

# *Lecture on the precautionary principle*

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By **Nicolas de Sadeleer**

Full professor of EU law, UCLouvain, St Louis,  
Jean Monnet chair

[www.tradevenvironment.eu](http://www.tradevenvironment.eu)

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**ICJ, *Legality of the threat or use of nuclear weapons*,  
1996, para. 29**

The Court recognizes that the environment is under daily threat. ... It also recognizes that the environment is not an abstraction but it represents the living space, the quality of life, and the very health of human beings, including generations unborn.

The existence of the general obligations of States to ensure that activities within their jurisdiction and control respect the environment of other States or of areas beyond national control is now part of the corpus of international law relating to the environment.



**Arbitral Tribunal, *Iron Rhine (« Ijzeren Rijn ») Railway*,  
2005, para. 59**

Today, both international and EU law require the integration of appropriate environmental measure in the design and implementation of economic development activities.



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# 1. Certain Risks: the Model of Prevention



**(1) Defined Outcomes:** Various possible outcomes can be fully described thanks to scientific analysis

Decision-makers have complete information on the range of actions

**(2) Known probabilities:** Probabilities are known objectively and can be assigned to each outcome



## Prevention of Risks

Where something is **scientifically certain**



**Principle of preventive action**

Uncertainty comes into play: exact time and magnitude of the occurrence of the risk



## Assessment of Risks

**Projects and activities subject to EIA:** preventive mechanism to pre-empt adverse environmental effects that might be associated with a proposed development (see ICJ, Pulp Mills, 2010 - EIA is a requirement under general international law)

**Products and substances subject to RA:** calculation of the magnitude of the potential loss, and the probability that the loss will occur



**Expected pay-off**



## Influence of science on environmental law

- Scientists uncover, identify and pose ecological problems which need to be answered by the law
- Take on a predominant role during the framing of environmental protection rules

→ Incorporation into legislation of scientific concepts such as ecosystem, natural habitat, species, and sub-species

→ Biogeographical region or trans-frontier hydrographic basins transcend national boundaries



## Influence of science on case law

Courts have elevated scientific assessment to a decisive criterion

'scientific advice must be based on the principles of excellence, independence and transparency' (Case T-13/99 Pfizer)



## Reviewing the scientific evidence

Absence of a complete examination of all the representative uses of a pharmacological product in order to assess the effect of this substance on wildlife means that the scientific dossier did not contain enough evidence

(Case T-229/04 [2007] *Sweden v. Commission*)

The export of dangerous waste to Member States which apply less stringent regulations 'must be measured, not by the yardstick of general considerations, but on the basis of relevant scientific research'

(Case C-277/02 *EU-Wood-Trading GmbH* [2004] )



## Law and Science

Though environmental law draws substantial inspiration from scientific facts, this does not affect its status as a legal discipline, or in other words as a technique for managing the social order that is capable of regulating conflicts with its own conceptual tools.

The concepts of species, sub-species, GMOs, substances and pollutants have a regulatory scope which does not necessarily follow the contours of scientific definitions.





## 2. Uncertain Risks: the Model of Anticipation



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- A. International Law
  - B. EU Law
  - C. French Constitutional Law
  - D. Customary Rule

## 2. Uncertain Risks: the Model of Anticipation

## Absence of scientific consensus

Given that scientific consensus is difficult to achieve, controversies have frequently been politically exploited in order to postpone or to delay action in relation to the perceived threat.



## A paradigmatic shift

**Traditional preventive approach:**  
determination that environmental risks are acceptable in light of relevant objective data

**Anticipatory approach:** give the environment the doubt about such risk (*in dubio pro natura*)



## A paradigmatic shift

Whereas, under a preventive approach, the decision-maker intervenes provided that the threats to the environment are tangible, pursuant to the PP authorities are prepared to tackle risks for which there is no definitive proof that there is a link of causation between the suspected activity and the harm or whether the suspected damage will materialise.

Its significance lies in its challenge to traditional legal systems, many of which are permeated by the need for certainty.

Praised by some, disparaged by others, the principle is no stranger to controversy.



## Precaution/Prevention

While prevention is based on the concept of certain risk, precaution is distinguished by the intrusion of uncertainty.



## A. International Law

A more precautionary approach has been called for in numerous new or revised treaties and protocols concerning conservation of various aspects and components of nature.



# International Law: Marine Pollution

1992 OSPAR Convention (art. 2, a)

1992 Helsinki Conventions on the Protection and Use of Transboundary Watercourses and International Lakes (art. 2)

1992 Helsinki Convention on the Protection of the Marine Environment of the Baltic Sea Area (art. 3(2))

1994 Charleville-Mézières Agreement concerning the Protection of the Scheldt and Meuse Rivers (art. 2, a et 3(2), a)

1994 Sofia Convention on Cooperation for the Protection and Sustainable Use of the Danube (art. 2(4))



the 1976 Barcelona Convention for the Protection of the Mediterranean Sea against Pollution (as amended in 1995) (Preamble)

1980 Athens Protocol for the Protection of the Mediterranean Sea against Pollution from Land-Based Sources and Activities (as amended in 1996) (Preamble)

1998 Rotterdam Convention on the Protection of the Rhine (art. 3(3)).



Given that the principle is applied  
in a variety of contexts, its  
formulation often differs from  
agreement to agreement.



## Principle or Approach?

Variations in terminology have emerged, reflecting the considerable controversy surrounding the principle.

As a matter of fact, disputes have arisen as to whether precaution should be labelled as a 'principle' or merely as 'an approach'.

This debate reflects different perceptions as to the suitable regulatory response to avoid environmental and health damages amid uncertainties.

Proponents of an 'approach' take the view that precaution is not legally binding, whereas a legal principle is clearly stated as such.



## Obligation or Approach?

Nodules and Sulphides Regulations transform the non-binding PP Rio Statement « into a binding obligation » (§127).

Moreover, the PP is « an integral part of the general obligation of due diligence of sponsoring States, which is applicable even outside the scope of the Regulations » (§130).

Accordingly, the PP is «*a contractual obligation*» (§133).

ITLOS, Seabed Dispute Chamber, 1 February 2011



**Conference on Environment and Development:** 'Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.'

**OSPAR:** The Contracting Parties shall apply the PP, 'by virtue of which preventive measures are to be taken when there are reasonable grounds for concern that substances .... introduced into the marine environment may bring about hazards to human health .... even when there is no conclusive evidence of a causal relationship between the inputs and the effects'



Threats of serious or irreversible damage

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Lack of full scientific certainty

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Cost-effective measures to prevent environmental degradation.

**1992 UN Conf.**

**1992 OSPAR**

Reasonable grounds for concern hazards to human health

→ Harm living resources

→ Damage amenities

→ Interfere with legitimate uses of the sea

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No conclusive evidence of a causal relationship between the inputs and the effects

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Preventive measures



## 1992 Framework Convention on Climate Change (UNFCCC)

to take precautionary measures to anticipate, prevent or minimise the causes of climate change and mitigate its adverse effects. Where there are threats of **serious** or **irreversible** damage, **lack of full scientific certainty** should not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be **cost-effective** so as to ensure global benefits at the **lowest possible cost**



## CDB, Preamble

Where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat.



## 1995 FAO straddling and highly migratory fish stocks Agreement

The precautionary approach is listed as one of the general principles to be applied by States to ensure the achievement of long-term conservation and sustainable use of straddling and highly migratory fish stocks (Article 5(c)).

The scope of the principle is not restricted to stocks targeted in the fisheries, but encompasses all living marine resources and the marine environment (Article 6(1)).



The obligation to endorse a precautionary approach reads as follows: 'States shall be more cautious when information is uncertain, unreliable or inadequate' (Article 6(2)).

States shall take measures to ensure that, when reference points are approached, they will not be exceeded. In the event that they are exceeded, States shall, without delay, take ..action ... to restore the stocks (Article 6(4)).



## 1995 Barcelona Convention for the Protection of the Mediterranean Sea against Pollution

The Contracting Parties shall apply, in accordance with their capabilities, the precautionary principle, by virtue of which where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation



## 2000 Cartagena Protocol on Biosafety (CPB)

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision ... in order to avoid or minimize such potential adverse effects



## Forest sector

Neither the International Tropical Timber Agreement nor the different Programmes of Work on forests refer to precaution.

Prevailing paradigm of State sovereignty over forest resources

Only Australia has been pre-eminent in referring to precaution



## B. EU Law

### Article 191 TFEU:

- EU policy on the environment (....) shall be based on the precautionary principle and on the principles that preventive action should be taken (....)

Despite the absence of definition, this provision is **mandatory**, even though EC institutions enjoy some **room for manoeuvre** while carrying out a precautionary policy.



PP is encapsulated increasingly in secondary law

directives and regulations,  
in particular those applying  
to environmental issues,  
GMOs and food safety



## C. French Constitutional Law

« Lorsque la réalisation d'un dommage, bien qu'incertaine en l'état des connaissances scientifiques, pourrait affecter de manière grave et irréversible l'environnement, les autorités publiques veillent, par application du principe de précaution et dans leurs domaines d'attributions, à la mise en œuvre de procédures d'évaluation des risques et à l'adoption de mesures provisoires et proportionnées afin de parer à la réalisation du dommage»

(Loi constitutionnelle n°2005-205 du 1er mars 2005 relative à la Charte de l'environnement).



1. Direct effect
2. Scope of ambit (issues): environment and not health
3. Scope of ambit (persons): public authorities
4. Cumulative thresholds: (a) significant damages; (b) provisional and proportionate measures; (c) science-based



## D. Customary Rule

Repeated use of State practice

Consistent *opinio juris*

are likely to transform precaution into a customary norm



## International case law

Southern Bluefin Tuna Cases (New Zealand v. Japan; Australia v. Japan),  
Provisional Measures (1999)

The MOX Plant Case (Ireland v. United Kingdom), Provisional Measures (2001)

Responsibilities and obligations of States sponsoring persons and entities  
with respect to activities in the Area (Request for Advisory Opinion submitted  
to the Seabed Disputes Chamber) (2011)

ICJ, Pulp Mills on the River Uruguay (Argentina v. Uruguay), Judgment of 20  
April 2010



## *Southern Bluefin Tuna Case, 1999*

Although there was scientific uncertainty regarding the conservation measures to be taken, ITLOS held that the Parties should 'act with prudence and caution to ensure that effective conservation measures are taken to prevent serious harm to the stock of southern bluefin tuna'.

Furthermore, ITLOS required a risk of 'serious harm', not of irreversible damage, to southern bluefin tuna stocks in order to take provisional measures to avert their further deterioration (§§77 and 80).

However, ITLOS avoided bringing further clarification as to the meaning and the status of the principle.



## ECtHR, TĂTAR c. ROUMANIE

Le principe de précaution recommande aux États de **ne pas retarder** l'adoption de **mesures effectives et proportionnées** visant à prévenir un risque de **dommages graves et irréversibles** à l'environnement en l'absence de certitude scientifique ou technique (para. 109).

La Cour rappelle l'importance du principe de précaution (consacré pour la première fois par la Déclaration de Rio), qui « a vocation à s'appliquer en vue d'assurer un niveau de de la santé, de la sécurité des consommateurs et de l'environnement, dans l'ensemble des activités de la Communauté ». (para. 109).



La Cour estime que la population de la ville de Baia Mare, y inclus les requérants, a dû vivre dans **un état d'angoisse et d'incertitude** accentuées par la **passivité des autorités nationales**, qui avaient le **devoir** de fournir des **informations suffisantes et détaillées** quant aux conséquences passées, présentes et futures de l'accident écologique sur leur santé et l'environnement et aux mesures de prévention et recommandations pour la prise en charge de populations qui seraient soumises à des événements comparables à l'avenir. A cela s'ajoute la crainte due à la continuation de l'activité et à la possible reproduction, dans le futur, du même accident (para. 122).



## ICJ, Pulp mills on the River Uruguay

In this sense, the obligation to protect and preserve, under Article 41a) of the Statute, has to be **interpreted** in accordance with a practice, which in recent years has gained so much acceptance among States that it may now be considered a **requirement under general international law** to undertake an environmental **impact assessment** where there is a risk that the proposed industrial activity may have a **significant adverse impact** in a transboundary context, in particular, on a shared resource.



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Moreover, due diligence, and the duty of vigilance and **prevention** which it implies, would not be considered to have been exercised, if a party planning works liable to affect the régime of the river or the quality of its waters did not undertake an environmental impact assessment on the potential effect of such works.



Moreover, due diligence, and the duty of vigilance and **prevention** which it implies, would not be considered to have been exercised, if a party planning works liable to affect the régime of the river or the quality of its waters did not undertake an environmental impact assessment on the potential effect of such works.

« ...while a precautionary approach may be relevant in the interpretation and the application of the Statute, it does not follow that it operates a reversal of the burden of the proof » (§164).





3. Thresholds  
Levels to which  
a precautionary  
measure  
appears to be  
subject

There is an array of criteria on the basis of which a pr. measure may be reviewed by a court

### EFTA Surveillance authority v Norway

'Such restrictive measures must be non-discriminatory and objective, and must be applied within the framework of a policy based on the best available scientific knowledge at any given time. The precautionary principle can never justify the adoption of arbitrary decisions, and the pursuit of the objective of "zero risk" only in the most exceptional circumstances.'

### 2000 EC Communication on the PP

proportionality

non-discrimination

consistency

CBA

examination of scientific developments



## Traditional Structured Risk Analysis

The probability of the occurrence of harm is determined using a *risk assessment* procedure, in which experts examine both hazard and exposure - generally by mathematical modelling - in order to calculate an acceptable or tolerable level of contamination or exposure.

A *risk management* decision must be taken by politicians, taking into account both legislative requirements and economic, political and normative dimensions of the problem

deciding *how safe is safe*.





## 4. Risk Assessment

## Risk Threshold

*"A preventative measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified"*

*(Pfizer, para. 143; see also Monsanto Agricoltura, para. 106; Com. v Dk, para. 49; EFTA Surveillance Auth. V. Norway, paras. 36 to 38)*



*"the precautionary principle can therefore only apply in **situations in which there is a risk**, notably to human health, which, although it is not founded on mere hypotheses that have not been scientifically confirmed, **has not yet been fully demonstrated**"*

*(Pfizer, para. 146)*



## RA: a four step approach

identification of the hazard (does the biological/chem./physical agent entail an adverse effect?)

dose-response assessment (how potent a carcinogen is it?)

exposure assessment (which groups of people are exposed to the substance, what is the environmental vehicle of exposure -air, water, soil-, for how long, and at what levels?)

risk characterisation (what is the likelihood that any particular exposed person will get cancer?)



# Risk Assessment

## International trade and envt. law

SPS (art 5(1))

TBT (art 2(2))

CBP (art 10(1) & 15)

## EU Law

Directive 93/67/EC laying down the principles for assessment of risks to man and the environment

Regulation 793/93 assessment of existing chemicals

Dir. 91/414/EC Pesticides

Dir. 98/8/EC Biocides



## Paradox

Whilst recognizing the inherent limitation of sciences, PP reckons upon a RA as complete as possible



# Evidence of the Risk in Face of Uncertainty



## Recognizing the limits of RA

In many cases, the assessment of those factors will demonstrate that there is a high degree of scientific and practical uncertainty in that regard.



# Uncertainty

Situation in which hazard/harm is known,  
but it is impossible to assign probabilities to  
its realisation lack of full evidence

- inconclusiveness
- contradictions
- indeterminacy
- ambiguity



## Insufficiency as a triggering factor

The various scientific disciplines involved in assessing the risk are not sufficiently developed to explain the cause-and-effect relationship



## Inconclusiveness as a triggering factor

The realities of science dictate that the scientists, whatever the quality of their investigations, will never be able to eliminate some uncertainties;

There may be too many unpredictable variables to enable the identification of the relative influences of each factor

Variability: individual responses to identical stimuli differ according to age, sex, individual characteristics, etc.



## Imprecision as a triggering factor

**Imprecision:** could be caused by the fact that the data to analyse the risks are not available or are out-of-date, information gaps, measurement errors, contradictions, indeterminacy, ambiguity ... of the results of studies conducted, but the likelihood of real harm to public health persists

Eg lack of opportunity for experimental testing; lack of long-term data sets, out-of-date information; systemic and random measurement errors; difficulties to extrapolate (from animal data to humans, from large to small doses, etc.)



## Indeterminacy as a triggering factor

Results from a genuine stochastic relationship between cause and effects, apparently non-causal or cyclical random events or badly understood nonlinear chaotic relationship (Klinke and Renn, *A new Approach to Risk Evaluation*).



## Uncertainty in the biodiversity context

Inherent complexity of ecosystems (variability, resilience, unforeseen response of wildlife, etc.)

Incomplete knowledge of ecosystem processes and mitigation measures

Incomplete knowledge of associated environmental changes (climate change, etc.)



# Different layers of uncertainty

**Scientific uncertainties**

**Implementation uncertainties** (unpredict results of human interventions, control of poaching, etc.)

**Schotastic uncertainty** of events that are unpredictable or uncontrollable (fires, floodings, eruptions, etc.)



# Environmental Stochasticity

Possible events and outcomes are unknown



# Ignorance

Situations in which the outcomes are not known and the probabilities are impossible to assign

CFC effects were unknown in the 70s



## Scientific Basis

provide **specific evidence** which, without precluding scientific uncertainty, makes it possible reasonably to conclude on the basis of

- a) the **most reliable scientific evidence available**
- b) the **most recent results of international research**

that the implementation of those measures is necessary.



## Particularities of the Risk

the **cumulative effect** of the presence of several sources, natural or artificial

the possibility of **delayed adverse effects**

the **persistency** and the **accumulation**

the **reversibility** of the adverse effects



# Allocation of the burden of proof



## Burden of proof

**Administrative approach:** the proponent of the activity should bear the burden with regard to resolving uncertainty over possible impacts

Inequality of knowledge/power (confidential information) between applicants and regulators





## 5. Risk Management



## Err on the safe side

"If consequences of a proposed activity are uncertain, the activities should not be undertaken until further research clarifies the risks.

*"Where there is **uncertainty as to the existence or extent of risks to human health**, the institutions may take protective measures **without having to wait the reality and seriousness of those risks become fully apparent**" (National Farmers' Union)*

The fact that it is **not possible to carry out a full scientific** RA does not prevent the public authorities *'from taking preventive measures, **at very short notice**, where such measures appear essential given the level of risk to human health which the authority has deemed unacceptable for society'* (Pfizer, para.160)



## Significance of the impacts on human health

The authority must give particular consideration to *"the severity of the impact on human health were the risk to occur, including the extent of possible adverse effects, the persistency or reversibility of those effects and the possibility of delayed effects as well as of the more or less concrete perception of the risk based on available scientific knowledge"* (Pfizer, para.153)



## Zero Risk v Acceptable Risk

**Low tolerance of adverse effect:** Seeking to reduce a risk to zero is permissible

Seeking a risk in the sense of absolute proof of safety is generally not admitted in EU law

Uttermost relevance issues ranging from fisheries, discharge of chemicals, nature conservation, marine pollution, etc.

As for its implementation, should action be limited exclusively to moratoria, or are control and surveillance measures sufficient?





## 6. Implications

## Symbolic effect

Recourse to a principle highlights  
the effort to assert the legitimacy  
of a new legal discipline



## PP as a rule of interpretation

Owing to its constitutional status, the PP may bear determinative influence on the interpretation of rules of a lower tier:

- a) determination of the ambit
- b) Determination of the procedure
- c) Burden of proof



## Companion principles

PP is merely a device in a battery of principles

- a) Other environmental principles
- b) General Principles of International law (non-discrimination, fundamental rights)



One should not make a mountain out of a molehill

## False Negatives > False Positives

- Fisheries
- Benzene
- Asbestos
- PCBs
- Halocarbons
- Tributyltin
- Mad cow disease



# Having more questions than answers

Status: Customary principle? General Principle of Law?

Scope of ambit: razione materiae? razione personae

Thresholds: should they apply differently to each sector?

Scientific requirements:

- a) what RA are we talking about?
- b) taxonomy of uncertainty?
- c) what kind of evidence is needed?

Other requirements: as regards economic impacts/contervailing risks?

Protection level:

- a) Zero risk or Acceptable risk?
- b) permissive or compulsory actions?
- c) shifting the burden of proof?

Proportionality: Human health-Env't, duty to re-examine,...



## Questions

Does the adoption of a precautionary measure require a minimum set of indications showing that the suspected risk is well founded, or are public authorities relieved of all requirements to furnish proof when confronted with an important risk?

Is there an obligation for scientists to disclose the uncertainties?



Do the scientists need to carry out in any case a risk assessment and according to which methodology?

Is it possible to draw the line between uncertainty and ignorance?

Must the decision-maker aver a serious, significant, irreversible or collective risk?

As for its implementation, should action be limited exclusively to moratoria, or are control and surveillance measures sufficient?

