The distinction between *intrinsic danger* and *risk of exposure* , between *safety* and *precaution*:

how to reasonably manage a biological crisis (ex virus) between *objective facts* and *opinions*.

Jacques de Gerlache
Dr Sc. Pharm., (eco)toxicologist
Crisis & environmental management expert
The GreenFacts Initiative

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Facts on Sustainability, Health and the Environment

“Houston, we have a problem ...«

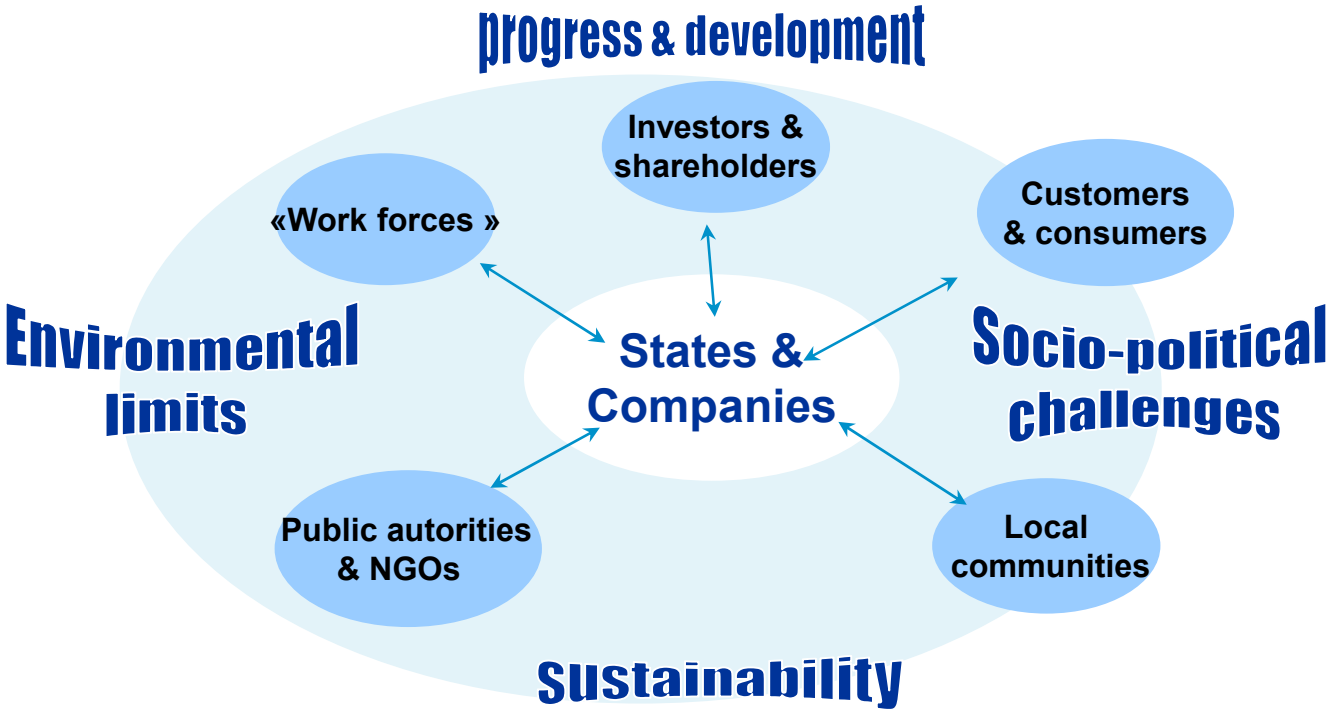
Jim Lovell, Apollo XIII

Act, but how?

”Agitation is not movement"

Lao Tseu ***(?)***

The society faces diverse challenges in a changing world



Decide about risks and security: first objectify the facts

Opinions must not precede the facts!

The challenge:

- **help to better distinguish among various elements and objectively take into account the facts, their context and their concrete meaning;**
- **On this systemic basis, help to form opinions to make important decisions (eg regulatory).**

There is a simple tool for finding your way around, developing an analysis grid, benchmarks:

a compass !

The four Poles of the compass to manage societal challenges without losing sight of the north!

Pole 1
Identify the HAZARD:
Intrinsic properties

Pole 4 :
Integrate EXPECTATIONS
between tolerated risks and expected benefits

Pole 2
Evaluate the RISK
related to the exposure to the hazard

Pole 3 :
Decide (regulate) the level of SAFETY
to be taken into consideration

Managing a health risk, such as the COVID-19 corona virus

Identify its intrinsic HAZARDS

Integrate EXPECTATIONS
between tolerated risks and expected benefits

Assess the RISKS
associated to its spread

Decide the appropriate SAFETY measures

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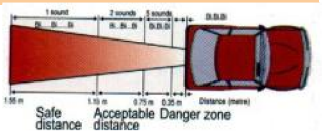

1st pole :
Identify the intrinsic hazards

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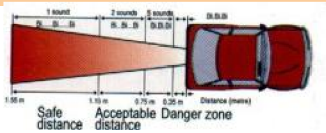

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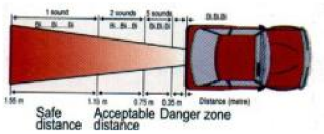

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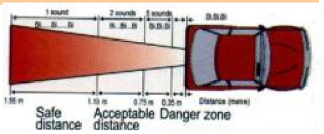

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1st pôle : Identify the hazard(s)

- The hazard describes the undesirable properties intrinsically associated with the nature of an element: microbes which kill, a salt which corrosives, speed is dangerous, dioxin which is toxic;
- For biological agents this dangerous nature is not linked to the intensity of the exposure to this effect.
- For physical or chemical agents, it is a combination of the dose and the duration or frequency of exposure to this adverse effect.
- Technical and (eco)toxicological tests make it possible to determine for most chemical, biological and physical agents a "*no effect level* ".

About acceptable limits and safety factors

- To define an *acceptable exposure limit value* for a dangerous biological agent and certain physical agents (eg radiation), the guidelines generally recommend safety distances and isolation measures;
- *For chemicals*, a safety margin is always included to take into account, for example, the possible differences between observations on animals and the reality and diversity of human exposures;
- These are generally between 100 and 1000, depending in particular on:
  - the type of effect : *irreversible or not*;
  - the degree of knowledge of the hazardous properties: *number and types of test studies carried out, etc..*

About the levels of safety factors

- **By comparison, on some highways, the following warning signs appear about safety distances between two vehicles:**

« One mark : danger ; two marks : safety »

The safety factor applied there is 2.

- **Given that a mark length is 25 m, should a safety factor of 100 be applied, what would be the distance between two vehicles?**

Among major health hazards that appeared in the 20th century

- Influenza, leprosy, malaria, polio, tuberculosis and other “age-old” diseases are now often fought with vaccines but continue to cause millions of victims;
- Among the dangerous viral and bacteriological agents presenting major risks which appeared in the 20th century are those of AIDS, Ebola, Chykungunya;
- Others also affect plants, such as the *Xylella Fastidiosa* bacteria that destroy olive trees or *Fomes annusus* for pine;

The challenge is always to identify the *hazard*(s) for everyone, measure the *risks* and take the appropriate *safety* measures

Methods for identifying infectious hazards

- Traditional methods of identifying a dangerous property for a species of an infectious agent rely on the multiplication in the laboratory of the potentially pathogenic agent in order to be able to identify it;
- These methods, such as giving birth to vaccines, are time-consuming and sometimes very expensive;
- Genetic engineering now makes it possible to identify many pathogens in a faster and more reliable way;
- Other methods are based on the identification of antibodies produced in reaction to the pathogenic effect.

Multidisciplinary toxicology: to identify the dangerous properties of chemical substances

This implies, to collect data rom the multiple disciplines of human and veterinary medicine:

- **Pharmacology including pharmacokinetics, (histo)pathology, hematology,…;**
- **analytical toxicology, "in vivo" and "in vitro"; experimental toxicology and clinical toxicology: toxicology of acute and repeated dose exposures: subacute, subchronic, chronic, multigenerational;**
- **clinical chemistry, cell toxicology, genetics (and "omics");**
- **immunotoxicity and toxicology of reproduction, carcinogenicity;**
- **Mechanistic toxicology and epidemiological toxicology;**
- **Biostatistics and mathematical modeling.**
- **…**

For hazards towards the environment, a complementary science: *ecotoxicology*

- **For "generic" substances, the ecotoxicity is tested in the laboratory and in a reproducible manner on representative type organisms of each trophic level:**
  - **For plants: micro-algae (blue - green algae, diatoms);**
  - **For crustaceans and molluscs: duckweed (daphnia);**
  - **For mammals: fish: (rainbow trout, exotic aquarium fish);**
  - **For the microorganisms in charge of biodegradation: specific bacteria or sample of wastewater treatment plant.**

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2d pole:
Evaluate the RISK(S)
of exposure to the hazard

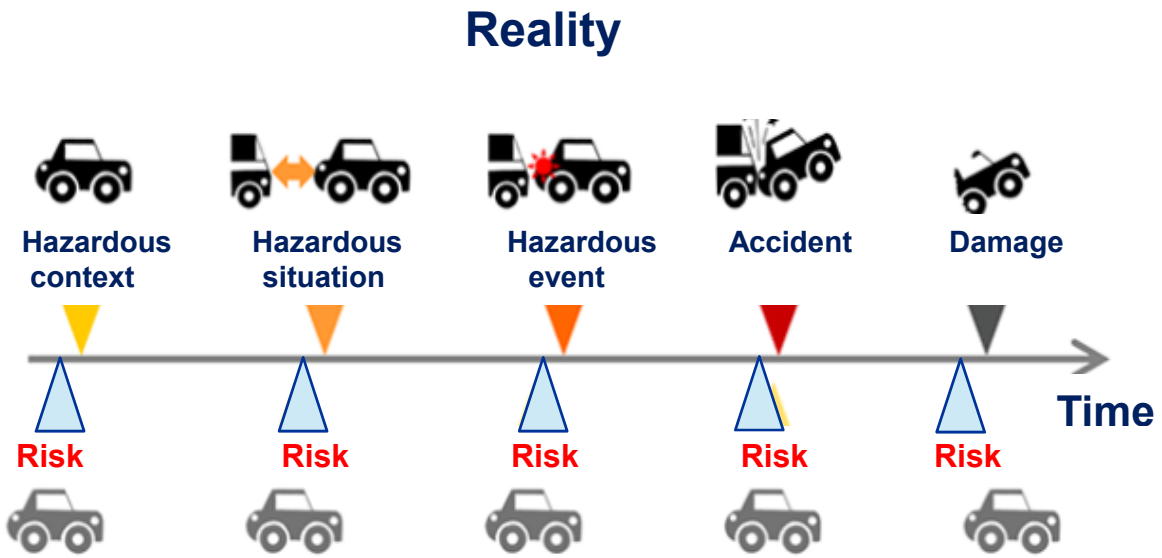
2d pole : Assess the risk(s)

- The risk is linked to the level of exposure to an agent with undesirable properties;
- The degree of risk depends on a combination of the frequency of exposure and the intensity of exposure;

Risk = danger x (frequency + intensity)

- Risk is defined as a probability and therefore incorporates a degree of uncertainty;
- Unlike an intrinsic hazard, it can often be controlled.

The relationship between hazard and risk:
the materialization of the probability of being exposed to it



2d pole : minimise the risks (1/2)

- Unlike an hazardous property which is intrinsic, a risk of exposure can be reduced, therefore it can be mastered;
- Risk reduction measures can target:
  - The reduction of the sources of the dangerous agent, either physical or chemical;
  - The reduction in exposure levels, especially for *infectious agents*, as their sources are not always manageable.

2d pole : minimise the risks (2/2)

- **The reduction measures decided may relate to:**
  - ***Prevention an/or restriction of use*** **/substitution of the hazardous agent itself;**
  - ***Reduction at the source*** **of emissions;**
  - ***Containment*****;**
  - ***Disinfection*****, depollution / dilution;**
  - ***Personal protection means*** **if exposure is unavoidable:** ***trainings, masks, gloves, etc.,***
- **Acceptable exposure limits can be decided on the basis of bacteriological or (eco) toxicological tests;**
- **Actual exposure levels must be measured or assessed (anticipated) if this is an unprecedented hazard.**

The risk of exposure to infectious agents

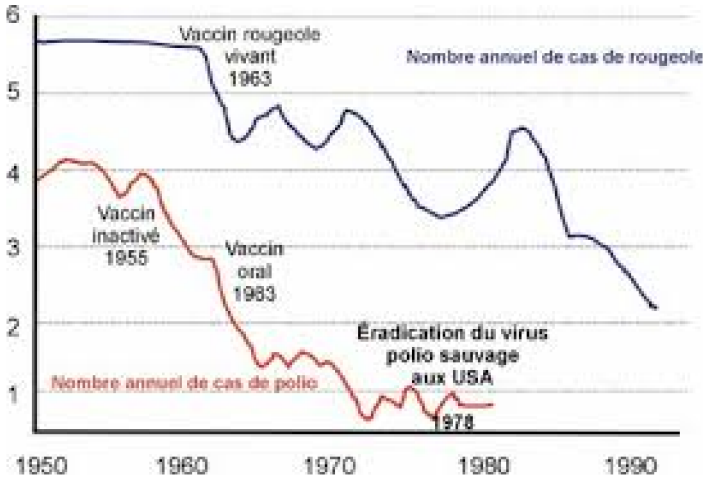
A peculiarity of infectious agents is that, unlike chemical or physical agents, they multiply spontaneously within target species;

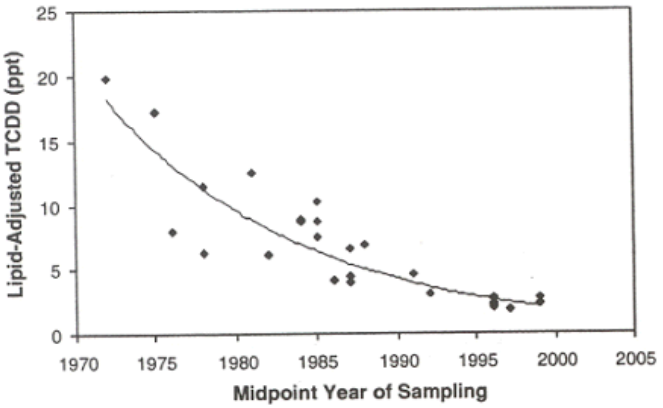
- **Therefore, it is possible that a single exposure reaches the threshold of probability of triggering the pathogenic effect;**
- **This risk will depend on various factors such as the *stability of the agent*, its *mode of propagation*, its *intrinsically pathogenic character* as well as, of course, the *immune capacity of the organism* to develop an adapted effective defense;**

Infectious risk will then to be measured as the *probability of point or single exposure,* therefore relatively independently of its "intensity" and duration.

Examples of managed risks

Some infectious diseases or human exposure to toxic lemicas like dioxins





Evolution of the risk of poliomyelitis and measles and human level of contamination by dioxin (TCDD)

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The case of « agents families »

- ***Examples: virus, GMO's, nanomaterials, … ;***

- **What are we doing to characterize their individual risks? "Case by case" or globally?**
- **The "risk" of GMO syndrome:**

"All in the same bag !"

- **Their hazards, and therefore their risks, are not necessarily comparable.**

Example : a GMO that produces insulin in a specialized laboratory cannot be compared to a genetically modified plant found in the wild;

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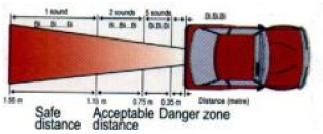
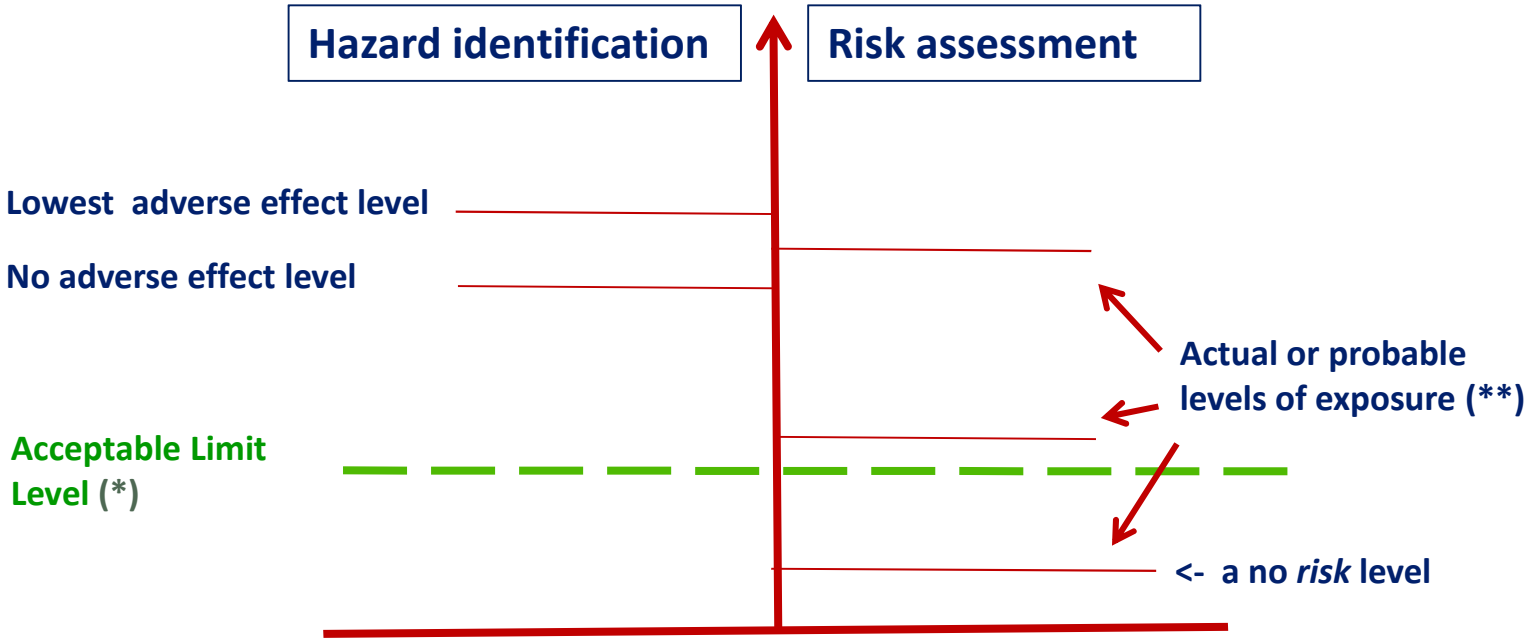


3rd pole:
Evaluate the level of acceptable SAFETY

Safety evaluation implies by definition the comparison between hazard and risk

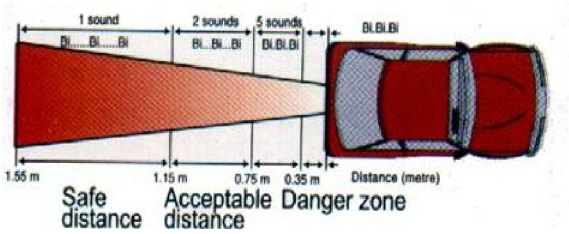


(*) *Includes safety factors*

(**) *Includes uncertainty factors*

3rd pole : the choice of a safety level

- ***Safety*** **is defined as a level of risk which is *chosen* to be considered by the civil society as "*acceptable*".**



- **the decision setting a risk as acceptable is not (only) based on science and medical considerations:**

it is also a ***political decision***

Safety and acceptable risk

- **Besides toxicity thresholds, regulatory decisions on safety have to include a series of other variables:**
  - **Technological performance available;**
  - **Social and economical constraints;**
  - **Conciliation between advantages and drawbacks,…**

But also:

  - **Cultural and/or ethical;**
  - **Political/democratic and "emotional" choices.**

Safety is thus not defined only in *absolute* terms

Safety through prevention

- **Controlling a risk most often involves preventive measures:**

Examples:

- *Disinfection of people, of water, of places,;*
- *Use conditions of hazardous products and their labeling; ;*
- *Protective equipment, restriction of use;*
- *Physical means such as seat belts, fire extinguishers in homes; … ;*
- *Retention basin under the oil tanks, safety caps on the bottles of dangerous products, etc ..*

- **These innumerable measures allow often to benefit from the advantages of the applications by limiting the disadvantages to an "acceptable" maximum.**

Criteria of *acceptable safety* for management decisions vary with the situations

For example, the difference between :

- **Exposure of kids and adults;**
- **Exposure of skilled workers and neighbors of a plant;**
- **Potential side effects of pharmaceutical drugs and safety of food ingredients;**
- **Safety of automobile and airplane transport;**
- **Drinking water quality and drinking alcohol;**
- **Speed restrictions for road driving and for car racing;**
- **DDT use in Northern and tropical countries;**
- **War and peace situations;**
- **…**

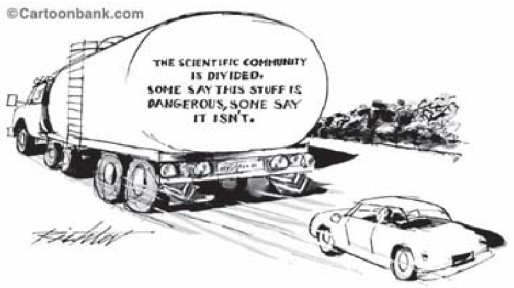
Personal use

Professional use

Facing uncertainty …

- **Some kinds of hazards may still resist to fully <u>quantifiable</u> hazard and risk assessment:**

  - **Some viruses (*H5N1 or H1N1, corona, …);***
  - **Greenhouse gases and climate change;**
  - **Some GMOs ;**
  - **Some nanomaterials;**
  - **Endocrine disruptors;**
  - **Some electromagnetic fields**
  - **…**



… taking some precaution.

" To prevent rather than to cure"

"Approach" (USA) or "Principle" (UE) ?

- **No common definition;**
- **introduced formally in some Treaties (UE,) or in Constitutions (France);**
- **E.U. Guidelines for its practical application**

The Precautionary Principle (EU legislation)

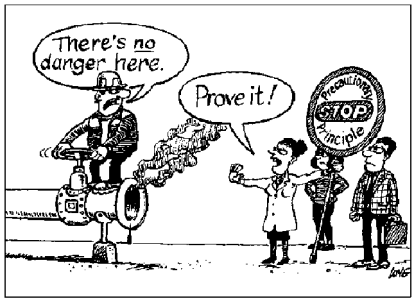
"When ***sufficiently established elements*** suggest that an activity is ***seriously*** expected to potentially produce ***irreversible*** damage to health or the environment,

measures should be taken even if the ***definite proof*** or the causal link is *not yet* ***formally*** *established* with ***absolute certainty***"

From precaution ...

- **Objective:** to "***manage uncertainty***" and give the means to decide and act politically when there is no expert consensus about the level of risk .

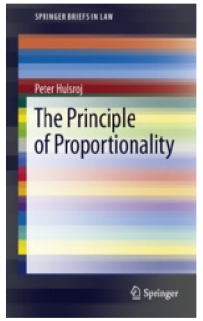
- **Challenge:** practically, the decisions should be ***proportional*** to the expected risk



… to proportion

- A Proportionality Principle is also written in the texts *(ex: penalties vs offense seriousness)* ..

- The EU guidelines on the application of the Precautionary Principle recommend explicitly to make the balance between:



"I think we need to take another look at your risk management strategy..."

Precaution and Proportion

A proportion in precaution

Precaution should remain *proportional:*

- **Relatively to the risk itself: *infectious, physical, chemical, environmental, economical, ..;***
- **Relatively to its systemic consequences.**

The challenge is to evaluate if the consequences of a *disproportionate precaution* would not be as "*undesirable*" than the risk tself:

- *life conditions, mobility of emergency services, water, energy food, pharmaceuticals distribution, …*
- *Transportation, access to critical services, economical impact,…*

Which implies *a balance* between:

Precaution and Proportion

A proportion in *substitution*

A "*substitution principle*" also tends to be introduced into the texts ...

The substitution of an agent (*physical, chemical, biological*) having "undesirable" properties is only legitimate if:

- **The "undesirable" properties of the agent are not equally "desirable" (essential); *ex: oxygen !;***
- **Adverse effects linked to these properties actually have a significant probability (*risk)* of occurrence: specific uses of *chemical substances, pesticides, pharmaceuticals, radiations, but also … alcohol and tobacco ...***

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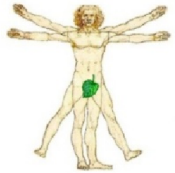
4d pole:
Evaluate the EXPECTATIONS
of involved stakeholders

4th pole : perceiving a risk and building an opinion about it



Risk perception **is not always in relation with its objective importance but also on its understanding and acceptation :**

Accepted **risk:**	**drink, smoke , skiing ,...**
Tolerated **risk:**	**road accident , vaccine, ...**
Imposed **risk:**	**food or water contamination , industrial plant , pesticide use, nuclear power , GMOs….**

The *acceptation* of a safety measure will depend on the level of perception and understanding of the risk

The risk/benefit balance is less obvious in our “modern” world or city

- **A benefit can be defined as the expected result from any initiative :**

For…	I have to ...
eating	*hunt*
heating	*chop wood*
selling	*produce*
keeping my health	*take vaccines*
ensuring my well being	*sport*

Any (non)-activity implies a level of risk: there is no “zero risk” ! …

The confrontation between *Facts* and *Opinions*

- The public is usually confronted to a clash of OPINIONS: authorities, industrial lobbies, NGOs, media, political organisations, …;
- In the meantime, the interest of all stakeholders is to have *balanced* regulatory decisions taken on the basis of FACTS;
- Facing this situation, an option is to help the stakeholders, including the public, *to build their own balanced opinion.*

The *emotional* dimension in risk perception

The perception of a risk includes an important emotional dimension

"No explanation, as brilliant it can be, will calm down an outraged public : the effort to calm outrage should come first"

Peter Sandeman

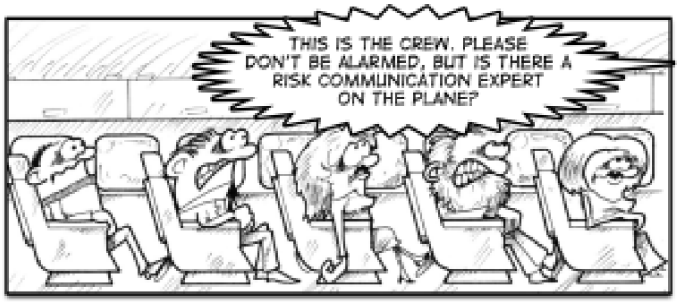
A conviction, once formed, is almost impossible to change !!

The emotional dimension in risk perception

- Risk and crisis communication are thus more effective when we are able to:

  - **Accept that feelings are an important** and valid part of why people react to risks or crisis the way they do;

  - **Take into account the psychological and emotional factors** involved when providing information about any given situation



Factors increasing the feeling of risk

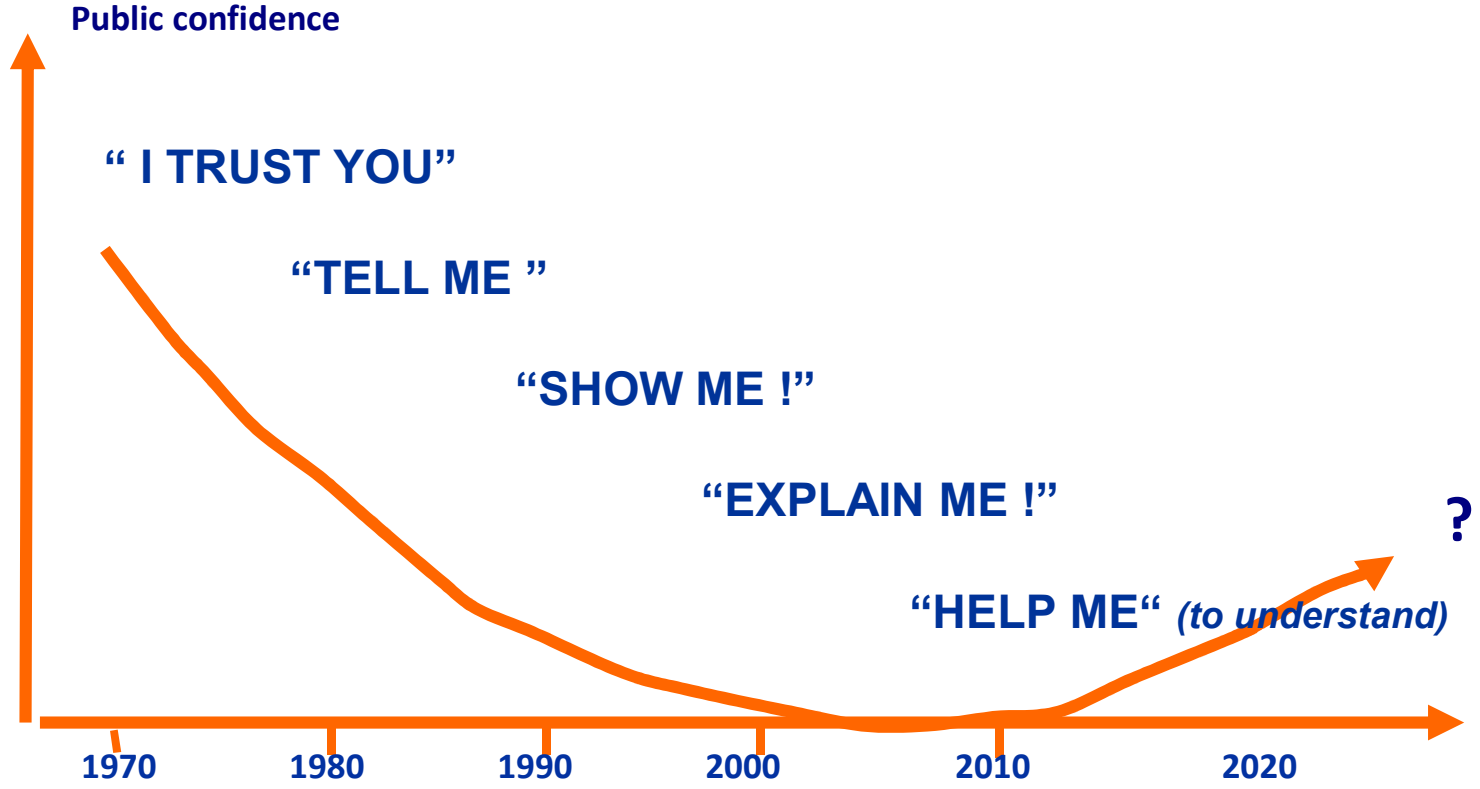
- **Trust**
  The less we trust the people the more afraid we will be. The more we trust, the less fear we feel.
- **Dread**
  A risk that kills you in a dreadful way evokes more fear than one that kills more benignly.
- **Uncertainty**
  The more uncertain we feel, the more we protect ourselves with precaution and fear.
- **Control**
  Do you feel pretty safe when you drive?
- **Choice**
  A risk we choose seems less dangerous than a risk that is imposed on us.
- **Children**
  Survival of the species depends on survival of our progeny. Mercury traces in fish eaten by children seems dramatic.
- **Natural or man-made**
  Anthropogenic risks, such as genetic modification of food, evoke more fear than 'natural' risks, such as the hybridization of species to develop new varieties.

.

Between messages from experts and public's expectations: an unavoidable gap !

Expectations of the public:	Legitimate answers of experts:
• Confidence ?	- "*Trust us !*"
• A Protection ?	- there is a "tolerable" risk !
• A certainty ?	- statistical uncertainties !
• Identification ?	- Justification !
• An emotion ?	- Reason !
• A "raison d'être" ?	- Competitiveness !
• Education ?	- Information !
• Nature ?	- Technique is unavoidable !
• A personalfree choice ?	- The "collective" interest !
• NIMBY !	- "Done deal", "*Fait accompli*" !

The evolution of public's expectations from the experts and from the authorities



4th pole: deciding on health and environmental risks

- This requires building a "*pedagogical dialogue*" which allows each stakeholder to understand that:
  - Risk and benefit are indivisible;
  - Accepting a risk implies "choosing" it;
  - That there is not necessarily an alternative (*substitute*) to manage each type of risk;

- Understand it so that it becomes possible to establish this equiibrium between:

PRECAUTION and PROPORTION

Convince by providing facts rather than selling « opinions » !

- It is at this stage that the ***scientific facts*** have to be provided to the stakeholders;
- Their opinions will be stronger if they build them by themselves !
- These facts need of course to be made available in a language accessible to the non specialist:
  - ***Simplified;***
  - ***Accurate;***
  - ***Faithful and peer reviewed:***
  - ***But strictly factual.***

- = > These summaries should thus be carefully prepared.

GreenFacts : a mean to communicate reliable source of peer reviewed information to non-experts

- **Strictly *factual* summaries : no comment, no opinion on te content**
- **Above 150 subjects covered in 2-level summaries written in an accessible language;**
- **Summaries in ENG, FR, SP, GER, NL ;**
- **About 4 million worldwide visits/yr**
- **Well ranked in search engines.**

The "*GreenFacts Highlights*"on the essentials about vaccines and vaccination

- **A faithful summary of the leading report producedthe *US Center for Disease Control and Prevention* (CDC) and the *World Health Organization* (WHO):**

https://www.greenfacts.org/en/vaccines/index.htm

- **Also the short animation video on vaccines and vaccination :**

https://www.youtube.com/watch?v=b0VwPMx3ENo

- **An animation video on Hazard, Risk & Safety Subtitles in English, French, German, Dutch, Spanish, Chinese and Russian;**

https://www.youtube.com/watch?v=PZmNZi8bon8

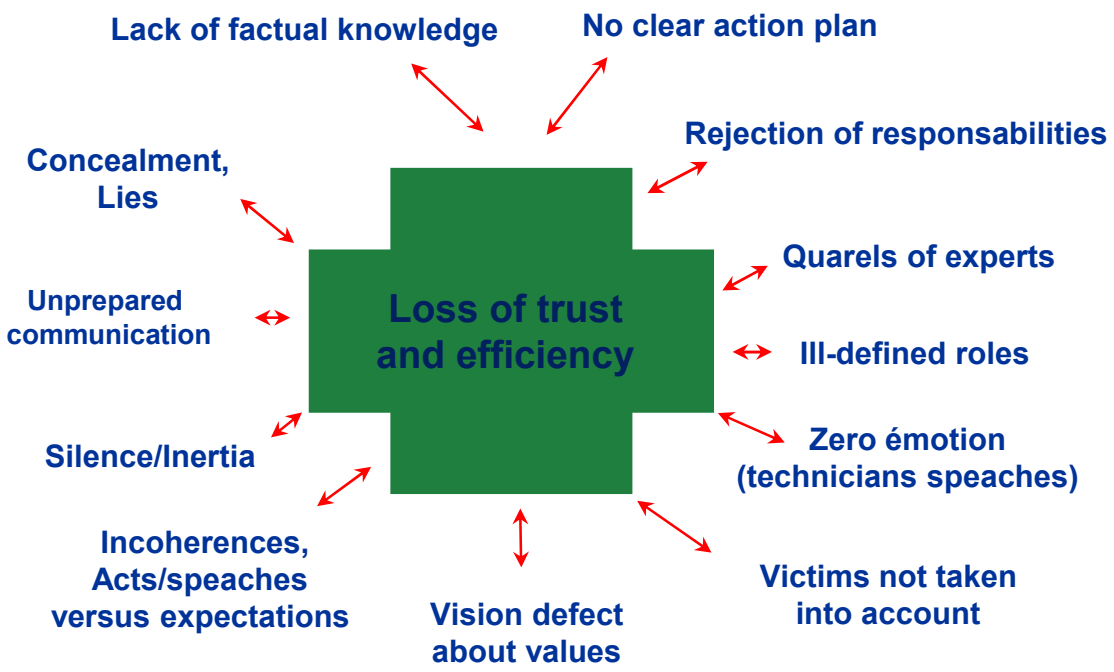
French speaking version:

https://youtu.be/wRmfvFYDNr8

The widening of crisis situations …

- **Crises are more and more numerous and more and more frequent;**
- **Their nature widens:**
  - **Health** crises: infections; soon out of control (corona virus, Ebola, Lyme;…);
  - **Sanitary and Food** crises**:** food security: legionellosis, dioxin crisis, foot and mouth disease,
  - **Natural** crises: climate change, storms, heat waves, floods,…
  - **Accidental** crises: Concorde, AZF, road,…
  - **Pollution** crises: oil spills,…
  - **Ecological** crises: biodiversity, over-exploitation, epidemics, etc.
  - **Economic** crises: energy transitions, financial, relocation, globalisation,
  - **Human resources** crises: restructuring, layoffs, …
  - **Justice and political** crises: governance, ethics, indictment of leaders, rigged elections…

The main pitfalls in crisis management



Good attitudes in the event of a crisis

1. **Above all: anticipate: (*almost*) all types of crisis are predictable !;**
2. **React quickly: a (public) opinion once installed is difficult to change!;**
3. **Adopt a systemic approach to the crisis, the only one capable of integrating all the issues and players in real time;**
4. **Ensure that opinions and therefore decisions are based on facts and not selected according to pre-established opinions: *public, political, economic, ideological, etc*...;**
5. **Present clear and consistent arguments.**

In brief: the challenges in Safety management

Identify the **Hazard**

Substitution ?

Assess the **Risk(s)**

Prevention ?

Manage the level of **Safety**

Precaution ?

Proportion !

Understand and **endorse** the safety

Communicate on the Facts & value of the agent !

GreenFacts
Facts on Sustainability, Health and the Environment

- **See the short animation video (subtitles in 6 languages: https://www.youtube.com/watch?v=PZmNZi8bon8**