Swiss Centre for Applied Human Toxicology
Schweizerisches Zentrum für Angewandte Humantoxikologie
Centre Suisse de Toxicologie Humaine Appliquée
Centro Svizzero di Tossicologia Umana Applicata

EUROTOX Basic Toxicology Course

Risk Assessment and Risk Management

Risk characterization, Use of human data, Risk management, Risk-benefit analysis, Risk perception, Risk communication

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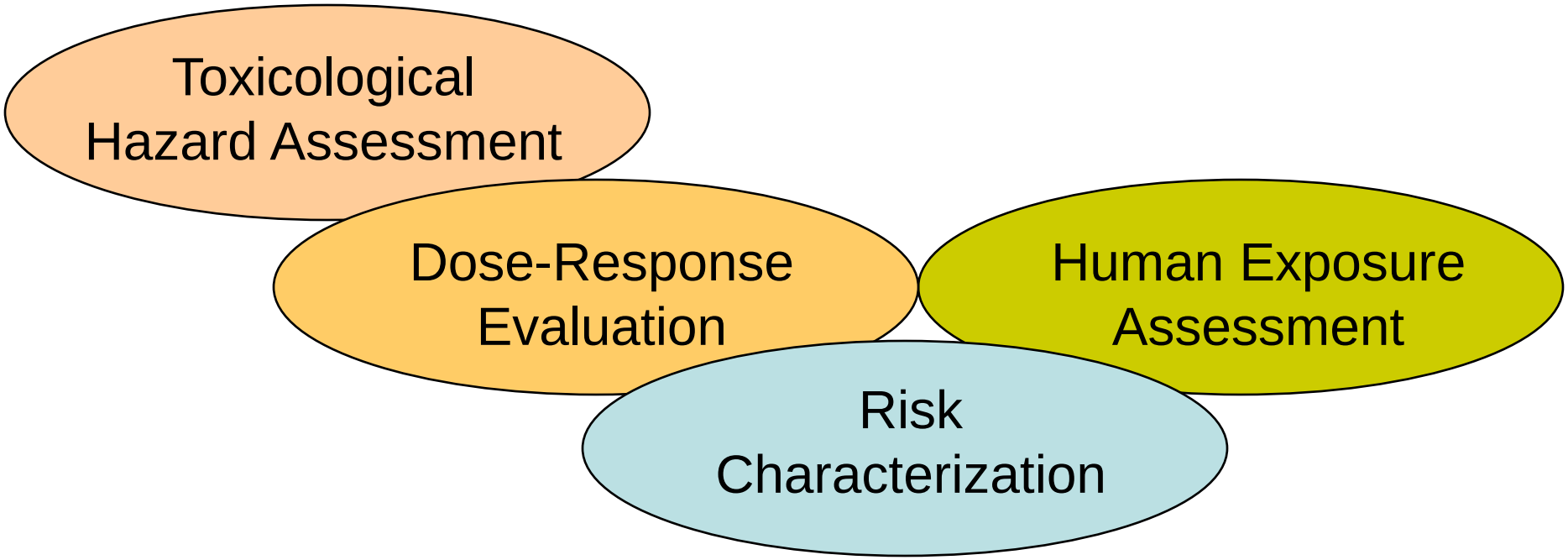
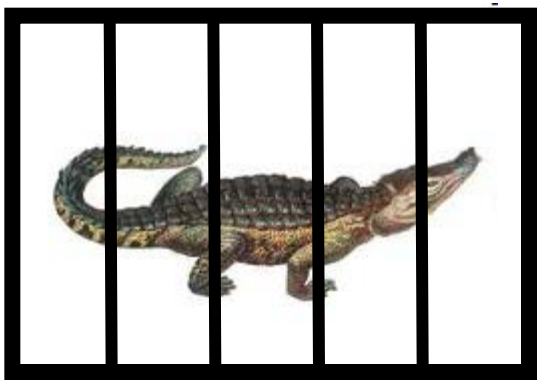
Stages of Risk Assessment

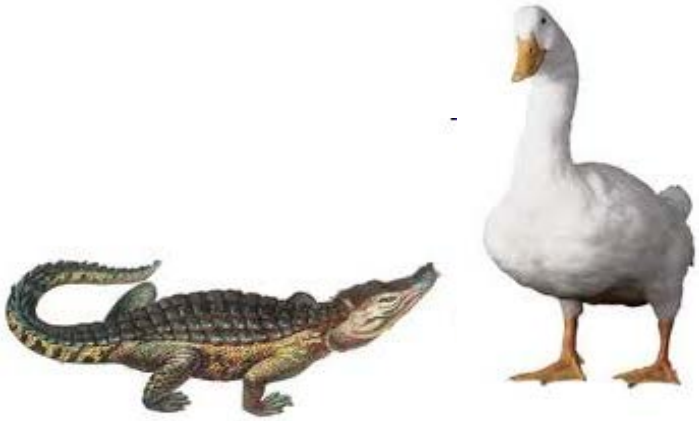


The qualitative and, wherever possible, quantitative determination of the probability of occurrence of adverse effects of an agent in an organism under defined exposure conditions.

Risk characterization



Hazard



Hazard x Exposure

= Risk

Risk characterization

What dose is used for risk assessment?

A: The dose which, with reasonably certainty, will not harm humans = Experimental threshold dose divided by uncertainty factors (interspecies, intra-individual, other)

$$RfD(mg/kg/day) = \frac{NOEL(mg/kg/day)}{Uf_{inter} * Uf_{intra} * Uf_{other}}$$

- Reference dose "RfD" (EPA pesticides, chemical): estimate of the amount of a chemical that a person can be exposed to on a daily basis that is not anticipated to cause adverse health effects over a person's lifetime. Sensitive subgroups are included, and uncertainty may span an order of magnitude.
- Acceptable daily intake "ADI" (WHO food additives): estimate of the amount of a substance in food or drinking water, expressed on a body mass basis (usually mg/kg body weight), which can be ingested daily over a lifetime by humans without appreciable health risk. For calculation of the daily intake per person, a standard body mass of 60 kg is used.
- Tolerable daily intake "TDI" (same as ADI but for contaminants)
- Virtually safe dose "VSD" (estimated lifetime cancer risk <10E-6)
- Threshold of toxicological concern

Risk characterization

Threshold of toxicological concern (TTC)

S. Barlow. ILSI Europe Concise Monographs Series 2005:1-31.

http://www.ilsi.org/Europe/Publications/C2005Thres_Tox.pdf

Threshold of toxicological concern (TTC)

- Based on database with >700 carcinogens
- Probability distribution of carcinogenic potencies was used to estimate daily exposure level (µg/person) of most carcinogens which would give rise to less than a one in a million (1 x 10E-6) upper bound lifetime risk of cancer ("virtually safe dose").
- Individual potency calculated by simple linear extrapolation from the dose inducing 50% tumour incidence in the most sensitive species and most sensitive site (TD50) to a 1 in 10E-6 incidence (several "worst case" assumptions).
- Standard TTC value = 1.5 µg/person/day.
- For substances with structural alerts that raise concern for potential genotoxicity, a 10-fold lower TTC (0.15 µg/day) is used, except in pharmaceuticals with benefit, for which a 10-5 lifetime risk of cancer can be justified
- Some very high potency genotoxic carcinogens are excluded from the TTC approach (aflatoxins, N-nitroso and azoxy compounds); substance-specific toxicity data are required for such substances

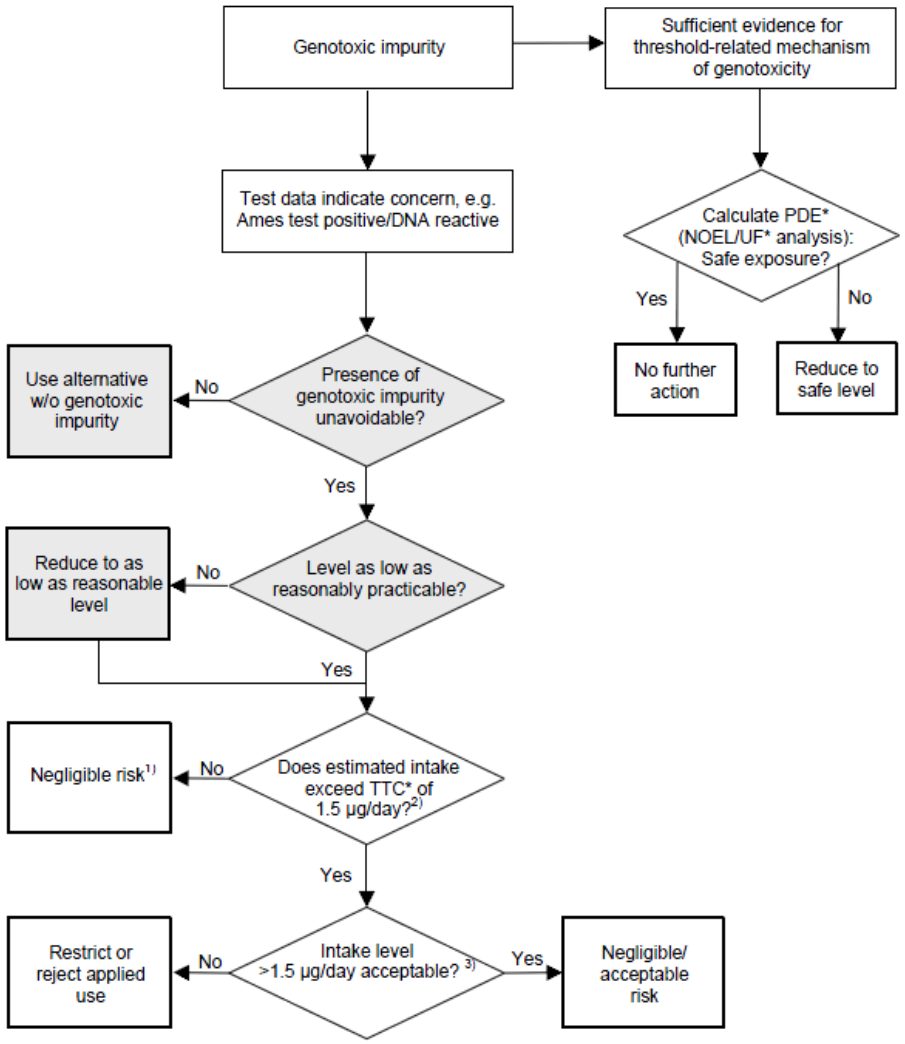
(http://www.ema.europa.eu/docs/en_GB/document_library/ Scientific_guideline/2009/09/WC500002903.pdf)

Risk characterization

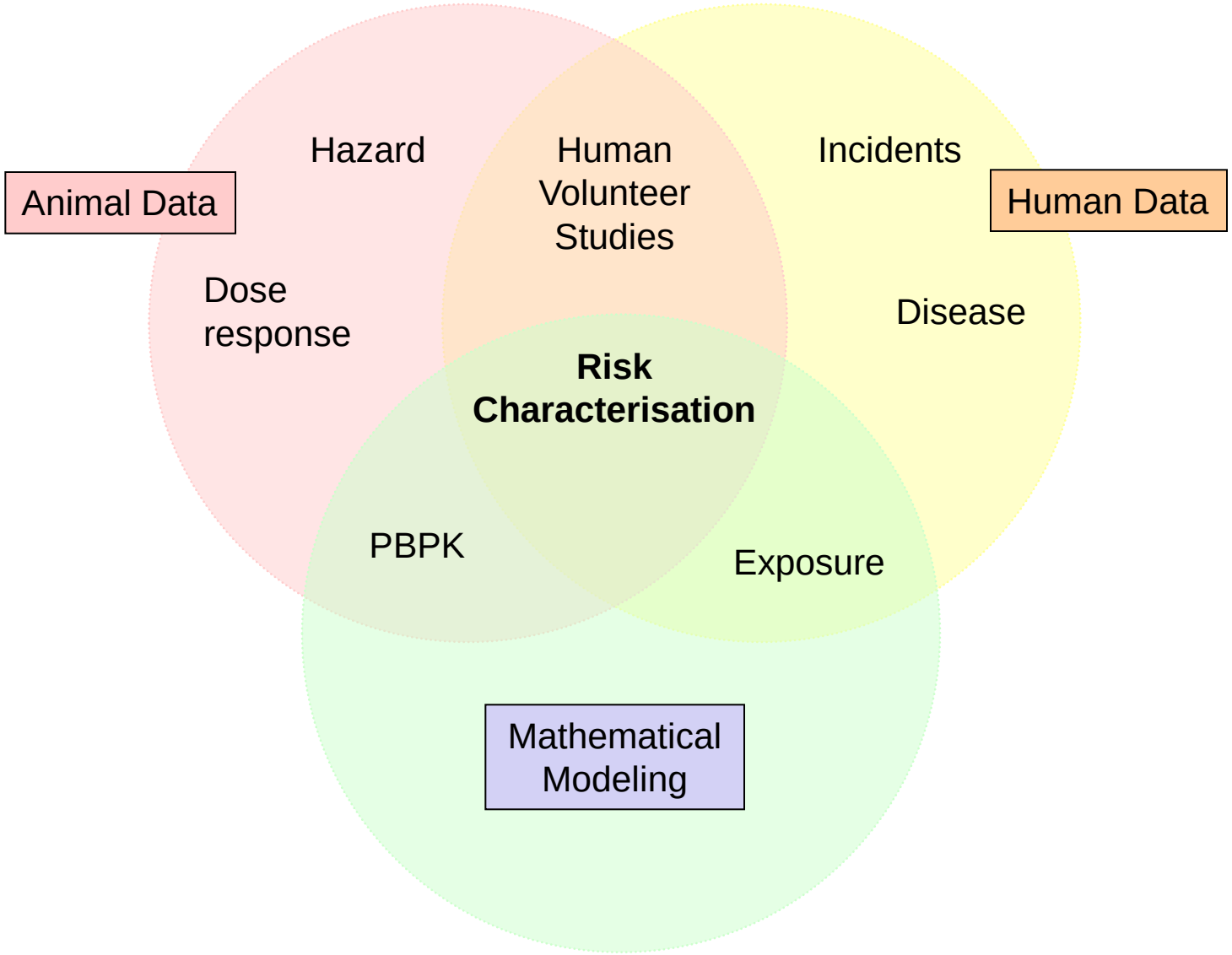
TTC example

Limits of genotoxic impurities

(CPMP/SWP/5199/02, EMA London, June 2006; http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002903.pdf)



Human Data in Risk Assessment?



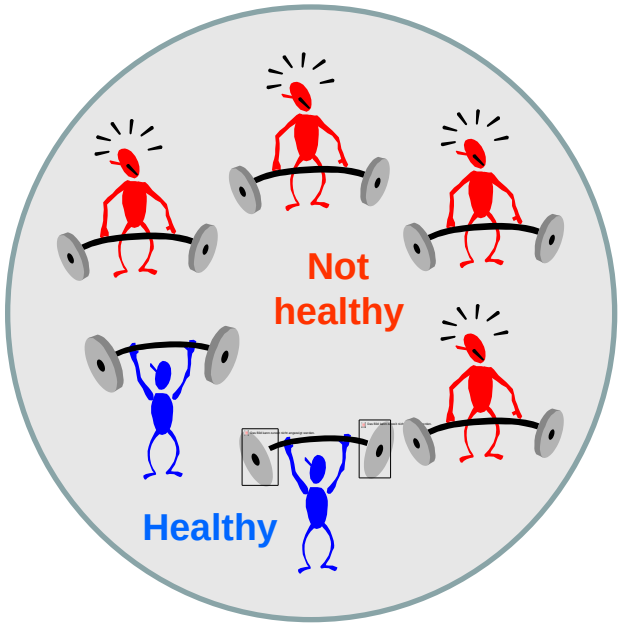
Common types of epidemiology studies

- **Ecological study**
- **Cohort study**
- **Case-control study**
- **Cross-sectional study**

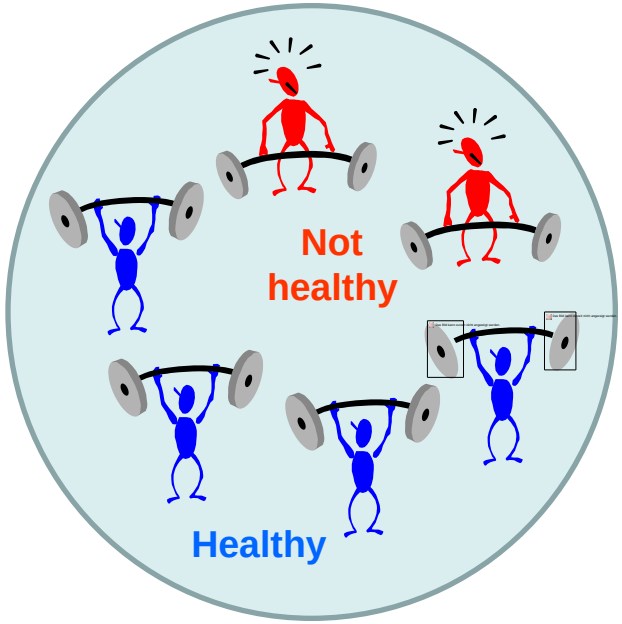
Ecological study

- Compares populations, not individuals.
- Investigates statistical associations between risk factors and health outcomes
- More suited for hypothesis-generating than hypothesis-testing

Area 1
'Exposed'

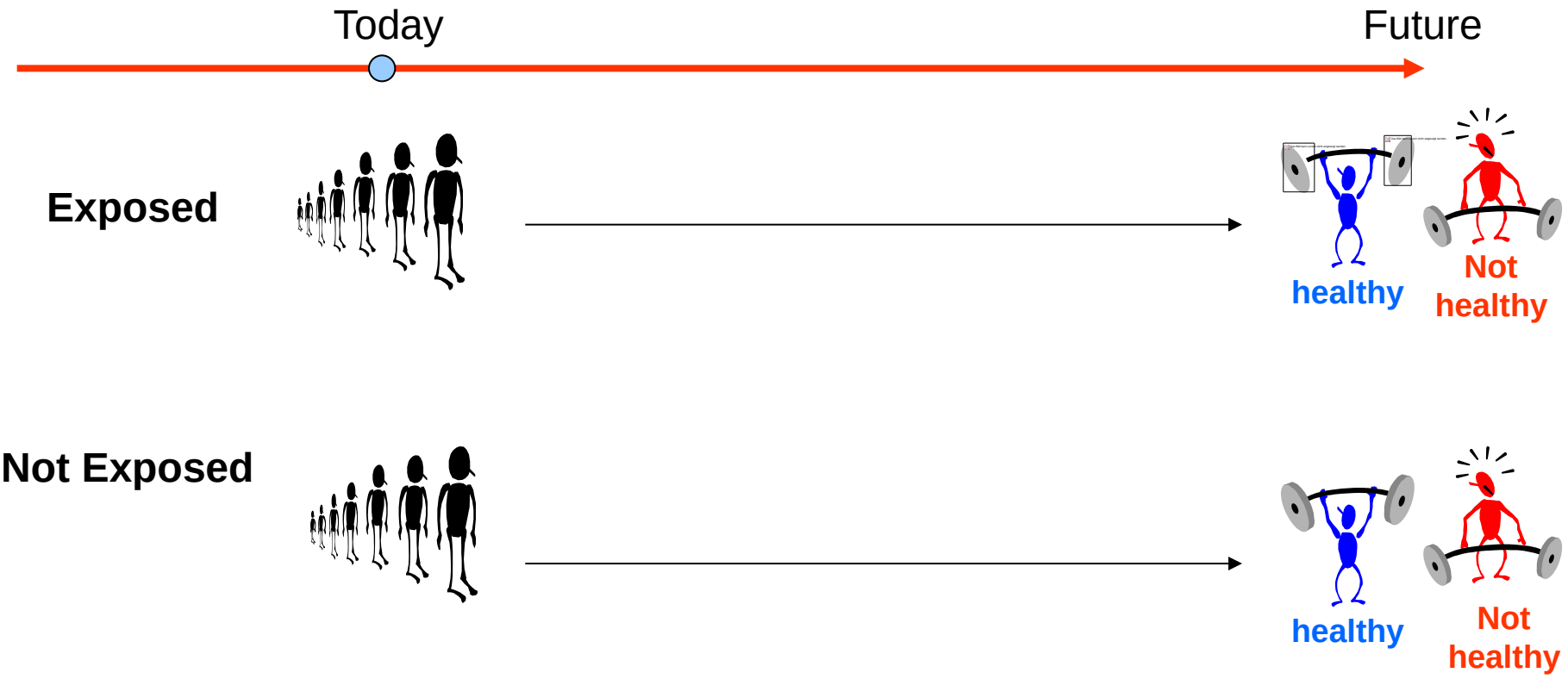


Area 2
'Not Exposed'



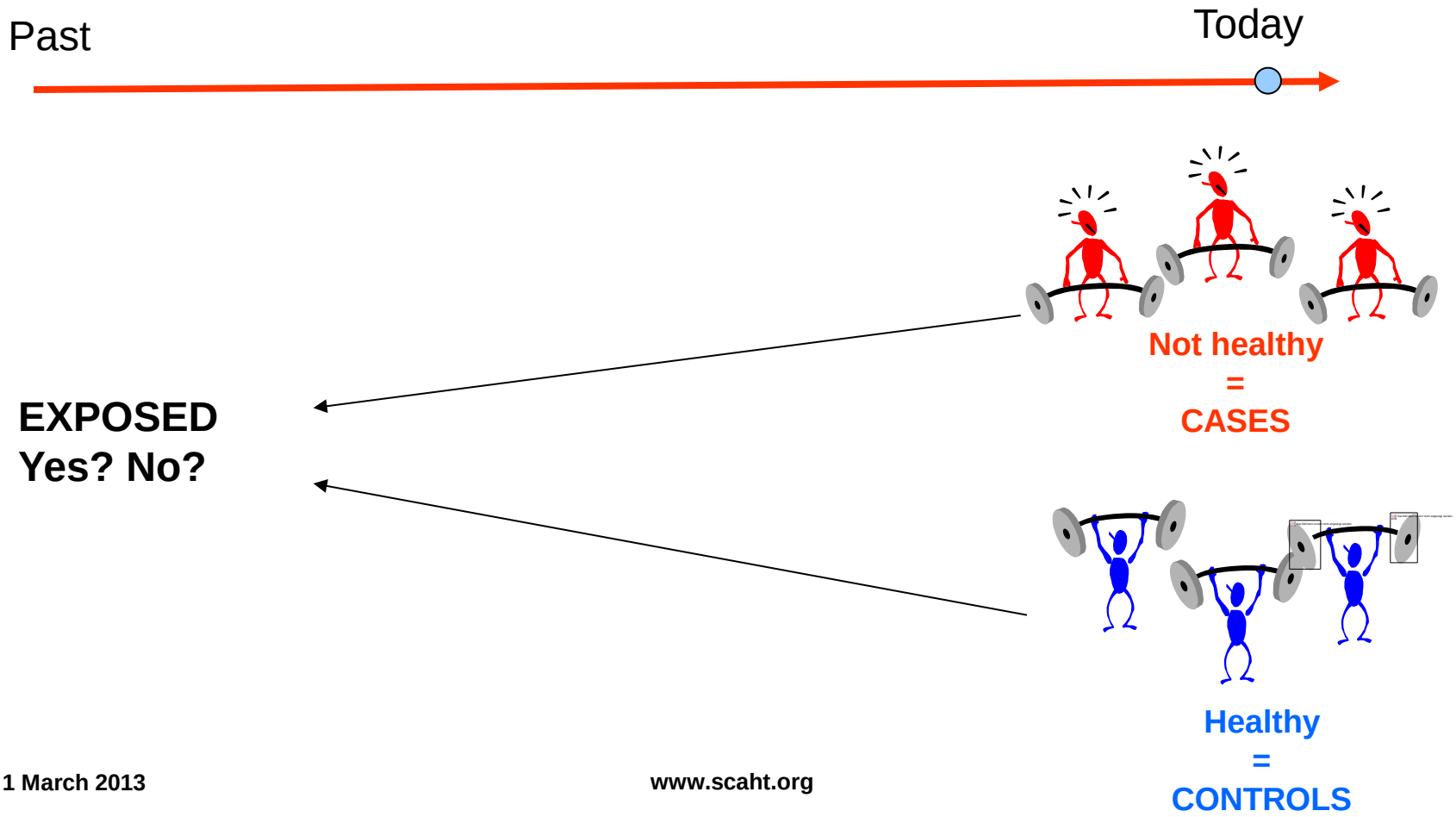
Cohort study

- Compares groups of people based on exposure.
- Identification of exposed and non exposed persons at the beginning of the study.
- Tries to determine whether disease occurs more or less frequently among a group of exposed people compared to a group of non-exposed people



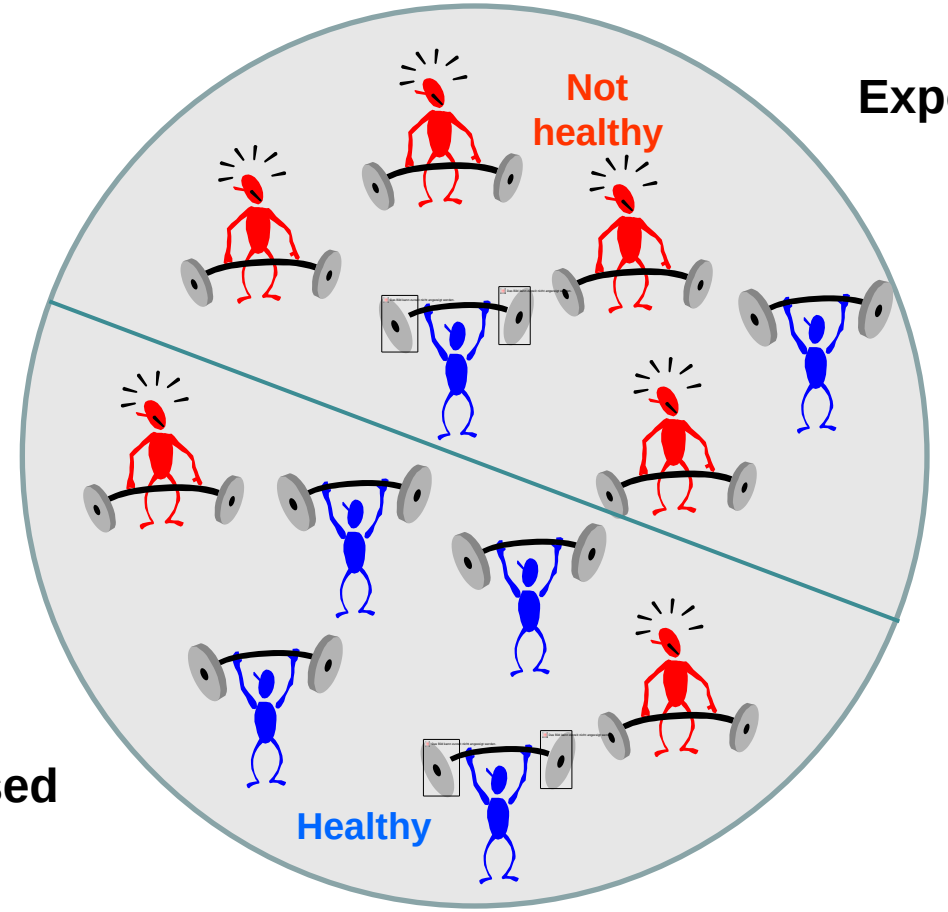
Case control study

- Compares groups of people based on disease.
- Identification of cases, controls at the beginning of the study
- It examines whether exposure occured more or less frequently in persons who have a particular disease than in persons who do not have the disease.



Cross-sectional study

- Information is collected over a short period of time.
- Investigates prevalence of health outcomes in relationship to risk factors
- May involve special data collection, but often relies on data originally collected for other purposes



Exposure assessment in epidemiology studies

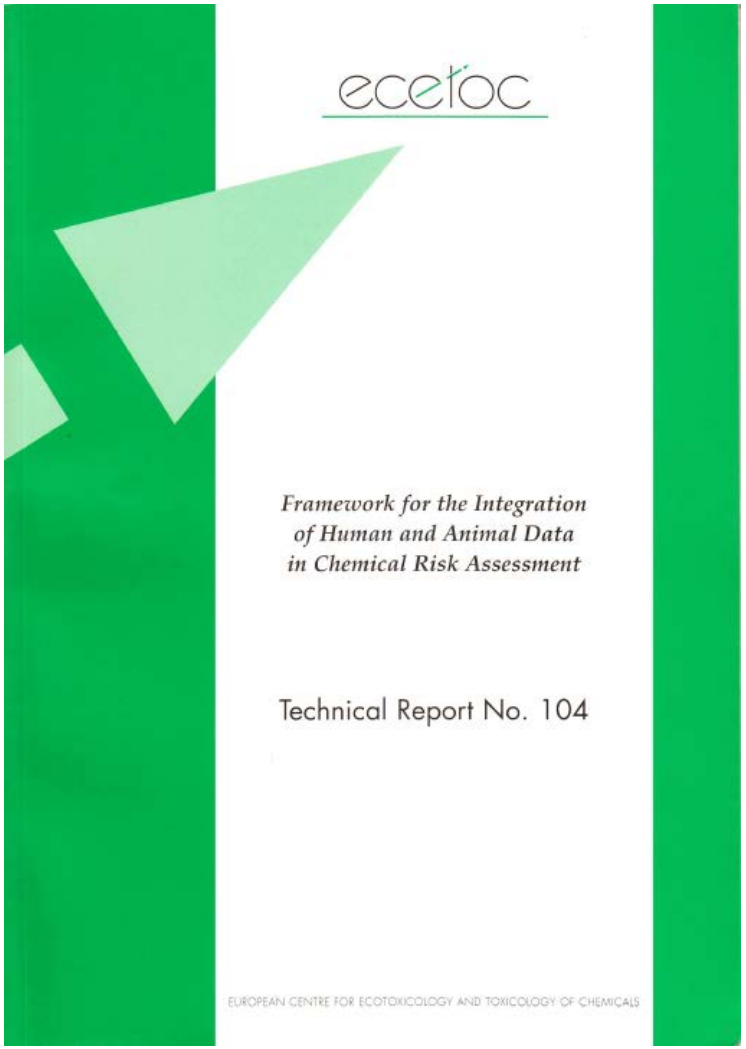
- **In epidemiology the primary goal of exposure estimation is to correctly rank individuals with regard to exposure levels in the study population, to avoid** MISCLASSIFICATION**:**
  - People not truly exposed could be classified as exposed people
  - People truly exposed could be classified as not exposed people
- **Problems of misclassification would tend to bias disease risk estimates associated with occupational exposure.**
- **To reduce exposure misclassification it is critical to separate the non exposed from the low and moderate exposures and to correctly identify the highly exposed individuals.**

Association vs. Causation – Bradford Hill 'Viewpoints'

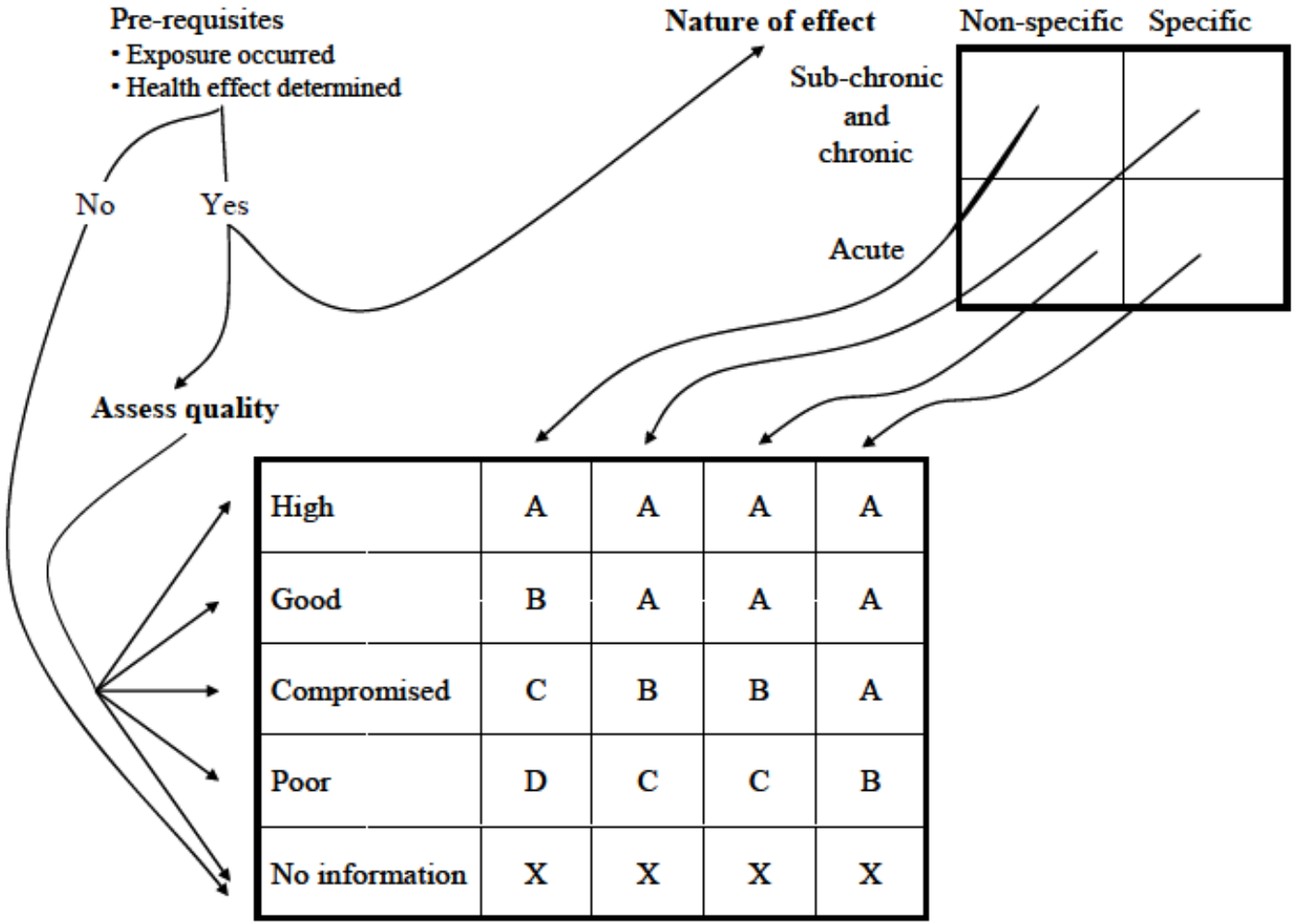
Strength	**The stronger the association, the more likely it is that the association is causal**
Consistency	**The reproducibility of a finding 'by different persons, in different places, circumstances and times' (Hill, 1965)**
Specificity	**A specific exposure should elicit a specific effect (e.g. vinyl chloride and hemangiosarcoma of the liver)**
Temporality	**Exposure must have preceded illness**
Biological gradient	**Dose-response, i.e. the higher the exposure, the more likely it is that disease develops**
Plausibility	**Is there a plausible mechanism? (NB. Depends on the knowledge of the time)**
Coherence	**The cause and effect interpretation should not seriously conflict with the known facts about the course and biology of the disease**
Experimental evidence	**Reduction in disease rates if the exposure diminishes (e.g. smoking cessation and lung cancer rates)**
Analogy	**Similarity of observed effects with similar agents or exposure circumstances**

Integrating Human and Animal Data

- **European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC)**
- **Workshops on human data**
  - Use of human data in risk assessment (2004)
  - Use of human data for derivation of no effect levels and minimum effect levels (DNEL, DMEL) (2007)
- **Task force (2006 – 2008)**

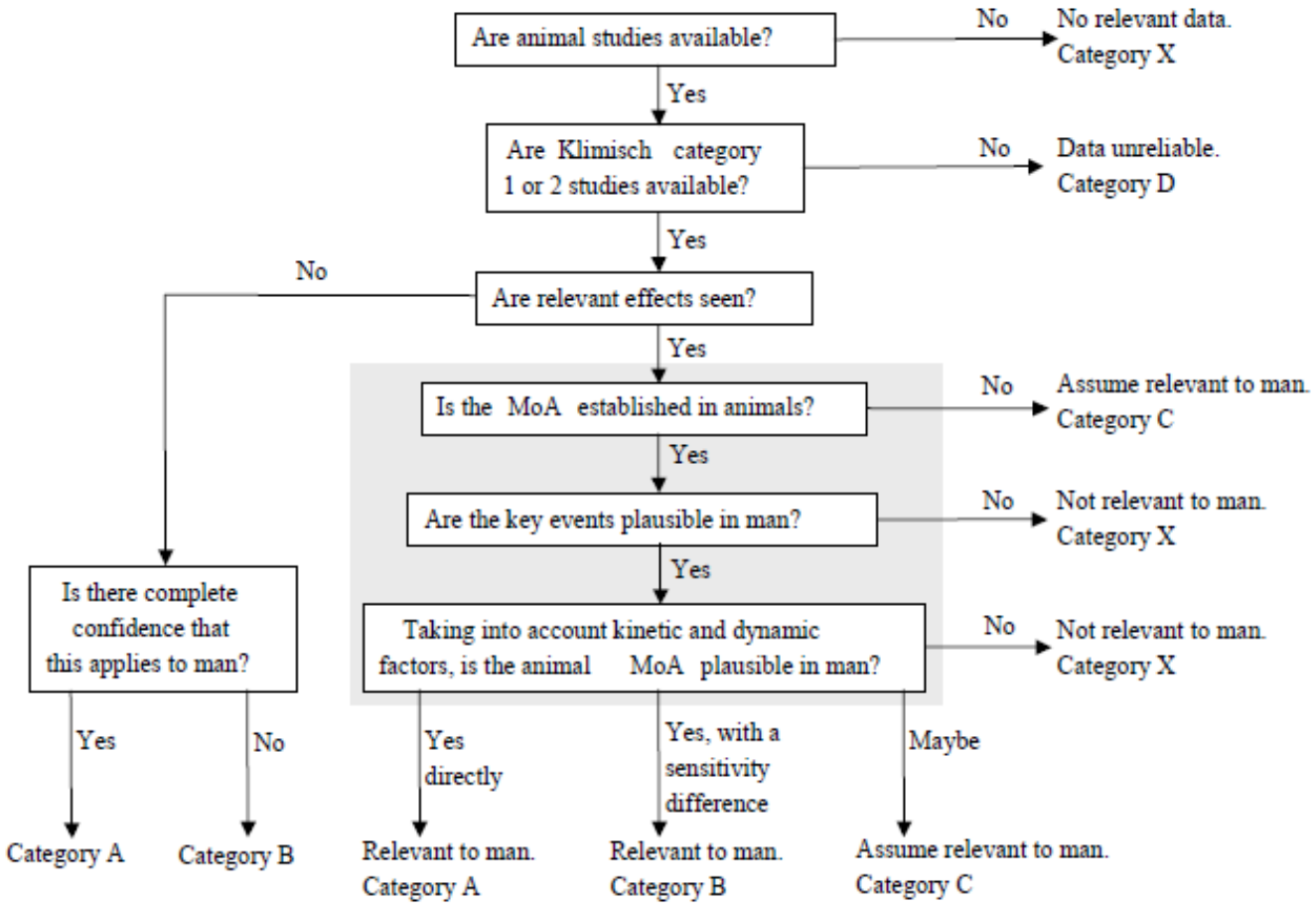


ECETOC Framework Step 1:
Assessing the quality of the human data set

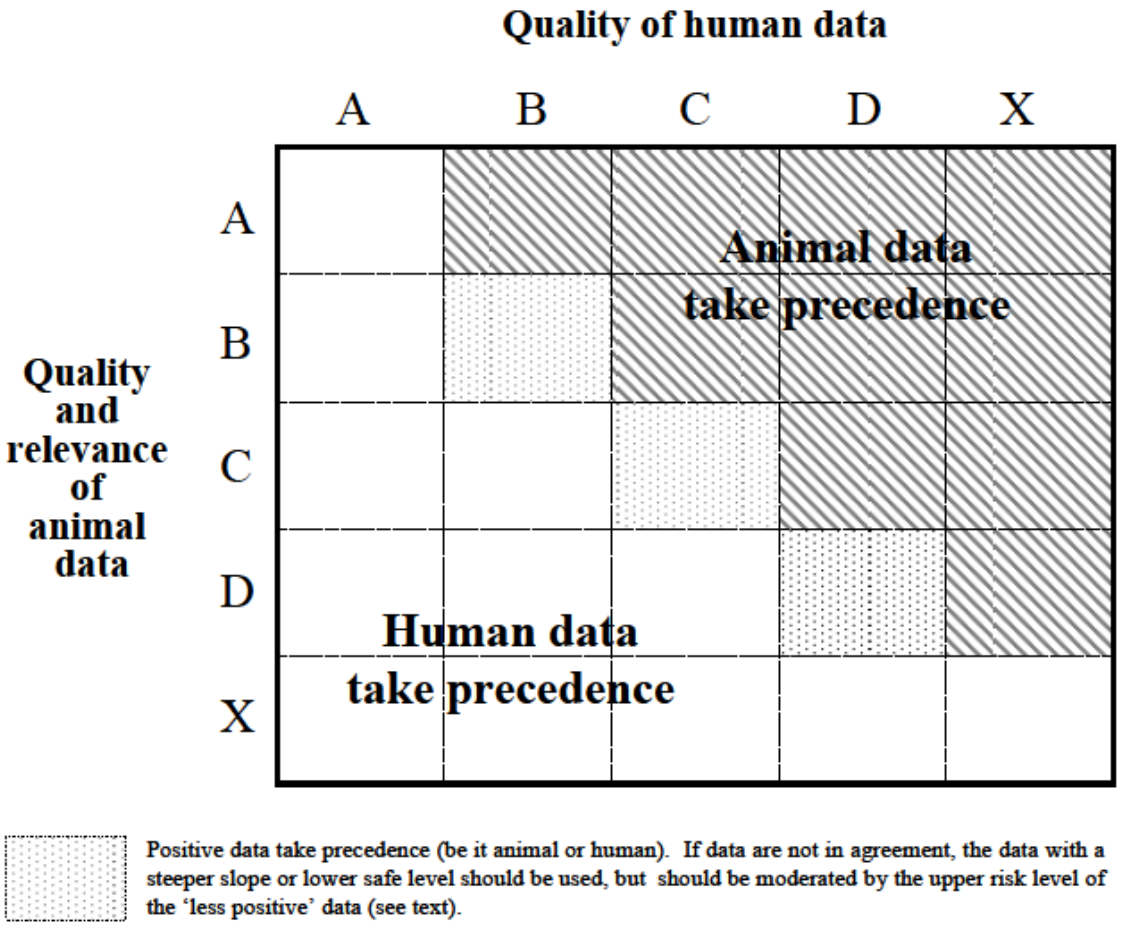


High	A	A	A	A
Good	B	A	A	A
Compromised	C	B	B	A
Poor	D	C	C	B
No information	X	X	X	X

ECETOC Framework Step 2:
Categorising the quality and relevance of the animal data set

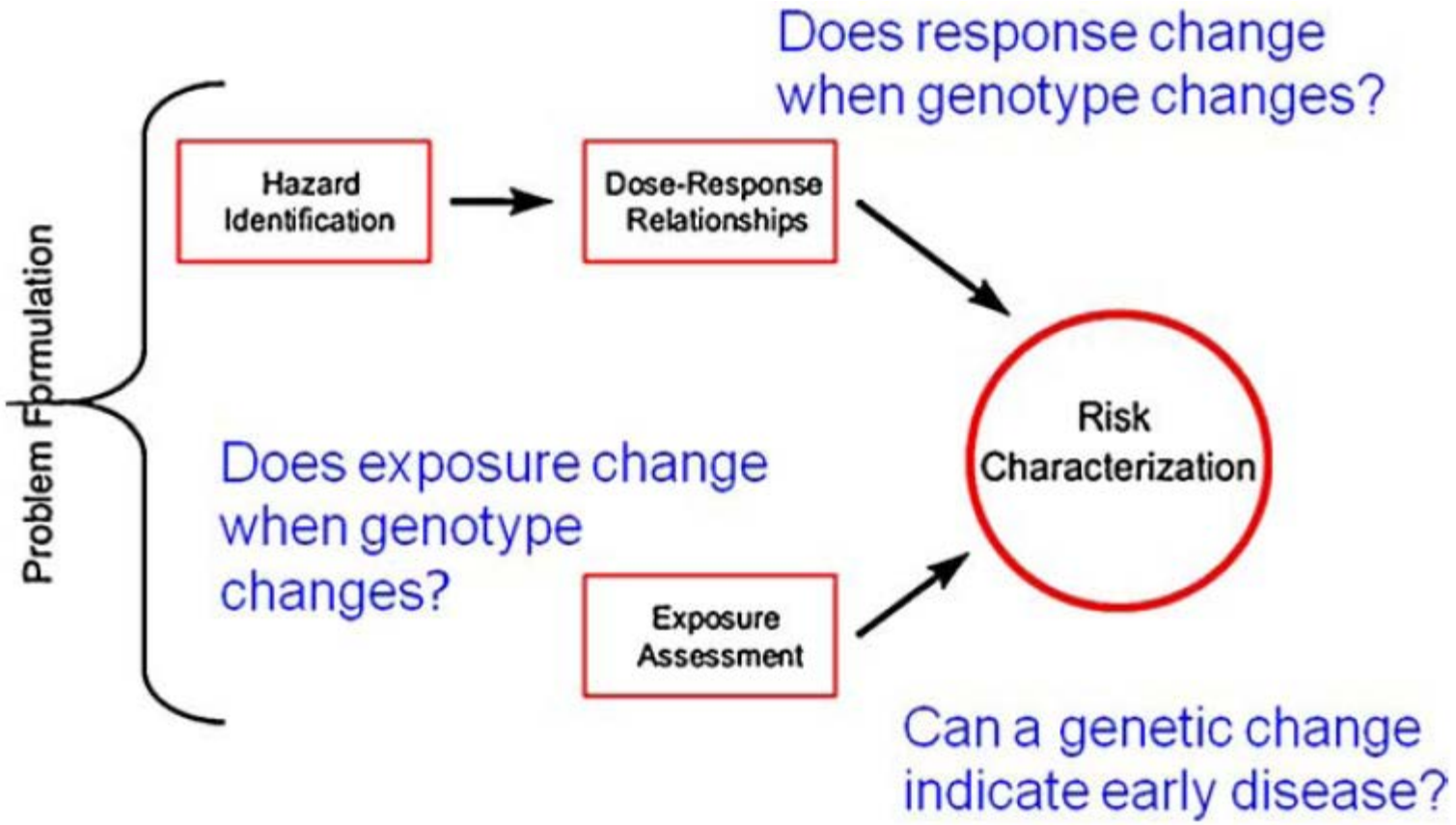


ECETOC Framework Step 3:
Integrating human and animal data



Risk characterization

Future – consider genotype

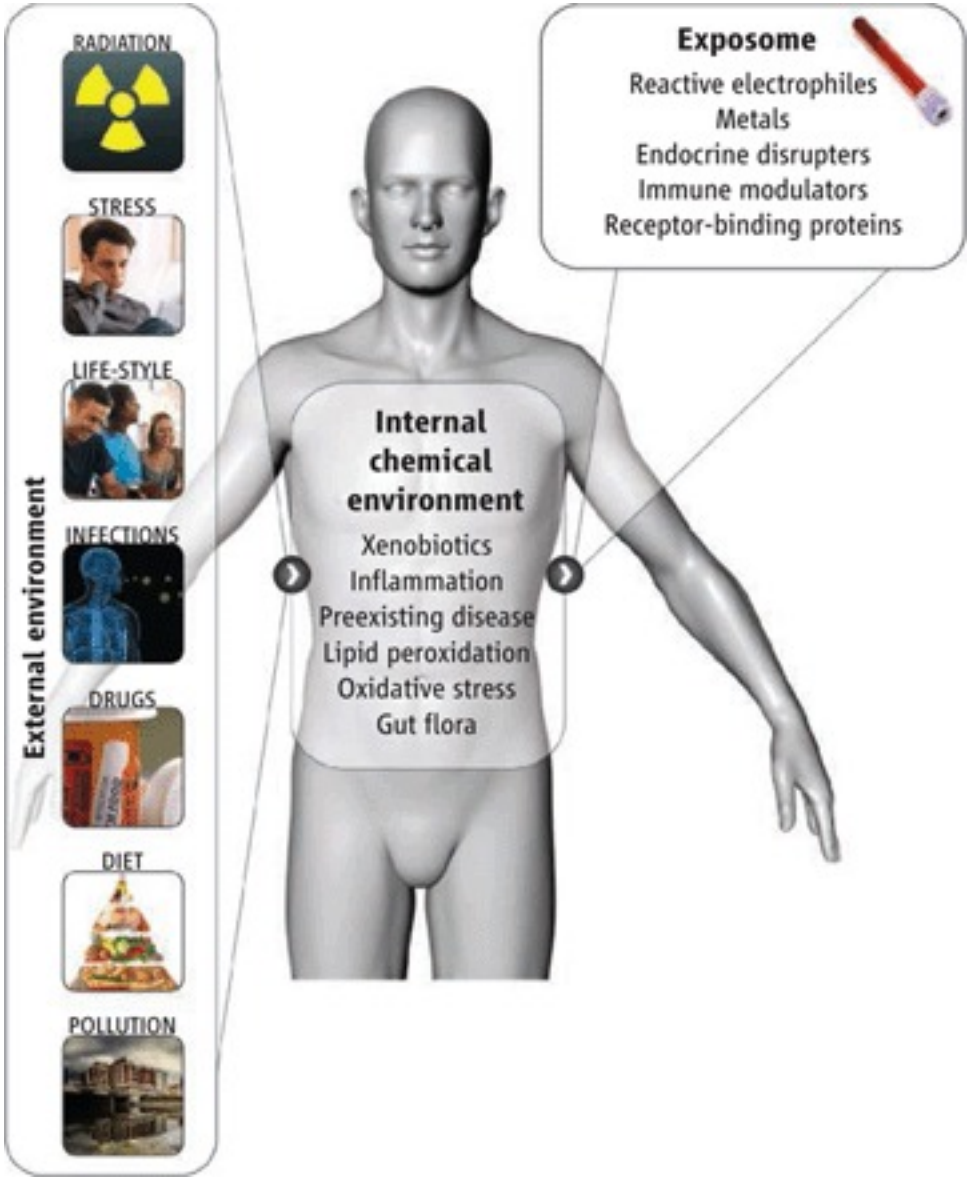


Curran et al. Incorporating genetics and genomics in risk assessment for inhaled manganese: from data to policy. Neurotoxicology. 2009 Sep;30(5):754-60.

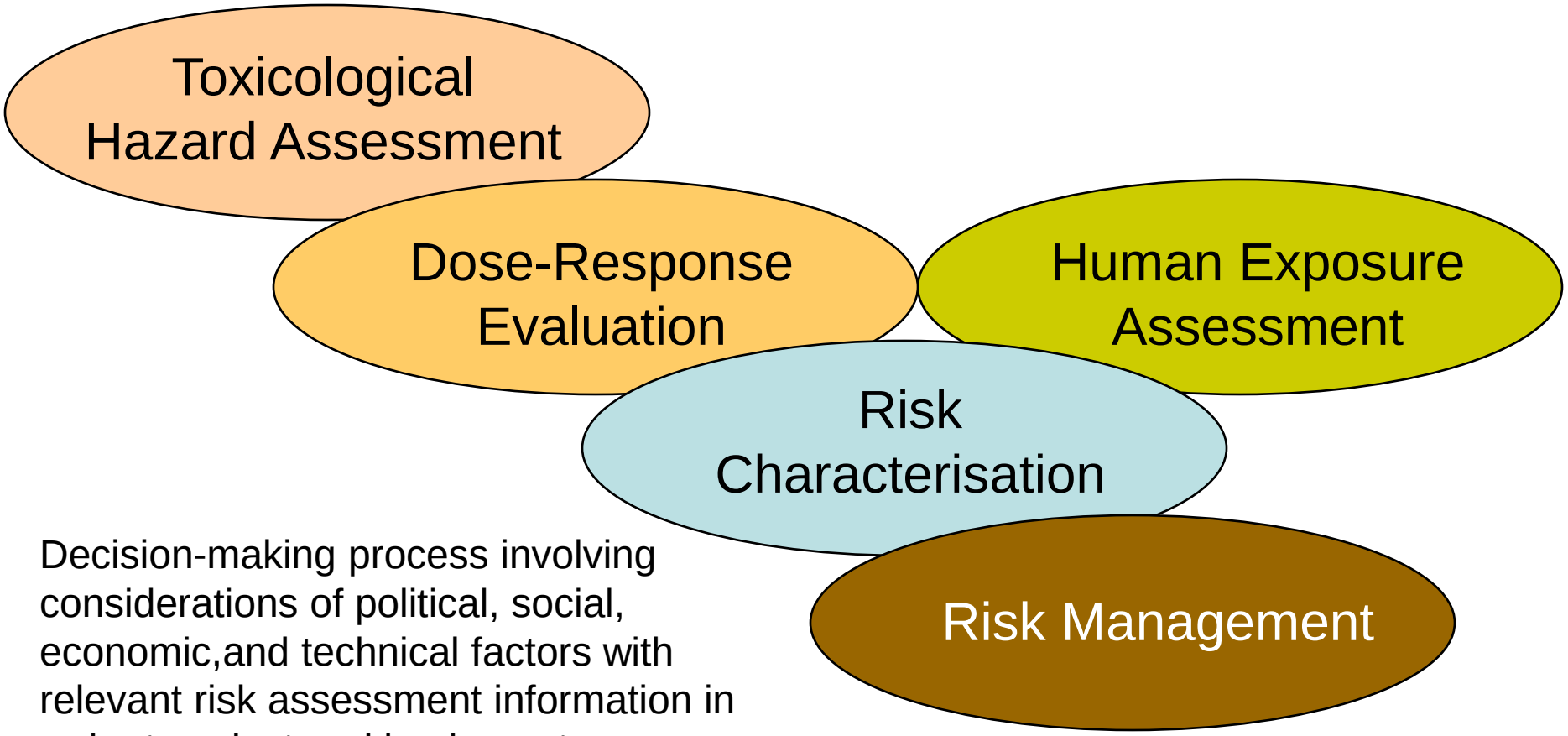
Exposome at the centre of future risk assessment?

‘With successful characterization of both exposomes and genomes, environmental and genetic determinants of chronic diseases can be united in high-resolution studies that examine gene-environment interactions. Such a union might even push the nature-versus-nurture debate toward resolution.‘

Rappaport SM & Smith MT
Science 330, 460 (2010)

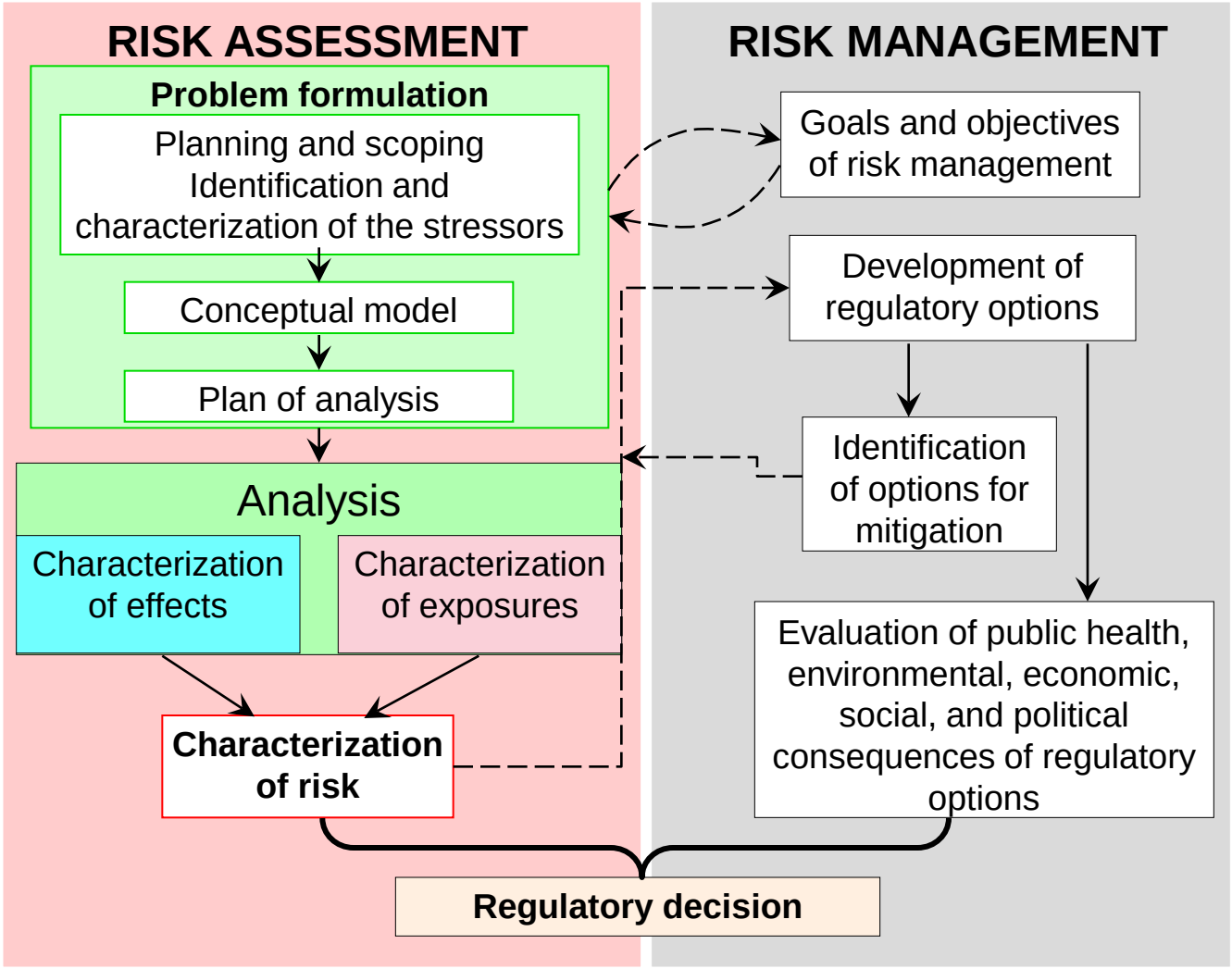


Stages of Risk Assessment



Decision-making process involving considerations of political, social, economic,and technical factors with relevant risk assessment information in order to select and implement appropriate regulatory response.

Framework for Risk Assessment and Management

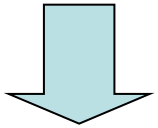


Examples of Risk Management

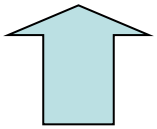
- **Safety information**
  - Classification and Labelling
  - Safety Data Sheets (MSDS)
- **Exposure mitigation**
  - Engineering controls
  - Awareness
  - Personal protection
- **Surveillance**
  - Toxicovigilance
  - Medical Surveillance

Regulatory framework

Regulation (EC) No.1907/2006 on the
Registration, **E**valuation, **A**uthorisation and Restriction of **CH**emicals **(REACH)**



Regulation (EC) No.1272/2008 on the
Classification, **L**abelling and **P**ackaging of Substances and Mixtures **(CLP)**



United Nations (2003, updated biannually)
Globally **H**armonised **S**ystem of Classification and Labelling of Chemicals **(GHS)**

Specific aims of CLP

- **Determine whether a substance or mixture displays properties that lead to a classification as ‘hazardous‘**
- **Communicate the identified hazard throughout the supply chain, including consumers, by means of hazard labelling**
- **Alert the user to the presence of a hazard and the need to avoid exposure and the resulting risks**
- **Set packaging standards to ensure the safe supply of hazardous substances and mixtures**

NB: Responsibilities for classification and related provisions are placed with the supplier of substances or mixtures

CLP is about hazard, not risk

Role of testing in CLP

- **CLP requires gathering relevant and available information on all hazardous properties of a substance or mixture**
- **Physical hazards**
  - Obligation to generate new data unless adequate and reliable information is already available
- **Health and environmental hazards**
  - No obligation to perform new testing
  - However, testing may be performed once all other means of generating information have been exhausted
  - With regard to CMR hazards, classification is normally based on individual ingredients (concentration thresholds apply)

GHS/CLP Acute Toxicity Hazard Categories

Exposure route	Category 1	Category 2	Category 3	Category 4	Category 5
					
Oral (mg/kg bw)	5	50	300	2000	5000
Dermal (mg/kg bw)	50	200	1000	2000	
Gases (ppmV)	100	500	2500	20000	
Vapours (mg/l)	0.5	2.0	10	20	
Dusts and Mists (mg/l)	0.05	0.5	1.0	5	

Values are expressed as (approximate) LD_{50} (oral, dermal) or LC_{50} (inhalation values) or as acute toxicity estimates (ATE)

GHS Hazard & Precautionary Statements

Acute Oral Toxicity

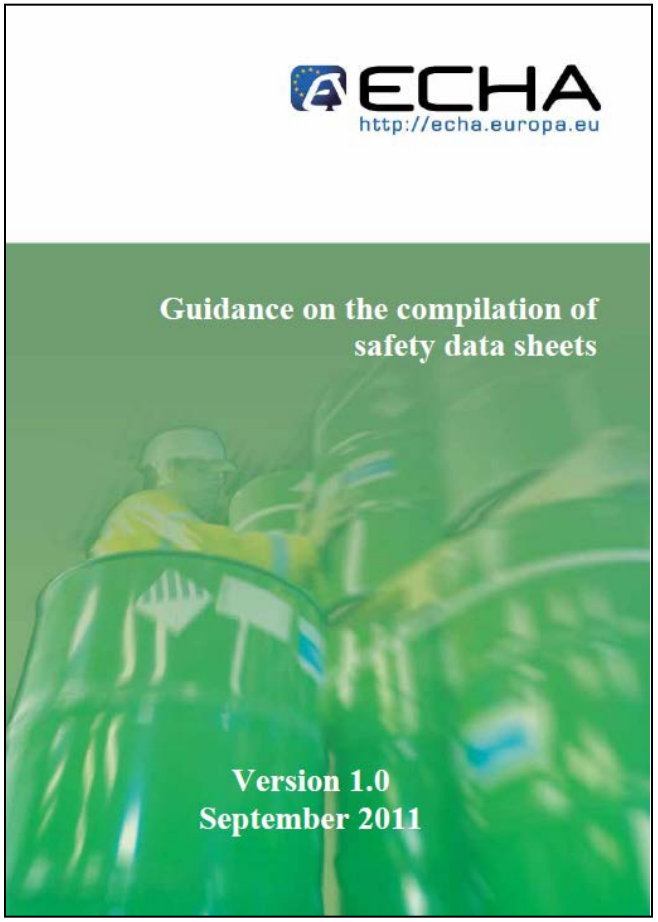
	Category 1	Category 2	Category 3	Category 4
				
Signal word	**Danger**	**Danger**	**Danger**	**Warning**
Hazard statement	**Fatal if swallowed**	**Fatal if swallowed**	**Toxic if swallowed**	**Harmful if swallowed**
Precautionary statements (Response)	If swallowed: Immediately call a poison center or doctor/physician. Specific treatment (see .. on this label) Rinse mouth.	If swallowed: Immediately call a poison center or doctor/physician. Specific treatment (see .. on this label) Rinse mouth.	If swallowed: Immediately call a poison center or doctor/physician. Specific treatment (see .. on this label) Rinse mouth.	If swallowed: call a poison center or doctor/physician if you feel unwell. Rinse mouth.

Safety Data Sheets

- **Integral part of REACH and adapted to comply with GHS**
- **Mechanism for transmitting safety information on substances and mixtures classified as**
  - **Hazardous**
  - **Dangerous (under previous regulations; until 2015)**
  - **Persistent, bioaccumulative or toxic (PBT)**
  - **Very persistent or very bioaccumulative (vPvB)**
  - **Subject to authorisation for other reasons, e.g. CMR 1&2, endocrine disruptors (case-by-case)**

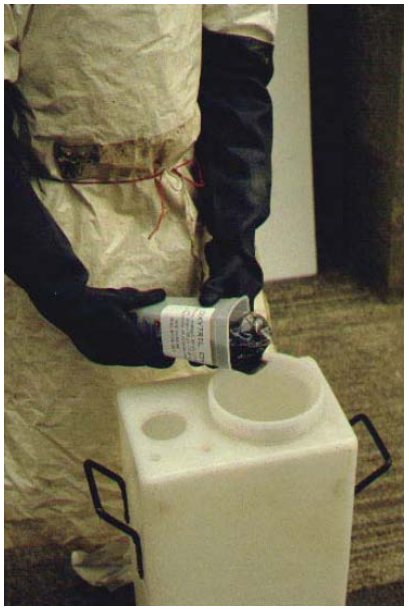
SDS Sections

1. Identification of the substance/mixture and of the company/undertaking
2. Hazards identification
3. Composition/information on ingredients
4. First aid measures
5. Firefighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure controls/personal protection
9. Physical and chemical properties
10. Stability and Reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport Information
15. Regulatory information
16. Other information



- **Engineering controls for pesticide applications**

Closed transfer device



Water soluble bag

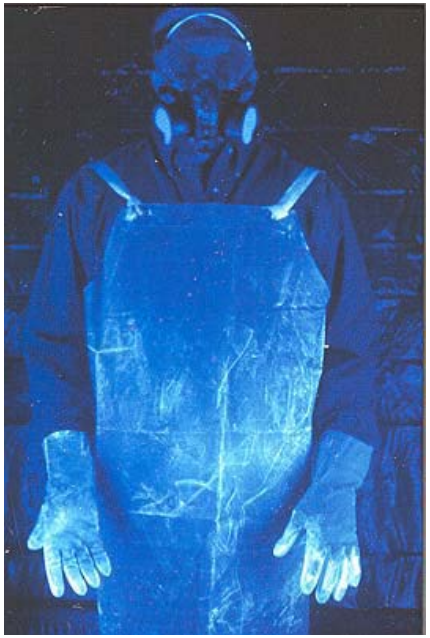
Container rinse system

Covered sprayers

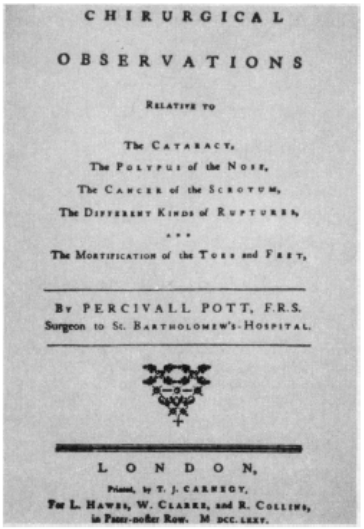
Low drift air-assisted nozzles

Personal protection

- **5 ‘golden rules‘ for pesticide applicators**
  - exercise caution at all times
  - understand the label
  - maintain spray equipment
  - practise good personal hygiene
  - use appropriate personal protective equipment



- Mortality/morbidity statistics
- Accident surveillance schemes
- Hospital admissions
- Incident reports
- Case reports / case series
- Poison centre data collection



CHIRURGICAL

OBSERVATIONS

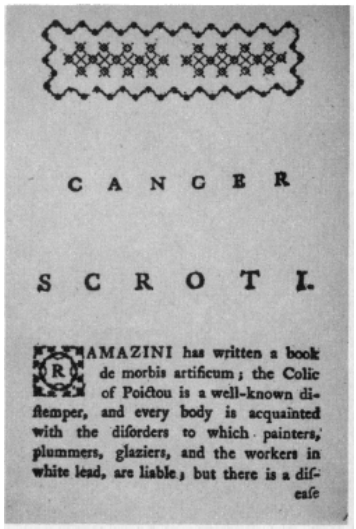
RELATIVE TO

The CATARACT,
The POLYPUS of the NOSE,
The CANCER of the SCROTUM,
The DIFFERENT KINDS of RUPTURES,
&c. &c.
The MORTIFICATION of the TOES and FEET,

BY PERCIVALL POTT, F.R.S.
Surgeon to St. BARTHOLOMEW's-HOSPITAL.

LONDON,

Printed, by T. J. CARNEGY,
For L. HAWES, W. CLARKE, and R. COLLINS,
in Paternoster Row. M DCC. LXXV.

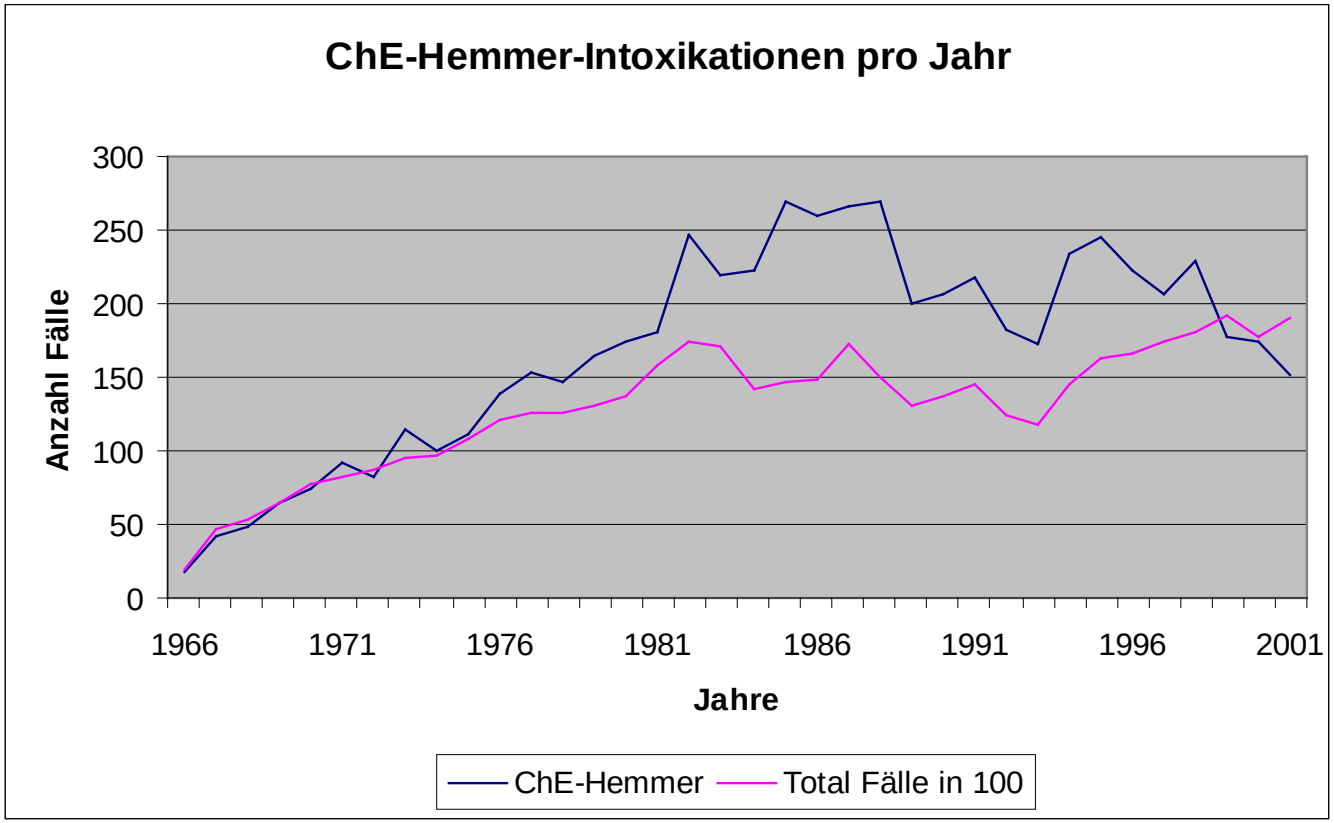


CANCER

SCROTI.

RAMAZINI has written a book de morbis artificum; the Colic of Poictou is a well-known distemper, and every body is acquainted with the disorders to which painters, plummers, glaziers, and the workers in white lead, are liable; but there is a disease

- Part of the project by the FOPH in Switzerland concerning a comprehensive evaluation of these compounds
- STIC analysis also included carbamates



Retrospective Evaluation of Enquiries to the STIC Concerning Organophosphate-Insecticides 1966 - 2001

- 5152 human exposures, 5086 with mild to moderate symptoms, 40 with severes symptoms, 26 fatal cases
- 430 products with 63 active ingredients were involved

	Oral	Circumstance		
		Suicide	Occupational	Accidental
Mild/Moderate (n=264*)	38%	10%	19%	61%
Severe/Fatal (n=66)	89%	73%	6%	17%

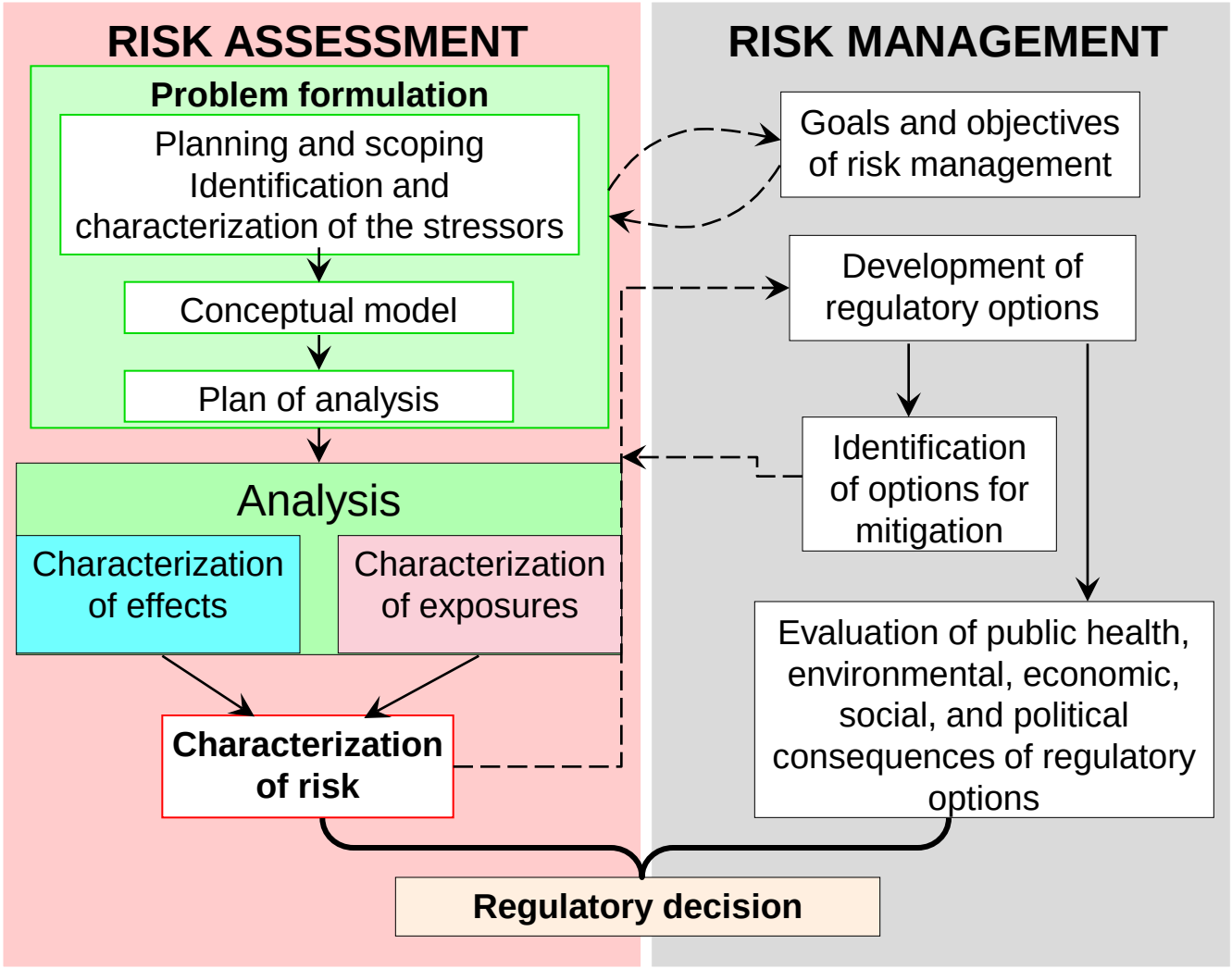
* Random selection of mild/moderate cases

Retrospective Evaluation of Enquiries to the STIC Concerning Organophosphate-Insecticides 1966 - 2001

- Relationship between hazard class and outcome: more severe/fatal cases in WHO Class IA / IB compared to II & III
- Since 1987 no severe/fatal case in children
- Nearly ¾ of severe and fatal cases in adults as a result of self harm
- No fatal outcome after occupational exposure; no severe case since 1977

Substance	WHO-Class	N =	Severe/ Fatal
Malathion	III	128	2%
Diazinon	II	1391	1%
Dimethoate	II	165	1%
Dichlorvos / Propoxur	II	96	1%
Phosalone	II	94	3%
Carbosulfan	II	43	5%
Oxamyl	IB	29	3%
Mevinphos	IA	197	5%
Parathion	IA	118	14%
Thioniazin	IA	31	10%
Fonofos	IA	30	17%
Aldicarb	IA	26	4%

Framework for Risk Assessment and Management



What should be the basis for risk evaluation?

- **Equity-based**
  - All individuals have unconditional rights to certain levels of protection
  - Standards applicable to all – maximum level of risk above which no individual can be exposed
  - Benefit not taken into account
- **Utility-based**
  - Compares benefits of measures to prevent risk (e.g. health screening) with their cost
  - Requires balance between benefit (e.g. number of lives saved) and cost
- **Technology-based**
  - Idea that satisfactory level of risk prevention is obtained when state-of-the-art control measures are introduced, whatever the circumstances

- **Human Medicines**
  - Balance between benefit of therapeutic effect in patient against risk of side effects
  - Different for anti-cancer drugs compared to OTC flu medication
- **Pesticides**
  - No individual benefit from most uses but exceptions e.g. prevention of fungal contamination of food
  - Societal benefit: security of wholesome and affordable food supply
- **Chemicals**
  - Individual risks from occupational or environmental exposures
  - Possible benefits: individual (employment), society (useful products)

- **USA – Executive Order No. 12866 Regulatory Planning and Review - Issued by President Clinton**
  - (6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.
- **EU – example**

Socio-economic analysis under REACH

- Tool to evaluate what costs and benefits an action will create for society by comparing what will happen if this action is implemented as compared to the situation where the action is not implemented.
  - An SEA is a compulsory part of an application for authorisation whenever the risks to human health or the environment from the use of a substance [identified as of high concern and subject to authorisation] are not adequately controlled.

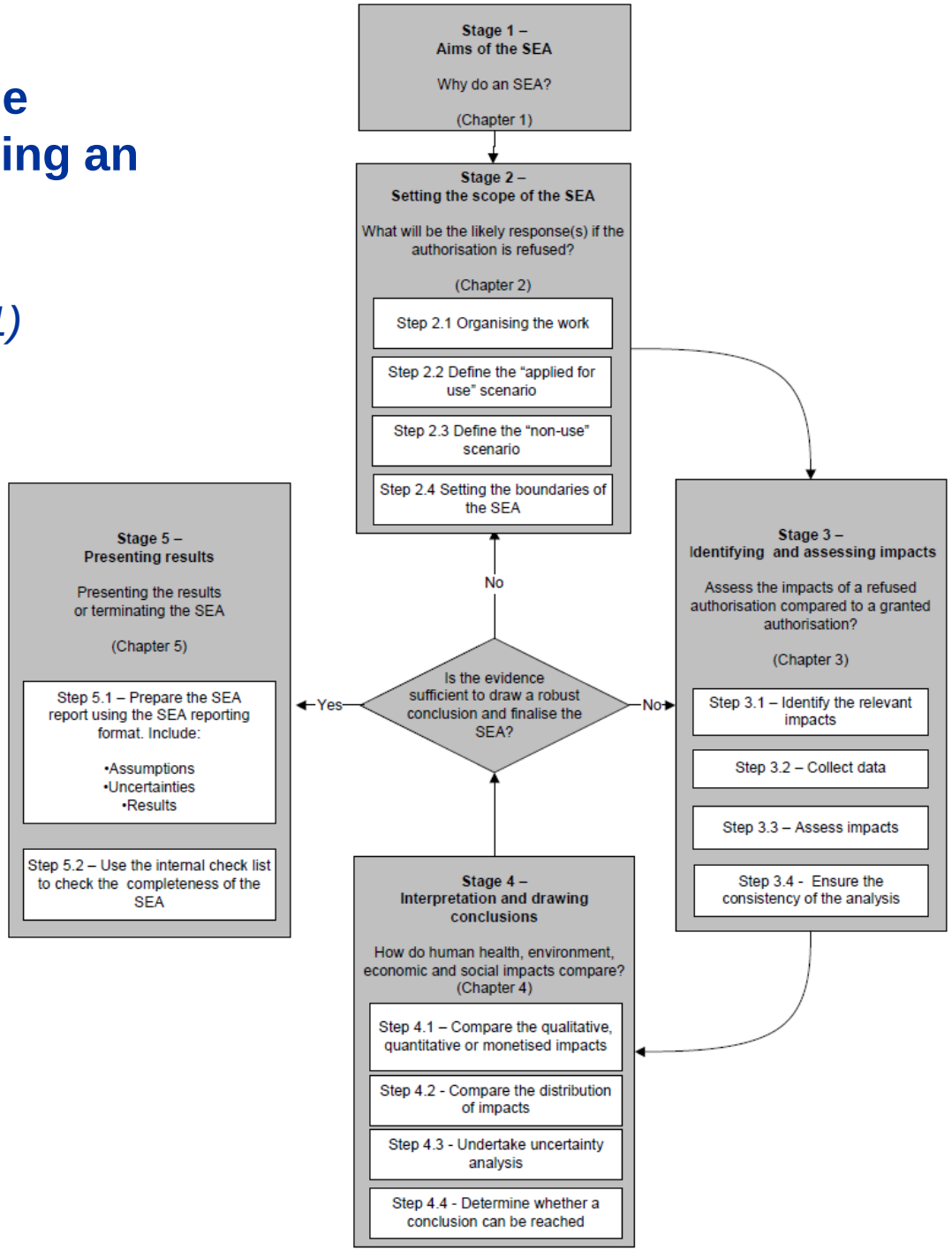
    ➔ **Socio-economic route**
  - When adequate control can be shown, an SEA may be produced by the applicant in support to his application.

    ➔ **Adequate control route**
  - An SEA may also be produced by any third party in support of information on alternatives.

ECHA Guidance, 2011

Flow diagram for the process of conducting an authorisation SEA

(ECHA Guidance, 2011)



Risk perception

Home
Our Earth
Teachers
Topics for Discussion
Toxic Chemicals
Our chemical world
Impacts on wildlife
Chemicals affect you
Reduce your risks
What's in your blood?
Risks unknown
Lessons of history
News

Chemicals affect you

Toxic chemicals are invading our bodies

Hazardous chemicals are found in the tissue of nearly every person on Earth and exposure to them has been linked to several cancers and to a range of reproductive problems, including birth defects.

The increasing incidence of some of these conditions, and our continued exposure to a cocktail of these chemicals, is alarming.

Results from WWF's first European-wide family blood testing survey found a total of 73 man-made hazardous chemicals in the blood of 13 families (grandmothers, mothers and children) from 12 European countries. Every family member tested was contaminated with a cocktail of at least 18 different man-made chemicals, many found in everyday consumer goods.

Likewise, a WWF-UK study of human contamination found evidence of DDT and PCBs, two dangerous chemicals banned decades ago, in 99% of the 155 people they tested. Women who had breast-fed their babies had lower levels of certain pcbs than men, indicating that they had 'off-loaded' these chemicals on to their babies. (Note: experts agree that breast milk is still best for young babies).

Reduce your risks

Find out what you can do to reduce your exposure to har chemicals And protect wildlife

From *Time Magazine* (June 30, 1947).

"DDT is good for me-e-e!"

The great expectations held for DDT have been realized. During 1946, exhaustive scientific tests have shown that, when properly used, DDT kills a host of destructive insect pests, and is a benefactor of all humanity.

Pennsalt produces DDT and its products in all standard forms and is now one of the country's largest producers of this amazing insecticide. Today, everyone can enjoy added comfort, health and safety through the insect-killing powers of Pennsalt DDT products . . . and DDT is only one of Pennsalt's many chemical products which benefit industry, farm and home.

GOOD FOR STEERS—Beef grows meatier nowadays . . . for it's a scientific fact that—compared to untreated cattle—beef-steers gain up to 50 pounds extra when protected from horn flies and many other pests with DDT insecticides.

Knox Out FOR THE HOME—helps to make healthier, more comfortable homes . . . protects your family from dangerous insect pests. Use Knox-Out DDT Powders and Sprays as directed . . . then watch the bugs "bite the dust"!

Knox Out FOR DAIRIES—Up to 20% more milk . . . more butter . . . more cheese . . . tests prove greater milk production when dairy cows are protected from the annoyance of many insects with DDT insecticides like Knox-Out Stock and Barn Spray.

GOOD FOR FRUITS—Bigger apples, juicier fruits that are free from unsightly worms . . . all benefits resulting from DDT dusts and sprays.

GOOD FOR ROW CROPS—*25 more barrels of potatoes per acre* . . . actual DDT tests have shown crop increases like this! DDT dusts and sprays help truck farmers pass these gains along to you.

Knox Out FOR INDUSTRY—Food processing plants, laundries, dry cleaning plants, hotels . . . dozens of industries gain effective bug control, more pleasant work conditions with Pennsalt DDT products.

PENN SALT
CHEMICALS
97 Years' Service to Industry • Farm • Home

PENNSYLVANIA SALT MANUFACTURING COMPANY
WIDENER BUILDING, PHILADELPHIA 7, PA.

Glenbow Archives NA-5600-6671a

The Life and Legacy of Rachel Carson

THERE WAS ONCE a town in the heart of America where all life seemed to live in harmony with its surroundings.

First Sentence, Silent Spring

-- Rachel Carson ©

Silent Spring, 1962

- **Cancer ‘accounted for 15% of the deaths in 1958 compared with only 4% in 1900‘**

- **Yes, but…**

All Cause Mortality in 1900

		1900		
	All causes----------		343,217	1,719.1
1	Pneumonia (all forms) and influenza----------	107-109,33	40,362	202.2
2	Tuberculosis (all forms) ----------	13-22	38,820	194.4
3	Diarrhea, enteritis, and ulceration of the intestines------	119,120	28,491	142.7
4	Diseases of the heart ----------	90-95	27,427	137.4
5	Intracranial lesions of vascular origin ----------	83	21,353	106.9
6	Nephritis (all forms) ----------	130-132	17,699	88.6
7	All accidents ----------	169-195	14,429	72.3
8	Cancer and other malignant tumors ----------	45-55	12,769	64.0
9	Senility ----------	162	10,015	50.2
10	Diphtheria ----------	10	8,056	40.3

Source: 1900-1940 tables ranked in National Office of Vital Statistics, December 1947

All Cause Mortality in 1958

Table 6-G. Mortality for 15 Leading Causes of Death: United States, 1958

(Includes only deaths occurring within the continental United States. Excludes fetal deaths. Rates per 100,000 estimated midyear population. Ranked on the basis of the List of 59 Selected Causes of Death; see table 6 -J. Numbers after causes of death are category numbers of the Seventh Revision of the International Lists, 1955)

Rank order	CAUSE OF DEATH		Rate	Percent of total deaths
	ALL CAUSES		950.8	100.0
1	Diseases of heart	400-402,410-443	367.7	38.7
2	Malignant neoplasms, including neoplasms of lymphatic and hematopoietic tissues	140-205	146.8	15.4
3	Vascular lesions affecting central nervous system	330-334	110.1	11.6
4	Accidents	E800-E962	52.3	5.5
...	Motor vehicle accidents	E810-E835	21.3	2.2
...	Other accidents	E800-E802,E840-E962	30.9	3.3
5	Certain diseases of early infancy	760-776	39.8	4.2
6	Influenza and pneumonia, except pneumonia of newborn	480-493	33.1	3.5
7	General arteriosclerosis	450	19.9	2.1
8	Diabetes mellitus	260	15.9	1.7
9	Congenital malformations	750-759	12.4	1.3
10	Cirrhosis of liver	581	10.8	1.1
11	Suicide	E963,E970-E979	10.7	1.1
12	Other diseases of circulatory system	45l-468	9.9	1.0
13	Chronic and unspecified nephritis and other renal sclerosis	592-594	8.0	0.8
14	Other hypertensive disease	444-447	8.0	0.8
15	Tuberculosis, all forms	001-019	7.1	0.8
...	All other causes		98.5	10.4

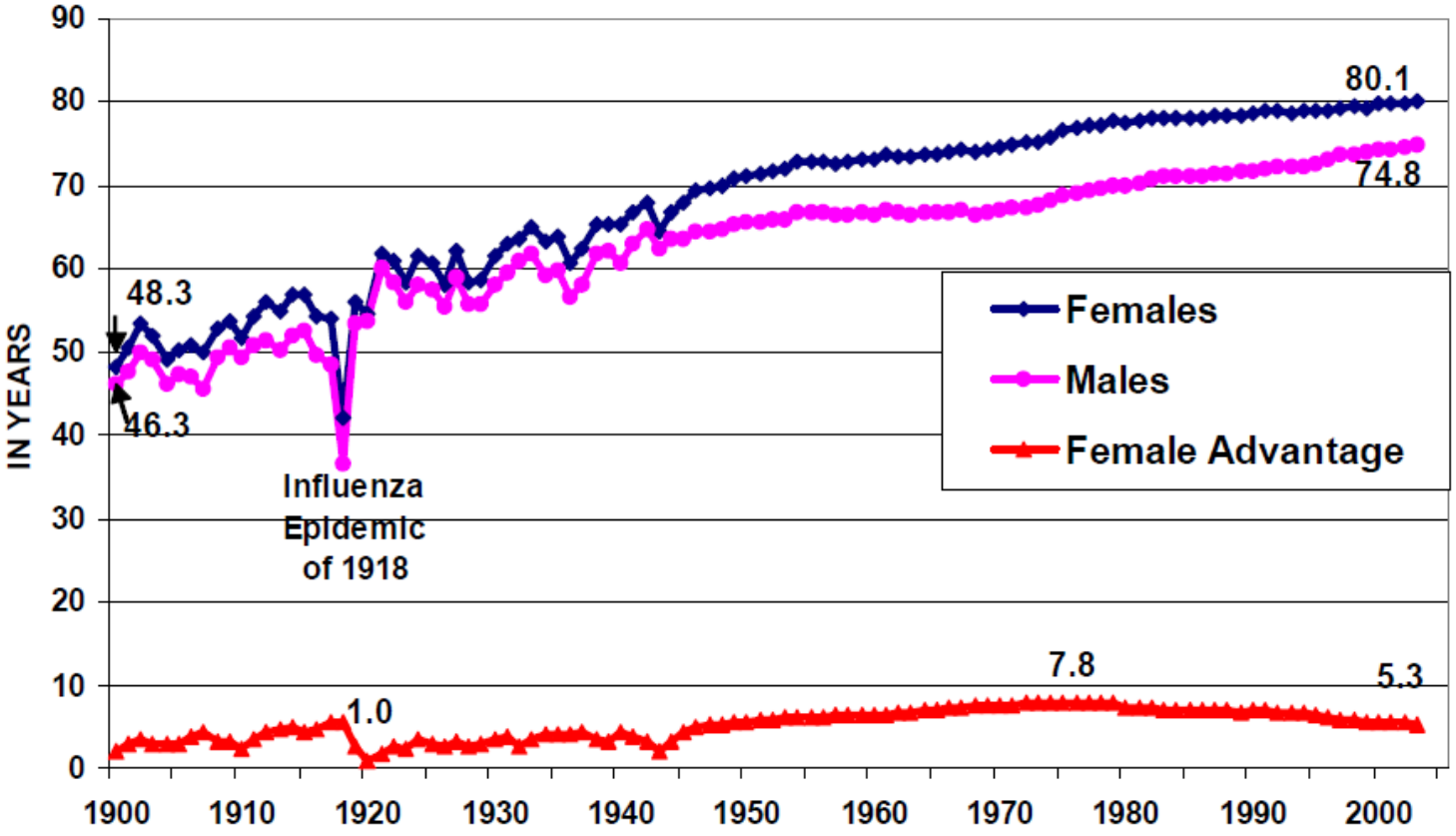
Table 2. Age-adjusted Death Rates for Various Causes of Death

(per 100,000 population)

Cause	1950	1980	2002
All causes	*1,446.0*	*1,039.1*	*832.7*
Diseases of heart	586.8	412.1	232.3
Malignant neoplasms	193.9	207.9	190.0
Cerebrovascular diseases	180.7	96.2	53.5
Chronic lower respiratory diseases	—	28.3	43.3
Influenza and pneumonia	48.1	31.4	22.0
Chronic liver disease and cirrhosis	11.3	15.1	9.3
Diabetes mellitus	23.1	18.1	25.3
Unintentional injuries (incl. motor accidents)	78.0	46.4	37.3

Source: CRS compilation from National Center for Health Statistics (NCHS), *Health, United States, 2005 with Chartbook on Trends in the Health of Americans,* Table 29.

Figure 1. Life Expectancy at Birth, by Sex: 1900 to 2003.



Absolute vs. Relative risk

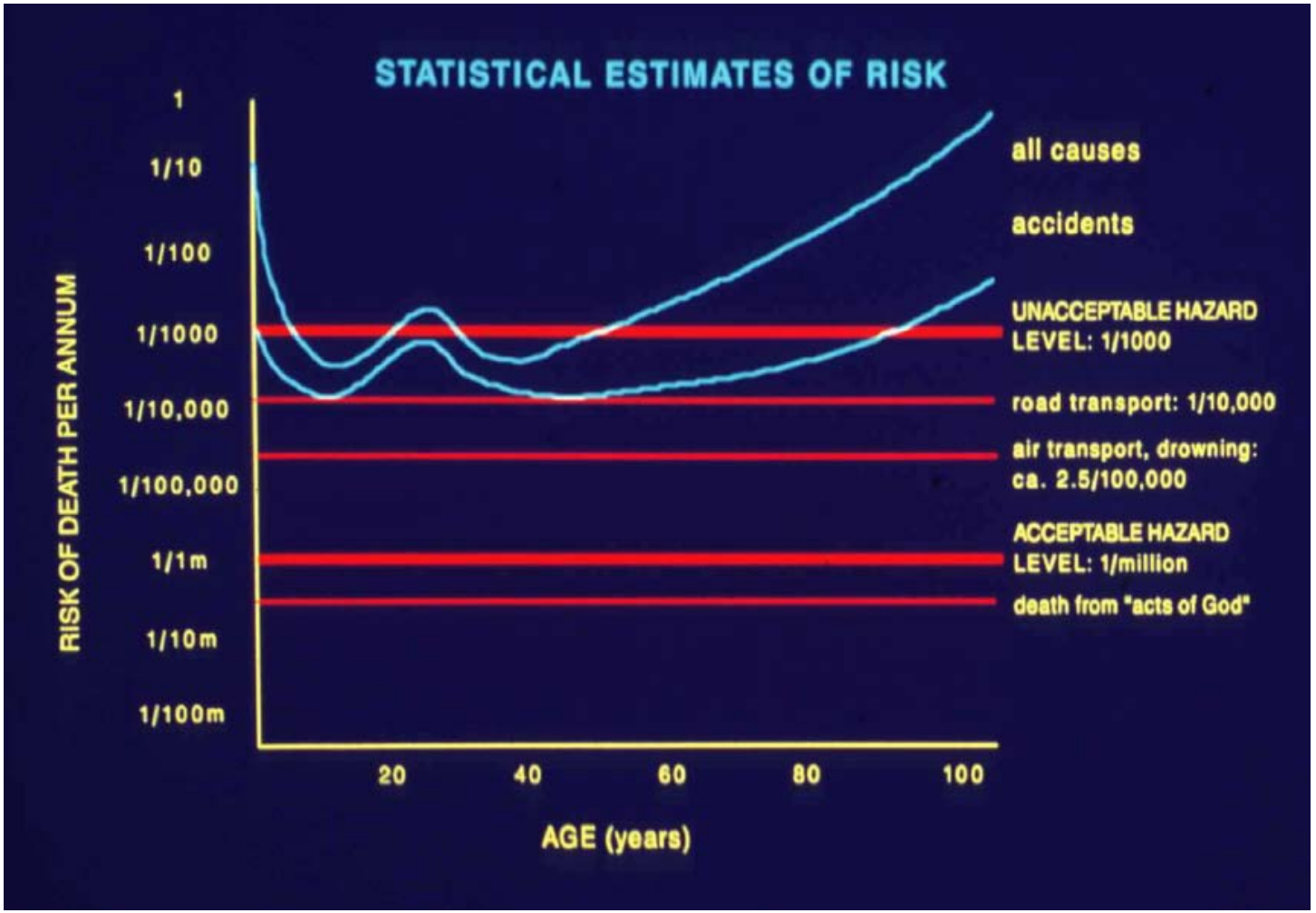
Absolute vs. Relative risk

- ***New York Times (2004)* "Aspirin is seen as preventing breast cancer" - reduced by 20%**
  - *20/1000* between 55 and 64 will develop breast cancer in 5 years.
  - 20% reduction from aspirin = 16/1000
- **No aspirin *2% affected vs 1.6% affected***

- ***In other words:***
  - Women who do not take aspirin have a 98% chance of remaining free of breast cancer in the next five years; for women who do the figure changes to 98.4%

The law of big numbers

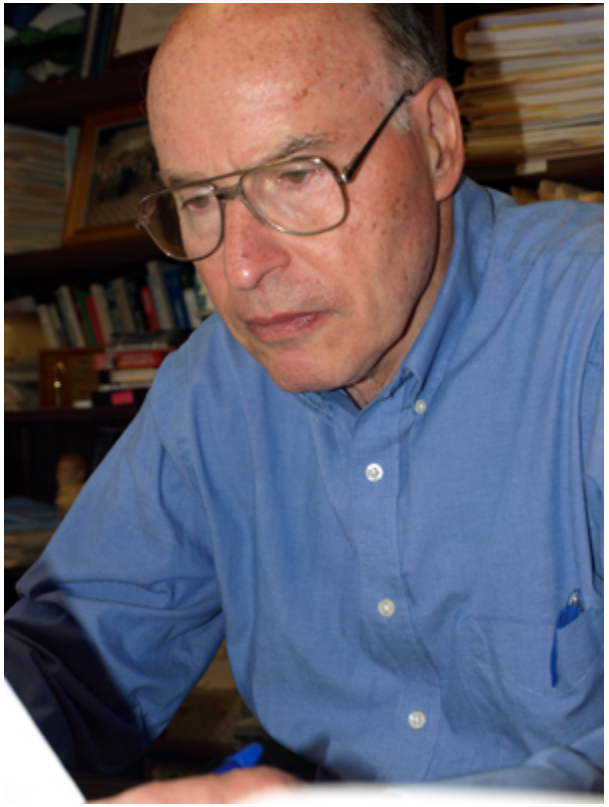
- **‘One death is a tragedy, one million deaths is a statistic’**


STATISTICAL ESTIMATES OF RISK
RISK OF DEATH PER ANNUM
1
1/10
1/100
1/1000
1/10,000
1/100,000
1/1m
1/10m
1/100m
20
40
60
80
100
AGE (years)
all causes
accidents
UNACCEPTABLE HAZARD LEVEL: 1/1000
road transport: 1/10,000
air transport, drowning: ca. 2.5/100,000
ACCEPTABLE HAZARD LEVEL: 1/million
death from "acts of God"

Risk Analysis, Vol. 19, No. 4, 1999

Trust, Emotion, Sex, Politics, and Science: Surveying the Risk-Assessment Battlefield

Paul Slovic[1]



Subjective and value-laden nature of RA

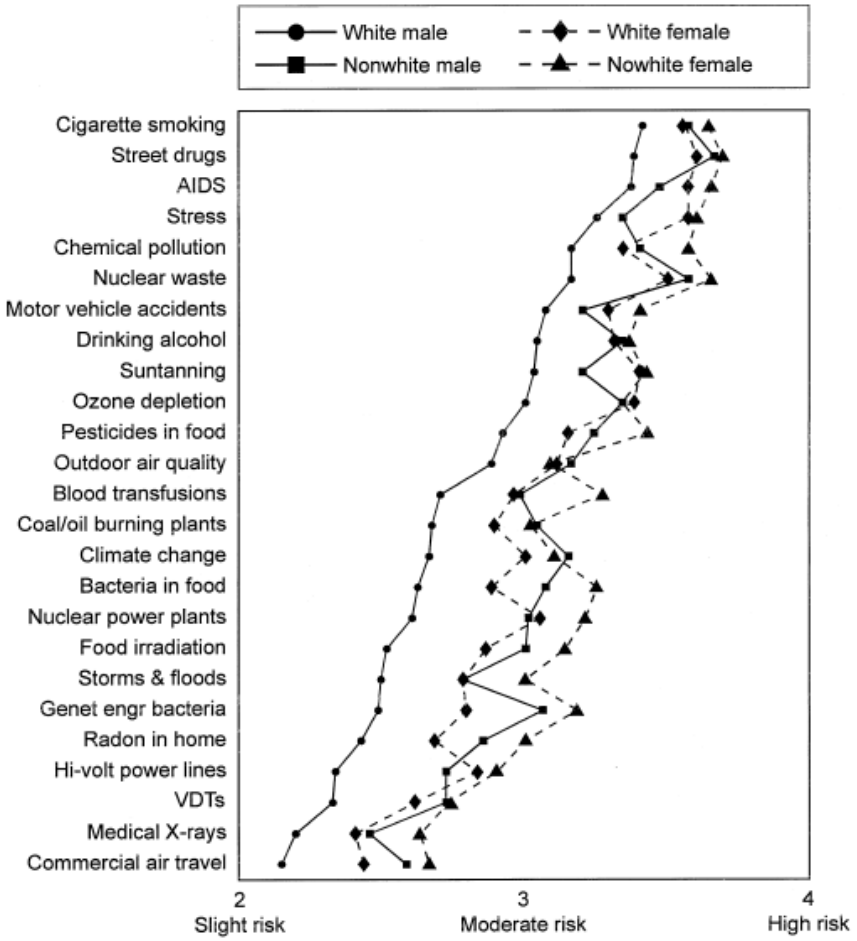
Table I. Some Ways of Expressing Mortality Risks

Deaths per million people in the population
Deaths per million people within *x* miles of the source of exposure
Deaths per unit of concentration
Deaths per facility
Deaths per ton of air toxic released
Deaths per ton of air toxic absorbed by people
Deaths per ton of chemical produced
Deaths per million dollars of product produced
Loss of life expectancy associated with exposure to the hazard

- Between 1950 and 1970, coal mines became much less risky in terms of deaths from accidents per ton of coal, but they became marginally riskier in terms of deaths from accidents per employee.

Sex and risk judgments

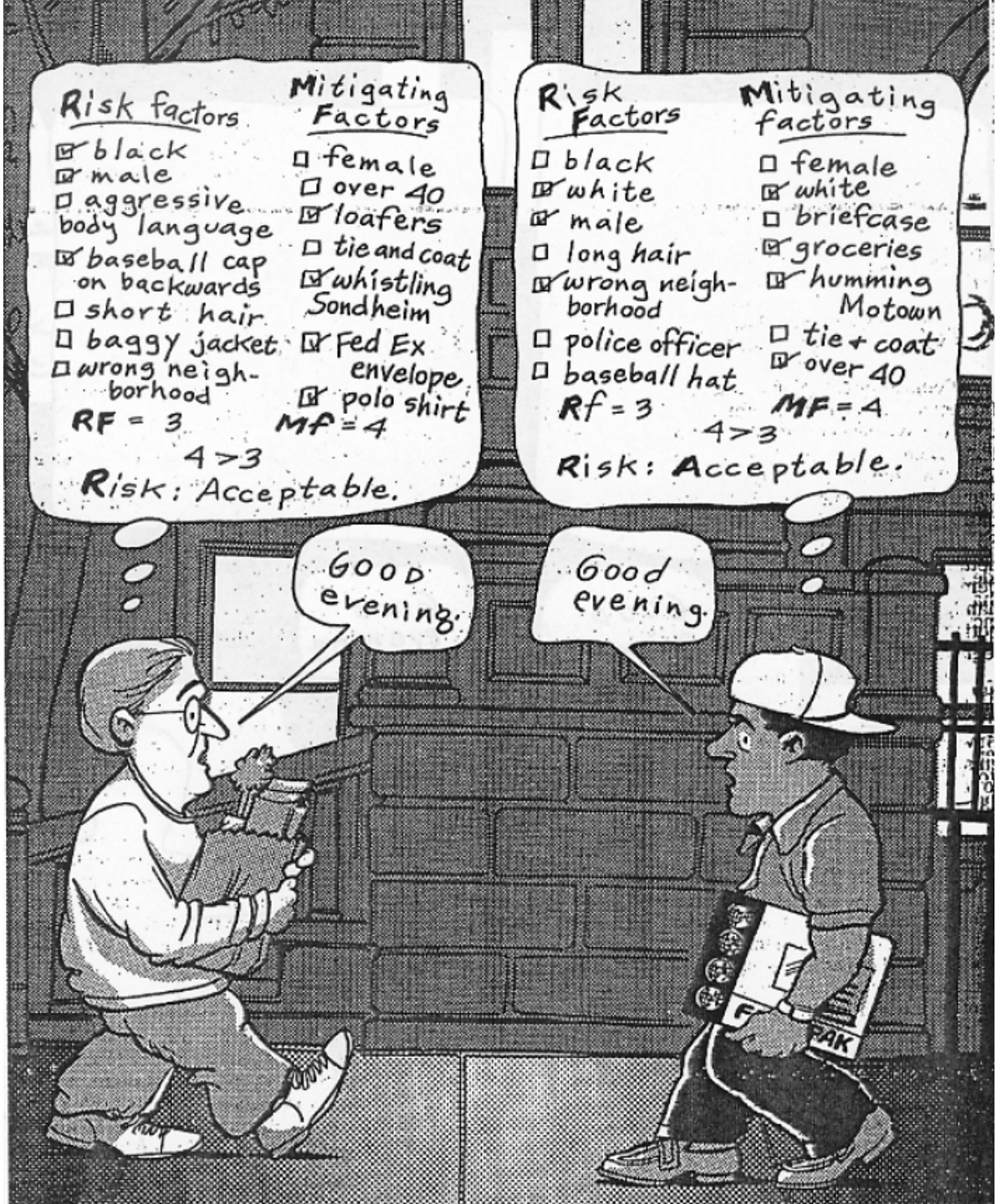
- **White males have consistently lower risk perception ratings than other groups**
- **The ‚white male effect‘ is caused by 30% of respondents who rate risks extremely low**
  - Better educated
  - Higher household incomes
  - More conservative



Street Calculus

By Garry Trudeau

- **Affect = positive or negative feeling towards a stimulus (hazard)**
- **Such evaluations occur rapidly and automatically (gut reaction)**



Affect and nuclear power

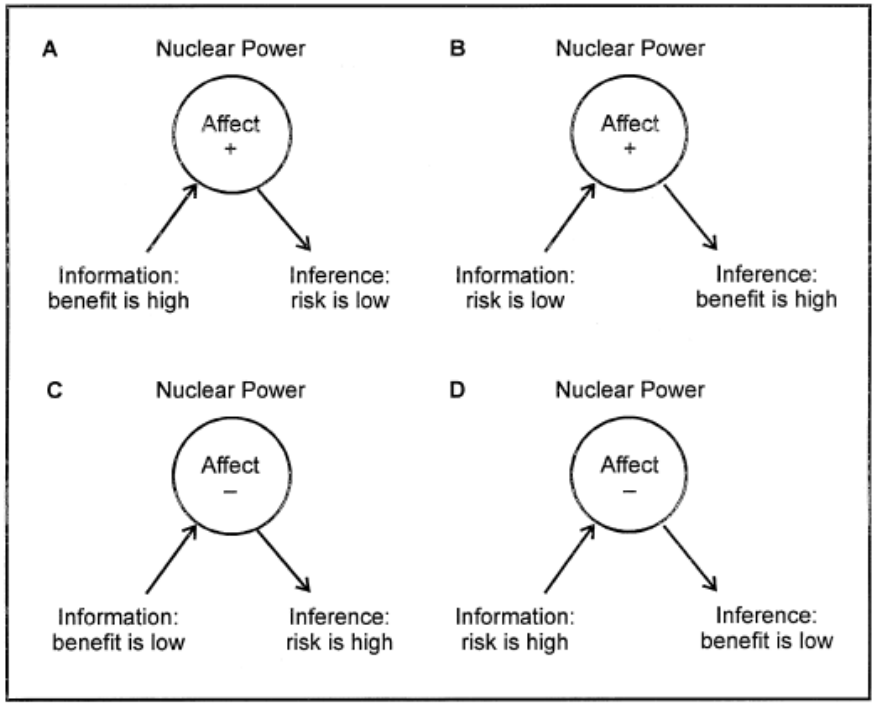


Fig. 2. Model showing how information about benefit (A) or information about risk (B) could create a more positive affective evaluation of nuclear power and lead to inferences about risk and benefit that are affectively congruent with the information input. Similarly, information could decrease the affective evaluation of nuclear power as in C and D, resulting in inferences that are opposite those in A and B. Source: Ref. No. 37.

- **Surveys of toxicologists and members of the general public in the USA, Canada and the UK during the 1990s**

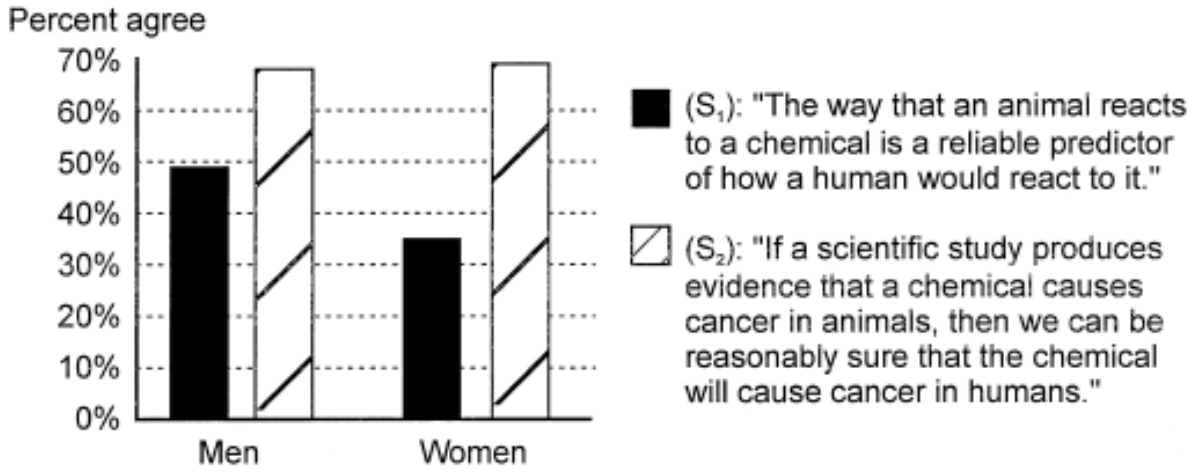


Fig. 3. Agreement among members of the public in the United States for Statements S_1 and S_2. Source: Ref. No. 40.

Intuitive toxicology

- S1: ‘‘Would you agree or disagree that the way an animal reacts to a chemical is a reliable predictor of how a human would react to it?’’
- S2: ‘‘If a scientific study produces evidence that a chemical causes cancer in animals, then we can be reasonably sure that the chemical will cause cancer in humans.’’

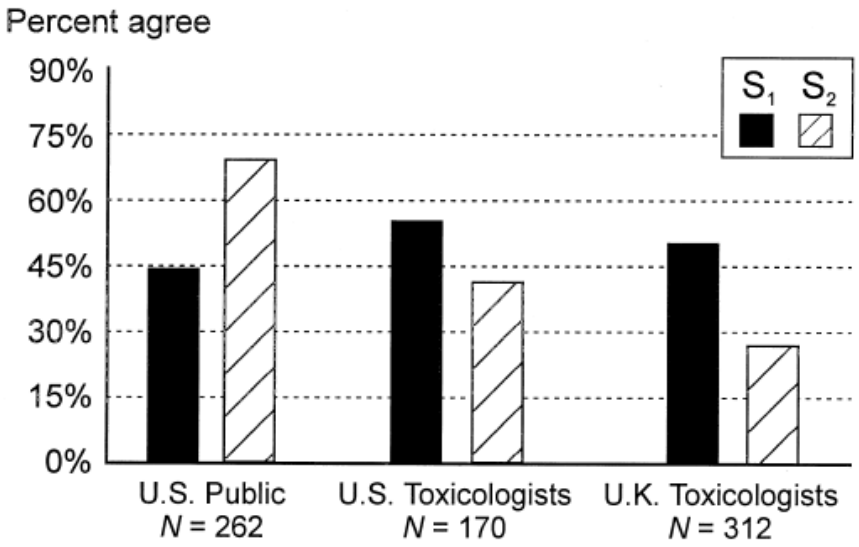


Fig. 4. Agreement with two statements, S_1 and S_2, regarding the extrapolation of chemical effects in animals to chemical effects in humans. Source: Ref. No. 41.

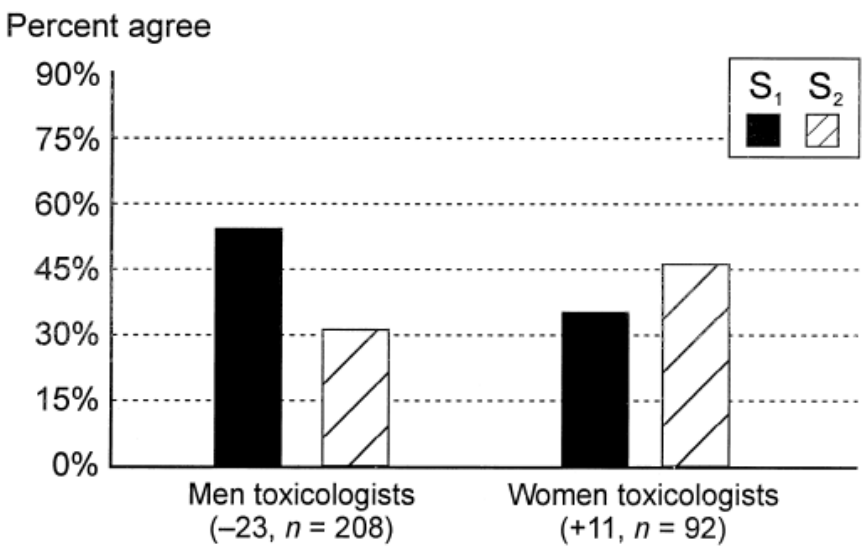


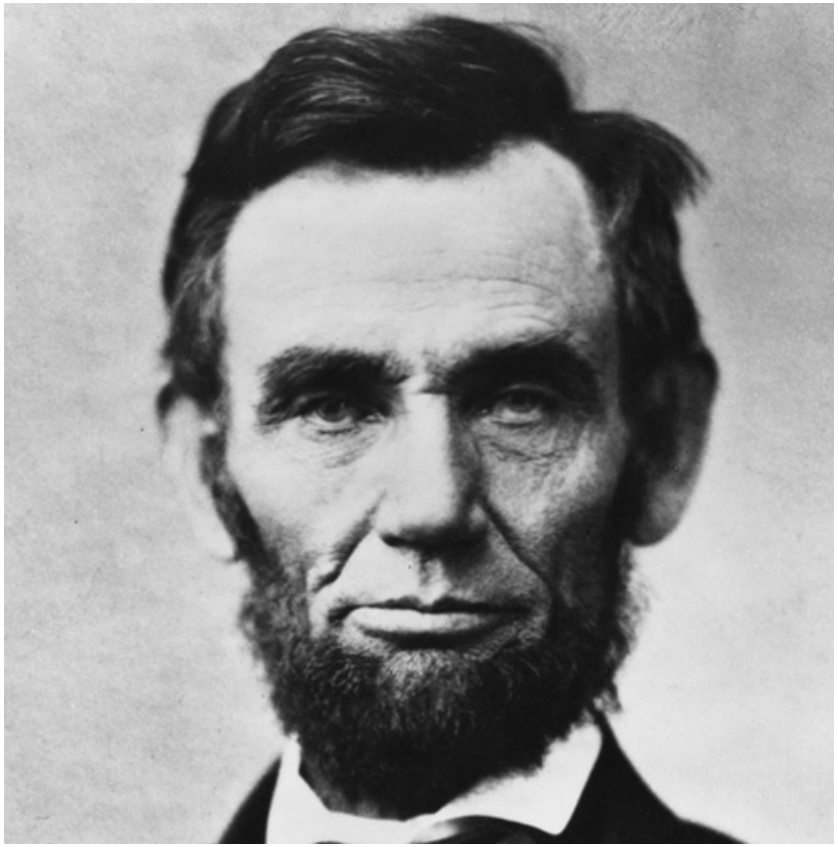
Fig. 5. Agreement of men and women toxicologists in the United Kingdom with two statements regarding extrapolation of chemical effects in animals to chemical effects in humans. Source: Ref. No. 41.

Worldviews, affect and UK toxicologists

- **Greater agreement with S2 compared to S1 associated with**
  - higher mean perceptions of risk across 25 hazards (the risk-perception index),
  - rating pesticides and industrial chemicals as ‘‘bad’’ on a task in which various items were rated on a scale ranging from *good* to *bad,*
  - being female,
  - being younger,
  - agreeing that ‘‘I have little control over risks to my health.’’
  - holding an academic position rather than a position in industry,
  - disagreeing that ‘‘technology is important for social well-being,’’ and
  - disagreeing that ‘‘economic growth is necessary for good quality of life.’’

Trust

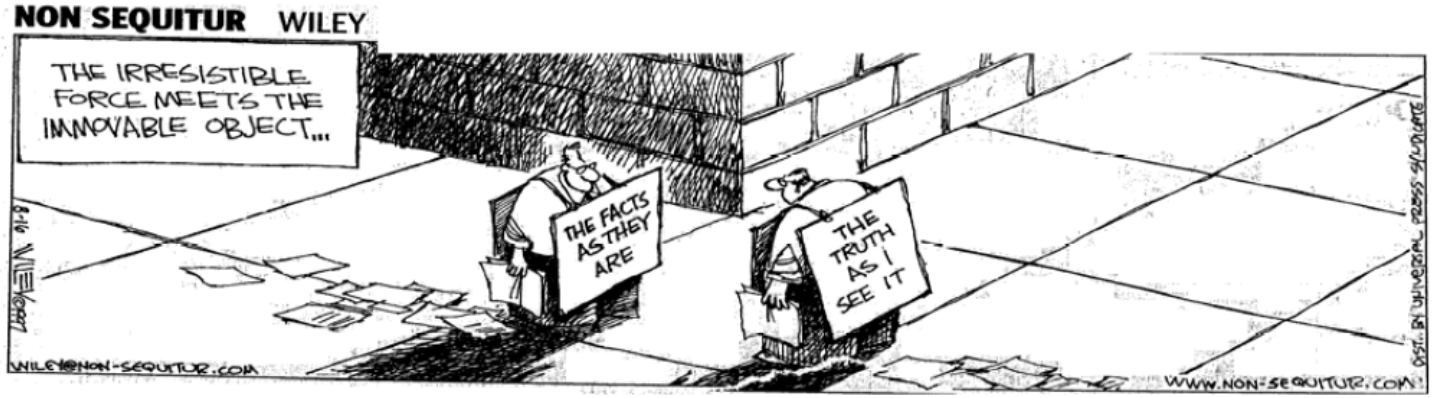
- ‘‘If you once forfeit the confidence of your fellow citizens, you can never regain their respect and esteem’’



Trust is asymmetric

- **Negative (trust-destroying) events are more visible or noticeable than positive (trust-building) events**
- **Sources of bad (trust-destroying) news tend to be seen as more credible than sources of good news**
- **Distrust, once initiated, tends to reinforce and perpetuate distrust**
- **Much of what the media reports is bad (trust-destroying) news**

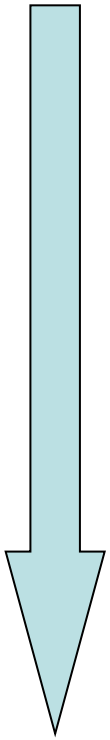
- **Technical solutions**
  - There is no doubt that technical analysis is vital for making risk decisions better informed, more consistent, and more accountable.
  - However, trying to address risk controversies primarily with more science is likely to exacerbate conflict



- **Process-oriented solutions**
  - Risk decision making is inherently subjective and represents a blending of science and judgment with important psychological social, cultural, and political factors
  - Introducing more public participation into both risk assessment and risk decision making in order to
    - make the decision process more democratic,
    - improve the relevance and quality of technical analysis,
    - increase the legitimacy and public acceptance of the resulting decisions.

Risk Communication

Developmental stages of risk communication



- All we have to do is get the numbers right
- All we have to do is tell them the numbers
- All we have to do is explain what we mean by the numbers
- All we have to do is show them that they've accepted similar risks in the past
- All we have to do is show them that it's a good deal for them
- All we have to do is treat them nice
- All we have to do is make them partners
- All of the above

Adler & Kranowitz, The Keystone Center, 2005

Seven golden rules of effective risk communication

- **Accept and Involve the Public as a Legitimate Partner**
- **Plan Carefully and Evaluate Performance**
- **Listen to Your Audience**
- **Be Honest, Frank and Open**
- **Coordinate and Collaborate with Other Credible Sources**
- **Meet the Needs of the Media**
- **Speak Clearly and with Compassion**

Adler & Kranowitz, The Keystone Center, 2005

Further reading