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PROGRESS REPORT

# MoniQA: an update of the European Union funded Network of Excellence in 2011

## Monitoring and quality assurance in the food supply chain: working for safer foods by harmonizing worldwide food quality and safety monitoring and control strategies

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**Abstract**

Monitoring and quality assurance in the total food supply chain (MoniQA, www.moniqa.org) is an EU-funded Network of Excellence (NoE), which involves experts from around the globe working for safer foods though harmonization of worldwide food quality and safety monitoring and control strategies. MoniQA is coordinated by the International Association for Cereal Science and Technology (ICC, www.icc.or.at), and the initial network of around 150 scientists from 20 countries has grown to more than 500 experts from some 40 countries across five continents. The consortium has committed its knowledge, international relationships, and communication resources to providing reliable information, globally agreed standards and tools to ensure safe foods, to support regulatory bodies in developing better regulations, and food manufacturers in the production of high-quality food and achieving legal compliance. MoniQA focuses on validation of methods used to analyse foods and food products for safety and quality. The main emphasis is on rapid methods and emerging new technologies, their applicability and reliability in routine testing. The work involves validation studies, design and development of reference materials, and validation guidelines, as well as socio-economic impact assessment for better future regulations. MoniQA's outputs will impact society at several levels, including research and development, industry and SMEs in food manufacturing, retail and food analysis, regulators, policy makers, associations, international organizations and consumers as well as international trade. Progress towards the goals of MoniQA and response to the original drivers for this project are considered, and MoniQA's sustainability plans are described in more detail by highlighting some selected outputs.

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## Introduction

With the rise of globalization, more and more products are being traded around the world. Ensuring foods are high quality and safe to eat demands reliable food analysis techniques. Different countries use different methods to detect harmful substances and microbial contamination, which are not always validated or do not meet the required

method performance criteria. The use of melamine to increase protein content of milk in China demonstrated that local challenges rapidly affect the wider market and therefore require global solutions.

Fragmentation of food safety and quality research and poor communication between research and standardization bodies means duplication of research, and in particular, validation of methods, is commonplace. Standardization and validation of analysis, particularly rapid or alternative methods including test kits are limited. There is growing demand for rapid methods throughout the food supply chain, but the lack of appropriate validation protocols including qualitative methods, which ideally generate positive/negative results rather than quantitative values, has affected confidence in these approaches, and the competence of operators as well as the reliability of results. New methods cannot be tested against standardized methods because the methods do not exist and/or because there are no suitable reference materials (e.g., food allergen detection methods and accepted reference materials). Furthermore, with the introduction of new European Union (EU) regulations (e.g., food allergens in 2005), there are no appropriate tools to quantify the financial impact of their introduction, in particular cost–benefit, compared with, for example, voluntary quality assurance schemes at micro- and macro-socio-economic levels.

The need for expertise and training in research, analytical laboratories, across the food chain and to support government as well as the introduction of food safety management systems and monitoring tools is clear; implementation, however, is more complex. Monitoring and quality assurance in the total food supply chain (MoniQA, FOOD-CT-2006-36337), is an EU-funded Network of Excellence (NoE), coordinated by the International Association for Cereal Science and Technology (ICC), which is set to receive €12.3 M between 2007 and 2012 from the Sixth Framework Programme (Topic T5.4.5.1: Quality and safety control strategies for food). The project has been described in full elsewhere (Poms *et al.*, 2009), but the drivers that stimulated its development are as relevant in 2011 as they were in 2007. This article aims to review these issues and the progress that MoniQA has made in addressing them over the last 4 years.

## MoniQA NoE

As a NoE, MoniQA aims to overcome the fragmentation of European expertise in food safety and quality analyses rather than undertaking research. Instead, MoniQA has focussed on validation and setting of performance criteria and requirements for methods suitable for analysing foods and/or food products safety and quality. Emphasis has been on establishing methods where there are none and, in particular, rapid methods and emerging technologies including test kits, and their suitability and reliability in routine testing. The work has involved validation studies, design and development of reference/testing materials and development of guidelines as well as assessing the socio-economic impact of new and amended regulations through international collaboration.

The food supply chain is a complex system of crossroads between suppliers and producers, retailers and the consumer. With each exchange documentation and quality control are required by each party as well as overseeing authorities. MoniQA aims to make the food chain safer by facilitating harmonization of criteria for methods used to analyse food for safety and quality rather than forcing adoption of European standards. Through a virtual laboratory comprised of experts along the food chain, participants are able to exchange knowledge and experience, and develop common strategies, which could form the basis of new standardized approaches that are acceptable to manufacturers, regulatory bodies and consumers, alike.

MoniQA aims to integrate European research and support harmonization of worldwide food quality and safety by creating a virtual laboratory, spreading excellence in research and relationships among stakeholders including regulators, the food industry and analysis laboratories. The network actively promotes sharing of data and knowledge as well as access to equipment, materials and expertise, and project outputs will impact society at a variety of levels including research and development, food manufacturing and retail, biotech and analysis laboratories, policy makers, associations and international organizations, and consumers, which collectively affect international trade and the (European) economy.

Reliable tools and robust methods assessing food safety and quality are essential to protect human health. New and emerging analytical methods offer high-throughput and easy-handling solutions for industry and control authorities, which complementing traditional testing techniques as well as allowing on-site testing. But, they are widely established and shelf-life means questions about cost-effectiveness are arising in parallel with existing analytical issues. In the long term, the consortium will continue to serve stakeholders after cessation of EU-funding by addressing these issues through the MoniQA Association, an independent, non-profit-distributing Association offering services and products for the food industry, analytical laboratories and

 

policy makers and regulators. Harmonized food quality and safety control – support by standards and independent research – will add-value in the food chain and promote consumer confidence.

MoniQA has responded to research drivers and the needs and gaps identified in 2007 by providing:

- Experts in food safety and quality analyses worldwide and increased international cooperation.
- Guidelines and protocols for implementation of international standards (CEN, ISO, etc.) for food manufacturers, quality control systems in the food industry and laboratories.
- Increased reliability and comparability of existing analytical methods including new and emerging rapid and test kit methods.
- Method validation studies and inter-laboratory ring-trials.
- New research projects and bi- and multi-lateral collaboration (agreements).
- Reference/testing materials for the food research and analytical communities.
- Reliable and validated information and expert advice to regulatory bodies, industry and new research initiatives including a fully searchable database on commodities and contaminants linked to relevant legislation and to analytical sampling methods.
- Scientific evidence supporting the activities of CEN, ISO, Codex Alimentarius and others initiatives in establishing harmonized validation criteria, minimum performance requirements, SOPs, etc.
- Technical support for stakeholders including the food industry, SMEs, laboratories, etc.
- Training and continuing professional development for research students and staff and analysts.

## Consortium and partnerships

The core consortium consists of 33 partner organizations (Table 1) including universities, institutes and SMEs representing the EU (15 countries), Northern Africa (1), Asia Minor and Near East (2), China and Southeast Asia (3) and New Zealand (1). An initial membership of around 150 scientists from 20 countries has grown to over 500 experts from 35 countries across five continents. MoniQA has established links with other EU-funded research projects in Frameworks 6 and 7, and globally to exchange information and enhance existing or develop new international collaborations. The network has also invited a range of stakeholders with a specific interest in MoniQA's activities or similar objectives to become associate partners. To date some 82 commercial and government organizations have signed a Memorandum-of-Understanding, which provides them with access to project outputs as well as reduced rates for events and training. Associate partners will have the option to join the MoniQA Association in 2011.

Collaboration with EU-funded projects and other international initiatives include:

- AFMNet (http://www.afmnet.ca): dissemination, joint network and meeting activities, researcher mobility.
- BASELINE (http://www.baselineeurope.eu): exchange of experts and speakers at meetings.
- BioCop (http://www.BioCop.org): dissemination, partner search and recruitment, proficiency testing schemes, method validation, reference materials.
- CEN (TC275, http://www.cen.eu): technical advice and support in developing standards, joint validation studies, contributing to various CEN Working Groups.
- Codex Alimentarius (http://www.codexalimentarius.net): technical advice and support in developing standards, technical/statistical training to CCMAS delegates in a joint venture with IAM, draft terms and definition.
- CommNet (http://www.fp6commnet.eu): joint press and media activities and conferences, dissemination.
- Conffidence (http://www.conffidence.eu): dissemination, method validation.
- DeployPromis (http://www.deploypromis.eu): evaluation of stakeholder approach and services providence.
- DG SANCO, DG Research, DG Enterprise (http://ec.europa.eu): better future regulations, socio-economic impact assessment toolbox, speakers and trainers.
- DREAM (http://dream.aaeuropae.org): advisory panel.
- ERA-ARD NET (http://www.era-ard.org): dissemination, training needs in Mediterranean and African countries.
- EuroPrevall (http://www.europrevall.org): joint stakeholder events, joint workshop, WG activities, joint publications, validation protocols and reference materials.
- EU Reference Laboratories (http://ec.europa.eu): information exchange, laboratory selection for ring-trials, joint validation studies, joint comparative (proficiency) testing.
- EuroFir and EuroFir AISBL (http://www.eurofir.net): dissemination, exchange of information, joint workshops and first-hand experience of NoE.
- Food for Life – European Technology Platform (http://etp.ciaa.eu): exchange of information and identification of industry needs.
- FoodFrenz (http://www.foodfrenz.com): research exchanges between EU and New Zealand.

**Table 1** List of MoniQA partners[1]

| No. | Short name | Organization full legal name | Country |
|---|---|---|---|
| 1 | ICC | International Association for Cereal Science and Technology | Austria |
| 2 | BOKU | Universität für Bodenkultur Wien | Austria |
| 3 | ASU | Ain Shams University | Egypt |
| 4 | CAMBRI | Campden BRI | United Kingdom |
| 5 | CER | Centre d'Economie Rurale (CER Groupe) | Belgium |
| 6 | Eurofins | Eurofins Analytik GmbH | Germany |
| 7 | Gaiker | Centro Tecnologico Gaiker | Spain |
| 8 | FERA | Food and Environmental Research Agency | United Kingdom |
| 9 | Q-Plan | International Quality and Environment Services S.A. | Greece |
| 10 | TUBITAK | Tübitak Marmara Research Center | Turkey |
| 11 | UFT | University of Food Technologies | Bulgaria |
| 12 | VTAG | Vocal Tag Ltd. | Israel |
| 13 | VTT | VTT Technical Research Centre of Finland | Finland |
| 14 | DSA | University of Naples Federico II | Italy |
| 15 | Nofima | Norwegian Institute of Food, Fisheries and Aquaculture | Norway |
| 16 | NTUA | National Technical University of Athens | Greece |
| 17 | RIVM | National Institute for Public Health and the Environment[2] | The Netherlands |
| 18 | SCU | Sichuan University | China |
| 19 | INRAN | Istituto Nazionale di Ricerca per gli Alimenti e la Nutrizione | Italy |
| 20 | BUTE | Budapest University of Technology and Economics | Hungary |
| 21 | ESR | Institute of Environmental Science and Research | New Zealand |
| 23 | NFNI | National Food and Nutrition Institute | Poland |
| 24 | HCTU | Hacettepe University | Turkey |
| 25 | CCOA | Chinese Cereals and oils association | China |
| 26 | IPB | Institut Pertanian Bogor | Indonesia |
| 27 | HUT | Hanoi University of Technology | Vietnam |
| 28 | IFR | Institute of Food Research | United Kingdom |
| 29 | CNR | National Research Council | Italy |
| 30 | RTDS | RTD Services | Austria |
| 31 | JRC | Joint Research Centre oft he European Commission | Belgium |
| 32 | Uni-Bonn | Rheinische Friedrich-Wilhelms Universität Bonn | Germany |
| 33 | ICCR | Interdisciplinary Centre for Comparative Research in the Social Sciences | Austria |
| 34 | UNIBO | University of Bologna | Italy |
| 35 | RIKILT | Institute of Food Safety | The Netherlands |

[1]Partner number 22 decided not to participate before the final project negotiations.
[2]Former partner RIVM moved to RIKILT, due to institutional re-structuring.

• Global Harmonization Initiative (GHI, http://www.globalharmonization.net): support for expert network and dissemination, Supervisory Panel members.

• HEALTHGRAIN and HG Forum (http://www.healthgrain.org): joint training courses on cereal safety and quality assessment, and acrylamid determination, e-Learning experience.

• Inter Agency Meeting (IAM) and Standardisation Organisations (SDOs, http://www.aocs.org): technical advice and support in developing food analytical and sampling standards, joint validation studies, various CEN/ISO Working Groups, advising Codex Alimentarius CCMAS, joint training courses.

• International Food Research Consortium (IFRC, http://www.afmnet.ca): joint meetings, training events, dissemination, joint workshops, research proposals and researcher mobility efforts.

• ISEKI (http://www.esb.ucp.pt): access to the university network, e-learning and educational programmes.

• International Organisation for Standardisation (ISO, http://www.iso.org): technical advice and support in developing food analytical and sampling standards, joint validation studies, various ISO Working Groups.

• MycoRed (http://www.mycored.eu): Advisory Panel, training events, dissemination, joint workshops.

• NuGO and NuGO Association (http://www.nugo.org): NoE experience, joint stakeholder events.

• PlantLibra (http://www.plantlibra.eu): project exploiting MoniQA research database.

• SAFEED-PAP (http://safeedpap.feedsafety.org): joint validation study and use of statistical data in Qualitative Methods WG for joint IUPAC/MoniQA protocol.
• TRACE (http://www.trace.eu.org): dissemination, Food Authenticity WG.

## Work packages (WPs) and working groups (WGs)

MoniQA is organized into four Work Programmes, namely Integration, Joint Research, Spreading of Excellence and Management. These Work Programmes are made up from 10 WPs; Integration WP1–3, Joint Research WP4–7, Spreading of Excellence WP8–9 and Management WP10. The Work Programmes address strategic objectives while WPs are responsible for specific deliverables.

In 2007, six analyte-specific WGs were established to work horizontally across the 10 WPs and seek input from stakeholders with the support of the MoniQA Advisory Panel. Three other WGs have been created subsequently: (1) Emerging Issues was established to provide information about 'food crises' following revelations about melamine (China) and dioxin (Ireland) as well as emerging issues, which are of concern to the consumer (e.g., nanoparticles in food products) but not including genetically modified organisms (Thomas *et al.*, 2010); (2) Horizontal Issues dealing with aspects common to all analyses (e.g., uncertainty); and (3) Validation of Qualitative Methods, which is a joint undertaking between IUPAC and MoniQA performing proof-of-principle studies generating sufficient data to serve as the basis for design of harmonized protocols for qualitative methods validation (e.g., dipstick assays).

The primary goal of these WGs is consensus for validation procedures and standards in food analysis and determine what methods are available including new/emerging rapid and/or test kits, whether methods fulfil existing performance criteria, if uncertainty been calculated, what sampling procedures have been defined if any, the availability of reference materials and calibrators, quality control procedures especially in relation to traceability, whether detection limits are covered by current legislation and if the cost of individual methods have been estimated. Each WGs has followed a flexible Work Plan involving stakeholders within and beyond the consortium to identify the state-of-the-art, future needs, existing difficulties and research gaps; some common issues (e.g., analytical uncertainty) have been delegated to the Horizontal Issues WG. In addition to these activities, MoniQA WGs have also contributed to:

• Coordination of inter-laboratory ring-trials for validation of food safety methods (WP4).
• Design, production and validation of reference materials for food allergens, mycotoxins and gluten (WP4).
• Development of socio-economic impact assessment tool box and case studies (WP7).
• Fact sheets and online information on specific topics (WP8).
• Harmonized protocols, identification of challenges and needs and prioritization of research gaps (WP4).
• Identification of infrastructure and its availability (WP1).
• Information and methods for the MoniQA methods database (WP6).
• Organization of technical sessions and round-tables discussion at MoniQA International Conferences (WP8).
• Prioritization of future activities and research agenda as defined by stakeholders (WP5).
• Publication of research papers, recommendations, reports and short communications (WP8).
• Technical sessions at conferences and workshops through expert speakers (WP8).
• Training workshops and e-learning (WP9).

During the first 2 years of MoniQA, network activities focussed on integration through sharing of information, expertise and infrastructure. Emphasis in year 3 (2009) was transforming activities into tangible outputs, which could be used to develop sustainable services and products, maintain and enhance existing relationships with stakeholders and provide training and continuing professional development. In year 4 (2010), these activities gained momentum, and where as outputs were previously generated, concepts and proofs-of-principle were demonstrated as valid.

Expected results generated are summarized in Poms *et al.* (2009). The most significant outputs are described below but, more specifically in Period 4 (2009–2010), MoniQA has achieved:

• Acceptance in Reuter's Scientific Impact Rating System after only 2 years following the launch of Quality Assurance and Safety of Crops and Foods, published by Wiley Blackwell.
• Comparative studies, validation and ring-trials:
  ○ Validation study: quantitative milk allergen ELISAs (2010).
  ○ Proficiency test: multi-mycotoxins LC-MS-MS method (2010).
  ○ Re-validation study: *Campylobacter* species PCR tests (2011).
  ○ Comparative study: microbiology dilution method (2011).
  ○ Comparative study: dioxins screening (CALUX) and confirmatory methods for dioxin analysis (2011).

○ Validation ring-trial: determination of freshness and ageing of brown rice (2011).
○ Validation of method(s) for verification of organic eggs (2011).
○ Developing guidelines for models based on expert judgement and mathematical models to assure safe use of nanotechnology in foods to support steps towards harmonized regulations (2012).
• Design and testing of Tool Box for socio-economic impact assessment (2011).
• Development of a MoniQA Laboratory Accreditation Support Tool (2010).
• Identification of research gaps and future needs in food safety and food safety management (2011).
• Improved integration and collaboration among partner organizations, globally.
• Links with EU-funded projects and initiatives through formal and informal mechanisms.
• More than 90 bursaries awarded for training/continuing professional development.
• Organization and participation in (joint) workshops, conferences and/or technical sessions.
• Preparation of reference materials:
○ Incurred reference material for milk and egg allergen analysis in bakery products and infant formulae at various concentrations (Dumont *et al*., 2010).
○ Gluten standard and incurred reference materials for low-gluten/gluten-free analysis (2011).
• Programme of 15 MoniQA Food Scientists' Training workshops, e-learning courses and webinars.
• Public access to the MoniQA Methods Database.
• Publication of articles including peer-viewed papers in a range of scientific and trade journals and online, and protocols and guidelines:
○ First harmonized guidelines/protocol: Harmonized validation guideline for quantitative food allergen ELISA methods for milk and egg (Abbott *et al*., 2010).
○ Food allergen ELISA validation guideline for gluten-free analysis (2011).
○ Guidelines for validation of LC-MS-MS for food allergen analysis (2010–2011).
○ Harmonized protocol for validation of LC-MS-MS methods for chemical food contaminants (2010–2011).
○ Supporting the ISO International Workshop Agreement on harmonizing bulk sampling procedures and resulting recommendations to ISO (2010).
○ Joint IUPAC/MoniQA protocol for validation of qualitative methods (2010).
○ Validation studies: basic requirements and checklist to be extended and supplemented with a practical guideline and template spread sheets (2011).
• Value-added content of MoniQA partner and infra-structure databases.

## MoniQA association

MoniQA NoE is funded by the European Commission for 5 years (2007–2012). Within this funding period, there is an expectation that the network will achieve sufficient momentum to ensure some form of sustainable presence, adding-value to the initial investment. The consortium has worked to establish products and services that will be offered to stakeholders and potential customers, and thus support sustainability. To this end, strategies and business models including monitoring and exploitation of intellectual property have been initiated to secure future financing. During Periods 4 and 5, the legal agreement necessary to create an independent non-profit-distributing Association, established in Austria, were sought from the consortium. Launched in 2011, the MoniQA Association will comprise of some original partner organizations – some are prevented by the legal statues from joining any organization offering commercial products or services – and new members from various stakeholder groups such as analytical laboratories, food manufacturers and retails, research organizations and government departments. The remit of the MoniQA Association will be collaborative research aimed at promoting a more secure and safer food supply, which will be achieved through:

• Disseminating and enabling access to validated and robust data and information for food safety through, for example, online databases.
• Improving the knowledge-based bio-economy through participation in relevant research programmes and facilitating bilateral/multinational research collaboration agreements.
• Promoting harmonization of analytical approaches involved in food safety and quality.
• Providing infrastructure for and establishing an international network for inter-laboratory validation trials for analytical methods and reference materials.
• Sharing expertise and understanding through:
○ Expert consultancy.
○ International exchanges of researchers, technologists, engineers, etc.
○ Publication especially but not exclusively through Quality Assurance of Crops and Food.

- Scientific conferences and symposia.
- Training courses.

MoniQA's Governing Council has approved the draft business plan, the Association Statutes and the Membership Structure and Benefits as well as the Code of Business Conduct and the MoniQA Prospectus, which were developed in P4 (2009–2010). The Association will be registered in Vienna (AT) and based at ICC Headquarters (Vienna, AT). The first General Assembly and Supervisory Board meeting will be held in Varna (Bulgaria) during the third MoniQA International Conference (27–29 September 2011).

## Significant outputs 2007–2010

### Harmonization of validation procedures for food analytical methods

Concerns about different regulations and practices in horizontal issues (e.g., sampling, measurement uncertainty) in Europe and other regions (e.g., Americas, Asia) have been identified, and problems associated with interpretation of analytical results or compliance considered. Information/data were collected from food laboratories, the regulatory environment and the food industry and used to identify specific challenges in the EU or between the EU and important trading partners, and develop suggests that would address knowledge gaps and research needs when comparing analytical results. This work was undertaken by MoniQA WGs focussing on food allergy, mycotoxins and microbiological contamination and, in addition to the initial publication (Oreopoulou *et al.*, 2009), a summary will be published at the end of 2011.

*Several validation protocols* have been developed by MoniQA in collaboration with other international consortia, EU-funded projects and International Standardisation Organisations (e.g., CEN, ISO, AOAC, IUPAC, ICC, and others) including:

(1) *ISO International workshop agreement on harmonizing bulk sampling procedures*: Several food contaminants occur in bulk commodities, which create a logistical problem with respect to sampling particularly in terms of complexity. In the case of loose commodities such as wheat, there are different sampling practices globally and existing guidelines are vague (e.g., ISO 13690: 1999: Sampling should observe a recognized system to produce samples, which are as fully representative as possible). Similarly, different sampling plans exist for a range of commodities within ISO. In some cases, commodities and transportation systems are comparable while sampling procedures differ significantly. Because of the structure of international standardization, different sampling plans are recommended by different groups for comparable commodities while some procedures do not take account of modern shipping and sampling technologies. In May 2008, AOCS hosted a meeting of experts from ISO committees, trade organizations, government departments and others stakeholders including MoniQA to discuss the creation of basic sampling guidelines that meet needs and address the diverse issues surrounding sampling of flowing grain and oilseeds. A general document was developed based on the then-current version of ISO/DIS 24333.2009, which has been discussed at various ISO levels since.

(2) *Joint IUPAC/MoniQA protocol for validation of qualitative methods*: Conducted by the MoniQA WG Validation of qualitative methods, this activity is a joint undertaking with IUPAC and aims to develop a harmonized protocol for validation of qualitative methods. Qualitative methods are understood to be those that do not provide a measurable answer (e.g., dipstick assays, PCR), typically rendering yes–no responses for the presence/absence of a substance at given limit. MoniQA aims to establish guidelines for validation of qualitative methods and the performance of validation studies. To achieve this, model studies have been performed using data from a variety of validation studies to investigate the minimum/optimum numbers of tests necessary. More specifically, (1) performance characteristics of qualitative methods and (2) specific challenges for validation of qualitative methods including (a) qualitative method where the evaluation of results is based purely on a qualitative yes–no basis and (b) qualitative methods based on a quantitative measurement.

(3) *Food Allergen ELISA validation guidelines for milk, egg and gluten*: One of the many problems in allergen analysis is validation of ELISA-based methods. Manufacturers use different validation methods making it almost impossible for laboratory-based user to assess the validity of their results. In collaboration with the AOAC Presidential Taskforce on Food Allergen Methods, kit manufacturers, and government and industry representatives, MoniQA has developed new guidelines for validation of food allergen ELISA-based test kits. This was peer-reviewed and published in April 2010 (Abbott *et al.*, 2010), and the guidelines implemented for the MoniQA validation study examining five ELISA-based kits for casein in 20 laboratories worldwide. The guidelines have already been adopted as the new standard for ELISA kit validation by numerous commercial ELISA companies. MoniQA will follow-up recently published guidelines for validation of quantitative ELISA tests for (cows') milk and (hens') eggs with specific guideline for determination of low-gluten/gluten-free

 

status working closely with the AOAC Presidential Taskforce on Food Allergens Methods, HealthCanada, the EC Joint Research Center IRMM and other Standardisation Organisations as well as test kit manufacturers. The draft guidelines are anticipated in 2012.

(4) *Guideline for validation requirements for LC-MS-MS for food allergen analysis*: MoniQA is developing best practice guidelines for analysis of food allergens by mass spectrometry (MS). Detection of allergens in foodstuffs and ingredients is an important part of allergen management by the food industry. Currently, either immunological methods (e.g., ELISA) or PCR are used but there is increasing interest in the potential for detection and quantitation using MS, particularly in complex mixtures and as an orthogonal method for validation of ELISA-based methods. A number of laboratories from the food industry, analysis laboratories, regulatory agencies and academia are currently developing MS methods for food allergens. However, while best practice and validation criteria are relatively well established for ELISA methods, no such guidelines exist for MS. A workshop held at IFR (UK) in September 2010 involving MoniQA and other key stakeholders established the current state-of the-art for allergen analysis by MS with the aim of developing best practice guidelines. A paper describing the outcomes of the workshop has been accepted for publication (Johnson *et al*., 2011).

(5) *Harmonized protocol for validation of LC-MS-MS methods for chemical food contaminants*: MoniQA is developing guidelines for the identification and quantification of chemical residues/contaminants using MS, which is used increasingly for identification as well as quantification. While the use of LC-MS-MS has increased, more recently LC-MS at high resolution is being used (e.g., TOF-MS at 20 000 resolutions, Exactive Orbitrap technology at 100 000 resolutions). Surprisingly, despite application of MS in trace analysis for more than 25 years, there are few internationally recognized protocols available offering guidelines for the use of these sophisticated tools in the identification and quantification of chemical residues and contaminants. Protocols have been published for the identification and quantification of dioxins/PCBs using high resolution GC-MS, and an EU Directive provides an unequivocal basis for identification of veterinary drug residues. Although these documents provide a useful starting point for chemical residues and contaminant, they should be updated urgently to reflect progress in new instrumentation. Generic guidelines establishing a common basis for identification and quantification using MS are needed although method validation is made difficult by the fundamental differences in LC-MS instruments from different manufacturers (e.g., quadruople versus ion-trap). It is far more problematic to carry out method validation using LC-MS than, for example, HPLC with UV- or fluorescence detection. Generic SOPs for LC-MS-MS need to be developed, based on minimum performance criteria rather than instrumentation, which can only be replicated on the same model. A better understanding of how different MS technologies behave when analysing samples is also needed if generic guidelines for LC-MS inter-laboratory method validation are to be achieved. To this end, a WG chaired by IFA-Tulln was formed during 2010, comprised of LC-MS-users who are working in the food safety/chemical residues/contaminants area. Participants were selected to ensure a range of different instruments from different manufacturers were available [e.g., LC-MS/MS (triple quadruple), LC/MS ion trap, LC-TOF/MS and Exactive LC Orbitrap technology]. Anticipated outcomes from MoniQA in these studies are (1) guidelines for the unequivocal identification of chemical residues/contaminants in food matrices using LC-MS, (2) a list of factors affecting inter-laboratory validation studies using LC-MS for chemical residues/contaminants in food and (3) a peer-reviewed publication of guidelines in QAS.

Based on developed and/or refined validation protocols, MoniQA has defined its own method validation requirements and using these principles in various validation studies, which have been completed or are on-going. MoniQA coordinates and manages an international ring-trials for the validation of analytical methods for regulatory and surveillance, supporting Standardisation Organisations around the globe including CEN, ISO and Codex Alimentarius. Participants and stakeholders include control and reference laboratories, industrial and research laboratories, method providers and test kit manufacturers, food manufacturers and food-related associations, universities and higher education institutions and policy makers. In principle, these MoniQA validation studies/ring-trials follow the requirements of the IUPAC/AOAC/ISO international protocol for collaborative trials (Horwitz, 1995). However, MoniQA also takes into account issues discussed recently at the Codex Alimentarius level, namely recovery, recovery correction, measurement uncertainty, etc. Requirements for the MoniQA validation studies serve as guidelines for organizers and evaluators of ring-trials within standardization programmes. A practical guide for international ring-trials and their statistical analysis are in preparation.

The following *inter-laboratory ring-trials* for validation of various food analytical methods and/or proficiency testing are underway or have been completed by MoniQA:

 

(1) *Multi-mycotoxin LC-MS-MS method proficiency test*: Recently, 19 control-, commercial- and research laboratories from 12 countries participated in a survey concerning the use of methods for determining mycotoxins in food and feed. The results of this survey revealed that 42% of participating laboratories routinely used LC-MS (MS) methods for single or simultaneous determination of several mycotoxins. However, LC-MS (MS) is not recognized by CEN and AOAC as a method for mycotoxin detection (Solfrizzo *et al*., 2009). MoniQA has organized a proficiency test for simultaneous determination of legislated mycotoxins in maize using LC-MS (MS) methods involving those laboratories with relevant experience.

Laboratories were not obliged to determine all legislated mycotoxins and they were free to report only those mycotoxins that can be determined simultaneously with their equipment and methods. Participants have also completed a comprehensive questionnaire describing their approach. Currently, more than 60 laboratories are reporting results for two materials: maize samples contaminated naturally with aflatoxins B1, B2, G1 and G2, ochratoxin A, deoxynivalenol, T-2 toxin, HT-2 toxin, zearalenone, fumonisins B1 and B2 and maize free from any contamination, which can be spiked with mycotoxins. MoniQA has provided (un)-contaminated maize test materials, common calibration controls and spiking solutions. These results will provide information not only about the proficiency of participant laboratories but also on methods currently used and their performances.

(2) *Quantitative food allergen ELISA ring-trial for milk in bakery products and infant formulae*: The MoniQA Allergen WG conducted a ring-trial with five commercially available ELISA kits (ELISASYSTEMS, Neogen, Morinaga, R-Biopharm, Tepnel) using each of the MoniQA reference materials (i.e., cookies and soya-based infant formula) at five different concentrations. Twenty laboratories around the world including Europe, Australia and North America participated in the ring-trial, and the data are being evaluated following completion of the experimental phase. In addition to this validation study, the reference standards are also being used in a proficiency-testing scheme coordinated by FAPAS. MoniQA will provide the reference materials, and partners are among the global network of participating laboratories. Negotiations with FAPAS® (UK) and the final arrangements for the study are currently underway. The study is planned for 2012.

(3) *Validation ring-trial: determination of freshness and ageing of brown rice*: A ring-trial for rapid pH testing of rice (dye color-chart method for pH determination of rice grains) has been organized with the China Grain Products R&D Institute Taipei, Taiwan (CGPRDI), an Associated Partner in MoniQA. This method is designed to determine pH for brown and milled rice grains, which is related to freshness, and involves 15 laboratories in Taiwan, Spain and Italy. The results have been elaborated by CGPRDI.

(4) *Validation of methodology for verification of organic eggs*: An in-house study at RIKILT (NL) using carotenoid HPLC-DAD profiling combined with k-nearest neighbour classification chemo-metrics reliably identifies production system (i.e., organic versus non-organic) for chicken eggs. The proposed international inter-laboratory trial aims to demonstrate if this approach is robust by applying the method in different laboratories and thereby determine its suitability for routine analysis. The method developed for verification of organic eggs is one of only a few for verification of organic produce with any degree of success. Many EU and non-EU countries could potentially benefit from this method and, furthermore, the concept could be applied to other foods. Currently, the model is based on Dutch eggs and validation requires testing with eggs from other countries. It is proposed to carry out a study to validate the method for eggs sourced from MoniQA partners' countries of origin.

(5) *Dioxins screening (CALUX) and confirmatory methods for dioxin analysis – a comparative study*: MoniQA is investigating the differences that arise between methods commonly used in the EU (e.g., screening and confirmatory) for dioxin and PCB monitoring to examine whether false positives in bioassay methods, such as CALUX, are caused by Ah-receptor ligands other than dioxins (e.g., related emerging contaminants). Two MoniQA partners, which rank among the foremost laboratories in this field, namely RIKILT (NL) and FERA (UK), have considerable experience in the use of bio-analytical methods (e.g., CALUX) and emerging contaminant research, respectively, are involved. The outcomes will promote a better understanding of the differences that sometimes arise between methods that use different scientific approaches and their subsequent interpretation.

(6) *Microbiological dilution method – a comparative study*: MoniQA is examining the affect of diluent choice on the performance of viable count methods. Microbiological analyses of foods differ markedly from the assessment other food contaminants (e.g., residues, chemicals), enumerating microorganisms in a sample either directly by counting colony-forming units or using indirect methods based on, for example, metabolic activity of the target organism(s). Because the analyte is a living/viable organism, it is easily affected by external influences such as pH, temperature, etc. This is

 

particularly important with respect to food, which contain a wide range of ingredients or additives, exerting a variety of effects on target organism(s). Microbiological results exhibit a high degree of variation although a (within) range outcome is widely accepted under practical conditions. Nevertheless, standard procedures have been developed for examination of microorganisms in food and published by several national and international standard organizations. These standards describe criteria for analysis (e.g., sampling, dilution media, growth media and incubation) with the aim of obtaining comparable and replicable results. Although the protocols from different organizations are generally the same, there are some significant differences. International standard procedures are the lowest commonly acceptable method and consequently not every aspect of the protocol is specified (e.g., choice of dilution media). Most standards list several (optional) diluents but do not define the preferred choice. It has been reported that the choice of diluent may influence significantly the performance of the method and therefore the results. To determine the affect of diluents (type and composition) on method performance, MoniQA is comparing viable counts obtained using different diluents. A performance assessment will be performed with a limited number of participating laboratories, which may potentially lead to the organization of an inter-laboratory ring-trial.

(7) *Re-validation of Campylobacter species PCR tests*: MoniQA aims to re-validate PCR-based test methods for determining *Campylobacter* species, which have experienced substantial taxonomic changes making identification, particular of newly described *Campylobacter* spp. and subsp., increasingly unreliable. Laboratories that establish a new assay for detecting a given taxon seldom re-validate specificity. This failure to re-validate can, in principle, mean strains of a closely related but non-target species give false positives in an established assay. *Campylobacter* spp. is a test case because taxonomy of these organisms changes constantly. There are many assays for *Campylobacter jejuni*, and good grounds to question their specificity and usefulness. This trial aims to provide a sound basis for improvements in procedures for harmonization and standardization of PCR-based tests. Purified DNA extracts from 25 strains, representing in particular newly described *Campylobacter* spp. such as *Campylobacter insulaenigrae*, *Campylobacter peloridis*, *Campylobacter volucris* and *Campylobacter lari* subsp. *concheus* as well as a few well-studied positive controls (e.g., genome-sequenced *C. jejuni* subsp. *jejuni*) have been included. The study will also check for repeatability and reproducibility, and intermediate repeatability with each laboratory repeating the analysis on two separate occasions (e.g., Monday and Thursday of the same week). Each laboratory will use its own in-house PCR-based assay for thermo-tolerant *Campylobacter* DNA samples and in-house positive and negative controls. Results of this study are anticipated by the end of 2011.

(8) *Collaborative trial for method validation and estimation of measurement uncertainty in multi-component analysis of regulated food additives*: Some additives (e.g., intense sweeteners and preservatives) are used in simple and complex food matrices at low concentrations. Food manufacturers can choose whether to use one or more existing compounds to obtain the desired product qualities. Multi-component analysis of high accuracy for the determination of analytes at low concentration is, therefore, essential. However, validation studies including estimation of measurement uncertainty are rare. MoniQA is conducting a collaborative study for method validation and estimation of measurement uncertainty in the simultaneous analysis of sweeteners and preservatives in foodstuffs using an EN method based on HPLC. EN 12856 will be used as a one-run method for sweeteners specifically acesulfame-K, aspartame and saccharin, and preservatives, namely sorbic and benzoic acid, in fruit juices and yoghurt. The method has been validated for the analysis of acesulfame-K and aspartame in several foods, but no inter-laboratory tests have been carried out for the simultaneous analysis of these sweeteners or preservatives. Because all of them are added to food in small quantities, amounting to several p.p.m., the study will consider among other things, the effect of uncertainty arising from recovery to the overall measurement uncertainty. A simple (fruit juice) and a complex (yoghurt) food matrix will be used for better interpretation of factors affecting measurement of uncertainty in both foods.

The current *need for reference materials* in some areas of food analysis is one reason for the limited availability of validation data and the lack of tools to assure comparable results between different methods for the same analyte. This is especially true for the analysis of food allergens, indeed a major shortfall in the management of food allergens is the lack of reference materials for ELISA kit calibration and performance evaluation. The MoniQA Food Allergen WG has addressed this by generating two commutable incurred reference materials for milk and egg allergen analysis: one cookie-based and the other soya-based infant formula. Reference materials have been produced for quantification of allergenic proteins from milk and egg, as well as more recently gluten (gliadin). In each case, the applied processed food matrix is a baked product (cookie), based on a recipe of Scaravelli and colleagues, and protein content measured

 

using ELISA. Most notably, the proteins can be found in a processed food matrix, homogeneity of (protein) distribution in the matrix is assured, and the measurable content of allergenic proteins was reduced by processing in each case. The mechanism behind this phenomenon is under investigation as well as a comparative study of different analytical methods using model products, scaling-up production of the reference material candidates and developing reference materials for multi-component analysis.

While test materials for milk and egg analyses have been produced, tested and validated (Dumont *et al*., 2010), only the milk reference material was produced in sufficient quantity to undergo validation in an international inter-laboratory ring-trial; the results will be published in due course. Both the cookies and soya-based infant formulae containing milk were produced by spiking the raw unprocessed materials with milk powder sourced from NIST. The materials were spiked and quality-controlled at MoniQA partner organization, the Joint Research Centre's Institute for Reference Materials and Measurements (JRC IRMM) and Centre d'Economie Rurale (CER). Different milk concentrations were added to the final products mimicking typical contamination levels in commercial samples. After extensive homogeneity testing at CER (BE), Eurofins (DE) and IFR (UK), these products were released for use in a ring-trial examining five ELISA kits for casein in 20 laboratories worldwide.

MoniQA will also contribute to the production of a global gluten standard in collaboration with ICC, Health Canada, Agri-Food Canada, FARRP USA, National Measurement Institute Australia and ESR-New Zealand. The plan is to source a range of wheat varieties in Europe, Canada, USA, Australia and New Zealand, respectively, and produce 2010-blends for each region, which should allow any differences in protein content and composition arising from variety or region to be detected. Wheat flours will be characterized with respect to protein and gluten content as well as the ratio between glutelins and gliadins, and used to establish whether there are any differences between regions in respect of gluten/gliadin detection and quantification, however, unexpected. Provided the differences are negligible, a single global blend will be created; otherwise the regional blends will be used. Wheat-, rye- and barley-free oats will be sourced in Canada and reference materials produced by blending these with low concentrations of wheat/rye/barley, and gluten-containing flours with gluten-free products, to create reference materials that take into account typical (gluten) food matrices and the Codex limits (20 p.p.m. for 'gluten-free', 100 p.p.m. for 'low gluten', no gluten in infant-formulae).

## Socio-economic impact assessment toolbox

Socio-economic impact of food safety and quality regulations is one of the most important issues covered by MoniQA (Mazzocchi *et al*., 2009), which aims to support systematic assessment of the socio-economic impact of European food quality and safety regulations in terms of efficiency, effectiveness and consistency and administrative costs as well as international trade among stakeholders (e.g., consumers, industry, regulatory and control bodies) at different levels (i.e., micro versus macro).

### Working for better future regulations

MoniQA has dealt with the systematic assessment of new regulations in food quality and safety by setting evaluation criteria (e.g., effectiveness, efficiency and consistency) and compared the impact of different options in qualitative, quantitative and financial terms including the administrative costs imposed by new regulations. The overall aim was to develop an evaluation toolbox to better predict the socio-economic impact at the various levels (i.e., EU and national administration, manufacturing and trading sectors, individual industries, companies and SMEs, and consumers) when regulations are changed or newly introduced. The evaluation tool has been tested with data from the MoniQA WGs, case studies within and beyond the project and peer-reviewed publications as well as data collected by the Universities of Bologna (IT) and Bonn (DE), and the Interdisciplinary Centre for Comparative Research in the Social Sciences (AT), supported by input from the European Commission's DG SANCO and DG Research. In 2009, the decision support system concept and resulting evaluation toolbox were presented to representatives from EC Directorates General and EFSA in a joint MoniQA-European Commission workshop, Better Regulations: Dealing with socio-economic impact assessment to support the establishment of better future regulations. The outcome confirmed the need for such a tool by legislators and potential users in industry and regulatory agencies globally.

While the impact on society may be economic, environmental, social and/or political, the cost may range from a few thousand Euros – to meet the direct cost of compliance or monitoring analysis – to many millions of Euros for court prosecutions, bankruptcy, product disposal, food legislation, monitoring and surveillance, damage to brand or reputation of the product or country, decline in tourist income or loss of life. In recent years monitoring and surveillance schemes have been implemented in many countries including the EU. These have potentially

 

prevented/reduced economic, environmental, social and political impact of such incidences. Establishment of EFSA, RASFF and global harmonization efforts in food safety monitoring and assurance have improved substantially consumer protection but these efforts are costly. Learning from past events and appreciating their magnitude will help refine and improve food safety assurance measures into the future. Thus, MoniQA aims to illustrate progression from disaster (chemical contamination) to prevention.

MoniQA's Socio-Economic Impact Assessment Toolbox was developed by the Universities of Bologna (IT) and Bonn (DE) and ICCR (AT) with input from ICC (AT), Camden-BRI (UK), FERA (UK), Eurofins (DE) and experts in the MoniQA WGs. It is currently being challenged with data from case studies and data from past incidents, in order to refine the tools and extend its scope. In an Expert Summit organized in New Zealand (17–19 May 2011), the toolbox was applied to assess impacts of chemical contaminants in foods and feedstuffs, generate a robust and comprehensive assessment of such incidents, which will be useful for the food industry and food regulators as well as food scientists and consumer representatives, and enable better appreciation of the impact of chemical contamination of food and the importance of food safety monitoring. The basis for discussion, and further development of the MoniQA Socio-Economic Impact Assessment Toolbox, is a list of major chemical contaminants incidents in food and feedstuffs and their economic, environmental, social and political impact. This list will be published in QAS and as a Wikipedia site, which can be kept up-to-date as incidents occur.

## MoniQA food scientists' training and continuing professional development

MoniQA Food Scientists' Training (FSTs) workshops are part of a module-based training programme developed by MoniQA and administered by BOKU. FSTs are tailor-made to the needs of the consortium, and lecturers are provided by MoniQA partners with competences in a range of food- and soft-skills (e.g., project management) and experts from the wider food safety community, both practice and research. The workshops are targeted at MoniQA members and stakeholders from the food industry, SMEs, food research and development centres, food control agencies and laboratories, and authorities and policy makers, consumer representatives and retailers, respectively. Examples of past MoniQA FSTs include:

- Use of food analysis in managing food chemical contaminant risk within the food industry.
- Science communications for PhD students and post-doctoral researchers.
- Food safety and risk assessment.
- Food safety issues in the cereal-based food chain.
- Criteria approach for method validation.
- Reference materials and method validation of rapid methods in food safety.
- Risk communication.

MoniQA hosts multidisciplinary, highly relevant training globally, facilitating knowledge- and technology-transfer as well as dealing with emerging issues, all of which require flexible programming. MoniQA FSTs are generally short, self-contained, highly interactive workshops (1–5 days duration). Some are supplemented with e-learning material but all the workshops follow the MoniQA QA scheme. In addition, MoniQA offers workshops and training courses specifically for experienced laboratory personnel, managers, decision makers, food technologists and food safety and quality mangers. These courses are taught by renowned experts and offer a very practical approach to hot topics in the form of continuing professional development. The lectures are selected carefully to meet the clients' needs in respect to their field of operation and geographical location, and participants benefit from the broad experience and wide expertise of a global organization.

In addition to face-to-face workshops, e-learning and remote learning are being developed for people unable attend MoniQA FSTs and CDP workshops due to a lack of time or resources as well as supporting learning following MoniQA FSTs. The advantages (e.g., learning time, reduced costs) compared with traditional face-to-face workshops are of particular interest to the international food-related community including research. Furthermore, SMEs can use remote and e-learning, overcoming language barriers, to offer internationally recognized, high-quality training for its employees. e-Learning is a flexible tool for training virtually anywhere on the globe.

An implementation guide for managing MoniQA FSTs according to ISO 9001 was developed to assure consistent quality in MoniQA's training, which is available through MoniQA Association.

To, MoniQA also offers financial support for PhD and Masters Students, post-doctoral researchers and senior staff, from partner organizations, participating in MoniQA training events. Full bursaries cover travel and accommodation costs as well as subsistence; travel bursaries are offered for MoniQA-related events. Exchange grants are available for all MoniQA members to support visits (from one partner to

another) and exchanges (from one to another and vice versa). Typically, these grants are for 1 week to 3 months, and are designed to encourage integration at the research level (e.g., learning new techniques subsequently established at the visiting partner's organization, development of new research proposals, teaching and/or technology and knowledge transfer). New funding streams will be sought for these activities when EC-funding ceases. These might be industry sponsorships, EC Instruments (e.g., projects and programmes such as Marie Curie) or trans-continental and bilateral exchange programmes facilitated through the MoniQA Association.

## Outlook

MoniQA is in its final year of EU-funding. During the first 4 years several outputs and services have been developed that will improve food safety along the total food supply chain. In the final year, MoniQA will focus on shaping these outputs and others as products and services for the wider community through MoniQA Association. Participating partners and new members of MoniQA Association, which will be established in Vienna (AT), will continue to build on established outputs and services, and refine products and services as well as access to expertise, infra-structure and new research projects. MoniQA has established a scientific network and provided the necessary infrastructure to boost international research cooperation in the areas of food quality and safety assessment way beyond EU borders. The MoniQA Association will offer members preferentially access to new project proposals as partners, third parties or subcontractors, support in searching for partners with specific skills/locations and project conception and proposal writing. A comprehensive list and a more detailed description of all MoniQA NoE outputs will be published shortly. The achievements of MoniQA can also be followed online (http://www.moniqa.org/keyresults), and will be showcased at the third MoniQA International Conference, in Varna, Bulgaria, 27–29 September 2011. This meeting will also host the first General Assembly and Supervisory Board meetings of the newly established MoniQA Association.

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