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METROLOGY FOR IMPROVED MEASUREMENTS IN INTERNATIONAL REGULATION AND TRADE: THE REGMET PROJECT

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Abstract – The operation of the economy on a global scale and the quality of life for the individual citizen depends on reliable measurements and tests, which are trusted and accepted internationally. 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. A partnership of nine European National Metrology Institutes, the European Commission's Joint Research Centre and the European Organisation for Conformity Assessment, with partial support from the European Commission, are engaged in the *RegMet* project with the regulatory community to overcome this historical legacy. This paper describes the aims, findings and progress of the *RegMet* project, including the concept of the development of a measurement template for regulators.

Keywords: Metrology, regulation, trade.

1. INTRODUCTION

Global trade and commerce depend on measurements and tests, which need to be reliable, trusted internationally and which do not form a barrier to trade. As fiscal barriers are removed, the impact of technical barriers to trade increases. In many areas, trade, commerce and increasingly quality of life are governed by the need to comply with regulatory requirements.

There has been major investment by the metrology community over the last few years in the negotiation and implementation of arrangements such as the CIPM Mutual Recognition Arrangement [1] and the ILAC Arrangement [2], aimed in part at providing the technical basis for wider agreements negotiated for international trade, commerce and regulatory affairs. For the full benefits of these agreements to be reaped, there is a need for these developments to be explained and disseminated to the wider world and for the metrology community to work effectively with the user community.

The regulatory process in Europe involves myriad players and in turn spans and encompasses the rationale underpinning the regulations, the development of legislation, the setting of technical limits and market surveillance. Consequently there is a somewhat fragmented approach in many sectors, exacerbated by historical legacies resulting from reorganisation and restructuring of responsibilities and the accumulation of traditional practices. Additionally variations in measurement practice can impact on the effectiveness of the regulation and the cost of compliance. There are therefore benefits to be gained from a more coherent process within Europe.

The advent of the CIPM MRA and the conclusions from the earlier ACCEPT project [3] initiated further European activity. The European Commission and EUROMET, recognising the need to support and exploit the CIPM MRA, identified several lines of action to further strengthen the European metrology in an international context. The European Commission is providing support to two linked projects to address these issues; the *RegMet* project¹ 'Improving dialogue between EU Regulatory Bodies and National Metrology Institutes' and the *MetroTrade* project 'Metrological Support for International Trade'. The *RegMet* project [4] addresses indirect measurement issues for trade and commerce, focussing on the European regulatory approach to measurement, whilst the *MetroTrade* project [5], [6] addresses direct measurement issues related to trade between regions.

2. REGMET PROJECT

The *RegMet* project 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

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

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. Historically there have been 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 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. 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, food, and transport. Some of the above are true sectors; others are rather cross-cutting issues.

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 understanding of metrological issues and utilisation of the metrological, accreditation and conformity assessment infrastructure amongst regulators
- Promote a systematic harmonised best practice approach by regulators to metrology policy and implementation
- Identify more precisely the metrological needs of regulatory bodies within the EU, including enhancing the on-going capture of future regulatory measurement needs

The project commenced in November 2000 and runs until autumn 2003. The project partners, who are drawn from European NMIs within the EU, EFTA and Accession countries together with two European organizations, are National Physical Laboratory (project co-ordinator - UK), Bureau National de Métrologie (France), Czech Metrology Institute (Czech Republic), Danish Institute of Fundamental Metrology (Denmark), European Organisation for Conformity Assessment, Joint Research Council - Institute for Reference Materials and Measurements, Justervesenet (Norway), NMI van Swinden Laboratorium (Netherlands), Physikalisch-Technische Bundesanstalt (Germany), Slovak Institute of Metrology (Slovak Republic) and Swedish National Testing Institute (Sweden).

The links between NMIs and regulators vary enormously, whilst some of these links work well, they are generally informal. Improvements in the interactive process are therefore advantageous to all parties. The benefits of dissemination of best practice both between countries and across sectors are immense, particularly increasing confidence and avoiding unnecessary costs and duplication of effort.

The first project workshop on 'Metrology for Regulation and Trade', held in May 2002 in Geel, attracted delegates from 13 countries including South Africa, South America and Australia. The workshop addressed the cross-cutting issues of the structure of world metrology, traceability, accreditation, uncertainty, the interrelationship between metrology, trade, regulation and conformity assessment, together with the presentation by regulators of some best practice solutions already developed within the regulatory community. The workshop provided regulators with an additional opportunity to input directly into the project, particularly influencing the concept of a template on measurement for regulators being developed within the project. A second RegMet workshop open to all interested parties will be held at the Bureau International des Poids et Mesures (BIPM) in Paris on 19 September 2003 and will draw together the activities within the project, including three case studies on the cross-cutting issues of uncertainty, accreditation and training.

Regulators outside the partner countries are able to benefit from the project through the workshops and dissemination activities. 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. Results are promoted through a web site <http://www.metrotrade.dk/> operated jointly with the related MetroTrade project.

3. INTERACTION WITH REGULATORS

Consultation has been undertaken with over 100 regulators across Europe, from a diverse range of sectors including avionics, EMC, environment, food, health and safety at work, legal metrology, medical devices and transport. One aim of this two-way dialogue has been to develop an understanding of the regulatory process; how measurement aspects 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.

During the dialogue with regulators, it has become apparent that 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. The RegMet project has found that, partly due to the fragmentation, most regulators have no overall common approach to metrology and measurement. 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 regulators have already made significant advances in addressing measurement issues and the changing international environment [7]. There have already been spin-off benefits from the project, including the establishment of a project by the Czech Ministry of Transport to improve the metrology system within the Czech transport and telecommunications sectors.

The project has highlighted the wide range of metrological challenges facing the regulatory community in the development and enforcement of regulatory legislation including:

- Regulatory requirements that 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 (EMC testing),
- 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 (genetically modified organisms),
- Requirements for dynamic and real-time measurements (environmental monitoring),
- Specified limits that 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),
- Legislation or standards that do not specify the maximum permissible level in an unambiguous manner (antibiotic residues)
- Lack of understanding of the impact of uncertainty of measurement on the setting of technical limits and the assessment of compliance
- The need to operate in a rapidly changing global environment

The causes of these problems may be found in limitations in technical capabilities and practical realisations, incomplete, inadequate or diverse sources of information, inconsistent recognition of materials supplied by diverse commercial

producers, the extreme ranges of physical quantities, trade, differences in regulations, legislation and mandated standards, differences in the implementation of existing legislation, de facto requirements or practice for traceability to national standards in a specified country or institute, historical practices, differences between metrological standards in different countries, variations in technology between countries, the lack of harmonisation of test and calibration procedures, political and economic factors, and the belief that metrological and technical issues will be dealt with 'downstream' of the formulation of regulations. Metrological technical barriers to trade can inadvertently be established due to for example, the historical practice of specifying technical limits of 'below detectable levels', 'no detectable levels' or 'zero'. As technology advances, detectable limits have reduced and levels of contaminants or hazardous materials, which were previously undetectable, are detected. This can result in goods that would previously have been generally accepted, being accepted by some countries but rejected by those with the most modern detection technology, despite the fact that neither the quality of the goods on the market nor the legislation have changed. One specific example relates to the limits for chloramphenicol in food [8], where the EC Directive 2377/90 includes 'antibiotic residues for which no maximum level can be fixed' and where a shipment was accepted by one country with one testing technique by rejected by another with a more sensitive technique.

4. DEVELOPMENT OF A TEMPLATE FOR 'MEASUREMENT IN REGULATION'

To achieve the necessary confidence within the regulatory field, measurements must be appropriate and robust; consequently measurement traceability and uncertainty are important issues (amongst others) when developing and implementing directives and regulations. For the public community at large to benefit from legislation, the specified technical limits must be meaningful, practical, measurable, enforceable, provide added value and be based on sound scientific and technical data. If limits are set without due consideration 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 needed and this requires interaction and collaboration between the metrological and regulatory communities. Improvements in measurement technology and its application may not just provide opportunities for establishing more appropriate limits and enhancing the ability to assess compliance, but can facilitate a more efficient and cost effective route to compliance. Ensuring these aspects are addressed throughout the regulatory process, that is from commissioning the underpinning research or surveys through to enforcement, would result in a more cohesive and effective process. In addition optimising the use of the metrological infrastructure and ensuring that the benefits from its development are captured (for example the CIPM MRA and multilateral agreements between regional accreditation bodies) is valuable.

The concept of developing a systematic and cross-sectoral ‘cradle to grave’ guidance on measurement for regulators, with the dual aim of improving regulation and preventing measurement related barriers to trade before they occur, has therefore evolved and gained momentum during the project. Whilst 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, there are many metrological issues that have a strong degree of commonality between sectors. This template concept, conceived and promoted as voluntary, has grown from the recognition that measurements are often required to underpin and to enforce regulation, that they must be appropriate, robust and defensible, and balance the cost of compliance against protection of the public. Data and information generated from underpinning research and surveys will have a direct and often significant impact on future decisions, for example the setting of technical limits. There is a growing recognition within some sectors that the research, development and data collation that are commissioned and underpin the regulatory process should therefore also be subject to appropriate assurance of quality.

Utilising and building on examples of current regulatory best practice, the template focuses on ensuring an appropriate approach to measurement when undertaking research that underpins and inputs to regulation, formulating regulations, legislation and supporting standards and undertaking market surveillance and ensuring optimum use of the metrological infrastructure. Specific sectoral needs may be incorporated within the template, though this is beyond the scope of the current RegMet project. The template will be made available to regulators, national governments and the European Commission for embodiment in policy and practice wherever they consider it advantageous to do so. A condensed version of the template will be publicly available through the second edition of the booklet *Metrology in Short*, to be published in 2003. It is intended that the template could be used at a number of stages during the regulatory process but particularly during the regulatory impact assessment.

The template’s primary objective is to ensure better regulation through better measurement. Additionally, a common and systematic approach offers a degree of transparency and helps avoid trade barriers and unfair competition, as well as providing a platform for interregional trade negotiations.

Early consultation and consideration of measurement issues is crucial within the regulatory process, thus enabling the underpinning research to be initiated in a timely manner and avoiding unnecessary duplication of effort. An environmental and international scan should be undertaken to identify key players, the current status, needs and activities within other countries. Identification of the parameters to be quantified and establishing the current status of measurement and risk analysis within the field is also important.

A variety of issues and topics are under consideration for inclusion in the template. The list below is not extensive but provides an indication of the scope that will be addressed.

- Identification of the parameters and quantities which need to be measured
- How far can the national, European and world measurement infrastructures be utilised, for example National Metrology Institutes, accredited laboratories and test houses, the CIPM MRA (including the KCDB), ILAC, EA and conformity assessment bodies?
- The availability of appropriate methods and procedures for all tests and/or calibrations, including utilising international, regional or national standards and accredited laboratories and test houses where available.
- Identifying whether there is more than one technical method for assessing compliance? If so, are the methods cross-validated or will it be necessary to specify the method to be used or undertake cross-validation?
- The identification of existing relevant written technical documentary standards and whether they could be used, for example with specific supplementary requirements if necessary. Do new written (documentary standards) need to be mandated?
- The availability and utilisation 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).
- What to do if traditional traceability to the SI is not feasible; for example confidence in the measurements might be provided by establishing traceability to appropriate measurement standards such as certified reference materials provided by a competent supplier.
- Will appropriate reference materials be required? Do suitable certified reference materials exist? Will new reference materials need to be commissioned?
- Do measurement standards and methods exist? If not, underpinning research may be required and should be initiated in a timely manner (preferably including consultation and participation at international and even interregional level to aid acceptance).
- Does suitable equipment and measurement technology exist to enable the measurements to be made? If there is a need or desire to regulate the equipment then the interaction with ‘legal metrology’ should be addressed.
- Is sampling likely to be a major issue? Will the sampling be random or selective? What is the impact of timing, seasonal or geographical variations?
- Will the required measurements be economic with regard to sampling issues, practicality and total cost?
- How are the technical limits established? Are appropriate data available of suitable quality to enable a risk-based approach? If not, data may need to be gathered or generated.

- It is advantageous that any limits set 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.
- Consideration should be given to the uncertainty of measurement and the impact on the effectiveness of the regulation.
- Other measurement issues that should be examined include: the designation of Notified Bodies, training and formal certification of personnel.

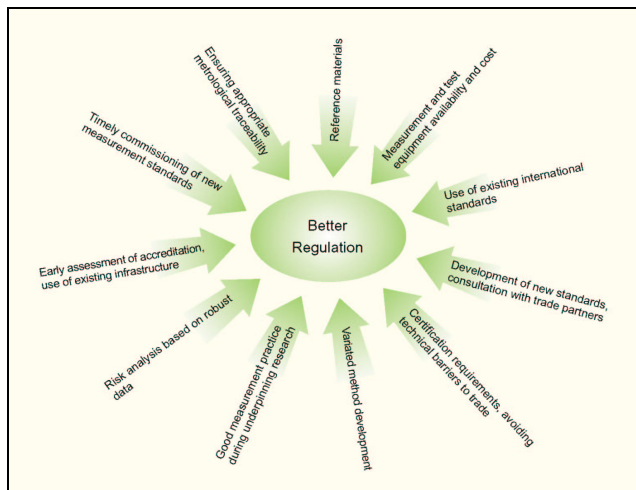


Fig. 1. Typical issues addressed in the RegMet template.

This work is still under development and regulators are welcome to input to the process by contacting the authors.

5. CONCLUSIONS

Industry, trade and the quality of life all depend on high quality regulations that are applied consistently and a thorough approach to measurement in regulation can contribute significantly to this aim, particularly when underpinned by timely research and development. Simply put, the RegMet project will promote better regulation through better measurement, the potential benefits of which are significant. Lessons can be learnt from examples of existing good practice and it is proposed to incorporate these findings within the ‘template on measurement for regulators’. It will be made available to regulators, national governments and the European Commission for embodiment in policy and practice wherever they consider it advantageous to do so. The template is foreseen as a continually evolving tool, perhaps by adaptation for sectoral requirements where this is beneficial, with an intended life beyond the end of the RegMet project.

Regulation, trade, and metrology increasingly operate in a global environment resulting in a growing need for greater consultation and collaboration both between countries and

regions. Optimising the relationship between these communities potentially brings benefits not just to industry but also to the public at large through improved regulation relying on robust measurement. An added bonus is that inappropriate technical trade barriers may be avoided by such an approach.

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REFERENCES

- [1] “Mutual Recognition Arrangement (MRA) for national measurement standards and for calibration and measurement certificates issued by national metrology institutes”: see the BIPM web site: <http://www.bipm.org>.
- [2] ILAC Multilateral Arrangement, see the ILAC website: <http://www.ilac.org>
- [3] Final report “Mutual Acceptance of Calibration Certificates between EUROMET and NIST under contract SMT4-CT97-8001”
- [4] F Redgrave and A Henson, Improving Dialogue in Europe between the Regulatory Bodies and the National Metrology Institutes through the RegMet Project, *Proc. 2002 NCSL International Workshop and Symposium*, National Conference of Standards Laboratories International, Boulder, CO, USA, 2002.
- [5] P. Howarth, "Metro Trade - Metrological Support to International Trade", *Proc. 2002 NCSL International Workshop and Symposium*, National Conference of Standards Laboratories International, Boulder, CO, USA, 2002.
- [6] Fiona Redgrave, Andy Henson, Diane Beauvais, “Metrology for improved measurements in international regulation and trade: The RegMet and MetroTrade Projects”, *Proc XVII IMEKO World Congress*, 2003, in press.
- [7] S. Newstead, “Setting the Regulator’s Standards for Environmental Monitoring”, *Proc. 2001 NCSL International Workshop and Symposium*, National Conference of Standards Laboratories International, Boulder, CO, USA, 2001.
- [8] H Källgren, M Lauwaars, B Magnusson, L Pendrill, P Taylor, “Role of measurement uncertainty in conformity assessment in legal metrology and trade”, MetroTrade workshop, January 2003.

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