
Protected Property and Protection Level in Regulatory Toxicology

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Abstract

The modern determination of standards (benchmarks, threshold values, etc.) is achieved in a multistep process, beginning with the definition of the subjects of protection as well as protection goals and levels of protection, respectively (Fig. 1). The process is not strictly divided from step to step. The assessment of data from one step often requires a feedback to the primary subjects of protection and protection goals.

Subjects of Protection

Human being itself or the animated or inanimated environment can represent subjects of protection. In this context, two objects of legal protection are of significant importance:

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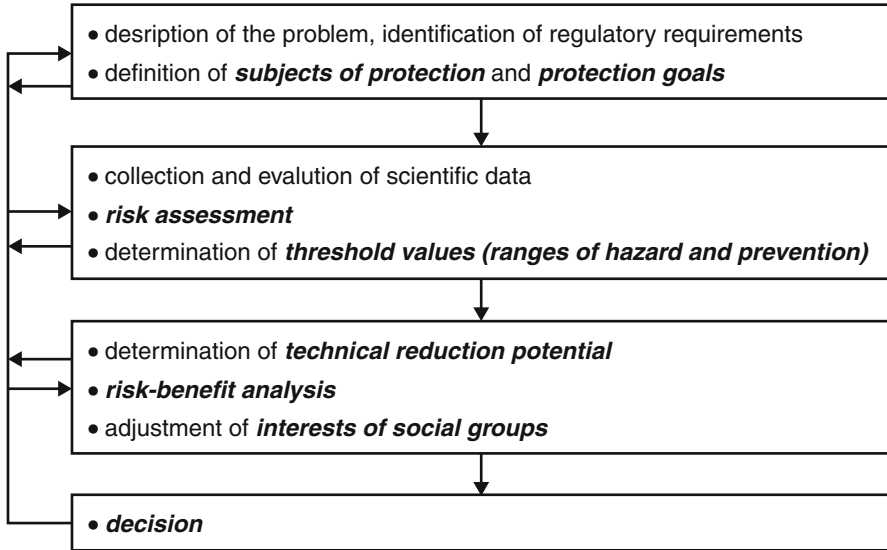


Fig. 1 Determination of environmental standards

- “Physical integrity” (physical health)
- “Conservation of natural resources” (environment: ground, water, air, fauna, and flora)

In many countries, these objects of legal protection are firmly established in the constitution. Therefore, they have to be respected even if they are not explicitly addressed in a relevant law. Additional constitutionally protected objects, which have to be considered in this context, are “**professional freedom**” and the “**common freedom of action.**” These basic rights are very relevant in the economic sector. They ensure the freedom to perform the profession of one’s own choice, the use of manpower against payment, the possibility for businessmen to compete, and the entrepreneurial freedom of action.

Against this background, for example, in Germany, the ad hoc commission “reorganization of proceedings and structures for risk assessment and standardization in environmental health protection” (risk commission) defined three subjects of protection:

- Human life
- Diversity of species and types
- Economic power

These three subjects of protection depend on each other. They are fundamental in context of the global action program for the twenty-first century “Agenda 21” and the resulting strategy of “Sustainable Development,” compiled in 1992 in Rio de Janeiro by the “Conference of the United Nations on Environment and Development.”

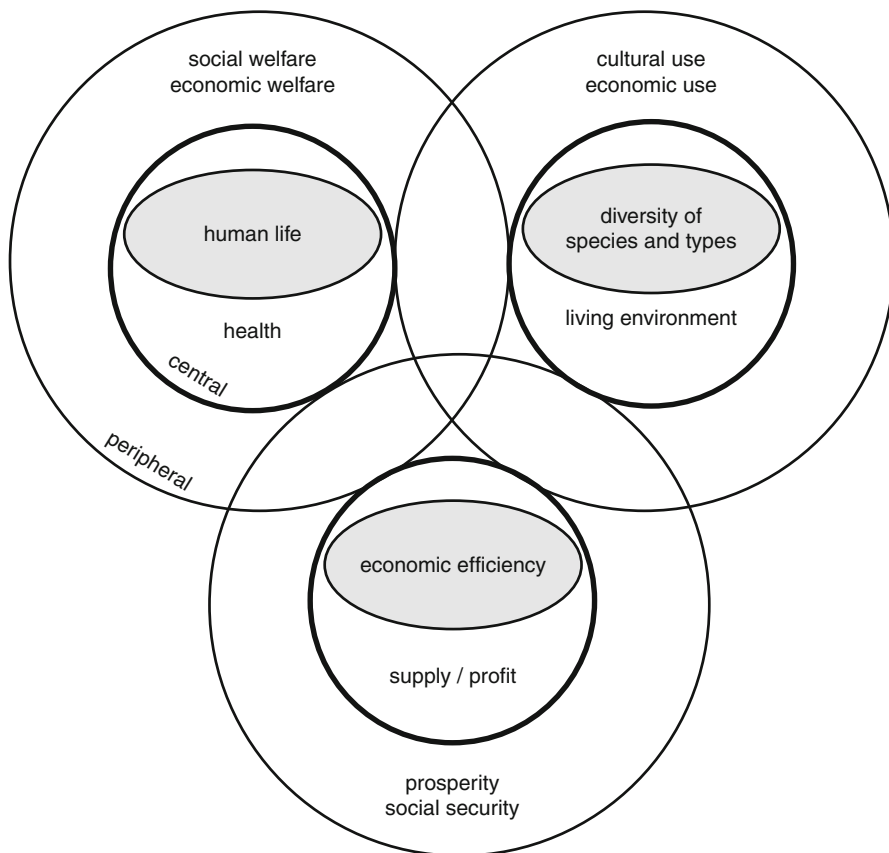


Fig. 2 Areas and subjects of protection

When concrete measures are planned or evaluated, these three subjects of protection can come into conflict with each other. In such cases, it is recommended to distinguish between **central and peripheral areas within the subjects of protection** (Fig. 2). For human beings, the protection of health and, for nature, the protection of the natural living environment represent the central area (anthropocentric versus ecocentric protection of the environment or nature). The peripheral areas cover especially socially, culturally, and economically associated subjects which influence and determine the central areas. These subordinated, peripheral areas overlap and often cannot be precisely assigned to a distinct subject of protection. If it comes to a conflict between the central areas of the different subjects of protection, one should seek a measure which shifts the conflict into the peripheral areas, in order to protect the central areas as much as possible. In the peripheral areas, activities that carry risks become comparable and calculable. Additionally, in a concrete situation, it has to be

considered that upper-level objects of legal protection – normally, life and health of human beings – are favored compared to, e.g., economic objects. Compensatory measures should be considered for more affected subjects of protection. Moreover, risks depending on external influences should receive more weight than self-dependent risks.

Protection Goals and Levels of Protection

Besides the definition of subjects of protection, it is also important to define how far the protection should go.

Protection goals describe the degree of intended protection and thereby the **level of protection** aimed at. Their definition has significant impact on the quantification of standards and the following implications. Protection goals can be classified in two ways:

- Complete protection – partial protection
- Hazard control – prevention

Complete Protection – Partial Protection

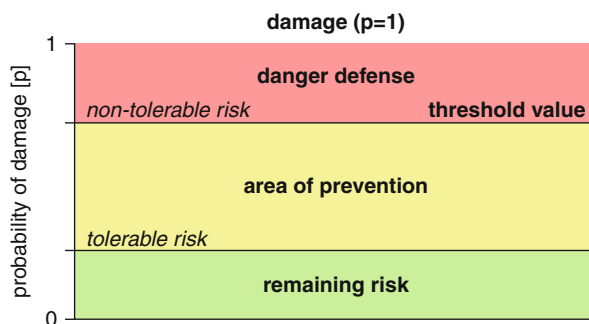
In this context, depending on the risks that are to be regulated and the subjects of protection, the following questions arise:

- Is complete protection of subjects of protection intended or are certain risks tolerable, because their complete exclusion is not possible, too expensive, or socially not accepted?
- Are entire systems (i.e., populations, ecosystems) to be protected or additionally each therein contained individual component, possibly including particularly sensitive components?

In the discussion of these questions, also constitutional criteria have to be considered, for example, suitability, requirement, and adequacy of a planned measure.

Hazard Control – Prevention

In many countries, law differs between damage, danger, prevention, and remaining (residual) risk. **Damage** means that the probability of a negative event (adverse effect) amounts to one, i.e., a negative event occurs with certainty or has occurred already. **Danger** means that damage is expected with a (inacceptable) high probability. In context of law, dangers have to be defended. The borderline separating danger from the range of prevention is determined by the level of non-tolerable risk. The borderline separating the range of prevention from a remaining (residual) risk is defined as **tolerable risk (traffic light principle, Fig. 3)**.

Fig. 3 Traffic light principle

Substantiation of Protection Goals: Deduction of Standards

If a protection goal is defined, this can – as far as possible and necessary – be substantiated for both protection levels, i.e., danger defense and area of prevention, respectively, by **quantitative risk assessment (QRA)**.

Generally, **danger defense** is implemented by definition of a normative **threshold value**. Threshold values generally separate the area of danger from the area of prevention. Exposures lower than the threshold values usually imply that affected objectives have no risk of damage. On the other hand, this does not imply that an exposure exceeding the threshold value automatically leads to damage.

An important source for the deduction of threshold values is toxicological data resulting from dose-effect or dose-probability estimations, respectively. In this context, it is important to differ between agents with dose-effect curves revealing a level beneath which no effect is observable or expected from agents for which such a level is not apparent. The last applies particularly for genotoxic agents, e.g., benzene or benzo(a)pyrene.

For **agents with a threshold of effect**, regulatory values are generally defined using the ADI concept of the WHO. Point of origin in this context is the “no observed [adverse] effect level” (NO[A]EL) or alternatively the “lowest observed [adverse] effect level” (LO[A]EL). The threshold for human beings, at which lifelong no harm for health can be expected (convention, not toxicologically evidenced), is calculated by division by a safety (respectively uncertainty) factor (normally 100).

A method used for **agents without a no observed effect level** (e.g., genotoxic agents) is, for example, the **unit risk method** of the Environmental Protection Agency (EPA). The unit risk of an agent describes the estimated additional lifelong cancer risk posed on a person exposed for 70 years with 1 μg of the agent per m^3 air. An additional lifelong cancer risk between 1:10,000 and 1:1,000,000 is discussed as acceptable. The dose corresponding to a risk of 1:1,000,000 is called “virtually safe dose.”

The protection philosophy of threshold values based on quantitative risk assessment can be found e.g., in the WHO “Air Quality Guidelines” and the “Guidelines for Drinking-Water Quality” for Europe or the “Maximum Residue Limits” of the WHO.

The **precautionary principle** implies that (environmental) exposure should be prevented or reduced far before the risk of danger occurs. This principle is particularly applied in case of a suspected risk of agents for which scientific data for (quantitative) assessment are not yet sufficient to define threshold values. This is, for instance, the case when causal correlation between an exposure and damage is likely but not (yet) proven. In these cases, the principle of exposure reduction as far as economically and socially justifiable (ALARA, “as low as reasonably achievable”) or as far as technically possible (ALATA, “as low as technically achievable”) can be applied. In these cases, the precautionary principle is often not related to measurable effects and refers to the principles of “sustainable development” and protection of environment for further generations.

The **protection level** aimed at the individual case (i.e., how safe is safe enough? definition of “tolerable” or “negligible” risks, respectively) and the subsequent options of action are generally defined in the course of a normative (political) process of decision making. At best, science can contribute by describing scenarios using objective scientific data. Modern, socially accepted regulatory processes additionally require adequate information and participation of the public and transparent reproducible decision-making policies.

Recommended Reading

- European Commission: first report on the harmonisation of risk assessment procedures, Part 1: the report of the Scientific Steering Committee’s Working Group on harmonisation of risk assessment procedures in the scientific committees advising the European Commission in the area of human and environmental health, 26–27 Oct 2000
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- Renn O, Klinke A (2004) Systemic risks: a new challenge for risk management. *EMBO Rep* 5(Suppl 1):S41–S46
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- Wiedemann PM, Schütz H (2005) The precautionary principle and risk perception: experimental studies in the EMF area. *Environ Health Perspect* 113:402–405

Resources (Last Date of Access: April 17, 2013)

- Academy of technology assessment in Baden-Württemberg. <http://elib.uni-stuttgart.de/opus/portal/ta/>
- Action program environment and health. www.apug.de
- Council of experts for environmental issues. www.umweltrat.de