

RMs and regulation: putting the cart before the horse?

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I am convinced that those who write regulations depending on reliable measurement of some sort of analyte, particularly when in a biological, environmental or complex formulated matrix, have either a complete lack of understanding of the capabilities of analytical chemistry or concern about the consequences of the legislation. Three examples can be cited.

In 2000 the EU reacted to concern about the possible presence of GMO materials in food by amending Council Regulation (EC) No 1139/98 on the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms.

The new Regulation 49/2000 stated: "it is necessary to establish a de minimis threshold for the adventitious presence in food ingredients of material derived from the abovementioned genetically modified soya and maize; for the purpose of clarity, it is appropriate to fix a threshold in terms of a single percentage value; the value of 1% best serves the purpose of establishing a tolerance level which simultaneously remains low and takes into account the necessary feasibility along the production chain. Detection methods already *provide or shortly will provide the necessary tools to implement this value*. (Authors italics) Nonetheless the 1% value is to be seen as a maximum..."

This statement shows a total lack of understanding of metrology. First, the 1% threshold value does not have a uncertainty value. Maize is, as any botanist knows, octaploid. That means it has 8 sets of chromosomes. Commercial maize is normally an F1 Hybrid between a GMO and non GMO stock. So it can contain from one to four sets of GMO genes. So what can 1% mean to the analyst?

The EC Scientific Committee on Cosmetics and Non-food Products (SCCNFP) has identified 26 fragrance ingredients that have the potential to cause contact allergies. Sixteen of these chemicals are found naturally in essential oils and include essential oils such as lavender, rose, citrus oils, bergamot and many others that have been used safely for years. A new list from The European Parliament has ruled that concentrations as low as 0.001% for "leave-on" products and 0.01% for "rinse-off" products may cause allergenic reactions, so any cosmetic containing these products must be labelled if present in excess of the trigger levels.

The regulations have been written seemingly without consideration of the way these substances can be reliably analysed when present at low levels in complex formulated matrices, or the availability of high quality reference materials that have been prepared by an organisation or company accredited to do so.

The UK is not immune to these problems. A new development takes the Environment Agency's (EA) MCERTS programme into soil testing with an application of ISO 17025:2000 specifically for the chemical testing of soil. Administered by the United Kingdom Accreditation Service it now covers all the key activities associated with soil analysis, from sampling to data reporting.

Accreditation to the MCERTS performance standard will be mandatory for laboratories providing soil test results are to be submitted to the EA for regulatory purposes, including Part IIA of EPA 1990, Pollution, Prevention and Control (England and Wales Regulations) 2000 and Waste Management Licensing Regulations 1994.

The MCERTS Standard is performance based, so it is method free but labs must

show their ability to perform. The guidance notes issued by the EA "suggest" that for each analyte every laboratory must demonstrate competence when analysing the three most common soil types: sandy loam, loam and clay loam. The list of analytes is lengthy with 21 specified metals and organo-metallic analytes, six inorganics and 29 organics, including groups of analytes, such as "dioxins" and "PAHs".

To achieve full conformity with the standard each lab has must find soil CRMs of three types, each having certified values for all the controlled analytes at normal, abnormal and detection limit levels. This means that a minimum of 36 different CRMs are needed, plus a similar number of QCRM samples for day to day QC and a suitable PT programme.

The EA did not appreciate the task they were setting the providers of matrix soil CRMs. As far as this author knows, there is no commercial facility in Europe that is accredited to ISO 17025 and ISO Guide 34 for the production and certification of soil matrix CRMs. Earlier this year the US based specialist CRM producer, RT Corporation started work on a programme to considerably expand its offering of soil matrix CRMs and QCRM to meet the needs of MCERTS. At the same time an MCERTS PT programme is under development. But it will probably take another six months before there is a full programme of CRMs, QCRMs and PT to meet the needs of MCERTS accredited laboratories.

So, what can be done to stop this sort of "horse before cart" approach? There are no clear answers, but one thing is certain: dialogue between Standard Setting bodies and RM producers is essential. The difficulty is finding a way of establishing a dialogue!