SECOND SUPPLEMENT TO THE GIBRALTAR GAZETTE

No. 3886 of 27 October, 2011

LEGAL NOTICE NO. 218 OF 2011.

PUBLIC HEALTH ACT

INTERPRETATION AND GENERAL CLAUSES ACT

PUBLIC HEALTH (WATER FRAMEWORK) (AMENDMENT NO.2) RULES 2011

In exercise of the powers conferred upon it by sections 337 of the Public Health Act as read with section 23(g)(i) of the Interpretation and General Clauses Act and for the purpose of transposing into the law of Gibraltar 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, the Government has made the following Rules-

Title and commencement.

1. These Rules may be cited as the Public Health (Water Framework) (Amendment No.2) Rules 2011 and come into operation on the day of publication.

Amendment of rules.

2.(1) After rule 22 of the Public Health (Water Framework) Rules 2004 insert the following heading and rule-

"Miscellaneous

23. Where these Rules require the monitoring of water status, sediment and biota or the analysis of such results, that monitoring or analysis shall be undertaken in conformity with the rules and criteria set out in Schedule 11.".

(2) After Schedule 10 to the Public Health (Water Framework) Rules 2004 insert the following Schedule-

"Schedule 11

Minimum performance criteria for methods of analysis and rules for demonstrating the quality of analytical results

Interpretation of Schedule.

- 1. In this Schedule-
- "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;
- "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;
- "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.

Methods of analysis.

 All methods of analysis, including laboratory, field and on-line methods, used for the purposes of chemical monitoring programmes carried out under these Rules must be validated and documented in accordance with EN ISO/IEC-17025 standard or other equivalent standards accepted at international level.

Minimum performance criteria for methods of analysis.

3.(1) The minimum performance criteria for all methods of analysis applied shall be 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 subparagraph (1), monitoring shall be carried out using best available techniques not entailing excessive costs.

Calculations of mean values.

- 4.(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 in subparagraph (1) is below the limits of quantification, the value shall be referred to as 'less than limit of quantification'.
- (3) Subparagraph (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.

Quality assurance and control.

- 5.(1) The Competent Authority shall ensure that laboratories contracted by it or parties contracted by such laboratories apply quality management system practices in accordance with EN ISO/IEC-17025 or other equivalent standards accepted at international level.
- (2) The Competent Authority shall ensure that laboratories contracted by it or parties contracted by such 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 paragraph 2 of measurands at levels of concentrations that are representative of chemical monitoring programmes carried out under these Rules, 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 paragraph 3(1).
- (3) The proficiency testing programmes referred to in subparagraph (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.".

Dated 27th October, 2011

P R CARUANA, Chief Minister, For the Government

EXPLANATORY MEMORANDUM

These Rules amend the Public Health (Water Framework) Rules 2004 so as to transpose Commission Directive 2009/90/EC which provides for the technical specification for chemical analysis and monitoring of water status.

1630