How is industry contributing to the development of science-based approaches to the environmental risk assessment of pollutants

Martin Holt

Environmental Sciences Manager

ECETOC

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Presentation Outline

- **Principles of risk assessment**
  - Management of chemicals should be based on a risk assessment that considers both hazard and exposure
- **Provide overview of ECETOC activities**
  - TFs and workshops to review current scientific knowledge, identify significant data gaps, define and prioritise research needs
  - CEFIC LRI research activities
- **Specific modelling and "investigative" monitoring projects**
  - GREAT-ER
  - MonitoringBase

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European Centre for the Ecotoxicology and Toxicology Of Chemicals

Founded in 1978 by 50 major companies to provide a scientific forum in which the extensive specialist expertise of the European Industry could be harnessed to research, review, assess and publish studies on the ecotoxicology and toxicology of chemicals.

- Industry Sectors represented:
  Basic chemicals, specialty chemicals, pharmaceuticals, agrochemicals, consumer products
- Directed by a Scientific Committee
- Non-Profit
- Non-Commercial
- Non-Lobbying

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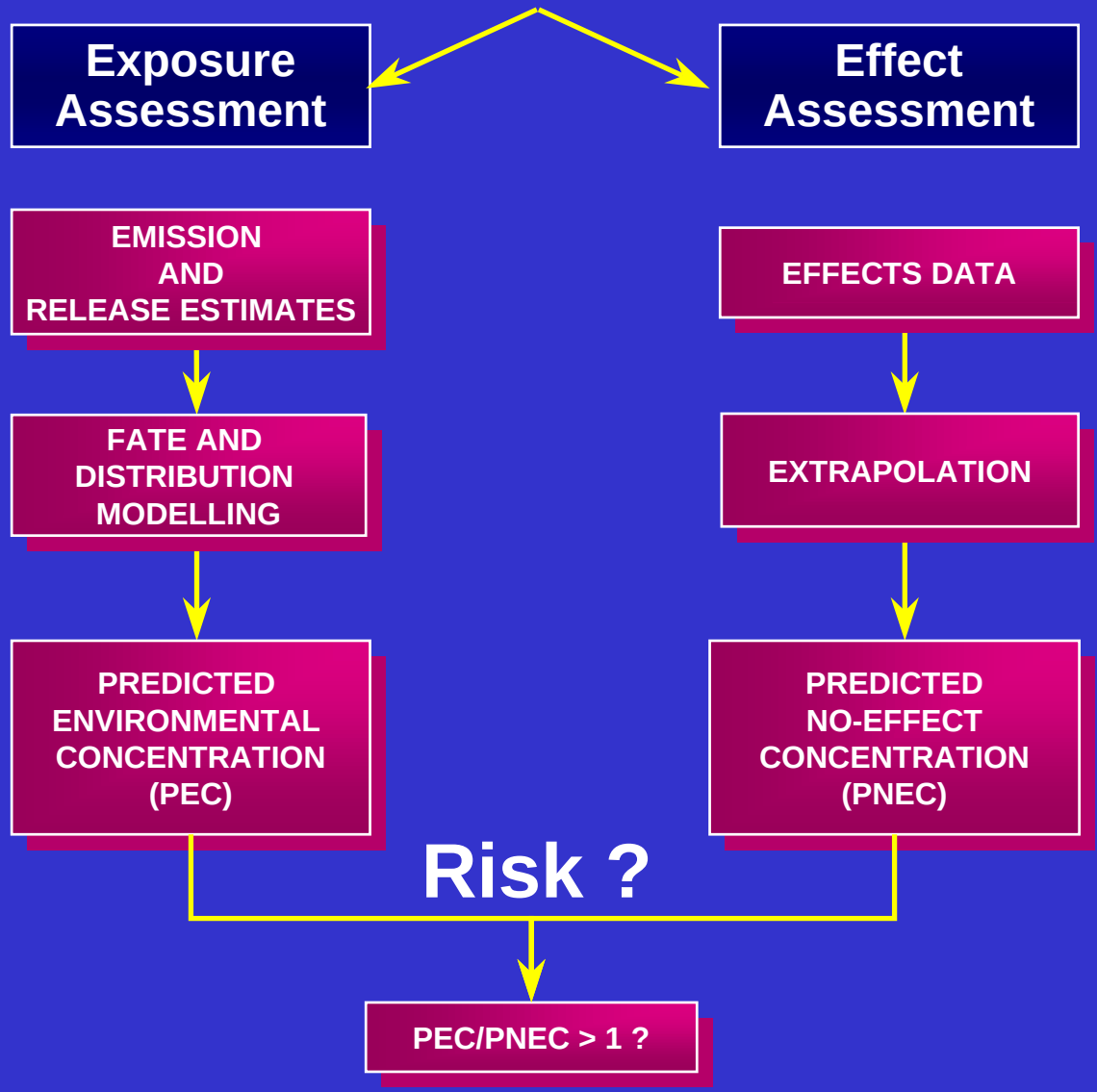
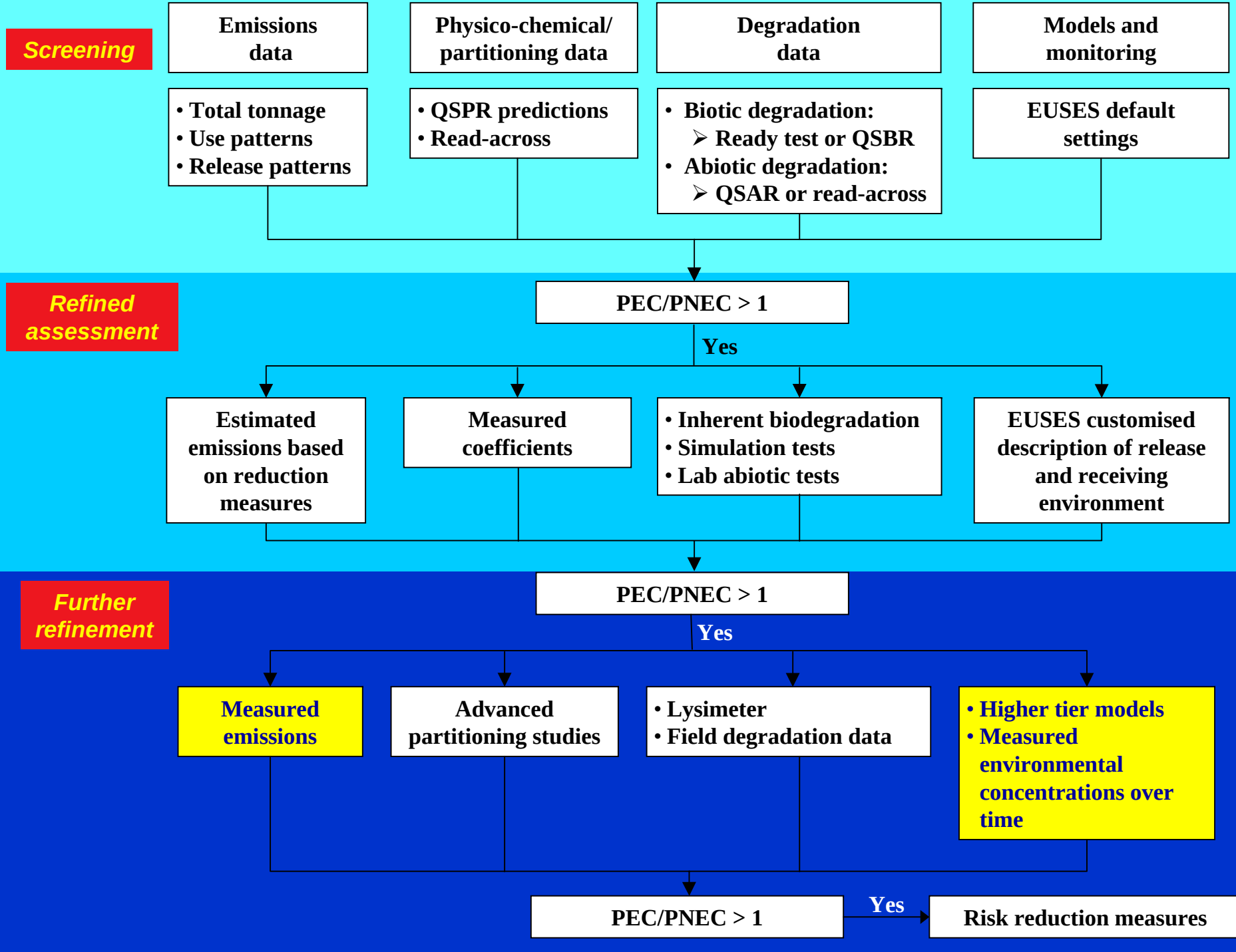
Principles of Environmental Risk Assessment (ERA)

- ERA is a science-based process combining hazard and exposure and forms an essential element in chemical legislation and management worldwide
- ERAs are usually tiered to ensure cost-effective generation of data proportional to the risks that exist.
- Sources of uncertainty exist in ERA:
  - due to true variability - inherent properties of the environment, for example rates of biodegradation
  - extrapolation, for example, from laboratory to field, short- to long-term effects within species, from test species to other species and from structure to process
- Uncertainties can be reduced through generation of more detailed information (higher tier) and through the use of more sophisticated models



Risk assessment is an iterative process, each refinement demands more information to improve the confidence in, and accuracy of, the risk estimate.

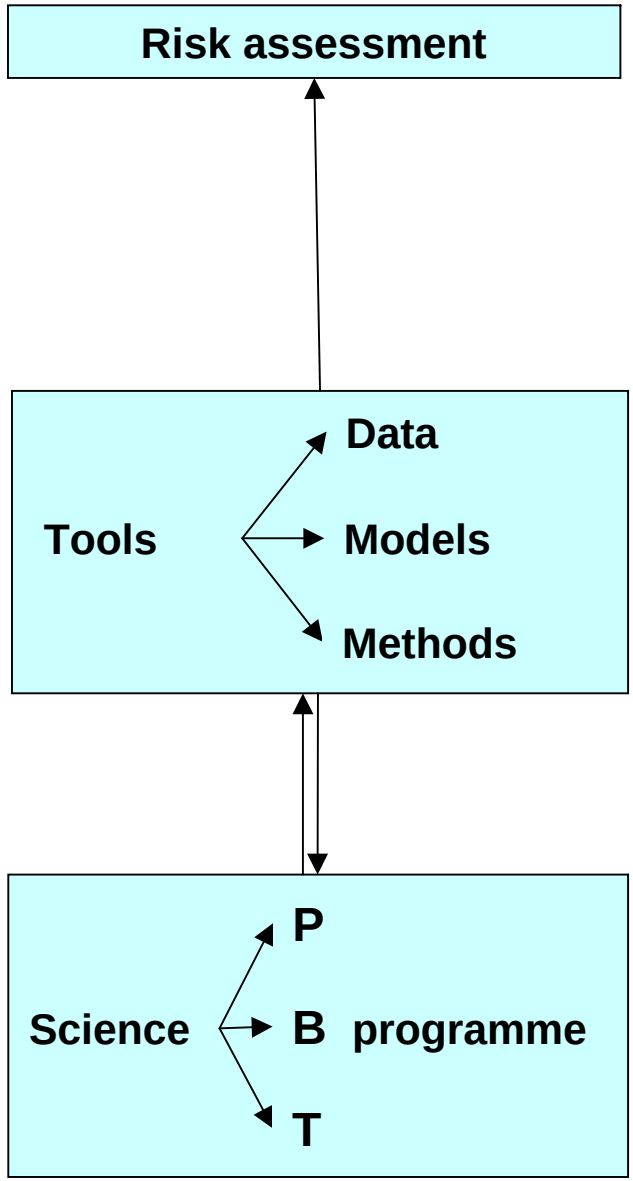

Screening
Emissions data
Physico-chemical/ partitioning data
Degradation data
Models and monitoring
• Total tonnage
• Use patterns
• Release patterns
• QSPR predictions
• Read-across
• Biotic degradation:
➢ Ready test or QSBR
• Abiotic degradation:
➢ QSAR or read-across
EUSES default settings
Refined assessment
PEC/PNEC > 1
Yes
Estimated emissions based on reduction measures
Measured coefficients
• Inherent biodegradation
• Simulation tests
• Lab abiotic tests
EUSES customised description of release and receiving environment
PEC/PNEC > 1
Further refinement
Yes
Measured emissions
Advanced partitioning studies
• Lysimeter
• Field degradation data
• Higher tier models
• Measured environmental concentrations over time
PEC/PNEC > 1
Yes
Risk reduction measures

Recent ECETOC Task Forces and Workshops

- **Recognition that more attention needs to be given to risk assessment:**
  - **Targeted risk assessment**
  - **Risk assessment of PBT-type chemicals**

- **Increased emphasis on TOOLS, DATA, and METHODS needed to determine exposure and effects**
  - **Persistence of chemicals in the environment**
  - **Biodegradation kinetics**
  - **Monitoring and modelling of industrial chemicals**
  - **Geography referenced environmental assessment tool for European rivers (GREAT-ER)**
  - **Using mode of action information in ecotoxicology testing of specifically acting chemicals**

- **Advice to CEFIC on the science content of the LRI**



LRI Environment Programme

Exposure

- **Development and validation of fate and distribution models to improve predictions of exposure, develop databases and tiered model system.**

PBT and long-term risk to ecosystems

- **Develop an understanding of the significance of the factors that affect bioavailability, and ecotoxicity in various compartments**
- **Development of methods to measure degradation and, improvements in the extrapolation from laboratory studies to the prediction of environmental half-lives**
- **Tools for modelling bioaccumulation, understanding of biotransformation in food chains**
- **Improve understanding of 'mode of action' and critical body burden**
- **Details on www.cefic-lri.org**

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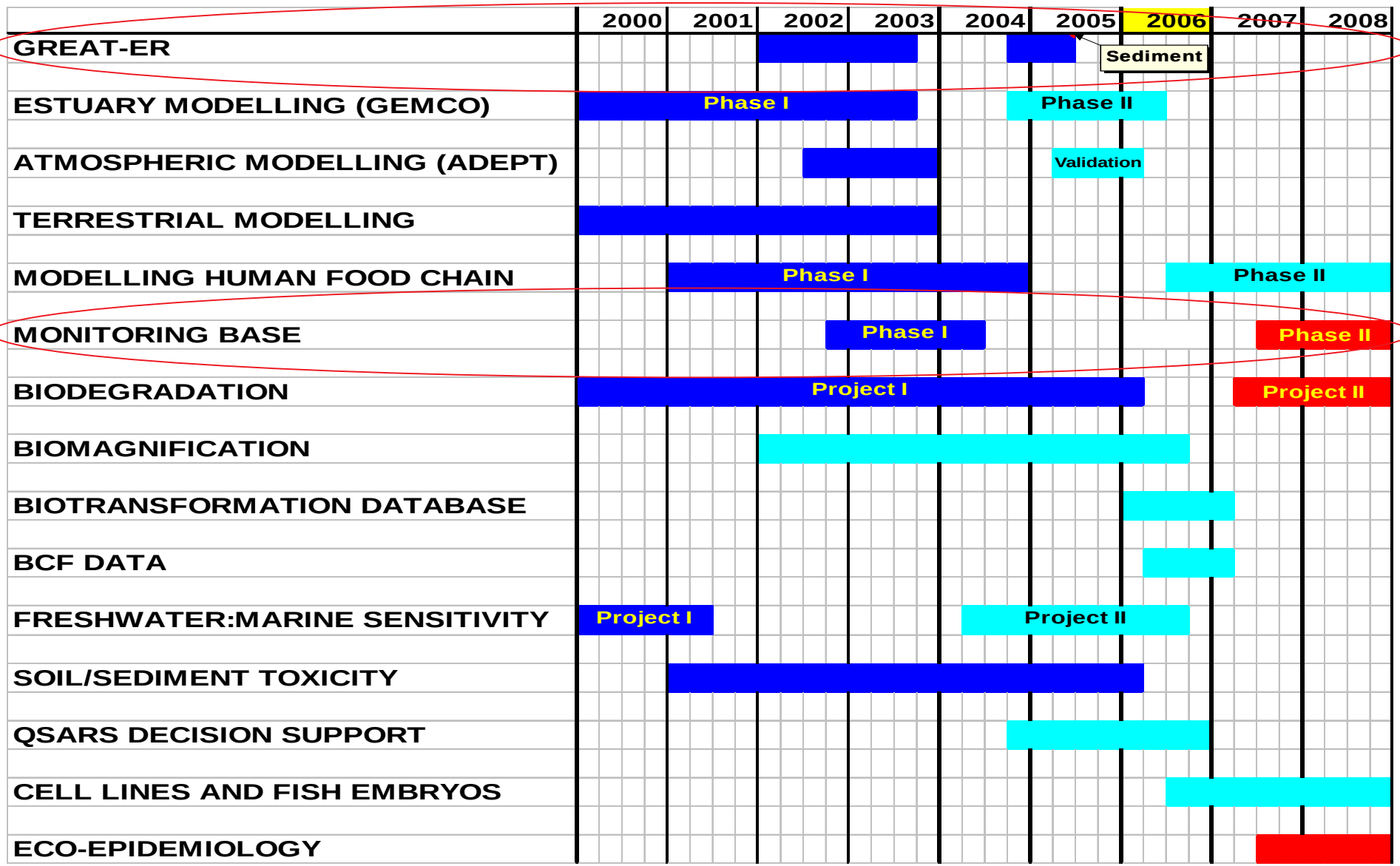
LRI Environment Programme



GREAT-ER

Geography-referenced Regional Exposure Assessment Tool for European Rivers

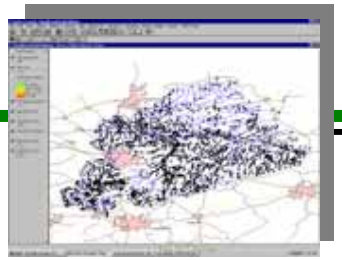
1999: GREAT-ER 1.0 CD: Model development: 1,200,000 EUR

2003: GREAT-ER 2.0: Desktop and web version: 400,000 EUR

2006: Sediment module (available soon): 100,000 EUR

Website: http://www.great-er.org

GREAT-ER (River Model):
A few Words about GREAT-ER

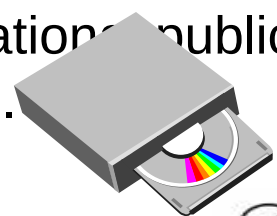


- Partners: AISE/CESIO, UK-EA (sponsors), ECETOC (co-ordinator) + Univ Osnabruck, Gent, Milan, IHH, Yorkshire Water and other basin agencies

- Objective: GIS-Assisted environmental modelling tool for risk assessment and management of chemicals in river basins

- Expected Benefit: Tier 2 (i.e. advanced, site-specific) tool for EU Risk Assessment. Refinement of EUSES predictions for local and regional scenario for freshwater

- Status: ~ 12 river basins available, > 40 international publications about design, validation and use of GREAT-ER.



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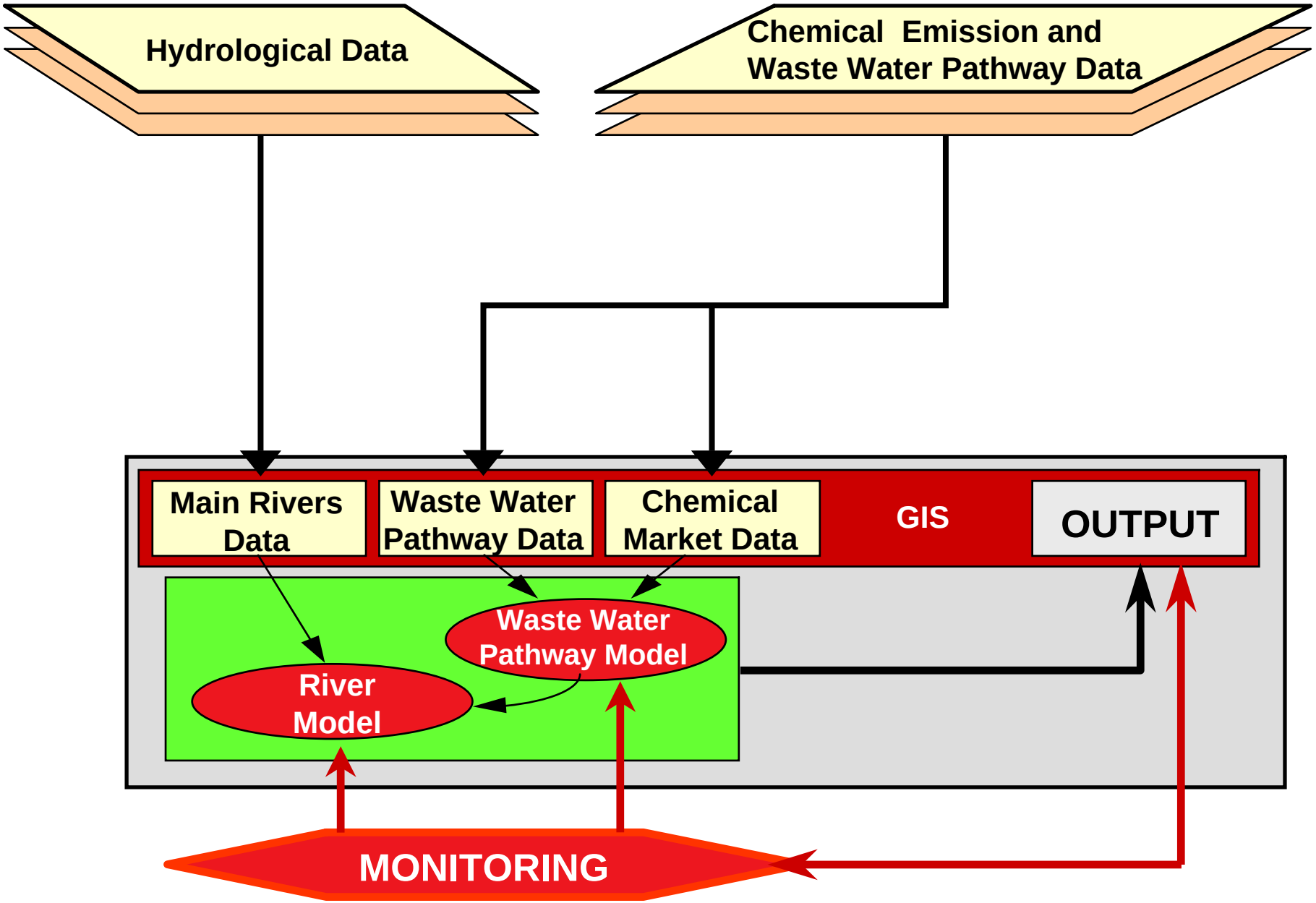

Hydrological Data
Chemical Emission and
Waste Water Pathway Data
Main Rivers
Data
Waste Water
Pathway Data
Chemical
Market Data
GIS
OUTPUT
Waste Water
Pathway Model
River
Model
MONITORING

Roles of UK GREAT-ER Monitoring Team Members

Role	Partner
Overall UK project leadership	ECETOC
Project design-monitoring expertise	All
Identification of representative sites	EA/Yorkshire Water
STW characterisation	Yorkshire Water/EA
Pilot study	ECETOC
Sample collection - effluents	Yorkshire water
Sample collection - rivers	EA
Analysis of all samples	EA analytical laboratory
Hydrological information	CEH Wallingford

LAS Removal in Sewage Treatment Plants

6 Trickling filter plants in 4 catchments

7 Day sampling programme

Automatic samplers - 12 x 2 hour (4 x 30 mins) flow proportional composites of raw sewage influent and final effluent per day

Preservative added at 3% prior to sampling

In field standard additions

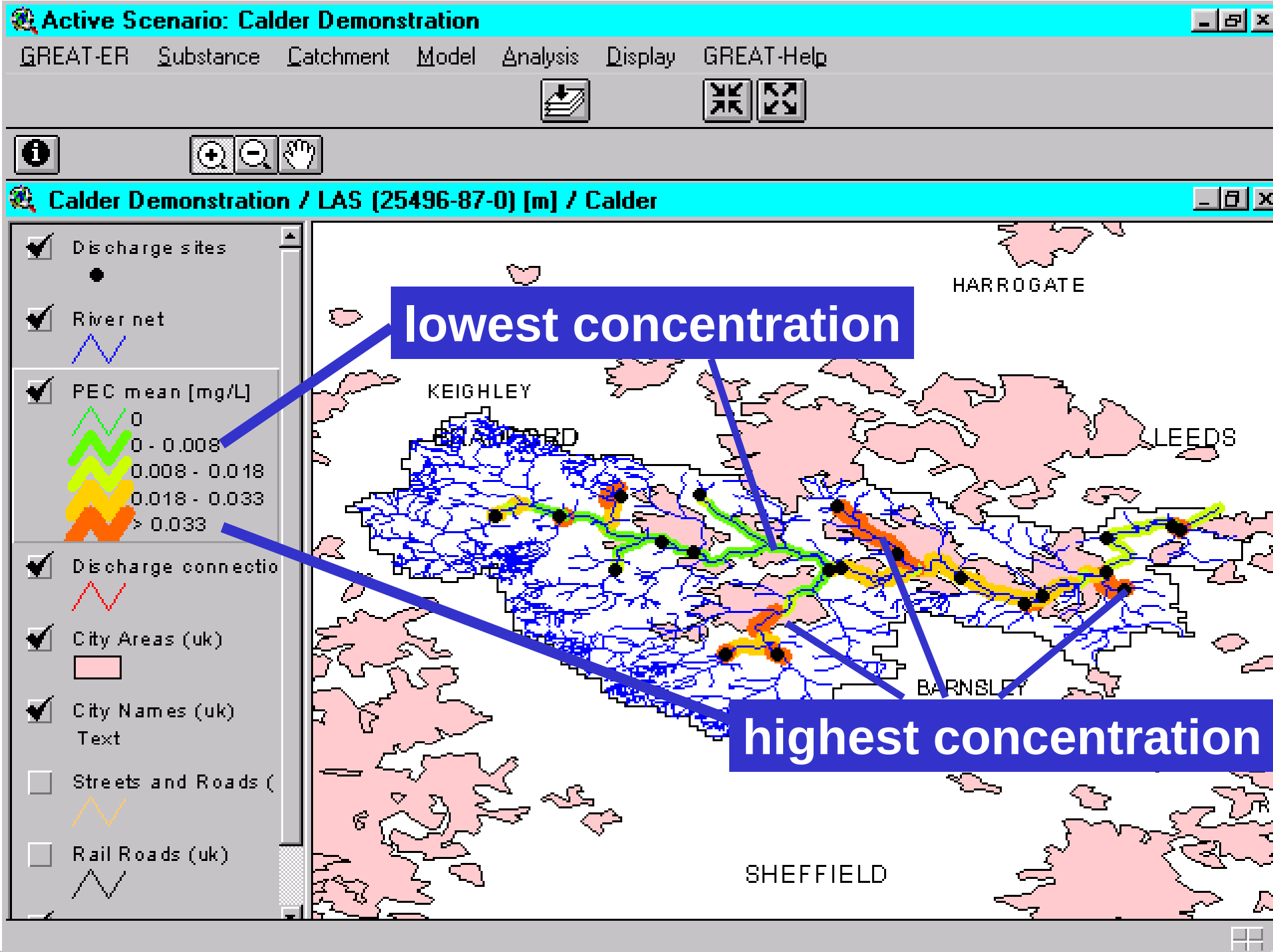
>1000 sewage liquors analysed

Consumer use estimated from boron measurements which was used as a conservative tracer

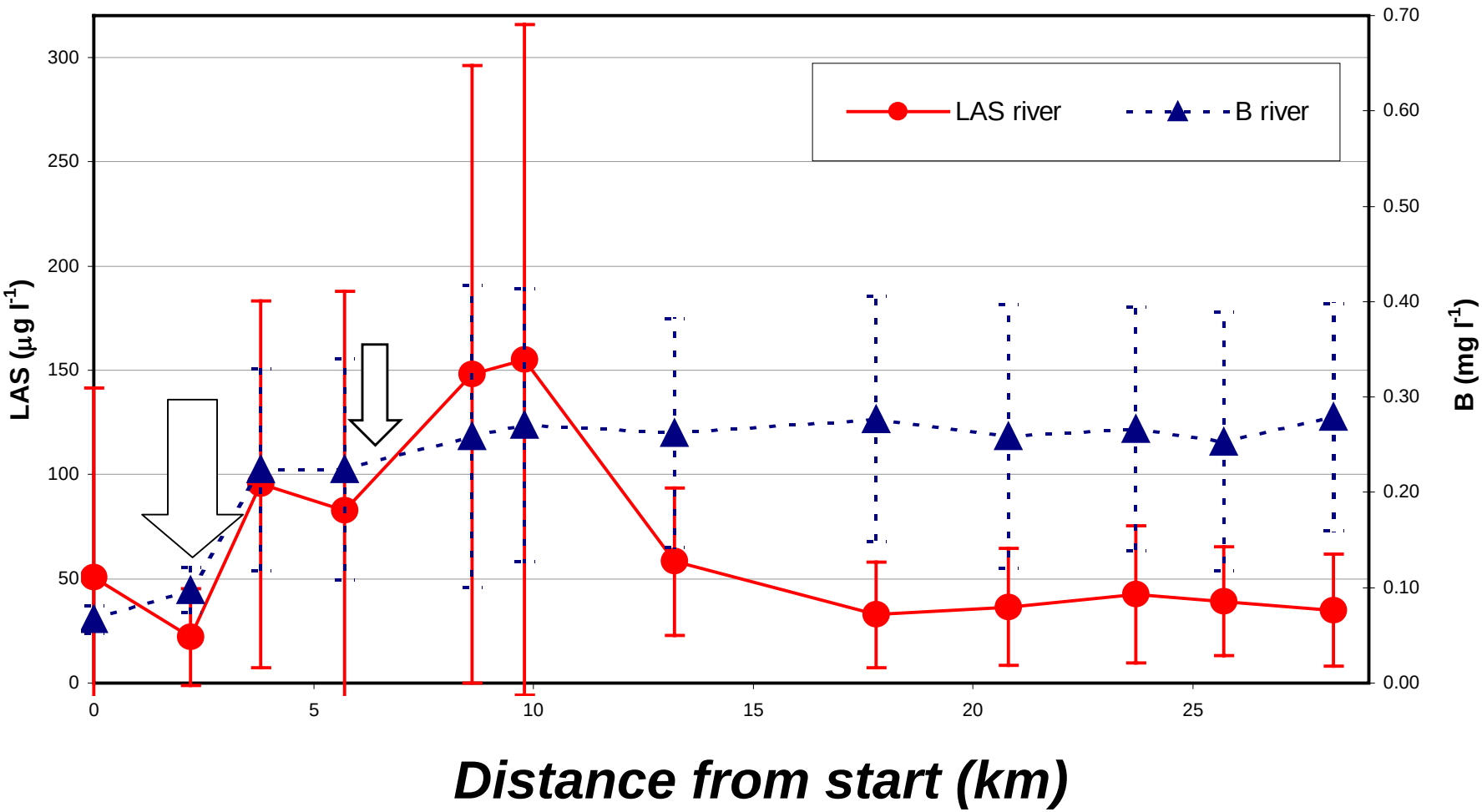
In sewer removal (>50%)

UK Catchment Validation Programme

- **24-month sampling programme – 4 catchments**
- **STW effluents - minimum 26 grab samples per site (every 2 weeks)**
- ***Total – more than 1,000 effluents***
- **River samples - minimum 12 grab samples per site (every 4 weeks)**
- ***Total – more than 2,500 river waters***


Active Scenario: Calder Demonstration
GREAT-ER
Substance
Catchment
Model
Analysis
Display
GREAT-Help
Calder Demonstration / LAS (25496-87-0) [m] / Calder
Discharge sites
River net
PEC mean [mg/L]
0
0 - 0.008
0.008 - 0.018
0.018 - 0.033
> 0.033
Discharge connectio
City Areas (uk)
City Names (uk)
Text
Streets and Roads (
Rail Roads (uk)
lowest concentration
highest concentration
HARROGATE
KEIGHLEY
LEEDS
BARNSLEY
SHEFFIELD

LAS in monthly grab samples - Lambro, Italy



Learnings from GREAT-ER Monitoring Programme

- **Establish a balanced steering group, with involvement of all interested parties from the earliest stages**

- **Set clearly defined objectives**

- **Carry out pilot study:**
  - **Site characteristics, operating conditions and sampling regime**
  - **On-line flow measurements**
  - **Good historical database**
  - **Analytical and QA procedure**

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Examples of How GREAT-ER is Being Used

- **What if scenarios, e.g.:**
  - **Increased sales**
  - **STP modifications**

- **To predict the concentration of down the drain chemicals such as pharmaceuticals and personal care products**

Pharmaceuticals Pilot Study

- Pilot study in rural catchments in the UK - 2005
- Modelling and monitoring of pharmaceuticals and PCP
- Compound list:

Atenolol

Cimetidine

Diclofenac

Felodopine

Fluoxetine

Metformin

Triclosan

Metoprolol

Naproxen

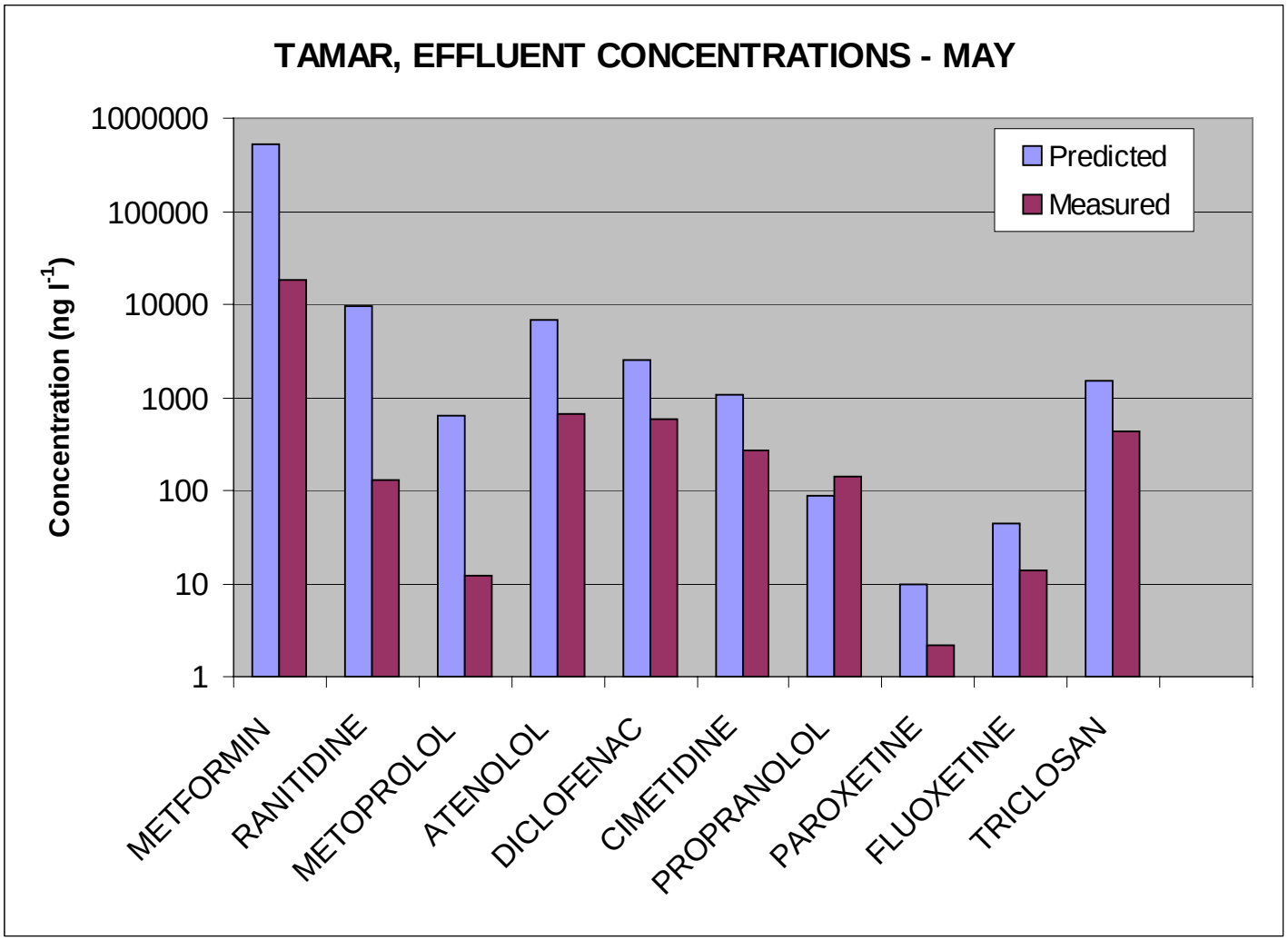
Norfluoxetine

Paroxetine

Propranolol

Ranitidine

Pharmaceutical Pilot Study - Effluent concentrations



Pharmaceuticals Pilot Study - Conclusions

Measured influent and effluent concentrations consistently lower than predicted

- Typically within an order of magnitude
- Larger difference for effluent concentrations suggest better STP removal than predicted

Further understanding of model parameters needed

- Regional use patterns
- Human metabolism
- In-sewer removal
- STP removal (e.g. adsorption vs degradation)
- Dilution mechanisms
- In-stream removal

MonitoringBase

MonitoringBase

Version 1.0, June 2004

MonitoringBase

MonitoringBase contains information on planned, on-going and completed monitoring, survey and screening studies for contaminants in the European aquatic environment. The database also contains measured concentration data on a selected set of organic chemicals in water, sediment and biota mainly determined in the European aquatic environment. In addition, information is provided where data can be found on measured concentrations in databanks available on Internet.

The database can be used to help you to find information on the following topics:

- Which compounds in which compartments are monitored in the European aquatic environment?
- Who is monitoring contaminants, when and where?
- Where can I find information on environmental measured concentrations (e.g. useful for trends analysis, spatial distribution)?
- Field data for a selected set of compounds, stored in MonitoringBase. This can serve as input or validation data for environmental models (e.g. exposure models, food chain models).
- Availability and accessibility of databases on Internet that contain information on environmental measured concentrations.

Monitoring programmes

- Substance search
- Environment and country/sea search
- Detailed search

Measured concentrations

- MonitoringBase
- Internet

Other

- Users' manual
- Links

- Exit database

Dr Pim Leonard
RIVO Institute for Fisheries Research

Overall Goals of the Project

- To identify on-going and planned European institutional field monitoring programmes, including the Arctic, that can be joined into to maximise the amount of data and limit the number of samples
- To review and catalogue available measured environmental concentration data of organic chemicals in water, sediment and biota from the freshwater and marine environments.
- To support and accelerate the harmonisation of (a) Europe-wide monitoring database and to improve accessibility to data

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Specific Goals for MonitoringBase Project

- **Which contaminants in which compartments have and/or are being monitored?**
- **Who is monitoring contaminants, when and where?**
- **Where can information on environmental measured concentrations be found? (e.g. useful for trends analysis, spatial distribution)**
- **What concentrations have been measured in the field for a selected set of contaminants? (Data for 71 chemicals stored in MonitoringBase can serve as input or validation data for environmental models, e.g. exposure models, food chain models)**
- **Where can databases containing information on environmental measured concentrations be found on internet?**
- **www.rivo.dlo.nl/ftp_dir/Environment_FoodSafety/pim**

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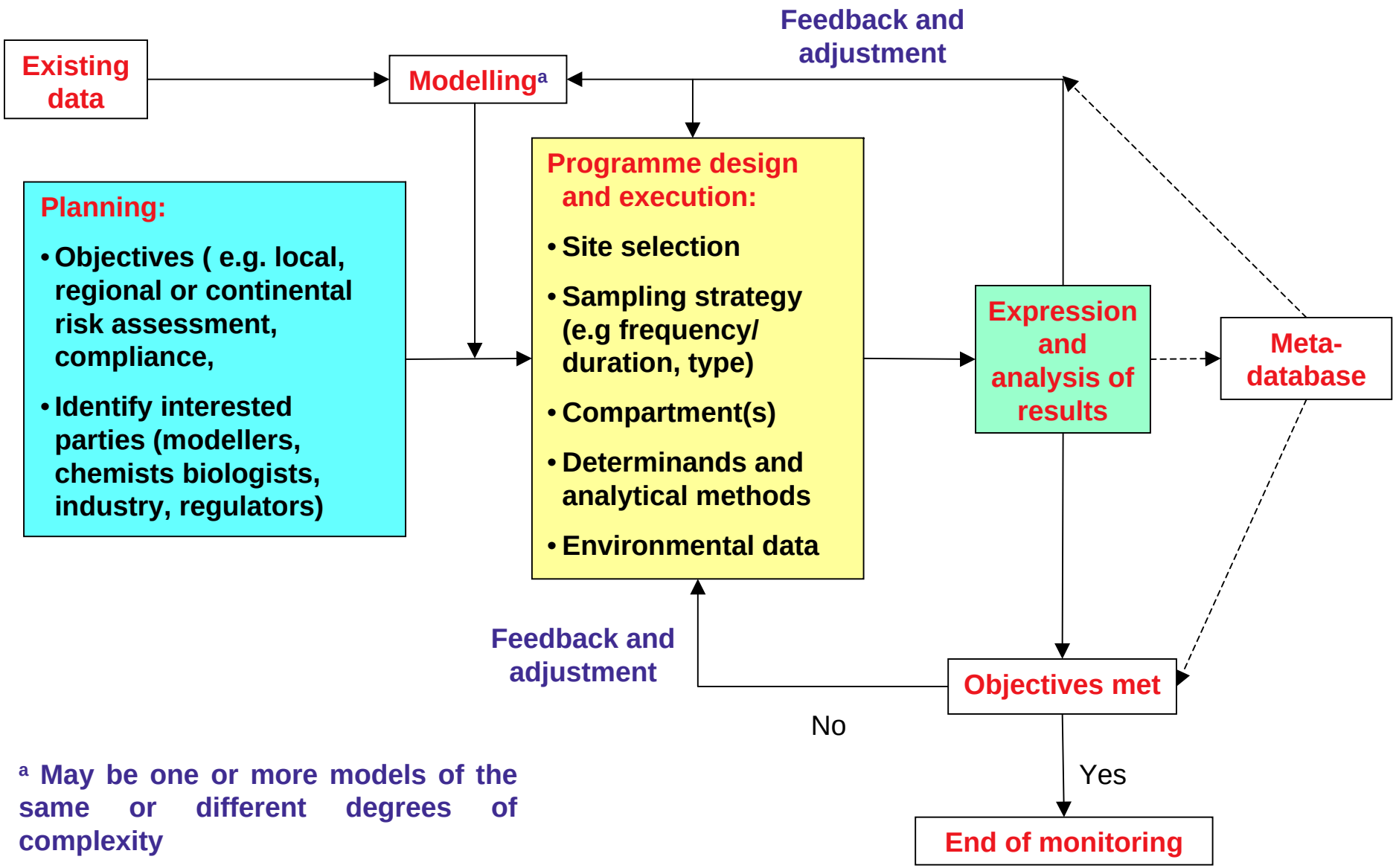
Results - MonitoringBase

Consists of 2 parts:

- ***Programmes section***
  - Gives details on 160 planned, ongoing and completed monitoring programmes in Europe and Arctic
  - Covers > 90% of programmes in Europe and Arctic
  - Who is measuring what, where, how often, etc.

- ***Measured Concentrations section***
  - Contains data on WFD priority substances (32), excluding metals, pesticides
  - Substances with large datasets which could flood the database have been excluded (PCB, PAH, etc.)
  - Contains other substances (total 71)
  - Contains a number of substances with data which may be useful in addressing food webs and to identify time trends
  - Provides links to extractable measured data, e.g. databases available on internet

Integrated Monitoring



[a] May be one or more models of the same or different degrees of complexity

Summary

Whilst measured data (chemical and biological) have a major role in the assessment of emerging pollutants

- Many aspects relating to the **design** and the **coordination** of monitoring programmes and the **interpretation** of the data need to be much more fully and widely debated.
- Project **teams** should comprise individuals from different **scientific disciplines** together with other relevant **expertise** from all interested parties – integrated modelling programmes.
- **Monitoring** and **modelling** play a major role in exposure assessment but there is still much to do to
  - improve the quality and **applicability domain** of higher tiered models and
  - optimise the use of **resources**.
- **Validation** of models is complex issue; need to continue to develop and link to **new databases**. **Accessibility** to data is a major problem.
- Industry has **ongoing programmes** committed to improving the way that risk assessments are performed by addressing knowledge gaps essential for the improvement and **reduction in uncertainty** within the process.
- Neither **hazard potential** nor **measured concentration** should be used in isolation to manage chemicals Exposure and hazard must be considered **jointly** and all decisions should be based on **risk**.

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Parting Thoughts - Chemicals in the Environment

- **What does detection of a chemical in a given compartment indicate?**
- **What does its presence mean in terms of environmental effects?**
- **What do the results of individual species effects studies mean in terms of environmental relevance?**