

## Boundaries of Regulatory Science

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Since the 1970s, industrialised countries increasingly try to evaluate environmental hazards of chemicals substances. These evaluations are performed before chemicals are allowed to circulate through the world, but also of chemicals that have been produced for a long time. Prominent among these chemicals were the three groups that form the focus of this study: pesticides, effluent discharges to surface water, and industrial chemicals, including substances such as paint thinners or plastics. For these three groups of chemicals, complex regulatory procedures have been developed. For the construction and implementation of these procedures, rules have been established, agencies have been installed, toxicity tests developed, laws voted, new research institutes installed, international agreements made and broken, and scores of experts have been hired. Together, these heterogeneous elements form complex configurations, which in their combination produce evaluations of the size and acceptability of environmental hazards of chemicals; configurations we can call regulatory regimes. Even though complex and ramifying, in practice regulatory regimes are delimited by their jurisdiction, embedded in a law or a division of labour between government departments.

When comparing regulatory regimes, between countries or even between sectors of environmental policy, one quickly starts to notice differences in how evaluations of chemical hazards are organised and performed, in spite of a long tradition of harmonisation efforts. Different toxicity tests may be preferred or different sources of knowledge may be considered in the evaluations. Sometimes the evaluations are extremely formalised in very detailed protocols, while sometimes they depend almost entirely on expert judgement, cast in a very general legal mandate. Such differences are related to a wide variety of ways to integrate expertise in decision making, the different forms boundaries between experts and policy makers can take. This study analyses how these boundaries have taken shape in the regulation of wildlife hazards of chemicals in the US, England, and the Netherlands between 1970 and 1995. In this period, aquatic hazards of chemicals were prominent on the agenda of regulatory research and policy and hence the study has focused on the evaluation of hazards to freshwater wildlife.

Ecologists and environmental toxicologists were the scientists who provided the expert knowledge on these hazards. There were some interesting boundaries between these research fields, contentious divisions of labour in the rich new professional domain of environmental regulation. Ecologists and environmental toxicologists frequently disagreed over what was the best approach to aquatic hazard evaluations. During the 1970s, environmental toxicologists had managed to produce a wide range of aquatic toxicity tests on the principle that the physiology of the individual organism provided the most practical and meaningful point of impact of toxicants. Hence, they set up tests with one single organism, with fish that could be

easily raised in the laboratory, or with a small population of organisms of the same species, such as the water flea *Daphnia magna*. In these 'single species tests', a series of organisms would be put in a series of test tanks containing water of known composition, including known concentrations of a toxicant. After a certain period, the experimenter would count how many of these organisms were still alive. From these measurements, it was statistically inferred at which concentration of toxicant 50% of the organisms would survive. Therefore, the most important deleterious effect of a chemical that was tested in this approach was individual mortality, based on the physiological capacity of an organism to survive a relatively brief exposure to a substance. From these measurements, extrapolations were then made to the natural environment.

Ecologists, on the other hand, had major objections to this approach and tended to favour multispecies tests, in which several species of organisms would be present in a test tank or pond. They argued that the reductionism of the individual organism was not a good representation of actual effects in the environment. For example, an organism could perhaps survive, but might become slower and thus an easy prey for predators, disturbing food web relations. In other words: ecologists argued that even if little or no mortality was measured, other negative effects could arise at ecological levels of analysis. Environmental toxicologists objected to the high cost of multispecies tests, as well as the lack of one clear indicator of toxicity. In addition, they argued, the evaluation of environmental hazards of chemicals was not an issue of precise prediction, but of effective protection of the environment. By means of considerable safety margins, to compensate for the extrapolation from single species test results to the complexities of natural environments, single species were defended as affordable and reliable indicators of environmental hazards.

In order to describe the processes of standardisation of toxicity tests, I suggested the simple mnemonic of texts, objects, and people (TOP). Standardisation of toxicity tests, being the stabilisation of test results in the specific locations for which they were designed, could be achieved through all three of these elements and by using one to calibrate the other. For example, one of the effects regulatory experts envisaged with standardisation was that toxicity tests would provide reliable results even when performed in different laboratories. In order to guarantee this reliability, they could rely on the competency of trained researchers. However, the trajectory chosen in the US was to rely first and foremost on objects and textual and instruments of standardisation. Over the years, test protocols became highly detailed 'cook books', indicating how to raise fish, how to build fish tanks, or exactly what fish feed to use. These cook books could also rely on the predictability of already standardised objects, such as the glass and glues available for building fish tanks, or even the reliable composition of commercially available bottled mineral water. In coupling these instruments, we see the familiar bootstrapping of standardisation processes: standards build on other standards, strung together to frame newly stabilised practices. As an extra guarantee, toxicologists also developed methods of calibration, for example by performing toxicity tests in different labs with test materials from one central source.

A detailed analysis of the development of these tests over a period of more than two decades provides interesting insights into the arguments between ecologists and environmental toxicologists, while shedding light on the boundary work between the two research fields. For example, single species testing started with relatively large fish in natural conditions, exposed to chemicals over longer periods in so-called chronic toxicity tests. The cost of these tests was comparable to a small multispecies test, but years of investment in the development of chronic outdoor tests produced

shorter, less labour intensive, ever cheaper and more standardised tests. The standardisation meant that these tests could be performed with personnel of lower qualification. With a delay of about ten years, similar attempts at standardisation were made for multispecies tests, but by that time, single species had such a large head start that multispecies tests seemed excessively expensive and ambiguous.

In addition, a comparison between regulatory regimes provides some interesting differences with respect to the acceptability of test results. What is 'too ambiguous' a test result appears to vary widely between regulatory regimes. Highly standardised single species tests appeared to function particularly well in regulatory regimes that aspired to a strict separation of 'scientific' and 'political' aspects of regulatory decision making, using highly formalised procedures for the evaluation of environmental hazards. Such regulatory regimes were typical of the US. In regulatory regimes relying more on expert judgement, usually involving more informal negotiation with applicants, results of multispecies tests were more readily considered in the evaluations. In some cases of evaluation of pesticide hazards in England, these results even involved multispecies tests that had been rejected in the US for being 'insufficiently standardised'.

In comparing regulatory regimes within the US, varying strategies followed in attempts to introduce multispecies tests in regulatory evaluations show how standardisation operates in regulatory regimes where the possibility of deconstruction by counter expertise in a legal setting is always a background threat. By means of long and extensive consensus building among experts from industry, government agencies, and universities, regulatory hazard evaluations become more predictable, to the advantage of all parties involved.

Because of such processes, varying structures in regulatory decision making have consequences for what kind of knowledge can and cannot be taken into consideration and for the kind of knowledge that will be stimulated as potentially useful by regulatory agencies – and hence for the selective opportunities of research fields to develop. In the US, the most resourceful actors in the evaluation of environmental hazards, the Environmental Protection Agency and the chemical industry, were also by far the largest financers of regulatory research. In the Netherlands, in contrast, science policy was more involved in the efforts to develop knowledge of use for regulatory decision making, for example in the form of interdepartmental funding initiatives. This both mitigated the pressure from evaluation procedures to selectively support the already advantaged single species tests and created new opportunities to develop ecological research on pollution into practicable expertise. The selective chances to participate in regulatory regimes hence also created selective chances for ecology and environmental toxicology (and interdisciplinary efforts) to develop, varying with different structures and strategies of regulatory regimes.

A nice illustration of these selective opportunities is the debate between ecologists and ecotoxicologists over the meaning of the term 'ecotoxicology'. Starting in the early eighties, ecologists tried to mobilise the new buzzword to argue for a stronger integration of environmental toxicology and ecology. (To stay neutral in the debate, I use eco/toxicology to refer to both fields together, including whatever boundary is advocated or organised between them.) Both fields were to conglomerate in a new research field. In the US, this project led to disillusionment; in the UK to limited success; while in the Netherlands 'ecotoxicology' became a more popular albeit contested concept, often presented as a cooperation between disciplines on an equal footing.

The historic boundaries in eco/toxicology cannot be reduced to the opportunities these fields managed to secure in regulatory regimes. Eco/toxicologists themselves were the experts who signalled the hazards of pollution and advocated them onto political agendas in the sixties and seventies. They helped to identify and define what are environmental hazards and from there on were crucial in the construction of the regulatory regimes that were to deal with these new problems. A closer look at these early and formative periods shows that ecologists actually originally played a more prominent role in the evaluation of environmental hazards of chemicals. In addition, the sometimes locally sharp boundary between ecology and environmental toxicology is a boundary that was created only later, as regulatory regimes started to take shape. In contrast to ecology, environmental toxicology developed almost exclusively in the shadow of regulatory regimes, especially in the seventies, when ecologists were just carving out a relatively stable position for themselves at universities. Here too, the pattern is somewhat different for the Netherlands, where a relatively large group of even university ecologists remained involved in environmental hazard assessments.

Remarkable about England was that there was a strong separation between the experts who were involved in policy making and scientists at universities. Only from the early nineties onward did university researchers become somewhat more involved in regulatory eco/toxicology in England. Up until that time, regulatory agencies relied mostly on experts from their own research institutes, from whom could be expected that they stuck to the culture of strong secrecy and identified with the closed elite of regulatory decision makers. The pattern can be identified as that of a royal court, relying on personal trust and shared conviction, rather than rules or standardised test devices (i.e. people, rather than texts and objects).

Regulatory regimes are hence organised around complex and contested divisions of labour. Two recurring ones in the regimes evaluating chemical hazards are the division of labour between policy makers and experts, and the division of labour between different research fields, in these case primarily eco/toxicology. There is a lot of activity involved in these divisions of labour: actors try to make distinctions where others try to efface them, try to construct or disrupt cooperation, try to redefine terms of mutual engagement. These are the activities we call boundary work. It is not only performed by attempting to redefine the relations between people, but also by deploying discursive and material devices. The results of boundary work can in turn be embedded in new social patterns of interaction, in material objects such as toxicity tests, or in the rules of the textual device of a test protocol. Computer models, toxicity tests, or assessment protocols distribute issues between what is to be considered the domain of expertise and the domain of policy, the work that has been performed by experts and the work of evaluating outcomes that is left to policy makers. In the complex world of regulatory regimes, concatenations of texts, objects, and people are mobilised to establish, reproduce, stabilise, or shift boundaries, demarcating what can and cannot be considered true and necessary, what can and cannot constitute an issue of choice. To the extent that these devices give rise to routinised practices, we can therefore speak of 'boundaries', the institutionalised counterpart of 'boundary work'.

On a theoretic level, this approach is presented as an alternative to two extreme positions in science and technology studies, which use diametrically opposed approaches to boundaries. The first can be called the 'cage model' and can be found most clearly in functionalist sociology of science, such as of Talcott Parsons or more recently Niklas Luhmann. This approach proposes to identify the key criteria to establish a priori which activities or communications do and do not belong to

‘science’ and which must be marked as, for example, ‘politics’. Consequently, this analytic demarcation is used to describe what occurs within these institutional confines, or at best to show how both domains exchange with each other. In the opposing model of the seamless network, every form of a priori distinction between science and politics is abandoned. This tradition, found in its most extreme form in Actor Network Theory, refuses to establish any kind of analytic boundary, but chooses to show how science and politics are inextricable enmeshed.

Both traditions have great difficulty in describing the complex divisions of labour of regulatory regimes. They tend to reduce the negotiations over shifting boundaries to misrepresentations, either by imposing analytic distinctions between science and policy that are of very limited practical use (‘independent science’), or by discarding these negotiations as rather trivial skirmishes in a network that is actually seamless, trying to establish distinctions where there are none (‘politics is everywhere’). Consequently, both traditions create unnecessary difficulty in relating to the practices of organising and reorganising boundaries in expertise used for decision making, and in weighing the strengths and weaknesses of different models for these divisions of labour. The opposition between both extreme models, the cage and the seamless network, is one of the hurdles STS needs to take in order to contribute to the debates on how scientific expertise can or should be organised. Boundaries of regulatory science can be taken seriously, without reifying them, landing in essentialist criteria for what is ‘science’; or nullifying them, landing in a tempting but ultimately meaningless holism.

This approach implies that STS needs to develop more attention for political theory and cannot continue to use participatory democracy as a stopgap for all complex issues involved in the divisions of labour between and among experts and policy makers. Attention for boundaries force us to face the sticky question of who should be included, and who should not, what is to be a issue on the precious but also inherently limited political agenda of our democratic institutions and what relegated to the technical.

The analysis of boundaries in regulatory regimes from the perspective of STS also contributes to the comparative study of environmental regulation. In contrast to the analysis in policy sciences, STS digs deeper in the role experts play in the construction and implementation of regulatory policy. By bringing the role of experts and the varying patterns in science/policy boundaries, it can be shown how boundaries relate to typical ‘national styles of regulation’, but also that national styles do not hold equally strong in all regulatory regimes. In fact, some regulatory regimes appear to resemble regimes in the same sector in other countries more than in other sectors in the same country. It appears that the international networks of experts can provide the channels by which this institutional isomorphism is created, not only because of the relatively international orientation of expert communities, but also because boundaries embedded in texts and objects transport models of science/policy boundaries from one regulatory context to another.