World Health Organization

REGIONAL OFFICE FOR Europe

Revision of Annex I of the Council Directive on the Quality of Water Intended for Human Consumption (Drinking Water Directive)

Background paper on chemical and physical parameters

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Version

15 September 2016

Table of contents

1 Introduction

The Council Directive 98/83/EC on the Quality of Water Intended for Human Consumption, the Drinking Water Directive (DWD), was published in November 1998 and lists 26 chemicals or groups of chemicals in Annex I Part B and 15 chemical, physical or organoleptic parameters in Part C.

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 Organisation'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 published in 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 guideline values 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 is to be published in 2016. Information gathered on the occurrence and concentrations of the parameters in Parts B and C of Annex I indicates that there is a need to consider whether the parameters and parametric values in the Directive should be brought up to date.

2 Parametric values in the Drinking Water Directive and the WHO Guidelines for Drinking-water Quality

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 characterised differently between the Directive and the 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 European Commission's policy decision to regard a risk of 10^{-6} as acceptable in contrast to the WHO benchmark risk of 10^{-5}. The approach to calculating risk depends on mathematical models to extrapolate from the high doses used in laboratory animal studies. These models are designed to be conservative and usually do not take account of factors such as DNA repair and pharmacokinetics. The risk presented is the upper 95% confidence interval on the calculation. By contrast the risk associated with the lower 95% confidence interval is usually less than zero. This essentially means that the risk at 10^{-5} can be considered negligible. It is also theoretical and cannot be considered to be the number of cases that will occur. Since choosing a risk value of 10^{-6} will add to the costs of achieving the stated concentration, it is important to consider whether the minimal benefits that will be achieved justify maintaining this general policy rather than considering each substance according to its circumstances.

In other cases differences are based on practical decisions agreed by stakeholders and the Commission but there are also differences because of updates in the Guidelines. The differences are summarised in Table 1.

The Guidelines do encourage Member States not to merely copy guideline values into national standards but should 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. If regulators decide to choose a lower value than the guideline value it is important that this is made clear so that in the case of an exceedance, inappropriate actions can be avoided.

Table 1. Parametric values (PV) for chemical parameters in DWD Annex I Part B and WHO guideline values (GV)

Parameter	DWD PV	WHO GV	Date of WHO review	Difference between PV and WHO GV	Other comments
Acrylamide	0.1 μg/L	0.5 μg/L	2011	Difference due to capability of achieving lower value in Europe Cancer risk extrapolation	Should be regulated under product specifications but there is now an analytical method available
Antimony	5 μg/L	20 μg/L	2003	WHO GV updated based on new scientific data that reduced uncertainty Threshold	
Arsenic	10 μg/L	10 μg/L	2011	Practical achievability	WHO GV is designated provisional as it is based on practical considerations; a problem for small supplies in some countries
Benzene	1 μg/L	10 μg/L	1993	Difference in acceptable level of risk (EC: 10^{-6}; WHO: 10^{-5}) Cancer risk extrapolation	Rarely seen in drinking-water; water is a very minor source of exposure; air is the predominant source
Benzo(a)pyrene	0.01 μg/L	0.7 μg/L	1993	EU retained WHO GV from first edition of Guidelines for precaution; WHO GV based on 10^{-5} risk using an unusual risk model to reflect the unusual protocol of the toxicological study Cancer risk extrapolation	
Boron	1 mg/L	2.4 mg/L	2009	WHO GV updated with new scientific data Threshold	Issue for desalination

Parameter	DWD PV	WHO GV	Date of WHO review	Difference between PV and WHO GV	Other comments
Bromate	10 μg/L	10 μg/L	2005	Practical achievability	WHO GV designated provisional on the basis of uncertainties in the toxicological data; probable non-linear dose response so GV conservative
Cadmium	5 μg/L	3 μg/L	2011	Difference due to rounding Threshold	
Chromium	50 μg/L	50 μg/L	1993	Practical achievability	WHO GV designated provisional due to uncertainties in the toxicological data
Copper	2 mg/L	2 mg/L	2004	Threshold	WHO GV is an acute value
Cyanide	50 μg/L	GV withdrawn	2009	Threshold	WHO GV withdrawn because primarily found due to accidental spills; acute and chronic health-based values available
1,2-dichloroethane	3 μg/L	30 μg/L	2003	Difference in acceptable level of risk (EC: 10^{-6}; WHO: 10^{-5}) Cancer risk extrapolation	Rarely seen in drinking-water
Epichlorohydrin	0.1 μg/L	0.4 μg/L	1993	Difference due to capability of achieving lower value in Europe Threshold	WHO GV designated provisional due to uncertainties surrounding the toxicity; should be regulated under product specifications; may not survive in water
Fluoride	1.5 mg/L	1.5 mg/L	2004	Threshold	

Parameter	DWD PV	WHO GV	Date of WHO review	Difference between PV and WHO GV	Other comments
Lead	10 μg/L	10 μg/L	2011	Threshold	WHO GV designated provisional because JECFA has withdrawn the PTWI on grounds that there is no discernible threshold
Mercury	1 μg/L	6 μg/L	2004	WHO GV updated based on new scientific data Threshold	WHO GV relates to inorganic mercury
Nickel	20 μg/L	70 μg/L	2004	WHO GV updated based on new scientific data in humans Threshold	Exposure likely to be small because the volume of taps is small and will be flushed quickly
Nitrate	50 mg/L	50 mg/L	2011	Threshold	Under continuous review
Nitrite	0.5 mg/L	3 mg/L	2011	PV based on precautionary approach combined with practical achievability Threshold	Considered in conjunction with nitrate
Pesticides	0.1 μg/L(total pesticides 0.5 μg/L)	Individual guidelines and health-based values	-	N/A	Policy decision to cover each individual pesticide and relevant metabolites; WHO proposes individual health-based values
Heptachlor and heptachlor epoxide	0.03 μg/L	GV withdrawn	2004	N/A	WHO GV withdrawn because no findings of occurrence in drinking-water; original GV based on 1% of TDI but levels in food have significantly reduced

Parameter	DWD PV	WHO GV	Date of WHO review	Difference between PV and WHO GV	Other comments
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 and they could be covered by the 0.1 µg/L rule for pesticides (see above)
Pesticides total	0.5 µg/L	As for pesticides	-	N/A	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	GV withdrawn	-	N/A Practical value	PV is based on 1984 Guidelines and is not health-based; WHO GV was withdrawn in 1993 because it was not possible to set a health-based value for most PAHs and benzo(a)pyrene was considered to be most important; this was reviewed and confirmed in 1998
Selenium	10 µg/L	40 µg/L	2011	WHO GV updated based on new data on occurrence and assessment of the quality of epidemiological studies Threshold	Western Europe is being considered to be marginal in dietary selenium
Tetrachloroethene and trichloroethene	10 µg/L	40 µg/L 20 µg/L	1993	PV based on precautionary approach (political decision) WHO - threshold.	WHO GV for trichloroethene designated provisional on basis of uncertainties in toxicological and epidemiological data

Parameter	DWD PV	WHO GV	Date of WHO review	Difference between PV and WHO GV	Other comments
Trihalomethanes total: – Bromoform – Bromodichloromethane – Chloroform – Dibromochloromethane	100 µg/L	 100 µg/L 60 µg/L 300 µg/L 100 µg/L	1993 and chloroform 1998	PV based on practical approach to reduce chlorination by-products WHO - Threshold except dibromochloro – cancer risk extrapolation	
Vinyl chloride	0.5 µg/L	0.3 µg/L	2004	WHO GV was updated in 2004, in combination with difference in acceptable level of risk (EC: 10^{-6}; WHO: 10^{-5}) Cancer risk extrapolation	Should be regulated under product specifications for PVC pipe

General considerations in guideline value derivation

The values determined for substances which may be carcinogenic are mostly established by the application of mathematical models, usually the linearized multistage model (e.g. benzene, 1,2-dichloroethane, vinyl chloride). 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 tolerable daily intake (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*."

The risk is stated as an increased risk of one additional cancer per 100,000 population exposed to two litres of water per day, containing the contaminant at that concentration, for 70 years. However, this 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. Taking a more precautionary approach may not provide any greater protection but it will frequently increase the cost of control.

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 to derive an acceptable or tolerable daily intake (e.g. boron, cadmium, tri and tetrachloroethene). 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.

For the great majority of chemicals the Guidelines are based on long-term exposure. This means that short-term exceedances of the guideline value, or standard, 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 value or standard.

Food and environmental quality aspects

WHO emphasises 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 acceptable daily intake (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 (MRLs)) and migration limits for food packaging materials. For other environmental contaminants there are levels above which the product should not be sold, but this is based on individual products of which there are many, e.g. metals in shellfish.

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 drinking-water in the European Union (EU) with foods considered on an average exposure basis while drinking-water is interpreted as an absolute maximum in any sample. 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, legislation on contaminants in water bodies, which may be sources of drinking-water, is primarily aimed at protecting aquatic life. The development of standards to protect 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. In protecting aquatic or terrestrial ecosystems the objective is to protect population stability while in mammalian toxicology looking at food and drinking-water the objective is to protect the individual. However, as indicated elsewhere, the common approach to protecting aquatic ecosystems and drinking-water quality lies in the prevention of water contamination and suggests a policy to improve sewage/wastewater treatment and also to develop management procedures to minimise diffuse contamination. In the case of the latter, river basin management plans are an important step towards this objective.

Role of indicator parameters

The parameters in Annex I Part C are designated as “indicator parameters” in the Directive. It should be noted that these parameters are not of direct health significance except possibly manganese.

Many of the indicator parameters are covered under “acceptability aspects” in the Guidelines and no formal guideline values are proposed by WHO 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 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 may have no direct health effects. However, water that is highly turbid, is highly coloured or has an 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 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 are more closely associated with ensuring that drinking-water treatment and disinfection processes are operating efficiently or relate to operational issues such as corrosion of distribution and plumbing materials, although some of these also have an acceptability dimension. Therefore, in line with the WSP approach, many of the indicator parameters are used in operational monitoring to assess whether the control measures in a drinking-water system are operating properly and/or to signal long-term or short-term changes of (source) water quality.

In the Directive these parameters are considered differently to those parameters included in Part B and are not generally regarded as posing health risks to consumers. The indicator parameters in Annex I Part C are considered in more detail in Table 2.

Table 2. Parametric values (PV) for indicator parameters in DWD Annex I Part C and WHO recommendations

Parameter	DWD PV	Date of WHO review	Main source/pathways in drinking-water	Comments
Aluminium	200 µg/L	2010	Primarily from use as coagulant in water treatment; it is also naturally occurring in some raw waters and can take part in the coagulation treatment process	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: 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.
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	In raw water from industrial discharges, surface run off of salt for de-icing, treated wastewater and also saline intrusion into groundwater	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	DWD 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 true colour units (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 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 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.
Hydrogen ion concentration (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 DWD 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	DWD PV	Date of WHO review	Main source/pathways in drinking-water	Comments
Manganese	50 µg/L	2011	Primarily 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 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 DWD PV of 50 µg/L reflects the discolouration. 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 of 50 µg/L should be protective. The presence of manganese in drinking-water may lead to the accumulation of deposits in the distribution system.
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. The DWD requirement for "acceptable to consumers and no abnormal change" remains appropriate.
Oxidisability	5.0 mg/L O_2	-	Measure of organic matter in water (largely superseded by TOC)	No health-based GV established. This parameter does not need to be monitored where total organic carbon (TOC) is monitored.
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	DWD 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 DWD 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 in bottle-fed infants. 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. The DWD requirement for “acceptable to consumers and no abnormal change” remains appropriate.
Total organic carbon (TOC)	No abnormal change	-	Naturally occurring in raw water and from discharges	No WHO health-based GV established. Indicator of organic matter, particularly in raw water. TOC is a useful operational water quality parameter to indicate change.

Parameter	DWD PV	Date of WHO review	Main source/pathways in drinking-water	Comments
Turbidity	Acceptable to consumers and no abnormal change	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 raw water as well as in coagulation filtration efficiency. Turbidity can also interfere with the efficiency of disinfection. To ensure effectiveness of disinfection well-run large supplies should be able to achieve < 0.2 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. It is important that it is made absolutely clear what turbidity is about in the Directive. Currently it is about acceptability to consumers but a footnote indicates that Member States should strive for <1 NTU if treating surface water. The important role turbidity in controlling filtration performance should be made much clearer and also the requirement that turbidity should be as low as reasonably achievable.

3 Prioritization of parameters in the context of a risk-based approach

Since the publication of the second edition of the 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 water safety plan (WSP) approach.

The change encourages a much more targeted approach to controlling and monitoring contaminants based on a local assessment of the risk of a contaminant being present close to or exceeding the guideline value or the standard as adopted by a particular EU Member State. The Commission has already started to introduce this approach by adopting **risk-based monitoring for chemical contaminants** in a recent modification to Annex II of the Directive. It is, therefore, to consider the priorities for 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 Guidelines.

Because there is a constant stream of research it is also necessary to look at new data, which may suggest the need for changes to existing parametric values which have not yet been updated by WHO and also to consider newly emerging contaminants of concern, which may warrant inclusion in the list of parameters. To some extent this process will depend on data from EU Member States as to the key contaminants encountered in their drinking-water supplies and the risk-based approach suggests that the most important of these should be included in Annex I of the Directive. To this end a preliminary assessment was undertaken and proposals for prioritisation were made that can be linked to appropriate parametric values and the identification of those parameters for which there is a need to consider new scientific data that could possibly result in an updated parametric value (Table 3).

A combination of the following criteria should be applied in proposing priorities in terms of retaining parameters in Annex I, removing parameters from Annex I and/or including new parameters in Annex I, including:

1. Significance for Member States in terms of occurrence in drinking-water;
2. Reported exceedances of the standard in Member States;
3. Known health effects associated with exposure through drinking-water even if significance is limited.

Those substances that are only encountered at concentrations below the parametric value as per Annex I of the Directive and show no or very few exceedances would be of low priority for inclusion unless of particular concern for health. Substances that are of significance for a majority of Member States would be a higher priority for inclusion. By contrast, substances which may be of much more restricted interest should be included in the standards adopted by those individual Member States of the EU that are affected. Some contaminants may be best controlled through other means than inclusion in Annex I since routine monitoring may not provide the necessary reassurance.

To allow for an informed review of the significance of substances in drinking-water, present widely at significant concentrations, occurrence data were requested from all Member States by letter of the EC of 19 May 2016. The request addressed parameters that, based on a preliminary assessment, were considered for possible deletion from Annex I, considered for change in parametric value, considered for possible inclusion in Annex I and those suggested for consideration by groups other than WHO and EC.

Data were received from 18 Member States, as well as from a range of individual water utilities. There was significant variation in the depth of the data and in the explanation of exceedances of the parametric values. For example, several appear to be associated with incidents rather than be associated with the normal circumstances for water supply. The consequence is that there is no simple approach that can be taken but the data have been used by applying a statistical scoring system to identify the potential priorities. In the case of the few substances known to cause adverse impacts on human health through drinking-water, these have been automatically retained as high priority, such as arsenic, fluoride and nitrate.

Much also depends on the way in which substances can be controlled and monitored. For example, those substances that would be controlled primarily through materials specifications, such as acrylamide, epichlorohydrin and vinyl chloride, could be considered in a separate table from those considered through routine monitoring. Pesticides were not considered because the values in the Directive are based on a stated policy position rather than considered as individual parameters on the specific scientific data associated with those substances.

The statistical scoring system is based on available exceedance and compliance data of the respective chemical parameter. For both exceedance and compliance scores were calculated which then were transferred into the categories of low, medium and high priority for the considered action. For some chemical parameters less than 18 Member States responded which caused some challenges in developing this scoring scheme. In these cases three different assumptions (overestimation, underestimation and extrapolation) were used to project the exceedance data to 18 Member States in order to allow for comparability. When conducting the transfer of the final score into the categories, the chemical parameters had to be split up into the ones which are considered for possible removal from Annex I and the ones considered for possible inclusion. The data for possible new parameters and substances of emerging concern are even more limited but what was available was taken into account in determining whether individual substances or groups of substances should be included as potential new parameters.

By applying the aforementioned criteria, preliminary priorities for assessment and inclusion of parameters in Annex I of the Directive are summarised in Table 3. Further detail of this preliminary assessment is presented in Appendix 1. Several groups and individual contaminants that are not mentioned in Annex I of the Directive are of emerging concern with regard to possible adverse health effects. It is important that these are considered and a preliminary assessment is presented in Table 3 and Appendix 2.

Table 3. Preliminary priorities for assessment, inclusion or removal of chemical, physical and organoleptic parameters in DWD Annex I

Parameter	Grouping	Priority for assessment	Priority for inclusion/ retention	Priority for removal
CHEMICAL PARAMETERS (ANNEX I PART B)				
Acrylamide	Treatment	Low	Low*	
Antimony	Internal plumbing	Medium	Low-medium	Medium-high
Arsenic	Raw water	Low	High	
Benzene	Raw water	Low	Low	High
Benzo(a)pyrene	Distribution	Low	Low	High
Boron	Raw water	Low	High	
Bromate	Treatment	High	Medium	
Cadmium	Distribution/ internal plumbing	Low	Medium	
Chromium	Raw water	High	Medium	
Copper	Internal plumbing	Low	Medium	
Cyanide	Raw water	Low	Low	High
1,2-Dichloroethane	Raw water	Low	Low	High
Epichlorohydrin	Treatment	Medium	Low*	
Fluoride	Raw water/treatment	Low	High	
Lead	Internal plumbing	Low	High	
Mercury	Raw water	Low	Low	High
Nickel	Internal plumbing	Medium	Medium	
Nitrate	Raw water	Low	High	
Nitrite	Raw water	Low	High	
Pesticides	Raw water	N/A	N/A	
Pesticides total	Raw water	N/A	N/A	
Polycyclic aromatic hydrocarbons	Distribution	Low	Low	High
Selenium	Raw water	Low	Low	High
Tetrachloroethene and trichloroethene	Raw water	Medium	Low	High
Trihalomethanes	Treatment	Low	High	
Vinyl chloride	Distribution	Low	Low*	
INDICATOR PARAMETERS (ANNEX I PART C)				
Aluminium	Treatment	N/A	High	
Ammonium	Raw water/treatment	N/A	Medium	
Chloride	Raw water	N/A	High	
Colour	Raw water	N/A	High	
Conductivity	Raw water	N/A	High	
pH	Raw water/treatment/ distribution	N/A	High	
Iron	Raw water/treatment/ distribution	N/A	High	
Manganese	Raw water	Medium	High	
Odour	Raw water/treatment/ distribution	N/A	High	
Oxidisability	Raw water	N/A	Low	High
Sulphate	Raw water	N/A	Medium	
Sodium	Raw water	N/A	Medium	

Parameter	Grouping	Priority for assessment	Priority for inclusion/ retention	Priority for removal
Taste	Raw water/treatment/ distribution	N/A	High	
Total organic carbon	Raw water	N/A	Medium	
Turbidity	Raw water/treatment/ distribution	N/A	High	
PARAMETERS OF EMERGING CONCERN				
Chlorate	Treatment	High	Medium-high	N/A
Chlorite	Treatment	Low	Medium-high	N/A
Endocrine disrupting compounds (EDCs)	Raw water	Low	Low	N/A
Haloacetic acids	Treatment	Low	Medium-high	N/A
Microcystin	Raw water	Low	Low-medium	N/A
N-Nitrosodimethylamine (NDMA)	Treatment	Low	Low-medium	N/A
Perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA)	Raw water	High	Medium-high	N/A
Pharmaceuticals	Raw water	Low	Low	N/A
Uranium	Raw water	Low	Low-medium	N/A
ADDITIONAL PARAMETERS SUGGESTED BY OTHER GROUPS				
Asbestos	Distribution	Low	Low	N/A
Calcium and magnesium	Raw water	Low	Low	N/A
Chlorophenols	Treatment	Low	Low	N/A
Glass fibres	Distribution	Low	Low	N/A
Nanoparticles	Raw water/treatment	Research	Low	N/A
Thallium	Raw water	Low	Low	N/A

* Low priority for inclusion in Annex I but a high priority for control through product approval and specification.

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. With 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.

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. There is limited evidence in humans that the unintentional by-products of disinfection of drinking-water by 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.

The risk-based approach encompassed in WSPs requires that the hazards through the supply from source to the point of delivery to the consumer should be identified and the scale of the risks from those hazards assessed in relation to exposure and the potential for exceedance of standards or health-based guideline values. Occasionally there will be contaminants present that are of interest

in a small number of specific circumstances and it is often not appropriate to include these in standards that relate to the 28 EU Member States. The Directive incorporates a clause which requires Member States to ensure that they do not supply water that contains any micro-organisms 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.

4 Options for the structure of chemical parameters of Annex I of the Directive

Currently the chemicals covered in Annex I 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 ways in which parameter groups are monitored and controlled vary. There are advantages in separating the parameters into different groups relating to the way in which they are monitored and/or controlled. For parameters covered by Annex I Part B, Table 4 below proposes five categories of parameters which are also reflected in Table 3 above. Such grouping makes the source of the contaminant and the actions required in monitoring and control much clearer, not only to regulators from Member States but also to politicians and the general public. Such grouping could also be beneficial for aiding in the assessment of hazards in small supplies for which there may only be limited resources and expertise available.

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 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 than trying to regulate concentrations in drinking-water by means of drinking-water standard.

Table 4. Possible grouping of parameters covered in DWD Annex I Part B

Group by primary source	Chemical	Primary control option	Monitoring
Raw water: naturally occurring	Arsenic, boron (particularly sea water), fluoride, chromium and selenium	Source selection and drinking-water treatment	At works in final water
Raw water: anthropogenic origin	Benzene, chromium, cyanide, 1,2-dichloroethane, mercury, nitrate/nitrite, pesticides, tetrachloroethene and trichloroethene	Pollution control, source blending and drinking-water treatment	At works in final water
Distribution	Antimony, cadmium, polycyclic aromatic hydrocarbons and benzo(a)pyrene and vinyl chloride	Material selection and distribution management or by product control (vinyl chloride)	In distribution or at tap; by product control (vinyl chloride)
Internal plumbing (buildings)	Antimony, cadmium, copper, lead and nickel	Product specification and corrosion control	At tap by tailored representative monitoring programmes
Treatment	Acrylamide, bromate, epichlorohydrin, [added fluoride] and trihalomethanes	Process control and product specification or by product control (acrylamide and epichlorohydrin)	At works in final water (fluoride and bromate); at tap (trihalomethanes); by product control (acrylamide and epichlorohydrin)

5 "Emerging" contaminants

In the time since the current Directive has been in place there has been a significant increase in knowledge about potential drinking-water contaminants. This has partly been due to advances in analytical methods but also in knowledge about the potential occurrence of a wider range of contaminants than were considered in the 1990s. This has been reflected in the activities of WHO in examining a number of such contaminants and covering them in either specific studies (e.g. cyanobacterial toxins and pharmaceuticals) or in the Guidelines themselves (e.g. uranium, n-nitrosodimethylamine).

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 in drinking-water treatment or are naturally occurring in either groundwater or surface water.

As a consequence of enhanced analytical capability a wider range of trace contaminants in water sources have been detected, mostly in very low, trace concentrations. In general the databases on these substances are limited in that systematic studies are limited in number and extent, since most studies consist of isolated grab samples often analyzed with differing techniques and varying quality control. 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. Since many of these groups of substances such as human hormones and pharmaceuticals

reach drinking-water sources through sewage it is highly probable that they have been present in sources receiving treated sewage effluent for decades and improvements in sewage and drinking-water treatment and control of chemicals will have actually reduced concentrations over time. These are considered in more detail in Appendix 2.

In terms of drinking-water management introducing standards for long lists of substances does not seem to be an efficient way of dealing with the problem, which in many cases, is primarily associated with perception as the risk assessments for substances such as pharmaceuticals and EDCs indicate that adverse health effects are unlikely to be associated with the concentrations currently encountered in drinking-water.

The approach of providing benchmark values to assess presence and removal and the efficiency of existing drinking-water treatment for those substances that are hydrophobic is useful but with groups of chemicals that show a wide range of chemical and physical properties such an approach is not likely to be helpful. Providing a benchmark approach for EDCs, which are of low water solubility could be helpful to provide public reassurance while for pharmaceuticals and personal care products this would not be helpful. However, the most appropriate approach under WSPs is to reduce or prevent entry into source water.

It is highly probable that further contaminants will emerge in the future as analytical techniques advance and as the knowledge base increases. In terms of the WSP approach this would also suggest that improvements in sewage treatment and standards for treated sewage discharges would be the most constructive way forward because there are greater concerns over the potential impacts on aquatic life. It is recognized that such a policy would need to be based on a long-term view but new developments in wastewater and sewage treatment mean that improvements are possible. In the short-term there is now a growing body of research into how best to optimize existing plant and doing this along with optimization of drinking water treatment would provide a constructive way forward that seeks to solve the problem in the long-term in a sustainable and cost-effective way.

Appendix 1

Technical overview of chemical parameters included in DWD Annex I Part B

Note that all priorities are subject to further evaluation of occurrence data received from Member States.

Acrylamide

Route 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. This has been controlled by specifying a maximum allowable amount of residual monomer combined with a maximum dose of the polymer in drinking-water treatment. More recently an analytical method has been developed to detect acrylamide in drinking-water at the low concentrations specified in the Directive.

Evidence for adverse health effects and basis for a standard

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 suggest that the risk is as high as animal studies might suggest. However, because controlling exposure from food is extremely difficult and it is probable that man has been exposed through food since cooking began, it is appropriate to maintain as low exposure from controllable sources as can be reasonably achieved.

In this respect acrylamide is best controlled by product specification through control of the residual acrylamide monomer in polyacrylamide and on the dose of polymer applied. The WHO GV and the DWD PV have resulted in significant improvements in the concentration of acrylamide in drinking-water and there is currently no evidence that would suggest that a change in the value is necessary.

Priority for inclusion

Acrylamide would be low priority for inclusion in Annex I but a high priority for control through product approval and specification.

Antimony

Route to drinking-water

Antimony reaches drinking-water primarily through metals used in the distribution system and in plumbing. It is frequently detected but usually below the current standard. Control would primarily be by product specification of metal fittings.

Evidence for adverse health effects and basis for a standard

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. The DWD PV of 5 µg/L is based on the assessment in the second edition of the 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 proportion of the TDI allocated to drinking-water is 10%, which may be conservative. Antimony is used as a stabilizer in PET bottles and packaging but the wider exposure to antimony from food is uncertain.

Priority for inclusion

Low to medium subject to data from Member States on occurrence and the concentrations encountered. Antimony was originally included because it was being proposed as a component in unleaded solders but this did not materialise.

Arsenic

Route to drinking-water

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 specific locations. It is a particular problem in small resource limited supplies. It may sometimes be found in discharges from mining, including abandoned mines for tin and associated minerals.

Evidence for adverse health effects and basis for a standard

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. 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 provisional tolerable weekly intake 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 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. WHO has retained the GV of 10 µg/L but in light of the withdrawal of the PTWI has designated it as provisional. Other high income countries have reviewed arsenic but have also retained the value of 10 µ/L because of the difficulties of meeting a lower value.

Priority

In view of its potential health significance from exposure through drinking-water, to arsenic is considered to be a high priority for inclusion in Annex I.

Benzene

Route to drinking-water

Benzene reaches drinking-water from spills of petroleum or from spills of benzene in industrial settings. It degrades in soil and is rarely if ever found by routine monitoring in drinking-water.

Evidence for adverse health effects and basis for a standard

Benzene is a human carcinogen in industrial settings but there is no evidence that exposure through the extremely low concentrations in drinking-water causes adverse health effects in humans. Drinking-water is by far the most minor source of exposure of the general population to benzene, with inhalation of petrol fumes being the greatest source. The WHO GV of 10 µg/L was developed for the second edition of the Guidelines and a recent review by Health Canada in 2009 indicates there is no need for a change. The standard in the Directive of 1 µg/L is extremely precautionary in view of exposure from other sources.

Priority for inclusion

Due to its very limited occurrence in drinking-water and marginal significance in terms of exposure route, benzene is of a very low priority for inclusion in Annex I and therefore a clear candidate for removal from the list of parameters.

Benzo(a)pyrene (B(a)P)

Route to drinking-water

B(a)P is a polycyclic aromatic hydrocarbon (PAH) (see also section on PAH below) released from old coal tar linings on cast iron water mains and, because of its low water solubility, is found associated with particulate matter and mostly dirty water. It has a low taste threshold. It is rarely found by routine monitoring, although it can be found when there are discolouration incidents in affected mains. This is considered to be primarily an operational problem.

Evidence for adverse health effects and basis for a standard

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. It 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. The WHO GV of 0.7 µg/L 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 DWD 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.

Priority for inclusion

B(a)P is a low priority for inclusion in Annex I because it is rarely if ever detected at significant concentrations by routine monitoring and is therefore a candidate for removal from the list of parameters. In Member States in which there are still historical coal tar lined cast iron pipes it would be potentially covered by the requirement not to supply discoloured or unacceptably tasting water and should be identified in hazard identification in the WSP. This is a diminishing issue as coal tar lined pipes are steadily replaced or refurbished.

Boron

Route 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. It can be found in groundwater in regions of high boron baring rocks. However, it is found at quite high levels in sea water and is not easily removed by reverse osmosis. It is a significant problem for Member States dependent on desalinated water.

Evidence for adverse health effects and basis for a standard

Boron is considered to be of relatively low toxicity and there are no data that show adverse health effects in humans from environmental exposure. It is found in food and is an essential element for many plants. 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, which was considered to be excessively precautionary.

Priority for inclusion

Boron is of high priority for inclusion in Annex I in view of the increasing dependence on desalination in many parts of the EU and the significant concentrations in sea water. It was used as perborate in detergents and was a pollutant in source waters receiving treated wastewater effluent but that use has now stopped. The current standard of 1 mg/L 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.

Bromate

Route to drinking-water

Bromate is formed in drinking-water treatment with ozone when bromide is present in the raw water. Control can be difficult. More recently it has been recognised as a significant contaminant in sodium hypochlorite used for chlorination when it is manufactured by electrolysis using brine that does not come from low bromide salt deposits.

Evidence for adverse health effects and basis for a standard

Bromate causes cancer in laboratory animals but there is no evidence that bromate causes health effects in humans from exposure through drinking-water. 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 over estimate the possible risks. The WHO GV of 10 µg/L is the same as the parametric value in the Directive and 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. The new data on toxicokinetics demonstrate that not only is 10 µg/L a safe value but it is excessively precautionary. In view of the significant volume of data on the kinetics of bromate in the human body, WHO is due to review the provisional guideline value for bromate but this process has not yet started.

Priority for inclusion

Bromate is an important treatment by-product. However, due to the lack of evidence that bromate causes adverse health effects in humans from exposure through drinking-water, it is considered a medium priority for inclusion in Annex I.

Cadmium

Route 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 but concentrations in drinking-water are generally less than 1 µg/L. It can also leach from some old galvanised pipe and is a potential contaminant in some alloys.

Evidence for adverse health effects and basis for a standard

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. The WHO GV of 3 µg/L is based on the allocation of 10% of a PTMI (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 DWD PV of 5 µg/L, which is not significantly different from the GV.

Priority for inclusion

Cadmium is still a widespread contaminant in the environment and can be present in metal materials used in contact with drinking-water. This should be controlled by product specification and approval but it remains a medium priority for inclusion in Annex I.

Chromium

Route to drinking-water

Chromium is found in the environment naturally and as an industrial pollutant. The indications are that it is of greater concern following specific pollution of groundwater because chromium in surface water can be removed to a great extent by coagulation. It is used in the manufacture of plumbing fittings, particularly taps, but does not seem to leach to a significant extent from this source although this should also be covered by product specification and approval.

Evidence for adverse health effects and basis for a standard

The current WHO GV was established prior to the first edition of the Guidelines and is based on protection of health from the effects of chromium VI which 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. Health Canada has recently proposed a new guideline for total chromium in drinking-water of 100 µg/L.

Priority for inclusion

Chromium does not appear to be widely found in drinking-water above the current DWD PV of 50 µg/L. Although chromium has a high political and media profile it is unlikely to pose significant threats to health through drinking-water, although control of discharges to water sources remains important. It is of medium priority for inclusion in Annex I.

Copper

Route to drinking-water

Copper is only found in drinking-water as a consequence of copper plumbing. It is an issue with aggressive waters, electrolytic corrosion and long contact times of water with copper piping in buildings.

Evidence for adverse health effects and basis for a standard

High concentrations of copper in drinking-water can cause gastric irritation giving rise to nausea. Copper was updated for the third edition of the Guidelines based on human data on gastrointestinal irritation to give a WHO GV of 2 mg/L. This is as a concentration rather than a dose and reflects the acute effects of high copper. It 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. The issue that has been debated is whether elevated copper 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.

Priority for inclusion

Copper is only rarely found at concentrations close to the standard and these relate to unusual circumstances in which water is in contact with the pipes for an extended period combined with circumstances in which the copper piping is at higher risk from corrosion. This is unlikely to be detected by routine monitoring at the tap and a different approach is required. The priority for inclusion in Annex I is therefore considered medium. Sampling and monitoring for plumbing-influenced parameters is important and needs to be considered separately.

Cyanide

Routes to drinking-water

Cyanide is normally only found as a consequence of accidental discharges, which constitute an emergency. Under some circumstances low levels of cyanide may be discharged to surface water; the impact of cyanide on aquatic life is an important marker of its presence at significant levels. Low concentrations in drinking-water may be encountered as a consequence of the formation and breakdown of cyanogens chloride as a disinfection by-product.

Evidence for adverse health effects and basis for a standard

Although cyanide is a metabolic inhibitor and exposure to high doses can give rise to acute adverse effects there is no credible evidence for cyanide in drinking-water impacting adversely on human health. The WHO GV was updated in the fourth edition of the Guidelines but no formal GV was proposed because routine monitoring is unlikely to detect a cyanide spill. Health-based values were determined for both acute and chronic exposure. The DWD PV in Annex I is slightly less than the GV of 70 µg/L in the second edition of the Guidelines.

Priority for inclusion

Routine monitoring is not appropriate under the great majority of circumstances. Cyanide is rarely encountered in drinking-water at more than trace levels. It is therefore a low priority for inclusion in Annex I and is a candidate for removal from the Directive.

1,2-Dichloroethane

Routes to drinking-water

1,2-Dichloroethane is almost exclusively used as an industrial intermediate in the manufacture of vinyl chloride that may reach surface or groundwater in industrial discharges or spills. It does not appear to be normally detected at significant concentrations in drinking-water, particularly since tighter controls on industrial discharges have been introduced.

Evidence for adverse health effects and basis for a standard

1,2-Dichloroethane has been shown to be carcinogenic in laboratory animals in studies in which it was administered by oral gavage in corn oil. It is known that this means of exposure increases the potential for carcinogenicity of this type of substance compared to exposure through drinking-water and so any risk extrapolation based on these data are likely to be highly conservative. The WHO GV was derived by low dose linear extrapolation using the gavage study and the GV of 30 µg/L represents a calculated upper bound 10^{-5} risk. The standard of 3 µg/L in Annex I represents an acceptable upper bound level of risk of 10^{-6}.

Priority for inclusion

There do not seem to be any reports of significant concentrations of 1,2-dichloroethane in drinking-water in recent times and so the priority for inclusion in Annex I is low and the substance is a candidate for removal from the Directive.

Epichlorohydrin

Routes 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. There is no suitable analytical method for routine use and control is through controlling the residual epichlorohydrin in polyamine coagulant aids along with the dose applied in drinking-water treatment.

Evidence for adverse health effects and basis for a standard

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. The WHO GV of 0.4 µg/L was derived by using a very large uncertainty factor because it was considered inappropriate to use linear extrapolation. This is marginally above the DWD PV of 0.1 µg/L.

Priority for inclusion

Epichlorohydrin would be a low priority for inclusion in Annex I but a high priority for control through product approval and specification.

Fluoride

Routes to drinking-water

Fluoride occurs naturally as a groundwater contaminant and a small number of Member States practice artificial fluoridation. It 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 adverse health effects and basis for a standard

High concentrations of fluoride cause dental fluorosis and higher concentrations cause skeletal fluorosis. 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. Fluoride intake through drinking-water is largely a problem for low and middle income countries in hot climates.

Priority for inclusion

Although there appear to be fairly limited problems with fluoride in drinking-water in Europe, its use in artificial fluoridation and the fact that it does cause adverse health effects in humans through drinking-water in some circumstances means that it is of high priority for inclusion in Annex I.

Lead

Routes to drinking-water

Lead is only 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 solder is an important source and should not be used in drinking-water systems. There are standards for low lead copper alloy fittings and only these should be used in drinking-water systems. 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. 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.

Evidence for adverse health effects and basis for a standard

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. The WHO background document was updated in the fourth edition in the light of the JECFA evaluation in 2010. JECFA agreed that there was no discernible threshold for lead toxicity and withdrew the PTWI. The GDWQ Group decided that it would retain the 10 µg/L value but the basis is that 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, but there remains a need to take as much action as is practical.

Priority for inclusion

Compulsory lead pipe replacement will be very expensive and very disruptive for consumers but it remains the only long term solution to the issue. Lead remains a high priority due to its adverse health effects in children. Sampling and monitoring for plumbing-influenced parameters is important and needs to be considered separately. It is most important to have a long term strategy for lead removal. It is particularly important that no new lead is introduced either in the form of lead solder or in high-lead copper alloy fittings, which can result in significant lead concentrations in buildings where historic lead plumbing has been removed or in new properties with no other source of lead. Prevention of new lead being introduced should be based on product approval.

Mercury

Route to drinking-water

Mercury in its inorganic form can be present at trace levels in surface and some groundwater. Organic mercury compounds are hydrophobic, adsorb to particulate matter and are not a concern for drinking-water.

Evidence for adverse health effects and basis for a standard

Mercury is a cumulative toxin and while there is clear evidence that exposure to high levels of mercury can cause neurological and other adverse effects in humans, there is no evidence of concentrations of concern in drinking-water. The WHO GV of 6 µg/L is conservative in view of the most recent evaluation of inorganic mercury by JECFA and could easily be higher. There is no evidence that mercury is found in drinking-water at more than trace levels in Europe.

Priority for inclusion

Due to its irrelevance in drinking-water mercury is of low priority for inclusion in Annex I but is a clear candidate for removal from the list of parameters.

Nickel

Routes to drinking-water

Nickel does occasionally arise in source water from nickel baring rocks 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 removed when the tap is turned on.

Evidence for adverse health effects and basis for a standard

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 sensitised to nickel, primarily through jewellery. 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 have recently evaluated nickel (2015) and have 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 standard of between 15 and 20 µg/L, which compares with the current DWD PV of 20 µg/L.

Priority for inclusion

Nickel is of medium priority for inclusion in Annex I because exposure to nickel from drinking-water can be elevated in some groundwater and is leached from nickel base plating of chromium plated taps and fittings. The data on occurrence from Member States will be important. There is also a need to revisit the Guideline value in the light of new information. Sampling and monitoring for plumbing-influenced parameters is important and needs to be considered separately.

Nitrate/nitrite

Routes to drinking-water

Nitrate is commonly found in surface and groundwater where it is mostly present as a consequence of agricultural activity. However, wastewater (treated sewage) can also be an important contributor. Nitrate from poorly operated septic tanks and manure can be an issue for small groundwater supplies. 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.

Evidence for adverse health effects and basis for a standard

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 has recently reviewed the data but has retained its original GV on the basis that the data do not justify any change. 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.

Priority for inclusion

Nitrate and nitrite remain a high priority for inclusion in Annex I because they are common contaminants in drinking-water and removal in treatment is not straight forward. There does not appear to be any requirement for a change in the standard(s). However, a greater understanding of nitrite occurrence in distribution would help to determine a suitable monitoring strategy and actions to be taken in the case that the nitrite standard is exceeded as disinfection efficiency should not be compromised in taking remedial action.

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 (available at: http://www.who.int/water_sanitation_health/dwq/chemicals/en/). 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. The DWD PV of 0.1 µg/L for individual pesticides and their relevant metabolites, and 0.5 µg/L for total pesticides are not health-based. While the Guidelines provide a basis for judging the possible impact on public health if the standard is exceeded, WHO cannot comment on what is an essentially "political standard".

Pesticides that are difficult to remove in drinking-water treatment may occur in drinking-water sources. It would seem appropriate to include a mechanism by which Member States can take a more flexible approach under such circumstances in order to give adequate time for pollution control action to be implemented rather than introducing expensive treatment for which consumers must ultimately pay.

Polycyclic aromatic hydrocarbons (PAHs)

Route to drinking-water

PAHs are only found in drinking-water as a consequence of deteriorating historical coal tar linings on cast iron water mains. They are primarily associated with sediments and particulates in water because they are of low water solubility. As a consequence PAH in surface water are readily removed by relatively basic drinking-water treatment. (Note that B(a)P is also a PAH; see also section on B(a)P above.)

Evidence for adverse health effects and basis for a standard

PAH as a mixture, including B(a)P, is known to cause skin cancer following occupational exposure but it is considered that there is no appreciable risk of adverse health effects from drinking-water. The DWD PV is based on an old WHO guideline that comes from documents that predate the first edition of the Guidelines and is only relevant for coal tar lined cast iron mains that have not been in production for several decades. The value is not health-based and drinking-water is a very minor source of exposure to PAH. A WHO GV of 0.2 µg/L for six named PAHs, including B(a)P, was included in the first edition of the Guidelines and this was not based on toxicological considerations but on the concept that drinking-water should meet the baseline for PAH in

unpolluted groundwater. WHO withdrew the GV for PAH in 1993 because it was not possible to set a health-based value for most PAH and benzo(a)pyrene was considered to be the most important. This was reviewed and confirmed in 1998.

Priority for inclusion

Due to its limited occurrence and health significance in drinking-water PAHs are of a low priority for inclusion in Annex I and are a clear candidate for removal from the list of parameters.

Selenium

Routes to drinking-water

Selenium does occur naturally in some groundwaters in areas with seleniferous rocks. However, in Europe this seems to be a very localised phenomenon.

Evidence for adverse health effects and basis for a standard

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. The provisional WHO GV is 40 µg/L based on an allocation of 20% of the upper tolerable intake.

Priority for inclusion

Selenium is a low priority for inclusion in Annex I. The very great majority of water supplies in Europe contain much less than 10 µg/L. Selenium is a candidate for removal from the list of parameters.

Trichloroethene and tetrachloroethene

Routes to drinking-water

Tri- and tetrachloroethene are sometimes found in groundwater as a consequence of historical pollution, usually related to poor handling and disposal of solvents in industrial settings. They are not found in surface water as they rapidly volatilise to atmosphere.

Evidence for adverse health effects and basis for a standard

Both of these substances have been shown to cause adverse health effects in humans in industrial settings and 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. The WHO GVs both relate back to the second edition of the Guidelines and are 20 and 40 µg/L, respectively. The DWD PV of 10 µg/L for the two combined is based on concerns over groundwater contamination and is to a significant extent a political statement about protecting groundwater. Since then the Groundwater Directive has taken this role.

Priority for inclusion

It is uncertain as to just how much of a problem tri- and tetrachloroethene are in Europe and the implementation of the Groundwater Directive should mean that all instances are associated with historical pollution. Under the WSP approach preventing contamination of source water is the most appropriate strategy. Both substances are therefore of low priority for inclusion in Annex I, depending on data on occurrence from Member States.

Trihalomethanes

Routes to drinking-water

THMs are chlorination by-products and are used as relatively arbitrary indicators of the wider level of chlorination by-products (DBPs). They are formed by the reaction of free chlorine with natural organic matter such as humic acids.

Evidence for adverse health effects and basis for a standard

While the evidence for direct adverse effects of the four trihalomethanes 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. The DWD PV of 100 µg/L for chloroform, bromodichloromethane, chlorodibromomethane and bromoform is an arbitrary but reasonable value for the intended purpose and is similar to standards for THMs in other countries. There is fairly consistent evidence is that there is an association between THMs (DBPs) 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.

The WHO Guidelines and the Directive emphasise that disinfection should not be compromised in attempting to control DBPs.

Priority for inclusion

THMs remain a high priority for inclusion in Annex I but there is a need for additional parameters (e.g. haloacetic acids; see also Appendix 2) to support the reduction of overall quantities of DBPs. There would be no need for supplies that do not use chlorine to monitor for DBPs as they will not be present.

Vinyl chloride

Routes to drinking-water

The primary route by which vinyl chloride reaches drinking-water is as residual vinyl chloride monomer in polyvinyl chloride pipes that are not manufactured to modern standards. It has been detected a breakdown product of some other small chlorinated solvents in groundwater, but there are few reports of its being found in groundwater at significant concentrations in Europe.

Evidence for adverse health effects and basis for a standard

Vinyl chloride is a known occupational carcinogen by the inhalation route but at exposure levels vastly greater than encountered in drinking-water. 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 risk of 10^{-5}.

Priority for inclusion

Vinyl chloride is controlled through limiting the residue in PVC pipe. There has been considerable improvement in the manufacture of PVC pipe. Vinyl chloride is of low priority for inclusion in Annex I but of high priority for control through product approval and specification.

Appendix 2

Technical overview of emerging and additional contaminants for possible inclusion in DWD Annex I

I. PARAMETERS SUGGESTED BY WHO

Disinfection by-products (DBPs)

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. The two groups present in the greatest quantity are the trihalomethanes (THMs), which are already included in Annex I of the Directive, and the haloacetic acids (HAAs), which are not. While it would 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. THMs have been used as a surrogate for the other by-products. However, THMs are not a good surrogate for all the by-products, e.g. the HAAs that are formed under more acidic conditions, so it is considered more appropriate to include the two groups of substances to provide two indicators covering different mechanisms of formation.

It would be possible to set a health-based value for each of these groups but the concentrations of by-products would be much higher than technically achievable and thus higher than necessary. 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 current DWD parametric value for four THMs (i.e. chloroform, bromodichloromethane, chlorodibromomethane and bromoform) is 100 µg/L. The USEPA established a pragmatic group parameter of 60 µg/L for five HAAs but to increase the range of HAAs covered a value 80 µg/L for nine representative substances (monochloro-, dichloro-, and trichloro-acetic acid, mono- and dibromo-acetic acid, bromochloroacetic acid, bromodichloroacetic acid, dibromochloroacetic acid and tribromoacetic acid) would be more appropriate. While these values are based on practical achievability they represent a useful 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 with a minimal increase in cost.

The United States Environmental Protection Agency (US EPA) uses standards of 80 µg/L for total THMs and 60 µg/L for a total of five HAAs. However, it should be noted that these refer to rolling average concentrations in contrast to the European approach of a maximum acceptable concentration.

Additional by-products are n-nitrosodimethylamine or NDMA, along with chlorite, which is the major by-product, or more accurately break-down product, of chlorine dioxide and chlorate, which arises from the breakdown of sodium hypochlorite in storage.

Haloacetic acids (HAAs)

Routes to drinking-water

Haloacetic acids are disinfection by-products (DBPs) formed from the reaction of chlorine with natural organic and inorganic matter in the raw water and so arise during drinking-water treatment. Trihalomethanes (THMs), which are already included in Annex I are also DBPs but reflect a different group of DBPs.

Evidence for adverse health effects and basis for a standard

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. Haloacetic acids are also DBPs that arise in chlorination and provide an additional parameter that, together with THMs, better reflects the overall DBP load. While WHO has set GVs for individual HAAs, 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. monochloro-, dichloro-, and trichloro-acetic acid, mono- and dibromo-acetic acid, bromochloroacetic acid, bromodichloroacetic acid, dibromochloroaetic acid 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.

Priority for inclusion

HAAs are a medium to high priority for inclusion in Annex I because of their important role in reflecting the overall DBP load in drinking-water. They should be considered in conjunction with total THMs.

Chlorate

Routes to drinking-water

Chlorate is a by-product formed in hypochlorite that is not fresh and properly stored. It is also a by-product of chlorine dioxide disinfection along with chlorite. It could be controlled through product specification, including proper use and storage of hypochlorite after purchase by the water supplier.

Evidence for adverse health effects and basis for a standard

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. EFSA has proposed a very low TDI of 3 µg/kg body weight, which would lead to a drinking-water standard of 70 µg/L if 80% of the TDI was allocated to drinking-water. This would rule out the use of sodium hypochlorite for disinfection. WHO has considered the new data but has retained a provisional GV of 0.7 mg/L, which uses an 80% allocation of the TDI to drinking-water.

Priority for inclusion

How chlorate should be included is unclear at the moment. It is a medium to high priority for consideration for either inclusion in Annex I or for action with regard to control through approval of materials and chemicals that are used in drinking-water, particularly the control of chlorate formation in sodium hypochlorite used for drinking-water disinfection.

Chlorite

Routes to drinking-water

Chlorite is a break down product from chlorine dioxide used for drinking-water disinfection.

Evidence for adverse health effects and basis for a standard

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. WHO has a GV of 0.7 mg/L and this would be adequate to also allow the use of chlorine dioxide.

Priority for inclusion

Chlorite is of medium to high priority for inclusion in Annex I unless there are difficulties with establishing a suitable product approval scheme as chlorite would be controlled by specifying the maximum dose of chlorine dioxide in disinfection.

N-nitrosodimethylamine (NDMA)

Routes to drinking-water

NDMA is found at low levels in some drinking-waters as a disinfection by-product. There are also occasionally products and chemicals used in treatment that can contain NDMA as a contaminant and these should be controlled through product approval schemes. Nitrosamines, including NDMA, can sometimes be found in surface water but this is not considered to be the major source.

Evidence for adverse health effects and basis for a standard

NDMA has been shown to be carcinogenic in a number of animal species. It is considered to be probably carcinogenic in humans and WHO has developed a GV of 0.1 µg/L for an increased cancer risk of 10^{-5}.

Priority for inclusion

Although NDMA can be found as a nitrogenous disinfection by-product at low concentrations and also occasionally in wastewater discharges, drinking-water is considered to be a very minor source of exposure, less than food and much less than endogenous formation. Therefore NDMA is of low to medium priority for inclusion in Annex I.

Endocrine disrupting compounds (EDCs)

Endocrine disrupting substances 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. While they are potentially a relatively diverse group of substances with diverse outcomes and WHO has stated that these will be considered on a substance by substance or group of related substances basis for the Guidelines, The most widely studied in relation to drinking-water are those that possess oestrogenic or oestrogen mimicking activity.

These substances include human hormones that are excreted naturally as sulphate and glucuronide conjugates to make them water soluble and which are converted back to the parent compounds in sewage treatment. They 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.

There are other substances that show oestrogenic activity and which are from industrial origin. Some are subject to control, such as the alkyl phenols, which are break down products from the alkyl phenol ethoxylates used in the past as building blocks for detergents. These too are relatively insoluble and rapidly adsorb to sludge and sediment. They are also of significantly lower potency than the 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. These include substances such as bisphenol a and f and some phthalates.

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 this was shown to be primarily due to natural and synthetic hormones such as oestrone, oestradiol and ethinyl oestradiol.

A study of rivers in the UK heavily impacted by treated sewage effluent using a highly sensitive *in vivo* bioassay showed that no activity remained at the intakes of drinking-water treatment works and this was confirmed by chemical analysis. Subsequently a large study funded by the EC, which examined a wide range of potential endocrine disrupting substances 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 (EVK1-CT-2000-00047).*"

Routine monitoring for endocrine disrupting compounds would be difficult, expensive and not effective at preventing contamination of drinking-water. 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. This can be done by improvements in sewage (i.e. wastewater treatment processes), which is long-term, and by ensuring that drinking-water treatment is optimized for the removal of particles.

Routes to drinking-water

WHO defines an endocrine disruptor as "an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations". At present the term constitutes a wide range of substances of widely varying activities. In water the endpoint considered most frequently is oestrogenicity which incorporates compounds such as human hormones as well as substances such as bisphenol A and alkyl phenols. The major route of EDCs to drinking-water is from wastewater effluents. EDCs were considered as a new parameter in the 2008 proposals for updating Annex I of the Directive.

Evidence for adverse health effects and basis for a standard

While EDCs have been shown to cause effects in fish in the environment and in laboratory animals, the evidence for adverse effects on humans of low concentrations in drinking-water is very limited. A study carried out on behalf of the EC by the Fraunhofer Institute in Germany concluded that the risks for humans through drinking-water were very limited. In 2008 the contractors proposed changes to Annex I suggesting precautionary benchmark values for three EDCs (oestradiol, nonyl phenol, bisphenol a) with the requirement to use them as a means of checking the need for treatment and the efficacy of treatment since all are of low water solubility.

Priority for inclusion

It is not possible to assign a single priority to such a diverse group of compounds. Human hormones are probably the subgroup about which concerns have been raised. These substances may reach surface water impacted by sewerage effluents but are readily removed by drinking-water treatment (e.g. coagulation, filtration, activated carbon) and so are low priority for inclusion. WHO does not consider EDCs as a group but if EDCs are considered to be important by the EC, an approach based on benchmark values to assure treatment efficiency would be most closely aligned with the WSP approach and would be the most appropriate.

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. The problem of toxic growths has been described for many centuries and so this is not an emerging issue but one about which there is emerging concern across Europe.

The most common toxins were thought to be the microcystins, a group of molecules of which the most commonly encountered and the most toxic is considered to be microcystin-LR. WHO has evaluated microcystin-LR which is the only congener for which there is sufficient toxicity data and has set a GV of 1.0 µg/L. However, there are other toxins that are produced by blue-green algae, such as cylindrospermopsin, for which toxicity data were considered to be inadequate to develop a guideline value. WHO has re-examined the data on microcystin and affirmed the previous

guideline value along with a short-term value and is considering new data relating to cylindrospermopsin.

Both the microcystins and cylindrospermopsin have been identified in drinking-water sources in Europe. It is possible that other toxins, such as the neurotoxins saxitoxin and anatoxin-a, are also produced by European blooms as they have been encountered elsewhere in the world. In this context, the impact of climate change on cyanobacterial occurrence, bloom formation and the formation of specific toxins in Europe remains uncertain.

Analysis is relatively complex but the toxins will only be present when there is a bloom. Measuring toxin production in blooms is possible in order to identify those that produce toxins but this can be misleading since the capability to produce toxins may be different in different parts of a bloom and at different times. It is therefore preferable to control the blooms and to avoid abstracting water from within the blooms. The water safety plan (WSP) approach recommended by WHO, in order of preference, is firstly to manage lakes and reservoirs to prevent bloom formation, second to manage intakes by adjusting the depth at which water is abstracted and third is to establish treatment processes that will remove the toxins.

Controlling toxins by routine monitoring of drinking-water would not be effective for protecting public health because consumers would already be exposed. Providing a benchmark value in the DWD context, such as the WHO GV for microcystin-LR, as a value for total microcystins would allow water supply managers to establish adequate treatment capability where blooms may not be fully preventable. The removal techniques suitable for microcystins also appear to be suitable for cylindrospermopsin.

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). These can be removed on activated carbon. Cyanobacteria can also produce mucopolysaccarides, which may be a problem for bathers but the threat to drinking-water comes from their interference with coagulation and the removal of pathogens.

Microcystin

Route to drinking-water

Microcystins are a group of naturally occurring substances that are released from blooms of cyanobacteria and are, therefore, present in slow flowing or still surface waters intermittently. It should be noted that microcystins are not the only toxic substances that can be released by such blooms, although they are arguably the most common at this time. However, 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.

Evidence for adverse health effects and basis for a standard

Microcystins are hepatotoxins and there is some 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 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. WHO recommends that the best approach to controlling cyanobacterial toxins is managing waters to prevent blooms.

Priority for inclusion

There is a demand from some Member States for the inclusion of a standard for microcystin-LR, even though microcystins are not the only possible toxins. Routine monitoring for microcystin in drinking-water is not likely to be the best way of managing the problem of toxins, which will only be present intermittently during algal blooms. However, the standard could be a benchmark for ensuring that treatment processes are adequate to prevent significant levels reaching consumers if blooms cannot be adequately managed in source waters. Microcystin-LR is of low to medium priority for inclusion in Annex I.

Perfluorinated substances

This is a group of substances that were used in the manufacture of non-stick coatings and wetting agents in fire-fighting foams. When the final product breaks down the perfluorinated building blocks are released. These are both persistent and water soluble so are relatively mobile and can reach groundwater. While at least one Member State reports that they find the highest levels in sewage and sewage effluent most high levels seem to be found in groundwater as a consequence of point sources such as discharges from factories which used or manufactured perfluorinated compounds or from heavy use of particular fire-fighting foams at airports or other oil-based fires. There may well be other sources associated with fire-fighting foams but these are not well collated.

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 3M and Du Pont stopped the manufacture of PFOA in 2015. 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 and some related intermediates and treatment is both difficult and expensive in terms of materials and energy used. They can be removed on some granular activated carbons but breakthrough is rapid and so there is a requirement for frequent replacement or regeneration. Under these circumstances setting a health-based benchmark standard would be of value to water managers while setting precautionary standards is likely to be counter-productive, resulting in either an increased carbon footprint or the necessity of abandoning otherwise safe and good quality sources.

Routine monitoring seems unlikely to be beneficial and so investigative surveys would seem to be the most effective way of identifying hitherto unidentified pollution that needs to be considered for risk assessment.

Perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA)

Routes to drinking-water

Perfluorinated compounds of which PFOS and PFOA are 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. There is also evidence that

discharges from industry are still occurring in some Member States. There is also a likelihood of more widespread low levels in surface waters impacted by wastewater discharges. It appears to be primarily a localised problem near some airports and sites where foams have been used or manufacturing has taken place. It has been recognised and the manufacture of the perfluorinated substances is ceasing and the foams have been replaced by other alternatives. The problem should soon be associated only with historical pollution.

Evidence for adverse health effects and basis for a standard

These substances are unusual in that they are persistent and water soluble, making them a significant problem for groundwater where they have been extensively used. They are of concern as potential human reproductive toxicants. WHO currently has no GV but it is on the list for evaluation. Where values have been set for these two substances they are very low with PFOS being less than 0.5 µg/L and PFOA up to ten times higher.

Priority for inclusion

They are of medium to high priority for consideration for inclusion in Annex I because there is increasing evidence of widespread occurrence, particularly in groundwater, and this would provide a benchmark for levels that would require intervention (e.g. wastewater effluent control, drinking-water treatment).

Pharmaceuticals

With advent of advanced chemical analytical techniques a number of pharmaceutical residues were identified at low concentrations, primarily in surface waters used as drinking-water sources. Some of these have been found in drinking-water at trace concentrations orders of magnitude below any concentration of clinical significance. The primary source of these pharmaceuticals is sewage effluent and substances that are excreted by humans. 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 they also include both medical and illicit recreational drugs. There is also a probability that some pharmaceuticals may reach water sources as a consequence of the release of slurry from intensive animal rearing facilities but data are limited and this is not likely to be more than a relatively minor input compared with treated sewage effluent.

It is difficult to generalize about which pharmaceuticals will be present in different countries due to differing use patterns and concentrations will vary according to circumstances and flows. Some pharmaceuticals and metabolites will be removed, at least to some extent, in wastewater treatment and most of those that remain will be reduced or removed in drinking-water treatment so that the number of pharmaceuticals that reach drinking-water will be very small.

Several studies have been carried out in Europe and the USA to examine the threat 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 typical concentrations in surface waters were typically less than 0.1 µg/L and in drinking-water typically less than 0.05 µg/L. These so far

represent the highest levels seen, 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 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, chemical hazards, such as naturally occurring arsenic and fluoride*."

However, this conclusion does not mean that the issue should be ignored. As the population increases and, perhaps more significantly, the proportion of older people increases, then there is a possibility that the quantities of pharmaceuticals consumed will increase over time. In terms of the WSP approach there are several actions that would be appropriate focusing on mitigating the quantities entering water sources.

One problem in assessing the extent of contamination is the paucity of systematic analytical studies that have been carried out to a high quality, with appropriate quality assurance procedures. This limits the conclusions that can be drawn regarding the effectiveness of different wastewater treatment processes. However, reducing inputs is the most sustainable long-term solution and that can be achieved in various ways, none of which is the ultimate solution but all of which can make a significant contribution. 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%.

In the long-term green chemistry is being used to develop products that are more readily degraded in biological treatment of sewage. However, as with EDCs, the greatest concern is for the impact on aquatic life in surface waters for which the reduction of inputs will be most important. Already improved methods of treating sewage are available that can significantly reduce inputs to the environment, although this is a long-term solution. Optimization of both sewage treatment and drinking-water treatment will also help to reduce inputs to source water and also intake into drinking-water.

Routes to drinking-water

The primary route to drinking-water is from excretion by the general population and, consequently, treated wastewater discharges. A limited number of pharmaceuticals are also EDCs, mostly included in oral contraceptives but others may be used to treat endocrinological abnormalities. Some arises by disposal of pharmaceuticals to toilets and there are other more minor sources that impact surface water and, more occasionally, groundwater, such as pharmaceuticals from livestock rearing.

Evidence for adverse health effects and basis for a standard

WHO recognises that pharmaceutical are a diverse range of compounds with very different properties and only a few substances have been found in drinking water. It has considered the studies that have been conducted on a wide range of individual pharmaceuticals and concluded that the very low concentrations encountered are not likely to pose any significant risk to health. The assessments considered also included mixtures of substances with similar mechanisms of

action. WHO has also suggested that there is no immediate need to set GVs or monitor. Several assessments in Europe and the USA have come to similar conclusions. While the issue should not be ignored, the most appropriate solution is through improved wastewater treatment, although this will be a long-term strategy.

Priority for inclusion

Pharmaceuticals are a low priority for inclusion in Annex I because they are present only at trace concentrations and there is significant removal in drinking-water treatment. Risk assessment shows that at this stage this would not be of concern for health at the present levels. The most appropriate point of control for the future would be wastewater treatment.

Personal care products

Personal care products are a wide group of products and the substances used in them also constitute a wide grouping. Most 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.

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.

However, following the WSP approach would suggest that improved sewage treatment would be the most effective way forward.

Uranium

Routes to drinking-water

Uranium is found naturally in some groundwaters 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

Evidence for adverse health effects and basis for a standard

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. 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 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. The GV based on chemical toxicity is well below the concentration that would be of concern for radioactivity from 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 guideline value of 30

µg/L would provide significant protection against radioactivity and would not exceed the screening value for α particles.

Priority for inclusion

Uranium is of low to medium priority for inclusion in Annex I because of concern by Member States for natural occurrence in groundwater.

II. ADDITIONAL PARAMETERS SUGGESTED BY OTHER GROUPS

Asbestos

Routes to drinking-water

Asbestos fibres may enter drinking-water via surface water contamination from natural sources but this is unlikely to be significant in Europe as all surface derived sources receive treatment that would be expected to remove such fibres. The primary source of asbestos fibres in drinking-water is asbestos cement pipe installed in the past.

Evidence for adverse health effects and basis for a standard

A number of evaluations of asbestos in drinking-water have been carried out and are largely reflected in the background document on asbestos in the Guidelines. The conclusion is that there is no convincing evidence from either epidemiological studies or from animal studies of adverse effects on health from ingested asbestos, including through drinking-water. It should be noted that the fibres in asbestos cement drinking-water pipes are different in form (short fat fibres) and, probably, surface properties from those that cause asbestos related lung disease. Currently there would be no suitable means of developing a meaningful standard and the measurement in water is extremely difficult and expensive.

Priority for inclusion

Asbestos would be considered a very low priority for inclusion in Annex I due to limited health significance through ingestion. However, there is merit in specifically excluding asbestos cement pipe from the list of approved products for several reasons, primarily for occupational health reasons but also because of the fact that it has a number of operational disadvantages and drilling the pipe from outside to make connections is potentially hazardous.

Calcium and magnesium

Routes to drinking-water

Calcium and magnesium are naturally present in most waters at varying concentrations and are key components of hardness.

Evidence for adverse health effects and basis for a standard

Calcium and magnesium are essential elements for humans. There is no evidence for adverse effects on health but there is some evidence for beneficial effects. In societies that are marginal for calcium or magnesium intake, drinking-water may make an important contribution but this will depend on a range of circumstances. WHO does not make recommendations regarding calcium and magnesium except to suggest that if desalinated water is to be re-mineralised then adding

calcium and magnesium salts should be considered. Calcium and magnesium can be significant in terms of the acceptability of drinking-water and are important in scale formation in drinking-water systems.

Priority for inclusion

Calcium and magnesium are of low priority for inclusion in Annex 1 but they may be an issue for individual Member States.

Chlorophenol

Routes to drinking-water

Chlorophenol(s) are usually found in drinking-water as a consequence of the chlorination of natural or anthropogenic phenolic substances in raw water.

Evidence for adverse health effects and basis for a standard

Chlorophenols are only found at very low concentrations that are considered not to be of concern to health in humans. They do give rise to taste problems at low concentrations, sometimes sub-microgram per litre. If they are methylated by heterotrophic organisms in the distribution system they form chlorinated anisoles, which have a taste threshold in the region of 10 ng/L.

Priority for inclusion

They are of low priority for inclusion in Annex I but would be covered by the acceptable taste requirement. They would not normally be identified by routine monitoring because their presence is usually intermittent and they are normally considered to be an operational problem. Where phenols are present from discharges, the control mechanism is to prevent the discharges.

Glass fibres

Routes to drinking-water

The primary route to drinking-water for glass fibres is from glass fibre reinforced plastic which is most usually found in glass reinforced pipe (GRP pipe) or GRP storage tanks. There are other potential issues associated with GRP with regard to styrene used as a solvent, which can give rise to taste and odour at very low concentrations.

Evidence for adverse health effects and basis for a standard

There is no convincing evidence that ingested glass fibres pose a risk to human health.

Priority for inclusion

Materials should normally be controlled through product specification and approval. There is no appropriate basis by which a meaningful standard could be set. Equally monitoring would not straightforward. Glass fibres are a low priority for inclusion in Annex I but regulation would normally be through product approval and specification.

Nanoparticles (including nanoplastics)

Routes to drinking-water

Nanoparticles are increasingly used for many purposes that may result in their loss to wastewater and potentially surface waters used as drinking-water sources. The particles most likely to reach drinking-water are nanoparticles of silver, aluminium, titanium dioxide and ferric oxide. There are only a limited number of studies on the removal of nanoparticles in drinking-water treatment and although these show that nanoparticles can be removed by conventional treatment, the removal efficiencies appear to be highly dependent on a range of water characteristics. Many synthetic nanoparticles have a tendency to aggregate in the environment to larger sizes that should be more readily removed by standard filtration.

Evidence for adverse health effects and basis for a standard

At present there is no credible evidence that nanoparticles ingested in drinking-water can cause adverse health-effects in humans, but the evidence is limited and methods for assessing the toxicology of nanoparticles are restricted and complex.

Priority for inclusion

Nanoparticles in drinking-water are currently a low priority for inclusion in Annex I. They remain contaminants of emerging concern and as such there is a requirement for a re-examination when more data emerge that will allow a realistic assessment.

Thallium

Routes to drinking-water

Thallium can reach water sources naturally and from industrial discharges. Concentrations are generally very low but thallium is not a substance that is frequently assessed. USEPA developed a maximum contaminant level of 2 µg/L but concentrations generally appear to be considerably below this concentration although there may be specific circumstances when higher concentrations are encountered.

Evidence for adverse health effects and basis for a standard

Although thallium is known to be toxic to humans and does accumulate there is no evidence for adverse health effects in humans from exposure through drinking-water.

Priority for inclusion

Thallium remains a low priority for inclusion in Annex I unless it is shown that thallium is found widely in drinking-water at concentrations of concern.