MoniQA Validation Studies – Principle Guideline

(Version 2012--02-02)

MoniQA – International Association for Monitoring and Quality Assurance in the Total Food Supply Chain, www.moniqa.org) involves experts from around the globe working for safer foods by harmonising worldwide food quality and safety monitoring and control strategies. The network includes control and reference laboratories, industrial and research laboratories, method providers and test kit manufacturers, food manufacturers and food related associations, universities, and policy makers. The network has committed its knowledge, international relations, and communication resources to providing reliable information, globally agreed standards and tools to ensure safe foods, to support regulatory bodies in drafting better future regulations, food manufacturers in achieving legal compliance and producing high quality foods, and finally avoiding remedial, legal or re-call costs, and improving the quality of life for consumers. MoniQA focuses on validation of and setting performance criteria/requirements for methods used to analyse foods and food products for safety and quality. The main emphasis is on rapid methods and emerging new testing technologies, and their applicability and reliability in routine testing.
MoniQA organises and manages international ring trials to validate methods for regulatory and surveillance purposes by supporting SDOs (Standardisation Organisations) around the globe, primarily CEN, ISO, and Codex Alimentarius.

Basic Requirements and Checklist

1. Principle:

In principle MoniQA validation studies/ring trials follow the requirements of the IUPAC/AOAC/ISO international harmonised protocol for collaborative trials. However, the MoniQA protocol also accounts for several issues that have been discussed at Codex Alimentarius level more recently (e.g. recovery, recovery correction, measurement uncertainty, etc.). The requirements for any MoniQA validation study are given below and may serve as guideline for organisers and evaluators of ring trials within the MoniQA standardisation programme. A practical guide for the preparation of an international ring trial and spreadsheets for the statistical analysis are in preparation.

2. Requirements:

- A minimum of 8 useful results from min. 8 laboratories, respectively (after elimination of outliers and non-compliant laboratories), MoniQA recommends at least 12 participating laboratories
- To be counted as an international ring trial, a minimum of 3 countries needs to be involved.
- No more than a maximum of 50% of the participating laboratories may show an organisational relationship (e.g. laboratories in various locations, but belonging to the same company or distribution network)

- A detailed description of the ring trial setup and a full report including a copy of all original data and statistical calculations must be provided to the relevant Working Group (WG) Leader and to MoniQA's statistician.
- The validation study report summarized by the WG Leader and the statistician are reviewed and finally approved by the MoniQA Supervisory Board.
- Before the start of a trial the validation study plan needs to be outlined and a draft budget developed. The technicalities need to be discussed with the respective WG Leader and MoniQA's statistician. The plan needs approval of the MoniQA Supervisory Board.
- Joint validation of methods in collaboration with related SODs (Standardisation Organisations) is recommended.
- A full report on the completed MoniQA validation study must be submitted for publication in QAS – Quality and Assurance of Crops & Foods, the official journal of ICC and MoniQA. Authorship of the report is shared between the organiser of the study, the involved MoniQA WG Leader and any other relevant contributors.
- If a method/appliance/test kit or reference material is jointly validated with other SODs a mutual recognition/equivalence needs to be stated in any standard/reference derived from the study.
- For final analysis of the results the statistical methods used must be clearly described. Statistical evaluation of the method must include the following parameters:

  a) Description of the method/appliance/test kit/reference material used
  b) Description of the "analyte"
  c) Description of the "sample"/reference material
  d) Homogeneity test results of the sample material (usually performed by the organising laboratory and/or confirmed by a1-2 additional laboratories, e.g. F-test, ANOVA on 10 replicate samples tested taken from the same lot)
  e) Detailed protocol
  f) Details of participating laboratories including name of operator, operator's function
  g) Copy of original results/data including lot number, serial number, etc.
  h) Repeatability
  i) Reproducibility
  j) Recovery/recovery correction, where applicable
  k) Limit of Detection (LOD) and Limit of Quantitation (LOQ), where applicable
  l) Measurement uncertainty
  m) Traceability to SI units, if applicable

3. Samples:

- Any material used as a sample needs to be well described (origin, ingredients, concentration, etc.)
- Homogeneity and stability needs to be tested, documented and monitored throughout the ring trial
- According to the IUPAC/AOAC/ISO international harmonised protocol for collaborative trials at least 5 different samples or 2 different matrix samples at 4 different concentration levels (including a zero/blank sample) shall be used
- The samples must be representative of the range of variation of the analyte in the matrix. The samples shall be selected to cover the relevant range of application of the method with concentrations distributed across the whole application range.

4. Costs:

a) Handling and organisational fee charged by MoniQA prior to the completing the outline
€ 2,000.—

b) Final statistical evaluation after all calculations are completed and all data is generated by the submitting party. Statistics will be reviewed by MoniQA's statistician and the respective WG Leader
€ 3,000.—

c) Optional: If raw data is received by MoniQA and all statistical evaluation is Performed by MoniQA
€ 6,000.—

d) Optional: If MoniQA is to organise and manage the ring trial
€ 10,000.—

e) Any additional costs such as shipping of materials, appliances, training of personnel, production of samples are covered by the method provider or added to the overall costs on a charge-out rate basis by the involved MoniQA members

f) The price of the label "MoniQA performance tested" is based on the volume of tests sold

5. Publication:

MoniQA requires the publication of the obtained results of the validation study in its peer-reviewed journal. The report shall be written and submitted for publication to the official ICC/MoniQA Journal "Quality Assurance and Safety of Crops & Foods".

6. Copy right and IPR:

Any submission of MoniQA validated methods to CEN, ISO, Codex Alimentarius, or any other SDO by any individual, national/regional government or other institution needs the approval of the MoniQA Supervisory Board and the authorship of MoniQA needs to be referred to in the publication/submission form.

The label "MoniQA performance tested" is owned by MoniQA and is awarded only after approval by the MoniQA Supervisory Board on successful completion of a MoniQA validation trial and/or MoniQA statistical analysis of the validation data. The label may be subject to an expiry date or a required re-evaluation depending on the method or appliance. MoniQA may reserve the right to withdraw a label "MoniQA performance tested", if performance has been found unsatisfactory due to negative user reports and/or failure to inform MoniQA secretariat about any changes in the method (e.g. reagents, incubation times, calibrants, etc.)

7. Liability:

MoniQA is only liable for the content and the performance data at the time of evaluation and publication. MoniQA is not responsible for deviations of performance quality due to manufacturing or non-compliant method application.

Any changes and/or additions to a MoniQA validated/performance tested method need to be communicated to the MoniQA Secretariat at the earliest. MoniQA reserves the right to request regular method revisions in certain intervals, if the advancements and method developments in a certain field of analysis demand a more rapid turnover.

The method provider is obliged to inform MoniQA Secretariat, if changes or additions have been made to a published validated/performance tested method. When changes have been made to a MoniQA performance tested method, MoniQA reserves the right to request a new ring trial for the altered/improved method/appliance for continued use of the label "MoniQA performance tested".

8. Application for method validation:

- Applications to have a method validated/standardised by MoniQA must be submitted to the MoniQA Secretariat.
- The application must include a short description of the principle of the method, its application, its current significance and potential future use. The ownership of the method must be clearly stated (generic or proprietary).
- Contact details of the method provider and the organiser of the ring trial must be provided to MoniQA Secretariat.
- Once the submitted method is considered for MoniQA validation, the payment for handling and publication must be received prior to validation/standardisation and is non-refundable irrespective of the results of the validation study.

9. Contact:

Roland Poms
MoniQA Secretariat
Marxergasse 2
A-1030 Vienna
Austria

Tel: +43 1 707 72 020
Fax: +43 1 707 72 04 0
Email: moniqa@moniqa.at
Web: http://www.moniqa.org