

Global Risks Management: from Perception to Governance

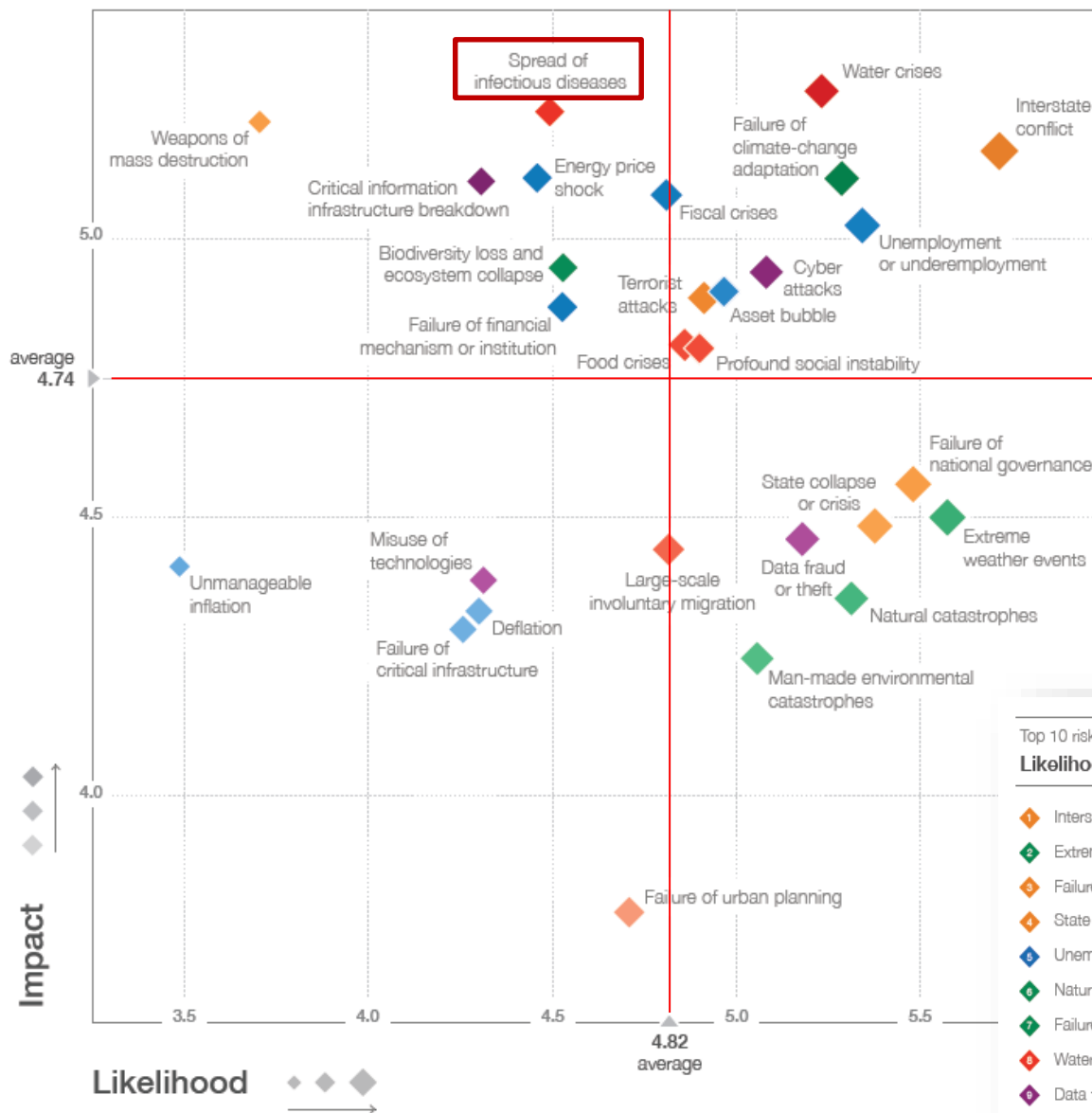
- Placing Blood Safety Risks into Perspective

Dr. Sebastien Delmotte

MAD-Environnement
France

OVERVIEW

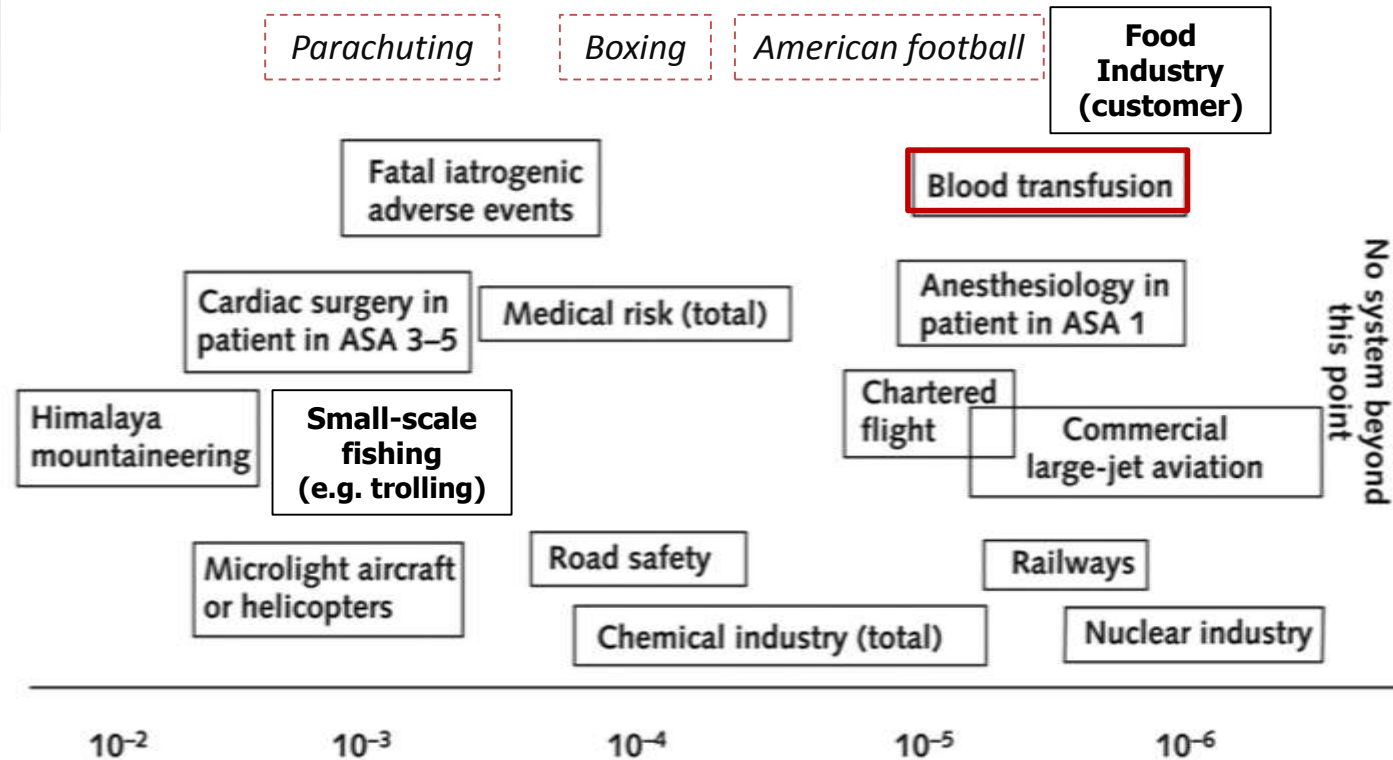
LIVING IN A HAZARDOUS WORLD....



**Source: Global Risks 2015.
World Economic Forum**

RISKS IN SOCIO-TECHNICAL SYSTEMS

AVERAGE RATE PER EXPOSURE OF CATASTROPHES AND ASSOCIATED DEATHS



Individual
achievement



High Reliability
Organizations
(HRO)

Amalberti R. et al, 2005. Five System Barriers to Achieving Ultrasafe Health Care. Annals of Internal Medicine, 3 May 2005, Vol 142, No. 9
Windsor et al., 2009. Mountain mortality: a review of deaths that occur during recreational activities in the mountains. Postgraduate Medical Journal, Vol 85.

BLOOD TRANSFUSION RISK IN FRANCE (2010-2013)

	Residual risk in 2010-2012 (per Distributed platelet concentrates)
HIV	4×10^{-7}
HTLV	5×10^{-8}
HCV	1×10^{-7}
HBV	4×10^{-7}

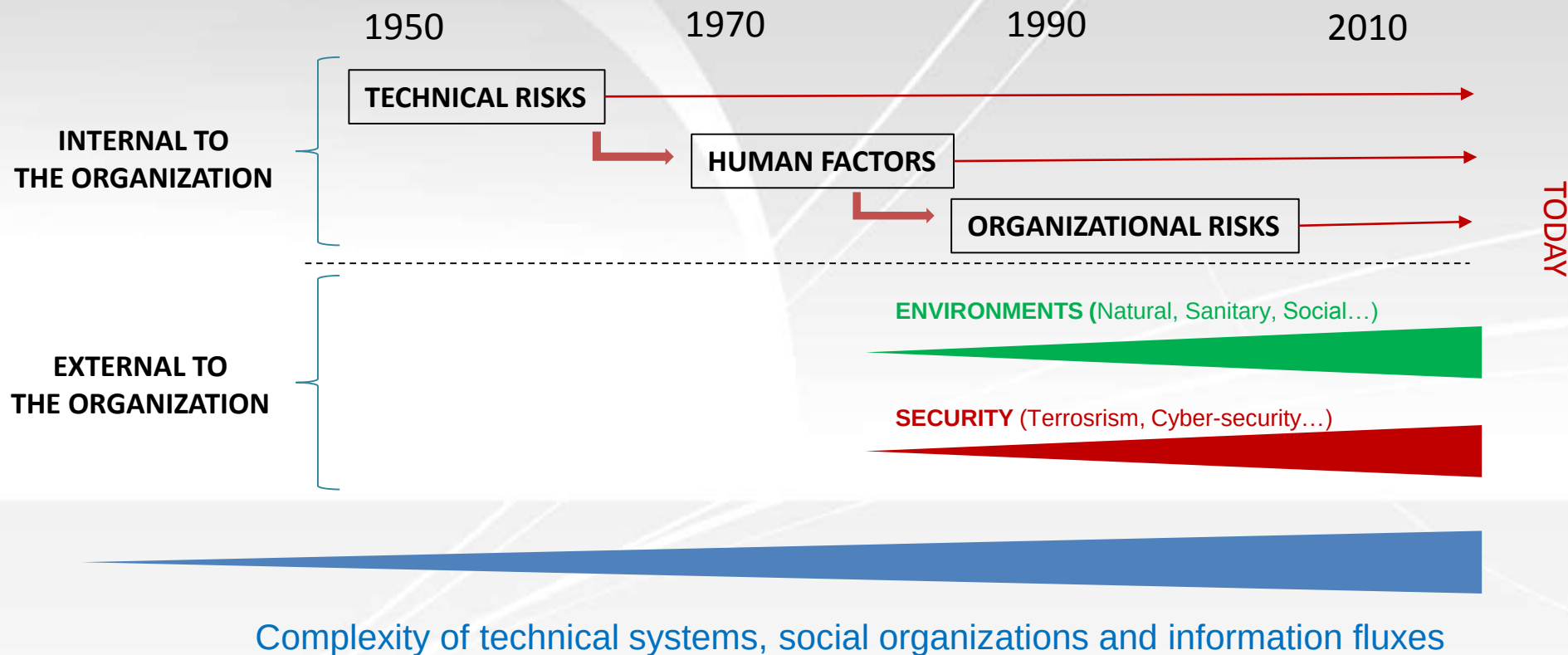
	Incidence rate (2013)
Recipient death (2013)	2×10^{-6} per distributed LBP
Recipient life-threatening (2013)	3×10^{-5} per distributed LBP
Donor death (2013)	3.5×10^{-7} per donations (unexplained)
Donor severe health damage (2013)	3×10^{-4} per donations

INVS- Surveillance épidémiologique des donneurs de sang en France – 1992-2012

Morel et al., 2013. Control of the bacterial risk of transfusion in France in 2013. TRANSFUSION CLINIQUE ET BIOLOGIQUE

ANSM, 2014. Rapport d'activité d'hémovigilance 2013.

EVOLUTION OF RISK MANAGEMENT THINKING....

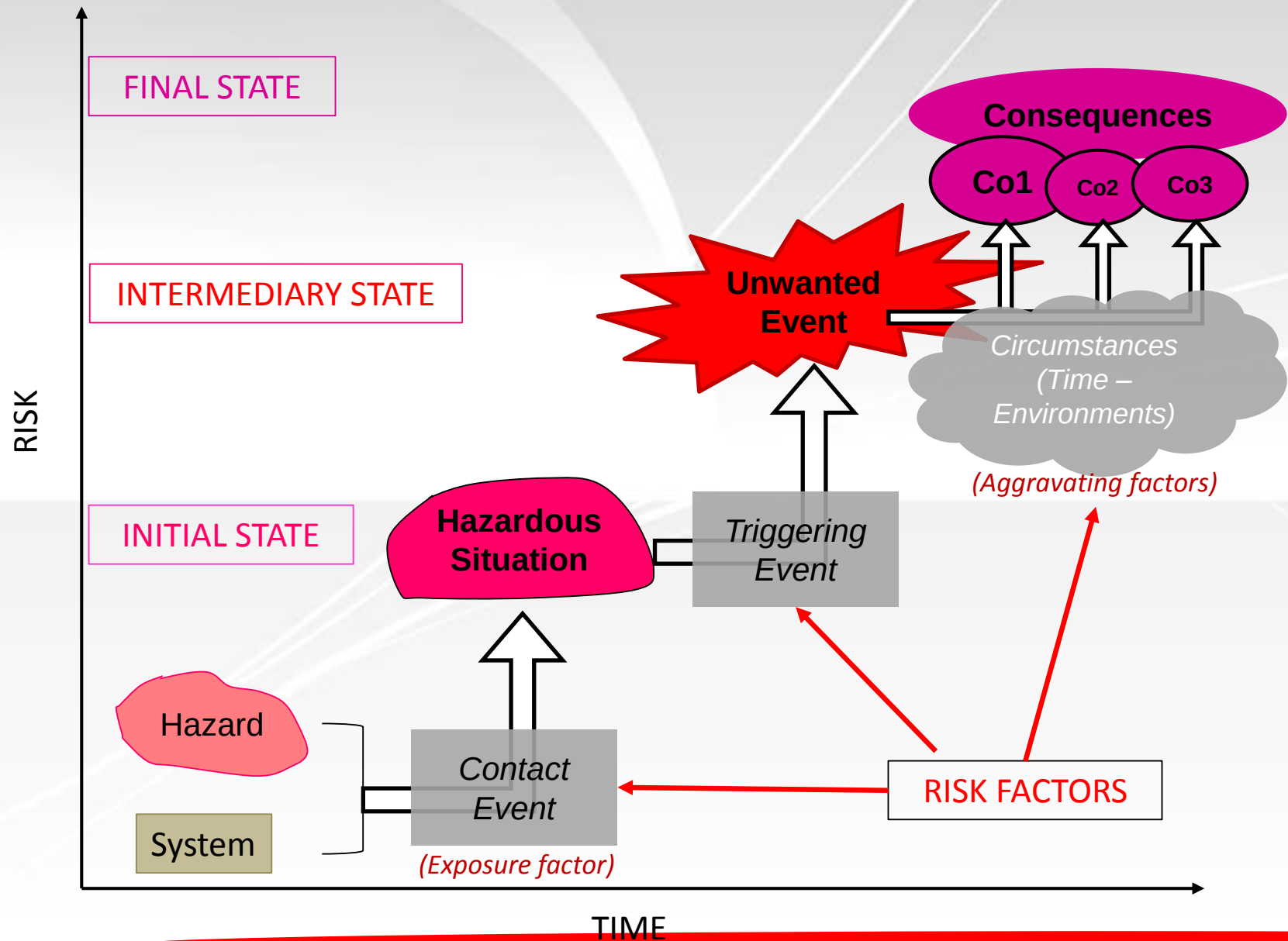


PARADOX

Safer is a system, **higher** is the **pressure** by customers, justice and media

RISK MANAGEMENT: CONCEPTS AND PRACTICE

RISK: ORIGIN, CONCEPT AND MEASURE (1)

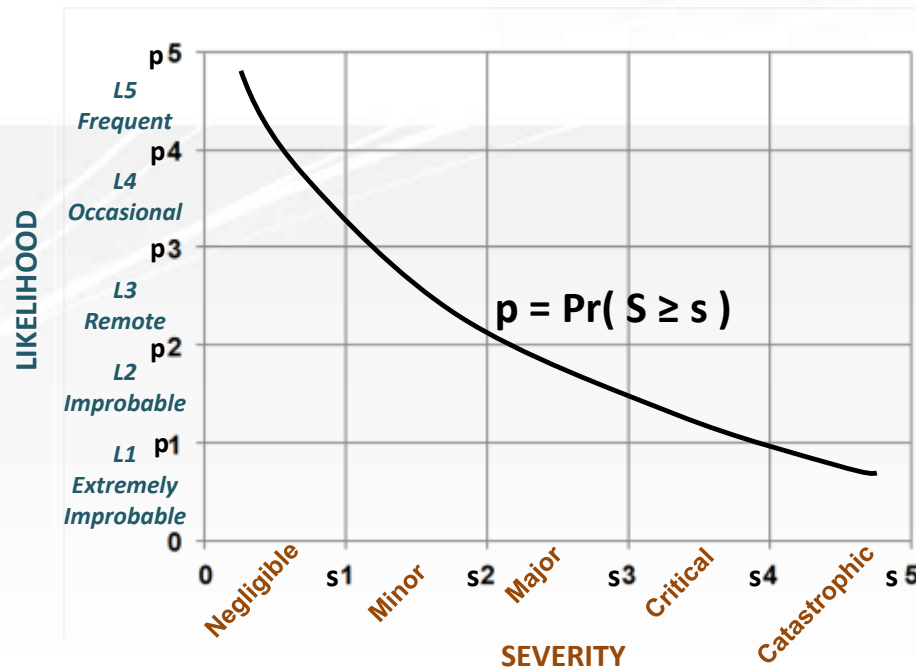


RISK: ORIGIN, CONCEPT AND MEASURE (2)

RISK is the MEASURE of an **unwanted event** defined

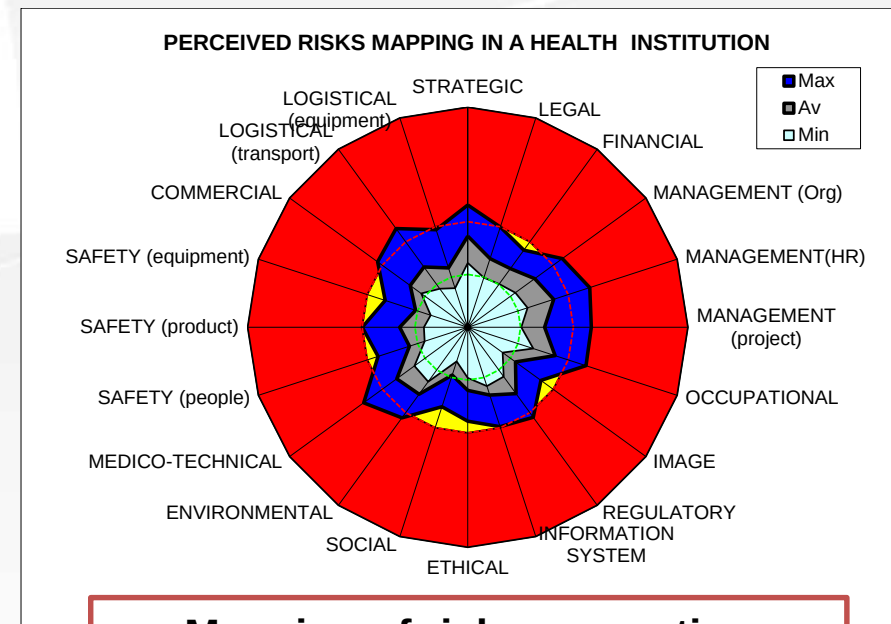
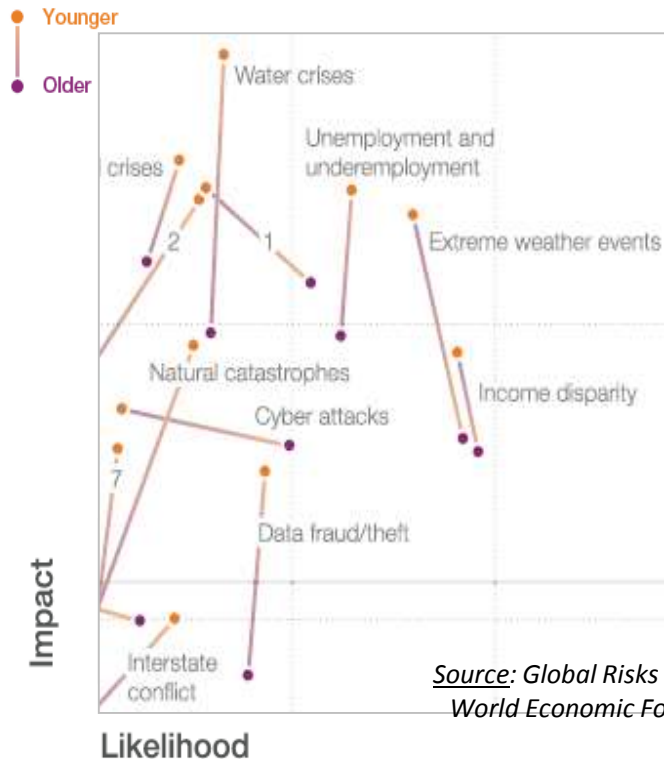
by **TWO INDISSOCIABLE** dimensions:

- The **SEVERITY (S)** of the consequences of the unwanted event
- The **LIKELIHOOD (p or L)** of the consequences of the unwanted event.



RISK PERCEPTION

- Risk perception reflects the stakeholder's needs, issues, knowledge, belief and values
- Risk perception deeply determines decisions and actions both at the individual and collective scales



Mapping of risks perception
=
photography of the risks of a system

RISK MANAGEMENT AND KNOWLEDGE

Elements can be specified
neither in a qualitative way
nor in a quantitative way

FIELD OF UNKNOWABLE

A given event can have
several causes and
several consequences

Elements **can** be specified both
in a qualitative and
in a quantitative way

Uncertainty area

FIELD OF KNOWABLE

RISK MANAGEMENT

Certainty area

A given event has
one cause and one
consequence

Theoretical determinism
Statistical determinism

CHANCE

From Desroches et al., 2014

PROBABILITY

- Giving a probability to an unknown event is a **nonsense**
the concept of probability has not any sense in the field of unknowable
- Probability does not say **when** the event will occur
- Who wants to quantify needs **data**
- Quantification **cannot** by itself **improve** the safety of a system

In RISK MANAGEMENT

it is s better to use

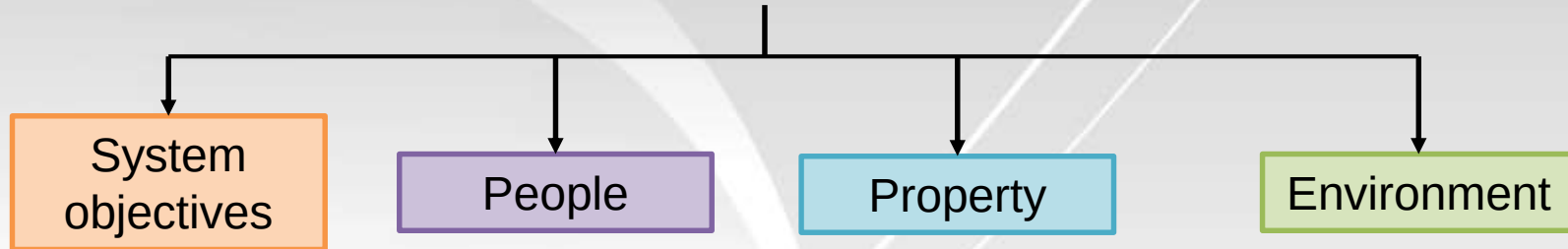
SUBJECTIVE PROBABILITIES

which is defined as

the level of confidence in a given information
(Bayes, Finetti, Savage)

SEVERITY OF CONSEQUENCES (EXAMPLE OF AIRCRAFT PRODUCTION FLIGHT TESTS)

HARM TO



Severity levels	Level name	Description of consequences
S1	Insignificant	No impact on the system's performances or safety
		Aircraft delivered with a delay of less than one week
		Aircraft delivered with less than 3 extra production flights
S2	Minor	Degradation of system's performances with no impact on safety
		Aircraft delivered with a delay of more than one week but less than one month
		Aircraft delivered with less than 2 extra customer acceptance flights
		Aircraft delivered with less than 6 extra production flights
		Local adverse publicity or significant adverse reaction for a single customer
S3	Major	Significant degradation or failure of system's performances with no impact on safety
		Aircraft delivered with a delay of more than 1 month
		Aircraft delivered with 2 or more than 2 extra customer acceptance flights, and/or with 6 or more than 6 extra production flights
		Possible injuries and significant increase in crew workload
		Aircraft refused by customer for technical reason
		Major international adverse publicity/effect on customer confidence
S4	Hazardous	Degradation of the system's safety or integrity
		Significant damage of the aircraft affecting its performance
		Serious injuries of any passenger, crew member or person in the vicinity of the aircraft
S5	Catastrophic	Significant degradation or failure of the system's safety or loss of integrity
		Loss of the aircraft
		Fatalities of any passenger, crewmember or person in the vicinity of the aircraft

S1-S3: Impact on performance

S4-S5: Impact on safety and integrity

SEVERITY OF CONSEQUENCES (EXAMPLE OF BLOOD TRANSFUSION)

System
objectives

People

Property

Environment

Severity levels	Level name	Description of consequences
S1	Insignificant	No impact on the system's performances or safety
		No consequence on the patient
		No degradation of ongoing care
		No consequence on the care unit or institution
S2	Minor	Degradation of system's performances with no impact on safety
		Delayed transfusion
		Discomfort of the patient / psychological impact
		Occasional disruption of the activities of the care unit
		Tense staff
		Non-effective quality system
S3	Major	Significant degradation or failure of system's performances with no impact on safety
		Prolonged hospitalization / momentary interruption of the care process
		Patient complaint / sense of insecurity
		Operational degradation in the care unit
		Stressed staff
		Additional costs (to be specified)
S4	Hazardous	Degradation of the system's safety or integrity
		Decline of the patient condition with reversible effects / complementary care or intensive care
		Compensation claim
		Major stress of the staff
		Disorganization of the care unit
		Loss of confidence of users
S5	Catastrophic	Significant degradation or failure of the system's safety or loss of the system
		Death, total disability, coma
		Viral or bacterial severe contamination
		Permanent cessation of activity / closure of the care unit
		Definitive loss of image and confidence of users (donors and recipients), health authorities and professionals

RISK ACCEPTABILITY: THE KEY OF RISK GOVERNANCE

ALARP- ALARA

As Low As Reasonably Practical - As Low As Reasonably Achievable

Criticality scale: decision and action

Criticality levels	Level name	Decisions and actions
C1	Acceptable	Nothing needs to be done
C2	Tolerable under monitoring	A close monitoring needs to be implemented in terms of risk management
C3	Unacceptable	Risk reduction measures need to be taken. Otherwise, the activity needs to be refused totally or partially

A common threshold of **risk acceptability** is the **individual average probability of death**
 10^{-7} per hour

An absolute threshold of **negligible risk** is the probability of **universe disappearance**
 10^{-11} per year

RISK ACCEPTABILITY: RESPONSIBILITY

Referential of risk acceptability has to
make **explicit** the **responsibility** of
the decision-makers and the risk owners

Risk owner has the responsibility to :

- **Reduce** an **unacceptable** risk to an **acceptable** or a **tolerable** level
- **Assume** the consequences of an **acceptable** risk
- **Maintain** a **tolerable** risk at this level

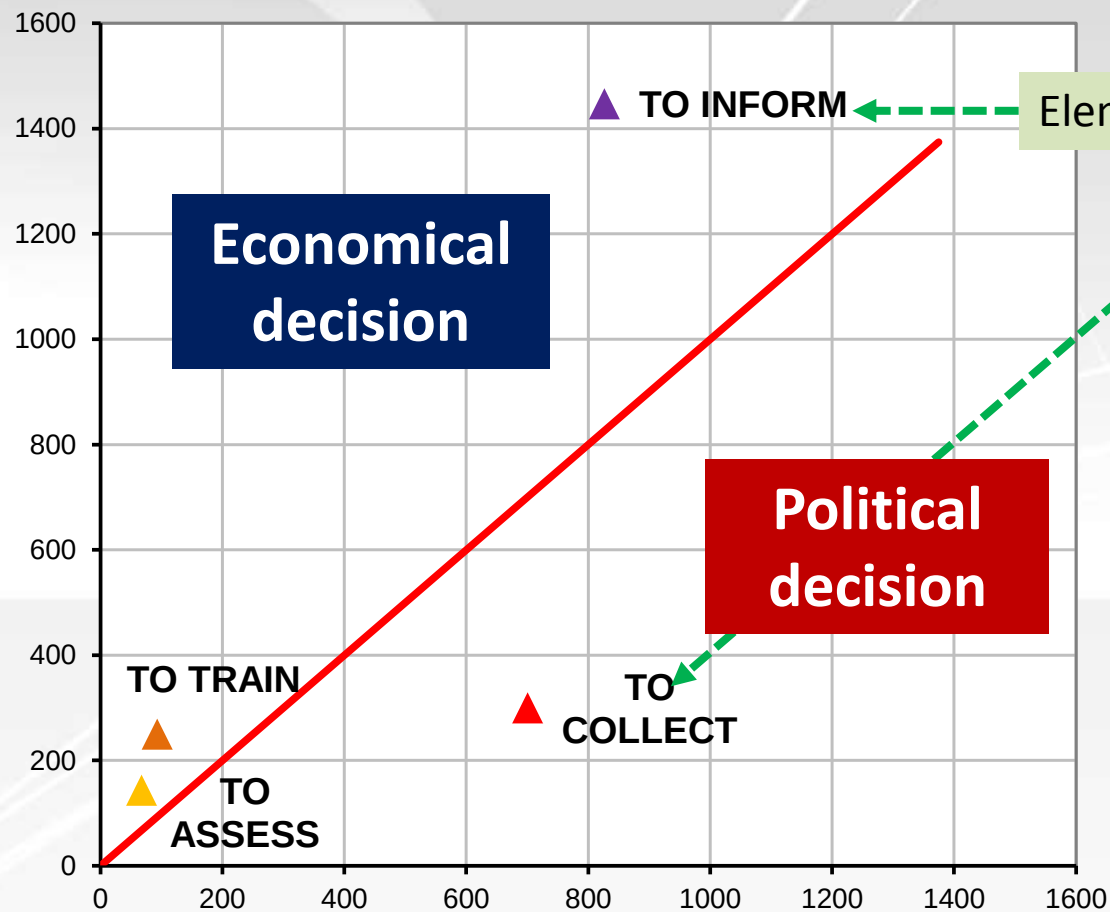
		Severity				
		1	2	3	4	5
Likelihood	5	Green	Yellow	Red	Red	Red
	4	Green	Yellow	Yellow	Red	Red
	3	Green	Green	Yellow	Yellow	Red
	2	Green	Green	Green	Yellow	Yellow
	1	Green	Green	Green	Green	Green

		Severity				
		1	2	3	4	5
Likelihood	5	Yellow	Yellow	Red	Red	Red
	4	Green	Yellow	Yellow	Red	Red
	3	Green	Green	Yellow	Yellow	Red
	2	Green	Green	Green	Yellow	Yellow
	1	Green	Green	Green	Green	Yellow

**Death can not
be refused.**

RISK FINANCING: COST / RISK ANALYSIS

Cost of the Risk without treatment



Cost of the treatments to reduce the risk

TOWARD THE GLOBAL RISK MANAGEMENT

TOWARD THE GLOBAL RISK MANAGEMENT IN ORGANIZATIONS

External	Governance	Technical Means	Studies & Production
Environments	Commercial	Infrastructures & Facilities	Studies & Projects
Politics	Communication & Crisis	Tools & Equipment	Operational
Security	Economics	Information System	Functionnal
Image	Organization		Human
Customers	Ethics & Compliance		Professional
	Finance		Products, waste and Debris
	Legal		Physical / Chemical
	Management	These various risks are treated by compartmentalized disciplines and specific tools: dependability, cybersecurity, survivability, fire safety... - No global vision of the risks of the system - Problems of costly duplication of actions of control - Over specifications - Inconsistencies threatening the security of the systems.	
	Programmatic		
	Social		
	Strategic		
	Technological		

Instead of using different approaches and methods for each of these risks categories, we need to assess them in the light of the same referential to

- Prioritize
- Decide
- Act
- Optimize

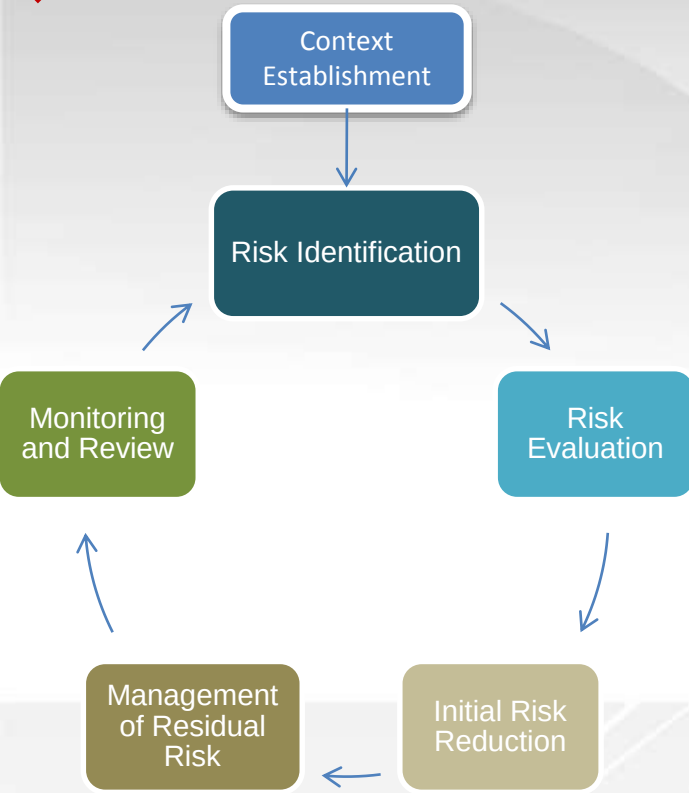
TOWARD THE GLOBAL RISK MANAGEMENT IN ORGANIZATIONS

- Risk analysis must be done at the **system level** (activity, project, product)
- All the hazards in presence of the system must be taken into account to induce scenarios (**structural and functional hazards**)
- Consequences of risks must be analysed in terms of impacts on **performance** and on **safety** and *not only on safety*
- Acceptability process must be **explicit** and all the risks must be analysed through an **unique referential of acceptability**. *Otherwise, risks cannot be compared and prioritized.*
- Risk analysis must provide to the decision-makers : risks mapping , major scenarios, critical elements of the system, prioritization of the risk treatments, financial analysis
- Risk analysis must provide a **risk reduction action plan**.
Risk management is build to act in the real world in reducing unacceptable risks and managing tolerable risks.

We need formalized methods fitting these prerequisites and designed to :

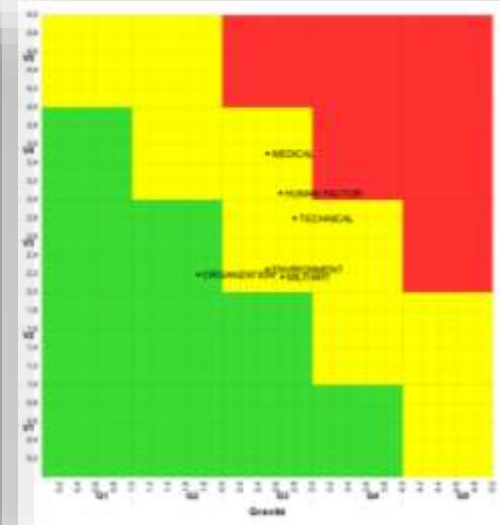
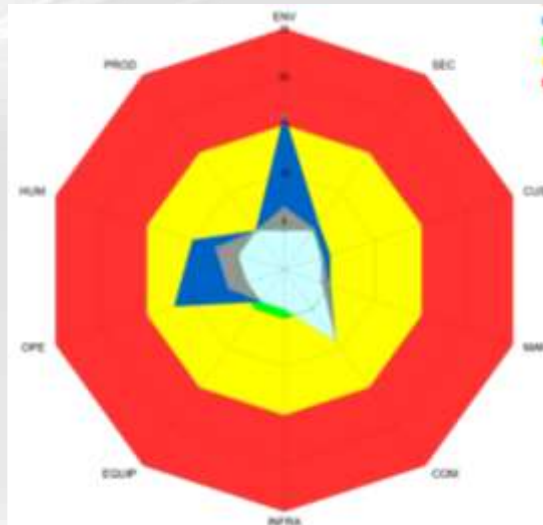
- Formalize existing knowledge
- Identify uncertainty and lack of knowledge
- Help thinking, deciding and acting

RISK MANAGEMENT PROCESS AND GLOBAL RISK ANALYSIS (GRA)

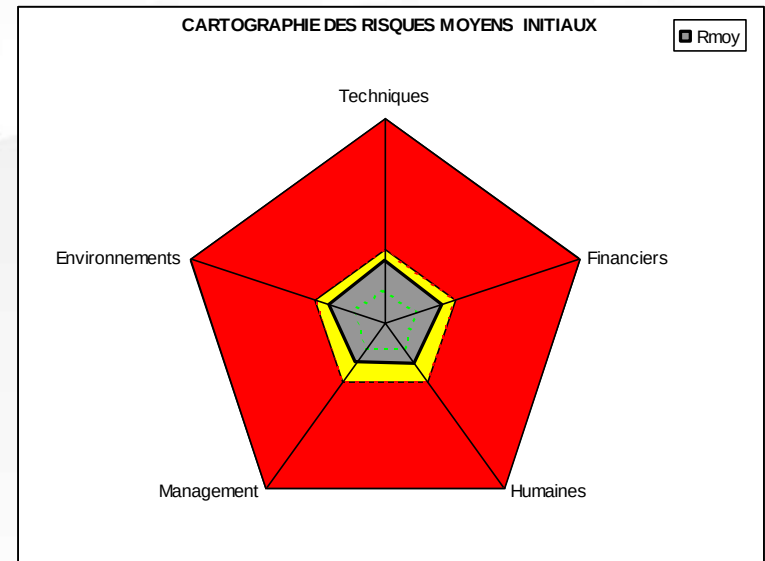
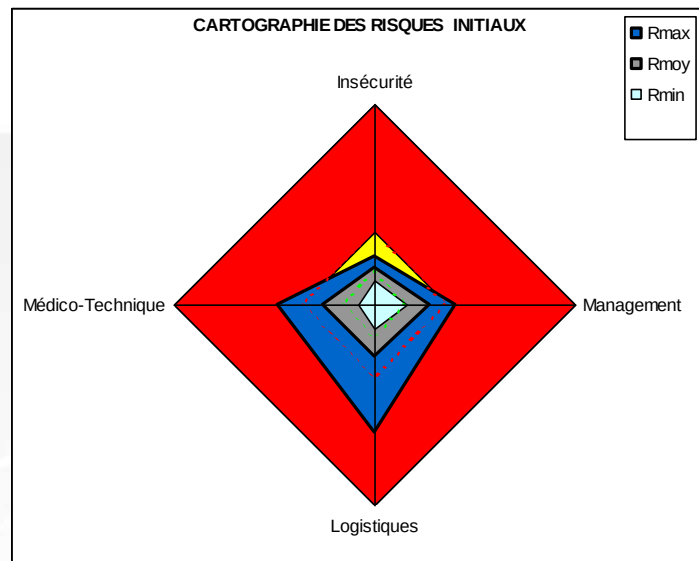
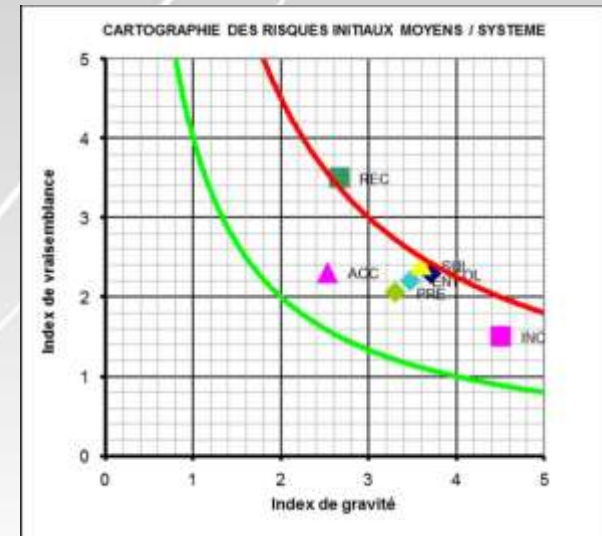
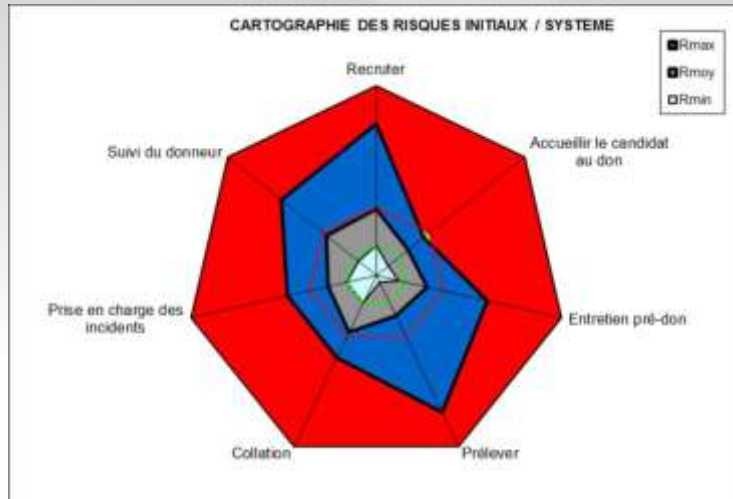


GRA METHOD

- Systemic assessment, mapping and management of risks
- Formalized method and invariant analysis process
- Covering both structural and functional risks during the entire life cycle of the system
- Include cost/risk analysis
- Planning and monitoring the actions of initial risks reduction and residual risks management
- Background of tens of applications in spatial, aeronautical, defence, industrial, sanitary and environmental fields
- Supported by a software



GLOBAL RISK ANALYSIS (GRA) IN A BLOOD INSTITUTION



SGHAIER W, 2014. *Méthode systématique de reconception des processus intégrant la maîtrise des risques : contribution à la réingénierie des processus de l'EFS*. Thèse de 3^{ème} cycle. Ecole Centrale Paris.

FURTHER READING

➤ IN ENGLISH

ISO / IEC GUIDE 51- **Safety aspects - Guidelines for their inclusion in standards**

ISO / IEC GUIDE 73 - **Risk management — Vocabulary**

ISO 31000:2009 - **Risk management — Principles and guidelines**

COOPER D. F., GREY S., RAYMOND G., WALKER P. (2005). *Project Risk Management Guidelines – Managing Risk in Large Projects and Complex Procurements*, Wiley and Sons, Chichester, 384 p.

GILBOA I., 2009. *Theory of Decision under Uncertainty*. Cambridge University Press, 215 p.

LOOSEMORE M., et al., 2006. *Risk management in projects*. 2nd Edition. Ed Taylor and Francis.

➤ IN FRENCH

Alain DESROCHES, AGUINI N., DADOUN M, DELMOTTE S, 2015 (to be published). *L'Analyse Globale des Risques – Principes et Pratiques*, 2de Edition - Ed Hermès Science – Lavoisier, 311 p.

Alain DESROCHES, MARLE F., RAIMONDO E. et VALLÉE F., 2010. *Le management des risques des entreprises et de gestion de projet*, Ed Hermès Science – Lavoisier, 392 p.

SGHAIER W, 2014. *Méthode systématique de reconception des processus intégrant la maîtrise des risques : contribution à la réingénierie des processus de l'EFS*. Thèse de 3^{ième} cycle. Ecole Centrale Paris.

DELMOTTE S, DESROCHES A. (2014). *L'Analyse Globale des Risques Quantitative (AGRq)*, Actes du 19^{ième} congrès Lambda-Mu de l'Institut de Maîtrise des Risques. Dijon, 21-23 octobre 2014.

Thank you for your attention

Thanks to the organization committee and particularly to Dr. Françoise Rossi for the very informative discussions