# OECD Perspectives on Testing and Assessment (Nice 16 November 2005)

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#### ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD)

- **Intergovernmental Organisation**
- 30 industrialised countries
  - North America
  - Europe
  - Asia/Pacific Region
- Observers from several countries with special status at the OECD
- Invited experts: industry, NGO, trade unions

#### **OECD ROLE**

- Discuss issues of mutual concern
- Work together to respond to international problems
- Co-ordinate and harmonise policies and tools
- Adopt legal instruments

(All stakeholders involved)

# Chemicals Programme objectives

- Develop high quality harmonized tools and policies for risk assessment and management
- Avoid duplication of work
- Facilitate work sharing
- Save time and money
- Avoid non-tariff trade barriers

# Hazard Assessment Tools (1)

- In vivo/In vitro tests
- Structure/Activity Relationships (Principles for validation Nov. 2004, guidance document, case studies)
- Read Across and Categories (Manual for Existing Chemicals)
- Toxicogenomics (plan to improve link between fundamental research and regulatory use)

### Hazard Assessment Tools (2)

- Initial discussions have begun on the use of integrated approaches to testing and assessment;
- Strong support from industry and some member countries, i.e. for pesticides;
- Need a better understanding of what integrated approach means to different groups;
- Is it a paradigm shift and revamp of overall approach to information requirements or subtle changes to existing approaches;

# **Mutual Acceptance of Data (MAD)**

- Test Guidelines and Good Laboratory
  Practices are core elements of MAD
- Tests accepted by all OECD countries
- Council Decisions
- US \$50-60 million saved each year
- Work with non-members

#### **Test Guidelines**

- **Physical Chemical Properties (21)**
- **Effects on Biotic Systems (21)**
- **Degradation and Accumulation (12)**
- Health Effects (48)

# Requirements for new/revised TGs

#### New and updated TGs should

- improve risk management in countries and/or
- lead to a further reduction of animal use and improvements in animal welfare (widespread support and endorsement of the principle of the 3Rs)

#### **ACSA** Initiative

- Fits the rationale for developing new tests or revising existing tests
- Has benefits for industry, regulators, animal usage
- Based on robust science, but validation could be complex;
- Consistent with OECD discussions on more integrated approaches to testing and assessment;
- Performance of tests and testing strategy will be pivotal to international regulatory acceptance;

# **Current Discussions on Refocusing the Test Guideline Programme**

- Simplify and streamline the process for new project proposals
- Transparent process to assist countries in decision-making for proposals for new or revised Test Guidelines: prior information on
  - Regulatory needs
  - Limitations
  - Resources

# Summary (1)

- A large number of projects are underway in the OECD Test Guidelines Programme;
- These are conducted to meet the regulatory needs of the member countries and to bring a high level of harmonization in testing approaches;
- An integrated approach to testing and assessment is being discussed within the OECD;

# Summary (2)

- Views of member countries, industry, NGOs and EC will be presented in Feb 06;
- The OECD needs to think about where this approach should be heading and what it hopes to deliver;
- ACSA initiative is one area of interest for the OECD;
- Any changes in testing approaches must meet the regulatory needs of member countries.