Government Chemist

Review 2010

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Foreword

The post of Government Chemist represents an expert UK authority with responsibility for resolving issues which may arise from scientific work carried out in the context of regulatory enforcement. This national safeguard is designed to help ensure that decisions and outcomes are reached fairly and cost-effectively. It involves making definitive measurements, mainly on the safety and composition of food and animal feed, in often challenging sample and analyte combinations. The work is variable and unpredictable, and requires the development and maintenance of capability spanning a very broad range of measurement disciplines including organic and inorganic analytical chemistry, molecular biology, and advanced technologies such as mass spectrometry, with a major emphasis on analytical quality control.

This review of the work of the Government Chemist in 2010 profiles (in section 2) casework that resolved a range of disputes pertaining to food and agricultural law. Coverage includes cases of alleged food contamination with cancer-causing nitrofuran substances, and the sale of unfit beer. A relatively high proportion of our annual caseload related to animal feed, including micronutrient levels and contamination by toxic moulds. Thus we helped to protect the welfare of farmed animals as well as safeguarding the final consumer.

At a time when science and value for money are in particular focus, increased emphasis was placed on delivering added benefits through defining new methods, dispute avoidance, training, scientific development, collaboration, dissemination and improved prediction of analytical requirements. Activities in each of these areas are described within section 3 of this review.

Scientific highlights included investment in technology that will enable measurement and characterisation of nanoparticles in food, and method development that enhanced the reliability of determining the presence of illegal dyes in particularly complex food commodities. These developments could be important in delivering Government Chemist casework in the future. Equally important in preparing to meet future demands is the ability to predict what kind of food and feed incidents might arise next. With this goal in mind, a collaboration was developed with Kingston University to enable improved capture and analysis of global food recall data.

I was also particularly pleased this year that we were able to run some excellent scientific events. In April, the annual Government Chemist dissemination event was expanded in collaboration with the Food Standards Agency, LGC Standards, Campden BRI and Leatherhead Food Research. Over 170 people attended the event that covered a range of important issues in food analysis, and we received excellent feedback on the usefulness of the scientific content and on the opportunities for networking.

The knowledge acquired from our work, and through LGC's other Government activities, delivers the capacity to provide wider advice to stakeholders on the measurement implications of regulation, policy and enforcement – a second and important part of my role, progress on which is outlined toward the end of this review.

Finally I would like to thank my team of scientists who continue to provide the dedicated input required of my role. I am also very grateful to the newly formed Government Chemist Working Group that has provided valuable insight and guidance over the course of the year.

I hope you enjoy reading this review and look forward to receiving your feedback.

Derek Craston
BSc PhD FRSC
Government Chemist

1 Remit

Public protection is at the heart of the Government Chemist function. We provide sound measurement practice to ensure effective yet lean regulatory activities across the spectrum of chemistry-using industries. We act to resolve potentially costly disputes linked to official sampling and analysis, most often in the food and agriculture sector. We also carry out chemical analysis to protect the public purse. All these responsibilities rely on the latest science and technology, as well as experience rooted in the historic Laboratory of the Government Chemist.

Statutory function

The Government Chemist has a science-based statutory function comprising duties prescribed under seven acts of Parliament. These duties (Box 1) centre on public protection, safety, health, value for money, and consumer choice. Much of our work relates to scientific dispute resolution – 'referee analysis' – that is to say, the provision of expert opinion, based on independent measurement, to resolve a dispute over tests carried out on behalf of an enforcement authority and a trader during a formal investigation. In these cases, the stakes can be high, so the credibility of the referee rests on first-class science, which is underpinned by the designation of our home laboratory, LGC, as the UK's National Measurement Institute for chemical and bioanalytical measurement.

In legislation governing sectors where consumer safety is paramount, such as food, agriculture and medicinal products, the provisions for official sampling and analysis tend to follow a similar form. The Food Safety (Sampling and Qualifications) Regulations 1990, pursuant to which many of our dispute resolution activities arise, are typical. Test samples are divided into three parts by an authorised officer. Both parties have the opportunity to perform independent analysis, while the third part of the sample is retained in case the referee is called upon to act. A Government Chemist referee analysis and opinion can be obtained without recourse to the law courts – or, if a judge orders the referral, can be adduced to minimise the trial costs.

A successful appeal to the Government Chemist may rescue a bona fide business operator from penalties prescribed under criminal law, costly compliance action such as a product recall, and, perhaps most importantly, loss of reputation. Conversely, if our findings are in agreement with those of the enforcement authority, action to protect the public can be pursued with renewed confidence and efficiency. In either case, everyone has the opportunity to apply the scientific lessons learnt and reduce the risk of recurrence of similar situations. We share our experience with the wider community through scientific publications, openly accessible advice and increasingly popular dissemination events.

► **Section 2** of this review highlights the year's completed referee cases.

Understandably, the need for referee analysis tends to arise from complex or novel cases. We do what we can to foresee likely areas of demand, for example by monitoring regulatory trends and global data on official controls. These intelligence gathering activities help to inform R&D priorities. Besides building capability to undertake referee analysis, our R&D spins out wider benefits.

► **Section 3** for an overview.

Box 1: The Government Chemist in legislation

The duties of the Government Chemist as referee analyst are defined in or under:
Food Safety Act 1990
Food Safety (Sampling and Qualifications) Regulations 1990
Food (Northern Ireland) Order 1989
Food Safety (Northern Ireland) Order 1991
Food Safety (Sampling and Qualifications) Regulations (Northern Ireland) 1991
Poultry Meat (Water Content) Regulations 1984
Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 2007
Materials and Articles in Contact with Food Regulations 2010
Plastic Materials and Articles in Contact with Food Regulations 2009

Agriculture Act 1970
Feed (Hygiene and Enforcement) Regulations 2005
Genetically Modified Animal Feed Regulations 2004

Medicines Act 1968
Farm and Garden Chemicals Act 1967

The Government Chemist is named and has other scientific responsibilities under:
Merchant Shipping Act 1995
Hydrocarbon Oil Duties Act 1979
Poisons Act 1972

The status and territorial extent of the Government Chemist are understood with reference to:
Freedom of Information Act 2000
Scotland Act 1998 (Cross-Border Public Authorities) (Specification) Order 1999
Administrative Provisions Act (Northern Ireland) 1928
Government Chemist Regulations (Northern Ireland) 1928

Advisory function

The Laboratory of the Government Chemist, developed on foundations laid in 1842, became established for nearly half the 20th Century as a free-standing central department, charged and equipped to investigate and analyse samples of all kinds on behalf of other government authorities. Chemistry and its related sciences continued to underpin industrial growth and a wide range of public goods.[1] So when LGC was privatised in 1996, an agreement with the Secretary of State underpinned the continuity of the broader public functions by appointing the Government Chemist 'as a source of advice for HM Government and the wider analytical community on the analytical chemistry implications on matters of policy and of standards and of regulations'.

This broad function is delivered in the main by responding to government calls for advice on analytical science, bringing together public and private sector stakeholders with a common interest in regulatory compliance, and working to ensure that measurement adds value to emerging policy, standards and regulations. The advisory function also aims to spur innovation by clarifying the requirements for chemical and bioanalytical measurement, helping businesses to risk-proof their value chains, plan confidently, address technology gaps in good time and avoid unnecessary costs.

► **Section 4** for more about the wider advisory function.

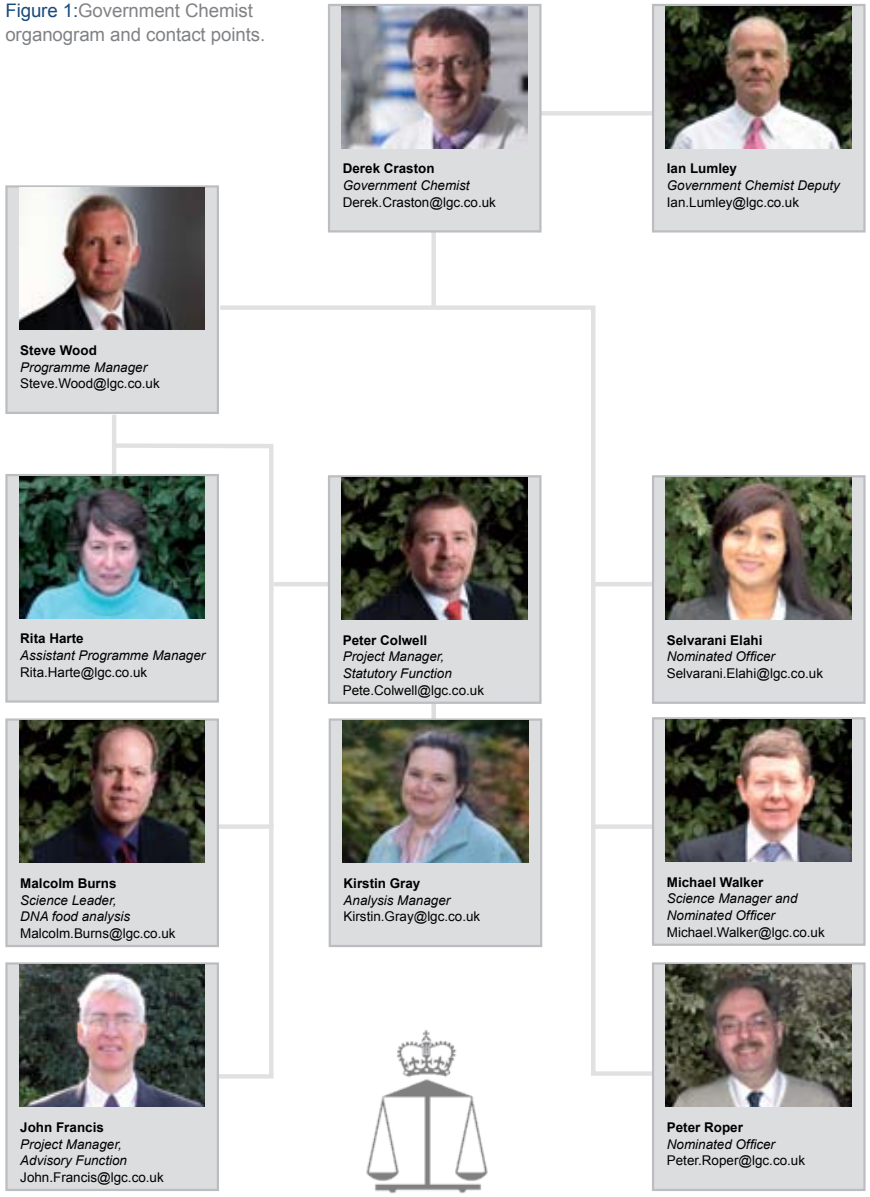
Governance

The Department for Business, Innovation and Skills (BIS) funds a programme to enable delivery of statutory casework and scientific advice, together with work and research necessary to maintain the effectiveness of the Government Chemist. Within BIS, responsibility for both the Government Chemist and the wider UK National Measurement System rests with the National Measurement Office (NMO).

Arrangements are in place to ensure that this Government Chemist programme is delivered competently – in particular, that impartiality, transparency and scientific standards are upheld. The Government Chemist Working Group (GCWG), which met for the first time in June, includes representation from regulators, enforcement agencies, industry representatives, trade associations and academia, and in addition to providing independent scrutiny, the new GCWG terms of reference extend to advising the NMO directly on programme priorities.

[1] Cf. Council for Science and Technology, A vision for UK research, March 2010: www.bis.gov.uk/cst/cst-reports#vision

Figure 1:Government Chemist organogram and contact points.



The new Government Chemist programme

The GCWG faced its first significant challenge in December, when called upon to prioritise projects for the next phase of the Government Chemist programme (2011-14). Since the established programme structure has proved successful, the next phase will be based around similar themes:

- Intelligence gathering: horizon-scanning projects on the scientific implications of policy development, emerging legislation and enforcement trends
- Capability building: innovative and intelligence-led R&D, designed to build capacity for a sound response to increasingly complex and diverse analytical casework
- Statutory activities: work carried out in relation to individual cases that are referred to the Government Chemist pursuant to an act of Parliament
- Knowledge transfer: dissemination of regulatory and analytical developments so that overall standards of measurement continuously improve, enabling more efficient dispute resolution to protect public health and save the taxpayer money. Such knowledge sharing also aims to help industry generate innovation in products and processes.

The GCWG was asked to rank proposals that had been developed over the course of the year by expert Government Chemist staff in liaison with key stakeholders. Subject to funding, we plan to phase in the highest ranking projects from April 2011. These focus on allergens, food fraud, vitamins, illegal dyes, mycotoxins, and horizon scanning.

People

LGC staff who directly support the Government Chemist function have clearly and independently defined roles (Figure 1). Within this framework, there are particular requirements for the management of statutory casework:

- Nominated officers, one of whom holds requisite statutory qualifications, have overall responsibility for case supervision. They prepare and sign Government Chemist certificates of analysis
- Only the Government Chemist or Deputy, once satisfied that the case has been properly completed, may countersign.

Analytical scientists undergo specific training and develop expertise through project-related R&D. They demonstrate competence through proficiency testing schemes as well as wider collaborative trials, organised for example by CEN or the European Institute for Reference Materials and Measurements (IRMM). More widely, LGC offers a diverse skill base of scientists and professionals, many with the contacts and absorptive capacity needed to benefit from globally important advances in science and innovation,[2] from whom advice and expertise can be effectively sought.

Work with us

The next phase of the Government Chemist programme looks set to open up exciting opportunities over the coming year. Research projects to develop scientific capabilities tackling the latest analytical challenges will benefit public health and safety, the wider scientific community and thus the UK resurgence in manufacturing industries.[3] Even with our best efforts, not all statutory casework can be foreseen, and to ensure that the referee has access to the best skills and expertise, we need to go on growing our stakeholder base (Figure 2). If you would like to discuss any aspect of our work, please see Figure 1 for a suitable contact point.

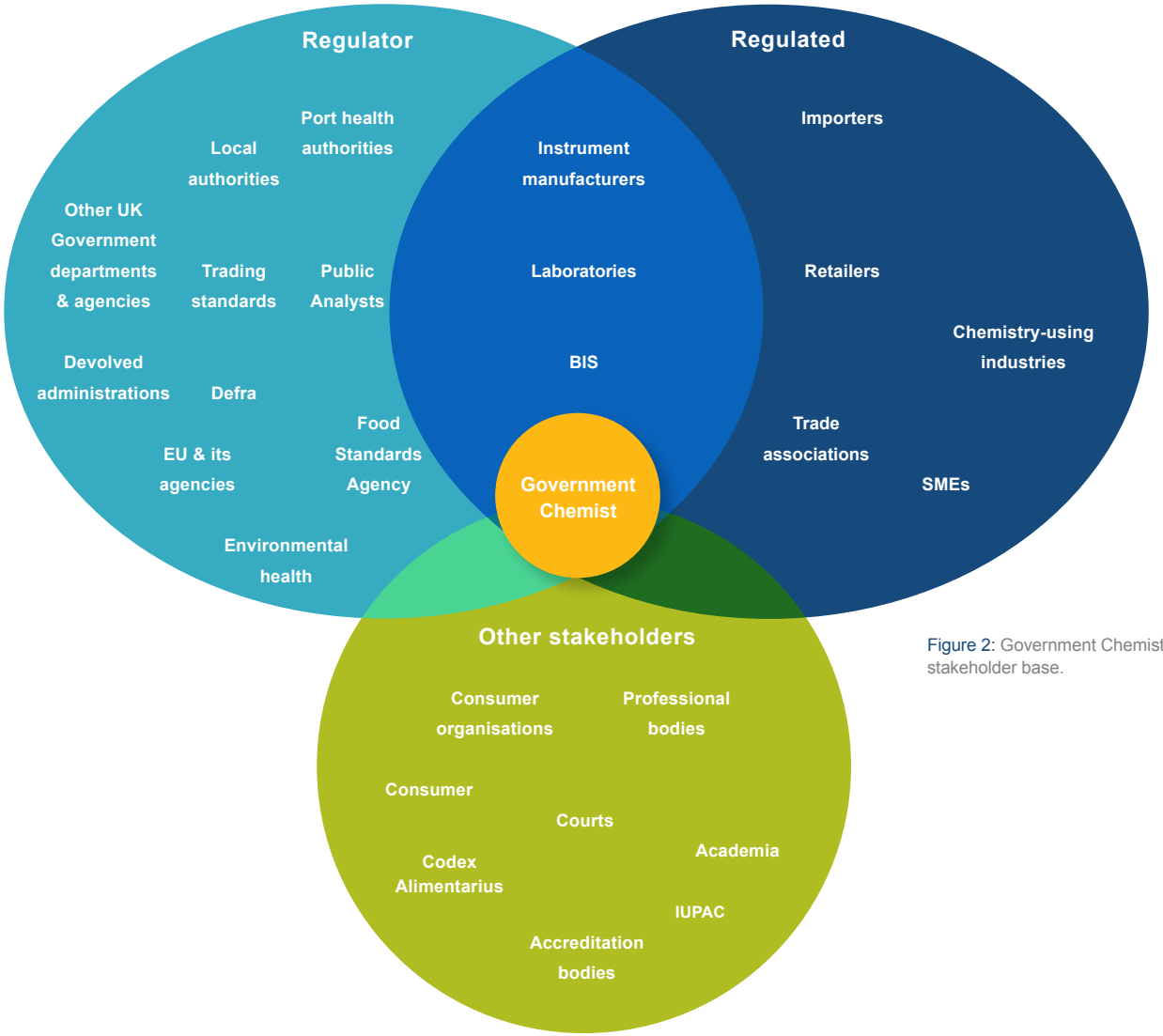


Figure 2: Government Chemist stakeholder base.

[2]Cf. Council for Science and Technology, Future science spending review (letter to Professor Adrian Smith dated 1 July 2010): www2.cst.gov.uk/assets/bispartners/cst/docs/files/letters/letter-adrian-smith.pdf

[3]Cf. Government Office for Science, Technology and innovation futures: UK growth opportunities for the 2020s, 4 November 2010: www.bis.gov.uk/foresight/our-work/horizon-scanning-centre/technology-and-innovation-futures

2 Science underpinning sound dispute resolution

At present, we are usually asked to analyse samples and develop related expert opinion according to the dispute resolution provisions in the Food Safety Act 1990, or for animal feed, the Agriculture Act 1970. These are 'formal samples', taken under statutory enforcement provisions and divided into parts for analysis on behalf of the authorities, the food and feed business operator (FBO) and, when required, the referee. During 2010, 14 cases were referred to the Government Chemist – 10 in connection with the Food Safety Act, and the remaining 4 in accordance with the provisions of the Agriculture Act. This section summarises the year's completed casework.

More about the referee function

Analytical results tend to be disputed in the more complex cases, or where there are recognised scientific uncertainties. The referee must apply sound science – including innovative exploratory studies, rigorous execution of a pre-planned analytical strategy, and specialised interpretive skills. We rely on the whole of LGC to challenge and inform our ways of working and thinking. For example, we apply forensic practices such as a documented chain of custody, the witnessing of key practical procedures, and specially designed facilities when needed to prevent interference from contaminants. Through LGC we have rapid access to world class advice on metrology, experienced statisticians, and over 20,000 reference standards. The organisational culture also ensures that we participate in a wide range of proficiency testing schemes to monitor staff competence with regard to specific analytical priorities.

It is now possible for a FBO to obtain a Government Chemist certificate of analysis without having its part of the formal sample analysed. This facility arises from Article 11(5) of Regulation (EC) No 882/2004 *on official controls,* which establishes the right to a supplementary expert opinion (SEO). FBOs choosing the SEO route will forego an opportunity to develop and discuss their own evidence with the enforcement authorities, and to avoid raising the profile of the case unduly. Demand for SEO has also had resource implications for the Government Chemist, which is responsible for ensuring that the final expert opinion on any formal sample is delivered with appropriate rigour. Therefore the fees for dispute resolution and SEO differ (£250 and £1,500 respectively). For a typical case, neither fee approaches the full cost borne by the Government Chemist; the balance is allocated from the funding programme managed by the National Measurement Office.

Nitrofurans

These substances were once widely used as veterinary antibiotics, but are now prohibited in food because they can cause cancer. The European Union adopted a zero tolerance approach to residues of nitrofurans in food producing animals. But, because practical methods of measurement cannot show that a sample is entirely free of contamination, an immediate non-compliance with the law only arises at concentrations in excess of a minimum required performance limit (MRPL) limit set by Decision 2003/181/EC. Nitrofurans are unstable in animal tissue and give rise to metabolites which can be measured as marker compounds.

We received two formal samples of black tiger prawns (Figure 3). In both cases, analytical results obtained on behalf of a UK port health authority indicated that nitrofuran metabolites were present, but the owner, being in possession of a pre-export certificate which stated the contrary, disputed the findings, and requested SEO. We homogenised the edible portions of the samples, and carried out a variant of our UKAS-accredited procedure employing acid hydrolysis to extract the nitrofuran metabolites. These were chemically modified before measurement, following a procedure developed to enhance the quality of the results, then analysed by LC-MS/MS, calibrated with isotopically-labelled standards.

In one sample, we found that, on the balance of probabilities, a metabolite derived from the nitrofuran furazolidone was present, but that its concentration did not exceed the MRPL of 1.0 µg kg^{-1}. However, we established that the second sample contained a marker compound for the nitrofuran nitrofurazone at a concentration exceeding the MRPL, and should therefore be prohibited from entering the food supply chain.

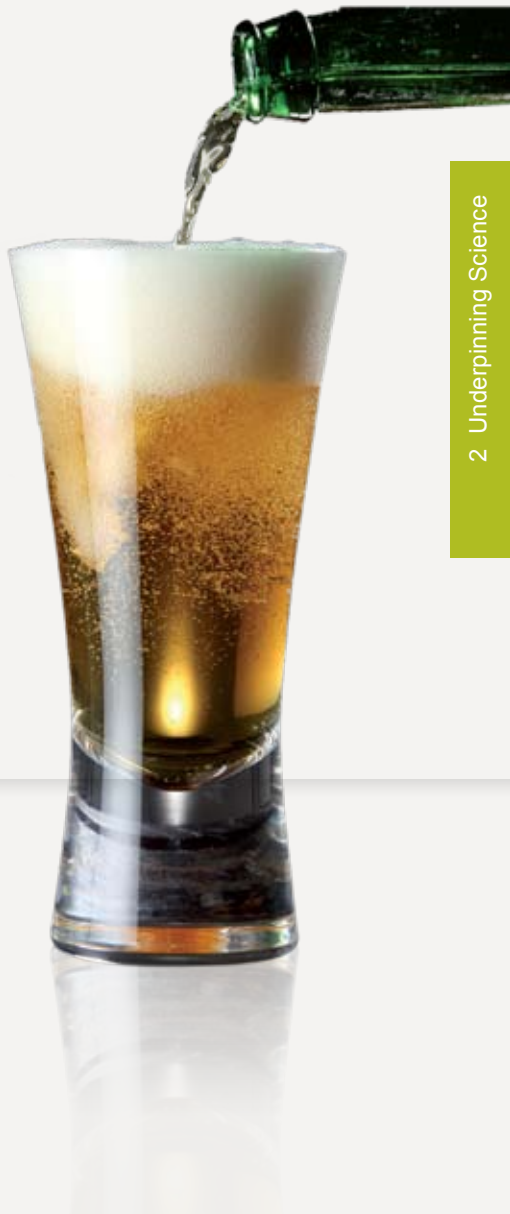
Figure 3: To obtain meaningful measurements, it is important to establish which parts of a sample will be analysed. Almost 50 % of this formal sample of peeled and deveined black tiger prawns was ice. We thawed and drained it, analysing only the edible portion.

Bottled beers

A routine inspection found that bottled beers were on sale many years after their best before date. Two formal samples were taken, and divided in the manner prescribed by food law. However, the retailer's part was lost, so the court ordered submission of the remaining sample to the Government Chemist for analysis.

Analysis of haze, colour and microbiological activity were undertaken by a specialised subcontractor, under the close personal supervision of Government Chemist staff. We issued a certificate stating that owing to the presence of excessive haze consistent with deterioration of the ale, the sample was unfit for human consumption within the meaning of Article 14(2)(b) and Article 14(5) of Regulation (EC) No 178/2002 *laying down the general principles and requirements of food law.* Article 14 prohibits the placing on the market of food that is unsafe, such as when it is unfit for human consumption through deterioration or decay.

The case went back to court in May 2010 and the defendant decided on the day of the trial to plead guilty. A fine of £4,500 and costs in excess of £3,000 were imposed.



Feed

We continued to represent BSI at CEN Technical Committee 327 (Animal feeding stuffs – Methods of sampling and analysis) – as well as in TC 327 working groups on inorganic analysis, organic contaminants, and sample preparation – aiming to ensure that outputs are fit for purpose and based on widely accessible technology. Committee participation provides awareness of the latest technical developments, which we can take into account when planning the referee analysis of formal feed samples.

Trace nutrients

Local authorities investigated a farmer's complaint about feed given to a flock of in-lamb ewes. The product had appeared substandard, and shortly after its administration one of the sheep had died. Copper poisoning was a possible explanation. The local Agricultural Analyst found that the copper content, though higher than usual, was not excessive; however, concentrations of selenium and zinc were above the applicable limits. The feed supplier disputed these measurements, so a sample was sent to the Government Chemist. We determined copper, zinc and selenium by ICP-MS after microwave pressure digestion of reproducibly prepared subsamples (Figure 4). We followed our established experimental design for Agriculture Act cases, which includes making all measurements three times per day over three days. Having measured high levels of selenium and zinc, we formed the opinion that the instructions accompanying this product were incorrect in allowing it to contribute up to 70 % of the daily ration of feed to ewes, which would result in both elements exceeding their maximum authorised limits, in breach of the Feeding Stuffs (England) Regulations 2005.

Selenium can readily form organic species that differ in their bioavailability, nutritive and toxic properties. Species such as selenomethionine (SeMet), the major form of the element found in most food, are known to be well absorbed and stored within the human body. Inorganic selenium is generally excreted more rapidly than SeMet, and is more toxic. LGC's expertise in speciating this trace element, and judicious use of reference materials under development (Box 2), enabled us to measure the inorganic forms, and, by difference, show that organic compounds accounted for close to 87.5 % of the selenium in the feed sample.

Box 2: Selenium in nutrition and healthcare

The human body needs trace quantities of selenium but, as with other nutrients and bioactive substances, some chemical forms are more beneficial than others, while excessive intake could be harmful: 'everything in moderation'. Global trade dynamics affect the supply of selenium-rich foods like North American wheat, but European intakes could be rebalanced for example by fortification and food supplements. Biofortification by applying selenium-containing fertilisers to selected crop varieties enables common, naturally occurring forms of the element, such as the amino acid analogue SeMet, to be incorporated into food supply chains.

LGC's National Measurement Institute laboratories are developing a range of reference materials to support the detailed product characterisation work needed to help consumers achieve a sufficient and safe selenium intake. A reference preparation containing SeMet enriched in the isotope ^{76}Se is now available for distribution. This is specifically tailored to underpin high accuracy IDMS quantification of selenium enrichment.

Matrix-based materials, containing certified concentrations of selenium species in wheat flour and yeast dietary supplement tablets, are nearing completion.

This expertise in selenium speciation builds on a fruitful collaboration with the Centre for Experimental Cancer Medicine at St Bartholomew's Hospital. There is evidence that selenium helps lymphoma patients respond to chemotherapy. *In vitro* studies of lymphoma cells have related this benefit to low concentrations of methylseleninic acid (MSA). Recent studies employed a specialised ICP-MS nebuliser to cope with the low chromatographic flow rates necessary for work with cell extracts, and improved detection limits for methylated species such as dimethylselenide by up to 12-fold. Research on selenium metabolism is still at an exploratory stage, so it was exciting to observe clear differences between the rates of MSA uptake by non-malignant and lymphoma cells, as well as in the selenium species subsequently detected. The results will inform clinical studies.

Figure 4: Rigorous sample preparation contributes to high quality measurement. A riffle splitter can provide representative subsamples of fragmented solids such as this animal feed product.

Handling uncertainties with rigour

In 2008, the EFSA recommended revised maximum levels of vitamin A in feed for most food-producing animals.[4] The EFSA statement was designed to minimise the risk that excessive vitamin A intake poses to human health. A local authority subsequently undertook sampling, and, when a dispute arose over the results of analysis, asked us to determine vitamin A in two formal samples. We used the LC-based method prescribed by Regulation 152/2009. Section 68 of the Agriculture Act 1970 requires the sale of feed products with a statutory statement including 'such particulars as may be prescribed of the nature, substance or quality of the material'. In both cases, we had to issue certificates stating that the vitamin A content did not correspond with the declaration in the statutory statement. In forming these opinions, we had regard both to analytical and industrial sources of uncertainty, in accordance with Regulation (EU) No 939/2010 *on permitted tolerances for the compositional labelling of feed materials or compound feed.* Our conclusions confirmed those of the Agricultural Analyst acting for the local authority.

In one of these cases, the Agricultural Analyst had also reported that the difference between the amount of fibre found in the sample and the amount declared was greater than the permitted limit of variation taking into account the uncertainty of measurement. We therefore determined crude fibre – a measure of fat-free organic matter that does not dissolve in acid or alkali – using a validated proprietary method considered equivalent to the prescribed procedure. We found that the crude fibre concentration was outside the limits of variation for any misstatement, as laid down by the Feeding Stuffs (England) Regulations 2005. Official advice was imposed on the manufacturer in view of the non compliant vitamin A and crude fibre concentrations.

The Agricultural Analyst reported that a further sample taken from the same manufacturer was deficient in magnesium. We analysed the sample in accordance with Regulation 152/2009 by a dual wavelength ICP-OES method, and determined the magnesium concentration to be 13 % less than that declared in the statutory statement. However, the Feeding Stuffs (England) Regulations 2005 provide for the fact that measured values will vary, and a deficiency of up to 15 % was permitted in the specific circumstances of this case.

Mycotoxins

Aflatoxins are a chemically related group of genotoxic carcinogens derived from *Aspergillus* moulds, which pose a high risk to the safety of imported food produce. They remain prominent in recent EU legislation setting priorities for official controls[5], and a steady stream of related cases have been referred to the Government Chemist. This experience has equipped us to generate high quality data efficiently, and build up a working knowledge of the uncertainties, including the sampling and interpretive issues given that contamination of a large consignment tends to be patchy.

The latest case concerned a consignment of wild bird feed under investigation in accordance with the Official Feed and Food Control (England) Regulations 2009. We were asked to carry out referee analysis after the authorities found two of four subsamples to be non-compliant with the legal limit for aflatoxin B_1 of 20 µg kg^{-1} set by the Feeding Stuffs (England) Regulations 2005 as amended (implementing Directive 2003/100/EC); the laboratory acting for the business operator had obtained much lower results. We found our part of the sample to contain aflatoxin B_1 at a concentration of more than ten times the legal limit. Consequently, we were able to form the opinion that:

- The sample was unsafe within the meaning of Article 15 of Regulation (EC) No 178/2002. Paragraph 3 of Article 15 stipulates that where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment fails to satisfy the feed safety requirement

- A detailed assessment of the rest of the consignment would in all probability demonstrate failure to satisfy the feed safety requirement.

We continued to optimise and validate high performance LC-MS/MS methods of analysis for a wider range of hazardous mycotoxins, including fumonisins, trichothecenes, nivalenol, deoxynivalenol, zearalenone, and ochratoxin A.

[4] European Food Safety Authority, Consequences for the consumer of the use of vitamin A in animal nutrition. Opinion on question number EFSA-Q-2006-121, adopted 19 November 2008: www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902310217.htm

[5] Regulation (EU) No 1099/2010 *amending Annex I to Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin*

3 Delivering the benefits

Some of the main benefits of the UK Government Chemist function are summarised in Table 1. The remainder of this section reviews our progress in food and agricultural measurement R&D; the activities covered, though primarily undertaken to support the effective delivery of our statutory duties, have a range of wider impacts and outcomes.

Benefit	Likely beneficiaries				
	Industry	Authorities	Public	Treasury	Other
Avoids or reduces costs of court resolving dispute	•			•	
Reduces time lost waiting for dispute resolution	•				
Prevents unnecessary waste of affected goods	•		•		
Prevents undeserved penalties	•				
Protects and builds confidence in supply chains	•		•		
Safeguard against loss of deserved reputation	•				
Helps level playing field for reputable businesses	•			•	
Helps regulators to take account of uncertainties	•	•	•		
Informs development & interpretation of regulation	•	•	•	•	•
Insight/influence on sound regulation overseas	•	•			
Improved science underpins better regulation	•	•	•	•	
Translates & applies NMS innovation	•	•	•		
EU & global standardisation (e.g. cuts red tape)	•	•			
Develops skills and expertise that are in short supply	•	•		•	
Via LGC, benchmarks Government & private practice				•	
Focal point for UK scientific response to new risks	•	•			•
Correct duty paid on hydrocarbon oils				•	
Wider advisory remit e.g. efficient REACH compliance	•	•		•	•

Table 1: Benefits of the Government Chemist function

Dispute avoidance

Unauthorised GMO in flax seed

Often, timely expert advice can save costs by helping traders and enforcement authorities resolve scientific issues without recourse to the referee analyst. For example, formal samples of raw and milled flax seed (linseed) were tested for the presence of the unauthorised GM event CDC Triffid Flax FP967. Grounds for a dispute arose when the OCL obtained positive results, whereas those reported by the laboratory acting for the owner of the sample were negative. The Government Chemist advised that re-sampling to a case-specific plan, taking into account EU guidance[6], would be needed to establish defensible data. Government Chemist staff drafted a suitable protocol, incorporating statistical advice from LGC, in consultation with the NRL. The protocol was endorsed by the CRL (Ispra, Italy) and passed on to the FSA and the parties involved. This protocol covered the size of the formal sample, the number of subsamples needed to create it, and the selection of retail packs with regard to the way the trader's available stock of milled flax seed was arranged for storage. Our advice reinforced the quality of the investigation, and enabled the parties to resolve their differences without further intervention.

Our expertise in the analysis of ingredients derived from genetically modified organisms (GMOs) is underpinned by LGC's appointment as the NRL for GMOs in food and feed, a function which provides practical advice to UK stakeholders, and is supported by an active role in the European Network of GMO Laboratories and associated working groups.

Access to knowledge about current industry practice

Composition of commercial salmon products

EU law requires the quantitative declaration (QUID) of characteristic or distinguishing ingredients in the labelling of pre-packed foods. The percentages of high value ingredients such as meat and fish may be determined from the manufacturer's recipe in the first instance, while analytical methods are available to confirm that the contents of the mixing bowl stay consistent during regular production. Internationally recognised methods measure nitrogen content as a proxy for protein concentration, which is closely related to the quantity of meat or fish present. Interpretation of the analytical data relies on nitrogen factors established for individual species of food-producing animal. For species containing significant amounts of fat or oil – meat, and some fish – it is appropriate to use a fat-free nitrogen factor. Laboratories also need to allow for any nitrogen contributed by other ingredients in processed products such as fish cakes and fish fingers.

Nitrogen factors for salmon have been under scrutiny because:

- They were last published in 1973 for wild salmon, and may differ for farmed stock
- A fish ingredient recovered after filleting, known as 'salmon frame mince', may have a distinct composition
- The value of using fat-free factors requires clarification for this species.

We reported previously on a strategic sampling and analytical programme to generate nitrogen factors for salmon based on current industrial practice. A cluster of requests for information and advice on nitrogen factors prompted us to publish summary advice based on the knowledge emerging from this collaborative project.[7]

[6] Recommendation 2004/787/EC *on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003*

[7] Farmed Atlantic salmon: quantitative ingredients declaration - Government Chemist update on nitrogen factors for QUID calculations, 16 August 2010: accessible from www.governmentchemist.org.uk/News.aspx?m=2&amid=1063

A unique collaborator

Unapproved glazing agent in apples

In recent months, collaboration has been widely highlighted as a way of extracting more value per pound spent by government. The Government Chemist has a special relationship with Public Analysts and industry laboratories which reflects our interlinked statutory functions and obligations. It is a priority to share expertise, and collaborate more actively in areas of particular need, as shown by the following example.

Morpholine is used as a carrier and emulsifier for fruit glazing agents. Its use is permitted in some countries but, in the EU, there has been no application for approval, so this substance should not be present in food on sale in member states.

A port health authority identified morpholine after taking informal samples from an imported consignment of Granny Smith apples. A local authority subsequently took formal samples, and the Public Analyst confirmed the port health authority's finding. The food business operator disputed the Public Analyst's finding and, by agreement with the local authority, one formal sample was sent to the Government Chemist for a SEO pursuant to a suspected breach of the Food Additives (England) Regulations 2009. As it turned out, the owner later obtained further information from a supplier, accepted the Public Analyst's results, and agreed to destroy or re-export the affected apples, but the case crystallised concerns that no official method of analysis exists. A variety of approaches could be suitable, so, in collaboration with the Public Analyst involved in this case, we are comparing the merits of the main candidate technologies, including GC-FID, GC-MS, LC-MS with or without derivatisation of morpholine, LC-MS/MS, and high accuracy ToF-MS, in order to establish a validated method.

Responsive R&D to safeguard the UK

Illegal dye in spice commodity

Azo dyes are synthetic industrial colours, and suspected genotoxic carcinogens. Their use as food colour additives, at any concentration, is forbidden by the EU. To protect the consumer, food products need to be monitored and tested regularly for assurance that they are free from illegal contaminants. Any presence of banned colouring could lead to food recalls, so reliable, specific and sensitive methods of analysis are required.

Public Analysts and regulators became concerned when an established method for detecting illegal dyes produced an anomalously high screening test result for the azo dye dimethyl yellow in a turmeric product. The sample matrix was a difficult one, a polysorbate emulsified oleoresin (Figure 5). Public Analysts resolved the initial false positive result, but the matrix proved damaging to the highly sophisticated analytical system (LC-MS/MS) required to do so.

The matter was closed by the authorities. However the case presented some novel difficulties, and the FSA indicated that further investigative work would be welcome as a national alert had been narrowly avoided.

The Government Chemist's team demonstrated that substances from the oleoresin matrix interfered with the routine method, and developed a clean-up by liquid-liquid partition, gel permeation chromatography and solid phase extraction that could be safely applied to LC-MS/MS. We prepared mixtures of dimethyl yellow and turmeric oleoresin, and used them to show that the new method could detect the dye at concentrations as low as 50 µg kg^{-1}. We then tested the formal sample: we did not detect the dye. As it is quite possible that lower dye concentrations can be detected and quantified, we plan to extend the validation study.

Figure 5: **Extraction of dimethyl yellow dye from a complex oleoresin product.** The sample as received was a viscous liquid (glass beaker). After mixing with suitable solvents, any dimethyl yellow dye present is found mainly in the top layer (centre left). This extraction step is repeated, the top layers are combined in a large glass tube, and the solvents are removed by accelerated evaporation (centre right). The residue is redissolved and further purified by gel permeation chromatography (not shown) and solid phase extraction with silica (far right). Subsequently, the extract is again evaporated and redissolved, then transferred to an autosampler vial for analysis by LC-MS/MS.

Figure 6: Solutions containing accurately known concentrations of vitamins B2 (yellow), B6 (clear) and B12 (pink) are among the calibrators needed to make quantitative micronutrient measurements.

Underpinning better nutrition

Improved vitamin measurement

Providing a healthy diet depends on knowledge that appropriate amounts of vitamins can be had from the available foods, products and supplements. To advance modern measurement methods for vitamins, we:

- Arranged for three laboratories to compare measurements of four B-group vitamins, and the oil-soluble vitamins A and E, made on multivitamin tablets and capsules. To help identify the main sources of measurement uncertainty, the laboratories employed the same chromatographic media, conditions and standard materials. The results for the B-group vitamins were generally in good agreement, but those for the oil-soluble A and E less so. These data will inform further work to pin down the uncertainties
- Compared the ability of chromatographic media to separate the B-group vitamins (Figure 6), as a step toward a rapid LC-MS measurement method
- Developed a sensitive and accurate method for vitamin B9 in infant milk powder, incorporating an optimised enzyme digestion procedure.

Informing and protecting consumer choice

Meat speciation and probiotic food characterisation

While food businesses clearly need to consider cost when selecting ingredients, a 'race to the bottom' in terms of quality is not in the public interest. Fortunately, UK consumers have rights to know what they are eating; detailed labelling regulations are implemented in the context of the wider legal framework of the Food Safety Act 1990, notably section 15 which prohibits false or misleading description. Many consumers wish to avoid certain animal species, and improved analytical methods are needed to ensure that their requirements are respected. We continue to study the performance of selected molecular methods designed to determine the beef, pork, lamb, chicken and turkey content of foods. Expertise in isolating the animal DNA from complex samples prior to testing contributes to the quality of measurements made. Specificity has been greatly improved, and we have shown that the methodology is transferable to alternative laboratory instrumentation, further increasing the scope of approaches that food analysts can use.

Probiotic foods and supplements may confer benefit to the consumer, but the intrinsic value of such products depends on several properties of the added microorganisms – their identity, number, viability and metabolic status. A range of technical approaches is needed to determine all these properties with confidence. Our work focused on genomic sequencing. DNA is amplified from reference standards for common strains of probiotic bacteria using methods that target conserved regions of the genome. It is then sequenced and compared to validated DNA databases. Meanwhile, in June, LGC demonstrated a novel PCR-RFLP technique, able to differentiate strains of the priority food pathogen campylobacter. We aim to apply this approach to probiotic species too. These new DNA techniques complement existing methods for bacterial identification based on culturing and microscopy.

Minimising wider safety risks

Food contact materials

We have specific referee analyst functions under the Materials and Articles in Contact with Food Regulations, which aim to ensure that items such as packaging, processing machinery and kitchenware are safe and consumer-friendly. This is a broad area of responsibility, so to respond effectively if formal samples are received, we need intelligence of specific risks. We identified current priorities by reviewing recent incidents reported by a range of sources including RAPEX (the EU rapid alert system for consumer products) and RASFF, as well as trends in the development of food contact reference materials and interlaboratory proficiency testing activities. This resulted in a shortlist comprising six substances of concern: formaldehyde, bisphenol A, heavy metals, azo dyes and associated primary amines, phthalate plasticisers, and allergens. Alongside the network of specialised laboratories that support compliance with food contact law, we first plan to modernise methods of measurement for formaldehyde, while ensuring that LGC capabilities, including migration measurement and advanced mass spectrometry techniques, can be exploited to best effect.

Putting world class measurement science to work

Food allergens

The prevalence of food allergy appears to be increasing. For those who are susceptible, the ingestion of certain allergens can be fatal.

Directive 2003/89/EC, together with the UK Food Labelling Regulations 1996 as amended, requires disclosure in the labelling of all pre-packed foods formulated to include any of a list of 14 priority allergens. These are mainly complex biochemical entities, so FBOs, regulators, and indeed the Government Chemist need a range of technical approaches to maximise confidence in the measurements they make. ELISA is the established technique for trace detection, and DNA methods such as PCR are also routinely employed. More recently, MS methods based on protein determination have begun to be adopted by the allergen analytical community.

Research is ongoing to understand the minimum conditions, or threshold, for an allergic response. We expect the development of reference methods and materials containing known amounts of specific proteins to improve comparability between measurements, helping to ensure that both research outcomes and regulatory decisions are soundly based.

Reference methodologies

In collaboration with the Institute of Food Research (IFR), LGC is working on the development of reference methods for food allergens and is establishing the feasibility of providing realistic laboratory quality control materials, informed by clinical observations on sufferers.

Many priority food allergens are detected on the basis of known protein constituents, for example, casein and β-lactoglobulin for milk. Any protein targets unique to the foodstuff may be used to infer the presence of the foodstuff itself. Reliable knowledge of the levels of these proteins in suitable reference materials would be a significant step toward more quantitative methods of analysis.

Methods for the accurate quantification of proteins in pure solvents are well established at LGC, but their application to food samples is much more complex. We have successfully demonstrated a reference method for the quantification of protein allergens using egg lysozyme protein in wine. Wine offers a relatively challenging model system, and lysozyme is potentially present owing to the use of egg white as a fining agent. First we generated and characterised peptide fragments of the lysozyme protein by LC-MS. We then used an iterative IDMS procedure to refine the concentration measurements, aiming to improve the detection limit to below one part per million whilst maintaining an uncertainty of less than 10%.

Complementary techniques

We led a collaborative project to develop a sensitive and accurate DNA-based screening method for the simultaneous detection of many allergens in food, including almond, Brazil nut, cashew, hazelnut, macadamia nut, peanut, pecan, walnut, and sesame seed. When each collaborator analysed eight processed food materials without knowing their allergen content, the applicability of the new DNA approach was conclusively verified. We began the translation of this technique to a more efficient and cost effective PCR-CE platform already used by many Public Analysts.

Although ELISAs are the workhorse technique for allergen detection, test kits from different manufacturers can yield differing measurements, and the results may not be straightforward to compare. Further, there are few published validated methods for ELISA. Through the Allergy Cluster of the IFR Food and Health Network, led by Professor Clare Mills, LGC collaborated with ELISA kit manufacturers, industry labs and Public Analysts in a preliminary ring trial to compare the performance of detection kits for egg and milk using samples representing complex processed foods. These materials had also been used in clinical studies. The trial confirmed that our performance compared favourably with other leading laboratories and demonstrated that convergence of ELISA results was an achievable objective. We will take part in the full ring trial in 2011.

We also plan to compare PCR and ELISA methods for chocolate containing walnut, a priority allergen. As a first step toward robust DNA-based measurements on real samples, we demonstrated the quantitative potential of a commercially available PCR kit by constructing a calibration curve using blends prepared from known proportions of walnut and chocolate.

Innovation to evaluate emerging technologies

Nanoparticles

The unique properties of nanomaterials are creating new hopes and opportunities across manufacturing industry, from food to pharmaceuticals and from coatings to cosmetic products. To make the most of the benefits to society, while minimising any potential for harm, many regulators are moving toward hazard and risk assessment on a product by product basis. Internationally, there is growing awareness that tailored chemical datasets will be needed to assess the hazards of such materials.[8] Nanoscale structures can be highly engineered so identifying tiny quantities of, for example, impurities or surface treatment chemicals may be critical. To evaluate the life cycles and possible effects of nanomaterials, samples taken from finished products, waste, environmental media and biological fluids will also need to be analysed.

All the usual challenges of working with complex sample types such as food and environmental media are redoubled because of unknowns posed by the novel materials themselves. A key issue is that many nanoparticles tend to aggregate, adhere to other substances, or break down, making them difficult to extract, isolate and describe quantitatively. The analytical community is being forced to reappraise all potential measurement options.

In collaboration with Exeter University, LGC's National Measurement Institute laboratories first applied ICP-MS to determine dissolution rates in hypothesis-driven research on the toxicity of silver nanoparticles, but a combination of techniques is required to provide more extensive data. Field flow fractionation (FFF), an established family of techniques for separating nanoscale particles by size, relies on simple physical forces such as laminar and cross flow, and minimises artefacts of analysis that could confound the already complex datasets obtained from samples containing engineered nanomaterials. LGC's National Measurement Institute laboratories coupled a market leading FFF system with the existing ICP-MS analyser to provide size-resolved data on the elemental composition of nanoparticles (Figure 7).

Within the food industry, nanotechnologies could be exploited to develop intelligent packaging that cares for its contents, and make healthy eating options more attractive to the consumer. LGC aims to establish a reference methodology for characterising the particle dose and dissolved metal content in preparations of inorganic nanomaterials just before their biological effects are determined using cell-based testing systems. The methods will be extended to extract and characterise nanoparticles added to food or supplements, or introduced through packaging, in terms of size and elemental composition.

Figure 7: Volker Nischwitz is using a state-of-the-art field flow fractionator with ICP-MS to perform size-based element speciation on engineered nanoparticles.

[8] Organisation for Economic Co-operation and Development, Guidance manual for the testing of manufactured nanomaterials: OECD's sponsorship programme, first revision, 2 June 2010: www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2009)20/rev&doclanguage=en

Knowledge transfer

The Government Chemist disseminates knowledge widely, including to regulators, academics, policy makers, the food industry, and professional bodies. Knowledge transfer occurs along traditional channels including scientific correspondence and discourse, but also through specialised working groups and collaborative events.

Dissemination of casework

We continued to explain and interpret our casework to a wide range of stakeholders, for example at the highly regarded Association of Port Health Authorities (APHA) conference in Belfast. Here we presented our case files on food forensics to around 70 delegates including Port Health Officers and FSA officials.

Sharing knowledge of priority science areas

In order to maintain Government Chemist credibility in GM food and feed analysis, we actively collaborate and participate in national and international harmonisation and standardisation activities. As part of this work, Malcolm Burns was invited to join an EU working group on method verification, aimed at providing practical guidance for the assessment of validation parameters associated with GMO analysis.

In line with our multidisciplinary research on food allergen detection, in July we hosted a meeting of the Allergy Cluster Group convened by the Institute of Food Research, bringing together research organisations, bioanalytical companies, food manufacturers, and regulatory authorities to discuss the latest developments. A more quantitative approach to the control of allergens may soon be possible because the evidence base is expanding rapidly.

Periodic participation in expert fora, such as the FSA Sampling and Co-ordination Working Group, the Local Government Regulation Food Standards and Labelling Focus Group, the Food Law Group, and the IFST Technical and Legislative Committee, enables us to address analytical measurement issues in the light of related stakeholder concerns. For example, drawing on our own horizon-scanning activities we were able to augment the knowledge base of several Official Food Control Laboratories in areas as diverse as additives in root beer, water retaining compounds in chicken and REACH compliance. We are helping to revise an IFST information statement on dietary fibre, and contributing to the organisation of a Local Government Regulation web-based 'Community of Practice'.

International collaboration

The Republic of Korea returned our recent visit, experts from industry and academia gathering at LGC's Teddington headquarters to discuss requirements, research strengths and issues in food safety, including the control and rapid detection of pathogens and contaminants. We contributed to EU-funded advice on requirements for a Georgian reference laboratory, and have been invited to further this project by visiting the proposed facilities. Collaboration with international experts enables us to gain a broader understanding of measurement challenges affecting regulators and industry worldwide.

Training

The expertise acquired by the Government Chemist through the referee function is put to good use in providing training for practising analysts. The cornerstone of this is the annual intensive one-week residential course we organise at Reading University. The course aims, in a two-year cycle, to touch on most of the syllabus for the Mastership in Chemical Analysis (MChemA), the statutory qualification required to practise as a Public Analyst. The MChemA is awarded by the Royal Society of Chemistry following a three-part series of examinations.[9] The course is the only dedicated formal teaching available to candidates and is pitched at postgraduate level. It has to meet a range of needs – affording the novice an opportunity to begin to get to grips with the syllabus, while enabling the experienced analyst to discuss finer points of practice with experts. The course is also viewed as a valuable opportunity for analysts who may not intend to take the exam to update their current experience, and perhaps consider further study.

Thirteen analysts attended this year's course, mainly from public sector OCLs (Table 2). Vocational sessions complemented a wide scientific programme which included:

- Food ingredients, contaminants and toxicology
- Industrial processing and food hygiene
- Food contact materials, articles and packaging
- Drinking and bottled waters
- Microbiology, plant microscopy, and foreign body identification
- Analytical quality assurance and measurement uncertainty.

Practical sessions were very well received, and delegates especially benefited from interactive sessions on food labelling.[10]

Food control laboratories (OCLs)		Private laboratories
Local authority	Private sector	
11 (84.6%)	2 (15.4%)	0

England	Scotland	Wales	Northern Ireland
8 (61.5%)	4 (30.8%)	1 (7.7%)	0

Table 2: Distribution of delegates attending the MChemA residential course (April 2010).

[9] Holders of a recognised MSc are exempt from Part A.
[10] For details, see www.publicanalyst.com/Training_/Training_Courses_2010/Reading_2010/Reading_Course_April_2010_Report.pdf

Government Chemist conference

This year's Government Chemist dissemination event, *Setting Standards in Food Analysis,* was a full two-day conference held at the prestigious Churchill Museum and Cabinet War Rooms in central London. Arranged in partnership with FSA, Leatherhead Food Research, Campden BRI and LGC Standards, it attracted a record-breaking total of 171 attendees.

Derek Craston's keynote speech outlined the Government Chemist function and its synergy with the UK National Measurement System, then provided foresight of emergent trends and challenges facing food science. This was followed by presentations on casework completed over the preceding year, highlighting best practice and lessons learnt which may help traders and enforcement authorities. The second day featured a session chaired by LGC Standards covering the need for, and use of, reference materials and proficiency testing schemes. Alongside presentations by senior figures from the food and drink sector, experts shared the latest progress in exploiting technologies from microscopy to proteomics. Almost every OCL in the UK was represented, while the growing popularity of this annual event with businesses, academics and professional bodies was heartening.

As referee, we made particular efforts to 'complete the consumer protection triangle' by securing full participation in the *Setting Standards* event from regulators and the regulated business communities. We were delighted to receive highly positive feedback from delegates and partner organisations.

Michael Walker explains dispute avoidance and resolution procedures at a plenary session of the dissemination conference.

Prioritising future work

Strategic priorities

Our longer term scientific priorities are set by the National Measurement Office on the basis of expert advice from the Government Chemist Working Group. In December the NMO organised a decision conference, applying a prioritisation tool established in BIS which provides a framework for the experts to score project proposals against agreed impact criteria, and to discuss and refine their results. The criteria were:

- Need for dispute resolution capability
- Support for standards, regulation, compliance and enforcement
- Scientific merit
- Economic benefit
- Impact on the quality of life, including human health, pollution, consumer choice, public concern, and animal welfare.

The decision conference recommended that the following projects be funded between 2011 and 2014:

- Improved analytical methods for food allergens, and more meaningful interpretation of the results
- DNA methods to detect food fraud, including more flexible speciation techniques with a new focus on herbal food supplements
- Methods to determine vitamins, tackling measurement issues linked to the oil soluble and B-group substances
- Method validation for illegal dyes in difficult sample types, for example oleoresins and those that contain surfactants
- Publication of robust methods for the determination of aflatoxins
- Further collaborative work to support future scientific and regulatory decision making by smarter use of the available data on risk-related alerts and product recalls.

Responsive priorities

Evidence of risks identified by regulators in the global food supply network gives us some indication of the potential upcoming demand for referee analysis, and thus the areas in which scientific capabilities need to be rapidly reinforced. We continually collate data on specific regulatory alerts, and on action to recall products from distribution and retail, as they are gathered by major authorities and databases: the FSA, the Food Safety Authority of Ireland, EFSA and RASFF, the US Food and Drug Administration and the Food Safety and Inspection Service of the US Department of Agriculture, and the Canadian Food Inspection Agency.

The patterns of non-compliance with food and feed legislation, its detection and responsive action by one or more authorities are complex. LGC is collaborating with Kingston University to develop more powerful data mining tools, using our quarterly reports, which could provide an objective basis for prioritising scientific capability building as well as official controls (Figure 8). Authorities and the food industry can take account of these outputs in deciding the distribution of monitoring between countries of export, times of the year (for seasonal produce), and types of food contaminant.

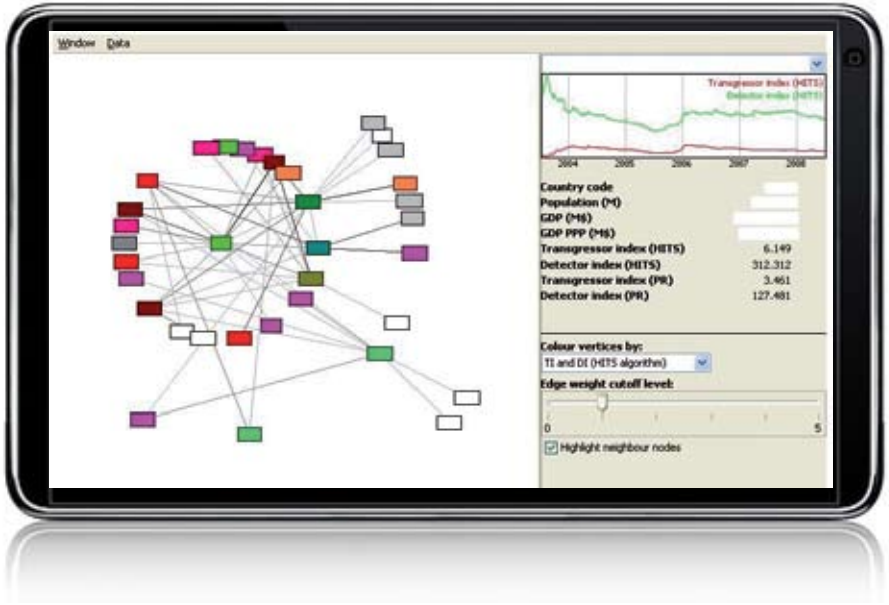


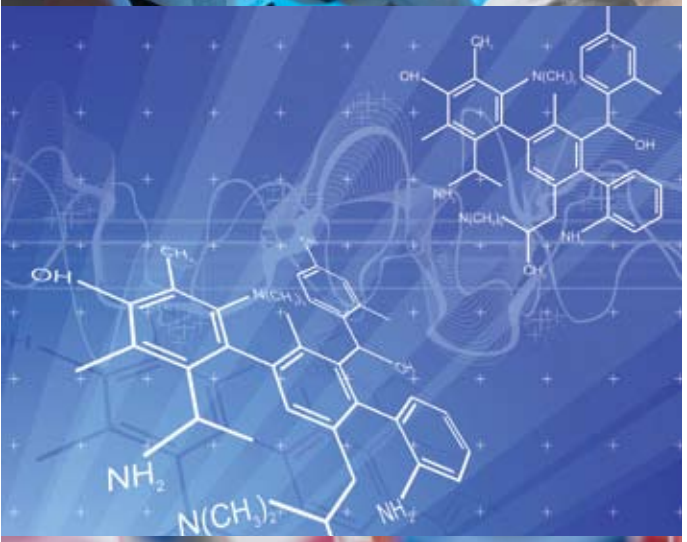
Figure 8: **Interactive network visualisation tool for analysing patterns of official reporting on non-compliant food or feed.**

Left: Snapshot of network map for a selected time point (country names omitted for clarity). The links between exporting and reporting nations are weighted according to the number of alerts.

Top right: Non-compliance (transgressor) and reporting (detector) statistics over time for a selected nation.

Centre right: Basic statistics and transgressor/detector indices calculated using two algorithms for the selected nation.

Bottom right: Facility to select the algorithm and the reporting frequency threshold (scale of 1-5) for the snapshot.



4 The wider advisory function

In addition to our statutory functions, we are responsible for advice to Government and the wider community dependent on analytical science. Alongside responsive and informative advice on a broad range of policy and regulatory developments, we continued to provide more proactive scientific support for the chemical and chemistry-using industries.

Addressing scientific issues with stakeholders

We progressed dialogue with stakeholders through a range of appropriate channels, briefed the Parliamentary and Scientific Committee on the Government Chemist function, and continued to follow developments in the UK Chemicals Stakeholder Forum and the Advisory Committee on Hazardous Substances closely. We provided further advice by responding to official consultations, including both strategic and more focused sectoral papers (Box 3). There was frequently much to commend in the proposals we reviewed. Some of the key issues which surfaced or resurfaced were:

- Benefits of science-based dispute resolution, which could be applied more widely to underpin lean, effective regulation. The delivery of the Government Chemist function at arm's length from both government and industry as a paradigm for independent scientific advice
- Flexible, innovation-friendly regulation allowing the adoption of modern, high performance analytical methods, such as sensitive LC-MS and in vitro bioassays. The complementarity between low cost, high throughput technologies and gold standard methods that provide added confidence
- Cost control by risk-based prioritisation and the valid use of existing data. The comparative roles of measurement, modelling and supply chain documentation in furnishing objective evidence for legislators and regulators
- Need for a balanced picture of scientific and technological uncertainties, including those contributed by the industrial processes being sampled. And within laboratories, adoption of rigorous sampling, control and standardisation procedures to minimise measurement uncertainties
- Role of analytical measurement in maximising the cost-effectiveness of research, opening up new markets, and securing global trade. Recognition that specialised scientific skills are a precondition for sustainable UK industries
- Value of a co-ordinated approach involving all appropriate experts when scientific advice can strengthen the national contribution to European legislative and regulatory decision making.

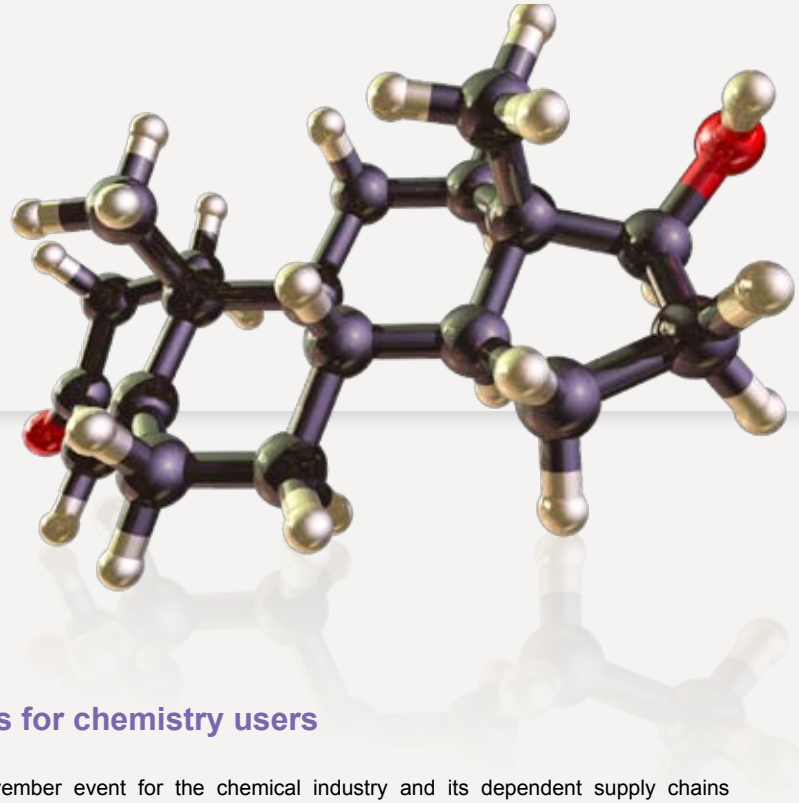
Alongside formal communication, we took up several opportunities to discuss key issues with senior Government officials. Over time this may help to ensure that advice on analytical measurement science is more widely understood and considered, as well as enabling us to gain balanced feedback on our contributions.

Box 3: Our public consultation responses

DECC	Guidance notes for the sampling and analysis of produced water and other hydrocarbon discharges
Defra	Contaminated dredged material in ports and marinas
Environment Agency	Guidance for spreading waste on land – how to comply with your environmental permit
European Medicines Agency	The European Medicines Agency Road Map to 2015
FSA	The Feed (Sampling and Analysis and Specified Undesirable Substances) (England) Regulations 2010
FSA	The FSA Foodborne Disease Strategy 2010-15
FSA	Proposal to amend Regulation (EC) No. 2074/2005 with regard to recognised testing methods for detecting marine biotoxins in live bivalve molluscs
Government Office for Science	Guidelines on Scientific Analysis in Policy Making – a consultation by the Government Chief Scientific Adviser
NMO	Review of the OIML Recommendation on atomic absorption spectrometer systems for measuring metal pollutants in water

Underpinning the measurement of trace elements in environmental media

In the environment, arsenic, like other trace elements, exists in a variety of chemical species which differ widely in their effects on biota and human health. In response to interest expressed by the GCWG and the Environment Agency, we verified that a method combining LC and ICP-MS could identify the key arsenic species in a landfill leachate reference material. This preliminary study could be extended by developing a quantitative procedure and using it to improve the availability of characterised quality control materials that are well matched with the properties of environmental samples. The underlying technique could be applied to determine the chemical forms of other trace elements in similar media.



Exciting times for chemistry users

Our established November event for the chemical industry and its dependent supply chains coincided with the run-up to two important regulatory deadlines. High-tonnage and certain high-hazard substances manufactured or imported in the EU had to be registered in accordance with REACH[11] by 30 November 2010. Meanwhile, hazardous substances placed on the market, regardless of quantity, were due for notification to the Classification and Labelling Inventory by 3 January 2011 under the CLP Regulation[12].These regulatory processes were closely linked, and entailed a number of shared scientific issues. To ensure that we could place the science fully in the context of European Chemicals Agency (ECHA) dossier submission requirements and obligations to communicate data in supply chains, we invited the Chemical Hazards Communication Society (CHCS) to collaborate. We jointly delivered *Science for REACH and CLP compliance* at LGC's Teddington laboratory on 4 November to an audience of over 75, including scientists as well as decision makers keen to understand the nature and quality of the data that regulators would require.[13]

The event opened with a presentation by ECHA's Substance Identity and Data Sharing Unit. The starting point for REACH is a clear definition of the regulated substances. Each company is responsible for providing adequate spectra, chromatograms and a full account of the laboratory work. Many REACH substances are complex mixtures, so, unless the composition and uncertainties are specified carefully, the legislation will lose its edge and be costly to keep on track.

[11] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, as amended. Consolidated (non-official) text: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20090627:EN:PDF

[12] Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures, as amended. Original act: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF

[13] For further information, see: www.governmentchemist.org.uk/Events.aspx?m=93&amid=1087

The Government Chemist's address outlined the principles of sound data generation, and the latest technologies for determining the identity, form, amount, effects and fate of chemical substances. The Chairman of CHCS spoke about the hazard and labelling implications of impure and mixed substances. LGC disseminated expertise in strategies for assessing the purity of organic chemicals. Indirect purity assessment relies on combining complementary analytical information, including data on thermal behaviour (Figure 9). Further technical approaches were explored through case studies on aldrin, a banned insecticide, and Solvent Yellow 124, a fiscal marker for liquid fuels, the latter illustrating a direct purity assessment strategy based on quantitative nuclear magnetic resonance (qNMR).

Delegates enjoyed visiting the National Measurement Institute laboratories at LGC, and units specialising in hydrocarbon oils, consumer safety, and pesticides. After the main programme, special interest groups persisted late into the day. LGC's Head of Consumer Safety shared scientific insights with public and private sector experts on REACH restrictions affecting certain substances and articles, such as heavy metals in jewellery and solvents in sticky tape. An industry-led group pursued the vexed question of how to classify substances when the available supply sources contain differing impurities. The event helped a wider range of opinion formers to recognise that sound science is needed to deliver the environmental, health and welfare benefits that the public want from REACH and CLP at a fair and sustainable price.

Figure 9: Raquel Gonzalez-Rodriguez uses this new thermogravimetric analyser as a key plank of LGC's multi-technology strategies for chemical purity assessment.

What's in a name?

The analytical identification and naming of substances are closely intertwined. Unless we define what we are looking for, how can we measure it?

The Government Chemist has been represented on the IUPAC Advisory Committee to Chemical Nomenclature and Structure Representation Division since its inception in 2002. This work is complemented at UK level by long-standing membership of the RSC Committee on Standards in Nomenclature, Terminology, Units and Symbols.

The IUPAC committee progressed a major review of the recommendations for naming organic compounds this year, although a number of outstanding issues remained. RSC committee business touched on the future role of software-based naming, it being observed that expert knowledge will remain necessary to ensure that names make sense to practical scientists whilst fulfilling legal requirements. We continued to advise on the precise naming of regulated substances or groups of chemicals as legislation was updated to reflect the latest policies and concerns, for example to control emerging drugs of abuse or protect consumer safety.

A highlight was the naming of element 112 as copernicium (Cn). We voted on this historic decision by special invitation.

Clarifying the measurement implications of REACH and CLP

Over recent years, we used industry-led case studies to develop advice about the emerging analytical implications of REACH, increasingly focused on the requirements faced by duty holders and the consequences for scientists supporting them. In July 2010 we issued more systematic advice, *Questions and answers on measurement implications of REACH and CLP*. This Q&A document concentrated on substance identity requirements for registration, drawing on our experience, ECHA publications and further industry contact.

The need for the Q&A arose from the fact that the analytical implications of REACH are dispersed across many official publications. These include the original series of technical guidance documents that were prepared in tandem with the REACH Regulation itself, presentations to stakeholders, software user manuals, and updates issued in advance of the 2010 registration deadline. The Q&A was also driven by the need to interpret official guidance in a scientifically sound yet pragmatic way, taking into account feedback emerging from companies that had already attempted to submit dossiers. We sought to include practical advice, such as on planning ahead to avoid duplication, information that laboratories should record, and how to communicate analytical data effectively. We considered possible scientific implications of CLP more briefly in the Q&A, recognising the close links with REACH requirements.

At the outset, we emphasised that development of the Q&A would be dependent on feedback from stakeholders. We issued an updated version in November after incorporating a first round of comments which in our view reflected acceptable practice.[14] The comments focused on natural products, additives, aqueous solutions, and impurities. REACH has further scientific implications which can be expected to surface during the evaluation of registration dossiers, and to lead to refinement of guidance as the 2013 registration deadline for mid-tonnage substances draws nearer. Subject to feedback, we may therefore extend the Q&A to cover topics such as nanomaterials, crystalline forms, the polymers exemption, substances in articles, strictly controlled conditions for chemical intermediates, and measurement to support hazard and exposure assessment.

[14] Questions and answers on measurement implications of REACH and CLP. November 2010: www.governmentchemist.org.uk/Generic.aspx?m=77&amid=1055

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Glossary

See the International Vocabulary of Metrology[15] for the current definitions of terms used in measurement science.

aflatoxins	mycotoxins produced by certain *Aspergillus* moulds that can grow on food or feed unless it is properly stored
Agricultural Analyst	agricultural analyst appointed under Section 67 of the Agriculture Act 1970
analyte	constituent or property which we desire to determine by analysis of samples
BIS	Department for Business, Innovation and Skills
BSI	British Standards Institution
CE	capillary electrophoresis: family of high performance techniques that use narrow-bore fused-silica capillaries to separate charged substances in an electric field
CEN	Comité Européen de Normalisation (European Committee for Standardization)
CHCS	Chemical Hazards Communication Society
CLP	Regulation (EC) No 1272/2008 *on classification, labelling and packaging (CLP) of substances and mixtures*, as amended
Codex	Codex Alimentarius - international system of food standards, codes of practice, guidelines and other recommendations
CRL	Community Reference Laboratory
DECC	Department of Energy and Climate Change
Defra	Department for Environment, Food and Rural Affairs
derivatisation	chemical modification of a substance, typically without changing its core structure, for example to facilitate measurement
determination	we use this term broadly, to mean qualitative analysis (detection or identification), quantitative measurement, or both
digital PCR	PCR variant based on determining presence or absence of a target DNA sequence in each of many small subsamples
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
ELISA	enzyme-linked immunosorbent assay (a type of immunoassay)
FBO	food business operator
FID	flame ionisation detector - a device that is sensitive to most organic compounds
fiscal marker	chemical marker or dye added to make the tax status of fuel evident
FSA	Food Standards Agency
FT-ICR-MS	Fourier transform ion cyclotron resonance mass spectrometry
GC-FID	gas chromatography with flame ionisation detection
GC-MS	gas chromatography-mass spectrometry
GCWG	Government Chemist Working Group

[15] International Bureau of Weights and Measures, International vocabulary of metrology - basic and general concepts and associated terms (VIM), Third Edition, JCGM 200:2008, 2008: www.bipm.org/utils/common/documents/jcgm/JCGM_200_2008.pdf

Glossary

gel permeation chromatography	size-based separation technique in which the progress of smaller molecules or particles through a column of porous material is slower because they penetrate the pores more fully
genome	one full set of an organism's DNA, containing one copy of each gene
genotoxic carcinogen	substance which can damage genetic material and cause cancer; Regulation (EC) No 1881/2006 *setting maximum levels for certain contaminants in foodstuffs* implies that no level can be considered safe
ICP-MS	inductively coupled plasma mass spectrometry – a modern technique for determining the chemical elements in a sample
ICP-OES	inductively coupled plasma optical emission spectrometry
IDMS	isotope dilution mass spectrometry; a technique capable of outstanding accuracy
IFST	Institute of Food Science and Technology
immunoassay	measures or detects a substance by means of its reaction with antibodies
IRMM	JRC Institute for Reference Materials and Measurements
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JRC	European Commission Joint Research Centre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS/MS	liquid chromatography-tandem mass spectrometry
LG Regulation	Local Government Regulation (formerly LACORS)
liquid-liquid extraction	extraction of either the required or unwanted components of a dissolved sample through intimate contact (e.g. shaking) with an immiscible solvent
migration	transfer of substances from a material into a solution or gas under controlled conditions that simulates normal use
MRPL	minimum required performance limit in animal products (see Decision 2002/657/EC *concerning the performance of analytical methods and the interpretation of results*)
MS	mass spectrometry
MS/MS	tandem (two-stage) mass spectrometry; ions selected from the first analysis can be fragmented for further study in the second
mycotoxins	toxins produced by moulds, which can grow on poorly stored food or feed
NMI	National Measurement Institute
NMO	National Measurement Office
NMR	nuclear magnetic resonance spectroscopy
NRL	National Reference Laboratory
OCL	official control laboratory
OES	optical emission spectrometry: determination of chemical substances by the characteristic wavelengths of light they emit when 'excited', e.g. heated

Glossary

OIML	Organisation Internationale de Métrologie Légale (International Organization of Legal Metrology)
PCR	polymerase chain reaction, a technique used to amplify DNA sequences so that they can be identified
peptide	chain consisting of amino acids (the chemical building blocks for proteins); may be formed by fragmenting a protein
proficiency testing	analysis of portions of an independently prepared sample by a number of laboratories, and assessment of their performance from the results returned
Public Analyst	analytical scientist appointed under statute by UK local authorities to provide an official food or feed control function and scientific advice for the enforcement of many acts of Parliament
qNMR	quantitative NMR, suitable for measuring concentration or purity because many sources of uncertainty have been addressed and minimised
RASFF	EU Rapid Alert System for Food and Feed
REACH	Regulation (EC) No 1907/2006 *concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals*, as amended
referee function	duty of the Government Chemist under acts of Parliament to provide impartial analysis in the resolution of disputes relating to the enforcement of regulation
RFLP	restriction fragment length polymorphism: size variation between DNA fragments that have been excised by the same specific (e.g. enzymic) process
ribosomal DNA	DNA encoding parts of the ribosome (the cell component that translates the genetic code into proteins)
riffle splitter	device comprising an array of alternately oriented channels, used to create equivalent portions of a granular sample
RSC	Royal Society of Chemistry
SEO	supplementary expert opinion in the context of Regulation (EC) No 882/2004 *on official controls*, Article 11(5)
SME	small and medium-sized enterprise
solid phase extraction	sample traverses a short column of a selected sorbent which effects separation by retaining either the analytes or unwanted components
speciation	(depending on context) analytical determination of either the combined forms of a chemical element, or the biological species present
surfactant	surface-active agent: substance, such as a detergent, emulsifier or wetting agent, that functions by reducing surface tension
thermogravimetric analysis	measurement of the amount and rate of weight change with temperature under controlled conditions
ToF	time of flight: the time taken for particles such as ions to travel a fixed distance is measured, and used to identify them

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