From Risk to Precaution

UCL Lecture on the Precautionary Principle

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by

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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 juridisction 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 a Risk Assessment**: 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

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.

CONVENTION DE BERNE
BERN CONVENTION

OSPAR
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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 gernal 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 imputs and the effects'

1992 UN Conf.	1992 OSPAR
Threats of serious or irreversible damage,	**Reasonable grounds for concern hazards to human health** • **Harm living resources** • **Damage amenities** • **Interfere with legitimate uses of the sea**
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Lack of full scientific certainty	**No conclusive evidence of a causal relationship between the imputs and the effects**
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Cost-effective measures to prevent environmental degradation.’	**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)).

1995 FAO straddling and highly migratory fish stocks Agreement

- 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.

EU LAW

- PP is encapsulated increasingly in secondary law

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

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 où 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).

ECtHR, *TĂTAR c. ROUMANIE*

- 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, whichin recent years has gained so much acceptance among States tha t 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.

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.

ICJ, *Pulp mills on the River Uruguay*

« …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)

Risk Threshold

- *"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

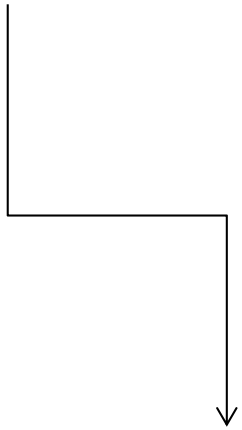
- SPS (art 5(1))
- TBT (art 2(2))
- CBP (art 10(1) &15)

EU Law

- **Regulation (EC) No 1107/2009 on** Pesticides
- **Regulation (EU) 528/2012 on** 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 stimulii 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.)

Indetermincay as a triggering factor

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

Uncertainty in the biodiversity context

- Inherent complexity of ecosystems (variability, resilience, unforseen 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 probabilites 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.

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
- Rule of interpretation
- Restricting other General Principles

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
- Tributylin
- Mad cow disease

Having more questions than answers

- **Status**: Customary principle? General Principle of Law?
- **Scope of ambit**: ratione materiae? ratione 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 compulsary actions?
  - c) shifting the burden of proof?
- **Proportionality:** Human health-Envt, duty to re-examine,…