Commission Directive (EU) 2015/1787 of 6 October 2015 amending Annexes II and III to Council Directive 98/83/EC on the quality of water intended for human consumption

COMMISSION DIRECTIVE (EU) 2015/1787

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amending Annexes II and III to Council Directive 98/83/EC on the quality of water intended for human consumption

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 11(2) thereof,

Whereas:

(1) Annexes II and III to Directive 98/83/EC lay down the minimum requirements of the monitoring programmes for all water intended for human consumption and the specifications for the method of analysis of different parameters.

(2) The specifications in those Annexes II and III should be updated in the light of scientific and technical progress and so as to ensure coherence with Union legislation.

(3) Annex II to Directive 98/83/EC grants a certain degree of flexibility in performing the audit monitoring and check monitoring, allowing for less frequent sampling under certain circumstances. The specific conditions to perform the monitoring of parameters at appropriate frequencies and the range of monitoring techniques need to be clarified in the light of scientific progress.

(4) Since 2004, the World Health Organisation has developed the water safety plan approach which is based on risk assessment and risk management principles, laid down in its *Guidelines for Drinking Water Quality*[(2)]. Those Guidelines, together with standard EN 15975-2 concerning security of drinking water supply, are internationally recognised principles on which the production, distribution, monitoring and analysis of parameters in drinking water is based. Annex II to Directive 98/83/EC should therefore be aligned to the latest updates of those principles.

(5) To control risks to human health, the monitoring programmes should ensure that there are measures in place throughout the water supply chain and consider information from water bodies used for drinking water abstraction. The general obligations for monitoring programmes should bridge the gap between water abstraction and supply. Pursuant to Article 6 of Directive 2000/60/EC of the European Parliament and of the Council[(3)], Member States must ensure the establishment of register(s) of protected areas. Such protected areas include all bodies of water used for the abstraction of drinking water, or intended for such use, under Article 7(1) of that Directive. Results from the monitoring of those bodies of water under the second subparagraph of Article 7(1) and Article 8 of

that Directive should be used to determine the potential risk for drinking water before and after treatment for the purposes of Directive 98/83/EC.

(6) Experience has shown that, for many (particularly physico-chemical) parameters, the concentrations present would rarely result in any breach of limit values. Monitoring and reporting such parameters without practical relevance imply significant costs, especially where a large number of parameters need to be considered. Introducing flexible monitoring frequencies under such circumstances presents potential cost-saving opportunities that would not damage public health or other benefits. Flexible monitoring also reduces the collection of data that provide little or no information on the quality of the drinking water.

(7) Member States should therefore be allowed to derogate from the monitoring programmes they have established, provided credible risk assessments are performed, which may be based on the WHO *Guidelines for Drinking Water Quality* and should take into account the monitoring carried out under Article 8 of Directive 2000/60/EC.

(8) Table B2 in Annex II to Directive 98/83/EC, which concerns water put into bottles or containers intended for sale, has become obsolete, as those products are covered by Regulation (EC) No 178/2002 of the European Parliament and of the Council[(4)]. Those products are also covered by the principle of 'hazard analysis and critical control point' (HACCP) laid down in Regulation (EC) No 852/2004 of the European Parliament and of the Council[(5)] and the principles of official controls as laid down in Regulation (EC) No 882/2004 of the European Parliament and of the Council[(6)]. As a consequence of the adoption of those Regulations, Annex II to Directive 98/83/EC de facto no longer applies to water put into bottles or containers intended for sale.

(9) Council Directive 2013/51/Euratom[(7)] introduced specific arrangements for monitoring for radioactive substances. Monitoring programmes for radioactive substances should therefore exclusively be established under that Directive.

(10) Laboratories applying the specifications for the analysis of the parameters laid down in Annex III to Directive 98/83/EC should work in accordance with internationally approved procedures or criteria-based performance standards and use methods of analysis that have, as far as possible, been validated.

(11) Commission Directive 2009/90/EC[(8)] provides for standard EN ISO/IEC 17025, or other equivalent standards accepted at international level, to be used to validate the methods of analysis. EN ISO/IEC 17025 is also one of the standards used under Regulation (EC) No 882/2004 for the accreditation of laboratories designated by the competent authorities in the Member States. It is therefore necessary to provide for that standard, or other equivalent standards accepted at international level, for the validation of the methods of analysis in the context of Directive 98/83/EC. In order to align Annex III to Directive 98/83/EC with Directive 2009/90/EC, the limit of quantification and uncertainty of measurement should be introduced as performance characteristics. However, Member States should be able to continue to allow the use of trueness, precision and limit of detection as performance characteristics under Annex III to Directive 98/83/EC for a limited period, thus providing laboratories with sufficient time to adapt to this technical advance.

(12) A number of ISO standards have been established for analysing microbiological parameters. Thus, EN ISO 9308-1 and EN ISO 9308-2 (for the enumeration of *E. coli* and coliform bacteria) and standard EN ISO 14189 (for the analysis of *Clostridium perfringens*) provide all necessary specifications for performing the analysis. Those new standards and technical developments should be reflected in Annex III to Directive 98/83/EC.

(13) For the purposes of assessing the equivalence of alternative methods with the method laid down in Annex III to Directive 98/83/EC, Member States should be permitted to use standard EN ISO 17994, which has already been established as the standard on the equivalence of microbiological methods in the context of Directive 2006/7/EC of the European Parliament and of the Council[(9)] and by Commission Decision 2009/64/EC[(10)]. Alternatively, they should be permitted to use standard EN ISO 16140 or any other similar internationally accepted protocols, as referred to in Article 5(5) of Commission Regulation (EC) No 2073/2005[(11)], to establish the equivalence of methods based on principles other than culturing, which are beyond the scope of EN ISO 17994.

(14) Annexes II and III to Directive 98/83/EC should therefore be amended accordingly.

(15) The measures provided for in this Directive are in accordance with the opinion of the Drinking Water Committee established under Article 12(1) of Directive 98/83/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 98/83/EC is amended as follows:

(1) Annex II is replaced by the text set out in Annex I to this Directive;

(2) Annex III is amended in accordance with Annex II to this Directive.

Article 2

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 27 October 2017 at the latest. 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 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 6 October 2015.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX I

‘ANNEX II

MONITORING

PART A

General objectives and monitoring programmes for water intended for human consumption

1. Monitoring programmes for water intended for human consumption must:

(a) verify that the measures in place to control risks to human health throughout the water supply chain from the catchment area through abstraction, treatment and storage to distribution are working effectively and that water at the point of compliance is wholesome and clean;

(b) provide information on the quality of the water supplied for human consumption to demonstrate that the obligations set out in Articles 4 and 5, and the parametric values laid down in Annex I, are being met;

(c) identify the most appropriate means of mitigating the risk to human health.

2. Pursuant to Article 7(2), competent authorities shall establish monitoring programmes complying with the parameters and frequencies set out in Part B of this Annex which consist of:

(a) collection and analysis of discrete water samples; or

(b) measurements recorded by a continuous monitoring process.

In addition, monitoring programmes may consist of:

(a) inspections of records of the functionality and maintenance status of equipment; and/or

(b) inspections of the catchment area, water abstraction, treatment, storage and distribution infrastructure.

3. Monitoring programmes may be based on a risk assessment as set out in Part C.

4. Member States shall ensure that monitoring programmes are reviewed on a continuous basis and updated or reconfirmed at least every 5 years.

PART B

Parameters and frequencies

1. General framework

A monitoring programme must take into account the parameters referred to in Article 5, including those that are important for assessing the impact of domestic distribution systems on the quality of water at the point of compliance, as set out in Article 6(1). When choosing

appropriate parameters for monitoring, local conditions for each water supply system must be taken into consideration.

Member States shall ensure that the parameters listed in point 2 are monitored at the relevant sampling frequencies as set out in point 3.

2. **List of parameters**

Group A parameters

The following parameters (Group A) shall be monitored in accordance with the monitoring frequencies set out in Table 1 of point 3:

(a) *Escherichia coli* (*E. coli*), coliform bacteria, colony count 22 °C, colour, turbidity, taste, odour, pH, conductivity;

(b) other parameters identified as relevant in the monitoring programme, in accordance with Article 5(3) and, where relevant, through a risk assessment as set out in Part C.

Under specific circumstances, the following parameters shall be added to the Group A Parameters:

(a) ammonium and nitrite, if chloramination is used;

(b) aluminium and iron, if used as water treatment chemicals.

Group B parameters

In order to determine compliance with all parametric values set out in this Directive, all other parameters not analysed under Group A and set in accordance with Article 5 shall be monitored at least at the frequencies set out in Table 1 of point 3.

3. **Sampling frequencies**

TABLE 1

Minimum frequency of sampling and analysis for compliance monitoring

Volume of water distributed or produced each day within a supply zone(See Notes 1 and 2)m^3		**Group A parameternumber of samples per year(See Note 3)**	**Group B parameternumber of samples per year**
	≤ 100	> 0 (See Note 4)	> 0 (See Note 4)
> 100	≤ 1 000	4	1
> 1 000	≤ 10 000	4 + 3 for each 1 000 m^3/ d and part thereof of the total volume	1 + 1 for each 4 500 m^3/ d and part thereof of the total volume
> 10 000	≤ 100 000		3 + 1 for each 10 000 m^3/ d and part thereof of the total volume
> 100 000			12

			+ 1 for each 25 000 m^3/d and part thereof of the total volume

Note 1: A supply zone is a geographically defined area within which water intended for human consumption comes from one or more sources and water quality may be considered as being approximately uniform.

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

Note 3: The frequency indicated is calculated as follows: e.g. 4 300 m^3/d = 16 samples (four for the first 1 000 m^3/d + 12 for additional 3 300 m^3/d).

Note 4: Member States that have decided to exempt individual supplies under Article 3(2)(b) of this Directive shall apply these frequencies only for supply zones that distribute between 10 and 100 m^3 per day.

PART C

Risk assessment

1. Member States may provide for the possibility to derogate from the parameters and sampling frequencies in Part B, provided that a risk assessment is performed in accordance with this Part.

2. The risk assessment referred to in point 1 shall be based on the general principles of risk assessment set out in relation to international standards such as standard EN 15975-2 concerning “security of drinking water supply, guidelines for risk and crisis management”.

3. The risk assessment shall take into account the results from the monitoring programmes established by the second subparagraph of Article 7(1), and Article 8 of Directive 2000/60/EC of the European Parliament and of the Council[(12)] for bodies of water identified under Article 7(1) that provide more than 100 m^3 a day on average, in accordance with Annex V to that Directive.

4. Based on the results of the risk assessment, the list of parameters in point 2 of Part B shall be extended and/or the sampling frequencies in point 3 of Part B increased, where any of the following conditions is fulfilled:

(a) the list of parameters or frequencies set out in this Annex is not sufficient to fulfil the obligations imposed under Article 7(1);

(b) additional monitoring is required for the purposes of Article 7(6);

(c) it is necessary to provide the necessary assurances set out in point (1)(a) of Part A.

5. Based on the results of the risk assessment, the list of parameters set out in point 2 of Part B and the sampling frequencies set out in point 3 of Part B may be reduced provided the following conditions are met:

(a) the frequency of sampling for *E. coli* must not be reduced below the one laid down in point 3 of Part B under any circumstances;

(b) for all other parameters:

(i) the location and frequency of sampling shall be determined in relation to the parameter's origin, as well as the variability and long-term trend of its concentration, taking into account Article 6;

(ii) to reduce the minimum sampling frequency of a parameter, as set out in point 3 of Part B, the results obtained from samples collected at regular intervals over a period of at least 3 years from sampling points representative of the whole supply zone must all be less than 60 % of the parametric value;

(iii) to remove a parameter from the list of parameters to be monitored, as set out in point 2 of Part B, the results obtained from samples collected at regular intervals over a period of at least 3 years from points representative of the whole supply zone must all be less than 30 % of the parametric value;

(iv) the removal of a particular parameter set out in point 2 of Part B from the list of parameters to be monitored shall be based on the result of the risk assessment, informed by the results of monitoring of sources of water intended for human consumption and confirming that human health is protected from the adverse effects of any contamination of water intended for human consumption, as laid down in Article 1;

(v) the sampling frequency may be reduced or a parameter removed from the list of parameters to be monitored as set out in points (ii) and (iii) only if the risk assessment confirms that no factor that can be reasonably anticipated is likely to cause deterioration of the quality of the water intended for human consumption.

6. Member States shall ensure that:

(a) risk assessments are approved by their relevant competent authority; and

(b) information is available showing that a risk assessment has been carried out, together with a summary of its results.

PART D

Sampling methods and sampling points

1. Sampling points shall be determined so as to ensure compliance with the points of compliance as defined in Article 6(1). 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 adverse change to the measured value of the parameters concerned. As far as possible, the number of samples shall be distributed equally in time and location.

2. Sampling at the point of compliance shall meet the following requirements:

(a) compliance samples for certain chemical parameters (in particular copper, lead and nickel) shall be taken at the consumer's tap without prior flushing. A random daytime sample of one litre volume is to be taken. As an alternative, Member States may use fixed stagnation time methods that better reflect their national situation, provided that,

at the supply zone level, this does not result in fewer cases of non-compliance than using the random daytime method;

(b) compliance samples for microbiological parameters at the point of compliance shall be taken and handled according to EN ISO 19458, sampling purpose B.

3. Sampling in the distribution network, with the exception of sampling at the consumers' tap, shall be in accordance with ISO 5667-5. For microbiological parameters, sampling in the distribution network shall be taken and handled according to EN ISO 19458, sampling purpose A.

ANNEX II

Annex III to Directive 98/83/EC is amended as follows:

(1) the introductory paragraph is replaced by the following:

> Member States shall ensure that the methods of analysis used for the purposes of monitoring and demonstrating compliance with this Directive are validated and documented in accordance with EN ISO/IEC 17025 or other equivalent standards accepted at international level. Member States shall ensure that laboratories or parties contracted by laboratories apply quality management system practices in accordance with EN ISO/IEC 17025 or other equivalent standards accepted at international level.
>
> In the absence of an analytical method meeting the minimum performance criteria set out in Part B, Member States shall ensure that monitoring is carried out using best available techniques not entailing excessive costs.;

(2) point 1 is amended as follows:

(a) the heading of point 1 is replaced by the following:
PART A**Microbiological parameters for which methods of analysis are specified**

(b) the third to the ninth paragraphs, including Note 1, are replaced by the following:

> The methods for microbiological parameters are:
>
> (a) *Escherichia coli* (*E. coli*) and coliform bacteria (EN ISO 9308-1 or EN ISO 9308-2)
>
> (b) *Enterococci* (EN ISO 7899-2)
>
> (c) *Pseudomonas aeruginosa* (EN ISO 16266)
>
> (d) enumeration of culturable microorganisms — colony count 22 °C (EN ISO 6222)
>
> (e) enumeration of culturable microorganisms — colony count 36 °C (EN ISO 6222)
>
> (f) *Clostridium perfringens* including spores (EN ISO 14189);

(3) point 2 is amended as follows:

(a) the heading of point 2 is replaced by the following:
PART B**Chemical and indicator parameters for which performance characteristics are specified**

(b) point 2.1 is replaced by the following:

1. **Chemical and indicator parameters**

For the parameters set out in Table 1, the specified performance characteristics are that the method of analysis used must, as a minimum, be capable of measuring concentrations equal to the parametric value with a limit of quantification, as defined in Article 2(2) of Commission Directive 2009/90/EC[13], of 30 % or less of the relevant parametric value and an uncertainty of measurement as specified in Table 1. The result shall be expressed using at least the same number of significant figures as for the parametric value considered in Parts B and C of Annex I.

Until 31 December 2019 Member States may allow for the use of "trueness", "precision" and "limit of detection" as specified in Table 2, as an alternative set of performance characteristics to "limit of quantification" and "uncertainty of measurement" as specified respectively in the first paragraph and Table 1.

The uncertainty of measurement laid down in Table 1 shall not be used as an additional tolerance to the parametric values set out in Annex I.

TABLE 1

Minimum performance characteristic "Uncertainty of measurement"

Parameters	**Uncertainty of measurement(See Note 1)% of the parametric value (except for pH)**	**Notes**
Aluminium	25	
Ammonium	40	
Antimony	40	
Arsenic	30	
Benzo(a)pyrene	50	See Note 5
Benzene	40	
Boron	25	
Bromate	40	
Cadmium	25	
Chloride	15	
Chromium	30	
Conductivity	20	
Acrylamide, epichlorohydrin and vinyl chloride to be controlled by product specification.		

Copper	25	
Cyanide	30	See Note 6
1,2-dichloroethane	40	
Fluoride	20	
Hydrogen ion concentration pH (expressed in pH units)	0,2	See Note 7
Iron	30	
Lead	25	
Manganese	30	
Mercury	30	
Nickel	25	
Nitrate	15	
Nitrite	20	
Oxidisability	50	See Note 8
Pesticides	30	See Note 9
Polycyclic aromatic hydrocarbons	50	See Note 10
Selenium	40	
Sodium	15	
Sulphate	15	
Tetrachloroethene	30	See Note 11
Trichloroethene	40	See Note 11
Trihalomethanes — total	40	See Note 10
Total organic carbon (TOC)	30	See Note 12
Turbidity	30	See Note 13
Acrylamide, epichlorohydrin and vinyl chloride to be controlled by product specification.		

TABLE 2

Minimum performance characteristics “Trueness”, “precision” and “limit of detection” — may be used until 31 December 2019

Parameters	**Trueness(See Note 2)% of the parametric value**	**Precision(See Note 3)% of the parametric value**	**Limit of detection(See Note 4)% of the parametric**	**Notes**
Acrylamide, epichlorohydrin and vinyl chloride to be controlled by product specification.				

	(except for pH)	**(except for pH)**	**value (except for pH)**	
Aluminium	10	10	10	
Ammonium	10	10	10	
Antimony	25	25	25	
Arsenic	10	10	10	
Benzo(a)pyrene	25	25	25	
Benzene	25	25	25	
Boron	10	10	10	
Bromate	25	25	25	
Cadmium	10	10	10	
Chloride	10	10	10	
Chromium	10	10	10	
Conductivity	10	10	10	
Copper	10	10	10	
Cyanide	10	10	10	See Note 6
1,2-dichloroethane	25	25	10	
Fluoride	10	10	10	
Hydrogen ion concentration pH (expressed in pH units)	0,2	0,2		See Note 7
Iron	10	10	10	
Lead	10	10	10	
Manganese	10	10	10	
Mercury	20	10	20	
Nickel	10	10	10	
Nitrate	10	10	10	
Nitrite	10	10	10	
Oxidisability	25	25	10	See Note 8
Pesticides	25	25	25	See Note 9

Acrylamide, epichlorohydrin and vinyl chloride to be controlled by product specification.

Polycyclic aromatic hydrocarbons	25	25	25	See Note 10
Selenium	10	10	10	
Sodium	10	10	10	
Sulphate	10	10	10	
Tetrachloroethene	25	25	10	See Note 11
Trichloroethene	25	25	10	See Note 11
Trihalomethanes — total	25	25	10	See Note 10
Turbidity	25	25	25	

Acrylamide, epichlorohydrin and vinyl chloride to be controlled by product specification.

(c) point 2.2 is replaced by the following:

2. **Notes to Tables 1 and 2**

Note 1	Uncertainty of measurement is a non-negative parameter characterising the dispersion of the quantity values being attributed to a measurand, based on the information used. The performance criterion for measurement uncertainty (k = 2) is the percentage of the parametric value stated in the table or better. Measurement uncertainty shall be estimated at the level of the parametric value, unless otherwise specified.
Note 2	Trueness is a measure of systematic error, i.e. the difference between the mean value of the large number of repeated measurements and the true value. Further specifications are those set out in ISO 5725.
Note 3	Precision is a measure of random error and is usually expressed as the standard deviation (within and between batches) of the spread of results from the mean. Acceptable precision is twice the relative standard deviation. This term is further specified in ISO 5725.
Note 4	Limit of detection is either: — three times the standard deviation within a

	— batch of a natural sample containing a low concentration of the parameter, or — five times the standard deviation of a blank sample (within a batch).
Note 5	If the value of uncertainty of measurement cannot be met, the best available technique should be selected (up to 60 %).
Note 6	The method determines total cyanide in all forms.
Note 7	Values for trueness, precision and uncertainty of measurement are expressed in pH units.
Note 8	Reference method: EN ISO 8467
Note 9	The performance characteristics for individual pesticides are given as an indication. Values for the uncertainty of measurement as low as 30 % can be achieved for several pesticides, higher values up to 80 % may be allowed for a number of pesticides.
Note 10	The performance characteristics apply to individual substances, specified at 25 % of the parametric value in Part B of Annex I.
Note 11	The performance characteristics apply to individual substances, specified at 50 % of the parametric value in Part B of Annex I.
Note 12	The uncertainty of measurement should be estimated at the level of 3 mg/l of the total organic carbon (TOC). CEN 1484 Guidelines for the determination of TOC and dissolved organic carbon (DOC) shall be used.
Note 13	The uncertainty of measurement should be estimated at the level of 1,0 NTU (nephelometric turbidity units) in accordance with EN ISO 7027.

(4) point 3 is deleted.

(**1**) OJ L 330, 5.12.1998, p. 32.

(**2**) http://www.who.int/water_sanitation_health/publications/2011/dwq_guidelines/en/index.html

(**3**) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

(**4**) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

(**5**) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

(**6**) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

(**7**) Council Directive 2013/51/Euratom of 22 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 (OJ L 296, 7.11.2013, p. 12).

(**8**) Commission Directive 2009/90/EC of 31 July 2009 laying down, pursuant to Directive 2000/60/EC, technical specifications for chemical analysis and monitoring of water status (OJ L 201, 1.8.2009, p. 36).

(**9**) Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality (OJ L 64, 4.3.2006, p. 37).

(**10**) Commission Decision 2009/64/EC of 21 January 2009 specifying, pursuant to Directive 2006/7/EC of the European Parliament and of the Council, ISO 17994:2004(E) as the standard on the equivalence of microbiological methods (OJ L 23, 27.1.2009, p. 32).

(**11**) Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

(**12**) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).'

(**13**) Commission Directive 2009/90/EC of 31 July 2009 laying down, pursuant to Directive 2000/60/EC of the European Parliament and of the Council, technical specifications for chemical analysis and monitoring of water status (OJ L 201, 1.8.2009, p. 36).'