

Workshop with Stakeholders on the "Use of Epidemiological findings in Regulatory Pesticide Risk Assessment"

Paris, 18 February 2015

# Key questions for the scientists

## *Antonio Hernandez-Jerez*

<b>3<sup>rd</sup> session: the key questions to support epidemiological outcome</b>		Chair: Karin Nienstedt, DG Santè
13.15	The key questions for the regulatory assessor	Karine Angeli, ANSES
13.30	The key questions for the scientists	Antonio Hernandez Jerez, University of Granada, EFSA PPR Panel
13.45	The key questions for the regulatory risk managers	Karin Nienstedt, DG SANCO COM



## BACKGROUND: KEY QUESTIONS TO SUPPORT EPIDEMIOLOGICAL OUTCOMES

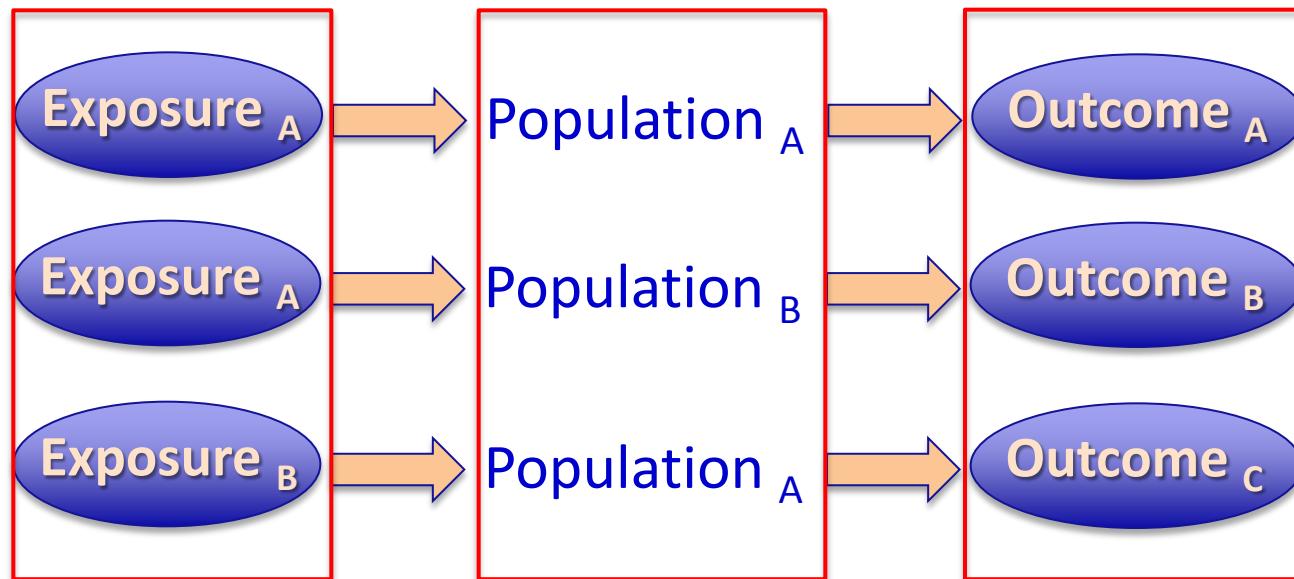
Epidemiological studies

↳ Health risks from chemical exposures  
↳ Could be applied for regulatory purposes?

## BACKGROUND: KEY QUESTIONS TO SUPPORT EPIDEMIOLOGICAL OUTCOMES

Epidemiological studies

Health risks from chemical exposures  
Could be applied for regulatory purposes?



Methodology used?

Target population

Outcome definition

Heterogeneity  
Inconsistency

Evaluation of consistency among epidemiological studies

Causal inferences for hazard identification





## BACKGROUND: KEY QUESTIONS TO SUPPORT EPIDEMIOLOGICAL OUTCOMES

### Ultimate goal for the scientists:

- Present epidemiological results informative for risk assessment.
- Provide a better understanding of the frequency, distribution and determinants of diseases in a quantitative way.
  - How?  
modern biostatistical techniques
- Define 'inconsistency' through a thorough interpretation of heterogeneity in the outcomes
- Properly define confounding factors
- Provide a link with experimental data



# ARE THE EPIDEMIOLOGICAL STUDIES FOR PESTICIDES A SPECIAL CASE ?

## Issues:

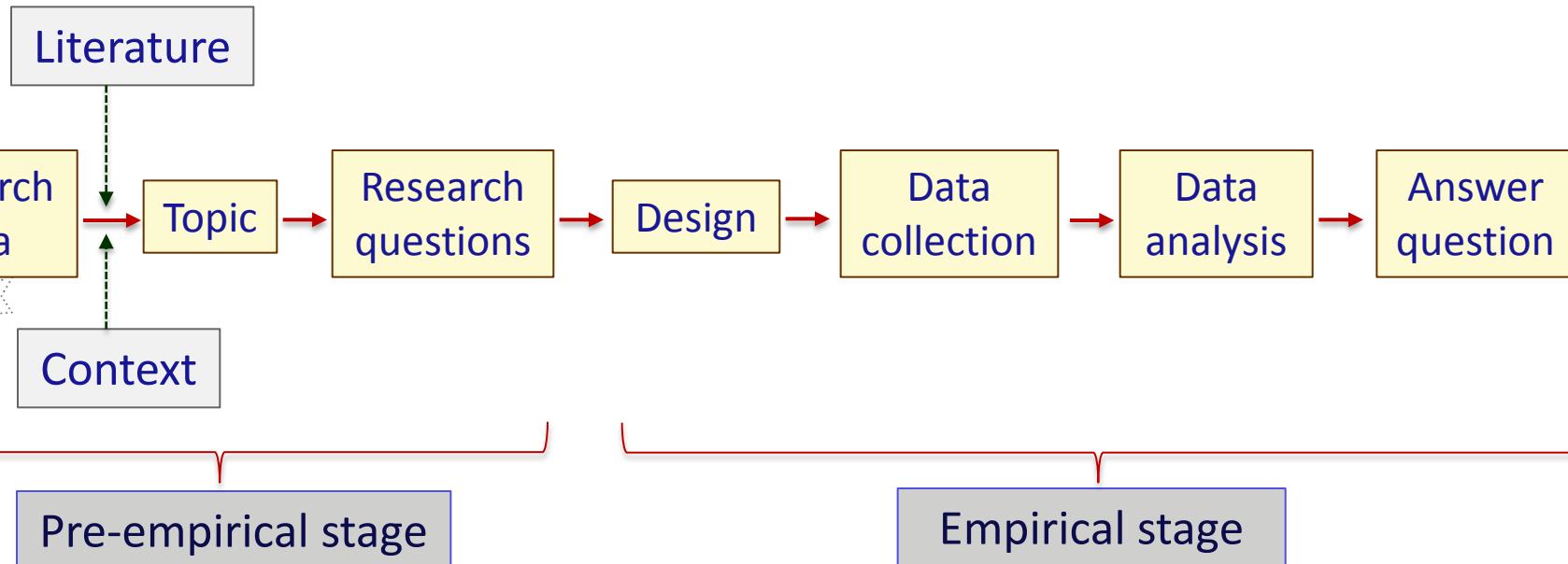
- When is an epidemiological study scientifically adequate?
- Should heterogeneity be evaluated as a qualitative step?
- Endpoints vs. 'upstream' effects; what is more sensitive in defining relationships?
- Can the AOP framework help in the assessment of plausibility through a biologically-based assessment of the study results?
- Can the AOP framework be used in a perspective evaluation of epidemiological data?
- Should the methodologies used for pesticide exposure assessment be improved and specified?
- Should biomarkers be introduced as a key step for the improvement of the exposure-effect relationship?
- Should we specify the key analytical tools for quantitative analysis?



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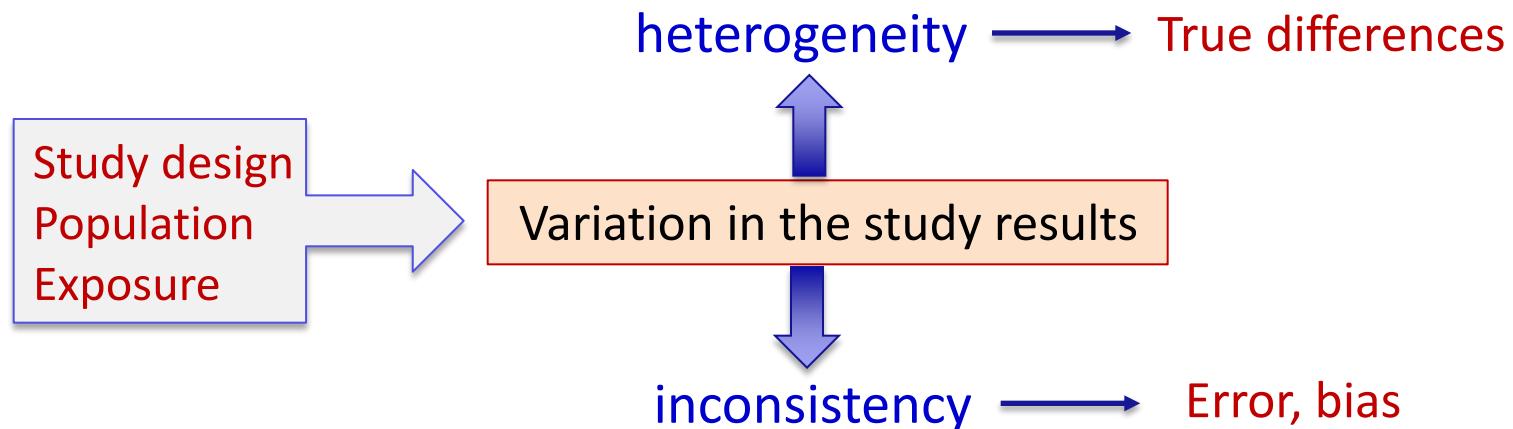




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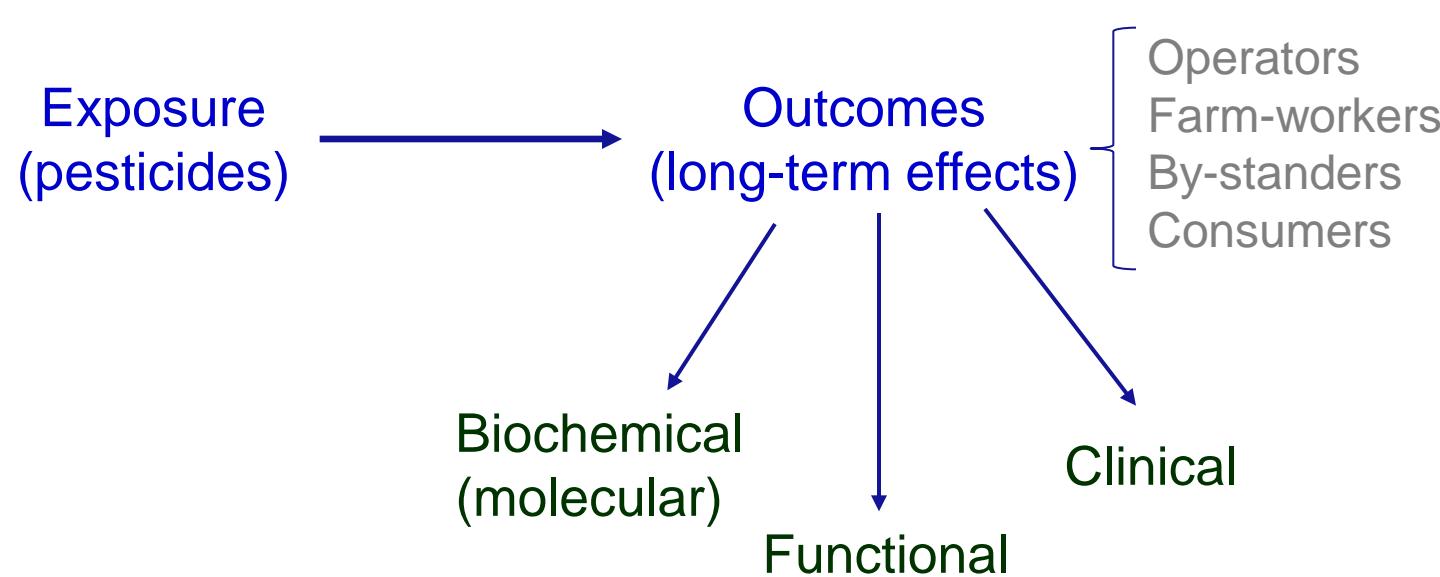




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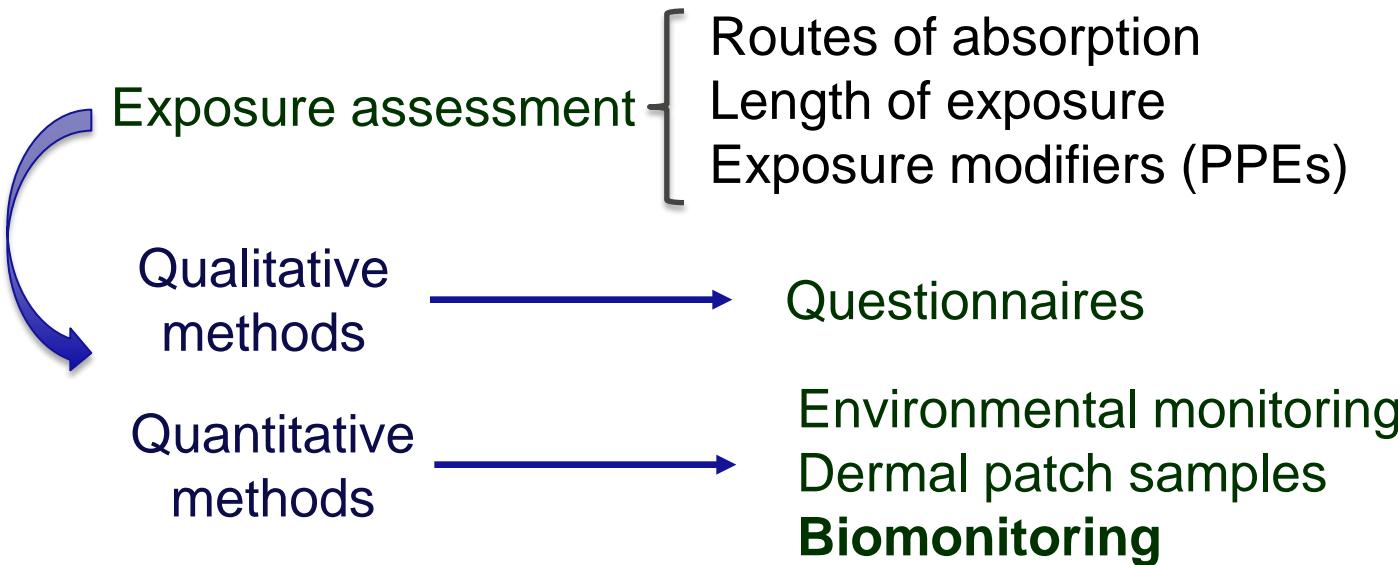
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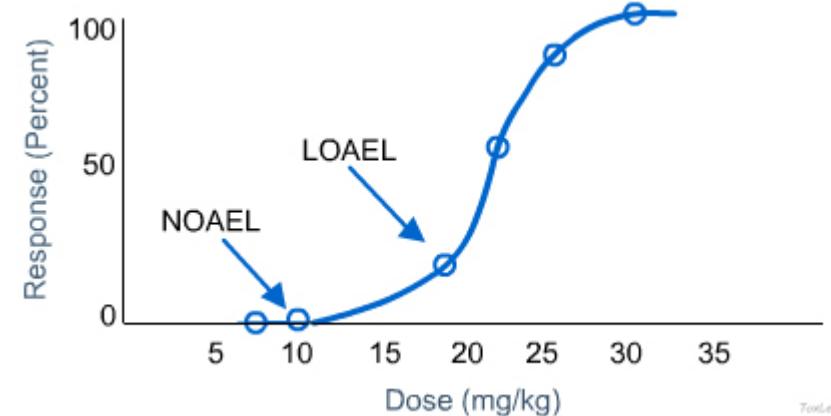
Toxicant	Macro-Molecular Interactions	Cellular Responses	Organ Responses	Organism Responses	Population Responses
Chemical Properties	Receptor/Ligand Interaction DBA Binding Protein Oxidation	Gene activation Protein Production Altered Signaling	Altered Physiology Disrupted Homeostasis Altered tissue development/ function	Lethality Impaired Development Impaired Reproduction	Structure Extinction



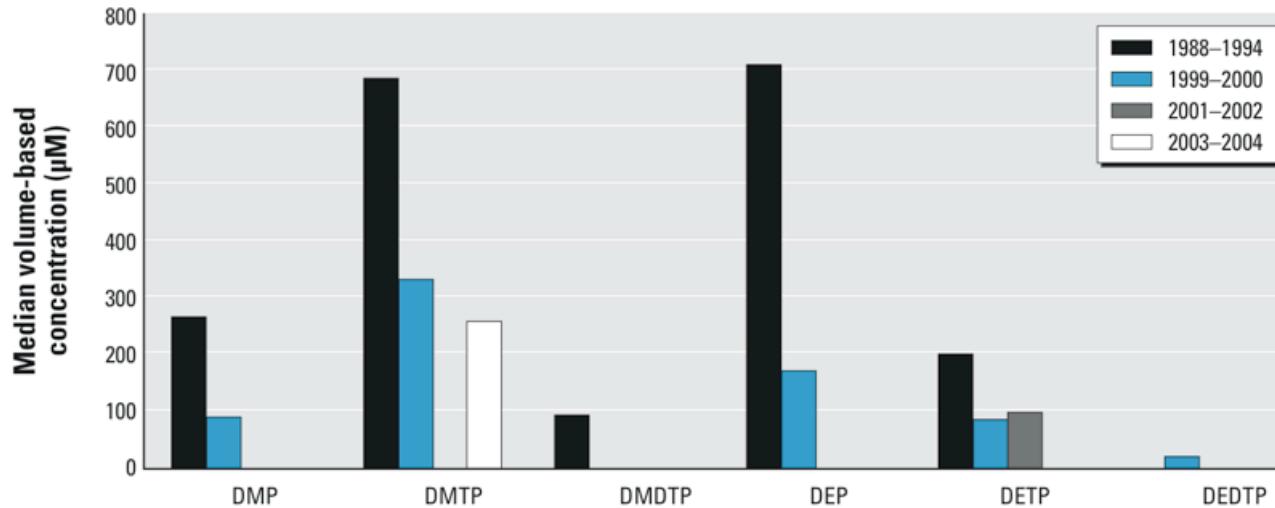
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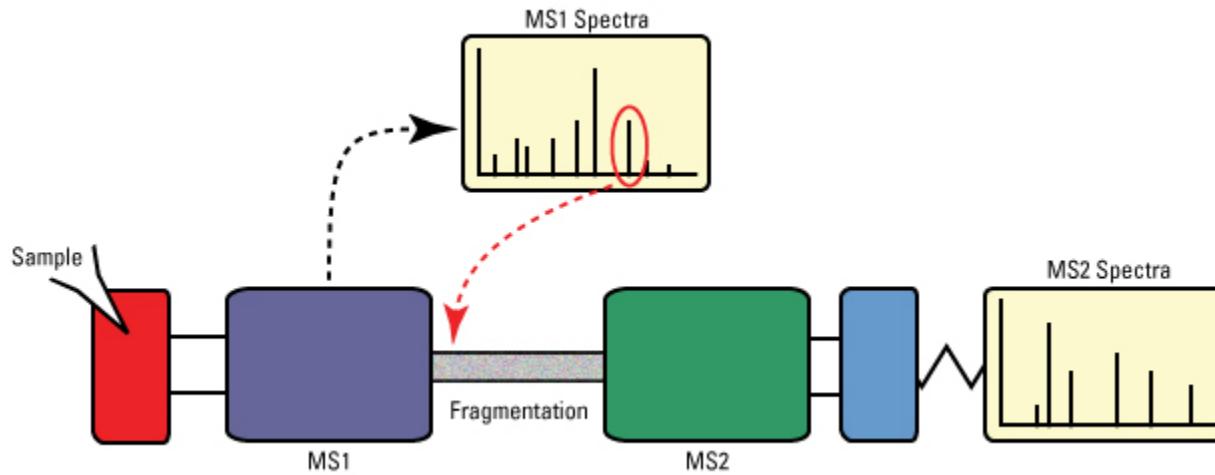
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## Interpretation of results?



- Should **biomarkers** be introduced as a key step for the improvement of the exposure-effect relationship?
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# QUESTIONS

