



AGENCE FRANÇAISE  
DE SÉCURITÉ SANITAIRE  
DES ALIMENTS

Maisons-Alfort, 21 July 2009

## **Scientific and Technical Support**

**from the French Food Safety Agency for revision of European directive  
98/83/EC on the quality of water intended for human consumption**

THE DIRECTOR GENERAL

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### **Context of the request**

The French Food Safety Agency (AFSSA) was contacted on 3 April 2009 by the Directorate General for Health (DGH) which requested scientific and technical support for revision of the microbiological parameters in Directive 98/83/EC on the quality of water intended for human consumption.

### **Context**

Having regard to the Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption;

Having regard to the documents produced by the European Commission's 'Expert Group on Microbiology' (EGM):

- This document contains the sections relative to the revision of the Drinking Water Directive of the draft minutes of the 2nd and 3rd Expert Group on Microbiology. The meetings were held on 17/18 October 2007 and on 27/28 February 2008 at the JRC Ispra, Italy - Issues agreed upon during the meeting of 17/18 October 2007,
- Review of Microbiological Parameters - Recommendations of the Expert Group on Microbiology - David Drury (Drinking Water Inspectorate, UK) - On behalf of the EGM,
- Revision of microbiological Parameters - Recommendations by EGM – UBA presentation<sup>1</sup> from 23/10/2007.

Having regard to the document produced by the European Commission's Ad-Hoc Working Group on 'Sampling and Monitoring': "The advice of the Ad-Hoc Working Group on Sampling and Monitoring to the Standing Committee on Drinking Water concerning sampling and monitoring for the revision of the Council Directive 98/83/EC" – EUR 23374 EN – ISSN 1018-5593 – 2008.

Having regard to AFSSA's Scientific and Technical Supports of 7 March 2008 (STS no. 2008-SA-0020) and of 24 December 2008 (STS n° 2008-SA-0367) for revision of the physico-chemical parameters in European Directive 98/83/EC on the quality of water intended for human consumption.

### **Method of expertise**

The emergency collective expert assessment group (GECU) entitled "Revision of Directive 98/83/EC on the quality of water intended for human consumption" was consulted by e-mail and met on 15 May and 3 June 2009.

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<sup>1</sup> German Federal Environment Agency (Umwelt Bundes Amt für mensch und umwelt).

## Argument and conclusions

### **Foreword:**

Article 2 of Directive 98/83/EC specifies that “*For the purposes of this directive, ‘water intended for human consumption’ shall mean: 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; [...]*”.

On this point, AFSSA considers that studies should not be limited to water for human consumption, with the exception of natural mineral water, and that they should be extended, as stipulated in the public health code, to include raw water (surface freshwater or groundwater and salt water if it is to undergo desalination) used to produce water intended for human consumption<sup>2</sup>.

Moreover, article 4 of the aforementioned directive specifies that “*water intended for human consumption shall be wholesome and clean if it is free from any micro-organisms and parasites and from any substances which, in number or concentration, constitute a potential danger to human health*”.

In this respect, AFSSA emphasises that an “ideal” indicator of microbiological contamination of faecal origin should be<sup>3</sup>:

- non-pathogenic,
- always found when pathogenic microorganisms are found,
- more abundant than pathogenic microorganisms,
- more resistant to disinfection treatments and environmental conditions than pathogenic microorganisms,
- fast and easy enumeration at a low cost,
- unambiguously identifiable in all sample types,
- randomly distributed in the sample to be analysed,
- unable to multiply in the environment.

There is no universal indicator capable of representing all pathogenic microorganisms found in water (bacteria, viruses, protozoa, fungi, etc.).

According to WHO<sup>3</sup>:

- it is important to distinguish between indicators of faecal contamination and treatment effectiveness indicators,
- a single indicator can only rarely be used for both purposes,
- parameters used as indicators are not necessarily microbiological parameters; this is the case, for example, of the “turbidity” and “residual disinfectant” parameters.

### **General comments:**

AFSSA:

- recommends harmonising the names of parameters and using those defined in the standards concerning analysis methods;
- underlines that a standardised European reference method is necessary to:

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<sup>2</sup> French raw water regulations transpose the provisions of Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States which was repealed by the European Parliament and Council Directive 2000/60/EC of 23 October 2000 establishing a framework for Community action in the field of water policy (FWD).

<sup>3</sup> W.H.O - Guidelines for drinking-water Quality – volume 1 – recommendations (2006) and Armon, R. and Kott, Y. (1996). Bacteriophages as indicators of pollution. *Critical Reviews in Environmental Science and technology* 26 (4), 299-335.

- ensure the homogeneous evaluation of treatment products and process effectiveness as well as their corresponding authorisations for marketing and implementation,
- compare the analytical results of the various Member States, with past results and keep a quality of water record,
- assess alternative methods;
- draws attention to the fact that:
  - in the field of food microbiology, the NF EN ISO 16140<sup>4</sup> standard specifies that an alternative method would be “*an analytical method for determining or estimating, for a given product category, the same analyte as the one measured with the corresponding reference method*”,
  - in the field of water microbiology, the NF EN ISO 17994<sup>5</sup> standard sets out the “*criteria for evaluating the average quantitative equivalence of results obtained from two microbiological analysis methods, one of which may be but is not necessarily a standardised or reference method*” (see STS no. 2007-SA-0192<sup>6</sup> provided by AFSSA's Laboratory for studies and research on hydrology);
- agrees with the EGM group that the expression of quality reference-values, which is currently set at “O CFU<sup>7</sup> in X mL” is not correct since the zero value is not acceptable given the test procedures used and recommends adopting the following expression: “not detected in X mL”;
- points out that to be able to evaluate the effectiveness of treatment stages (biocidal retention or disinfection), the same indicators must be enumerated in raw water and in treated water.

**Concerning samples, AFSSA:**

- agrees with the suggestion of the EGM group which recommends the harmonisation of guidelines relative to samples contained in the analysis standards in force and in the NF EN ISO 19458<sup>8</sup> standard,
- suggests that the latter be used as a reference except when analysis standard guidelines are more severe.

**Concerning enumeration methods, AFSSA** underlines that methods that use concentration/desorption steps do not detect all the microorganisms present in the sample. As a result, the total microorganism count is underestimated. For example:

- for standard NF T 90-455 (enumeration of *Cryptosporidium* oocysts and *Giardia* cysts), the recovery rate is only about 30 to 40%,
- for standard XP T 90-451 (enumeration of enteroviruses), the recovery rate is only about 5 to 10%.

Furthermore, AFSSA draws attention to the fact that hot water circuits are currently interconnected with cold water circuits since the water is combined in single-unit mixer taps used for human consumption, and so domestic hot water must be suitable for drinking as well.

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<sup>4</sup> NF EN ISO 16140 (October 2003): *Microbiology of food and animal feeding stuffs – protocol for the validation of alternative methods.*

<sup>5</sup> NF EN ISO 17994 (December 2004): *Water quality – Criteria for establishing equivalence between microbiological methods.*

<sup>6</sup> STS n° 2007-SA-0192: *Request for scientific and technical support on the equivalence of alternative methods versus reference methods with respect to drinking water.*

<sup>7</sup> CFU: Colony-forming unit.

<sup>8</sup> NF EN ISO 19458 Standard: *Water quality – Sampling for microbiological analysis.*

Finally, it emphasises that microorganisms other than those included in this Scientific and Technical Support may be screened for in the event of a suspected contamination or epidemic.

***This Scientific and Technical Support answers the questions raised by the DGS:***

**I – Revision of the microbiological parameters currently given in the directive**

**I.1 Revision of the parametric values and parameter analysis methods currently given in Directive 98/83/EC**

• **I.1.1 Escherichia coli**

This is an indicator of faecal contamination at the source (RP and RS<sup>9</sup> analyses), of treatment effectiveness at the point of exit from the treatment plant (P1 analyses) and/or of contamination during distribution (D1 analyses).

**I.1.1.1 Water intended for human consumption with the exception of bottled water<sup>10</sup> and natural mineral water**

AFSSA recommends:

- keeping the same quality limit: “not detected in 100 mL”,
- using the standardised enumeration method and the options in the standard that were then made mandatory by the 17 September 2003 order on water sample analysis methods and their performance characteristics<sup>11</sup>,
- using standard NF EN ISO 9308-1 as the reference analysis method in the new directive.

AFSSA emphasises that it would be a good idea to standardise the practices of various laboratories responsible for monitoring the quality of water intended for human consumption and therefore to have homogeneous and comparable results, in order to maintain high-quality monitoring. To this end, the French regulations make some of the options given in standard NF EN ISO 9308-1 mandatory such as incubation at  $(36 \pm 2)^\circ\text{C}$  and at  $(44 \pm 0.5)^\circ\text{C}$  for  $(21 \pm 3)$  hours and  $(44 \pm 4)$  hours as longer incubation times (44 hours) may be required for stressed bacteria in chlorinated water before they can be counted. Moreover, the

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<sup>9</sup> 11 January 2007 order on the sampling and analyses performed as part of the health inspection programme for water supplied from a distribution system, pursuant to articles R.1321-10, R. 1321-5 and R. 1321-16 of the [French] public health code specifying the monitoring programmes for the different sampling points ( RP, RS, P1, P2 or D2 analyses):

- RP corresponding to the monitoring programme carried out at the source groundwater catchments;
- RS corresponding to the monitoring programme carried out at the source surface water catchments;
- P1 corresponding to the routine monitoring programme carried out at the point of exit from the treatment plants;
- P2 corresponding to the monitoring programme complementary to P1 used to obtain the complete monitoring programme (P1+P2) carried out at the point of exit from the treatment plants;
- D1 corresponding to the routine monitoring programme carried out in taps that are normally used for human consumption (point of use);
- D2 corresponding to the monitoring programme complementary to D1 used to obtain the complete monitoring programme (D1+D2) carried out in taps that are normally used for human consumption (point of use).

<sup>10</sup> Water offered for sale in bottles or containers.

<sup>11</sup> Method for analysing total coliforms and Escherichia coli in water intended for human consumption: NF EN ISO 9308-1 under the following conditions:

- the analysis must be conducted according to the standard “reference” test and not use the “optional rapid test”,
- a second reading is mandatory after a 44 hours incubation period (+/- 4 hours),
- water that has a membrane where individual colonies cannot be picked must be declared “non-interpretable (significant interfering flora)”,
- for water produced from surface water or influenced by surface water, take a second measurement at 44°C. In this case, render the highest result.

selective character of the medium needs to be amplified by incubation at 44°C since the interfering flora that are present in certain cases, and particularly in the summer in supply water, can invade the culture medium and inhibit the growth of coliform bacteria and *E. coli*.

*1.1.1.2 Bottled water with the exception of natural mineral water*

AFSSA recommends:

- keeping the same quality limit: “not detected in 250 mL”,
- using the standardised enumeration method and the options in the standard options that were then made mandatory by the 17 September 2003 order<sup>11</sup>.

*1.1.1.3 Raw water used to produce water intended for human consumption, with the exception of bottled spring water and natural mineral water*

AFSSA recommends:

- keeping the quality requirements (quality limits and guideline values) set by annexes 2 and 3 to the 11 January 2007 order on the quality limits and references for raw water and water intended for human consumption mentioned in articles R. 1321-2, R. 1321-3, R. 1321-7 and R. 1321-38 of the public health code,
- using standardised enumeration methods and the options in the standard that were then made mandatory by the 17 September 2003 order on water sample analysis methods and their performance characteristics<sup>12</sup>.

- **1.1.2 Intestinal enterococci**

This is an indicator of:

- faecal contamination at source (RP and RS analyses),
- treatment effectiveness at the point of exit from the treatment plant, particularly as regarding disinfection as it is less sensitive to chlorine, ozone and chlorine dioxide than *E. coli* (P1 analyses),
- contamination during distribution, more relevant than *E. coli* (D1 analyses).

AFSSA supports the EGM group’s recommendation to use the same monitoring frequency for enterococci as for *E. coli*. It stresses that this is already standard practice in France but not in other Member States.

*1.1.2.1 Water intended for human consumption with the exception of bottled water and natural mineral water*

AFSSA recommends:

- keeping the same quality limit: “not detected in 100 mL”,
- using the standardised enumeration method recommended by the 17 September 2003 order, i.e., the NF EN ISO 7899-2 standard,
- using the NF EN ISO 7899-2 standard as the reference enumeration method in the new directive.

*1.1.2.2 Bottled water with the exception of natural mineral water*

AFSSA recommends:

- keeping the same quality limit: “not detected in 250 mL”,
- using the standardised enumeration method recommended by the 17 September 2003 order, i.e., the NF EN ISO 7899-2 standard.

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<sup>12</sup> Method for analysing *Escherichia coli* in raw water (surface freshwater and groundwater) used to produce water intended for human consumption:

NF EN ISO 9308-3 (surface and karstic water)

NF EN ISO 9308-1 (ground water) under the following conditions:

- the analysis must be conducted according to the standard “reference” test and should not use the “optional rapid test”,
- a second reading is mandatory after an incubant period of 44 hours (+/- 4 hours),
- water that has an invaded membrane where isolated colonies may not be picked must be declared “non interpretable (significant interfering flora)”.

I.1.2.3 Raw water used to produce water intended for human consumption, with the exception of bottled spring water and natural mineral water

AFSSA recommends:

- keeping the quality requirements (quality limits and guideline values) set by annexes 2 and 3 to the 11 January 2007 order on the quality limits and references for raw water and water intended for human consumption mentioned in articles R. 1321-2, R. 1321-3, R. 1321-7 and R. 1321-38 of the public health code,
- using the standardised enumeration methods recommended by the 17 September 2003 order: the NF EN ISO 7899-1 standard for surface and karstic water and the NF EN ISO 7899-2 standard for groundwater.

- **I.1.3 Coliform bacteria**

Coliform bacteria are an indicator not only of treatment effectiveness, more specifically of biocidal disinfection effectiveness (P1 analyses) but also of current contamination of a distribution network (D1 analyses).

The presence of coliform bacteria (*E. coli*, among others) in the water distribution network is a warning sign that may appear even though no intestinal enterococci or *E. coli* have been detected. This family of bacteria is found in larger quantities than intestinal *E. coli* and enterococci, which makes detection more likely in the event of contamination occurring.

I.1.3.1 Water intended for human consumption with the exception of bottled water and natural mineral water

AFSSA:

- recommends:
  - keeping the same quality reference: “not detected in 100 mL”,
  - using the standardised analysis method and the options in the standard that were then made mandatory by the 17 September 2003 order<sup>11</sup>.
  - using the NF EN ISO 9308-1 standard as the reference enumeration method in the new directive;
- suggests, contrary to the recommendation of the EGM group which wishes to stop its monitoring at the point of use, monitoring this parameter in the framework of water quality monitoring performed by local health authorities at the point of exit from the treatment plant (P1 analyses) and at point of use (D1 analyses);
- emphasises that the NF EN ISO 9308-1 standardised method is capable of determining coliform bacteria concentrations, during the first stage of the analysis, when screening for *E. coli* which is mandatory at the point of use.

I.1.3.2 Bottled water with the exception of natural mineral water

AFSSA recommends:

- keeping the same quality limit: “not detected in 250 mL”,
- using the standardised enumeration method and the options in the standard that were then made mandatory by the 17 September 2003 order<sup>11</sup>.

I.1.2.3 Raw water used to produce water intended for human consumption, with the exception of bottled spring water and natural mineral water

AFSSA recommends:

- keeping the quality requirements (guideline values) set by annex 3 to the 11 January 2007 order on the quality limits and references for raw water and water intended for human consumption mentioned in articles R. 1321-2, R. 1321-3, R. 1321-7 and R. 1321-38 of the public health code,
- using standardised enumeration methods and the options in the standard that were then made mandatory by the 17 September 2003 order: the NF EN ISO 9308-1 standard with a second mandatory reading after an incubation period of (44 ± 4) hours or, failing that, standard NF T 90-413 for highly turbid raw water,
- monitoring this parameter at the source (RP and RS analyses) in the framework of surveillance and, in particular, when implementing Water Safety Plans. This is

necessary so that the person responsible for water production and distribution (PRPDE) may evaluate and monitor the system, on a routine basis, for treatment effectiveness and especially for rate of removal of contaminants.

- **I.1.4 Spores of sulfite-reducing anaerobes**

As this parameter is an indicator of the effectiveness of retention treatments including filtration, it must be monitored at the point of exit from the treatment plant (P1 analyses) for units treating surface water or water influenced by surface water. However, monitoring it at point of use (D1 analyses) is not justified as there are other, more relevant indicators of water quality in the distribution network (coliform bacteria in particular).

Directive 98/83/EC recommends screening for *Clostridium perfringens* (including spores). Screening for spores of sulfite-reducing anaerobes, which include *Clostridium perfringens*, is a more efficient way of detecting a filter malfunction. Furthermore, since in normally aerated water, vegetative cells are unable to survive, breaking the dormancy of spores of sulfite-reducing anaerobes would make it possible to enumerate them while eliminating the interfering vegetative cells through 'pasteurisation'.

As a result, AFSSA requests that the new directive recommend the enumeration of spores of sulfite-reducing anaerobes as an indicator of filtration effectiveness and that it not be limited to the enumeration of *Clostridium perfringens* which is an indicator of faecal contamination.

I.1.4.1 Water intended for human consumption with the exception of bottled water and natural mineral water

AFSSA recommends:

- keeping the same quality reference: “not detected in 100 mL”,
- using the standardised enumeration method recommended by the 17 September 2003 order, i.e. , the NF EN 26461-2 standard,
- using the NF EN 26461-2 standard as the reference enumeration method in the new directive.

I.1.4.2 Bottled water with the exception of natural mineral water

AFSSA recommends:

- modifying the quality limit to: “not detected in 250 mL” to be consistent with quality requirements governing water from distribution systems and to use the same safety margin for bottled water<sup>13</sup>,
- using the standardised enumeration method recommended by the 17 September 2003 order, i.e., the NF EN 26461-2 standard.

I.1.4.3 Raw water used to produce water intended for human consumption, with the exception of bottled spring water and natural mineral water

AFSSA recommends screening for and enumerating spores of sulfite-reducing anaerobes at source (RP and RS analyses) in the framework of PRPDE surveillance and in particular when implementing the Water Safety Plan.

- **I.1.5 Enumeration of culturable micro-organisms at 22°C and 36°C**

This parameter is first and foremost an indicator of the overall microbiological quality of water in the distribution network (D1 analyses). It indicates a set of phenomena that cause the microbiological quality of water to deteriorate during distribution and particularly a

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<sup>13</sup> In the 3 January 1989 decree no. 89-3 on water intended for human consumption, with the exception of natural mineral water, the quality limit was 0/20 mL, whereas in the 20 December 2001 decree no. 2001-1220 that replaced it, the quality reference was 0/100 mL. As such, the safety margin was multiplied by 5 and the same should be done for bottled water, for which the current regulatory quality limit of 0/50 mL, comes from the 15 July 1980 Council directive on the harmonisation of the laws of Member States relating to the exploitation and marketing of natural mineral water.

temperature higher than 17°C<sup>14</sup>, a residence time that is too long, a drop in residual bactericide and the presence of nutritive elements leading to the development of biofilms.

*1.1.5.1 Water intended for human consumption with the exception of bottled water and natural mineral water*

AFSSA:

- suggests screening for these microorganisms at the consumer's tap (D1 analyses) in the framework of water quality monitoring performed by local health authorities and, if an anomaly is detected, asking the PRPDE to compare it with the situation at the treatment plant exit point (P1 analyses);
- recommends:
  - setting a quality reference, solely for routine analyses carried out at points of use (D1 analyses) and replacing the current value, "no abnormal change" with "no variation with a factor greater than 10 compared to the geometric average of the previous year's results in the relevant sector",
  - using the standardised enumeration method recommended by the 17 September 2003 order, i.e. , the NF EN ISO 6222 standard.

*1.1.5.2 Bottled water with the exception of natural mineral water*

AFSSA recommends:

- keeping the current quality limits: 100 CFU/mL for culturable micro-organisms at 22°C and 20 CFU/mL for culturable micro-organisms at 36°C,
- using the standardised enumeration method recommended by the 17 September 2003 order, i.e., the NF EN ISO 6222 standard, having specified that analyses must begin within twelve hours after packaging.

*1.1.5.3 Raw water used to produce water intended for human consumption, with the exception of bottled spring water and natural mineral water*

In order to characterise the vulnerability of this water, AFSSA suggests monitoring this parameter at source when the water is groundwater or is influenced by surface water (RP analyses), in the framework of PRPDE surveillance and especially when implementing Water Safety Plans.

**I. 2 - Inclusion of new specific pathogenic microorganisms and/or indicators**

In Europe, the main pathogenic microorganisms identified during investigations of waterborne gastroenteritis epidemics are<sup>15</sup>:

- *Campylobacter*,
- *Cryptosporidium* and *Giardia*,
- Norovirus.

Other microorganisms capable of proliferating in water distribution systems may become pathogenic through inhalation and through contact, for instance:

- *Legionella pneumophila*,
- *Pseudomonas aeruginosa*.

<sup>14</sup> Fransolet G., Villers G., Masschelin WG – 1985 - Influence of temperature on bacterial development in waters - Oz. Sc. Engi. 7, 3, 205-227.

Donlan RM, Pipes WD – 1988 - Selected drinking water characteristics and attached microbial population density - JAWWA, 80, 11, 70-76.

Piriou P., Dukan S., Levi Y., Guyon F., Villon P. – 1996 - Modélisation du comportement des biomasses bactériennes libres et fixées dans les réseaux de distribution d'eau potable - Rev. Sci. Eau, 3, 381-406.

<sup>15</sup> - InVs (December 2007): detection and investigation of infection epidemics related to the ingestion of supply water (see annex 7: Waterborne gastroenteritis epidemics investigated in France, 1998-2006 period).

- Journal of Water and Health (2009): rainfall and outbreaks of drinking water related disease in England and Wales. Gordon Nichols, Chris Lane, Nima Asgari, Neville Q. Verlander and Andre Charlett.

- Number of epidemics associated with the ingestion of public supply water between 1993 and 2002 (CDC data).



- **I.2.1 *Cryptosporidium* oocysts and *Giardia* cysts**

I.2.1.1 Water intended for human consumption with the exception of bottled water and natural mineral water

Protozoa are primarily eliminated through retention processes. Since *Cryptosporidium* oocysts are approximately 4 to 6 µm in size, that of *Giardia* cysts 10 to 15 µm and that of spores of sulfite-reducing anaerobes 1 to 2 µm, an effective retention process to remove spores of sulfite-reducing anaerobes would also remove the abovementioned parasites, consequently there is no need to screen for them.

However, in the event that there are spores of sulfite-reducing anaerobes or if turbidity is greater than 0.5 FNU<sup>16</sup>, which is a sign of ineffective filtering, AFSSA suggests monitoring both parameters at the point of exit from the treatment plant (P1 analyses), in the framework of water quality monitoring performed by local health authorities.

AFSSA recommends using the standardised enumeration method recommended by the 17 September 2003 order, i.e., the NF T 90-455 standard or, failing that, the ISO 15553<sup>17</sup> standard as long as the sample is filtered using a cartridge fitted with a polyethersulfone filter with a surface area of 1,300 cm<sup>2</sup> and porosity of 1 µm.

I.2.1.2 Bottled water with the exception of natural mineral water

If spores of sulfite-reducing anaerobes are present, *Cryptosporidium* oocysts and *Giardia* cysts are probably also present. However, there is no need to screen for these organisms since the water will then be considered as non-compliant with the regulations. Moreover, the detection limit of the analysis method is insufficient for water with low contamination<sup>18</sup>.

I.2.1.3 Raw water used to produce water intended for human consumption, with the exception of bottled spring water and natural mineral water

AFSSA suggests monitoring these two parameters in surface water sources and in groundwater sources influenced by surface water (RP and RS analyses) in order to assess their level of vulnerability.

This should be done systematically as part of the PRPDE surveillance, especially when implementing Water Safety Plans, whenever a request is made to authorise the use of water intended for human consumption.

AFSSA suggests enforcing the establishment of a treatment line that would allow for a minimum log reduction of 4 if *Cryptosporidium* oocysts or *Giardia* cysts are found in the source<sup>19</sup>.

- **I.2.2 *Legionella pneumophila***

I.2.2.1 Water intended for human consumption with the exception of bottled water and natural mineral water

AFSSA recommends screening for *Legionelle pneumophila* in the public distribution network at the point of supply to the subscriber (as close as possible to the water meter) when the "temperature" parameter exceeds 25°C, including in French overseas *départements*.

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<sup>16</sup> Formazin Nephelometric Unit.

<sup>17</sup> ISO 15553 (2006): Water quality – Isolation and identification of *Cryptosporidium* oocysts and *Giardia* cysts from water.

<sup>18</sup> The detection limit of the standardised analysis method is 1 oocyst/100L. If source contamination is 10 oocysts/10 L (common contamination level) and the treatment system produces a log reduction of 4 (for bottled water made suitable for drinking through treatment), the detection limit in drinking water to verify the system's rate of removal should be 1 oocyst/10 m<sup>3</sup>.

<sup>19</sup> AFSSA report on protozoan infections related to food and water: scientific assessment of the risks associated with *Cryptosporidium* sp. – September 2002.

Screening is to be performed in the framework of the PRPDE's surveillance and especially when implementing the Water Safety Plan.

AFSSA recommends:

- adopting the following target quality value: < 250 CFU/L, only at the point where water from the public distribution network is supplied to the subscriber (at the water meter),
- using the standardised enumeration method recommended by the 17 September 2003 order, i.e. , the NFT 90-431 standard.

#### 1.2.2.2 Bottled water with the exception of natural mineral water

Only water used in atomisers may involve a risk, but it is not the subject of this request for an opinion.

- **1.2.3 Pseudomonas aeruginosa**

#### 1.2.3.1 Water intended for human consumption with the exception of bottled water and natural mineral water

AFSSA also received a request from the DGS (Request no. 2008-SA-0117) on 11 April 2008 on health risks related to the presence of *Pseudomonas spp.* in water intended for human consumption. The relevance of screening for *P. aeruginosa* and of setting a quality limit and/or reference for water intended for human consumption for distribution systems will be treated under this request.

#### 1.2.3.2 Bottled water with the exception of natural mineral water

AFSSA:

- recommends keeping the same quality limit: “not detected in 250 mL”,
- draws attention to the publication of the NF EN ISO 16266 standard that has replaced the NF EN 12780 standard recommended in the 98/83/EC directive and in the 17 September 2003 order,
- insists that analyses of samples stored at room temperature must be undertaken 72 hours after bottling.

As this parameter is an indicator of proper maintenance of the bottling line, it does not need to be monitored at the source, except if a bottle is non-compliant.

- **1.2.4 Viruses including bacteriophages**

#### 1.2.4.1 Water intended for human consumption from distribution systems and bottled water made suitable for drinking through treatment

AFSSA:

- recommends promoting the screening for bacteriophage MS2 at point of exit from the treatment plant (P1 analyses) and in bottled water according to the standardised method prescribed in NF EN ISO 10705-1<sup>20</sup> in order to assess the ability of the treatment line to eliminate viruses,
- emphasises that these bacteriophages are not indicators of water contamination by enteric viruses but are indicators of the effectiveness of treatment applied against viruses. This screen is to be performed in the framework of the surveillance carried out by the PRPDE.

#### 1.2.4.2 Bottled spring water

As spring water is originally groundwater (see article R. 1321-84 of the public health code), there is no need to screen for viruses at the source point.

<sup>20</sup> NF EN ISO 10705-1 (October 2001): Water quality – Detection and enumeration of bacteriophages – Part 1: Enumeration of F-specific RNA bacteriophages.

I.2.4.3 Raw water used to produce water intended for human consumption, with the exception of bottled spring water and natural mineral water

AFSSA:

- suggests screening for viruses in the source when water comes from surface water or is influenced by surface water, in order to evaluate the source's level of vulnerability (see AFSSA's virus report in February 2007<sup>21</sup>). This screen should systematically be undertaken whenever a request to authorise the use of water intended for human consumption is submitted and should fit into the framework of the PRPDE surveillance and especially when implementing Water Safety Plans.
- recommends:
  - using the standardised methods XP T 90-451<sup>22</sup> (enteroviruses) or NF EN 14486<sup>23</sup> (enteroviruses),
  - carrying out campaigns to analyse noroviruses, hepatitis A viruses (HAV) and rotaviruses using non-standardised PCR (Polymerase Chain Reaction) methods in order to acquire data on source contamination levels;
- suggests enforcing the establishment of a treatment line that would allow for a minimum log reduction of 4 if viruses are found in the source.

- **I.2.5 Salmonella**

The French regulations stipulate that *Salmonella* are to be screened for in surface water sources used to produce water intended for human consumption and have set guideline values for their classification into groups A1, A2 and A3. These provisions are no longer justified due to changes in the epidemiology of 'major' *Salmonella* infections which are no longer waterborne<sup>24</sup>.

Moreover, given that this germ has a lower resistance to biocidal treatments than traditional indicators (enterococci), there is no need to screen for it at the point of exit from the treatment plant.

- **I.2.6 Campylobacter species**

Due to a lack of data on contamination of public distribution networks and information on the health risks related to the latter, AFSSA recommends screening for this bacterium only in the event of an epidemic.

- **I.2.7 Yeast and mould**

AFSSA also received a request from the DGS (Request no. 2007-SA-0194) on 19 June 2007 on health risks related to the presence of yeast and mould in bottled water. The relevance of screening for these germs and setting a parametric value for bottled water will be treated under this request.

- **I.2.8 Cyanobacteria**

Although the danger comes from the toxins released by cyanobacteria, AFSSA recommends enumerating cyanobacteria firstly in surface sources to evaluate their level of vulnerability and secondly at the point of exit from the treatment plant to assess the treatment line's ability

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<sup>21</sup> AFSSA report (February 2007): Review of knowledge concerning orally transmissible viruses to humans.

<sup>22</sup> XP T 90-451 (March 1996): Testing water – Detection of enteroviruses.

<sup>23</sup> NF EN 14486 (January 2006): Water quality – Detection of human enteroviruses by monolayer plaque assay.

<sup>24</sup> InVs (December 2007): detection and investigation of infection epidemics related to the ingestion of supply water (see annex 7: Waterborne gastroenteritis epidemics investigated in France, 1998-2006 period).

to eliminate them (see the AFSSA and AFSSET report of July 2006<sup>25</sup>). Screening should be undertaken systematically whenever a request to authorise the use of surface water to produce water intended for human consumption is submitted and in the framework of the PRPDE's surveillance and especially when implementing the Water Safety Plans.

The French regulations stipulate monitoring and measuring of microcystins in surface sources (RS analyses) and at the point of exit from the treatment plant (P2 analyses) only when visual and/or analytical observations identify a risk of cyanobacteria proliferation: as there is an available standardised analytical method for microcystins only, compliant results for the 'Total microcystins' parameter (quality limit: 1.0 µg/L) cannot guarantee that there is no danger in relation to other cyanotoxins.

## **II- Integration of the Water Safety Plan approach for water intended for human consumption, described by the World Health Organization (WHO) in 2004**

Because there is no universal indicator for all types of microorganisms (bacteria, viruses, parasites) and since there are not enough data on treatment effectiveness for certain parameters, it is essential to implement Water Safety Plans.

AFSSA draws attention to the fact that a Water Safety Plan:

- can only complement requirements for water quality control and may not under any circumstances replace them,
- should make it possible to reduce analysis frequency, but should not cancel out the analysis and monitoring of certain mandatory parameters,
- must be implemented in all UDIs (water distribution units). However, tools adapted to the size of UDIs as well as assistance and incentive measures must be offered. These tools need to specify the improvements, depending on available means, that are to be implemented to counter the health risks detected in the Water Safety Plans.

Regarding the various water quality control points, the EGM group's document distinguishes between the following points:

- the source (operational),
- the point of exit (operational),
- the public distribution network (operational),
- the point of distribution to subscribers (compliance),
- the tap (compliance).

and the document drawn up by the 'Sampling and Monitoring' group specifies that only results of analyses carried out at compliance points must be sent to the European Commission (EC).

In France:

- the regulations stipulate 3 levels for water quality monitoring performed by the local health authorities (compliance points):
  - the source,
  - the point of exit from the treatment plant,
  - the tap;
- the results of analyses conducted at the point of exit from the treatment plant and the tap are sent to the European Commission;
- control points where the regulatory D1 analyses are performed correspond to the last 3 control points chosen by the EGM group (the network, the point of distribution to the subscriber and the tap).

AFSSA:

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<sup>25</sup> AFSSA and AFSSET report: *Assessment of risks related to the presence of cyanobacteria and their toxins in water intended for consumption, swimming and other recreational activities – July 2006.*

- considers that it is not useful to distinguish between the point of distribution to the subscriber (point of entry) and the tap, unless there is a local non-compliance requiring that the quality of water at the point of distribution be checked and a screen done for *Légionella pneumophila*,
- emphasises, especially for microbiological parameters, the importance of taking water residence time in the network into consideration (possible stagnation) when drawing up the sampling plan,
- draws attention to the usefulness of certain physico-chemical parameters (turbidity and residual disinfectant in particular) as indirect indicators of treatment effectiveness,
- notes that the recommendation of the EGM and 'Sampling and Monitoring' groups to send the EC only the results of *E. coli* and enterococci analyses conducted at points of distribution to subscribers and the tap will not allow for a representative inventory of the microbiological quality of water in the various Member States,
- wishes to maintain the clause in the 98/83/EC directive that stipulates that "*Member States must take samples at the points of compliance as defined in Article 6(1) (taps that are normally used for human consumption) to ensure that water intended for human consumption meets the requirements of the Directive. However, in the case of a distribution network, a Member State may take samples within the supply zone or at the treatment plant for particular parameters if it can be demonstrated that there would be no adverse change to the measured value of the parameters concerned*".

The tables in the annex summarize the main points of this Scientific and Technical Support.

**ANNEX**

**Table 1**  
**Microbiological parameters to be analysed for water supplied by a distribution network**

Parameters	SOURCE		POINT OF EXIT FROM TREATMENT PLANT		SUPPLY (at the tap)	
	RP	RS	P1	P2	D1	D2
<i>E. coli</i>	x	x	x		x	
Enterococci	x	x	x		x	
Coliform bacteria			x		x	
Spores of sulfite-reducing anaerobes			X (surface water or water influenced by surface water)			
Enumeration of culturable micro-organisms at 22°C and 36°C					x	
<i>Cryptosporidium</i> oocysts and <i>Giardia</i> cysts			X (only if presence of spores of sulfite-reducing anaerobes or if turbidity > 0.5 (FNU))			

**Table 2**  
**Microbiological parameters to be analysed for bottled water, with the exception of natural mineral water**

Parameters	AT SOURCE	IN BOTTLED WATER
<i>E. coli</i>	x	x
Enterococci	x	x
Coliform bacteria	x	x
Spores of sulfite-reducing anaerobes	x	x
Enumeration of culturable micro-organisms at 22°C and 36°C	x	x
<i>Pseudomonas aeruginosa</i>	x	x

**Table 3**  
**Microbiological quality limits and references for water intended for human consumption, with the exception of bottled water**

Parameters	Quality limits (QLs)	Quality references (QRs)	Units
E. coli	Not detected		CFU/100 mL
Enterococci	Not detected		CFU/100 mL
Coliform bacteria		Not detected	CFU/100 mL
Spores of sulfite-reducing anaerobes		Not detected	CFU/100 mL
Enumeration of culturable micro-organisms at 22°C and 36°C		No variation having a factor greater than 10 compared to the geometric average of the previous year's results in the relevant sector	CFU/mL

**Table 4**  
**Microbiological quality limits for bottled water, with the exception of natural mineral water**

Parameters	Quality limits (QLs)	Units	Notes
<i>E. coli</i>	Not detected	CFU/250 mL	At source and during marketing
Enterococci	Not detected	CFU/250 mL	At source and during marketing
Coliform bacteria	Not detected	CFU/250 mL	At source and during marketing
Spores of sulfite-reducing anaerobes	Not detected	CFU/250 mL	At source and during marketing
Enumeration of culturable micro-organisms at 22°C and 36°C	100(22°C)	CFU/mL	During marketing
	20(36°C)	CFU/mL	During marketing
<i>Pseudomonas aeruginosa</i>	Not detected	CFU/250 mL	At source (if non-compliance during marketing) and during marketing