

ECOPA Workshop REAlity CHeck

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"What has been achieved under REACH?"

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EU Technology Platform for Sustainable Chemistry



European Technology Platforms ...



June 2004 Commission publishes FP7 outline (COM (2004) 353) & ETP discussion document:

ETP's are 1 of 6 priorities for FP7, and are a framework to unite stakeholders around:

- a common <u>vision</u> and approach for the technology concerned
- definition of a <u>Strategic Research Agenda</u> (SRA)
- An <u>implementation plan for the SRA</u>, mobilisation of a critical mass of research and innovation effort

European Technology Platform for Sustainable Chemistry is also an instrument to enhance stakeholder dialogue



SusChem ETP objectives and scope

Objective:

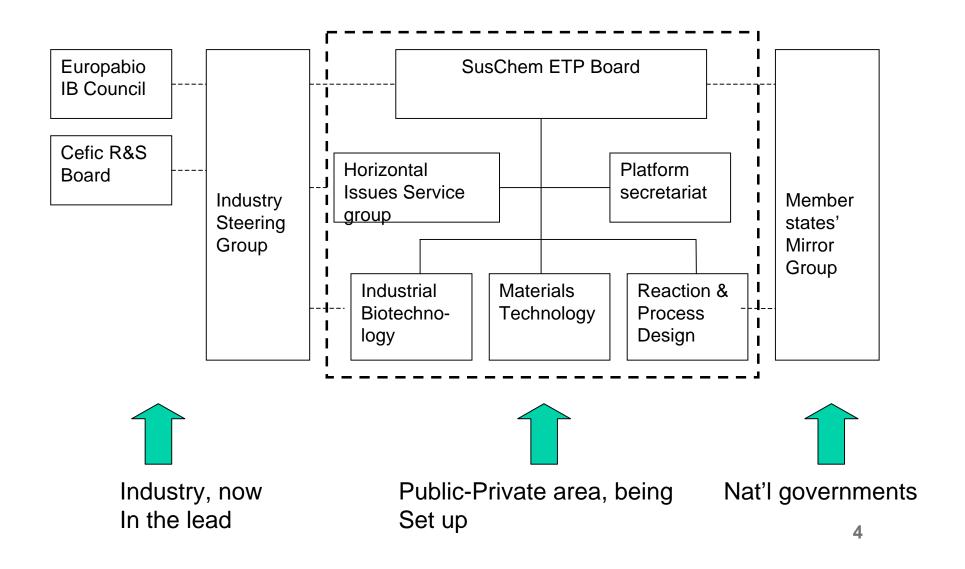
Shaping the research agenda and innovation framework conditions for a sustainable EU (chemical) industry

Scope

- Technology areas:
 - 1. Industrial biotechnology
 - 2. Materials technology
 - 3. Reaction and Process Design
- Horizontal issues: <u>Generic Barriers and constraints and stimulators</u> for chemistry innovation in <u>Europe</u>
 - Health, Safety & Environmental
 - Supportive Environment
 - Financial



Platform governance





What will be achieved under REACH?

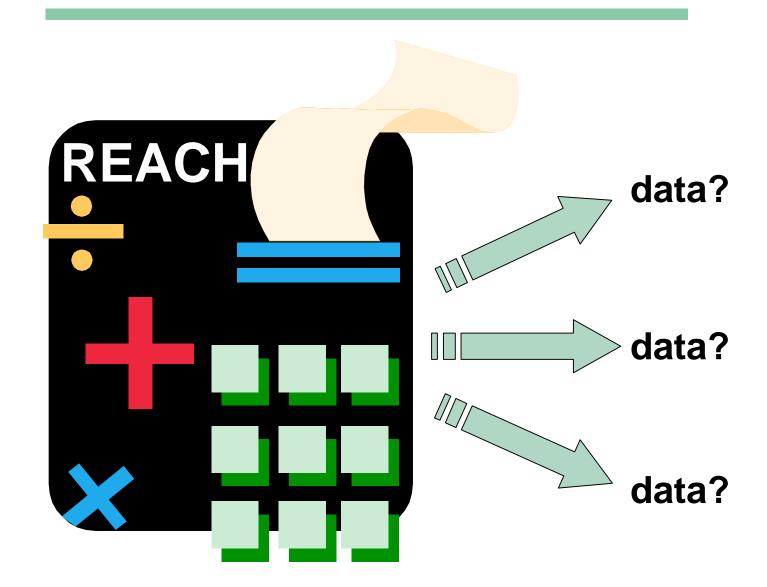


What will be achieved?

- consistent legislation in EU
- systematic inventory of substances and uses
- available data on the table
- Filling of most prominent data gaps
- More and improved risk assessments



However...





Needs for sustainable and innovative EU

- Sound scientific data and assessments
- reliable criteria for business development
- involvement of value chain
- public trust and acceptance
- intelligent approaches making best use of ressources

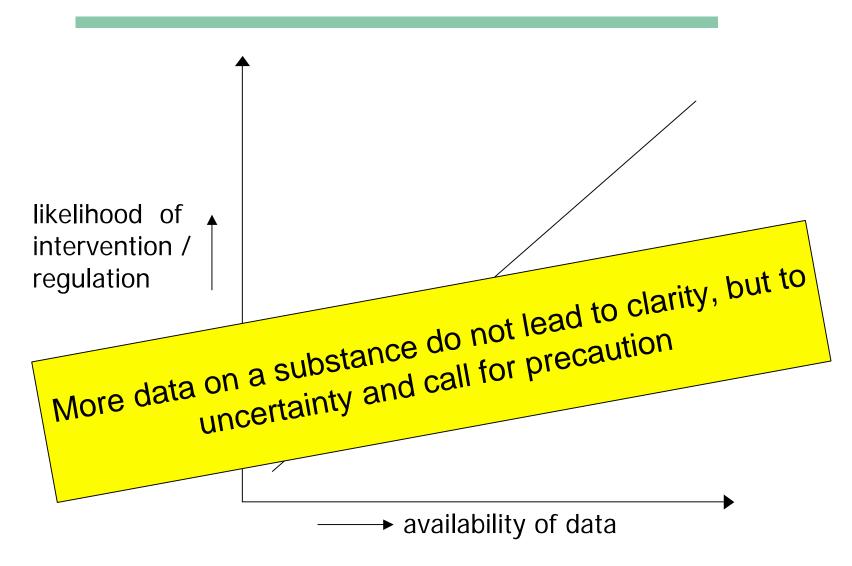


Reliable criteria?

- EU decisions based on extended risk assessment by-passed by other EU institutions
- Paradox that substances with REACH ++ Plus data and extensive risk assessments are still under "attack" by EU, member states and NGO's
- EU Strategies to remove the risk assessment paradigm



Challenge



EU Environment and Health Action Plan (SCALE)







SCALE <u>Science</u>, <u>Children</u>, <u>Awareness</u>, <u>Legal tools</u>, <u>Evaluation</u>

Why? (too many knowledge and policy gaps)

- Key children's diseases are on the increase (asthma, cancer, neurodevelopment)
- 1/3 of disease burden is due to environmental factors (env-health link)
- Previous policy addresses <u>single</u> 'pollutants' not <u>mixtures</u>, or <u>delayed effects</u>
- Children's "unique windows of susceptibility" not adequately addressed

What? (first cycle - 2004-2010: children in the urban environment)

Reduce the disease burden due to environmental factors in EU Identify/prevent new health threats caused by environmental factors Strengthen EU capacity for policy making in environment-health area

How? (get the information to support policy decisions)

Integrate environment policy and health policy

Create cause-effect framework through EU environment & health (bio)monitoring Research into 'emerging issues' (low-dose, delayed effects, mixtures...)

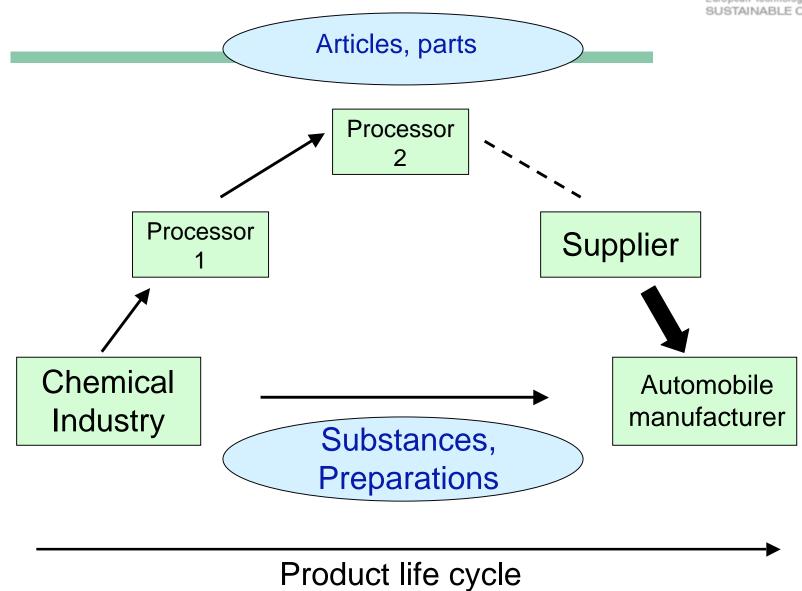


Involvement of supply chain

- Shared resonsibility along value chain needs to be better defined and more balanced
- Thresholds for the request to customers for input into safety reports needed
- Encourages free riders (e.g. late comers)
- Will shift assessment paradigm from risk to hazard
- in many cases EU is just a minor regional market

Information flows







Substance/Material declarations

Umbrella Specs

IPC Approach

Spreadsheets

IMDS

Synonyms

Different approaches

Word files

EICTA proposal

Different definitions

Green Partner

Rosetta Net

Different names

Individual databanks

Green Procurement

DIN 19220



Public trust and acceptance

- public and political hopes for REACH are far too high
- Stakeholder expectations (examples)
 - will deal with drugs for children, traffic pollution and noise (EEN)
 - will deal with lead in blood of children in Kosovo (WHO)
 - will deal with obsolete stocks of pesticides in Africa (WHO)
 - Cancers will be significantly reduced (EU)



One prominent example for conflicting target SUSTAINABLE CHEMISTRY

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Motor-Vehicle Safety Regualtion
  destrians (1975 - 2000)
                                               ↓ 41 % fatality (US)
              boaster seats
                                               ↓ 30 % fatality, but still misuse
      No zero exposure scenario, comparative risk assessment needed
21st Century Challenge
Enhance pedestrian safety the
Better public transport
Increase use of safety belts
Prevention strategies
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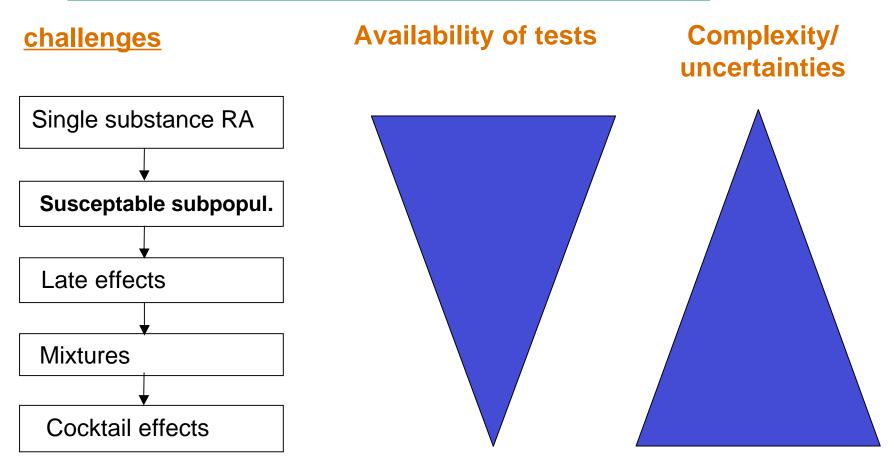


Long term reliability

- decision must be based on high level quality, validated science
 - quality criteria at science/policy interface
 - current research funding encourages low standards in validation
 - certain stakeholders need and create uncertainty in the public
 - Need for good science practice (GSP)







- REACH under public pressure will increase animal testing
- intelligent testing/assessment as well as consistent messages needed



Intelligent approaches

- REACH is in danger to become box ticking exercise
 - ED "un-intelligent" testing as an example for a newly to be established testing scheme

OECD Conceptual Framework* for the Testing and Assessment of Endocrine Disrupting Chemicals

Level 1

Sorting & prioritization based upon existing information

- physical & chemical properties, e.g., MW, reactivity, volatility, biodegradability,
- human & environmental exposure, e.g., production volume, release, use patterns
- hazard, e.g., available toxicological data

Level 2

In vitro assays providing mechanistic data

- ER, AR, TR receptor binding affinity
- Transcriptional activation
- Aromatase and steroidogenesis in vitro
- Ary I hy drocarbon receptor recognition/binding
- QSARs

- -High Through Put Prescreens
- Thy roid function
- Fish hepatocyte VTG assay
- Others (as appropriate)

Level 3

In vivo assays providing data about single endocrine mechanisms and effects

- Uterotrophic assay (72 animals per s)
- Hershberger assay (66 animals per s)
- Non -receptor mediated hormone function
- Others (e.g. thy roid)

- -Thy roid screening ??
- -Fish VTG (vitellogenin) assay (estrogenic related) (80 fish per

Level 4

In vivo assays providing data about multiple endocrine mechanisms and effects

- -enhanced OECD 407 (40 animals per s
- -male and female pubertal assays
- adult intact male assay

- -Fish 21 d gonadal (324 fish per s
- -histopathology assay
- Frog metamorphosis assay

Level 5

In vivo assays providing data on effects from endocrine & other mechanisms

- 1-generation assay (800 animals per
- 2-generation assay (TG416 enhanced)¹
- reproductive screening test (TG421 enhanced)1
- combined 28 day/reproduction screening test (TG 422 enhanced)¹
- 1 Potential enhancements will be considered by VMG mamn

 Partial and full life cycle assays in fish (1132 per s), birds, amphibiar invertebrates (developmental and reproduction

^{*} Framework based on 6th meeting of OECD EDTA Task Force, see www.oecd.org

OECD Conceptual Framework* for the Testing and Assessment of **Endocrine Disrupting Chemicals**



Level 1

Sorting & prioritization based upon existing information



20.000 substances of commercial interest

Level 2

In vitro assays providing mechanistic data

Level 3

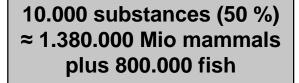
In vivo assays providing data about single endocrine mechanisms and effects

Level 4

In vivo assays providing data about multiple endocrine mechanisms and effects

Level 5

In vivo assays providing data on effects from endocrine & other mechanisms



2.000 substances (20 %) ≈ 60.000 mammals plus 648.000 fish

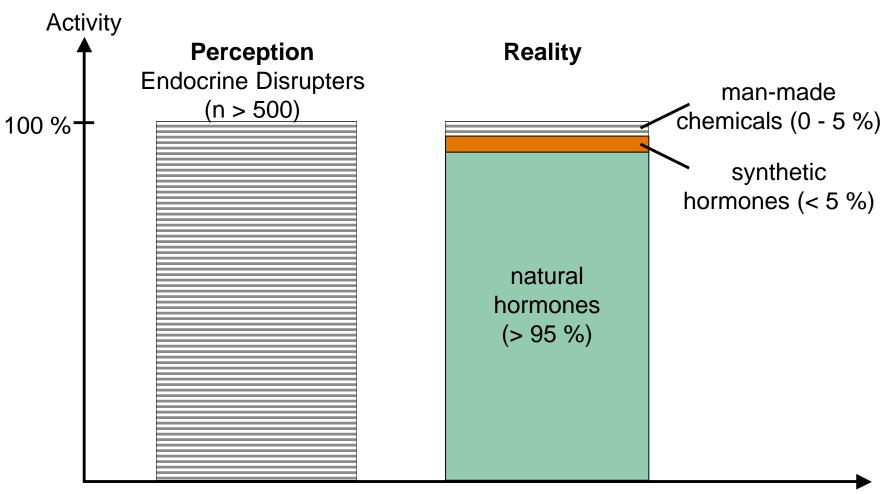
e.g. 800 mamalian animals/ 1100 fish per substance

^{*} Framework based on 6th meeting of OECD EDTA Task Force, see www.oecd.org

The real world



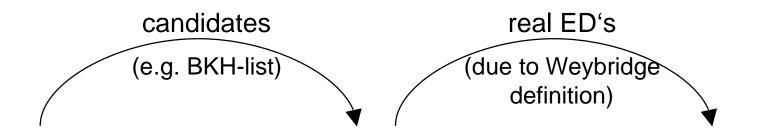
Hormonal load in environment





Industry proposal

Pragmatic approach in REACH



Registration

Evaluation (OECD 407-28 d study)

Authorisation



Mid term scenario

2006 - 2010

2008 -

Single substance hazard identification and assessment, data harmonization

- Existing legislation
- REACH
- 91/414
- WHO
- US programme
- IFCS



Policy based on new paradigms

- REACH ??
- Hazard driven
- Precaution
- Prevention
- Evidence based medicine
- Uncertainty/perception
- Costs
- Science/media axis

⇒ targeted to improve consumer confidence through regulations and market mechanisms

Take home messages



- REACH is not the solution but a new start
- process may be box ticking, under 3R aspects and health add-on refinement of testing strategies is needed
- shared responsibility along value chain has to be more clearly distributed
- criteria to act in risk management, but also when not to act further, have to be defined based on sound science
- public confidence is the responsibility of all stakeholders
- Regulators involvement in implementing related strategies needed
- Use of substances with data must be encouraged, promote confidence