Emerging concerns –

Established principles?

On regulating ‘novelty’

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Introduction

- Two main questions:
  - Do you have to regulate ‘novelty’?
  - How could you regulate ‘novelty’?
Starting point: principles

- Article 191 TFEU
  
  → Uncertainty / unknown risks → precautionary principle
  
  → Certainty / known risks → prevention principle

- + trend towards making the precautionary approach part of customary international law
Precautionary principle

- No legally binding definition

- European Environment Agency (EEA, 2013):
  - “The Precautionary principle provides justification for public policy and other actions in situations of scientific complexity, uncertainty and ignorance, where there may be a need to act in order to avoid, or reduce, potentially serious or irreversible threats to health and/or environment, using an appropriate strength of scientific evidence, and taking into account the pros and cons of action and inaction and their distribution”
Precautionary principle

Key aspects

→ Scientific uncertainty
  × Can flow from insufficiency, inconclusiveness or imprecision of studies

→ Potentially serious or irreversible?
  × <-> European Court of Justice (ECJ): it is for the decision-maker to assess whether potential risks exceed the threshold of what is acceptable to society
Precautionary principle

→ ! Science
  × Identification of potentially negative effects
  × + risk assessment/evaluation, as objective and complete as possible
  × ! Inconsistency is to be expected from complexity

→ Other constraints: general principles of risk management, such as:
  × Proportionality
  × Non-discrimination
  × Cost-benefit analysis
Precautionary principle

- Obligation or permission to regulate (and adopt protective measures)?

  → ECJ: permission (it expands rather than contracts the regulatory freedom)

  → BUT: for example NGOs can use it to challenge national decisions and require action
    × E.g. C-127/02 Waddenzee; on mechanical cockle fishing licenses → now banned)
Precautionary principle

- Burden of proof?
  → Generally regulating authority needs to produce evidence of existence of potential risk

→ However, prior authorisation of products is widespread (e.g. REACH) → burden of proof reversed, because of:
  × Analogy from known hazards
  × Novelty (low ‘knowledge/ignorance ratio’)
  × …
Precautionary principle

Case law:

→ Most cases by manufacturers whose product has been excluded
  × E.g. EU restrictions on use of certain neonicotinoid insecticides to protect bees → restrictions ok (T-429/13 and T-451/13)

→ Sometimes country against continued use
  × E.g. Sweden against herbicide paraquat → Commission’s decision annulled (T-229/04)
Precautionary principle

- Fear for ‘false positives’?
  → EEA, *Late lessons from early warnings*, 2013: misplaced
  × 88 cases identified to be alleged false positives → only 4 real false positives (US swine flu, saccharin, food irradiation and Southern leaf corn blight)
  × Precautionary actions can stimulate innovation
  × ! Take early warning signals seriously
  × Research overly focuses on well-known rather than unknown hazards
Other (new) principles?

- Quid an innovation principle?
  - European Risk Forum, 2015:
    - “Whenever policy or regulatory decisions are under consideration the impact on innovation as a driver for jobs and growth should be assessed and addressed.”
  - Capable of freezing the precautionary principle?
  - Important to incorporate consumer and environmental safeguards and accept that innovation goes hand in hand with precaution
Other (new) principles?

- Quid the product choice principle (or substitution principle)?
  → REACH Regulation, art. 55: “analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.”
Potential instruments / ways to regulate?

- Ban/prohibition
  → E.g. Stockholm Convention on POPs (2001)

- Restrict trade through PIC procedure
  → E.g. Rotterdam Convention (1998)

- Prior autorisation
  → E.g. REACH Regulation (2006)
Potential instruments / ways to regulate?

- Norms
  - E.g. for soil; non-ionising radiation;...

- Use of permit procedure
  - E.g. according to the Water Framework Directive (2000) priority substances have to be taken into account
Potential instruments / ways to regulate?

- When evidence of harm emerges: taxes and charges ~ polluter pays principle

- Role of life cycle assessments?
Potential instruments / ways to regulate?

- Enforcement / compliance
  - Liability regimes
    - Two main types of liability
      - Fault liability
      - Strict liability → expansion of scope?
Is our current legal framework fit for purpose?

- No (direct) EU soil regime

- Often hesitation for new legislation

- RISK: potentially 27 different regimes + courts start taking over (~GMOs)
  - → ~ high opportunity costs; e.g. during due diligence

- Thus: industry should see it as an opportunity and create support for EU framework