

Toward Harmonization of International Standards for Food Safety and Quality Assessment

ROLAND E. POMS



As an international standardization organization in the cereal and food areas and in the interest of globalization of trade and technology transfer, ICC (International Association for Cereal Science and Technology) has prioritized its current tasks toward the harmonization of international standard methods for food safety and quality assessment. This is intended to achieve a close collabora-

tion with related national and international institutions such as ISO, CEN, FAO, WHO, AOAC International, AACC International, AOCS, DIN, AFNOR, CCOA, and others, as well as through the participation or coordination of international research projects and networks.

According to ICC's mission statement, the ICC will be the pre-eminent international association in the field of cereal science and technology committed to international cooperation through the dissemination of information and development of standard methodologies for the well-being of all people.

ICC was founded in 1955 as an independent, nonpolitical, nonprofit institution. The ICC has become an internationally recognized organization with consultative status to the United Nations' Food and Agriculture Organization (FAO), World Health Organization (WHO), and Industrial Development Organization (UNIDO) and plays an important role in various working groups of the International Organization for Standards (ISO) and European Committee for Standardization (CEN). With the help of a large and competent global network of cereal scientists and technologists, food safety specialists, and internationally operating companies, universities, and research centers, ICC is an important contributor and publisher of International Standard Methods for cereals, and more generally, food quality and safety, many of which have since been adopted by ISO, CEN, and other international organizations. Standardization and methods validation is coordinated by ICC headquarters. The actual research and communication activities of the ICC are for the most part carried on by more than 40 working and study groups and several task forces (e.g., mycotoxin analysis, sampling, food allergens).

Method Validation and Standardization

The core tasks of ICC are the validation and standardization of analytical methods for cereal/food quality and safety. Thus far, more than 70 methods have been standardized and published.

The importance to laboratories and users of laboratory accreditation for ISO 17025 or equivalent standards has further

pressured laboratories and companies to prove that their methods work, that they are applicable to their stated purpose, and that they fulfill the minimum criteria for such methodologies in terms of limits of detection (LOD), limit of quantitation (LOQ), repeatability and reproducibility (RSD), recovery, precision, and specificity/selectivity, all within the limits of measurement uncertainties.

This leads to an ever increasing demand for rigorous procedures for method validation and also for rapid methodologies in all areas of food analysis (e.g., microbiology, mycotoxins, food allergens, etc.) because of regulatory pressures, (ever lowering existing limits and establishing new limits, e.g., for mycotoxins), industry demands (faster results are needed), and to feed the market for analytical test kits (more test kits made available from many different local and international providers).

There are broadly two distinct but equally important validation types:

- Internal laboratory validation or in-house validation that all laboratories must do when adopting any new test method (rapid or not). This type of validation is done essentially to show that a method works within that laboratory and can be used to give "correct" results.
- External third-party validation or (international) interlaboratory validation (ring trials). This tends to be a more rigorous evaluation of a new method. The validation is organized by a third party and gives potential users confidence that the method in question operates correctly and generates results equivalent to a given reference methodology.

It is important to note that a method that successfully achieves third-party validation must still be validated in-house to demonstrate to accreditation organizations that the user laboratory can use the method correctly. Therefore, an additional distinction must be made between ring trials undertaken for proficiency testing and those undertaken for method validation. The latter will have more stringent requirements for following specified protocols and will generate information about the test methodology performance rather than that of the laboratory.

Rapid Methods and Test Kits

Various methodologies and formats for rapid food safety assessments are available. The choice of methodology depends largely on specific needs and costs. Preference should be given to methods or kits validated by interlaboratory evaluations. The urgent need for methodology standardization for rapid methods and test kits is recognized by the international analytical community and has recently led to the establishment of a new working group in the technical committee on Food Horizontal Methods (TC 275) of the CEN, which works in close collaboration with ISO.

American and European institutions have taken the initiative to validate the analytical performance of several test kits for various food contaminants. Reference methods are in place for most analyses, and the various test kits can be compared and validated against official and generally accepted standards. An example is the comparison of a traditional HPLC method for the mycotoxin deoxynivalenol (DON) with an enzyme-linked immunosorbent assay (ELISA) test and a lateral flow device/dipstick assay, which shows good correlation between the results. Problems arise when no generally accepted reference methodologies are available and the rapid-test format is the only available methodology. This is the case for many food-allergen test systems, for example.

Validation studies are often costly to conduct and rapid-test kit suppliers are often small enterprises that cannot afford such validation studies. There are a number of validation systems offering external third-party validation throughout the world, but few that are universally accepted. There is no single validation system for analytical methodologies in place that is universally accepted throughout the world. The closest to this ideal are the systems operated by AOAC International or EN ISO validation standards. The goal of international recognition is hampered not by any major arguments on the operation of validation requirements, even though several protocols exist, but much more so by the question of which reference method to use as a comparative benchmark. Perhaps this question will finally be answered when we have universal, internationally recognized reference methods and materials.

AACC International and ICC Harmonization Initiative

In addition to the lack of bilateral or international recognition of validation or standardization protocols for various validated analytical methodologies, users of these methodologies in question are often confused by similar, but not totally identical, methodologies for the same analyses. In the cereal field, AACC International and ICC standard methodologies are the most important and most widely accepted analytical methods for assessing the quality and safety of cereal-based products and ingredients. Since 2004, AACC International and ICC have initiated efforts to harmonize their methodologies. Only recently, a Harmonization Working Group consisting of experts from both organizations have finalized the harmonized methods for:

- Moisture determination (replacing AACC International Approved Method 44-15 A, Moisture-air-oven methods and ICC Standard No. 110/1, Determination of moisture content of cereals and cereal products-practical method).
- Crude protein (nitrogen) determination by the Kjeldahl Method (replacing AACC International Approved Method 46-12, Crude protein-Kjeldahl method, boric acid modification and ICC Standard No. 105/2, Determination of crude protein in cereals and cereal products for food and feed).
- Wet gluten determination (AACC International Approved Method 38-12A, Wet gluten, dry gluten, water-binding capacity and gluten index and ICC Standard No. 137/1, Mechanical determination of the wet gluten content of wheat flour [glutomatic]).

The third method is currently under review. The next analytical methodologies planned for harmonization are AACC International Approved Method 08-01: Ash-basic method and ICC Standard No. 104/1: Determination of ash in cereal products. The first two methods have already been approved by AACC International and ICC and the final text is currently being edited for publication and replacement of the existing method proto-

cols. AACC International and ICC will offer the new harmonized methods for sale in 2007. A detailed description of the modifications made to the original standards will be published in a future issue of CEREAL FOODS WORLD. The harmonization efforts between AACC International and ICC are an important contribution to making global communication and trading easier and improve the service to the community.

ICC Task Force on Mycotoxins and Sampling

During 2005, ICC established the ICC Task Force on mycotoxins and sampling. This is a global network of scientists, method providers, and analysts and it currently consists of approximately 85 professionals from 26 countries from all continents.

There is a worldwide need for standardization and validated methods for the detection of mycotoxins in cereals. There is also a need for protocols for screening methods, sampling, and sample preparations. Currently, individual countries have developed such methods on an ad hoc basis. A coordinated approach to the issues would be beneficial to all countries, so that harmonized methods might be developed that would enable global standards to be established and approved by each country's regulatory approval entities.

A number of steps are envisioned to achieve these goals:

- Investigation of the status quo—to determine what methods currently exist or are under development and collect all the methodologies currently used by manufacturers.
- Identification of gaps—where methodologies are still needed and identify requirements that are unique to particular countries.
- Collection of validation criteria.
- Publication of collected information in trade journals and the scientific press and to bring information on the initiative to the attention of all interested parties.

Once the information has been gathered, relevant, efficient, cost-effective, and widely acknowledged methodologies can then be developed.

Sampling protocols would be investigated parallel to the development of analytical methodologies. This should be representative of and relevant to the materials being tested as well as being practical for industry to use. It was envisaged that the test providers would play an important role in this process.

The goals would be similar to those proposed for evaluating methodologies (above), along with the identification of gaps and the publication of information.

It was suggested that deliverables for the task force would be:

- “New standards” or rather, “global agreement” with respect to existing standards.
- Guidelines.
- Networking of interested parties.
- Validation studies.

ICC Is Coordinator of the EU-Funded MoniQA NoE

MoniQA (**M**onitoring and **Q**uality Assurance in the food supply chain) is an EU-funded project coordinated by Roland Ernest Poms, Secretary General of ICC.

MoniQA is a network of excellence (NoE) in the thematic area of quality and safety control strategies for food that will aim at the harmonization of analytical methods for monitoring food quality and safety in the food supply chain.

The MoniQA (“toward harmonization of analytical methods for monitoring food quality and safety in the food supply chain”)

NoE seeks to establish durable integration of leading research institutions, industrial partners, and SMEs working in complementary fields of analytical methodologies for food quality and safety. MoniQA aims at overcoming European and worldwide fragmentation in food quality and safety (Q&S) research by integrating key organizations into a core consortium. Associate partners (i.e., associate) will also benefit through dissemination of information and joint research. The core consortium partners or members will seek to establish mechanisms for coordinating and finally merging research activities, personnel, and infrastructure. The industry and SME sector will benefit through application of the harmonized detection methodologies and technologies, as will consumers of high-quality and safe foods.

The core consortium comprises a network of 34 members. The geographic diversity covers 11 EU member states (21 partners), 2 associated candidate countries (3 partners), 2 associated countries (2 partners), 1 MPC country (1 partner), and 4 Asian/Oceanic countries (5 partners). From the 34 members, 14 are research institutions (RES), 13 are centers of higher education (HE), 2 are industry partners, and 5 are other organizations (NGO, small companies). A total of 155 researchers, including more than 40 doctoral students are integrated into the network and the whole project will be funded by the European Union with 12,300,000 euro for 5 years.

The key deliverables of the project are expected to be:

- An operational system to facilitate sharing of research infrastructure, equipment, and databases.
- A fully functional mobility program, allowing for the easy and regular exchange of personnel between network member organizations.
- A sustainability program to ensure economic durability and long-term cooperation of the network and the network management.
- Harmonization guidelines for risk assessment and standardization of detection methods and emerging technologies.
- Report on potential for modernizing monitoring and quality assurance in the food supply chain, by employing advanced on-line technologies, including a research agenda (2010–2020), and the initiation of new international research projects in the area of food safety and quality.
- A database of food quality and safety issues and corresponding analytical tools for food production and supply chain, available to network members and associates.

- Economic analyses on the impact of new regulations and the implementation of harmonized detection methods and technologies applied to new HACCP systems.
- Knowledge management platform and culture, dissemination activities, website and dissemination materials, annual network meetings including associates and biannual conference taking place in various countries.
- International curricula of mutually recognized training courses (including e-learning) and qualifications for both university and industry.
- An efficient and quality assured network management scheme that can be sustained beyond the EU funding.

Conclusions

The harmonization of validation and standardization protocols is necessary for mutual recognition (between countries and organizations) of international standards. For efficacy and cost efficiency, it is extremely important to establish coordinated efforts for methods standardization. Currently, there is a lack of information and communication between validation organizations that has led to numerous independent and redundant studies performed by various (national or international organizations) lacking a mutual recognition of the results.

The current costs for validation studies are often unacceptable: certificates are often only valid in certain countries or regions, requiring several certificates to be purchased, each requiring their own validation trial.

Harmonization in this area is a challenge for the future, but it is a necessary one, should for instance, rapid methodologies reach an internationally accepted standard through certification by an international standardization authority at an acceptable cost. Organizations such as ICC can play a vital role in the standardization process for cereal foods analyses, but may play an even broader role in standardizing horizontal methodologies that can be applied to a broad variety of food commodities.

The harmonization efforts between AACC International and ICC standard methods provide a very good example of a successful international harmonization in the area of cereal (products) analyses.

Roland E. Poms is Secretary General of The International Association for Cereal Science and Technology (ICC). Poms can be reached at gen.sec@icc.or.at.

An advertisement appeared here
in the printed version of the journal.