Environmental and Health Risk Regulation: Interplay between Science and Law

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We Are Living in a Risk Society

- **Environmental and Health Risks are today a subject of great debate and concern**

- **Climate change, loss of species and spread of disease have become, among others, central issues of science, policy and legal development**

- **National governments and international organizations are preoccupied by current Environmental and Health Risks**

The three stages of risk regulation

1. **Risk Assessment**
2. **Risk management**
3. **Risk communication**

Risk Assessment

The general term refers to the scientific element in risk regulation and contains four steps: Hazard Identification, Dose-Response Assessment, Exposure Assessment, Risk Characterization

a. Hazard Identification:

-The process of determining whether exposure to an agent in the environment can cause an adverse health effect

-It relies upon different kinds of information (human tests, epidemiological studies, animal studies etc)

b. Dose-Response Assessment:

-The process of characterizing the relation between the received dose of the hazard and the likelihood of an adverse health effect in the exposed population

-It is based on observations in human exposures and on mathematical models

c. Exposure Assessment:

-The measurement or estimate of the intensity, frequency, and duration of human exposure to an agent in the environment

-Because of the dearth of empirical data, risk assessors frequently rely upon mathematical models to assess exposure

d. Risk Characterization:

-The process of combining the results of the exposure and dose-response assessments in order to produce an estimate of the type and magnitude of the effect that will occur from exposure and the probability that each effect will occur

-For carcinogens, the estimate is most often expressed either as the increased probability an individual will experience the effect or as the number of additional cases of disease a population will incur in a year or lifetime as a result of the exposure

Limits of Science

-Contemporary science is incapable of completely resolving the level at which an agent (chemical, nanoparticle, electromagnetic fields etc) will pose some specified, quantitative risk to humans, especially over the longer term

-In some cases the uncertainties can be resolved with policy choices because of the current limitations of scientific knowledge, in other cases uncertainties may be capable of being resolved by further scientific studies

Environmental and Health Risk Assessment is pervaded by uncertainty (known unknowns) even ignorance (unknown unknowns)

Specifically:
-The hazard identification process involves substantial uncertainty and value judgments concerning issues as how an agent works in humans

-The dose-response assessment involves great uncertainty and controversy with regard to the judgments necessary to extrapolate dose-response associations from animals to humans and from high doses to low doses

-Exposure assessment also is penetrated by uncertainty and controversy, because little is known about the fate and transport of chemicals in the environment and there may be wide variability of exposures between individuals

Risk Management

-Risk management is the legal and political phase of Risk Regulation

-Risk management has been defined as the process of evaluating alternative regulatory actions and selecting among them

-The risk management phase needs to ensure a high degree of legitimacy and accountability

-Scientists are not accountable to the public in the same way that politicians or other public officials are

-It is important that the final decision rests within a structure that can be held accountable within established democratic systems

Competing risk regulatory paradigms: sound science and the precautionary principle

The sound science risk regulatory paradigm

-The paradigm of sound science has come to stand for reliance in decision-making on 'hard science': scientific studies that are verifiable, reproducible and certified through rigorous process of expert peer review ('sound science' versus 'junk science')

-The paradigm of sound science supports the strict separation between the risk assessment and risk management stages

-Sound science is the cornerstone of the risk assessment phase and cost-benefit analysis plays a vital role in risk management

Risk regulation and the precautionary principle

-Rio Declaration [1992], Principle 15:
"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"

-Recognition of the limits of science

-The precautionary principle is not compatible with cost-benefit analysis

-Perception of risk and public participation

-In EU legislation the precautionary principle aims at a high level of environmental and health protection