

Understanding the Organisation for Economic Co-operation and Development - OECD -

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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

OECD



MEMBERSHIP

→ 30 countries
European Commission

STRUCTURE

→ Council
Working Groups
Committees
Secretariat

INSTRUMENTS

→ Decisions
Recommendations

OECD

❖ WHAT IT IS

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

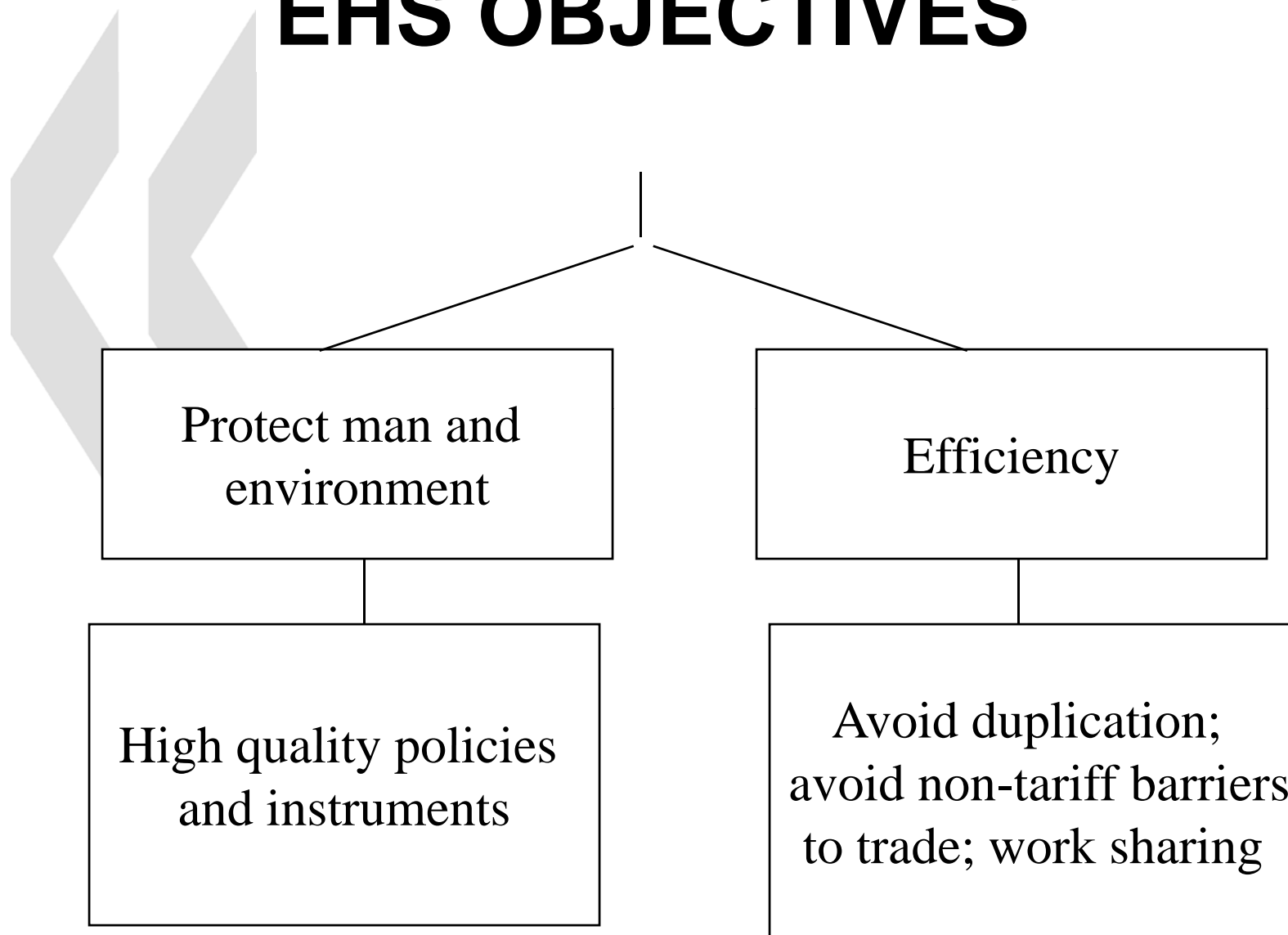
❖ WHAT IT IS NOT

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

ENVIRONMENT, HEALTH AND SAFETY PROGRAMME

- **Chemicals**
- **Pesticides and Biocides**
- **Manufactured Nanomaterials**
- **Chemical Accidents**
- **Pollutant Release and Transfers Registers**
- **Biotechnology / Biosafety**
- **Safety of Novel Foods and Feeds**

EHS OBJECTIVES



ACHIEVE OBJECTIVES THROUGH:

- Harmonisation
- Co-ordination / Co-operation
- Outreach to
 - stakeholders
 - non-member countries

BENEFITS OF HARMONISATION

- Trade
- Quality
- Comparability
- Basis for worksharing



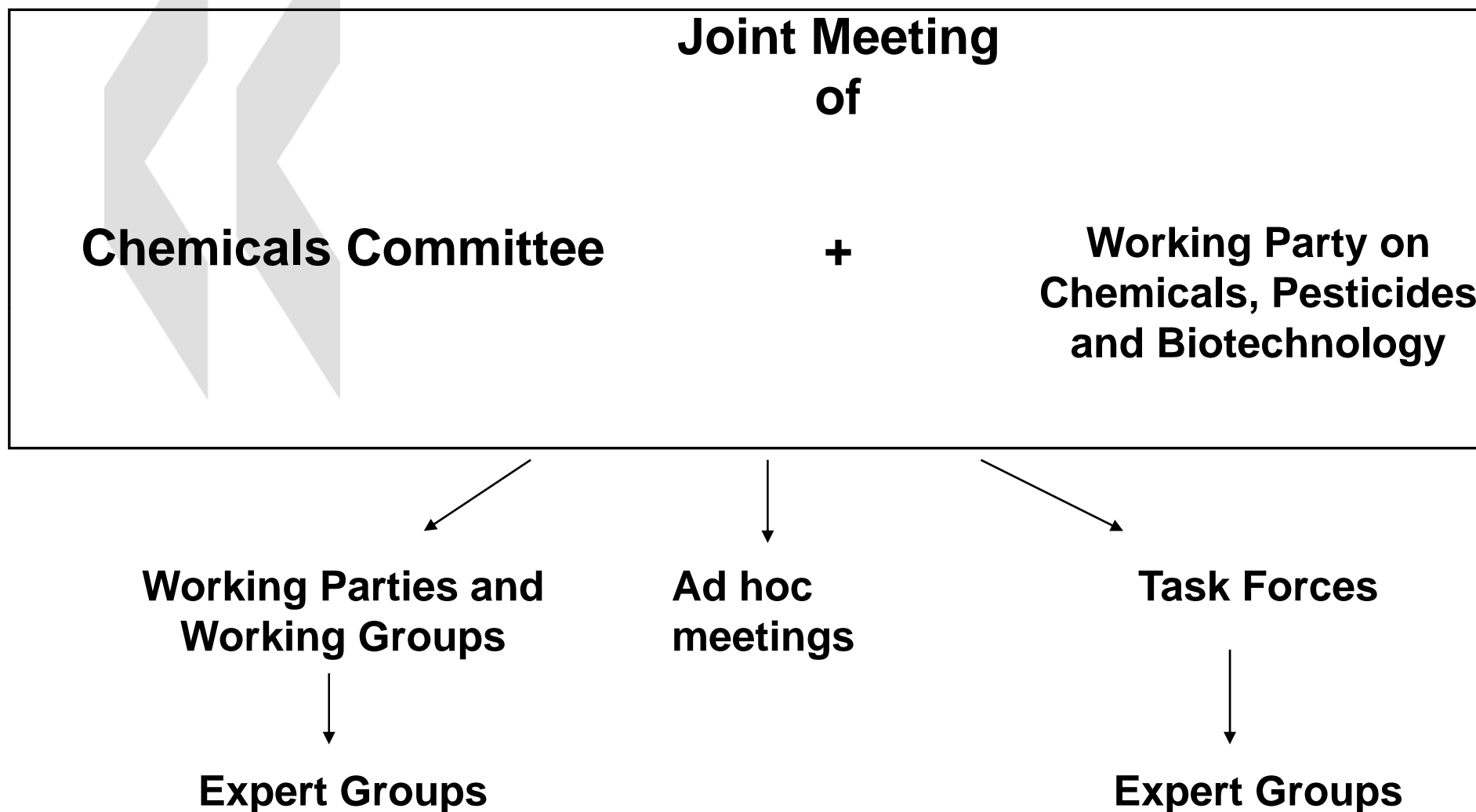
BENEFITS OF CO-ORDINATION / CO-OPERATION

- Efficiency through work sharing
- Mutual understanding
- Consistency

OECD WORK ON CHEMICAL SAFETY SUPPORTS

- ❖ National and Regional regulations regarding:
 - Test Guidelines
 - Good Laboratory Practice
 - New chemicals
 - Existing chemicals
 - Pesticides
 - Biocides
 - Manufactured Nanomaterials
 - Classification and labelling

IMPLEMENTATION OF EHS WORK



PARTICIPATION IN EHS WORK

- Members (make decisions)
- Selected non-member countries
- Other Inter-governmental Organisations
- Industry
- Trade Unions
- Environmental NGOs
- Animal Welfare NGOs (as appropriate)

OECD HPV Chemicals Programme (1)

Activity:

- Elaborate Agreed Initial Hazard Assessments for all OECD HPV Chemicals

Benefits:

- Save resources, avoid duplicative work, assessments.
- Use of assessments by member countries for national priority setting, classification, risk assessment, risk management.
- Availability of internationally agreed assessments (Agenda 21, Chapter 19 commitment)

OECD HPV Chemicals Programme (2)

Process

- Priority setting: production volume (currently 4843 substances on OECD HPV List)
- Selection of substances to be assessed
- Gathering of existing information and assessment of their quality - SIDS

OECD HPV Chemicals Programme (3)

Process (cont.)

- Further testing if necessary (to address in principle all SIDS elements)
- Co-operative assessment of the hazards (SIDS Initial Assessment Meeting - SIAM)
 - Participation of non-members and stakeholders
 - Conclusions on the hazards
 - Recommendation for further work, if needed
- Any post-SIDS work

SIDS (1)

- **Chemical identity**
- **Exposure information**
 - Production volume
 - Use pattern
 - Sources of exposure
- **Physical-chemical data**
 - Melting point
 - Boiling point
 - Vapour pressure
 - Water solubility
 - Octanol-water partition coefficient

SIDS (2)

- **Environmental Fate and Pathways**
 - Biodegradation
 - Abiotic degradability
 - Distribution estimates
- **Ecotoxicological data**
 - Acute toxicity to fish and Daphnia
 - Toxicity to algae
 - If needed:
 - Chronic aquatic toxicity
 - Terrestrial toxicity

SIDS (3)

- **Toxicological data**
 - Acute toxicity
 - Repeated dose toxicity
 - Genetic toxicity
 - Point mutation
 - Chromosomal aberration
 - Reproductive toxicity – information:
 - Fertility
 - Development

Contributions to the Programme

- Governments in OECD Countries
- US HPV Challenge Program (2800 US HPV chemicals)
- ICCA initiative (1000 HPV chemicals)
- Japan HPV Challenge Programme

Ultimate Objective:

- SIDS available for all OECD HPV Chemicals

Current Status

Status of HPV Chemicals (as of October 2006)	Total number of chemicals (number emanating from the ICCA Initiative)	
Ongoing information gathering and review	489	(360)
In preparation	67	(56)
Conclusions and Recommendations finalised	666	(420)
Total*	1222 *	(836)
*: Including 68 non-HPV chemicals included in chemical categories emanating from the ICCA initiative.		

Result:

- For many relevant HPV Chemicals:
 - SIDS Data available
 - Co-operative assessment available
- International confidence in assessment process

International dissemination:

- UNEP – CD-ROM & Web
- WHO – INCHEM
- Tracking through OECD HPV data base

Based on ongoing work:

- Improve information availability
- Facilitate data transfer
- Use experience to increase efficiency and effectiveness

Related work:

- eChem Portal
- Electronic Templates
- QSAR Application Tool Box

eChemPortal (1)

Objective

- Public access, free of charge, to information on properties of chemicals:
 - Physical chemical properties
 - Environmental fate and behaviour
 - Ecotoxicity
 - Toxicity

eChemPortal (2)

- Identify existing and relevant datasets and assessments and provide direct access to these data/reports
- Simultaneously query datasets stored in the participating databases by chemical identity and properties and provide direct links to the requested information - users can easily locate additional information about the selected chemicals

eChemPortal (3)

- Provide direct access to the data or document collection.
- Provide information about the source of the retrieved data.
- Provide description of the type of review the data have undergone.

Staged Implementation

- First phase to be released during the second quarter of 2007:
 - Identify by chemical identity datasets and assessments and provide direct access to them
- Second phase to follow in 2008/2009:
 - Simultaneously query datasets stored in participating databases by chemical identity and properties

eChemPortal: First Phase

- Hosted by the OECD Secretariat on the OECD website
- Search for information by CAS Registry Number, substance name or synonym in one or all participating databases
- Each link will direct the user either directly to the corresponding report or dataset or to the home page of the database or collection of reports
- List of referenced chemicals is not limited to High Production Volume Chemicals

European Chemical Substances Information System (ESIS)

- Maintained by the European Commission
- ESIS is an IT system which provides information on chemicals related to:
 - EINECS (European Inventory of Existing Commercial Substances)
 - ELINCS (European List of Notified Chemical Substances)
 - List of EU HPVs (High Production Volume chemicals) and LPVs (Low Production Volume chemicals) including the EU Producers & Importers
 - Classification and Labelling (Directive 67/548/EEC)
 - IUCLID chemical datasets for ca. 2,500 HPVs (data on toxicity, ecotoxicity and classification and labelling)
 - EU Priority lists for risk assessment, Risk assessment process and tracking system for the Existing Substances Regulation (ESR), (Council Regulation (EEC) 793/93) and Risk assessment reports

High Production Volume Information System (HPVIS)

- Maintained by the United States Environmental Protection Agency (USEPA)
- Released in Spring, 2006
- Public access to technical health and environmental effects information on chemicals submitted through the USEPA HPV Challenge Program
- Users search a database for existing data summary information, test plans, and new data on HPV chemicals as they are developed

Chemical Safety Information from Intergovernmental Organizations (INCHEM)

- Maintained by the International Programme for Chemical Safety (WHO) in collaboration with the Canadian Centre for Occupational Health and Safety
- Public access to thousands of searchable full-text documents on chemical risks and the sound management of chemicals

Data that can be searched through INCHEM include:

- Concise International Chemical Assessment Document (CICADS)
- Environmental Health Criteria (EHC) monographs
- Health and Safety Guides (HSGs)
- International Agency for Research on Cancer (IARC) - Summaries and Evaluations
- International Chemical Safety Cards (ICSCs)
- IPCS/CEC Evaluation of Antidotes Series
- Joint Expert Committee on Food Additives (JECFA) - Monographs and evaluations
- Joint Meeting on Pesticide Residues (JMPR) - Monographs and evaluations
- Pesticide Data Sheets (PDSs)
- Poisons Information Monographs (PIMs)
- Screening Information Data Set (SIDS) for High Production Volume Chemicals

Chemical Risk Information Platform (CHRIP)

- Maintained by National Institute of Technology and Evaluation (NITE), Japan
- Information on Biodegradation and Bioconcentration, test conditions, conclusions
- Chemicals assessed under the Chemical Substances Control Law (Japan)
- Also access to other related information, e.g. phys-chem properties, aquatic toxicity, mammalian toxicity.

OECD High Production Volume (HPV) Database

- Maintained by the OECD Secretariat in collaboration with OECD member countries
- Provides information on the status of all HPV chemicals within the process of investigation in the OECD HPV Chemicals Programme
- Provides access to published OECD Assessment Reports and Screening Information Data Sets (SIDS)

To be added:

- REACH-IT dissemination site: data submitted under REACH (Registration, Evaluation and Authorisation of Chemicals - new EU policy on chemicals)
- Maintained by the European Chemicals Agency

Roles and Responsibilities of Participating Databases

- Descriptions of the review the data have undergone (e.g., peer review by governmental authorities, other peer review, no peer review)
- Responsibility for maintaining and updating links to information and responding to user inquiries and feedback

eChemPortal: Second Phase

- A feasibility study is being conducted to identify the ideal hosting and maintenance option for the second phase of the Global Portal
- The second phase of the portal will feature enhanced search and query options to retrieve and compile specific data from participating databases

OECD Electronic Templates (1)

- An OECD electronic template is a standard format for reporting a summary of the results of a test on a chemical. These templates can be used for any type of a chemical (e.g., pesticides, biocides, new and existing industrial chemicals).

OECD Electronic Templates (2)

- The templates are aimed at developers of database systems as they prescribe the formats by which such information can be entered into and maintained in databases. By use of these templates, governments and industry will easily be able to electronically exchange test study summary information.
- XML Schemas are made – link to eChem Portal work

How electronic templates work (1)

- The templates have been developed for robust summaries of studies (i.e., not the full study).
- While templates will be prepared for each OECD Test Guideline, the templates can also be used to summarise studies not performed according to OECD Test Guidelines.

How electronic templates work (2)

- The elements can be reported by a test lab, a company or a government; it is up to each government to decide who completes what
- Each government would also decide which parts of a template are applicable to their programme
- *General* guidance on the use of the templates is provided; individual elements in a template contain guidance *specific* to those elements

How electronic templates work (3)

- Templates adopted by the Joint Meeting are posted on the public web site
- Governments will be encouraged to use the templates and XML schema
- Each government would determine
 - when to begin using the templates and schema
 - which elements in the template are relevant to their programmes

The QSAR Application Toolbox

- Required data from testing for hazard and risk assessments are available for a small percentage of chemicals
- Computational methods offer a non-testing alternative to fill data gaps and set priorities
- Many methods are computer-based but are viewed too complex for assessments
- A Toolbox will make QSAR methods more accessible and reduce the complexity in their use for generating reliable estimates

QSAR Application Toolbox

-Proof-of-Concept-

- Demonstrate that the Toolbox concept will make many QSAR methods readily accessible
- Apply computational methods to the formation of chemical categories and filling data gaps – link to HPV work
- Illustrate the importance of the domain of application in making reliable estimates
- Integrate existing data, expert knowledge and computational methods to facilitate hazard assessments

Outline of the QSAR Application Toolbox (1)

- The QSAR Toolbox will house QSAR models, databases and an application chassis
- Countries use OECD principles for QSAR validation for regulatory purposes to decide on inclusion of models

Outline of the QSAR Application Toolbox (2)

- The Toolbox chassis is a flexible simulator of the normal workflow of hazard assessors including experts and specialists
- The chassis will link the tools needed by the users for find information and fill data gaps
- User interfaces will be designed to reduce complexity

Possible use of the QSAR Application Toolbox (1)

- Inclusion in regulatory inventories or existing chemical categories
- Assessment states in various agencies/ organisations
- Search for available experimental data on assessment endpoints for each chemical
- Structural alerts indicating possible effects of a chemical structure

Possible use of the QSAR Application Toolbox (2)

- A chemical list for possible analogues for each chemical
- Groupings of chemicals based on molecular similarity analysis
- Identification of chemicals with anomalous metabolic pathways or toxicity mechanisms
- Groupings of chemicals based on common metabolite
- Customised outcome of analogue or metabolic pathway search

Possible use of the QSAR Application Toolbox (3)

- Filling data gaps in a chemical category using read-across, trend analysis or QSAR models
- Design of a data matrix of a chemical category for printing/exporting results



Schedule of Development (proof-of-concept version)

- Start of project: March 2006
- beta-version: September 2007
- roll-out: March 2008

Conclusions (1)

- Goals of Agenda 21, Chapter 19 and World Summit on Sustainable Development, set targets for international chemical safety work
- The many safety data on HPV chemicals which are becoming available at increased rate address the targets for assessments

Conclusions (2)

- The best way to make progress is through co-operation of
 - OECD countries
 - Stakeholders
 - Non-members
- Co-operation concept is successful and has capacity building function

Conclusions (3)

- Global availability of information through
 - eChem Portal and facilitated through use of
 - harmonised electronic templates
- Increased diligent use of QSARs using OECD Application Tool Box will add to pool of available information which is widely relied upon for assessments

Web-site:

www.oecd.org/ehs

OECD HPV Database:

<http://cs3-hq.oecd.org/scripts/hpv>

Template

Study design	No entry field. Heading only	
Test type	>Picklist: # static # semi-static # flow-through # Field study # no data # other:<specify>	List of values (open)
Test vessel	>Picklist: # open # closed # no data >Guidance: indicate whether test vessels were closed or open over the duration of the test.	List of values
Water type	>Picklist: # Fresh # Saline # no data	List of values
Total exposure duration	No entry field. Heading only (block of fields)	
(Lower) Exposure duration	>Guidance: enter value or lower value in case of range	Numeric
Upper exposure duration	>Guidance: enter upper value in case of range	Numeric
Unit	>Picklist: # minute(s) # hours # days # other:<specify>	List of values (open)
Post exposure observation period	>Guidance: indicate the post-observation period (with unit) if appropriate	Text
Effect measurement(s)	>Picklist: # mortality # growth # appearance # size # behaviour # no data # other:<specify> >Guidance: Indicate the effects recorded; multiple entry possible.	List of values (open+multiple)
Test conditions	No entry field. Heading only	
Hardness	>Guidance: enter hardness as CaCO ₃ in mg/l	Numeric
Test temperature	>Guidance: mean and range of test temperature during test	Text
pH	>Guidance: mean and range of pH during test	Text
Dissolved oxygen	>Guidance: mean and range of dissolved oxygen during test	Text
Details on test conditions	>Guidance: enter any relevant information of test system and conditions (delete/add items as applicable): TEST SYSTEM - Test vessel (material, size, headspace, fill volume, closed, aeration): - Type of flow-through (e.g. peristaltic or proportional diluter): - Renewal rate of test solution (frequency/flow rate): - No. of organisms per vessel: - No. of vessels per concentration (replicates): - No. of vessels per control / vehicle control (replicates):	Text >Note: In a data entry screen, the list could appear automatically as a freetext template

XML schema

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- <block
  name="TESTTYPE_AQUATOX">
  <prop name="LIST_SEL" />
  <prop name="LIST_SEL_TEXT" />
</block>
- <block name="TESTVESSEL">
  <prop name="LIST_BELOW_SEL" />
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- <block name="WATERTYPE">
  <prop name="LIST_BELOW_SEL" />
</block>
- <block name="EXP_DURATION">
  <prop name="LOVALUE" />
  <prop name="UPVALUE" />
  <prop name="UNIT" />
</block>
- <block name="POSTEXP_PERIOD">
  <prop name="TEXT_BELOW" />
</block>
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- <block name="EFF_MEASUREMENT">
  <prop name="FREETEXT_BELOW" />
</block>
- <block name="HARDNESS">
  <prop name="NUMBER_5" />
</block>
- <block name="TEST_TEMP">
  <prop name="TEXT_BELOW" />
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- <block name="PH">
  <prop name="TEXT_BELOW" />
</block>
- <block name="DISS_OXYGEN">
  <prop name="TEXT_BELOW" />
</block>
- <block
  name="TESTCONDIT_DETAILS">
  <prop name="FREETEXT_BELOW" />
</block>
```

