*Czech National Workshop*

# Recommendation for good legislative practice for measurement - the RegMet template

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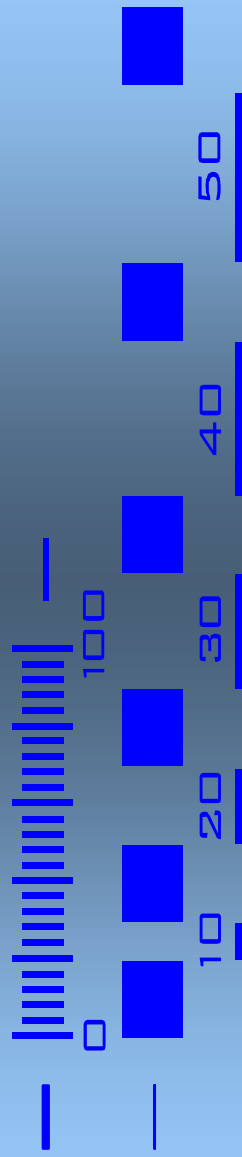

# Rationale for the template

- Regulation increasingly operates in a global environment
- Increased complexity of measurement in regulation
- Increased importance of regulation in trade
  - tariff barriers are being removed
  - WTO requirements to avoid technical barriers to trade
- Increased focus on the quality of life for the ordinary citizen

# What have we learnt from RegMet?…..

- Many underlying issues turn out to be non sector specific

- Consequently we've developed the concept of providing guidance on a systematic approach to measurement to aid those involved in the regulatory process when considering measurement issues – the "template"

  - A core set of principles and guidelines addressing relevant measurement issues through the regulatory life cycle across a wide range of regulatory fields

  - Optimising use of the international measurement infrastructure

  - Allowing specific sectoral needs to be incorporated

# Template – The regulatory life cycle

Ensuring an appropriate approach to measurement when:

- Undertaking research or utilising existing data which will potentially influence regulation
- Formulating regulations, national, EC regulations, directives a supporting standards etc
- Undertaking market surveillance

Achieved in a manner that is transparent, consistent and avoids technical barriers to trade.

# Broad principles

The template is:

- Not binding – it would ultimately be the regulator's decision to use it
- Provides a guideline
- Promotes use of existing infrastructures
- Aims to simplify and improve existing situation
- Incorporate existing best practice
- Benefits
  - Harmonisation between regulatory fields and countries
  - Supporting trade
  - Avoiding erecting unnecessary barriers to trade
  - An aid to developing countries

# Regulatory impact assessment

- "Regulatory Impact Assessment (RIA): A way of evaluating a policy before it is put in place that shows what the likely consequences will be, including the likely risks, benefits and costs associated with all of the possible options. As an integral part of the whole policy making process, an RIA can be a useful tool for creating better regulation." *UK Cabinet Office*

- The project focuses on the regulatory impact assessment because……

  - How effective can your RIA be if you don't consider the measurement issues?

  - The template allows the complete lifecycle of the regulation to be addressed during the RIA

# Format for the template

The template aims to be:

- A short, concise document
- Easily understood
- A guidance note for regulators
- Suitable for use as input to the Directives?

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# Template – Issues addressed


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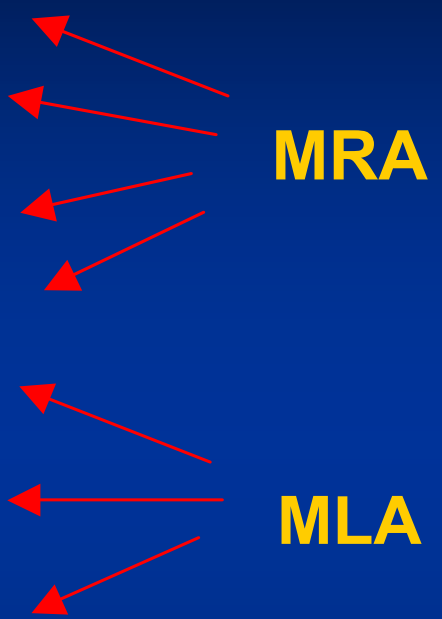
# Template - Issues addressed

- Appropriate methods, procedures and standards
- Provision of specific requirements in addition to supplement existing standards
- Validated methods?
- Use of measurements traceable to the SI (where feasible)
- Estimate of uncertainty of measurement and its impact
- Initiating appropriate research in a timely manner when no appropriate measurement standards, methods and data exist
- Robust technical limits avoiding unnecessary TBTs

# Benefiting from existing infrastructure

- National Metrology Institutes
- Regional Metrology Organisations
- CIPM Metre Convention
- CIPM Mutual Recognition Arrangement
- Accredited laboratories and test houses
- Accreditation bodies
- European Accreditation co-operation
- ILAC
- WELMEC & OIML
- Notified bodies
- International Standards such as ISO 17025

- Plus many others



# Template – Components

**CHECKLIST**

Issues to be considered

**GUIDANCE**

Information on the issues, how they might be addressed and who can help

**DEFINITIONS & BACKGROUND INFORMATION**

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# Template – Checklist structure

## Rationale for the regulation

- Identification of the drivers
- Collection and collation of existing data
- Commissioning of R&D to support the rationale

## Development of the regulation

- Assessment of the current state of play
- Setting of the technical limits
- Commissioning of R&D to establish solutions
- Establishing the level of detail to be prescribed

## Enforcement, monitoring and compliance

- Using feedback from surveillance
- Identifying technological developments which impact on the regulation

# Template – Questions

- Q1 What is the driver for the regulation?
- Q2 Is the rationale for the regulation fully supported by data of appropriate quality and reliability?
- Q3 Is new data required to underpin the regulation?
- Q4 What parameter or quantities will need to be measured?
- Q5 What measurement and regulatory infrastructure exists for the relevant quantities
- Q6 Is suitable measurement technology available for the relevant quantities?
- Q7 Can regulatory limits be set which provide an appropriate balance of risk and cost
- Q8 What, if any, new research does the regulation require?
- Q9 How much detail will be prescribed in the regulation?
- Q10 How will the effectiveness of the regulation be enhanced by feedback from surveillance in the marketplace?
- Q11 How might future developments impact the regulation?

# Example - checklist

▶ **Q6** Is suitable measurement technology available for the relevant quantities?

Measurement technology encompasses equipment, measurement procedures, data analysis techniques and underlying scientific understanding. When surveying the existing technology, the following factors should be considered against the regulator's and industry's knowledge of the conditions under which the regulation will be enforced:

- Existence of suitable measurement equipment
- The status of data analysis techniques (consistent, or different techniques in use?)
- Commercial availability (or not) of measurement equipment
- The measurement uncertainty available from the equipment
- The level of expertise needed to operate the equipment
- The behaviour of the equipment under conditions likely to be encountered during enforcement
- The impact of sampling parameters on the measurements, if relevant
- The traceability route used in the measurement area, whether to the SI or other specified means if direct traceability to the SI is not possible (for example in some chemical and biological fields), utilising the CIPM MRA and ILAC MLA where possible
- Existence of suitable physical standards, or reference materials
- Validation (or cross-validation if more than one technique exists) of measurement techniques
- Whether best measurement practice is currently the limiting factor in the field
- The state of the science underlying the measurements, whether well understood, or controversial

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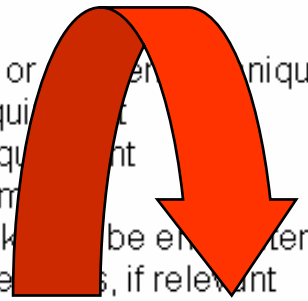

GUIDANCE

# Example - guidance

6.5
The traditional route for obtaining traceability to the SI would be for the end user (for example, an organisation responsible for checking regulatory compliance) to have their instruments, measurement standards or reference materials calibrated by an NMI or accredited laboratory, who would be able to demonstrate that their calibration was traceable to the SI system, either directly or via calibration from another body with direct traceability. This could be achieved through an unbroken auditable chain via an NMI who is a signatory to the CIPM MRA and who declares appropriate calibration and measurement capabilities (CMCs) in the BIPM key comparison database (KCDB). SI traceability is most readily established for the measurement of physical quantities such as force, power, length, time and electric current, where it provides the basis for robust, internationally agreed measurement standards. Traceability is less straightforward for measurement of more complex quantities such as chemical or biological concentrations. For some parameters it might not be possible to establish traceability to the SI in the traditional sense and the use of consensus standards may be required for example. Wherever possible requirements for traceability to a specific NMI should be avoided as it creates barriers to trade and unfair competitive advantage. In addition the CIPM MRA provides for the mutual recognition of national measurement standards and of calibration and measurement certificates issued by national metrology institutes, and is founded on the efforts of each individual national metrology institute to base its measurements and measurement uncertainties on SI units.

# Example - guidance

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DEFINITIONS

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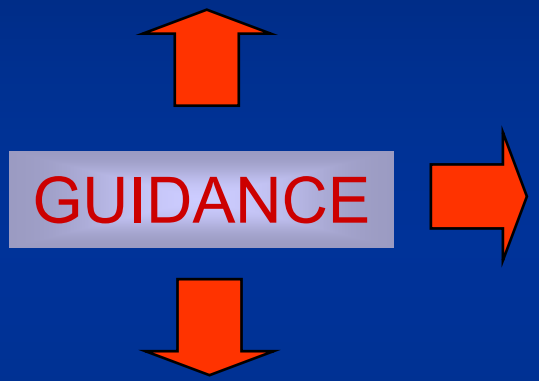
# Example - definitions

**CMC** Calibration and Measurement Capability. To support the Mutual Recognition Arrangement, national metrology institutes must declare the highest level of calibration or measurement normally offered to customers, together with the associated uncertainties of those measurements, expressed in terms of a confidence level of 95%, sometimes referred to as best measurement capability. These capabilities are subject to peer review, and published by the BIPM in appendix C of the Key Comparison Database (KCDB).
http://kcdb.bipm.org/




**Traceability** Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain o comparisons [the traceability chain] all having stated uncertainties. (1)

**CIPM MRA** Mutual Recognition Arrangement. At a meeting held in Paris on 14 October 1999, the directors of the national metrological institutes (NMIs) of thirty-eight Member States of the Metre Convention and representatives of two international organizations signed a Mutual Recognition Arrangement (MRA) for national measurement standards and for calibration and measurement certificates issued by national metrology institutes. This MRA is 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. It is supported by the system of Key Comparisons, the results of which are published by the BIPM on the Key Comparison Database (KCDB), and the declaration by national metrological institute of their Calibration and Measurement Capabilities (CMC's). An end user seeking measurement services could use the CMC's to identify a number of laboratories meeting their needs, and then use the KCDB to find the level of agreement between those laboratories when measuring the quantity of interest. This information will assist the user in deciding which institutes they should accept certificates from.
http://www.bipm.org, then follow to MRA

# Template aims

The template (voluntary) aims to assist regulators to achieve more effective regulation through:

- Identification and adoption of measurement best practice, including utilisation of existing infrastructures
- Improved confidence in results obtained within regulatory fields
- Increased harmonisation, consistency and avoidance of duplication of effort
- Provision of a common platform for interregional trade negotiations and the avoidance of TBTs

# Template aims……in short

The template (voluntary) aims to assist regulators to achieve more effective regulation, reducing barriers to trade, through:

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The template (voluntary) aims to assist regulators to achieve more effective regulation, reducing barriers to trade, through:

- Better measurements

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The template (voluntary) aims to assist regulators to achieve more effective regulation, reducing barriers to trade, through:

- Better measurements
- Better regulations

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# *RegMet* project

Information on the RegMet project may be found at

**www.regmet.dk**

***THANK YOU***

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