



What does REACH need from environmental scientists?

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RIVM/NVT/KNCV Does science REACH policy? 01-12-2006



Action 1311
Assessment
of Chemicals

Action 1313
Support to REACH



EUROPEAN CHEMICALS BUREAU

<http://ecb.jrc.it>

Action 1314
REACH-IT
&
Informatics

Action 1321
Computational
Toxicology
(QSARs)

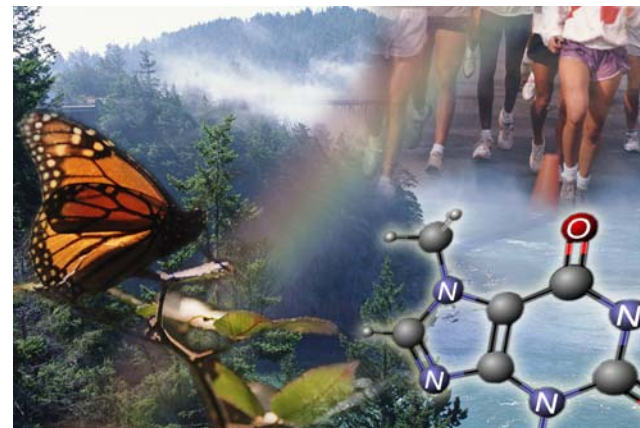


Actions in FP6 year 2006

1313 REACH

Action Mission:

Support to future chemicals legislation and the adoption and Implementation process of the REACH legislation



- ECB delivers technical and scientific support to REACH implementation
- Refocusing of current activities to prepare for REACH
- General support on request (from DG ENV and ENTR)
- Specific support: RIP projects



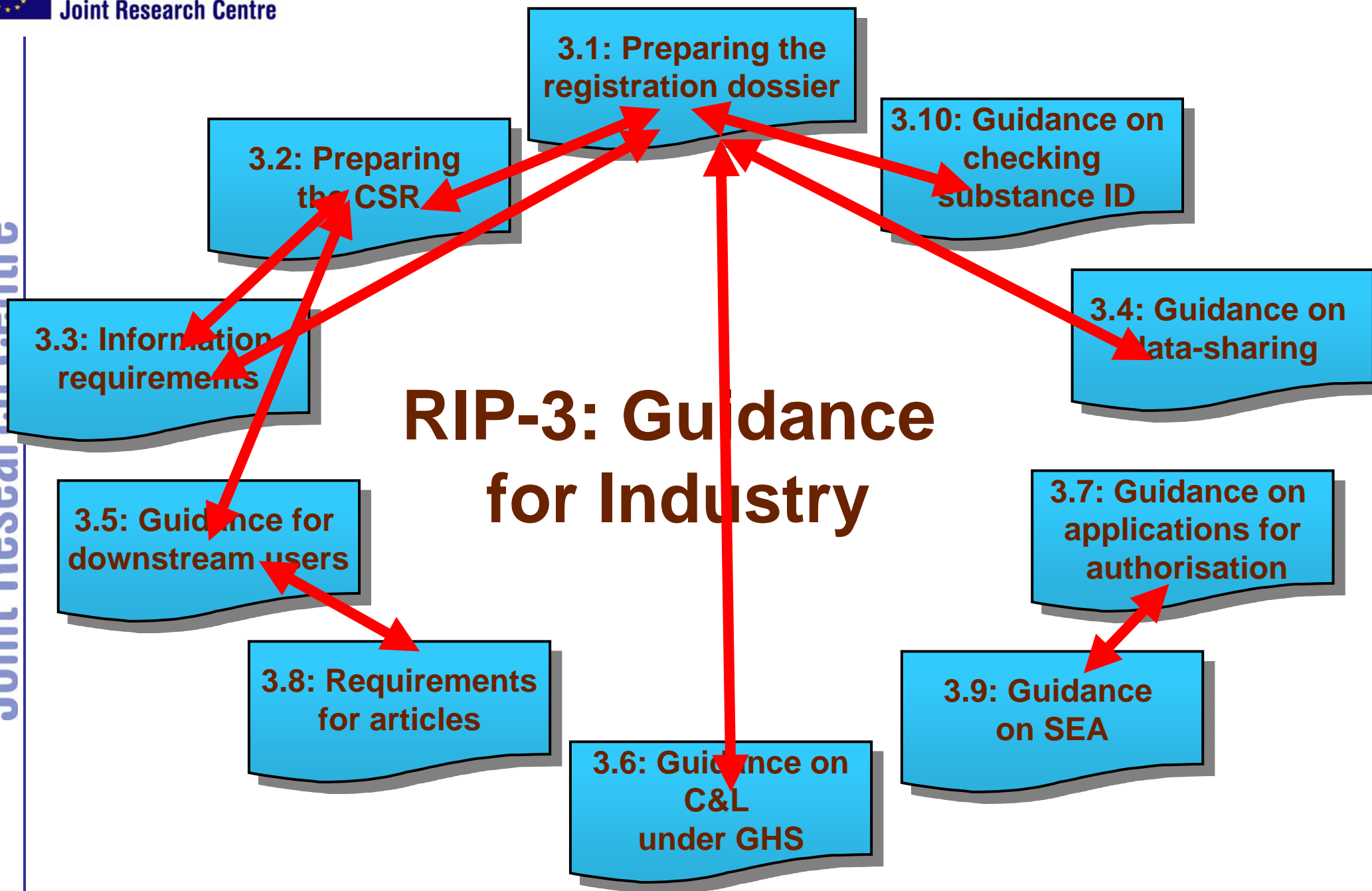
Start 2003

Preparations for REACH: Commission Interim Strategy

REACH Implementation Projects (RIPs):

- RIP 1: Process descriptions
- RIP 2: Development of IT systems (IUCLID database and REACH-IT)
- RIP 3: Guidance Documents for industry
- RIP 4: Guidance Documents for authorities
- RIP 5/6: Setting up the (pre-)Agency

AIM: In close collaboration with all stakeholders develop guidance to help fulfil the obligations under REACH





4.1: Guidance on dossier evaluation

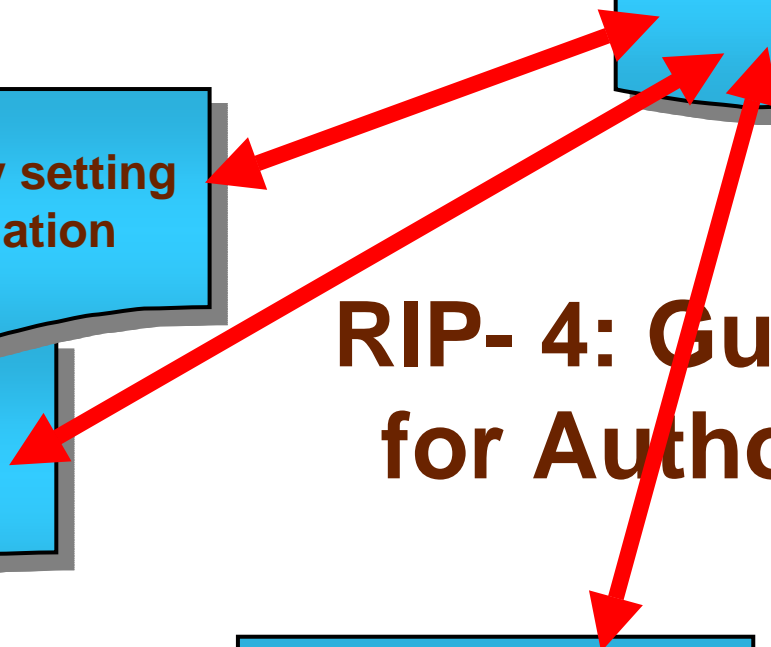
4.2: Guidance on substance evaluation

4.5: Priority setting for evaluation

4.3: Inclusion of substances in Annex XIV

RIP- 4: Guidance for Authorities

4.4: Preparation of Annex XV dossiers





General management of the RIP 3/4 projects

- Overall process coordinated by the European Chemicals Bureau (ECB) of the JRC
- Most projects are tendered out via open call for tenders
- Stakeholder Expert Groups (SEG) follow closely the development process
- Industry, Member States, NGOs and the Commission take part in the SEG meetings and provide input and written comments
- Final reports are being discussed and commented by the Technical Committees following the current chemicals legislation



Stakeholder Expert Group participation

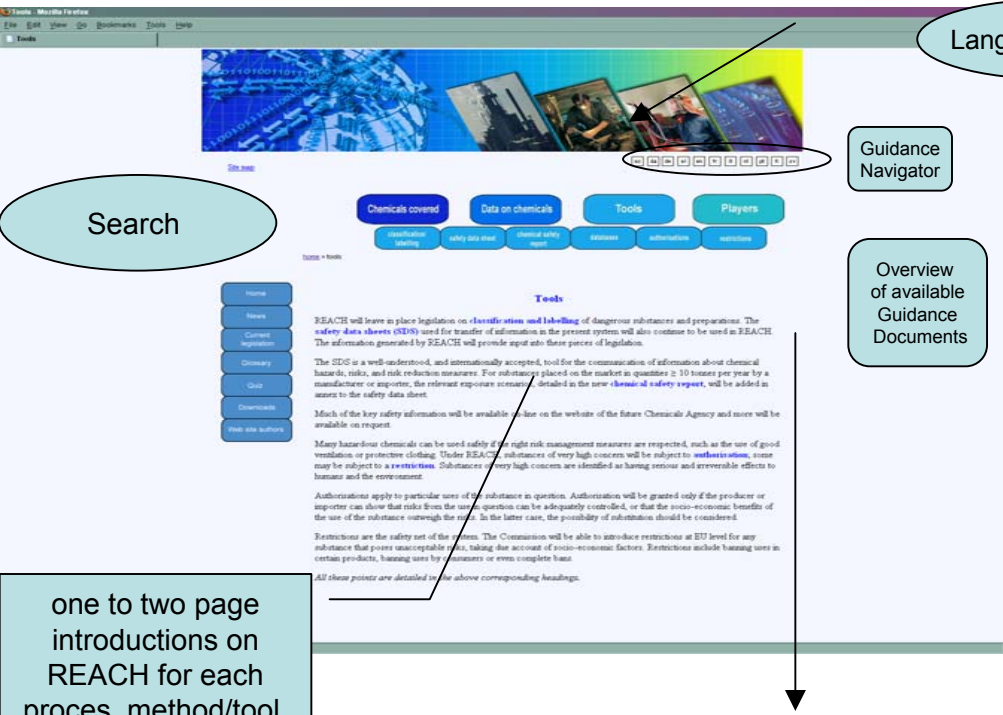
More than 200 experts follow the process in the SEGs:

- 19 MS or accession countries;
- Many industry organisations:
 - CEFIC, CEPE, CEPI, CONCAWE, DUCC, ESIA, Euratex, Reach Alliance, EuPC, BLIC, EDANA, Eurocommerce, AISE, ASD, FECC, UNICE, ESBA, CIA, EPIA, VCH, 3M
- Many NGO's:
 - ETUC, FoE, WWF, ECEAE, BUAV, EEB, Greenpeace
- Others:
 - OECD, US-EPA, Health Canada, Japan Business Council in Europe

Framework for the overall guidance package

REACH Overall Guidance Start Page(s)
 Example: <http://www.prc.cnrs-gif.fr/reach/anglais/home.htm>

Navigator



Objective is to help industry to figure out their obligations and to guide them to the relevant parts of the guidance, tools and formats in order to fulfill these obligations:

- Are you dealing with:
 - Radioactive substances?
 - Non-isolated intermediates?
 - Substances subject to customary inspection?
 - Waste?

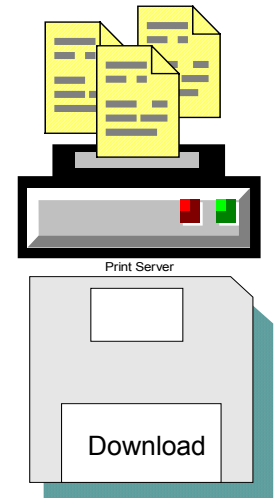
YES NO

Guidance on question

one to two page introductions on REACH for each proces, method/tool, main actors (roles and obligations)

Detailed guidance documents:

- 5-10 page summaries
- links to other guidances
- links to formats



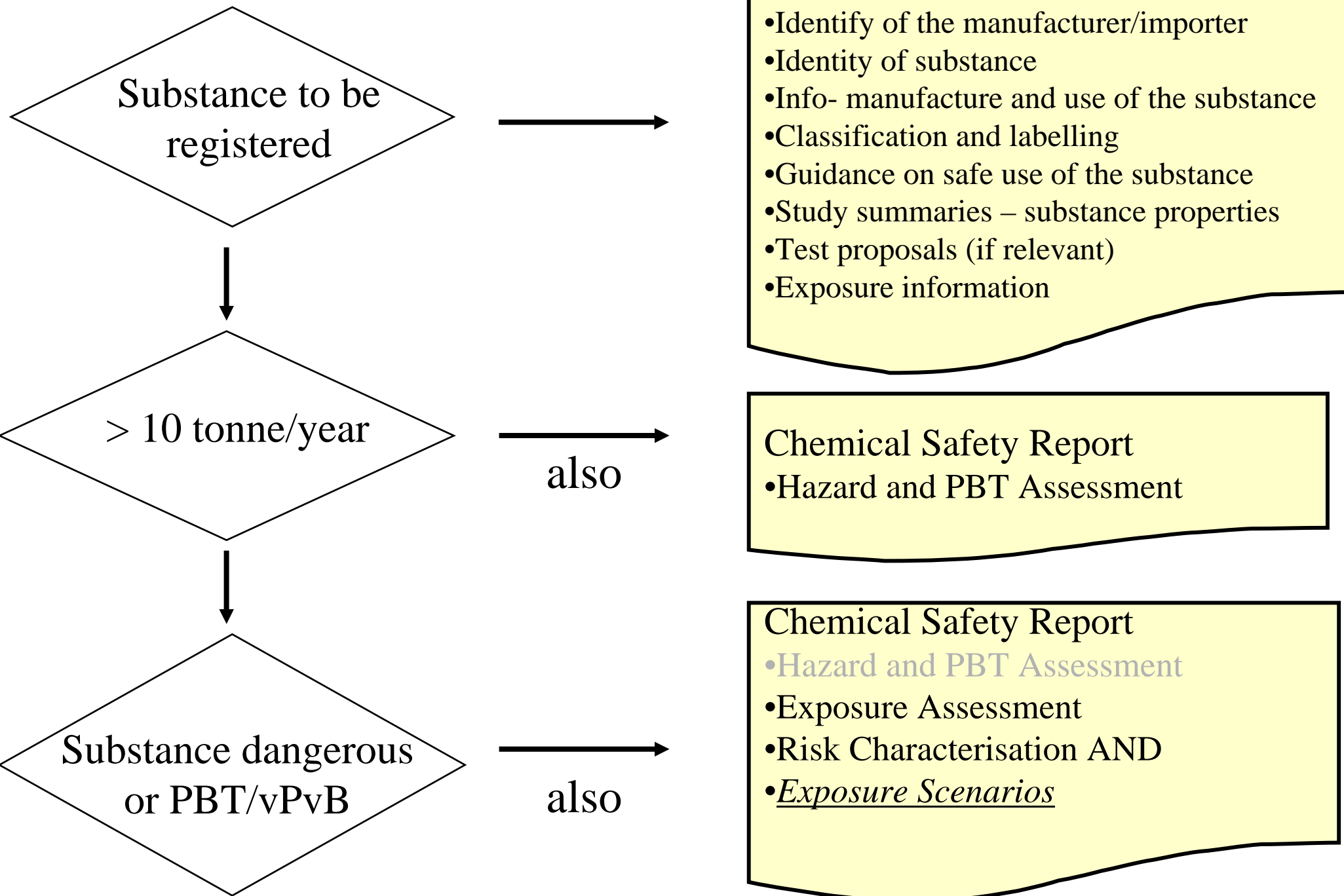


Does science reach REACH?

New:

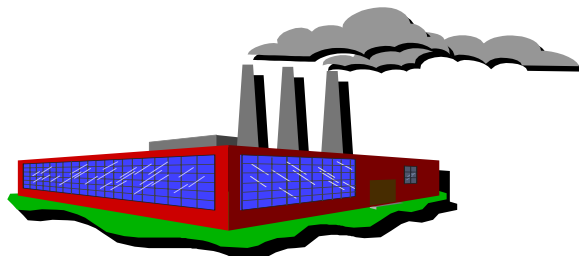
- Industry and MS change roles
 - Communication up and down the supply chain
 - Socio-economic analysis
 - Articles
 - Forced data sharing for vertebrate testing
 - Risk management measures
-
- Is there a change in the risk assessment paradigm? → RIP 3.2 and RIP 3.3

Registration dossier - content



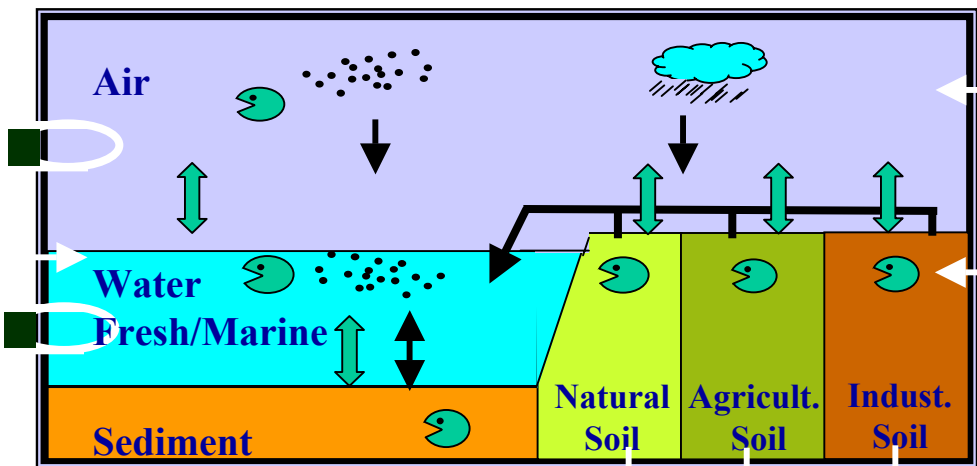


Environmental Exposure Assessment



Emission

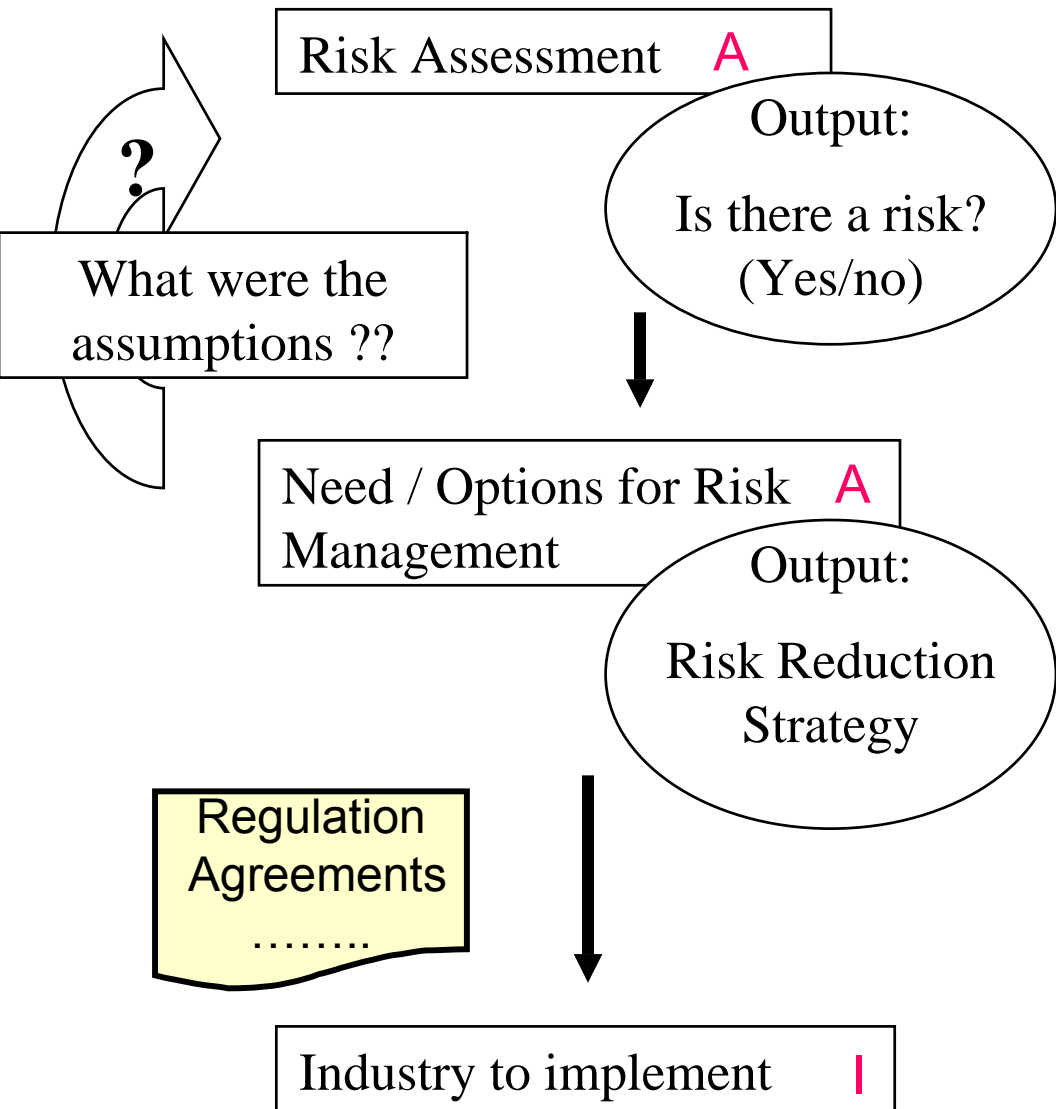
Models



**Partitioning
Degradation
Transformation**

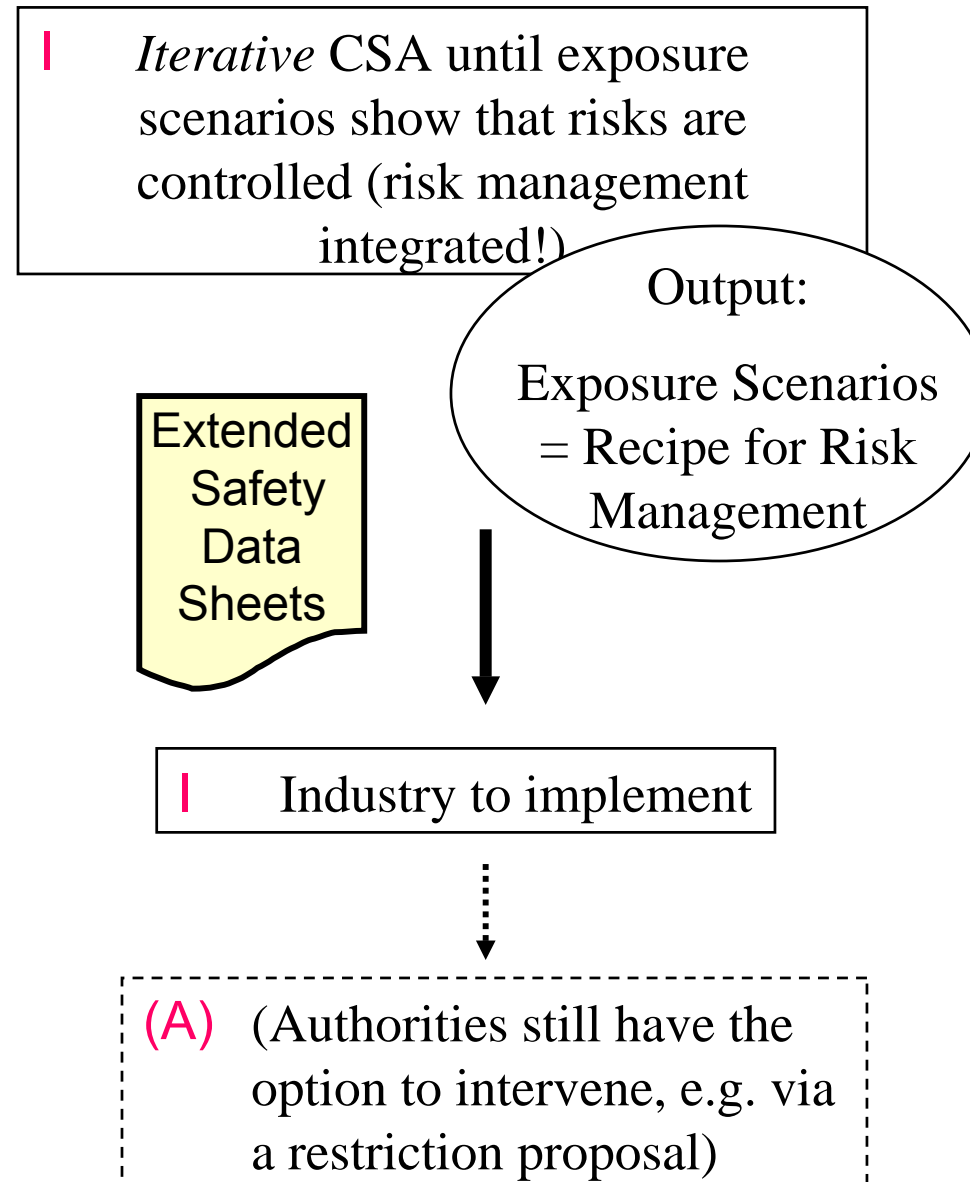
**Environmental
Concentrations**

Today



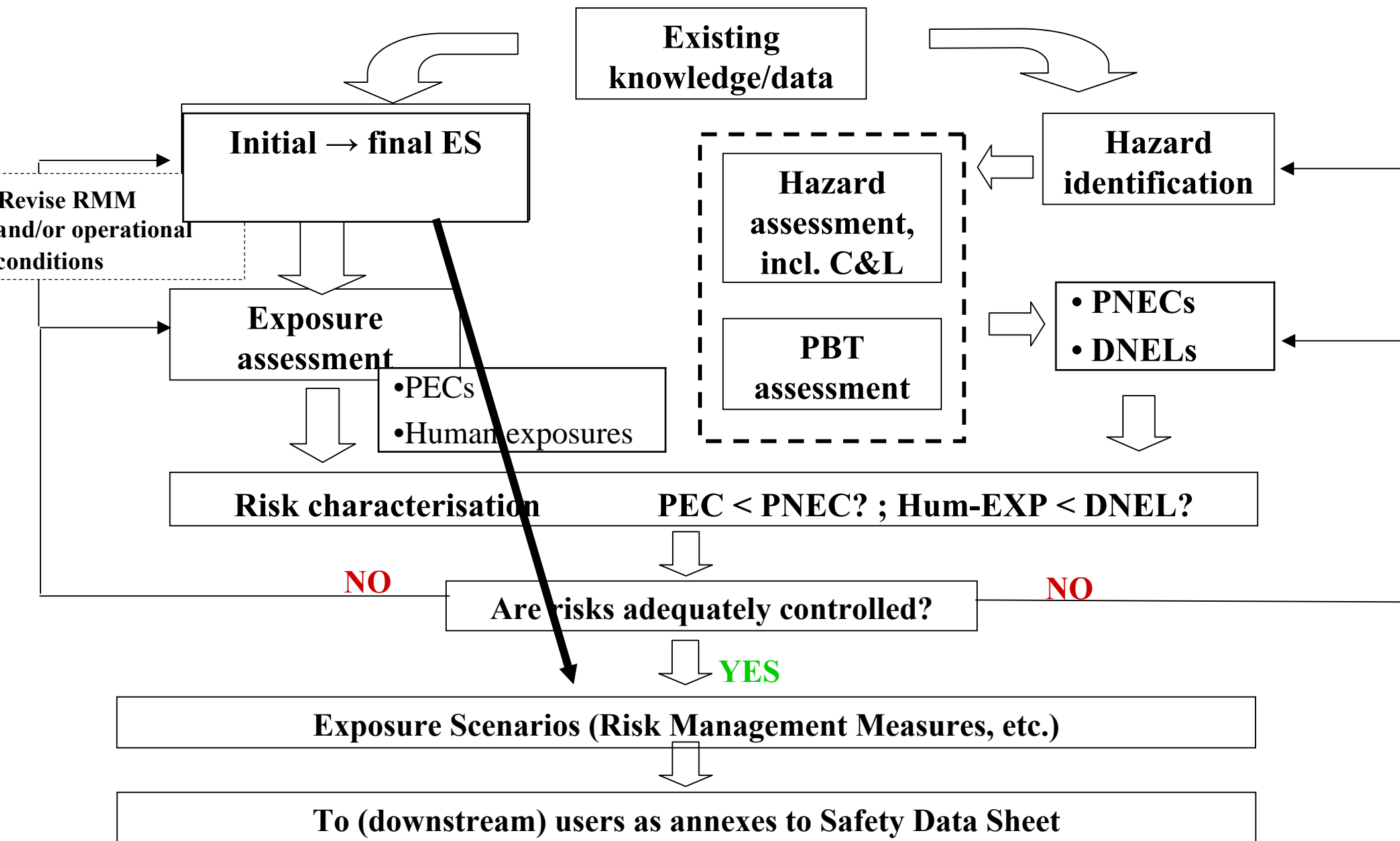
A = Authorities

Future



I = Industry

Chemical Safety Assessment





What is an Exposure Scenario (ES) ?

- Conditions for use:
 - Process description (incl. quantity used)
 - Operational conditions (incl. frequency and duration of specified operations)
 - Risk Management Measures
 - process control (e.g. closed system and local exhaust)
 - emission control
 - personal protective equipment
 - good hygiene / working practice

- Other relevant information

'Final ES' as annexed to the SDS: Fictive Example

Process:	Spray painting (Automated closed process)
Substance:	"Substance X". Concentration in paint: Max. 10% (w/w) Max. 10 tonne paint/year
Duration and frequency:	8 hours/day, 200 days/year, 10 manual interventions/hour, cleaning of equipment 1 / day
Equipment:	State-of-the art (type xx or yy) – exhaust ventilation required
Air emissions:	Air filter with an efficiency of at least 90% towards substance X
Waste water:	Equipment is cleaned with hot water and detergent. Cleaning water discharged to a standard WWTP
Hazardous waste:	Used air filters, paint remnants and spills
Volume waste:	Empty containers and air-dry clothing
Workers protection:	Good occupational hygiene assumed, operators must wear gloves and change working clothes frequently



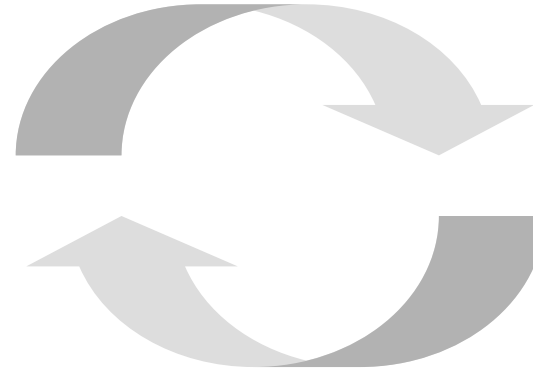
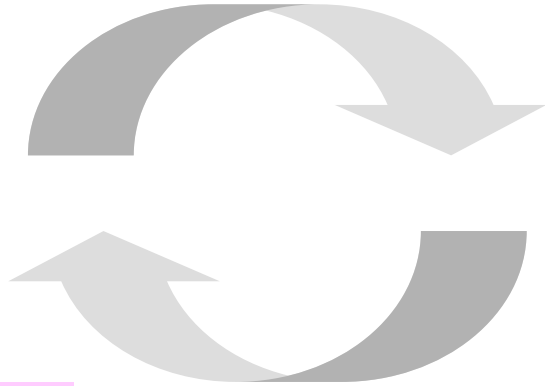
Dual role of exposure scenarios

1. *Basis for exposure estimation (in preparing the CSA)*
Exposure Scenarios enable a quantitative release and exposure estimation by describing the *determinants* of exposure; i.e. the parameters that affect the exposure level
2. *Communication (CSA output, annex to SDSs)*
ES is the communication tool to the user on how to use the chemical in a way that risks are controlled, including specifying the necessary Risk Management Measures

Overall approach

- Identification of uses
- Conditions of use
- ES building
- M/I CSA

- Identification of uses
- Conditions of use
- ES building
- DU CSA



substance producer

substance producer

sector groups, associations

formulator

formulator

associations

final DU

final DU

associations





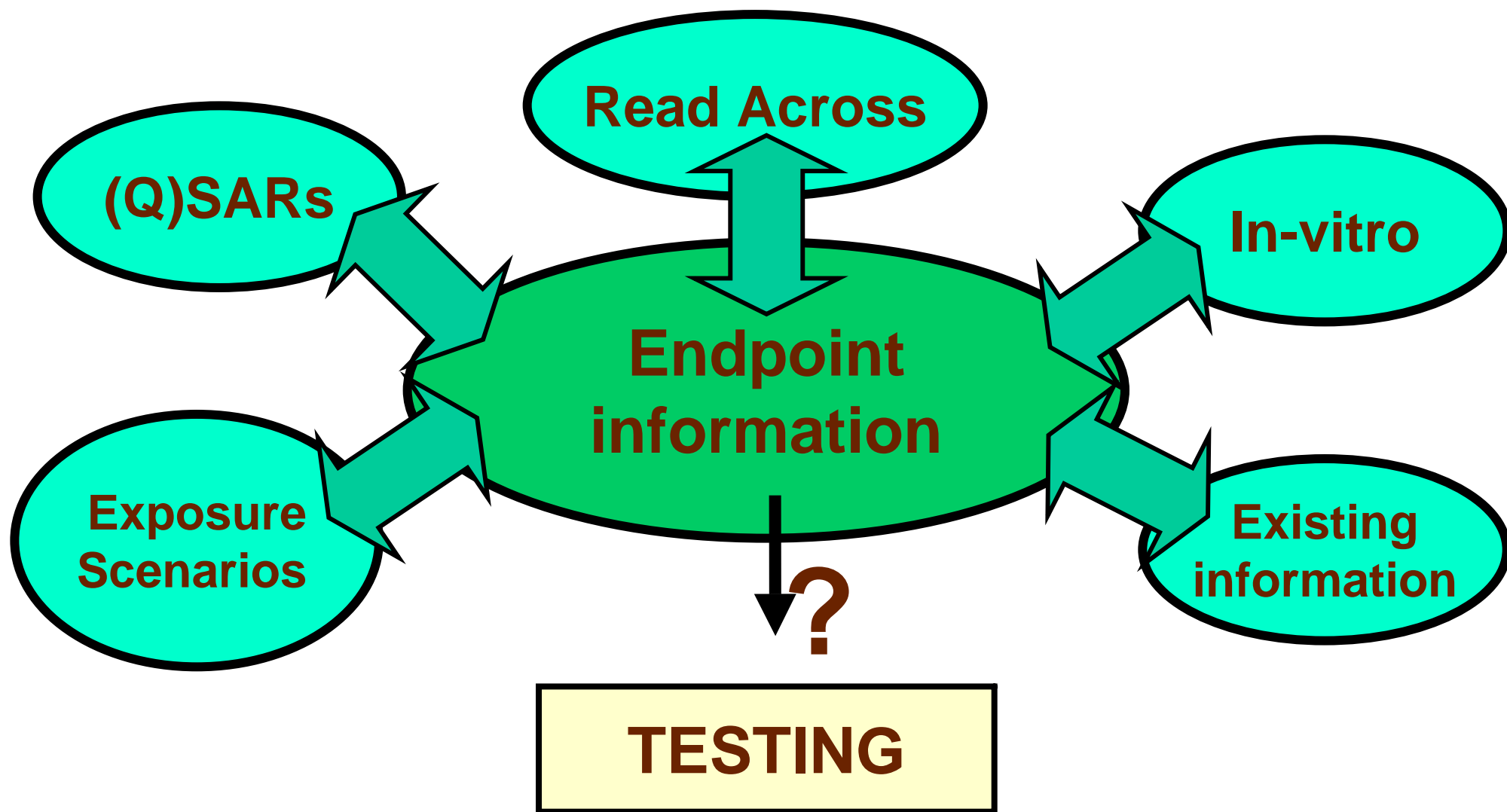
Conclusions exposure scenarios / estimation

- Establish processes for communication up and down the supply chain is crucial: formats and tools
- Information on RMM: availability and substance specific
- How to prevent a 'model jungle'?

Is there a role for environmental science?



INTELLIGENT TESTING STRATEGIES





General process registration (1)

- 1 **Gather + share** existing information on
 - Properties: test results, QSAR estimates, human data,...
 - Uses: current and foreseen
 - Exposure
 - Risk Management Measures: implemented or proposed

- 2 **Identify precise information needs** on the basis of
 - Tonnage
 - Use
 - Exposure
 - Risk Management Measures



General process registration (2)

3 Identify information gaps and consider how missing information can be generated

Consider (Annex XI):

- Testing not scientifically necessary:
 - Quality GLP and Annex X quality data exists
 - Adequate non-GLP or non-Annex X data exists
 - human data
 - weight of evidence
 - QSAR
 - grouping or read across
 - *in vitro* data
- Testing is technically not possible
- Substance-tailored exposure-driven testing (consider exposure scenarios)

4 Generate new information or propose testing strategy according to Annexes VII to X



Guidance on ITS for specific endpoints

- Guidance on identifying information sources and how to ensure the reliability of the used information)
- A testing strategy for 11 endpoints to help registrants provide adequate and relevant information for registration sufficient for:
 - Carry out Chemical Safety Assessment (CSA)
 - Classification and labelling (C&L)
 - PBT assessment
- Guidance on when and how to use alternative information (instead of (animal) testing) including guidance on what is “adequate and reliable documentation”



Guidance on cross-cutting issues

1. explanation of key concepts: SARs, read-across and categories (including sub-categories)
2. how to perform qualitative and quantitative read-across
3. how to build a category (including special cases)
4. how to justify and report the “adequacy” of a read-across or category proposal ⇒ appropriate reporting formats



Conclusions effects assessment

- Fulfilling information requirements is no box ticking under REACH
- How to use all available information is the question to be answered
- Need for validated alternative methods (*in vitro* or (Q)SAR)) but we shall not forget animal testing



After Entry into Force?

1. Intelligent testing strategies: further development
2. QSAR and *in vitro* toolbox
3. Assessment of polymers and preparations
4. Data mining: search for SVHC (registered substances and transformation products); priority setting
5. Science as usual: further development of exposure, effect and risk assessment methods for all substances