
*Revision of Annex II and Annex III*

<table>
<thead>
<tr>
<th>Document:</th>
<th>Draft text of ANNEX II - MONITORING For consultation</th>
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<tbody>
<tr>
<td>Prepared by:</td>
<td>DG Environment, unit C.2</td>
</tr>
<tr>
<td>Date prepared:</td>
<td>29 Oct 2013</td>
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</tbody>
</table>

Please take note that this document has been prepared with the support of several working groups and does not necessarily represent the opinion of the European Commission.
COMMISSION DIRECTIVE ../…/EU of X X 2014 amending

Annex II

on the quality of water intended for human consumption

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 290 thereof,

Having regard to Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption\(^1\), and in particular Article 7 (5) (b) and (c) and Article 11 thereof,

Whereas:

(1) Article 11 (2) of Council Directive 98/83/EC requires the Commission to adapt Annex II to scientific and technical progress at least every five years.

(2) Regulation (EC) No 178/2002 of the European Parliament and the Council 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\(^2\) has introduced the concept of risk analysis including risk assessment, risk management and risk communication as systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect public health.

(3) Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules\(^3\) has introduced the concept of hazard analysis and critical control points (HACCP) as a tool for the feed and food business operators in performing the required checks on water intended for human consumption that is put into bottles or containers intended for sale.

(4) Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs\(^4\) lists the principles of HACCP as applicable to water intended for human consumption that is put into bottles or containers intended for sale.

(5) Recital 16 of Directive 98/83/EC refers to the World Health Organisation (WHO)’s ‘Guidelines for Drinking Water Quality’ on which the standards for the parameters of Annex I of this Directive are based. The proposed amendments are to reflect last updates of these guidelines for the monitoring of these parameters set out in annex II.

(6) In 2004, the World Health Organisation (WHO) has introduced the water safety plan (WSP) approach which is based on risk assessment and risk management principles; this approach has been developed 'to organise and systematise a long history of management practices applied to drinking-water and to ensure the applicability of these practices to the management of drinking-water quality'. The WHO refers to the

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\(^1\) OJ L 330, 5.12.1998, p. 32–54
\(^3\) OJ L 165, 30.4.2004, p. 1-141
\(^4\) OJ L 139, 30.4.2004, 0.1-54
concept of WSP in ‘The guidelines for Drinking-water Quality’\(^5\) and published the methodology for the implementation of the water safety plan approach in ‘The Water Safety Plan Manual’\(^6\).


(8) Monitoring of final product only provides retrospective information that the product does or does not meet appropriate standards. The Water Safety Plan approach takes a preventive perspective and provides a management framework for anticipating problems and ensuring that procedures are in place to assure that preventive control measures ensuring safety are operating at their optimum at all times.

(9) The current system has resulted in significant differences in the understanding and implementation in the Member States such as the differences in minimum number of samples applied in different Member States as a result of a different understanding of Table B1 or the different understanding on the sampling locations.

(10) Member States' experts developed recommendations for the update of table B1 in Annex II in the light of scientific progress and provided a set of clarifications in relation to parameters' sampling locations\(^7\).

(11) Annex II allows in its current form for a certain level of flexibility in performing the audit monitoring (except certain of its parameters) and check monitoring (which allows for reduction in the frequency of sampling under certain circumstances). However, the conditions which allow for these exceptions need to be clarified. Furthermore, more flexibility is needed as regards the possibility to use complementary techniques other than monitoring of parameters (such as visual inspection).

(12) The risk-based approach provides a solid basis for addressing the aspects mentioned above and in addition, for adjusting the monitoring programme depending on the Directives' requirements but also based on the local conditions/circumstances of the respective water supply zone.

(13) In performing the risk assessment and presenting the information to the public, Member States should consider those parameters laid down in Article 4 and 5 of Directive 98/83/EC including the parameters laid down at national level in accordance with Article 5.3 of that Directive.

(14) Increased flexibility in monitoring should be complemented by introducing a minimum set of information to be made publically available aiming at ensuring a level playing field which will also be used by the Member States for meeting their obligations as regards reporting (Article 13).

(15) Water Framework Directive 2000/60/EC\(^8\) provides in its Article 6 that Member States shall ensure the establishment of register(s) of all areas lying within each river basin district which have been designated as requiring special protection including in Article 7 such safeguard zones for the supply of drinking water. The monitoring which should be carried out in these zones in accordance with Article 8 of that Directive should be


\(^{6}\) http://www.who.int/water_sanitation_health/publication_9789241562638/en/

\(^{7}\) http://publications.jrc.ec.europa.eu/repository/handle/11111111/1331

used in order to determine the potential risk for drinking water before and after treatment.


(17) Council Directive [XXX] of [X October 2013] laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption introduces a specific regime for radioactive substances on the basis of the EURATOM Treaty. The application of the monitoring obligations under that Directive should be coordinated with the provisions of this Directive to ensure the coherence of the monitoring and reduce unnecessary administrative burden.

(18) Monitoring imposes significant costs when there is a large number of parameters to be considered. However, many of these parameters, particularly physico-chemical, will rarely be present in concentrations that would be likely to result in any breach of standards. Introducing flexible monitoring frequencies under such circumstances presents a cost saving with no loss in public health protection or other benefits. It also reduces data that provides little or no information regarding the quality of the drinking-water.

(19) In accordance with the Joint Political Declaration of Member States and the Commission of 28 September 2011 on explanatory documents \(^{10}\), Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.

(20) The measures provided for in this Directive are in accordance with the opinion of the [...] Committee.

HAS ADOPTED THIS DIRECTIVE:

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\(^9\) OJ L 164, 26.6.2009, p.45
Article 1

Annex II of Directive 98/83/EC shall be replaced by the Annex to this Directive.

Article 2

Member States may continue to apply existing monitoring programmes for a maximum of five years after the entry into force of this Directive provided they fulfil the minimum requirements in relation to the list of parameters and frequencies as set out in Part A and B.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive within 18 months after the entry into force of this Directive. They shall forthwith communicate to the Commission the text of those provisions. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 4

This Directive shall enter into force on the day following that of its publication in the Official Journal of the European Union.

Article 5

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission
On behalf of the President

Commissioner
PART I: Monitoring of drinking water (except for waters used in food production put in bottles or containers in food businesses)

To meet the obligations under Art 7 (2), Member States shall establish appropriate monitoring programmes for waters supplied from a distribution network or from a tanker ensuring that:
   a. Processes and controls are working effectively and guarantee safety of the waters throughout the water supply chain applying a risk-based approach as set out by the World Health Organisation (WHO) in its Guidelines for Drinking-water Quality.
   b. Regular information on the quality of the water supplied for human consumption is provided, in order to determine whether or not water intended for human consumption complies with the obligations set out in Article 4 and 5 and, at least, the parametric values laid down in Annex 1.
   c. The necessary investigation and analysis is carried out in cases where the reasons for the non-compliance cannot be determined easily or the measures to reduce the risk for human health need to be determined in the most effective way.

For the purpose of ensuring compliance with Art 4, Member States shall guarantee that all stages in a water supply system, from source to tap, are subject to a regularly reviewed monitoring programme that is based on the outcome of a risk assessment as set out in this annex.

The purpose of monitoring is to confirm that processes and controls are working effectively and to ensure that the water available to consumers is wholesome and clean through meeting the requirements of the Directive. This monitoring may consist of water quality analysis (automated or discrete samples) and complemented by other monitoring controls (e.g. visual inspections, sanitary conditions of supply infrastructures). In addition, Member States shall consider the monitoring results obtained through the programmes under article 8 of the Water Framework Directive 2000/60/EC\textsuperscript{11} for the safeguard zones for drinking water established under Article 7 of this Directive when designing the monitoring programmes under this Directive.

The monitoring programme shall focus on parameters of relevance to the individual water supply system and parameters important to assess the impact to domestic distribution systems (Article 6 (2)). The choice of appropriate parameters for monitoring must take into consideration local conditions for each water supply system. Parameter selection and sampling frequencies shall be decided based on water supply specific risk assessment based on the principles set out in the WHO ‘Guidelines for Drinking-water Quality’\textsuperscript{12}, the methodology for the implementation of the water safety plan approach in WHO ‘Water Safety Plan Manual’\textsuperscript{13}, the WHO guidance on ‘Water Safety Plans’ for buildings\textsuperscript{14}, and the standard EN 15975:2013 concerning security of drinking water supply, guidelines for risk and crisis management\textsuperscript{15}.

In doing so, Member States shall consider, as a starting point, the list of parameters and the related sampling frequencies as set out in parts A and B of this annex.

\textsuperscript{11} OJ L 327, 22.12.2000, p. 1–73
\textsuperscript{13} http://www.who.int/water_sanitation_health/publication_9789241562638/en/
\textsuperscript{14} http://www.who.int/water_sanitation_health/publications/2011/9789241548106/en/
\textsuperscript{15} https://www.cen.eu/cen/Pages/default.aspx
If the risk assessment demonstrates that this list of parameters or frequencies is not sufficient to meet the obligations under Article 7(2) and to provide for the necessary assurances, in particular as specified in point a. above, Member States shall, in accordance with Article 7 (6), extend this list of parameters and / or increase the frequencies as necessary on the basis of the results of the risk assessment.

In order to provide the regular information specified in point b. above Member States shall, as a minimum, monitor the list of parameters in the related sampling frequencies as set out in parts A and B of this annex.

Member States may, however, decrease the frequency or change the list of parameters to be monitored on the basis of a regularly reviewed risk assessment, subject to the following conditions:

1. The frequency for sampling microbiological parameters cannot be reduced under any circumstance;
2. For a chemical parameter, the location and frequency of sampling shall be determined by its principal source and variability in its concentrations and bearing in mind the provisions of article 6 of the Directive (compliance points and effect of domestic installations). The minimum frequency may be reduced if the results obtained from samples distributed equally in time and location during a period of at least three successive years are in all cases below 50% of the parametric value or the limit of quantification as set out in annex III has not been reached.
3. The risk assessment demonstrates there is no risk to human health, the substance has not been detected (applying the detection limits set out in Annex III) and there is no other evidence of a potential risk, taking into account the monitoring results of raw water before treatment as provided for by Article 8 in of the Water Framework Directive 2000/60/EC, taken in the safeguard zones specified in Article 7 of that Directive;
4. The risk assessment shall be updated at least every 3 years. It shall be updated more regularly in case risk potentials occur by monitoring result.

Further details on sampling points are presented in the notes listed at the end of this annex.

The risk based approach for the assessment shall be approved by the competent authority and be subject to quality control by an independent certified body and a regular peer review process. In accordance with Article 13 (1), Member States shall, as a minimum, provide the following information on the approach and its implementation to the public:

1. Information on the risk-based approach, the approval process by the competent authority and the quality control by the independent accredited body;
2. Validation/certification of the RA including a summary of the risk assessment performed, e.g. methodology, conclusions, measures; parameters exempted from monitoring and parameters monitored with reduced frequency.
3. Levels of compliance for the parameters set in accordance with Article 4 and 5 and specifications on monitoring results or risks identified in relation to a water supply zone.
4. How failures to meet the parametric values set in accordance with Article 5 are investigated and managed immediately in accordance with Article 8 including information on the control measures taken to prevent those risks.
5. Information on the interruptions of services due to non-compliances with the parametric values;
6. Any incidents of identified potential risks to human health.
7. Up-to-date information on the risk management procedures and the results of their application.

Information provided in accordance with sub-paragraph 7 shall be provided online and be updated annually.

**Part A: List of parameters**

**Group A Parameters**

In order to regularly provide information on the organoleptic and microbiological quality of the water supplied for human consumption in a water supply zone, the monitoring frequencies for the following parameters (Group A Parameters) shall be in accordance with those set out in Part B Table 1:

- Escherichia coli (E. coli), Enterococci, coliform bacteria, colony count 22°C, colour, conductivity, odour, pH, turbidity and ammonium;
- Aluminium and iron (when used as flocculants);
- Nitrite (when chloramines used for disinfection and of the level of ammonium is higher than the threshold as indicated in annex 1 part C of the Directive);
- Taste (where it is suspected that the microbiological quality of drinking water does not meet the parametric values in the DWD (e.g. if a pollution event or treatment plant malfunction has occurred), the water shall not be tasted as it may present a risk to health);
- Clostridium perfringens when checking performance of the filtration;
- Other parameters identified as relevant in the monitoring programme through the risk-based approach; including any microorganisms, parasites and substances which, in numbers or concentration, may constitute a potential danger to human health (as set out in Article 4 (1)).

**Group B parameters**

In order to determine whether or not all of the Directive’s parametric values are being complied with, all parameters set in accordance with Article 5(2) shall be monitored at the frequencies set out in Part B Table 1.
**Part B: Sampling frequencies**

**TABLE 1:** Minimum frequency of sampling and analysis for compliance monitoring from a distribution network or from a tanker

**Option 1:**

<table>
<thead>
<tr>
<th>Volume of water (in m(^3)/day) distributed or produced each day within a supply zone (Note 1 and 2)</th>
<th>Number of samples per year (frequency) for parameter group A</th>
<th>Number of samples per year (frequency) for parameter group B (Note 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤10</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>≤100</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>≤1000</td>
<td>12</td>
<td>1</td>
</tr>
<tr>
<td>≤3000</td>
<td>12</td>
<td>1</td>
</tr>
<tr>
<td>≤10,000</td>
<td>12 for the first 3,000 m(^3)/day of the total volume + 3 for each additional 1,000 m(^3)/day and part thereof of the total volume</td>
<td>1 for the first 3,000 m(^3)/day of the total volume + 1 for each additional 3,000 m(^3)/day and part thereof of the total volume</td>
</tr>
<tr>
<td>≤100,000</td>
<td>12 for the first 3,000 m(^3)/day of the total volume + 3 for each additional 1,000 m(^3)/day and part thereof of the total volume</td>
<td>4 for the first 10,000 m(^3)/day + 1 for each 10,000 m(^3)/day and part thereof of the total volume</td>
</tr>
<tr>
<td>&gt; 100,000</td>
<td>12 for the first 3,000 m(^3)/day of the total volume + 3 for each additional 1,000 m(^3)/day and part thereof of the total volume</td>
<td>12 for the first 25,000 m(^3)/day + 1 for each 25,000 m(^3)/day and part thereof of the total volume</td>
</tr>
</tbody>
</table>
**Note 1:** A supply zone is a geographically defined area within which water intended for human consumption comes from one or more sources and within which water quality may be considered as being approximately uniform.

**Note 2:** The volumes are calculated as averages taken over a calendar year. A Member State may use the number of inhabitants in a water supply zone instead of the volume of water to determine the minimum frequency, assuming a water consumption of 200 l/day/capita.

**Note 3:** As regards radioactivity, provisions under the Council Directive [2013…/Euratom](#) laying down the requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption shall be applied.

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**Option 2: keeping current table B1**

<table>
<thead>
<tr>
<th>Volume of water distributed or produced each day within a supply zone (Notes 1 and 2) m³</th>
<th>Check monitoring number of samples per year (Note 4)</th>
<th>Audit monitoring number of samples per year (Notes 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 100</td>
<td>(Note 4)</td>
<td>(Note 4)</td>
</tr>
<tr>
<td>&gt; 100</td>
<td>≤ 1 000</td>
<td>4</td>
</tr>
<tr>
<td>&gt; 1 000</td>
<td>≤ 10 000</td>
<td>4 + 3 for each 1 000 m³/d and part thereof of the total volume</td>
</tr>
<tr>
<td>&gt; 10 000</td>
<td>≤ 100 000</td>
<td>3 + 1 for each 10 000 m³/d and part thereof of the total volume</td>
</tr>
<tr>
<td>&gt; 100 000</td>
<td></td>
<td>10 + 1 for each 25 000 m³/d and part thereof of the total volume</td>
</tr>
</tbody>
</table>
Note 1: A supply zone is a geographically defined area within which water intended for human consumption comes from one or more sources and within which water quality may be considered as being approximately uniform.

Note 2: The volumes are calculated as averages taken over a calendar year. A Member State may use the number of inhabitants in a supply zone instead of the volume of water to determine the minimum frequency, assuming a water consumption of 200 l/day/capita.

Note 3: As regards radioactivity, provisions under the Council Directive 2013…/Euratom laying down the requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption shall be applied.

Note 4: The frequency is to be decided by the Member States concerned, in accordance with Article 3 (2) (b) of the Directive.

**Part C: Sampling methods and sampling points**

As far as possible, the number of samples should be distributed equally in time and location. Member States must take samples at the points of compliance as defined in Article 6 (1) 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 works for particular parameters if it can be demonstrated that there would be no change to the measured value of the parameter concerned.

Sampling taps in the distribution network with the exception of the consumers’ tap shall follow the general design guidelines of ISO 5667-5 (2006). Compliance samples for microbiological parameters shall be taken and handled according ISO 19458. The attached devices shall be removed, and a sufficient volume of water used for flushing to allow stagnant water to flow out. For other parameters sampling taps shall only be flushed. Flushing for three times the total volume of sampling line and tap with the tap fully open shall be deemed sufficient. Monitoring of the temperature stabilisation of the flushed water may be carried out as an alternative when the water from the distribution network is cooler than the ambient temperature.
PART II: Monitoring of water used in food production put in bottles or containers intended for sale or provision as an alternative to tap water

The minimum frequency of sampling and analysis for water intended for human consumption put into bottles or containers intended for sale or provision as an alternative to tap water shall be in accordance with those set out in table 3.

The following parameters shall be included for parameter group A:

- ‘colony count at 37° C’ and
- Pseudomonas aeruginosa (for bottled water)

For bottled ‘spring water’, as defined in article 9 of Directive 2009/54/EC, the relevant provisions of Directive 2009/54/EC apply.

The selection of parameters under group A and B and the minimum frequencies referred to in table 3 shall be without prejudice to:

- the requirements of Regulation (CE) 178/2002 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;
- the principles of HACCP as required by Regulation (EC) 852/2004 on the hygiene of foodstuffs;
- the principles of official controls as laid down in Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

**TABLE 3: optional**

Minimum frequency of sampling and analysis for water intended for human consumption to be put into bottles or containers intended for sale or provision as an alternative to tap water (Parameters Group A and Group B)

<table>
<thead>
<tr>
<th>Volume of water (m$^3$) produced for offering in bottles or containers each day (Note 1)</th>
<th>Frequency for parameter group A (Note 1)</th>
<th>Frequency for parameter group B (Note 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\leq 10$</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>$&gt; 10$</td>
<td>12</td>
<td>1</td>
</tr>
<tr>
<td>$&gt; 60$</td>
<td>1 for each 5 m$^3$ and part thereof of the total volume counted from zero</td>
<td>1 for each 100 m$^3$ and part thereof of the total volume counted from zero</td>
</tr>
</tbody>
</table>

Note 1: The volumes are calculated as averages taken over a calendar year.

Note 2: In the event of intermittent short-term supply the monitoring frequency of water distributed by tankers is to be decided by the Member State concerned. The competent authority should secure the hygienic condition of the tankers, hygienic transport conditions and give necessary instructions of the water users to prevent potential danger to human health.

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16 Minimum requirements in table 3 still needs further verification against minimum requirements on frequency under HACCP.