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EU health protection at the crossroad of innovation and precaution

Steven Lierman
Leuven Institute for Healthcare Policy,
KU Leuven

Jean Monnet Summer School EU4GH

Influence of the precautionary principle on health law

- Decision-making in the context of scientific uncertainty: examples and history
- Status of the precautionary principle in international law and the hormone-treated beef case (WTO)
- Status of the Precautionary principle in EU Law
- Precautionary principle and the ECtHR
- Precaution … but who is liable?

Decision making in the context of scientific uncertainty

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Precaution and the limits of science

- Late lessons from early warnings (European Environmental Agency): asbestos, Thalidomide, PCB, …
- Environmental protection: climate change, genetically modified organisms, biodiversity, marine environment, …
- Health protection: electromagnetic fields, low level of ionising radiation, long term-risks of pharmaceuticals, food safety, growth hormones, dioxin, BSE, …
- New information technologies: AI, smart cities…?

Historical context of the precautionary principle

- Decision-makers have to convert scientific uncertainty into social certainty
- Since the 1980s the principle has been adopted in several international declarations and treaties
  - Declaration of the Northsea, Rio declaration on environment and development, UN Convention on Climate Change, …
- Treaty of Maastricht (1992) adopted the precautionary principle in the context of environmental protection
- Many European secondary sources and national regulations (e.g. French Constitution) refer to the PP

Status in international law

Status of the principle under international law: Northsea conferences

- Second international Northsea conference 1986
  - "in order to protect the North Sea from possible damaging effects of the most dangerous substances, a precautionary approach is necessary which may require action to control inputs of such substances even before a causal link has been established by absolutely clear scientific evidence"
- Third international Northsea conference 1990
  - "The participants … will continue to apply the precautionary principle, that is to take action to avoid potentially damaging impacts of substances that are persistent, toxic and liable to bioaccumulate even where there is no scientific evidence to prove a causal link…"

Status of the principle under international law: Rio declaration 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” (1992)

The PP gives rise to many questions

- Must one aver a serious, irreversible or collective risk?
- Does the adoption of a measure require a minimum set of indications showing that the suspected risk is well founded?
- Should action be limited exclusively to moratoria or can surveillance measures be sufficient?
- How long should the measures apply?

WTO Dispute Settlement Body (DSB): hormone-treated beef-case

- Art. 5.7 Agreement on the application of Sanitary and PhytoSanitary measures
- "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time".

WTO Dispute Settlement Body (DSB): hormone-treated beef-case I

- European ban of import of hormone treated beef contested
  - European Commission refers to the PP to justify its measures
  - Canada argues that the PP cannot yet be considered a principle of international customary law
- WTO Panel and Appelate Body (1997-1998) state that the ban was not based on a risk assessment as required by the SPS agreement
  - PP was reflected in the Agreement but it does not override the specific obligations in the agreement (art. 5.7)
- EU replaced the definitive ban by a provisional ban (Directive 2003/74/EC) and US and Canada increased custom duties on EU products

WTO Dispute Settlement Body (DSB): hormone-treated beef-case II

- EU argued that there was “insufficient information” available to assess the risks in the sense of art. 5.7 SPS Agreement
- “Scientific experts were asked whether the scientific evidence relied upon by the European Community supports its contention that new scientific studies since 1997 have identified new important gaps, insufficiencies and contradiction in the scientific information and knowledge now available on these hormones such that more scientific studies are necessary before the risk to human health from the consumption of meat from cattle treated with these hormones for growth promotion purposes can be assessed”

WTO Dispute Settlement Body (DSB): hormone-treated beef-case II

- WTO Panel (March 31, 2008):
  - backed EU complaint against unilateral decision to maintain sanctions without doing recourse to WTO rules and procedures
  - BUT no new scientific data giving rise to call into question previous knowledge
- WTO Appelate Body (322 p.) reversed Panel (16 October 2008): allowing the US to continue its trade sanctions, but allowing the EU to maintain its ban
  - It reverses the Panel's finding that "there must be a critical mass of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence…"
  - No need for a paradigmatic shift in the scientific knowledge (§725)

Status in EU-law

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Status of the principle in EU-law

- TFEU explicitly refers to the principle in the context of environmental protection (191(2) TFEU)
- Communication of the European Commission (February 2000, COM(2000) 1)
- Endorsed by the Council of Ministers' Nice Resolution (adopted at the end of the European Council in Nice on 8 December 2000)
- References in European secondary sources
- Clarifications brought by the European courts: health and food safety cases

Council of Ministers' Nice Resolution (2000)

- "where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are "reasonable grounds" for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection." (p. 10)

Commission Communication (2000) advises that measures should meet certain requirements

- proportional to the chosen level of protection;
- Non-discriminatory in their applications;
- consistent with similar measures already taken;
- based on an examination of the potential benefits and costs of action or lack of action;
- subject to review, in light of new scientific data;
- capable of assigning responsibility for producing the scientific evidence necessary for a comprehensive risk assessment.

The PP gives rise to a wide range of measures

- The strong version of the PP
  - A call for absolute proof of safety before new technologies or products can be adopted
  - Uncertainty necessitates stringent actions, such as prohibition
- The weak version of the PP
  - Uncertainty may justify regulation if there are plausible grounds for believing that it may be harmful
  - Emphasis on gathering evidence about the chance and severity of the harm
  - Duty to inform consumers

No (single) definition in EU legal acts

- EU General Food Law 2002 (art. 7) provides a definition
  - for application in that sector
  - explicit reference in art. 5 Regulation 609/2013 on food intended for infants & young children, special medical purposes and total diet replacement
- EU environmental legislation provides no equivalent definition
- Reviews of EU legal acts reveal that application of PP varies in strength from weak to strong precaution
  - Garnett, K., Parsons, D.J., in: Risk Analysis 2017, 37
  - De Smedt K., Vos E., in H.A. Mieg (ed.), The responsibility of Science, 136

Art. 7 Regulation 178/2002 – General food Law

1. In specific circumstances where, following an assessment of available information, the **possibility of harmful effects on health is identified but scientific uncertainty persists**, **provisional risk management measures necessary to** ensure the high level of health protection chosen in the Community may be adopted, **pending further scientific information** for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraph 1 shall be **proportionate and no more restrictive of trade than is required** to achieve the high level of health protection chosen in the Community, regard being had to **technical and economic feasibility** and **other factors regarded as legitimate in the matter under consideration**. The measures **shall be reviewed** within a **reasonable period** of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

EU Health and food safety cases

- Lawsuits brought by private party against an EU precautionary measure
  - Private freedoms versus EU public interest
  - Case T-13/99 Pfizer Animal Health v. Council [2002]; Case T-70/99 Alpharma v. Council [2002]; T-74/00, ... Artegodan GMbH and Others v. Commission [2002]; Case T-392/02 Solvay Pharmaceuticals BV v. Council [2003]; Case C-77/09 Gowan, …
- Cases brought by the Commission against the MS
  - EU public interest versus national public interest
  - Stricter application of the PP to the extent that the measures can jeopardize the functioning of the internal market
  - Case C-473/98 Kemikalieninspektionen v. Toolex Alpha AB; case C-24/00, Commission v. French Republic; Case C-3/00, Commission v. Denmark, …

Definition of Court of Justice

"where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of these risks become fully apparent"

(EU Court of Justice, 5 May 1998, C-157/96 and C-180/96)

PP as a general principle of Union law

- General Court states that it is an autonomous principle of EU law (Artegodan)
- Objectives of environmental policy also embrace those of the protection of health (art. 191(1) TFEU)
- All policies/actions should ensure a high level of protection
- Integration clauses in the areas of environmental (11 TFEU) and health (168 TFEU) protection

Constituent parts of the PP?

- Reasons for triggering the use of the PP?
- Considerations that regulator must take into account?
- Requirements that any resulting measures must comply with?

- See for a recent review: De Smedt K., Vos E., “The application of the Precautionary Principle in the EU, in: H.A. Mieg (ed.), The responsibility of Science, 2022, 136

Lessons learned from health and food safety cases

- Risk assessment as a prerequisite for the taking of protective action
  - Triggers for adopting the precautionary principle?
  - How much information is necessary?
  - ‘Uncertainty paradox’ (Van Asselt and Vos): what is sufficient evidence to conclude that there is insufficient scientific information about the prevalence of a risk
- Risk management: setting the level of protection
  - Large degree of discretion of EU-institutions and member states
  - Discretionary powers must be exercised in conformity with constraints stemming from EU-law

How much scientific information is necessary?

- Serious and significant risks and risk of irreversible damage
- Protective measures cannot be based on a purely hypothetical risks, but exact level of uncertainty needed is difficult to assess
- There must exist a threshold of scientific plausibility
  - Solid, convincing and up to date evidence
  - Absence of nutritional need cannot, by itself, justify a total prohibition (Commission v. French Republic)
  - New scientific criteria to classify risks is not sufficient

- “The PP requires the suspension or withdrawal of a marketing authorisation where new data give rise to serious doubts as to either the safety or the efficacy of the medicinal product in question and those doubts lead to an unfavourable assessment of the benefit/risk balance of that medicinal product”
- “Against that background, the competent authority need do no more than provide, in accordance with the general rules of evidence, **solid and convincing evidence**, which, while not resolving the scientific uncertainty, **may reasonably raise doubts** as to the safety and/or efficacy of the medicinal product”

(General Court, Artegodan, T-74/00, …)

- *In casu*: general consensus that therapeutic efficacy in the treatment of obesity required a significant and lasting loss of weight.
- “the withdrawal … must in principle be regarded as justified only where a new potential risk or the lack of efficacy is substantiated by new, objective, scientific and/or medical data or information”
- “mere changes in a scientific criterion or, in more concrete terms, in good clinical practices… even if based on a ‘consensus’ in the medical community, cannot on their own justify the withdrawal … where … thoses changes are not based on new scientific data or information”

(General Court, Artegodan, T-74/00, …)

“Scientists should be on tap, but not on top” (W. Churchill)

- EU institutions are not bound by scientific opinions but…
- …a thorough risk assessment is a prerequisite for the taking of protective action:
    - EU-courts emphasise the important role of the (inter)national scientific committees
    - But: scholars stress the lack of a proper risk assessment and a lack of consistency in the review of the Court
    - Formal review: irregular expert report leads to irregular government decision (Artegodan)

Required level of uncertainty is difficult to assess

- Insufficient, incomplete, imprecise scientific results
  - Insufficiency: scientific disciplines are not sufficiently developed
  - Inconclusiveness: too many unpredictable variables
  - Imprecision: measurement errors, data is not available/ out-of-date, contradictions
- Can diverging expert opinions legitimize the application of the PP (Phizer)?
- Can Court argue in terms of analogy with other substances?
  - “All antibiotics and all nitrofurans have similar characteristics and should be treated in the same way” (Alpharma)

Gowan case (C-77/09): a step back in time?

- Dir. 2006/134 (plant protection products directive) imposes severe restrictions on the use of fenarimol…
- …despite positive assessment of the rapporteur MS and the Standing Committee on the Food Chain
- Restrictions on the ground of "concerns" regarding the intrinsic toxic effects of this active substance
- Concerns cannot be considered to be based on purely hypothetical considerations
    - Commission referred to several (general) studies/reports
    - OECD test guidelines are still being developed

Risk management: setting the level of protection is a discretionary power

- Determining the acceptable level of protection is a political decision
  - Recourse to the PP will depend “on the level of protection chosen by the competent authority”
  - Multiple operational spheres of the precautionary principle
  - TFEU: high level of health protection!
- EU-institutions & MS do have a large margin of appreciation in a context of scientific uncertainty: ‘manifest error’ or ‘misuse of power’

It is *not* lonely at the top

- Principles strengthening the PP:
  - sustainable development, precedence to health considerations over economic considerations
- Principles limiting the PP:
  - free movement-rules, non-discrimination, principle of proportionality

Precautionary measures must be proportionate

- Precautionary measure is adequate and efficient to reach the objective (health protection)
- Precautionary measure is necessary to ensure that specific products/activities do not present any danger
- Balance pros and cons of the measure and its objective effects
  - Required cost-benefit analysis cannot be interpreted in a strict manner
  - The principle of giving precedence to health over economic considerations is placed on equal footing
  - Provisional character of the measures: requirement to review the measure in light of new scientific data

Precautionary principle and ECtHR

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Tãtar v. Romania (2009)

- Roman authorities granted a permit to operate a goldmine/ did not stop the company's industrial operations after a serious environmental accident
- ECtHR applies the PP in the context of art. 8 ECHR, with reference to EU law
- the Romanian authorities had failed to take appropriate measures to protect the right of the applicants, who lived in the vicinity of a gold mine, to enjoy a healthy and protected environment
- PP demands that States do not wait with taking effective and proportional measures to prevent serious and irreversible damage to the environment because of the absence of scientific or technical certainty
- But reluctance of the court to consider PP in context of ECHR in later cases

Verein KlimaSeniorinnen Schweiz and others v. Switzerland (April 2024): change of approach?

- Landmark judgement relating to climate change
- ECHR acknowledged challenges related to causation and proof in the context of climate change…
- … but accepted it's competence to litigate on the impacts of climate change on human rights
  - "given the necessity of addressing the urgent threat posed by climate change, and bearing in mind the general acceptance that climate change is a common concern of humankind'
- PP is not mentioned explicitly in the Court's assessment, but had a major role in the parties' arguments
- What about cases beyond the environmental context?

Precaution… but who is liable?

Precaution… but who is liable?

- Precautionary measures are expensive… but too little precaution can lead to serious damage
- Precautionary principle as a standard of due care?
  - Risk of hindsight bias
  - Risk insurance
  - Liability for too little or too much precaution?

Liability of EU institutions for too little precaution?

- Case T-304/01, 13 December 2006:
- 482 Spanish breeders claimed compensation for losses due to mismanagement of BSE-crisis (too litle precaution)
- Applicants: appropriate measures were only adopted in 2000
- EU-institutions: measures were proportionate, non-discriminatory and consistent
- Claim was dismissed because no causal link had been established between allegedly wrongful conduct and the losses

Liability of EU Institutions for too much precaution?

- Case T-344/00, T-345/00, 26 February 2003:
- Pharmaceutical companies claimed compensation for losses due to inaction of Commission
- Commission did not put pharmaceuticals on a list of authorised substances in time
- MS withdrew pharmaceuticals from the market
- Despite the scientific and political difficulties, the European Commission could have taken provisional measures to protect the interests of the companies

Liability of EU institutions for too much precaution? (2)

- C-198/03, 12/07/2005: appeal of Commission seeking annulment of decision of 26/02/2003
- CFI did not explain why it followed a scientific opinion and disregarded differing opinions
- CFI did not examine the scope of the discretion enjoyed by the Commission
- In delicate and controversial cases the Commission must have a broad discretion

Some final remarks

The precautionary principle is here to stay, but…

- PP should be based on sound science and aim at a fair allocation of the burden of proof and a realistic level of the standard of proof
- Need for coherent and predictable procedures for the application of PP
- What can we expect from the courts?
  - Procedural justice and … substantive justice?
  - No amateur scientists but courts cannot be ignorant: need for a minimum scientific understanding
  - Courts could make provisional/interim orders pending further research (Rogers, Journal of Risk Research 2011, 481)