



## OECD Activities on Chemical Safety

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## Main topics

- OECD (mainly EHS)
- Mutual Acceptance of Data (MAD)
- Test Guidelines (TG)
- Good Laboratory Practice (GLP)
- Other recent activities



# OECD

(Organisation for Economic Co-Operation and Development)  
Intergovernmental Organisation grouping 30 industrialised countries

## EU

- Austria
- Belgium
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Luxembourg
- The Netherlands

- Poland
- Portugal
- Slovak Republic
- Spain
- Sweden
- United Kingdom

## EUROPEAN NON-EU

- Iceland
- Norway
- Switzerland
- Turkey

## NAFTA

- Canada
- Mexico
- United states

## ASIA - PACIFIC

- Australia
- Japan
- New Zealand
- South Korea

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# OECD

MEMBERSHIP

→ 30 countries  
European Commission

STRUCTURE

→ Council  
Working Groups  
Committees  
Secretariat

INSTRUMENTS

→ Decisions  
Recommendations

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## OECD

### ❖ WHAT IT IS

- Forum for policy dialogue and development
- Centre for policy analysis
- Facilitator to achieve harmonisation, co-operation and work sharing

### ❖ WHAT IT IS NOT

- Provider of technical assistance
- Supranational rule-making body
- Bank

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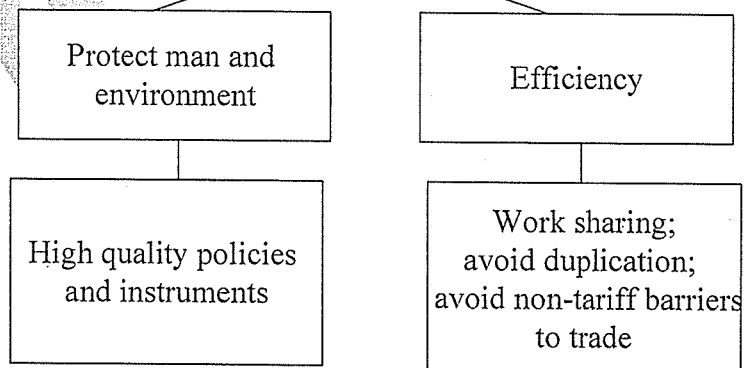


## ENVIRONMENT, HEALTH AND SAFETY PROGRAMME

- Chemicals
  - Pesticides and Biocides
  - Chemical Accidents
  - Pollutant Release and Transfers Registers
  - Regulatory Oversight in Biotechnology
- Food Safety

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## EHS OBJECTIVES



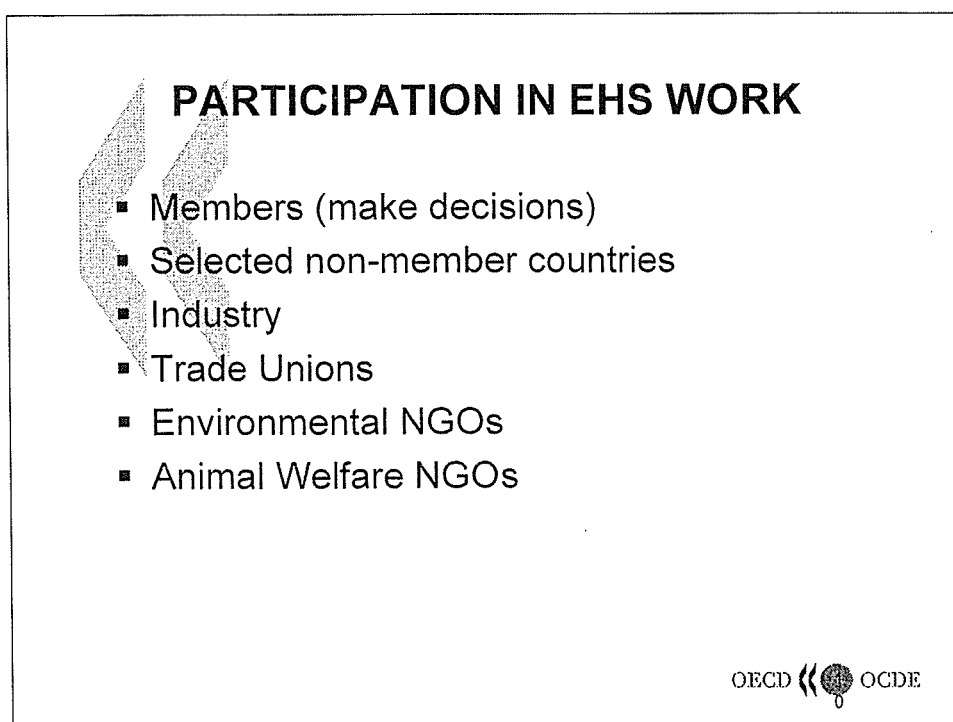
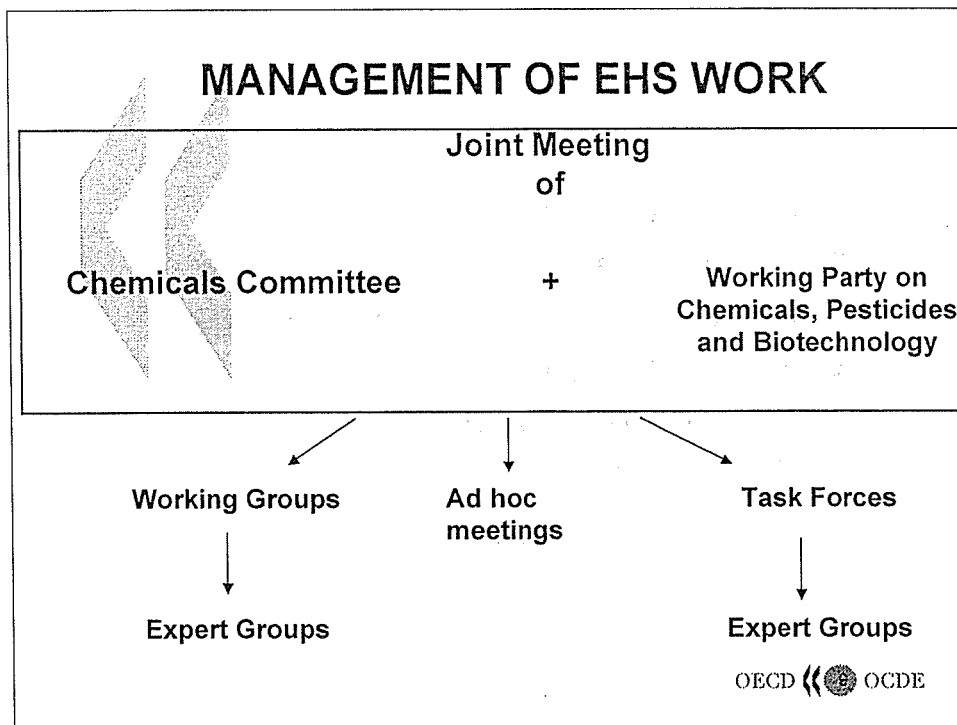
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## OECD WORK ON CHEMICAL SAFETY SUPPORTS

❖ National and EU regulations on:

- Test Guidelines
- GLP
- New chemicals
- Existing chemicals
- Pesticides
- Biocides
- Classification and labelling


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## OECD COUNCIL DECISIONS AND RECOMMENDATIONS

- If Member countries consider it appropriate, an agreement can be embodied in a formal action by the Council either by:
  - a *Council Decision* which is binding on all Member countries; or
  - a *Council Recommendation* which, while not legally binding, carries a strong moral obligation

## Mutual Acceptance of Data (MAD)



## 1981 “MAD” DECISION

### *OECD Council Decision on Mutual Acceptance of Data in an Assessment of Chemicals including Pesticides C(81)30(Final)*

“Decides that the data generated in the testing of chemicals in an OECD Member country in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of man and the environment.”



## DATA QUALITY ENSURED BY

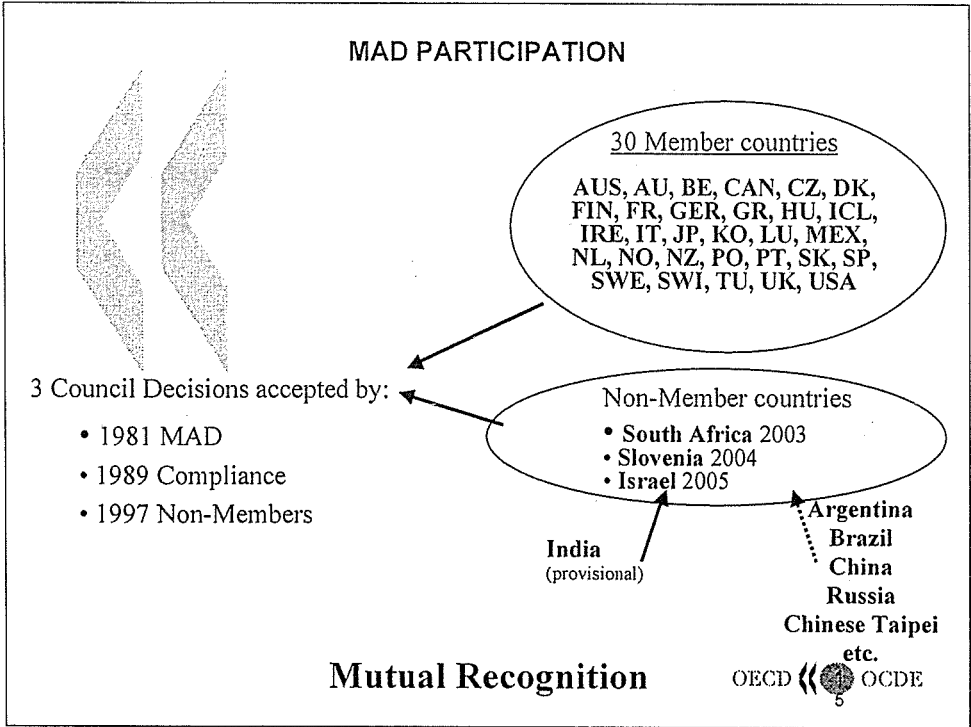
Test Guidelines

Good Laboratory Practice

Mutual Acceptance of Data

**Avoid:** duplication of testing by industry  
non-tariff trade barriers

**MAD Council Decisions open to non-members**



### YEARLY COSTS AND SAVINGS RESULTING FROM MAD (ESTIMATED IN EUROS)

<b>Costs for governments and industry in participating in MAD</b>	<b>Estimated savings for governments and industry in the banking, insurance and approval of financial products</b>
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# Test Guidelines (TG)



## OECD - TEST GUIDELINES

- ❖ More than 100 Test Guidelines:
  - Physical-chemical properties
  - Human toxicity
  - Ecotoxicity
  - Bio-degradation and accumulation

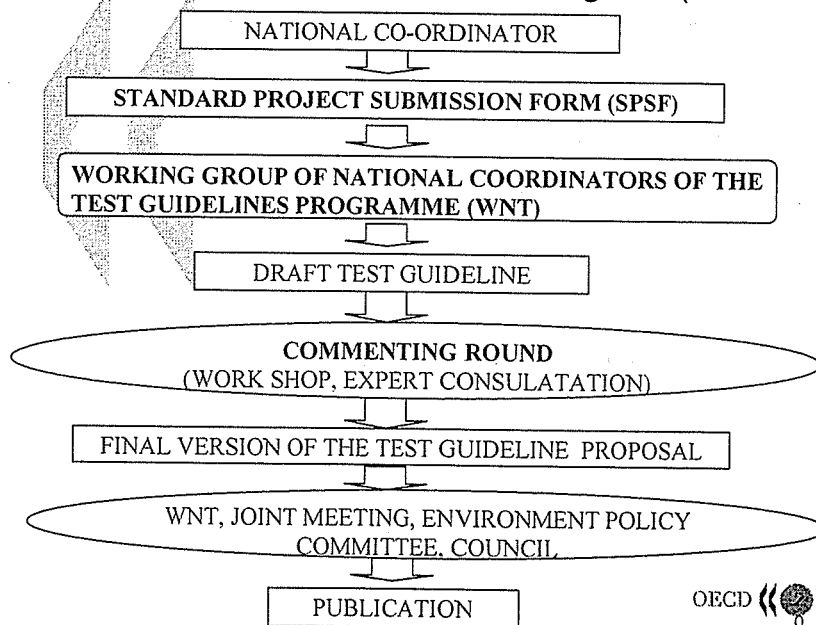
\*Series on Testing and Assessment (More than 50 documents)

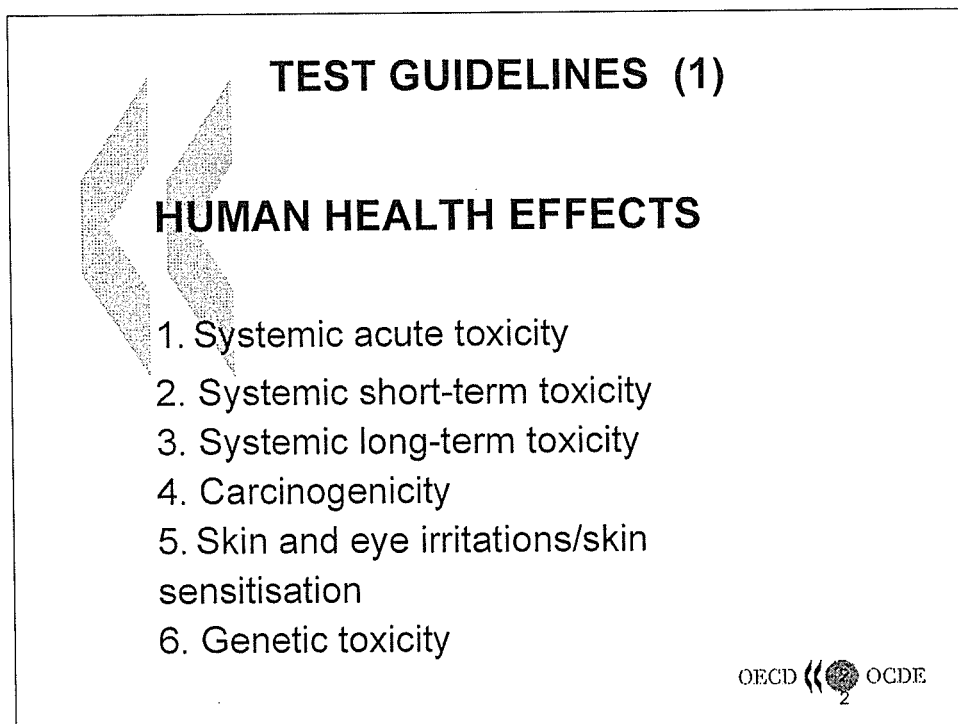
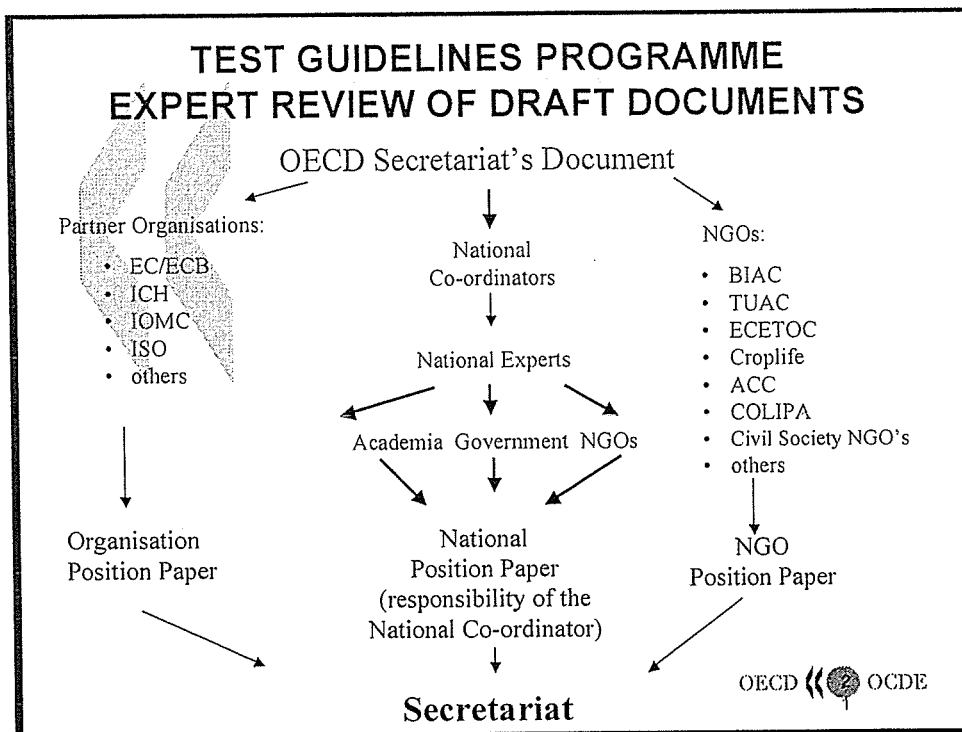
- DETAILED REVIEW PAPER (DRP)
- GUIDANCE DOCUMENT (GD) / GUIDANCE NOTE

## TEST GUIDELINES WORK

- New Test Guidelines
- Updating
- Expert networks
- Animal welfare issues

### OECD TG development flow diagram (OUTLINE)





## TEST GUIDELINES (2)

### HUMAN HEALTH EFFECTS

7. Neurotoxicity
8. Phototoxicity
9. Reproductive and developmental effects
10. *In vitro* toxicity/alternatives
11. Immunotoxicity
12. (Occupational) Exposure

## TEST GUIDELINES (3)

### 47 & 48 Series (Adapted Test Guidelines) [I]

- 471 Bacterial Reverse Mutation Test  
(Updated Guideline, adopted 21st July 1997)
- 473 *In vitro* Mammalian Chromosomal Aberration Test  
(Updated Guideline, adopted 21st July 1997)
- 474 Mammalian Erythrocyte Micronucleus Test  
(Updated Guideline, adopted 21st July 1997)
- 475 Mammalian Bone Marrow Chromosomal Aberration Test  
(Updated Guideline, adopted 21st July 1997)
- 476 *In vitro* Mammalian Cell Gene Mutation Test  
(Updated Guideline, adopted 21st July 1997)
- 477 Genetic Toxicology: Sex-Linked Recessive Lethal Test in *Drosophila melanogaster*  
(Updated Guideline, adopted 4th April 1984)
- 478 Genetic Toxicology: Rodent Dominant Lethal Test  
(Updated Guideline, adopted 4th April 1984)
- 479 Genetic Toxicology: *In vitro* Sister Chromatid Exchange Assay in Mammalian Cells  
(Original Guideline, adopted 23rd October 1986)

## TEST GUIDELINES (4)

### 47 & 48 Series (Adapted Test Guidelines) [II]

- 480 Genetic Toxicology: *Saccharomyces cerevisiae*, Gene Mutation Assay  
(Original Guideline, adopted 23rd October 1986)
- 481 Genetic Toxicology: *Saccharomyces cerevisiae*, Mitotic Recombination Assay  
(Original Guideline, adopted 23rd October 1986)
- 482 Genetic Toxicology: DNA Damage and Repair, Unscheduled DNA Synthesis in Mammalian Cells *in vitro*  
(Original Guideline, adopted 23rd October 1986)
- 483 Mammalian Spermatogonial Chromosome Aberration Test  
(Original Guideline, adopted 21st July 1997)
- 484 Genetic Toxicology: Mouse Spot Test  
(Original Guideline, adopted 23rd October 1986)
- 485 Genetic Toxicology: Mouse Heritable Translocation Assay  
(Original Guideline, adopted 23rd October 1986)
- 486 Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells *in vivo*  
(Original Guideline, adopted 21st July 1997)

## TEST GUIDELINES (5)

- No34. Guidance Document on the Validation and International Acceptance of New or Updated Test Methods for Hazard Assessment
- No49. Report from the Expert group on (Quantitative) Structure-Activity Relationships [(Q)SARs] on the Principles for the Validation of (Q)SARs



## TEST GUIDELINES (6)

Rolling workplan for the test guidelines programme  
2006/2008 (Section 4: Health)

- Development of a Working Paper/DRP on Cell Transformation Assays
- New TG for in vitro SHE Cell Transformation Assay
- New TG (487) *In vitro* Micronucleus Test
- New Guideline on Transgenic Rodent in vivo Gene Mutation Assays
- Revision of TG 451, 452, and 453 on Chronic Toxicity and Carcinogenicity

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## Good Laboratory Practice (GLP)

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## OECD SYSTEMS FOR GOOD LABORATORY PRACTICE

- **Major components:**
  - 1981 Council Decision on Mutual Acceptance of Data [C(01)]30/Final]
  - 1989 Council Decision/Recommendation on Compliance with Principles of Good Laboratory Practice [C(89)87(Final)]



## OECD PRINCIPLES OF GLP (1)

A single quality standard for test facilities throughout OECD and applied for testing of all chemical substances

## OECD PRINCIPLES OF GLP (2)

### Management Tool

- Address the responsibility of and requirements for a test facility's organisation and personnel, quality assurance programme, physical plant, apparatus, materials and reagents.
- Principles governing the following are provided:
  - conditions for establishing and maintaining test systems;
  - receipt, handling, sampling, characterisation and storage of test and reference substances;
  - standard operating procedures;
  - performance of the study;
  - reporting of results;
  - storage, retention and retrieval of records and materials

## OECD PRINCIPLES OF GLP (3)

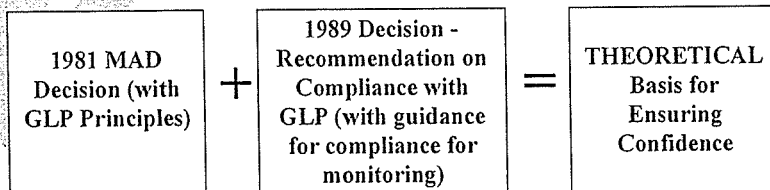
### Regulatory Tool

Unless specifically exempted by national legislation,

“apply to all non-clinical health and environmental safety studies **required by regulations** for the purpose of registering or licensing pharmaceuticals, pesticides, food and feed additives, cosmetic products, veterinary drug products and similar products, and for the registration of industrial chemicals.”



## COMPLIANCE MONITORING (1)



In practice:

- ↳ OECD assists Member countries to implement these Council Acts
  - 1990: OECD Working Group on GLP
  - 1998: Evaluation through Mutual Joint Visits (on-site evaluation)
- ↳ OECD assists non-Member countries to implement GLP and Compliance Monitoring
  - 1997: Council Decision on Adherence of non-Member countries

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## COMPLIANCE MONITORING (2)

**GOAL:** Recognition (by Country A) of Country B's assurance that specific data have been generated under GLP

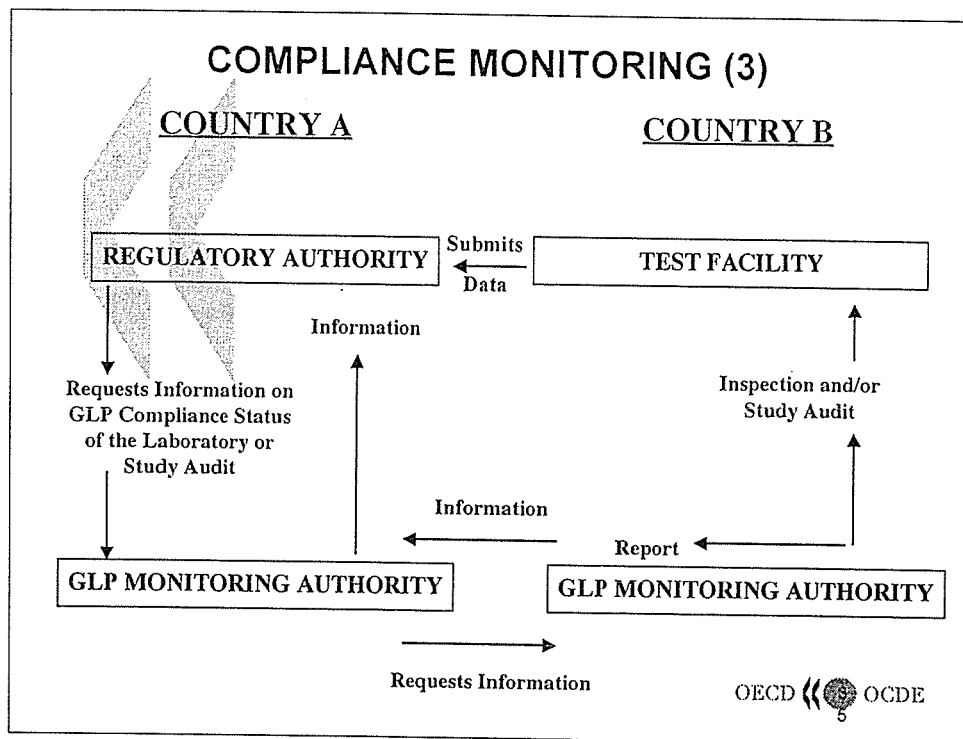
**MEANS:** Country A's confidence in Country B's procedures for Monitoring Compliance with GLP


**BASED IN:** Knowledge and understanding of Country B's procedures

### OECD'S ROLE: Working Group on GLP

- Promote the flow of information
- Establish harmonized procedures
- On-site evaluation

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- ### OECD WORKING GROUP ON GLP (1)
- Work on:
- GLP Compliance Monitoring: mutually acceptable procedures
  - Interpretation of GLP Principles: Consensus Workshops
  - International liaison: network of national Monitoring Authorities (Working Group on GLP)
  - Regulatory requirements: scope of application of GLP
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## OECD WORKING GROUP ON GLP (2)

Comprises representatives of national Monitoring Authorities (~ 40)

- Meets at least once a year (reports to the Joint Meeting)

### Products:

- Consensus (or Advisory) documents
  - Archiving
- Training courses
  - OECD Inspector Training Course – Edinburgh, UK (17th – 22nd September, 2006)
- Mutual Joint Visits
  - Austrian programme for medical products (Autumn, 2006)

## OECD SERIES – GLP COMPLIANCE MONITORING (1)

1. OECD GLP Principles
2. Guidelines for Compliance Monitoring
3. Guidelines for Conduct of Inspections and Study Audits
4. Quality Assurance and GLP
5. Compliance of Laboratory Suppliers
6. Application of GLP to Field Studies
7. Application of GLP to Short-term Studies
8. Role/Responsibility of Study Director

## OECD SERIES – GLP COMPLIANCE MONITORING (2)

9. Guidance for Preparation of Inspection Reports
10. Application of GLP to Computer Studies
11. Role/Responsibility of Sponsor
12. Requesting/Carrying Out Inspections and Study Audits in Another Country
13. The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies
14. The Application of the Principles of GLP to in vitro studies

## Future activities

- On-site evaluation programme
- Document on Archiving
- Event Involving Industry