

# The Precautionary Principle in EU Policies



An Overview of Recent Developments

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# The story of the Tour Madou

LSC asks the Commission to abide by the principle of caution (principe de précaution) that it recommends in all its other policies, and postpone further negotiations until these concerns have been thoroughly investigated, before any decision to take over the Tour Madou is made”



# Better Regulation & Precautionary Principle

- PP is applied across the Commission
- Need to have a regulatory framework for the application of PP:
  - Creates legal certainty for operators
  - Needs to be periodically updated/revised in the light of international and internal developments

# History of the Precautionary Principle

- 1970's: German Environmental Legislation (*Vorsorgeprinzip*) / US Clean Air Act
- 1980's: Multilateral Environmental Agreements (1985 Vienna Convention on Ozone Depleting Substances)
- 1992: Rio Declaration - Principle 15
- Maastricht: Article 130 R (now Article 174 of the EC Treaty) for Environmental Policy
- 2000: European Commission's Communication on the Precautionary Principle + EP Resolution & Council Conclusions

# What is the Precautionary Principle?

- The distinction between Preventive Measures and Precautionary Measures
- The distinction between Risk and Uncertainty
- The thresholds of (a) non-negligible risk and (b) costs of regulatory inaction
- Shifting the burden of proof

# Commission's Communication on the Precautionary Principle

"When scientific evidence as to the safety of a product or action is found to be insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates 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 high level of protection chosen by the EU"

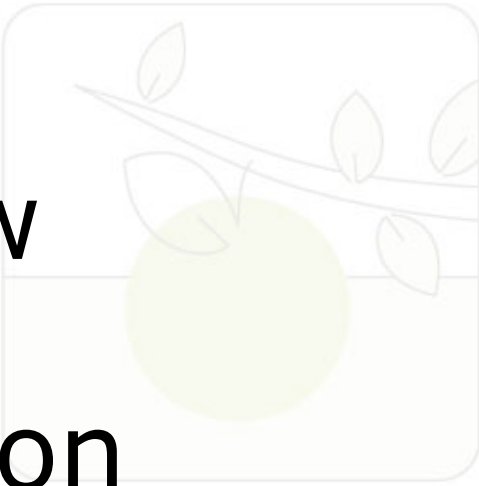
# Guidelines for Application

- Precautionary Measures must be:
  - proportional
  - non-discriminatory
  - based on cost/benefit analysis
  - subject to review
  - assigning responsibility for producing scientific evidence

# Overview of internal developments

1. Case-law

2. Legislation





# The recent judgements of the CFI

## *Pfizer Animal Health v Council & Alpharma v Council*

- The conditions to apply the Precautionary Principle:
  - ~ precautionary measures can be taken only when there is a real risk
  - ~ precautionary measures must be proportionate to the policy objective
  - ~ a risk assessment must be carried out
  - ~ the final decision must be taken by the authority with political responsibility

# *Alpharma v Council*

## ■ Non-negligible Risk:

- risk that resistance to antibiotics will be transmitted to human beings
- resistance to antibiotics is a major public health problem

## ■ Status of Scientific Knowledge:

- with respect to bacitracin zinc, not yet clarified the link between use of antibiotics as growth promoters and the development of resistance

# *Alpharma v Council*

- *Alpharma's argument: "Zero-Risk"*  
Approach applied by the Council
- *Council's argument: no need to carry out a quantitative risk assessment*

# CFI's arguments:

## *Alpharma v Council*

### ■ Concept of **Risk**:

- ⚡ BSE Jurisprudence - no need to wait for materialisation of the adverse effect
- ⚡ The risk must be adequately backed up by scientific data

### ■ The 2 components of **Risk Assessment**:

- ⚡ Defining the unacceptable risk - *Refusal of the zero-risk approach*
- ⚡ Scientific assessment of the risk - *Importance of scientific experts*

# ***CFI's arguments:***

## ***Alpharma v Council***

- **Absence of opinion from the relevant scientific committee:**
  - It must be considered the scientific background at the time of the adoption of the contested Council Regulation
  - Several Recommendations from various International Bodies - The precautionary measures can be taken

# ***Pfizer Animal Health v Council***

- Opinion from the Scientific Committee:  
insufficient scientific evidence
- The final decision on the ban is for the Public Authority and must be based on:
  - PROPER, CAREFUL AND IMPARTIAL EXAMINATION OF ALL RELEVANT ASPECTS OF THE CASE INCLUDING THE FINDINGS OF THE SCIENTIFIC COMMITTEE

# Issues for the Future

- Confusion between precautionary and preventive measures - 2 different principles in the EC Treaty
- Which are the exceptional circumstances when precautionary measures can be taken in absence of an opinion from the relevant scientific committee? (see *Alpharma Case*)

# Precautionary Principle – Application under Food Law

- PP used when there are potential harmful effects on health but scientific uncertainty remains
- 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.



# EU Legislation: the case of REACH

## ■ Main requirements:

- All chemicals used in commerce over 1 ton per year have basic toxicity and risk information within an 11 year period.
- For chemicals of very high concern, only uses approved by government authorities before going to market will be permitted.

## ■ Shifts the burden of proof (proponent of an activity to test their own products for safety).

## ■ Alternative analysis (some substances are de facto banned, unless a compelling case is made why they should continue to be used in particular circumstances)

# Overview of international developments



1. Case-law

2. International Agreements

# ICJ Developments in the '90

- *Nuclear Test Case*: principle of customary international law relating to environment
- *Nuclear Weapon Case*: general principle of international environmental law
- *Gabcikovo-Nagymaros*: EIA is a specific application of the larger principle of caution

# WTO Case against GMO Moratorium

- **Previous WTO case-law:** Shrimp/Turtle case, Beef-Hormone case, etc...
- **Complainants:** US, ARG, CA
- **Complaint:** Moratorium since October 1998 on planting and imports of biotech products
- **Unjustified under the SPS Agreement :**
  - “sufficient scientific evidence”
  - “undue delay”

# The WTO SPS Agreement

## ■ Article 5, paragraph 7:

(a) precautionary measures when scientific evidence is insufficient

(b) conditions for application:

1. provisional measures
2. obligation to seek additional information
3. obligation to review within a reasonable period of time

# The entry into force of key MEAs

## ■ **Cartagena Biosafety Protocol**

- Lack of scientific certainty due to insufficient relevant scientific information ...not prevent that Party from taking a decision with regard to the import of LMOs, in order to avoid or minimize such potential adverse effects
- In light of new scientific information ...review and change a decision regarding an intentional transboundary movement.

## ■ **Kyoto Protocol on Climate Change**

- The Conference of the Parties shall periodically review this Protocol in the light of :
  - the best available scientific information
  - assessments on climate change and its impacts
  - relevant technical, social and economic information.

# Codex Alimentarius

- Procedural Manual of the Codex Alimentarius Commission – Chapter III on Risk Analysis
- Draft Working Principles for Risk Analysis for Food Safety: Risk Assessment / Risk Management (degree of uncertainty and characteristics of the hazard) / Risk Communication

# Conclusion: A new Magna Charta?



- Need to revise the Commission's Communication on IA?
  - Internal developments
  - International developments
- Follow the Canadian Approach?



# Issues for Clarification

- Definition issue: non negligible risk, lack of sufficient scientific data, serious or irreversible risk, etc...
- Relationship between precautionary and proportionality principles
- Alternative analysis: alternative / substitute products are available?
- Time-frame for reviewing precautionary measures.
- Unintended consequences
- The relationship between IA and PP
- Training staff applying the PP to avoid / reduce differences in the application.