ANSES Scientific and Technical Support
Request No. 2018-SA-0027

The Director General

Maisons-Alfort, 30 May 2018

Revised NOTE of 23 March 2018[1] by the French Agency for Food, Environmental and Occupational Health & Safety

on a request for scientific and technical support relating to the revision of Directive 98/83/EC as amended on the quality of water intended for human consumption

ANSES undertakes independent and pluralistic scientific expert assessments.
ANSES primarily ensures environmental, occupational and food safety as well as assessing the potential health risks they may entail.
It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.

It provides the competent authorities with the necessary information concerning these risks as well as the requisite expertise and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).

Its opinions are published on its website. This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 30 May 2018 shall prevail.

On 20 February 2018, ANSES received a formal request from the Directorate General for Health (DGS) to undertake the following expert appraisal: request for scientific and technical support relating to the revision of Directive 98/83/EC as amended on the quality of water intended for human consumption.

1. BACKGROUND AND PURPOSE OF THE REQUEST

On 1 February 2018, the European Commission published a revision proposal for Directive 98/83/EC as amended on the quality of water intended for human consumption. This proposed text[2] was submitted for public consultation until 29 March 2018.

Work was undertaken within the European Council and the Parliament with a view to adopting the proposed text at the end of 2018.

The DGS asked ANSES for scientific and technical support on the following points, to help it formulate the position of the French authorities:

- technical points related to materials in contact with water, and water treatment products and processes (see Recital 12 of the Commission's proposal);

[1] This note is a translation of the revised French version dated 30 May 2018

[2] Referenced proposal Brussels, 1.2.2018 COM(2017) 753 final
http://ec.europa.eu/environment/water/water-drink/review_en.html

- updated parametric values or proposed values for the new parameters added for monitoring water quality (see Annex I of the Commission's proposal);
- updated laboratory performance characteristics or proposed characteristics for analysing the new parameters added for monitoring water quality (see Annex III of the Commission's proposal).

The French High Council for Public Health (HCSP) also received a formal request from the DGS on this matter. The request to the HCSP concerned the ranking of new parameters added to Annex I of the Commission's proposal in terms of health issues, while also taking technical-economic issues into account.

2. ORGANISATION OF THE EXPERT APPRAISAL

The expert appraisal was carried out in accordance with French Standard NF X 50-110 "Quality in Expert Appraisals – General Requirements of Competence for Expert Appraisals (May 2003)".

It was carried out by the "Revision of the Drinking Water Directive" Emergency Collective Expert Appraisal Group (GECU). Telephone meetings in sub-groups were organised and the GECU met on 16 March 2018.

The Expert Committee (CES) on "Water" was consulted during the meeting of 6 March 2018.

In view of the amendments proposed by the EC and ANSES's ongoing work, other expert groups were consulted: the Working Group (WG) on "Materials in contact with water 2", the WG on "Relevant pesticide metabolites" and the WG on "Updating of the risks associated with the presence of cyanobacteria and their toxins in water intended for human consumption, bathing and other recreational activities".

ANSES analyses interests declared by experts before they are appointed and throughout their work in order to prevent risks of conflicts of interest in relation to the points addressed in expert appraisals.

The experts' declarations of interests are made public via the website of the Ministry of Solidarity and Health (https://dpi.sante.gouv.fr).

Given the time constraints imposed by the formal request, the GECU was not able to carry out a review of the scientific literature to conduct its work, and therefore essentially relied on the following documentation:

- The documents associated with the Commission's proposal and available on the Commission's website, in particular:
  - The recommendations of the World Health Organisation (WHO) (2017) – Support to the revision of Annex I Council Directive 98/83/EC,
  - The impact assessments carried out by the Commission;
- The opinions, reports and studies (TDS2, iTDS, etc.) produced by the Agency, as well as its ongoing work;
- The results of the analysis campaigns carried out by ANSES's Nancy Laboratory for Hydrology (LHN).

For some parameters, these data were supplemented by an analysis of recent scientific publications.

3. ANALYSIS AND CONCLUSIONS OF THE GECU

3.1. General provisions of the draft revision of the Drinking Water Directive

The European regulatory framework for drinking water is provided by Directive 98/83/EC on the quality of water intended for human consumption.

It concerns:
- all water either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes, regardless of its origin and whether it is supplied from a distribution network, from a tanker, or in bottles or containers;
- all water used in any food-production undertaking for the manufacture, processing, preservation or marketing of products or substances intended for human consumption unless the competent national authorities are satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form.

The Directive's purpose is to protect consumers from the adverse effects of any contamination of drinking water and therefore to permanently guarantee water posing no risk to human health for all consumers in the European Union (EU). Achieving this objective mainly requires setting up a multi-barrier approach for treatment systems and establishing minimum quality limits at the EU level.

The main changes proposed by the Commission concern the following:

- the approach based on hazard analysis and risk control from the raw water resource through to the consumer's tap;
- the updating of the list of parameters to be analysed and the associated parametric values according to the latest scientific findings;
- improved access for consumers to recent information on water quality;
- access to water for all the citizens of the EU, particularly vulnerable and marginalised groups;
- harmonisation of the provisions relating to materials in contact with drinking water via the adoption of standardisation mandates in the framework of the Construction Products Regulation.

Some elements of the draft revision of the Drinking Water Directive (DWD) also aim to foster sustainable management of drinking water and therefore of the resource, restore consumer confidence with regard to drinking water, and contribute to reducing the consumption of bottled water. This objective is in line with the EU's efforts to reduce emissions of greenhouse gases and marine waste, and with the European strategy on plastics.

The EC also wishes to harmonise the legislation established within the EU in the area of water, particularly with the Water Framework Directive (WFD), as these two directives are complementary despite their scope being different.

■ Scope of the draft revision of the DWD

Spring water (SW) (prior to bottling) is included in the scope of the Commission’s proposal whereas natural mineral water (NMW) remains excluded since it falls within the scope of Directive 2009/54/EC.

Recital 3 of the Commission's proposal states that "*In the case of water intended for human consumption put into bottles or containers intended for sale or used in the manufacture, preparation or treatment of food, the water should comply with the provisions of this Directive until the point of compliance (i.e. the tap), and should afterwards be considered as food, in accordance with the second subparagraph of Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council*".

Spring water and water made drinkable through treatment (WMDT) once bottled are therefore not taken into account in the draft revision of the Directive. Moreover, the water used in food companies as defined in Article 2 of Directive 98/83/EC no longer seems to be taken into account.

Article 6 states that the parametric values set shall be complied with for spring water at the point at which the water is put into the bottles or containers. The table presenting the microbiological parameters to be screened for in bottled water and their specific parametric values has been deleted from the Commission's proposal. However, the provisions described for bottled SW in Article 9 Paragraph 4 of Directive 2009/54/EC on NMW remain in force. The microbiological quality requirements for bottled NMW therefore still apply to bottled SW (Article 5).

- **Assessments of the hazards and risks (Articles 7, 8, 9, 10)**

Article 7
Article 7 presents the overall risk-based approach and introduces the general obligations relating to this scheme. This provision, introduced in 2015 in Directive 2015/1787 amending Annexes II and III of Council Directive 98/83/EC on the quality of water intended for human consumption, **becomes mandatory** and entails a major change in practices for the people responsible for water production and distribution (PRWPD). It is a comprehensive approach seeking to permanently guarantee the safety of the supply of drinking water. The most effective way to achieve this is to apply a general strategy of prevention and anticipation involving the assessment and preventive management of risks, covering every step in the water supply process, from abstraction through to the consumer's tap.
The Water Safety Plans (WSPs) advocated by the WHO rely on methods for hazard analysis and risk control, and the historical principle of multiple sanitary barriers, in order to meet the basic requirements: availability and quality in health and organoleptic terms of the water supplied to the population. Under WSPs, a hazard study is carried out leading to an appropriate action plan applied to the entire water production and distribution system and established over the long term (continuous improvement approach) (information memo DGS/EA4/2018/9[3]).
This approach should help prevent all health risks especially short-term ones (microbiological).

Article 8
Article 8 introduces the obligations relating to the hazard assessment of bodies of water used for the production of drinking water. This assessment is important for defining preventive measures to protect the catchment areas included in these water bodies and mitigation measures to combat the sources of pollution, and for designing suitable treatment systems and establishing additional supervision.

Article 9
Article 9 introduces the obligations relating to the supply risk assessments to be carried out by water suppliers.
These provisions had already been introduced in 2015 by the amendment to Annex II of Directive 98/83/EC (Part C).

[3] Information Memo No. DGS/EA4/2018/9 of 09/01/18 on plans for managing the safety of water intended for human consumption

Article 10
Article 10 introduces the obligations relating to the domestic distribution risk assessments, as well as to the monitoring of the "lead" and "*Legionella*" parameters, focusing on priority premises (hospitals, healthcare facilities, penal institutions, campgrounds, etc.).

- **Monitoring (Article 11 and Annex II)**

The Commission's proposal lays down provisions relating to monitoring for the purposes of verifying compliance and monitoring for operational purposes.
Recital 23 states that "*Most of the monitoring carried out for the purposes of this Directive is performed by water suppliers*".

Part A of Annex II clarifies the concept of regular monitoring described in Article 11. It introduces the concept of operational monitoring, which provides a rapid overview of any problems relating to operational performance or water quality, to enable prompt application of the corrective measures laid down when the WSPs were established. This operational verification programme takes into account the results of assessments of the hazards and risks associated with supply and aims to confirm the effectiveness of all the monitoring measures applied to abstraction, and during treatment, distribution and storage. The turbidity parameter is imposed as a mandatory parameter to be monitored in the operational monitoring programme, and a parametric value and monitoring frequency are associated with it.

Monitoring of the parameters listed in Annex I, Parts A and B can be adapted on the basis of a supply risk assessment, except for the core parameters (*E. coli*, *Clostridium perfringens* spores and somatic coliphages), which must always be checked according to the frequencies listed in Table 1 of Part B, Annex II.

- **Derogations**

The EC proposes deleting Article 9 of Directive 98/83/EC enabling Member States (MSs) to provide for derogations from the parametric values, without however specifying the procedures for managing the derogations currently in place in the MSs.

3.2. Provisions relating to materials in contact with water and to treatment products and processes

Article 10 of Directive 98/83/EC concerns all products and materials coming into contact with water from the abstraction point through to the consumer's tap. Its unclear wording has led to the introduction in the MSs of a wide variety of measures (which already existed before 1998 in several MSs) for monitoring products and materials. There is a long-standing need (pre-dating 1998) for harmonisation of practices by the MSs to ensure a high level of consumer health protection in the EU and to remove barriers to the free movement of products intended to come into contact with drinking water.
The steps taken in this regard since the early 1990s, in the framework of the Directive and then Regulation No 305/2011/EC on construction products (CPR)[4], have not led to a common protocol for assessing products in contact with drinking water.

[4] Regulation No 305/2011/EC of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products.

Article 10 of Directive 98/83/EC also concerned treatment products and processes. These have not been taken into account, either in the Commission's proposal or in the CPR.

Article 10 as written in the revision proposal only deals with "domestic distribution risks" and more specifically in "priority premises" (defined in Article 2 of the Commission's proposal), and no longer includes any requirement concerning products and materials used in the public network. In addition, it transfers the requirements relating to products in contact with drinking water (PDW) in domestic networks to the CPR.

The GECU understands domestic distribution systems to mean the networks inside buildings.

On 21 February 2018, the WG on "Materials and products in contact with water 2" (Drinking water products working group [DWPs WG]) was consulted on the provisions proposed in Article 10 of the Commission's proposal.

The DWPs WG emphasised that:

- Materials and products used for the abstraction, treatment and distribution of drinking water are installed for several decades and represent a significant financial investment for local authorities. It is therefore essential that they meet stringent safety requirements to avoid adversely affecting the quality of drinking water.
- The hygiene and health requirements of the CPR (Requirement 3 of Annex I)[5], just like the current provisions of Article 10 of Directive 98/83/EC, are not sufficiently precise and give the MSs too much discretion to formulate national requirements. As a reminder, the standardisation work initiated more than 15 years ago (2001) in response to Mandate 136[6] has still not led to publication in the Official Journal (OJ) of "product" standards needed for CE marking of products in contact with drinking water.
- The safety requirements for all materials in contact with drinking water (PDW in "public" and "private" distribution networks) and for all water treatment products and processes (WTP&P) should be defined and specified at EU level, which would make it possible to implement the European harmonisation that has been needed for a number of years. The list of authorised substances for the manufacture of organic materials (or the list of accepted compositions for metallic materials), as well as the criteria for acceptability of PDW and WTP&P, should be defined in a European regulation and not in "product" standards.

In the absence of any harmonised European requirements for all the PDW and WTP&P that are conceivable in the near future, **the DWPs WG recommends:**

- **not removing the existing minimum requirements in the current Article 10 of Directive 98/83/EC concerning PDW and WTP&P so as to avoid giving the impression that less stringent health requirements apply to them;**

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[5] "*The construction works must be designed and built in such a way that they will, throughout their life cycle, not be a threat to the hygiene or health and safety of workers, occupants or neighbours, nor have an exceedingly high impact, over their entire life cycle, on the environmental quality or on the climate during their construction, use and demolition, in particular as a result of any of the following:*

e) the release of dangerous substances into drinking water or substances which have an otherwise negative impact on drinking water;".

[6] Mandate M136 of the European Commission to CEN/CENELEC concerning the execution of standardisation work for harmonised standards on construction products in contact with water intended for human consumption. http://www.rpcnet.fr/

- **using the technical assessment documents drafted by the 4MS Group[7] as a European reference standard for PDW in "public" and "private" distribution networks;**
- **adding a requirement according to which only products (pipes, coatings, tanks, joints and fittings, etc.) manufactured with approved or certified materials may be used.**

Indeed, **all materials and products in contact with drinking water, as well as WTP&P, should fall within the scope of the Directive, even if they are not within the scope of the CPR.** As a reminder, the legislation referred to on construction products only covers products used for the transport, storage and distribution of drinking water, i.e. used after the treatment plant (see Mandate 136, withdrawn in 2016). In addition, ready-mixed concrete does not fall within the scope of the CPR.

The way Point 2 (c) of Article 10 is written: "*take other measures, such as appropriate conditioning techniques, in cooperation with water suppliers, to change the nature or properties of the water before it is supplied so as to eliminate or reduce the risk of non-compliance with the parametric values after supply;*" should be revised. Water quality should be corrected in the treatment plant rather than at the point of use in a building for public or private use. **The WG therefore proposes adding to the Directive a statement indicating that distributed water must not be aggressive or corrosive with regard to the materials in public and private distribution networks.** The addition of a supplementary treatment should be confined to specific situations (with buildings for collective use, these treatments are only currently authorised for domestic hot water production).

The DWPs WG supports the Commission proposal to organise training for plumbers and other professionals working on indoor water systems. Indeed, it has been clearly identified that the lack of training and information on the design rules, the regulatory requirements to be complied with for MDW, and the maintenance practices followed by these actors are responsible for situations in which the water quality is degraded.

The quality of drinking water can also be strongly affected by the products or processes used to treat it; just like the materials in contact with water, these must undergo an assessment and be subject to health provisions governing their use and their placing on the market. **The WG recommends including in the new Directive the requirements of Article 10 of Directive 98/83/EC in force and supplementing them by requiring evidence of effectiveness for WTP&P.**

At its meeting on 16 March 2018, the GECU adopted the findings and recommendations of the DWPs WG.

3.3. Parameters, parametric values and performance of analytical methods

The existing parametric values laid down in Annex I of Directive 98/83/EC are generally based on the WHO's recommendations for the quality of drinking water. However, the EC has proposed a different approach for some of the parameters in this draft revision of the Directive.

Annex I presents the minimum requirements relating to the parametric values used to assess the quality of drinking water. It is broken down into three parts: Part A concerning the microbiological parameters, Part B relating to chemical parameters, and Part C concerning the parameters

[7] https://www.umweltbundesamt.de/en/topics/water/drinking-water/distributing-drinking-water/approval-harmonization-4ms-initiative.

relevant for assessing the risks associated with domestic distribution systems. Part C in the current version of the Directive listing the indicator parameters has been deleted (see Section 3.3.2.4).

As previously stated, setting up WSPs will enable the analysis frequency of the parameters listed in Annex I of the Commission's proposal to be adapted according to the results of the risk analysis carried out on the water resource, but also at the point of production and in drinking water distribution networks.
The parameters identified as "core" (*E. coli*, *Clostridium perfringens* spores and somatic coliphages) must however always be checked according to the frequencies given in Table 1 of Part B, Annex II.

The method followed by the GECU was based on an analysis of the reports and data available on characterisation of the hazard by the oral route and exposure of the population. For the chemical parameters, the health risk assessment was carried out on the basis of the general methodology published by the Agency in 2007 (AFSSA 2007). In the interests of brevity, the risk assessments have not been detailed for any parameters that have already been appraised; the associated opinions are available on the ANSES website (www.anses.fr).

Besides any parameters for which an ANSES opinion was required, the GECU also provided comments on the relevance of taking certain parameters in drinking water into account, in view of the recommendations of the WHO (2017) and the work published by ANSES, particularly regarding the assessments of the health risks associated with their presence in drinking water and the total diet studies (TDS2 and iTDS). The GECU paid particular attention to substances for which drinking water is a major contributor (10% or more) to total dietary exposure and for which a risk cannot be ruled out for certain groups of consumers (ANSES 2011a, 2016a).

3.3.1. Microbiological parameters

In view of the planned exclusion of bottled water from the scope of the draft revision of the Directive, the table showing the microbiological parameters to screen for in bottled water has been deleted from Annex I. With regard to the analysis of spring water, the GECU stresses that the decrease in analytical volume (analysis at the packaging point on a 100 mL sample instead of 250 mL in the current Directive) will reduce the probability of detection for all the biological parameters analysed.

3.3.1.1 New microbiological parameters

- **Somatic coliphages**

The GECU welcomes the inclusion for the first time in European legislation on drinking water of issues related to the presence of viruses in drinking water. A parametric value of 0/100 mL has been established for somatic coliphages.

The Commission proposes including this parameter in the list of core parameters to be analysed systematically, according to the EN ISO 10705-2 standard[8].

It should be emphasised however that bacteriophages are not indicators of water contamination by enteric viruses but indicators of the effectiveness of treatment applied against viruses.

[8] NF EN ISO 10705-2 (October 2001) Water quality – Detection and enumeration of bacteriophages – Part 2: Enumeration of somatic coliphages

The coliphages regarded as somatic belong to the bacteriophages (viruses of bacteria) and consist of a capsid containing a genome consisting of DNA (single or double strand). They specifically target *Escherichia coli*. These bacteriophages bind to lipopolysaccharide receptors or receptor proteins of the bacterial cell wall and can cause lysis of the host cell in 20 or 30 minutes in optimal conditions. They do not interact with the F receptor (sex receptor). F-specific RNA bacteriophages, meanwhile, are only able to infect bacteria possessing the F plasmid or sex plasmid initially detected in the original K-12 strain of *Escherichia coli*. They are also phages and consist of a cubically symmetric capsid with a diameter between 21 nm and 30 nm and a single-stranded RNA genome.

As indicated in the Agency's report published in 2007 (AFSSA. 2007) and that of the WHO published in 2016, screening for F-specific RNA bacteriophages, and not somatic coliphages, is generally recommended in order to assess the effectiveness of treatments. In its scientific and technical support note of 2009 (AST 2009-SA-0093), the Agency recommended promoting research into MS2 bacteriophages (F-specific RNA coliphages).
The GECU underlined an inconsistency in the report of the WHO's recommendations dating from 2017. In the text, the WHO experts explain that monitoring the effectiveness of treatments must be carried out with somatic coliphages, whereas in the Appendix, it is stated that F-specific RNA phages may be more appropriate.

The Commission's choice to retain somatic coliphages could be explained by the fact that it is simpler to detect them, from a purely methodological point of view.

It should be noted that the parametric value set (0/100 mL) implies the use of a volume of 100 mL and therefore a sample concentration for which there is no standardised method available. The WHO report indicates two publications that offer concentration methods, requiring either pretreatment of the sample before use of a charged membrane, or two steps of adsorption and then elution to be carried out.

In the latest version of the EN ISO 10705-2 standard cited in the Commission’s proposal, dating from 2000, reference is made to a future concentration method (Section 1). Pending a new standardised concentration method, and in order to be able to measure somatic phages in a sample volume of 100 mL, 10 to 20 Petri dishes with a diameter of 14 cm should be inoculated, or the most probable number approach should be followed, by depositing drops of different dilutions. However, this latter approach does not seem feasible in view of the expression of the results defined in the Commission’s proposal (PFU/100 mL).

Currently in France, as far as the GECU is aware, just one laboratory is accredited by COFRAC[9] for the analysis of phages according to the EN ISO 10705 standard, and only for Part 1 relating to F-specific RNA phages.

The GECU indicates that from a health point of view, the introduction of a "virus" parameter (adenovirus for example) would be more relevant than the introduction of somatic coliphages.

However, due to the technical difficulties associated with analysing viruses, the GECU approves the introduction of bacteriophages in the draft revision of the DWD with a parametric value of 0 PFU/100 mL. It insists on the fact that bacteriophages are indicators of the effectiveness of treatments to eliminate viruses and not indicators of contamination of water by viruses.

Screening for bacteriophages is relevant in the context of applications for authorisation to use

[9] COFRAC: French Accreditation Committee (https://www.cofrac.fr/)

water to produce drinking water and for setting up WSPs (hazard study). The GECU recommends not considering this parameter as "core".

The GECU stresses that the parametric value proposed by the EC involves the use of a sample concentration technique for which there is no standardised method.

Despite the technical constraints, the GECU believes that screening for human enteric viruses (adenovirus, enterovirus, norovirus, etc.) in raw water (surface water and groundwater when it is influenced by the former) may be relevant in the context of applications for authorisation to use water to produce drinking water and when setting up WSPs. The analysis of coliphages would then supplement that of viruses (enteric viruses used to determine the contamination level of the resource, phages for monitoring the effectiveness of treatment).

- ***Legionella***

The *Legionella* parameter has been added to Part C of Annex 1 as one of the "parameters relevant for the domestic distribution risk assessment". The Commission's proposal provides for:

- screening for *Legionella*, in 1 litre of water (unit: number per L), with a parametric value <1000 CFU/L;
- screening for *Legionella pneumophila* after resampling if the *Legionella* count obtained the first time is greater than 1000 CFU/L;
- establishment of a threshold at 10,000 CFU/L for *Legionella* in the absence of *L. pneumophila*.

The GECU questions the relevance of re-sampling when the first *Legionella spp.* analysis is >1000 CFU/L, to verify whether the concentration of *L. pneumophila* is <1000 CFU/L, as the respective proportions of *L. spp.* and *L. pneumophila* can be determined from the outset with the first analysis.

In France, with respect to domestic hot water (DHW), the requirements concern only *L. pneumophila,* with the threshold set at 1000 CFU/L (Ministerial Order of 1 February 2010[10]), which is therefore consistent with the one proposed in the Commission's proposal. In addition, the regulations applicable to cooling towers (CTs) of classified facilities for environmental protection (ICPEs) only set an alert threshold at 10^3 CFU/L for *Legionella pneumophila* in water, with the *Legionella spp.* parameter no longer having an associated regulatory threshold, although it is monitored as an indicator of the risk of development of *Legionella pneumophila* in the CT.
In healthcare establishments, Ministerial Order of 1 February 2010 specifies that counts of *Legionella pneumophila* must be "*lower than the threshold of detection at all points of use at risk* (…)". The threshold of detection is 10 CFU/L according to the latest version of the NF T 90-431 standard published in 2017[11].

In its report of 2017, the WHO recommended introducing specific provisions for the control of *Legionella* in hot water systems in priority buildings.
However, the Commission's proposal does not specify whether sampling should be carried out on the cold water and/or hot water network. This detail is important because temperature is a key factor that can influence the proliferation of *Legionella* in water.

Concerning the sampling and analysis of *Legionella*, the following points should also be emphasised:

[10] Ministerial Order of 1 February 2010 on the monitoring of *Legionella* in facilities for the production, storage and distribution of domestic hot water

[11] NF T 90-431 (August 2017) Water quality – Detection and enumeration of *Legionella spp.* and *Legionella pneumophila* – Method by direct inoculation and after concentration by membrane filtration or centrifugation

- The EN ISO 19458[12] standard cited in Annex II does not describe the specific characteristics of *Legionella* sampling. These are however contained in the FD T90 522 guide[13];
- According to the Commission's proposal (Annex II, Part D), samples must be taken at the consumer's tap without prior flushing of the water. A random daytime sample is to be taken. The French regulations stipulate that samples should be taken after 2 to 3 minutes of flow (although an alternation of the sampling methods and the use of the "first stream" method are advocated in establishments taking a large volume of samples, particularly healthcare institutions);
- The Commission's proposal recommends the use of the EN ISO 11731 standard[14] for detecting *Legionella*. This standard offers the user many methodological variants, which may introduce a diversity of practices, and therefore a discontinuity in analytical monitoring and performance differences according to the various analytical strategies. In France, the NF T 90-431 standard describes the methodology to be followed for detection and enumeration by culture of *Legionella spp.* and *Legionella pneumophila* bacteria in all types of water;
- The broad spread of results obtained when testing for *Legionella*: according to the reproducibility data provided by AGLAE[15] following the inter-laboratory tests conducted using the NF T 90-431 standard, there was a 1 to 32 ratio between the results communicated by the different laboratories when applying this standard (ANSES 2017a).

The GECU supports the introduction of the *Legionella* parameter in the draft revision of the Directive, considering that its screening will take place with regard to the risk analysis conducted in "domestic" systems.

The GECU recommends simultaneously testing for *L. spp.* and *L. pneumophila* and clarifying the proposed thresholds, by indicating a parametric value of "<1000 CFU/L" for *L. pneumophila* and "<10,000 CFU/L" for *L. spp.*

The GECU believes that priority should be given to carrying out screening on domestic hot water networks and networks in which the temperature can exceed 25°C.

The GECU notes that the method for sampling at the points of use proposed in the Commission's proposal (monitoring of exposure) differs from that advocated in the French regulations (monitoring of the network control conditions).

It also draws attention to:
- the considerable variability of results obtained when testing for *Legionella* according to the NF T 90-431 standard,
- that the methods proposed in the EN ISO 11731 standard may lead to a diversity of practices also resulting in variability of results.

Practices need to be homogenised to enable interpretation of the results.

Lastly, the GECU stresses the importance of defining the typology of priority institutions and ranking them according to the hazard and the risks to the exposed population.

[12] NF EN ISO 19458 – Water quality – Sampling for microbiological analysis
[13] FD T90-522 (July 2006) Water quality – Sampling technical guide for detection of *Legionella* in water
[14] NF EN ISO 11731 (July 2017) Water quality – Enumeration of *Legionella*
[15] General Association of Analytical and Testing Laboratories

3.3.1.2 Other parameters

- ***E. coli,* enterococci and coliform bacteria**

These three parameters are listed in Annex I, Part A.

In the Commission's proposal, Annex III specifies standardized methods[16] to be used for the analysis of these three parameters.

As indicated earlier, the hazard assessment of water resources is taken into account in the Commission's proposal (article 8). In view of the scope of application of the standards listed in Annex III, some methods, in particular those based on filtration, might not be adapted for the analysis of water loaded with suspended matter and/or containing a significant amount of interfering flora.

The GECU notes that **coliform bacteria** have been introduced in Annex I whereas in the current Directive they are considered to be an indicator parameter. The GECU stresses that coliform bacteria are an indicator of the effectiveness of the disinfection and contamination treatment within the distribution network. The fact that this parameter is no longer regarded as an indicator parameter (with an associated quality reference and not a quality limit at the national level) could cause management problems.

The GECU notes that **enterococci** have not been included in the list of "core" parameters. Screening for these bacteria in water can therefore be adapted according to the risk assessment. It is regrettable that this parameter has been separated from the *E. coli* parameter because enterococci are considered good indicators of faecal contamination even if they are present in lower concentrations than *E. coli* in the human digestive tract or in the environment (at a point close to the origin of contamination). It should also be remembered that they are more resistant than *E. coli* bacteria, both in the environment and with regard to disinfection treatments. Their detection in water provides significant additional information. Lastly, the term "Enterococci" should be replaced by "Intestinal enterococci", for the sake of clarity and consistency with the EN ISO 7899-2 standard.

In conclusion, with regard to *E. coli*, coliform bacteria and enterococci, the GECU proposes:

- replacing the value of "0 in 100 mL" by an expression of the result as "not detected in 100 mL";

- specifying the methods to be used for the analysis of these parameters in raw water;

- as advocated by the WHO, adding intestinal enterococci to the list of "core" parameters in the same way as *E. coli*, with regard to their resistance to disinfection treatments and their ease of analysis;

- keeping coliform bacteria as an indicator parameter of the effectiveness of treatment.

- **Culturable aerobic flora**

This parameter is an indicator of the overall microbiological quality of the water in the distribution network.

[16] EN ISO 9308-1 or EN ISO 9308-2 for enumeration of *Escherichia coli* and coliform bacteria
EN ISO 7899-2 for enumeration of intestinal enterococci

The EC proposes removing the colony count at 36°C and therefore focusing on saprophytic germs that only develop at around 20°C and not in conjunction with the flora at 36°C that develop at an equivalent temperature to that encountered in the human body.

Interpretation of the result obtained for flora in a water sample largely depends on the type of water considered and the objective of the monitoring. In the resource, it means obtaining information on the number of bacteria, which can fluctuate according to the seasons. In water leaving the treatment plant, flora is measured to monitor any possible degradation of the microbiological quality of the water during distribution and storage.

The GECU notes that even if the analytical principle of the standard is the same regardless of the type of water analysed, the test sample volume will need to be adapted according to the bacterial concentration measured in raw water.

In France, the regulations stipulate that the result should not vary by more than a factor of 10 compared to the usual value, even if the applicability of such a limit is often subject to interpretation.

The GECU questions the relevance of removing the enumeration of culturable aerobic flora at 36°C. Although in practice the result of the count at 36°C is rarely used either by the PRWPD or the Regional Health Agencies (ARSs), the GECU considers that the colony counts at 22°C and 36°C provide two useful and complementary types of information on the quality of the water in the distribution network.
The statement "no abnormal change" should also be clarified.

- ***Clostridium perfringens* spores**

The EC proposes including spores of *Clostridium perfringens* with the core parameters. The term "*Clostridium perfringens*, including spores" has been replaced by the term "*Clostridium perfringens* spores" in the Commission's proposal. The GECU supports this change in term.

The GECU specifies that if it is used as an indicator parameter of faecal contamination, it should include screening for vegetative forms and not only the spores. If it is used as a parameter for assessing the effectiveness of treatments, in particular those relying on filtration processes, screening for the spores alone is sufficient. Indeed, *Clostridium perfringens* spores can be used to assess the effectiveness of treatments particularly with regard to protozoa.

The Commission's proposal mentions in Annex III the method for enumerating vegetative cells and spores of *Clostridium perfringens*, namely the EN ISO 14189 method[17]. This is not consistent with the annotated specification in Annex I, which only targets screening for spores and not vegetative forms.

In the same way as for somatic coliphages and coliform bacteria, the GECU reiterates that *Clostridium perfringens* spores are indicators of the effectiveness of treatment of drinking water.

The GECU recommends not including *Clostridium perfringens* spores in the "core" parameters, so that their screening can be adapted according to the risk analysis carried out in the framework of the WSPs.

[17] NF EN ISO 14189 (May 2017) Water quality – Enumeration of *Clostridium perfringens* – Method using membrane filtration.

The GECU believes that screening for the spores of sulphite-reducing anaerobic (SRA) micro-organisms, which include the spores of *Clostridium perfringens* but also other *Clostridia* spores (NF EN 26461-2[18]), may be relevant for the detection of any anomaly relating to the filtration treatment.
This screening is relevant in the context of applications for authorisation to use water to produce drinking water and for setting up WSPs.

- ***Pseudomonas aeruginosa***

The occurrence of *Pseudomonas* in drinking water is related to their natural tropism for hydrous environments but also to colonisation of private systems whose configurations encourage prolonged water stagnation.

In the current version of Directive 98/83/EC, *Pseudomonas aeruginosa* appears in the list of parameters to be analysed in "water offered for sale in bottles or containers" (Part A of Annex I). This list has been deleted in the Commission's proposal. Indeed, the EC now indicates that bottled water no longer falls under this Regulation and is regarded as a foodstuff.

The GECU notes that in Annex III, the method for detecting *Pseudomonas aeruginosa* has been maintained, which is inconsistent with the removal of this parameter from List A of Annex 1.

The GECU recommends maintaining the *Pseudomonas aeruginosa* parameter in Annex I of the Commission's proposal because:

- it is a potentially pathogenic bacterium that can induce disease in immuno-deficient individuals and its detection is relevant, particularly in healthcare facilities. Like *Legionella*, for which the Commission's proposal stipulates surveillance in domestic systems in premises regarded as priority, *Pseudomonas aeruginosa* could be included in Part C of Annex I. As indicated earlier, it would then be necessary to define the typology of priority institutions and rank them in view of the hazard and vulnerable populations.
- it is an indicator that the bottling line is being effectively maintained. Although bottled water does not fall within the scope of the Commission's proposal, screening for *Pseudomonas aeruginosa* remains relevant at the bottling point. The GECU emphasises the need to perform the analysis 72 h after taking samples, which must be kept at ambient temperature.

- **Parasites: *Cryptosporidium* oocysts and *Giardia* cysts**

These two protozoa responsible for waterborne illness outbreaks do not appear in the Commission's proposal. The WSPs set up should enable assessment of the hazard associated with this parameter in the resource and in the treatment system used.

In these conditions, the systematic screening for these two pathogens in drinking water treated by filtration is unnecessary, particularly if systematic screening is set up for SRA spores, whose size (1 to 2 µm) is significantly smaller than that of oocysts (4 to 6 µm) or cysts (10 to 15 µm).

[18] NF EN 26461-2 (July 1993) Water quality – Detection and enumeration of the spores of sulfite-reducing anaerobes (clostridia) – Part 2: Method by membrane filtration

There are standardised analytical methods for their detection in water: NFT 90-455 or failing this the ISO 15553 standard[19].

The GECU believes that screening for *Cryptosporidium* oocysts and *Giardia* cysts would be relevant in raw water (surface and groundwater influenced by surface water) in the framework of applications for authorisation to use water to produce drinking water and for setting up WSPs.

Screening for these two parameters at the distribution point could be recommended in the event of the presence of SRA spores in filtered water or variations in turbidity leading to the value of 0.5 FNU being exceeded in the filtered water, reflecting an inefficiency in the filtration treatment.
There should be a threshold value of 0/100 L for drinking water.

- **Turbidity**

This parameter is included in the list of microbiological parameters appearing in Annex I although it does not directly measure micro-organisms. It should be regarded as an indicator of:

- the effectiveness of disinfection, as water that is too turbid cannot be disinfected correctly. As such, the Commission's proposal suggests monitoring it in operational control programmes with a set parametric value ("0.3 NTU in 95% of cases");
- the effectiveness of filtration, with a value of 0.5 FNU being recommended (see the section above relating to parasites);
- the control of water quality at the distribution point and while it is being transported in private and public networks.

In Annex I, the parametric value associated with the "turbidity" parameter is "<1 NTU".

In line with the WHO recommendations, the GECU proposes setting a limit value of 1 FNU at the drinking water distribution point and setting a value of 2 FNU at the consumer's tap in order to take into account any possible degradation of water quality in private and public networks (mainly corrosion problems). This last value should be included in the list of chemical indicator parameters (see Section 3.3.2.4).

With regard to operational monitoring (Annex II), the GECU supports the introduction of turbidity monitoring and the values set for this parameter, because it is a good indicator for ensuring the control of short-term risks. The GECU specifies that this parameter should be monitored at the drinking water distribution point (after the disinfection step).

Moreover, the GECU suggests, in addition to turbidity, adding the monitoring of residual disinfectant (free chlorine, total chlorine) when the water is disinfected. This residual can be measured easily and continuously when it is higher than the limits of detection/quantification of the methods currently available. As a reminder, a threshold was set at national level by Circular DGS/SD7A No. 2003-524/DE/19-03[20].

[19] ISO 15553 (November 2006) Water quality – Isolation and identification of *Cryptosporidium* oocysts and Giardia cysts from water

[20] Circular DGS/SD7A No. 2003-524/DE/19-03 of 7 November 2003 on the measures to be implemented in the area of protection of systems supplying water intended for human consumption, including bottled water, in the framework of application of the Vigipirate plan

Furthermore, in the framework of operational monitoring, the table should specify the number of samples to be analysed to ensure that the indicated value of 0.3 NTU is complied with in 95% of cases, when the volume of water produced on a daily basis is less than or equal to 10,000 m^3.

The FNU unit should also be used instead of NTU, as defined in the EN ISO 7027-1 standard[21] cited in the Annex of the Commission's proposal. It would also be useful to set a parametric value of 0.30 FNU, with the second significant digit being relevant in the framework of continuous use of a turbidimeter, as online analysers are more sensitive than the method used in the laboratory.

The WSPs set up will help determine the number and location of turbidimeters necessary to control water quality right through to the user's tap and comply with the parametric value set in Annex I.

3.3.2. Chemical parameters

The list of chemical parameters proposed by the Commission is presented in Annex I, Part B.
With regard to laboratory performance, the Commission's proposal states that the analytical methods used must have a limit of quantification corresponding to at least 30% of the parametric value. The "uncertainty of measurement" is presented for each parameter in Annex III, in Table 1 of Part B.

In general, the GECU is surprised that certain parameters have been introduced in Annex 1 with parametric values that are not based on the risk to human health. This choice is contrary to the overall approach of the revision of the Directive, driven by the concept of protection of consumer health, and based on the assessment of actual risks mainly through the WSP approach.

Without prejudice to the environmental objectives of the WFD, the ultimate objective of this draft revision of the DWD should be put into context, namely for consumers (users) to have permanent access to water that does not pose any risk to their health throughout their entire life. The parametric value established must guarantee this on the basis of the knowledge available in the areas of toxicology and epidemiology at the time it was established. If a lower value is set on another consideration (environmental, in application of the precautionary principle, etc.), this should be clearly indicated, and communication and information to consumers must be provided. This type of action is consistent with the declared objective of transparency with regard to citizens in the draft revision of the DWD.

In addition, the GECU insists on the need to specify the CAS numbers of the compounds mentioned in the list of parameters.

3.3.2.1. New parameters

a) Disinfection by-products

The GECU stresses that the change in concentration of disinfection by-products in the distribution network should be taken into account in the monitoring of these parameters. Three types of behaviour can indeed be observed:

- A gradual increase (observed particularly for trihalomethanes (THMs) along the network);

[21] NF EN ISO 7027-1 (August 2016) Water quality – Determination of turbidity

- A slow increase at the beginning of the network followed by a decrease in concentrations at the end of the network, as observed particularly with haloacetic acids (Mouly *et al.* 2009);
- A change that depends on chlorine dioxide residuals and the number of rechlorination stations (found particularly with chlorites and chlorates).

Analyses on leaving the treatment plant and within distribution units are therefore needed to determine population exposure.

In addition, the GECU insists on the importance of efforts to reduce organic matter, and to assess its concentration at the disinfection step, with a view to limiting the formation of disinfection by-products. It also stresses the need to keep total organic carbon (TOC) as an indicator parameter (see Section 3.3.2.4).

Chlorates

Origin

The presence of chlorates in water may have several origins:

- The first is related to the use of processes for manufacturing chlorine dioxide from solutions of sodium hydrogen sulphite and sodium chlorite. In 2014, ANSES issued a stay of proceedings concerning a chlorine dioxide manufacturing process generating high concentrations of chlorates (Request 2014-SA-0043).

- The second is related to the oxidation of chlorites into chlorates during ozonation of water, or possibly post-chlorination (with fairly slow kinetics).

- The third is the formation of chlorates in sodium hypochlorite solutions during their storage. The NF EN 901 standard[22] states that the sodium chlorate content must not exceed a mass fraction of 5.4% chlorine at the time of delivery. Therefore, a treatment rate of 5 mg/L of chlorine from a fresh liquid bleach containing 180 g/L of chlorine would provide 0.2 mg/L of chlorate ions[23]. However, sodium hypochlorite solutions are not stable and the higher the initial concentration and temperature, the greater their degradation. For example, a concentration loss of 10 to 15 g/L of chlorine per week has regularly been observed on a concentrated solution of sodium hypochlorite containing 160-170 g/L of chlorine. This degradation alone leads to the formation of 3.5 g of chlorates per litre of hypochlorite solution. Furthermore, when the temperature is high, there is an observed loss of 1% of the chlorine concentration in one day, which would lead to 300 mg of chlorates per litre of sodium hypochlorite solution and per day of storage. Therefore, as the chlorine concentration of the solutions decreases, greater volumes will be added to ensure a constant treatment rate, leading to higher levels of chlorates. Strict management of the sodium hypochlorite stocks used for water disinfection is necessary to guarantee disinfection and therefore safety of the water (hypochlorite delivery times and limited stocks).

Occurrence

At the request of the DGS, ANSES's LHN carried out a national analysis campaign on drinking water in 2015-16 for chlorate ions. With around 300 sites analysed, covering all the metropolitan

[22] NF EN 901 (July 2013) Chemicals used for treatment of water intended for human consumption – Sodium hypochlorite

[23] 5.4% x 180 g/L = 9.72 g/L of $NaClO_3$ or 0.21 mg/L of ClO_3 given the molar masses of sodium chlorate (106.5 g/mol) and chlorate ion (83.5 g/mol).

and overseas *départements*, in terms of the flow rate considered, this sampling campaign represented the water supplied to around 20% of the population.

The results revealed a generally satisfactory situation: out of 286 samples of treated water analysed, 10 analysis results exceeded the value of 0.25 mg/L, of which two had values above 0.7 mg/L.

Analytical method and performance

Concerning the analytical aspects, chlorates are covered by a European analysis standard (NF EN ISO 10304-4[24]).

In France, on 1 February 2018, 18 laboratories were accredited for chlorate ion testing, in the context of monitoring the quality of drinking water. The performance reported by the laboratories is compatible with the requirements regarding the limit of quantification (30% of the parametric value) and uncertainty (30%) proposed in the Commission's proposal.

Toxicology and reference values

The proposed parametric value for chlorate ions in the Commission's proposal is 0.25 mg/L. This new value for the chlorate parameter does not follow the WHO's provisional proposal of 0.7 mg/L formulated in 2011 and then reiterated in 2017 (WHO 2017).

It should be noted that the pivotal study and critical effect selected in the WHO guidelines published in 2011 were not the same as those used in its updated guidelines of 2016 (WHO 2016).

In its report of 2017, the WHO relied partly on the approach of JECFA[25] (leading to a rounded value of 0.3 mg/L based solely on health considerations) but also on a management/feasibility compromise between toxicity and the risk of restricting disinfecting power by limiting the use of hypochlorite, whose contamination is sometimes unavoidable. To "manage" this compromise, the WHO also put forward the idea of an average annual guideline value of 0.35 mg/L and a maximum value of 0.7 mg/L (Table 19 of the report of 2017).

The Commission's position is based on JECFA's acceptable daily intake (ADI) of 0.01 mg/kg bw/d (JECFA 2008), which is based on a two-year chronic toxicity study in which thyroid effects were observed in F344/N rats (US NTP 2005). As a result, the EC proposes retaining 80% of this toxicity reference value (TRV) as well as an exposure scenario relating to 60 kg bw subjects consuming two litres of drinking water daily. The parametric value of the chlorate ion thus calculated is 0.24 mg/L rounded up to 0.25 mg/L. This is the same value that the WHO had rounded up to 0.3 mg/L in its 2016 monograph (WHO 2016).

The WHO and JECFA both selected the thyroid effects observed in rats induced by exposure to chlorate ions as transposable to humans. However, in a 2015 opinion on the risks for public health related to the presence of chlorate in food, EFSA concluded, like JECFA, that rats may be more sensitive than humans to effects relating to the homeostasis of thyroid hormones but, unlike JECFA, did not believe that the toxicological studies in rats relating to thyroid effects induced by chlorate ions were transposable to humans. Based on a cross-reading with perchlorate, EFSA proposed another TRV for chlorate ions of 3 µg/kg bw/d (EFSA 2015a). In addition, EFSA suggested that the average dietary intake (for food produced primarily in Germany according to the

[24] NF EN ISO 10304-4 (June 1999) Water quality – Determination of dissolved anions by liquid chromatography of ions – Part 4: Determination of chlorate, chloride and chlorite in water with low contamination

[25] Joint FAO/WHO Expert Committee on Food Additives

report) may be higher than this TRV for certain population groups, even with concentrations in the water far below 0.7 mg/L. These results could call into question the 80% allocation factor and the relevance of the value of 0.7 mg/L.

ANSES has not conducted an expert appraisal on chlorate ions in drinking water and there are no data for assessing the share of chlorate ion intake from food, excluding drinking water, in the population.

The GECU supports the introduction of the chlorate parameter in the draft revision of the DWD.

The GECU notes that:

- a reference value of 0.25 mg/L has been selected by the Commission for chlorate ions on the basis of a JECFA ADI from 2008, and therefore on the basis of a toxicological endpoint;
- a value of 0.35 mg/L was cited by the WHO in 2017 as an average annual guideline value for chlorate ions. This value corresponds to half the maximum value of 0.7 mg/L;
- the maximum reference value of 0.7 mg/L proposed by the WHO in 2017 is based on a TRV that is no longer used and also on a compromise between management and feasibility.

The GECU stresses that the formation of chlorate ions is mainly related to the storage time of sodium hypochlorite solutions. The GECU therefore reiterates the importance of assessing the risk/benefit ratio to avoid compromising disinfection.

The GECU recommends paying particular attention to the purity and maximum chlorate concentration mentioned in the standards relating to chemicals used for treating drinking water. It is important to formulate recommendations for the PRWPD relating to good practices in the supply, use and storage of sodium hypochlorite.

The analytical performance criteria defined in the Commission's proposal for the chlorate parameter are compatible with current laboratory performance.

■ Chlorites

Origin

On page 18 of the Commission's proposal, chlorite ions are presented as being by-products of hypochlorite solutions. However, according to the opinion by AFSSA (2007), chlorite ions are detected in water as by-products of pre-oxidation or of disinfection of water by chlorine dioxide.
The GECU specifies that chlorite ions are formed from the degradation of chlorine dioxide in the presence of organic matter in the water. In general, chlorine dioxide consumption generates 50% of chlorites (e.g. 0.25 mg/L of chlorites from a residual of 0.5 mg/L at the end of disinfection).

Occurrence

According to the French water quality monitoring database (SISE-Eaux), 20 to 30% of facilities treating water with chlorine dioxide exceed the 0.20 mg/L quality reference laid down in the French regulations. In distribution units, the concentrations measured were higher than the 0.25 mg/L

value in 20% of cases and higher than the 0.7 mg/L value in 1% of cases, according to data extracted for the years 2013, 2014 and 2015.
However, some of these results may be overstated by 30% to 50% depending on the facilities because the recommended analysis standard is not suitable for water treated with chlorine dioxide (see below).

Analytical method and performance

Chlorites are covered by a standardised analytical method (NF EN ISO 10304-4[26]). In the presence of chlorine dioxide, testing for chlorites must undergo a specific pre-treatment not provided for in the standard, to avoid an overstatement of the results (ANSES 2017c).

On 1 February 2018, 37 laboratories were accredited in France for chlorite ion testing, in the context of monitoring the quality of drinking water. The performance reported by the laboratories is compatible with the requirements regarding limits of quantification and uncertainty expected in the Commission's proposal.

Toxicology and reference values

As a reminder, although it is a new parameter in the Commission's proposal, the Ministerial Order of 11 January 2007 on the quality limits and references for raw water and drinking water laid down a quality reference for the chlorite parameter of 0.20 mg/L.

The proposed parametric value for chlorite ions in the Commission's proposal is 0.25 mg/L.
The Commission's proposal adopts the same approach as for chlorate ions, which is debatable because in 2008 JECFA proposed a different ADI for chlorite ions (0.03 mg/kg bw/d) to that of chlorate ions (0.01 mg/kg bw/d).

This new value for the chlorite parameter does not follow the WHO's proposal of 0.7 mg/L (WHO 2017).

The Agency has assessed the health risks associated with exceeding the quality reference for chlorite ions in drinking water. The conclusion of its Opinion stresses that the health risks associated with chlorite ions can be assessed based on a tolerable daily intake (TDI) of 0.03 mg/kg bw/d, which corresponds to the WHO's position of 2004 reiterated in 2017. Ultimately, the same value of 0.7 mg/L was proposed by the Agency as an exceptional value overriding the quality reference of 0.20 mg/L (AFSSA 2007).

The GECU stresses that the formation of chlorite ions is mainly related to the action of chlorine dioxide on organic matter. It therefore reiterates the importance of eliminating organic matter before treatment with chlorine dioxide. In the same way as for the other disinfection by-products, it reiterates the importance of assessing the risk/benefit ratio of the disinfection step.

The GECU considers as acceptable the argument developed by the WHO leading to a guideline value of 0.7 mg/L being established on the basis of toxicological data.

The analytical performance criteria defined in the Commission's proposal for the chlorites parameter are compatible with current laboratory performance.
The GECU reiterates that in the presence of chlorine dioxide, testing for chlorites must undergo a

[26] NF EN ISO 10304-4 (June 1999) Water quality – Determination of dissolved anions by liquid chromatography of ions – Part 4: Determination of chlorate, chloride and chlorite in water with low contamination

specific pre-treatment not provided for in the standard, to avoid an overstatement of the results.

Haloacetic acids

The proposed parametric value for haloacetic acids (HAAs) in the Commission's proposal is 80 µg/L.
This concentration is relative to the sum of the concentrations of the following nine representative substances: chloroacetic acid (MCA), dichloroacetic acid (DCA) and trichloroacetic acid (TCA), bromoacetic acid (MBA) and dibromoacetic acid (DBA), bromo(chloro)acetic acid (BCA), bromo(dichloro)acetic acid (BDCA), dibromo(chloro)acetic acid (DBCA) and tribromoacetic acid (TBA).

Occurrence

As part of the LHN's work programme, national campaigns on drinking water and bottled water were carried out in partnership with the DGS:

- Concerning drinking water, a national analysis campaign was carried out in 2015-16 for the nine HAAs (unpublished results). With around 300 sites analysed, covering all the metropolitan and overseas *départements*, in terms of the flow rate considered, this sampling campaign represented the water supplied to around 20% of the population. The findings revealed results consistent with the Commission's proposal and only one site (on leaving the drinking water treatment plant) presented a cumulative content greater than 80 µg/L.
- Concerning bottled water, out of 83 samples analysed (SW and WMDT) in the campaign conducted in 2014, only two spring water samples contained DBA respectively at 2 µg/L and 3 µg/L, and one WMDT sample contained DCA at 3 µg/L. The presence of HAAs in the sample of WMDT may be related to the disinfection treatment used. The presence of DBA in both spring water samples, which do not undergo any disinfection treatment, is potentially related to the processes used to clean the refillable water containers.

Analytical method and performance

Haloacetic acids are subject to a standardised analytical method (NF EN ISO 23631[27]) covering only six of the nine compounds.

The number of accredited laboratories varies according to the compound in question. On 1 February 2018, there were eight laboratories accredited for MCA, one for DCA, TCA, MBA, DBA and BCA, and none for BDCA, DBCA and TBA. Even though the laboratories do not currently assay all nine of the HAAs, the performance level required in the Commission's proposal should not present any major technical difficulties.

Toxicology and reference values

The position of the European Commission follows that of the WHO (2017), which is to adopt an approach similar to that used for trihalomethanes (THMs) in drinking water. The WHO (2017) reiterates that the parametric value associated with the HAAs is not based on a toxicological or

[27] NF EN ISO 23631 (June 2006) Water quality – Determination of dalapon, trichloroacetic acid and selected haloacetic acids – Method using gas chromatography (GC-ECD and/or GC-MS detection) after liquid-liquid extraction and derivatisation

epidemiological endpoint. It has proposed guideline values in drinking water for three compounds from the family of HAAs: monochloroacetic acid, dichloroacetic acid and trichloroacetic acid, with guideline values of 20 µg/L, 50 µg/L and 200 µg/L, respectively.

Some North American health risk assessment bodies have set standards for five HAAs (MCA, DCA, TCA, MBA and DBA): 60 µg/L for the US EPA (1998) and the NYSDOH (2015), 80 µg/L for Health Canada (Health Canada 2008).

ANSES has not to date issued an opinion on assessment of the health risks of HAAs in drinking water. Nevertheless, an ANSES report was published in 2011 with toxicological reference values (TRVs) for three HAAs (DCA, TCA and DBA) in a context of assessing the health risks associated with bathing (ANSES 2011c).

The GECU supports the inclusion of haloacetic acids in the draft revision of the DWD, in addition to screening for THMs, which are already contained in the Directive.

Extending the list of HAAs from five to nine compounds seems relevant, in order to take into account the brominated species likely to be formed in certain types of water.

Even if there are currently very few laboratories in France accredited for the analysis of these compounds, testing these nine compounds in drinking water should not pose any particular difficulties.

The Agency's work on HAAs focused on three substances (DCA, TCA and DBA) in the specific context of bathing water. The work of Health Canada conducted in 2008 in the context of drinking water should also be noted, with the establishment of other TRVs for certain HAAs.

ANSES has not conducted any health risk assessments relating to HAAs in drinking water and does not have the information that would enable it to reach a conclusion on the toxicological relevance of the proposed parametric value of 80 µg/L for the sum of the nine HAAs.

The GECU nevertheless reiterates the importance of assessing the risk/benefit ratio of the water disinfection step given the coexistence of a possible microbiological and chemical risk. Accordingly, the GECU recommends limiting the potential for the formation of disinfection by-products by reducing the organic matter content prior to the disinfection step.

b) Other contaminants

- **Per- and polyfluoroalkyl substances**

Definition of PFAs

In the Commission's proposal, the proposed parametric value for perfluorinated compounds is designed to regulate the group of PFAs, as defined by the OECD (OECD 2013), with values of 0.1 µg/L for each PFA separately and 0.5 µg/L for all the PFAs, similar to the choice made with pesticides for management and protection of the resource in Directive 98/83/EC.

By "PFAs", the Commission means each particular per- and polyfluoroalkyl substance (chemical formula: $C_nF_{2n+1}-R$). Note that this definition of PFAs uses the OECD definition, which refers to the article by Buck *et al.* (2011), which was also mentioned in the ANSES opinion of 21 December 2017 on PFAs.

Analytical method and performance

The ISO 25101 standard[28] describes the analytical method for perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS).

International standardisation work has also been initiated with a view to proposing an EPS LC-MS/MS method for 27 PFAs.

On 1 February 2018, four laboratories were accredited for at least one compound. The most frequently approved compounds are PFOA and PFOS. In total, six compounds have been approved.

As a reminder, in accordance with the Ministerial Order of 11 January 2007[29] as amended, PFOS should be analysed in the surface water resource when the sampled flow is greater than 100 m^3/day on average, as an additional control.

Subject to the availability of standard solutions according to the list of compounds to be screened for, the performance expected by the Commission's proposal should not pose any major analytical difficulties for the profession.

Toxicology and reference values

The WHO's position, which was not followed by the Commission, was to calculate guideline values in drinking water for PFOS and PFOA from the TDIs established by EFSA in 2008 (EFSA 2008), by taking 10% of these reference values for exposure via water and considering an exposure scenario for 60 kg bw subjects consuming two litres of drinking water daily. The guideline values in drinking water proposed by the WHO were 0.4 µg/L for PFOS and 4 µg/L for PFOA (WHO 2017).

However, work is under way at EFSA to assess the toxicity of PFAs in food and it is possible that new TDIs may be proposed for PFOS and PFOA.

The ANSES opinion of 21 December 2017 on the assessment of the health risks of PFAs in drinking water proposed maximum health values (V_{MAX}) for eight compounds, including PFOS and PFOA (ANSES 2017b). Three polyfluoroalkyls (6,2-FTSA, 6,2-FTAB and 8,2-FTSA) could not be assessed due to the absence of TDIs. The V_{MAX} were calculated according to the same assumptions as used by the WHO (2017), i.e. by taking 10% of the TDI and considering an exposure scenario for 60 kg bw subjects consuming two litres of drinking water daily. However, the TDIs of PFOS and PFOA selected by the WHO are different from those of ANSES because the latter were based on Health Canada's approach in 2016. The final V_{MAX} proposed by ANSES in 2017 were respectively 0.18 µg/L and 0.075 µg/L for PFOS and PFOA in drinking water.

Note that ANSES's V_{MAX} for PFOS and PFOA are lower than the guideline values proposed by the WHO, and that the V_{MAX} for PFOA is lower than that for PFOS whereas the opposite is true for the WHO. The V_{MAX} for PFOA is also lower than the value chosen by the Commission for each compound (0.1 µg/L).

There are no criteria for taking mixtures of PFAs into account in the ANSES opinion of 21 December 2017, with the exception of one criterion concerning PFOS and PFOA with the

[28] ISO 25101 (March 2009) Water quality – Determination of perfluorooctanesulfonate (PFOS) and perfluorooctanoate (PFOA) – Method for unfiltered samples using solid phase extraction and liquid chromatography/mass spectrometry

[29] Order of 11 January 2007 on the sampling and analysis programme for monitoring the quality of water supplied by a distribution network, in application of Articles R. 1321-10, R. 1321-15 and R. 1321-16 of the French Public Health Code.

assumption of the additivity of toxic effects in the event of the simultaneous presence of both compounds in drinking water, i.e. the criterion:

$$\frac{[PFOA]}{V_{max}(PFOA)} + \frac{[PFOS]}{V_{max}(PFOS)} < 1$$

The GECU notes that the values proposed by the Commission for the sum of PFAs and the individual compounds are not based on health considerations.

In view of the large number of compounds in the chemical family of per- and polyfluoroalkyl substances, the GECU stresses the need to define a list of compounds to be screened for (with their CAS numbers) and to add individual values to them.

It reiterates that the WHO has recommended the inclusion of two compounds with known health impacts (PFOS and PFOA) and for which guideline values of 0.4 and 4 µg/L have been proposed. In its Opinion of 21 December 2017, the Agency proposed V_{MAX} for PFOS and PFOA in drinking water, of respectively 0.18 and 0.075 µg/L, which are lower than the WHO's guideline values.

Subject to the availability of a closed list of compounds and of standard solutions, the analytical performance expected by the Commission's proposal should not pose any major difficulties.

- **Endocrine disruptors: bisphenol A, nonylphenol, beta-oestradiol**

The WHO has not recommended monitoring endocrine-disrupting compounds (endocrine disruptors) nor proposed any guideline values, but has suggested, since aquatic organisms are far more susceptible to the effects of oestrogenic endocrine disruptors (EDs) than mammals, including humans, the possibility of using reference values based on the precautionary principle close to existing, or even future, environmental quality standards, in order to protect aquatic organisms. The WHO has thus proposed the following three representative EDs by default, with the reference values indicated:

- β-oestradiol: 1 ng/L;
- nonylphenol: 300 ng/L;
- bisphenol A (BPA): 10 ng/L.

Even though the WHO has indicated that there is currently no evidence of any health risks due to exposure to EDs via drinking water, considered as a minor source of exposure, and that these risks are unlikely, the Commission decided to include these three endocrine disruptors in the revision of the Directive, on the basis of the precautionary principle, with the minimum requirements proposed by the WHO (WHO 2017) relating to the parametric value for assessing the quality of drinking water.

Occurrence

In France, the LHN has conducted analysis campaigns for these three parameters in drinking water (raw water and treated water). The results of these campaigns are presented in Table I.

Table I. Concentrations in the resources used for the production of drinking water **(raw water) and in tap water (treated water) measured in France by the LHN in the framework of national campaigns (ANSES 2013b, Colin *et al.* 2014, ANSES 2011d)**

	LD	LQ	Raw water				Treated water			
	in ng/L		n	% > LD	% > LQ	Cmax in ng/L	n	% > LD	% > LQ	Cmax in ng/L
β-oestradiol	17	50	285	0	0	-	285	0.5	0.5	77
4-nonylphenol	35	100	291	19	3.4	605	291	8.6	2.4	505
Bisphenol A	8	25	291	14	6.2	1430	291	3.8	0.7	50

Note that:

- 86% of the resources used for the production of drinking water and 96% of the drinking water collected from the consumer's tap and analysed did not contain a detectable concentration of bisphenol A (BPA) (<8 ng/L) (Table I). BPA was not quantified in any of the samples from the water supply matched to samples from resources with quantifiable concentrations of BPA. In tap water, only two samples (less than 1%) presented quantifiable concentrations of BPA, which were 25 ng/L and 50 ng/L. For these two sites, BPA was not found in the abstraction water analysed upstream of the distribution unit (ANSES 2013b, Colin *et al.* 2014).
- 100% of the resources used for the production of drinking water and 99.5% of the drinking water collected from the consumer's tap and analysed did not contain a detectable concentration of β-oestradiol (<17 ng/L) (Table I). In tap water, only one sample presented quantifiable concentrations of β-oestradiol, with a concentration of 77 ng/L (ANSES 2011d).
- 81% of the resources used for the production of drinking water and 91% of the drinking water collected from the consumer's tap and analysed did not contain a detectable concentration of 4-nonylphenol (<35 ng/L) (Table I). In tap water, only seven samples (2.4%) presented quantifiable concentrations of 4-nonylphenol, with a maximum concentration of 505 ng/L (Colin *et al.* 2014).

As a reminder, in France, in accordance with the Ministerial Order of 11 January 2007 as amended, 4-nonylphenol is one of the parameters screened for as an additional control on the resource, when the sampled flow of water is greater than 100 m^3/day on average.

Analytical methods and performance

BPA and nonylphenol are covered by a standardised analytical method (NF EN ISO 18857-2[30]) with quantification limits slightly higher than those proposed in the Commission's proposal for BPA. The measurement uncertainty laid down in the Commission's proposal is 50%.

On 1 February 2018, three laboratories were accredited for BPA and five for nonylphenol, with performance compatible with the requirements of the Commission's proposal for nonylphenol but not for BPA. Nevertheless, this performance seems achievable subject to the control of inter-contamination and removal of any ambiguity about the compounds assayed (particularly for nonylphenol).

With regard to BPA, there is a high risk of sample contamination, particularly at the limit of quantification considered. The sources of contamination are analytical but also come from the

[30] NF EN ISO 18857-2 (February 2012) Water quality – Determination of selected alkylphenols – Part 2: Gas chromatographic-mass spectrometric determination of alkylphenols, their ethoxylates and bisphenol A in non-filtered samples following solid-phase extraction and derivatisation

sampling (but to a lesser extent than for environmental water). Implementation in the laboratories therefore requires particular attention but remains feasible.

However, analysis of BPA and nonylphenol[31] in the framework of assessing PDW may prove to be more complex (see section below). Besides contamination of the resource, the presence of BPA and nonylphenol in water can indeed be related to PDW. Establishing a parametric value in drinking water for BPA and nonylphenol[32] (respectively 10 ng/L and 0.3 µg/L) will have an influence on the assessment of organic materials whose formulations contain these substances. As a reminder, the common approach of the 4MS Group[33] for migration tests sets a maximum tolerable concentration at the consumer's tap (MTC_{tap}) in view of the parametric value in drinking water when one exists, or the specific migration limit (SML_{food}) laid down in Regulation (EU) No 10/2011:

- MTC_{tap} (mg/L) = parametric value in the Drinking Water Directive (mg/L) / 10;
- or MTC_{tap} (mg/L) = SML_{food} (mg/kg of food) x 1 (kg) / (2 (L) x 10).

The DWPs WG believes that the criteria of acceptability set for migration tests of PDW with regard to these limits could be difficult to control in view of the analytical methods available (MTC_{tap} = 1 ng/L for BPA and MTC_{tap} = 30 ng/L for nonylphenol, considering 10% of the parametric value).

The analytical constraints for assaying β-oestradiol at a concentration below 1 ng/L are very severe and require major pretreatment steps with sophisticated equipment[34]. No laboratory in France is currently accredited for the analysis of this compound in drinking water.

Beta-oestradiol was recently monitored in the framework of European Directive 2013/39/EC (watch list for surface water) with the same parametric value, which has provided some feedback. In France, achieving such analytical objectives has required a great deal of methodological work by an expert laboratory. Feedback from the European level has tended to show that not all laboratories have managed to achieve a sufficient level of performance.
These complex implementation conditions make routine monitoring of such a parameter difficult, and the laboratories are not currently prepared.
The high instability of this compound requires on-site stabilisation of samples or analysis within 24h.
In the area of environmental monitoring of this parameter, the data provided by AQUAREF[35] are available (Togola and Ghestem 2017, Aquaref 2017).

For the three compounds proposed by the Commission, great care should be taken regarding the risk of contamination of the sampling and analysis equipment and false positive results, as well as false negatives in the event of more than 24 hours elapsing between sampling and analysis due to the rapid degradation of β-oestradiol.

Toxicology and reference values

β-oestradiol

ANSES (2016a) indicated that in the absence of a robust TRV, it is not currently possible to confirm the existence of possible health risks associated with dietary exposure to 17β-oestradiol. Similarly, the GECU does not have the data needed to reach a conclusion as to the relevance of the parametric value proposed for β-oestradiol in view of the health risks.

[31] While the new DWD does not specify the CAS number of the substance to be screened for, Directive 2000/60/EC of 23/10/2000 establishing a framework for Community action in the field of water policy states: "*Nonylphenol (CAS: 25154-52-3), including isomers 4-nonylphenol (CAS: 104-40-5) and 4-nonylphenol (branched) (CAS: 84852-15-3)*".

[33] https://www.umweltbundesamt.de/sites/default/files/medien/374/dokumente/160302_common_approach_for_pl_on_organic_materials-1.pdf

[34] http://publications.jrc.ec.europa.eu/repository/bitstream/JRC94012/lb-na-27046-en-n%20.pdf

[35] National Reference Laboratory for the monitoring of aquatic environments, created from the networking of expertise and research capabilities of the five public establishments directly concerned: BRGM, IFREMER, INERIS, IRSTEA, LNE.

BPA

In the context of its infant total diet study (iTDS), ANSES reported that the contribution of water to total dietary exposure of children under three years of age was still less than 0.2% (ANSES 2016a).

In this same study, in view of the uncertainties concerning the health effects of BPA, ANSES deemed it relevant to assess the health risks associated with BPA in food with regard to the values proposed firstly by ANSES (2013b) (lowest toxicological benchmark of 0.083 µg.kg bw/d) and secondly by EFSA (2015b) (4 µg/kg bw/d).

Exposure to BPA via drinking water was calculated using the method presented in Annex 2 with a BPA concentration equal to the parametric value proposed by the Commission (0.01 µg/L). This exposure is:

- 0.00185 µg/kg bw/d for infants, corresponding to 2% of the lowest toxicological benchmark selected by ANSES (2013b) and 0.05% of the TRV of EFSA (2015b);
- 0.000286 µg/kg bw/d for adults, including pregnant women, corresponding to 0.3% of the lowest toxicological benchmark selected by ANSES (2013b) and 0.007% of the TRV of EFSA (2015b).

With regard to materials, the DWPs WG indicated that:

- if BPA is present in the formulation of a material, ANSES (2013a) proposes analysing it during migration testing according to a method able to achieve a limit of detection (LD) of 10 ng/L and considers that BPA must not be detected in the migration water;
- Regulation (EU) No 10/2011 as amended[36] laid down an SML_{food} of 0.05 mg/kg of food for varnishes and coatings, as the use of BPA for the manufacture of polycarbonate infant feeding bottles, cups or bottles is not authorised. This restriction would lead to a MTC_{tap} of 2.5 µg/L being established, which is well above any value that would be established on the basis of the parametric value in drinking water (MTC_{tap} = 1 ng/L).

Nonylphenol

In the context of the iTDS, ANSES (2016a) reported that the contribution of water to total dietary exposure of children under three years of age to nonylphenols was still less than 0.4%.

AFSSET (2010) proposed establishing two specific TRVs for effects on development and reproduction: one for linear nonylphenol of 30 µg/kg bw/d and the other for branched nonylphenol, also 30 µg/kg bw/d. Given the effects on development, which indicate endocrine disruption and whose critical window of exposure corresponds to the gestation period, the TRV is applicable for sub-chronic exposure. Due to the lack of data for men, this TRV is applicable by default to both genders.

These TRVs were used to characterise the risk associated with all nonylphenols (linear and branched) in the diet of children under three years of age. The expert appraisal concluded that on the basis of current knowledge and available data, dietary exposure of the infant population to nonylphenols was deemed tolerable (ANSES 2016a).

Exposure to nonylphenols via drinking water was calculated using the method presented in Annex 2 with a nonylphenol concentration equal to the parametric value proposed by the European Commission (0.3 µg/L). This exposure is:

- 0.0555 µg/kg bw/d for infants, corresponding to 0.2% of the TRV;

[36] Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials

- 0.0086 µg/kg bw/d for adults, including pregnant women, corresponding to 0.03% of the TRV.

The GECU stresses the importance of the issue relating to exposure to endocrine disruptors and is aware of the serious concerns expressed about the potential health impact of these compounds.

The GECU also stresses the need for knowledge that would enable the issue of EDs in drinking water to be taken into account. Indeed, in the long term it would be useful to carry out the quantitative detection of ED effects in surface water or in groundwater resources influenced by surface water and used in the production of drinking water, based not on screening for specific compounds but on measurement of the effects overall. This detection could be carried out with one or more biological and/or biochemical tests using an *in vitro* and/or *in vivo* approach. However, analytical challenges and difficulties in interpreting the results obtained via biological and/or biochemical tests intended to measure an overall effect currently pose a problem for assessing the health risks and therefore for defining the associated management measures.

In the current state of knowledge, the GECU therefore considers that introducing parameters for endocrine disruption in Annex I of the Commission's proposal is premature.

With regard to the three compounds proposed by the Commission, the GECU stresses:
- the very severe analytical constraints associated with assaying β-oestradiol at a concentration below 1 ng/L, as well as the risk of sample contamination during sampling and analysis of BPA and nonylphenol;
- the minor contribution of drinking water to total dietary exposure to BPA and nonylphenol, demonstrated in children under three years of age;
- that the proposed parametric values for nonylphenol and BPA are far lower than the existing health reference values;
- that the available data mean that it is not possible to propose a parametric value based on health considerations for β-oestradiol;
- their low persistence in chlorinated water (Li *et al.* 2017, Lane *et al.* 2015);
- the substitution processes under way for BPA and nonylphenol.

Moreover, the three proposed compounds are not representative indicators of all endocrine-disrupting effects but only of oestrogenic effects. There are other compounds with other types of endocrine-disrupting effects (androgenic, thyroid, etc.), such as phthalates, etc.

Consequently, the GECU does not believe that the introduction of these three substances in Annex I of the DWD is relevant.

However, if these compounds were to be maintained in Annex I of the draft Directive, it would be necessary to specify the form of nonylphenol to be screened for and to clarify the CAS number targeted.

- **Microcystin-LR**

In France, the established quality limit of 1 µg/L relates to the sum of the concentrations of the different variants of intracellular and extracellular microcystins screened for (LR, YR, RR, etc.).

The Commission has adopted the interim guideline value established by the WHO in 1998 for total MC-LR[37] and equal to 1 µg/L. This value was derived from a no observed adverse effect level (NOAEL) of 40 µg/kg bw/d for a hepatic disorder (Fawell, James, and James 1994).

In 2006, the Agency published an opinion on the assessment of risks associated with the presence of cyanobacteria and their toxins in drinking water, and in water for bathing and other recreational activities.
This expert appraisal reflected the interim guideline value proposed by the WHO.

In 2016, the Agency was asked to update this expert appraisal and the work is under way. An in-depth review of the literature on the toxicity of microcystin highlighted the appearance of health effects at doses far below the NOAEL determined in the study by Fawell, James, and James (1994). The WG in charge of this revision is therefore examining the possibility of reviewing the guideline value proposed by the WHO.

With regard to the analysis of microcystins, there is a standardised method (ISO 20179[38]) and a draft standard for the use of a LC-MS/MS method with ELISA pre-screening (ISO CD 22 104[39]). In France, 14 laboratories are accredited for the analysis of microcystins in water. The median uncertainty obtained for these laboratories is 47%, whereas this uncertainty has been set at 30% in the Commission's proposal.

Pending the conclusions of the expert appraisal under way at ANSES, the GECU recommends:

- proposing a parametric value for all quantifiable microcystins and clarifying that it relates to the sum of intracellular and extracellular microcystins, even if it can be assumed that only the extracellular fraction will be present in drinking water;
- screening for and counting the number of cyanobacteria in the water resource, in the framework of the WSPs;
- extending the required uncertainty concerning the analytical performance criteria from 30 to 50%.

Uranium

The proposed parametric value for uranium (understood to mean natural uranium) in the Commission's proposal is 30 µg/L.

This proposal is consistent with the opinion of the French Nuclear Safety Authority (ASN), which favours including measurement of the natural uranium concentration in water quality monitoring in France and establishing a limit in the regulations on the quality of water intended for human consumption (ASN, DGS, and IRSN 2011).

The WHO (2017) proposal for the uranium parameter is a guideline value of 30 µg/L based on the toxic chemical effects of uranium on the kidneys. This value is derived from a Finnish

[37] Equivalent to MC-LR

[38] ISO 20179 (October 2005) Water quality – Determination of microcystins – Method using solid phase extraction (SPE) and high performance liquid chromatography (HPLC) with ultraviolet (UV) detection

[39] CD ISO 22104 – Water quality – Determination of microcystins – Method using liquid chromatography and tandem mass spectrometry (LC-MS/MS) with pre-screening by immunoassay

epidemiological study, which investigated a possible association between exposure via water to natural uranium in 95 men and 98 women, and effects on renal function (Kurttio *et al.* 2006). The starting point of the WHO's guideline value was a daily intake of 637 µg, corresponding to the lower bound of the 95% confidence interval for the exposure of individuals in this study. After applying a factor of 10 to take account of the variability within this population and considering daily water intake of 2 litres, the WHO calculated a guideline value of 30 µg/L for natural uranium.

The Agency's proposal is developed in the opinion of 13 January 2010 (AFSSA 2010). On the basis of a lowest observed adverse effect level of 60 µg/kg bw/d derived from a subchronic toxicity study in Sprague-Dawley rats where renal lesions of the proximal convoluted tubule were observed (Gilman *et al.* 1998), the Agency applied an inter- and intra-species uncertainty factor of 100 to establish a TDI of 0.6 µg/kg bw/d. In the absence of any French data on exposure via water to natural uranium, the Agency retained 80% of the TDI for exposure via water of a 60 kg subject consuming two litres of drinking water daily, which led to a limit value of uranium in drinking water of 15 µg/L, according to an approach identical to that of the WHO in 2004.

Although the Agency's position based on a toxicological approach diverges from that of the WHO (2017), which is based on an epidemiological approach, the recent animal toxicology data for natural uranium or depleted uranium (equivalent nephrotoxicity) indicate the possibility of raising the limit value of uranium in drinking water to 30 µg/L. Indeed, these studies (Dublineau *et al.* 2014, Poisson 2013, Poisson *et al.* 2014, Grison *et al.* 2016) published since 2010 show no nephrotoxic effects of uranium in rodents (rats and mice) after 3, 6 or 9 months of chronic contamination via drinking water containing uranium at more than 40 mg/L (concentrations in water of 40, 120, 160 or 600 mg/L relative to no effect doses from 2.67 to 40 mg/kg bw/d). Moreover, the value of 30 µg/L is compatible with the maximum daily incorporation value of 140 µg proposed by Thorne and Wilson (2015) on the basis of recent biokinetic models for uranium.

From the point of view of the analytical methods, only quadrupole ICP-MS can reach the value of 30 µg/L, unlike ICP-AES (ICP-OES), flame-AAS or furnace-AAS. The limit of quantification is 0.10 µg/L by ICP-MS for the mass concentration of uranium (ISO 17294-2). By alpha spectrometry, the limit of detection is 5 mBq/L, the equivalent of 0.40 µg/L for a 500 ml test sample (ISO 13166). The measurement uncertainty for uranium is 10% for values ≥ 1 µg/L with ICP-MS, and 15-20% for alpha spectrometry.

This performance is therefore compatible with the criteria defined in the Commission’s proposal.

Around 20 laboratories are currently accredited for the measurement of uranium, including 17 for measuring the mass concentration in µg/L. In 2017, three drinking water distribution units exceeded 30 µg/L out of a panel (produced at random) of 117 samples, or 2.6%.

Concerning the bottled water analysed during the campaign carried out by the LHN, out of 83 samples analysed (SW, WMDT), 11 had a uranium value higher than 1 µg/L, with the maximum concentration being 7 µg/L.

In view of the recent toxicological data identified, the GECU supports the introduction of the uranium parameter with a parametric value of 30 µg/L.
The requirements defined in the Commission’s proposal in terms of analytical performance are compatible with the methods used by the laboratories for the analysis of uranium.

3.3.2.2. Parameters whose parametric value has been lowered in the Commission's proposal

- **Lead**

The Commission proposes reducing the minimum requirement relative to the parametric value for lead from 10 to 5 µg/L after a transitional period of 10 years.

This position is not supported by the WHO, which advocates provisionally maintaining the quality limit at 10µg/L; this position is related to the fact that there is no threshold value for health effects. The WHO recommends requiring the Member States to put in place an action plan to replace lead piping within five years of adoption of the Directive, with the objective being to reach the value of 5 µg/L within an appropriate period of time given the difficulties associated with the replacement of pipes.

In humans, the harmful effects of lead (lead poisoning) are correlated with the level of exposure, which can be estimated from the blood lead levels. Lead poisoning is more frequent and severe in young children. There are many sources of lead exposure; drinking water represents only one of them, particularly in older housing still containing lead pipes and/or connections. In France, the Home-Lead study (Lucas *et al.* 2012) estimated using modelling that around 2.9% of homes were supplied by drinking water exceeding the quality limit set at 10 µg/L.

There is therefore the question of the contribution of drinking water to overall exposure to lead. The available data tend to show that the ingestion of lead via drinking water rarely leads to cases of lead poisoning in France. According to the French studies available (including TDS and iTDS), the contribution made by drinking water to lead exposure is between 2% and 40% (ANSES 2017d). However, positive relationships have been found between the concentration of Pb in drinking water and blood lead levels of exposed children.

When the lead concentration exceeds 20 µg/L in drinking water, the HCSP estimates that 5% of potentially exposed children may have blood lead levels exceeding 50 µg/L (the "threshold for rapid intervention" value). The current data cannot be used to link precisely the critical blood lead levels proposed by EFSA (2010) (12 µg/L) and ANSES (2013c) (15 µg/L) to concentrations of lead in drinking water. However, a reduction in the lead concentration in drinking water, to the lowest value possible, is a step towards limiting the risk of lead poisoning.

In Canada, the Federal-Provincial-Territorial Committee On Drinking Water proposed establishing a maximum acceptable concentration of Pb in drinking water sampled at the tap of 5 µg/L, considering that this value (i) is measurable, (ii) can be achieved at a reasonable cost and (iii) has a major impact on the blood lead levels of children (Health Canada 2017). It considers that for children, lowering the maximum allowable concentration (MAC) from 10 to 5 µg/L will decrease exposure in such a way that the geometric mean of blood lead levels higher than 50 µg/L will decrease from 9.4% to 2.2%.

In its Opinion 2015-SA-0094, ANSES (2017d) considered that reducing population exposure to lead remains a priority public health objective and requires a combination of measures. Concerning the reduction in exposure associated with drinking water, treatment with orthophosphates is one possible collective protection measure, but is not in itself sufficient. Use of a treatment with orthophosphates would not enable the value of 5 µg/L to be complied with at all times and points. In any case, a parametric value set at 10 or 5 µg/L involves replacing all the public connections, as well as indoor lead piping, particularly for networks supplied by drinking water with a high potential for lead dissolution.

The DWPs WG believes that in France, the presence of pipes and/or connections in lead or metal alloys containing lead (galvanised steel, brass and bronze)[40] could result in drinking water exceeding the new parametric value for lead (5 µg/L) more frequently than at present. The common approach for the assessment of metallic materials[41], as well as the authorised compositions in the 4MS common list[42], could be reviewed in light of the new parametric value proposed.

Concerning the analysis of lead in drinking water, the median limit of quantification of the methods used by the laboratories in the framework of water quality monitoring in France is 1 µg/L, which corresponds to 20% of the parametric value of 5 µg/L.

In view of lead's toxicity, the GECU can only approve of the actions aimed at reducing the exposure of the population.
With regard to exposure via water, the GECU questions the contribution of drinking water to overall exposure to lead. The GECU is conscious of the management problems associated with compliance with a parametric value set at 5 µg/L in drinking water, which requires the elimination of lead piping in public and private distribution networks and even the replacement of certain alloys (brass/bronze for example) in PDW. It notes however that a transitional period of ten years is proposed by the Commission before reducing the parametric value from 10 to 5 µg/L for the lead parameter.

- **Chromium**

Following the announcement of the revision of the WHO's guideline value for total chromium (chromium III + chromium VI) (WHO 2017), the Commission proposes reducing the minimum requirement relating to the parametric value of total chromium from 50 to 25 µg/L in Annex I, Part B of the Directive, specifying that "*the value shall be met, at the latest, by [10 years after the entry into force of this Directive]. The parametric value for chromium until that date is 50 µg/L.*"

In 2012, ANSES recommended reducing the quality limit of chromium in drinking water, due to effects potentially induced by chromium VI (ANSES 2012a). After an assessment of the health risks on the basis of the toxicity of chromium VI, ANSES considered that a maximum chromium VI concentration of 6 µg/L would be a realistic goal on a provisional basis. However, given the current analytical difficulties associated with measuring such a low concentration of chromium VI, total chromium could be measured initially. If this threshold of 6 µg/L were exceeded in total chromium, an additional analysis could measure the proportion of chromium VI (ANSES 2012a).

More recently, an analysis campaign by the Nancy Laboratory for Hydrology (ANSES not published) on chromium speciation in areas known or assumed to be heavily contaminated with chromium helped determine a conversion factor (median) between total Cr and Cr(VI). This factor, 75% of total Cr in the form of chromium VI, was applied to chromium concentrations in the consumer's tap water in the framework of the iTDS (ANSES 2016a).

[40] Annex 1 of the Ministerial Order of 29 May 1997 as amended on materials and items used in permanent facilities for the production, treatment and distribution of drinking water.

[41] https://www.umweltbundesamt.de/sites/default/files/medien/374/dokumente/4ms_approach_for_metallic_materials_part_a_2nd_revision.pdf

[42] https://www.umweltbundesamt.de/sites/default/files/medien/421/dokumente/8th_revision_4ms_scheme_for_metallic_materials_part_b_20171220.pdf

Accordingly, in view of the toxicity of chromium VI and the proportion of chromium VI potentially present in drinking water, the GECU supports reducing the parametric value of chromium in drinking water, but considers that the proposed value should be around 6 µg/L for chromium VI.

3.3.2.3. Maintained parameters

For some of the parameters maintained in the draft revision of the DWD, the Commission has not followed the WHO's recommendations. These are antimony, boron and selenium, for which the WHO proposes increasing the parametric value, and also cyanide, benzene, 1,2-dichloroethane and polycyclic aromatic hydrocarbons (PAHs), which it suggests deleting from Annex I. The GECU believes that the Commission's proposals for these parameters contradict the guidelines of the draft revision of the DWD and particularly the approach based on the analysis of health risks for the consumer.

Like the WHO in 2017, the AFSSA and ANSES opinions relating to boron, selenium and antimony proposed an increase in the parametric values for the revision of Directive 98/83/EC. For selenium, taking into account ANSES's approach, based on an EFSA opinion, the parametric value could be changed to 30 µg/L (ANSES 2012b).

It should however be noted that the Agency's opinions relating to antimony, selenium and boron all concern assessments of the health risks in situations where the quality limits are exceeded in drinking water. The regulatory framework corresponds to the derogations from the parametric values laid down by Directive 98/83/EC in force, transposed into French law in the Public Health Code (CSP). The derogation is therefore temporary: it can only be granted after authorisation by the local health authorities for a period of three years, renewable once. A third derogation may be granted in exceptional cases, with the decision being taken by the Commission.

However, as indicated above, the Commission’s proposal plans to delete the provision concerning the derogations.

- **Antimony**

The presence of antimony in drinking water is mainly related to potential leaching by polyethylene terephthalate (PET) used to manufacture water and soft drink bottles. The analysis campaign conducted by the LHN in 2013-2015 showed that in 83 samples of bottled water (SW, WMDT), no result was found above the limit of quantification (1 µg/L). However, it should be remembered that bottled water is not considered in the Commission’s proposal.

The proposed parametric value for antimony in the Commission’s proposal is 5 µg/L.

The WHO (2017) proposes a guideline value of 20 µg/L for antimony. This value is obtained from a TDI of 6 µg/kg bw/d, then retaining 10% of this TDI for exposure via water and considering an exposure scenario relating to a 60 kg individual consuming 2 litres of drinking water daily.

The Agency's proposal is developed in a "non-compliance" sheet from June 2004 available in a report published in 2007 (AFSSA 2007). The conclusion of this opinion reiterates that the health risks associated with antimony can be assessed using the TDI of 6 µg/kg bw/d (*ditto* WHO (2017)). In this opinion, dietary intakes of antimony were estimated to be 20 µg/day on the basis of American data cited in a WHO (1996) monograph, which exceed the French estimates from the

TDS2 study by a factor of approximately 3, including in the subjects most heavily exposed to antimony (ANSES 2011b). Ultimately, the value of 30 µg/L was proposed by the Agency as an exceptional value overriding the quality limit of 5.0 µg/L (AFSSA 2007).

Therefore, the WHO's guideline value of 20 µg/L and the Agency's exceptional value of 30 µg/L for the antimony parameter in drinking water are based on the same toxicological assumptions but with different assumptions relating to exposure via water.

The parametric value for antimony proposed by the Commission in the draft revision of the DWD is 5 µg/L. Due to the time constraints imposed for conducting this expert appraisal, the GECU did not conduct a literature review of the toxicological data relating to antimony. However, the GECU considers as acceptable the WHO's argument in favour of a guideline value of 20 µg/L being established.

- **Boron**

The Commission proposes maintaining the parametric value of boron at 1.0 mg/L in the draft revision of the DWD.

The WHO's 2017 proposal for boron consists of a guideline value of 2.4 mg/L, which is compatible with the implementation of seawater desalination by reverse osmosis (WHO 2017).

ANSES's proposal is developed in the opinion of 25 July 2016 (ANSES 2016b). The conclusion of this opinion reiterates that the maximum concentration in drinking water posing no risk to the health of a person consuming this water for a limited period of time in a situation of derogation from the quality limit for boron can be set at 2.4 mg/L, on the basis of the WHO's reference value.

The Commission proposes maintaining the parametric value of boron at 1.0 mg/L in the draft revision of the Directive. The GECU believes that in view of the data presented in the Agency's opinion on boron published in 2016, the value of 2.4 mg/L proposed by the WHO is acceptable.

- **Selenium**

The proposed parametric value for selenium in the Commission’s proposal is 10 µg/L, corresponding to the value laid down in the version of the Directive in force.

In France, situations of non-compliance persist. Depending on the value set for selenium, certain contaminated resources could be abandoned. Implementing specific treatments entails a significant cost for small communities that have no alternative resource. Data on contamination of drinking water are presented in the Agency's opinion of 4 October 2012 (ANSES 2012b).
As for bottled water, no non-compliances with regard to the value of 10 µg/L were found during the analysis campaign conducted by the LHN in 2013-2015.

The proposal of the WHO (2017) for selenium is a guideline value of 40 µg/L. The pivotal studies consist of two epidemiological studies carried out in China on cases of selenosis (Longnecker *et al.*

1991, Yang and Zhou 1994) where the WHO had identified an upper tolerable intake of 400 µg/day by application of an uncertainty factor of 2 to a no-effect dose of 0.8 mg/day.

The Agency's opinion of 4 October 2012 updated an earlier AFSSA opinion from September 2004 available in a report published in 2007 (AFSSA 2007). The conclusion of this opinion reiterated that the health risks of selenium can be assessed using an upper intake level (UIL) of 300 µg/day calculated for different age groups according to body weight (ditto EFSA (2006)). This upper intake level was established on the basis of a no-effect dose of 850 µg/day relating to cases of selenosis observed in China (Yang *et al.* 1989) with application of an uncertainty factor of 3. In view of the conclusions of ANSES's opinion of 4 October 2012, a derogation from the quality limit for selenium of 10 µg/L is possible up to 30 µg/L for the entire population, taking into account the average daily dietary intake of selenium.

Ultimately, the approaches of the WHO (2017) and ANSES (2012b) for selenium are very similar, although the ANSES position is significantly more conservative due to application of an uncertainty factor of 3 instead of 2 by the WHO and the decision to stratify the upper intake level across different age groups according to body weight, as EFSA (2006) chose to do.

The proposed parametric value for selenium in the draft revision of the DWD is 10 µg/L. In view of the arguments developed by the WHO and the Agency's opinion published in 2012, the GECU proposes retaining the value of 30 µg/L for selenium in drinking water.

- **Benzene, cyanide, mercury, 1,2-dichloroethane, polycyclic aromatic hydrocarbons (PAHs)**

The Commission proposes maintaining these parameters, contrary to the WHO, which suggests deleting them.

The presence of these contaminants in the resource is essentially due to accidental pollution; it is therefore localised and ad hoc.

With regard to PAHs, their presence in drinking water can be related to leaching from old steel or cast-iron pipes lined with hydrocarbon products (tar, coal-tar pitch, bituminous paints) (see the Opinion 2010-SA-0184).

Cyanide ions are among the agents to be taken into account in "NRBC"[43] risks. Moreover, they are not removed by reverse osmosis. However, the GECU believes that maintaining this parameter has no relevance in the DWD and it should be included in other texts or benchmarks.

These parameters are covered by standardised analytical methods. The expected performance requirements in Commission's proposal are generally compatible with the state of the art of the profession, with the exception of benzene, for which only 37% of accredited laboratories currently meet the limit of quantification of 0.3 µg/L.
For PAHs, the median uncertainty of the accredited laboratories is slightly higher than the value of 30% in the Commission's proposal (32 to 37% depending on the compounds).

[43] Nuclear, radiological, biological and chemical risks

To the extent that the draft revision of the DWD enables an adjustment of the list of parameters to be analysed based on the results of the risk analysis (WSP), the GECU supports the maintenance of PAHs, because of the potential presence of old pipes coated with hydrocarbon products in the drinking water distribution network.

The GECU proposes removing the cyanide, mercury, 1,2-dichloroethane and benzene parameters. Because their presence in water is essentially accidental, taking these parameters into account in the draft revision of the DWD does not seem relevant.

- **Acrylamide, vinyl chloride, epichlorohydrin**

Directive 98/89/EC states that the concentration of these three parameters can be determined by calculation based on specified purity criteria for the products (polymers used in materials or products for treating drinking water).

The Commission's proposal introduces performance characteristics for these three parameters: uncertainty of 50% for vinyl chloride and epichlorohydrin, and 30% for acrylamide.

Efforts to improve the current performance of the accredited laboratories would nevertheless be needed to achieve the requirements introduced by the Commission's proposal.

Fifteen laboratories accredited for monitoring water quality in France are accredited for epichlorohydrin analysis, but none of them have reported achieving the limit of quantification of 0.03 µg/L (ensuring compliance with the set quality limit of 0.1 µg/L).

With regard to acrylamide, epichlorohydrin and vinyl chloride, and in view of progress in analytical performance, the GECU considers that use of the analysis to determine compliance with the parametric value is possible, and is recommended at the risk analysis stage.

Concerning acrylamide, in view of the state of the art of the profession and the analytical principles used, and in the interests of consistency with vinyl chloride and epichlorohydrin, an uncertainty level of 50% should be maintained, instead of 30% as proposed by the Commission in the draft revision of the DWD.

- **Pesticides**

These parameters have been maintained in the framework of the Commission's proposal. The definition of pesticides and the associated parametric values remain unchanged: 0.10 µg/L per pesticide and relevant metabolite except for four pesticides[44] and 0.50 µg/L for the sum of all pesticides (screened for) detected and quantified in the framework of the monitoring procedure.

As a reminder, the quality limit of 0.10 µg/L in drinking water is not based on a toxicological approach and has no health basis, but was set with the aim of protecting the resource. This limit was set during discussions to establish the first European DWD (Directive 80/778/EEC[45]). Determination of pesticides in water was not straightforward at the time, and the limit of detection of the compounds screened for in the water was 0.1 µg/L.

[44] Aldrin, dieldrin, heptachlor and heptachlor epoxide for which the parametric value is set at 0.030 µg/L.

[45] Council Directive 80/778/EC of 15 July 1980 on the quality of water intended for human consumption.

The Commission's proposal introduces a definition of relevant metabolites and refers to Article 3 (32) of Regulation (EC) No 1107/2009[46] to define them. The concept of degradation and reaction products disappears from the Directive.

The above-mentioned Regulation defines a metabolite as follows: "*any metabolite or a degradation product of an active substance, safener or synergist, formed either in organisms or in the environment*".

Moreover, *"a metabolite is deemed relevant if there is a reason to assume that it has intrinsic properties comparable to the parent substance in terms of its biological target activity, or that it poses a higher or comparable risk to organisms than the parent substance or that it has certain toxicological properties that are considered unacceptable. Such a metabolite is relevant for the overall approval decision or for the definition of risk mitigation measures;"*

ANSES is currently conducting an expert appraisal on relevant metabolites in response to a formal request from the DGS, with the assistance of a "Relevant pesticide metabolites" WG whose work is focused on defining and establishing criteria for assessing the relevance of pesticide metabolites in drinking water. The GECU's position is based on the comments obtained from this WG, which was consulted on 13 February 2018.

The "Relevant pesticide metabolites" WG issued the following comments and proposals:

- It believes it is imperative to introduce a definition of relevant pesticide metabolites and supports this principle;
- With regard to the proposed definition,
    - It notes that degradation products in the environment are taken into account but not the reaction products liable to form in the water treatment plants, and calls for them to be taken into account in the definition of pesticide metabolites;
    - This definition and therefore the assessment of the relevance should cover all drinking waters, whether produced from groundwater or surface water; the WG therefore notes that the DG SANCO 221/2000 guide, which proposes an approach to assess the relevance of metabolites of active substances in groundwater, cannot be a sufficient reference for assessing the relevance of pesticide metabolites in drinking water;
    - It believes that the relevance of metabolites in drinking water should not be defined in view of the risk *"for organisms"* but only with respect to risks to the consumer;
- Consequently, the WG defines the following objective and proposes the following definition (ANSES 2017, not published), without prejudice to the final conclusions of the expert appraisal:
    - The concept of relevance should be linked to the objectives attached to it: level of information required in an approval procedure, protection of the consumer's health, protection of the resource, protection of aquatic organisms, etc.
    - The WG considered that the concept of "relevance in drinking water" should be guided by the objective of protecting the consumer's health and proposes defining a metabolite "relevant in drinking water " as follows:
      "*A pesticide metabolite is deemed relevant in drinking water if there is reason to consider that it has intrinsic properties comparable to those of the parent substance in terms of its pesticide target activity or that it generates (itself or its transformation products) an unacceptable health risk to the consumer*".
- It notes that the question of non-relevant metabolites is not taken into account in the

[46] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

Commission's proposal.

The GECU at its meeting on 16 March 2018 adopted the position of the "Relevant pesticide metabolites" WG.

In addition, the GECU reiterates the importance of defining a list of substances to be screened for and is aware of the difficulty of such an exercise. The method for compiling this list, which will be defined by countries or regions, by use, etc., should however be harmonised at European level between the MSs.

- **Arsenic**

The Commission does not propose changing the minimum requirement relative to the parametric value of arsenic, currently set at 10 µg/L. The WHO's guideline value for this parameter, regarded as provisional, is also 10 µg/L (WHO 2017).

Currently, 78% of accredited laboratories are capable of achieving a limit of quantification of 3 µg/L, in accordance with the regulations (corresponding to 30% of the parametric value).

In 2004, the Agency assessed the health risks associated with exceeding the quality limit of arsenic in water intended for human consumption (AFSSA 2007). It estimated that the risk level associated with the quality limit of 10 µg/L for arsenic in drinking water was around 6.10^{-4}.

The second French total diet study (TDS2) revealed the fact that water is the main contributor to inorganic arsenic exposure in both adults and children over three years of age (≥19% in adults and children regardless of the assumption). This study concluded that the possibility of a risk associated with exposure to inorganic arsenic via food (including drinking water) could therefore not be excluded for certain groups of consumers (ANSES 2011b).

In the iTDS, in view of the very low margins of exposure reflecting a situation of concern for children under three years of age, and the contribution to total dietary exposure to arsenic of the water used to reconstitute infant formula, ANSES (2016a) believed it important to update its own work on assessment of the health risks associated with the quality limit of arsenic in drinking water and natural mineral water, and to examine the advisability of reducing this quality limit.

In view of the health risks associated with the concentration of 10 µg/L of arsenic in drinking water, the GECU recommends examining the advisability of lowering the minimum requirement relative to the parametric value of arsenic in drinking water.

3.3.2.4. *Indicator parameters*

In general, the GECU regrets the removal of the list of indicator parameters that appeared in Annex I, Part C and the associated parametric values (quality references in the French regulations).

The GECU notes that most of the indicator parameters are mentioned in Annex IV concerning information to be accessible to users, which implies that these parameters need to be analysed on a regular basis. Point (5) of this Annex states that information must be provided on indicator parameters and associated parametric values. The GECU regrets that these values are however not indicated. Moreover, the following should be noted in this Annex IV:

- the absence of total organic carbon (TOC), whereas the WHO proposes keeping it because it is used to justify the removal of oxidability;
- the addition of the "sulphide" parameter: although sulphides are present in some resources (particularly confined groundwater in a very narrow context), they are very rapidly oxidised to sulphates in water that has been aerated and chlorinated,
- the absence of any statement related to the microbiology of the water.

Although the draft revision of the DWD is based on the preventive management of health risks, implying that the PRWPD monitor the indicator parameters, the GECU would like to restore in the draft text a list of indicator parameters with their associated parametric values, defined for all the MSs. This list of parameters will be useful when setting up WSPs.
The GECU recommends keeping the list of indicator parameters as defined in the version of the Directive currently in force (Annex I, Part C):

- while however removing the "oxidability by potassium permanganate" parameter as well as the "*Clostridium perfringens* spores" parameter already mentioned in Annex I of the Commission's proposal;
- while adding the "total organic carbon" parameter with a value of 2 mg/L;
- while establishing a parametric value for the "turbidity" parameter (see Section 3.3.1.2).

The GECU also wishes to make additional comments on the following parameters:

- **Manganese**

Manganese is currently one of the indicator parameters with a parametric value of 50 µg/L.

ANSES proposes a maximum permissible health value of 60 µg/L for manganese in drinking water, on the basis of its neurodevelopmental effects by ingestion in infants and young children (ANSES 2018, validation under way). This is a protective value for the entire population.

In addition, in 2017 France published a document justifying the harmonised classification of potassium permanganate under REACH-CLP, because of doubts about the potential reprotoxic effects of this substance[47]. This proposal, along with a call for additional tests, is currently being examined by the European Chemicals Agency (ECHA).

In view of the toxicity of manganese for the neurodevelopment of infants and young children, the GECU considers it necessary to maintain a minimum requirement for manganese in drinking water in the draft revision of the DWD.
If this parameter is no longer associated with the parametric value of 50 µg/L as an indicator parameter, the GECU proposes including manganese in Annex I, Part B of the Commission's proposal with a minimum requirement relative to the parametric value of 60 µg/L, without prejudice to the final conclusions of the Agency's opinion.

[47] https://echa.europa.eu/documents/10162/eadc7f1f-0f58-ef78-a64f-82004e142129

- **Sulphate**

According to the WHO, sulphate is classified among the parameters that are "not of health concern at levels found in drinking water". The presence of sulphate in drinking water can have a noticeable effect on taste, and very high concentrations can have a laxative effect in unaccustomed (naive) consumers. Depending on the associated cation, various taste thresholds have been proposed: from 250 mg/L for sodium sulphate to 1000 mg/L for calcium sulphate. No value based on health criteria has been proposed by the WHO.

In France, the aforementioned Ministerial Order of 11 January 2007 established a quality reference of 250 mg/L for sulphate.

In 2005, during an assessment of the health risks associated with exceeding the quality reference for sulphate in drinking water, the Agency stressed the low toxicity of sulphate ions, but recognised their laxative effect. This effect is particularly marked when sulphate is associated with magnesium. However, in view of the data available, the Agency considered that it was not possible to define a minimum threshold for health effects, but that the sulphate concentration of 500 mg/L could be selected as a taste threshold. The Agency stated, however, that for infants, due to possible laxative effects, the use of water with a concentration higher than the quality reference for drinking and food preparation was not recommended (AFSSA 2007).

Moreover, in its Opinion of 2 December 2003 on the establishment of quality criteria for bottled NMW and SW enabling consumption without any health risk by infants and young children, the Agency stated that "*sulphate intake via water must not be higher than that in breast milk, which is used as a reference (...). The sulphate content of breast milk is 140 mg/L on average, while in cow's milk it can vary between 250 and 360 mg/L (...). In these conditions, AFSSA proposes selecting a maximum level of sulphate of 140 mg/L for bottled water used to reconstitute infant formula*" (AFSSA 2003).

In view of the laxative effects of sulphate and to protect vulnerable populations, particularly infants, the GECU considers it necessary to maintain a minimum requirement for this parameter in drinking water.
If it is no longer considered as an indicator parameter, the GECU proposes listing sulphates in Annex I, Part B of the Commission's proposal, with a parametric value of 250 mg/L.

- **Aluminium**

Aluminium is monitored to ensure the proper functioning of systems, as aluminium salts can be used during the coagulation-flocculation step. This step serves primarily to eliminate turbidity in the water and thus to reduce the presence of micro-organisms (bacteria, viruses, parasites), improve the colour, and achieve a water quality that guarantees the effectiveness of the disinfection step. Aluminium is also naturally present in certain water, depending on the geological context.

Aluminium's toxicity is known (ATSDR 2008), particularly its neurotoxic potential from repeated exposure, which is probably the critical effect, although the contribution made by water intake to the development of disease is more debatable:

- Associations between aluminium in water and degenerative diseases such as Alzheimer's are most often proposed on the basis of ecological type epidemiological studies that are unable to reach any conclusions in terms of causation;

- In humans, apart from occupational exposure, the main recognised route of exposure is food ingestion, which constitutes 95% of daily intake. The amount of aluminium provided by the water supply therefore accounts for less than 5% of intake.

According to the total diet studies (TDS2 and iTDS), water is not a major contributor to total dietary exposure, except for infants aged 1-4 months in whom the intake via water accounts for more than 10% of total intake.

In order to assess the health risks associated with aluminium in the diet, ANSES (2011b) used the provisional tolerable weekly intake (PTWI) of 1 mg/kg bw set by JECFA (2006). This PTWI was established from toxicity studies on reproduction and development.
Similarly, on the basis of a review of the existing TRVs, with the aim of assessing the risks associated with food in children under three years of age, ANSES (2016a) used this PTWI of 1 mg/kg bw, although in 2011 JECFA had proposed revising this value to 2 mg/kg bw.

Although the WHO also adopted this toxicity limit of 1 mg/kg bw, the guideline values established by the WHO and confirmed in the document of 2017 were proposed using a management-based approach taking into account:

- the technical feasibility of obtaining and maintaining a value below 200 µg/L, or even 100 µg/L (the WHO's 2017 recommendation was to maintain the value at 200 µg/L for small production units but to reduce it to 100 µg/L for large units, with the aim of keeping exposure at the lowest level reasonably possible. In addition, the WHO only recommends measuring aluminium when its salts are used for coagulation-flocculation);
- the fact that higher values reflect an anomaly in the flocculation and/or filtration system, likely to expose the consumer to microbiological risks;
- the analytical feasibility, which is confirmed in France.

The GECU believes it necessary for a parametric value to be associated with the "aluminium" parameter in drinking water, considering:
- the use of aluminium salts during the coagulation-flocculation step;
- the strong societal demand and questions concerning studies on the role of waterborne aluminium in degenerative diseases.

The GECU emphasises, however, that according to the total diet studies (TDS2 and iTDS), water is a major contributor (more than 10% of intake) to total dietary exposure to aluminium only in infants aged 1 to 4 months.
In the absence of any recent expert appraisal that would enable a health value to be proposed for this parameter in drinking water, the GECU proposes retaining the parametric value of 200 µg/L.

3.3.2.5. *Other parameters*

- **Perchlorates**

Perchlorate ions do not appear in the list of parameters in Annex I of the Commission’s proposal.

The presence of perchlorate ions in water can be due to industrial discharges, as perchlorate salts are used in various applications, particularly in the military and aerospace fields, but also due to the historical use of Chilean saltpetre (sodium nitrate) as an agricultural fertiliser. There is also a link between the presence of perchlorates in the environment and the combat zones of the First World War.

In France, the analysis campaign carried out by the LHN in 2011-2012 showed that contamination of the water resource and drinking water was localised. Perchlorate concentrations in drinking water below 4 µg/L were found in 97% of cases, and below 15 µg/L in 100% of cases (ANSES 2013d).

Perchlorate ions inhibit iodine uptake by the thyroid, thus interfering with thyroid hormone synthesis. An opinion on the assessment of the health risks associated with the presence of perchlorate in drinking water was published by ANSES in 2011 (ANSES 2011a). In this opinion, ANSES proposed a toxicity reference value (TRV = 0.7 µg/kg bw/d) and a guideline value in drinking water (15 µg/L). This TRV, based on an early biological effect, was proposed to take account of the most vulnerable populations (particularly pregnant women, newborns and children under 6 months of age).

At the request of the DGS, work is currently under way at ANSES to decide on the relevance of reassessing the health risk associated with exposure to perchlorate ions in drinking water.

In view of their potential health effects, the GECU believes that screening for perchlorate ions would be relevant in the framework of setting up WSPs and that a parametric value should be set for drinking water. The GECU reiterates that work on the health risks associated with the presence of perchlorates in drinking water is currently under way at the Agency.

3.4. Other comments on the draft revision of the DWD

The GECU has questions about the economic impact of the proposed amendments in this draft revision of the DWD, and particularly the addition of new parameters to be screened for. It also notes that the HCSP was asked to rank the new parameters added, taking not only health issues but also technical-economic issues into account.

- **Harmonisation of regulations**

The Commission states that the draft revision of the DWD is consistent with the legislation established at EU level in the area of water, mainly the Water Framework Directive (WFD), the Marine Strategy Framework Directive (MSFD), the Urban Waste Water Treatment Directive (UWWTD) and the Nitrates Directive.

The GECU stresses that these texts differ in their objectives and timescales. The environmental objectives are set over much longer timescales.

The risk-based approach as developed in the draft revision of the DWD should make it possible to assess the risks of accidental pollution, which are not taken into account in the WFD. Nor does the latter take the microbiological quality of the water into account, unlike the MSFD.

The concept of water body should be considered on a smaller scale in the case of the catchments used for the production of drinking water, catchments for which a precise knowledge of the hydrogeological context is essential.

The GECU reiterates that work is under way at European level to review the WFD and its daughter directives with a view to a possible revision.

- **Risk-based approach**

The GECU supports the setting up of WSPs, an approach that seeks to improve and maintain the safety of water supplied to the population. In addition, the WSP is a lever for risk prevention and management, and an effective means of combating regional health inequalities relating to the safety of the supply of water intended for human consumption. This approach also responds to demands by consumer associations, whose confidence in the safety of tap water could be improved. The WSP can also represent a lever for adaptation to climate change by anticipating the consequences of episodes of drought or flooding affecting the exploited water resource directly or indirectly, in both quantitative and qualitative terms. It can also help anticipate crisis situations on a functioning system (floods, electrical faults, technological risks, contingency plans, ORSEC water emergency response plans, etc.). The WSP can enable savings to be made in the medium or long term, for example in operating costs, by streamlining the planning of infrastructure renewal and investment, especially with regard to public health issues (renewal of pipes, changes to the treatment system, etc.), and improving the efficiency of the facilities.

These provisions are consistent with the actions planned as part of the 2015-2019 National Environmental Health Plan (PNSE3), namely:

- promoting the implementation of "drinking water supply" safety plans (Action 55),
- continuing to protect catchments used for the drinking water supply from accidental and diffuse pollution (Action 56).

The GECU stresses that setting up WSPs requires expertise and very precise knowledge of the facilities, their operation, and their environment in order to identify the areas of improvement and corrective actions that can be implemented.

The GECU also supports the Commission's proposal to give more time (six years) to small water suppliers compared to the time (three years) granted to large and very large water suppliers to apply the risk-based approach.

The GECU emphasises that the water body approach is necessary but not sufficient to ensure good quality raw water. Indeed, the operation of groundwater catchment facilities can be affected by phenomena related to pumping (changes in flows, leakage between aquifers or saltwater intrusion, for example) that need to be approached on a more limited spatial scale.

With regard to the domestic distribution risk assessment, the GECU underlines the complexity of this assessment, particularly from a legal point of view. The current version of the Directive (Article 6.2) states that "*Member States shall be deemed to have fulfilled their obligations [...] where it can be established that non-compliance with the parametric values set in accordance with Article 5 is due to the domestic distribution system or the maintenance thereof except in premises and establishments where water is supplied to the public, such as schools, hospitals and restaurants*". These provisions on the responsibility of MSs disappear in the Commission's proposal.

- **Monitoring**

The GECU supports the inclusion of provisions for operational monitoring, as this measure helps ensure that the treatment system is working correctly and that the corrective measures laid down by the hazard analysis are applied promptly. The operational monitoring plans should be adapted according to the risks identified. The WHO gives examples of operational monitoring plans (WHO, 2017). In addition, when setting up WSPs, indicators of the effectiveness of treatment should be defined with levels of alert. It would be useful to set limit values for these indicators (see Section 3.2.2.4).

The GECU insists on the need to maintain two levels of monitoring: self-monitoring by operators (operational monitoring), and quality monitoring (verification of compliance) that should be implemented by the Member State in order to guarantee that such monitoring is independent.

With regard to the provisions set forth in this draft revision of the DWD, water quality monitoring needs to evolve and should essentially be based on the inspection of facilities, validation of the supply risk assessment and checking of operational monitoring data.

The GECU considers it appropriate to establish a minimum frequency for monitoring the parameters set out in Annex I because no monitoring will be performed by the PRWPD if they have established the absence of risk associated with these parameters (except for the "core" parameters). In addition, no monitoring frequency has been associated with the "indicator" parameters mentioned in Annex IV.

- **Derogations**

The GECU interprets the deletion of Article 9 of Directive 98/83/EC, enabling MSs to provide for derogations from the parametric values, as a consequence of the establishment of WSPs in which corrective actions must be implemented if quality limits are exceeded, making the concept of "derogation" obsolete.

The GECU highlights the difficulties associated with the practical application of these new provisions, with a need for clarification on the following points in particular:

- Definition of the procedures for managing the derogations currently in place in the MSs and the associated action plans;
- The ability of MSs to implement management procedures (prohibition or restriction of consumption, etc.) if a parametric value is exceeded, as advocated by the Commission. These measures can be very difficult to implement and do not seem justified for each case of a parametric value being exceeded.

Instead of deleting this Article, the derogation system should be retained with the concomitant establishment of an action plan, so as to encourage good risk management practices without introducing disproportionate measures. In return, the GECU proposes removing the possibility of renewing these derogations after a period of three years in order to compel the PRWPD to implement corrective solutions in the short term.

- **Bottled water**

The Commission's proposal stipulates that bottled SW and WMDT must meet the obligations of European regulations on foodstuffs, particularly as regards the "Hygiene Package" (mainly Regulations 178/2002[48], 852/2004[49] and 882/2004[50]). These texts stipulate:

- official controls of compliance of foodstuffs (and therefore bottled water), which must be documented in an annual report sent to the European Commission, with the frequency of these controls being left to the discretion of the MSs;

[48] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

[49] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

[50] Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

- that operators are responsible for the quality of the products they place on the market and must implement a quality process based on hazard analysis and critical control points (HACCP).

However, these texts do not specify the parameters to be analysed nor their frequency of analysis.

While some of the quality requirements for NMW apply to bottled SW as mentioned previously (see Section 3.1), Directive 2009/54/EC does not lay down any requirements for bottled WMDT.

Bottled WMDT, increasingly found on the European market, particularly in refillable containers for water fountains, should be subject to the same health requirements as other bottled water (SW and NMW).

The GECU has reflected on the possibility of establishing a single regulation (quality limits, frequency and methodology of monitoring, analytical methods, etc.) for all bottled water (SW, WMDT and NMW), which would therefore be clearer to the consumer.

Concerning the water used in food companies, the term "food production" contained in Article 2 of the Commission's proposal is too vague and should be clarified.

■ Alternative methods for analysing water quality

The specifications for the analysis of water quality parameters are listed in Annex III of Directive 98/83/EC. Commission Directive (EU) 2015/1787 of 6 October 2015 has amended this Annex and in particular introduces the concept of equivalence of analytical methods (point 13).

However, the GECU notes that the provisions relating to equivalence of methods and the reference to the EN ISO 17994[51] or 16140[52] standards have not been included in the Commission's proposal.

The GECU therefore recommends including in the draft text the clarifications made in Directive 2015/1787 concerning the assessment of alternative methods.

4. AGENCY CONCLUSIONS AND RECOMMENDATIONS

The French Agency for Food, Environmental and Occupational Health & Safety endorses the GECU's conclusions.

Dr Roger GENET

[51] NF EN ISO 17994 – April 2014 – Water quality – Requirements for the comparison of the relative recovery of microorganisms by two quantitative methods

[52] NF EN ISO 16140-2 – September 2016 – Microbiology of the food chain – Method validation – Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method

KEYWORDS

Eau destinée à la consommation humaine, réglementation, Directive 98/83/CE
Drinking water, regulation, Directive 98/83/EC

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ANNEX 1

Presentation of participants

PREAMBLE: The expert members of the Expert Committees and Working Groups or designated rapporteurs are all appointed in a personal capacity, *intuitu personae*, and do not represent their parent organisation.

WORKING GROUP

Chair

Ms Sophie AYRAULT – Team Leader / Doctor authorised to supervise research, CEA, Gif-sur-Yvette – Chemistry of water including mineral chemistry

Members

Mr Jean CARRE – Honorary Professor, EHESP – Hydrogeology

Mr Fabrice DASSONVILLE – Sanitary Engineer, ARS PACA – Water regulations, Environmental health, Management of health risks

Ms Isabelle DUBLINEAU – Assessment Officer for control of radiological and nuclear risks – IRSN, Fontenay-aux-Roses – Toxicology

Mr Benoît GASSILLOUD – Head of Water Microbiology Unit, ANSES Nancy Laboratory for Hydrology – Microbiology, Monitoring water quality

Mr Laurent MOULIN – Research Department Manager, Eau de Paris water services company – Water quality, Molecular biology, Microbial ecology

Mr Jean-Ulrich MULLOT – Head of the Navy Surveillance Analysis and Expertise Laboratory (LASEM) in Toulon – Armed Forces Health Service – Analytical chemistry, Assessment of environmental and occupational health risks

Mr Christophe ROSIN – Deputy Head of Water Chemistry Unit, ANSES Nancy Laboratory for Hydrology – Analytical chemistry, Monitoring water quality

Ms Marie-Pierre SAUVANT-ROCHAT – Professor, Clermont Auvergne University – Public health, Environmental health, Epidemiology

Ms Anne TOGOLA – Project Leader, BRGM – Analytical chemistry, Emerging substances

Ms Bénédicte WELTE – Retired – Water treatment products and processes, Treatment plants, Water chemistry

ANSES PARTICIPATION

Scientific coordination

Ms Justine JOUËT – Water Risk Assessment Unit – ANSES

Scientific contribution

Ms Morgane BACHELOT – Water Risk Assessment Unit – ANSES

Mr Thomas CARTIER – Water Risk Assessment Unit – ANSES

Ms Anne NOVELLI – Water Risk Assessment Unit – ANSES

Ms Pascale PANETIER – Water Risk Assessment Unit – ANSES

Administrative assistance

Ms Virginie SADÉ – ANSES

ANNEX 2

Method of calculating exposure via drinking water

The calculations of exposure via drinking water were made with the following formula:

$$Expo = \frac{Cwater \times Conso}{BW}$$

Where:

- Expo = exposure in µg/kg bw/d
- C_{water} = concentration in the water in µg/L
- Conso = daily consumption of drinking water in L/d
- BW = body weight in kg

Using:

- For infants: daily consumption of water relative to body weight of 0.185 L/kg bw/d, corresponding to the P90 of water consumption for infants aged 1 to 4 months in metropolitan France (iTDS data)
- For adults, including pregnant women: body weight of 70 kg and water consumption of 2 L/d.