8 Standard-setting in Environmental Law[1]

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Standards are the working level of regulatory environmental law. Environmental law which has not been put into operation by means of standards rarely 'works' in practice, but will often remain exhortative. Standards can be used as a general term which breaks down into process-related technical requirements and maximum threshold values. *Thresholds* are the form of standards most frequently used in environmental law. The thrust of this chapter will therefore be concentrated on these.

The chapter explores:

- what kinds of standards exist;
- in what procedures standards are found;
- how and to what extent standards are given binding force;
- whether and how standard-setting should be improved.

1 This chapter is based on the introduction to G. Winter (ed.), *Grenzwerte*, Düsseldorf: Werner Verlag, 1986.

I TAXONOMY OF STANDARDS[2]

Thresholds differ first according to their addressees: they are individually set if they are the object of a condition attached to a licence and addressed to only one polluter limiting the emission of pollutant chemical substances from the licensed installation. They are of general validity if addressed to all polluters, for example, through a legislative measure. General standards can be specific (that is, limiting each single pollutant) or they can be summative if covering all pollutants in a given area as a whole.

Thresholds differ also according to the object or goals of protection: human health, animals and plants as well as inanimate nature (such as water) or buildings. For a long time, priority was given to human health; the other entities in need of protection were only indirectly protected by the thresholds directed at human beings (as, for example, plants by means of pollution thresholds) or were merely used as a medium for the protection of human health (for example water quality standards as a precondition for its use as drinking water). However, more and more voices and initiatives have recently been pushing for the recognition of the need to protect nature as such, and to have separate standards set for this purpose. Thus in the amendments to the German Technical Guideline for Air Pollution Control (*Technische Anleitung Luft – TA Luft*) of 1983,[3] special pollution values for carbonate fluoride and sulphur dioxide were established in order to protect particularly sensitive plants and animals.[4] Ultimately, however, this protection also remains oriented towards the benefit which the so-called things (such is the legal classification) offer humans.

There are various, partially intertwined, routes of pollution between the sources of pollutants and the object in need of protection. Thresholds can be distinguished according to the route they are regulating. Pollution at work is regulated by standards for maximum concentrations at the workplace (MAK Standards[5]), called *occupational health standards*. Pollution conveyed by the environment and reaching human beings, for example, in the form of air, soil or water pollution is regulated so-called environmental standards. A third route of contamination intertwined with both of those mentioned above is found during the production of intermediate or end products when pollutants endangering the health of the consumer are incorporated into (or not properly extracted from) the product. Standards dealing with this route usually limit the concentration of such pollutants in the product. Examples are thresholds for pesticides in food or for pollutants in drinking water. We call them *product quality standards*.

In a route of contamination thresholds can be distinguished according to whether they are fixed close to the source, to an intermediate object or to the polluted object. So-called emission thresholds are fixed directly at the source: they limit the emission of pollutants. Examples are the thresholds for sulphur dioxide emissions from coal power stations or minimum requirements for the direct discharge of waste water into public waters under various EC Directives. So-called immission thresholds[6] such as, for example, thresholds for suspended particles in the air or for noise in the neighbourhood, refer to media (that is, to media capable of transporting pollutants such as air or water). In this context, intermediate or end products containing toxic substances or emitting pollutants or noise may be considered as well. The corresponding thresholds have already been introduced above as product quality standards. Finally there are thresholds determining tolerance limits in contaminated objects or better, in receiver organisms, especially such as the so-called biological thresholds for risks from production materials (BAT Standards)[7] in occupational health regulation, which are meant to make it possible to decide whether a worker may be exposed to further toxic substances or if his or her capacity to take in such substances is exhausted.

Why these classifications? They are more than just a game, rather they help to pose questions. Thus a comparison between occupational health values and environmental protection values for pollutants in the air shows that the former are often considerably more liberal than the latter. For instance, the German MAK values for cadmium and lead are 50 and 100 µg/cbm of air, whereas the environmental maximum contamination concentrations (MIK values) are 0.04 and 2 µg/cbm, respectively. This means that the MAK value for cadmium is thousandfold and the one for lead fiftyfold more lax than the MIK value. The same can be observed regarding product quality values: drinking water is, in relation to its heavy metal content, more strictly regulated than vegetable and animal food for

2 See, for a similar taxonomy, S. Ball, S. Bell, *Environmental Law*, London: Blackstone, 1991, p. 61 *et.seq*.

3 An English version is reprinted in G. Winter (ed.), *Environmental Law in Germany: Basic Law Texts and Introduction*, The Hague: Kluwer, 1994.

4 No. 2.2.1.2 a, subpara. 2 with Appendix A, TA Luft. The threshold is unfortunately specific in the above defined sense – that is, it limits the individual source rather than the total sum of all relevant sources. Summative standards for the protection of sensitive plants and animals were deemed too costly. Only one summative standard protecting sensitive plants and animals is contained in the TA Luft: No. 2.2.1.4 requires sulphur dioxide contamination to be kept to a limit of 0.05 or 0.05mg/cbm air in areas which meet this value.

5 MAK = Maximale Arbeitsplatzkonzentration.

6 The term 'immission' refers to the endpoint where an 'emission' arrrives. Originating in the language of German environmental law, the term is being used also in English legal language where 'pollution' is the more familiar term. Based on the German term one can speak of 'immission standards' instead of what are 'environmental quality standards' in the British terminolgy.

7 BAT = Biologische Arbeitsstofftoleranzwerte.

human beings, because the ubiquitous background contamination of plants and animals is usually taken as natural baseline. The stepping downwards is once more repeated in relation to animal feed which is even less strictly regulated than vegetable and animal food for human beings.

However, differences in threshold values must not necessarily lead to differences in real damage or risk. Thus MAK values are valid for an 8-hour (workday) exposure of (mainly) adults, while MIK values are valid for a 24-hour exposure of everybody including children. Nevertheless, a closer analysis of the consequences of the American lead thresholds of 50 µ/cbm and 1.5 µg/cbm has shown that the resulting real risks are clearly different, the threshold (which amounts to 50 per cent of the German value) still implying neurologic damage, kidney trouble and light anaemia for about 10,000 employees.[8]

All this shows that it is worth exploring reasons for different strictness of standards in more debth than it is possible here. Variations between standards for different pollution routes or substances will often be more difficult to explain (if not by sheer arbitrariness), than differences concerning the same substance and stages of the same pollution route. For instance, a source-related emission value for substance X should be in line with the pollution value for the same substance fixed on the medium or receiver organisms.

II STANDARDS AND OTHER INSTRUMENTS FOR CONTROLLING POLLUTION

Thresholds set a framework for behaviour. They leave the decision of how to act to the party being regulated. The entrepreneur, for instance, maintains discretion as to the technology to apply in order to abide by the threshold. The situation is different with process-related standards. They intervene in the set framework and stipulate certain processes for production or waste treatment. Examples can be found in countless regulations of autonomous standard-setting organizations, but rarely in legally binding regulations.

Standards can be formulated as commands which are immediately applicable or as guiding values towards which the actor is oriented without being strictly bound. If framed as commands they leave the operator no choice as to whether to keep within them or exceed them. In this regard the standardizing technique differs from market-simulating instruments.[9] A system of pollution charges would allow such a choice; the higher the emission of pollutants or noise, the more is to be

[8] D. R. Hattis, R. Goble, N. Ashford, Airborne Lead: a Clearcut case of Differential Protection, *Environment*, **24**(14), 1982.

[9] For a more detailed account of these see G. Bándi (chapter 13 in this volume).

paid. But even such a system could not exist entirely without thresholds, because they have to be used to set the desired quality goals (for example for air or water) in order to enable judgement as to whether the charge is high enough to act as an incentive towards preventing pollution. Something similar applies to a system of environmental certificates or pollution rights that are traded at market prices. In this case quality goals are the basis for deciding how many certificates are to be issued on the market.

A question arising in this context is whether, in connection with market simulating instruments, the problem of an enforcement deficit that can frequently be observed when dealing with thresholds can better be solved. This may be doubtful because administrative monitoring and inspection remains necessary also in the framework of a charges or certificate system. It is furthermore questionable whether the virtue of greater efficiency (that is, pollution avoidance at the least cost) ascribed to the market approach does indeed materialize: also, in a regulatory system reliant on binding standards, the supervisory agencies could focus their enforcement activities on those who can abate pollution at the least cost.

III HISTORY OF STANDARD-SETTING

Occupational health and environmental protection went hand in hand during the industrialization era in Germany, both legally and in administrative practice. Art. 16 of the Industrial Code (*Gewerbeordnung*) from 26 July 1900 regulated the requirements for environmental protection and in Articles 120 a–c those for protection at work. The Prussian 'Technical Instruction Regarding the Approval of Industrial Plants', dated 15 May 1885, contained requirements for licensing plants which closely linked aspects of protection at work with environmental protection. Thus it can be read, for example, in relation to oil destillation plants:

> Therefore it has to be stipulated upon licensing these plants that they are provided with well equipped, completely impervious distillation devices, which are suited to achieving condensation of vapours which is as complete as possible and that the working areas are fireproof and preferably subject to massive vaulting.

As shown also by the above quotation, the method of regulation comprised mainly instructions regarding plant process technology, care also being given to orientate the instructions towards the desired result ('complete condensation', 'fireproof') and to leave the details of execution up to the operator. Initially, thresholds existed only sporadically, as a means of limiting the risk of accidents, mainly caused by the bursting of pressure containers. For example:

> Before being used, collection containers from which distillates are extracted by pressure ... must undergo a water pressure test during which 1½ times the working pressure, but at least 1 atmosphere more than the working pressure is applied.

In the following period the regulations for protection at work and environmental protection developed separately, ending with the separation of the air pollution rules out of the Industrial Code by the Federal Immission Protection Act of 1974 and the setting up of specific work protection ordinances.

In the course of this legal development the societal perception of industrial hazards was increasingly being directed from disastrous accidents to the 'normal functioning' of an installation and the possible harmful consequences arising therefrom, especially through chemicals and noise. The scientific basis for establishing contamination thresholds for the protection of human health was initially provided by workplace medicine the empirical basis of which (the many occupational diseases) was as tragic as it was rich, because at the workplace harm was more serious, more visible and therefore more easily traced back to its causes than was possible in the environment at large. All the while that dose-response research on environmental interrelations was lacking, knowledge derived from the study of occupational diseases was frequently extrapolated to make dose-response assumptions for environmental processes. The usual rule of thumb was to divide the hazardous dose found in the workplace context by a factor of 10–20 to get the tolerable environmental dose.

IV PROCEDURES OF THRESHOLD-SETTING

There are two versions of descriptions of the procedures by which thresholds are set. One version regards thresholds as derivations from findings of natural and applied science – that is, as a kind of hard science; the other version perceives thresholds as the results from a wide range of cognitive and valuation considerations – that is, as a kind of soft science, or even policy. For a long time the second version was reserved for insiders and critical outsiders, while the first version was intended for the general public, being suitable for justification purposes in contexts up to the jurisprudence of the highest courts, which have, in Germany, understood thresholds as pre-set expert opinions – pre-set in the sense that the courts must observe the expert opinions and need not recheck them in each individual case. In the meantime, and most recently when it became clear, for instance, that the 'experts' responsible for the sulphur dioxide thresholds did not anticipate that those thresholds would allow the emergence of acid rain and forest damage, the second version is penetrating the official and judicial level as well. Some commentators favour pluralistically formed committees and disclosure of value judgements. Others adhere to the concept of expert committees, but also demand at least a higher level of opinion for scientifically unresolved value judgements.

Before the first or second, or maybe even a completely different third, conclusion is drawn, it would seem appropriate to take a clear look at the second version of description which obviously is the more realistic one, since only a precise and realistic threshold setting can justify proposals for reform. In so doing I suggest making a distinction between the perspective deriving from the context of justification of thresholds – that is, the analysis of the participants' patterns of argument – and the perspective deriving from the context of discovery – that is, the analysis of interests and forms of organization during the decision-making process. Both levels relate to each other: an analogy would be the description of a conversation with respect to its contents on the one hand and its group dynamic aspects on the other. If asked for their opinion as to the most convincing participant in the conversation, the argumentation theorists would choose the participant with the clearest and soundest arguments, whereas the social psychologists would tend to identify the participant with the best conversational tactics or the highest authority. Both points of view illuminate important facets of reality and are legitimate in their own right.

1 Patterns of argumentation in threshold-setting

Ideally, the argumentation of scientifically based thresholds develops in three steps:

1. The law forbids contaminations which are harmful to the health.
2. Science indicates at which dosage the symptoms of disease start to appear.
3. This dosage is made the threshold.

In analogy, the argumentation of thresholds (principally emission limits), based on applied science, develops as follows:

1. The law forbids emissions in so far as it is possible to reduce these according to the given state of the art.
2. Engineering sciences indicate what the state of the art is and up to what limit it allows a reduction of emissions.
3. This limit is made the standard.

The reality of threshold-setting is completely different. Three deviations from the picture of exact scientific method can be observed:

a) In the framework of the relevant natural and engineering sciences implicit speculations or assumptions are made.
b) The necessity for socio-economic scrutiny is underestimated.
c) Valuations (for example, the balancing of the virtue of protecting life against the cost of protective measures) are carried out.

These deviations are discussed below.

a) The role of speculations and assumptions in scientific argumentation

Natural scientists, especially when involved in threshold-setting processes, do not limit themselves to statements that are conclusively proved. In particular, inaccuracies bridged by speculations and assumptions, are to be found in the following areas.[10]

Investigative methods *Epidemiologic investigations*, for example, into the relationship between certain atmospheric pollutants and diseases are usually of low reliability because the causes searched behind the observed effects frequently differ only little from the 'background noise' of other factors. The isolation of specific causative chains is, among other reasons, difficult because, for instance, the areas marked by distinct effects and therefore selected for comparison show overlapping factors, the rate of response to survey is low, the self-diagnosis possibly demanded by the questionnaire is unreliable and so on.

Animal testing in order to find dose-response relationships are of doubtful evidential value, because it is uncertain whether and to what extent the results can be transferred to human beings. Experiments on human beings made to the same purpose, due to their necessary voluntary nature, allow only a limited formation of characteristic groups for comparison, can only deal with small samples, and are usually carried out over short periods of time.

One usually tries to balance out these inaccuracies by collecting as many studies as possible, comparing the results (regarding, for example, dosages causing a specific effect), sorting out exceptional cases and finally choosing from within the spectrum a value close to the lower (cautious) end. This is a questionable procedure due to the fact that the different studies may all show the same inaccuracy. Errors having the same origin do not neutralize each other. It also happens that experiments with low concentrations which have not found significant correlations are not published just because of the negative outcome and the low esteem connected with such kind of publication.

10 See, for the following, the contributions by Pflanz, Koller, Schlipkötter in Umweltbundesamt (ed.), Medizinische, biologische und ökologische Grundlagen zur Bewertung schädlicher Luftverunreinigungen, *Sachverständigenanhörung*, 24 February 1978.

Subject of assessment Not only are the methods of investigation imperfect, but the subject itself is poorly defined. The connections between pollutants and diseases are much more complex and intertwined than the legislation regarding dosage-response envisages and is willing to accept. Thinking along the lines of thresholds for a given response neglects the multitude of effects which only one pollutant might bear, the increase of this multitude through a combination of intervening substances and the biological variability of the receiver organisms. Particularly high uncertainty exists regarding substances causing and intensifying cancer. There is reason to believe that these kinds of substance have effects at extremely low concentrations, a hypothesis which nevertheless can hardly be proved because of the very nature of a low concentration. One is stuck with making extrapolations from tests with higher dosages, which gives them a strongly speculative character. It is important though to understand that the problem of small quantities arises not only with carcinogenic substances but also with other sensitizing substances.

Statistics Ideally, the mathematical depiction of the results of a scientific investigation should precisely mirror the extent of the uncertainty. However, the method of depiction contains inaccuracies in itself. For example, the researcher has a choice between a number of mathematical models for representing the experiment results. Even in ostensibly neutral statistics one can find a hidden tendency towards the acceptance of risks and against cautiousness: when the harmfulness of a substance is being assessed, an error margin of 5 per cent is usually chosen for the correctness of the positive hypothesis. In the case of a negative result, the harmfulness is negated although, according to statistical calculation, a margin of error of up to 95 per cent for the negative result is possible.[11] This consequence can manifest itself especially when dealing with substances (for example, carcinogenic substances) for which the concentration of exposure occurring is extremely low.

Deductions of thresholds from doses Even when a specific dose-response relationship (for example the critical concentration of cadmium which impairs the functioning of kidneys) has been extensively researched, the tolerable pollution value (that is, the admissible concentration of cadmium in the air) is not automatically given. Thus additional research is necessary to determine the intake through respiration, food and drink, reabsorption, excretion, and possible accumulation or decomposition by the affected organism. Such research is usually fragmentary, and once again speculations and assumptions have to fill the gaps.

11 G. Osius, Mathematisierung von Dosis- Wirkungsbeziehungen und statistische Analyse von Beobachtungsdaten, in: G. Winter (1986), *op. cit.*, p. 49 *et seq.*

Taking the example of the German threshold proposed for cadmium,[12] the oral intake of this substance was totally neglected, with only respiration intake being taken into account. Moreover the period of intake through respiration was limited to only 50 years. Therefore the average human being who does not contract a disease due to the threshold resulting from these calculations is assumed to live on nothing but air, and this only for 50 years. On the other hand, out of two values proposed in the literature for the reabsorption period (the so-called biological half-life value), the higher one was taken on – that is, the one assuming a longer reabsorption period. This means that the so-called conservative approach was applied.

Safety factors The multiple uncertainties found in the subject itself, as well as in the methods used and the conclusions drawn are summarily taken into account by the application of safety factors – that is, by multiplying the resulting threshold by, for instance, 1 to 10, 1 to 100 or even 1 to 1000. The factor used will differ greatly according to the knowledge accumulated about the pollutant under consideration. It is often not at all clear what kind of uncertainty is 'absorbed' by this factor and in particular what is its relationship to the statistical statements regarding confidential areas. The following could be named:

- number of tests performed;
- size of tested sample;
- method of testing;
- steepness of the dose-response curve;
- patho-physiological mechanisms of the pollutant;
- accumulation and degradation of the pollutant;
- severity of the disease effected by the pollutant.

On the other hand it has been asserted that safety factors cover the area of total ignorance, while in areas where even fragmentary information exists, one should work with statistical methods. Besides, the safety factor may not be in the least influenced by considerations of how easy it is both politically and economically to carry through a reduction of each existing level of pollution.

Measurement provisions Thresholds are understood as limits of pollutants or noise which actually exist and have an effect. The degree of the actual contamination is not evident; rather it has to be measured. Measurements, however, are always constructions of reality, never an exact copy. Inaccuracies occur more frequently, the more strongly the contaminations fluctuate in time and location. Due to the fact that it is impossible to measure everything permanently, measurement provisions must be added to the thresholds in order to deal with these fluctuations.

12 See the proposal and its justification by J. Krause-Fabricius in Winter (1986), *op.cit.*, p. 285 *et.seq*.

For instance, when determining short-term pollution values of the German TA Luft the highest 2 per cent of the actually measured values can be disregarded and, for the long-term threshold, an average is taken of the values measured in a (again especially constituted) reference area, leading to a result far from realistic value. This applies even more so if, when approving new plants, contamination prognoses are involved, which are to be extrapolated from emission data about a not yet existing installation and transformed into pollution data by application of often highly controversial simulation models on the distribution of emissions by air and water. In this way, reality is not only scientifically reconstructed, but the relevant science (in this case meteorology) is, in turn, legally reconstructed. The distance from actual contamination and, with it, the uncertainty is thus doubled.

b) The use of socio-economic argumentation

When a more or less well founded dose-response curve connecting different concentrations with corresponding harmful effects is derived from the natural sciences, it may be asked which point on the curve should be chosen as the threshold. In order to answer this question socio-economic arguments which are often not made explicit or are based on rather rough guesses come into play. It is worth considering whether the relevant sciences – sociology and economics – should not be consulted more. The still rough, but possibly improvable, assumptions used consider, for instance, at which point the benefit derived from the threshold exceeds the costs of its realization. If a threshold is to be achieved which is so strict that the cost of anti-pollution investment is higher than the benefit derived from the saved health care costs, then this would speak against it and in favour of a less strict value.

Later we shall discuss whether such cost-benefit considerations are legally permitted at all (doubts arise because of the non-monetarizable concerns). We are dealing here only with a description of actual decision-making processes, where socio-economic discussion undoubtedly does take place.

An example of a scientific approach is a study which shows that a decrease of benzol emission from certain plants from 0 to 90 per cent costs 2.9 to 3.6 million $ per avoided death from cancer, a decrease from 90 to 97 per cent 32.7 to 40.7 million $ and a decrease from 97 to 99 per cent 32.8 to 94.4 million $. But science cannot truly judge the value of one life.

Even in cases of such apparently exact analysis the question arises as to the limits of scientific methods and the role of speculations and assumptions. Uncertainty and inaccuracy[13] often exist regarding the cost of waste avoidance and

13 N. Ashford in Winter (1986), *op.cit.*, p. 116 *et seq*.

clean-up procedures or the development of new products and also fail to take account of the fact that

- the required anti-pollution technologies will become cheaper and the more benign products more profitable with the general penetration of the market which will follow a technology-forcing threshold; and
- management will learn to act more efficiently in the newly designed framework.

Regarding the benefit derived from different thresholds there is wide dissent about assumptions on

- the expression of the value of human lives, human health and other basically non-monetarizable goods in monetary terms;
- the comparison of present and future benefit: in particular, how a future benefit can be discounted – that is, be calculated as a current benefit;
- the taking into account of such beneficial side effects of standards, as, for example, the advantages of modernization to be gained in connection with required avoidance technologies;
- the fact that the particular industrial branch might have invested into pollution avoidance technology even without the standard being applied.

c) Valuations

Speculations and assumptions which fill gaps in the knowledge of the natural and social sciences can, themselves, only partially be supported by scientific findings. Instead, they are heavily influenced by value judgements. Value judgements are even more relevant when it has to be decided for which substances standards shall be set and for which not. For instance, only about ten dangerous substances have been selected for pollution thresholds to be set by the German TA Luft whereas the other hundreds of, sometimes also very hazardous substances, were left unregulated.

Opinions differ widely with respect to such value judgements. The probably most important crossroad leads to the question of the burden of proof when a harmful effect cannot be clearly determined. One side shifts the burden of proof to the causative party and requires the most extensive safety measures until research is far enough advanced to signal the 'all clear'. The other side chooses the traditional path of economic liberalism: as long as damage has not been proven by research, there is no reason to initiate protective measures (or at least not expensive ones).

Criteria for valuations can be brought into play from the relevant laws. These contain hierarchies and exclusions amongst such criteria as human health, natural environment, economic gain, job creation, cost saving and so on.

A good example of the significance of value judgements is the above-mentioned difference between occupational health and environmental protection thresholds. The difference can be explained by the attitude in the cases of MAK standards, which are based on a tradition of compensation for workplace diseases, to think along the lines of diseases and the robustness of the organism, whereas in cases of environmental thresholds which are stimulated by more or less suffering neighbours one tends to look rather from the point of view of indisposition and sensitivity. Behind the differences of criteria that are applied *de facto* and directed by law, lie differences in history and differences in the political power basis of the working and living world. Health protection at work had to emancipate itself from a much higher level of 'normal' incidence of harm to human health than environmental protection, and was supported by the labour organizations which were politically far weaker than the bourgeosie which supported environmental protection.

2 Organization of standard-setting

The way in which thresholds are established cannot be fully understood if only the level of argumentation (with scientific findings, assumptions, value judgements) is examined. The *context of discovery* in other words, the social organization of threshold-setting should also be considered.[14] Utmost significance has been given here, among other things, to the composition of the committees which propose thresholds or actually determine them.[15] As far as individual but not general standards are concerned, the negotiation process between the operator and the authority plays an important role. When considering standard-setting by committees, the qualification and affiliation of their members is of prime importance.

In approaching the issue in terms of the level of argumentation or the *context of justification* it is logical to expect that all sciences relevant for the envisaged topic are represented as, for instance, chemical science, medicine, ecotoxicology, engineering and economics for the establishment of immission thresholds for toxic substances. Experts in moral judgement, for instance theologists, could be added. Furthermore, in this perspective the appointment of persons representing different strands in scientific controversies, for instance as to the risk of fissile nuclear power, would probably be demanded. In fact, standards are indeed often formulated by scientific committees. However, in most cases, experts from the soft sciences (economics, ethics – if they are sciences at all) are missing, and little care is taken to have scientific controversies represented on the committees. In the latter

14 See also chapter 15 by E. Rehbinder in this volume.

15 See, for instance, M. Böhm, Rechtliche Probleme der Grenzwertfindung im Umweltrecht, *Umwelt- und Planungsrecht,* 1994, p. 132 *et seq.*

respect the Consensus Workshop practised in the USA[16] could serve as a model. In this workshop are represented any scientists who have worked on a certain subject irrespective of whether this work was commissioned or carried out independently, thereby giving a representation of a broad spectrum of opinions. Admittedly, the result may not be a threshold proposal but rather only a summary of what has been researched, illuminated or remains open. But, even then it is valuable material for follow-up evaluation and identification of standards.

Following the logic of the 'context of discovery' one would start off with the assumption that standard-setting is principally influenced by socio-economic interests. Even science appears as an interest in this perspective. The scientific training and professional practice of the scientists do not confer on them an independence, even insofar as university teachers are concerned. Research appointments and grants from external sources which they are always eager to receive may make them less independent than scienstists employed by industry. The fact that scientific affiliation and independence do not go hand-in-hand cannot be emphasized too strongly, particularly in view of the fact that the opposite belief is so widespread. The interest-based perspective would require that the interests affected by the subject envisaged for standard-setting must be represented in the relevant committee including, in the environmental field, environmental associations.

An example of a pluralistically formed committee is the Committee for Dangerous Working Materials at the German Federal Ministry for Work and Social Order. Representatives of the employers, the employees, the authorities and the universities (mostly scientists having a certain affiliation with the pertinent interest group) are equally appointed to this committee. Standards concerning environmental risks, however, are still mainly being developed in committees in which representatives of the associations for environmental protection are completely missing. Thus, for example, the Committee for Nuclear Technology (KTA) at the Federal Ministry for the Interior includes: 20 representatives of manufacturers and operators of nuclear installations; 10 representatives from the supervisory authorities; 10 representatives from expert and consulting organizations, and 10 representatives from other authorities, the institutions for nuclear research, insurances, labour unions and the Deutsches Institut für Normung (DIN). Although there have long been numerous scientists opposed to the exploitation of nuclear energy, none of them has been invited to be a member. Although regulations from the KTA on technical safety are published before their final approval and thus made available for critical comment, this can in no way substitute for working on the committee itself, with access to the background material of the technical regulation and the debates in the committee sessions.

16 See DiMento in Winter (1986), *op.cit.*, p. 103 *et seq.*

The situation in Germany in this respect still lies behind the concept of 'balanced representation' which is demanded by the US Federal Advisory Committee Act 1972. The scenario is further complicated in the case of international standard-setting. On the international level not only divergent national cultures of risk perception, but also different national economic interests come into play. The European Union has established a peculiar structure to reflect this fact – the so-called comitology. Very frequently, EC legislative Acts delegate powers of technical standardization to the Commission, but with the proviso that the Commission must consult a committee of Member State representatives (mostly experts from the relevant high authorities), and that, if the committee's qualified majority dissents (which proves that the question is not merely technical), the Council may revoke the decision.[17]

I have presented two different perspectives of standard-setting which can intellectually be separated from each other. In the real world, however, it must be decided which path to take. For instance, in the German Act on Genetic Engineering (*Gentechnikgesetz*) a combination of both approaches has been tried: the Committee for Biological Safety (*Zentrale Kommission für Biologische Sicherheit*) which, among other things, gives advice on safety standards for biotechnology, comprises experts from a number of relevant sciences on the one side and representatives of different societal interests on the other. I am not sure that a simple summation of the scientific and the interest approach is a viable solution. It is interesting to note in this respect that the representative of the environmental associations has given up her membership because she did not have the financial means to collect the necessary scientific background information.

It is probably best to differentiate with respect to the subject matter which is to be standardized. Sometimes the problem is primarily of a scientific nature. Then the first approach should be applied, possibly modified by a proviso requiring the appointing minister to consult the relevant interest groups before he nominates the members. If the matter is more political and value-laden a pluralist composition is preferable; this may even include laypersons as possible candidates for membership. In any case it would be advisable to have as a chairperson someone trained in fair procedures, most probably a lawyer experienced in identifying controversial points and separating factual from value arguments.

V THE BINDING FORCE OF STANDARDS

Having described the creation and development of thresholds, we should now clarify in what way thresholds are binding on those who are to comply with them.

17 See, for details of the procedural variants, Chapter 20 by G. Goldenman in this volume.

1 Definition of threshold transgression

Regardless of whether or not non-compliance is connected with legal sanctions, non-compliance must first be defined. This depends on the wording of the threshold and may differ according to the area of application.

Thresholds may depict maximum limits that are not to be exceeded, as, for example, emission and immission values in environmental protection; they may be indicative of values that must, on average, be complied with; and they may be approximate values which serve as guidelines for both operators and authorities.

This differentiation raises the question of whether the variability of technical processes and, in particular, the likelihood of minor accidents (for example, in chemical plants) allows for the setting of strict maximum values at all. For this reason, special thresholds are sometimes set for exceptional cases.[18] Alternatively, measurement and calculation provisions can level peak values resulting from minor accidents, or maximum values can even generally be understood such that a modest transgression does not necessarily entail a sanction but gives reason to initiate an investigation into the causes of the transgression.

2 Legal consequences of threshold transgression

When the threshold is legally enforceable, transgression entails legal consequences which vary greatly according to the legal area. For example, the authorization for the construction and running of a plant may be refused or withdrawn, subsequent orders may be imposed (for example, to install filtering devices or observe certain duties as to occupational health), the marketing of a product may be restricted or forbidden, a fine may be imposed.

Alongside legal areas one can furthermore distinguish between legal consequences which demand a certain behaviour from the polluter (for example, reduction of emissions, not to distribute the produce, not to employ young people at a certain workplace) and legal consequences which cause official interventions (for example, denial of a permission, prohibition of product's distribution, enforcement of compliance and so on). The differentiation serves to emphasize that the polluter must comply with standards even if no special official measure is taken; for instance, he must carry out of his own accord any decrease in emission which becomes technically possible and may not, relying on the originally granted approval, wait for a subsequent official order.

Nevertheless, when thresholds are legally binding this by no means signifies that legal consequences will always follow. In practice there are numerous strategies of evasion. In this respect, thresholds are often merely negotiating positions forming a basis upon which the authority may barter with the polluter.

Yet another differentiation merits consideration: the legal consequences are usually directed at the party causing the emission or immission. Sometimes, however, the victims of the contamination by pollutants or noise are those who are blamed. The German biological tolerance values (BAT Standards) may serve as an example. When the BAT value of an employee for a pollutant is exceeded, this does not necessarily force the employer to improve the working conditions; on the contrary, depending on the applicable law, it may instead allow the employer to transfer the victim to another workplace or even to dismiss him or her. A similar oblique burden affecting the wrong party can be observed when a farmer is not allowed to feed grass if the threshold for lead contents for animal feed are exceeded because of pollution from a nearby lead factory, or when fishermen are not allowed to sell their catch because, due to the polluted sea, the fish meat does not comply with the thresholds of the foodstuff laws.

3 Legal force of thresholds

In order to be legally binding – that is, to cause legal consequences of the aforementioned kinds – thresholds have to be recognized by legal norms which tie such legal consequences to certain conditions, specially on the transgression of certain thresholds. This happens most obviously through the explicit incorporation of a threshold in the text of a law or regulation. One example of this is the German Regulation for Coal Power Plants 1983 (*Großfeuerungsanlagenverordnung*) which contains emission thresholds categorized according to plant type and age.

A weaker form of the legal recognition of thresholds is the so-called reference (*Verweisung*). Here the legal norm refers to thresholds being set by autonomous or administrative authorities for a closer description of criteria outlined verbally by the norm itself. One must distinguish between references which are complementing and references which are concretizing legal criteria. Both kinds of references can be static or dynamic – static meaning that the threshold referred to is already formulated and shall remain the same, dynamic meaning that any future change in the formulation of the threshold is also referred to. References of a law complementing nature which are dynamic are problematic because they delegate power to institutions which are not democratically legitimized. This is why they are held to be unconstitutional by German doctrine.[19] Alternatively, one could postulate the creation of a legitimizing basis for the autonomous standard-setting by requiring certain procedural safeguards as, for example, the representation of the concerned sciences and interests as well as public notice and comment requirements. This could then be taken as a partial substitution for the parliamentary legitimation.

18 This is the case with German nuclear power plants for which thresholds for contamination from manageable accidents are set that are higher than the thresholds for the normal operation of the plant. See Art. 28, para. 3, Strahlenschutzverordnung.

19 P. Marburger, Die Regeln der Technik, 1979, p. 390 *et seq.*

Such a conception would also fit better with the EC level where, on the one hand, law complementing dynamic references is frequent practice and, on the other hand, parliamentary legitimation is a particularly scarce resource.

The weakest form of legal recognition of thresholds are so-called 'hinge concepts' (*Scharnierbegriffe*) – rather vague terms, used in law which are operationalized through quantified thresholds. An example may clarify this.

In German environmental protection law a characteristic double approach has evolved. The first relates its criteria of environmental protection to the possible harm and marks the threshold of the harmful dosage (the so-called *danger threshold*); the second relates its criteria of protection to the available avoidance technology and marks the threshold of the technically possible (the so-called *precaution threshold*).[20] The interpretation of the relevant legal terms should normally allow the definition of what gravity of pollution a 'danger' or at which emission level an inadequate realization of the 'best feasible technology' is to be assumed: for instance, the term 'danger to health' might, by recourse to legal materials or through teleological interpretation, be read to mean 'causing vegetative malfunctioning of the human vegetative system'. This level of language is sufficiently concrete to be related to the level of empirical knowledge which can be obtained from experts through administrative or court procedures. From them one might deduce that the above-mentioned malfunctioning starts to occur from a daily dosage of 100 μg. This value would then be taken as the precise expression of the danger limit.

General thresholds offer the advantage that the point to which the legal consequence (for example, approval/denial of approval) is attached must not be established anew for each case but is established once and for all. Such an operationalization of the legal term could well be carried out by the courts themselves. They already act in this manner as, for instance, in family law when establishing alimony tables and adjusting them periodically. In environmental law, however, the courts do not see themselves as capable of doing so and prefer to take recourse to the thresholds prepared by administrative or autonomous bodies. In the case of 'hinge concepts' where there is no explicit incorporation of, or reference to, a specific standard, standards cannot be called binding by law. Legal doctrine had therefore to invent auxiliary principles which make the transfer of extra-legal rules into the law plausible.

The German Federal Administrative Court in its *Voerde* decision of 1978 decided in favour of a concept of procedural law applying the rule that expert opinions can be taken as evidence for related allegations: extra-legal thresholds may be accepted as evidence if, for their formulation, the available scientific knowledge was extensively taken into consideration. This allows for them to be taken as 'anticipated' expert opinions, anticipated in the sense that they do not have to be

20 Compare G. Winter, Chapter 3 in this volume.

reassessed in individual cases. As with all expert opinions they may only be refuted if reasonable doubts exist as to their validity.[21]

This jurisprudence has been widely criticized. In particular it has been asserted that the volitive not cognitive elements of threshold-setting are being overlooked. If applied to our example this critique would probably state the following: first, the threshold of 100 μg contains an interpretation of the norm in setting the danger threshold at vegetative malfunctioning rather than at the more cautious point of indisposition. Second, it contains uncertainties at many points, even where dose-response ratios based on seemingly 'hard' science have been established. These uncertainties are compensated by speculations, assumptions and valuations. Finally, even when the setting of thresholds appears to be made from a purely medical point of view, economical consequences are also being taken into consideration, if only in disguise.

Under pressure from this kind of criticism the Federal Administrative Court came to feel the need to replace the hypothesis of the anticipated expert opinion by a formula which reflects the political elements in the expert judgement. In the *Wyhl* decision of 1985 the Court acknowledged the executive power to possess the capacity for standardization.[22] This doctrinal shift can best be explained in terms of separation of powers: the earlier attempt to trust in science as a source of quasi-legal standardization thereby instituting science as a kind of constitutional power has failed. Looking for another power into which the capacity for standardization could be invested the Court, echoing an earlier decision of the Federal Constitutional Court,[23] found neither the legislative branch nor the judiciary to be equipped for detailed and flexible standard-setting. Therefore, it took recourse to the executive branch.

It is doubtful whether this was an optimal solution. Upon a closer look the executive agencies are often unequipped for providing both the scientific knowledge and the rational evaluation required for standard-setting. Procedures will have to be developed and given legitimate value which activate the participation of expertise and interests. On the other hand the courts should not restrain themselves too much from this field. They have to play a role in checking whether the procedures were followed, whether diverging scientific and technological opinions were not overlooked, whether or not evaluative elements hidden in the scientific and technological reasoning were brought out into the open, and whether or not relevant arguments were left out of consideration.

21 Decision of 17 February 1978, BVerwGE 55, 250.
22 Decision of 19 December 1985, BVerwGE 72, 300.
23 Decision of 8 August 1978, BVerfGE 49, 89.

VI REFORM CONSIDERATIONS

Reform considerations may be based upon four essential findings:

- Thresholds schematize interrelations which in fact follow highly variable and individual courses.
- Thresholds pretend knowledge which in reality does not exist; furthermore they stabilize the erroneous assumption that a potential for harm is to be assumed only when positive scientific scrutinies are at hand.
- Thresholds are influenced by valuations and thus also by interests.
- Thresholds tend to maximize the protection of a medium thereby risking that the pollution is shifted to another medium (for example, from air to water).

In view of these, and other, shortcomings of thresholds one might consider whether the instrument of threshold-setting should be given up altogether, especially thresholds derived from a thinking backwards process from harm to health and nature contaminations. As almost every quantum of toxic or non-degradable chemicals being released must be considered as too much, consequent avoidance, inclusion and recovery is required. In this respect, a proactive approach forcing technological innovations has up to now proved to be especially effective (and then in the form of emission thresholds which usually follow spectacular accidents). But emission thresholds can still be employed in the area of persisting routine, albeit no longer as a permanent marker but rather only as an instrument which has to be revised according to plan and which serves as an instrument for a stepwise reform towards minimal emission.

Nevertheless, immission thresholds also remain essential because the approach of minimizing emission does not exclude the possibility that dangers to health and the environment might appear – due, for example, to the multitude of the sources being individually minimized. But these thresholds must first be understood anew as only first steps (due to the fact that no exact knowledge can be established) which are tightened systematically and regularly not only in light of new positive findings but also because of the uncertainty of their scientific basis. Such utilization of standards implementing substantive law criteria like prevention and avoidance of harmful effects will also be indispensible in future. But the procedure of threshold-setting needs to receive more intensive attention than it has hitherto because standards are never set without the influence of interests. A wider range of scientists must be involved, as well as a provision for greater publicity of the procedure or the incorporation of a lay element in the decision-making committees.[24]

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24 For more detailed suggestions in this respect see H. v. Lersner, Verfahrensvorschläge für umweltrechtliche Grenzwerte, *Natur und Recht,* 1990, p. 193 *et seq.*