

**ECOPA Workshop**  
**REALity CHeck**  
**Bruxelles, February 1, 2006**

**„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 **vision** and approach for the technology concerned
- definition of a **Strategic Research Agenda** (SRA)
- An **implementation plan for the SRA**, 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

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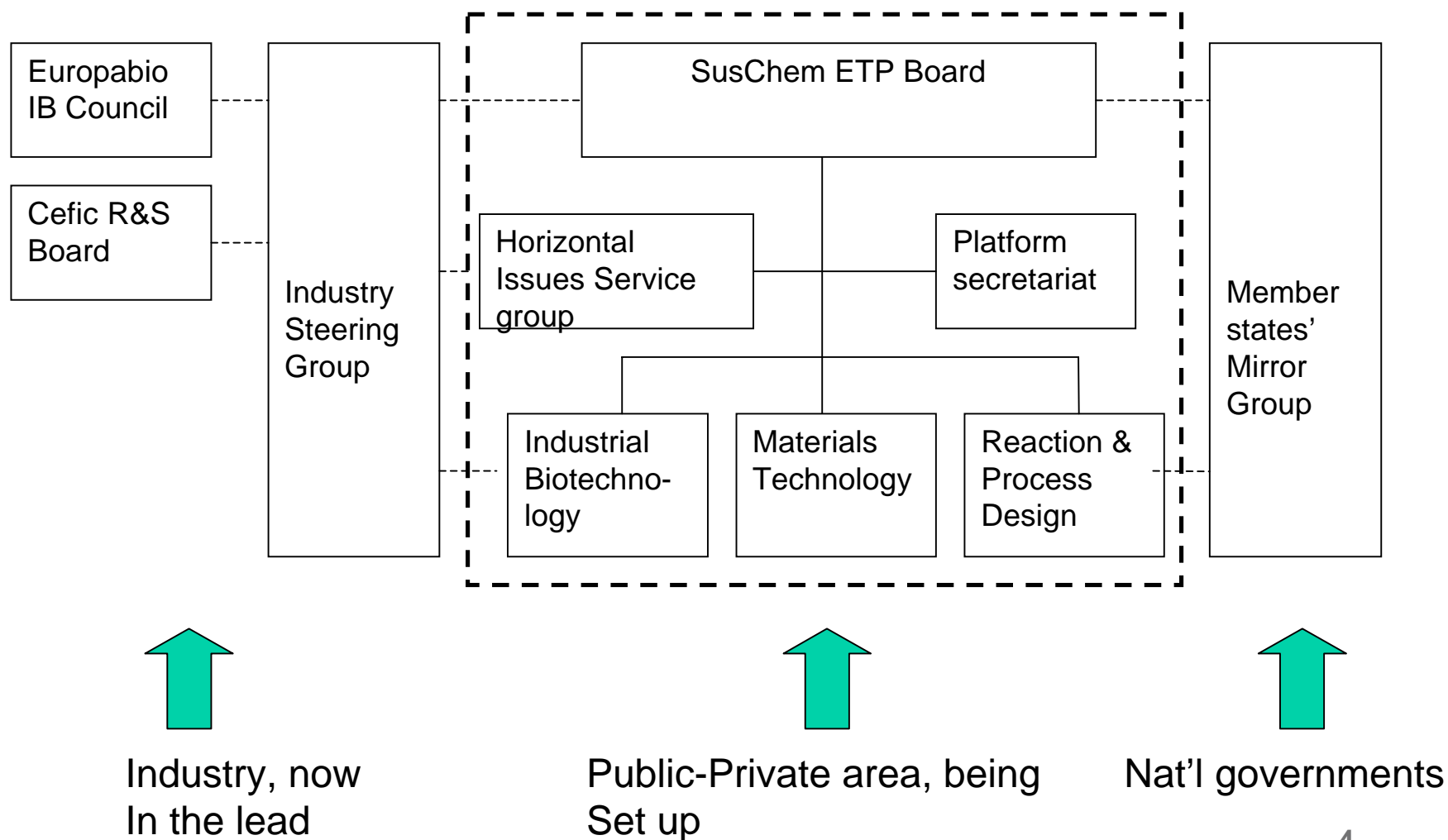
## **Objective:**

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: Generic Barriers and constraints and stimulators for chemistry innovation in Europe
  - Health, Safety & Environmental
  - Supportive Environment
  - Financial

# Platform governance



# What will be achieved under REACH?

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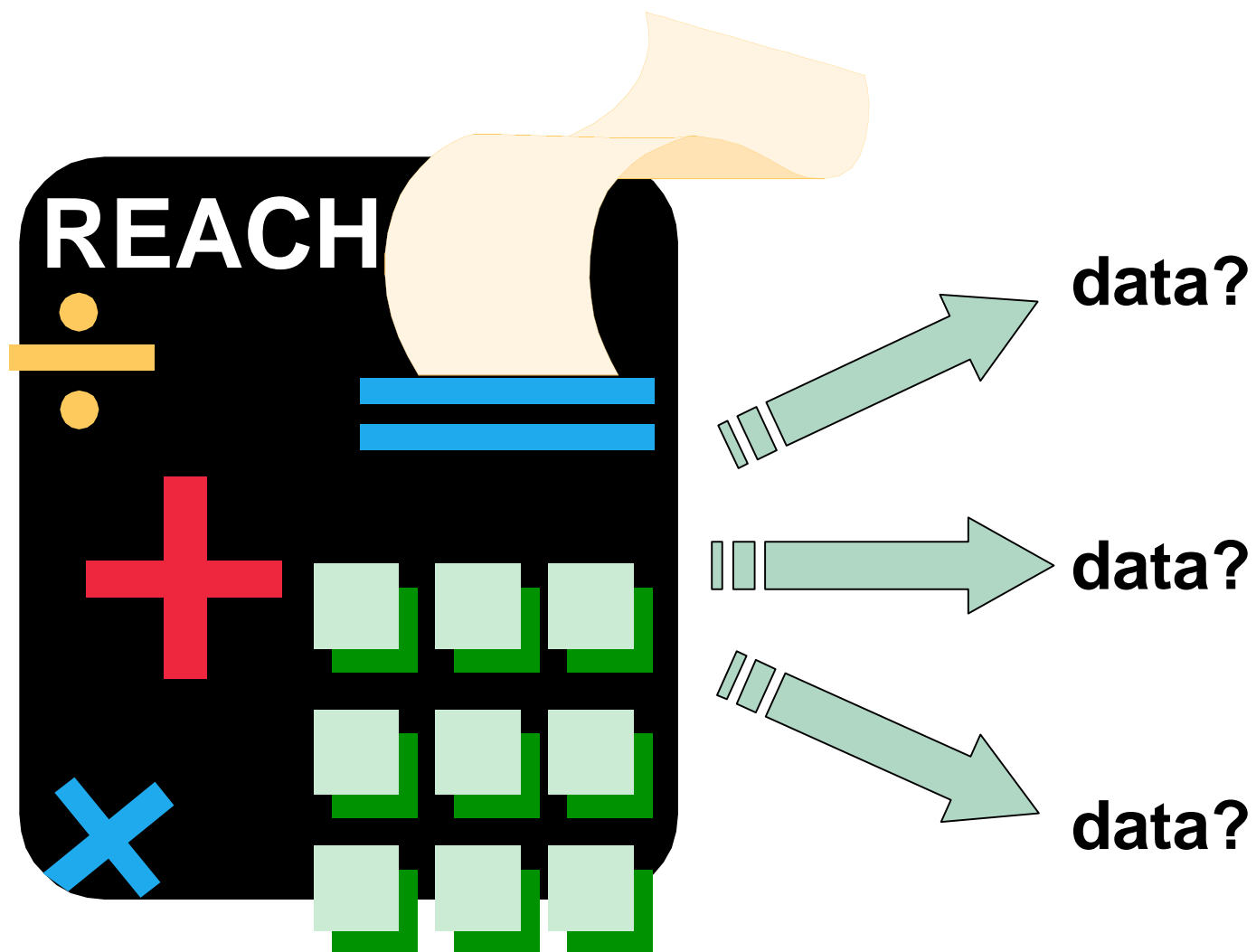
## What will be achieved?

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- 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...

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## Needs for sustainable and innovative EU

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

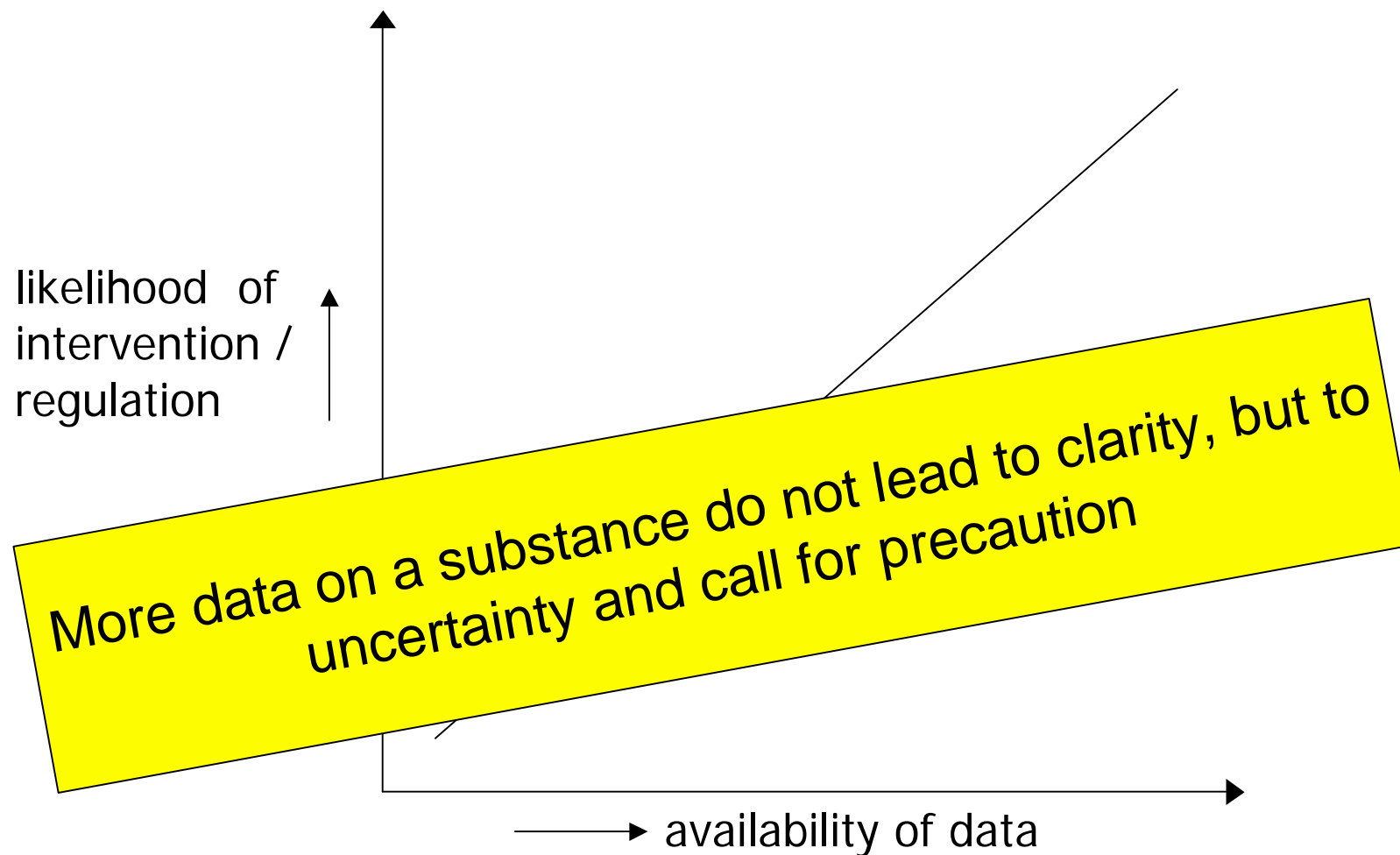


## Reliable criteria?

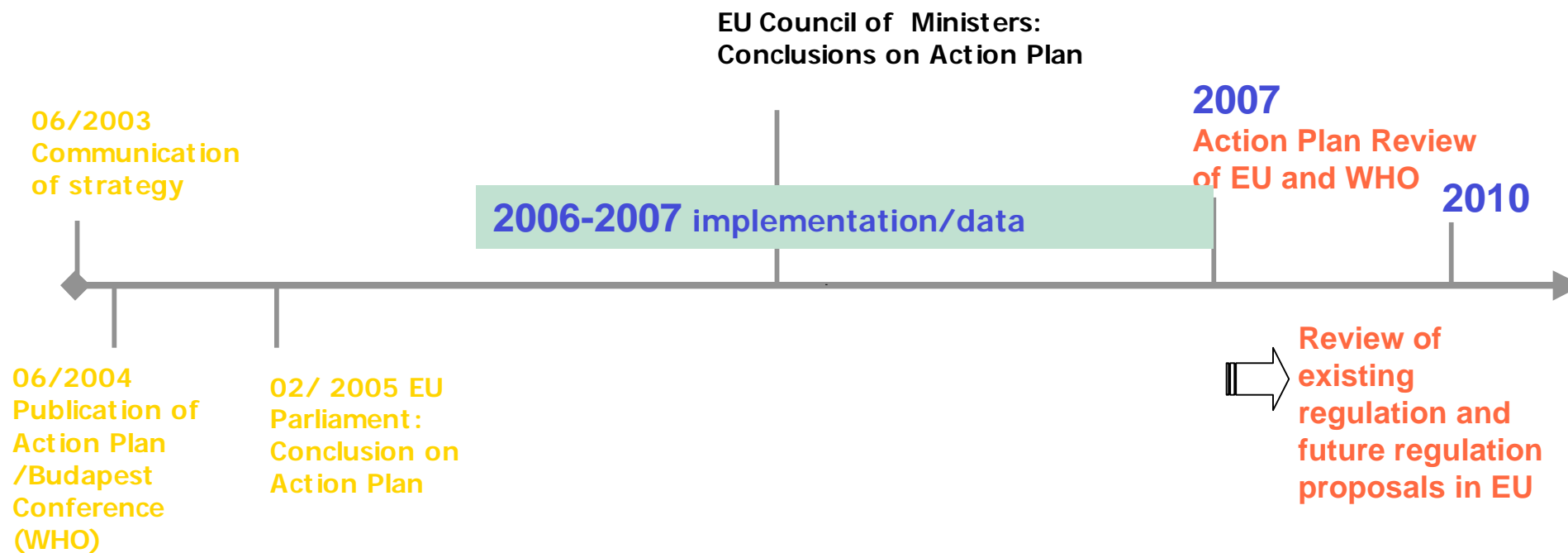
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- EU decisions based on extended risk assessment by-passed by other EU institutions
- Paradox that substances with REACH ++ Plus data and extensive risk assessments are still under “attack” by EU, member states and NGO’s
- EU Strategies to remove the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

# Challenge



# EU Environment and Health Action Plan (SCALE)



# SCALE Science, Children, Awareness, Legal tools, Evaluation

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## Why? (too many knowledge and policy gaps)

- Key children's diseases are on the increase (asthma, cancer, neuro-development)
- 1/3 of disease burden is due to environmental factors (env-health link)
- Previous policy addresses single 'pollutants' not mixtures, or delayed effects
- 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

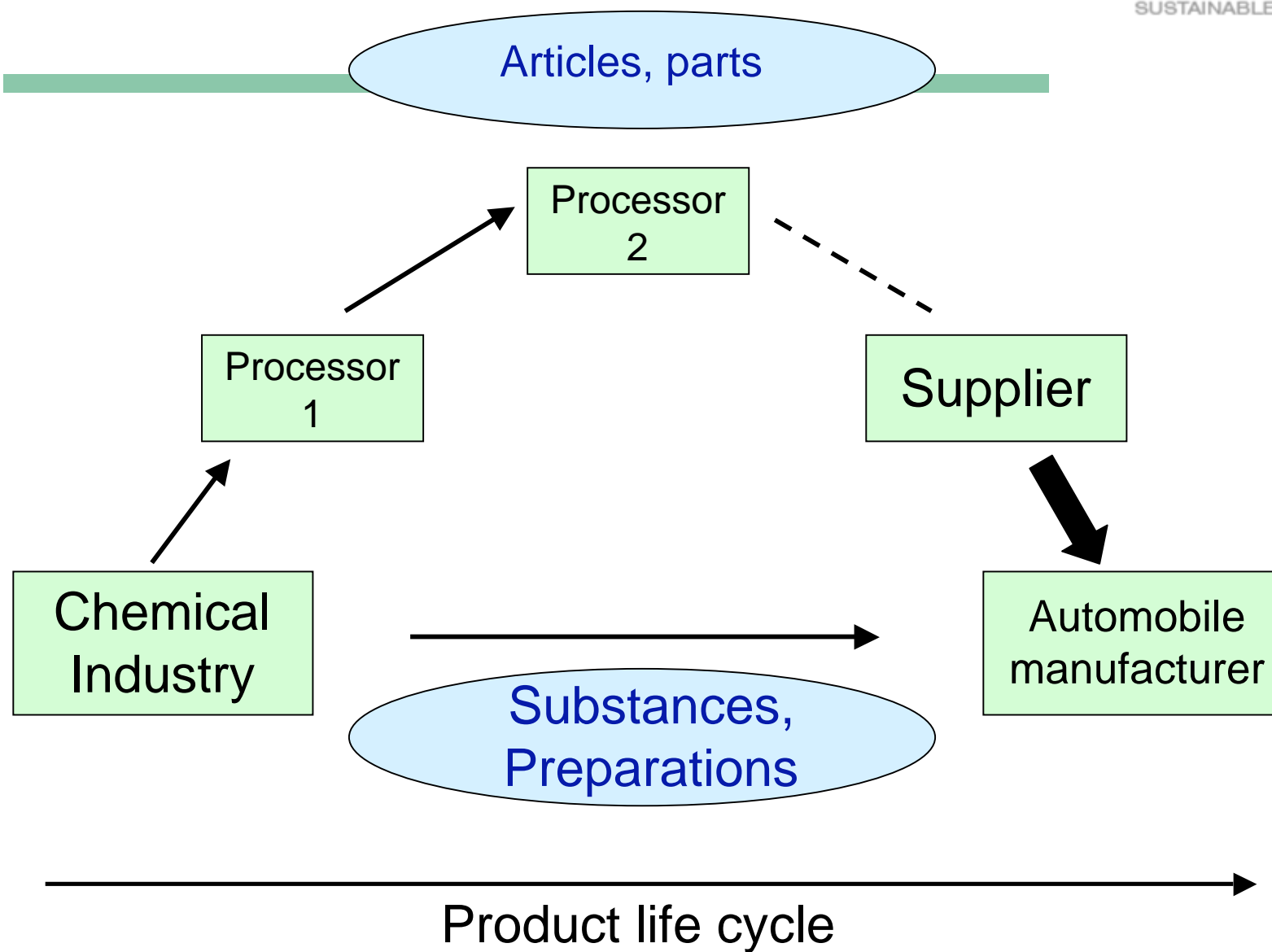
Research into 'emerging issues' (low-dose, delayed effects, mixtures...)

## Involvement of supply chain

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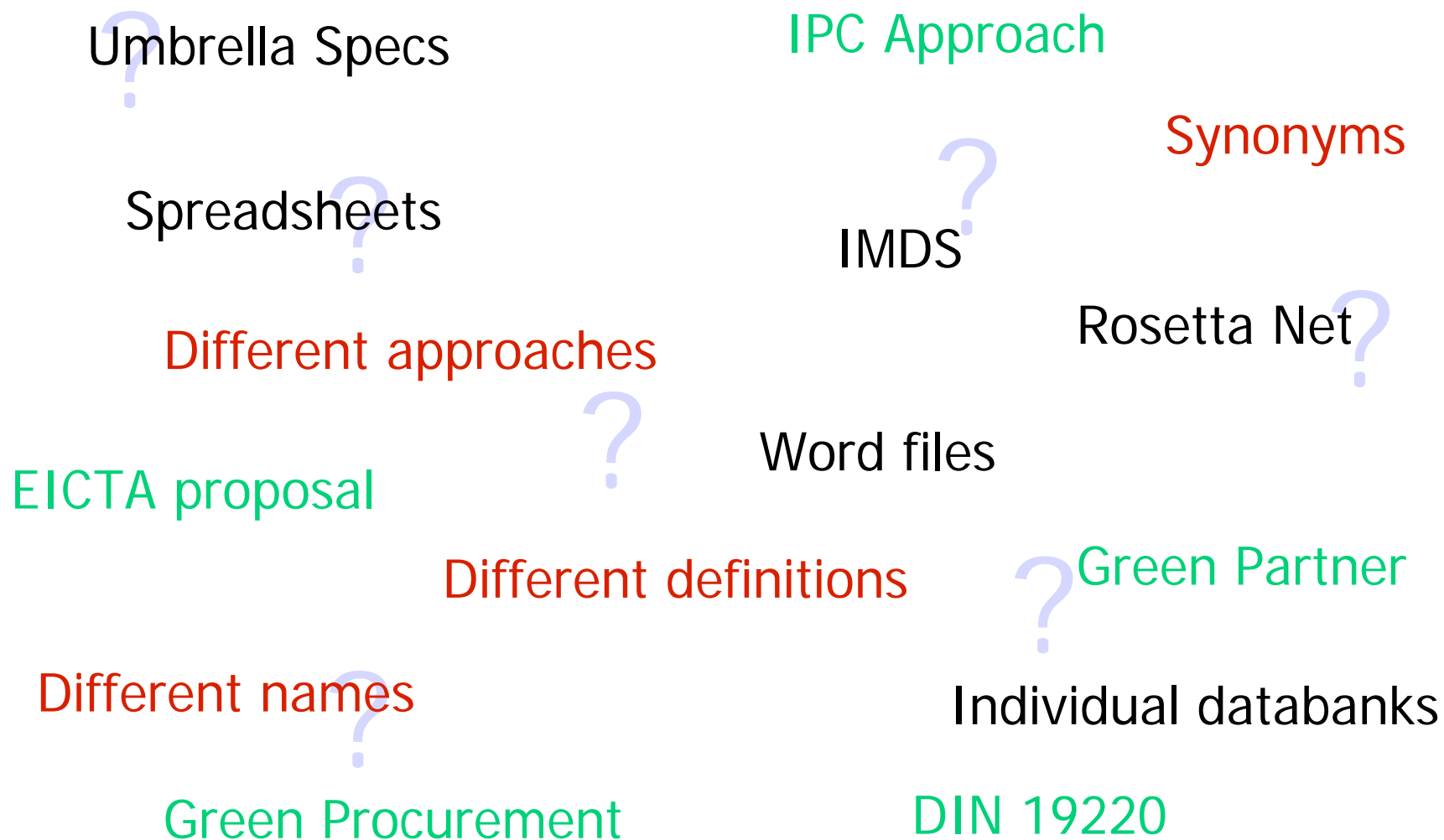
- Shared responsibility along value chain needs to be better defined and more balanced
- Thresholds for the request to customers for input into safety reports needed
- Encourages free riders (e.g. late comers)
- Will shift assessment paradigm from risk to hazard
- in many cases EU is just a minor regional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

## Information flows



## Substance/Material declarations

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## Public trust and acceptance

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- 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 targets

### Motor-Vehicle Safety Regulation

**Pedestrians (1975 - 2000)**

↓ 41 % fatality (US)

**and booster seats**

↓ 30 % fatality, but still misuse

44, 14, 16;

Standards

**No zero exposure scenario,  
comparative risk assessment needed**

### 21st Century Challenges

**Enhance pedestrian safety through**

**Better public transport**

**Increase use of safety belts**

**Prevention strategies**

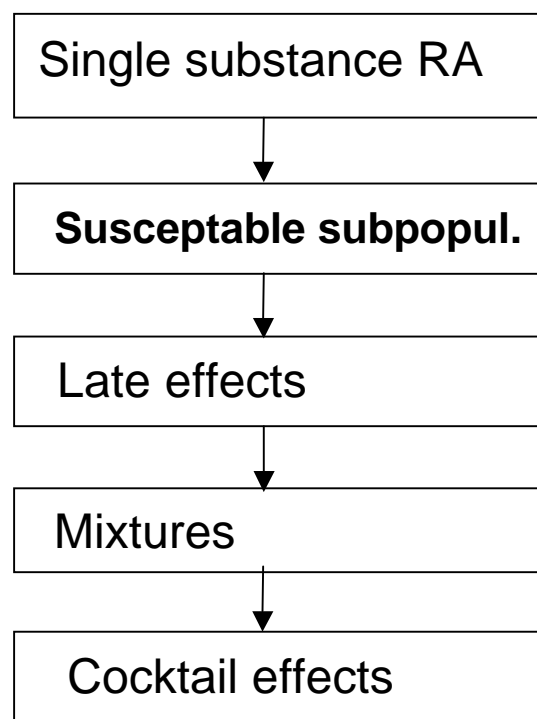
## Long term reliability

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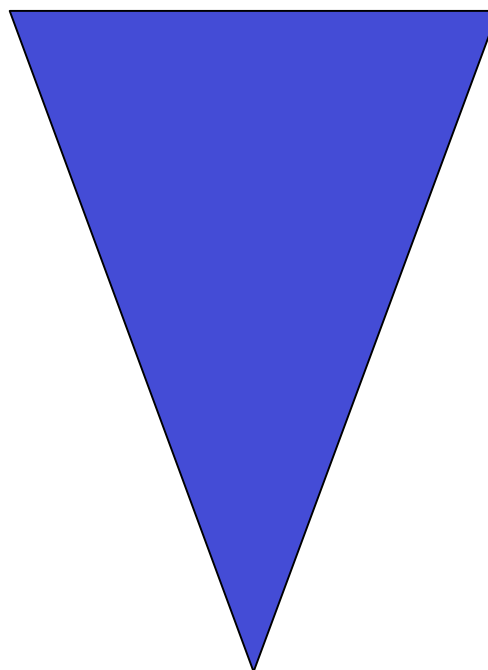
- decision must be based on high level quality, validated science
  - quality criteria at science/policy interface
  - current research funding encourages low standards in validation
  - certain stakeholders need and create uncertainty in the public
  - Need for good science practice (GSP)

# Complexity/uncertainty and 3R

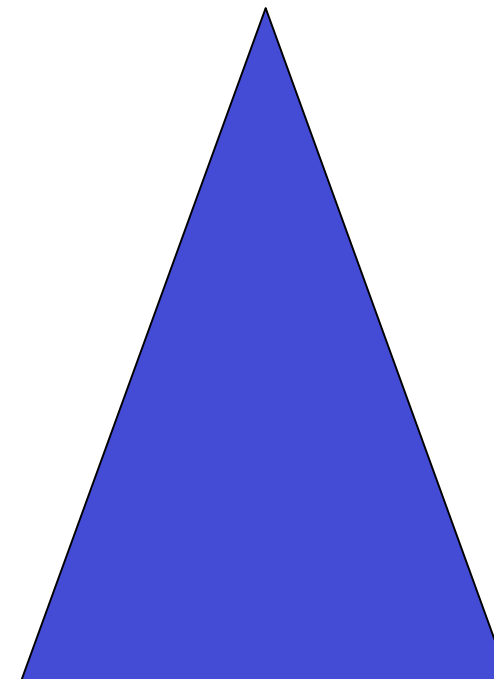
## challenges



## Availability of tests



## Complexity/ uncertainties



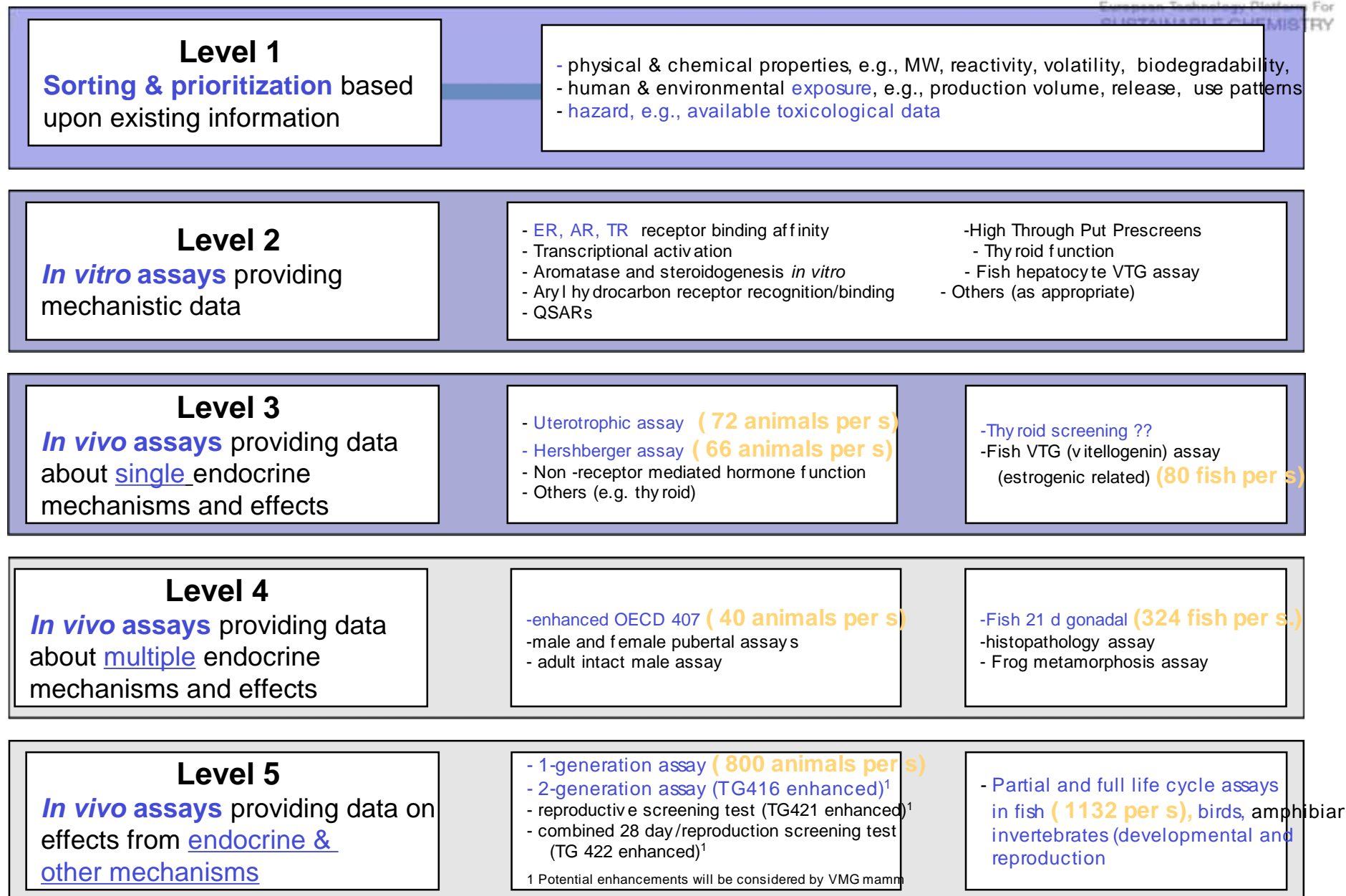
- REACH under public pressure will increase animal testing
- intelligent testing/assessment as well as consistent messages needed

## Intelligent approaches

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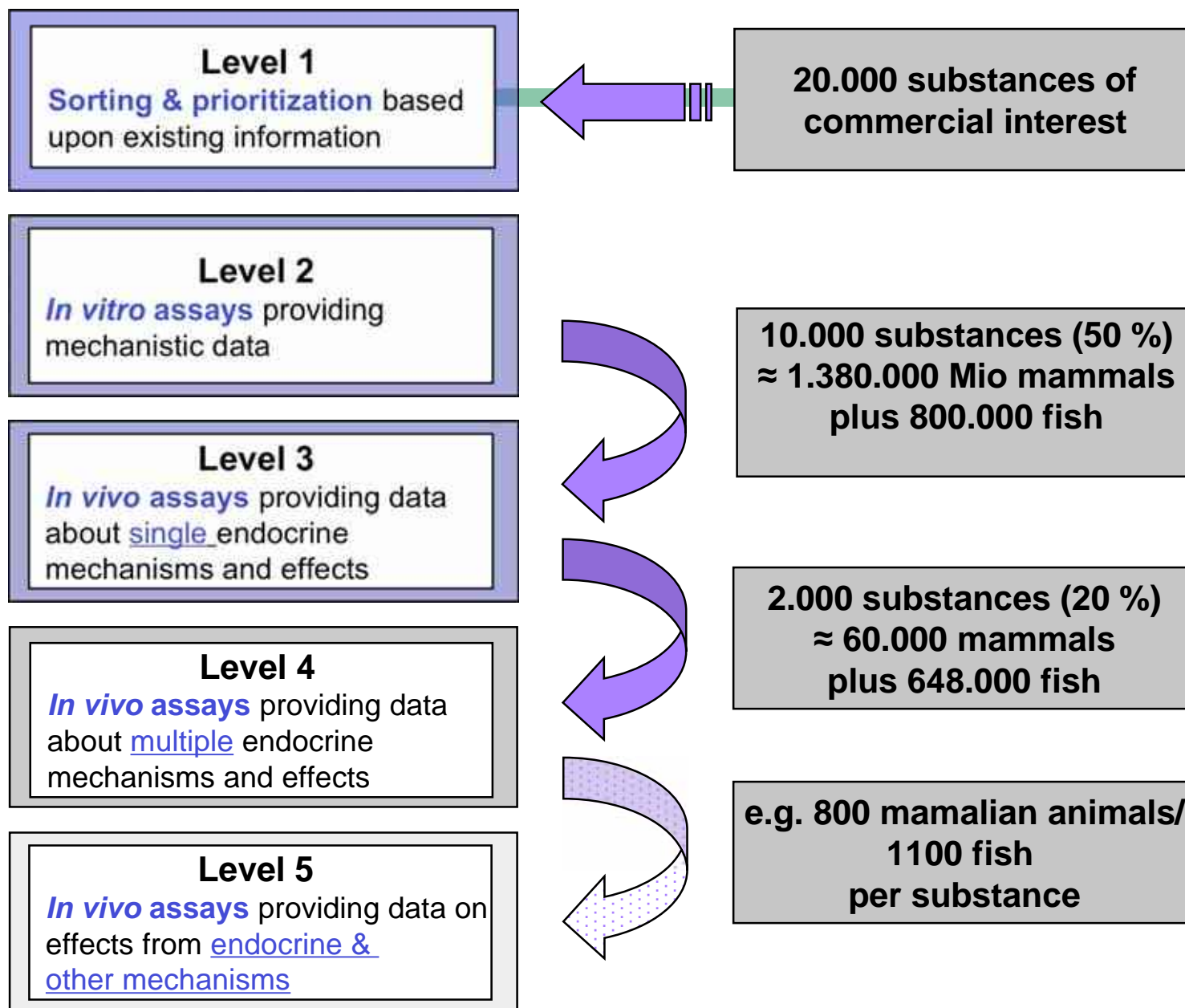
- REACH is in danger to become box ticking exercise
  - ED “un-intelligent” testing as an example for a newly to be established testing scheme

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



\* Framework based on 6th meeting of OECD EDTA Task Force, see [www.oecd.org](http://www.oecd.org)

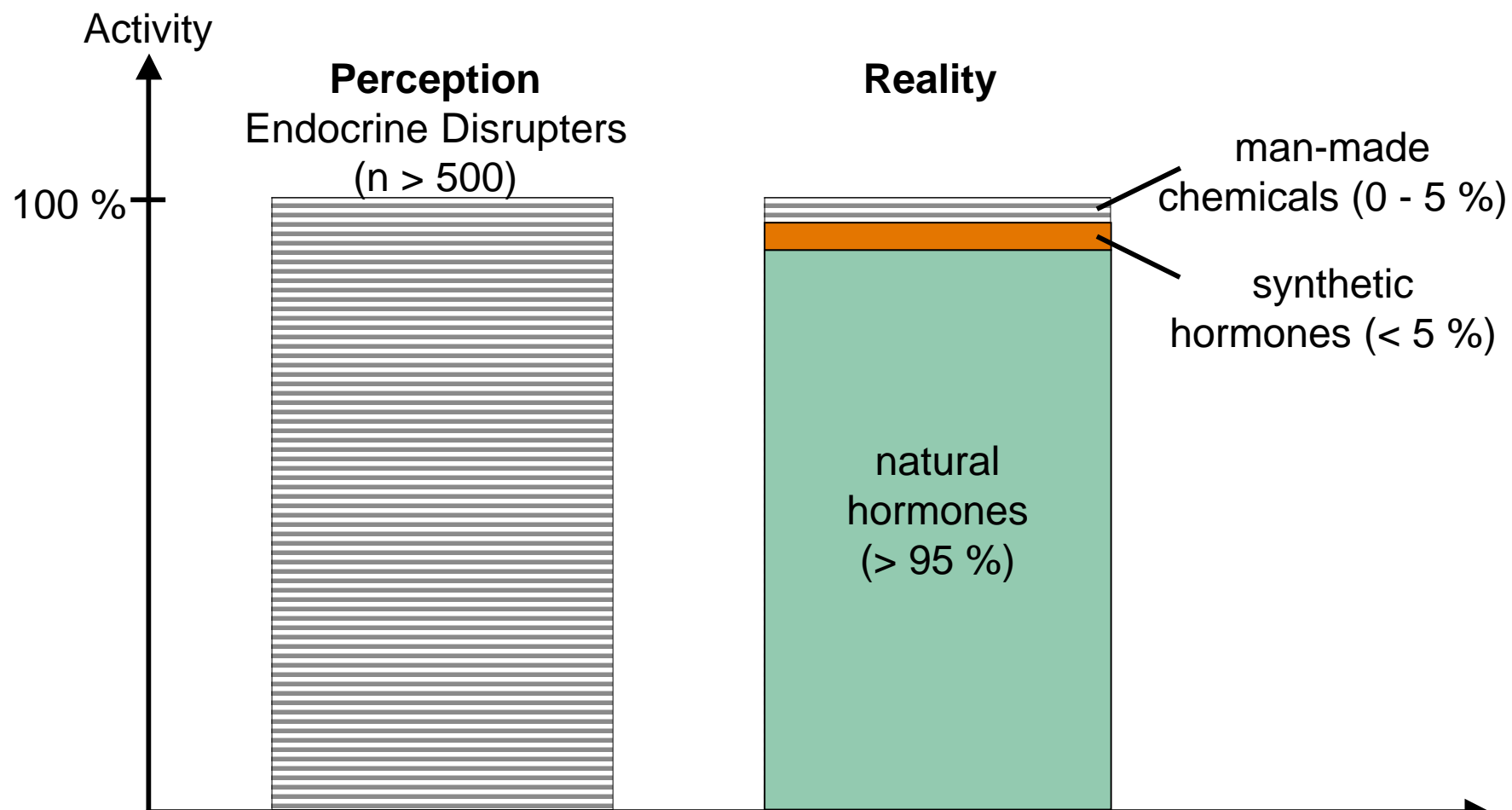
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# The real world

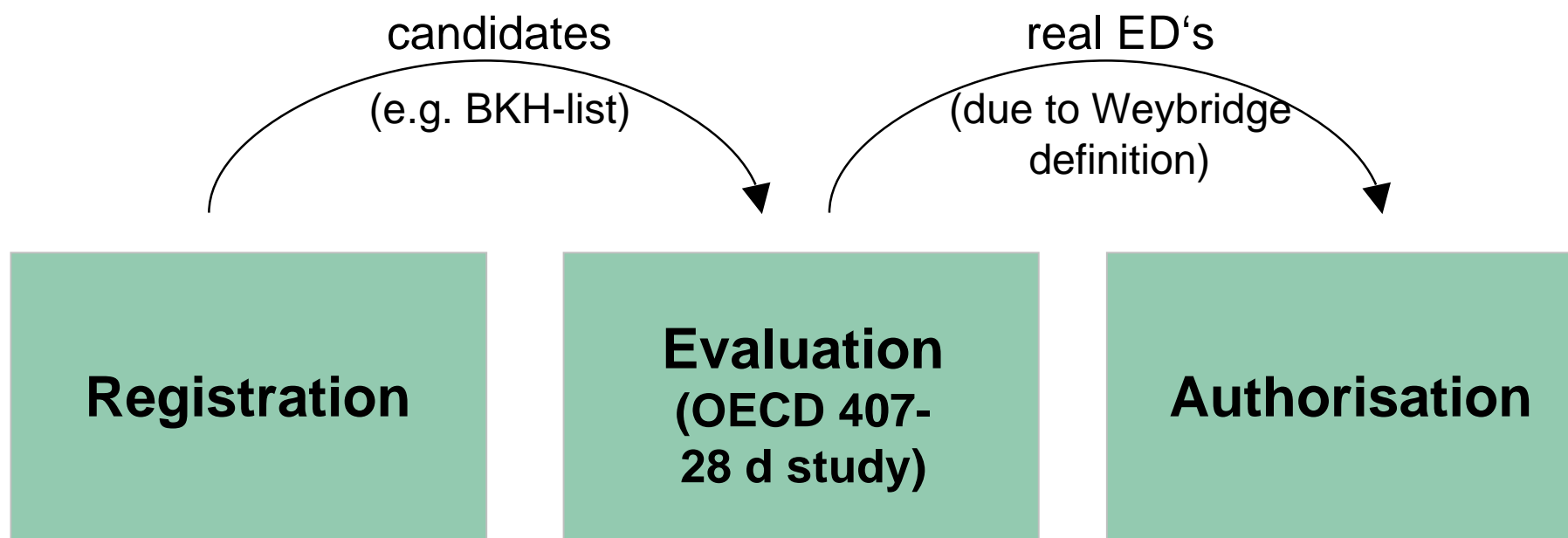
## Hormonal load in environment



# Industry proposal

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## Pragmatic approach in REACH





## Mid term scenario

2006 - 2010

### Single substance hazard identification and assessment, data harmonization

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



2008 -

### 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

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- 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