



**IS THERE A RISK USING PESTICIDES ?**

**SHOULD WE TRUST THE SCIENTISTS ?**

**HERMAN AUTRUP  
PROFESSOR EMERITUS**

# EU RISK ASSESSMENT PROCESS

NGO



SPECIAL  
INTEREST  
GROUPS

EUROPEAN COMMISSION

SCIENTIFIC COMMITTEES

EXPERT WORKING GROUPS

# SCIENCE IS THE JUDGE



GUILTY

RISK

NOT GUILTY

NO RISK  
SUSPECT

In toxicology it is nearly impossible to judge no-risk--perhaps risk

Some politicians:  
Ban the compound

# WHY ARE THE PUBLIC AGAINST PLANT PROTECTION PRODUCTS ?

GREEN TSUNAMI – Everything has to be back to nature – ecological farming

Different messages from scientists

Suffering from chemophobia

Do not trust the big industry and scientists working for the industry

# CONVENTIONAL vs ORGANIC FOOD

RISK

A photograph showing four individuals wearing full-body white protective suits and respirators, sitting around a dark wooden table. They are holding and examining fresh vegetables, including leafy greens and broccoli. The scene is set in a plain room with light-colored walls and a wooden floor. The overall tone is serious and cautionary, suggesting a high level of risk associated with the food being handled.

Pesticider!? Det fik vi også  
i går



# PESTICIDES IN DRINKING WATER

## HAZARD vs RISK



# HAZARD vs RISK



Hazard and high risk  
– potential exposure



Hazard and low risk  
no exposure

# HOW TO OBTAIN TOXICITY / HAZARD DATA

## QUALITY OF DATA !

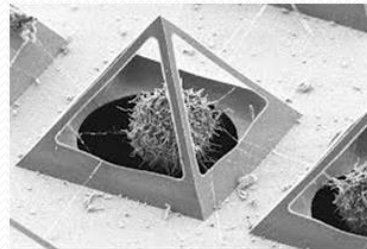
Relevance, complexity, costs



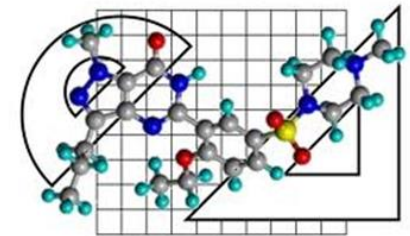
Humans



Animal  
experiments



*In vitro*



*In silico*

Uncertainty



# QUALITY OF ANIMAL DATA -

- ❖ **OECD Guidelines**
- ❖ **Compliance with GLP**
- ❖ **Scoring of quality of study**

**Klimish criteria**

**Scores 1 (reliable) and 2 (reliable with reservation)**

**Weight of evidence**

# TRANSPARENCY OF DATA

EPA(US) proposes to eliminate the use of publications in its policy discussions for which not all underlying data are not publicly available

NATURE/SCIENCE: A mechanism for suppressing important scientific evidence in policy-making, thereby threatening the public's well-being.

Arguments: Scientists (reviewers) are judging research publications even without the access to all underlying data. Scientists integrate results across multiple publications.

# QUALITY OF EPI STUDIES

## Golden standard

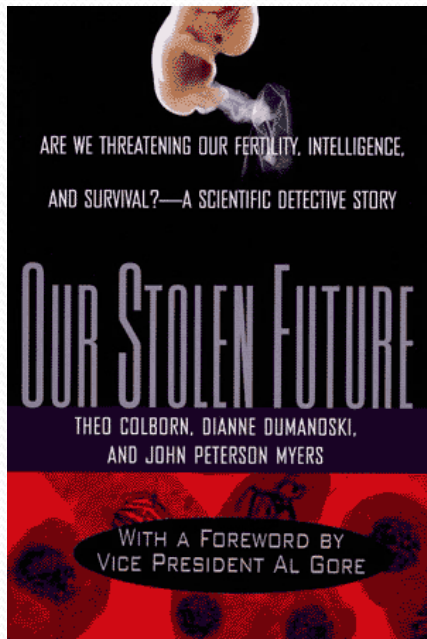
- Cohort-studies and Case-Control
- Hypothesis well defined by authors
- Use of many different pesticides – who is the culprit
- Poor exposure assessment – land and pesticide use

# ARE WE SUFFERING FROM CHEMOPHOBIA ?

Afraid of synthetic chemicals  
Misinformation or lack of knowledge  
Political or ethical issues  
Perception risk vs hazard  
Accidental episodes



# CONCERN: FEAR FOR CHEMICALS



# CONCERN: CHEMICALS IN BLOOD

**Danish Female 27 years**

**2 Phthalates (plastic softeners)**

**3 Heavy metals**

**5 Flameretardents**

**2 Artificial fragrant substances**

**2 Surface substances (PFOS/A)**

**4 Pesticides**

GreenPeace

**The presence of a chemical in blood is an indicator of exposure but is not a marker of risk**

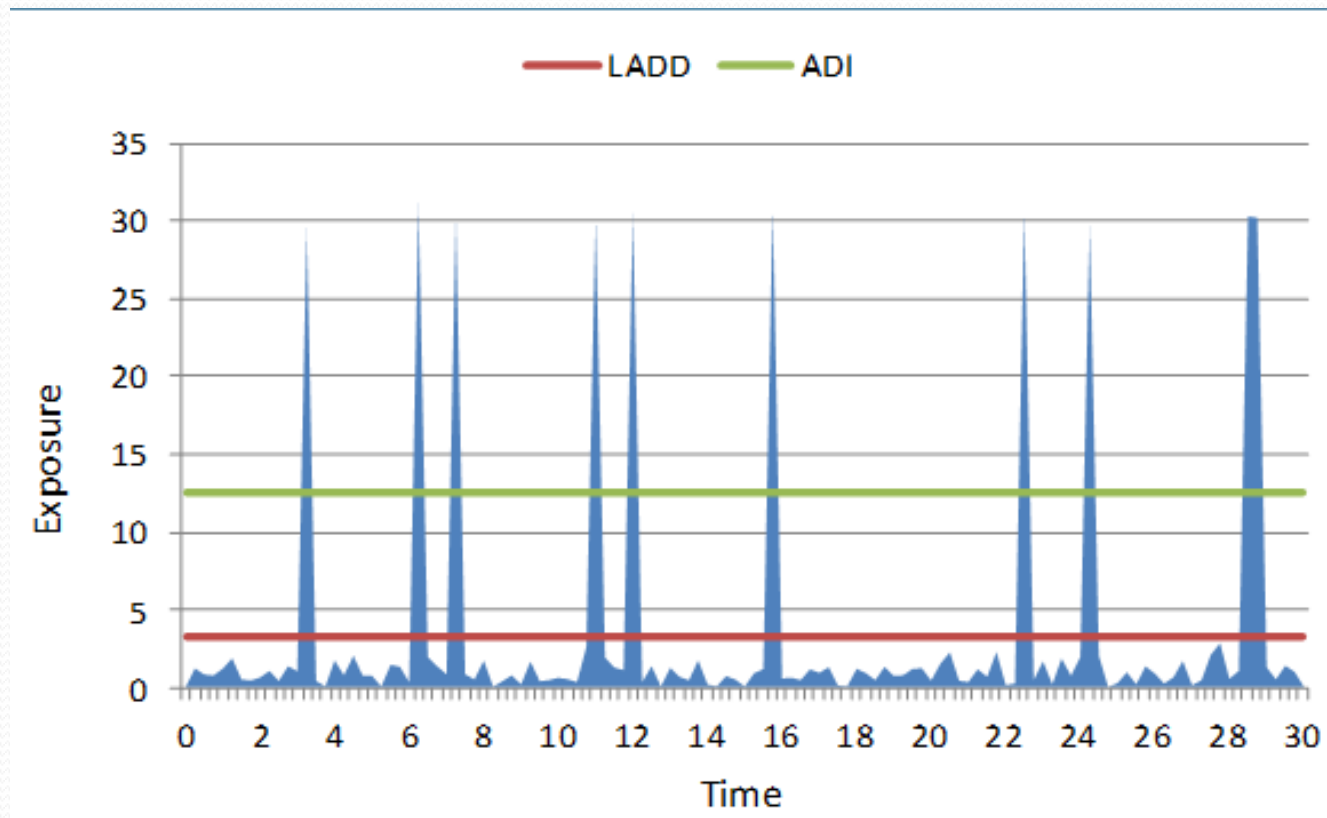
# CONCERN: FUTURE GENERATIONS



Windows of susceptibility

# RISK = DOSE x HAZARD

## LIFETIME ADJUSTED DAILY DOSE



TDI  
ADI  
MRL  
LADD

Concerns: Acute toxicity  
Bioaccumulation



# CONCERN : COCKTAIL EFFECTS

PUBLIC CONCERN: We are exposed to many different pesticides

Most likely not concomitant exposures to different pesticides

Synergisms or antagonisms are not expected to occur at low environmentally relevant dose level

# PLAYERS IN THE CONCERN CHAIN

SCIENTISTS

Publish in high ranking journals  
Self-promotion - more money for research

JOURNALISTS

News story on frontpage  
Primetime news on TV  
Case histories

PUBLIC

POLITICIANS

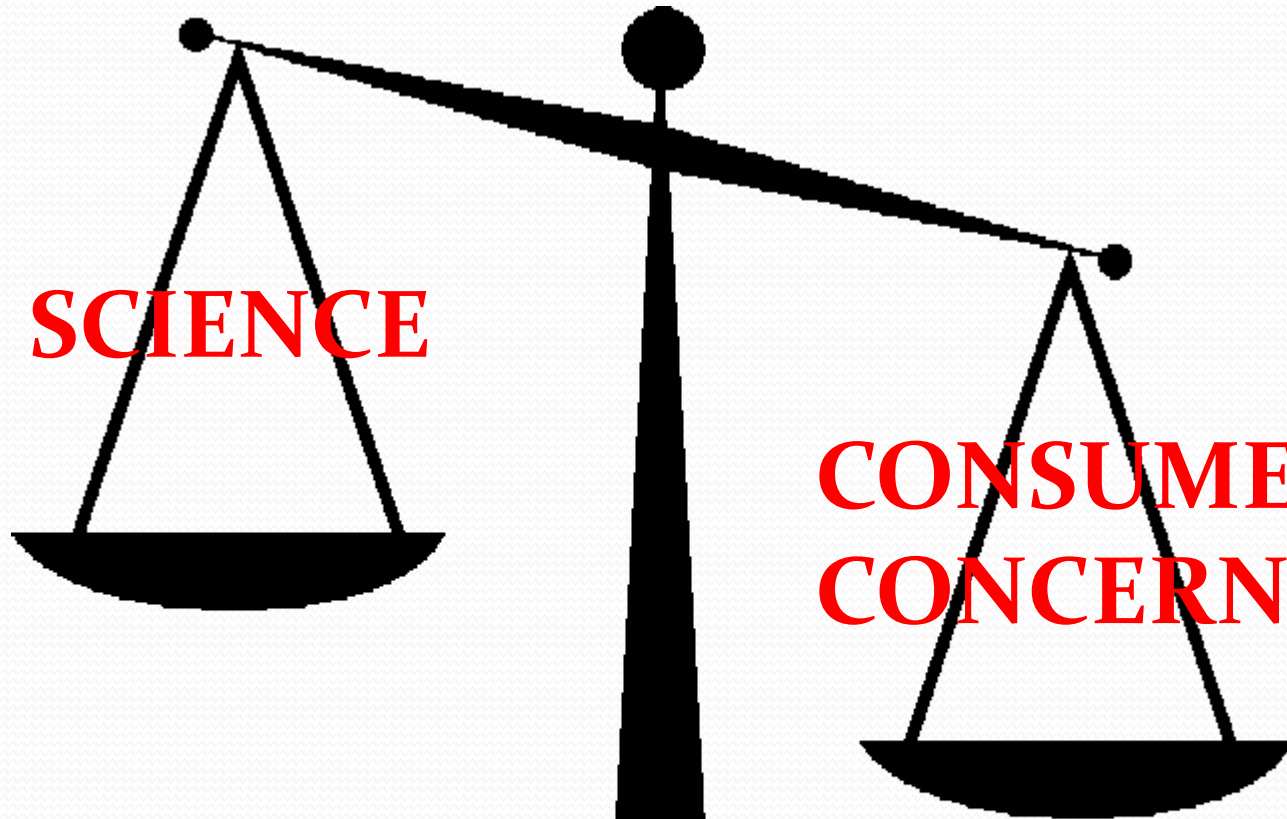
Promote issues for their political constituency  
Self-promotion on primetime news

NGO

Create concern - fundraising  
Raising awareness



# CONSUMERS ARE THE JUDGES



**SCIENCE**

**CONSUMERS  
CONCERN**

**RISK ASSESSMENT**  
Based upon facts

**PERCEPTION**  
Based upon emotions

# GLYPHOSATE CASE

## WHEN RISK ASSESSMENT CONFUSED THE PUBLIC



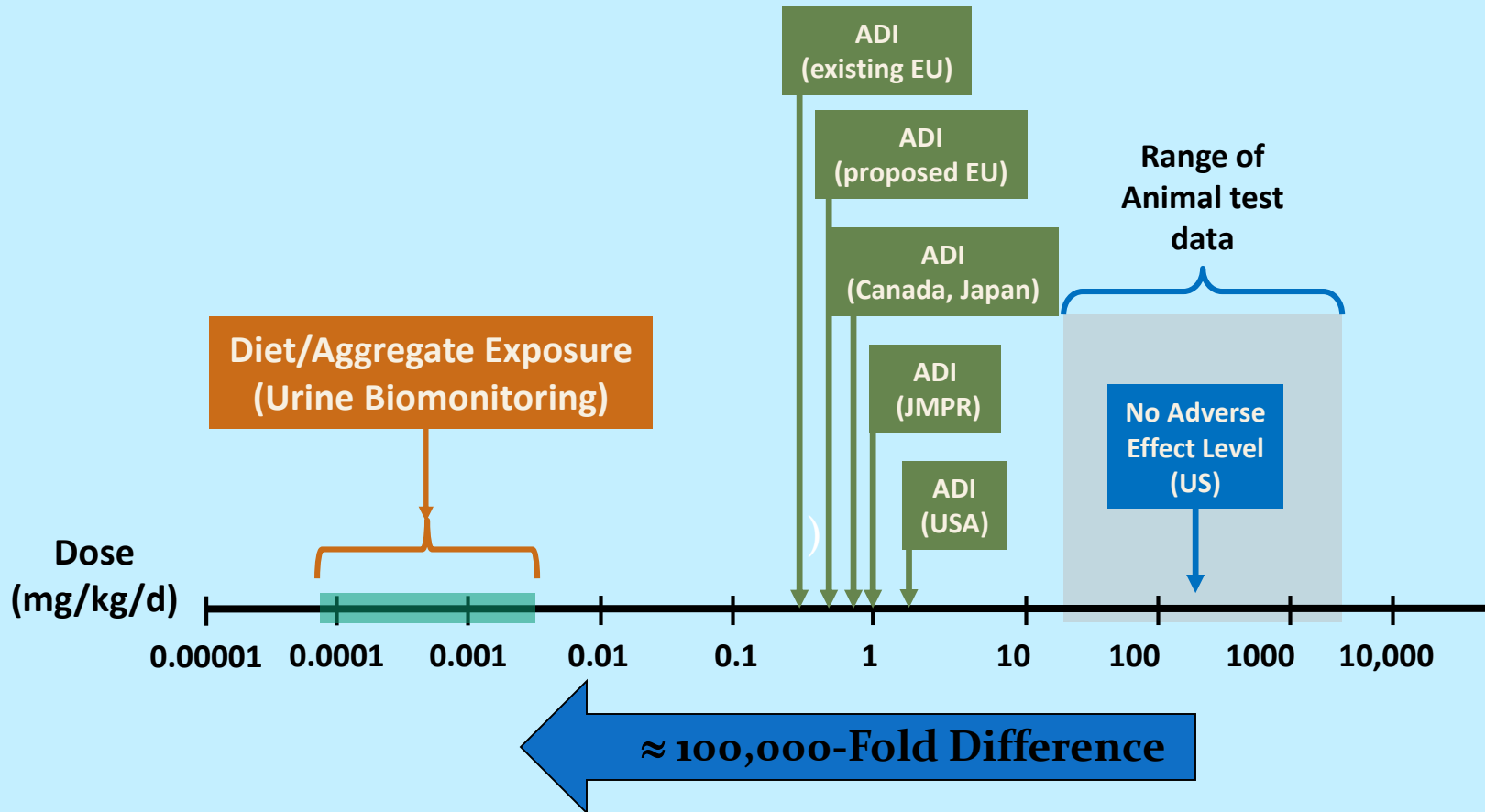


# GLYPHOSPHATE –CASE STUDY

## WHEN RISK ASSESEMENT CONFUSED THE PUBLIC

- ❖ Largest selling herbicide
- ❖ Large agrochemical company
- ❖ Linked to cultivation of GMO products
- ❖ Different conclusion between IARC and JMPR
- ❖ Become political rather than scientific

# GLYPHOSATE – DIETARY EXPOSURE OF GENERAL POPULATION (BASED ON URINARY EXCRETION)



ADI = Allowable Daily Intake

# WHO/IARC EVALUATION OF CARCINOGENS



## GLYPHOSATE GROUP 2A MARCH 2015



Evaluation of hazard (4 groups) and not risk

# IARC CONCLUSIONS

- ❑ Limited evidence from epidemiological studies  
Non-Hodgkin lymphoma  
3 retrospective case control studies (yes/no exp)  
Ignoring negative studies and AHS
- ❑ Sufficient evidence of carcinogenicity in experimental animals – Klimish criteria ?
- ❑ Strong evidence from mechanistic studies  
Genotoxicity and induction oxidative stress

Problem "Round up" rather than glyphosate

# EPA EVALUATION OF EDC – TIER 1 GLYPHOSATE

Application of Weight of Evidence  
Principle

No convincing evidence of potential  
interaction with estrogen, androgen or  
thyroid pathways

No additional testing (tier 2) is needed



# HOW TO DO RISK ASSESSMENT

**First,  
Kill  
All the  
Lawyers**

There Is One Lawyer  
Licensed in DC for  
Every Ten People.  
Are They Too Greedy?  
Are They Making Our  
Lives Miserable?  
Here's the Good,  
the Bad, and the Ugly.

Can Renee Poussaint  
Save Channel Seven?

Acupuncture, Herbs,  
Hypnosis, and Other  
Medical Alternatives

Readers Pick Their  
Favorite Restaurants



# Jury orders Monsanto to pay \$289 million to cancer patient in Roundup lawsuit



Extention for 5 years approved by the EU parliament on  
27/11-2017



## LIVING IN HARMONY WITH CHEMICALS

HAZARD  $\longrightarrow$  RISK  $\longleftrightarrow$  BENEFITS

# EU PROVISIONAL CRITERIA (2017)

❑ A substance (in PPP) shall be considered as having endocrine disrupting properties that may cause adverse effects in humans if they meets all of the following:

- ❑ It shows an adverse effect in an intact organism or its progeny
- ❑ It has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system
- ❑ The adverse effect is a consequence of the endocrine mode of action

❑ Considered as an EDC unless there is information demonstrating that the adverse effects identified are not relevant to human

❑ This is therefore a hazard based approach with a possible waiver for negligible exposure