Risk management: ensuring safety without stifling growth

Panel Session "Back to basics - Quality Infrastructure in Working Party 6"

Valentin Nikonov, GRM, WP.6

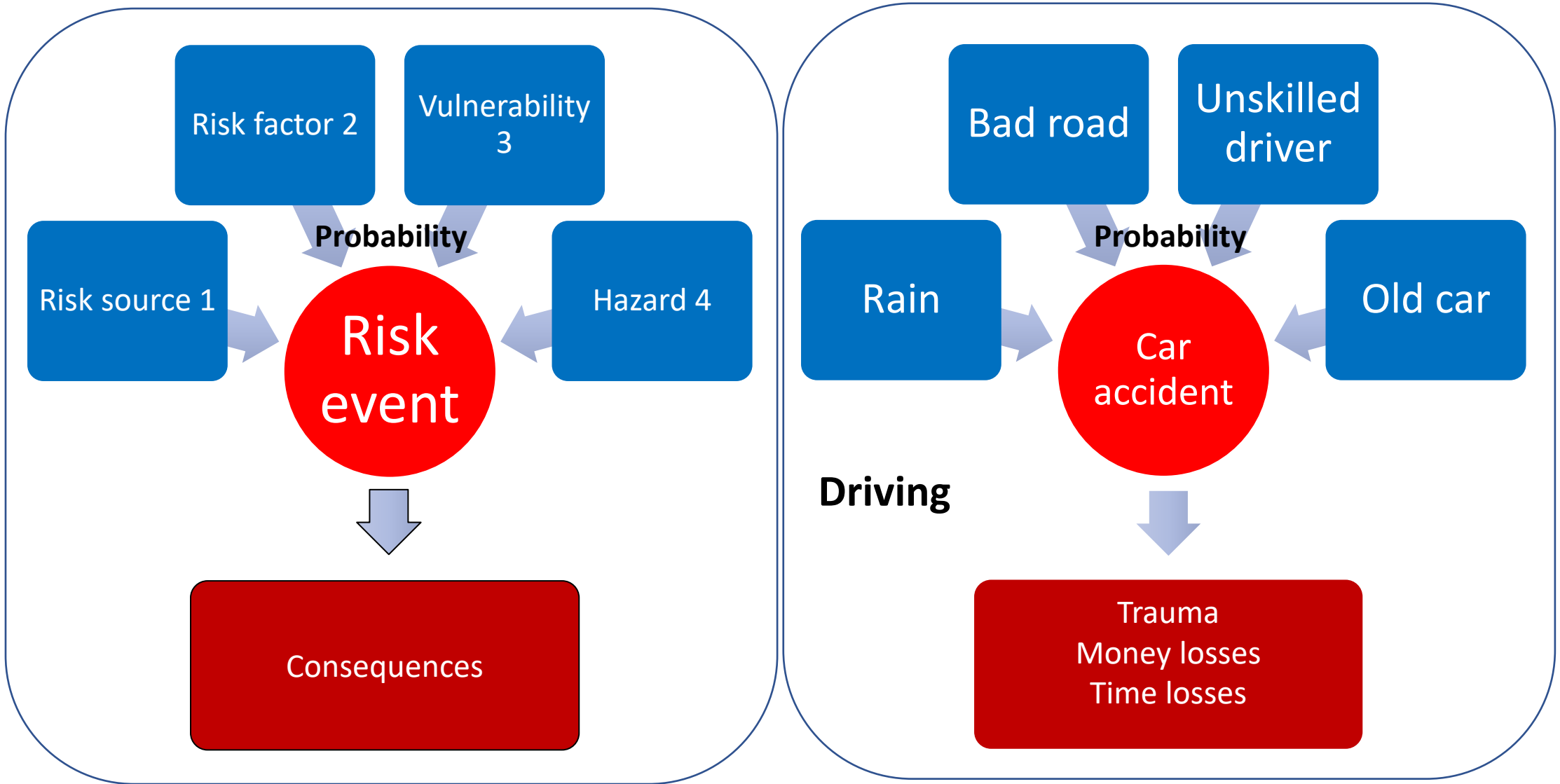
Risk management in key areas of work of WP.6

- Risk management and standardization/overview of risk management
- Risk management in regulation and its contribution to legitimate regulatory objectives (safety/environment/technology) and level playing field
- Management of non-compliance risk: risk management in conformity assessment and market surveillance
- Risk management in international trade
- Future challenges related to risk management in regulatory frameworks (sustainability/digitalization)

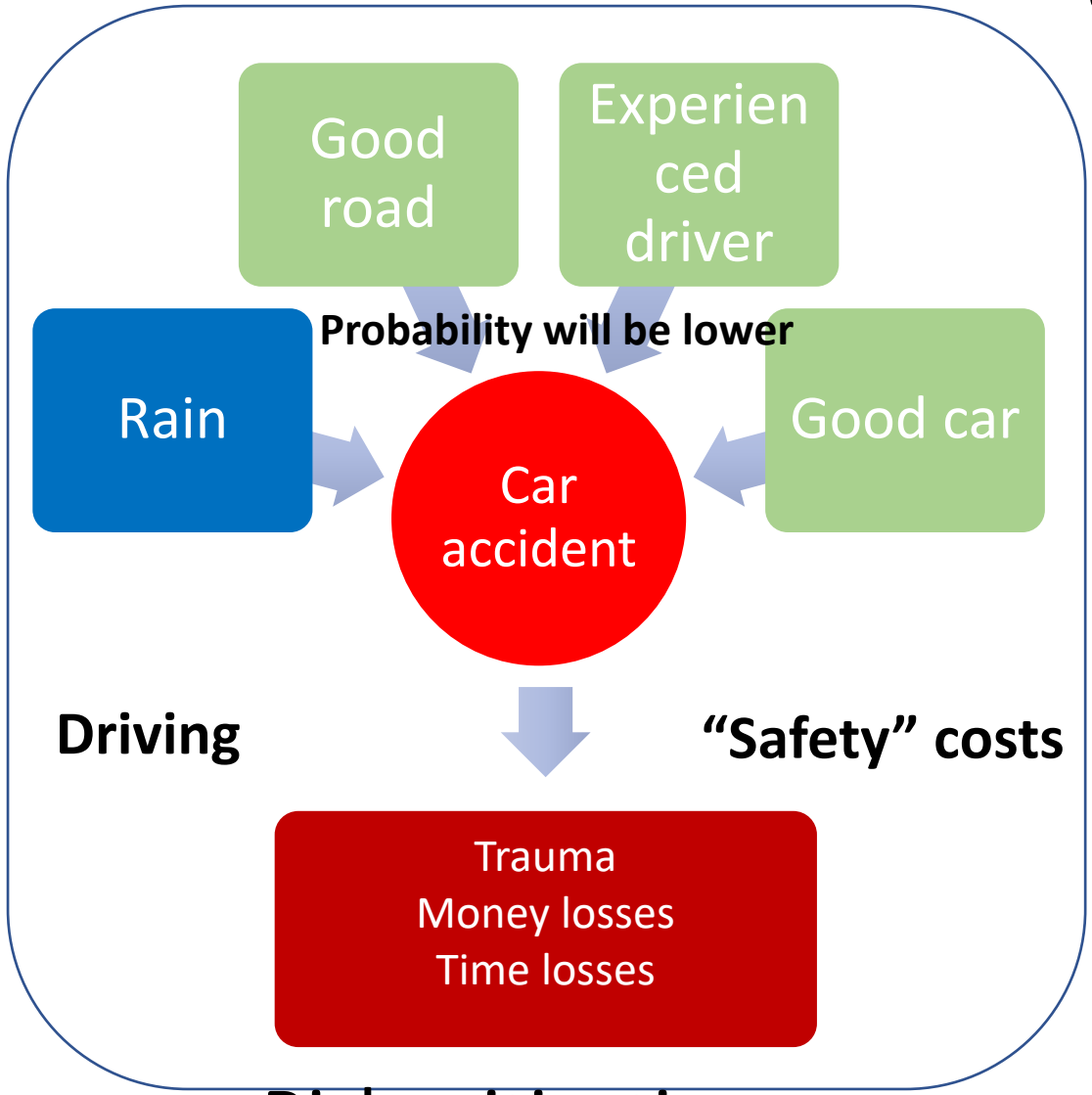
Risk management and standardization

Overview of risk management

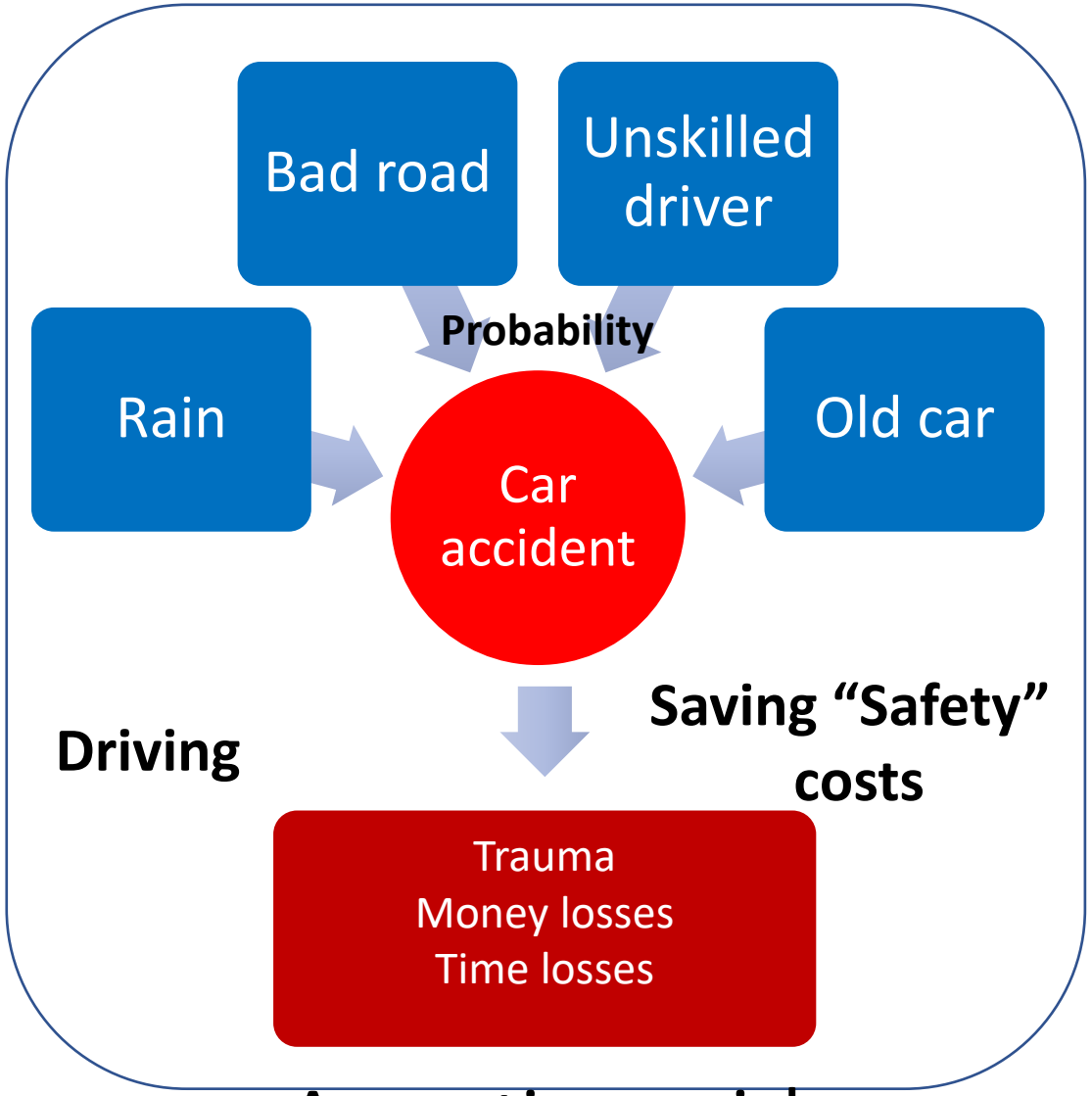
“Effect of uncertainty on objectives”



Risk treatment strategies

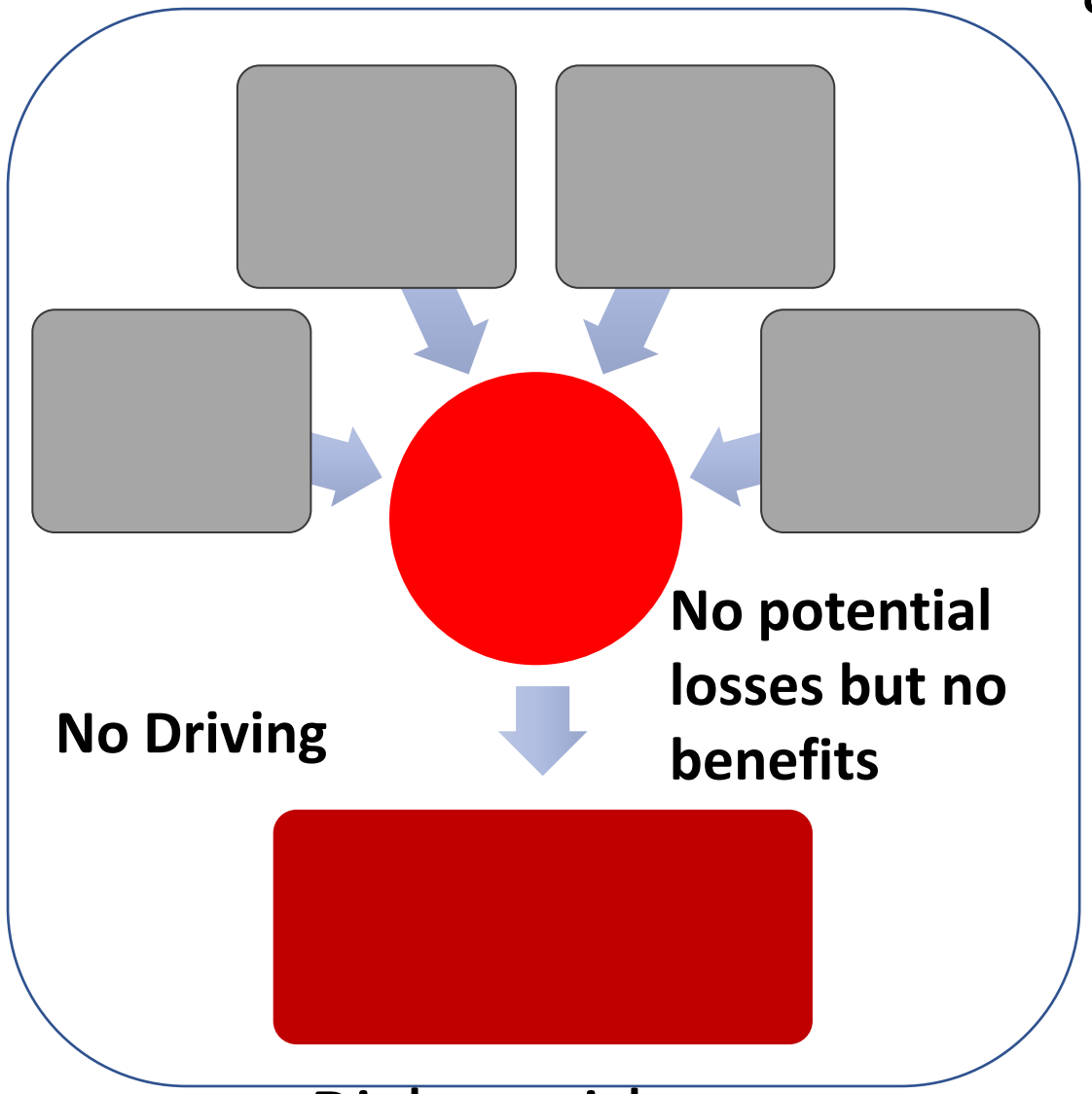


Risk mitigation

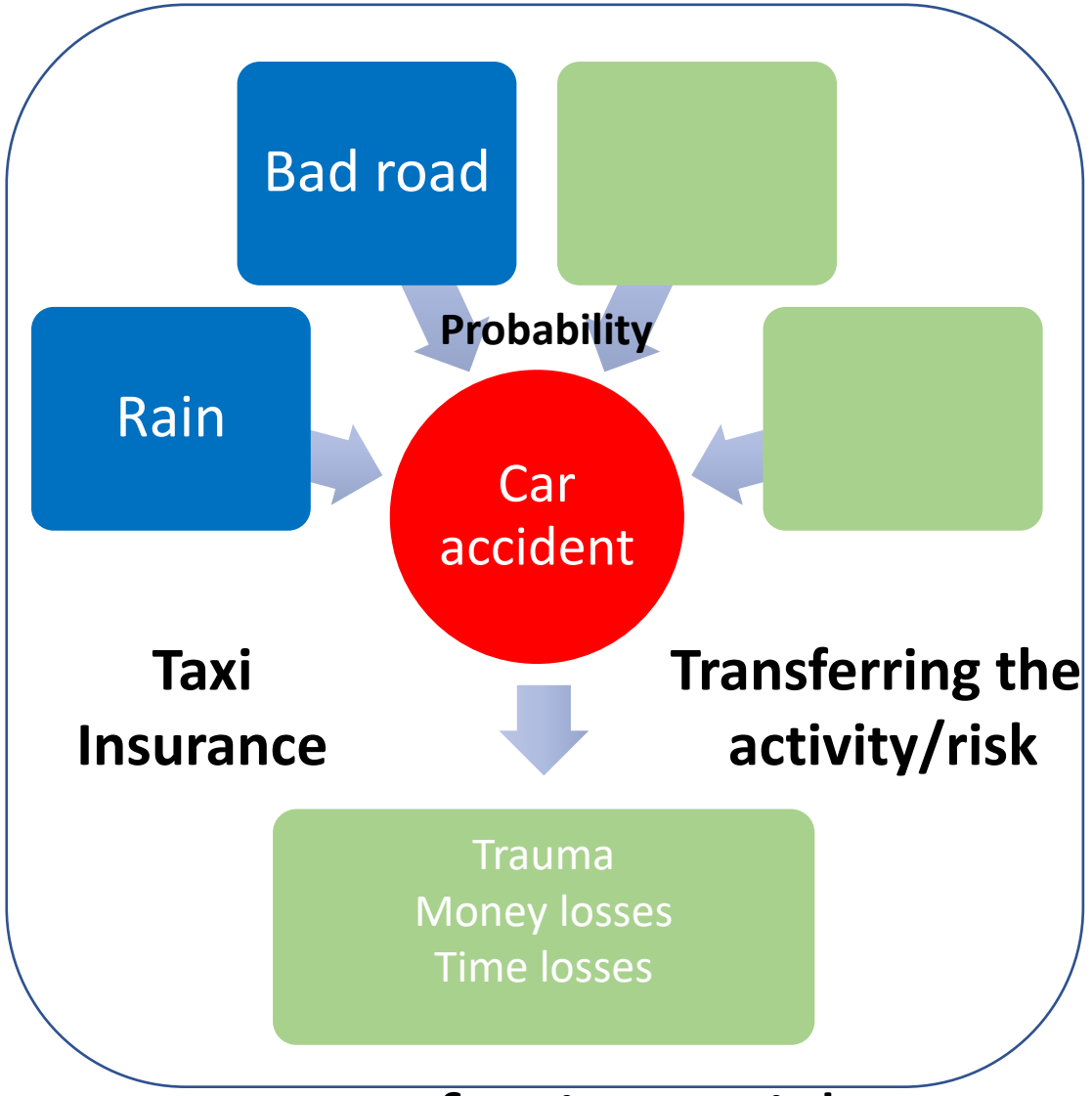


Accepting a risk

Risk treatment strategies



Risk avoidance



Transferring a risk

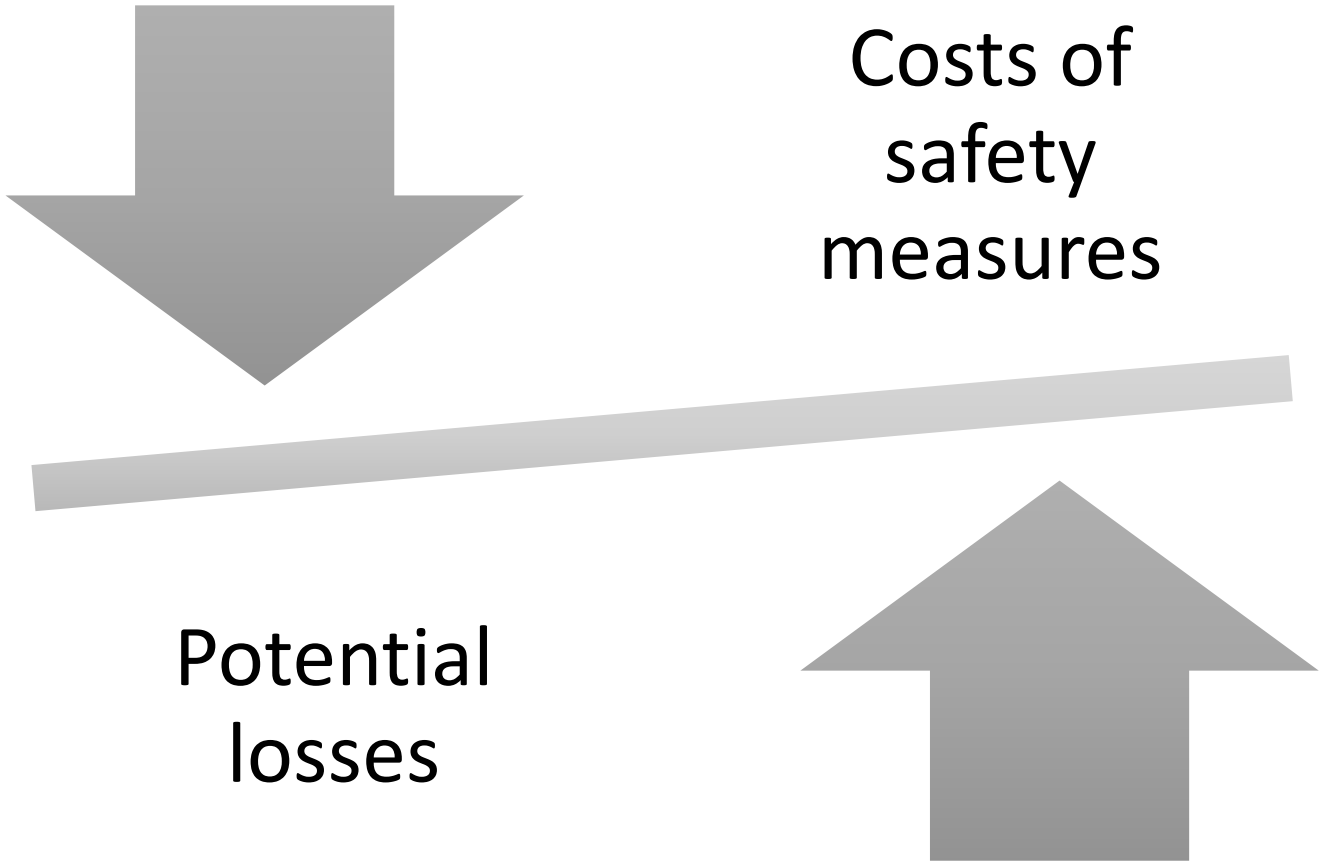
Risk in a form of a data table

- Structure of a neuron within a Neural Network (Machine Learning/AI algorithms)
- Basis for applying Machine Learning and AI tools for evaluating probability

Rain	Bad Road	Unskilled driver	Old Car	Accident
1	1	1	1	1
1	0	1	0	0
….	….	…	…	…
0	0	0	0	1

Objectives of risk management: bringing risks to a tolerable level

Finding the right balance:



Good risk management:

Establishing the context
- Objectives, stakeholders, assets

Risk identification
- Risks are identified in a timely fashion

Risk evaluation
- The most critical risks are given the highest priority

Choosing risk treatment strategies
- A balanced risk treatment is chosen

Implementing the strategy
- Risk treatment is efficiently implemented

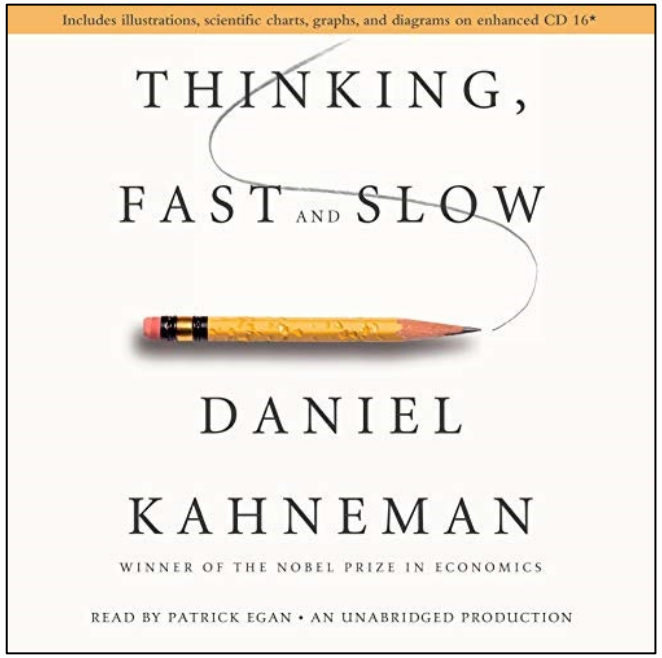
Contingency planning
- Contingency plans are developed, tested and remain relevant, and resources are available to implement them

The need for a formal risk management

Judgment under Uncertainty: Heuristics and Biases

Biases in judgments reveal some heuristics of thinking under uncertainty.

Amos Tversky and Daniel Kahneman



More stable and constant are risk losses, higher are the chances that its probability will be underestimated

More associations people have when thinking about a risk, higher are the chances that its likelihood will be overestimated

Losses caused by objectively low risks are often overestimated

Losses caused by objectively high risks are often underestimated

Easier it is to identify a risk, higher are the chances that its probability will be overestimated

Risk management and standardization

Risk management standards (examples)

← ICS ← 03 ← 03.100 ← 03.100.01

ISO 31000:2018

Risk management — Guidelines

← ICS ← 03 ← 03.100 ← 03.100.01

IEC 31010:2019

Risk management — Risk assessment techniques

Safety standards based on risk management

I'm looking for safety

2741 results found (6 ms)

Random sample:

ISO 19353:2019(en) Safety of machinery — Fire prevention and fire protection

- 5 Strategy for fire risk assessment and risk reduction
  - 5.1 General
  - 5.2 Determination of the limits of the machinery
  - 5.3 Identification of fire hazards
  - 5.4 Risk estimation
  - 5.5 Risk evaluation
  - 5.6 Risk reduction

Risk management and standardization

Management system standards (examples)

← ICS ← 35 ← 35.030

ISO/IEC 27001:2022

Information security, cybersecurity and privacy protection — Information security management systems — Requirements

- 8 Operation
  - 8.1 Operational planning and control
  - 8.2 Information security risk assessment
  - 8.3 Information security risk treatment

← ICS ← 03 ← 03.100 ← 03.100.70

ISO 9001:2015

Quality management systems — Requirements

0.3.3 Risk-based thinking

Risk-based thinking (see Clause A.4) is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in previous editions of this International Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analysing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

All other standards

Risk management in regulation

Contribution to legitimate regulatory (safety/environment/technology) and level playing field

WP.6 Recommendation R

UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE

Recommendations on regulatory cooperation and standardization policies

Working Party on Regulatory Cooperation and Standardization Policies

UNITED NATIONS

R. Managing Risk in Regulatory Frameworks

The Working Party on Regulatory Cooperation and Standardization policies,

Recognizing that mitigating risk that may affect society and hamper economic development is an important goal for policy-making,

Underlining that risk management is an important tool for promoting regulatory convergence at international and regional levels,

Emphasizing the role of risk management in achieving sustainable development goals, Stressing that risk-management tools are essential to enhancing the efficiency of regulatory action and of regulatory systems,

Recognizing the need of regulatory authorities, standardization, conformity assessment and accreditation bodies, as well as market surveillance authorities, economic operators, consumers, as well as other regulatory stakeholders, in promoting coherent, consistent, efficient, effective and systemic application of risk management in regulatory systems,

Taking into account international standards related to the management of risk, such as ISO 31000:2009, ISO 9001:2008, ISO/IEC 17000:2004, and other standards, including sector-specific standards, such as ISO/IEC 27001:2005,

Underlining that regulation in many cases may not be the best response to risk, and that absolute safety cannot be a regulatory outcome, as it is impossible, as well as undesirable to make the world risk-free,

Recommends that:

R.1 Regulatory authorities and other regulatory stakeholders should use the concept of "risk" to evaluate how balanced regulations are against two extremes:

(a) Excessive or over regulation, i.e. regulations that are too stringent with respect to the risk they set out to address;

(b) Insufficient regulations that fail to address risk and unnecessarily or inordinately expose citizens and economic operators to threats.

R.2 All functions of the risk management process, as they are presented in the text of this recommendation, should be consistently described in legislation that lays out the regulatory framework at a general level or for a specific sector. Legislation should specify allocation of responsibilities for performing the risk management functions outlined in the model.

Risk-based technical regulation

- Harmonized
- Proportionate

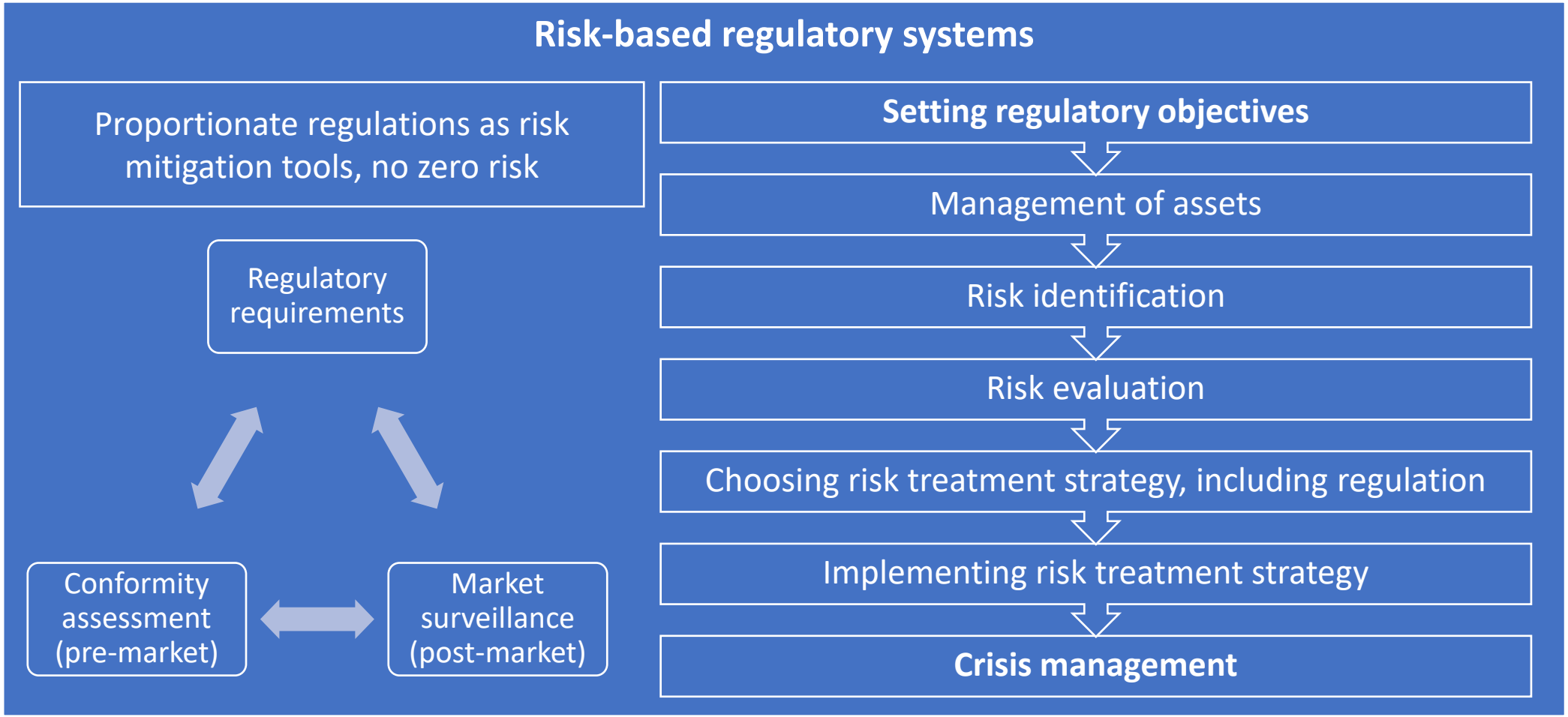
→

- Ensuring safety (protecting environment)
- Without stifling growth (approving new technologies)

→

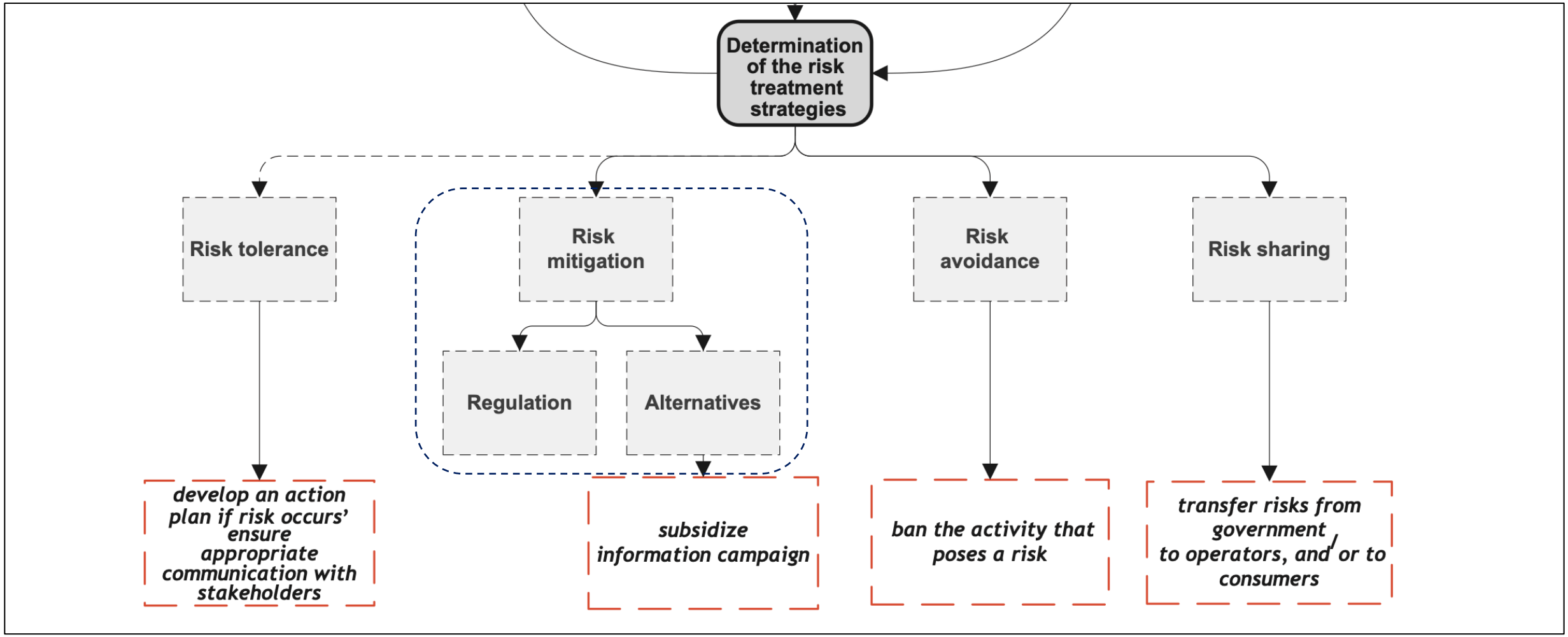
Without creating technical barriers to trade/ensuring level playing field

Managing Risks in Regulatory Systems



- Risk management is an important tool for promoting regulatory convergence
- Target level of risk as one of the tools for proving equivalency of technical regulations

Regulation as one of the available risk mitigation tools



Setting proportionate regulatory requirements - ensuring safety without stifling growth

Safe as “free from unreasonable risk” - bringing risks to a tolerable level

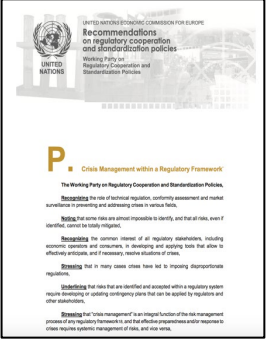
Level of risk of a **compliant product** is considered to be tolerable

Determining the tolerable level of risk remains to be a challenging task

GAME principle – ”globally at least equivalent” for new technologies

- Referring to existing regulatory requirements, if not possible -
- Gap analysis with an existing (similar) system/product, if not possible -
- Detailed risk analysis

ALARP principle – “as low as reasonable practical”



Crisis Management in Regulatory Systems: when risks occur

Risk-based regulatory systems

- **Setting regulatory objectives**
- Management of assets
- Risk identification
- Risk evaluation
- Choosing risk treatment strategy, including regulation
- Implementing risk treatment strategy
- **Crisis management**

- Situations which are beyond the capacity of normal organizational structures and processes
- International Standards and best practice in establishing crisis management function, preparation, contingency planning, etc.
- Immediate focus on affected individuals
- Data collection processes
- Reducing regulatory interventions that have compliance costs
- Avoiding imposing disproportionate regulations as a response
- Highligthing the difference in managing national and international crises

Setting priorities in market surveillance

Management of product non-compliance risk

Non-compliance risk of a product

Regulatory requirements set for groups of products

Risk of a compliant product is considered to be tolerable

Risk of non-compliance can be different for different products within a group

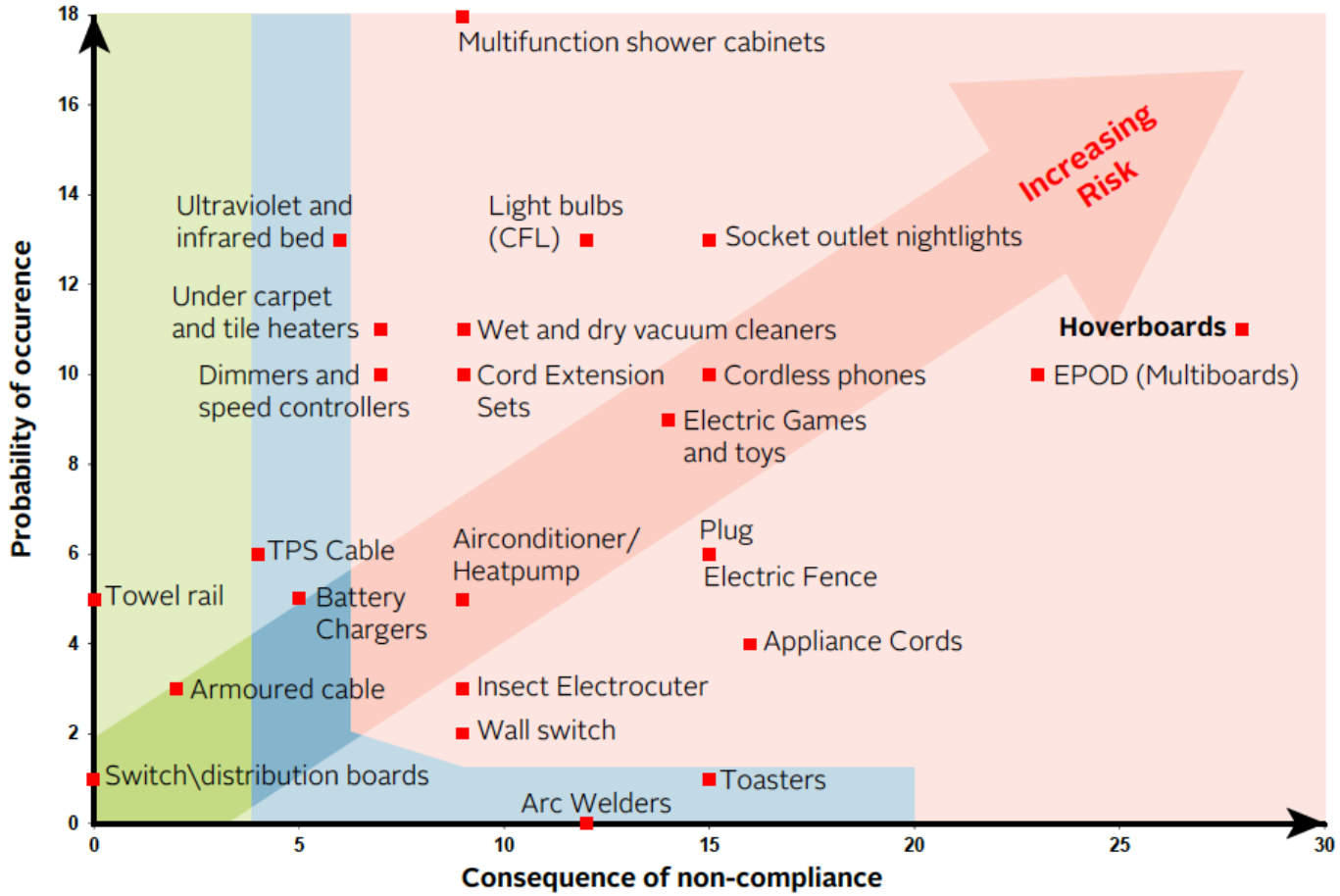
- Probability of non-compliance
- Consequences of non-compliance

WP.6 Recommendation S: Setting priorities in market surveillance

Applying predictive risk management tools for targeted market surveillance

How dangerous is a non-compliant product?

Probability to find a non-compliant product?



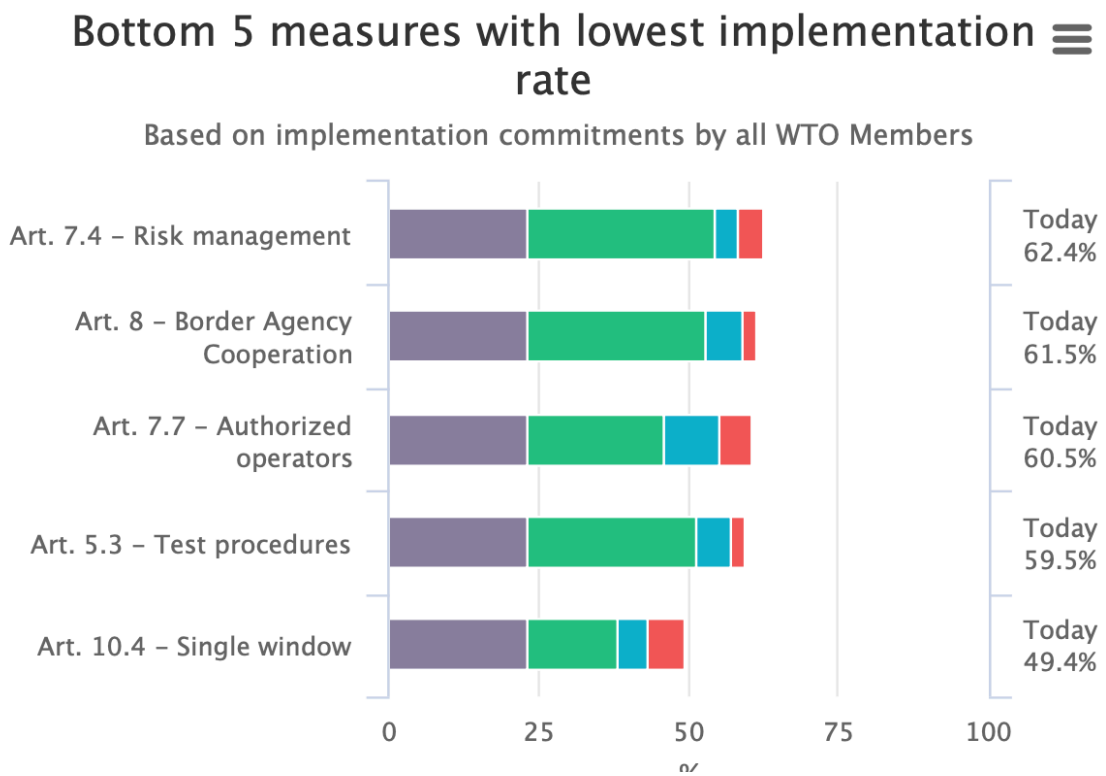
Approaches can be applied for choosing conformity assessment schemes

Risk management in international trade

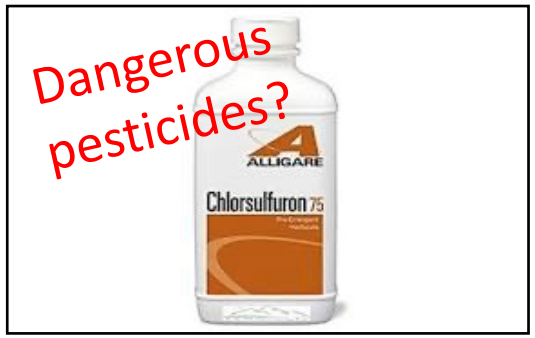
Risk management and technical barriers to trade and trade in general

Risk management and trade facilitation

- **WTO TFA**: 'Each Member shall concentrate customs control and, to the extent possible other relevant border controls, on **high-risk consignments** and expedite the release of **low-risk** consignments' (article 4.3)
- **WTO TBT**: 'technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create'
- **WTO TBT**: regulatory authorities to design compliance procedures so they are not 'stricter ... than is necessary to give ... the adequate confidence that products conform with the applicable technical regulations'



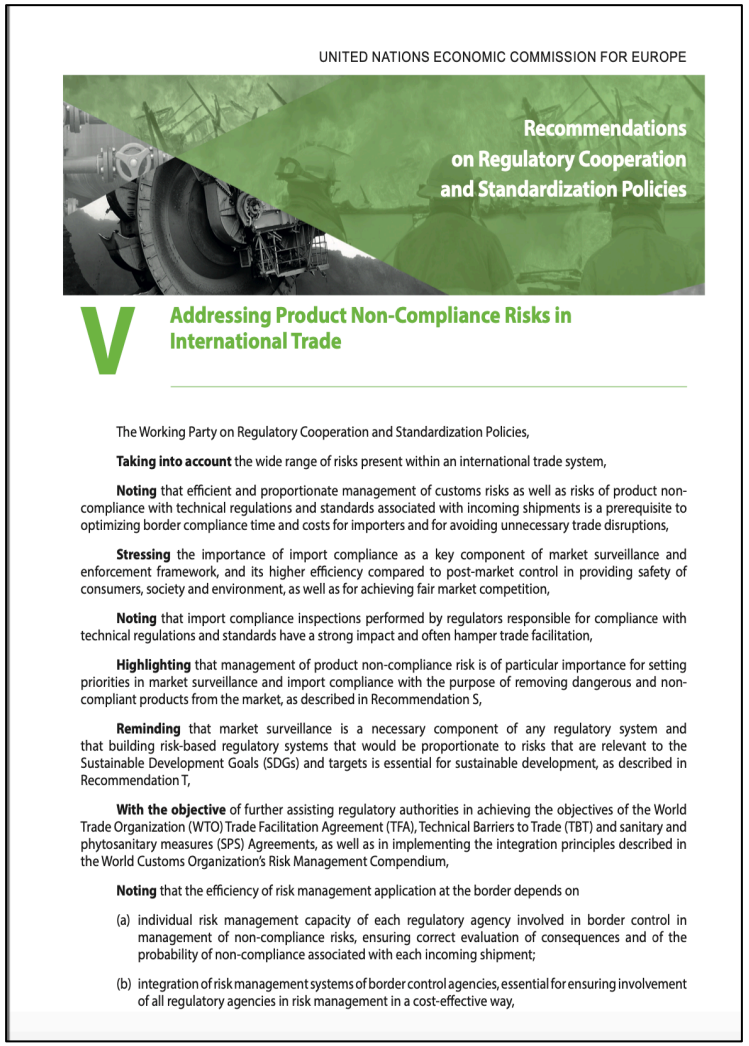
Risk of product non-compliance in international trade



Non-compliant shipment?

?

WP.6 Recommendation V and ITC/UNECE Guide



UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE

Recommendations on Regulatory Cooperation and Standardization Policies

V Addressing Product Non-Compliance Risks in International Trade

The Working Party on Regulatory Cooperation and Standardization Policies,

Taking into account the wide range of risks present within an international trade system,

Noting that efficient and proportionate management of customs risks as well as risks of product non-compliance with technical regulations and standards associated with incoming shipments is a prerequisite to optimizing border compliance time and costs for importers and for avoiding unnecessary trade disruptions,

Stressing the importance of import compliance as a key component of market surveillance and enforcement framework, and its higher efficiency compared to post-market control in providing safety of consumers, society and environment, as well as for achieving fair market competition,

Noting that import compliance inspections performed by regulators responsible for compliance with technical regulations and standards have a strong impact and often hamper trade facilitation,

Highlighting that management of product non-compliance risk is of particular importance for setting priorities in market surveillance and import compliance with the purpose of removing dangerous and non-compliant products from the market, as described in Recommendation S,

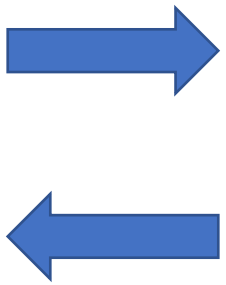
Reminding that market surveillance is a necessary component of any regulatory system and that building risk-based regulatory systems that would be proportionate to risks that are relevant to the Sustainable Development Goals (SDGs) and targets is essential for sustainable development, as described in Recommendation T,

With the objective of further assisting regulatory authorities in achieving the objectives of the World Trade Organization (WTO) Trade Facilitation Agreement (TFA), Technical Barriers to Trade (TBT) and sanitary and phytosanitary measures (SPS) Agreements, as well as in implementing the integration principles described in the World Customs Organization's Risk Management Compendium,

Noting that the efficiency of risk management application at the border depends on

(a) individual risk management capacity of each regulatory agency involved in border control in management of non-compliance risks, ensuring correct evaluation of consequences and of the probability of non-compliance associated with each incoming shipment;

(b) integration of risk management systems of border control agencies, essential for ensuring involvement of all regulatory agencies in risk management in a cost-effective way,



Managing Risk for Safe, Efficient Trade

GUIDE FOR BORDER REGULATORS

International Trade Centre

In collaboration with

UNECE

Optimizing border compliance time and costs while maintaining regulatory requirements

Integrated risk management strategy

- All non-compliance risks within one system
- Overall border compliance time and costs as metrics

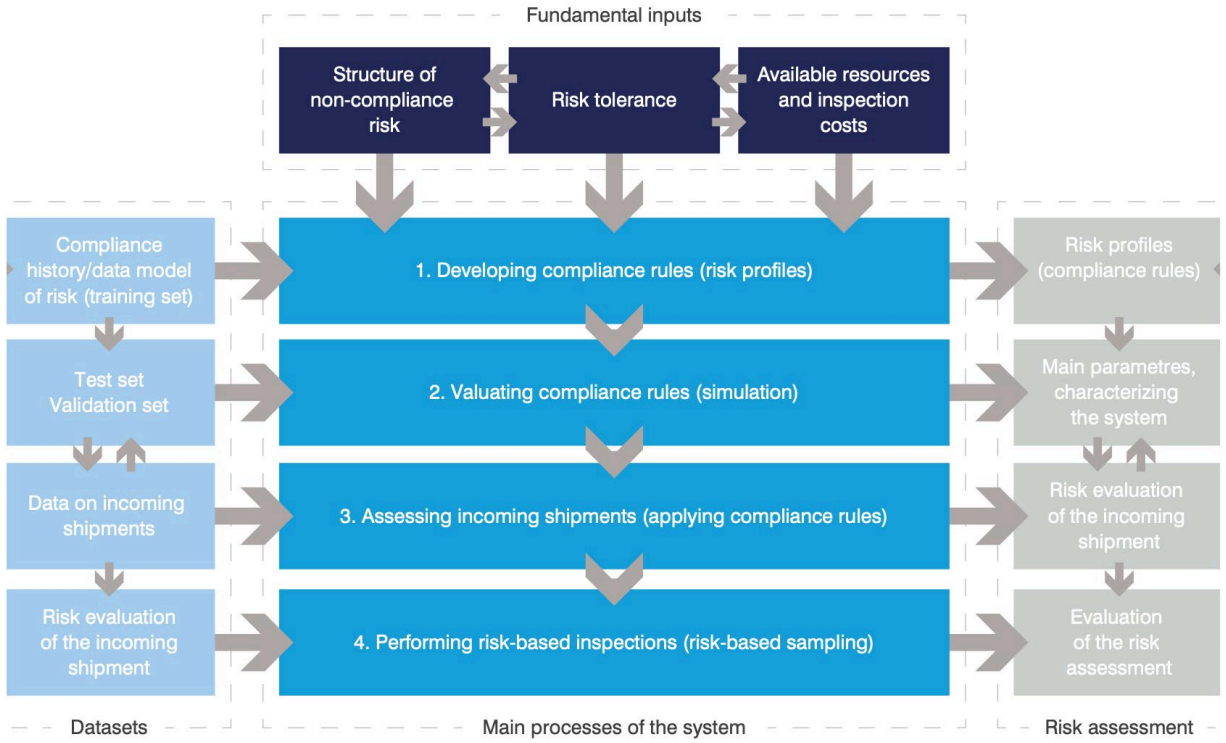
Harmonized – cross agency – criteria for evaluating different non-compliance risks

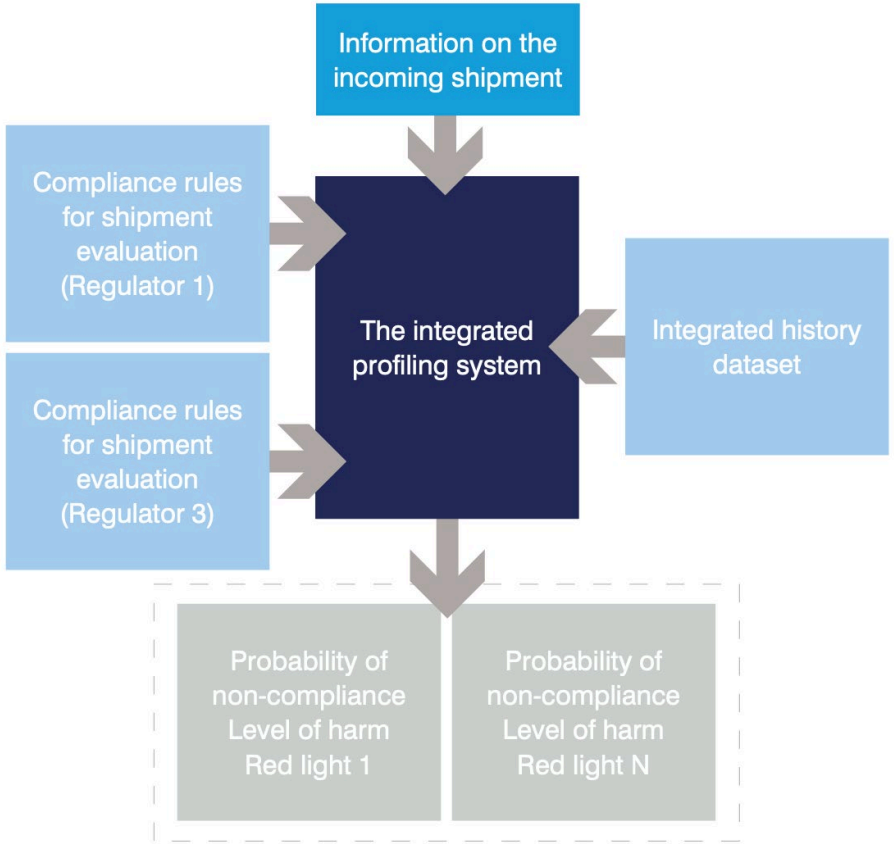
- Common denominator for very different risks
- Based on regulatory objectives linked to SDGs

Strengthening the role of import compliance in market surveillance

- Building individual risk management capacity of each border control agency:
  - Approches of Recommendation S
  - Annex I: a reference model for targeting non-compliance at the border
- Integrating risk management systems of product regulators and the Customs:
  - Methodology
  - Data
  - IT resources
  - Risk management expertise
  - Applying compliance rules at the border
  - Annex II: a reference model of an integrated system
- Both Annexes reference the UNECE/ITC Guide

Addressing the risk of product non-compliance in international trade: integrated risk management at the border





Future challenges

Sustainability

- Each SDG is supported by one or several regulatory frameworks
- Building risk-based regulatory frameworks in support of Sustainable Development Goals (Recommendation T) - challenging complex projects

Digitalization

- More and more products that are grey/black boxes
- Development of risk assessment tools for such products
- Establishing proportionate regulatory requirements, conformity assessment and market surveillance procedures

Risk management

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