Protected Property and Protection Level in Regulatory Toxicology

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Contents

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. 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.

Keywords

Subject of protection · Protection goal · Protection level · Quantitative risk assessment · Threshold

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Introduction

Subjects of general legal protection such as human being itself or the animated or inanimated environment are established in the constitutions of many countries worldwide.

Besides such general determinations of subjects of protection, it is equally 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. If a protection goal is defined, this can be substantiated by quantitative risk assessment (QRA).

These general definitions will be explained in terms of toxicology in the following chapter.

Subjects of Protection

Human being itself or the animated or inanimated environment can represent subjects of protection (Fig. 1). In this context, two objects of legal protection are of significant importance:

- "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

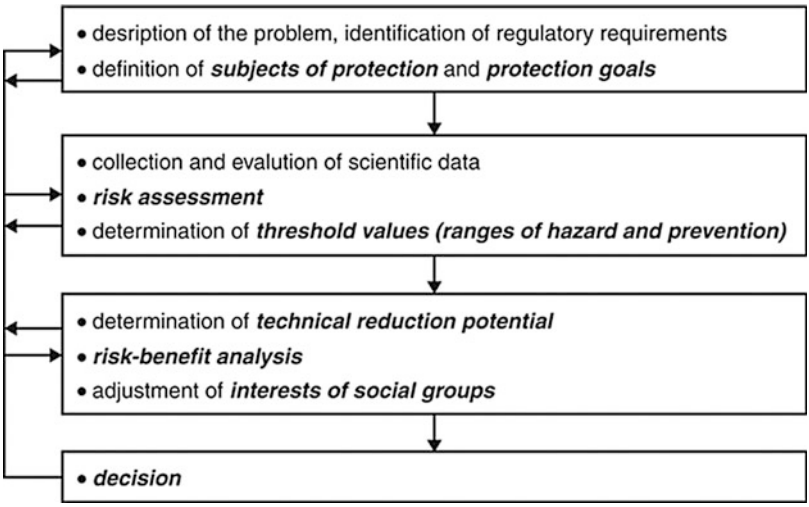

Fig. 1 Determination of environmental standards

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," that was a basis for the United Nations Sustainable Development Goals of 2015.

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.

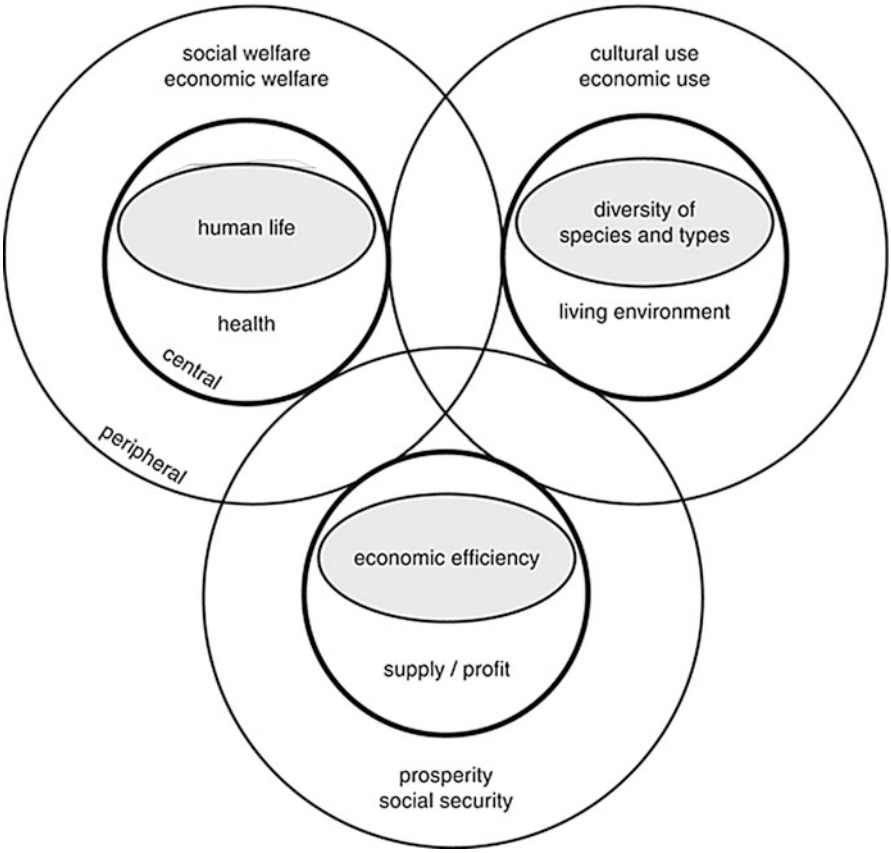

Fig. 2 Areas and subjects of protection

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).

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

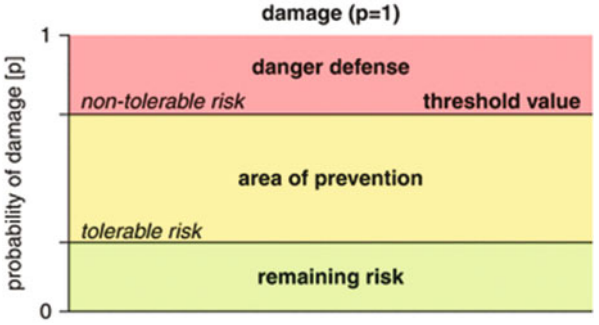

Fig. 3 Traffic light principle

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.

Cross-References

► Precaution Principle Versus Danger Prevention in Toxicology
► Risk Comparison in Toxicology

► Risk-Benefit Considerations in Toxicology
► The Regulatory Process in Toxicology
► Toxicological Risk Assessment in Different Jurisdictions

Recommended Reading

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