

QUA-PRA-010

QUALITY IN ANALYTICAL LABORATORIES
European Criteria

• **Context**

The European decision 2002/657/EC was adopted to harmonize the characterization and validation procedures of analytical method performances. This decision provides rules on how methods are to be used in the testing of official samples according to Article 15, paragraph 1, second sentence of Council Directive 96/23/EC, as well as common criteria for the interpretation of analytical results of official control laboratories for samples collected according to the same document. One particular emphasis of this decision is related to the definition of strict identification criteria for residues and contaminants in biological matrices.

• **General objective(s)**

The first objective is to illustrate and explain the theoretical concepts introduced in the 2002/657/EC decision (i.e. limit of decision limit $CC\alpha$, detection capability $CC\beta$, unambiguous identification, ion ratio) through a set of commented and analysed practical real case studies. The second objective is to provide and explain one example of a fit-for-purpose guideline (computer file template) for checking the identification criteria fulfilment. Focused on mass spectrometry as a measurement technique, this module aims at a proper implementation of this major analytical quality issue in the participating laboratories.

• **Main items**

2002/657/EC decision / MS identification criteria / analytical limits ($CC\alpha$ & $CC\beta$) / ion ratio

• **Pedagogical objectives**

- ✓ To apply correctly the rules of the 2002/657/EC decision in terms of maximal tolerated variability (for retention time, signal, and ion ratio) to a real set of experimental data.
- ✓ To use properly with autonomy the provided file template to interpret a real set of experimental data.

• **Pedagogical tools**

- ✓ PowerPoint slide show (+ paper printout and PDF file copy) and copy of the 2002/657/EC decision
- ✓ Individual computer for practical exercises on the proposed file template

• **Duration**

4 hours

• **Pre-requisite**

- ✓ Theoretical concepts and rules introduced in the 2002/657/EC decision regarding identification criteria (QUAL-THE-010)
- ✓ Basics of PC management (Windows Operating System) and Excel software (cell, formulae,...)