits of covering mixtures of chemicals in drinking-water with the practical and cost considerations of increasing regulatory complexity.

The WHO (2017) document addressing drinking-water provides a series of questions that aid in determining whether consideration as a mixture is necessary, appropriate or practicable and the management approaches that might be taken. These include:

1. Do the chemicals always occur as a mixture and, if not, how frequently do they occur together and under what circumstances?
2. Does the proportion of substances vary and is there a small number that usually dominate?
3. Are they of similar water solubility?
4. Can one or two substances act as a surrogate for the others (for both risk assessment and management)?
5. Is there evidence for non-additive behaviour between the mixture components?
6. How stable is the mixture, i.e. is it always similar?
7. Can the components of the mixture be measured by the same analytical method?
8. How readily will components of the mixture be removed in the available drinking-water treatment?
9. Are there other upstream interventions that can be applied?

In deciding whether or not an assessment of a mixture is appropriate, it is important to have a clear view as to why this is the case and what the objective of such an assessment is.

Approaches for assessing mixtures of chemicals

WHO/IPCS have prepared a Framework for the risk assessment of combined exposure to multiple chemicals (WHO, 2009; Meek et al., 2011; OECD, 2011) to try to harmonize the methodology at an international level. This framework is designed to consider appropriate groupings of chemicals on the basis of both co-exposure and potential hazard. The primary focus of the framework is not drinking-water and the aforementioned WHO (2017) document on chemical mixtures in source and drinking-water is designed to take a closer look at how the framework might be applied in the drinking-water context.

The WHO/IPCS framework is based on a hierarchical and iterative approach. Each level becomes more refined resulting in a reduction in conservatism and uncertainty as more data is incorporated but at the same time becomes increasingly complex and requiring significantly more expertise, toxicological data and exposure data. There are several tools available that can assist in the process of applying the framework, including hazard index, relative potency factor, reference point index/point of departure index, and physiologically-based toxicokinetic and toxicodynamic models.

The intention of the framework is that many, if not most, circumstances will be able to be resolved using the early, less resource intense phases. The framework does, however, help to show whether more detailed assessment is necessary, or would be beneficial, before a risk assessment for a group of substances can be carried out to the required standard.

The three broad groupings of the way in which mixtures of chemicals interact are (i) dose or concentration addition; (ii) independent action; and (iii) complex interaction.

i. Dose/concentration addition

For substances that have a similar mode of action it is appropriate to assume that they act additively and this is strongly supported by the evidence available. In terms of regulation, the approach used by WHO for nitrate/nitrite is a good example of dose/concentration addition for developing a guideline value for a mixture. The difference in potency between the two substances is taken into account by developing separate health-based guideline values (hazard component) which provide a basis for using the ratio of the concentration of each (exposure component) divided by its guideline value to show whether the ratio exceeds 1.

This approach has also been applied to mixtures of pharmaceuticals to determine whether the risk warrants immediate attention from a drinking-water perspective. However, in this case a margin of exposure was used that was developed from the lowest dose used to deliver a pharmacological effect with a margin of 1000 to give a tolerable concentration. For example, groups of non-steroidal anti-inflammatory drugs and cholesterol lowering drugs (statins) were considered as part of a risk assessment carried out for the United Kingdom Drinking Water Inspectorate to identify possible pharmaceuticals of interest for screening in drinking-water samples (Watts et al., 2007).

ii. Independent action

Independent action relates to substances that have dissimilar modes of action but affect the same target organ and makes the assumption that the action of the mixture can be calculated from the response of the individual components. However, in dealing with this, evidence supports the view that dose/concentration addition is an appropriate approach. This could be applied to a group of chemicals that occur together but have differing structures. It is difficult to identify any clear examples from drinking-water.

iii. Interactions

Complex interaction assumes that one or more components of the mixture can affect the behaviour of other components in biological systems resulting in increased or decreased effects, i.e. synergistic, potentiating or supra-additive, or antagonistic, inhibitive or sub-additive. The factors which can have a significant impact are if the dose levels are below the level required to have an effect, or absorption is too low to result in sufficiently high internal concentrations to have an effect.

The interactions that can occur include:

- Toxicokinetic interactions that change metabolism such as enzyme induction (increased enzyme activity) or inhibition so that one substance affects the metabolism of another, such as the potentiation of pyrethrins by piperonyl butoxide

by blocking the enzymes that detoxify the pyrethrins. In humans antabuse is used to block acetaldehyde dehydrogenase in the pathway for the detoxification of ethanol with the build-up of acetaldehyde. Interaction may also take the form of modifying absorption, retention or excretion, although this more usually applies to metals.

- Toxicodynamics are interactions between biological responses that result from the effects of the individual chemicals such as two substances competing for the same target binding site.

However, Boobis et al. (2011) found little evidence of synergistic interactions at low doses. Where there was evidence of interaction it was very small and of very limited impact when the size of uncertainty factors used in deriving individual regulatory values is considered. This implies that synergism is of very limited relevance for considering mixtures of chemicals in drinking-water, except perhaps in a spill situation.

Different approaches for use with dose/concentration addition

There are three main approaches that are applied to develop risk assessments for mixtures of substances that have a similar mechanism of action:

i. *Hazard index* is the approach used by WHO for nitrate/nitrite and is the sum of the ratios of the exposure of each substance in the mixture to the reference value. This can be the acceptable or tolerable daily intake (ADI or TDI) or the standard or guideline value for drinking-water.

ii. *Reference point index (point of departure index)* is similar to the hazard index but in this case it uses the toxicological point of departure that would be used in developing an ADI or TDI, instead of the reference value. The main difference is that the point of departure is not influenced by uncertainty factors, which introduce an element of judgement but also reflect confidence in the data. This is usually only used for substances that are toxicologically similar and for which there are adequate dose response data.

iii. *Relative potency factor* is applied to classes of structurally similar chemicals where there are extensive data and understanding about one or a small number of the substances in the class but less is known about other members. Other names are toxic equivalency factor or potency equivalency factor. These are used to express the toxicity of individual chemicals against the toxicity of the reference chemical to gauge the toxicity of the mixture. Examples that are well known are dioxins and polychlorinated biphenyls.

Mixtures of chemicals with dissimilar modes of action have not been considered to the same extent as mixtures of similar structure/mechanism. The following approaches apply:

i. *Response addition* in which the effects of the combination of chemicals are estimated by the sum of the probability that individual substances in the mixture will adversely affect the organisms that are exposed to the mixture. However, it should be noted that chemicals that are present at levels below the NOAEL are not included because

they are not expected to contribute to the total effect. The approach is of very limited applicability to drinking-water although it is of value in assessing the impact of mixtures on aquatic organisms in ecotoxicology.

ii. *Relative potency factors* are adapted from the approach discussed above but components are grouped according to mode of action and the potency factors calculated for each similar sub-group and the estimates of risk are added to give a mixture risk estimate.

For interactive chemicals, the only approach that has been proposed is the development of a hazard index to which an uncertainty factor is applied to account for interactions. This factor would be determined from an evaluation of the overall weight of evidence.

In terms of similar endpoints, the issue of substances that are considered to cause cancer and whether the presence of several such substances requires an additive approach has been raised. This approach relates to substances for which a risk value has been calculated using low dose extrapolation, most usually from laboratory animal data. However, it is important to note that this approach is only feasible when the target organ is the same and, potentially, when the mechanism of action is also the same. In addition, the considerable uncertainties inherent in the risk calculations should be considered so as not to create practical problems in achieving any standard with unintended consequences that result in other known risks to health, mislead consumers as to the scale of risk in relation to other risks or divert resources to dealing with comparatively minor risks.

Tiered risk assessment

Tiered risk assessments start with a basic level 0 assessment of both exposure and hazard. These consist of broad estimates of both. In the event that margin between exposure and hazard is considered to be inadequate then tier 1 requires further information to refine one or both of hazard and exposure. Tier 2 requires a much more detailed refinement and requires significantly more data on both.

An example of the approach used by Watts et al. (2007) comes from the assessment of risks to consumers from pharmaceutical residues posed through drinking-water. In this study the pharmaceuticals most extensively used in the United Kingdom were considered for risk assessment. The approach was to select the lowest dose used clinically for each pharmaceutical assuming that all consumed substance was excreted unchanged and reached drinking-water without any degradation in five actual catchments. Where the margin of exposure was less than 1000 then a second tier exposure assessment was carried out taking into account metabolism, degradation in wastewater treatment and removal in drinking-water treatment. Several groups of pharmaceuticals of similar structure and activity were also considered as mixtures assuming dose addition; these included non-steroidal anti-inflammatory drugs, anti-cholesterol drugs (statins) and oestrogenic hormones. In this case there was no requirement to further refine the risk assessment as all were well above the 1000 margin of exposure.

An additional example could be taken from the toxins that can be produced by cyanobacteria, which can form blooms in still and slow flowing drinking-water sources. The most common group of toxins is the microcystins, which are liver toxins, and microcystin-LR is considered to be one of the most common, if not the most commonly encountered of >80 different variants. Microcystin-LR is also considered to be the most toxic and is the best studied of the group and the WHO provisional guideline value is 1.0 µg/L. A study on Lake Taihu in China was carried out because this lake has had a number of significant cyanobacterial blooms affecting drinking-water supplies. The highest concentration of microcystins measured was 55 µg/L, which is significantly above the WHO provisional guideline value for microcystin-LR. It is assumed that all microcystins are of the same order of toxicity as microcystin-LR, although this is a precautionary assumption. Using this as a tier 0 assessment, tier 1 would require a refinement of the exposure assessment or the toxicity assessment.

The tier 1 risk assessment looks at the total microcystins load but also examines the available mitigation measures, including lowering the intake to the drinking-water plant below the level of the bloom and also considering removal in drinking-water treatment. By considering both, it was shown that the actual exposure was an order of magnitude below the provisional guideline value. If this had not been the case a tier 2 risk assessment would have been required that would have examined the hazard index that took into account the different microcystins present and the proportion that had a lower toxicity than microcystin-LR.

Discussion

While the consideration of mixtures of chemicals is an important part of the overall risk assessment process, most of the key work relates to circumstances in which the mixtures are fairly predictable and stable. The greatest effort has been directed towards consumer products, occupational exposure and food. In general the greatest efforts have also been directed at circumstances in which significant concentrations are present. In drinking-water there are possible circumstances when this will be useful. The examples given above of groups of pharmaceuticals with similar structure and the same mechanism of action are useful for determining whether further regulatory action is needed, the urgency of action and also where the most effective interventions can be made. In the case of the pharmaceuticals there is greater concern regarding the impact on aquatic life, i.e. the margin of exposure for aquatic organisms is much smaller, which suggests that the most effective interventions will be upstream.

In the case of microcystins or petroleum products mentioned above, the assessment is made in relation to accidents and intermittent situations. In the case of microcystins it relates to whether the existing treatment and other management interventions are adequate and whether there is a need for additional interventions, either in raw water management or in requiring additional drinking-water treatment. In these cases a marker compound has been used to establish the appropriate safe level but it is primarily a conservative approach and monitoring still needs to consider a wider range of substances.

Some groups of substances are considered because of the potential for their acting on the same group of biochemical receptors. In the case of EDCs with oestrogenic activity the hormones, natural and synthetic, have significantly greater activity than other synthetic substances. However, they may act additively and at present there is no credible evidence for other interactions. The approach suggested in the proposals for revisions to the Directive made to the EC in 2007 (Jørgenson et al., 2007) for EDCs was not to set a standard but to have indicator values for a three representative substances from different groups. These would not be health-based values but would provide a means of assessing the risk of exposure by measuring at the drinking-water intake and, if measured above the indicator concentrations, after treatment to determine if treatment was adequate. This is similar to the approach used for microcystins in the event of a bloom. Fawell et al. (2001) used the trout vitellogenin bioassay to determine whether there were oestrogens (oestrogenic activity) present at the intake but bioassays are difficult to apply and there are issues with chlorinated water.

EU (2012) considered the assessment of the toxicity of mixtures of chemicals as discussed above. They drew the following conclusions:

1. Under certain conditions, chemicals will act jointly in a way that the overall level of toxicity is affected.
2. Chemicals with common modes of action will act jointly to produce combination effects that are larger than the effects of each mixture component applied singly. These effects can be described by dose/concentration addition.
3. For chemicals with different modes of action (independently acting), no robust evidence is available that exposure to a mixture of such substances is of health or environmental concern if the individual chemicals are present at or below their zero effect levels.
4. Interactions (including antagonism, potentiation, and synergies) usually occur at medium or high-dose levels (relative to the lowest effect levels). At low exposure levels, they are either unlikely to occur or are toxicologically insignificant.
5. In view of the almost infinite number of possible combinations of chemicals to which humans and environmental species are exposed, some form of initial filter to allow a focus on mixtures of potential concern is necessary.
6. With regard to the assessment of chemical mixtures, a major knowledge gap at the present time is the lack of exposure information and the rather limited number of chemicals for which there is sufficient information on their mode of action. Currently, there is neither an agreed inventory of modes of action, nor a defined set of criteria on how to characterize or predict a mode of action for data-poor chemicals.
7. If no mode of action information is available, the dose/concentration addition method should be preferred over the independent action approach. Prediction of possible interaction requires expert judgement and hence needs to be considered on a case-by-case basis.

The general consensus from Boobis et al. (2011), EU (2012) and WHO (2017) is that the scientific evidence supports dose addition or no interaction as the most credible situation, particularly at the low doses normally encountered in drinking-water.

In terms of drinking-water regulations there is currently fairly limited utility in attempting to regulate contaminants by assessing mixtures, except in limited circumstances, for the reasons outlined above. It is certainly useful in carrying out risk assessments, such as the example given above for pharmaceuticals, but much less useful for setting standards. The only risk-based standard that considers mixtures is for nitrate and nitrate.

In terms of the use of marker substances as indicators of a wider group of substances, THMs and HAAs as markers for chlorination by-products are useful and logical, but this is not based on a detailed risk assessment but instead a pragmatic way of managing formation in drinking-water.

The consideration of mixtures in drinking-water standards and legislation has been limited but a number of regulatory authorities, including the EC have incorporated regulatory parameters that do take into account groups of chemicals that always occur as mixtures and one that sometimes occurs as a mixture. Generally this takes a more pragmatic approach that takes into account the difficulties of monitoring and it is likely that there will be more standards aimed at controlling mixtures of chemicals in drinking-water in the future.

References

Boobis A, Budinsky R, Collie S, Crofton K, Embry M, Felter S, Hertzberg R, Kopp D, Mihlan G, Mumtaz M, Price P, Solomon K, Teuschler L, Yang R, Zaleski R. (2011). Critical analysis of literature on low-dose synergy for use in screening chemical mixtures for risk assessment. Critical Reviews in Toxicology 41(5): 369–383.

EU (2012). Toxicity and assessment of chemical mixtures. Opinion of the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). Available at: http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_155.pdf (accessed on 28 June 2017).

Fawell JK, Sheahan D, James HA, Hurst M and Scott S (2001). Assessment of oestrogens and oestrogenic activity in raw and treated water in Severn Trent Water. *Water Research* 35(5): 1240-1244.

Jørgenson C, Buckardt Boyd H, Fawell J, Hydes O (2007). Establishment of a list of chemical parameters for the revision of the drinking water directive; ENV.D.2/ETU/2007/0077r. Available at: https://circabc.europa.eu/webdav/CircaBC/env/Water%20Industries/Library/DRINKING%20WATER/Z_old_library/DW%20Review%202007-2009/stakeholder_consultation/stakeholder_2008/stakeholder%204%20april%20chem%20parameters.pdf (accessed on 28 June 2017).

Meek ME, Boobis AR, Crofton KR, Heinemeyer G, Van Raaij C, Vickers C. (2011). Risk assessment of combined exposures to multiple chemicals: a WHO/IPCS framework. Reg. Toxicol. Pharmacol. 60: S1–S7.

OECD (2011). WHO OECD ILSI/HESI International Workshop on Risk Assessment of Combined Exposures to Multiple Chemicals. Workshop Report. Organisation for Economic Co-operation and Development. OECD Environment, Health and Safety Publications: Series on Testing and Assessment: No. 140. Available at: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2011)10&doclanguage=en (accessed on 28 June 2017).

Watts C, Maycock D, Crane M, Fawell J, Goslan E (2007). Desk based review of current knowledge on pharmaceuticals in drinking water and estimation of potential levels. Report to Defra. Available at: http://dwi.defra.gov.uk/research/completed-research/reports/dwi70-2-213.pdf (accessed on 28 June 2017).

WHO (2009). Assessment of combined exposures to multiple chemicals. Report of a WHO/IPCS International Workshop. World Health Organization: Geneva. Available at: http://www.inchem.org/documents/harmproj/harmproj/harmproj7.pdf (accessed 28 June 2017).

WHO (2017). Chemical mixtures in source water and drinking-water. World Health Organization: Geneva. Available at: http://www.who.int/water_sanitation_health/publications/chemical-mixtures-in-water/en (accessed on 28 June 2017).

Appendix 6:
Chemical fact sheets

The fact sheets cover the following chemical parameters and parameter groups which are suggested to be retained and/or included in Annex I Part B of the Directive:

The fact sheets are largely based on the chemical fact sheets as per the first addendum to the fourth edition of the WHO Guidelines. Complementary sources of information include the *Synthesis report on the quality of drinking water in the Union examining Member States' reports for the 2011-2013 period, foreseen under Article 13(5) of Directive 98/83/EC* (EC, 2016). Information on the drinking-water standards established in Australia, Canada, Japan and USA were derived from Australian National Health and Research Council (2011), Government of Canada (2017), Japanese Ministry of Health, Labour and Welfare (2015) and US EPA (2017). References to the relevant WHO background documents are provided in the individual fact sheets. References to any further information sources are also provided in the fact sheets.

Acrylamide

It is recommended to retain the current Directive PV of 0.1 µg/L.

WHO guideline value and Directive parametric value

The WHO GV for acrylamide is 0.5 µg/L. In contrast to this the Directive PV is 0.1 µg/L. The rationale behind this difference is that an additional cancer risk of 10^{-5} is considered acceptable by WHO, whereas in the EU a risk of 10^{-6} is accepted. Moreover, treatment capabilities in the EU are better than in many other regions, therefore lower values are achievable and currently this is the lowest value consistently achievable.

Standard values in selected countries are shown in the following:

Country	Value (µg/L)
Australia	0.2
Canada	No value assigned
Japan	No value assigned
USA	0.5

Source and pathways to drinking-water

The primary, if not exclusive, source of acrylamide in drinking-water is from the presence of acrylamide monomer in polyacrylamide coagulant aids used in drinking-water treatment. Coagulation is an important barrier to pathogens and many chemicals that attach to particles. It is also an important process for removal of natural organic matter that is a precursor to DBPs.

Occurrence in drinking-water in the EU

There is no data on the overall compliance for acrylamide in the EU synthesis report on drinking-water quality for the period 2011-2013. According to Annex III of the Directive, acrylamide does not need to be measured in drinking-water but is controlled by product specification. There is now an analytical method that can achieve a sufficiently low limit of quantification but this is not yet widely available.

Evidence for risk to health

JECFA considered acrylamide in 2010 and while the WHO GV was developed by extrapolation from animal studies, acrylamide is considered to be of concern for public health. However, the primary source of exposure is from cooked food and exposure from this source is both ubiquitous and higher than previously considered. Because exposure is so widespread, refining the risk assessment through epidemiological studies is difficult although studies in industrially exposed populations do not indicate that the risk is as high as animal studies might suggest. Because controlling exposure from food is difficult, it is appropriate to maintain as low exposure from controllable sources as can be reasonably achieved.

WHO guideline value derivation

Combined mammary, thyroid and uterine tumours observed in female rats in a drinking-water study were considered the most sensitive endpoints. The GV was derided by using a linearized multistage model.

Control

As stipulated by Annex III of the Directive, acrylamide is best controlled by product specification allowing a maximum amount of residual monomer in polyacrylamide, combined with a maximum dose of the polymer in drinking-water treatment. Some larger water utilities can refine the control by analysis of residuals in treated water. There is REACH control on polyacrylamide grout used in the environment but not on polyacrylamide coagulant aids.

Monitoring

Acrylamide monomer is monitored by ensuring that the quality of polyacrylamide and the dose of polyacrylamide are adequate to meet the standard. Where analytical methods are employed monitoring should be immediately post-treatment.

Analysis

More recently an analytical method has been developed to detect acrylamide in drinking-water at the low concentrations specified in the Directive. Acrylamide can be analyzed by high-performance liquid chromatography (HPLC) coupled with tandem mass spectrometry (MS) after solid-phase extraction (SPE) with an activated carbon-based sorbent. The resulting limit of quantification (LOQ) is 0.01 µg/L. An international standard is currently not available. The described procedure is adopted from the German standard method DIN 38413-6:2007.

WHO background document

WHO (2011). Acrylamide in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/acrylamide.pdf (accessed, 22 March 2017).

Antimony

It is recommended to adopt a new Directive PV of 20 µg/L.

WHO guideline value and Directive parametric value

The WHO GV for antimony is 20 µg/L. In contrast, the current Directive PV is 5.0 µg/L. The WHO GV is based on newer data reducing uncertainty thus allowing for a higher health-based GV.

Standard values in selected countries are shown in the following:

Country	Value (µg/L)
Australia	3.0
Canada	6.0
Japan	20 (target value)
USA	6.0

Source and pathways to drinking-water

Antimony reaches drinking-water primarily through metal alloys used in the distribution system and in plumbing.

Occurrence in drinking-water in the EU

According to the EU synthesis report on drinking-water quality for the period 2011-2013, the average compliance rate for the current Directive PV for antimony was 99.94%. Antimony is frequently detected but usually below the current standard. According to data requested from Member States in 2016, nine countries reported exceedances of the Directive PV; the highest maximum value reported was 76 µg/L but the highest median value was only 1 µg/L.

Evidence for risk to health

There is no evidence that antimony causes adverse health effects in humans from exposure through drinking-water. The form of antimony affects the toxicity but in drinking-water it would be expected to be primarily in the less toxic antimony (V) oxo-anion. There is evidence of carcinogenicity of antimony trioxide by the inhalation route but there are no data that indicate that it is carcinogenic by the oral route. In laboratory animal studies it caused reduced body weight, reflecting non-specific toxicity.

WHO guideline value derivation

The Directive PV of 5 µg/L is based on the assessment in the second edition of the WHO Guidelines. Since then more data was made available that allowed a reduction in the uncertainty factor in determining the TDI and the WHO GV was increased to 20 µg/L in 2003. The TDI of 6 µg/kg body weight is based on the NOAEL of 6.0 mg/kg body weight per day for decreased body-weight gain and reduced food and water intake in a 90 day study in rats

administered potassium antimony tartrate in drinking-water with an uncertainty factor of 1000. The proportion of the TDI allocated to drinking-water is 10%, which may be conservative. Antimony is used as a stabilizer in polyethylene terephthalate bottles and packaging, but the wider exposure to antimony from food is uncertain.

Control

Conventional treatment processes do not remove antimony. However, antimony is not normally a raw water contaminant. As the most common source of antimony in drinking-water appears to be dissolution from metal plumbing and fittings, primary control of antimony would be by product specification and approval.

Monitoring

Antimony is rarely encountered as a source water contaminant and arises in distribution and plumbing within buildings. Monitoring should be at the tap but an appropriate sampling protocol should be developed to take into account the variation in concentrations associated with the variable contact period of water with the plumbing material.

Analysis

The elemental analysis of antimony is based on inductively coupled plasma (ICP) with MS detection as per ISO 17294-2:2016. The LOQ is 0.2 µg/L.

WHO background document

WHO (2003). Antimony in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/antimony.pdf (accessed, 22 March 2017).

Arsenic

It is recommended to retain the current Directive PV of 10 µg/L.

WHO guideline value and Directive parametric value

The WHO GV for arsenic is 10 µg/L. The Directive PV is identical.

Standard values in selected countries are shown in the following:

Country	Value (µg/L)
Australia	10
Canada	10
Japan	10
USA	10

Source and pathways to drinking-water

Arsenic is a chemical element which is introduced into water through the dissolution of rocks, minerals and ores, from industrial effluents, including mining wastes, and via atmospheric deposition. Arsenic is usually present in drinking-water as a consequence of release from natural sources and it is much more frequently found in groundwater than surface water. In water, it is most likely to be present as arsenate, with an oxidation state of 5, if the water is oxygenated. Under reducing conditions, it is more likely to be present as arsenite, with an oxidation state of 3.

Occurrence in drinking-water in the EU

Inorganic arsenic is naturally present at high levels in the groundwater of a number of EU countries, including in Hungary and Italy. In Hungary, for example, arsenic concentrations in groundwaters, which are used for public water supply, may reach up to 50-60 µg/L; the use of sources showing significant higher concentrations was discontinued (personal communication). Arsenic is a particular problem in small resource limited supplies. According to the EU synthesis report on drinking-water quality for the period 2011-2013, the average compliance rate for arsenic was 98.85%. This is the lowest rate of all chemicals. Nevertheless, the compliance rate increased in most countries between 2011 and 2013.

Evidence for risk to health

There is a considerable body of evidence to show that arsenic causes a range of adverse health effects as a consequence of extended exposure at high enough levels from drinking-water. Signs of chronic arsenicism, including dermal lesions such as hyperpigmentation and hypopigmentation, peripheral neuropathy, skin cancer, bladder and lung cancers and peripheral vascular disease, have been observed in populations ingesting arsenic contaminated drinking-water. Dermal lesions were the most commonly observed symptom, occurring after minimum exposure periods of approximately five years. The IPCS considers

that long-term exposure to in drinking-water is causally related to increased risks of cancer in the skin, lungs, bladder and kidney.

WHO guideline value derivation

The concentration of arsenic in drinking-water below which no effects can be observed remains to be determined, and there is a need for identification of the mechanism by which arsenic causes cancer, which appears to be the most sensitive toxicity end-point.

JECFA assessed the new data on arsenic in 2010 and this was included in the WHO consideration of arsenic in the fourth edition of the Guidelines. The PTWI was withdrawn, but the overall assessment indicated that the risks from a drinking-water concentration of less than 10 µg/L would be difficult to measure with an appropriate level of confidence. This is particularly important since most of the epidemiological studies are from rural districts of low and middle income countries where the level of exposure can easily be underestimated and the impact of poor nutrition is difficult to assess so extrapolation to lower exposure levels in high income countries is problematical.

In view of the practical difficulties in removing arsenic from drinking-water, particularly from small supplies, the WHO GV of 10 µg/L is retained but in light of the withdrawal of the PTWI it is designated as provisional.

Control

It is technically feasible to achieve arsenic concentrations of 5 µg/L or lower using any of several possible treatment methods. However, this requires careful process optimization and control, and a more reasonable expectation is that 10 µg/L should be achievable by conventional treatment (e.g. coagulation). Such is not normally available for groundwater sources, particularly in small supplies. Appropriate point of use or point of entry devices may be used in such settings.

A possible solution is to use alternative sources of water that are low in arsenic to blend with higher-arsenic sources to lower the concentration to acceptable levels. However, it is important that this does not result in risk substitution, for example, if the alternative water source, although low in arsenic, increases exposure to waterborne pathogens and results in acute gastrointestinal infections. There is an increasing number of effective small-scale treatment techniques, usually based on coagulation and precipitation or adsorption.

Monitoring

Arsenic is a source water contaminant and can be monitored immediately post-treatment. Arsenic can adsorb onto the walls of pipes in distribution and where arsenic is present there should be a programme of distribution maintenance to prevent build up over long periods.

Analysis

The elemental analysis of arsenic is based on ICP-MS as per ISO 17294-2:2016. The LOQ is 0.1 µg/L.

WHO background document

WHO (2011). Arsenic in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/arsenic.pdf?ua=1 (accessed, 18 February 2017).

Benzo(a)pyrene

It is recommended to retain the current Directive PV of 0.01 µg/L.

WHO guideline value and Directive parametric value

The WHO GV for B(a)P is 0.7 µg/L. In contrast, the Directive PV is 0.01 µg/L. The EU retained the GV from the first edition of the WHO Guidelines for precautionary reasons, whereas the current WHO GV is based on a toxicological evaluation.

Standard values in selected countries are shown in the following:

Country	Value (µg/L)
Australia	0.01
Canada	0.04
Japan	No value assigned
USA	0.2

Source and pathways to drinking-water

B(a)P is a PAH released from old coal tar linings on cast iron water mains. Because of its low water solubility, it is almost exclusively found associated with sediments, particulates and dirty water. Anecdotal evidence indicates that B(a)P has a low taste threshold, possibly in combination with other PAHs. It is rarely found by routine monitoring, although it can be found when there are particles present or discoloration incidents in affected mains. B(a)P is also an indicator of other low solubility PAH from the same source.

Occurrence in drinking-water in the EU

According to the EU synthesis report on drinking-water quality for the period 2011-2013, the average compliance rate for B(a)P was 99.96%. According to data requested from Member States in 2016, 13 countries reported exceedances of the Directive PV with a maximum concentration of 25 µg/L, and one country reporting exceedance of the WHO GV.

Evidence for risk to health

B(a)P is a known human carcinogen, causing skin cancer following long-term occupational skin contact, usually in the form of soot or contaminated oil. B(a)P is extremely rare today because of improved industrial hygiene. There is no evidence that B(a)P could cause adverse health effects following exposure through drinking-water.

WHO guideline value derivation

WHO withdrew the GV for PAH in 1984 because it was not possible to set a health-based value for most PAHs, and B(a)P was considered to be the most important. This was reviewed and confirmed in 1993 and 1998. The WHO GV of 0.7 µg/L for B(a)P is based on an evaluation for the second edition of the Guidelines and on an alternative extrapolation

model designed to take into account the non-standard experimental design of the only oral carcinogenicity study available. The Directive PV of 0.01 µg/L was proposed as a value in the first edition of the Guidelines and later recommended as a more precautionary value by the relevant European Scientific Committee.

Control

In Member States in which there are still historical coal tar lined cast iron pipes, PAHs would be potentially covered by the requirement not to supply discoloured or unacceptably tasting water. This is a diminishing issue as coal tar lined pipes are steadily replaced or refurbished. Where B(a)P is present in surface water, a concentration of less than 0.05 µg/L should be readily achievable using coagulation and B(a)P would be adsorbed to granular activated carbon.

Monitoring

B (a)P is of very low water solubility. Routine monitoring is not reliable in detecting incidents of disturbance in distribution when B(a)P may be present attached to particles. An investigation should be carried out to identify if and where coal tar linings are present and the distribution system should be managed to minimize the risk of sediment disturbance, but when this does occur water samples should be taken and analyzed for B(a)P.

Analysis

International standard analytical methods of selected PAHs provides the liquid-liquid extraction (LLE) of analytes with nonpolar solvents (e.g. *n*-hexane) and the determination by HPLC coupled with fluorescence detection, as per ISO 17993:2002, or by gas chromatography (GC) coupled with MS detection, as per ISO 28540:2011. Using these methods, individual LOQs of 0.005 µg/L can be achieved.

WHO background document

WHO (2003). Polynuclear aromatic hydrocarbons in drinking-water. Background document for development of WHO guidelines for drinking-water quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/polyaromahydrocarbons.pdf

Boron

It is recommended to adopt a new Directive PV of 2.4 mg/L.

WHO guideline value and Directive parametric value

The WHO GV for boron is 2.4 mg/L. In contrast, the current Directive PV is 1.0 mg/L. The rationale behind the difference is that WHO used newer studies for deriving its GV, including a higher allocation of the TDI to drinking-water.

Standard values in selected countries are shown in the following:

Country	Value (mg/L)
Australia	4.0
Canada	5.0
Japan	1.0
USA	5.0

Source and pathways to drinking-water

Boron used to be found in surface water from borates used in washing powders. This source has largely disappeared and so concentrations have fallen significantly. Boron can be found naturally in groundwater in regions of high boron baring rocks. It is found at high levels in sea water and cannot be easily removed by reverse osmosis. Thus, boron is a significant problem for Member States dependent on desalinated water or where there is significant saline intrusion requiring desalination.

Occurrence in drinking-water in the EU

According to the EU synthesis report on drinking-water quality for the period 2011-2013, the average compliance rate for the current Directive PV for boron was 99.85%. According to data requested from Member State in 2016, eleven countries reported exceedances of the Directive PV, five of which reported exceedances of the WHO GV.

Evidence for risk to health

Boron is considered to be of relatively low toxicity and there are no data that show adverse health effects in humans from environmental exposure. Boron is found in food and is an essential element for many plants. However, it does cause adverse reproductive effects in laboratory animals.

WHO guideline value derivation

Boron has been the subject of a considerable amount of pharmacokinetic and dynamic research and the WHO GV was updated in the fourth edition of the Guidelines using the new data to determine a conservative value of 2.4 mg/L. The value of 1 mg/L in the Directive was considered by the appropriate EU scientific committee to be more appropriate than the

previous provisional WHO GV of 0.5 mg/L. The current Directive PV can be considered to be excessively precautionary and is a barrier that impacts on the introduction and costs of desalination in Member States that may have limited choices as to new sources of drinking-water.

Control

Boron was used as perborate in detergents and was a pollutant in source waters receiving treated wastewater effluent but that use has now largely stopped. Conventional water treatment (coagulation, sedimentation and filtration) does not significantly remove boron, and special methods need to be used in order to remove boron from waters with high boron concentrations. Blending with low-boron supplies may be the only economical method to reduce boron concentrations in fresh waters where concentrations are high.

In Member States with significant water resource problems, where desalination is one of the few viable sources of fresh water, boron in seawater is considered a significant problem in the desalination process. It is found at high levels in sea water and cannot be easily removed by reverse osmosis but requires double pass reverse osmosis, which has higher capital costs and, more importantly, significantly higher operational costs. The process is energy intensive and bears a high carbon footprint.

Monitoring

Boron is a source water contaminant that does not change in distribution so monitoring should be at the end of treatment.

Analysis

The elemental analysis of boron is based on ICP-MS as per ISO 17294-2:2016. The LOQ is 1.0 µg/L.

WHO background document

WHO (2003). Boron in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/boron.pdf (accessed on 22 March 2017).

Bromate

The WHO GV is currently under revision.

It is recommended that the Directive PV is the health-based GV currently being developed by WHO. If the revised GV is not adopted by WHO in time for the revision of the Directive, we recommend to retain the current Directive PV of 10 µg/L

It is recommended that compliance is determined on the basis of an annual average value.

WHO guideline value and Directive parametric value

The WHO GV (under revision) and the Directive PV for bromate are 10 µg/L.

Standard values in selected countries are shown in the following:

Country	Value (µg/L)
Australia	20
Canada	10
Japan	10
USA	10

Source and pathways to drinking-water

The main source of bromate in drinking-water is its formation in drinking-water treatment with ozone when bromide is present in raw water. It can also be a significant contaminant in sodium hypochlorite solutions used for chlorination when it is manufactured by electrolysis using brine that does not come from low bromide salt deposits.

Occurrence in drinking-water in the EU

According to the EU synthesis report on drinking-water quality for the period 2011-2013, the average compliance rate for bromate was 99.88% but this could change with more periods of drought and low river flows leading to increased bromide concentrations.

Evidence for risk to health

Bromate causes cancer in laboratory animals but there is no evidence that bromate causes adverse health effects in humans from exposure through drinking-water.

WHO guideline value derivation

There is a considerable body of evidence that shows that the dose response curve for bromate carcinogenicity is non-linear and that linear extrapolations will significantly overestimate the possible risks. The WHO GV of 10 µg/L is designated as provisional because of the technical difficulty of achieving the upper bound estimate associated with an acceptable level of risk of 10^{-5} from the linear cancer extrapolation. New data on

toxicokinetics demonstrate that not only is 10 µg/L a safe value but it is excessively precautionary. WHO is assessing the data on bromate and preparing a revised GV.

Control

Bromate is difficult to remove once formed. By appropriate control of disinfection conditions, it is possible to achieve bromate concentrations below 10 µg/l. Formation of bromate in hypochlorite solution would need to be controlled by product specification limiting bromide in salt deposits. Water utilities employing ozonation as a treatment step report increasing difficulties in managing to meet the Directive PV for bromate at periods of low river flows when the concentration of bromide is increased. Ozonation is important as a treatment for removal of a number of important organic contaminants and as a barrier to pathogens.

Monitoring

Since bromate is formed during treatment it can be monitored in final water at water works. It is recommended that compliance is determined on the basis of an annual average value.

Analysis

According to ISO 11206:2011, the concentration of bromate can be determined by ion chromatography with UV detection. With this method an LOQ of 0.5–1 µg/L can be achieved.

WHO background document

WHO (2005). Bromate in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/bromate260505.pdf (accessed on 22 March 2017) (under revision).

Cadmium

It is recommended to retain the current Directive PV of 5 µg/L.

WHO guideline value and Directive parametric value

The WHO GV is 3 µg/L and the Directive PV 5 µg/L. The minor difference is explained by rounding.

Standard values in selected countries are shown in the following:

Country	Value (µg/L)
Australia	2
Canada	5
Japan	3
USA	5

Source and pathways to drinking-water

Cadmium is found in the environment as an industrial pollutant, in treated wastewater and as a diffuse pollutant from some phosphate fertilizers. It can also leach from impurities in zinc in old galvanized pipes and solders, and it is a potential contaminant in some alloys.

Occurrence in drinking-water in the EU

According to the EU synthesis report on drinking-water quality for the period 2011-2013, the average compliance rate for cadmium was 99.99%. As old galvanised pipe is replaced then that source of cadmium will disappear. Cadmium content of any new galvanised pipe or metal alloy fittings should be sufficiently low not to contribute to the Directive PV being breached.

Evidence for risk to health

Cadmium is a cumulative substance that can cause kidney dysfunction over time. There is no evidence that it causes adverse health effects as a consequence of exposure through drinking-water, which is a minor source of exposure as compared to food.

WHO guideline value derivation

The WHO GV of 3 µg/L is based on the allocation of 10% of a provisional tolerable monthly intake to drinking-water. The control of cadmium in food and food contact materials means that this allocation is likely to be conservative and this is reflected by the Directive PV of 5 µg/L, which is not significantly different from the WHO GV.

Control

Cadmium concentrations of 2 µg/l should be achievable using coagulation or precipitation softening where cadmium is present in source water as a consequence of pollution. Where

cadmium leaches from alloys in contact with drinking-water, primary control would be by product specification and approval and, at the consumer's point of consumption, by flushing taps before using the water.

Monitoring

Where cadmium is shown to arise from the distribution system, monitoring should be at the tap. If cadmium is found in source water but not from distribution, monitoring should be post-treatment.

Analysis

The elemental analysis of cadmium is based on ICP-MS as per ISO 17294-2:2016. The LOQ is 0.1 µg/L.

WHO background document

WHO (2011). Cadmium in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/cadmium.pdf (accessed, 22 March 2017).

Chlorate

New parameter: It is recommended to adopt a Directive PV of 0.7 mg/L.

It may be considered feasible to set a lower value of 0.35 mg/L if evidence shows that this is readily achievable in drinking-water while retaining adequate disinfection, which should never be compromised in meeting the PV.

It is recommended that compliance is determined on the basis of an annual average value.

WHO guideline value and Directive parametric value

The provisional WHO GV is 0.7 mg/L. Chlorate is currently not listed in Annex I to the Directive.

Standard values in selected countries are shown in the following:

Country	Value (mg/L)
Australia	No value assigned
Canada	1.0
Japan	0.6
USA	No value assigned

Source and pathways to drinking-water

Chlorate is formed during the decomposition of hypochlorite solutions, used for disinfection with chorine, that are not fresh and stored for long periods, particularly at warm temperatures. Hypochlorite is expected to be the major route of exposure to chlorate through drinking-water. Chlorate (as well as chlorite) is also a breakdown-product from the use of chlorine dioxide as a disinfectant.

Occurrence in drinking-water in the EU

Since chlorate is currently not listed in Annex I of the Directive, there is no data on compliance. According to data requested from Member States in 2016, three countries reported exceedances of the provisional WHO GV but the concentrations reported through stakeholders are generally below 0.3 mg/L. Data provided by EFSA also show that “tap water” is generally below 0.3 mg/L but as with data from Member States there are some very high concentrations in individual samples, in excess of 1 mg/L. It is difficult to interpret the data from EFSA for which there is no detail on the source and circumstances of sampling but the data from Member States demonstrate mean values well below 0.3 mg/L.

It must be emphasised that the data available do not reflect a systematic analysis and more systematic data are required to make a proper analysis of the situation across the EU. Such an analysis would allow the EC to identify which Member States were having difficulty in controlling chlorate levels and the precise levels that would be achievable.

Evidence for risk to health

While there is no direct evidence for chlorate causing adverse effects in humans, there is evidence for effects in laboratory animals exposed to high levels over long periods. One of the primary concerns is the inhibition of iodine uptake by chlorate in experimental animal studies, but there remains significant uncertainty regarding the extrapolation of this finding to human populations as rats are considered to be more sensitive to effects on thyroid. At high doses it causes effect on red blood cells in laboratory animals.

WHO guideline value derivation

The WHO GV is based on a TDI of 0.3 mg/kg body weight based on a NOAEL of 2.9 mg/kg body weight per day from a two generation study in rats with an uncertainty factor of 100. The JECFA ADI of 0.01 mg/kg body weight was based on a benchmark dose that took the lowest 95% limit on a lifetime study in rats for effects on thyroid with an uncertainty factor of 100 (WHO, 2007b). EFSA (2015) used data from a human study on perchlorate and extrapolated to chlorate. WHO allocated 80% of the TDI to drinking-water; the data from EFSA imply that this may not be appropriate. However, JECFA stated that the estimates of mean to the 95%-percentile of dietary exposure for Member States was 0.3-0.6 µg/kg body weight, which would suggest that this may not be excessive using the JECFA TDI, and would give a GV for water of 0.24 mg/L based on a 60 kg adult.

EFSA was requested to examine the risks to health of chlorate in food and developed a TDI of 3 µg/kg body weight. EFSA also found data that indicated that chlorate levels in food were sufficient to exceed the TDI for some population groups. The conclusion was that the source of chlorate in food was drinking-water chlorinated with hypochlorite used in food processing, as well as chlorination processes in the food industry to protect against pathogen contamination. The TDI would give rise to a very low drinking-water value that would threaten the use of chlorination by hypochlorite. WHO considered this evaluation and concluded that the TDI approach was excessively conservative and retained the existing guideline value of 0.7 mg/L, which is significantly above the value that would be determined using the EFSA TDI.

WHO has a world-wide remit and considers that the adequate disinfection of drinking-water must never be compromised in meeting guideline values for DBPs and disinfection breakdown products. The concern that chlorate exposure through food is too high needs further investigation and WHO still retains the current guideline value. The fact that the data from water suppliers, although limited, indicates that with large and well-resourced suppliers concentrations rarely exceed 0.3 mg/L, suggests that a lower value may be achievable in the EU – for example 0.35 mg/L, approximately half of the WHO GV. WHO does not regard the GV as a value to work up to and if it is reasonable to meet lower values, without compromising adequate disinfection, then this would be encouraged.

An additional approach might be to set a maximum value of 0.7 mg/L in any sample and measure the PV as an annual average value. This would potentially reduce exposure through both food and drinking-water, while potentially allowing for variation in concentrations and maintaining disinfection. However, it would be important to consider the possible impact in warmer climates, including the impact of increased periods of hot weather on small resource limited supplies and on other Member States than those from which the data was provided.

Control

Chlorate can be controlled through product specification. It is also important to ensure that sodium hypochlorite used in both drinking-water and food processes, after purchase is stored in such a way as to minimize the concentration of chlorate. It should be emphasized that difficulties in meeting the WHO GV must never be a reason for compromising adequate disinfection.

There is a need for a more systematic study to determine what best practices under different circumstances. What is clear from the data on concentrations in drinking-water is that there are instances of the WHO GV being exceeded in Europe and that there is a requirement to make sure that Member States and their water suppliers are aware of the need to control chlorate levels in drinking-water.

Monitoring

Chlorate is a by-product of treatment processes and can thus be monitored in final water. It is recommended that compliance is determined on the basis of an annual average value.

Analysis

Chlorate can be detected by ion chromatography with conductivity detection as per ISO 10304-4:1997. The LOQ is 0.03 mg/L.

WHO background document

WHO (2016). Chlorine dioxide, chlorite and chlorate in drinking-water. Available at: http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/chlorine-dioxide-chlorite-chlorate-background-jan17.pdf?ua=1 (accessed on 22 June 2017).

Chlorite

New parameter: It is recommended to adopt a Directive PV of 0.7 mg/L.

It is recommended that compliance is determined on the basis of an annual average value.

WHO guideline value and Directive parametric value

The provisional WHO GV is 0.7 mg/L; chlorite is currently not listed in Annex I of the Directive.

Standard values in selected countries are shown in the following:

Country	Value (mg/L)
Australia	0.8
Canada	1.0
Japan	0.6
USA	1.0

Source and pathways to drinking-water

Chlorite is the main by-product resulting from the use of chlorine dioxide as a disinfectant. Chlorine dioxide is used for drinking-water disinfection in some Member States but it is much less common than sodium hypochlorite, although it should be noted that chlorine dioxide use may also be used in buildings for *Legionella* control. Chlorine dioxide breaks down to chlorite and lower concentrations of chlorate. Where chlorine dioxide is used as a disinfectant, the major route of environmental exposure to chlorite is expected to be through drinking-water.

Occurrence in drinking-water in the EU

Since chlorite is currently not listed in Annex I of the Directive, there is no data on compliance. According to data requested from Member States in 2016, four countries reported exceedances of the WHO GV. There are few data available on chlorite concentrations in drinking-water. It is generally monitored by monitoring the dose of chlorine dioxide applied in drinking-water treatment.

Evidence for risk to health

Although chlorite has been shown to cause some adverse effects in laboratory animals given high doses over multiple generations, there is no evidence to indicate that it will adversely impact on human health at the much lower concentrations encountered in drinking-water. It does cause effects on red blood cells in laboratory animals at high doses.

WHO guideline value derivation

WHO has set a provisional GV of 0.7 mg/L and this would be adequate to also allow the use of chlorine dioxide. This is based on a JECFA TDI of 0.03 mg/kg body weight with an allocation of 80% of the TDI to drinking-water.

Control

It is possible to reduce the concentration of chlorine dioxide and chlorite effectively to zero (<0.1 mg/L) by reduction; however, it is normal practice to supply water with a chlorine dioxide residual of a few tenths of a milligram per litre to provide some protection against microbial regrowth during distribution. It should be emphasized that difficulties in meeting the WHO GV must never be a reason for compromising adequate disinfection. It should be noted that if chlorine dioxide is followed by an oxidative process such as ozonation, this can result in the oxidation of chlorite to chlorate.

Monitoring

Chlorite is a by-product of treatment processes and can thus be monitored in final water. It is recommended that compliance is determined on the basis of an annual average value to allow some variation to meet the need to vary chlorine dioxide dose to address raw water quality variation.

Analysis

Chlorite can be analyzed by UV or amperometric detection as per ISO 10304-4:1997. The LOQ is between 0.01–0.05 mg/L.

WHO background document

WHO (2016). Chlorine dioxide, chlorite and chlorate in drinking-water. Available at: http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/chlorine-dioxide-chlorite-chlorate-background-jan17.pdf?ua=1 (accessed on 22 June 2017).

Chromium

It is recommended to retain the current Directive PV of 50 µg/L for total chromium (chromium VI and chromium III).

The WHO GV is currently under revision.

WHO guideline value and Directive parametric value

The WHO GV is 50 µg/L (under revision) and thus equivalent to the Directive PV.

Standard values in selected countries are shown in the following:

Country	Value (mg/L)
Australia	50
Canada	50
Japan	50
USA	100

Source and pathways to drinking-water

Chromium is found in the environment naturally and as an industrial pollutant. It is the 21st most abundant element in the earth's crust and is released from naturally occurring chromium by oxidation. It appears to be more frequently detected in groundwater and where there are industrial sources this will be a more significant issue because the chromium will be persistent. It occurs as chromium VI and chromium III. Chromium VI is the more soluble form. Chromium is used in the manufacture of plumbing fittings, particularly taps, but does not seem to leach to a significant extent from this source.

Occurrence in drinking-water in the EU

According to the EU synthesis report on drinking-water quality for the period 2011-2013, the average compliance rate for chromium was 99.98%. Sazakli et al. (2014) carried out a significant study of four areas of Greece in which 572 samples were analysed for chromium VI. This showed a median concentration of 17 µg/L with a range of <3-196 µg/L and 25 and 75 percentiles of 9 and 24 µg/L; respectively. A study in Greece provided limited data on chromium VI in drinking-water and all were effectively below 50 µg/L (Linos et al., 2011). EFSA (2014) put out a call for data and most of the data received was from one Member State (Germany). The report did not provide details of drinking-water concentrations but indicated that exposure from all sources was not of concern except possibly for the upper 95 percentile in children. The report did indicate that few data on chromium reported the speciation. There remains a need to gather more data on the levels of chromium VI in European drinking-water.

Evidence for risk to health

Chromium VI is significantly more toxic than chromium III, which is an essential element for humans. However, chromium III is less well absorbed than chromium VI and the form of chromium can change as a consequence of oxidation/reduction in the environment and in the body. Chromium VI is carcinogenic to humans by inhalation of welding fume. Recent long-term studies in rats and mice with chromium VI administered in drinking-water showed an increase in tumours of the stomach or upper small intestine at high dosages. There is substantial evidence that the dose response is non-linear because chromium VI is reduced to chromium III in the upper gastrointestinal tract.

EFSA (2014) concluded that for non-neoplastic lesions and haematological effects the current exposure levels to chromium VI via drinking water are of no concern from a public health point of view. They also concluded that for neoplastic effects, the current levels of exposure to chromium VI via the consumption of all types of drinking-water or of bottled water only are of low concern for the average consumers. There might be a potential concern for high consumers particularly in the younger age groups.

WHO guideline value derivation

The current WHO GV was established prior to the first edition of the Guidelines and is based on the protection of consumers from dermatitis caused by chromium VI. The WHO GV was designated as provisional because of uncertainties in the toxicological database; there were no adequate toxicity studies available to provide a basis for a NOAEL.

Health Canada has carried out a detailed evaluation of the risk from chromium VI in drinking-water that has undergone international expert peer review. This study resulted in the development of a guideline value of 50 µg/L and this is the basis of the ongoing WHO guideline value re-evaluation. There is substantial evidence that the dose response is non-linear because chromium VI is reduced to chromium III in the mouth and upper gastrointestinal tract and the expert group has considered the new experimental data and other models of the reduction of chromium VI in the gastrointestinal tract of humans and has initially concluded that the Canadian approach is appropriate. WHO will propose a guideline value for total chromium, which is based on chromium VI. The approach developed by Health Canada has undergone international peer review and also by the WHO expert group.

Control

The indications are that it is of greater concern in groundwater because chromium in surface water can be removed to a great extent by coagulation with concentrations of 15 µg/L achievable. Removal from groundwater will require the introduction of specialized treatment, such as ion exchange. Chromium should also be considered in the product specification and approval of metal fittings and alloys for use in contact with drinking-water.

Monitoring

Where chromium is found in source water but is not found as a consequence of leaching from plumbing, it should be monitored post-treatment.

Analysis

The elemental analysis of chromium is based on ICP-MS as per ISO 17294-2:2016. The LOQ is 0.1 µg/L.

WHO background document

WHO (2003). Chromium in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/chromium.pdf?ua=1 (accessed on 22 March 2017) (under revision).

Copper

It is recommended to retain the current Directive PV of 2.0 mg/L.

Copper requires to be monitored at the tap but sampling needs to be designed to take into account variation in concentrations. The PV is essentially an acute value and thus a maximum value in any sample of drinking-water.

WHO guideline value and Directive parametric value

The WHO GV is 2 mg/L and thus equivalent to the Directive PV.

Standard values in selected countries are shown in the following:

Country	Value (mg/L)
Australia	2.0
Canada	No value assigned
Japan	1.0
USA	1.3

Source and pathways to drinking-water

The primary source of copper in drinking-water is copper plumbing. It is used to make pipes, valves and fittings and is present in alloys and coatings. Copper is an issue with aggressive waters, electrolytic corrosion and long contact times of water with copper piping in buildings. The concentration of copper is variable depending on the period that the water has been in contact with the pipes. Copper sulphate pentahydrate is sometimes added to surface water for the control of algae but this rapidly adsorbs to sediment and particulate matter.

Occurrence in drinking-water in the EU

According to the EU synthesis report on drinking-water quality for the period 2011-2013, the average compliance rate for copper was 99.93%. It is probable that any failures relate to long contact times in buildings with aggressive water supplies.

Evidence for risk to health

High concentrations of copper in drinking-water can cause gastric irritation giving rise to nausea. The issue that has been debated is whether elevated copper intake can cause or is implicit in a condition called childhood liver cirrhosis. Recently, there appears to be little support for there being a causal relationship in the absence of significant genetic susceptibility. Individuals with Wilson's disease have a genetic mutation that prevents them from handling copper normally, in spite of the fact that copper is an essential trace element. Such individuals have to control copper intake from all sources of which drinking-water is a minor one.

WHO guideline value derivation

Copper was updated for the third edition of the WHO Guidelines based on human data on acute gastrointestinal irritation to give a GV of 2 mg/L. It should provide an adequate margin of safety in populations with normal copper homeostasis. The GV is as a concentration rather than a dose value and reflects the acute effects of high copper intake. The GV is the same as the provisional GV developed for the second edition of the Guidelines but that was based on a TDI for chronic exposure to copper.

Control

Metallic materials used in contact with drinking-water should be controlled for copper by product specification and approval and, at the consumer's point of consumption, by flushing taps before using the water. Copper is not removed by conventional treatment processes. However, copper is not normally a raw water contaminant.

Staining of laundry and sanitary ware occurs at copper concentrations above 1 mg/l. At levels above 2.5 mg/l, copper imparts an undesirable bitter taste to water; at higher levels, the colour of water is also impacted.

Monitoring

Since copper arises almost exclusively from copper in domestic plumbing, it should be monitored at the tap but with appropriate sampling protocols that reflect the variation in concentration with the period of contact with copper pipes. These protocols should be targeted at identifying problems and where corrosion control is appropriate. Determination of concentrations above the Directive PV is an indicator that improved management of water quality in the building is required and if found widely then it is usually an indicator of the need for centralized corrosion control.

Analysis

The elemental analysis of copper is based on ICP-MS as per ISO 17294-2:2016. The LOQ is 0.1 µg/L.

WHO background document

WHO (2004). Copper in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/copper.pdf (accessed on 22 March 2017).

Epichlorohydrin

It is recommended to retain the current Directive PV of 0.10 µg/L.

WHO guideline value and Directive parametric value

The WHO GV is 0.4 µg/L and the Directive PV 0.1 mg/L. The difference is due to capability of achieving a lower value in the EU by product control.

Standard values in selected countries are shown in the following:

Country	Value (µg/L)
Australia	0.5
Canada	No value assigned
Japan	No value assigned
USA	0.2

Source and pathways to drinking-water

Epichlorohydrin comes from the use of some coagulant aids and is basically the residual monomer in the polymer. There is some doubt as to whether it survives in water as it does hydrolyse.

Occurrence in drinking-water in the EU

There is no data on the overall compliance for epichlorohydrin in the EU synthesis report on drinking-water quality for the period 2011-2013. According to Annex III of the Directive, epichlorohydrin does not need to be measured in drinking-water.

Evidence for risk to health

Epichlorohydrin has been shown to be carcinogenic at the point of contact in laboratory animals (nasal epithelium by inhalation and fore stomach by gavage) but there is no evidence that it causes adverse effects in humans through drinking-water.

WHO guideline value derivation

The WHO GV of 0.4 µg/L is considered to be provisional because of the uncertainties surrounding the toxicity of epichlorohydrin and the use of a large uncertainty factor because it was considered inappropriate to use linear extrapolation.

Control

Conventional treatment processes do not remove epichlorohydrin. As stipulated Annex III of the Directive, epichlorohydrin in drinking-water is best controlled by product specification and approval limiting the epichlorohydrin content of polyamine flocculants and/or the dose applied in drinking-water treatment. Where Member States have an approval system for materials and chemicals in contact with drinking-water the guideline value will be achieved.

In the absence of a European-wide approval scheme the PV remains an important means of ensuring Member States take action to control both the epichlorohydrin residual in polyamine coagulant aids and the maximum dose into drinking-water.

Monitoring

Epichlorohydrin cannot be easily measured in drinking-water at this time and so it is best achieved by specification of the permitted residual epichlorohydrin in polyamine coagulant aid and the allowed dose of the polymer in drinking-water treatment.

Analysis

According to EN 14207:2003, epichlorohydrin can be analyzed by GC-MS after SPE with styrol-divinylbenzene copolymer. The LOQ is equal to the Directive PV of 0.1 µg/L.

WHO background document

WHO (2004). Epichlorohydrin in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/epichlorohydrin.pdf?ua=1 (accessed on 22 March 2017).

Fluoride

It is recommended to retain the current Directive PV of 1.5 mg/L.

It is recommended that Member States should ensure that for fluoride added for the prevention of dental caries, the average concentration should not be greater than 1.0 mg/L to ensure that the PV is not exceeded.

WHO guideline value and Directive parametric value

The WHO GV is 1.5 mg/L as is the Directive PV.

Standard values in selected countries are shown in the following:

Country	Value (mg/L)
Australia	1.5
Canada	1.5
Japan	0.8
USA	4.0

Source and pathways to drinking-water

Fluoride is a common element that is widely distributed in Earth's crust and exists in the form of fluorides in a number of minerals. Traces of naturally occurring fluorides are present in many waters, with higher concentrations often associated with groundwater. A small number of Member States practice artificial fluoridation in order to provide protection against dental caries. The amounts added to drinking-water are such that final concentrations are usually between 0.5 and 1 mg/l. The fluoride in final water is always present as fluoride ions, whether from natural sources or from artificial fluoridation.

Occurrence in drinking-water in the EU

According to the EU synthesis report on drinking-water quality for the period 2011-2013, the average compliance rate for fluoride was 99.57%. Fluoride is found to exceed the standard in a limited number of sources affected by naturally occurring fluoride in a limited number of Member States.

Evidence for risk to health

High concentrations of fluoride in excess of 4 mg/L cause dental fluorosis and higher concentrations cause skeletal fluorosis. However, much depends on overall intake of fluoride from all sources. Health effects from fluoride intake through drinking-water are largely a problem for countries in hot climates. There is clear evidence from a number of countries (including India, China and the rift valley of Africa) that skeletal fluorosis occurs at higher intakes, approximately 14 mg/day and above. There is suggestive evidence for of an increased risk of effects on the skeleton at total intakes above 6 mg/day. However, there is

also evidence that concentrations in drinking-water above approximately 0.5 mg/L have a beneficial effect in preventing dental caries in children and adults.

WHO guideline value derivation

The WHO GV of 1.5 mg/L is based on a level that will not generally cause dental fluorosis but this will depend on the amount of water drunk and also other possible sources of fluoride exposure. Epidemiological evidence suggests that concentrations above the WHO GV carry an increasing risk of dental fluorosis and that progressively higher concentrations lead to increasing risks of skeletal fluorosis.

Where fluoride is added to drinking-water the average concentration should be no greater than 1 mg/L.

Control

Levels of 1 mg/l should be achievable using activated alumina. A possible solution is to use alternative sources of water that are low in fluoride to blend with higher-fluoride sources to lower the concentration to acceptable levels. However, it is important that this does not result in risk substitution, for example, if the alternative water source, although low in fluoride, increases exposure to waterborne pathogens and results in acute gastrointestinal infections.

Monitoring

Fluoride can be monitored in the final water at water works, since its concentration does not increase in the distribution system.

Analysis

The analysis of the inorganic anion fluoride can be effectively achieved by ion chromatography as per ISO 10304-1:2007. The LOQ is 0.05 mg/L.

WHO background documents

Fawell J, Bailey K, Chilton J, Dahi E, Fewtrell L, Magara Y (2006). Fluoride in drinking-water. Geneva: World Health Organization. Available at: http://www.who.int/water_sanitation_health/publications/fluoride_drinking_water_full.pdf (accessed on 24 June 2017).

WHO (2004). Fluoride in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: https://www.who.int/water_sanitation_health/dwq/chemicals/fluoride.pdf (accessed on 22 March 2017).

Haloacetic acids (HAAs)

New parameter: It is recommended to adopt a Directive PV of 80 µg/L for the sum of nine representative haloacetic acids (mono-, di- and trichloroacetic acid, mono- and dibromoacetic acid, bromochloroecetic acid, bromodichloroacetic acid, dibromochloroacetic acid and tribromoacetic acid).

WHO guideline value and Directive parametric value

Currently there is neither a WHO GV nor a Directive PV for HAAs as a group parameter. The WHO GVs for dichloroacetic acid and for trichloroacetic acid are 50 µg/L and 200 µg/L, respectively.

Standard values in selected countries are shown in the following:

Country	Value (µg/L)
Australia	No value assigned
Canada	80
Japan	No value assigned
USA	60

Source and pathways to drinking-water

HAAs are DBPs formed from the reaction of chlorine with natural organic and inorganic matter in the raw water and so arise during drinking-water treatment. THMs, which are already included in Annex I of the Directive, are also DBPs but are derived from different natural precursor organic substances and so reflect a different range of DBPs.

Occurrence in drinking-water in the EU

Since HAAs are currently not listed in Annex I of the Directive, there is no data on compliance. Some non-systematic data from the United Kingdom indicates that most water utilities would comply with this value but this was not always the case.

Evidence for risk to health

While there is evidence for possible adverse health effects of DBPs, it is not possible to infer causality in spite of a considerable body of research conducted over many years. However, it is prudent to reduce the load of DBPs as this can be done without compromising disinfection. Most of the research has been based on THMs but these are not a very good measure of the overall range and quantity of DBPs on their own. HAAs are also DBPs that arise in chlorination and provide an additional parameter that, together with THMs, better reflects the overall DBP load.

WHO guideline value derivation

While WHO has set GVs for individual HAAs (i.e. dichloroacetic acid and trichloroacetic acid), one approach that has been adopted by regulators is to treat them similarly to THMs as a group parameter. The US EPA, for example, established a pragmatic group parameter of 60 µg/L for five HAAs, but a better approach might be to use a value of 80 µg/L for nine representative substances (i.e. mono-, di- and trichloroacetic acid, mono- and dibromoacetic acid, bromochloroacetic acid, bromodichloroacetic acid, dibromochloroaetic aciid and tribromoacetic acid). A group value for HAAs of 80 µg/L would be achievable while providing a benchmark for the reduction of by-products formed by similar routes.

This is based on a pragmatic approach similar to that adopted by the EC for total THMs for which the value is 100 µg/L for four named substances but the THMs are usually present in greater concentrations. HAAs and THMs together represent a way of controlling the large range of different disinfection by-products without disinfection being compromised.

Control

The primary approach to controlling DBPs is to remove the precursor substances in drinking-water treatment, i.e. by installing or optimizing coagulation or by controlling the pH during chlorination. The WHO Guidelines and the Directive emphasize that disinfection should not be compromised in attempting to control DBPs.

Monitoring

HAAs are a by-product of treatment processes and therefore should be monitored in final treated water.

Analysis

The five most common HAAs can be detected by GC coupled with electron capture detectors or MS after LLE and derivatization with diazomethane, as per ISO 23631:2006. The LOQs vary between 0.05 and 0.5 µg/L.

WHO background documents

WHO (2003). Trichloroacetic acid in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/trichloroaceticacid.pdf (accessed on 22 March 2017).

WHO (2004). Brominated acetic acids in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/brominatedaceticacids.pdf (accessed on 22 March 2017).

WHO (2005). Dichloroacetic acid in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/dichloroaceticacid0505.pdf (accessed on 22 March 2017).

Lead

It is recommended to retain the current Directive PV of 10 µg/L.

Lead requires to be monitored at the tap but sampling needs to be designed to take into account variation in concentrations.

It is recommended that Member States should be required to take steps to minimise lead as low as possible and to establish programmes for removing existing lead pipes.

WHO guideline value and Directive parametric value

The WHO GV is 10 µg/L as is the Directive PV. The WHO GV is considered provisional as there is no discernible threshold.

Standard values in selected countries are shown in the following:

Country	Value (µg/L)
Australia	10
Canada	10
Japan	10
USA	15

Source and pathways to drinking-water

Lead is rarely present in tap water as a result of its dissolution from natural sources. It is primarily found in drinking-water as a consequence of lead service connections and lead plumbing with a contribution from old high-lead joint solder, leaded brass fixtures and copper alloy fittings, which also contain lead to improve milling characteristics. Lead concentrations vary from property to property and at different times of the day, reflecting the period that the water is in contact with the lead and also temperature. The amount of lead dissolved from the plumbing system also depends on pH and alkalinity, with soft, acidic water being the most plumbosolvent.

Occurrence in drinking-water in the EU

According to the EU synthesis report on drinking-water quality for the period 2011-2013, the average compliance rate for lead was 99.73% but compliance will depend on the status of individual buildings and the time over which the water in the sample has been in contact with lead pipe, solder or lead containing alloy fittings.

Evidence for risk to health

Infants and children are considered to be the most sensitive subgroups of the population. Lead is known to cause neurological effects in children, which are quite subtle at low blood lead levels, and also to increase systolic blood pressure in adults with the same caveats as with neurological effects.

WHO guideline value derivation

The WHO GV was previously based on a JECFA PTWI, which has been withdrawn, and no new PTWI has been established on the basis that there does not appear to be a discernible threshold for lead toxicity. The WHO GV is maintained at 10 µg/L but is designated as provisional on the basis of which would be achievable in systems with existing lead pipes. In Europe, average blood lead levels in children have fallen dramatically since a number of environmental sources of lead were removed, particularly lead in petrol. Blood lead levels in children in most developed countries are now much lower at 2 µg/dL of blood compared to around 10 µg/dL or more 20 years ago, prior to the ban. The actual impact of declining blood lead levels is less certain and the contribution from water is likely to be relatively small. As the WHO GV is no longer health-based, concentrations should be maintained as low as reasonably practical. It is recommended that consideration should be given to requiring Member States to submit and institute action plans for removal of existing lead plumbing within five years following the adoption of the Directive with the objective of meeting a target value of 5 µg/L after a suitable period, taking into account the difficulties of achieving lead pipe removal.

Control

Most lead in drinking-water arises from lead service connections and plumbing in buildings and the remedy consists principally of removing service connections, plumbing and fittings containing lead. Complete lead pipe replacement will be very expensive and very disruptive for consumers but it remains the only long term solution. It is recognized that not all water will meet the WHO GV or Directive PV immediately; meanwhile, all other practical measures to reduce total exposure to lead, including corrosion control, should be implemented. Lead can be controlled by dosing orthophosphate into the treated water but it is difficult to achieve concentrations lower than the current standard of 10 µg/L without extensive removal of lead pipe, including plumbing in older houses. In new installations or repairs, lead-free service connections and solder and low lead alloy fittings should be used to prevent the introduction of contamination. In places where lead service connections and plumbing in buildings are in place, flushing taps before using the water is an important option.

Monitoring

Since lead arises almost exclusively from lead in domestic plumbing, it should be monitored at the tap. The sampling protocol adopted (e.g. first draw, random daytime sampling or flushed) will depend on the objective of taking the samples, and need to reflect the variation in concentration with the period of contact with lead-containing materials.

Analysis

The elemental analysis of lead is based on ICP-MS as per ISO 17294-2:2016. The LOQ is 0.1 µg/L.

WHO background document

WHO (2011). Lead in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: www.who.int/water_sanitation_health/dwq/chemicals/lead.pdf (accessed on 22 March 2017).

Microcystin-LR

New parameter: It is recommended to adopt a Directive PV of 1 µg/L.

Member States should make every effort to minimise the risk of cyanobacterial blooms in source waters and if this is not possible to ensure that treatment is capable of removing toxins.

WHO guideline value and Directive parametric value

The WHO GV for microcystin-LR is 1 µg/L. The Directive does not cover microcystin-LR.

Standard values in selected countries are shown in the following:

Country	Value (µg/L)
Australia	1.3
Canada	No value assigned
Japan	0.8[a]
USA	No value assigned

[a] From category "items for further study". They include items whose toxicities have not yet been determined, or where concentrations in drinking-water are not clear.

Source and pathways to drinking-water

Microcystins are a group of naturally occurring substances that are released from blooms of cyanobacteria and are, therefore, present intermittently in slow flowing or still surface waters. Microcystins are not the only toxic substances that can be released by such blooms, although they are arguably the most common at this time. Other cyanotoxins include cylindrospermopsins, saxitoxins, anatoxin-a and anatoxin-a(s). Demonstrating that microcystins are not present does not guarantee the absence of other toxins or that a bloom will not change from non-toxin-producing to toxin-producing. High levels of microcystins are found in the cells of microcystin-producing cyanobacteria and are released when the cells are disrupted. Concentrations in raw water are very low except when blooms are present. Among the more than 80 microcystins identified to date, only a few occur frequently and in high concentrations. Microcystin-LR is among the most frequently occurring and most toxic microcystin congeners.

Occurrence in drinking-water in the EU

Since microcystin-LR is currently not listed in Annex I of the Directive, there is no data on compliance. Concentrations from drinking-water in the USA and Canada rarely exceeded 1 µg/L but on occasion concentrations of up to 10 µg/L have been seen. In Europe, concentrations of microcystin-LR in reservoir water in excess of 10–70 µg/L have been observed, although concentrations are more frequently below 10 µg/L. Concentrations in drinking-water with granular activated carbon as a treatment would be expected to be below the PV. However, concentrations in source water in blooms can be many hundreds of

micrograms per litre. The potential for contamination exists and some Member States have included microcystin-LR in their own drinking-water standards.

Evidence for risk to health

Microcystins are potent hepatotoxins and there is evidence for tumour promotion. Other algae derived toxins are also hepatotoxins and some are neurotoxic. The evidence for adverse effects in humans from drinking-water is limited, certainly in Europe where increasingly there are good standards in water treatment and lake and reservoir management to prevent blooms.

WHO guideline value derivation

WHO has developed a GV of 1.0 μg/L for microcystin-LR, which is believed to be the most toxic variant, but not for other toxins. The WHO GV is provisional, as it covers only microcystin-LR. The database is limited and new data for the toxicity of cyanobacterial toxins are being generated and considered by WHO.

Control

Actions to decrease the probability of bloom occurrence include catchment and source water management, such as reducing nutrient loading or changing reservoir stratification and mixing. If blooms cannot be prevented, management options include adjusting the depth of intakes at which water is abstracted and establishing treatment processes that will remove the toxins. Treatment effective for the removal of cyanobacteria includes filtration to remove intact cells. Treatment effective against free microcystins in water (as well as most other free cyanotoxins) includes oxidation through ozone or chlorine at sufficient concentrations and contact times, as well as granular activated carbon and some powdered activated carbon applications. The removal techniques suitable for microcystins also appear to be suitable for other toxins such as cylindrospermopsin.

Monitoring

The preferred approach is visual monitoring (including microscopy for potentially microcystin-containing genera) of source water for evidence of increasing cyanobacterial cell density (blooms) or bloom-forming potential and increased vigilance where such events occur.

Routine monitoring for microcystin in drinking-water is not the best way of managing the problem of toxins, which will only be present intermittently during algal blooms. The standard provides a benchmark for ensuring that treatment processes are adequate to prevent significant levels reaching consumers if blooms cannot be adequately managed in source waters.

Analysis

The ISO 20179:2005 provides the analytical procedure for the analysis of three compounds (microcystin-LR, -RR and -YR) by HPLC-separation and quantification by UV/photo diode array after SPE. The ISO standard also provides the confirmation of the results by using MS. The pursued instrumental LOD of the HPLC-UV/photo diode array in the ISO is ≤ 0.1 mg/L.

Considering the provided concentration factor of 1000 by SPE, a LOD of ≤ 0.1 µg/L can be achieved.

WHO background documents

Chorus I, Bartram J (eds.) (1999). Toxic cyanobacteria in water: A guide to their public health consequences, monitoring and management. London: E & FN Spon. Available at: http://www.who.int/water_sanitation_health/resourcesquality/toxcyanbegin.pdf (accessed on 24 June 2017).

WHO (2003): Cyanobacterial toxins: Microcystin-LR in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/cyanobactoxins.pdf (accessed on 16 May 2017).

Nickel

It is recommended to retain the current Directive PV of 20 µg/L.

The WHO GV is currently under revision. Although the probable GV will be lower, the current Directive PV seems to be achievable in the EU.

Nickel requires to be monitored at the tap but sampling needs to be designed to take into account variation in concentrations.

WHO guideline value and Directive parametric value

The WHO GV is 70 µg/L (under revision) and the Directive PV 20 µg/L. WHO uses data from humans for deriving the GV whereas the PV is based on data obtained from rats.

Standard values in selected countries are shown in the following:

Country	Value (µg/L)
Australia	20
Canada	No value assigned
Japan	20[a]
USA	No value assigned

[a] Target value.

Source and pathways to drinking-water

Nickel does occasionally naturally arise in source water from nickel baring rocks, usually from oxidation in aquifers, and traces arise from stainless steel but the main source seems to be chromium-plated taps which have a base layer of nickel on to which the chromium is plated. In such circumstances, the volume of high nickel water is therefore small and will be rapidly flushed when the tap is turned on and exposure will be very small.

Occurrence in drinking-water in the EU

According to the EU synthesis report on drinking-water quality for the period 2011-2013, the average compliance rate for nickel was 99.66%.

Evidence for risk to health

Nickel can cause a number of adverse effects at high exposures, such as those usually encountered in occupational settings. The main concern from environmental exposure is the potential to elicit skin reactions (allergic eczema) in individuals who are sensitized to nickel, primarily through jewellery.

WHO guideline value derivation

The WHO GV is 70 µg/L based on a study in women who were allergic to nickel challenged by a large single dose in drinking-water. EFSA has recently evaluated nickel (2015) and has

proposed a much lower value than the WHO GV. WHO is re-evaluating nickel at the present time. The EFSA evaluation is conservative but would lead to a GV of about 20 µg/L, which is the same as the current Directive PV.

Control

A concentration of 20 µg/L should be achievable by conventional treatment (e.g. coagulation). Where naturally occurring nickel is mobilized in groundwater, removal can be achieved by ion exchange or adsorption. Where nickel leaches from alloys in contact with drinking-water or from chromium- or nickel-plated taps, primary control would be by product specification and approval and, at the consumer's point of consumption, by flushing taps before using the water.

Monitoring

As nickel is primarily introduced into drinking-water by the plumbing system, it should be monitored at the tap. An appropriate sampling protocol should be developed to take into account the variation in concentrations associated with the variable contact period of water with the plumbing material. Where it is present in source water sampling should be immediately post-treatment.

Analysis

The elemental analysis of nickel is based on ICP-MS as per ISO 17294-2:2016. The LOQ is 0.1 µg/L.

WHO background document

WHO (2005). Nickel in drinking-water. Background document for development of WHO Guidelines for Available at: http://www.who.int/water_sanitation_health/gdwqrevision /nickel2005.pdf (accessed on 22 March 2017) (under revision).

Nitrate and nitrite

It is recommended to retain the current Directive PVs for nitrate of 50 mg/L.

It is recommended to retain the Directive PV for nitrite of 0.5 mg/L post-treatment and 0.1 mg/L in distribution where chloramination is practiced.

It is recommended to retain the formula concentration of nitrate/50 + concentration of nitrite/3 ≤ 1.

WHO guideline value and Directive parametric value

The WHO GV is 50 mg/L for nitrate and 3 mg/L for nitrite; the sum of the ratios of the concentrations of each of nitrate and nitrite to its GV should not exceed 1. The Directive PVs are 50 mg/L for nitrate and 0.5 mg/L and 0.1 mg/L for nitrite post-treatment and in distribution, respectively, but the same formula is applied.

Standard values in selected countries are shown in the following:

Country	Value (mg/L)
Australia	50 (nitrate) and 3 (nitrite)
Canada	45 (nitrate) and 3 (nitrite)
Japan	10 (nitrate and nitrite)[a]
USA	10 (nitrate) and 1 (nitrite)[a]

[a] Measured as nitrogen: equals 45.7 mg/L and 3.3 mg/L for nitrate and nitrite, respectively.

Source and pathways to drinking-water

Nitrate is commonly found in surface and groundwater where it is mostly present primarily as a consequence of agricultural activity, specifically through excess application of inorganic nitrogenous fertilizers and manures. Wastewater (treated sewage) can also be an important contributor; poorly operated septic tanks can be an issue for small groundwater supplies. When nitrate is released from agricultural land it will depend on the nature of the geology of the aquifer as to how quickly the nitrate will reach the water.

Nitrite is normally found only in anaerobic waters but is formed in small amounts in distribution systems if ammonia is present, such as when chloramine is added to provide a residual disinfectant.

Occurrence in drinking-water in the EU

According to the EU synthesis report on drinking-water quality for the period 2011-2013, the average compliance rate for nitrate was 99.92% and for nitrite 99.66%. In several Member States nitrate concentrations in groundwater are elevated. In Germany, for example, 28% of measurements during 2012–2014 were above the Directive PV (BMUB & BMEL, 2017). Concentrations in some groundwaters can continue to increase because of the time taken for nitrate in the ground to reach groundwater from the surface even when inputs have been reduced. Under these circumstances it will be increasingly difficult to meet the

Directive PV without treatment. The natural occurrence of nitrate in water bodies will depend on the environment of the water body but levels of 2-3 mg is considered to be a level that could be naturally occurring with no anthropogenic activity. In upland regions the levels are likely to be lower.

Evidence for risk to health

The primary concern regarding adverse health effects for nitrate and nitrite, which have similar modes of action, has been the formation of methaemoglobin in bottle-fed infants. This is now quite rare although it can be seen in some Member States as a consequence of very high levels of contamination in small rural supplies. The body of evidence does not support the contention that nitrate or nitrite in drinking-water is a cause of gastrointestinal or other cancers. There remain some questions as to whether high nitrate levels could contribute to thyroid disease by blocking iodine uptake but the current standards seem to be reasonably protective.

WHO guideline value derivation

WHO has recently reviewed the data but has retained its original GVs on the basis that the data do not justify any change. The WHO GV for nitrate is to be protective against methaemoglobinaemia and thyroid effects in the most sensitive subpopulation, bottle-fed infants, and, consequently, other population subgroups. The WHO GV for nitrite is to be protective against methaemoglobinaemia induced by nitrite from both endogenous and exogenous sources in bottle-fed infants, the most sensitive subpopulation, and, consequently, the general population. The extent of childhood methaemoglobin formation due to nitrate has been challenged because methaemoglobin is formed in cases of infantile diarrhoea without the input of extraneous nitrate or nitrite. This implies that the current standard is sufficiently protective.

Control

Good management practices in agriculture and sanitation are primary controls to prevent contamination of source waters.

For nitrate, effective central treatment technologies involve the physical/chemical and biological removal of nitrate and include ion exchange, reverse osmosis and biological denitrification, which are capable of removing over 80% of nitrate from water to achieve effluent nitrate concentrations as low as 13 mg/l; conventional treatment processes (coagulation, sedimentation, filtration and chlorination) are not effective. For nitrite, *t*reatment usually focuses on nitrate, because nitrite is readily converted to nitrate by many disinfectants. Water systems that practice chloramination should be managed in order to minimize nitrite formation in distribution.

Methaemoglobinaemia is complicated by the presence of microbial contamination and subsequent gastrointestinal infection, which can increase the risk for bottle-fed infants significantly. Authorities should therefore be all the more vigilant that water to be used for bottle-fed infants is microbiologically safe when nitrate is present at concentrations near or above the WHO GV.

Monitoring

Both substances can be monitored at water works in final water. Where chloramination is used to provide a residual disinfectant, close and regular monitoring of disinfectant and nitrite levels in distribution is recommended.

Analysis

The combined analysis of nitrite and nitrate can be effectively achieved by ion chromatography as per ISO 10304-1:2007. Improved LOQs may be achieved by using manual and automated photometric methods for nitrate and nitrite analysis as per ISO 13395:1996. The LOQs for nitrate and nitrite are 0.5 and 0.1 mg/L, respectively.

WHO background document

WHO (2011). Nitrate and nitrite in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/nitratenitrite2ndadd.pdf (accessed on 22 March 2017).

Perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA)

New parameters: It is recommended to adopt Directive PVs for PFOS of 0.4 µg/L and for PFOA of 4 µg/L.

Where both substances are present it would be possible to take a pragmatic view in order to account for the mixture by applying the formula concentration of PFOS/0.4 + concentration of PFOA/4 ≤ 1.

WHO GVs are currently under preparation.

WHO guideline value and Directive parametric value

Currently there is neither a WHO GV nor a Directive PV for PFOA and PFOS, however, WHO GVs are in preparation.

Standard values in selected countries are shown in the following:

Country	Value (mg/L)
Australia	No regulatory values assigned
Canada	No regulatory values assigned
Japan	No regulatory values assigned
USA	No regulatory values assigned

Several countries have proposed non-statutory advisory values of around 0.1 µg/L or less. These provide a trigger for taking further action, often preventing further contamination. Health Canada, for example, has proposed screening values for nine PFCs, including PFOS and PFOA, that range from 0.2 to 30 µg/L. The US EPA has established non-enforceable health advisory levels for PFOA and PFOS of 0.07 µg/L. The German Environment Agency has established non-statutory health-based values of 0.1 µg/L for both PFOA and PFOS. The Institute of Health in Italy has developed values of ≤ 0.03 µg/L for PFOS, ≤0.05 µg/L for PFOA and ≤0.5 µg/L for ten other PFCs based on the basis of as low as technically achievable but not health. These values are to be applied locally in one affected region and can be potentially applied elsewhere.

Source and pathways to drinking-water

PFCs of which PFOS and PFOA are usually the most common, are found in groundwater primarily as a consequence of contamination of soil by fire-fighting foams, which break down to these and some other perfluorinated substances. Groundwater is of the greatest concern because of the persistence of these substances. There is also evidence that discharges from industry are still occurring in some Member States. There is a likelihood of more widespread low levels in surface waters impacted by wastewater discharges. PFOS and PFOA appear to be primarily localized near some airports and sites where foams have been used or manufacturing has taken place. A range of other PFCs can also be found but data still remain relatively limited. The problem with PFOS and PFOA has been recognized and the manufacture of the PFCs is ceasing and fire-fighting foams have been replaced by other

alternatives. PFOS is now prohibited in the EU under Directive 2006/122/EC that came into force in June 2008. Both PFOS and PFOA have been phased out by major manufacturers. The problem should soon be associated only with historical pollution. While newer substances that are less persistent are being proposed, these should be prevented from causing the same problems by the extensive regulation of chemicals in place within the EU.

Occurrence in drinking-water in the EU

Since PFOA and PFOS are currently not listed in Annex I to the Directive, there is no data on compliance. According to data requested from Member States in 2016, maximum values of 11.5 µg/L for PFOA and 0.41 µg/L for PFOS were reported. Extensive investigative monitoring programmes were established in areas which experienced widespread contamination events, as for example in Germany and Italy. In the German state of North Rhine-Westphalia, for example, more than 5,400 water samples of surface water used for drinking-water production were analyzed for PFOS and PFOA between 2006 and 2010. In about 77% of the samples the concentration of both chemicals was below 0.3 µg/L; in about 55% of the samples the concentration of all ten perfluorinated substances analyzed was below 0.1 µg/L (NRW, 2012).

When PFOS and PFOA are found they are usually the dominant species of PFCs but there is a wider range of substances with varying chain lengths that may be present usually at lower concentrations. These can include the perfluoroalkyl carboxylic acids (including PFOA), perfluoroalkane sulfonic acids (including PFOS), perfluoroalkane sulfinic acids, fluorotelomer alcohols and perfluoroalkane sulphonamides. Data on occurrence of the wider group of substances is limited but the database is increasing.

Evidence for risk to health

These substances are unusual in that they are persistent and water soluble. They are of concern because of the long time taken to eliminate them from the body, their potential to damage the liver and as potential human reproductive toxicants.

Currently while there are studies in laboratory animals that suggest possible health effects at relatively low doses, the data from epidemiology on occupationally exposed populations do not identify adverse health effects. The fact that the substances are so widespread and persistent is of concern. Although drinking-water does not seem to generally be an important source of exposure, where there are incidents of higher levels of contamination, drinking-water could be a much more significant contributor to exposure. Setting PVs for PFOS and PFOA would not only raise awareness but it would help Member States to take more preventative steps.

Although there is a wider range of substances with varying chain lengths, there are much more limited data on the toxicology. These include five perfluoroalkane sulfonic acids (including PFOS) and 15 pefluoroalkyl carboxylic acids (including PFOA) along with a number of other related compounds. There is controversy over potential standards with a wide range presented, although the most conservative are non-statutory guidelines which are advisory in nature.

While there are issues over the presence of mixtures it would be potentially appropriate to consider the two groupings of perfluoroalkyl sulfonic acids and perfluoroalkyl carboxylic

acids separately due to differences in toxicity. It is difficult to propose health-based values that would constitute statutory standards at this time.

WHO guideline value derivation

WHO is currently developing GVs for both substances. Based on the TDI for PFOS of 0.15 µg/kg body weight developed by EFSA (2008), for a 60 kg adult and allowing 10% of the TDI from water gives a GV of 0.4 µg/L, and for PFOA a GV of 4.0 µg/L (i.e. ten times higher). These values require final confirmation by WHO.

Control

Conventional treatment is not effective for PFOA and PFOS removal. Granular activated carbon adsorption is effective; however, proper operation of the system is essential to ensure that the performance is not affected by the presence of natural organic matter in the source water. Membrane filtration techniques (reverse osmosis and nanofiltration) and anion exchange may also be effective.

Monitoring

PFOS and PFOA are present in raw water and thus should be monitored in final water at water works.

Analysis

For analysis of PFOS and PFOA, HPLC-MS/MS after SPE are applicable, as per ISO 25101:2009, for the determination of concentrations ≥2 ng/L for PFOS and ≥10 ng/L for PFOA.

WHO background document

As yet, there is no background document available.

Pesticides

The WHO Guidelines consider pesticides based upon individual toxicity. A number of these are covered in the Guidelines and in the relevant list of background documents which are available at: http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/en/ (accessed on 30 June 2017).

WHO is no longer setting formal guideline values for drinking-water to discourage inappropriate inclusion of long lists of pesticides in national standards. However, health-based values are being determined to provide guidance on safe levels.

While WHO cannot comment on precautionary values, which are a matter for WHO Member States, since these include considerations that are specific to those states, it is important to control pesticides in drinking-water just as any other anthropogenic chemical contaminant. In the current Directive there are lower values than the PV for aldrin, dieldrin, heptachlor and heptachlor epoxide. These were based on GVs in the second edition of the WHO Guidelines when exposure in the environment was much higher and taking into account accumulation in fatty food. The allocation of the TDI to drinking-water was 1% but exposure from food and other sources has fallen significantly in the EU and including these in the general provision for any pesticide would be appropriate, particularly as they very hydrophobic.

The term “relevant metabolites“ has caused some confusion. It would seem that “relevance” should be defined as where the metabolite retains pesticidal activity and where it also retains significant toxicity.

Selenium

It is recommended to adopt a new Directive PV of 40 µg/L.

WHO guideline value and Directive parametric value

The WHO GV is 40 µg/L and the current Directive PV 10 µg/L. The WHO GV is based on updated data on occurrence and new assessment of quality of epidemiologic studies.

Standard values in selected countries are shown in the following:

Country	Value (µg/L)
Australia	10
Canada	50
Japan	10
USA	50

Source and pathways to drinking-water

Selenium does occur naturally in some groundwater sources in areas with seleniferous rocks. In Europe this seems to be a rather localized phenomenon.

Occurrence in drinking-water in the EU

According to the EU synthesis report on drinking-water quality for the period 2011-2013, the average compliance rate for selenium was 99.83%. According to data requested from Member States in 2016, nine countries reported localized exceedances of the current Directive PV with the highest maximum value of 38 µg/L and the highest median value of 1 µg/L.

Evidence for risk to health

Selenium is an essential element for humans. In Europe the relative contribution of selenium from drinking-water is likely to be small even in seleniferous areas. The greatest concern that has been raised for Europe is areas of low selenium intake. High selenium can cause a number of adverse health effects. Clinical signs of selenosis include hair or nail loss, nail abnormalities, mottled teeth, skin lesions and peripheral neuropathy, but these seem to be strongly influenced by a number of additional factors, including overall health and nutritional status.

WHO guideline value derivation

The provisional WHO GV is 40 µg/L based on an allocation of 20% of the upper tolerable intake. The GV is designated as provisional because of the uncertainties inherent in the scientific database.

Control

Selenium is not removed by conventional treatment processes; significant removals of selenium from water using activated alumina adsorption, ion exchange, reverse osmosis and nanofiltration have been reported.

A possible solution is to use alternative sources of water that are low in selenium to blend with higher-selenium sources to lower the concentration to acceptable levels. However, it is important that this does not result in risk substitution—for example, if the alternative water source, although low in selenium, increases exposure to waterborne pathogens and results in acute gastrointestinal infections.

Monitoring

As selenium is naturally occurring it can be monitored at water works in final water.

Analysis

The elemental analysis of selenium is based on ICP-MS as per ISO 17294-2:2016. The LOQ is 0.1 µg/L.

WHO background document

WHO (2011). Selenium in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/selenium.pdf (accessed on 22 March 2017).

Tetrachloroethene and trichloroethene

It is recommended to retain the current Directive PV of 10 µg/L for the combined total of tetrachoroethene and trichloroethene.

The WHO GVs are currently under revision.

WHO guideline value and Directive parametric value

The WHO GVs are 40 µg/L for tetrachlorothene and 20 µg/L for trichloroethene (both under revision). The Directive PV is 10 µg/L as a sum for both substances. The difference is due to the fact that the PV was based on precautionary considerations whereas the WHO GVs are based on a threshold approach but considered provisional because of uncertainties.

Standard values in selected countries are shown in the following:

Country	Value (µg/L)
Australia	50 (tetrachlorothene) and none assigned (trichloroethene)
Canada	10 (tetrachlorothene) and 5 (trichloroethene)
Japan	10 each
USA	5 each

Source and pathways to drinking-water

Tetra- and trichloroethene are sometimes found in groundwater as a consequence of historical pollution, usually related to poor handling and disposal of solvents in industrial settings and commercial dry cleaning. They are not found in surface water as they rapidly volatilize to atmosphere.

Occurrence in drinking-water in the EU

According to the EU synthesis report on drinking-water quality for the period 2011-2013, the overall compliance rate for tetra- and trichloroethene was 99.94%. According to data requested from Member States in 2016, five countries reported exceedances of the Directive PV with a maximum value of 46 µg/L. In a number of cases it is known that concentrations in groundwater exceed the Directive PV but treatment has been installed to remove contamination. Contamination should be largely historical if the WFD and the Groundwater Directive are being effectively implemented.

Evidence for risk to health

Both tetra- and trichloroethene have been shown to cause adverse health effects in humans in industrial settings, including hepatotoxic effects. Although there have been a number of epidemiological studies relating to water contamination in the USA, there remains no convincing evidence of adverse health effects in humans through drinking-water.

WHO guideline value derivation

WHO is currently revising the GVs for tetra- and trichloroethene for which the mechanism of toxicity is different. The GV for tetrachloroethene was derived based on hepatotoxicity in laboratory animal studies with 10% of the TDI allocated to drinking-water. The GV for trichloroethene was based on developmental toxicity in laboratory animals with 50% of the TDI allocated to drinking-water. The Directive PV of 10 µg/L for the two combined is based on concerns over groundwater contamination and is to a significant extent a statement about protecting groundwater. However, the PV is in line with standards in a number of other countries.

Control

Concentrations of 1 µg/L for tetrachloroethene and 2 µg/l for trichloroethene should be achievable using air stripping, possibly in combination with granular activated carbon adsorption.

Monitoring

Both substances are of anthropogenic origin and introduced into the raw water, they can be monitored at water works in final water. They are not found in surface water because they are rapidly lost to atmosphere, so risk-based monitoring would only relate to vulnerable groundwater sources.

Analysis

Tetra- and trichloroethene can be analyzed together with sufficient sensitivity by GC as per ISO 10301:1997. The LOQ is 0.1 µg/L.

WHO background documents

WHO (2003). Tetrachloroethene in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/tetrachloroethene.pdf (accessed on 22 March 2017) (under revision).

WHO (2005). Trichloroethene in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/trichloroethene/en (accessed on 22 March 2017) (under revision).

Trihalomethanes

It is recommended to retain the current Directive PV of 100 µg/L for the total of chloroform, bromodichloromethane, dibromochloromethane and bromoform.

WHO guideline value and Directive parametric value

For the four THMs covered in the Directive, WHO has set individual GVs: bromoform (100 µg/L), bromodichloromethane (60 µg/L), chloroform (300 µg/L) and dibromochloromethane (100 µg/L) individually. The Directive PV of 100 µg/L is the sum for all four substances.

Standard values in selected countries are shown in the following:

Country	Value (µg/L)
Australia	250 (sum)
Canada	100 (sum)
Japan	100 (sum)
USA	80 (sum)

Source and pathways to drinking-water

THMs are chlorination by-products and are used as indicators of the wider level of chlorination by-products. They are formed by the reaction of free chlorine with natural organic matter such as humic acids. The rate and degree of THM formation increase as a function of the chlorine and humic acid concentration, temperature, pH and bromide ion concentration. Chloroform is the most common THM and the principal DBP in chlorinated drinking-water. In the presence of bromides, brominated THMs are formed preferentially, and chloroform concentrations decrease proportionally. It is assumed that most THMs present in water are ultimately transferred to air as a result of their volatility.

Occurrence in drinking-water in the EU

According to the EU synthesis report on drinking-water quality for the period 2011-2013, the overall compliance rate for THMs was 99.73%.

Evidence for risk to health

While the evidence for direct adverse effects of the four THMs specified in the Directive, and for which GVs were developed by WHO, is limited, these are primarily used as an indicator of the overall quantity of chlorination by-products present.

There is fairly consistent evidence that there is an association between THMs and bladder cancer in non-smokers but the weight of evidence is insufficient to infer causality, in spite of many tens of studies in different parts of the world. In addition, THMs are not a reliable marker for all possible DBPs. More recently, a study in laboratory animals in the USA administering bromodichloromethane in drinking-water did not show any sign of

carcinogenicity, although this was not the case in earlier studies when bromodichloromethane was dosed by gavage in corn oil. In spite of the limited evidence for actual adverse effects on public health of DBPs and the substantial need to balance the benefits of chlorination, it is prudent to try and limit the levels of DBPs in drinking-water as far as is reasonable by removing the natural organic precursors.

WHO guideline value derivation

WHO has developed GVs for bromoform, bromodichloromethane, chloroform and dibromochloromethane, based on adverse effects in laboratory animals, primarily toxicity to the liver and kidneys. The Directive PV is based on the aim of reducing chlorination by-products. The Directive PV of 100 µg/L for the aforementioned THMs is a practical and precautionary but reasonable value to encourage management of chlorination to minimise all chlorination by-products which is similar to standards for THMs in other countries.

Control

The primary approach to controlling DBPs is to remove the precursor substances in drinking-water treatment, i.e. by installing or optimizing coagulation or by controlling the pH during chlorination. The WHO Guidelines and the Directive emphasize that disinfection should not be compromised in attempting to control DBPs.

Monitoring

Since THMs can also develop in the plumbing system, monitoring has to be performed at tap.

Analysis

THMs can be analyzed by purge-and-trap and LLE and direct aqueous injection in combination with GC**.** The LOQ is 0.1–0.2 µg/L.

WHO background document

WHO (2005). Trihalomethans in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/THM200605.pdf (accessed on 22 March 2017).

Uranium

New parameter: It is recommended to adopt a Directive PV of 30 µg/L.

WHO guideline value and Directive parametric value

The WHO GV is 30 µg/L; currently uranium is not listed in Annex I of the Directive.

Standard values in selected countries are shown in the following:

Country	Value (µg/L)
Australia	17
Canada	20
Japan	2.0[a]
USA	30

[a] From category "Complementary items to set targets for water quality management". Items in this category do not need to be included in the standards because of the low detection levels or provisional evidence of toxicity.

Source and pathways to drinking-water

Uranium is found naturally in some but not all groundwater across the EU as a result of leaching from natural deposits but can also be released in mill tailings from uranium mining and processing and from the use of some phosphate fertilizers that contain uranium as a contaminant. Uranium in drinking-water appears primarily an issue for smaller supplies.

Occurrence in drinking-water in the EU

Since uranium is currently not listed in Annex I of the Directive, there is no data on compliance. The extent to which uranium is of significance in Member States is uncertain, although Ireland, Finland and Germany at least, do have a number of affected supplies in which significant concentrations can be found. According to data requested from Member States in 2016, several countries reported exceedances of the WHO GV with a maximum value of 160 µg/L, but a highest medium value of 18 µg/L.

Evidence for risk to health

There is evidence from animal studies that uranium can cause kidney damage but epidemiological studies support the view that humans are less susceptible than laboratory animals.

WHO guideline value derivation

The WHO GV of 30 µg/L is based on a meta-analysis of epidemiological studies and is probably very conservative. The GV is designated as provisional because of scientific uncertainties surrounding uranium toxicity. The GV based on chemical toxicity is below the concentration that would be of concern for radioactivity from natural uranium. The data show that there is no significantly increased risk of radiation induced cancers from levels of

natural uranium found in drinking-water. The GV of 30 µg/L would provide significant protection against radioactivity and would not exceed the screening value for alpha particles assuming the only source was natural uranium.

Radioactivity in drinking-water in the EU is controlled by Council Directive 2013/51/Euratom of 22 October 2013. The standards are based on an indicative dose of 0.10 mSv, which is the same value as that in the WHO Guidelines and represents a very low level of risk that is not expected to give rise to any detectable adverse effects. This is monitored by screening for gross alpha and gross beta particles with screening values of 0.1 Bq/L for gross alpha (WHO: 0.5 Bq/L) and 1.0 Bq/L for gross beta. If these screening values are not exceeded the indicative dose will not be exceeded. If they are exceeded then there is a requirement to carry out more detailed analysis to identify the radionuclides present (e.g. natural uranium, uranium-238) to determine whether the dose is still below the indicative dose as the different radionuclides also differ in the radiation dose they deliver. Natural uranium is 95% uranium-238 and delivers a very low radiation dose.

Control

A concentration of 1 µg/L should be achievable using conventional treatment (e.g. coagulation or ion exchange) although this is not normally applied to groundwater, which may not be suitable for coagulation.

A possible solution is to use alternative sources of water that are low in uranium to blend with higher-uranium sources to lower the concentration to acceptable levels. However, it is important that this does not result in risk substitution, for example, if the alternative water source, although low in uranium, increases exposure to waterborne pathogens and results in acute gastrointestinal infections.

Monitoring

As raw water is the source for uranium, it can thus be monitored in final water at water works.

Analysis

The elemental analysis of uranium is based on ICP-MS as per ISO 17294-2:2016. The LOQ is 0.1 µg/L.

WHO background document

WHO (2012). Uranium in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/publications/2012/background_uranium.pdf (accessed on 22 March 2017).

Vinyl chloride

It is recommended to retain the current Directive PV of 0.50 µg/L.

WHO guideline value and Directive parametric value

The WHO GV is 0.3 µg/L and the Directive PV is 0.5 µg/L. The GV was updated in 2004.

Standard values in selected countries are shown in the following:

Country	Value (µg/L)
Australia	0.3[a]
Canada	1
Japan	No value assigned
USA	2

[a] Limit of detection.

Source and pathways to drinking-water

The primary route by which vinyl chloride reaches drinking-water is as residual vinyl chloride monomer in PVC pipes that are not manufactured to modern standards. Vinyl chloride has also been detected as a breakdown product of some other small chlorinated solvents in groundwater, but there are few reports of it being found in groundwater at significant concentrations in Europe.

Occurrence in drinking-water in the EU

There is no data on the overall compliance for vinyl chloride in the EU synthesis report on drinking-water quality for the period 2011-2013. According to Annex III of the Directive, vinyl chloride does not need to be measured in drinking-water.

Evidence for risk to health

Vinyl chloride is a known occupational carcinogen by the inhalation route but at exposure levels vastly greater than encountered in drinking-water. As vinyl chloride is a known human carcinogen, exposure to this compound should be avoided as far as practicable, and levels should be kept as low as technically feasible.

WHO guideline value derivation

The WHO GV of 0.3 µg/L was established based on a linear extrapolation to determine the upper bound concentration associated with an increased cancer risk of 10^{-5} for liver cancers in laboratory animals.

Control

Vinyl chloride is primarily of concern as a potential contaminant from some grades of PVC pipe and is best controlled by product specification and approval. If vinyl chloride is present

in raw water, concentrations of 1 µg/l should be achievable using air stripping. The Directive PV should ensure that counties that do not have an approval process for materials and chemicals in contact with drinking-water make sure that any imported PVC pipe is of an adequate quality. It also provides a guide if vinyl chloride is found in groundwater.

Monitoring

Vinyl chloride is not monitored directly in drinking-water but is controlled by specifying the maximum level of residual vinyl chloride monomer in PVC pipes. This should be maintained by ensuring only approved products are used by water utilities. Where analytical methods are employed monitoring should be post-treatment.

Analysis

The recently approved ISO 17943:2016 describes the determination of 63 volatile and semi-volatile organic compounds in water, including vinyl chloride, by using headspace solid-phase micro-extraction followed by GC-MS. The LOQ is 0.01 µg/L.

WHO background document

WHO (2004). Vinyl chloride in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/vinylchloride.pdf (accessed on 22 March 2017).