

# ***The REACH baseline study***

***European Commission – Eurostat  
Environment Statistics***

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**Consequences of REACH for other legal and administrative  
environmental instruments**

**– Evaluating the environmental effectiveness –**

**Workshop, Berlin, Ernst Reuter Haus, 11-12 October 2007**



Directorate E: Agriculture and environment statistics; Statistical cooperation  
Unit E3: Environment statistics



# ***Eurostat's Environment Statistics – mission statement:***

**“To provide the European Union and the wider global  
community with a high-quality official statistical  
information service for  
Environmental Statistics and Accounts,  
in order to support the definition, implementation and  
monitoring of EU environmental policies.”**

**6<sup>th</sup> Environment Action Programme**  
*- and its implementing -*  
**“Thematic Strategies”**



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# ***Indicators on (toxic) chemicals – Motivation***

- **Headline objective for “Public Health” in the Community Sustainable Development Strategy:**  
**“By 2020, ensure that chemicals are only produced and used in ways that do not pose significant threats to human health and the environment.”**
- **6th Environment Action Programme: Requests new EU policy on chemicals ( >>> REACH);  
Implementation / effectiveness shall be monitored with suitable indicators.**



# ***Towards the REACH baseline study:***

## **Workshop in March 2005:**

**(Commission services, scientific experts)**

➤ ***“We need to set the baseline and a monitoring instrument for REACH, as REACH will have to be reviewed”***

**+ Difficult task**

**+ Indicators should be risk based, not damage based**

**+ Pragmatic approach to be chosen**

**= Eurostat shall do it. (neutral, impartial, ...)**



# ***Possible (???) REACH indicators***

- **Policy or administrative indicators - Level 1 indicators:**
  - Number of registered chemicals
  - Number of animal tests
  - Rate of re-classification of substances
  
- **Midpoint indicators - Level 2 indicators:**
  - Risk-based indicators: exposure levels at workplace
  - exposure modelling, intake modelling
  
- **Endpoint or damage indicators - Level 3 indicators:**
  - Cancer rates
  - Occupational skin diseases



# ... REACH Baseline Study ...

## Objectives:

### ➤ Set the “baseline”

*(... of the potential risk for consumers, workers, the environment and humans exposed via the environment)*

**before REACH is in place: “Snapshot 2007”**

### ➤ Develop a monitoring instrument

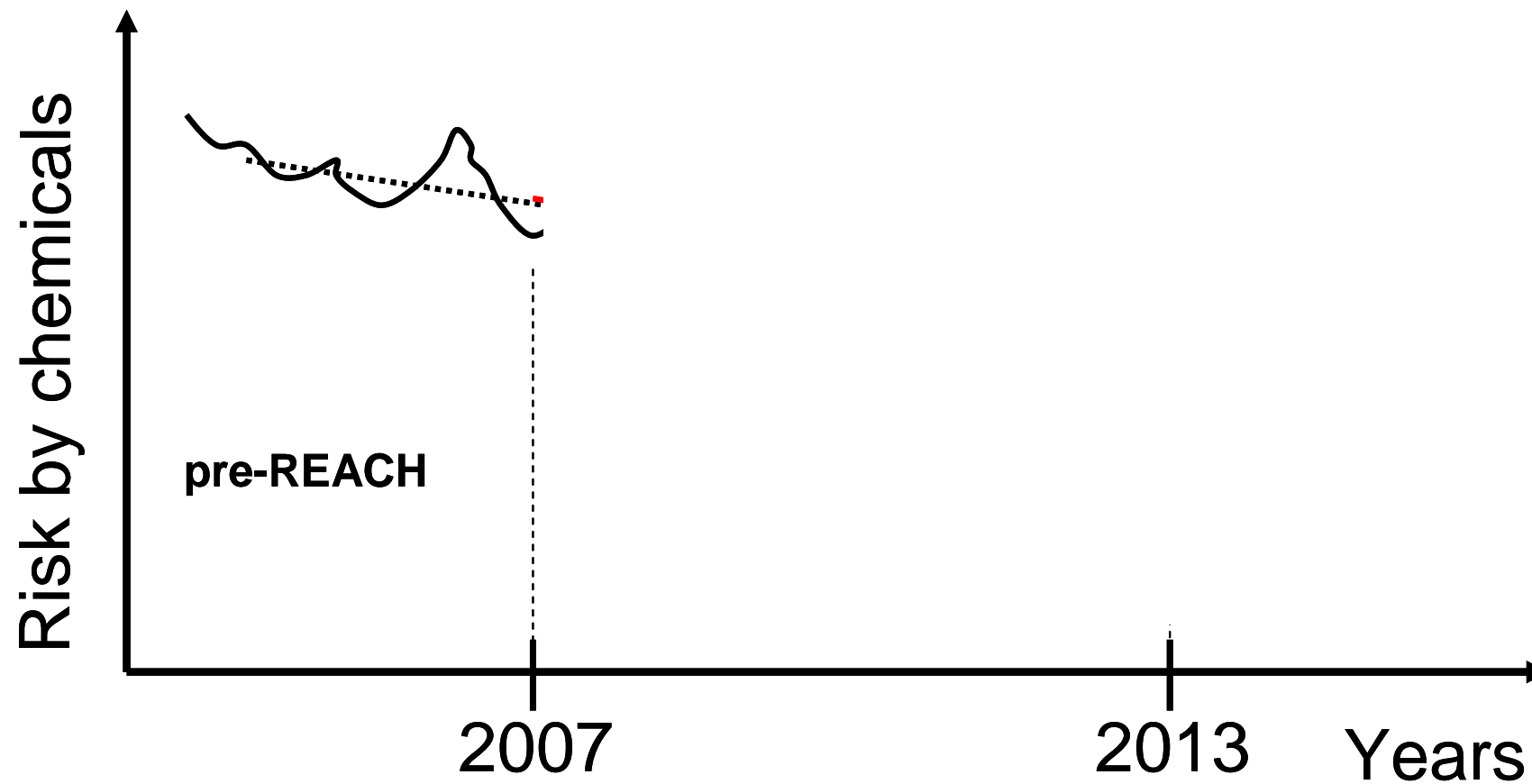
*(... indicators ...)* **to measure the effectiveness of REACH**

*( ... repeat the study every 6 years to identify changes)*

**“Snapshot 2013”**



## *The ideal indicator:*



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# ***... REACH baseline study ...***

## **Project management group:**

**Eurostat with**

- + DG Enterprise and Industry**
- + DG Environment**
- + Joint Research Centre (ECB)**

## **Project consortium:**

**CALL**  
**FOR TENDER**

## **Steering committee:**

**Statisticians**  
**Scientists (Government**  
**and private experts)**  
**Industry Association**  
**other services**

**3 meetings in**  
**2006/2007**



# ... REACH baseline study ...

## Project partners:



Institut für Angewandte Ökologie • Institute for Applied Ecology • Institut d'écologie appliquée

(Wolfgang Jenseit, Dirk Bunke)

**INERIS**

(Celine Boudet, François Le Goff,  
Corinne Mandin)

**FoBiG**

(Fritz Kalberlah, Jan Oltmanns)

**DHI**

(Dorte Rasmussen, Morten Birkved)

## Steering committee:

Agnes Palovics, Alick Morris, Andreas Ahrens, Axel Hahn,  
Dik van de Meent, Gabi Schöning, Gigilola Fontanesi,  
Kathrine Loe Hansen, Leo Heezen, Michael Hauschildt,  
Peter Pärt, Viveka Palm and Slawomir Czerczak



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# *The framework*

## Three pillars

Administrative  
Indicators

Risk & Quality  
Indicator System

Supplemental  
Indicators



Central Elements & Objectives of REACH	Baseline Study Indicator System		
	Administrative indicators	R&Q Indicator System	Supplemental Indicators
Registration of chemicals	✓		
Evaluation of chemicals	✓		
Authorisation and restriction of chemicals	✓		
Establishment of a central agency (ECHA)	(indirect)		
Protection of human health and the environment		✓	✓
Improvement of knowledge on properties and safe uses of chemicals		✓	✓
Assessment of existing and new chemicals in a single, coherent system			✓
Increased transparency and consumer awareness			(✓)
Promotion of alternative methods for assessment of hazards of chemicals			✓
Maintenance and enhancement of the competitiveness	<i>Not in the scope of the baseline study</i>		
Prevention of fragmentation in the internal market			
Conformity with EU international obligations under WTO			

# ***Risk & Quality indicator system***

## ***- methodology***

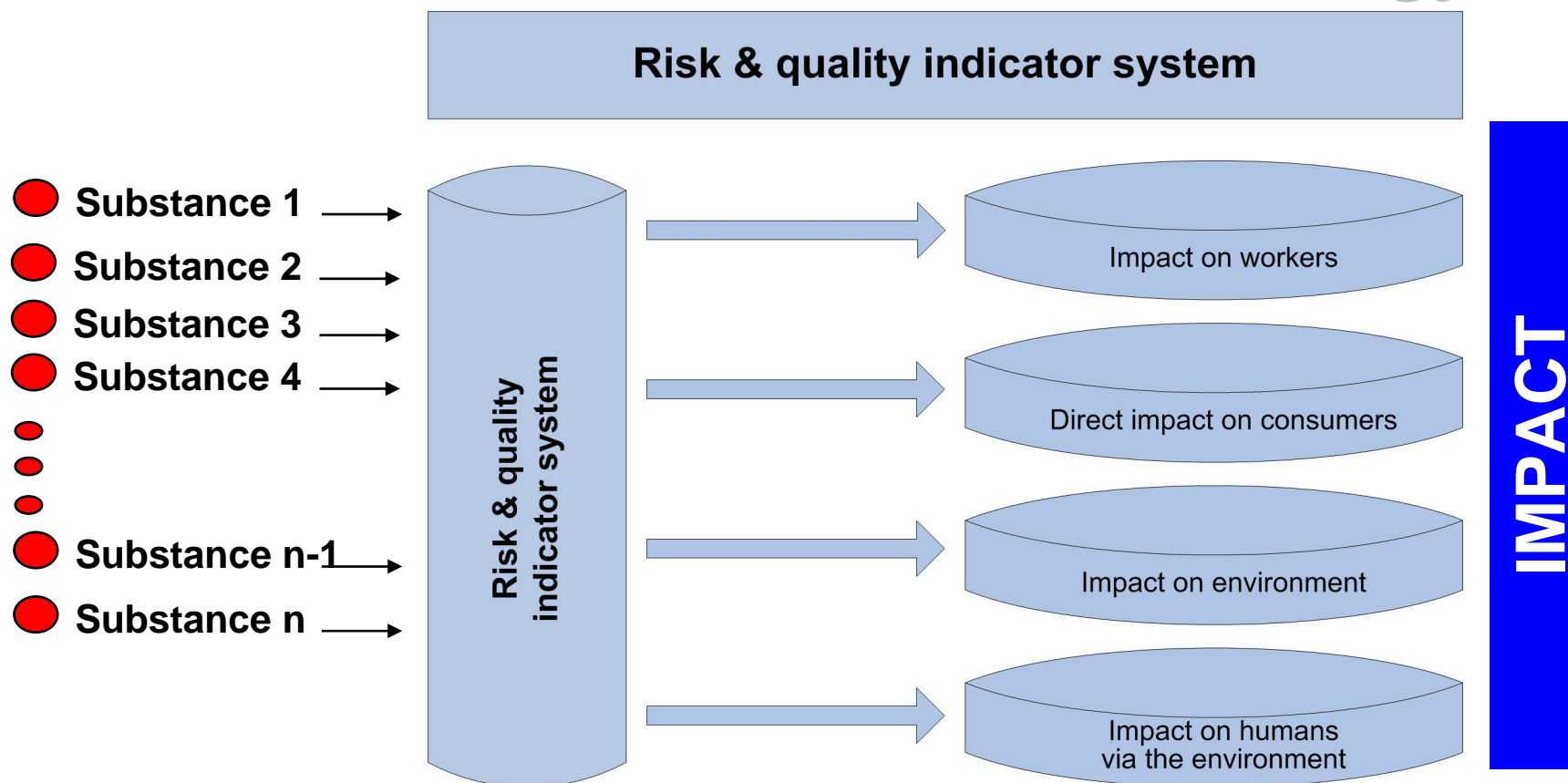
**Two key questions to monitor the success of REACH:**

- **How does the (health and environmental) risk change after implementation of REACH ?**
- **How qualified is the information obtained on the dangerous properties and the exposure towards these substances?**

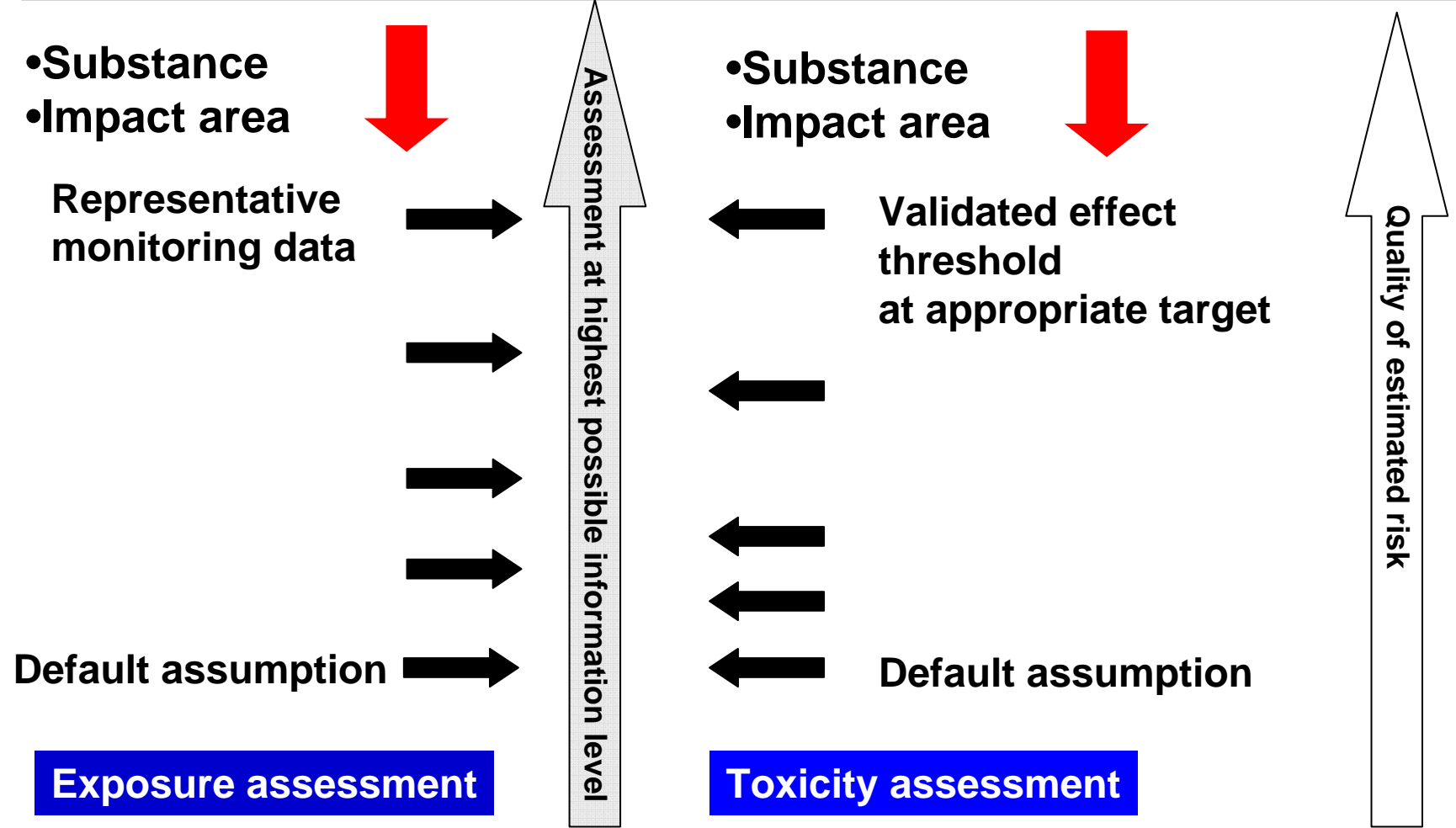


# *Risk & Quality indicator system*

## *- methodology*



**Indicator at RISK LEVEL (based on estimated effect/exposure ratio)**



# ***Risk & Quality indicator system***

## ***- methodology***

- **Assess and determine critical production conditions and uses**
- **Assess and quantify exposure**
- **Assign quality score to assessed exposure**
- **Assess and quantify toxicity**
- **Assign quality score to assessed toxicity**
- **Assign population risk modifier**
- **Determine overall risk score and overall quality score**



# ***Risk & Quality indicator system***

## ***- methodology***

- **Avoid „expert judgement“, if possible**  
**Consequence: some loss in quality**
- **Identical or similar results should come up, independently from assessor**
- **Limited number of sources to be checked**
- **If expert judgement still used, rationale has to be documented**
- **Link tools and sources to REACH-tools or to current assessment tools for existing substances**



# ***Risk & Quality indicator system*** ***- results***

## **Aggregation of:**

- **Exposure score**
- **Toxicity score**
- **Risk characterisation ratio (RCR)**
- **Exposure quality score**
- **Toxicity quality score**
- **(Population risk modifier)**
- **Risk score**

- **Aggregated risk score**
- **Aggregated quality score**
- **Aggregated toxicity score**



**various analyses**



# *Risk & Quality indicator system*

## *- results*

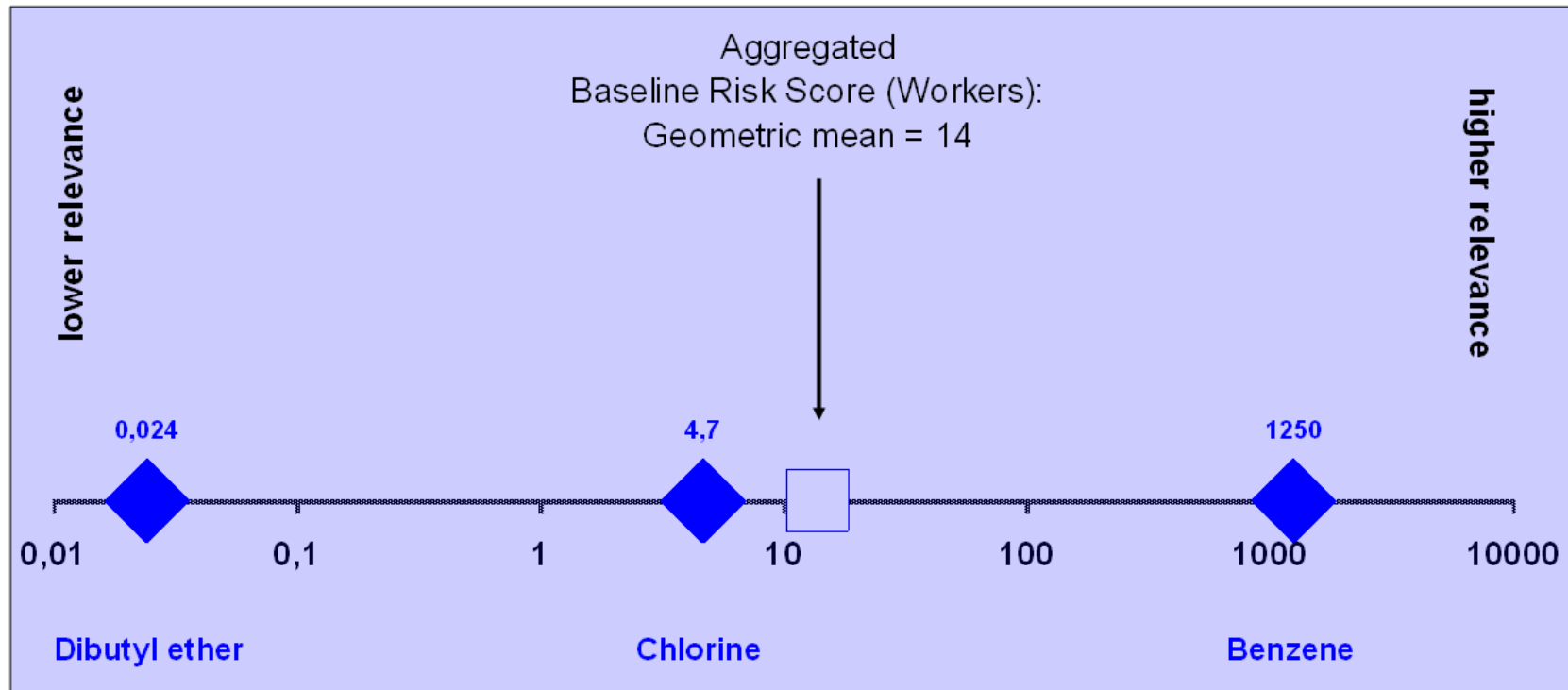
- 115 substances (randomly selected LPVs – MPVs – HPVs) + 22 SVHC substances
- Results are presented in three levels of aggregation:

- Summary level
- Profile level
- Analysis level

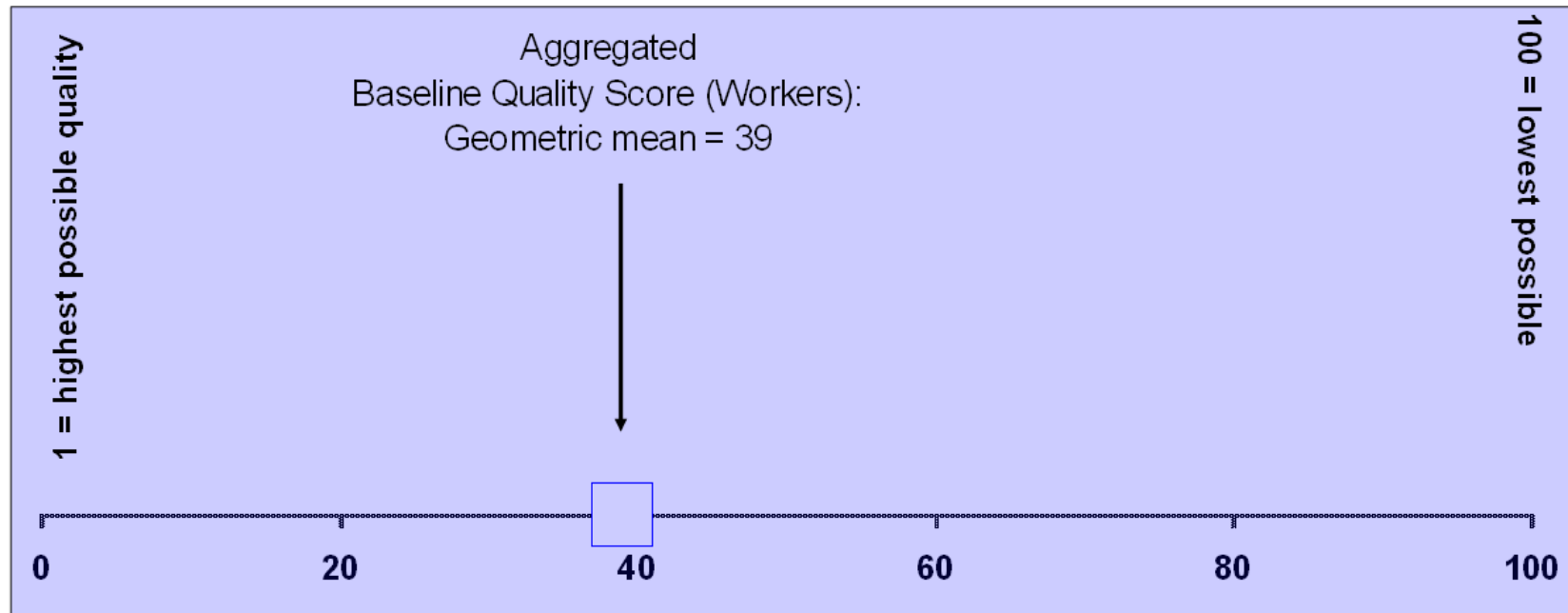
*... for all four impact areas,  
but **no aggregation** or  
direct **comparison** over  
impact areas (!)*



# Baseline risk score for workers = 14 (Summary level)



# ***Baseline quality score for workers = 39*** ***(Summary level)***



# *Baseline results, expected changes (Profile level)*

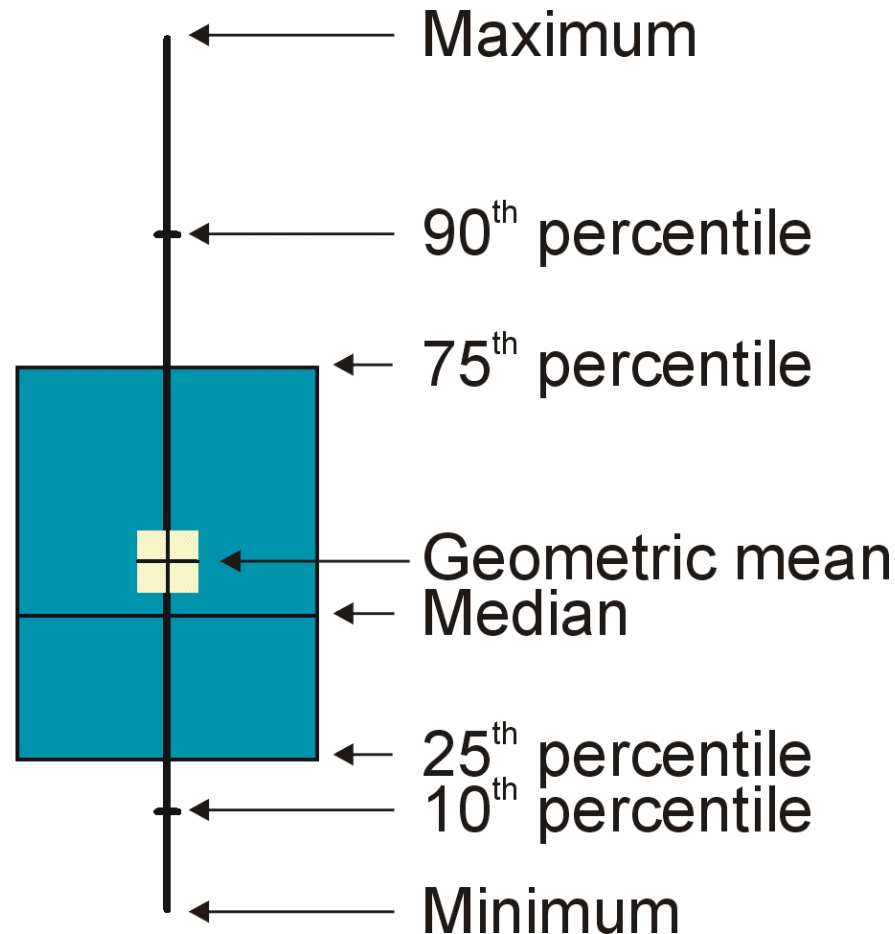




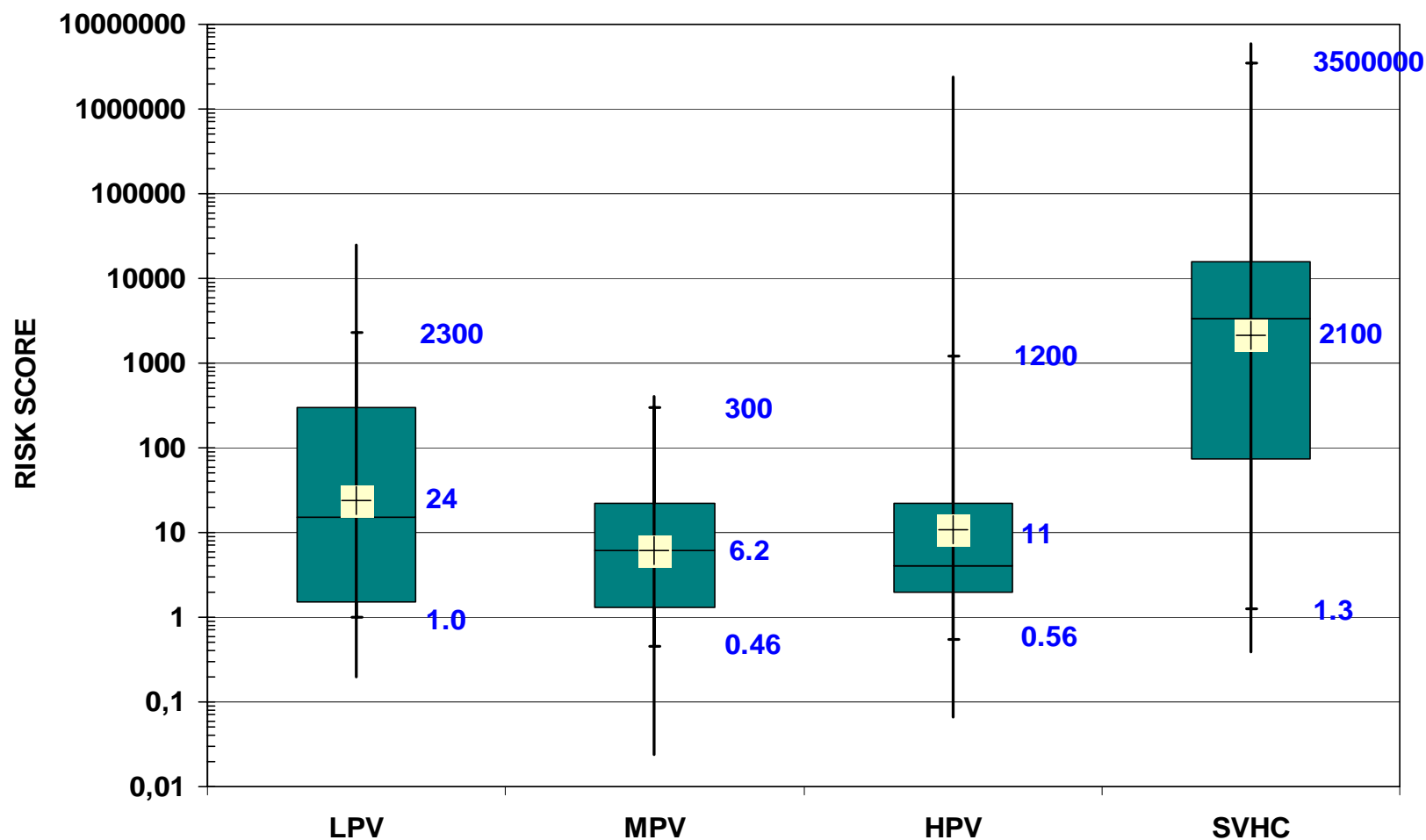
# Baseline results for workers

(Profile level)

Whisker-  
box plot  
- legend



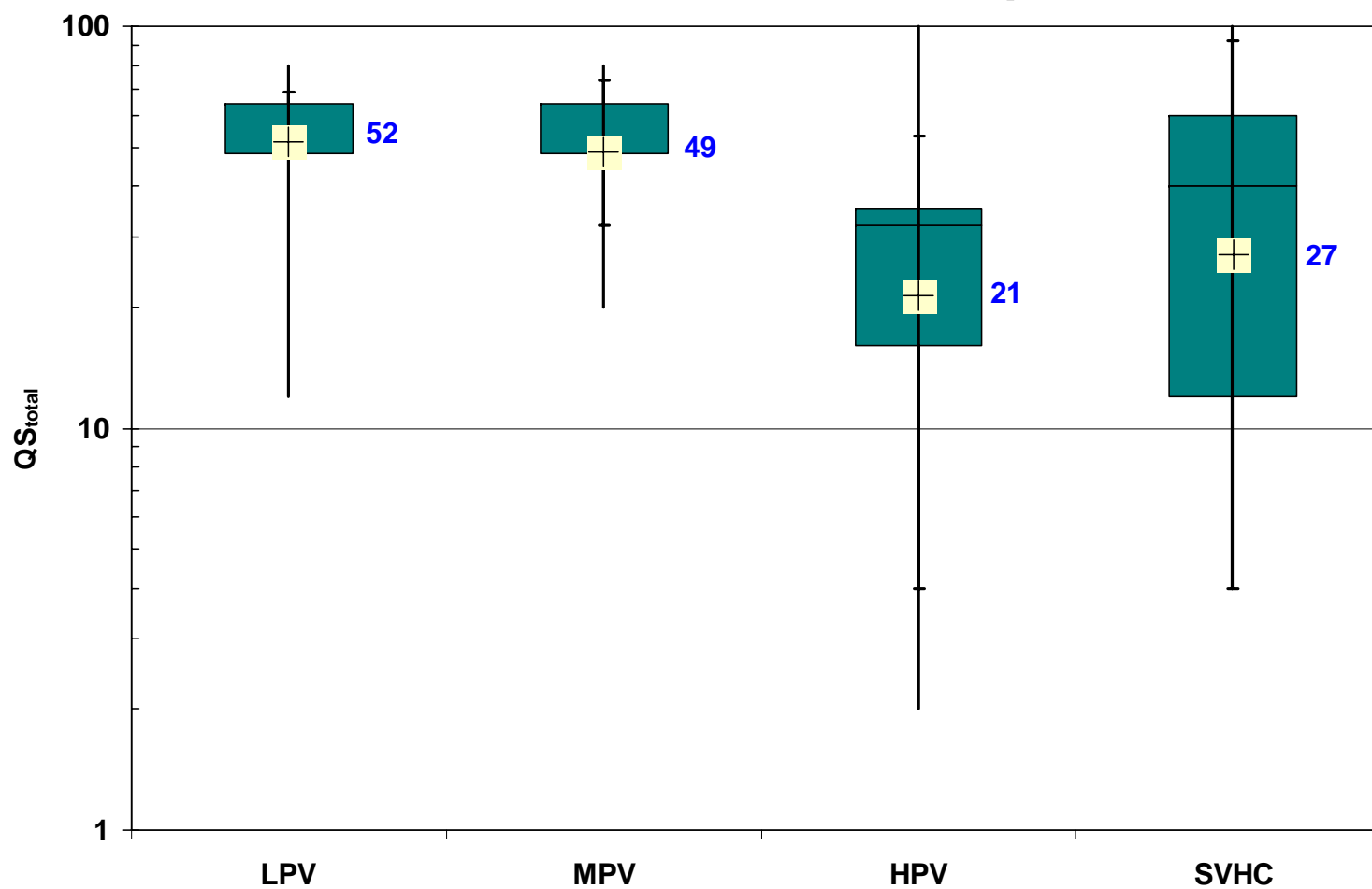
# Baseline risk scores for workers (Profile level)



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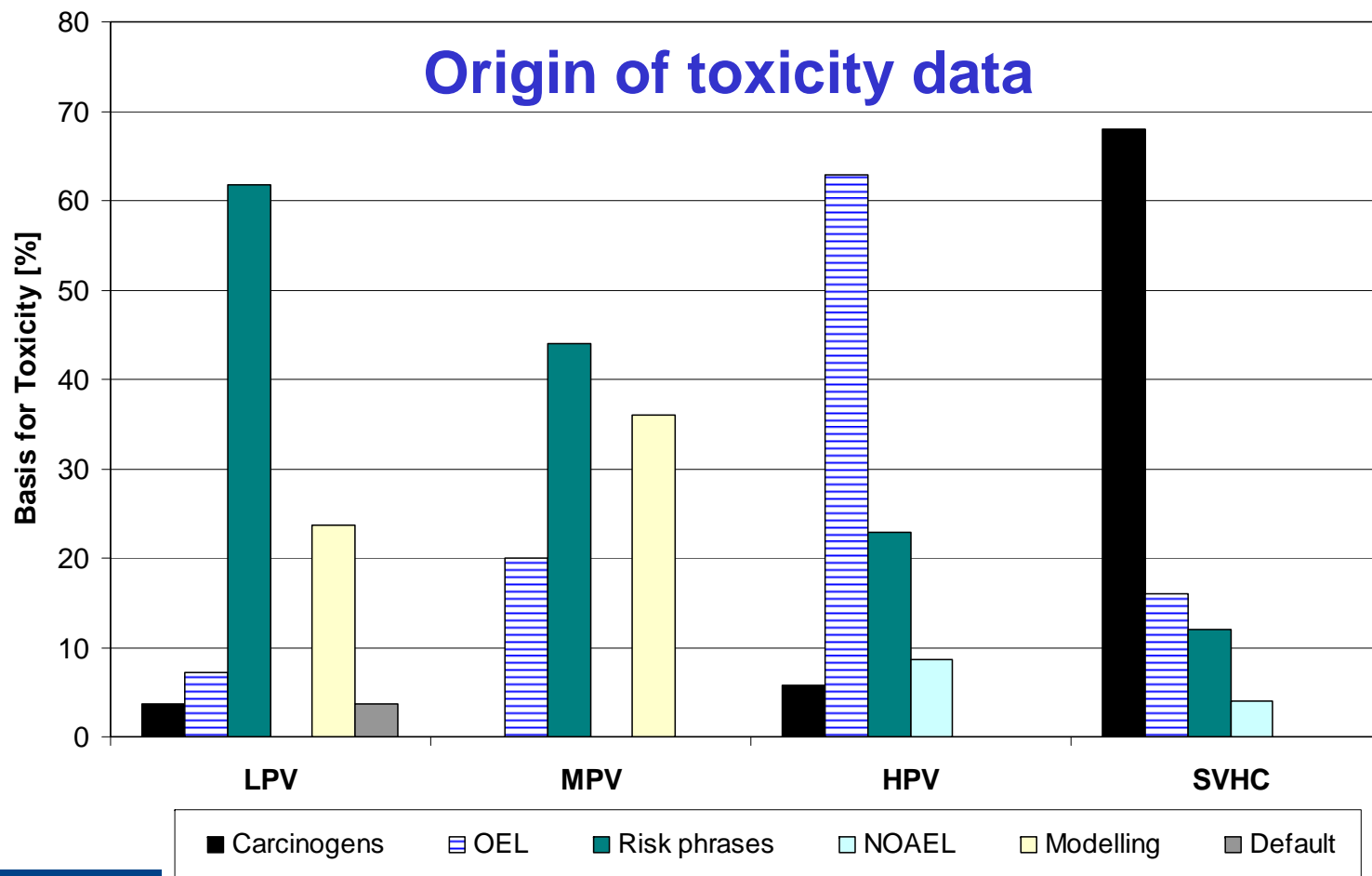


# Baseline quality scores for workers (Profile level)



# Baseline results for workers

(Analysis level)

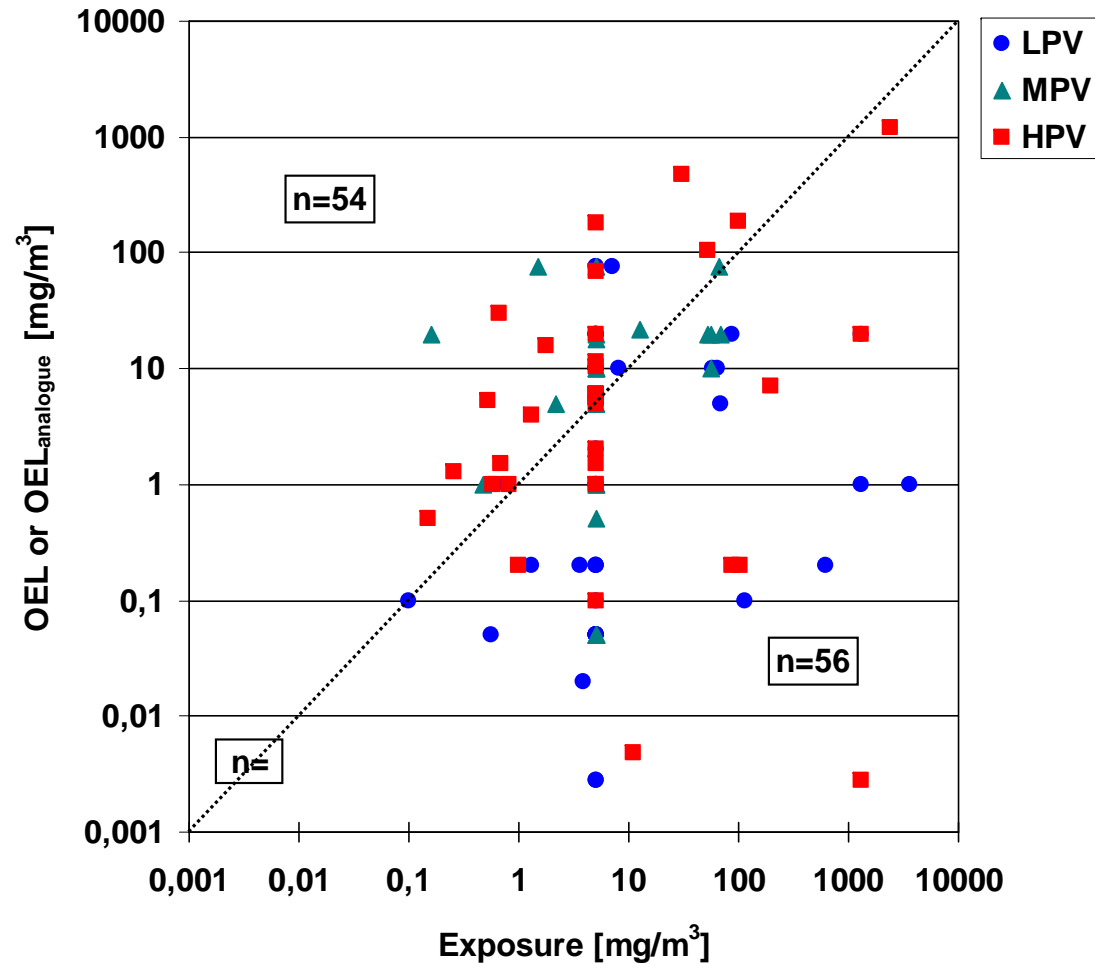


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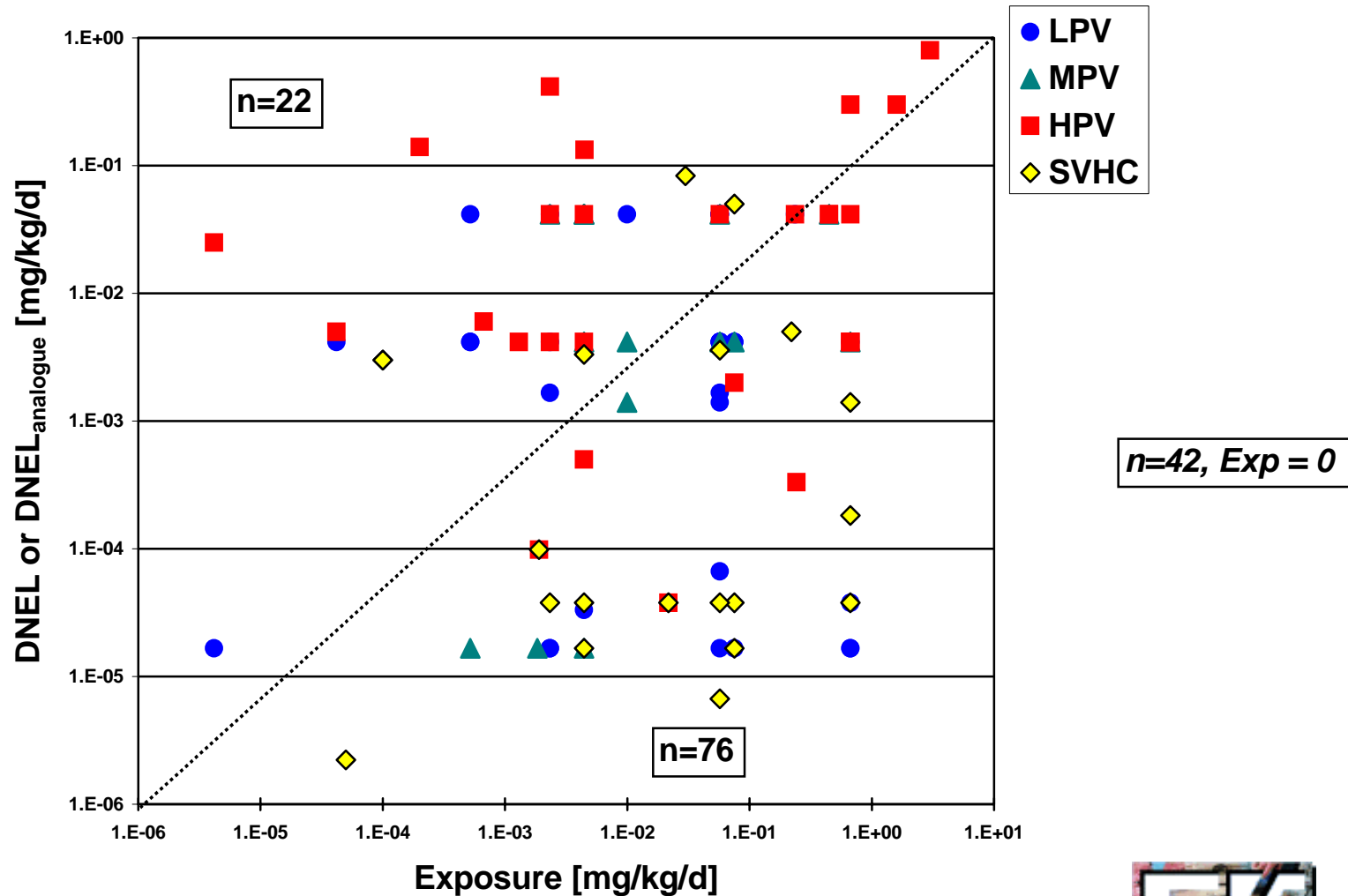
# Baseline results for workers

(Analysis level)

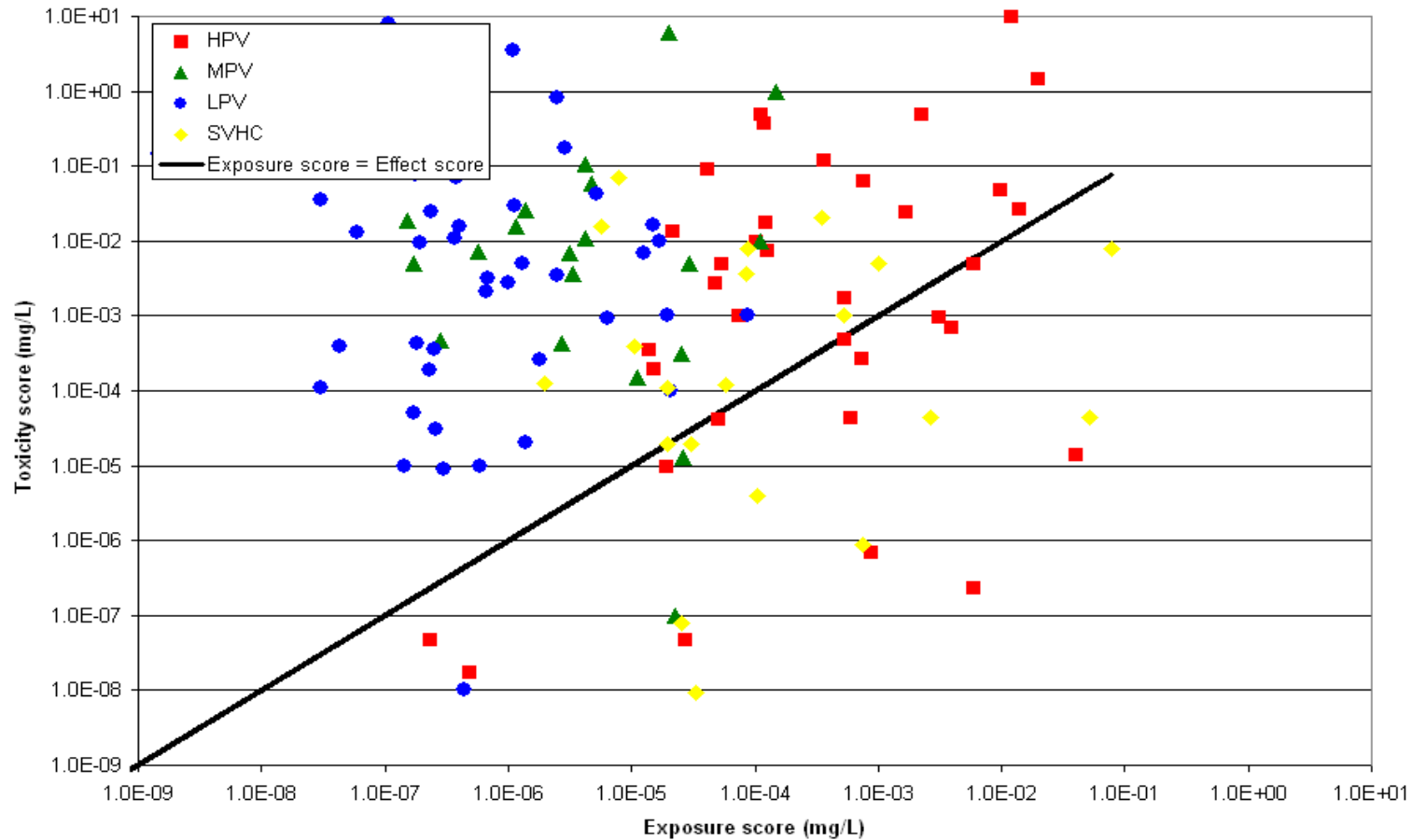


# Baseline results for consumers

(Analysis level)



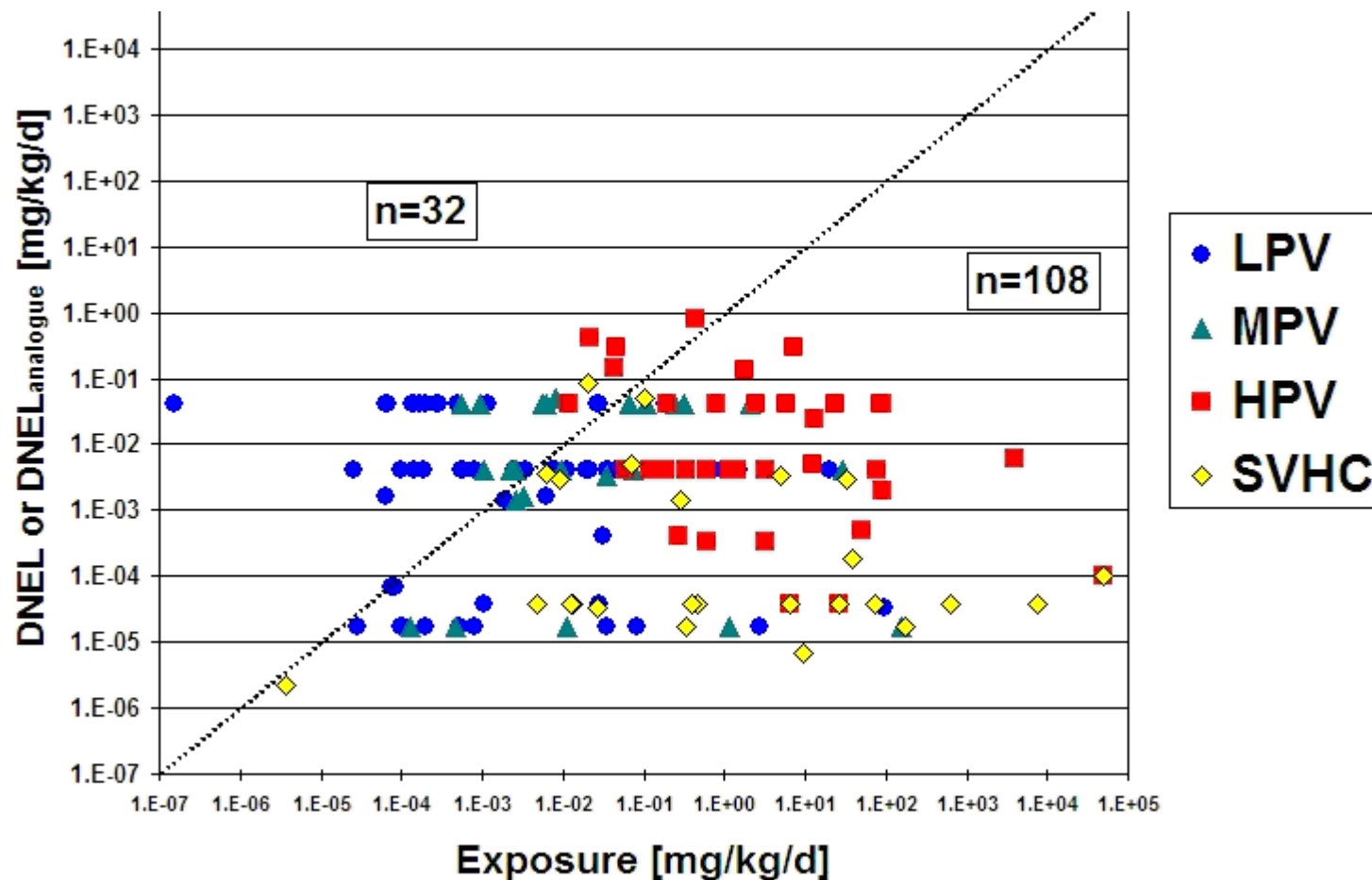
# Baseline results for the environment (Analysis level)



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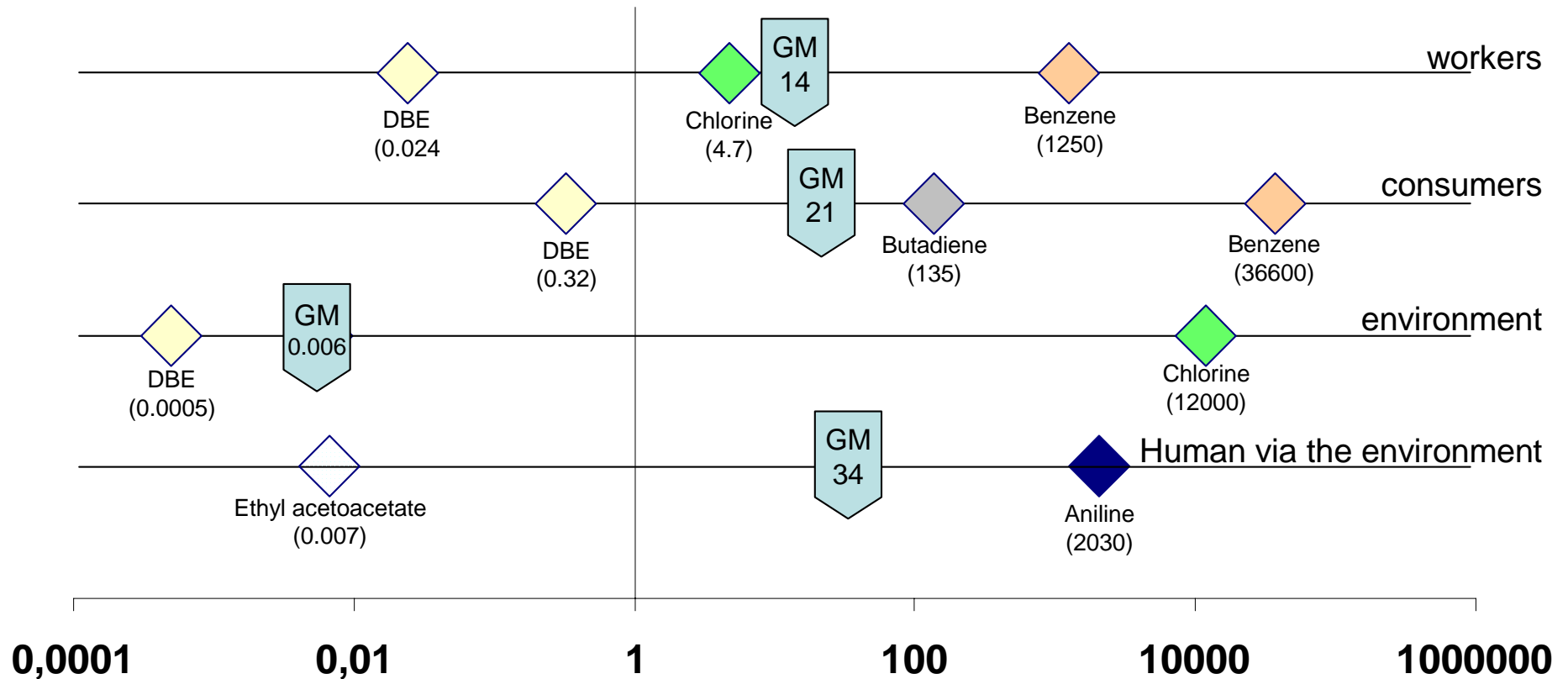
# Baseline results for humans via the environment (Analysis level)



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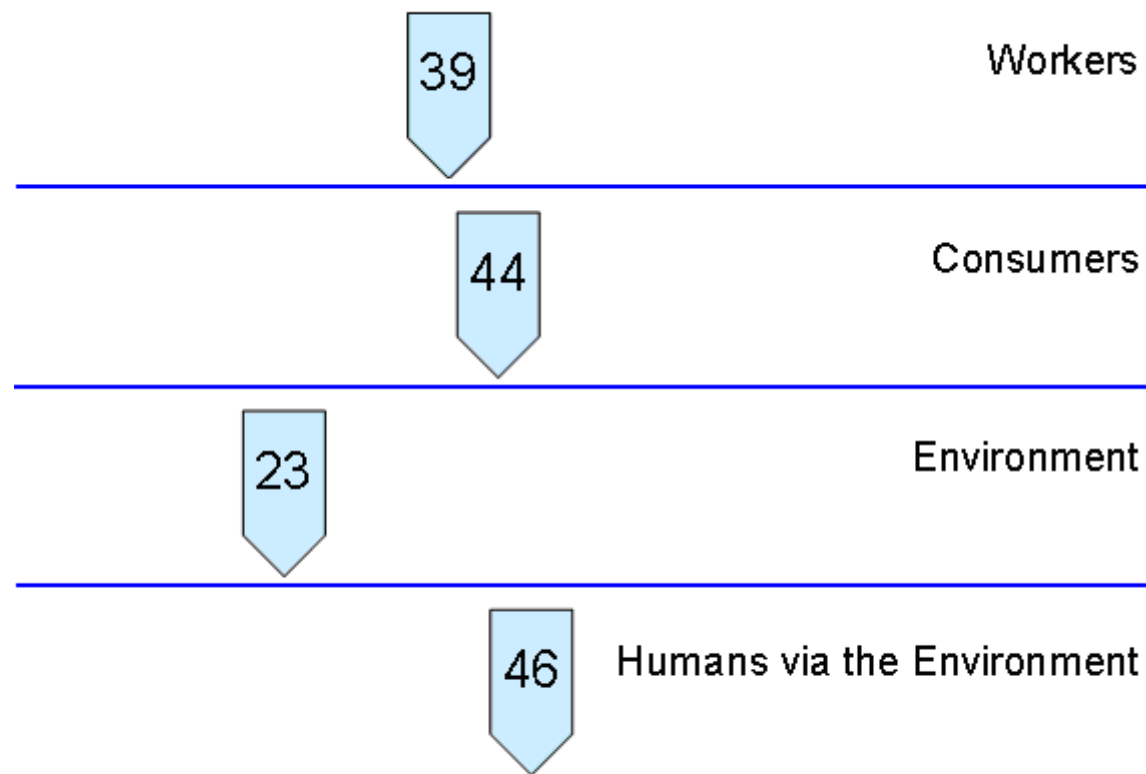
# Baseline risk scores for all impact areas (Summary level)



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# Baseline quality scores for all impact areas (Summary level)



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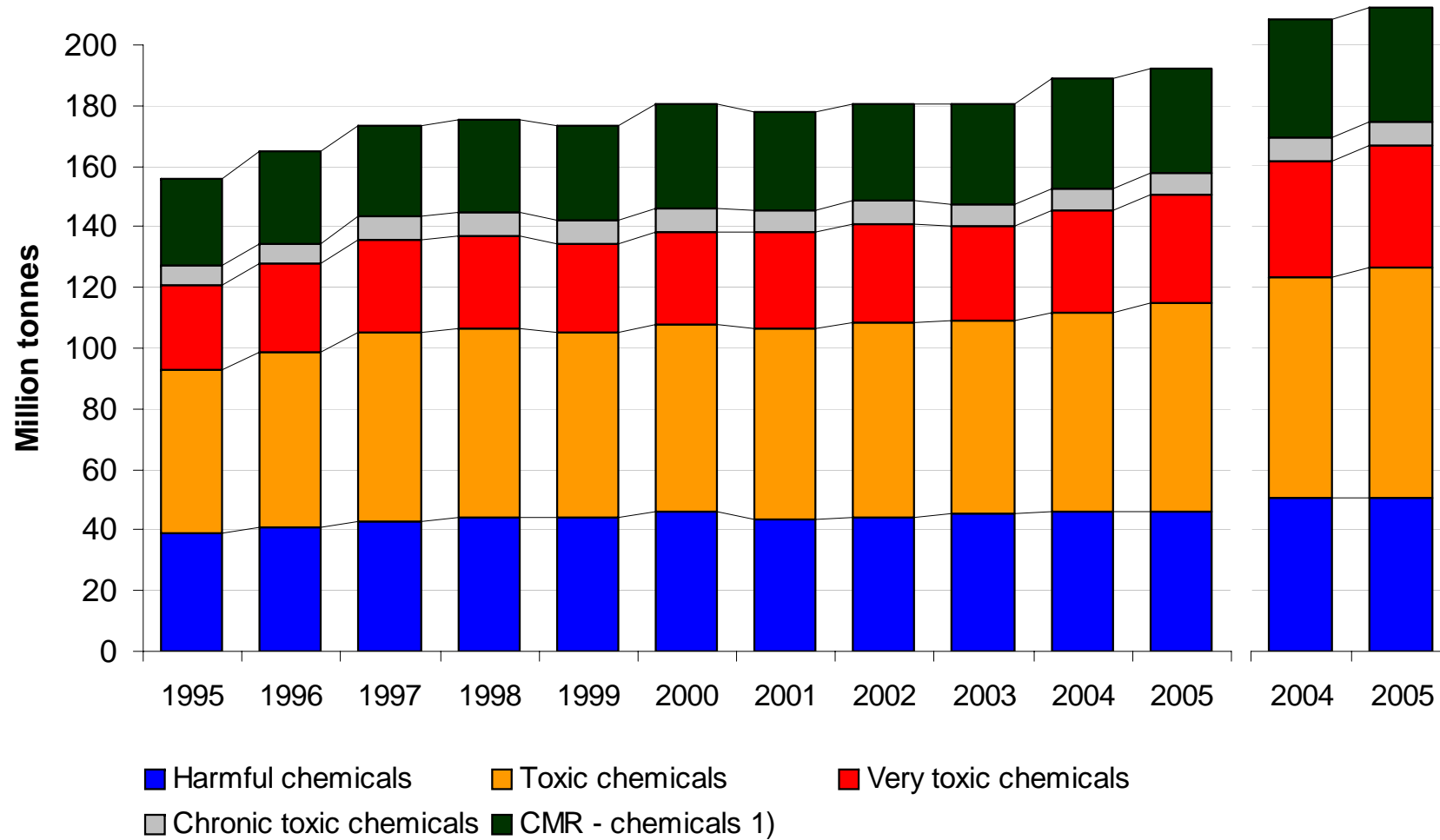


## ***“Supplemental” indicators***

- **Changes in quality of safety data sheets**
- **Availability of hazard data**
- **Availability of use and exposure data**
- **Toxic chemicals in households**
- **Production of toxic chemicals**
- **Trans-boundary transport of toxic chemicals**
- **Occupational skin diseases**
- **Changes in use patterns in Scandinavia**
- **Changes in classification and labelling**
- **Registration of new chemicals**
- **Use of alternative methods (non-testing and non-animal testing methods) for assessment of properties of chemicals**



PUBLIC HEALTH  
**Index of production of toxic chemicals, by toxicity class**  
 Measured in million tonnes per year for EU-15 (1995-2005) and EU-25 (2004-2005)



Source: Eurostat

1) Confidential data has been excluded, but makes no significant difference to the result

## ***“Supplemental” indicators***

- **For many supplemental and administrative indicators the baseline 2007 is zero, but methodology sheets are available and future database and database holder is identified**
  
- **For the other indicators:**
  - **snapshot 2007 is established**
  - **methodology sheets are available**
  - **reference database is „frozen“**
  - **future database and database holder is identified**



# Overall results, comments

- **Don't mix impact areas, don't aggregate to the meaningless**
- **risk scores span 8 orders of magnitude, broad differences in quality**
- **As an example of analysis, QS-total is almost identical for LPVs and MPVs, but a better quality is observed for HPVs**
- **Significant differences between groups of substances occur despite relative low total number of selected substances**



## ***Overall results, comments***

- **Resulting risk term is always a mix term between “real” changes and changes in quality of information, which could not be perfectly discriminated (nominal risk, relative score!)**
- **Not all effects by REACH covered by the R&Q system, but very crucial ones, and the system is accompanied by administrative and supplementary indicators**
- **Reasonable results, differentiation and sensitivity to changes**



## ***Overall results, comments***

- **Calculated figures correlate with a plausible risk profile, but absolute interpretation of the risk scores or the risk characterisation ratios should not be performed**
- **Relative comparisons between substances from the different production bands**
- **Quality scores seem to reflect what is expected: more information on HPV-substances and identified SVHC substances is available**
- **Many very informative analyses possible based on this indicator system now, but ...**  
**... the most relevant REACH - relevant changes we will see in 6 years from now**



# Outlook

- **2007: Publish report as Eurostat working paper**
- **in 2008: Improve statistical coverage by processing 100 additional substances**
- **Calculate supplemental indicators (e.g. toxic chemicals in households), maintain existing ones (e.g. Production / consumption of toxic chemicals)**
- **Follow administrative indicators in close collaboration with ECHA (e.g. registration of new chemicals)**
- **“Freeze” database for use in 2013**
- **Further investigate in supplemental indicators**
- **... / ... / ...**



## ***Further reading:***

**Project website:**

**<http://circa.europa.eu/Public/irc/dsis/reachbaselinestudy/library>**

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**Eurostat website:**

**<http://ec.europa.eu/eurostat>**

**ECHA website:**

**<http://ec.europa.eu/echa/>**



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