



AGENCE FRANÇAISE
DE SÉCURITÉ SANITAIRE
DES ALIMENTS

Maisons-Alfort, 24 December 2008

THE DIRECTOR GENERAL

Scientific and technical support

from the Agence française de sécurité sanitaire des aliments (French Food Safety Agency) for revision of European Directive 98/83/EC on the quality of water intended for human consumption

Context of the request:

The French Food Safety Agency (Afssa) was requested on 25 November 2008 by the Directorate General for Health (DGS) for scientific and technical support to revise the chemical, physical and organoleptic 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 revision proposals of the European Commission (EC) of 16 June 2008;

Having regard to Afssa's Scientific and Technical Support of 7 March 2008 on the revision of European Directive 98/83/EC on the quality of water intended for human consumption (AST no. 2008-SA-0020).

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 mail and met on 17 December 2008.

Argument and conclusions

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

1 – The proposal by the Commission for the next directive would be to move from two lists of chemical parameters and indicators in the current directive (Annex 1 – parts B and C) to three lists (as stated in the DGS request letter), which, in particular, contain eight new parameters.

I-1 – Does this distribution of parameters into three lists appear to be relevant to you?

I-2 – Do the parameters included in each of these lists appear to be appropriate to you?

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Afssa notes that the distribution of parameters into three lists is associated with the EC proposal to define four categories of supply units (UDI) classified depending on the size of the population served. Each category, if not limited to a single household, is linked to test chemical parameters which may change depending on local conditions and/or on the risk assessment performed.

The second French National Environment and Health Action Plan (PNSE II) clearly describes in the current draft the principles for reducing inequalities of access to drinking water and Afssa considers that the new proposals in the directive on the quality of water for human consumption could lead to disparities in hazard exposure between users in communities of different sizes.

Moreover smaller communities generally do not have the necessary resources to perform risk assessments and choose the relevant parameters to control.

Afssa is not therefore in favour of the EC proposal to define three lists of parameters and set quality limits based on category of UDI. The same parameter lists should apply to all UDI to enable citizens to have the same access to quality water. The testing frequency for some of these is the only variable which is liable to be changed depending on the size of the UDI. This could be modified depending on the conclusions of the "water safety plans" and relevance of the different parameters in terms of the water treatment systems and processes.

In addition, as "quality limits"¹ are set for all of the parameters, the proposal of three lists appears to take away the concept of "quality references"².

Afssa is not in favour of this and, for improved legibility by producers and users, recommends breaking down the physico-chemical and organoleptic parameters into two lists and retaining the distinction between quality limits and quality references :

- **List 1 (cf. annex 1):** Parameters carrying a risk to public health (parameter origin : natural, pollution, treatment and water supply system) : mandatory quality limits for water for human consumption.
- **List 2 (cf. annex 2):** Parameters indicative of the effectiveness of treatments or operation of the drinking water supply systems : quality references for water for human consumption.

N.B.: In view of the conclusions of the "water safety plan", some parameters identified in the annex may not be monitored.

I-3 – Is it appropriate to add these eight new parameters?

- **Uranium**

Afssa was also requested on 4 December 2008 by the DGS to set a quality requirement for uranium in water for human consumption and on the health risks due to situations in which this requirement was exceeded (Request 2008-SA-0380). This question will be examined in the permanent Afssa working group " Assessment of the health risks associated with non-compliance with quality references and limits in water intended for human consumption"

The main effect of uranium in humans is renal toxicity, although there is little information available about the chronic effects associated with environmental uranium exposure. According to WHO³, a guideline value of 30 µg/L should not cause renal toxicity. Pending the processing of the aforementioned request, Afssa approves the addition of this parameter and recommends the adoption of the guideline value of 30 µg/L set by WHO.

¹ *Quality limits: limits set for parameters which if present in water are liable to cause immediate or long-term effects on consumer health.*

² *Quality references: indicative values established for the purposes of monitoring water production and supply systems and for assessing the risk to human health. Failure to satisfy these quality references may also cause discomfort or disorders in consumers and in the case of some parameters even constitute a health risk.*

³ *Guidelines for Drinking Water Quality –Third Edition (incorporating first Addendum) – Volume 1 – WHO 2006.*

- **Aggressivity**

Afssa approves the introduction of this parameter, although recommends that the term "calco-carbonic balance", which is the relevant parameter for determining water aggressivity, be added. The title of the paragraph would then be : "Aggressivity (Calco-carbonic balance)".

Afssa emphasises that the parameter value proposed by the EC appears to refer to corrosivity and not aggressivity.

- **Chlorates**

Afssa approves the addition of this parameter, with a quality limit of 0.7 mg/L which is consistent with the guideline value set by WHO.

- **Chlorites**

Afssa approves the addition of this parameter, with a quality limit of 0.7 mg/L which is the same as the value proposed in its opinion of 5 July 2004 related to the assessment of health risks associated with non-compliance with quality references for chlorite ions in water intended for human consumption.

- **"Total halo-acetic acids" (HAA)**

In its Scientific and Technical Support of 7 March 2008 (AST no. 2008-SA-0020), Afssa approved the addition of the parameter "dichloroacetic acid" with a quality limit of 50 µg/L.

With no available data justifying the choice of the 9 compounds⁴ to be tested, method by which the guideline value proposed by the EC was established nor information on the assessments performed on each of these parameters, Afssa cannot provide an opinion about the relevance of adding this parameter or on the quality limit proposed.

In addition, there are at present no standardised analytical methods to test for these 9 substances. Standard NF EN ISO 23631⁵ only describes an assay method for 7 substances (bromochloroacetic acid, 2,2-dichloropropionic acid, dibromoacetic acid, dichloroacetic acid, monobromoacetic acid, monochloroacetic acid, trichloroacetic acid) and it must be ensured that the present method is indeed applicable to the other substances.

- **Endocrine disruptors**

Afssa considers that, as knowledge currently stands, it is not appropriate to search these parameters in water for human consumption. The 3 substances proposed are also not representative indicators of all endocrine disrupting effects, but only of oestrogenic effects. There is at present no standardised analytical method to test for these. Other molecules with endocrine disrupting effects (androgens, thyroids, hormones etc) exist such as the phthalates, PCB, polybromide flame retardants and there are at present no standardised analytical methods to test for these.

Afssa stresses, however, that it would be useful to undertake quantitative detection of the endocrine disrupting effects in surface water sources or those influenced by surface water used for the production of water for human consumption based not on testing for specific

⁴ Sum of the 9 following compounds: bromochloroacetic acid, bromodichloroacetic acid, dibromochloroacetic acid, monobromoacetic acid, dibromoacetic acid, tribromoacetic acid, monochloroacetic acid, dichloroacetic acid, trichloroacetic acid.

⁵ Standard NF EN ISO 23631 (June 2006) "Water quality - Assay of dalapon, trichloroacetic acid and selected haloacetic acids - Gas phase chromatography method (GC-DCE detection and/or GC-MS) detection after liquid-liquid extraction and derivation".

molecules but on measuring the global effects using one or more *in vitro* and/or *in vivo* biological and/or biochemical tests.

- **Cyanobacterial toxins**

Afssa recommends:

- that the name of the parameter be changed to : "total microcystins",
- that analysis of the main microcystins be recommended,
- that a quality limit be set of 1 µg/L (*cf.* AST no. 2008-SA-0020 of 7 March 2008).

- **NDMA**

Afssa approves the addition of this parameter because of its carcinogenic effects and suspicions that it is formed during the treatment of water for human consumption. Although the use of chloramines to disinfect water for human consumption is not permitted in several European countries, including France, possible contamination of water by NDMA cannot be excluded.

Afssa nevertheless draws attention to the fact that there is at present no European standardised analytical method, only an EPA method⁶.

Afssa approves a quality limit of 0.1 µg/L being set, which is consistent with the guideline value set by WHO.

I-4 – Should other parameters such as radon be added?

Radon is a highly volatile substance. WHO considered that the total indicative doses from its presence in water are very low (0.025 mSv/year for inhalation and 0.002 mSv/year for ingestion) compared to the risk from radon present in the atmosphere (1.1 mSv/year) at the "natural" dose of 2.4 mSV/year. Afssa considers as a result that it is inappropriate to set a quality limit in water for human consumption but recommends initially that information be obtained to assess the risks from exposure in drinking water.

II – In addition, the EC proposes removing 10 parameters featuring in the current directive.

II-1 – Do these removals appear appropriate to you?

- **Benzene**

Afssa would like this parameter, which is a marker of hydrocarbon pollution, to be retained in list 1. The frequency with which this is analysed could however be changed depending on the application of "water health safety plans" (list 1*).

It proposes that a quality limit of 1 µg/L be retained.

- **Cyanides**

Afssa approves the EC proposal to remove this parameter (*cf.* AST no. 2008-SA-0020 of 7 March 2008) as free cyanides are removed by chlorination in treatment filters. It does, however, highlight that in some European countries, water is not treated by chlorination.

⁶ EPA/600/R-05/054 – Method 521 – Determination of nitrosamines in drinking water by solid phase extraction and capillary column gas chromatography with large volume injection and chemical ionisation tandem mass spectrometry (MS/MS) – September, 2004 – J.W. Munch, M.V. Bassett.

- **1, 2 - dichloroethane**

Afssa approves the EC proposal to remove this parameter.

- **“Total pesticides”**

Afssa approves the EC proposal to remove this parameter.

- **Aldrin/dieldrin/heptachlor/heptachlor epoxide (by individual substance)**

Afssa approves the EC proposal to remove these parameters.

- **Oxidizability**

Afssa approves the EC proposal to remove this parameter which is replaced by the parameter “total organic carbon”, to which a quality reference should be attached (*cf. paragraph III-2*).

- **Sulphates**

Afssa does not support the removal of this parameter, as sulphate monitoring is required not only for management of water supply networks but also because of the health risks which sulphates may carry. It is also involved in calculating the calco-carbonic balance⁷ (*cf. Afssa opinion of 13 May 2005 on the request to evaluate the health risks of exceeding the quality reference for sulphates in water for human consumption*).

Afssa proposes that this be added to list 2.

- **Sodium**

Afssa considers that this parameter should be retained as it is required for managing water supply networks (particularly from knowledge of water aggressivity⁷).

Afssa therefore proposes that this be added to list 2.

- **Tritium and Total Indicative Dose (radioactivity)**

Although the assessment of risk from radioactivity is outside of its administrative scope, Afssa approves the removal of these parameters but recommends that testing for total alpha and total residual beta activity be introduced to keep a warning signal about radioactivity in water.

II-2 – Should other parameters be removed from current lists of chemical or indicative parameters?

- **Mercury**

Afssa proposes that this parameter be removed (*cf. AST no. 2008-SA-0020 of 7 March 2008*), except for areas at specific risk (for example French Guiana).

⁷ Assay of this parameter is required to measure the calco-carbonic balance using the calculation model from the “Legrand and Poirier” method.

III – In addition, for each parameter, a parametric value is attributed. These could be amended for some of the parameters retained from the current directive.

III - 1 – Do these amendments in parametric values appear to be justified to you?

▪ **Antimony**

Afssa approves the raising of the quality limit for this parameter to 20 µg/L, as proposed in its opinion of 5 July 2004 related to the assessment of health risks associated with non-compliance with the quality reference for antimony in water intended for human consumption. .

▪ **Boron**

Afssa recalls that the WHO guideline value is set at 0.5 mg/L and the US-EPA VTR at 0.7 mg/L. It does not therefore approve the proposal to change the quality limit for this parameter to 2.5 mg/L and recommends that the quality limit of 1 mg/L be retained.

▪ **Cadmium**

Afssa approves the quality limit of 3 µg/L set for this value as this corresponds to the WHO guideline value.

▪ **Copper**

Afssa would like the quality limit for this parameter to be lowered to 1 mg/L as it is an indicator of corrosion (*cf.* Afssa opinion of 22 May 2006 related to the assessment of health risks associated with non-compliance with the quality limit for copper in water intended for human consumption and AST no. 2008-SA-0020 of 7 March 2008).

▪ **Nickel**

Afssa recalls that the WHO guideline value for this parameter is 70 µg/L and, in the absence of justification of the value proposed by the EC (30 µg/L), considers that the WHO guideline value should be retained.

▪ **Selenium**

Afssa recalls that in its opinion of 28 September 2004 related to the assessment of health risks associated with non-compliance with the quality limit for selenium in water intended for human consumption and in its AST of March 2008, it proposed to set a quality limit of 20 µg/L.

▪ **Trichloroethylene and tetrachloroethylene**

Afssa approves the adoption of the quality limits proposed for these two parameters (*cf.* Afssa opinion of 28 December 2006 related to the assessment of health risks associated with non-compliance with the quality limit for trichloroethylene or tetrachloroethylene in water intended for human consumption.).

▪ **Benzo [a] pyrene**

Afssa approves setting the quality limit of 0.7 µg/L for this parameter as this corresponds to the WHO guideline value and recalls that this substance is classified as a priority substance in Directive 2000/60/EC of the European Parliament and Council of 23 October 2000 establishing a framework for Community action in the field of water policy.

- **Conductivity**

Afssa does not approve the removal of this parametric value or its replacement with the wording “acceptable and no abnormal change” as this is liable to be interpreted differently by different people.

It proposes that a value between 200 and 1100 $\mu\text{S}/\text{cm}$ at 25°C be set in accordance with current French regulations.

- **Aluminium**

The joint Afssa/Afsset/InVS report of November 2003 on "assessment of health risks from exposure of the French population to aluminium", states that, as knowledge currently stands and in light of the risk assessment performed, it did not appear necessary to set a quality reference value other than 200 $\mu\text{g}/\text{L}$ nor to prohibit the use of water treatment products containing aluminium. It would, however, appear desirable to aim for a high performance level with an objective of 100 $\mu\text{g}/\text{L}$ aluminium at the output from treatment systems. The Afssa opinion of January 2005 related to the assessment of health risks associated with non-compliance with quality references for aluminium in water intended for human consumption concluded that treatment systems using aluminium salts would need to be designed and operated in order to permanently guarantee that the quality reference of 200 $\mu\text{g}/\text{L}$ be met. In addition, the new human toxicity value (HTV) proposed by the "Joint Expert Committee on Food Additives" (JECFA) does not cast doubt over the aluminium quality reference in water for human consumption as by allocating 5% of the HTV to water and using an individual body mass of 60 kg and consumption of 2 litres of water per day, the limit value would be above 200 $\mu\text{g}/\text{L}$.

Afssa does not therefore approve setting a parametric value of 100 $\mu\text{g}/\text{L}$ for aluminium and proposes that a quality reference of 200 $\mu\text{g}/\text{L}$ and a “target value” of 100 $\mu\text{g}/\text{L}$ be set for water which has been coagulated with aluminium salts.

- **Turbidity**

Afssa highlights that the unit to be used is the FNU⁸ and not the TNU⁹ (cf. Standard NF EN ISO 7027¹⁰) and proposes that the following be set :

- ❑ for surface water and water influenced by surface water, the quality reference of 0.5 FNU after the filtration stage and 1 FNU at the factory output for remineralisation treatment or a pH adjustment by adding limewater,
- ❑ the quality limit at the distribution point of 1 FNU,
- ❑ the quality reference at the consumer tap of 2 FNU.

- **Vinyl chloride**

Afssa approves the lowering of the quality limit for this parameter to 0.3 $\mu\text{g}/\text{L}$ although emphasises that the tests must be on the water for human consumption and not on test water for materials intended to be used to transport or store water for human consumption.

III - 2- Should other parametric values be changed?

- **Ammonium**

Afssa recommends that the following quality references be set :

⁸ FNU: formazine nephelometric units.

⁹ TNU: turbidity nephelometric units.

¹⁰ NF EN ISO 7027 (March 2000): Water quality - determination of turbidity.

- ❑ 0.5 mg/L for underground water, if the ammonium is shown to be of natural origin;
- ❑ 0.1 mg/L for surface water and water influenced by surface water at the distribution point in order to avoid interfering with water disinfection.

- **Colour**

Afssa recommends setting a quality reference of 15 mg/L or less¹¹ in order to avoid variable assessment between different people.

- **pH**

Afssa recommends that the quality reference be set between 6.5 and 9 pH units.

- **Total organic carbon (TOC)**

Afssa recommends that a quality reference value be set in order to avoid different assessments for different people.

The experts agree on a quality reference between 2 and 3¹² mg/L, although there is no consensus on the precise value. Afssa cannot provide an opinion about a more specific value as this point will need to be re-examined in particular in light of the results of the water health control.

Key words.

Drinking water, Directive 98/83/EC, quality of water for human consumption, chemical, physical and organoleptic parameters.

¹¹ in accordance with the terms of the decree of 11 January 2007 on the quality limits and references for untreated water and water for human consumption stated in articles R. 1321-2, R. 1321-3, R. 1321-7 and R. 1321-38 of the Code of Public Health.

¹² 3 mg/L is equivalent to 70% reduction in the regulatory quality limit of 10 mg/L set for untreated water.

ANNEX 1

Parameters carrying a risk to health
(origin of parameters: natural, pollution, treatment and water supply system)

Mandatory quality limits for water intended for human consumption

Parameter	Quality limit
Dichloroacetic acid	50 µg/L
Acrylamide*	0.10 µg/L
Antimony	20 µg/L
Arsenic*	10 µg/L
Benzene*	1.0 µg/L
Benzo [a] pyrene*	0.7 µg/L
Boron *	1 mg/L
Bromates*	10 µg/L
Cadmium	3 µg/L
Chlorates*	0.7 mg/L
Chlorites*	0.7 mg/L
Vinyl chloride *	0.30 µg/L
Chromium	50 µg/L
Copper	1.0 mg/L
Epichlorohydrin*	0.10 µg/L
Fluorides*	1.5 mg/L
² Polycyclic aromatic hydrocarbons (PAH)*	0.1 µg/L
³ Total microcystins*	1 µg/L
Nickel	70 µg/L
Nitrates	50 mg/L
Nitrites (at distribution point)	0.1 mg/L
Nitrites (at tap)	0.5 mg/L
N-nitrosodimethylamine* (NDMA)	0.1 µg/L
Pesticides (by individual substance)	0.1 µg/L
Lead	10 µg/L
Selenium*	20 µg/L
Tetrachloroethylene*	40 µg/L
Trichloroethylene*	10 µg/L
¹ Total trihalomethanes (THM)*	100 µg/L
Turbidity (at distribution point)	1 NFU
Uranium*	30 µg/L

* : parameters for which the frequency of analysis may be modified depending on the application of the "water safety plans" .

¹ Sum of concentrations of the following 4 compounds:

- chloroform,
- bromoform,
- dibromochloromethane,
- bromodichloromethane.

² Sum of concentrations of the following 4 compounds:

- benzo[b]fluoranthene,
- benzo[k]fluoranthene,
- benzo[g,h,i]perylene,
- indeno[1,2,3-c,d]pyrene.

³ Sum of the concentrations of all of the mycrocystins detected and quantified.

ANNEX 2

Parameters indicative of the effectiveness of treatment or operation of drinking water supply systems

Quality references for water intended for human consumption

Parameter	Quality references
Aggressivity (Calco-carbonic balance)	The water must not be aggressive. It must be at the calcium carbonate balance or slightly hard
Aluminium	<ul style="list-style-type: none"> ☐ 200 µg/L ☐ 100µg/L for water which has undergone coagulation with aluminium salts
Ammonium	<ul style="list-style-type: none"> ☐ 0.5 mg/L for underground water if the ammonium is shown to be of natural origin. ☐ 0.1 mg/L at the distribution point for surface water and water influenced by surface water
Total organic carbon (TOC)	2 to 3 mg/L
Chlorides	250 mg/L
Conductivity	between 200 and 1100 µS/cm (at 25°C)
Colour	15 mg/L or lower (Pt)
Iron	200 µg/L
Manganese	50 µg/L
Odour/Taste	Acceptable for consumers and no abnormal change.
pH	$6.5 < \text{pH} < 9$
Sodium*	200 mg/L
Sulphates*	250 mg/L
Turbidity (at distribution point)	0.5 NFU
Turbidity (tap)	2.0 NFU

* Parameters necessary to measure the calco-carbonic balance.