

EuroGentest

OECD Guidelines for Quality Assurance in Genetic Testing

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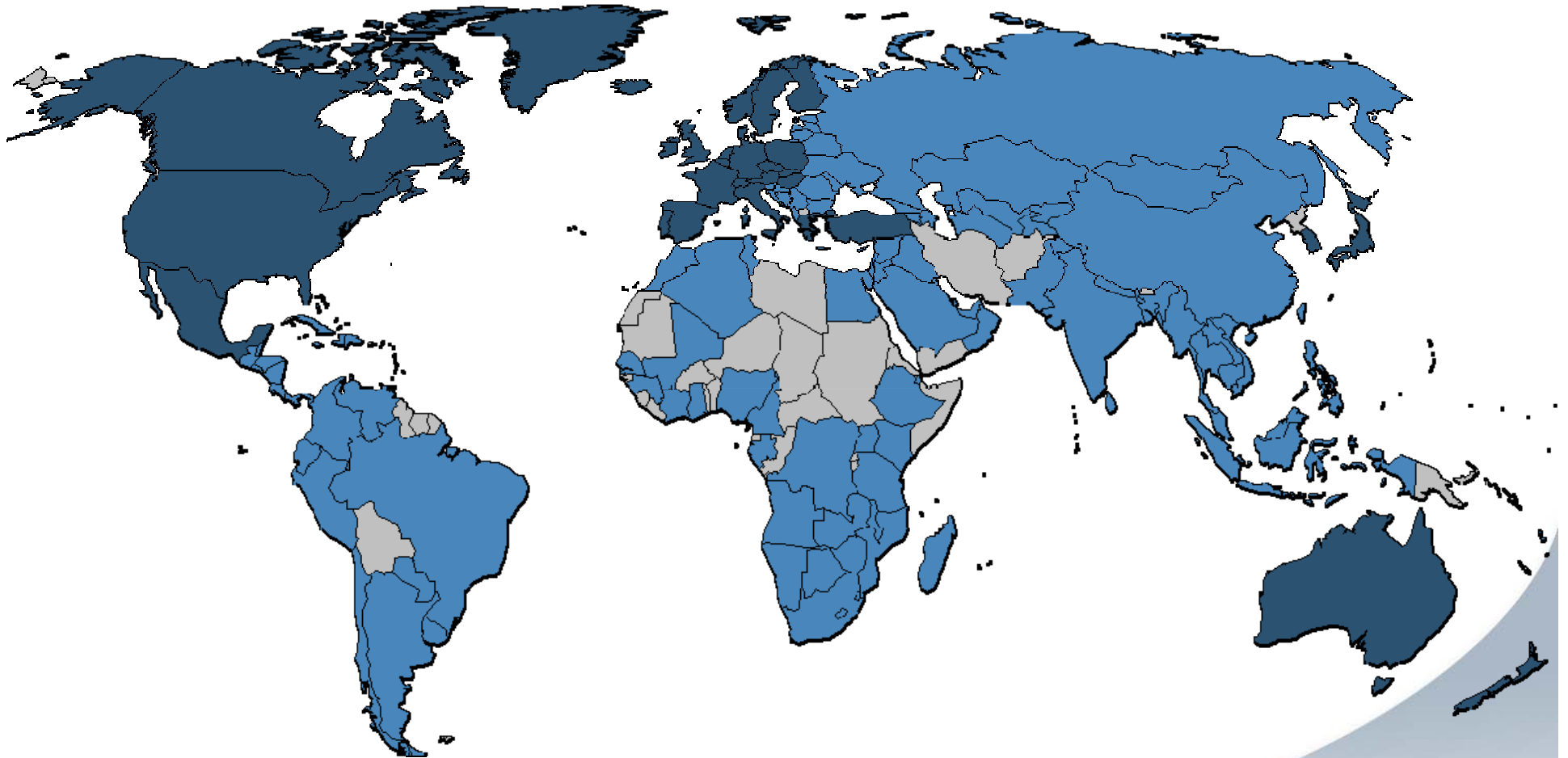
What is the OECD?

Organisation for Economic Co-operation and Development

- Intergovernmental organisation of 30 member countries
- Provides comparative data, analysis and forecasts.
- So that governments can:
 - compare policy experiences
 - seek answers to common problems
 - identify good practice
 - co-ordinate policies



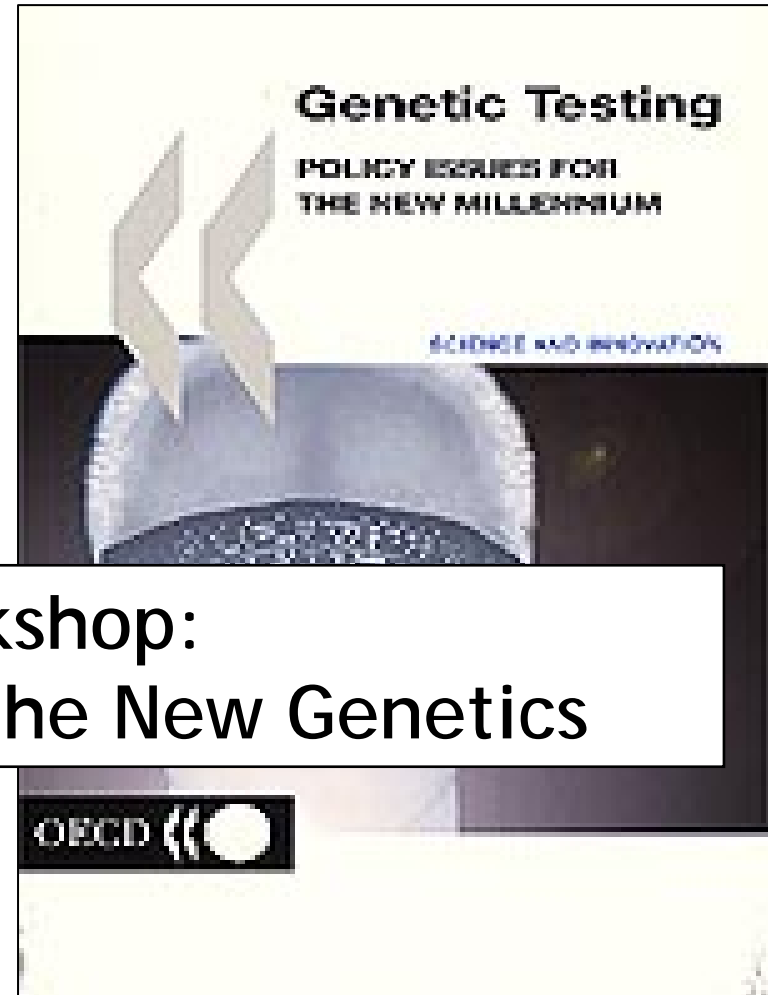
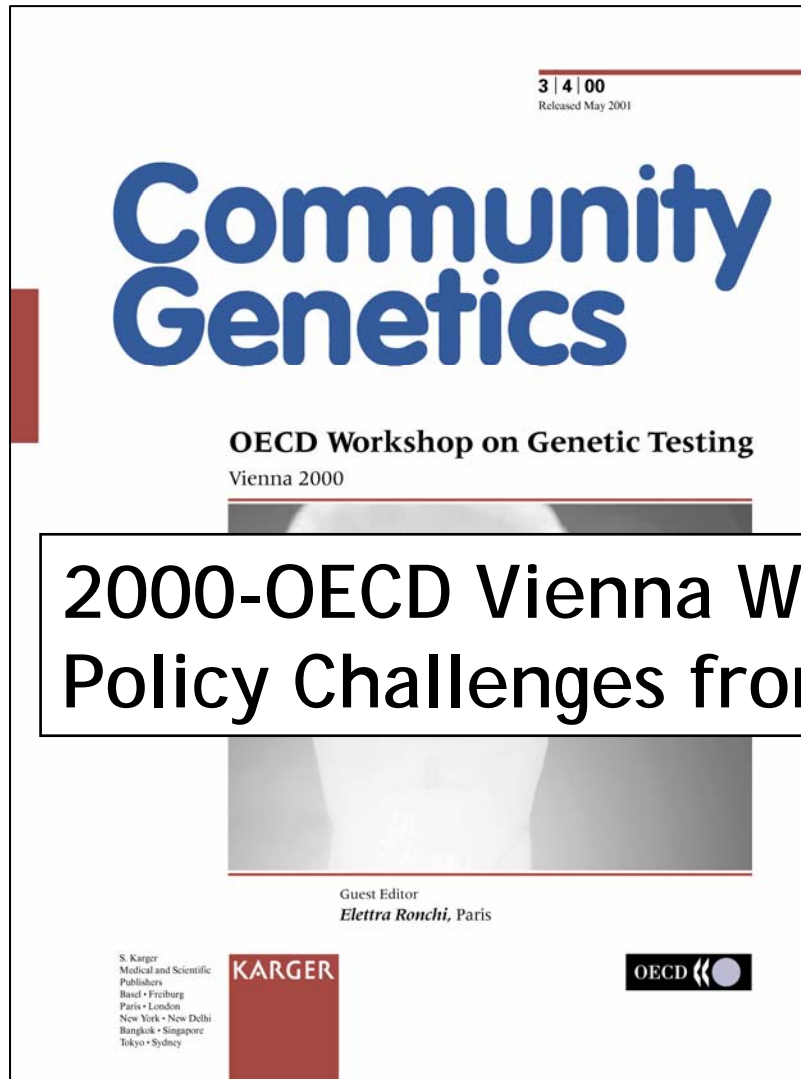
Working with countries around the world



Economies with which the OECD has working relationships



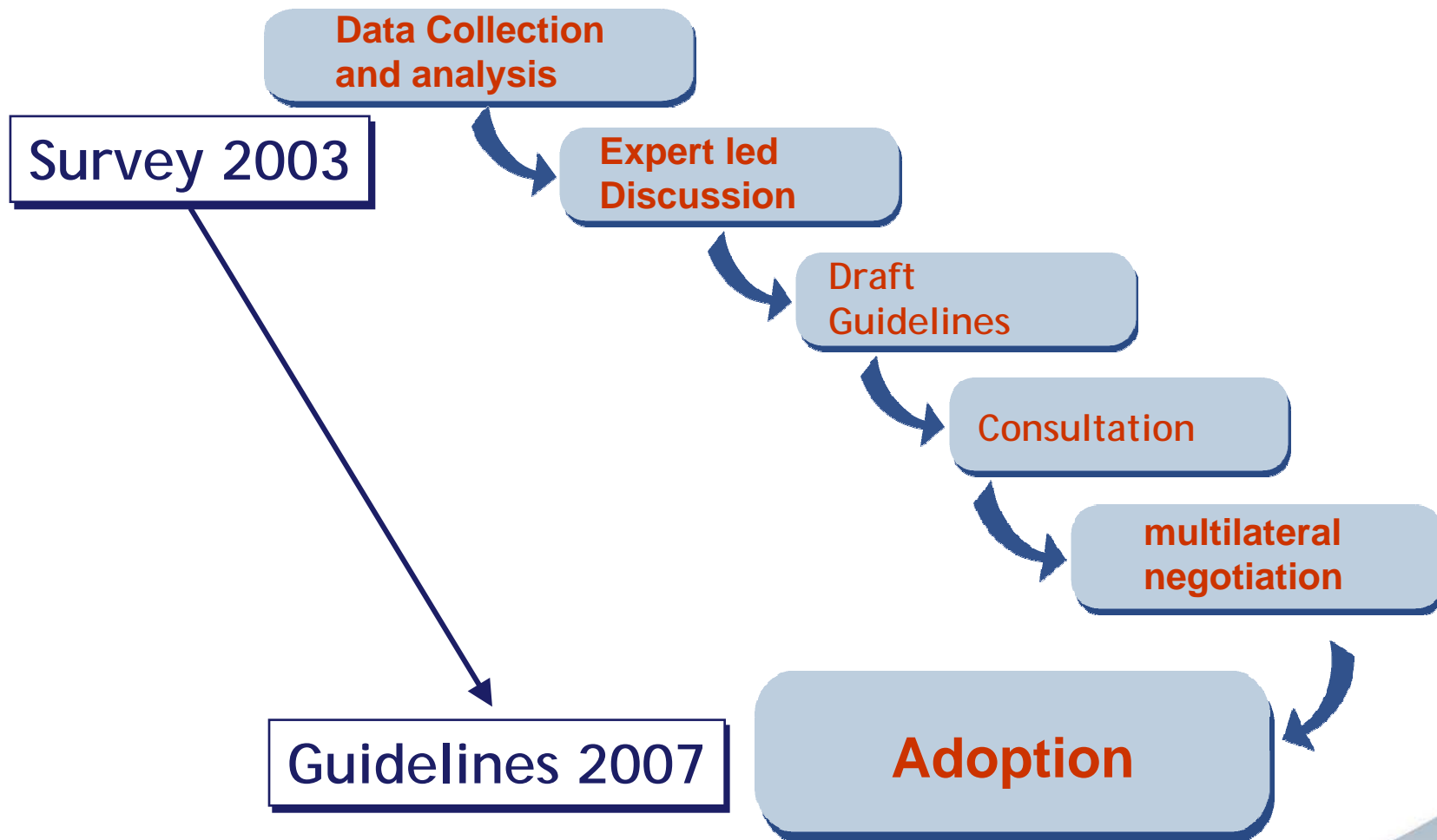
Background to the Guidelines



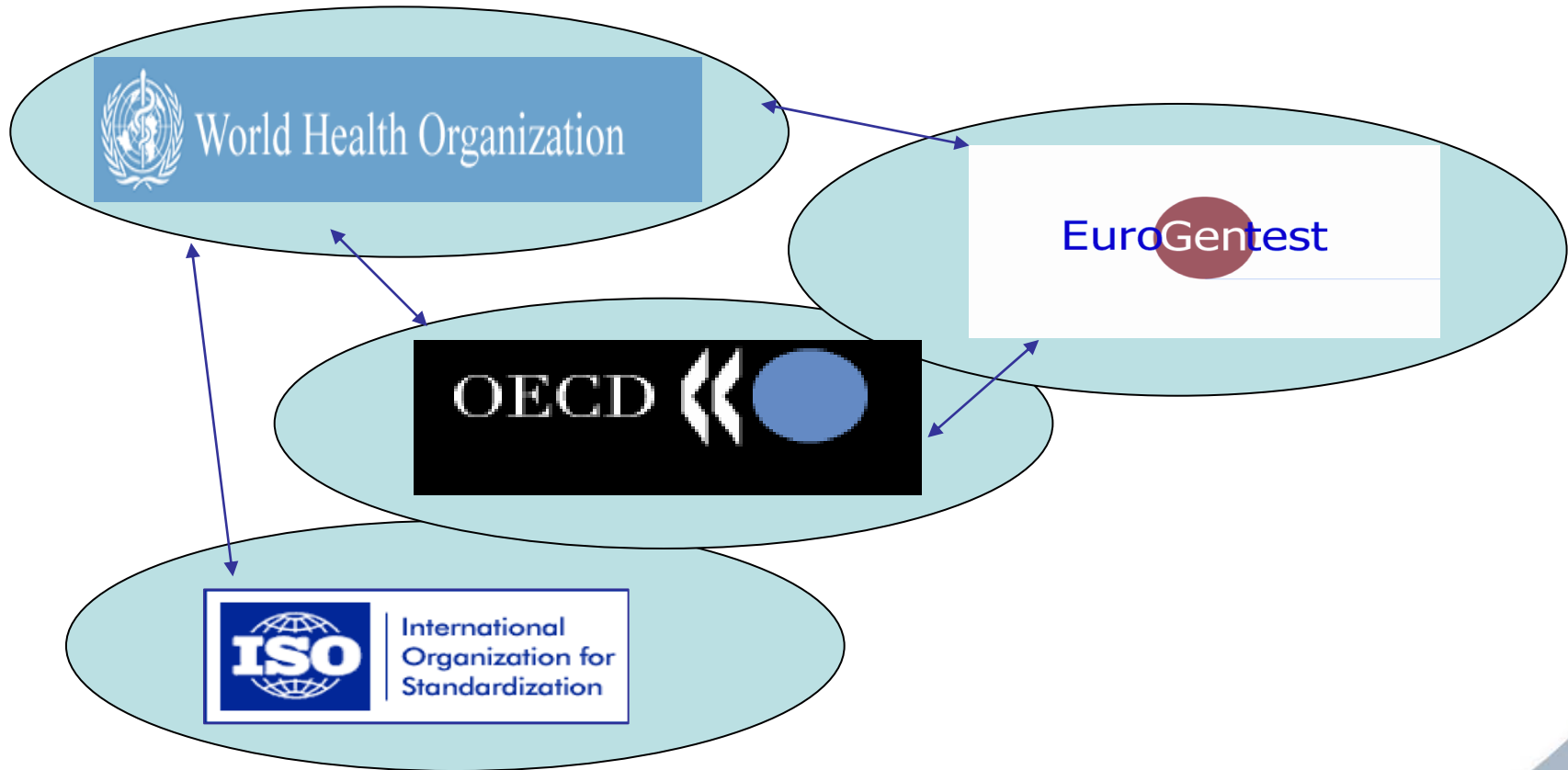
2000-OECD Vienna Workshop: Policy Challenges from the New Genetics



OECD Process



An international collaborative effort



Survey results published by OECD

Report of an international survey of molecular genetic testing laboratories

McGovern MM, Elles R, Beretta I, Somerville MJ, Hoefler G, Keinanen M, Barton D, Carson N, Dequeker E, Brdicka R, Blazkova A, Aymé S, Schnieders B, Muller CR, Dalen V, Martinez AA, Kristoffersson U, Ozguc M, Mueller H, Boone J, Lubin IM, Sequeiros J, Taruscio D, Williamson B, Mainland L, Yoshikura H, Ronchi E
Community Genet. 10(3):123-31, 2007

Quality Assurance and Proficiency Testing for Molecular Genetic Testing : Survey of 18 OECD Member countries (OECD; 2005)

<http://www.oecd.org/dataoecd/25/12/34779945.pdf>



Information Collected

- Laboratory Setting and Personnel Qualifications
- Referral Across National Boundaries
- Informed consent and confidentiality policies
- Types of Analyses
- Methods
- Standard Operating Procedures
- Reporting Practices
- Personnel qualifications
- Licensing, Accreditation and Proficiency Testing
- Patents



Survey Results

- **International exchange** is a widespread feature of Molecular Genetics service provision.
 - 64% of Laboratories received specimens from other countries
 - Over 18,000 specimens crossed borders in 2002
- Variables contributing to a high Quality Score ($p < 0.005$):
 - ✓ Accreditation of the laboratory
 - ✓ Participation in proficiency testing
 - ✓ Director having formal training in molecular genetics
 - ✓ Affiliation with a Genetics Unit



Why guidelines for MGT?

Molecular Genetic Testing:

- An economic activity
- An international activity
- Increasing role in improving healthcare
- Potential risks of mis-application of tests with high predictive value
- Relevance of test results to other family members
- Direct access by the public



Guidelines - Target audience and format

- Principles (general statements)
 - Policymakers and regulators in OECD member countries/non-member countries
- Best Practices (operational statements)
 - Professionals offering molecular genetic test services
 - Accreditation inspectors
- Explanatory notes and glossary



What do the Guidelines do?

- Set minimum standards
- Encourage best practice:
 - OECD countries are asked to implement the guidelines
 - Non-member countries invited to use them to set policies
- Progress report and review in 2011



Guidelines Structure

- A. General principles of MGT
- B. Quality Assurance systems
- C. Proficiency Testing
- D. Result Reporting
- E. Education and training



General principles and best practices for MGT

Principles

- Ethical standards
- Testing should be part of healthcare
- All tests should be Quality Assured
- Informed consent and availability of counselling
- Privacy
- Benefits of international co-operation
- Use of patient samples
- Advertising claims



General principles and best practices for MGT

Best Practices

- Is adaptation of existing QA frameworks required?
- Information on validity of tests
- Role of referring health-care professionals in interpreting tests



Quality Assurance Systems

Principles and Best Practices

- Governments should make clear what they require of labs – and use standard QA terminology
- All labs should be ‘accredited’ to international standards
 - role of research labs
- Encouraging lab accreditation
 - overcoming barriers
 - addressing problems
 - training assessors
- IQC procedures
 - validating tests
 - public information
- Developing and using reference materials



Proficiency Testing (EQA)

Principles and Best Practices

- Measuring lab performance
 - encouraging participation
 - setting standards
 - addressing problems
 - public information
- Supporting and recognising effective and competent proficiency testing
 - keeping pace with technology



Quality of Reporting

Principles and Best Practices

- Effective patient/family-centred reporting
- Role of health professionals in the information cycle
- Confidentiality
- Technical content, terminology
- The integrity of transferred information



Education and Training

Principles and Best Practices

- Ethical practice
- Recognising Medical Genetics as a specialty
- Specialist competence-based training and qualifications – related to other lab disciplines
- Role of lab accreditation in requiring competent personnel
- Individual certification
- Development and recognition of specialist programmes by government and professions
- Continued professional development
- International recognition of qualifications



In conclusion

- Guidelines are relevant to OECD and non-OECD countries
- Encourage your Government to adopt the Principles
- Implement the Best Practices in your own laboratories
- Spread the quality message
- EuroGentest is available to help!
 - Workshops
 - Documentation
 - Validation
 - Advice
 - EQA

www.eurogentest.org

