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 (Text with EEA relevance)

COMMISSION DIRECTIVE 2009/90/EC

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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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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[(1)], and in particular Article 8(3) thereof,

Whereas:

(1) The quality and comparability of analytical results generated by laboratories appointed by competent authorities of the Member States to perform water chemical monitoring pursuant to Article 8 of Directive 2000/60/EC should be ensured. The EN ISO/IEC-17025 standard on general requirements for the competence of testing and calibration laboratories provides appropriate international standards for the validation of the methods of analysis used.

(2) In order to fulfil validation requirements, all methods of analysis applied by Member States for the purposes of chemical monitoring programmes of water status should meet certain minimum performance criteria, including rules on the uncertainty of measurements and on the limit of quantification of the methods. To ensure comparability of chemical monitoring results, the limit of quantification should be determined in accordance with a commonly agreed definition.

(3) Where there are no methods which comply with the minimum performance criteria, monitoring should be based on best available techniques not entailing excessive costs.

(4) The calculation of mean values should take account of measurement results that are below the limit of quantification of methods of analysis. Rules to be used in this respect should be provided.

(5) Technical operations to ensure the quality and comparability of analytical results should follow quality management system practices accepted at international level. For that purpose, the practices set out in EN ISO/IEC-17025 are appropriate. It is appropriate to ensure that laboratories performing chemical analysis demonstrate their competence through the participation in internationally or nationally recognised

proficiency testing programmes and through the use of available reference materials. In view of harmonising practices at the Community level, the organisation of proficiency testing programmes should be based on relevant international standards. To that end, ISO/IEC guide 43-1 on proficiency testing by interlaboratory comparisons — Part 1: Development and operation of proficiency testing schemes provides an appropriate guide. The results of those programmes should be evaluated on the basis of the internationally recognised scoring systems. In this regard, ISO-13528 on statistical methods for use in proficiency testing by interlaboratory comparisons provides appropriate standards.

(6) The Committee referred to in Article 21(1) of Directive 2000/60/EC was consulted on 15 May 2008 and delivered a positive opinion on the draft Commission Directive laying down, pursuant to Directive 2000/60/EC, technical specifications for chemical analysis and monitoring of water status. On 6 June 2008 the Commission submitted the said draft for scrutiny by the European Parliament and the Council. The European Parliament did not oppose the draft measures within the set deadline. The Council opposed the adoption by the Commission indicating that the proposed measures exceeded the implementing powers provided for in Directive 2000/60/EC. As a consequence, the Commission did not adopt the draft measures and submitted an amended draft of the concerned Directive to the Committee referred to in Article 21(1) of Directive 2000/60/EC. The Committee was consulted on the said draft by written procedure launched on 28 January 2009 and delivered a positive opinion.

(7) The measures provided for in this Directive are in accordance with the opinion of the Committee referred to in Article 21(1) of Directive 2000/60/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1 U.K.

Subject matter

This Directive lays down technical specifications for chemical analysis and monitoring of water status in accordance with Article 8(3) of Directive 2000/60/EC. It establishes minimum performance criteria for methods of analysis to be applied by Member States when monitoring water status, sediment and biota, as well as rules for demonstrating the quality of analytical results.

Article 2 U.K.

Definitions

For the purpose of this Directive, the following definitions shall apply:

1. ‘limit of detection’ means the output signal or concentration value above which it can be affirmed, with a stated level of confidence that a sample is different from a blank sample containing no determinand of interest;

2. ‘limit of quantification’ means a stated multiple of the limit of detection at a concentration of the determinand that can reasonably be determined with an acceptable

level of accuracy and precision. The limit of quantification can be calculated using an appropriate standard or sample, and may be obtained from the lowest calibration point on the calibration curve, excluding the blank;

3. ‘uncertainty of measurement’ means a non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

Article 3 U.K.

Methods of analysis

Member States shall ensure that all methods of analysis, including laboratory, field and on-line methods, used for the purposes of chemical monitoring programmes carried out under Directive 2000/60/EC are validated and documented in accordance with EN ISO/IEC-17025 standard or other equivalent standards accepted at international level.

Article 4 U.K.

Minimum performance criteria for methods of analysis

1 Member States shall ensure that the minimum performance criteria for all methods of analysis applied are based on an uncertainty of measurement of 50 % or below (k = 2) estimated at the level of relevant environmental quality standards and a limit of quantification equal or below a value of 30 % of the relevant environmental quality standards.

2 In the absence of relevant environmental quality standard for a given parameter, or in the absence of method of analysis meeting the minimum performance criteria set out in paragraph 1, Member States shall ensure that monitoring is carried out using best available techniques not entailing excessive costs.

Article 5 U.K.

Calculation of mean values

1 Where the amounts of physico-chemical or chemical measurands in a given sample are below the limit of quantification, the measurement results shall be set to half of the value of the limit of quantification concerned for the calculation of mean values.

2 Where a calculated mean value of the measurement results referred to paragraph 1 is below the limits of quantification, the value shall be referred to as ‘less than limit of quantification’.

3 Paragraph 1 shall not apply to measurands that are total sums of a given group of physico-chemical parameters or chemical measurands, including their relevant metabolites, degradation and reaction products. In those cases, results below the limit of quantification of the individual substances shall be set to zero.

Article 6 U.K.

Quality assurance and control

1 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.

2 Member States shall ensure that laboratories or parties contracted by laboratories demonstrate their competences in analysing relevant physico-chemical or chemical measurands by:

a participation in proficiency testing programmes covering the methods of analysis referred to in Article 3 of this Directive of measurands at levels of concentrations that are representative of chemical monitoring programmes carried out under Directive 2000/60/EC, and

b analysis of available reference materials that are representative of collected samples which contain appropriate levels of concentrations in relation to relevant environmental quality standards referred to in Article 4(1).

3 The proficiency testing programmes referred to in paragraph 2(a) shall be organised by accredited organisations or internationally or nationally recognised organisations which meet the requirements of ISO/IEC guide 43-1 or of other equivalent standards accepted at international level.

The results of participation in those programmes shall be evaluated on the basis of the scoring systems set out in ISO/IEC guide 43-1 or in the ISO-13528 standard or in other equivalent standards accepted at international level.

Article 7 U.K.

Transposition

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive at the latest two years after its entry into force. 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 8 U.K.

Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 9 *U.K.*

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 31 July 2009.

For the Commission

Stavros DIMAS

Member of the Commission

(**1**) OJ L 327, 22.12.2000, p. 1.