1. Risk and the regulatory State – various aspects regarding safety and security in the fields of technology and health*

Klaus Vieweg

I. INTRODUCTION

The topic of safety and security is a classic problem which, following the process of industrialization, continues to appear in a variety of new forms. Examples of current problems include risks arising from various sources, starting with toys and children’s jewellery and extending to the risk of infection in hospitals and while flying, as well as risks attached to nuclear power plants and international terrorism. Reactions to technical developments can be observed in the areas of business, law and in society in general. A good historical example is the founding of boiler monitoring organizations in Germany in the late 1800s, which was a direct result of frequent cases of boilers exploding. These organizations later became the Technische-Überwachungsvereine (TÜV), which are non-commercial organizations for the monitoring of technical installations. Industrial mass-production and globalization are two further relevant developments in the business world. These developments were accompanied by political decisions, for example to create a European single market.

The matter of safety and security is a multidisciplinary topic the world over. In this chapter, however, as a German lawyer, I wish to concentrate mainly on the legal systems and practical experience in Germany and Europe. The most important decisions in the field of safety and security are made in the areas of politics, technology, economics and law. A

* Original wording of lecture without citations. With thanks to Mairéad Boland for the translation.
considerable amount of background information is provided by persons and bodies in the areas of science, psychology, sociology, philosophy, ethics and history. The starting point for most of those decisions is usually a set of undesired circumstances and occurrences which may be described by terms such as ‘endangerment’, ‘risk’, ‘danger’ and ‘damage’. These decisions are not generally made in accordance with a unified method or approach. Rather, these tend to diverge depending, on the one hand, on the function and subject-specific alignment of the person making the decision, and, on the other, on the type and level of the undesired circumstances or occurrences. The debate as regards safety and security must also be mentioned. Too rigid a focus on one’s own area of competence and, more importantly, the ignoring of decisions reached in the areas of politics and law, can mean that the diagnostic value of scientific experiments must be relativized considerably. On the other hand, the establishment of bridges between the various disciplines can improve the quality of decision-making and avoid time-wasting and additional costs.

In this chapter, I will first address the issue of consistency between terms and scenarios. I will then talk about tasks and responsibilities, and, finally, I will discuss decision-making processes.

II. CONSISTENCY REGARDING TERMS AND SCENARIOS

1. The terms used in the area of technical security and safety reflect the different roles and responsibilities of the various disciplines involved in this field (for example, technical measures in order to avoid or reduce undesired circumstances and occurrences, or legal provisions relating to the quality and composition of objects, responsibility, competence, and liability of persons and organizations). The terms used in different areas diverge substantially from one another for the most part. Even within individual areas, the meanings of particular terms and definitions diverge and so the assessment and weighting of particular areas are concealed (for example, the anthropocentric containment of the subjects requiring protection, the acceptance of risks, the fading-out of so-called development risks).

2. The coining of working definitions leading to an interdisciplinary – as the case may be, an intradisciplinary – and, where possible, international agreement is recommended. This is vital for the solution of difficult factual problems. Definitions used within a legal system and in technical standardization (DIN, VDE, DKE, DVGW, CEN, CENELEC,
ETSI, ISO, IEC\textsuperscript{1}) are of particular importance. These should almost be viewed as non-negotiable terms of reference. They should be framed so as to match each other.

3. The starting point for the clarification of definitions is that an absolute outright state of security or safety cannot exist. In particular, the following questions should be posed: ‘How safe is safe enough?’ and ‘Who decides, and according to which principles and criteria?’

4. The working definitions must facilitate agreement in relation to the following questions:

- Who and/or what is the object of protection? Is it man and his (material) goods, or can assets which are not attributable to him – that is, goods which are ‘unattached’ to a particular person – also be taken into account (here, the problem of so-called ecological risk, or rather, damage, must be addressed)?

- Against what is the object of protection to be safeguarded? Against targeted attacks and interferences (security) and/or other negative effects of undesired conditions and occurrences (safety – technical error, human and organizational error, natural occurrences)? Should undesired situations and occurrences (so-called development risks, that is, risks which are not yet known, but the occurrence of which cannot be excluded should new technology be developed) be included?

- In each individual case, one must ask whether the problem relates to undesired situations and occurrences which can be ascertained statistically, or at least estimated, or whether it relates to tactically adjusted behaviour, or a dynamic process (for example, a terrorist attack; but also – as a natural occurrence – the mutation of viruses which can then lead to their resistance to treatment)?

\textsuperscript{1} The acronyms stand for the following: DIN – Deutsches Institut für Normung (German Institute for Standardization); VDE – Verband der Elektrotechnik Elektronik Informationstechnik (German Association for Electrical, Electronic and Information Technologies); DKE – Deutsche Kommission Elektrotechnik Elektronik Informationstechnik im DIN und VDE (German Commission for Electrical, Electronic and Information Technologies of DIN and VDE); DVGW – Deutscher Verein des Gas- und Wasserfaches (German Technical and Scientific Association for Gas and Water); CEN – Comité Européen de Normalisation (European Committee for Standardization); CENELEC – Comité Européen de Normalisation Electrotechnique (European Committee for Electrotechnical Standardization); ETSI – European Telecommunications Standards Institute; ISO – International Organization for Standardization; IEC – International Electrotechnical Commission.
Should measures be put in place even at the starting point? In other words, should measures be put in place where a factual situation exists which may be defined as an unwanted situation or occurrence; that is, should this state of affairs result in repercussions (for example, the implementation of technical-organizational measures, the intervention of an authority, the refusal to grant permission for the operation of a factory, liability, penalization)?

Should advantages and chances also be included in the definition even if they extend beyond the level of the undesired situation or occurrence (the potential extent of damage) and the probability of the occurrence of this undesired situation (taken together, these two aspects form the classic risk definition)? If yes, how? Should, for example, quantifications of risk be decisive? Should the principle of proportionality hold good in the weighing up of the risk and its accompanying advantages and chances?

Should cost-related aspects be included? If yes, how (quantification problems, weighting problems)?

5. Consistency – both between the various disciplines and, in particular, consistency between the legislature, administrative decisions and case law – requires transparency in the methodical approach.

The steps which occur in the various disciplines between the identification of problems (risks) and the solution of problems (reduction of the risks) should be made clear. In relation to the multitude of risks and the measures taken in order to reduce them, simplifications are unavoidable in order to create a basis for understanding. As a basis for orientation, it is suggested that all scenarios are systematically included in a ‘risk grid’ which is made up of sources of risk – human error (including organizational error), technical error, natural occurrences, the unauthorized interference of third parties – and three ideal types of regulatory models to be found within legislation (self-regulation, cooperative regulation and imperative regulation). These regulatory models reflect the affected interests (individual and general) and correspond (ideally) to the principle of proportionality. The measures included in the grid as examples of risk reduction are the results of weighing-up exercises in the areas of utility and proportionality (see Table 1A.1). Of course, various combinations of the sources of risk and gradations in the three regulatory models are common in practice.

Further differentiations and variations of the – very rough – ‘risk grid’ are possible. In each individual case, it must be examined whether or not the taking into account of additional aspects is helpful. In this way, the differentiation by the ‘regulatory (legal) instruments’ between criminal
responsibility, civil liability and public law obligations can be targeted at regulation of behaviour. It is of no help in cases of intentional interferences by third parties (in particular, in the case of terrorist attacks). Differentiation based on the intention of the person causing damage – whether the damage is desired or not – does not get us any further because the most important cases of the intentional causing of damage are already to be found in the ‘risk grid’ classified as interferences by third parties.

The ‘risk grid’ serves not only as a source of information but also as a touchstone for the integrity of a transverse systems theory. By making reference to the ‘New Approach’ and the ‘New Legislative Framework’, the ‘risk grid’ also makes clear the function of technical standardization which, in practice, has achieved an importance which should not be underestimated, and which the EU legislators have carried over into their specification of general security requirements in the standardizing organizations CEN, CENELEC and ETSI.

III. TASKS AND RESPONSIBILITIES

1. The general goal of security and safety is generally pursued in an aim-oriented manner by the assignment of tasks and obligations according to technical qualifications and interests. This assignment takes place in various different ways. It is important to the extent that the regulations set out in statute allow self-regulation or contain concrete guidelines. It must be taken into account that, in this area, lobby groups are hugely influential.

Cases of self-regulation are characterized by the facts that the individual interest of the endangered party takes priority over the interests of society in general, and that the legislator chooses not to take action, but rather deems the general legal framework to be sufficient. The assignment of tasks and obligations ensues bilaterally on a contractual basis between those who wish to allay an undesired risk and those who claim to be able to prevent the risk, or at least to reduce it to an acceptable level (for example, the testing of electrical terminal equipment by an expert, the installation of a lightning conductor to protect against lightning or an alarm system to protect a (‘single family’) detached house against burglary). Should the risk be wholly dependent upon a human error made by the endangered person, then safeguarding against financial damage ensuing from the risk could take the form of insurance.

If the risk extends beyond the individual person and, above all, if third parties are in need of protection because their (material) assets could be
affected (for example, fire protection), the assignment of tasks and responsibilities takes place on a tri- or multilateral basis. As a rule, there are provisions set out in statute intended to regulate the types of cases which relate to concrete risk. In particular, standards relating to the jurisdiction of authorities and courts, criminal responsibility and civil liability must be taken into account.

2. Insofar as the assignment of tasks and obligations takes place in accordance with legislative standards (tri- or multilaterally), two legislative regulatory approaches should, ideally, be differentiated from one another. First, ‘classic’ imperative regulation by concrete orders and prohibitions plays as important a role today as it did in the past, both on a national as well as on a European level. This becomes particularly important when substantial interests of the general public are affected. Secondly, the meaning of cooperative regulation between the EU and the State, on the one hand, and between the affected company and private individual on the other, is clearly gaining in importance. The ‘New Approach’ (1985) and the ‘New Legislative Framework’ (2008) are particularly practice-oriented. Usually, cooperative regulation is rooted in the interest of the general public, as well as in the interests of the individual.

The differentiation made in some sections of theory and practice between so-called ‘safety problems’ and ‘security problems’ has not yet fully manifested itself in legal regulations (for example, there are still no special regulations for terrorist attacks on nuclear power plants). There are two probable reasons for this: first, a time-lag within the legal system which can be denoted as a ‘legal lag’ (ever since 11 September 2001, it has been clear that terrorist attacks cannot be prevented by the threat of punishment) and, secondly, an overreaching legislative protection concept which – in relation to the risk – does not differentiate between ‘safety’ and ‘security’ but has regard to the protection of legally protected interests.

IV. DECISION-MAKING PROCESSES

1. Regarding the regulatory model of self-regulation (where individual interests are affected above all) and the risk source of unauthorized third-party interference (see Table 1A.1), the decision process (individual decision of the endangered party) may be characterized as laid out in Figure 1A.1.

The knowledge, experience, feelings and interests of the endangered party shape the individual assessment of risk, for which the extent of the
damage, the probability of occurrence, individual measures (such as
insurance) and the degree of fear that damage will occur are also of
importance. In addition, all relevant information provided by those
technical experts who have been consulted for advice will be taken into
account. The solutions suggested by technical experts will also be
individually assessed by the endangered party under the headings of the
expected increase in safety, costs, time input, alternatives and con-
sequences. The internal weighing-up process of the endangered party is of
central importance. His negotiations with technical experts result – in
contract form – in the selection of a technical solution, the level of safety
of which he regards as being optimal in view of all relevant costs and
time-input. In the case of a negative decision, the situation will remain a
hazardous one.

2. As to the regulatory model of cooperative regulation and European
or national imperative regulation on the one hand and the sources of risk
emanating from technical error, natural occurrences and the interference
of unauthorized third parties on the other, the decision process relating to
the solution of security and safety problems (simplified) can be charac-
terized as demonstrated by Figure 1A.2.

The decision process is, on the one hand, influenced to a large extent
by statutory regulations which exist in relation to the prevention or the
reduction of risks. Standards relating to competence, responsibility, the
process of arriving at a decision, all relevant technical, organizational and
administrative procedures, and insurance solutions, as well as – above all
– security and safety standards, must be included under this heading. On
the other hand, information regarding the risk plays a substantial role – in
other words, information about the starting point, as well as the technical
possibilities available to solve the problem. Legal standards, as well as
information regarding the risk, influence communication and cooperation
between those responsible for the source of risk, technical experts and the
State, in particular, the authorities with competence for these matters. The
decision regarding the solution of the safety problem is therefore
dependent upon concrete legal regulatory approaches which are specific
to the risk.

3. In the point of view of an individual drawing up regulations – in
particular in the European or national context – a systematic approach in
relation to a concrete risk (for example, a terrorist attack on a nuclear
power plant or another plant requiring authorization) could be laid out as
follows:

- identification of the risk (or, possibly, risks) and decision regarding
  whether regulations are necessary;
formulation of the security or safety aim for the concrete scenario within the scope of the legislative aim;
- determination of the regulatory approach regarding the affected interests and the principle of proportionality;
- investigation of any relevant preventative, compensatory or repressive measures which could prevent or reduce the risks (for example, technical or administrative measures, user information);
- determination of the tasks and obligations of the decision-makers (authorities, industry in general, producers and delivery companies, standardization organizations, technical experts, operators/users/consumers);
- regulation of the decision-makers’ behaviour (civil liability, costs relating to administrative measures such as recall, penalization, loss of reputation);
- determination of regulations for the prevention or reduction of the risks (for example, technical or administrative measures, user information) for the purpose of assessment of risk.

The question of whether the regulations which have been in place until this point are based upon a similar systematic approach and, in particular, whether the constitutional principle of proportionality is taken into account must be clarified. Independently of this, a transparent procedure should lead to a mutual understanding between all parties concerned. The difficulties faced by those drawing up regulations become clear when the various contexts are viewed in a regulatory circuit model (see Figure 1A.3).

V. CONCLUSION AND RECOMMENDATIONS

As an interdisciplinary and international topic, there must exist within the area of security a common understanding regarding definitions and methodical approaches. Problems of comprehension lead to time-wasting, cause additional costs and, frequently, lead to a reduction in the quality of decision-making.

The working definition of ‘risk’ is taken as a starting point. The term can then be further defined by characteristics such as ‘potential level of damage’ and ‘probability of occurrence’. Proceeding from this point, an efficient harmonization of definitions can be facilitated by considering differences between definitions and by restructuring the relationships between definitions. The differentiation between definitions relates in particular to the obligation to take certain measures on the one hand, and,
on the other, to the assertion that no measures must be taken because the risk is acceptable. Furthermore, it can be clarified conceptually whether advantages and chances may be taken into account in weighing up the decision.

A glossary of all definitions used in the context of security and safety problems – including details of how they relate to one another – would be useful. Keeping in mind the process of decision-making in practice, these glossaries should be compiled within the three key areas of technology, law and business – on a national as well as an international level. In doing so, the area of technology could be represented by technical standardization; the area of law by all relevant legislation, administration and case law; and the area of business by the insurance industry and various groups of companies. The foundations have already been laid by DIN technical report 144\(^2\) and the results of the working group ‘Taxonomie’.

Using these glossaries as a basis, it would be advisable to clarify in a second step whether or not the definitions can be used and understood consistently within each individual area, between disciplines and internationally, or if the terms require harmonization.

As regards the methodical approach which characterizes safety and security decisions, it is suggested that a ‘risk grid’ based on the four sources of risk – human error (including organizational error), technical error, natural occurrences and the unauthorized interference of third parties – as well as on the three ideal-typical legal regulatory models – self-regulation, cooperative regulation and imperative regulation – should be used as a means of clarifying the process. To this end, the framing of methodical approaches within a grid of 12 fields arranged as described above would be a step in the right direction. Leading safety experts also play an important role in the areas of technology, technical standardization and in those areas of risk which have not yet been covered by technical standardization. Considerable advances have been made by the preliminary work of standardization organizations on the one hand, and by the acatech\(^3\) working group ‘Creation of System Capability’ on the other. In addition, legislation, administration and case law, as well as the insurance industry and company groups, are of importance. Taking the aforementioned risk grids as a basis, it should be clarified if, and to what extent, the methodical approaches correspond to each other, or


\(^3\) acatech (Deutsche Akademie der Technikwissenschaften) is the German Academy of Science and Engineering.
if they require harmonization or clarification. In this case, solutions specific to particular branches and products should also be taken into account.
## APPENDIX

### Table 1A.1 Risk grid

<table>
<thead>
<tr>
<th>Source of risk</th>
<th>Human error (including organizational error)</th>
<th>Technical error</th>
<th>Natural occurrence</th>
<th>Interferences by unauthorized third party, in particular an attack from external sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-regulation (personal interest of the endangered party and, possibly, of his contractual partner)</td>
<td>Domestic accident, e.g. fall from a stool which was being used incorrectly as a substitute for a ladder</td>
<td>Fire caused by incorrect wiring, wear and tear (after the item has been placed on the market and its guarantee has expired)</td>
<td>Flooding of basements by heavy rain; strike by lighting of a detached single family house (lightning conductor not compulsory)</td>
<td>Burglary of a detached single family house (State intervention occurs after the act only)</td>
</tr>
<tr>
<td>Cooperative regulation (general public interest and personal interest)</td>
<td>Operational error which runs contrary to the behavioural requirements set out in the New Approach and the New Legislative Framework</td>
<td>Lightning/flooding in industrial plant which requires planning permission – section 3 sub-section 2 No. 2 in connection with section 9 sub-section 1 No. 2 Accident Regulation (Störfall-VO); (See Enforcement Aid 9.2.6.1.2 in connection with appendix 12.1.1 and 12.2))</td>
<td>Intentional causing of an interference in an industrial plant which requires planning permission – section 3, sub-section 2, No. 3 in connection with section 9, sub-section 1, No. 2, Accident Regulation (Störfall-VO); SFK Guidelines, GS 38. (See Enforcement Aid 13.3)</td>
<td></td>
</tr>
<tr>
<td>European/State imperative regulation (considerable general public interest)</td>
<td>Infringement of, e.g. - ban on alcohol for learner drivers – section 24 c, Road Traffic Regulations (StVO) - certificates of proof of technical qualifications - obligation to wear protective equipment - section 21 a, Road Traffic Regulations – safety belt - protective helmet (StVO)</td>
<td>Sources of risk are contained within the security report (directed specifically at industrial plants) – section 9, Accident Regulation (Störfall-VO); 7.903 industrial plants within the meaning of section 3, subsection 5, Federal Emission Control Act – BMWiG (within Germany)</td>
<td>- earthquakes, interpretation of industrial plants which require planning permission – section 5 sub-section 1 No. 1, Accident Regulations (Störfall-VO); - lightning-lightning conductor required for all places of assembly – Art. 38 para. 2 No. 4 Federal Criminal Code and Regulations of Bavaria (LStVG); Art. 44 of the Bavarian Building Regulations (,BaybG) - protection against fire for all buildings - protection against floods (building prohibition, dam height)</td>
<td>Targeted causing of a disturbance in an industrial plant which requires planning permission – section 3, sub-section 2, No. 3 in connection with section 9, sub-section 1, No. 2, Accident Regulations (Störfall-VO); (See Enforcement Aid 13.3)</td>
</tr>
</tbody>
</table>

Risk and the regulatory State
Knowledge, feelings and interests of the endangered party

Starting point
- Extent of damages
- Probability of damage or loss occurring
- Measures taken personally (e.g., insurance)
- Degree of fear of damage or loss occurring

Suggested technical solutions
- Increase in level of security/safety (also, increase in level of trustworthiness)
- Costs
- Time involved
- Alternatives (technical, organizational, economic)
- Consequences (e.g., increase in value, damage to neighbourhood in the event of a false alarm)

Internal weighing-up process of the endangered party

Negotiations and possible conclusion of contract with the technical expert

Result
- Choice of technical solution, the level of safety of which will be chosen based on costs, time involved and the optimum balance between these two and the technical solution (the starting point may even remain unchanged)
- Realization of solution taking into account all relevant standards within the field (e.g., technical standards)

Information and suggestions from technical experts

Information relating to the starting point
- Expert
  - Neutral and doing justice to the relevant interests or bound by the relevant interests

Suggested technical solutions
- Expert
  - Neutral and doing justice to the relevant interests or bound by the relevant interests (in particular expenses/time involved in relation to profit made)

No legal standards/provisions

Self-regulation

Figure 1A.1 Bilateral security/safety solution in the event of individual endangerment (for example, alarm system for a detached, one-family house)
Figure 1A.2  Tri/multilateral safety/security solution in the event of general endangerment (in particular, endangerment of third parties and the assets of third parties, as well as assets of the general public)
European Union

National legislating bodies, e.g. Bundestag (lower house of German Parliament) and Bundesrat (upper house of German Parliament)

Legal regulations: requirements relating to quality and composition, and to behaviour

Other abstract normative standards which are generally of application (e.g. technical regulations and precedents)

Bodies which apply the law (e.g. public authorities, courts)

Information regarding socio-economic sector

Information regarding the circumstances of the case which is to be decided (conflict)

Decision in each individual case (e.g. judgment)

Legal entities (natural and legal persons)

Figure 1A.3 Legislating and applying the law