ORIGINAL ARTICLE

Food quality and safety issues in the priority areas within MoniQA

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Abstract

MoniQA (Monitoring and Quality Assurance in the total food supply chain) is a Network of Excellence funded under the EU 6th Framework Programme. Its aim is to work towards the harmonization of worldwide food quality and safety monitoring and control strategies by establishing durable integration of leading research institutions, industrial partners and small and medium enterprises working in complementary fields of food quality and safety analysis. One of the main objectives of the project is to 'develop harmonization guidelines for validation and standardization of detection methods and technologies in food safety and quality'. To achieve this, the relative importance of the range of contaminants and residues causing problems in food needed to be established. This paper outlines the methodologies adopted for prioritizing harmonization issues and identifying needs for research and development of analytical methods within the areas of natural contaminants (bio-toxins, food allergens), microbiological contaminants, chemical contaminants originating from environmental sources (heavy metals, etc.), industrial activity (dioxins, polychlorinated biphenyls, etc.) or agricultural practices (pesticides and veterinary drag residues), food additives (colourants, sweeteners, etc.), processing contaminants (acrylamide, *trans* fatty acids, etc.) and authenticity (cheaper substitutes, fraud, etc.). Qualitative methods are also included in the prioritized activities, as there are no internationally accepted validation protocols.

Introduction

Food safety is an essential public health issue, the importance of which was spelled out in the White Paper on Food Safety, published by the European Commission (EC) in 2000 (Commission of the European Communities, 2000). This set forth far-reaching and rigorous proposals for protecting citizens from food-borne health risks, established the foundation for a modern framework of food safety, proposed the formation of a European food authority and paved the way for regulation (EC) No 178/2002, the General Food Law. Subsequent regulations have continued to increase the safety of food by setting specific limits on allowable levels of contaminants and residues, but there is a need for reliable tools and methods to monitor whether the foods we eat are of high quality and conform to EU legislation.

New technologies in contaminant analysis are emerging that offer high throughput and easy handling solutions for industry and control authorities. Complementing traditional methods, some of these new rapid methods allow on-site testing of food quality and safety. However, they are not widely established and the limited shelf life of test kits raises new cost and efficiency issues as well as the need for standardized validation procedures. For consumers and the food industry alike to benefit, it is essential that we develop procedures and define requirements for evaluating new methods with respect to reliability and performance including accuracy, repeatability, reproducibility and robustness.

One of the main goals of the MoniQA NoE is to reach a consensus for validation procedures and standards in food analysis. To reach this goal, however, priorities for research in the food safety arena had to be set. This paper describes the methodology used to decide upon the seven groups of thematic priorities, or 'hot topics', which were selected and assigned to working groups for addressing priority and harmonization issues: Microbiological Contaminants, Mycotoxins and Phycotoxins, Chemical Contaminants, Food Allergens, Food Additives and Processing Toxicants, Food Authenticity and Guidelines for Qualitative Method validation.

Methodology-selection criteria

To prioritize among food quality and safety issues an extended analysis of data was undertaken. This analysis was based on literature survey of food hazards and quality challenges, information concerning the available official and non-official analytical and rapid detection methods, regulations and limits set by European legislation, Rapid Alert System for Food and Feed (RASFF) data for 2004–2006, information from EU websites, data from standardization organizations as well as other sources of information. Additionally, comments and suggestions from the MoniQA partners – experts in each field – were considered.

While priorities should ideally be based on risk rather than hazard, the absence of available data on exposure in many cases precludes a risk-based assessment and hazard is therefore the closest parameter available as a function of risk (risk being a product hazard and exposure). Furthermore, both the European Commission and Parliament intend to assess the suitability of continued approval of individual pesticides based on hazard in the proposed EU Authorization Regulation (replacing Directive 921/414/EEC on the placing of plant protection products on the market). This approach would therefore appear to be in line with current EC policy.

Consideration of a hazard or quality issue as a hot topic was mainly based on the following selection criteria:

- Risk and severity of a hazard, or impact of a quality issue;
- Frequency of occurrence;
- Legislative regulations and limits

though other issues, such as those listed below, were also considered:

- Existence of reliable detection methods;
- Need for improvement of existing or development of new/rapid method.

Microbiological contaminants

General issues

Microbiological contaminants are a major problem for a wide range of food products. They may cause serious health effects and quality deterioration in products. Although rates of illness will be affected by reporting systems, illnesses caused by microbiological hazards that may be foodborne can be assigned to broad categories that apply across most countries:

- >50 per 100,000 population: campylobacteriosis
- 10–50 per 100,000 population: salmonellosis (nontyphoidal), giardiasis, cryptosporidiosis
- 1–10 per 100,000 population: shigellosis, yersiniosis, verocytotoxin-producing *Escherichia coli* and Shiga toxin-producing *E. coli* (VTEC/STEC), hepatitis A infection
- <1 per 100,000 population: listeriosis, typhoid fever, paratyphoid fever, cholera.

The proportion of infections considered to be of foodborne origin has been assessed by a number of studies. Published summaries (Mead *et al*., 1999; Hall *et al*., 2005), based on data from the United States and Australia, reported that for bacteria the proportion was $>70\%$ in most cases, while a wide range was estimated for parasites (5–100%) and viruses (1–40%).

Data from rapid alert system for food and feed (RASFF)

Considering only alert notifications, microbiological contaminants were the most frequently encountered category in RASFF notifications, accounting for 31%, 27% and 16% of all alert notifications from 2004 to 2006, respectively. Notifications of (potentially) pathogenic microorganisms amounted to 515 (214 alert and 301 information) in 2004, 584 (264 alert and 320 information) in 2005, and 270 (130 alert and 140 information) in 2006. Notifications were dominated by the occurrence of *Salmonella*, mainly in poultry and other meats, but with significant numbers of notifications in herbs and spices in 2005 and animal feed in 2006. *Listeria monocytogenes* was the second-most important pathogen encountered, particularly in seafood. Indicators of poor microbiological quality, such as *E. coli* were mainly found in herbs and spices. A significant number of notifications for moulds were observed in 2006.

European legislation

The current European legislation [Regulation (EC) 2073/2005] on microbiological criteria for foodstuffs sets food safety criteria as follows: *Salmonella* and *L. monocytogenes* for certain foodstuffs, *Staphylococcal* enterotoxins for milk products, and *Enterobacter sakazakii* for dried infant formula. It also sets process hygiene criteria including *Salmonella*, *Staphylococcal* enterotoxins, enterobacteriaceae, and *E. coli*.

Mycotoxins and phycotoxins

General issues

Mycotoxins are toxic metabolites of filamentous fungi while phycotoxins are toxins produced by algae. Both may contaminate foods and were selected as priorities among other naturally occurring toxins and biotoxins.

The consumption of mycotoxin-contaminated feed and foodstuffs can produce toxic symptoms in animals and humans, which are known as mycotoxicoses. The most important mycotoxins and the related foods are listed below (The Rapid Alert System for Food and Feed (RASFF) Annual Report, 2007):

Aflatoxins: B1, B2, G1 and G2 occur in oilseeds and nuts (including pistachios and peanuts), grains (maize) and certain subtropical fruits (e.g. figs) etc. Aflatoxin M1 occurs in milk and milk products.

Ochratoxins: Ochratoxins especially ochratoxin A occur in cereals, beer, wine, cocoa, coffee, dried vine fruit, spices and meat products (through contamination).

Fumonisins: FB1 and FB2 occur in cereal grains (mostly corn and corn products).

Patulin: occurs in apples, carrot juice, apricots, grapes, grape fruit, peaches, pears, olives and cereals.

T-2 and HT-2 (trichothecenes A): occur in unprocessed cereals and cereal products.

Deoxynivalenol (trichothecenes A): occurs in cereal crops (wheat, maize, barley, oats and rye) and processed grains (malt, beer, pasta and bread).

Zearalenone: occurs in cereal crops (maize, barley, oats, wheat, rice and sorghum) together with their related products (e.g. bread and pasta). There is a potential occurrence in amaranth and black pepper.

Other mycotoxins (Sterigmatocysin, Citrinin): Sterigmatocystin occurs in corn, rice, wheat and hay and citrinin occurs in grains and coconut products (often co-occurring with ochratoxin A) and in some cereal products.

Data from RASFF

Mycotoxins dominated the RASFF with regard to information notifications, but have comparatively few alert notifications in comparison, accounting for only 6%, 9% and 8% of alert notifications from 2004-2006, but 44%, 40% and 40% of information notifications over the same period. Among the mycotoxins, aflatoxins retained their primary role as identified risks or hazards via RASFF in the recent years. A total of 877 notifications on mycotoxins were received in 2006, of which 800 concerned aflatoxins (The Rapid Alert System for Food and Feed (RASFF) Annual Report, 2007). Fewer notifications referred to ochratoxin A (54), fumonisins (15) and patulin (7). Similar patterns were seen in 2005 and 2004.

A number of alerts of phycotoxin contamination have been issued over the period 2004–2006 considered here. Diarrhoeic shellfish poisoning (DSP), azaspiracid shellfish poisoning (AZP), paralytic shellfish poisoning (PSP) and amnesic shellfish poisoning (ASP) have all been reported, though in low numbers annually, largely from mussels, clams, oysters or crabs.

European legislation

The current European legislation [Regulation (EC) 1881/2006] sets maximum levels for certain mycotoxins: aflatoxins (B1, B1+B2+G1+G2, M1), ochratoxin A, patulin, deoxynivalenol, zearalenone in various foodstuffs, fumonisins (B1+B2) in unprocessed and processed maize and its products, and the sum of T-2 and HT-2 toxins in unprocessed cereals and cereal products. Sampling plays a crucial part in the precision of the determination of the levels of mycotoxins, which are very heterogeneously distributed. Provisions for the sampling and analysis for the official control of the maximum levels of mycotoxins are mentioned in Regulation (EC) 401/2006. For aflatoxins, Commission Decision 2006/504/EC (currently being amended) lays down special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins. For ochratoxin A there is Commission Directive 2005/5/EC amending Directive 2002/26/EC, regarding sampling methods and methods of analysis for the official control of its levels in certain foodstuffs. For *Fusarium* toxins there is Commission Directive 2005/38/EC laying down the sampling methods and the methods of analysis for the official control of its levels in foodstuffs. No regulatory limits for Sterigmatocystin and Citrinin have been established by the European Union.

Commission Decision 2002/225/EC lays down detailed rules for the implementation of Council Directive 91/492/EEC as regards the maximum levels and the methods of analysis of certain marine biotoxins in bivalve molluscs, echinoderms, tunicates and marine gastropods (notified under document number C(2002) 1001). Commission Regulation (EC) No 2073/2005 sets the appropriate sampling plan, the regulatory limits and the analytical reference method for histamine in fishery products placed on the market during their shelf-life.

There is no direct legislation of regulatory limits concerning plant toxins by the European Union, though Regulation (EEC) 315/93 prevents placing on the market food containing 'a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at a toxicological level'.

Chemical contaminants and residues

General issues

Chemical contaminants and residues in food are generally distinguished in the following categories:

- Environmental contaminants (inorganic, organic, chemical migrants from food packaging and food contact materials),
- Pesticides residues, and
- Veterinary drug residues.

When their concentrations exceed maximum levels, chemical contaminants or residues may render food unsafe. Environmental sources are the main contributors to contamination of food with heavy metals and other elements. Their presence in food can also be the result of contamination from certain agricultural practices (e.g. cadmium from phosphate fertilizers) or manufacturing processes (e.g. tin in canned foods). Organic contaminants in food are either produced by industry or are by-products of industrial activity, like dioxins, polycyclic aromatic hydrocarbons (PAHs) and polychlorinated biphenyls (PCBs).

Data from RASFF

From the RASFF data, of the notifications received, environmental contaminants include inorganic heavy metals, organic contaminants, contaminants migrating through food contact materials, pesticide residues, and veterinary medicine residues. All these hazards have been identified as potentially dangerous.

Notifications of heavy metals amounted to 96 in 2004, 202 in 2005 and 187 in 2006, while the number for organic environmental contaminants was reported to be 68 in 2006. Migration phenomena from contacting materials rose from 0 in 2004, through 118 in 2005 to 176 in 2006. For pesticide residues, 48, 72 and 62 cases were reported in 2004, 2005 and 2006, respectively, while notifications for veterinary medicine residues varied from 142 in 2004, 167 in 2005 to 120 in 2006.

Among environmental contaminants, notifications for inorganic heavy metals have shown a sharp increase from 96 in 2004 to 187 in 2006. In this category, cadmium has been responsible for the largest number of incidents over the 3 years, with mercury and lead in lower numbers. From the 2006 alerts, cadmium occurred in a wide variety of food stuffs including fish, shellfish, walnut kernels, frozen raw banana prawns, horse meat and frozen spinach. Mercury alerts were restricted to fish and shellfish. Swordfish is the species with the highest number of notifications followed by shark. The number of notifications for the other fish species was considerably lower (The Rapid Alert System for Food and Feed (RASFF) Annual Report, 2007). Arsenic occurred in mineral water, granulated tea, dried seaweed and food supplements, with tin in cereals and meat groups. Lastly, lead occurred in a diverse range of foods including teas, consumption salt, food supplements, calabash chalk, crude sunflower seed oil, fresh pig meat, fresh mullet and walnuts.

For organic environmental contaminants, in 2005 the RASFF received four notifications on dioxins, which concerned products for animal feeding, while the number of notifications in 2006 increased to 14 cases, with three references to animal feeding. Dioxins (PCDDs, PCDFs, TCDD) occurred in fish, meat and meat products. In 2006, 46 cases of contamination with PAHs (benzo(a)pyrene, benzo(a)antharacene) were detected, mainly in smoked fish and oils. PCBs occurred in fatty fish and oilseeds, chlorinated hydrocarbons (aliphatic hydrocarbons: TCE, PCE) in meat, milk, fish and raisins and phthalic acid esters (DEHP, DBP, BBP, DPP, DIPP, etc.) in oils.

For contaminants migrating from food packaging and food contact materials, a high number of notifications concerned chromium and nickel migrating from metal ware, while fewer notifications concerned lead and cadmium in ceramic ware. Primary aromatic amines (PAA) were considered as a serious hazard during 2005. Twenty-one notifications were received, most of them being related to the migration from kitchen utensils made of nylon imported from China. However, a considerably lower number of notifications was received in 2006. Finally 11 notifications in 2005 and 20 in 2006 were received for 4,4-diaminodiphenylmethane.

Considering the notifications for pesticide residues, there was a slight decrease from 72 cases in 2005 to 62 in 2006. The notifications concerned mainly fruit and vegetables and in a few cases herbs and spices.

For veterinary drugs the metabolite nitrofuran – nitrofurazone (SEM), in raw headless shell-on shrimps and prawns, was the principal hazard in 2006, followed by malachite and leucomalachite green, chloramphenicol and substances like dichlorobenzene, quinolones, etc. Notifications concerning crustaceans were also predominantly linked to nitrofurans in 2005. The majority of notifications concerning residues of veterinary medicinal products issued in 2005 concerned fish, with the unauthorized fungicidal dye malachite green being the most commonly detected. Chloramphenicol is an antibiotic banned in the EU and was found mostly in honey and royal jelly. These products are mainly imported from India, China, Bangladesh and Vietnam, where this antibiotic seems to be still in use.

Concerning the determination of veterinary drugs in food samples of animal origin, practically no standard methods exist. In addition, ring trial-validated methods are available only for a small number of analyte/matrix combinations. In consequence, the vast majority of methods applied within the frame of official control are exclusively single-laboratory validated. However, these methods have to be validated according to the procedures specified in Commission Decision 2002/657/EC. This legally binding document also contains method performance criteria, against which the suitability of analytical methods for official control is evaluated.

European legislation

Demanding regulatory limits for controlling heavy metals in foodstuffs have been established in the Commission Regulation No 1881/2006/EC. Provisions for methods of sampling and analysis for the official control of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs are laid down in Commission Regulation (EC) No 333/2007/EC. Interestingly, the Regulation does not specify specific methods to be applied for official controls, but establishes method performance criteria that the specific method selected by the laboratory has to fulfil. Alternatively, the laboratory can apply a defined uncertainty function in order to demonstrate fitness for purpose (Thompson & Wood, 2006) of the proposed method. Commission Regulation No 1881/2006/EC sets also maximum limits for nitrates depending on species of vegetable, harvest time, and growing method.

For the environmental organic contaminants, the European Union has established demanding regulatory limits for controlling PAHs, dioxins and PCBs in foodstuffs (Regulation No 1881/2006/EC) and feed (Commission Directive 2006/13/EC) while Commission Regulation 1883/2006 lays down methods of sampling and analytical criteria for their official control.

Food contact materials are regulated by three types of directives, the Framework Regulation (EC) No 1935/2004, specific Directives on single groups of materials and Directives on individual substances or groups of substances, used for the manufacturing of materials intended for food contact. Specific directives exist for three groups of materials and articles: ceramics, regenerated cellulose film and plastics.

The European Commission has adopted the policy of using restrictions (mostly specific migration limits, SMLs) to control the safety of food contact materials and articles. There are several hundred SMLs in Directive 2002/72/EC and amendments (Directive 2004/1/EC, Directive 2007/19/EC), which have been assigned to plastic monomers and additives.

Ceramics are regulated by the Council Directive 84/500/EEC as amended by Directive 2005/31/EC. The Directive concerns the possible migration of cadmium and lead from ceramic articles that are in contact with foodstuff.

Regenerated cellulose film is defined by the Commission Directive 93/10/EEC (which has been amended by Directive 93/111/EC). The Directive 93/10/EEC sets a positive list of authorized substances and the conditions under which they can be used. A recent amendment Commission Directive 2004/14/EC introduced changes for plastic coated regenerated cellulose film.

The maximum levels of pesticide residues have been set by Commission Regulation 396/2005 and related Annexes. Pesticides that cannot be used in agricultural production intended for the production of infant formulae and follow-on formulae and specific MRLs of pesticides or metabolites of pesticides in infant formulae and follow-on formulae are described in Commission Directive 2006/141/EC.

Furthermore, the presence of veterinary and chemical drugs in foods is controlled by official inspection and analytical services following EC Directive 96/23/EC and its implemented Commission Decision 2002/657/EC on measures to monitor substances and residues in live animals and animal products. For some animal products (milk, eggs, honey, rabbits and game meat) further rules on sampling frequencies and levels are provided by Commission Decision 97/747/EC.

Food allergens

General issues

With a growing distribution network to deliver food around the world and expanding use of food crops in processed foods, there is interest in measuring the quantity and relative potency of food allergens. The characterization of protein allergens has always relied on a variety of methods to characterize their structure and function (McClain, 2008). Food allergies and adverse reactions are a major concern for allergic consumers, the food industry and enforcement authorities.

Data from RASFF

The presence of undeclared substances on labelling of food products has increased dramatically over the period studied here. From only eight notifications in 2004, 14 in 2005 to 27 in 2006, the figure for 2007 was 64. Most of them referred to milk, soy, gluten, or nuts.

European legislation

The notification of certain substances on labelling of food products is obligatory under European legislation ('Food labelling' Directives 2000/13/EC and 2003/89/EC, and Regulation 2006/142/EC) to protect susceptible individuals. EU labelling regulation (2006/142/EC) includes in Annex IIIa the list of foods that should be declared.

Additives and food processing toxicants

General issues

There are several additives used in food to improve colour, taste, texture, overall appearance and acceptance by consumers. Additives may become a hazard if improperly or illegally used. Processing toxicants on the other hand are newly recognized hazards. They are produced during processing, mainly cooking, and include acrylamide, nitrosamines, heterocyclic amines, and *trans* fatty acids.

Priorities selected among food additives are colours, preservatives, antioxidants and sweeteners, because of their broad use. Carbon monoxide and hydrogen peroxide, which are used as processing additives, will be examined because they constitute a serious hazard. Among processing toxicants, acrylamide, *trans* fatty acids and nitrosamines will be reviewed because they attract high scientific and consumer interest.

Synthetic dyes have been accounted as a potential risk to human health (Minioti *et al.*, 2007). Apart from Sudan (I–IV) dyes, which are not permitted, there are other colours such as auremine and rhodamine, which are hazardous to human health and prohibited in food. Some azo dyes are genetically not toxic to humans since their metabolites are biologically active (Calbiani *et al.*, 2004; Mejia *et al.*, 2007). Most of them are considered to be carcinogenic (Mejia *et al.*, 2007; Tripathi *et al.*, 2007).

Safety has also been a controversial issue for some intense sweeteners. For example, aspartame has raised suspicions in terms of carcinogenicity, and as a result has undergone extensive investigations, which included experimental animal and human studies, intake studies and post marketing surveillance [European Food Safety Authority (EFSA)]. However, it has been evaluated as safe for use in foodstuffs, and its acceptable daily intake (ADI) has been set at 40 mg/kg of body weight.

As far as preservatives are concerned, despite their low toxicity, sorbic and benzoic acid, if abused, can threaten consumers' health. Sulphites are also associated with several human diseases, such as stomach irritation, abdominal pains and vomiting, as well as a sensitivity reaction with symptoms similar to those of an allergic reaction. Nitrites can be converted to carcinogenic nitrosoamines in food products, as well as within the human digestive system. They have also been associated with methaemoglobinemia, a disease characterized by the decreased ability of blood to carry oxygen around the body (World Health Organization).

Several antioxidants, such as BHA, BHT and TBHQ, have been associated with health risks. In particular, BHA has raised suspicions in terms of carcinogenicity to humans. BHT might have the ability to affect allergic diseases in humans such as allergic rhinitis and asthma (Yamaki *et al.*, 2007). TBHQ has also been accounted for allergenic properties and carcinogenicity (Gharavi *et al.*, 2007).

Trans isomers of unsaturated fatty acids are formed from *cis* unsaturated fatty acids during biohydrogenation by rumen microorganisms and by commercial partial hydrogenation during processing of vegetable and fish oils. The consumption of *trans* isomers of fatty acids has been associated with the increase of plasma low density lipoprotein-cholesterol and the decrease of high density lipoprotein-cholesterol concentration (Mensink & Katan, 1990). They may also increase the risk of cardiovascular disease by association with higher plasma lipoprotein (a) level (Almendingen *et al.*, 1995). Acrylamide is generated primarily in fried, grilled, and baked products at temperatures above 120 °C (Skog & Alexander, 2006), while its possible risk to public health remains unclear. *N*-nitrosamines are in most cases strongly carcinogenic, with *N*-nitrosodimethylamine (dimethylnitrosamine, NDMA) being by far the most frequently encountered member of this group of compounds. In 1997, the US Environmental Protection Agency (EPA) reported *N*-nitrosodimethylamine (NDMA) as a probable human carcinogen, estimating its 106 lifetime exposure cancer risk at 0.7 ng/L in drinking water [US Environmental Protection Agency, *N*-Nitrosodimethylamine, CASRN 62-75-9, Integrated Risk Information System (IRIS) Substance File, 1993].

Data from RASFF

Notifications for food additives in 2006 reached 337 cases in comparison to 240 in 2005. Sulphites, illegal use of some colorants and carbon monoxide were on top of RASFF notifications. During the first semester of 2008, 96 notifications of unauthorized use or high levels of food additives were reported. Most notifications (55) concerned preservatives, with 40 referring to sulphites. Colours followed in number of notifications (37), including illegal dyes. Fewer notifications concerned sweeteners and antioxidants.

European legislation

Food additives, as well as the categories in which they are divided, are defined according to Directive 89/107/EEC. More specifically, the sweeteners for use in foodstuffs with permissible limits are presented in Directive 94/35/EC, with their permissible limits, while food colours are covered by Directive 94/36/EC. Food additives other than colours and sweeteners, like preservatives, antioxidants etc., are defined in Directive 95/02/EC. Finally, concerning heat–generated food toxicants, the European Union has established Commission Recommendation of 3 May 2007 on the monitoring of acrylamide levels in food (2007/331/EC), though no legal levels have yet been set. Levels of *trans* fatty acids and *N*-nitrosamines in food are not regulated directly by law.

Food authenticity

General issues

Food authenticity was selected as a thematic priority among other quality topics, like shelf-life indicators, processing and storage indicators, because it affects the quality and nutritional value of many foods that are broadly consumed (milk, cereals, vegetable oils, etc.) and has a severe economic impact on trade.

The authenticity of foods is of major concern for researchers, manufacturers, policymakers and consumers. An authentic raw material or finished food must be in compliance with labelling in terms of ingredients, production technology and genetic identity. The main foods where adulteration is observed are: milk and dairy products, cereals, vegetable oils, fruit juices, meat products, wine, honey, and coffee.

Qualitative methods

Qualitative methods, i.e. methods where the result for a target analyte is often expressed in terms of 'present' or 'not present', are being increasingly used in food and feed analysis. These methods cover both *screening* tests (e.g. lateral flow devices) and confirmatory tests such as feed microscopy or endpoint PCR. Since the result of analysis is not given as a figure (e.g. mg/kg), classical statistics, as recommended by IUPAC and ISO protocols for method performance and method validation, are not applicable. Another challenging aspect is that *qualitative* methods are employed in quite different fields ranging from microbiology, detection of contaminants to research on allergenic food.

Before utilizing *qualitative* methods for practical application, the users need to demonstrate that these methods are fit for their intended purpose. This is normally achieved by conducting a validation study. However, there are no internationally accepted validation guidelines that address these mentioned aspects. In consequence, organizers of validation studies are missing concrete guidance when establishing the experimental design of the study. Accordingly, there is a great need for establishing such guidelines. In 2005, IUPAC launched a project for the development of a corresponding guideline and afterwards it was decided to amalgamate these activities with the work of MoniQA. This will be one of the prioritized activities within the MoniQA project.

Towards harmonization

Performance criteria

The Codex Alimentarius Commission (CAC) has adopted the criteria approach proposed by the Codex Committee on Methods of Analysis and Sampling (CCMAS). The criteria required include accuracy, applicability, detection limit, quantification limit, precision (repeatability intra-laboratory, and reproducibility inter-laboratory), recovery, selectivity, sensitivity, and linearity.

At the present time few standard methods include all such information (e.g. most include precision data but few recovery data). It is essential to collect and collate validation data to meet the criteria. The development of international guidelines for the validation of qualitative methods would also be necessary.

Within the European Union the official control to check for compliance with legal limits has to be carried out according to Regulation (EC) No 882/2004. Regarding the selection of appropriate analytical methods, official food and feed laboratories have to apply the cascade principle as specified in article 11 of this Regulation attributing high priority to Community methods followed by CEN or ISO standards and methods that have been validated through an interlaboratory study. Given the fact that for many analyte/matrix combinations no harmonized standards or ring-trial validated methods exist, official laboratories can utilize single-laboratory validated methods, but only if other methods of higher priority are not available. Regulation (EC) No 882/2004 also specifies that international standards such as the IUPAC harmonized protocol, or for specific analyte/matrix cases Commission Decision 2002/657, need to be applied. The regulation also introduces the concept of criteria compliance tests, which has already been mentioned in this document.

Conclusion

Food legislation controls all aspects of the food chain in order to ensure that the demanding requirements of consumers are met and the food they eat is safe and wholesome. While the range of food quality and safety issues is vast, and new hazards are continually appearing in the food chain, the resources of projects such as MoniQA are limited and prioritization of research effort is paramount. This exercise set the direction for initial research in the main topic areas of concern in the EU, though the project allows new and emerging issues to be considered during its life span. For this reason, an additional working group on qualitative method validation has since been established. Having established a prioritization of 'hot topics' in the food arena, the project will now proceed concentrating on developing common strategies for the harmonization of validation and standardization protocols for the detection and quantification of biological and chemical contaminants of food.

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