

**Improving dialogue between
the European Regulatory Bodies and the
National Metrology Institutes through the *RegMet* Project**

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ABSTRACT

The European regulatory infrastructure depends on measurements and tests, which need to be reliable, trusted internationally and which do not form a barrier to trade. Although broadly harmonised, differences in measurement practice amongst regulators and associated bodies still exist even within the EU. This is because the approach by the regulatory community in Europe is still influenced by historical practice and awareness of measurement issues varies significantly. Equally, development of national measurement capability does not always take optimum account of the regulatory perspective.

With partial support from the European Commission a partnership of nine European National Metrology Institutes, the EC Joint Research Centre and the European Organisation for Conformity Assessment are engaged in the *RegMet* project with the regulatory community to overcome this historical legacy. This paper describes the aims and progress of the *RegMet* project, including identified areas of best practice and potential routes forward.

1 INTRODUCTION

The European regulatory infrastructure depends on measurements and tests which need to be reliable and trusted internationally and which do not form technical barriers to trade. Variations in measurement practice can significantly affect the cost of compliance and the approach by the regulatory community in Europe and the EU Accession States tends to vary due to historical practice. In 1997 a joint project, known as ACCEPT [1], was initiated by the European Commission, the National Institute of Standards and Technology (NIST) and a number of EU National Metrology Institutes (NMIs) to investigate the lack of mutual acceptance of calibration certificates between countries. The project found that in general, differences in measurement capability were not the cause of the problems encountered. None of the difficulties identified (of practical importance) were due to the lack of metrology equivalence between European NMIs and NIST. The project reported that where measurement certificates from NMIs are not fully mutually accepted between regulatory bodies in two regions, the origins are non-technical. Historical practice was identified as the main cause of the various problems that exist.

In October 1999 the directors of the National Metrology Institutes of thirty-eight Member States of the Metre Convention and representatives of two international organizations signed a Mutual Recognition Arrangement [2] for national measurement standards and for calibration and measurement certificates issued by NMIs. This Mutual Recognition Arrangement, now referred to as the International Committee of Weights and Measures Mutual Recognition Arrangement (CIPM MRA), was a response to a growing need for an open, transparent and comprehensive scheme to give users reliable quantitative information on the comparability of national metrology services and to provide the technical basis for wider agreements negotiated for international trade, commerce and regulatory affairs. One aspect of the CIPM MRA is the development of the BIPM Key Comparison Database, which holds information on the calibration and measurement capabilities (CMCs) of the NMIs and the supporting scientific key comparisons. The CMCs are described and laid out in a common format and before entry in the database they undergo extensive peer review.

The advent of the CIPM MRA and the conclusions from the ACCEPT project initiated further European activity and support to address the issues identified. The European Commission and EUROMET, recognising the need to support the CIPM MRA and trade, identified three lines of action to further strengthen the European metrology in a trade context. The EUROMET NMIs are undertaking a joint project to ensure that the quality system obligations of the CIPM MRA are met by the EUROMET NMIs (the QS Forum/Initiation project). A second project is focusing directly on trade barriers that are related to measurement issues (the MetroTrade project). The third activity aims to improve the dialogue within Europe between the regulatory bodies and the National Measurement Institutes through the *RegMet* Project, the subject of this paper.

2 REGMET PROJECT

The RegMet project [3] recognises the need to address three specific aspects relating to regulation and measurement. Firstly, that in some instances there is insufficient awareness amongst regulators of measurement issues, particularly the impact of traceable measurements

and testing on the development of regulations and the assessment of compliance. Secondly, the advent and implementation of the CIPM MRA has resulted in a significant step forward towards a more cohesive metrological infrastructure, including improved transparency in the measurement capabilities of the NMIs. For the impact of the CIPM MRA to be fully optimised, the level of awareness and understanding of its benefits have to be increased and to permeate through all levels of the regulatory, trade and user communities as a whole. Hence there is an onus on the measurement community to ensure that these developments are explained and disseminated to the wider community. Thirdly, development and implementation of regulatory legislation can be limited by existing measurement technology and capabilities. Currently there are few mechanisms for the NMIs to capture the on-going measurement needs of the regulatory community and hence limited opportunity for regulators to influence the formulation of research priorities in a timely manner.

Nowadays much of the legislation is developed at a European level, but implementation is the responsibility of the individual member states and it is necessary to ensure a consistent approach to avoid unfair influence on competitiveness. There is therefore need for dialogue at a European level to ensure optimum use is made of best practice and that common issues are addressed consistently both across countries and, where possible, between sectors.

This 30 month project, which commenced in November 2000, is partly funded by the European Commission¹. The partners include NMIs from six Member States, two Accession States, one EFTA country, plus two trans-national partner organisations. The project is co-ordinated by the National Physical Laboratory (UK) and the other partners are the Bureau National de Métrologie (FR), the Czech Metrology Institute (CZ); the Danish Institute of Fundamental Metrology (DK), the European Organisation for Conformity Assessment (BE), the Institute for Reference Materials and Measurements (CEC), the Justervesenet (NO), the NMi van Swinden Laboratorium (NL); the Physikalisch-Technische Bundesanstalt (DE); the Slovak Institute of Metrology (SK) and the Swedish National Testing Institute (SE). The inclusion of the EOTC in the project helps to ensure that the industrial stakeholders are appropriately engaged.

RegMet is also registered under the EUROMET Interdisciplinary Metrology Group (INTMET) as project 508, thus ensuring that all EUROMET members are kept informed of progress and are able to benefit from the project.

The RegMet project aims to improve the effectiveness of the European regulatory infrastructure concerning measurement aspects of regulation. The principle objectives are to:

- promote a greater awareness and understanding of metrological issues and international agreements, including the CIPM MRA, amongst regulators,

¹ European Commission's Fifth Framework Programme, under contract G7RT-CT2000-05005, part of the Competitive and Sustainable Growth thematic Programme

- identify more precisely the metrological needs of regulatory bodies within the EU and develop mechanisms aimed at capturing, on an on-going basis, the regulator's view of future measurement needs with a view to influencing the formulation of research priorities and activities,
- promote a more harmonised approach to metrology policy and implementation by regulators to ensure appropriate measurement best practice is incorporated into regulatory legislation and implementation,
- establish networking arrangements to improve the working of the current systems, including enabling regulators to interact with other European regulators through the project,
- provide access to the results from outside the EU, including the accession states.

The project started in November 2000 and an overview of the structure of project is shown schematically in Figure 1.

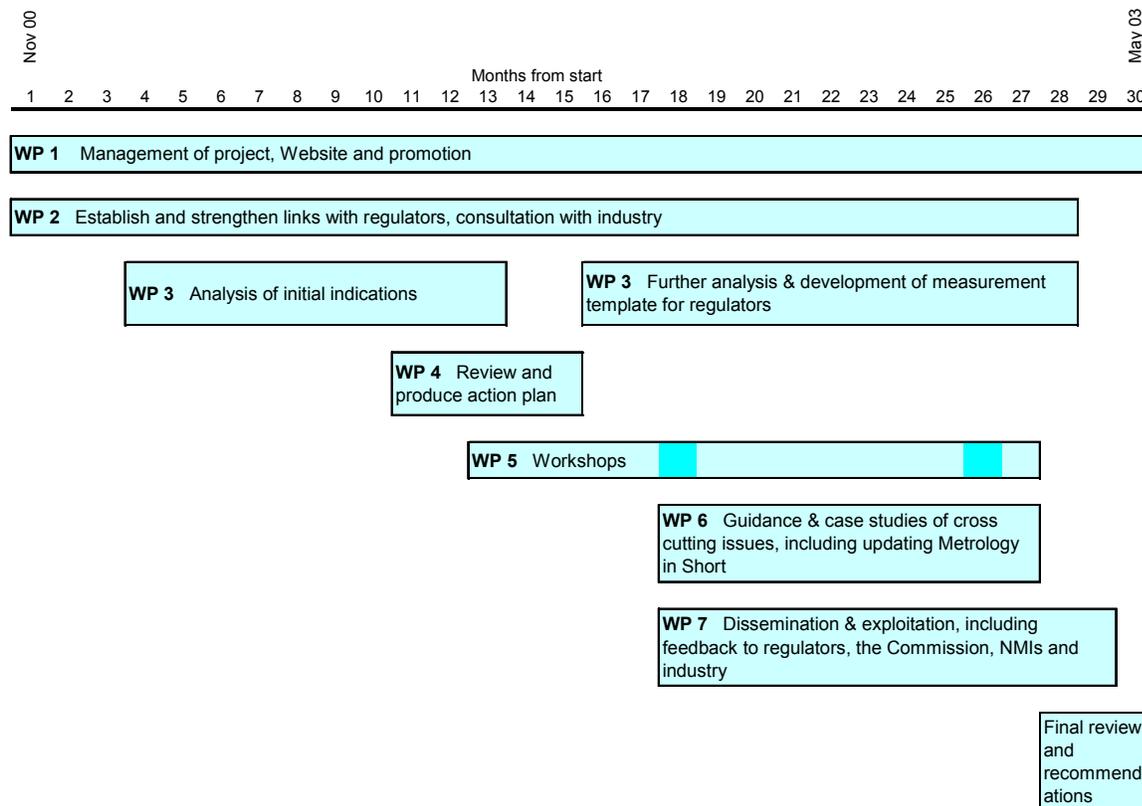


Figure 1. Structure of RegMet project.

The project focuses on areas which impact on significant industrial and individual activity within the community: avionics, electromagnetic compatibility and testing (EMC), environmental requirements, health and safety at work, legal metrology, medical devices, reference materials for food, and transport. Some of the above are true sectors; others are rather cross-cutting issues.

The sectors include priority areas defined for Key Actions under the Template V “GROWTH” Programme with a broad overlap with the EU-US Conformity Assessment MRA sectors.

Results are promoted through a web site <http://www.metrotrade.dk/> operated jointly with the related MetroTrade project (contract G7RT-2000-05004 – ‘Metrological support for international trade’).

3 INTERACTION WITH REGULATORS

In the first half of the project intense dialogue has been undertaken with the regulatory bodies. The aim has been to develop an understanding of the regulatory process; how measurement aspects including traceability, calibration, accreditation and quality are dealt with during formulation and enforcement of regulations and any mechanisms regulators have for ensuring that their future measurement needs are addressed. As a result of these discussions a number of examples of best practice already implemented have come to light, together with areas where improvements would benefit not just the regulatory community but also the wider public.

Due to historical practice and local requirements the structure of regulatory bodies varies significantly both between countries and across sectors, with enforcement of regulation often devolved to regional or lower tier bodies. Some sectors, for example environment, are already heavily influenced by regulation at a European level whilst for others such as health and safety, the regulation is still predominantly driven nationally. There is a significant disparity in the level of metrological awareness, both between and within individual sectors and bodies. Some bodies have considerable in-house capability including their own scientific measurement specialists and laboratories, but many do not and there is generally limited awareness of the CIPM MRA. Partly due to the fragmentation, most regulators have no overall common approach to metrology and measurement, validating the value of the project. Broadly they welcome a process improving the links between the metrological infrastructure and their area of regulation together with the provision of guidance on a robust approach to measurement issues.

Some problems relating to both the development and enforcement of regulatory legislation identified during the first half of the project include:

- regulatory requirements which are difficult to test in practice,
- standards which are not sufficiently specific and allow the use of a range of methods which have not been cross-validated and provide different results,
- a lack of suitable certified reference materials (particularly for some chemical, food and microbiological testing, where achieving traceability in the strictest interpretation can be exceedingly difficult),
- insufficient reliable data to undertake scientifically rigorous risk assessments,
- requirement for dynamic and real-time measurements,
- specified limits which are very close to the physical limits of detection (residue of genetically modified organisms, mercury in water and conductivity of solutions are just a few examples).

The reasons for these problems may be found in gaps or limitations in technical capabilities and realisations, incomplete or diverse sources of information, trade and economic factors, recognition of materials supplied by diverse commercial producers, the extreme ranges of physical quantities and a lack of understanding of metrological and technological issues during the formulation and implementation of regulations. Some regulations only require that equipment is verified rather than calibrated (the equipment is only checked to ensure that the value it outputs lies within a specified tolerance, ignoring the uncertainty). Verification is cheaper than calibration, but it is most appropriate for instrumentation used at the lowest level of the regulatory structure as problems arise when verified instruments are subsequently used for calibration in a lower tier body. Surprisingly the issue of uncertainty is not addressed within the Measuring Instruments Directive.

Conversely, some areas have made significant advances in addressing measurement issues and the changing international environment, and below are just two examples of best practice that have come to light during the project. Events over the last few years (for example food scares such as BSE) have driven a major restructuring of the food regulatory sector within Europe, often with the separation of food safety responsibility from agriculture and food production. Within the UK a new body with responsibility for food safety has been established. This organisation, together with a referee laboratory, has significant in-house knowledge of measurement and the restructuring has allowed the regulator to develop a modern clean-sheet approach to measurement requirements. In this case the regulator relies on international standards (ISO 17025 [4]), has entered into an agreement with the national laboratory accreditation body and provides specific guidance when the international standard is not deemed sufficiently detailed.

The environmental sector within Europe has changed substantially over the last decade as development of international requirements such as the Kyoto Agreement and the EU Integrated Pollution Control Directive establish increasingly demanding requirements thus necessitating a more robust approach to measurement. The advent of emissions trading and the requirement to report emissions data to Brussels has highlighted the need for consistent data between member states if competitive disadvantage is to be avoided. More importantly, however, is the need for this data to be reliable and robust as it is now used as the basis for major policy decisions with the Commission. There is therefore a direct link between the measurements made and the cost of compliance. In response to these developments the UK Environment Agency has established a Monitoring Certification Scheme (MCerts) [5], which provides for the accreditation of test house laboratories, product certification and competency certification of personnel. The scheme operates under the requirements of international and European standards (ISO 17025 for laboratories, EN45011 for product certification and EN45013 for the certification of personnel). The equivalent agency in Germany, the Umweltbundesamt (UBA), independently developed a similar scheme and the two regulatory bodies have worked closely together to align the schemes as far as possible.

4 DEVELOPMENT OF A ‘MEASUREMENT IN REGULATION’ TEMPLATE

To achieve the necessary confidence within the regulatory field, measurements must be appropriate and robust; consequently traceability and uncertainty are important issues when developing and implementing directives and regulations. For the public community at large to benefit from legislation, the specified technical limits they contain must be meaningful, practical, measurable, and enforceable and provide added value. If limits are set independently of knowledge of the technological, scientific and metrological background, then they may fail to achieve the desired objectives. At the same time, for more appropriate limits to be implemented, additional scientific research and development may be required by NMIs and other organisations and this requires interaction and collaboration between the metrological and regulatory communities. It is important that optimum use is made of the metrological infrastructure and the changes occurring within it. Improvements in measurement technology and application may not just provide opportunities for establishing more appropriate limits and enhancing the ability to assess compliance, but can provide for a more efficient and cost effective route to compliance.

The development of a broad metrological template, which could be used by regulators when considering measurement issues during formulation and subsequent enforcement of regulations, would be beneficial, particularly as potentially this could be incorporated in or used as a guide when drafting primary legislation such as EU Directives. It is accepted that there are technical sectoral differences, for example the variability of sampling in food and environmental monitoring or the ratio of safety margin in avionics regulation compared with the measurement errors. However, there are many metrological requirements have a strong degree of commonality between sectors, although often not in the manner in which they are addressed. These are:

- the need for measurements to enforce regulation,
- the desire for these measurements to be appropriate (but always with some cost/benefit aspect to this definition),
- the need for measurements and testing to be robust and defensible,
- the need to balance the protection of the public (thus avoiding risks to public safety) against the erection of trade barriers (imposing unnecessary additional requirements). This implies the need to ensure that barriers do not arise as a result of a perceived lack of equivalence between countries,
- the ability to utilise and benefit from the existing and evolving national, European and world measurement infrastructure.

Measurement as a tool for effective regulation

As highlighted in the examples of best practice in the previous section, some regulators have already addressed some of these issues. A potential template, with two threads, which might be used by regulators, is outlined below:

- To ensure an appropriate approach to measurement when formulating regulations and directives. Consideration should be given to the potential interpretation, consultation with the metrology community particularly the early commissioning of research and development work if needed (regulators are stakeholders in the national measurement

systems), consultation on technical limits (for example identifying validated measurement techniques, accepted measurements that do not form technical barriers to trade, traceable measurements at appropriate level).

- To ensure appropriate market surveillance measurements during enforcement. Measurements should be traceable to the SI (as far as possible), robust, practical and of suitable uncertainty to enable an adequate assessment of compliance.

In satisfying the aims above, it is necessary that they be achieved in a manner that is consistent, fair and avoids technical barriers to trade.

This could require:

- The use of appropriate methods and procedures for all tests and/or calibrations, utilising international, regional or national standards and accredited laboratories and test houses where available.
- That if technical written standards are not available, then the issue of validated methods should be specifically addressed.
- The use of traceable measurements (traceable to the SI through an unbroken, auditable chain via an NMI who is a signatory to the CIPM MRA and who declares appropriate CMCs in the BIPM database). Specification should be made as to whether lower tier laboratories are required to be accredited.
- The inclusion of an estimate of uncertainty of measurement together with a stated coverage factor, normally $k=2$.
- Where traceability to the SI is not feasible; confidence in the measurements should be provided by establishing traceability to appropriate measurement standards such as certified reference materials provided by a competent supplier to give reliable physical or chemical characterisation of the material, the use of specified methods or consensus standards that are clearly described and participation in a suitable programme of interlaboratory comparisons.
- Where no appropriate measurement standards and methods exist, appropriate research should be initiated in a timely manner (this should include consultation and participation at international and preferably interregional level to aid acceptance). This might be achieved either by the direct commissioning of research or by prioritising the research of the NMIs and other organisations, for example the European Commission's Framework programme.
- The need for limits established within regulations, directives or mandated standards to be risk based, measurable, either method independent or with the method(s) specified (this may require cross validation of methods) and economic for example with regard to sampling issues and total cost. The limits should be agreed on as wide a basis as possible (at least European wide and preferably interregional) as this is a prime area where disputes can arise and technical barriers to trade can inadvertently be established.

It is clearly onerous for regulators to ensure that the above aspects are addressed consistently and effectively during the development and implementation of regulations. However, the existing metrology and conformity assessment community infrastructures can be used (and are already used by some regulators) to ensure many of the above requirements are achieved as a matter of

routine practice. It is however recognised that in some instances not all these aspects may be appropriate, nor may the infrastructure be sufficiently developed. Accreditation to ISO 9000 provides confidence in a quality system, but this standard does not address technical aspects, which are dealt with instead by ISO 17025 (the international standard for ‘General requirements for testing and calibration laboratories’). Under ISO 17025 there is an obligation for the traceability and uncertainties to be declared and independently assessed, two aspects important for the technical assessment of compliance, in addition to the quality system requirements. It should however be noted, that ISO 17025 is the standard covering calibration and testing in all contexts and therefore incorporates a degree of flexibility, which may be inappropriate for regulatory compliance. For example, the standard allows the use of alternative methods and specifications providing there is an agreement between the laboratory and the client. It may therefore be necessary to specify particular constraints and/or indeed additional requirements, which will need to be met in order to comply with regulatory legislation. If this is the case, it would be appropriate for regulators to consult with other EU partners in their sector when developing the specifications for the additional requirements or constraints, in order to ensure consistency and avoid technical barriers to trade.

It should be noted that the MRA and accreditation or compliance with ISO 17025 are not necessarily a precondition (there may be instances where this is not possible nor appropriate). However, this does provide a robust and cost effective route towards compliance and on this basis some regulators have elected to make compliance with ISO 17025, supplemented by specific sector requirements, mandatory. Alternative routes can be chosen, but the assessments to ensure compliance at all stages will tend to need to be more extensive.

5 DISSEMINATION AND WORKSHOPS

During the course of the project it has become apparent that whilst there are differences between sectors, particularly relating to individual technical challenges, many of the issues faced by regulators are common across sectors. The world metrology structure is complicated and extended, especially when considering the route from NMIs, through accredited and other calibration and testing laboratories, to the end user. World metrology has undergone major changes since the CIPM MRA was adopted in 1999, and is still undergoing considerable evolution.

The links between NMIs and regulators vary enormously. Legal metrology has close links with the NMIs, firstly because the body responsible for legal metrology often falls within the same government department as the NMI or is even part of the NMI and secondly because of the high measurement content within legal metrology work. However, for some other sectors the contacts are often on an ad-hoc basis only, based on historical links, accidental contact, person-to-person contact or departmental links. Whilst some of these links work well, excluding legal metrology, there are few formalised links between NMIs and regulatory bodies and this is part of the reason why the development of measurement capability has not always taken account of the regulatory perspective. Improvements in the interactive process would therefore be beneficial to all parties.

Dissemination and exchange of information and best practice is therefore an important aspect of the project. There is a responsibility on the NMIs to provide assistance, advice and explanation of the metrological structure to end-users, together with metrological information for regulators in a form that is readily accessible and comprehensible. As mentioned earlier, a number of examples of best practice have been highlighted during the project, in at least one case similar practice was developed independently in two partner countries and steps have been taken to harmonise the two schemes as far as possible. The benefits of dissemination of best practice both between countries and across sectors is immense, particularly avoiding unnecessary costs and duplication of effort, but must overcome the 'not invented here' syndrome from regulators who are naturally cautious by definition.

As part of the interaction and dissemination process a workshop for regulators and others interested in measurement issues related to regulations and their enforcement will be held in conjunction with the MetroTrade project on 30-31 May 2002, at the Institute for Reference Materials and Measurement in Geel, Belgium. The workshop will address the cross-cutting issues of the structure of world metrology, traceability, accreditation, uncertainty, the interrelationship between metrology, trade and regulation and conformity assessment together with the presentation of some best practice solutions already developed within the regulatory field. The workshop will also provide regulators with an additional opportunity to input directly into the project, particularly influencing the measurement template.

6 CONCLUSIONS

The dialogue with regulators over the first half of the project has confirmed the value of this approach, particularly amongst those regulators who do not have significant in-house measurement capability. The links between the metrological and regulatory communities are uneven and broadly regulators welcome a process improving the links between the metrological infrastructure and their area of regulation, together with the provision of guidance on a robust and effective approach to measurement issues. Regulators must necessarily engender public confidence in their actions, consequently they are understandably not always keen to admit publicly that they have concerns about their approach to measurement, although they have been willing to do so within the confines of the project.

Across Europe the approach to measurement varies from one regulator to another, both within and across sectors, and hence there are significant benefits from greater horizontal dialogue, particularly regarding the development of regulations and dissemination of information and best practice. Currently the measurement requirements of the regulatory community are not always addressed particularly effectively. Better mechanisms are required to ensure on-going capture of these needs by the NMIs and that best use is made by regulators of the research capabilities of the measurement community, particularly by commissioning of research at an optimum period within the regulatory cycle. It is important that regulators have timely access to up-to-date metrological information that they can act upon. Significant metrological and conformity assessment infrastructures already exist but improvements in awareness of their existence and the benefits they can offer, especially with regard to the provision of expert advice, information and assistance would be beneficial. The project has identified instances where regulators have

already considered these measurement issues and have constructed a practical and comprehensive approach, which can be regarded as ‘best practice’, utilising the existing infrastructure as far as possible. The project proposes to capture the combined expertise of ‘best practice’ regulators and the metrology community and incorporate the information within a so-called template. This template would be made available to all regulators and the European Commission for embodiment in policy, legislation and practice wherever they consider it advantageous to do so.

Trade, regulation and metrology increasingly operate in a global environment with a growing need for greater consultation and collaboration between countries and regions. Collaboration on the development of industrial mandated standards supporting regulation on an interregional basis, with the potential for avoidance of technical barriers to trade, would be of immense benefit. When researchers from different regions collaborate in the development of measurement and testing methods necessary for regulatory purposes, the adoption of these methods through the international standardisation process is eased immensely. Optimising the relationship between the measurement community and the regulatory bodies potentially brings benefits not just to industry but also to the public at large through improved regulation relying on robust measurement.

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