

**Area of tension in
chemicals management
between REACH
and the
Water Framework Directive**

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Chemicals management

➤ In REACH

- ❑ Based on effect and exposure assessment
- ❑ “Old” TGD, further elaborated in future RIP 3.2 guidance, provides the scientific methods
- ❑ Three approaches:
 - Registrant’s chemical safety assessment results in “minimal” risk accompanied with (recommended) risk reduction strategy
 - EU-wide severely restrictions based on Annex V format substance evaluations
 - Required authorisation for use of authorised (selected identified SVHC) substances

➤ In WFD

- ❑ Based on effect assessment for aquatic environment
- ❑ “Old” TGD provides the scientific method, but focused on aquatic environment
- ❑ Approach
 - Combination of emission limit values and environment quality standards
 - Target priority substances

REACH Chemicals Management

Main characteristics:

- EU harmonised decisions (authorisation or restrictions)
- Decisions directly in force (no national implementation)
- Assessment principles according to TGD current legislation
 - ❑ Hazards (effect) assessment → Predicted no-effect concentration
 - ❑ Exposure / emission assessment → Predicted environmental conc.
 - ❑ Risk characterisation → PEC / PNEC ratio
- Chemicals management principles according to TGD
 - ❑ Local / regional scale, where relevant (= Member State versus EU)
 - ❑ PEC / PNEC ratio < 1 (no extra safety factor)

WFD Chemicals Management

Main characteristics:

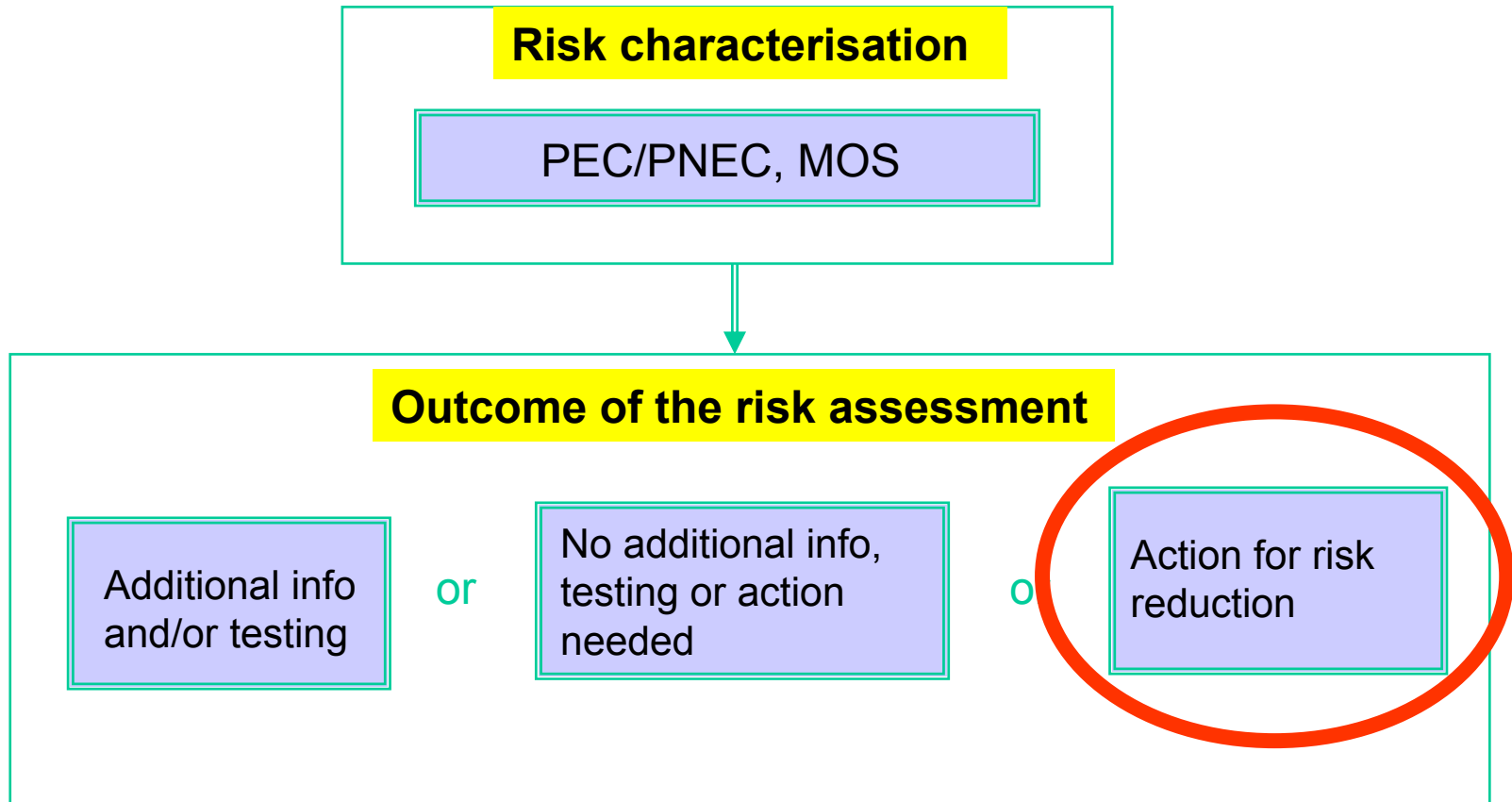
- EU target: “Good status of water”
 - ❑ To achieve by 2015
 - ❑ Combined approach of emission limit values and environmental quality standards for 33 priority substances → Proposal for EU EQSs
- National implementation in permits on emission in river basins
 - ❑ Integrated approach, EQSs and source based approach
 - ❑ Future: emission limits to meet EQSs for priority substances
 - ❑ Standards for water, sediment or biota
 - ❑ Progressive emission limits for other dangerous substances
- Assessment principles partly according to TGD
 - ❑ Hazards (effect) assessment → Safe levels based on predator and human consumption of aquatic products
- Chemicals management principles according to WFD
 - ❑ Local scale emission limits

Reference water environment

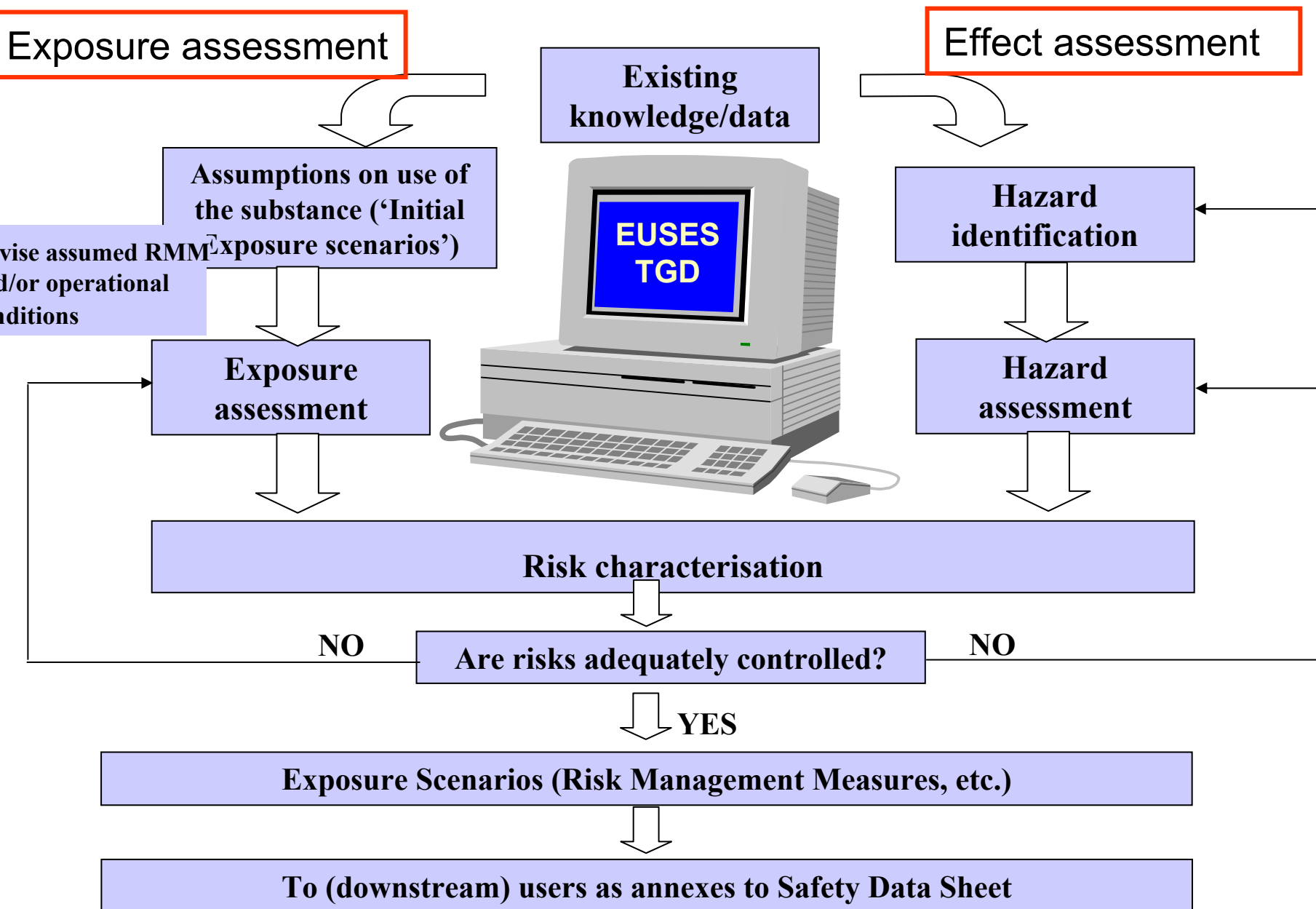
- **REACH – Regional (EU)**
- **WFD – Local situation**

.... but which reference ?

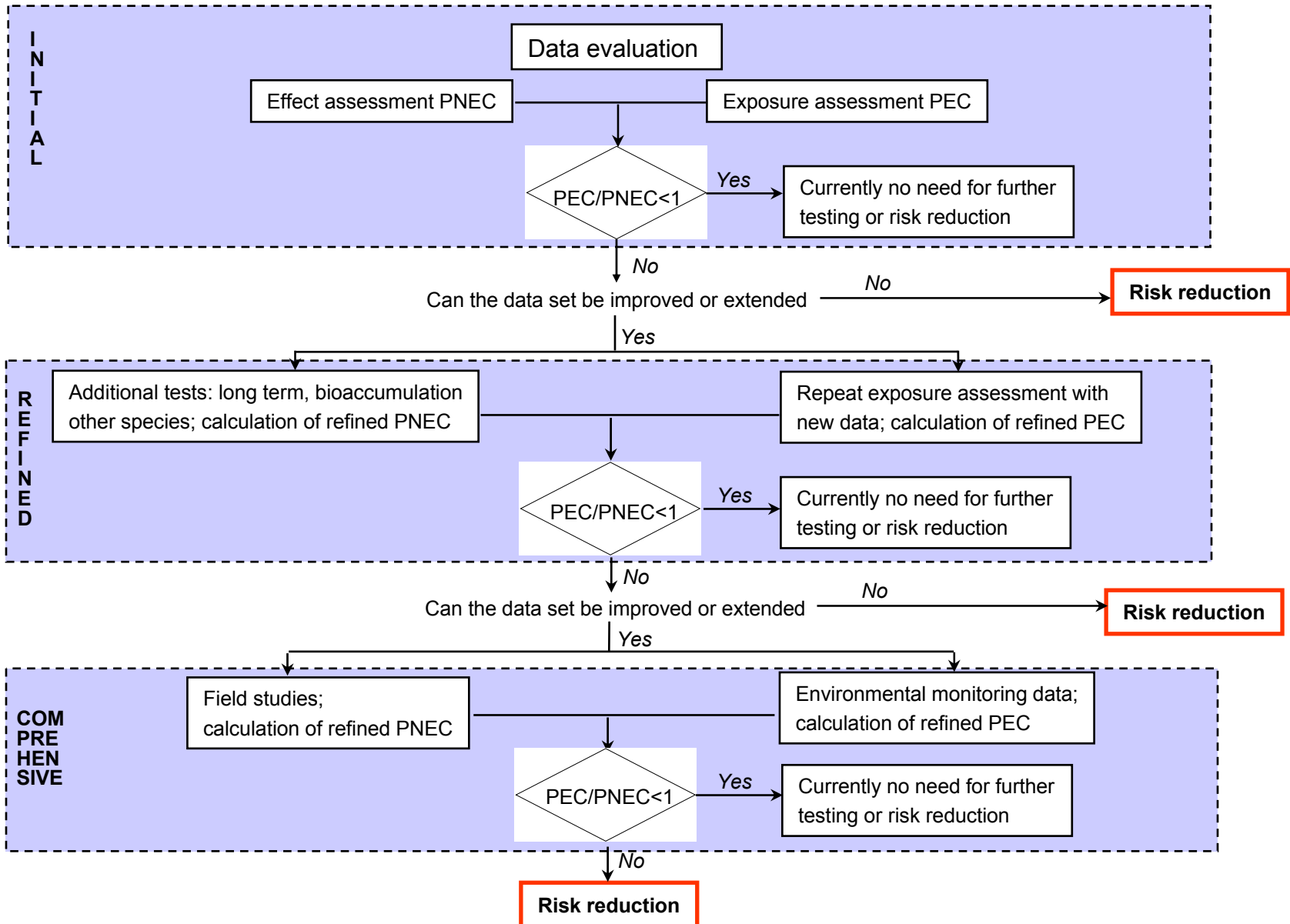
General principle of risk assessment



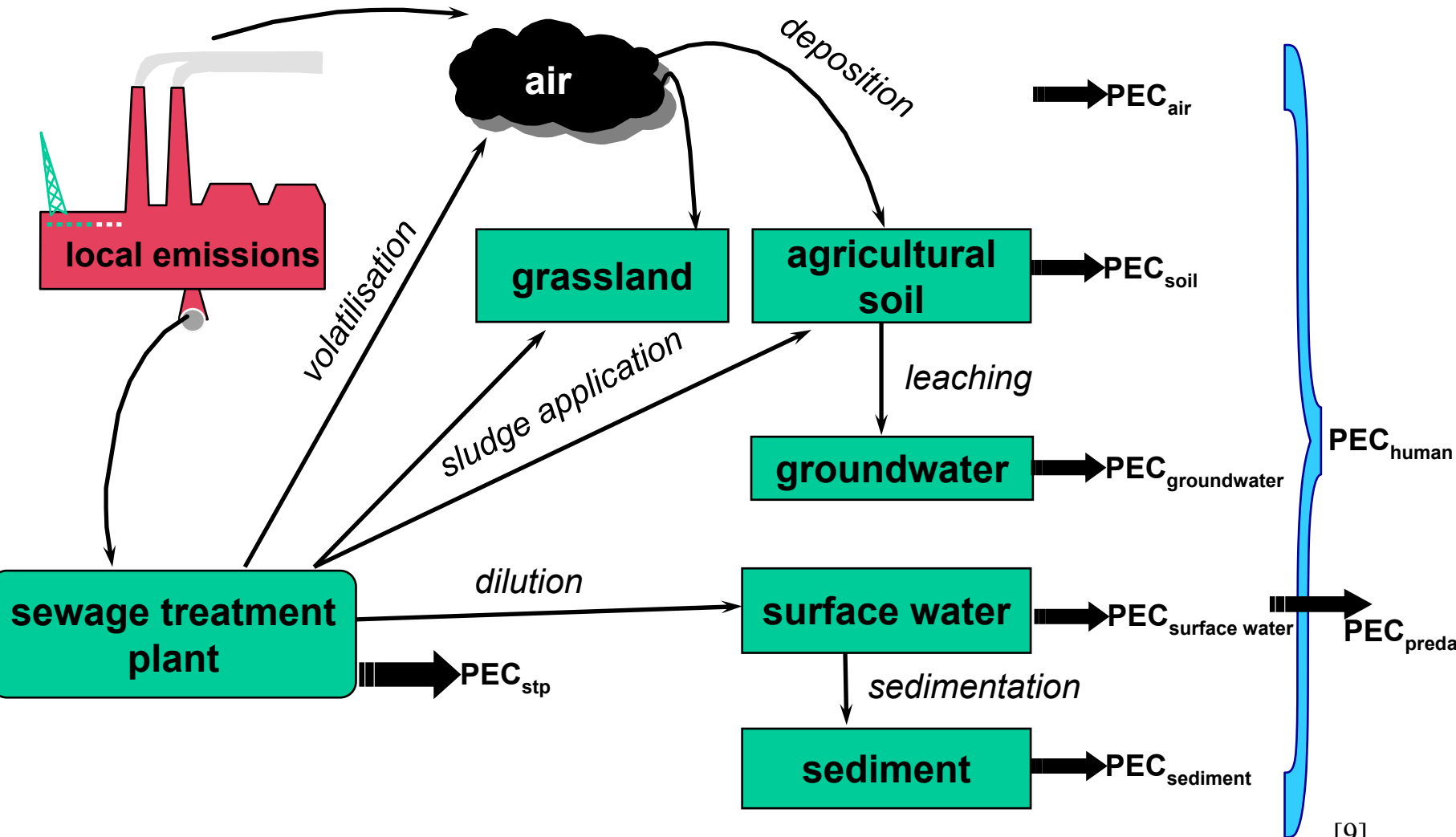
REACH - Chemical Safety Assessment



Risk evaluation - iterative process



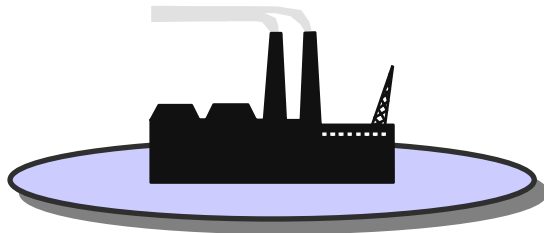
Exposure assessment: Local emission and distribution



Exposure assessment: Spatial scales

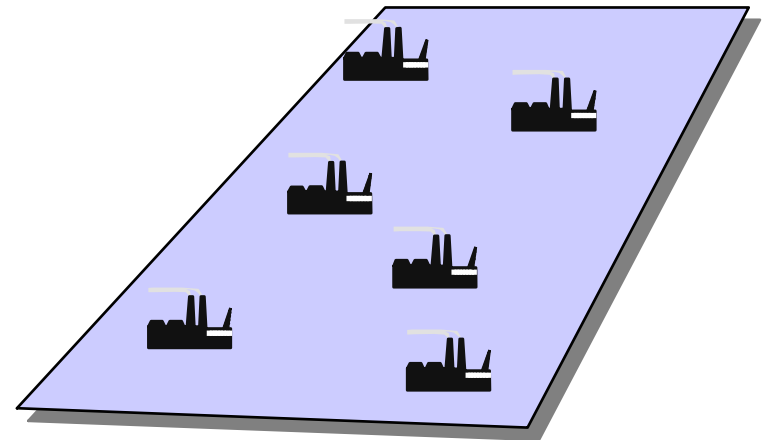
➤ Local scale

- Area around one point source
- Average EU environmental characteristics
- “Reasonable worst case” scenario

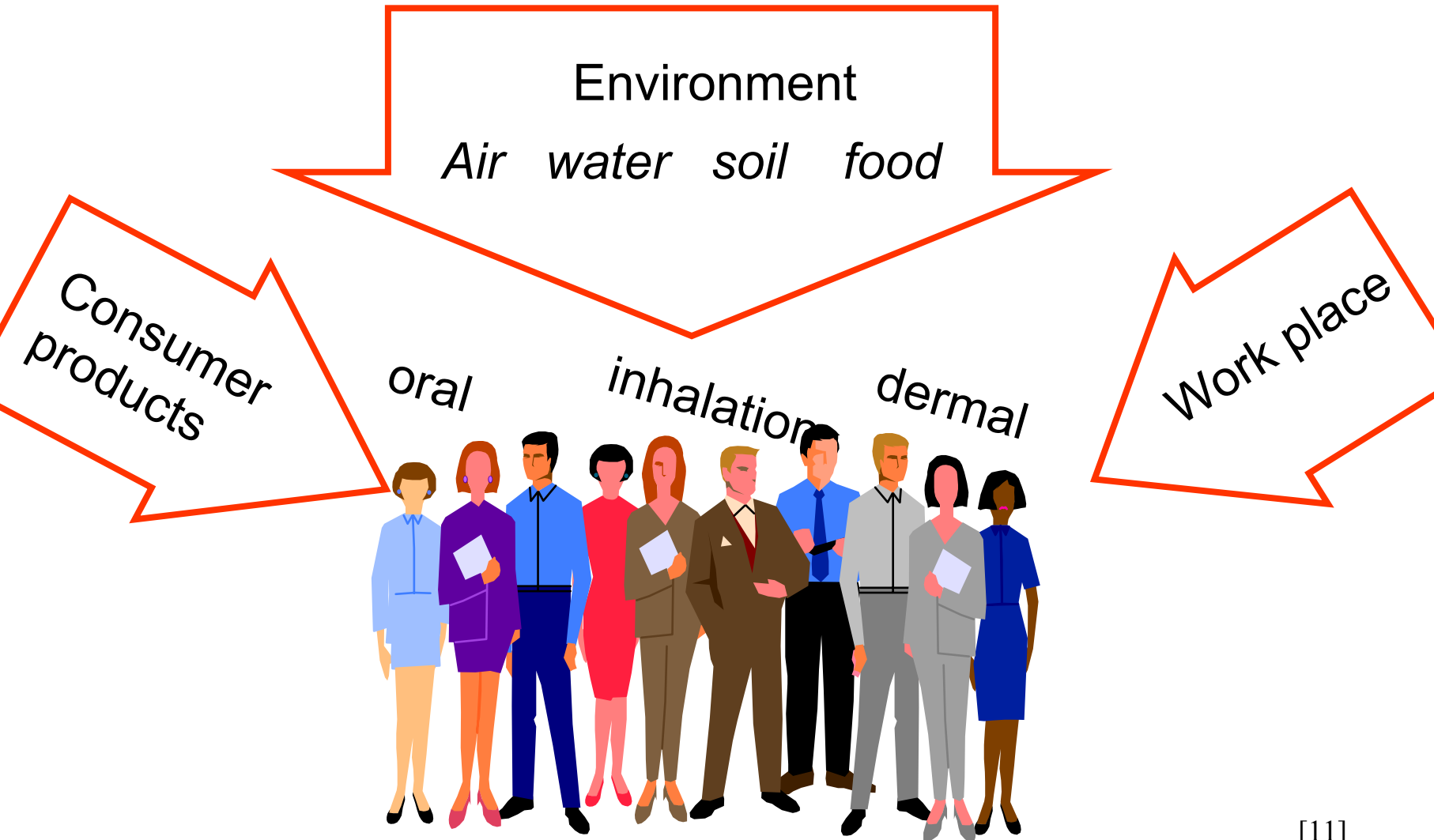


➤ Regional scale

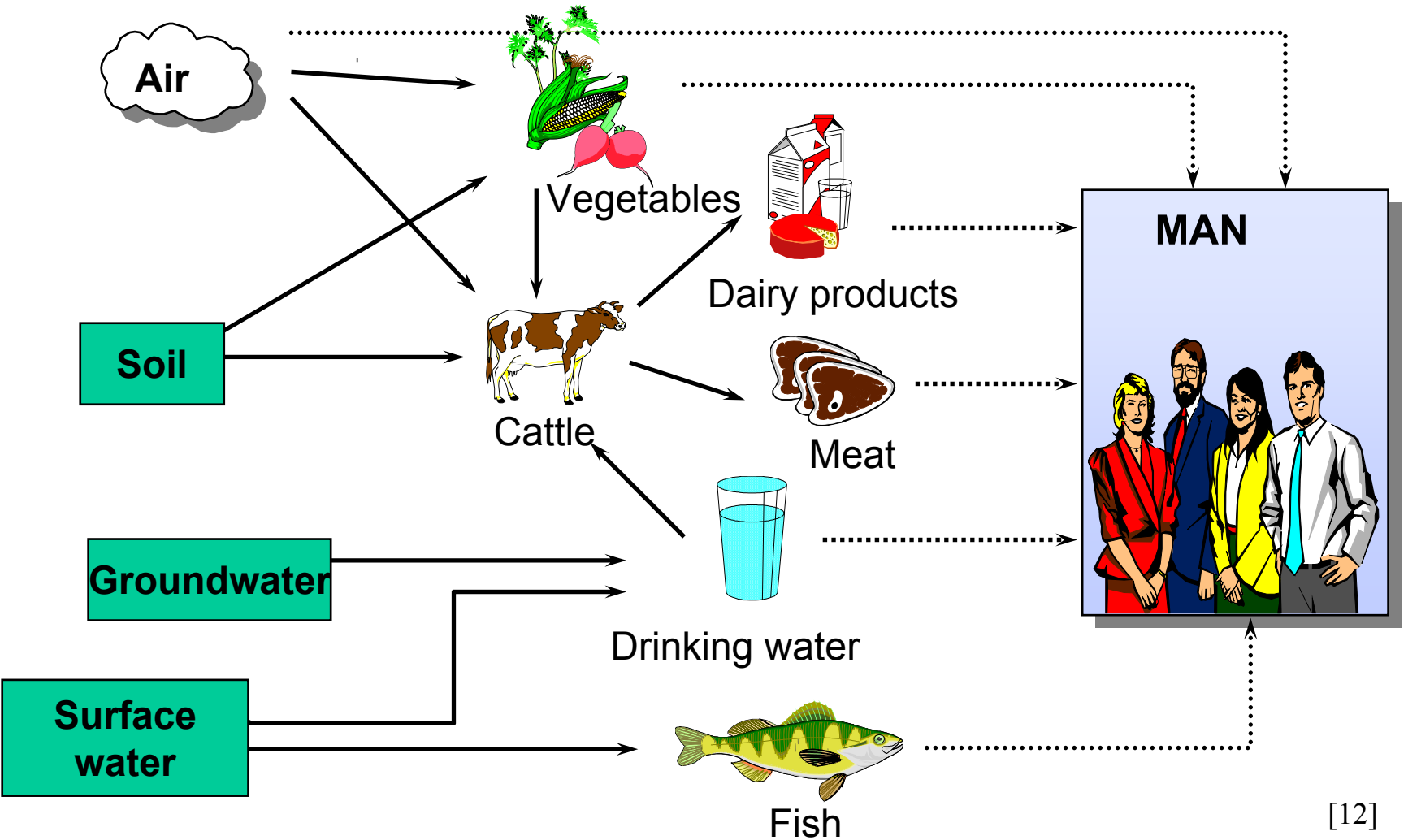
- Area of 200 x 200 km
- 20 million inhabitants
- 10% of EU production
- Average EU environmental characteristics



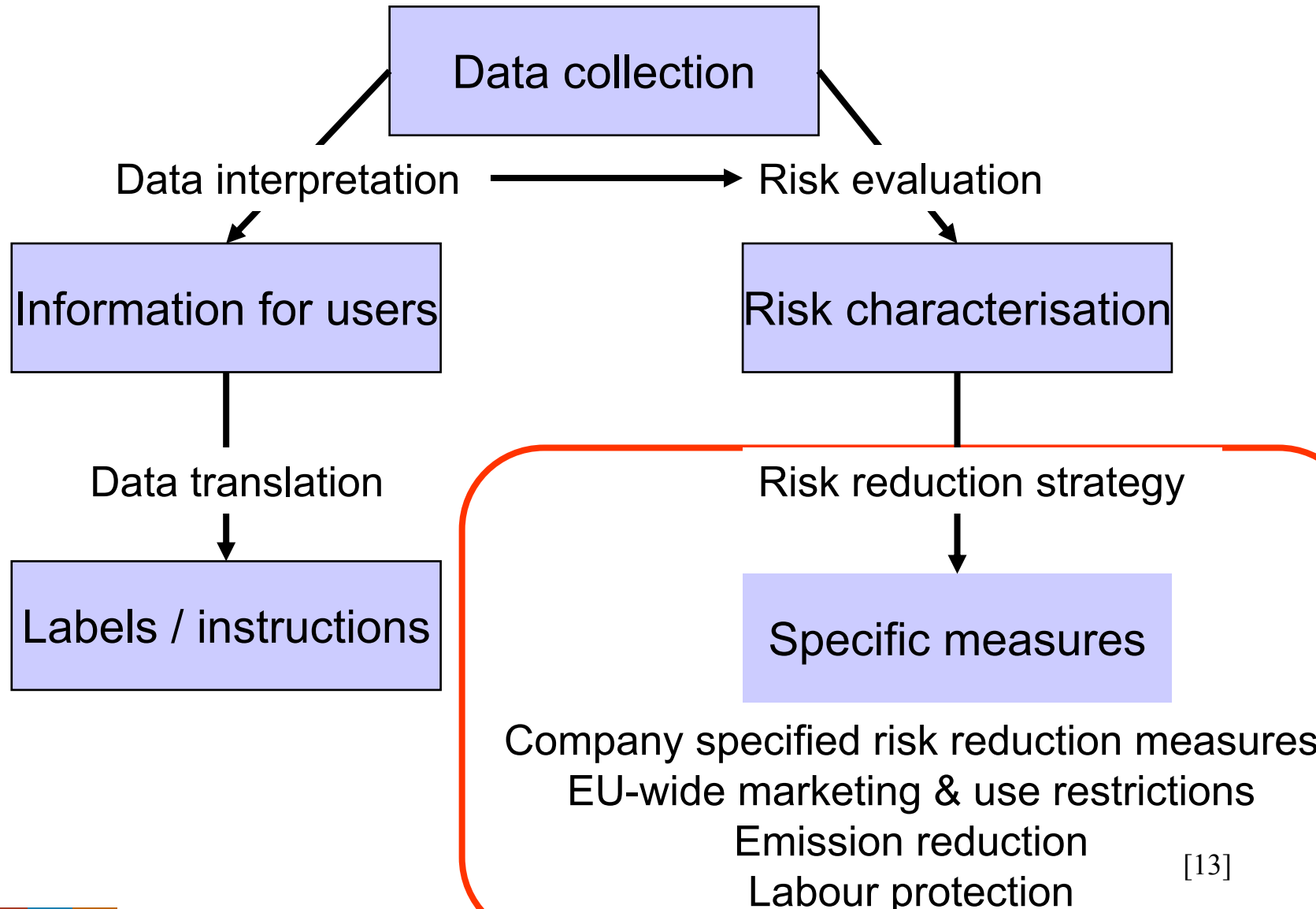
Direct exposure to man



Indirect exposure to man



Principles of REACH Chemical Safety Assessment



REACH & WFD:

Differences in target environment

REACH – TGD

- **Fresh water + sediment**
 - ❑ Local (point sources)
 - ❑ Regional (multiple + diffuse sources)
- **Marine environment + sediment**
 - ❑ Local (point sources)
 - ❑ Regional (multiple + diffuse sources)
- **Air**
- **Terrestrial environment**
- **Sewage treatment plants**

WFD

- **Fresh water + sediment**
- **Marine environment + sediment**
 - ❑ Coastal area
 - ❑ Transitional area
 - ❑ Territorial area

Risk assessment approach

Used for identifying risk for man and the environment via all possible routes and during whole life cycle of the substance

For determining EQS in aquatic and marine environment

Used for protecting human and the environment from contamination of the water phase

Differences in methodology for exposure assessment (non limitative selection of items)

REACH – TGD

- **Human risk**
 - ❑ Overall exposure from all sources
- **Groundwater contamination**
 - ❑ Human exp. through drinking water + groundwater protection
- **Drinking water**
 - ❑ Integrated in total human exposure
- **Aquatic food**
 - ❑ Relevance route case-by case
 - ❑ Integrated in total human exposure
- **Bioavailability**
 - ❑ Dissolved compound
- **PBT substances**
 - ❑ Special attention
- **Metal bioavailability in sediments**
 - ❑ AVS/SEM approach in certain cases
- **Partitioning between compartments**
 - ❑ Partitioning processes taken into account
 - ❑ $PNEC_{\text{sediment}}$ from $PNEC_{\text{water}}$ if no data

WFD

- **Human risk**
 - ❑ Exposure through drinking water + aquatic food
- **Groundwater contamination**
 - ❑ Aim = good status
- **Drinking water**
 - ❑ Drinking water standards
 - ❑ Human uptake <10% of threshold
- **Aquatic food**
 - ❑ Human uptake < 10% of threshold
 - ❑ Triggers for QS calculation
- **Bioavailability in water**
 - ❑ Total content of dissolved compound + conc. in suspended matter
- **PBT substances**
 - ❑ Priority – detection limit as borderline QS
- **Metal bioavailability in sediments**
 - ❑ AVS/SEM approach rejected
- **Partitioning between compartments**
 - ❑ QS_{sediment} from QS_{water} if no data

Summary

➤ **Effect assessment**

- ❑ Major overlap in methodology (both TGD)
- ❑ Differences partly at detailed level:
 - o WFD applies lowest safe water concentration as QS
 - o REACH uses lowest safe level for each compartment separately

➤ **Exposure assessment**

- o WFD focuses on exposure via water
- o REACH evaluates cumulative exposure via all relevant routes

Consequence:

- ❑ **REACH assessment method may differ in result**
- ❑ **Recommended control measures based on registrant's CSAs will conflict often with WFD approach because of differences in results from effect and exposure assessment**

My guess

- The EQS fact sheets still contains 'extreme worst-case' assumptions; specifically for bioaccumulating substances. The industry has pinpointed that fact at every possible occasion.**
- The secondary poisoning often 'overrules' the EQS for direct aquatic toxicity. This means that the toxicity test data carried out by industry are worthless.**
- WFD permit authorities will be confronted in future by industry claims based on submitted registrations under REACH.**