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Limit values and the boundaries of science and technology

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ABSTRACT

Limit values are an important instrument of regulatory science and politics.[1] The focus of this article is on occupational exposure limits in the Federal Republic of Germany from the 1950s to the 1980s. Public statements of a chairman of a regulatory commission are studied with respect to the representation of the relationship of science and technology. The article closes with some thoughts about the coincidence of models for the relationship between science and technology dominating innovation theory with models underlying regulation.

In many industrialized countries, threshold limit values decide on the quantities of chemical compounds that are to be tolerated in the vicinity of human beings. At the workplace and in the environment at large, limit values are the favorite choice of regulators for dealing with the risks of chemical production and the uses of chemicals. The foundation of the concept of limit values is the definition of a hazardous substance as a "concentration of a substance that cannot be tolerated physiologically" [1]. Thus, hazard (and safety) are constituted by numbers. Most famously, and often quoted, Paracelsus' dictum of the dose making a poison represents the respective mode of thinking about potentially harmful chemicals. Limit values are not restricted to chemical substances, however. In the mid-1990s, and in the Federal Republic of Germany, approximately 10,000 so-called "environmental standards" (most of them limit values) were collected in 154 lists, covering chemical production, radiation, noise, and waste, to name but a few areas [2].

Usually, the problematic issues of regulating with the help of limit values have been approached in terms of the interaction of science and politics. The threats for these two social fields, respectively, have been couched either in terms of compromising scientific ideals and damaging the autonomy of science, or in terms of giving rise to technocracy, the dictatorship of the scientific elite. A quote by the chairman of a German regulatory commission, Dietrich Henschler, in 1983, sketches the prevailing opinion of regulatory scientists of that time very well:

> "There always has been unanimous agreement in the scientific community that the creation and evaluation of data relative to effects and thresholds are entirely scientific issues which have nothing to do with political or socio-economic parameters nor with technical feasibility. What differs from country to country is the degree to which scientists are ready to participate in the political decision process. Nourished by the above-mentioned inadequacies of the present system of standard setting and being further pressurized by the rapidly increasing numbers of newly introduced substances, a tendency for a steady strengthening of social and political influences can be foreseen. Up to now, we have been successful in trying to keep the business clean. Whether and how long this position can be held will depend mostly upon the speed and extent with which scientific progress can fill the existing gaps and also on the natures of the persons engaged in these matters: persons who have to survive in a classical conflict situation between *Homo sapiens* and *Homo politicus*. Are our forces facing the compromise of unification?" [3].

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Quite typically, Henschler opined that the scientific part of the regulatory system has to be kept "clean", thus, free from political interventions. His was the view of an opposition of science and politics. However, Henschler also mentioned problems and pointed to "inadequacies", giving rise to social pressure. In the following, I will try to pin down some inherent problems of the German regulatory regime, presenting the case of occupational exposure limits between the 1950s and the 1980s. In this period, the regulatory regime shifted from a phase when its public defense was based on epistemic authority alone to a phase when the impact of socio-economic forces was openly admitted, and even called for. In the case of occupational exposure limits, this shift was triggered by the increasing awareness of the hazards of carcinogenic chemicals [4].

More important, however, for the purpose of this article is the observation that the dichotomy of science and politics is too simple to analyze the issues at stake. Equally important are technical and economic circumstances and forces. *Homo sapiens* and *Homo politicus* have to be supplemented by *Homo faber* and *Homo oeconomicus*. Of course, this observation is not new, as almost any criticism of the regulatory system stresses the dominance of economic interest. Also, the technical problems accompanying measurement regimes in the factory are well known, and described by the regulators themselves. My point here is a different one. I will argue that we gain additional insight by analyzing the different types of regulatory regimes regarding the relationship of science and technology. Thus, my focus will be on the interaction of *Homo sapiens* (if we accept Henschler's notion as a stand-in for science) and *Homo faber* (representing technology).

My overall aim is to establish a new category inside the realm of studies inquiring into the boundaries of science and technology. First, and most famously, the interaction of science and technology has been studied through their respective roles in innovation. The number of studies dealing with this category is legion [5]. Second, and also well-established, is the interplay of science and technology via technical instruments and their influence on the course of science, especially in the realm of experimentation [6]. The third field, however, arguably has received scant attention. Studying the relationship of science and technology *qua* regulation hopefully enables us to better understand the complex interplay of socio-epistemic forces in modern society.

First of all, this article concerns the boundaries between science, on the one hand, and technology, on the other. However, as we will see in the course of the argument, the way the relationship between science and technology is represented also affects the interaction of science, on the one hand, and politics and economics, on the other. Picturing science and technology as separated in the regulatory system also leads to a rift between science and politics/economics. Shaping science and technology as a closely intertwined endeavor strengthens the viewpoint of a high impact of politics and economics on the joint enterprise. Thus, the ways how the boundaries between science and technology are drawn has consequences on how the two fields together are seen with respect to other social forces. In order to analyze this issue, I will interpret some of the published articles of one key figure in the German regulatory system of chemicals at the workplace, Dietrich Henschler. Thus, I will make use of only a small part of the public discourse. It is important to note that my aim here is not unravel the inner working modes of the German regulatory regime. Instead, I am interested in how the actors themselves sketched their tasks and pictured their limitations and constraints.

1. Limit values as a scientific concept

In the 1950s — with penicillin, nylon, the atomic bomb, and other gadgets originating in the efforts of the scientific enterprise before and during World War II still present in the public conscience — it was not necessary to emphasize that science had technical and economic consequences. The link between science and technology in innovation was an obvious one. What about the connex in regulation? As a result of an increasing awareness that anthropogenic changes in the workplace, in nutrition as well as in the environment at large were taking place, scientists argued that science should not only be applied to foster innovation, but should also control its consequences. One of the concepts used in this regard were limit values, most broadly defined as quantitative indicators for limiting anthropogenic effects on the population, or parts of it [7].

From the 1950s onward, occupational exposure limits (in German "maximum allowable concentrations", *Maximale Arbeitsplatzkonzentrationen*, MAK values) were a crucial part of the regulatory regime of occupational health in the chemical industry.

In the mid-1970s, MAK values were defined as:

> "... the concentration of a chemical substance as gas, vapour or particulate matter in the workplace air which, according to current knowledge generally does not have adverse effects on the health of the employee even when the person is repeatedly exposed during long periods, usually for 8 hours daily but assuming on average a 45-hour working week. MAK-values are established on the basis of the effects of chemical substances; when possible, practical aspects of the industrial processes and the resulting exposure patterns are also taken into account. Scientific criteria for the prevention of adverse effects on health are decisive, not technical and economic feasibility." [8]

There are a number of points in this quotation that deserve to be emphasized. First of all, the definition attempts to establish the independence of science versus technical and economic constraints. The mentioning of the effects of chemical substances points to a specific discipline, i.e., toxicology, as being in charge of setting the values. Moreover, as a reference is made to "current knowledge", the possibility of correcting the scientific findings is stressed. Nevertheless, at the foundation of the definition are working hours and, as we will see, crucial notions such as health and adverse effects which are notoriously hard to fix.

When Dietrich Henschler described the "history, philosophy, future development" of exposure limits to

his colleagues at the annual conference of the British Occupational Hygiene Society at Edinburgh University in 1983, he opined in strong words that "without such limits occupational health protective activities would be reduced to a state of uncertainty and chaos" [9].

In the early 1980s, three major systems were in charge on an international scale. Since the 1940s, the threshold limit values of the American Conference of Governmental Industrial Hygienists dominated the Western block while the USSR used a different concept and published their own recommendations. Since 1969, West Germany set up its own independent list of threshold limit values (MAK values), which was compiled by a scientific commission of the German Research Council (*Deutsche Forschungsgemeinschaft*, DFG), the principal research-funding agency in the Federal Republic of Germany. Other industrialized nations were either latecomers (such as Sweden and Holland), or, like France, resorted to publishing the American, Soviet, and German lists without further ado, thus lacking a clear recommendation. Although various attempts for international cooperation, and even unification, started already in the 1950s, they had been unsuccessful so far. In his speech, Henschler attributed the failure to introduce a uniform international standard to the differences of the scientific concepts, the varying states of industrial development, and the discrepancies in overall performance of the scientific and medical systems involved [10]. Thus, we may argue that the link between science and technology in regulation was a tenuous one, depending on a whole array of different conditions.

Not in principle, though, for Henschler. That science had something to say about the action principles of chemicals at the workplace was his adamant view. Limit values had a secure foundation in science. Henschler traced it back to the work of German pharmacologists Ferdinand Flury and Wolfgang Heubner, published in 1919, about the threshold values of the toxic chemical hydrocyanic acid [11]. Flury's and Heubner's work, however, was not a fruit of pure science. Their work context was the German research effort to develop poison gas in World War I, under the guidance of the chemist Fritz Haber. Previously, Haber had found that a given value of the product of concentration and time of the poison gas phosgene shows a regular relation with a given effect. Thus, it took longer to cause the same effect with phosgene of low concentration when compared to exposure to a higher concentration. Even very low concentrations could result in damage if the time of exposure was long enough. For occupational chemicals this could, of course, be a worker's lifetime in the factory. Flury and Heubner, in contrast, established that a threshold existed for some chemicals below which no damage would occur, regardless of the length of exposure time. By extrapolating curves representing effects of the chemical, the pharmacologists proved that the curve would not reach zero, and would never cross a certain line. This line would be the limit value of the chemical in question. Physiological reasoning called for a process inactivating the poison at a rate sufficiently high to counterbalance the effect at the level of the limit value. In this special case, the physiological mechanism eliminating the poison was found approximately 15 years later, in 1933 [12].

The reasoning that "safe" concentration values of chemical substances, even poisons, did exist and could be scientifically determined, was the basis for the hierarchical relationship of science and technology in the case of occupational hazards. The workplace, seen here as a volume filled with air and other gases, and the human and animal bodies were the study objects of the regulatory toxicologist. However, there were certain inherent caveats for the scientists to be aware of. First, the no-effect-level was not a thin line, but rather a "band", the uncertainties caused by the imprecision of methods. Second, limit values based on dose-effect relations could only be established by animal studies, but it was not clear if the test animals were more or less sensitive than humans. Third, some persons could be more sensitive than others, and the interplay of chemical substances in mixtures could not be taken into account in precise terms. These inherent uncertainties were, however, of epistemic origin, and could be dealt with scientifically. As a precaution, the limit values were set lower than the established no-effect-levels. According to Henschler, the correct setting of limit values as standards had to follow some additional constraints: Toxic effects must either be completely reversible or reach a steady-state level that was deemed tolerable. Furthermore, the mechanisms governing toxication and detoxication must be scientifically elucidated [13]. Among the necessary criteria, he later included transparency of the regulatory process and continuous medical surveillance. He emphasized that scientific data taken into account for the decision-making process had to be published [14].

A close look at an example between the late 1950s and early 2000s, however, reveals that not in all cases the self-imposed regulatory standard of using published data only has been followed. In the setting of the MAK value for phosgene in 1971, the personal communication of an industrial occupational hygienist was mentioned when alluding to conditions of manufacturing units [15]. Another problem, of course, was that in this case it should not be possible to establish a no-effect level, because phosgene was following the above-mentioned rule of Haber. However, published results of animal experiments of the 1940s, 1950s and 1960s have shown that an additive effect did not exist after several short-term exposures, and even a protective effect of subacute doses could be shown. The MAK value had been lowered already in 1958 from 1.0 to 0.1 ppm. The reasoning for that was based on acute toxicity tests and on "subjective irritating effects." The smell of phosgene can be recognized already at a concentration value starting with 0.1 ppm, and this has been explicitly mentioned in the MAK report of 1971. Thus, it seems that in addition to the results of toxicology based on animal experiments, the possibilities of the exposed workers to detect the poison played a crucial role in lowering the limit value in 1958. However, the authors explicitly stated that investigations of long-term effects were lacking. The 1984 setting did not change the limit value, and included statements based on epidemiological studies [16]. In 1996, the MAK value for phosgene was lowered again, to 0.02 ppm. Then, the epidemiological studies were regarded as invalid. Because there did exist a study showing changes in the lungs of rats at very low

concentration levels, the precautionary principle was followed, awaiting further clarification [17]. The MAK value was changed again in 2008, back to the value of 0.1 ppm. The underlying report was a substantial 19-pages document. Here, the authors argued against the validity of some older studies because of technical difficulties of the measurement procedures. They also cited new animal studies, opposing the single study which had given cause to the 1996 lowering to 0.02 ppm. Furthermore, as the new studies were done with dogs, and not rats, the authors opined that the values found were much more valid for humans [18].

The documentation of setting the MAK value for phosgene between 1958 and 2008 is a carefully arguing text that allows one to trace back the reasoning for the several changes. Moreover, it enables the reader to understand the weighing of results of different disciplinary fields such as epidemiology and toxicology. However, although the precautionary principle has been followed in the 1996 ruling and the 2008 revision has been very carefully established, in the decades before the setting did not seem to be based on unshakeable empirical ground.

Even if all epistemological criteria had been fulfilled, the regulatory scientists found themselves in a quandary. Henschler named the ways out of this quandary "compromises" [19], or "additional provisions" [20]. In contrast to the above-mentioned criteria, these compromises reflected social issues, and did not belong to the scientific sphere in the thinking of Henschler. First of all, the definition of health was not clear. Thus, the very goal of the whole system, the protection of the workers' health, found itself on shaky ground. However, Henschler thought that if regulatory scientists adopted a "pragmatic" approach, and were "willing to continually revise the general criteria for standard settings as well as the standard of a given compound", all would be fine. Also critical was the lack of valid data, based on long-term studies, especially for humans. In addition, the consequences of time-averaged values or peak exposures were still unclear, as was the interaction of chemical effects of mixtures. Essentially, a flexible approach, and more and refined uses of scientific methods could resolve the issues at stake. The system was not perfect but could be improved with the established guidelines of the scientific enterprise untouched [21]. This especially concerned one of the key principles of scientific research, the ability for swift self-correction if improved data or new theoretical insights called for revision of previously accepted knowledge. If limit values were to be fixed legally, this would make it much harder to change them according to new knowledge. Furthermore, a legal binding might convince legislators, judges, and lay people alike to regard situations as completely safe if the limit values were not exceeded, and dangerous if they were exceeded (which, according to the scientists' point of view, was not correct in both cases). Thus, "legal fixation is inhibitory, rather than stimulating to scientific efforts to improve the data base for a given standard" [22].

To sum up, Henschler was convinced that the flexibility of science allowed for a rather smooth functioning of the regulatory system. This flexibility was endangered if the autonomy of science was limited, even if only partially. In order to fulfil his task, the most important rule for the regulatory scientist was to ban every influence from politics and economics. This 'linear model' of scientific regulation stated that "strictly *scientific* facts" should form the basis of advice, while the influx of "economic factors" into the scientific realm had to be prevented, by being punished with "discredit". Once this separation had been established, the scientific side of the regulatory enterprise had the central obligation to continuously check and improve its statements and methods. For that, an increase in "research capacity" [23], especially of an interdisciplinary nature in toxicology, had to be secured by the state, and work in these fields had to "be made more attractive". Furthermore, the supremacy of science over technology guaranteed a happy outcome of the dilemmas of chemical production:

> "In particular, emphasis should be placed on *fundamental research* and the *development of new methods* which will help us to obtain more meaningful results more quickly and at reduced cost. A principle of "more research, less testing" will help to recruit better candidates for an urgent task: conquest of the dark side of chemical progress" [24].

On the other hand, of course, in order to fulfil their tasks, scientific limit values had to connect to the technical, economic, legal and political spheres.

2. Limit values as a regulatory concept

The necessary, if loose, connection of limit values to other social spheres was not the only exception from a purely scientific concept. Even inside science, limit values showed some unusual features. An important difference of science-based standard setting with respect to "normal" science had to be admitted by the scientists involved. If the concept of no-effect-levels was to be upheld, the toxicology of occupational chemicals actually was a "non-toxicology", as its aim was "to demonstrate the *absence* of an effect" [25]. As a certain proof of the absence of an effect is always hard, maybe even impossible to obtain, this clause may be considered the Achilles' heel of the regulatory system based on no-effect-levels. However, this impossibility had to be accepted, as it belonged to science. Thus, it was unscientific to demand of science a statement according to which an effect could be excluded with 100% certainty, as some regulators did.

This tension led to problems in the relationship of regulatory science and its clients in industry and politics. In the opinion of both regulators and lay people, a limit value meant promising clear, unambiguous safety. For scientists, this could not be guaranteed as a matter of principle. In my opinion, the socio-political functioning of limit values is bound to this discrepancy, or ambiguity [7].

Limit values, on the one hand, are governmental decrees, or part of them. They constitute reglementation in Foucauldian terms. On the other hand, they are scientifically determined values, representing "natural" regulations of toxic substances with and inside the human body. They represent regulation, understood here as

control on the basis of the "natural" (i.e., scientifically determined) laws of the systems in question. Foucault described this in his lectures on governmentality and biopower at the Collège de France in 1977 and 1978. Furthermore, he briefly described the emergence of governmental regulation during the 19th century [26]. In his sense, governing could be successful in the long run only if the laws and logics of the systems that politicians wished to govern were respected, Foucault's most famous example being the population. Understanding the natural laws of population development made sense only with the help of the sciences of demography and statistics. Going one step further, this understanding of biopower as regulation is bound to two simultaneous, and seemingly contradictory, logics: the ability (of politicians, scientists, etc.) to intervene; and the ability (of the system) for self-organization, or self-regulation.

Knowledge produced and used in the regulatory procedures, is, as any scientific knowledge, bound to uncertainty. It shares with other types of knowledge the fate of being superseded, falsified, and corrected. As we have seen, the involved scientists regarded this as virtue, not as vice. However, regulatory knowledge has to lead to decisions. Decision-making under uncertainty is one of the pre-eminent characteristics of regulatory knowledge. The other important feature of regulatory knowledge is its ability for prognosis [27]. Limit values are a very special kind of prognostic tool. In the same way they predict the safety (or unsafety) of a chemical in terms of medical or scientific knowledge, they also constitute its safety or unsafety in legal terms. Here, the scientific and the legal-political spheres only work in connection. Setting up a limit value by law alone could be self-defeating; setting it up by science alone would be senseless. It is based on a self-fulfilling prophecy.

On the other hand, limit values allow one to deal with risk, or uncertainty, because they separate the two spheres. Accountability can only be avoided if one sphere, say the law, attributes it to the other sphere, say science. Laws often contain the notion of the state of science and technology as the basis for its rulings. This is a shift of accountability. Science, on the other hand, always proclaims that it stays within its own boundaries. As a result, accountability oscillates between the two spheres. Thus, all in all, the setting up of limit values only works when politics, industry, and science are in a state of connection by demarcation. Boundary work in Gieryn's terms is a constitutive part of the functioning of regulatory knowledge. Limit values work as boundary objects, or loose concepts, do [28].

Although participating scientists claim that their findings are based on exact methods and sound theories, and are guaranteed by the certification and communication system of modern science, boundary values differ from each other, depending on their system of origin. Yet, most countries renounce to set up values of their own, but adopt those of the US and/or Germany, varying only a small number of values according to self-generated knowledge and special circumstances. Thus, limit values leave space for adjustment to economic, cultural, and political circumstances.

Although limit values should not have legal effects without being transformed into law, the German jurisdiction and administration quite often referred to them as "state of science and technology" (*Stand der Wissenschaft und Technik*), and ruled that manufacturers etc. should abide by them. This is, however, a dynamic reference as the state of science and technology is continuously changing. At first glance, and in the opinion of the experts, boundary values do not constitute a verdict about the safety, or dangerousness, of chemical substances. They are not understood to count as proofs for the cause of an impairment if they have been exceeded, and, vice versa, if they have been undercut, this does not rule them out as cause of a health-detrimental effect. In the opinion of their scientific originators, they should not be used as "anticipated expertise". But in contrast to the scientists, some German courts did regard them as such [29].

MAK values refer to pure substances only. At the workplace, most substances are encountered in mixtures, but the resulting interactive effects are too complex to be taken into account. In a sense, the MAK system is a model of an ideal state that is not encountered in nature or technology. In contrast to a laboratory experiment explicitly ruling out certain factors, or estimating errors, an MAK ruling sets a value *as if* there are no other factors involved. The vagaries of real world situations are ruled out by force in order to allow science to step in.

MAK values are only given for a small number of chemical substances (in the 1980s, approx. 400). For most, no values exist at all, although some of them are covered by limit values set up by the industry. For carcinogens, there can be, by definition, no MAK value. For them, TRK values (technical occupational exposure levels, *Technische Richtkonzentration*) are given, based on the technical constraints of handling them. The setting of TRK values is arranged for by a separate commission, set up by the federal ministry of labor and social affairs. There also exist values for biological materials (especially for metabolites). The definitions of limit values are set according to the special fields they are made to control.

The function of boundary values lies in their capacity to differentiate between the approved and the non-approved, between the "safe" and the "dangerous". In doing so, they bring determinism into a situation that can only count, at best, on probabilities of events. Thus, boundary values conventionally create a certainty in the present that enables societies to cope with uncertain effects in the future. They do away with contingency.

As a scientist, Henschler was well aware of the pitfalls of this latter function, which in his view was based on a misunderstanding between scientists, lawyers, and lay people. In asking: "How Safe is "Safe?" he made clear the following:

> "The above discussion of the limitations of epidemiological methods and animal experiments shows plainly that it is impossible to predict with absolute certainty whether a toxic effect in man must be expected or can be ruled out with particular substances. Despite this, the authorities expect, the press demands, and many manufacturers promise "safety" from injury to health

through environmental poisons. Legislators use the term "harmlessness" in laws and regulations. Both "safety" and "harmlessness" imply a guarantee, and inevitably persuade the layman that it can in fact be given. Unfortunately, biological experiments are fundamentally incapable of providing such a guarantee. In Germany, the layman's understandable desire for security is also nurtured by a linguistic misunderstanding, to which journalists are particularly prone: The English "safety" is glibly translated by "Sicherheit". In actual fact, by "safety" we mean that it is sure or likely that no harm will result [...] whereas the German "Sicherheit" denotes "an absence of danger, protection from any threat"." [30].

3. The limits of limit values

In the early 1970s, another obstacle aside from linguistic misunderstandings appeared on the scene. It had long been suspected that carcinogenic substances did not show a no-effect-level, even in theory. To the contrary, carcinogenic effects were proved to be cumulative over long periods. Thus, for an increasing number of occupational and environmental chemicals, the limit value concept seemed to be no longer tenable. The whole "philosophy" of the regulatory regime was at stake. At that time, however, Henschler still tried to defend the applicability of threshold limit values also in the case of carcinogenic substances. In arguing with an analogy to the activities of trace elements, he opined that it was always necessary to introduce a certain amount of material into the body to achieve an effect. Furthermore, as the body constantly renews itself, the possibility for self-repair should be taken into account. As a last resort, even the definition of toxicity should be changed accordingly:

"A biological process induced by foreign substances only becomes toxic when the change produced in the structure and/or function has an adverse effect on the stability and renewal of the body as a whole." [31].

Even before the publication of this article, however, it had become clear that for carcinogenic chemicals, no limit values could be established according to the self-imposed rules and stipulations of the DFG commission. In 1971, a separate committee was established within the ministry of labor and social affairs, the committee for hazardous materials (*Ausschuß für Gefahrstoffe*), comprising representatives of employers, employees, politics, and science [32].

The commission of the German Research Council, which was chaired by Henschler and consisted mainly of academic and industrial scientists, in the end refused to establish limit values for carcinogenic chemicals on the reasoning that there would be no scientific basis for doing so. In contrast, the ministry committee for hazardous materials explicitly embraced technical, analytical, and economic reasoning as the basis for the setting of another kind of standards. As a result, rather than changing the science-based regulatory system as such, carcinogenic chemicals have been 'expelled' from this system: they were decided upon by a separate commission under political control, and taking into account technical and economic issues. Thereafter, Germany applied next to threshold limit values for hazardous chemicals, the so-called *Maximale Arbeitsplatz-Konzentrationen* (Maximum Allowable Concentration at the Workplace, MAK), special values for carcinogens, the so-called *Technische Richtkonzentrationen* (Technical Occupational Exposure Levels, or TRK). What is important for the following is the switch in competence for carcinogens: as already stated, the TRK values were developed and published by the committee institutionalized by the ministry of labor (and therefore by a political institution), whereas the MAK values were still developed by the DFG-Senate commission (a scientific institution). TRK values were based on the state of the manufacturing technology, not the state of scientific knowledge.

Thus, for an important and fast growing part of the regulatory system the final dictum now was placed inside the realm of technology. Technical feasibility to a large extent decided on the limit values of carcinogenic (and mutagenic) chemicals at the workplace. With only slight exaggeration, one could say that the technological system was now regulating itself. However, this did not mean that the two commissions did not have links. Most importantly, it was the commission of the German Research Council that decided which chemical was classified as carcinogenic and which was not. For this purpose, the commission developed a rather complex classification system of carcinogens, enabling a finer division due to established methods of proof [33]. Soon, the largest part of the workload of the scientific commission consisted of working on carcinogens and mutagens, and less on establishing 'classical' limit values for toxic substances. In 1991, Henschler expected that, in the near future, more than fifty percent of all occupational chemicals listed would be carcinogens and mutagens [34]. For this reason, Henschler did not want to give in to the technical demands. If no-effect-levels for carcinogens could not be established, novel methods of cancer research had to be developed in order to quantify the risk. As the rapid introduction of new chemicals excluded the use of epidemiological data for establishing risk (because of latency periods, and lack of comprehensive data, these numbers would come too late), he called for novel predictive approaches based on animal testing and mechanistic studies [35].

4. The boundaries of science and technology

In the above, we have seen that the 'connection-by-demarcation' of science and technology is the *sine qua non* of regulation by limit values. In the kind of regulatory system described in the first part of this article, the separation of science and technology has been rather strict: Scientific results served as the (sole) basis of regulation, while any influence of the technical had to be barred, with the exception of research data. Regulatory scientists working under the impression of such a hierarchical mode implicitly accept an equality of the technical and the natural. Both are treated as given study objects. Scientists study and control technology in the same ways as in the traditional view the sciences used to

inquire into nature: Technology is seen as passive as nature has been seen. Technology is here defined as comprising the manufacturing facilities, including the workforce and their exposure to chemicals. An important feature of this approach of the regulatory approach towards technology-as-nature is that, in contrast to the experimental approach towards nature, it cannot completely control, or manipulate, the design of its study object. While in scientific experiments disturbing effects are ruled out by the set-up of the experiment, or are counted in by calculations, this cannot be achieved in the regulatory systems, as they are part of the real world. Thus, certain parameters are set *as if* no other factors are involved.

In 1972, speaking before the assembly of German scientists and physicians, Henschler put the natural environmental situation unchanged by technology on an equal footing with the modern, technology-based society. Merely quantitative aspects separated the caveman from modern man:

> "What is certain is that the continuing large-scale introduction of new synthetic materials has multiplied the number of potential dangers, and is still doing so all the time. Therefore, in attempting to redress the balance and control the adverse effects of progress, we must begin by analyzing the nature and the extent of the risks to health from individual substances as well as their combined effect." [36]

It may be just a coincidence that the regulatory system that stressed the independence of science from technology (and with it, economics and politics) came to full blossom at the same time as the 'linear model' dominated opinions in innovation. In short, the linear model of innovation states that the innovation process consists of a cascade originating in basic or fundamental research, and trickling down through applied science and development to the diffusion of technology in the market place and society at large [37]. While knowledge transfer is essential to the whole process, it is organized as a one-way street. Basic, or fundamental, research has to be kept pure (or clean) and thus separated from economic and political pressure. Seemingly, technology has been regarded as the entrance gate of socio-economic interest, contaminating the ideal of pure science. There exist a number of versions of the linear model allowing for the reflux of information, and even knowledge, from the technical domain to the scientific realm. However, this transfer is mostly restricted to information that is needed by the scientist in order to solve practical problems. The linear model is built to ensure the autonomy of science, while proclaiming the usefulness of the scientific enterprise for society in technical, and in the end, military or economic terms. Its promise has been that a "free" (i.e., autonomous) science achieves the best results, also in terms of value for the economy. Pressure of any kind would thus not only be against the values of a "free" (i.e., democratic) society, but also against the practical interest.

One may opine that the linear model is not more than fiction, serving pure rhetorics of the post-war United States, entering a new, the cold, war. This may be a correct description. However, it is exactly the rhetorics that often counts for establishing institutions, and social routines. In the case of the linear model, one of its origins is the 1945 report to the US president, *Science: the endless frontier*, penned by Vannevar Bush and his team in order to secure funding for science while avoiding direct military interference. It has been drafted with the background of an engineer, serving on leading positions in the US programs to secure science and technology for armament, including the Manhattan Project leading to the atomic bomb. One of the consequences of the report was the founding of the National Science Foundation, serving as self-organizing scientific agency for allocating federal money for science. In West Germany after World War II, the linear model did not just serve the purpose of keeping science "clean" from the pressure of military research. Before the regaining of sovereignty and the establishment of the West German army, this was not a major problem. The linear model present in the West German community of scientists, and science managers, had amongst its major aims to purify the scientific estate from its intermingling with National Socialism. Erecting a boundary between science and technology was useful to present a separation of science and Nazi, and later Communist, ideology.[2]

It is not yet clear to me, if the 'linear model of regulation' and the linear model of innovation have more in common than rough dates of appearance and a coarse similarity in outlook towards the separation of science and technology. In both fields, the rift between science and technology resonated with the ideological demands of West German culture in general, and the German Research Council in particular.

The linear model of innovation met with resistance, starting in the 1960s with Project Hindsight questioning the supposedly scientific origins of US armament [38]. Later on, historians of technology argued for taking technological knowledge at least as seriously as scientific knowledge in the process of innovation [39]. One does not have to go so far to state the "primacy of technology" [40] to recognize a shift in attitude in the 1970s towards the relationship of science and technology.

In regulation, technology-driven aspects (not only in the case of carcinogens) point to a shift at about the same time. Arguably, the change came from within the regulatory system [4], and, interestingly, it was connected to the very successes of science-based regulation:

> "Suspicion is supported by the tremendous improvement of analytical methodologies at the chemical, biochemical and biophysical level. The new techniques detect, with ever increasing sensitivity and specificity, even the slightest changes of biological functions from exposure to chemicals, but they cannot integrate them into real diagnostic procedures for separating states of disease from health. The sensitized layman is tempted to demand protection from any deviation from the

[2] At the University of Bielefeld, Gregor Lax is currently pursuing a PhD project to unravel the complex uses of the linear model in post-war West German discourse.

normal. As a consequence, pressure is put on administrators and politicians to influence the procedure of setting exposure levels. One approach in this direction is not to keep exposure levels as high as tolerable, but as low as technically and economically possible; this is equivalent to the funeral of conventional standards." [41]

Indeed, the new regulatory regime for carcinogens at the workplace put technology first, and science second. This was not a "funeral" of the old system, though, as it had been kept in place for conventional toxicants. For a growing part of the technical system under scrutiny, however, regulatory science had to shift gears not only in practice, but also in its rhetorics. It was no longer a standard-setting ruler, but it became a warner who had to make sure to be heard. As a result, the boundaries between science and technology, economics, and politics had to be bridged by an effort of the scientific estate itself.

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