



Flanders
State of
the Art

**Emerging concerns –
Established principles?
On regulating ‘novelty’**

Prof. dr. Bernard Vanheusden
Faculty of Law, Hasselt University (Belgium)

Prof. dr. Geert Van Calster
Faculty of Law, KU Leuven (Belgium)

WE MAKE
TOMORROW
BEAUTIFUL
OVAM

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 autorisation 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

- × K. Garnett, G. Van Calster and L. Reins, “Towards an innovation principle: an industry trump or shortening the odds on environmental protection?”, *Law Innovation and Technology* 2018, 1-14.

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