European Commission

Directorate-General Enterprise and Industry

GLP in the European Union - Overview and Role of the Commission and the Member States

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Outline

- What is GLP? How has it developed?
- The role of the Member States
- The Role of the European Commission

Good Laboratory Practice - Definition:

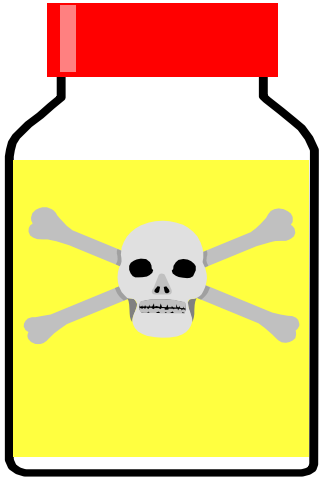
- **Quality system** concerned with the organisational process and the conditions under which **non-clinical** health and environmental **safety studies** are planned, performed, monitored, recorded, archived and reported.

GLP – General Objectives:

- promote the **quality and validity of data** generated in the testing of chemicals
- facilitate their **recognition**
- **protection** of human health and the environment

GLP – Detailed Objectives:

- Assurance of quality and validity of test data
- Avoidance of duplicative testing
- Animal welfare
- Time and resource efficiency
- Avoidance of non-tariff barriers to trade

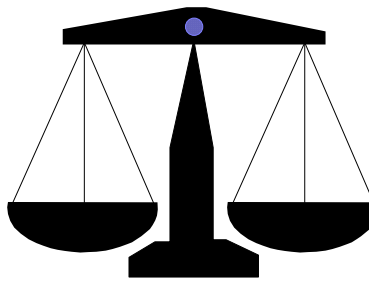


GLP - History:

- **1976 : GLP regulation of FDA on non-clinical laboratory studies**
- 1978 : OECD establishes expert group
- 1981 : OECD Council Decision on Mutual Acceptance of Data (MAD): GLP-Principles contained in Annex II
- 1983 : Recommendation concerning compliance monitoring
- **1987/88 : EU adopts GLP Directives**
- 1989 : OECD Council Decision-Recommendation on Compliance
  - Guides for Compliance Monitoring Procedures for GLP
  - Guidance for the Conduct of Laboratory Inspections and Study Audits
- 1995 : REVISED GUIDANCE FOR GLP MONITORING AUTHORITIES FOR COMPLIANCE MONITORING PROCEDURES FOR GOOD LABORATORY PRACTICE (GUIDES) + New expert group on GLP - Principles
- 1997 : Adoption of Revised GLP- Principles
- **1999 : Amendment of EU GLP Directives following OECD**

GLP in the EC - Legal Framework

- Directive 2004/10/EC
  - on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of GLP



- Directive 2004/9/EC
  - on the inspection and verification of GLP

= Codified versions of Directive 87/18 EEC and Directive 88/320/EEC + amendments.

GLP in the EC - Legal Framework

- Internal Market

For Chemicals:

  - Directive 67/548/EEC (classification, packaging and labelling of chemical substances)
  - Directive 88/379/EEC (extending testing requirements to all preparations, replaced by Dir. 1999/45/EC)
  - Regulation (EEC) 793/93 (risk assessments of existing substances)

GLP in the EC - Legal Framework

- Internal Market

  Directives for special chemicals:

  - Medicinal Products (Directive 2001/83/EC amended by 2003/63/EC)
  - Veterinary Medicinal Products (Directive 2001/82/EC)
  - Plant Protection Products (91/414/EEC)
  - Biocides (98/8/EC)
  - Feed Additives (87/153/EEC)
  - Food Additives (89/397/EEC; 93/99/EEC)
  - Cosmetics (76/768/EEC, 93/35/EEC as amended)

- External Trade Implications : Art. 133

GLP: Role of the Member States

Practical implementation of GLP Principles and compliance monitoring:

- adoption of necessary legal measures
- creation of national compliance programmes
- inspections and study audits
- annual reports

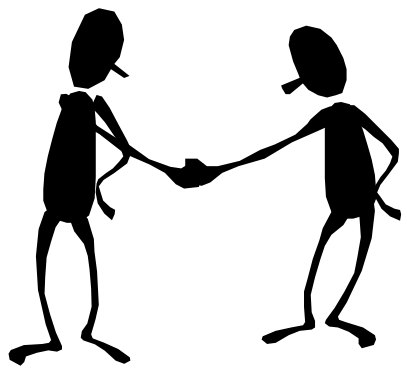
GLP: Role of the Member States

Article 3.1 of Directive 2004/10/EC:

Member States shall adopt the measures necessary for verification of compliance with the principles of good laboratory practice. These measures shall include, in particular, **inspections and study checks in accordance with the recommendations of the OECD** in this area.

GLP: Role of the Member States

- Acceptance of data from other MS
- Co-operation in OECD



GLP in the EU - Practicalities

Role of the Commission inside the EU:

- ensure uniform application of the GLP principles and compliance monitoring in all Member States
- facilitate acceptance of data among MS

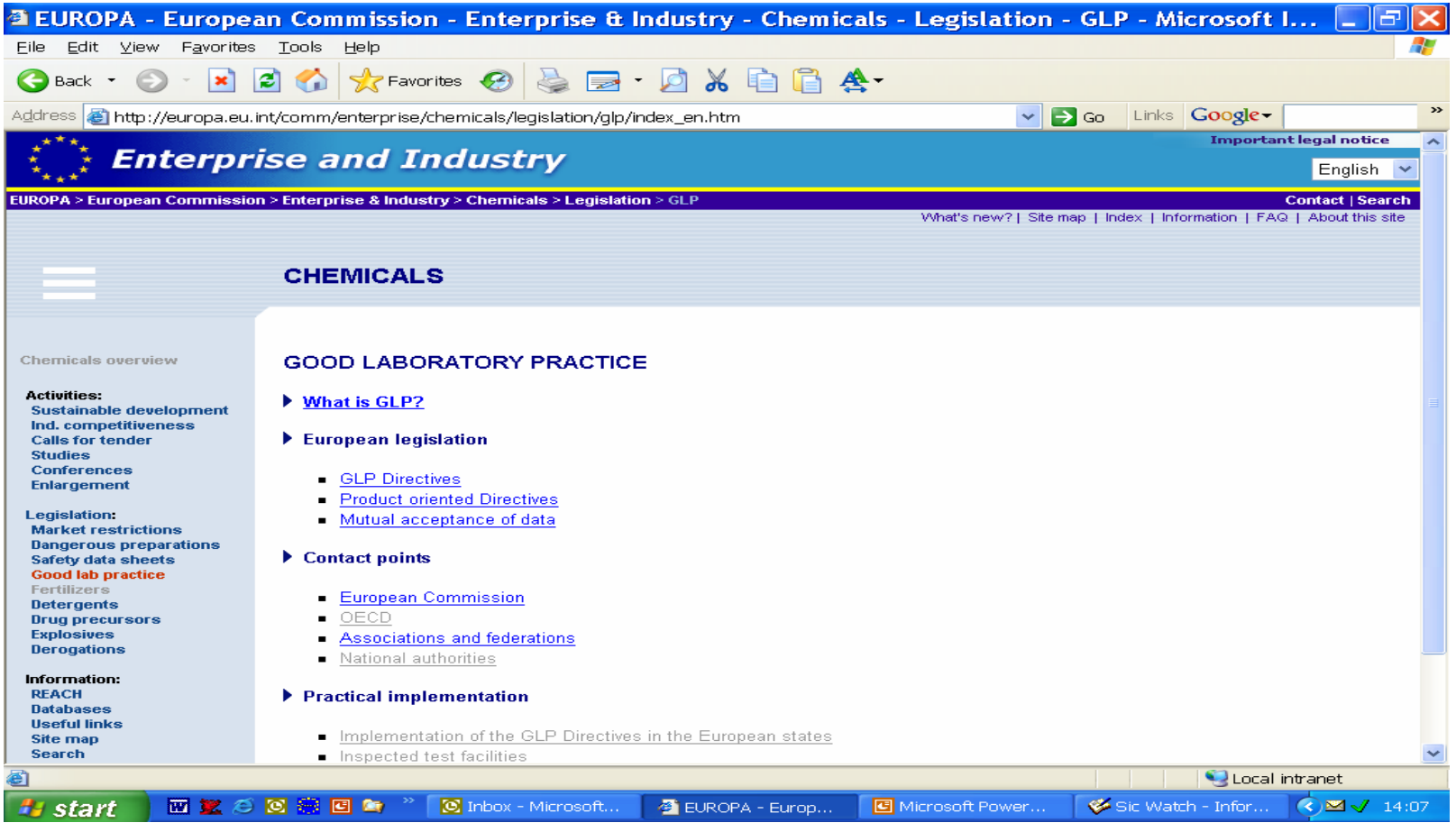
GLP - Role of the Commission inside the EU

What we do to achieve this:

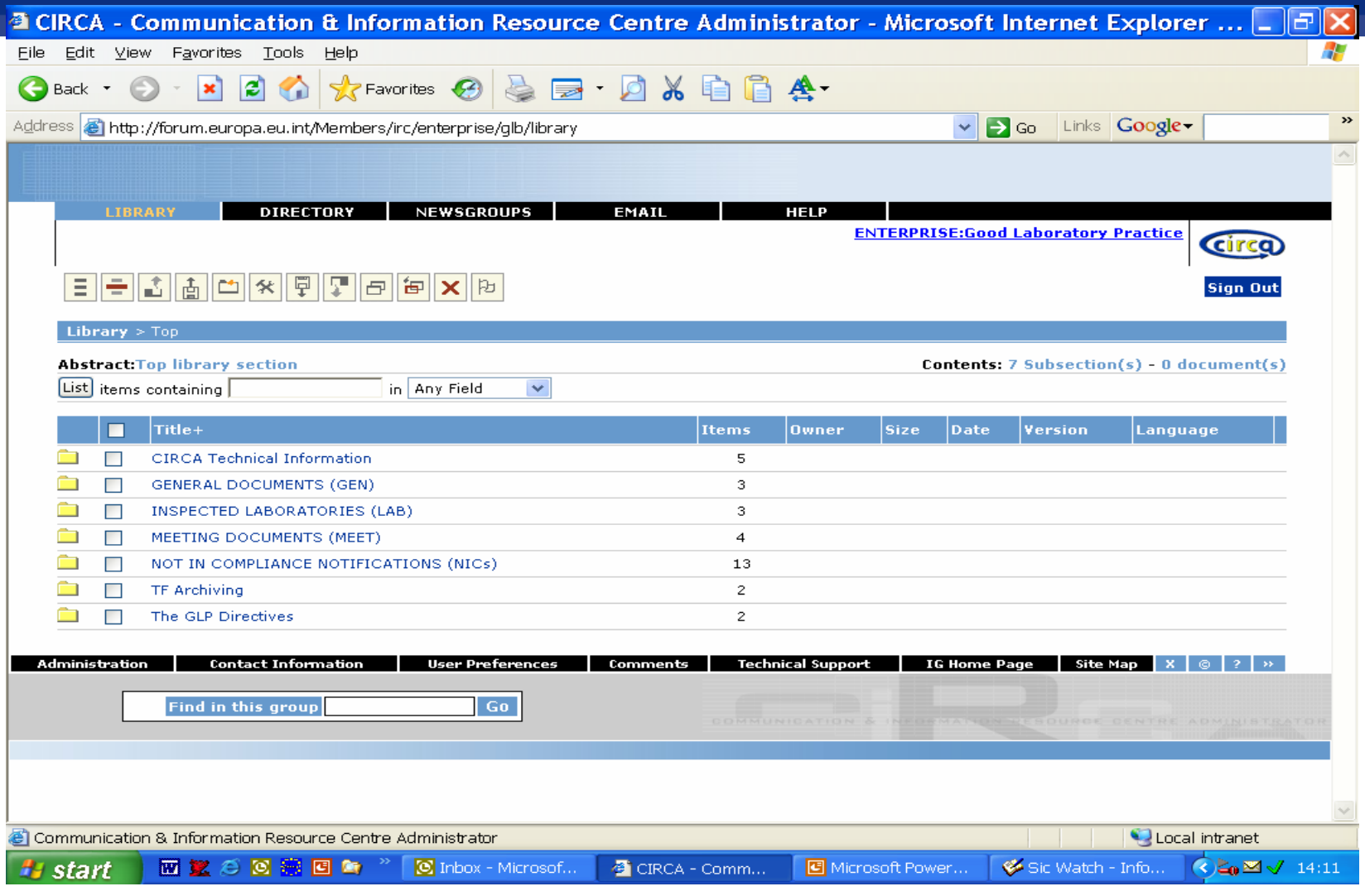
- Regular meetings of Member State experts in the Working Group on Good Laboratory Practice
- Management of lists of inspected laboratories (CIRCA website)
- Build up contacts between receiving authorities and monitoring authorities (e.g. EMEA)
- Specific exercises for confidence building: evaluation visits

The GLP web site

http://europa.eu.int/comm/enterprise/chemicals/legislation/glp/index_en.htm



The password-protected CIRCA web site



GLP in the EU - Foreign Relations

Role of the Commission outside the EU:

- supplement and co-ordinate views of MS in international fora (OECD)
- correct application of MAD Decision between EU and other OECD countries
- acceptance of data through formal agreements on Mutual Recognition (MRA)

  (Japan, Switzerland, Israel)

GLP in the EU - Foreign Relations

OECD:

- The OECD Principles of GLP are an integral part of the 1981 Council Decision on the Mutual Acceptance of Data in the Assessment of Chemicals (revised 1997)

- Countries can have confidence in the quality and rigour of safety tests

GLP in the EU - Enlargement

Assistance to enlargement candidate countries and new Member States

- Invitation to GLP working group
- Mutual Joint Visits (Poland)
- Twinnings (e.g. Sweden-Poland)
- Acceptance of data through formal Protocols to the Europe Agreements (PECAs):
  - Hungary, Czech Republic
  - Option for Turkey and Croatia

GLP in the EU - Conclusions

- EU has strong interest in effective and correct implementation of GLP in the Member States:
  - Necessity for Internal Market
  - High level of protection of Health and Environment
- Commission and MS have their roles in close co-operation
- GLP is there for you (receiving authorities): make use of it !

The End

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