

Chemical Metrology for supporting Regulations and Conformity Assessment

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Main fields of application of Chemical Metrology

- | Food and feed (composition, contaminants, residues)
- | Waters
- | Environmental
- | Clinical/Medical
- | Pharmaceuticals/Drugs



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Food International Framework

- WTO AGREEMENT ON TECHNICAL BARRIERS TO TRADE
- WTO AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES
- JOINT FAO/WHO FOOD STANDARDS PROGRAMME



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WTO AGREEMENT ON TECHNICAL BARRIERS TO TRADE (I)

2.2 Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade

For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create.

Such legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; **protection of human health or safety, animal or plant life or health, or the environment.**



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WTO AGREEMENT ON TECHNICAL BARRIERS TO TRADE (II)

- | In assessing such risks, relevant elements of consideration are, *inter alia*: **available scientific and technical information**, related processing technology or intended end-uses of products.
- | 6.1 Members shall ensure... that results of conformity assessment procedures in other Members are accepted, even when those procedures differ from their own, provided they are satisfied that **those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures.**



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WTO AGREEMENT ON TECHNICAL BARRIERS TO TRADE (III)

It is recognized that prior consultations may be necessary in order to arrive at a mutually satisfactory understanding regarding, in particular:

6.1.1 adequate and enduring **technical competence of the relevant conformity assessment bodies** in the exporting Member, so that confidence in the continued reliability of their conformity assessment results can exist; in this regard, **verified compliance, for instance through accreditation, with relevant guides or recommendations issued by international standardizing bodies shall be taken into account as an indication of adequate technical competence;**



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WTO AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES(I)

- 1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health
- 2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, **is based on scientific principles and is not maintained without sufficient scientific evidence**



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WTO AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES(II)

DEFINITIONS

1. *Sanitary or phytosanitary measure* - Any measure applied:

.....
(b) to protect human or animal life or health within the territory of the Member from risks arising from **additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;**
.....



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WTO AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES(III)

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; **testing, inspection, certification and approval procedures**; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and **methods of risk assessment**; and **packaging and labelling requirements directly related to food safety**.



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WTO AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES(IV)

3. *International standards, guidelines and recommendations*

(a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, **methods of analysis and sampling**, and codes and guidelines of hygienic practice;



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WTO Agreements Measurement Requirements SUMMARY

- ü available scientific and technical information
- ü conformity assessment procedures that offer an assurance of conformity with applicable technical regulations or standards
- ü technical competence of the relevant conformity assessment bodies with verified compliance, for instance through accreditation, with relevant guides or recommendations issued by international standardizing bodies
- ü SPS measures (including testing, inspection, certification and approval procedures and methods of risk assessment) based on scientific principles and not maintained without sufficient scientific evidence



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WTO Agreements

Risk assessment based on scientific principles and available scientific and technical information

Regulations, standards, guidelines and recommendations
Composition and Food Safety
Technical Standards

Conformity assessment procedures and bodies

Methods of analysis and sampling



JOINT FAO/WHO FOOD STANDARDS PROGRAMME Codex Alimentarius

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Twenty-fourth Session

Budapest, Hungary, 18-22 November 2002

CX/MAS 02/13

THE USE OF ANALYTICAL RESULTS: SAMPLING, RELATIONSHIP BETWEEN
THE ANALYTICAL RESULTS, THE MEASUREMENT UNCERTAINTY,
RECOVERY FACTORS AND THE PROVISIONS IN CODEX STANDARDS



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Regulations and Measurement Uncertainty (I)

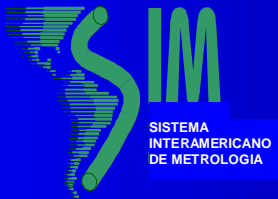
Potential problems with the reporting of results for which there is a specification

Specification of $4 \mu\text{g}/\text{kg}$ for the analyte being analysed.

Measurement uncertainty for the analysis of the order $\pm 45\%$ of the analytical

result, i.e. the analyst would determine for nominal concentrations of 3, 6 and $10 \mu\text{g}/\text{kg}$, the following concentrations including their uncertainties:

- a. $3.0 \pm 1.3 \mu\text{g}/\text{kg}$,
- b. $6.0 \pm 2.6 \mu\text{g}/\text{kg}$, and
- c. $10.0 \pm 4.4 \mu\text{g}/\text{kg}$



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Regulations and Measurement Uncertainty (II)

Situation a

Here the level reported is below the specification. All countries would take the same view and accept the material.

Situation b

Here the level reported is above the statutory limit but the true value lies in the range 3.4 to 8.6 $\mu\text{g}/\text{kg}$. **The level and its uncertainty would be reported.**

Here some countries would report the sample as containing not less than 3.4 $\mu\text{g}/\text{kg}$ of the analyte and because it is not beyond reasonable doubt that the limit has been exceeded, no action will be taken.

However, other countries may take action on the 6.0 $\mu\text{g}/\text{kg}$ result, **without taking uncertainty into account.** For these countries, the material will be deemed to be non-compliant.



Regulations and Measurement Uncertainty (III)

Situation c

Here the level reported is above the specification and the true value lies in the range 5.6 to 14.4 $\mu\text{g}/\text{kg}$. All countries will state that the material is non-compliant with the specification.

Conclusion

In situation b there is the possibility that different countries will make opposite decisions as to whether the material conforms with the specification. **The approach to be used must be indicated by the Codex Commodity Committee when negotiating the Codex Commodity Standard.**



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Chemical metrology support for regulators and conformity assessment (I)

- ü When formulating regulations (establishing technical limits): assurance of appropriate approach to measurement through the identification of validated methods of analysis with traceable results at the appropriate level
- ü During enforcement: ensure appropriate surveillance measurements traceable to SI, robust, cost balanced and of suitable uncertainty to enable an adequate assessment of compliance of the technical limits established



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Chemical metrology support for regulators and conformity assessment (II)

- ü Provide confidence in measurements, establishing traceability to the SI (or to appropriate CRM) through an unbroken, auditable chain via an NMI signatory to the CIPM MRA and who declares appropriate CMCs in the BIPM data base
- ü Provide appropriate research when no measurement standards and methods exist ensuring that technical limits are robust and avoid unnecessary barriers to trade (risk based, measurable, either method independent or method specified , economic, agreed on as wide a basis)



Chemical metrology support for regulators and conformity assessment (III)

Provide the laboratories of appropriate measures to ensure that it is capable of providing and does provide data of the required quality.

Such measures include:

- using validated methods of analysis;
- using internal quality control procedures;
- participating in proficiency testing schemes; and
- becoming accredited to an International Standard, normally ISO/IEC 17025. Accreditation to ISO/IEC 17025 specifically addresses the establishment of traceability for measurements



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Benefits of Chemical metrology support for regulators and conformity assessment

- ü Identification and adoption of measurement best practice
- ü Improved confidence in results obtained within regulatory fields
- ü Increased harmonization, consistency and avoidance of duplication of effort between sector and countries
- ü Provide a common platform for interregional trade negotiations



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THANK YOU!

MUCHAS GRACIAS!

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