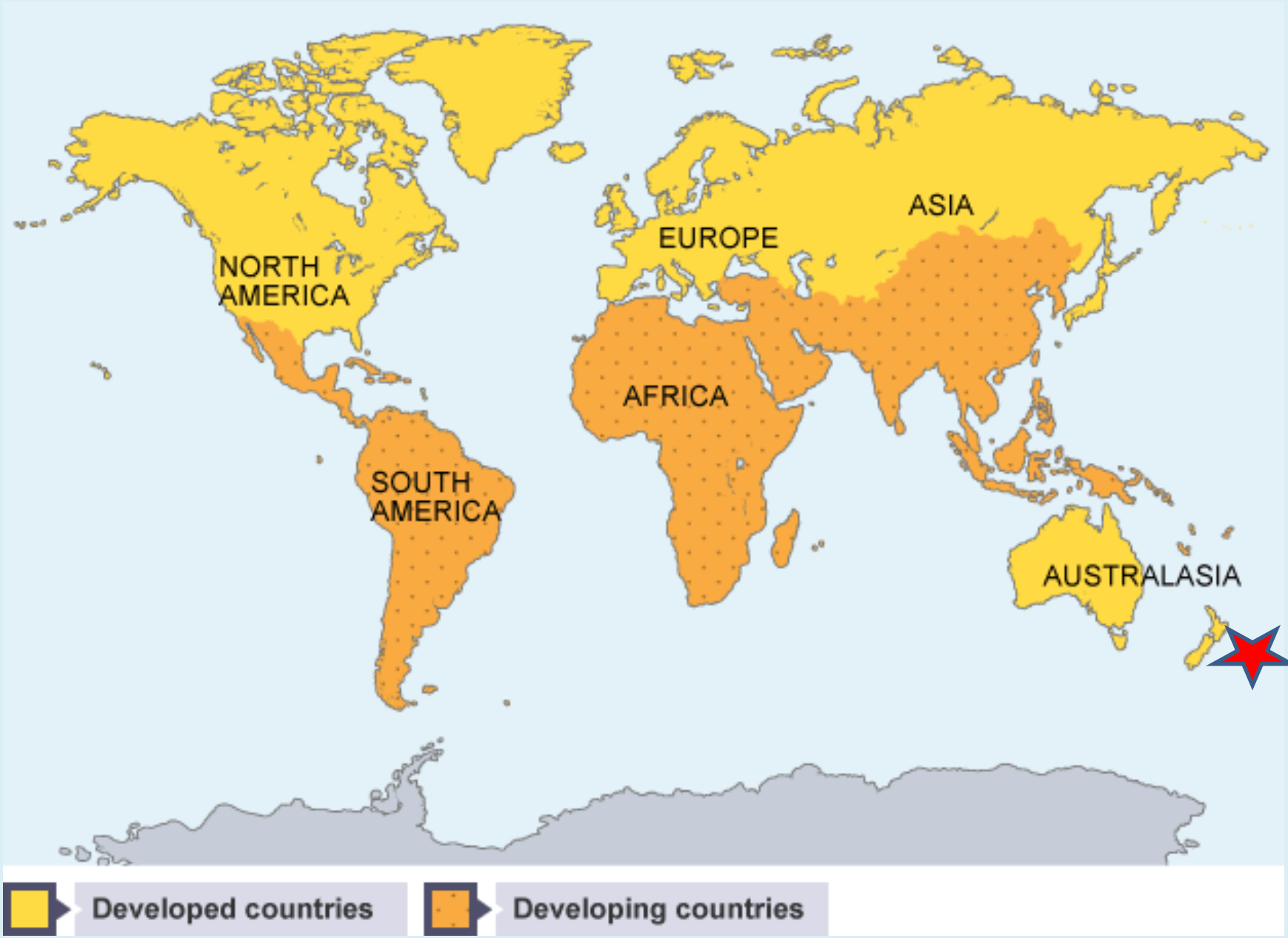
Current Status and Prospects of Metrological Traceability in Chemistry and Biology in New Zealand

Dr. LALY SAMUEL

Chair, Cooperation on International Traceability in Analytical Chemistry (CITAC)

New Zealand


NORTH AMERICA
EUROPE
ASIA
AFRICA
SOUTH AMERICA
AUSTRALASIA
Developed countries
Developing countries

New Zealand is situated about 1,500 kilometres (900 mi) east of Australia across the Tasman Sea.

It was one of the last lands to be settled by humans.

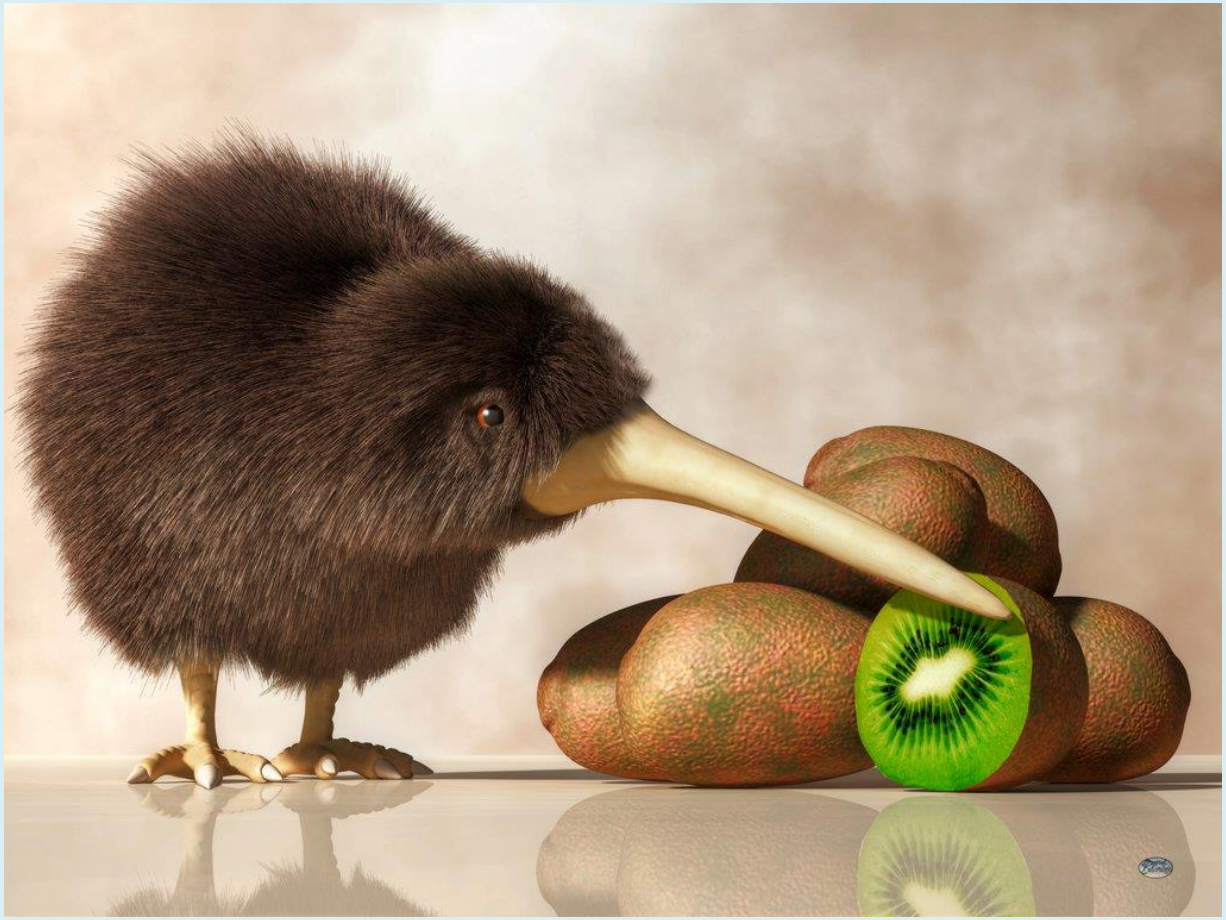
During its long isolation, New Zealand developed a distinctive biodiversity of animal, fungal and plant life.

Population
4.5million

30 million Sheep
10 million Cattle

Introducing.. New Zealand

KIWIS



New Zealand Culture

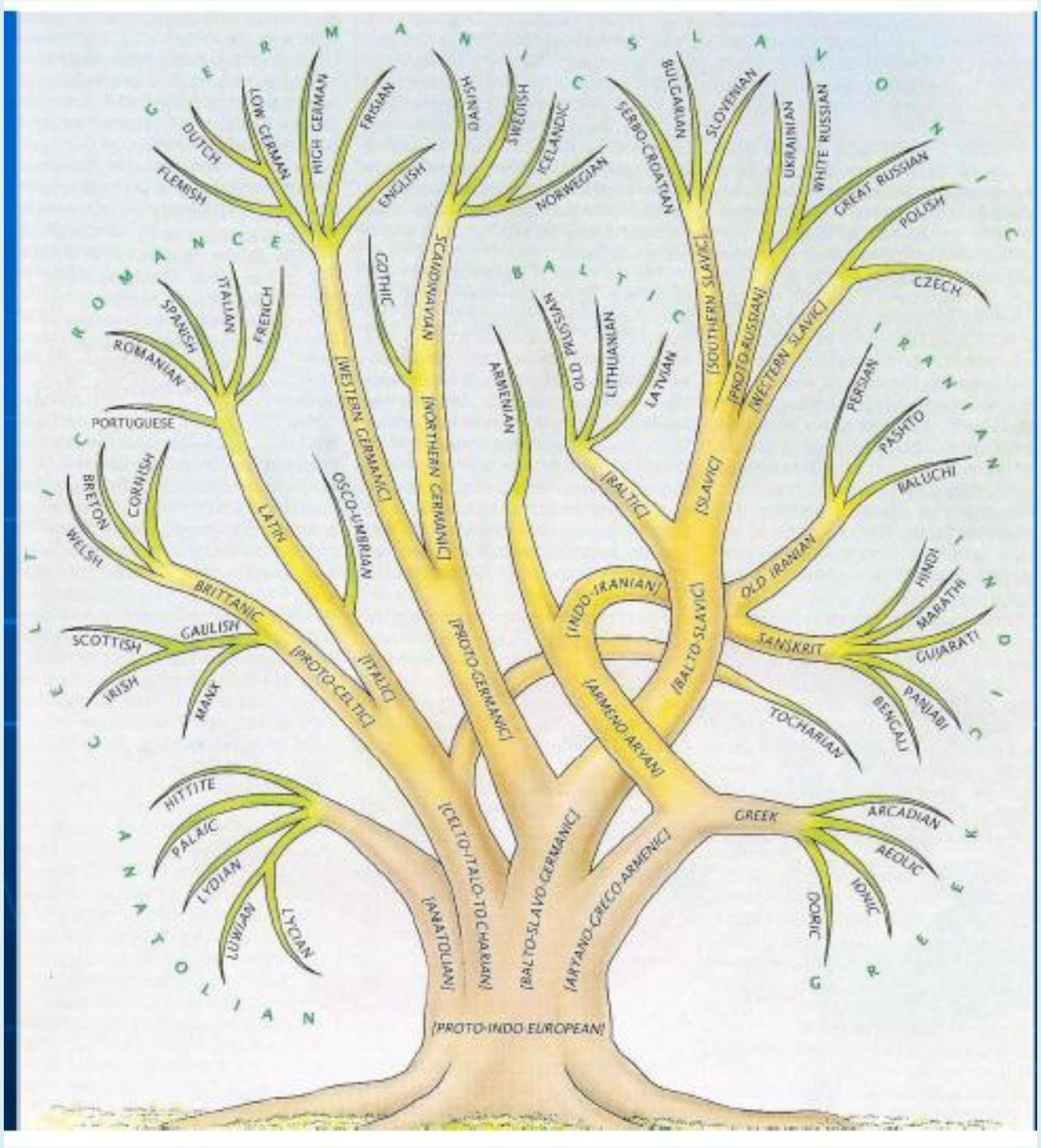
GDP PER CAPITA

International Links

- NZ is signatory to the Metre Convention (SI)
  - MSL holds base SI units for length, mass, time, electricity, temperature and light
  - MSL is signatory to the CIPM MRA
- NZ is signatory to the OIML Convention (legal metrology)
  - Measurement and Product Safety Service (MAPSS) of the Ministry of Consumer Affairs provide the relevant services
- NZ is a member of Codex Alimentarius commission
  - New Zealand Food Safety Authority (NZFSA)

The importance of Traceability

- ‘The ability to demonstrate the accuracy of a measurement result in terms of appropriate national or international standards’
- Traceable to the SI
- Comparable
- Fit for purpose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Why Traceability for Chemical and Biological Measurements

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 of comparisons all having stated uncertainties
- To SI, whenever possible; mol, kg, m, etc. or any combination (multiple, sub-multiple)
- To “next best” internationally agreed reference if SI is not possible

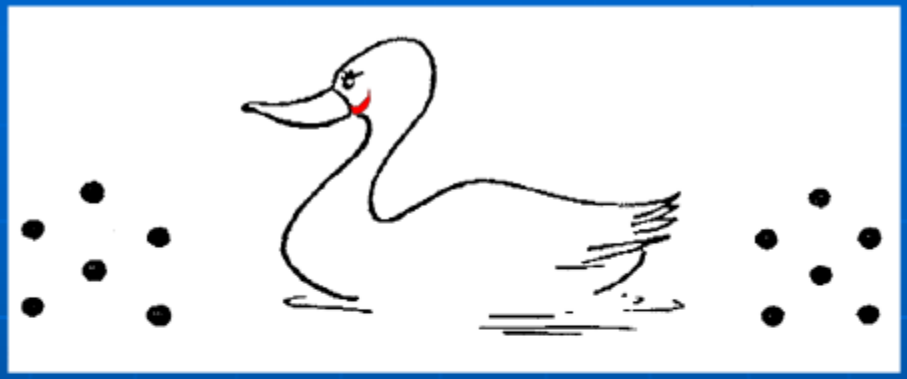
Demands....

- ISO/IEC 17025 will require laboratories to consider traceability and uncertainty in all types of measurement.
- All countries involved in international trade must participate in the international approaches now being developed to demonstrate comparability of results.
- It is not only a problem of larger economies
- The demonstration of comparability between chemical results will always be more difficult than between results from physical measurements

International Trade

- International trade issues are vital for people in our primary production sector
- Public Health for small population

Measurement accuracy



ON THE AVERAGE THE DUCK WAS DEAD (!?)

A hunter fired both barrels of a shotgun at a duck.
The first hit two feet in front, the second hit two feet behind.
On the average the duck was dead.
In duck hunting one wants to keep trying until a ***single shot*** hits the mark.

Source: J Ruzicka 1980 (at the habilitaion of K Heydorn KØBENHAVN)

It is cheaper to perform less measurements,
but have sufficiently small uncertainty every time,

than making many measurements and use the average

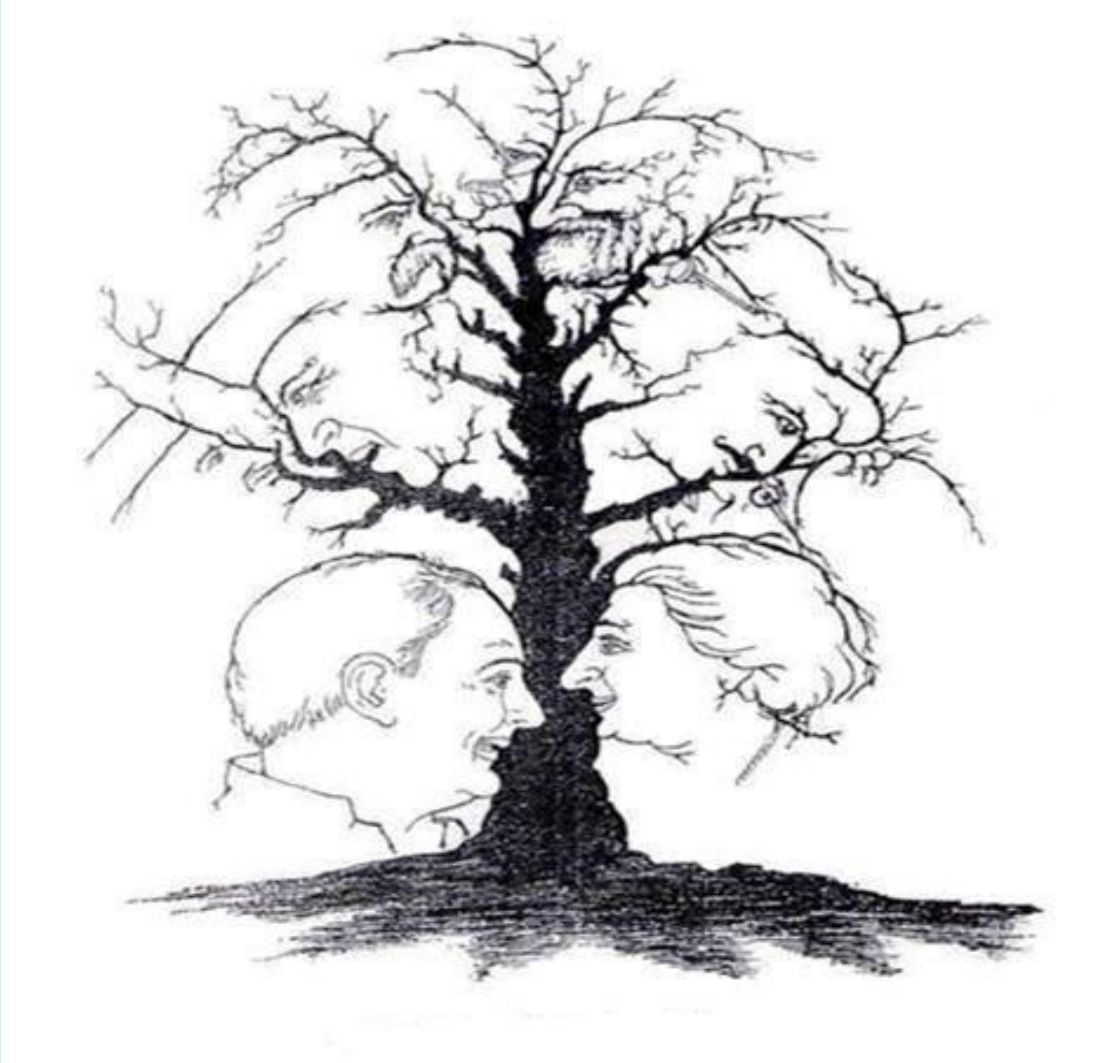
Chemical Measurements

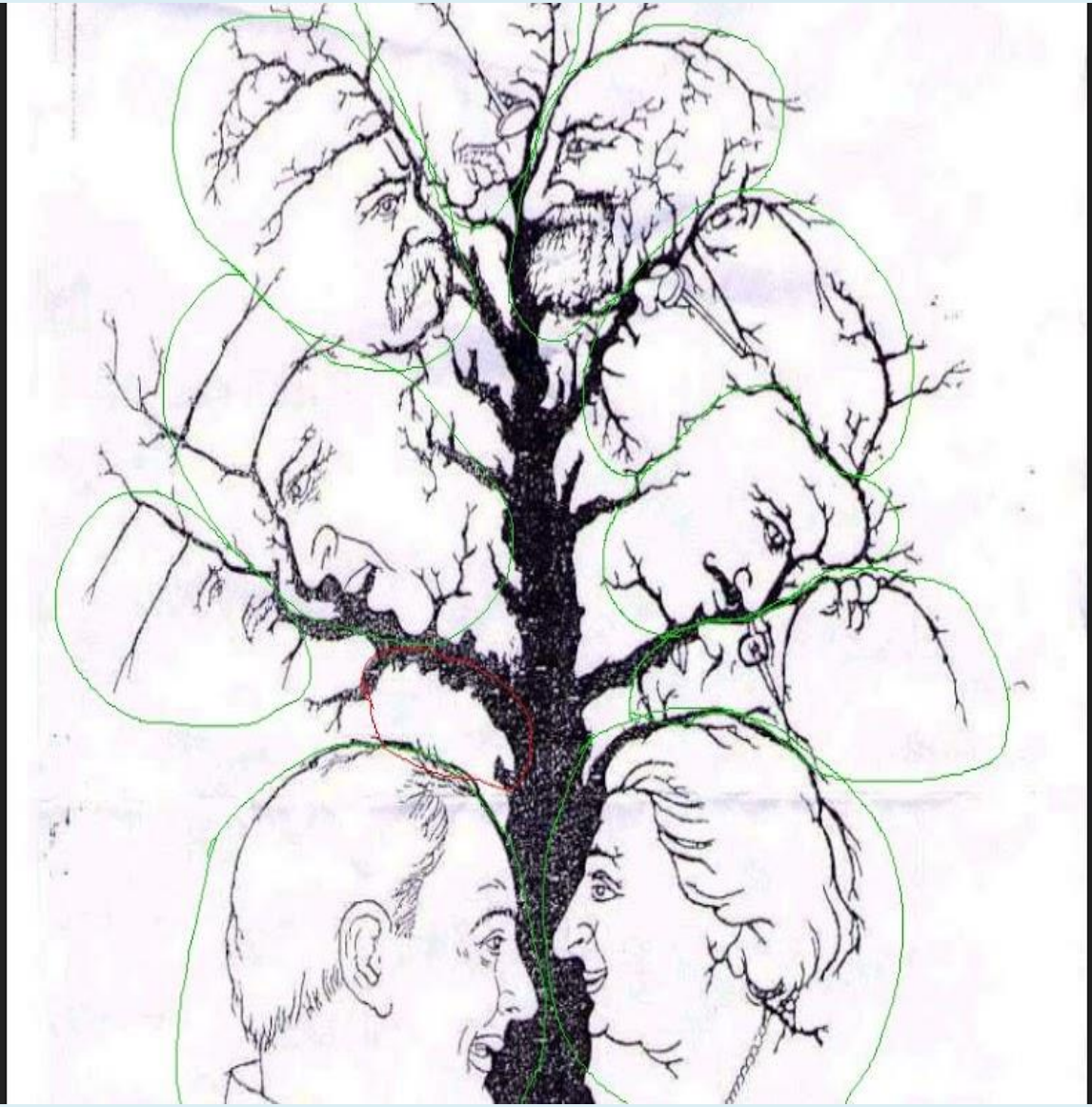
- Depend on reference method. If the method is changed there is always the potential for the change to alter the result measured.
- Chemical measurements depend on calibration standards, and the reliability of statements of purity of the standard, if they exist, are often unknown.
- It offers concepts, disciplined strategies and systems which help to ensure that measurements are traceable to a firm reference point, preferably the International System of Units (SI)

Chemical Measurements

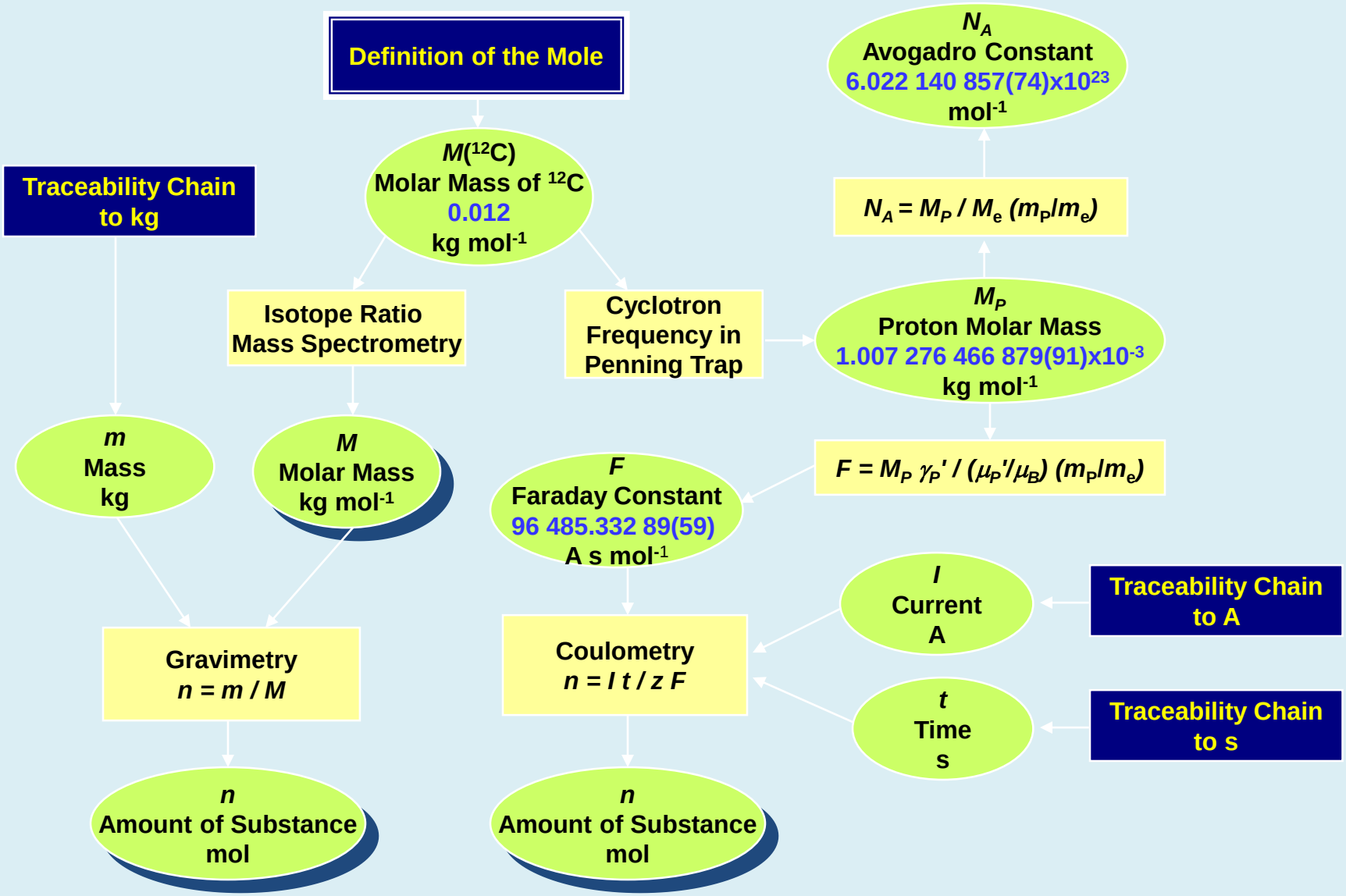
- Chemical measurements are matrix- and concentration-dependent
- Because chemical measurement normally destroys the test sample, it is impossible for several laboratories to all check the same set of samples and demonstrate comparability of their analytical measurements.
- Demonstration of comparability of analytical chemical measurements, therefore,
  - requires development and use by laboratories of well-characterized reference materials
  - participation in proficiency systems and inter-laboratory comparisons.
  - Demonstrate the ability to estimate uncertainty

Identify the sources of uncertainty





Traceability chains in chemistry for the realization of the mole



Comparability of results

- Results linked to a common reference can be compared.
- Scope of reference defines scope of comparability.
  - Global network
    - SI (International System of Units)

Exporter  Importer

Credibility of the product

Guarantee the quality of the product

Safe guard the country

Measured once accepted everywhere

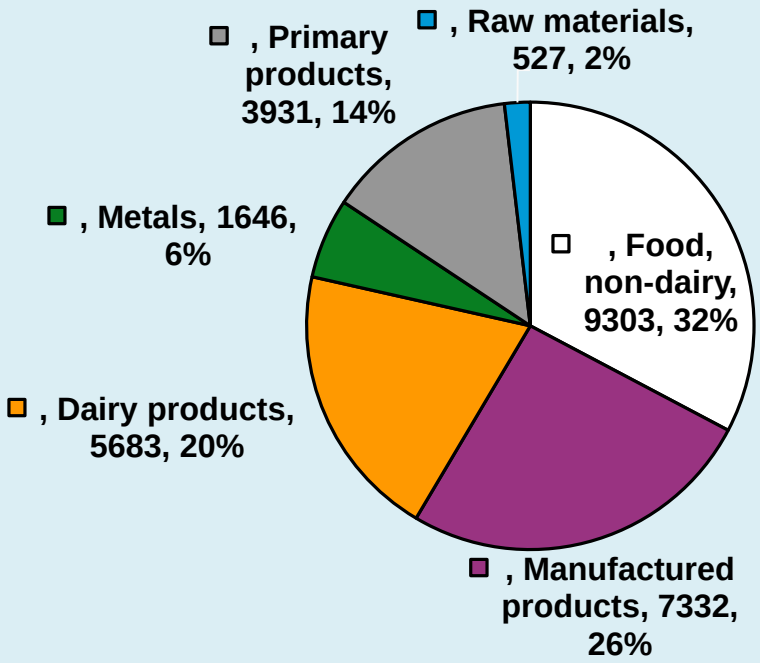
New Zealand Situation

- Even though New Zealand is a very small isolated country where it is difficult to exploit economies of scale, she is an efficient producer of a range of products that are subject to some of the world's highest trade barriers.
- Majority of trade related measurements are chemical or biological in nature.

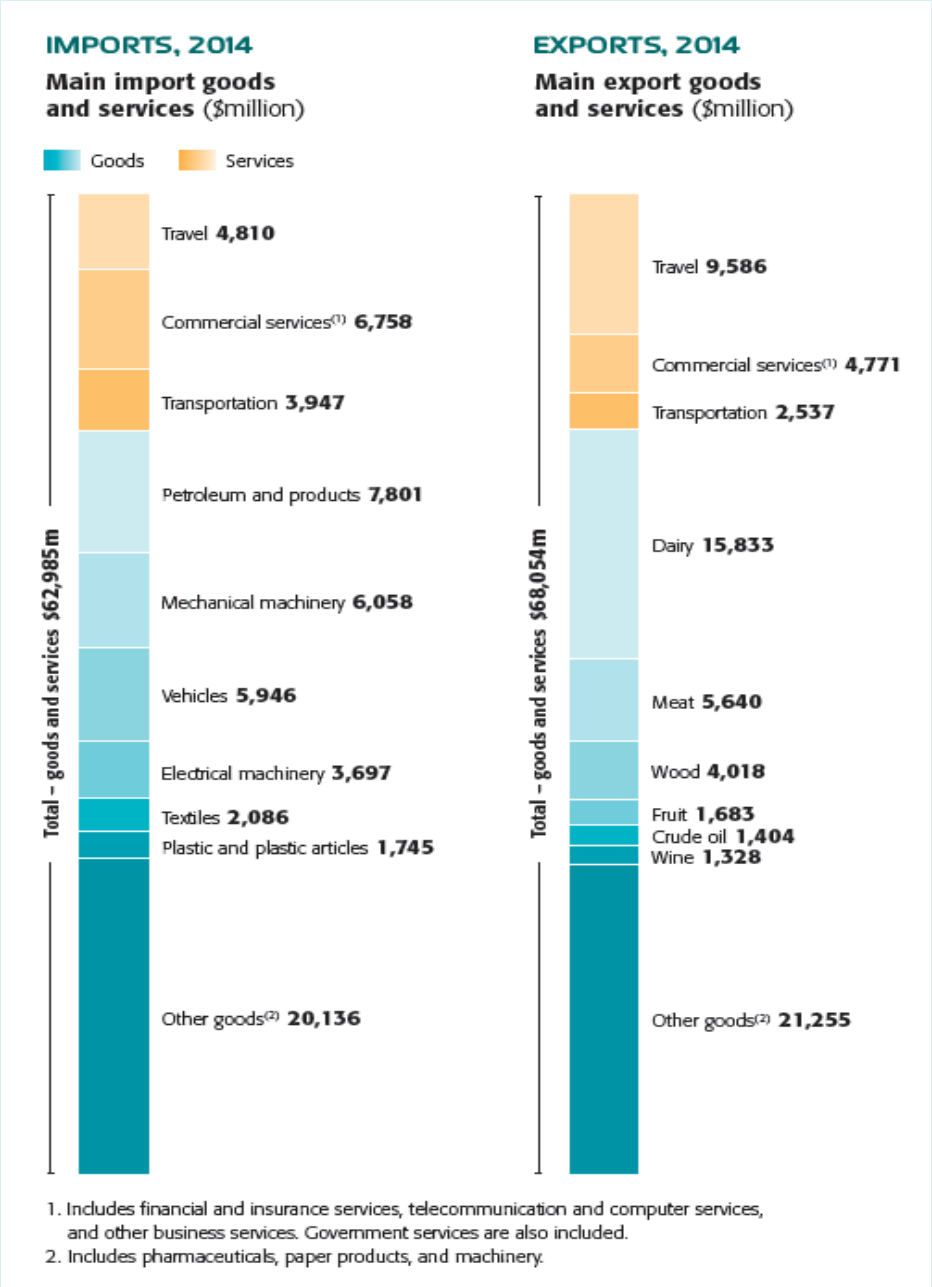
NZ's key exports

- Dairy products
- Timber
- Meat
- Seafood
- Horticultural products (including organics)
- Tourism (not included in this presentation)

New Zealand exports



Import- Export details



Market

- More than 90 percent of all dairy products produced in New Zealand are exported.
- 90 percent of all lamb, and 80 per cent of all beef, is exported.
- Market access matters - if New Zealand loses access to key markets, we all suffer.”

Product safety

- **Animal Welfare**
- **GM** – retailers and brand owners don't want it
- **Timber** –demand for certified product
- **Seafood** –key sustainability issue – demand for certified product
- **Dairy products** – NZ's clean green image definite selling point
- **Meat and fresh produce** – increasing demand for farm assurance schemes including environment and community welfare

Food

- Food is big business in New Zealand. The food industry produces 23% of New Zealand's manufacturing GDP, and represents half the total value of merchandise exports.

- *According to a recent Massey University study, value-added food and beverage exports made up 54 per cent of NZ total food exports.*

Our interest

- Food Safety
- Water Quality
- Population & Environmental Health, and
- Communicable Disease

Measurements

- **Chemical and Microbiological hazard identification and risk assessment**
- **Food contaminant and residue analysis and interpretation, including compliance with regulations and standards;**
- **Food safety through the investigation of natural food components influencing health and disease;**
- **Testing of foods implicated in food poisoning and investigation of food-borne illness outbreaks.**

Food safety

- **Although food is now safer than it has ever been, and people are living longer, food scares still occur**
- **Some of these arise from a lack of understanding, or trust, in the part that science and the food industry play in bringing food to our table.**

Health concerns

- Foodborne Bacterial infection
- Foodborne viral infection
- Waterborne deceases
- Bovine Spongiform Encephalopathy (BSE)
- GE food (GMO's)
- Food additives
- Pests and Pesticides

Ect …etc.

Campylobacter

- Quantification of *C. jejuni* is of interest as

  - it is a common cause of gastrointestinal illness and

  -is of public health significance in many countries and

  -is of particular concern in New Zealand
- The *C. jejuni* genome is a molecule approximately 1.7 mega base pairs long

Why campylobacter jejuni

- In 1980, campylobacteriosis became a noticeable disease in New Zealand.
- Since then, reported cases of gastroenteritis, are mainly due to the bacterial species Campylobacter jejuni and Campylobacter coli.

- Available statistics for the year ending 2000 support evidence that New Zealand has the highest reported incidence of campylobacteriosis in the developed world

- Studies places the total cost of foodborne infectious disease in New Zealand at $88.8million with the contribution attributed to Campylobacter species of $61.7 million.

Table 1 showing recorded incident rates for six developed countries

Country	Rate (per 100,000)
New Zealand (2001)	271.5
USA (2000)	20.1
England and Wales (1998)	111
Canada (1986-1998)	39-54
Denmark (1999)	78
Australia, excluding NSW. (2000)	107

Source of data: Lake et al. (2003).

Campylobacter jejuni

- Human infections are primarily due to exposure to contaminated food and water.
- Transmission Routes
  - Through Water
  - Through Uncooked meat, especially chicken
  - Milk
- Calibration preparations are known to have problems of both long-term stability when used as a calibrant for PCR and characterisation of the DNA before use as a calibrant.

NZ bio-metrology project

- Identification

  -Development of potential calibration standards for the PCR quantification of the micro-organism *Campylobacter jejuni*.
- Development of PCR calibration standards

  - equivalent standard to those in other areas of chemistry.

  -Calibration standards must be of known and documented composition

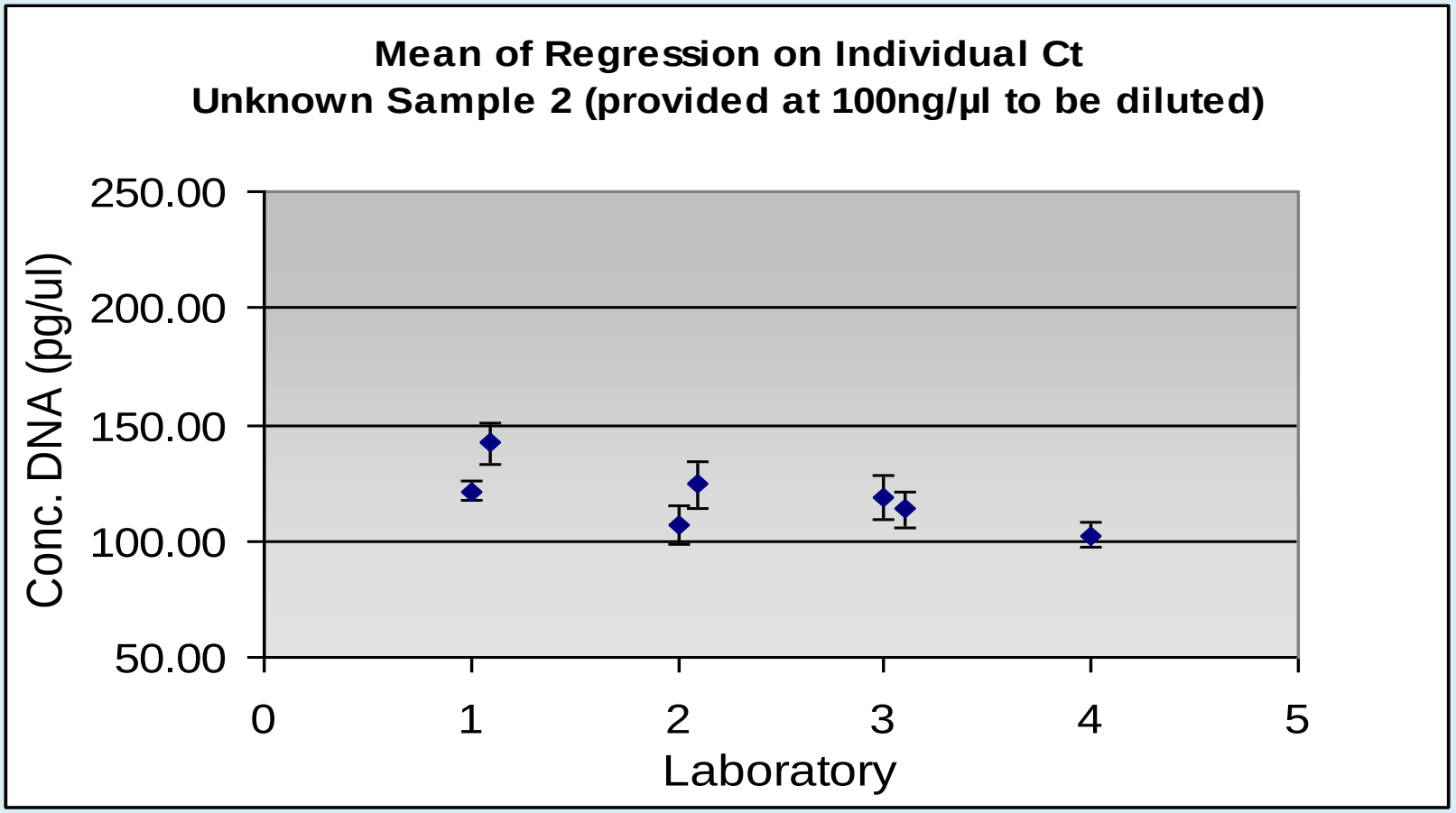
  - this must include demonstrated stability from time of characterisation until time of use.

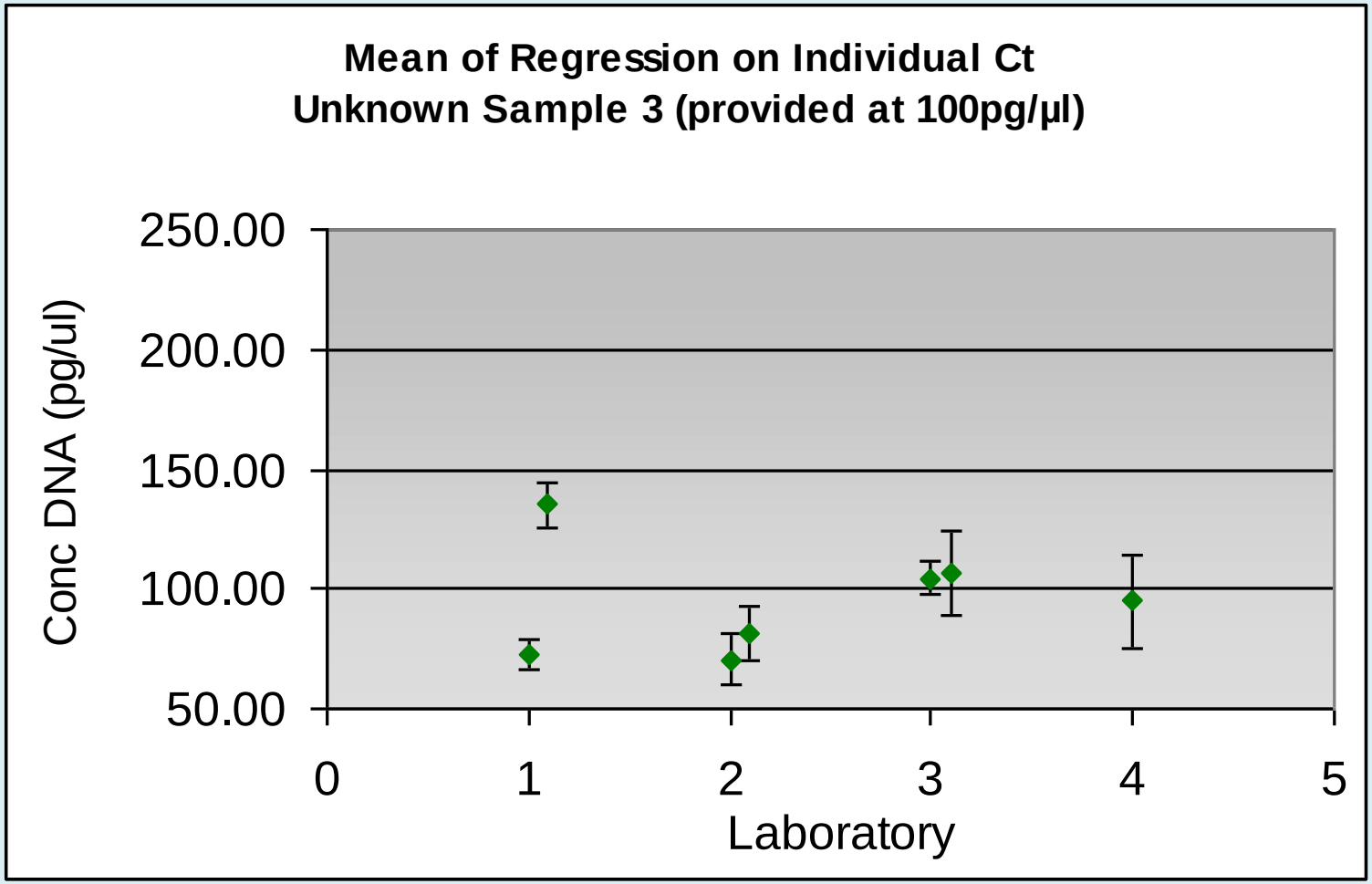
Selection of target genes

- Genomic DNA from c.jejuni has many potential genes that can be used as the basis for a PCR detection method
- However, to be useful as a basis of quantification, the selected gene must be
  - well understood,
  - known to be present in all isolates of that organism
  - but absent from other organisms from which it has to be distinguished
  - the number of copies must be consistent within the genome of the target population.

The DNA Calibration Standard

- Two most stable samples were taken and sent for two ring/comparison trials
  - National and
  - International
- Developed a detailed uncertainty budget for the PCR measurement


Mean of Regression on Individual Ct
Unknown Sample 2 (provided at 100ng/µl to be diluted)
250.00
200.00
150.00
100.00
50.00
Conc. DNA (pg/ul)
0
1
2
3
4
5
Laboratory

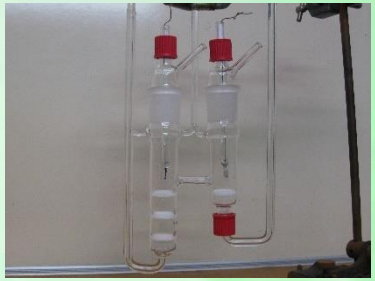

Mean of Regression on Individual Ct
Unknown Sample 3 (provided at 100pg/µl)
Conc DNA (pg/ul)
250.00
200.00
150.00
100.00
50.00
0
1
2
3
4
5
Laboratory

Traceable pH measurements –National pH Standard

- pH measurements are made traceable to the SI by pH buffers whose value is determined by a primary method of measurement;
- Electrochemical cell *without transference* using a hydrogen gas electrode and a silver-silver chloride reference electrode:a "**Harned Cell**"

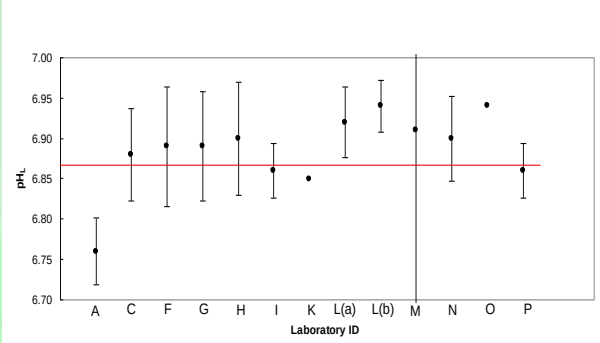
pH measurements at MSL

- MSL has developed an operating Harned cell system.
- Developing traceability with international NMIs
- Currently: U(pH) = 0.006 (k=2 95% CI)
- Planned: U(pH) ≈ 0.004
- Collaborating with AsureQuality to provide reference values for proficiency trials (potable and effluent waters).



MSL Inter-laboratory comparison:
pH of phosphate buffer

- Measurements made with glass electrode/meter assembly with bracketing calibration procedure.
- Reference value of sample determined with primary method (Harned cell).



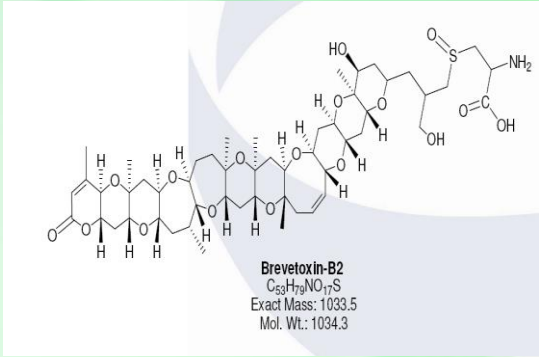
- pH measurement of unknown sample when calibration performed with standard buffers used by participating laboratory during standard measurement procedure.
- Red line – Reference value determined by primary method analysis (Harned cell). Provided by co-ordinating laboratory.
- Error bars – Expanded uncertainty (k = 2) giving a 95% level of confidence. See notes for details of uncertainty calculation.

MSL Measurement Standards Laboratory of New Zealand

IRL

Neurotoxin Shellfish poisoning : New standard in shellfish Biotoxin testing

Neurotoxin Shellfish poisoning (NSP) is a syndrome caused by the consumption of shellfish contaminated with a class of natural toxins called brevetoxins. Consumers are protected from NSP by the regular testing of shellfish and since the 1950's this testing has been via a mouse bioassay. The NSP mouse bioassay protocol is unethical (it requires 5 mice of specified body weight) and is not validated. The mouse bioassay protocol is also labourious and requires the use of large amounts of diethyl ether which is dangerous and difficult to handle in the laboratory. Obviously a replacement assay is desirable; however the complex nature of NSP contamination and the restrictions of food testing make this a challenging problem.

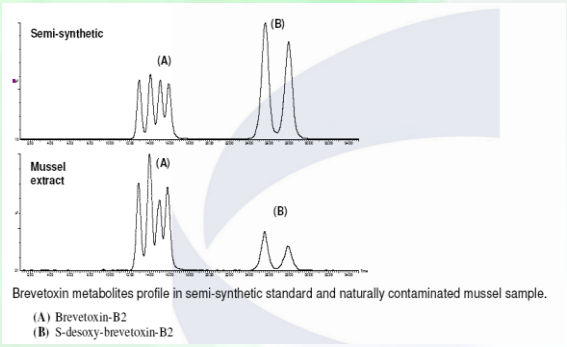


World first

A precise and powerful technique for detecting toxins in shellfish is a step closer to being accepted as a worldwide standard after validation by IRL's Measurement Standards Laboratory (MSL) and endorsement from the United States Food and Drug Administration (FDA).

Method

A chemical detection method using liquid chromatography coupled to mass spectrometry (LC-MS) was developed, validated and implemented for brevetoxins testing.
NSP is screened using an LCMS method for two brevetoxins (PbTx-2 and PbTx-3).
When either compound is detected the regulatory mouse bioassay is performed.
Pure brevetoxin metabolites were prepared and structure and purity were confirmed by NMR and LC-MS.



Brevetoxin metabolites profile in semi-synthetic standard and naturally contaminated mussel sample.
(A) Brevetoxin-B2
(B) S-desoxy-brevetoxin-B2

Result

- The new ASP/DSP/NSP method tests a total of 29 toxins in a single LCMS run including two brevetoxins (BTX-B2 and desoxy BTX-B2).
- New Zealand is leading the world in the adoption of improved non-mouse test methods for biotoxin testing.
- New Zealand Food Safety Authority (NZFSA) approved the Cawthron LCMS method for regulatory use in New Zealand – this was the first such approval issued world-wide.
- The LCMS method has proved to be faster, more sensitive, and more specific than the mouse bioassay.
- USFDA is collaborating with Cawthron Institute to develop this method
- CRM will be available through Institute of Marine Biosciences (IMB), Canada

MSL Measurement Standards Laboratory of New Zealand

IRL

Preparation and Testing of a Bovine IgG Certified Reference Material

Why Is IgG Important?

IgG is the main antibody found in bovine colostrum

Antibodies are responsible for immune function

Bovine colostrum

- Obtained from cow's milk collected in first few days after calving and manufactured into a powder.
- High value product
- Dietary supplement - supports human immune system
- New Zealand colostrum - high quality and purity
- Colostrum is often evaluated and compared by IgG content

Background

- Bovine IgG is a mix of IgG_1 and IgG_2 molecules
- Difference between IgG_1 and IgG_2 - minor variations in amino acid sequence in Fc region
- Bovine serum and colostrum IgG have different proportions of IgG_1 and IgG_2 (1)
  - Serum 56:44
  - Colostrum 90:10
  - Immunological differences

IgG Reference Material

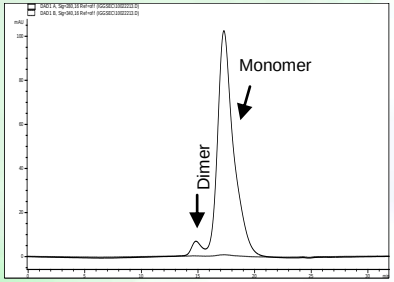
- Commercially available bovine IgG - serum derived powder (Sigma)
  - Comparability, reconstitution, purity and traceability?
  - Issues reported for immunological assays of colostrum and milk with serum standard
- Conclusion – Colostrum-derived IgG reference best for colostrum assays

IgG Purification from Colostrum

1. Dissolution of powdered colostrum at high concentration -50 mg/mL
2. Acid precipitation of casein and some aggregate
3. Purification by preparative scale chromatography
   - Step 1- affinity (Protein G binding)
   - Step 2- size exclusion (SE-HPLC)
4. Monitoring of purification process using analytical scale chromatography
   - Protein G HPLC (IgG concentration)
   - SE-HPLC (10-500 kDa column for antibody purity)

$2 Coin

Preparative vs. Analytical Scale



Colostrum IgG After SE-HPLC Purification – SE-HPLC purity 96% monomer 4% dimer

Preparative Scale SE-HPLC Purification

Project Outcomes

Cawthron produced colostrum derived IgG CRM for Industrial Research Limited (185 mg)

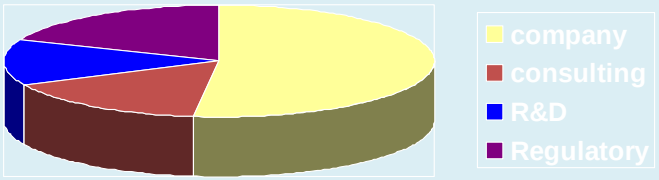
MSL Measurement Standards Laboratory of New Zealand

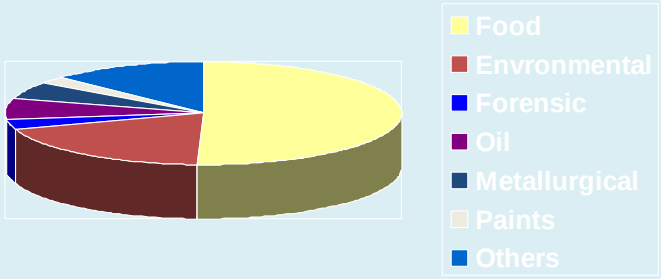
IRL

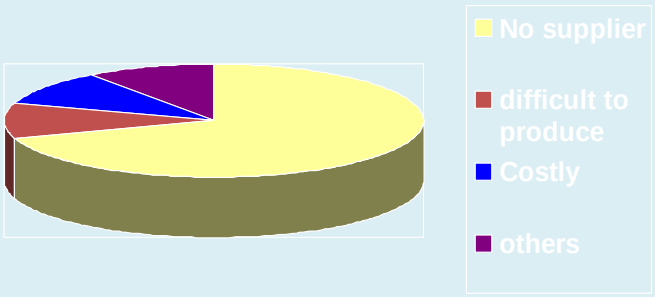
Dissemination of Traceability

- Disseminating traceability is not so simple
- In NZ, about 60% of industries use chemical and biological measurements at some stage such as
  - As part of the process for purchase and approval of raw materials
  - Quality control in the manufacturing process
  - Confirmation that the finished product complies with regulatory and customer specification requirements
- During the recent years several surveys on needs of New Zealand laboratories have been carried out

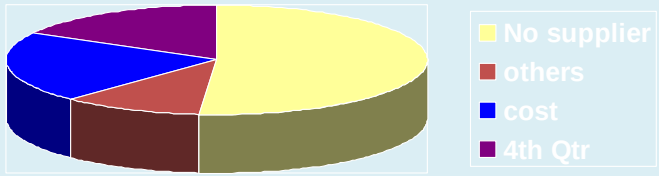
Questionnaire Survey 2011







Not using RM(16%)



Not participating PT(27%)

Survey results

- Both survey results showed strong need for
  - More interlaboratory programmes(ILCP)
  - More matrix relevant CRMs
  - More training

General trends….

- Validation is in general quite well established
- Measurement uncertainty
  - Many laboratories can estimate
  - Complicated in many sense
    - Legal purpose
    - Product screening

- Traceability
  - Due to the large varieties of analytes, traceability in chemistry comes from abroad
  - Use CRMs in some cases and mostly RMs
  - Price and availability are two identified problems

Dissemination

- National metrology Institutes who provide traceability are concerned with dissemination of traceability to the field laboratories
- In the same time field laboratories who provide the actual measurement are concerned with the demonstration of their traceability to satisfy accreditation and regulatory agencies

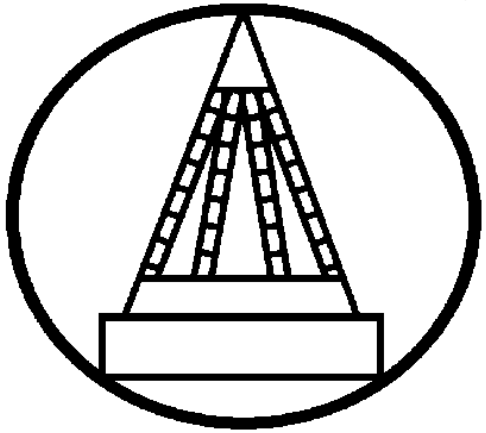
Dissemination to field laboratories

Essential elements to demonstrate traceability

- SI traceable
- Use of CRMs
- Use of quality management system
- Use of standardised measurement procedure

There is no guarantee that these elements automatically lead to reliable results

CITAC

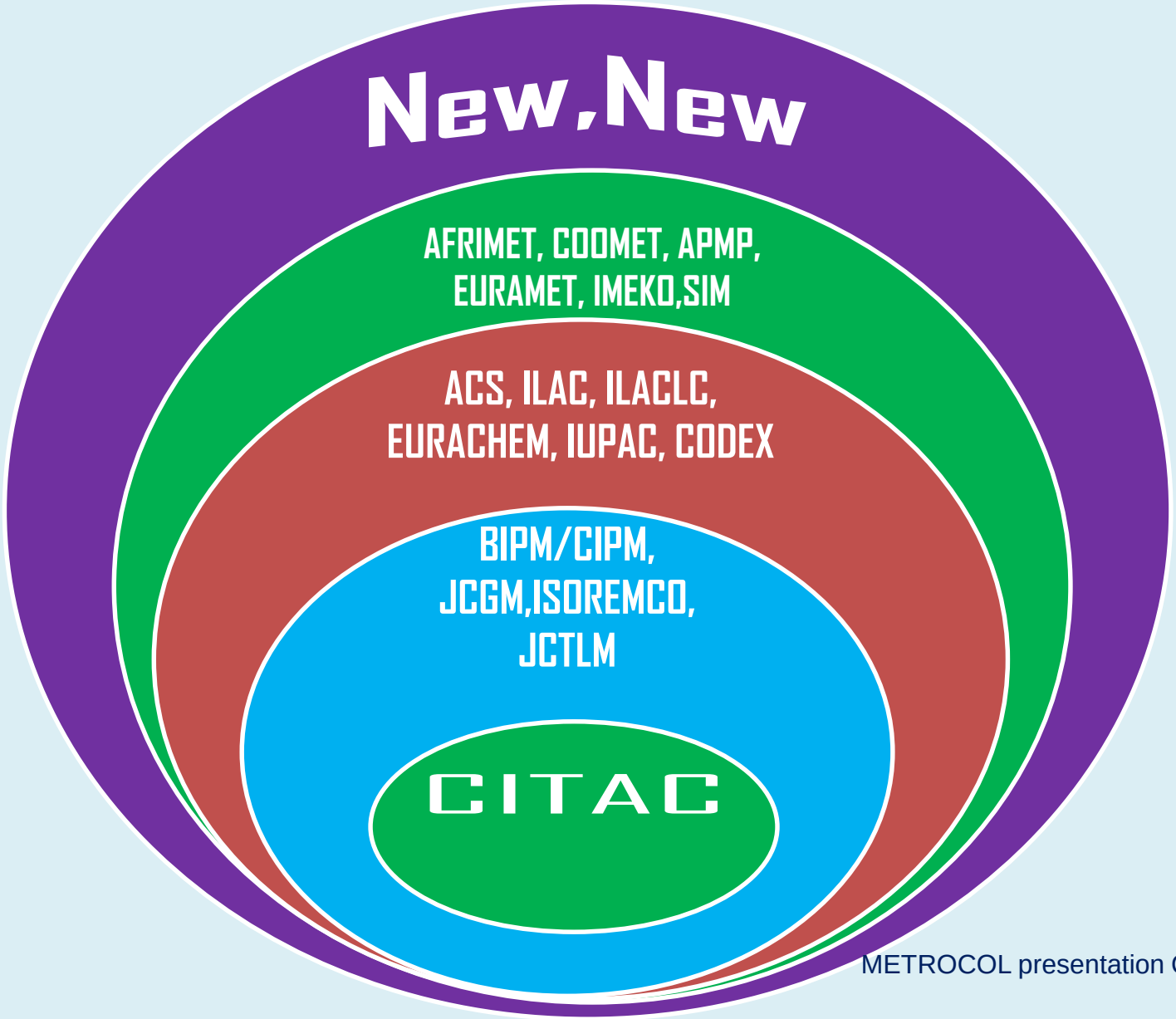


Co-Operation on International Traceability in Analytical Chemistry

MISSION

To improve traceability of the results of chemical measurements everywhere in the world

Connections



Membership

- 37 members from 6 continents
- Representing Metrology organisations, Universities, Industries, NGO's and Non-NGO's –with a common goal to promote traceability in analytical measurements.

CITAC Objectives

- Foster collaboration between existing organisations to improve the international comparability of chemical measurement
- To examine the practicality of traceability structures for various chemical measurements
- Defining criteria for establishing traceability to the mole
- To promote & harmonize quality practices in the analytical chemistry laboratory
- Preparation of quality system guidelines for the production of reference materials

STRATEGIES (1)

- To provide a truly international forum for the exchange of information with respect to worldwide traceability of results of chemical measurements;
- To provide tools for analytical laboratories for establishing traceability to “stated references”;
- To share views, clarify important concepts and raise the awareness of the needs and possibilities leading to traceability in chemical laboratories;
- To prepare guides, discussion papers and scientific papers for Journals in relation to traceability, uncertainty and quality assurance issues;
- To organise seminars, symposia and workshops and participate in conferences to promote the message of traceability;

STRATEGIES (2)

- To play a bridging role between industry, governments, universities, metrologists and accreditation bodies and provide guidance to the analytical community;

- To work closely with other groups – *e.g.* CCQM, ISO/REMCO, IUPAC, ILAC, AOACI,regional and national professional chemistry societies and institutions, like EURACHEM– without duplicating work already being conducted by other groups – using these societies and institutions to act as a conduit to the field laboratories;

- To initiate and, where needed, coordinate work for the harmonisation and validation of methods;

- To initiate and, where needed, coordinate work for the harmonisation and validation of analytical methods based on traceability and other metrological concepts..

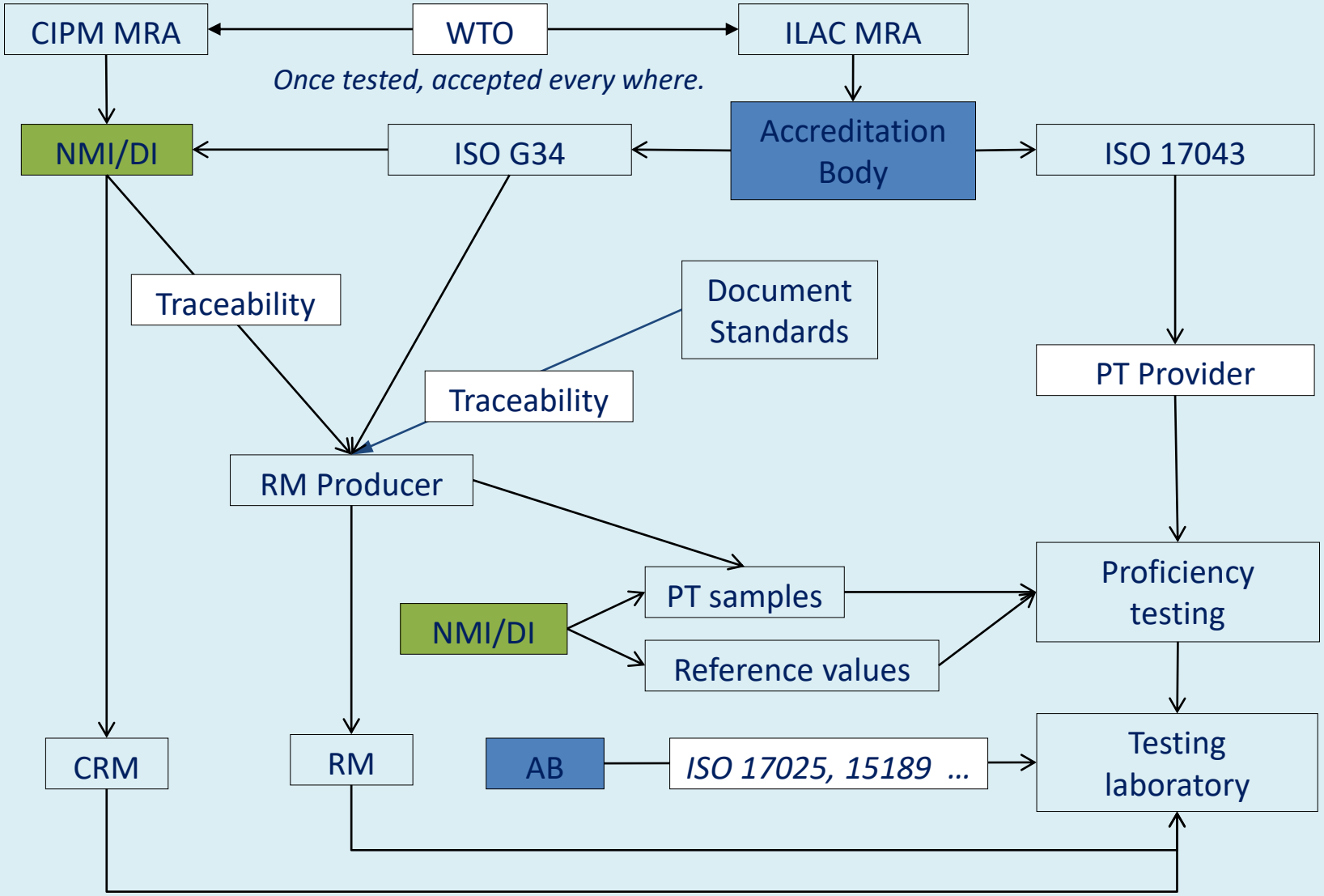
Dissemination through awareness

- Create awareness in the measurement community
- Create awareness in the accreditation community
- Create awareness in the regulatory community
- Make necessary changes in the legal system

Dissemination through cooperation

- Collaboration with stakeholders
  - Collaboration with accreditation agencies
  - Collaboration with metrology providers
  - Collaboration with standards organization
  - Collaboration with educators

Collaboration with Accreditation Body



Present situation ….

- NZ laboratory's technical competence is accredited by IANZ (New Zealand accreditation agency)
- IANZ accreditation common to most activities, and is increasingly relied on by regulators
- Accreditation programmes undertaken by IANZ are overseen by Accreditation Advisory Committee (AAC)
- Professional Advisory committee (PAC) are formed within IANZ to provide technical advice and review of specific areas of technology

Present Status

- MSL has an MoU with IANZ and advises through professional advisory committees (Metrology and Calibration, Chemistry Biology and Dairy)
- Some regulators utilising different paths
- Overseas regulators not using harmonised systems

Existing Dissemination support

- Providing RM and PT info through our website
- Provide advice to client inquiry
- Uncertainty estimation tools available through MSL website free of cost
- Facilitating international comparison studies
- Advise accreditation agency through professional advisory committee
- Provide information regarding international developments in the metrology in chemistry area
- We provide training, consultation and calibrations

Small size

- Cannot afford to build a comprehensive measurement system
- Difficult to establish and maintain efficiency of a complete hierarchy scheme
- The total resources of the country will be limited
- The number of testing laboratories might be quite small

Reference materials

- Most of the matrix reference materials are still certified by inter-laboratory comparisons or chosen from proficiency samples
- Small economies have difficulties to demonstrate that the locally assigned values have comparability to other countries
- Lack of national facility or the ability of a national facility to offer or afford all measurements

Dissemination…….

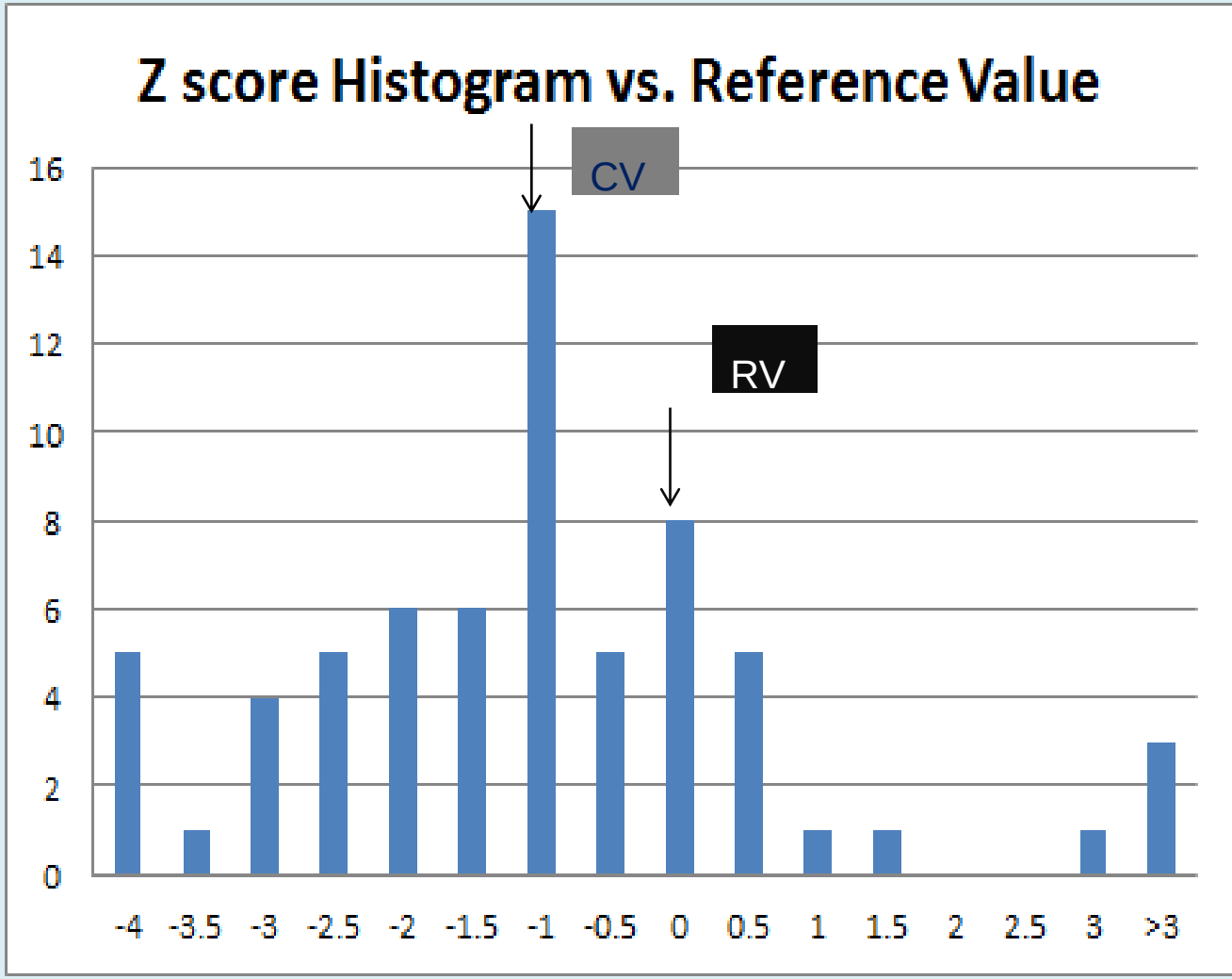
- Dissemination through value assigned PTs

  - Supply reference values with an uncertainty and traceability that is demonstrated at the highest metrological level.
- Participating laboratories can use these values to establish degree of equivalence of their measurements
- SI traceable result does not necessarily coincide with the median or average of the participants results
- On the basis of the picture participant's performance can be objectively assessed by any designated body (eg accreditation body)

Reference Value or Consensus Value

A good example of the outcome.

- Apparent bias was found in recent APLAC PT Program 'PAH in Sediment'
- What is the best way to make the feed back to the Laboratories?



Proficiency Test Providers

- PT programme in NZ is mainly run by an accredited organization –Global proficiency services
- They provide PT programmes for microbiological and chemical testing for a range of applications including dairy products, meat and food, water quality and pathogens
- Global proficiency's PT programmes are used by the National Association of testing Authorities, Australia for APLAC rounds
- There are over 200 participating laboratories for APLAC rounds

Establishment Process

- Identify
  - Stakeholders
    - for feedback on priorities
  - User groups
    - to establish requirements
  - Partners
    - to implement specialist requirements
- Agreements with partners
  - manage conflicts of interest
  - clear public good focus (for funding)
- Investment in new capabilities

Dissemination

- The country must maintain a sufficient range of local tests
- Able to demonstrate that local results are equivalent to those produced overseas

Identify the national stakeholders who will drive the process to create and implement a good chemical measurement system

- Are there particular industry sector groups that should be engaged ?
- Which government departments should be most involved ?
- Which regulatory bodies might need a good measurement support system to be in place ?
- Is there a national accreditation organisation that should be engaged as a partner ?
- Are there any proficiency testing providers in chemistry ?
- Which other service providers (e.g., education, chemical analysis) might be included ?
- Are there professional scientific associations that might be interested ?

Identify the national needs for chemical measurement

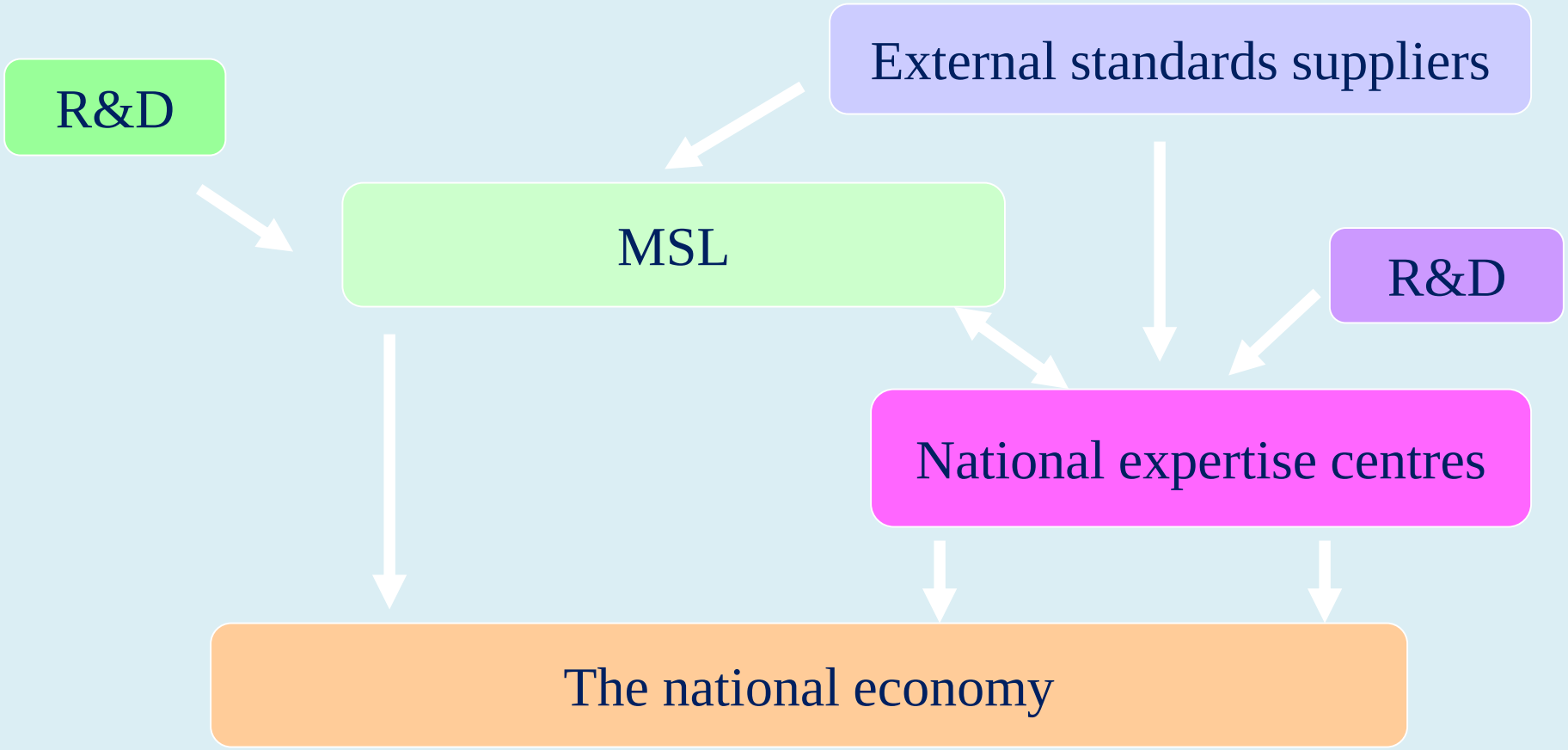
Which areas of the national economy should be given priority (and why)?

- Agriculture ?
- Animal production ?
- Manufacturing industry ?
- Mineral resources?
- Seafood ?
- Other ?

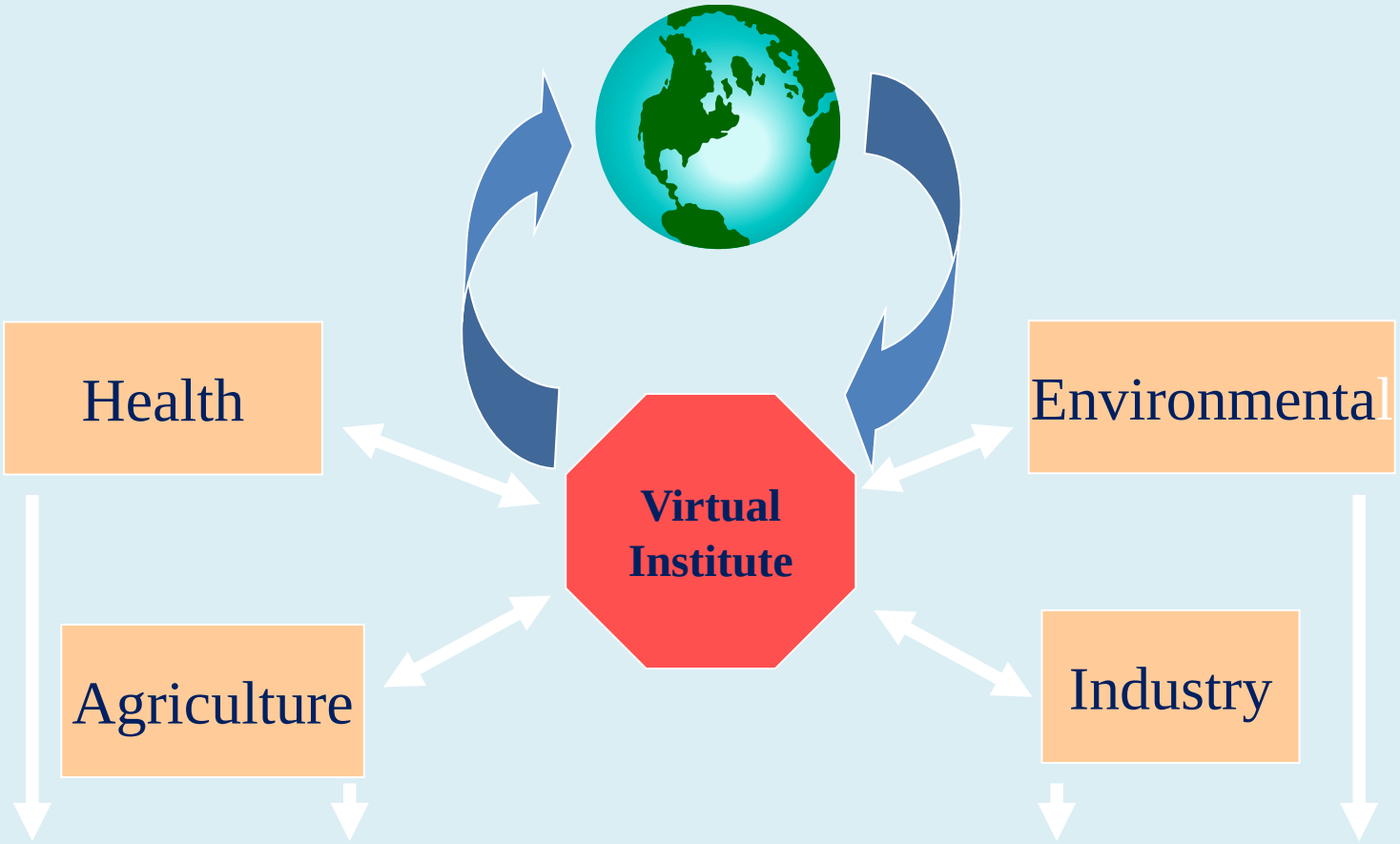
Which areas relating to national well-being should get priority (and why)?

- Food safety ?
- Health services ?
- Environment ?
- Law enforcement ?
- Consumer protection ?
- Other ?

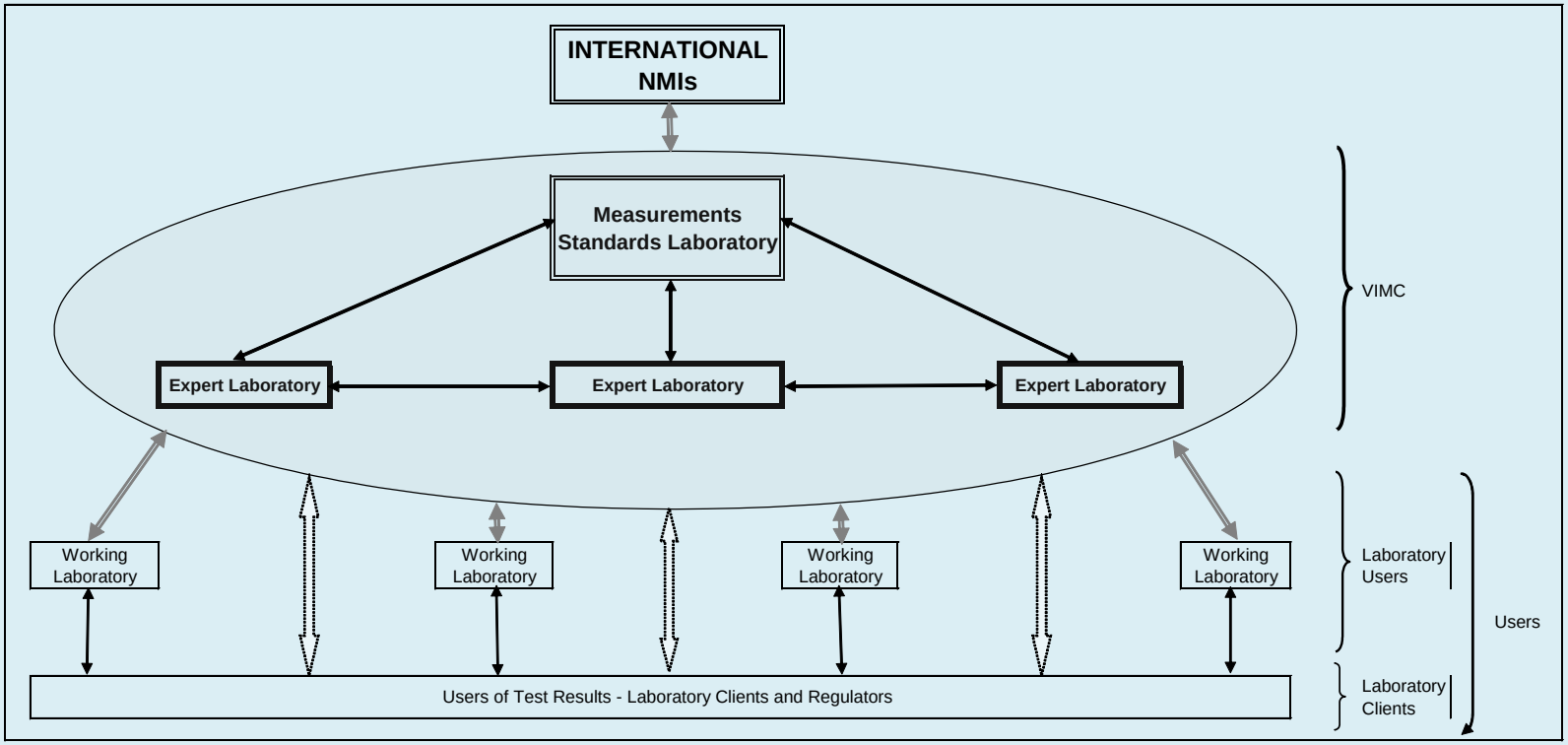
A Virtual Institute for Metrology in Chemistry



Virtual Institute Relationships



Relationships of the VIMC To NMIs and New Zealand user groups



Conclusion

- To achieve traceability and to disseminate traceability
  - Interests from government, traceability providers and users are necessary
  - Willingness to spend money from both the government and organizations are vital
  - Willingness to accept international changes/movements versus fit for purpose
  - Education and Training
  - Cooperation and collaboration

Thank you

INFRASTRUCTURE DEVELOPMENT GUIDE

APMP Guide

- The creation of a national infrastructure to ensure that a nation's chemical and biological measurement results are fit for their purpose has been recognised as a necessity in the modern world of a global economy and trading environment.
- Nations should ensure that internationally recognised and harmonised activities in accreditation and standardisation are available.
- The ultimate goal is to provide testing facilities and services that are internationally accepted.

Key Steps for Establishing Activities for the National MiC Infrastructure

1. Awareness raising with national stakeholders
2. Identification of needs
3. Capability Assessment
4. Gap Analysis
7. Obtaining Government Commitment
5. Prioritisation of needs
8. Capability Building
6. Selection of Appropriate Model or strategy
9. Dissemination of services

Awareness Raising with National Stakeholders

- One of the first steps in establishing the MiC infrastructure is raising the awareness of government, the community and other stakeholders of the importance of good measurement.
- The national metrology institute (NMI) cannot achieve such reform on its own. It must have the active support of stakeholders who are absolutely convinced of the value to be delivered by such a system.
- This degree of ownership is critical in ensuring a better national foundation for good measurements in chemistry.
- It is important to recognise that awareness raising activities must be part of the ongoing development of MiC programs.

Identification of Needs

- Before anything else is attempted it is vital that the reasons for creating or improving such a system and the outcomes that are expected to be delivered by that process are firmly established.

The primary common factors behind all of these areas are:

  - the need to be able to compare measurements effectively when they are made at different places and/or different times, and
  - the need to be able to rely on the accuracy of the measurements.

Need

The infrastructure and the expected deliverables from it will relate to one or more of the following areas:

- National welfare of the people
- Reliable and efficient health services;
- Effective environmental management/protection;
- Effective implementation of the law
- Consumer protection;
- Consumer safety.

National economic performance

- Ensuring quality of exports and facilitating trade
- Efficiency of industrial production, more effective process control;
- Support of innovation and industrial development;
- Surveillance of the quality of imported goods.

Identifying a national need

Scenario

- One nation might identify the need for the measurement of trace particles in cosmetic products.
  - The reason could be either to protect its own nation's health, including with respect to imported products, or to safeguard the product's export market. The particular analytes might be identified as being of interest. However, what is also needed is the recognition of the level of contamination that needs to be detected for each analyte and the level of uncertainty associated with that measurement result that will render the measurement fit for purpose.

Input from others

- For input on both aspects it is essential that the organisation identifies the stakeholders who will drive the process and who have the detailed knowledge to give direction to the process, and then involve them in consultation. These stakeholders might be drawn from the following areas:
- regulatory bodies •accreditation organisations • quality assurance organisations • proficiency testing providers •industry groups •certified reference material producers •trade organisations •maintenance and service providers •government departments • health care institutes • education sector (universities, etc.) • testing laboratories • consumer protection organisations • standards-setting bodies • scientific professional bodies

Government Input

- Government policy is an absolutely vital guiding tool. If the national government has already set priorities for development, these must be taken into consideration as presumably they have been based on mature consideration of the economy's needs.
- Quite apart from anything else, it will be easier to obtain funding from both the government and private sectors for work in such areas already identified by government as being important.

National Welfare of the People

Good reference systems are needed for:

- Reliable and efficient health services
- Clinical diagnostic and therapeutic measurements
- Quality of pharmaceuticals
- Effective environmental management/protection

- Keyenvironmental measurements- Contaminants in air, water, soil

Effective implementation of the law

- Substance abuse detection: Illicit drugs, alcohol • Customs and tariff requirements • Toxic residues • Origin of products • Forensic chemistry/biology/biochemistry • National security
- Consumer protection • Product composition • Accurate product labelling • Nutrient levels • Adulteration
- Consufer safety • Contaminant and residue levels • Import restrictions

Export data

- For the economic sector, a vital source of information is the national collection of statistics on exports – which exports are the most important for the nation now, which are growing rapidly in impact, which are selling into international markets that are sensitive to quality and involve intensive regulation?
- Ensuring quality of exports, and facilitating trade
- Meeting the requirements of markets for chemical composition, maximum allowable levels of contaminants and residues
- Reducing the need for duplication of measurements at source and destination
- Complying with the WTO Sanitary and PhytoSanitry Measures and reducing Technical Barriers to Trade
- Preventing despatch of inferior-quality product

National Economic Performance

- Surveillance of the quality of imported goods
  - Meeting national requirements
  - Meeting standards for energy sources (oil, gas, biofuels)
- Efficiency of industrial production, more effective process control
  - Ensuring replication of production conditions at different sites and times
  - Monitoring chemical composition and specification of product
  - Meeting production specifications set by foreign parent company or client
- Support of innovation and industrial development
  - Providing the measurement base for effective development
  - Facilitating the adoption of foreign technologies
  - Matching new products to foreign specifications
  - Attracting foreign investment through provision of suitable infrastructure
  - Developing new, alternative energy sources (biofuels, hydrogen)

Methods of Collecting Information on Needs

- Postal, internet and telephone surveys must be used to collect information because of the scale of the task,
- the face-to-face interview method is the most valuable method.
- The responses to the questionnaires will give valuable insights,
  - key stakeholders will be identified and involved in such in-depth interview processes.
  - It is expensive and time consuming, but the quality of information yielded by them can be far superior to even the best-designed questionnaire.
  - Furthermore they build ownership of the process into the person or organisation being interviewed, thus delivering value beyond the pure information content.
- After the results of the survey have been collected and consolidated, is to convene a general workshop on the outcomes.
- The workshop might involve all of the stakeholder organisations.
- At the workshop the views of these stakeholders would be sought to provide a reality check on the outcomes of the survey and proposed subsequent actions.

Capability Assessment

- Once the spectrum of national needs is established, an evaluation must be undertaken of the economy's ability to meet these needs.
- Which analytes can be measured?
- In which matrices?
- Over what measurement ranges?
- To what level of uncertainty?
- Which organisations have this capability?
- How much capability lies within the national metrology institute?
- Are there institutes in the economy that might become designated institutes (see Box on page 15), acting as an NMI for certain quantities, measurands, matrix composition and measurement ranges?
- Is there traceability of these measurement results to a national reference either in the country or abroad?
- If there is a national reference, is that linked to international references?

Gap Analysis

- The next step is to attempt to match the capability to the needs and discover where the gaps lie in terms of needs not addressed by existing capability within the economy.

Selection of Appropriate Model or Strategy

Prioritisation of Needs

- Having identified which needs are not currently adequately addressed, the next stage is to rank those needs in order of importance.
- Match of the need with national policy • Requirements on traceability and/or measurement uncertainty as stated in existing legislation and mandatory written standards in the country
- Availability of funding • Technical difficulty of task • Length of time required • Cost involved • Difficulty of disseminating the standards produced • Availability of potential partners
- It is important to recognise situations in which: a. Better measurement can make a difference and b. Better measurement can't make a difference