ANALYTICAL MEASUREMENT AND REGULATION: The Role of the Government Chemist

Nick Boley
Technology and Policy Consultant to the Government Chemist
LGC, Teddington

The role of the Government Chemist was established in 1842 to detect adulterants in tobacco for Her Majesty's Customs and Excise. Since then, the Government Chemist's function has developed with the responsibility to investigate a range of samples and problems on behalf of Government authorities and the public. For nearly half of the 20th Century the Government Chemist existed as a free-standing independent department.

Today the Government Chemist has a statutory role under several Acts of Parliament, including the Food Safety Act, the Agriculture Act and the Medicines Act. Analyses are carried out to resolve disputes between regulatory authorities and traders, and a programme of research develops robust analytical methodology to underpin this work. Dr Derek Craston, the current Government Chemist, is supported by a team of internationally reputable measurement scientists who are on call when queries arise.

The Government Chemist also has an important role within Government. Following privatisation in 1996, an agreement between the Secretary of State for Trade and Industry and LGC secured the continuity of our 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 of matters of policy and of standards and of regulations". This recognised the importance of chemistry and related sciences in many sectors and products within the UK economy. Today the work of the Government Chemist is funded by the National Measurement Office within the Department of Business, Innovation and Skills.

The advisory function is delivered by responding to Government or by publishing consultations, where analytical science plays an important role. These provide information to a broad range of stakeholders who have an interest in developing policy, legislation, and standards on chemical measurement needs associated with regulation. The advisory function also looks at emerging issues requiring new regulation and analytical measurement, and highlights paths to be taken. Small research projects are commissioned in areas of emerging interest, such as the separation of toxic nanosilver from ionic silver. Nanosilver is used as an antimicrobial agent in socks which leaches out during washing and enters waste water streams or to investigate contaminants in carbon dioxide streams in carbon capture and sequestration applications.

A close interaction with policy makers is critical to the Government Chemist role. We therefore recognise the need to build strong relationships with relevant Departments and Agencies to help focus our activities.

It is clear from the activities of the Government Chemist that analytical measurements are important in the development and enforcement of legislation and regulation. Where regulation needs analytical measurements for effective enforcement there is a clear link between the development of regulations and the analytical methodology available. **A regulation that cannot be effectively enforced using existing widely available analytical methodology represents poor regulation.** This is true regardless of whether enforcement would be by an official laboratory, or self-declaration from industry carrying out measurements in-house, and applies equally to UK and EU legislation.

UNDERSTANDING THE MEASUREMENT IMPLICATIONS OF REGULATORY CHANGE

An example of where regulation and analytical measurement capability are potentially out of step comes from the EU's Water Framework Directive (WFD). Discussions are on-going regarding the addition of pharmaceutical products – specifically 17 β-estradiol (E2), 17 α-ethinylestadriol (EE2) and diclofenac – to the list of controlled toxic substances under the WFD. The proposed maximum levels to be permitted in water are extremely low (0.27 parts per trillion (ppt) for E2 and 0.035 ppt for EE2), and the challenge for analytical laboratories in being able to measure these substances accurately and reliably at these levels is huge. The European Commission's Directorate General for the Environment has stated that member states need to solve this problem themselves, effectively distancing themselves from the technical measurement issue. In our opinion, this represents poor legislation, with a stringent measurement requirement being set with apparently no regard for the practicalities of enforcement. **If policies set limits that cannot be effectively monitored, this calls into question the limits and the policies themselves.** It would be preferable initially to set levels commensurate with measurement capability, and commit investment into R&D to lower limits of detection to the desired level, leading to a subsequent downward revision of the limits.

The situation is similar with allergens in foods. There has been an increase in recent years in the percentage of the population who present themselves with a food allergy. For many of these people only a tiny concentration of the allergen is needed to provoke a severe allergic reaction. These levels of

allergens are extremely difficult to measure accurately. Although there are many test-kits on the market, their sensitivity and specificity are often insufficient. Some laboratories, including LGC, are working to improve existing methods and developing new methods based upon liquid chromatography linked to mass spectrometry (LC-MS) for proteins, and DNA based approaches. These developments will enable food allergens to be measured more accurately in support of emerging, and necessary, legislation.

Another area where measurement capability needs to keep pace with developments in regulation, as well as the fast rate of innovation in manufacturing and applications, is in the field of nanomaterials. **The recent proposal from the European Commission for a definition of a nanomaterial had something of a mixed reception.** Some scientists believe that a nanomaterial should not be defined solely by its size, but should include its functionality. Our view is that verifying a material is or is not a nanomaterial on the basis of functionality is not straightforward, and can be open to interpretation.

The proposed definition of a nanomaterial is "a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm." **Experts in the field of nanomaterials may debate whether the defined parameters are or are not appropriate, but at least this definition is measurable.** Analytical methodology has advanced over the past few years, enabling both the size and the number of nanoparticles to be measured. This makes the proposed definition and associated regulations on nanomaterials enforceable.

ENSURING RELIABLE MEASUREMENT

One recurring theme over the past year has been the significant burden of regulation for industry, and the need to ensure regulation is simple and effective. This is particularly pertinent where laboratories in, or engaged by, manufacturers are carrying out important analytical measurements to demonstrate compliance with legislation or regulation. **"Self-regulation" removes the need for time consuming and costly controls by third party regulators, but should be implemented with care.**

A good example of this is for manufacturers of items which are covered by the Restriction of Hazardous Substances (RoHS) directive. Manufacturers self-declare that their products comply with the directive, and do not contain any of the restricted substances above the prescribed limits. But how can we be certain that these measurements are of sufficient accuracy? We are fortunate in the UK that measurement laboratories, in all sectors, have a strong quality ethos, and that there is a national body which is able independently to review the quality of laboratory measurements – UKAS, the United Kingdom Accreditation Service.

Any laboratory making these important measurements in support of regulation can apply to become accredited to the international standard ISO/IEC 17025 for the measurements of interest. To gain, and maintain this accreditation, companies undergo assessment and periodic audits by UKAS, which demonstrate impartially and independently the quality of the laboratory's procedures, and therefore confer confidence in the measurements. Our advice, when responding to consultations, has often included reference to assuring the quality of measurements needed to support proposed legislation. Accreditation is an effective way to achieve this, along with the use of appropriate reference standards and methods.

REDUCING THE NEED FOR ANIMAL TESTING

Complementary to analytical testing is the field of toxicity testing. REACH (Registration, Evaluation, Authorisation & restriction of Chemicals) legislation requires the identification of substances of very high concern and their progressive replacement by suitable and viable alternative substances or technologies. Although it is recognised that this would require the generation of additional toxicological data which would necessitate some additional tests on animals, **REACH clearly states that animal testing should only be carried out at a last resort, and that companies have an obligation under EU law not to test on animals.** Many observers believe that the rate of reduction of animal testing in support of legislation such as REACH and the EU Cosmetics Directive is insufficient, is happening too quickly and runs the risk of making the EU uncompetitive in the cosmetics sector. One of the most significant obstacles is the availability of alternative tests which can provide the same information, with the appropriate confidence level as animal tests. One area showing promising developments for alternative *in-vitro* testing, hence excluding the need for animals, is the field of toxicogenomics. Researchers at LGC have been developing reliable *in vitro* assays that may soon be suitable for regulatory toxicity risk assessment.

Toxicogenomics merges toxicology with genomics and bioinformatics to investigate effects of chemicals in model biological systems. While this has been known over the past 10 to15 years in the pharmaceutical and chemical industries, recent improvements in microarray technology have made measurement platforms more robust, thereby offering a suitable alternative to costly and ethically provocative animal testing. Developments such as these are important in helping the chemical industry carry out toxicity testing more efficiently and effectively, saving industry considerable sums of money. Regulators also need to promote these novel tests and, where appropriate, accept their data, so that animal tests become the last resort when all else fails.

BRINGING ANALYTICAL SCIENCE TO GOVERNMENT

The above examples illustrate that **a close liaison between regulators, legislators and measurement scientists is critical for successful regulation.** This message echoes the enquiry by the House of Lords Scientific and Technology Committee last year into the role of Chief Scientific Advisors, which the Committee stated they would like to see strengthened.

The work of the Government Chemist advisory function provides a unique and valuable resource for Government Departments and Agencies, including in the devolved administrations, in any field where analytical measurement is required to support legislation and regulation. Government Departments and Agencies are key stakeholders in the work we carry out, and we welcome any feedback on how we might improve our services.