Boundaries of regulatory science: Eco/toxicology and aquatic hazards of chemicals
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Chapter 6: Contrasting patterns in regulatory regimes

And my good guide, with ready hands undaunted
Thrusting me towards him through the tombs apace,
Said: “In thy speech precision is what’s wanted.”
Inferno X:37-39, 6th Circle, the Heretics.

1 The specificity of US regulatory regimes

In the previous chapter, I described the ways in which the divisions of labour between experts and policy makers were structured in regulatory regimes in the US. I have pointed at standardisation strategies in eco/toxicity testing that were geared to the specific requirements of the specific regulatory regimes for pesticides, industrial chemicals, and surface water pollution. The standardisation process was largely directed by the US EPA, which, in many cases, had members of its regulatory offices in key positions. The end products of this standardisation were highly ‘depersonalised’ tests, steering assessment towards single species testing. In these regulatory regimes, these boundary objects operated to support strict demarcations of science and politics. As regards eco/toxicology, these regulatory regimes led to the (unintended) consequence of a sharper boundary between the fields of ecology and environmental toxicology. This did not mean the isolation of environmental toxicology from ecology, but rather that ecological forms of knowledge were forced into a secondary position as a regulatory science, i.e. used for validation, for general background knowledge, or occasionally as a resource to question restrictive single species test results.

How idiosyncratic are the patterns in the division of expert labour in these US regulatory regimes? In this chapter, I will use contemporary examples from regulatory regimes in the Netherlands and England in order to refine our understanding of how different regulatory regimes structure (and are structured by) science/policy boundaries, and how these regulatory regime developments affected the boundaries between the fields of ecology and environmental toxicology. After the detailed treatment of eco/toxicity testing intricacies in the previous chapter, I will mainly stick to a few specific English and Dutch examples in order to show contrasts between both patterns in regulatory regimes and the way eco/toxicology was positioned in them.

The dominant view of comparative research on regulation is that regulatory regimes are strongly shaped by national political institutions and
especially national cultures of decision making.\textsuperscript{1} In the previous chapter, I indicated how the presence of adversarial legal institutions and the perceived threat of legal deconstruction played a specifically important role in the construction of highly standardised tests – boundary objects that in turn helped to reproduce the specific format of strict science policy boundaries. (At least in the actual decision-making process: we have also seen how the staging of this strict boundary in the front region of regulatory decision making tends to require extensive negotiations of a more blurred kind in the back region of regulatory science.)\textsuperscript{2}

However, regulatory scientists do not only operate in a national context. So far, interesting insights into the meticulous work that went into the organisation of science/policy boundaries have come from the subtle differences between the US regulatory regimes. The story of eco/toxicity testing in the US also shows how regulatory regimes differ, for example, between the highly conflictual pesticides regulatory regime and the one for industrial chemicals. In addition, actors in these regulatory regimes may choose different strategies to deal with the typical tensions in regulatory regimes. We have seen the choices regulators have made to either engage in standardisation negotiations for more than a decade, or to avoid such negotiations. We have seen examples of regulatory scientists who took the time to travel to all the standardisation committee meetings, and of academic scientists who considered these a waste of time.

Hence, there are three issues to be explored in this chapter. The first issue concerns differences in the division of expert labour in regulatory regimes in England and the Netherlands. Previous research has indicated that the structure of regulatory regimes in England and the Netherlands differs radically from that of the US (see chapter 3). Since strategies for developing and using eco/toxicological knowledge are geared to the specific structure and tensions of a regulatory regime, we can therefore expect differences in the way eco/toxicological knowledge is mobilised and positioned in these countries. Secondly, since eco/toxicity testing methodology travels, is exchanged between countries, and is subject to international standardisation processes, we may wonder what happens if a testing methodology that was developed for very specific regulatory regimes, or standardisation strategies developed for these, ends up in regulatory regimes with a different structure. For example, I have already indicated that the development of highly depersonalised tests became a self-evident strategy in the US. What happened when regulatory actors in differing regulatory regimes started using these same strategies? Thirdly, can we trace differing connections between national research traditions, styles of

\textsuperscript{1} Bakker and Van Waarden, eds., \textit{Ruimte Rond Regels}; Vogel, \textit{National Styles of Regulation}; Brickman, Jasanoff, and Ilgen, \textit{Controlling Chemicals}.

\textsuperscript{2} Jasanoff, \textit{The Fifth Branch}.
decision making, or legal institutions with regulatory regimes, thereby refining our understanding of the importance of national contexts? In this chapter, I will present the stories that can help to answer these questions, starting with England in the following section, and the Netherlands in the next. A discussion of the relevance of national contexts – and what that national context actually consists off – will follow in chapter 7, with general conclusions being presented in chapter 8.

2 England: a regulatory court

2.1 The court: personalised trust

In 1975, Lord Solly Zuckerman gave a public lecture at the University of Oxford, explaining his views on the importance of rational, scientific expertise for policy making. Although also critical of the role of experts themselves, especially the scientists that had developed the atom bomb, his main objective was to separate the wheat from the chaff. He identified the irrationality of the ‘self-appointed experts’ of the environmental movement as the main threat to fair regulatory policy. Environmental policy was best off when advised by people who knew what they were talking about and lay involvement in such issues would only lead to uninformed, emotional responses that would undermine the possibilities of sound policy making. He saw extensive public access to regulatory information through the media as part of this problem:

(….) the daily press and the broadcasting services are continually subjecting the government, Parliament, and the electorate to a barrage of comment about scientific and technological matters, with the result that official advice is now almost always tendered against a background of what is usually well-publicised, but not infrequently superficial, fact and opinion.

In the case of public anxiety, he insisted, the best way to repair damaged trust was to install an official committee, based on solid science and responsible experts. The specific role of government was to guarantee the rationality of these experts. Hence, the choice of advice should always remain a responsibility of government.

Lord Zuckerman was not a novice in matters of policy advice. His advisory work dated back as far as the Combined Operations HQ in WWII, encompassing an appointment as the first chief scientific adviser to the British

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3 Zuckerman, Advice and Responsibility.
4 Zuckerman, Advice and Responsibility, pp. 6-7.
5 Zuckerman, Advice and Responsibility, pp. 30-32.
Boundaries of regulatory science

Cabinet between 1964 and 1971, followed by life peerage. More relevant in this context was his experience as chairperson of the Zuckerman Working Parties of the 1950s, routinely acclaimed as the basis of the British approach to the control of pesticides’ hazardous effects. In many respects, his lecture gave a description of the role of science in regulatory policy that was typical of England in the seventies. The official language regarding regulatory practice maintained a distinct boundary between science and politics, and especially between science and the irrational or ‘unreasonable’. Experts and their personal integrity were seen as the guarantee for such a sound decision-making process. However, not just any expert would do. In regulatory affairs, experts were seen primarily as advisors to government, not to ‘the public’ or a public decision-making process. According to Lord Zuckerman, it was therefore specifically up to government to select these reasonable advisors, as not just any accredited scientist would do.

In this logic, the division of expert labour in England was largely based on co-optation, which, in turn, was based on personalised trust. Instead of depersonalised procedures and texts, people took a central position in English expertise. When deemed appropriate, even environmental organisations could be co-opted in regulatory decision making, as long as they could be considered reasonable and trustworthy. Therefore, at least as important as the boundary between science and irrationality, was the boundary between the co-opted and the excluded, in the form of a personalised guarantee of ‘being reasonable’. The potentially disruptive interference of the ‘uninformed’ and the ‘irresponsible’ was also the traditional argument for English regulatory

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9 Especially in nature conservation, England had a long tradition of cooperation between government and (quasi-)NGOs. The ‘Royal’ prefix was traditionally a typical marker of their assimilation as part of official governance structures. (Bramwell, Ecology in the 20th Century; Yearley, The Green Case; Lowe and Goyder, Environmental Groups in Politics, p. 36; Vogel, National Styles of Regulation, pp. 46-52.

10 Cf. the importance and exclusivity of gentlemanly culture for the reproduction of scientific rationality in 17th and 18th century England. (Shapin and Schaffer, Leviathan and the Air Pump; Shapin, A Social History of Truth; Morrell and Thackray, Gentlemen of Science)
regimes’ high degrees of secrecy. A fair balance of societal interests could only be guaranteed with a sufficient dose of discretion, in order to allow for productive informal negotiation and – where need be – bargaining. Combined with a style of governance that stressed restriction and a modest role for government, the classic format of English regulatory regimes can be described as:

(...) several distinctive elements: an absence of statutory standards, minimal use of prosecution, a flexible enforcement strategy, considerable administrative discretion, decentralised implementation, close cooperation between regulators and the regulated, and restrictions on the ability of non-industrial constituencies to participate in the regulatory process.\(^{11}\)

Such regulatory regimes hinge upon the sharp distinction between who is and is not part of the community of reasonable decision makers. I will call the stereotype of such a regulatory regime a court, based on its tendencies to co-opt members into a sharply defined community of regulators and their advisors, much like a sovereign and his or her entourage.\(^{12}\) The metaphor of a (royal) court is not meant to reduce the complexities of English regulatory regimes to some essential pattern, but rather as a tool to show the development and differences between them and practices in other regulatory regimes. It does, however, identify a radically different strategy of organising science/policy boundaries and reaching closure in regulatory debates.

2.2 Pesticides and eco/toxicology

2.2.1 Monks Wood and PSPS

During the 1960s, the Monks Wood Experiment Station was a key source of expertise on the hazards of pesticides for wildlife.\(^{13}\) Monks Wood was a research institute of what was then the Nature Conservancy, an organisation responsible for the management of nature reserves and related research. Being part of this organisation, research at Monks Wood traditionally focused on problems of nature conservation, predominantly structured along research in (terrestrial) ecology. Research in pesticide hazards for wildlife was started by

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\(^{11}\) Vogel, *National Styles of Regulation*, p. 70. See also: Royal Commission on Environmental Pollution, *Sixteenth Report: Freshwater Quality*; Brickman, Jasanoff, and Ilgen, *Controlling Chemicals*.

\(^{12}\) The metaphor was suggested to me by Robin Grove-White, Lancaster.

\(^{13}\) In chapter 4, I used the handbook of ecotoxicology by Frederick Moriarty as a means to described the ongoing rhetorical boundary work between ecology and environmental toxicology. Moriarty was a researcher at this institute. (Moriarty, *Ecotoxicology*)
the Nature Conservancy in response to early indications of pesticide hazards to especially birds of prey. By investing in this research, the organisation wanted to participate in the early regulatory debate and get rid of the aura of a ‘dilettante organisation, devoted to lobbying and bird-watching’. After the Experiment Station was founded in 1960, a special Section on Toxic Chemicals and Wildlife was set up in the next few years. After its formation in 1963, the Section combined ecological field research with knowledge of analytic chemistry to investigate the effects of organochlorine substances such as DDT, dieldrin, and PCBs.14

Although the study of long-term effects of pesticides was new for English ecology, attention for conservation work was not. Since its foundation in 1949, the Nature Conservancy had been instrumental in increasing the role of ecology in nature conservation to the extent of considering itself an ecological research council.15 Thus, in striking contrast to the US, ecology and a nature conservation agenda were the driving forces behind the concerns regarding pesticide hazards for wildlife, alongside problems with farm workers’ or consumers’ health.16 In addition, the Nature Conservancy had successfully urged for a research committee on nature conservation in the Natural Environment Research Committee (NERC), which was established in 1965.

After a period of consolidation and integration of the Conservancy into NERC, the organisation of research changed radically in the slipstream of the 1971 Rothschild report. This review of the research system had been ordered by the Conservative Heath government, employing the young Margaret Thatcher, already deeply committed to a reduction of public expenditure, as Secretary of State for Education and Science. The report struck the right cord when it argued for more contract research by appropriate government departments. The following debates even threatened the existence of research councils such as NERC. More than the other research councils, NERC found itself in a position where it had to bid for funding from various departments. The Conservancy was also affected by the reorganisations. Most of its research tasks were taken over by NERC, while the management of nature reserves and a small budget for applied research were transferred to a new body, the Nature Conservancy Council. Nevertheless, the prominent role that ecology had played in the Conservancy was further embedded in NERC’s structure. Monks Wood

14 On the founding of Monks Wood and the early years of pesticide hazard research, see Sheail, *Pesticides and Nature Conservation*, pp. 37-49; quote p. 37, p. 108-17 on birds of prey research; Moriarty, “Toxic Pollutants in Aquatic and Terrestrial Ecosystems”.
Experiment Station became part of NERC’s new Institute for Terrestrial Ecology with a total staff of approximately 250.\textsuperscript{17}

As part of the reorganisation, the broad interdisciplinary teams of Monks Wood were disbanded, as was the Section on Toxic Chemicals and Wildlife.\textsuperscript{18} Nevertheless, the new zoological section continued the old general research interests. Several of the birds of prey studies had shown the difficulties of extrapolating the physiological effects of pesticides in laboratory animals to animals in the wild. Hence, the ecologists of Monks Wood argued for the study of the effects of pesticides on animals in the field, while their laboratory work was simultaneously increased to include more physiological research.\textsuperscript{19} In this context, the 1983 Moriarty handbook of ecotoxicology (see chapter 4) did not just represent his specific interpretation of ecotoxicology. It was also a propagation of the Monks Wood research agenda, with the prominent role of ecology in pollution research, but clearly combined with supporting physiological and toxicological work.\textsuperscript{20}

In contrast to the US, the development of highly standardised tests, let alone the focus on single-species tests, was not characteristic of this research. Such lack of standardised tests did not prevent these researchers from producing expert knowledge that could be assimilated in regulatory decision making. Already in the fifties, the scientists of the Nature Conservancy had played a pivotal role in putting the hazards of pesticides on the British political agenda and in providing expertise for pesticide hazard assessment.\textsuperscript{21} The Nature Conservancy was formally represented on the Advisory Committee of the Pesticides Safety Precautions Scheme (PSPS), the voluntary notification scheme that was the backbone of pesticide hazard control in England from 1957 to 1985. (See chapter 3) After the founding of the Toxic Chemicals and Wildlife Section, it became an important source of expertise in the regulatory arena.

Norman Moore, the head of the Section, was a member of the scientific subcommittee and wildlife panel of PSPS. Moore was an ecologist with extensive experience in nature conservation work. Throughout the sixties,


\textsuperscript{19} Osborn, “Pesticides and British Wildlife”.

\textsuperscript{20} Moore, \textit{The Bird of Time}, p. 162 et seq.

\textsuperscript{21} For example, in the early fifties, the Ministry of Agriculture consulted the Conservancy to set up field trials with dinitroresol in Norfolk and Berkshire and the Conservancy played an important role in the regulation of roadside spraying by the Ministry of Transport (Moore, \textit{The Bird of Time}, p. 149).
experts from the Conservancy and the ecologists of Monks Wood, in particular, debated the hazards of organochlorines. They tried to indicate the hazards of substances such as aldrin, dieldrin, and DDT to wildlife, using their research and all the data they could find in the scientific literature. They contributed to the landmark *Reviews of the Persistent Organochlorine Pesticides* of 1964 and 1969, the basis for regulatory policy on organochlorine pesticides. Beyond the specific problems with organochlorines, these experts also argued for new evaluation criteria in the consideration of hazards to the Advisory Committee. These criteria included parameters such as the cumulative effects of small doses under varying physiological conditions, sublethal effects on reproduction, and the availability of substances to animals in the field.\(^{22}\)

After the Section was dissolved, the representation of the conservation point of view on the Advisory Committee was continued by the new Conservancy Council. Moore became the Chief Advisory Officer of the Council (1974-83), as one of its small scientific staff.\(^{23}\) Thus, conservation issues such as the wildlife effects of pesticides, were effectively represented in PSPS. In this representation, ecologists took crucial positions, even though the direct links between research practices such as at Monks Wood were severed after 1973.\(^{24}\)

The actual influence of the Monks Wood ecologists on pesticide regulation should not be exaggerated. In his memoirs, Norman Moore does not hide his frustrations with the long-winded process and the lack of forceful regulatory limitations on the use of organochlorine pesticides:

> Like most scientists who were new to politics I thought that changes in opinion and action were mainly produced by obtaining facts and arguing logically from them. I was soon disillusioned. I found that there were immense obstacles to implementing the general restrictions we wanted.\(^{25}\)

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\(^{23}\) Moore, *The Bird of Time*, p. xxi. With him, several other members of the Section went to the Council (Sheail, *Pesticides and Nature Conservation*, p. 236). The representation to the Advisory Committee was stopped in 1983, when an attempt was made to make the Advisory Committee more independent through a composition of scientists without governmental or industrial affiliation. However, the Conservancy Council continued its representation as scientific assessor of pesticide hazards (Ministry of Agriculture, *The COPR Handbook*, p. 6:1 (Part One)).


The PSPS framework was not designed for general restrictions on pesticide marketing. The Scheme was set up as a way to pacify the concerns about pesticides, based on a voluntary notification procedure and adherence prescriptions of pesticide use. Regulatory action aimed at changes in the way pesticides were applied (process standards), rather than at restrictions of pesticides availability on the market (i.e. product standards). Industry would report its new substances and discuss their properties with the regulators. The regulatory regime was based on consulting, negotiation, and persuasion, although PSPS did entail some effective means of pressure. For example, membership of the British Agrochemical Association was conditioned upon notification to the Scheme and a corresponding delay in marketing. The Association was recognised as the sole representative by government and controlled approximately 90% of domestic and foreign sales. A similar exclusive position was reserved for the National Farmers Union. Within the Scheme, the scientific sub-committee was the main arena for this informal self-regulation. Although the scientific sub-committee formally only treated scientific issues in order to report these to the Advisory Committee on Pesticides, on which a selection of interest organisations were represented, the boundary between the roles of scientists and policy makers was never very sharp in practice. The assessment of pesticide hazards per se was similarly informal. There were no fixed data requirements, just informal eco/toxicological guidelines. Experts from industry were invited to come and discuss their assessments and there was negotiation at almost every step of the procedure.26

The informal atmosphere and shared goal of reaching a ‘reasonable consensus’ even extended beyond the Committee proceedings, in any case during the sixties and seventies. Experts from industry and the Nature Conservancy also met at scientific meetings or exchanged information.27 Ecological knowledge was not only present in the regulatory regime of pesticides through the ecologists of the Conservancy: their industrial colleagues were equally investigating possibilities. This extended to multispecies testing. Although the precise date is hard to trace, around 1980,


27 For example, both Moore and Sheail mentioned ‘amiable’ and ‘harmonious’ contacts with Monsanto (Moore, “Environmental Effects”, p. 196; Sheail, Pesticides and Nature Conservation, p. 210).
interests in artificial streams and other forms of model ecosystem tests were at least present at (English branches of) ICI, Monsanto, and Shell.\textsuperscript{28}

Although these experts could introduce ecological knowledge into pesticide evaluation, their approach encountered criticism. The ecologists felt they needed physiological evidence, as this was seen as ‘harder’ than the ‘circumstantial’ evidence of ecological studies.\textsuperscript{29} Lack of standardisation may not have been an obstruction as such, conceptions of what was and was not ‘hard’ methodology could present limitations. Nevertheless, even though methodology was frequently an issue in the deliberations, the answer was not the development of strict and formally standardised test methods. ‘Guidelines’ and general principles were formulated, but rather as a framework that facilitated debate among ‘court’ experts, than to reduce the role of expert interpretation of data. Ecologists of the Conservancy were prepared to suggest means of testing effects of chemicals, but their interest in the standardisation of such methods was low. In the early sixties, they even deferred such tasks to the Ministry of Agriculture, partly out of a concern that such tests would be used to promote pesticides in question. Even the Ministry never took this task further than general guidelines of assessment and test performance.\textsuperscript{30}

The regulatory regime of pesticides of PSPS showed the characteristics of a court-like institutionalisation of a regulatory regime. The same arguments used by Lord Zuckerman, sometimes in identical phrasing, can be found here. For example, Moore originally believed the distribution of research findings through the press would help to bring about measures to control deleterious effects of pesticides.

Sometimes the press got hold of one of our scientific papers and produced an article about it. The wish to tell a good story frequently meant that the original work was distorted or exaggerated. This was distressing since we naturally wanted to keep our reputation of objectivity. As a result of such distortions by the media, we developed an ambivalent attitude to the press and broadcasting and television organisations. We welcomed the fact that they brought our work and its message to a wider audience, but we were embarrassed by the inaccuracies (...).\textsuperscript{31}

\textsuperscript{29} Moore, \textit{The Bird of Time}, pp. 189-90.
\textsuperscript{30} Sheail, \textit{Pesticides and Nature Conservation}, p. 34.
\textsuperscript{31} Moore, \textit{The Bird of Time}, pp. 184-5.
As Sheail put it, on some occasions, these experts went through great lengths ‘to distance themselves from this other kind of ecologists’ by stressing the strictly scientific nature of their work. The ‘other ecologists’, environmental movements that were not ‘reasonable’ and not ‘scientific’, were not part of the court. They were not co-opted and could not partake in the deliberations. M. Sharratt, representing the Department of Health and Social Security, at a symposium in 1974 stated:

One must keep an open mind all the time and discussions with the activists are often made difficult because it appears that some have already made up their minds.

Although critical and ‘on the side of the environment’, the Conservancy was definitely part of this court and its scientists made sure they protected the reputation that guaranteed their informal membership. However, by the standards of more radical environmentalists, their strategy was seen as a sell-out co-optation, the position of ‘a watchdog without teeth’.

We also see reflections of this position the Monks Wood ecologists in the pesticide regulatory regime in Moriarty’s handbook of ecotoxicology. Moriarty’s blend of ecotoxicology presented the kind of knowledge that was developed at Monks Wood and that operated in regulatory decision making. His insistence on the importance of developing tests for evaluating pesticide hazards at higher levels of biological organisation, on the importance of population ecology, and on the evaluation of a variety of sub-lethal effects, was based on the experiences in this specific regulatory setting where ecological knowledge was integrated with toxicological results as part of the regulatory rationale. In this setting, Moriarty originally took the optimistic stance of further blurring the boundary between ecology and environmental toxicology. It was his attempt at improving a knowledge practice for regulatory purposes, at a time of high pressure on NERC and the Institute of Terrestrial Ecology to deliver more commissioned research. By the time

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32 Sheail, *Pesticides and Nature Conservation*, p. 230, describing the Irish Sea bird wreck of 1969. However, remembering the same event, Moore states that “scientific purity” was used as an excuse not to take the action demanded by a commonsense appraisal of the total situation’ (Moore, *The Bird of Time*, p. 199)

33 In the discussions reported in Irvine and Knights, *Pollution and the Use of Chemicals in Agriculture*, p. 127. One of the participants at this symposium was F. Moriarty, apart from various other regulatory scientists and industrial representatives.


35 From 1979 onward, a decade of contraction set in for NERC, in terms of finances and personnel. The position of ITE was especially difficult. See Sheail, *Natural
Moriarty wrote his second 'pessimistic' edition of the ecotoxicology handbook in 1990, things had changed.

2.2.2 Reform of pesticide regulations and eco/toxicologists
The PSPS system survived until 1985. On several occasions, cases were made for a more formal, statutory system, but the voluntary notification of PSPS had survived with only minor modifications. The strongest arguments for its reproduction were that it guaranteed pragmatic and achievable regulation of pesticide usage, in cooperation with industry rather than against it. It was defended by government, especially the Ministry of Agriculture, as a system that could fine-tune the balance of agricultural and environmental or health interests, in as far as such interests could be considered 'serious'. The secrecy that came with such an approach was seen as a necessity, partly to protect commercial interests, but at least as importantly also to keep the irrationality of those that did not belong to the court at a safe distance. No one outside the 'court', not even scientists, had systematic insight into information that was presented by industry, how it was evaluated, nor which specific criteria were used. The sixties' Reviews of the Persistent Organochlorine Pesticides were not only a landmark, they were also just about the only reports on environmental hazards of specific pesticides ever published during the regime of PSPS.


36 Occasions at which the basic structure of PSPS were reconfirmed were, for example, the 1971 revision of PSPS, two reports by the Royal Commission on Environmental Pollution, of 1971 and 1979, and the respective governmental responses of 1972 and 1983. (Bates, “Legislation Regarding the Use of Chemicals”, p. 87 et seq.; Gillespie, “British ‘Safety Policy’ and Pesticides”; Sheail, Pesticides and Nature Conservation, pp. 197-8.) In 1974, Dr. M. Sharratt of the Department of Health and Social Security, defended PSPS as follows: ‘This country is fortunate in having a first-class agriculture industry backed by a first-class agrochemical industry, which is highly conscious of its responsibilities not to impair the health and well-being of agricultural workers and population at large. (...) The close cooperation of the industry with [Government] in the safety precautions scheme (...) is of great advantage to this country. The very responsible attitude showed by the industry and this cooperation ensures that both the farmer and the consumer can benefit greatly from the careful and controlled use of agrochemicals without there being more than minimal risks to health.’ (Sharratt, “The Effects on Man of the Use of Chemicals in Agriculture”, p. 86) The emphatic support for a non-statutory notification scheme went back to the very origins of PSPS in the 1950s, as found when files at the Public Records Office were opened 30 years later (Rose, “Pesticide Controls”, pp. 136-40). Even Thatcher’s Minister of Agriculture, John MacGregor, continued to defend the PSPS arrangements by the time it was clear that it was no longer tenable. (Rose, “Pesticides: An Industry out of Control”, p. 156.)
Initially, the Thatcher government supported the voluntary principles of PSPS, as it was generally opposed to strict state-controlled environmental regulation. In the early years of Thatcher government environmental regulation was relaxed and the staff of the Department of the Environment cut. Nevertheless, pressures were building up to alter pesticides policy and environmental regulatory policy more in general. Environmental groups received wide public support and environmental activists increased their pressure to gain insight in regulatory decision making and to implement a stronger regulatory stance. On their side, they found the labour unions, which had just engaged in a public dispute with the Advisory Committee on Pesticides and the pesticide producer Ciba-Geigy over the assessment hazards to farm workers of the herbicide 2,4,5-T. Meanwhile, the European Commission increasingly urged for more harmonised regulation of pesticide licensing, with plans that were largely based on the statutory and more formal Continental regulatory approaches, a prospect that appealed to segments of pesticide producers that operated multinationally.

These pressures led to the Food and Environment Protection Act of 1985, giving pesticide regulation a statutory footing. Pesticide regulation was brought under the prime responsibility of the Ministry of Agriculture, Fisheries, and Food (MAFF). The technical secretariat for pesticide assessment, the Pesticides Safety Directorate, received agency status to enable some degree of independence from the Ministry. All the preparatory work for the evaluation of pesticides was done at this Directorate, located at Rothamstead Experiment Station near Harpenden, a well-established laboratory of the Ministry of Agriculture. After data assessment, recommendations were then sent to scientific advisory committees (the Advisory Committee on Pesticides and its Scientific Subcommittee, now made statutory), leaving the formal responsibility for regulatory action shared amongst six Ministries. Contrary to the voluntary scheme, Ministries now had the legal basis to keep a pesticide off the market or to legally restrict usage to specific purposes or specific conditions. In spite of responsibilities formally shared among departments, the Ministry of Agriculture kept a firm grip on pesticide regulation, not only through the limited advisory status of committees involved, but also by ‘coordinating’ the appointments to the Advisory Committee and its Sub-Committee responsible for assessments. On

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37 Wynne and Crouch, “United Kingdom”, p. 409; Brickman, Jasanoff, and Ilgen, Controlling Chemicals, pp. 229, ch.8 on the controversy on 2,4,5-T, in full 2,4,5-Trichlorophenoxyacetic acid, one of the substances in the Agent Orange defoliant of the Vietnam War; see also Wynne, “The Social Viability of Technology”, p. 21 et seq. Some of the original research on plant hormones leading to this pesticide was described in another Science Dynamics thesis, see Faasse, Experiments in Growth.
all of the committees and panels, civil servants constituted the bulk of membership, combined with scientists from government laboratories.\(^{38}\)

Although the change of PSPS into a statutory scheme seemed a radical break with the informality of the past, there were also some remarkable continuities, especially with respect to the practice of hazard evaluations. For example, the high degree of secrecy of the old scheme only gave way very gradually. The public availability of information on pesticide assessment increased slowly after 1986. In 1986, MAFF printed the ‘Data Requirements Book’, primarily to improve communication with companies submitting data.\(^{39}\) Although not widely spread, the document was available to interested parties. Around 1988, MAFF started to produce ‘evaluation documents’, describing the considerations behind pesticide assessments. Initially, these documents were very terse. Only ten to twenty pages long, they contained no references to the actual studies and individual eco/toxicity test results were mentioned only in a synopsis of a few lines each. Usually, the documents were made available about a year after the actual assessment. Over the following years, these documents became more extensive. Around 1993, they had become files of several hundreds of pages, with complete descriptions of tests, standards used, and literature references to the actual research. They now also appeared shortly after the review process (rather than with years of delay). The evaluation documents were still not easily accessible. They were only available at a few locations and there were strict limitations to the copying of information. The official reason for this was that the documents contained commercially valuable information: they could be used to submit risk assessments to regulators in other countries, without having to invest large sums of money. Nevertheless, regulatory assessors gradually found out that (more or less) publicly available information did not have to lead to excessive environmental contestation, and even that dialogue with parts of the environmental movement was possible, after the Pesticides Trust was invited to be represented on one of the subcommittees advising the Advisory Committee in 1994.\(^{40}\)

Changes in the practice of hazard evaluation, as far as these can be traced, were also very gradual. As under PSPS, the risk assessors still negotiated the details of testing requirements with companies during the assessment process. Their position in the negotiations had become stronger:


\(^{39}\) Ministry of Agriculture, *Data Requirements for Approval under the Control of Pesticides Regulations 1986*.

with the legal pressure of a statutory scheme, the regulators could require that companies would submit test results considered essential for a good evaluation. After this base set of data was submitted by a pesticide producer, the assessors at the Pesticides Safety Directorate then had 120 days to make a primary assessment. Based on a first review, they would then get in contact with the producer and negotiate further testing. In the words of a risk assessor:

At times, we end up saying: ‘Well, we just need to know more (...)’. So we have the company [come] in here and we say to the company: ‘We have a problem with your molecule. Let’s talk together; let’s see whether we can resolve this. A series of studies are required. The bottom line is, if you go away and say you are doing nothing, we are just going to refuse to give you the authorisation.’ And we have got that, we can say that, and we are supported by our Ministries at the end of the day, (...) providing the decision is sensible. So we normally work out some studies (..), provided they are done to some sort of GLP assessment that we will agree to.\(^{41}\)

Company representatives could argue their case in every part of the procedure: at the technical secretariat of the Pesticides Directorate, at the Subcommittee, as well as at the Advisory Committee.\(^{42}\)

Although a list of kinds of eco/toxicological data that could most likely be required was drawn up, risk assessment remained a matter of general guidelines. For example, in contrast to the strictly formalised use of assessment factors in the US, English assessors used informal guidelines that were often not even on paper. In other words: a safety margin for extrapolation from test data to ‘the field’ was a matter of expert interpretation.\(^{43}\) To be acceptable, additional studies were to be performed as agreed with the assessors, following the general rules of Good Laboratory Practice as a quality guarantee rather than highly detailed assessment protocols. This practice of tailoring tests for the specific properties and effects of individual pesticides was itself seen as a guarantee for a better quality of assessments.

Similarly, the discourse of ‘reasonableness’ by no means disappeared. Claims for additional testing could be made as far as they were considered ‘sensible’, the Ministry of Agriculture being the guardian of moderation. Although the formal possibility of legal action existed, this process effectively prevented court cases. Reasonableness was seen as the guarantee for sound

\(^{41}\) Interview with Tooby, Harpenden, Pesticides Safety Directorate, June 1994.
\(^{42}\) Ministry of Agriculture, *Data Requirements for Approval under the Control of Pesticides Regulations 1986*, pp. 6 (Section III, no. 23).
\(^{43}\) Interview with Tooby, Harpenden, Pesticides Safety Directorate, June 1994,
evaluation of pesticides, adapted to the peculiarities of individual substances. As the regulatory assessor commented:

In my experience, and I have been doing this for several years now, every single application is different. There is always something, some odd thing that is there to catch you out. If you had everything written down, (...) you could get some administrator just to sit down and tick boxes. And we don’t want to do that. 44

There is more than just the mistrust of rigid procedure here, but also the presentation of the scientist and his/her ability of experience-based lateral thinking to guarantee sound decisions. Or, as the guideline document for companies submitting data stated it:

It is impracticable to specify any rigid wildlife research programme for all types of pesticidal chemicals just as it is hard to provide hard and fast methods of assessing the significance of any observed effects. (...) A knowledge of past wildlife problems is of the greatest value in deciding what lines of investigation to pursue when attempting to judge the possible effects of chemicals on wildlife. 45

If deemed necessary, eco/toxicity tests could be adapted during the assessment process according to what was considered good scientific practice, not necessarily according to the textual rules of standardised testing protocols. When such protocols would not be available, even novel experimental designs could be negotiated during assessment negotiations. For example, English assessors found the precise assessment of exposure of wildlife in the field very important, but this exact exposure is often hard to establish.

Consequently, most assessments now have to [contain] a field assessment of (...) what the environmental concentration is likely to be. (...) If they have a persistent chemical associated with particulates, they have to do some work and try to assess biological availability [in soil]. There are no standard tests, we are making it up as we go along. 46

The precise assessment of actual exposure is especially important in non-restrictive regulatory regimes. Especially in English pesticide regulation, the tendency to regulate use patterns rather than to ban active ingredients in a

45 Ministry of Agriculture, Data Requirements for Approval under the Control of Pesticides Regulations 1986, p. 69 (Appendix 7).
more generic way, led to the negotiation of precisely how much of a chemical was tolerable, even though its eco/toxicity was high. The alternative way to assess exposure was to use computer models, but the uncertainties in these models require large safety factors. The use of field tests can indicated exposure rates with smaller safety factors than computer models.

Field studies and controlled outdoor experiments had been performed at MAFF's Fisheries Research Centre since the mid-seventies. In a first series of tests, colloquially called the 'overspray studies', the distribution of pesticides over soil, biota, and water after sprayed application was studied on small ponds. In 1987, a major field research project was started that followed the distribution of pesticides through soils, soil water, drainage water, and into streams, funded by, among others, the Pesticides Safety Directorate and MAFF. Although such tests were mainly focused on exposure measurements, these could involve ecological studies of biota, not necessarily just the chemical and physical behaviour of a substance.

The kind of field tests that regulators looked for in an assessment procedure would have very specific intentions, defined before the actual testing. Rather than to introduce ecological research as broad-ranged explorations of possible unforeseen hazardous effects that could occur, ecological tests were used when the comparison of environmental toxicity and exposure assessments led to borderline results, or when the assessors could argue that there was sufficient reason to expect specific hazards, such as specific food chain effects. Thus, for example, a company could be urged to research the culinary mores of mice, as a regulatory assessor explained the case of one pesticide:

The firm should, therefore, demonstrate whether sugar beet seed is likely to be taken by mice and also indicate whether the treated pellet is likely to be consumed by mice.

In addition, companies could submit ecological test results where available and did so, even if not urged by the regulators. In the most striking cases, the very mesocosm test results that had been produced for USEPA pesticide assessments and were left unused because of insufficient standardisation,

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47 The Fisheries Research Centre became the Centre for Environment, Fisheries and Aquaculture Science, with Agency status, in April 1997. (Ministry of Agriculture, Press Release)


49 Matthiesen et al., “Monitoring Pesticide Runoff and Leaching in a Surface-Dominated Catchment”.

50 MAFF, Evaluation of fully Approved... Evaluation of Imidacloprid for Agricultural Use, 130.
were submitted, accepted, and used in the English evaluations. Although it is difficult to assess how big the impact of these studies was on the final decision – especially since regulators tend to avoid discussion of specific assessment procedures – there are indications in publicly available evaluation documents that they could be presented as key arguments in evaluations.

Even though multispecies tests were often designed for specific evaluation processes, this did not mean that there were no principles of what was good research. In one case, a company was asked to perform a mesocosm study to lift labelling restrictions, but the study submitted was considered to be of ‘unsatisfactory standards’ and to lead to ‘inconclusive results’. Inversely, sometimes studies were rejected even if they had been performed according to (foreign) standard protocols. For example, a typical reason to reject eco/toxicity studies in England – and not just in the case of multispecies and/or pesticide assessments – was the use of nominal concentrations. The concentration in tests water is then determined by the amount of toxicant that is added, rather than by the amount that actually remains in the test water, which can change due to processes such as adhesion or decomposition.

Although such rules of thumb sometimes remained unwritten, the English pesticide regulators developed guideline documents with general descriptions of test requirements. The 1986 ‘Data Requirements Book’ produced by MAFF that contained a general description of the kind of data that should be submitted, included general methodological guidelines, but insisted on the importance of discussion with regulators:

The scope and type of research into effects on wildlife will vary with the nature of the chemicals concerned and their proposed uses, and it is emphasised that the above notes are not intended to describe a rigid, recommended research programme, but to provide a guide which applicants will have to expand and modify as seems appropriate.

EARLY DISCUSSION WITH THE OFFICIALS CONCERNED

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52 For example, in the case of Atrazine, where the company submitting the data was able to argue that the toxicity tests were too conservative, this was substantiated with American mesocosm and microcosm studies (Ministry of Agriculture, Evaluation of Atrazine (2)). In a sample of 22 evaluation documents from between 1988 and 1994, I found nine with indications of mesocosms or field trials, although a few of these seemed to pertain to environmental fate exclusively.
53 Ministry of Agriculture, Evaluation of Anilazine in 'Dyrene'.
54 Interview with Tooby, Harpenden, Pesticides Safety Directorate, June 1994.
WITH THE RECEIPT OF APPLICATIONS IS STRONGLY RECOMMENDED.\textsuperscript{55}

Working Documents produced by the regulators contained suggested protocols for wildlife toxicity tests and terrestrial field trials. The protocols were set in general terms, with limited use of standardised objects.\textsuperscript{56} In these guidelines for testing, even problem-identifying field trials were suggested, since ‘it is not possible to foresee all the eventualities’.\textsuperscript{57}

Part of the reasons why guidelines were developed was the need of industry to get a better sense of what was expected in regulatory negotiations. Especially for the most complex tests, field trials, additional guidelines were developed and published in the years after the implementation of the statutory scheme.\textsuperscript{58} The typical way to develop these was to set up expert workshops. For example, in July 1991, a workshop was held at Monks Wood to develop guidelines for aquatic mesocosm studies with pesticides. The workshop was organised by mesocosm specialists from industrial laboratories and from MAFF’s Fisheries laboratory at Burnham-on-Crouch, under the auspices of SETAC-UK and SETAC-Europe (the Society for Environmental Toxicology and Chemistry, see chapter 4). Present also were several international

\textsuperscript{55} Ministry of Agriculture, \textit{Data Requirements for Approval under the Control of Pesticides Regulations 1986}, Appendix 7, p. 73 (caps in original); similar Section III, no. 21-5.

\textsuperscript{56} For example, the protocol for an acute aquatic toxicity test with fish consisted of a little over 5 pages. In these, only the glassware for the test tanks used some standard objects (wash bottle heads, sockets, and a burette, all according to British Standard specifications). The method was virtually identical to one developed over twenty years earlier for pesticides screening and water effluent testing. (Ministry of Agriculture, \textit{Data Requirements for Approval under the Control of Pesticides Regulations 1986}; cf. Alabaster and Abram, “Development and Use of a Direct Method of Evaluating Toxicity to Fish” of 1965). Apparently, there had been very little attention for test development and standardisation from the side of the regulators. The species suggested for testing was the small Harlequin fish (\textit{Rasbora heteromorpha}), popular among aquarium holders for being decorative yet easy to keep. Although the choice is understandable from the practical side, the choice of a tropic fish that is a native species of Thailand, Malaysia, and Sumatra is not evident, especially in light of the practice of rejecting data from non-native species by English regulators. (E.g. in water quality standards: Seager and Oakley, \textit{Proposed Environmental Quality Standards for Organotins in Water}, p. 29.)

\textsuperscript{57} Ministry of Agriculture, \textit{Data Requirements for Approval under the Control of Pesticides Regulations 1986}, p. 72 (Appendix 7).

\textsuperscript{58} Ministry of Agriculture, \textit{Data Requirements for Approval under the Control of Pesticides Regulations 1986}, Additional Working Document, 31.12.1990: field trials with beneficial arthropods (bees), again a generic protocol of approximately seven pages.
mesocosm experts, as well as English pesticide regulators, to assure the coordination with regulatory needs. The guideline document stressed two characteristics that were crucial to the role mesocosm studies could play in English pesticide assessments. One was the generic nature of the document. Although the document made extensive recommendations on the performance of studies in series of small ponds, actual studies would have to be designed to answer very specific questions, to be negotiated with regulators. The second pertained to the nature of these questions: mesocosms were intended first and foremost as studies of environmental fate, to determine actual exposure to biota. In contrast to the American mesocosms, a smaller size seemed more appropriate: test ponds were to be from 1 to 25 m³ and occasionally to 100 m³, whereas the original American protocols had required a minimum of 300 m³. Although the ‘environmental realism’ of smaller ponds (without predators) was considered lower, they were also easier to replicate and more prone to produce clear results, especially when designed to test specific parameters.  

As a corollary of these regulatory possibilities of multispecies tests, some companies had continued to invest in mesocosm research. The laboratory of Shell at Sittingbourne, in Kent, became an important place for the development of mesocosm methodology, either for purposes of actual testing or validation. In one study, funded by the European Commission, its outdoor artificial streams were used in a validation study of chronic single species toxicity tests (see figure 12).  

In sum, the development of assessment of environmental hazards of pesticides after 1986 provided a stronger position for the regulators, but continued to rely of personalised expertise with high degrees of negotiation with industry applicants. Methodological guidelines were developed, but not in the form of highly standardised protocols of US pesticide evaluations, not even after the regulatory regime was given a statutory basis. The development of these very general guidelines were discussed with industry scientists, without going through the lengthy standardisation procedures we found in the case of industrial chemicals in the US. The negotiation with regulators of the design of actual experiments based on these guidelines was strongly

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59 The UK document became the input for further debate on the use of fresh water field tests with high involvement of SETAC-Europe. (Society for Environmental Toxicology and Chemistry-Europe, Guidance Document on Testing Procedures for Pesticides in Freshwater Mesocosms; Interview with Tooby, Harpenden, Pesticides Safety Directorate, June 1994.)

Contrasting patterns in regulatory regimes

This allowed non-standardised multispecies test results to be included in hazard assessments, in some cases even the very same tests that had been rejected as useless for regulatory purposes in the US. Apparently, the strategy of relatively low standardisation of mesocosms that had failed for pesticides in the US produced acceptable data in the English regulatory regime, whether as fact-finding or as specific hypothesis-testing experiments. However, given the intermittent development and extensive validation of single species tests, there was a tendency to use mesocosm for more specific testing, with stress on exposure measurement.\textsuperscript{61} Nevertheless, ecological forms of knowledge were part of this regulatory regime.\textsuperscript{62}

\textbf{figure 12}: Shell artificial stream (from Commission of the European Communities, \textit{Development and Validation of Methods for Evaluating Chronic Toxicity to Freshwater Ecosystems}).

\textsuperscript{61} Crossland \textit{et al.}, \textit{European Workshop on Freshwater Field Tests}, p. 19.
\textsuperscript{62} Not only through the tests: the Institute of Terrestrial Ecology continued to be represented in the hazard assessment, with a representative on the Environment Panel of the Sub-Committee on Pesticides. Ministry of Agriculture, \textit{The COPR Handbook.}, p. 6 (Part One).
2.3 English water

2.3.1 Eco/toxicology at the court

As described in chapter 3, the regulation of surface water pollution in England relied heavily on water quality standards throughout the period researched. The philosophy behind this approach was that what counted in water pollution control was the end result: the quality of river water, rather than the quality of effluent or the level of effluent treatment. River water was considered to have a certain ‘carrying capacity’, a potential for dealing with effluent that could be used if managed with care and reasonableness. Although all dischargers were required to have a ‘consent’ for discharging effluents after the Control of Pollution Act of 1974, the approach of the river basin based Water Authorities was to negotiate these consents in light of self-imposed water quality objectives. As self-imposed targets, these objectives had no statutory value: neither citizens nor industry could use them to challenge discharge consents. (To avoid any such suggestion, regulatory authorities later called them ‘Environmental Quality Standards’, rather than ‘objectives’.) Only in 1988 did the Department of the Environment announce strict effluent standards, but only for a limited group of highly toxic chemicals, published in 1989 as ‘the Red List’.63 In 1990, Statutory Water Quality Objectives of the 1989 Water Act were announced, but not implemented for years to come.64

Because of the high reliance on water quality standards throughout the period researched, there were some particular problems that needed to be resolved in the regulatory regime. Regulatory scientists tried to define meaningful quality standards, ways to translate these general standards into quality standards that could be used by local water authorities, as well as

63 Under pressure of the EC: the Red List was a subset from the EC (candidate) ‘black list’ substances, which would require stricter regulation. (Environmental Data Services, Dangerous Substances in Water, p. 8)

64 Anonymous, “Declining Rivers Show up Government Promises”. Water quality was then brought under the centralised responsibility of the National Rivers Authority. Even after the major industrial works were brought under the technology standards of Her Majesty’s Inspectorate of Pollution in 1992, an administrative agreement still stipulated that water quality objectives were to remain limiting conditions for discharge permits. (Royal Commission on Environmental Pollution, Sixteenth Report: Freshwater Quality; Environmental Data Services, Dangerous Substances in Water; Hawkins, Environment and Enforcement; Interview with Carlyle, London, Her Majesty’s Inspectorate of Pollution, 7 June 1994; Allott, Integrated Pollution Control; see also Chapter 3.) In a major reshuffling of regulatory tasks, responsibilities of the National Rivers Authority and Her Majesty’s Inspectorate of Pollution were bundled to form the Environment Agency. In spite of what its name suggests, many regulatory tasks are still managed by other regulatory authorities, such as licensing of pesticides and industrial chemicals. (See Environment Agency, Environment Agency Home Page)
some indication of how to use these standards for the purpose of designing discharge consents. With heavy reliance on water quality indicators came crucial chances for ecologists.

Ways to assess overall river water quality could not only be used to design consents, but also to assess the result of regulatory action in monitoring programmes. From 1974 on, the Department of the Environment set up a harmonised monitoring scheme that was to measure 80 (and later 100) parameters at 200 locations all over Britain. The harmonisation was meant to make measurements comparable between sites and over time. However, in practice, only 25 parameters were effectively and systematically recorded. During the mid-1980s consistent data collection ceased because the Department of the Environment withdrew its funding. Throughout the period researched, public availability of these data was only very partial, for example as they were used in evaluation reports of river water quality.\(^\text{65}\) As far as I have been able to assess, these data only contained chemical and physical parameters, and at most very basic biological indicators.

Starting in 1980, more systematic water quality surveys were held for all of England, directly coupled to environmental quality standards. For these surveys, the National Water Council (NWC) devised a classification scheme in four classes of water, mainly based on chemical and physical parameters. Classes ranged from high-class fishery waters with high amenity values (class 1A), down via high quality, “but of less high quality than Class 1A (class 1B), via fair quality (2), poor quality (3), to bad quality (4). The scheme and its parameters were proposed by 1978, but remained unaltered until the early 1990s, when the Royal Commission on Environmental Pollution thoroughly criticised it. One source of problems was the set of parameters for toxic substances. Categories 1 and 2 suggested that water should be “non-toxic to fish in EIFAC terms (or best estimates if EIFAC figures not available)”.\(^\text{66}\) On this criterion, the Royal Commission on Environmental Pollution remarked:

The NWC scheme has some features which reduce its value both as a management tool and as a general indicator of the state of water bodies. First, it purports to incorporate both the EC surface water directive and the European Inland Fisheries Advisory Commission (EIFAC) criteria. This inevitably makes it impossible to see a clear picture of the state of the water, since the same determinants have different limits under these instruments. The same stretch of water could be classified either as class 1A or class 3 under the NWC scheme depending on whether its

\(^{65}\) Royal Commission on Environmental Pollution, Sixteenth Report: Freshwater Quality, p. 39.

ammonia concentration was judged against EIFAC or the surface water directive.\textsuperscript{67}

Clearly, the margins of interpretation for the classification scheme were considerable. Not only were there these inconsistencies, which required resolution via expert judgement, but also the number of criteria published by EIFAC was very limited: in 1978 EIFAC had criteria for 11 different substances. Partly, these margins of interpretation were used by government to avoid strict environmental regulation. For example, in 1977, the Ministry of the Environment had made it clear that it found the classification scheme of the then EEC too severe and 'unrealistic', hence creating its own scheme.\textsuperscript{68}

From our perspective, it is interesting to see that an only very generally defined scheme of water classification and water quality indicators could operate in this regulatory regime for so long. In contrast: by the end of the 1970s, the US EPA was producing quantified and very strictly defined water quality criteria for a large number of substances.

The European Inland Fisheries Advisory Commission was (and still is) an international forum for discussion of inland fisheries and aquaculture, founded in 1957 by the Food and Agricultural Organisation. Its member countries were represented by either civil servants from ministries or scientists from (government) aquatic research institutes. With concerns about pollution effects on the quality of freshwater fisheries, EIFAC started to produce documents on specific pollution parameters in the mid-sixties, with reports on suspended solids (1964), effects of extreme pH values (1968), temperature (1969), and ammonia (1970) among its usual reports on suitable food for carp, economic valuation of fisheries, and tack for eel fishing. By 1975, EIFAC discussed toxicity tests and had turned its attention to pollution by heavy metals and phenols.\textsuperscript{69} Its activities in quality criteria and toxicity faded after the mid-eighties, but until the early eighties, English water authorities used EIFAC as an independent international source of criteria.

There are two especially interesting aspects here. One was the close connection between the use of single species toxicity tests and these criteria. From a fisheries perspective, the main interest in this period was the effect of a toxicant on specific species of commercially interesting fish. The use of single species tests was not only economical in terms of test design, but also

\textsuperscript{67} Royal Commission on Environmental Pollution, Sixteenth Report: Freshwater Quality, p. 30.
\textsuperscript{68} The EEC used chemical and physical parameters for so-called salmonid and cyprinid rivers, different types of fish fauna. Frankel, The Social Audit Pollution Handbook, p. 136.
\textsuperscript{69} European Inland Fisheries Commission, EIFAC - European Inland Fisheries Advisory Commission Home Page.
self-evident from the perspective of protection of specific species (and their nutritional value) rather than ecosystems. The second interesting aspect was the role of English eco/toxicologists in EIFAC. For example, in 1982, EIFAC published its second edition of an overview of freshwater quality criteria. Its main editor was J.S. Alabaster, pioneer of aquatic toxicity tests of the Water Research Centre (WRC) in Medmenham. Together with his colleague J. Solbé, WRC eco/toxicologists were among the prominent experts in EIFAC. While EIFAC could be presented as an outside source, the Water Research Centre was one of the key regulatory laboratories in freshwater pollution and a main source of eco/toxicity data and expertise, for EIFAC as well as for English regulatory authorities.

The Water Research Centre was formed in 1974 as a government research centre, but with close links to industry, which provided contract-based funding. It was mainly formed out of the Water Pollution Research Laboratory, which went back to 1927 as a government research institute advising on water pollution control. As in most older regulatory water pollution research laboratories, sewage treatment and related water engineering had always been a main focus, but already in the 1940s, there was research on effects of pollution on fish, resulting in attempts to develop toxicity tests with fish in the following decades. By the mid-1960s, the laboratory was considered one of the main research centres on aquatic pollution in Europe.

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71 E.g. Herbet, “Measurement of the Toxicity of Substances to Fish”, once again focusing on the construction of the diluter as the main experimental bottleneck. The paper mentioned the need to compare river pollution as the main reason for development of a test protocol. By 1965, Herbert’s test had become a 2-page protocol for a static/renewal acute toxicity test with Harlequin fish (a small and easily bred aquarium fish) or minnows. It had a formula for the ‘Ministry’s Standard (Soft) Dilution Water’ and general indications for temperature of test water, fish handling, test temperature, treatment of samples (of effluents or river water), dimensions of the test, and rate of water renewal. (Alabaster and Abram, “Development and Use of a Direct Method of Evaluating Toxicity to Fish”). Judging from the publication, it was especially directed at testing of effluent for consenting of effluent discharges by local water authorities. The method was referred to as an acceptable way of setting up aquatic toxicity tests in England for decades. (E.g. Ministry of Agriculture, *Data Requirements for Approval under the Control of Pesticides Regulations 1986*, p. 87)

72 The Water Research Centre comprised the old Water Pollution Research Laboratory at Stevenage (specialist in ‘dirty water’), the Water Research Association at Medmenham (which had done ‘clean water’ and had water supply companies as subscribers), and the research division of the Water Resources Board.
The Water Research Centre continued a tradition of providing expertise for government. In fact, the Water Research Centre developed an almost exclusive position as the source of expertise on water pollution for the Department of the Environment and the Water Authorities. The cooperation was so close, that in many cases it performed the technical preparation of policy in pollution affairs. WRC reviewed the literature and recommended water quality objectives, worked on the water quality classification scheme, supported water sampling, and developed and performed eco/toxicological testing. For example, the eco/toxicological justification of England’s resistance to uniform emission standards in Europe in favour of localised quality objectives was prepared by the WRC.

By the end of the 1970s, WRC employed 500 people, comprising research on sanitation engineering, drinking water provision, but also an extensive research programme on eco/toxicity. Part of the programme was the development of chronic toxicity tests, based on work started in 1966, ranging in duration from 3 months to 2 years, in the case of studies of the effect of cadmium on rainbow trout. (Note the contrast with chronic toxicity at the US EPA laboratory in Duluth, which by then had concentrated on radically reducing the duration of chronic toxicity tests.) There were also research lines comparing toxicity between different life stages and between species, studying the effects of fluctuating concentrations, and research on field validation of single species tests, involving extensive fish monitoring as well as artificial streams in which algae and fish were studied. WRC was also working on the kind of live fish monitoring systems that Cairns had advocated in the US in the early 1970s.

Overview of its research and history in Solbé, “Studies on the Effects of Pollution on Freshwater Fish”; see also Council of Europe, Fresh Water Pollution Control in Europe, pp. 87-88; Water Research Centre, Annual Reports.

73 Interview with Hedgecott, Medmenham, WRC, June 1994.

74 Water research Centre, Emission Standards in Relation to Water Quality Objectives.

75 The WRC fish monitor was developed for water companies to safeguard their potable water supplies. Starting in 1975, researchers investigated the possibilities of using measurements of ECG, gill movement, whole body activity, and stress signs, later also heartbeat and ‘couching’, using trout. (Solbé, “Studies on the Effects of Pollution on Freshwater Fish”, p. 15 and Pascoe and Edwards, “Single Species Toxicity Tests”, pp. 103-4; cf. Cairns, Sparks, and Waller, “Biological Systems as Pollution Monitors”). The development continued into the eighties, for example with the ‘MK III’ version of it in 1985 (according to WRC, Publications Catalogue).
Valve

Numbered valves open in the numerical order shown

Figure 13: Scheme for diluter, mixing toxicants in water for aquatic toxicity tests, 1965 (from Alabaster and Abram, “Development and Use of a Direct Method of Evaluating Toxicity to Fish”).
Some of the work was directly oriented at the very specific needs of local regulatory English authorities. For example, research on combination toxicology attempted to provide regulatory officers in the field with some way of calculating the toxicity of complex effluents from knowledge of their chemical composition. The ultimate objective was to predict the state of a fishery from knowledge of effluents, in other words: to find out how to achieve a certain level of water quality by regulating discharges. Expertise on toxicity studies with fish was also provided for the regulation of pesticides, although overall water regulation seems to have dominated the research agenda.

Judging from the publication list, the methodological work of the 1960s and 70s in eco/toxicology shifted to more specific regulatory tasks, especially the review of literature for the purpose of environmental quality standards. The development of eco/toxicity methodology was only resumed around 1990. Meanwhile, WRC prepared water quality standards for the Department of the Environment through expert review of eco/toxicity data. For example, in 1984, it proposed environmental quality standards for chromium, inorganic lead, zinc, copper, nickel, and arsenic. In 1988, more standards followed for organotins, sulphides, ammonia, etc. In contrast to the US, these quality standards were not derived with a formalised calculation, but by means of a literature review, prepared by between two and four WRC scientists. For example, a document proposing environmental quality standards for organotins of 1986 (not disclosed at the time), evaluated the eco/toxicity data for these substances, controversial for their use in anti-fouling paints on ships. The document paid explicit attention to potential food chain effects, reviewed results of acute and chronic toxicity, as well as the pseudo-hormonal effects on snails, by which male sex characters were ‘superimposed on the reproductive anatomy of females’ (the ‘imposex’ effect). In evaluating the data, frequent use was made of ad hoc expert judgement calls: results for exotic species were discarded as irrelevant for England, imposex effects weighed less heavily in the evaluation because its effect on population decline was not clear, etc. In another example, a review of 1990 for purposes of environmental quality standards, risk evaluations of the US EPA, and some of

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76 Solbé, “Studies on the Effects of Pollution on Freshwater Fish”.
77 E.g. Tooby, Hursey, and Alabaster, “The Acute Toxicity of 102 Pesticides and Miscellaneous Substances to Fish”, in cooperation between the Salmon and Freshwater Fish Laboratory of MAFF and WRC, using Alabaster’s dilution technique.
78 WRC, Publications Catalogue.
79 Seager and Oakley, Proposed Environmental Quality Standards for Organotins in Water.
the eco/toxicity data that they were based on, were discarded because they did not involve species indigenous to England.\(^8\)

Apparently, WRC later used a general quality assurance system for the derivation of environmental quality standards,\(^8\) but the system was never based on strict rules and assessment factors as it was in the US. This did not mean that WRC scientists or even regulators of the Department of the Environment were against quantitative evaluation techniques. For example, for the prioritisation of toxic substances in preparation of the North Sea conferences, which identified pollutants for priority action, the Department of the Environment asked WRC to produce a computerised evaluation scheme, which resulted in a priority list by 1991.\(^8\) Similarly, more formal prioritisation procedures for Red List substances were devised after 1989.\(^8\) It does mean that formalisation of evaluations, standardisation of tests or procedures, in other words: the shift of expertise to texts or objects, was not a requirement to produce boundary devices in this regulatory regime, but merely another tool that could be used, particularly for prioritisation screening.

After the production of the expert review, the proposed water quality standard would go to the Department of the Environment to be reviewed and discussed, possibly with the Ministry of Agriculture or the water authorities. Consequently, the department consulted with industry and ‘other parties’, before the standard would be included in a Circular. However, the availability of the expert assessment was normally very limited. For example, the organotin report discussed earlier was distributed under embargo in approximately 39 copies, 11 of which were for internal use in WRC.\(^8\) Since the WRC was part of the civil service, or to be precise: the science service, its members were held to the same rules of secrecy as the civil servants in government positions. Although these scientists could present research at scientific conferences, they were well aware that the Official Secrets Act applied to them too and apparently the Department of the Environment

\(^8\) Mallet, *Determination of Ecotoxicological Effects*.

\(^8\) British Standard 5750, Interview with Hedgecott, Medmenham, WRe, June 1994.


\(^8\) Environmental Data Services, *Dangerous Substances in Water*, pp. 8-9.

\(^8\) Seager and Oakley, *Proposed Environmental Quality Standards for Organotins in Water*; WRC, *Provisional Environmental Quality Standards for Azinphosmethyl in Water*. These reports stated the number of copies that were prepared on the first page.
effectively controlled what technical information was released to wider circles. Here is a typical instruction from a 1975 report:

This report has been prepared for the confidential use of members of the Water Research Centre and of Government Departments covered by the Department of the Environment Quasi Membership Scheme. Its content must not be further published without the permission of the Director of the Water Research Centre.

The ‘quasi membership’ referred to who could be considered an insider to the policy process, a quasi member of the Department of the Environment, of the ‘court’. The privatisation wave that started under the Thatcher government and reached the WRC in the mid-eighties, hardly changed this configuration. The first research programme of the new company, now called WRc, for 1986-1991, showed the continued reliance on the Department of the Environment for the bulk of its funding. Even though the Department was now formally required to tender for contractors, most of its regulatory projects were so specific that WRc remained the main source of expertise. WRc also held a central position in the technical expertise of the National River Authority (NRA), which superseded the 10 River Water Authorities in 1989. During interviews at NRA, I was simply referred to WRc when issues

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85 Interview with Hedgecott, Medmenham, WRc, June 1994.
86 Ranson, Non-Flame Devices in Atomic Absorption Spectrometry.
87 Privatisation under Thatcher only effectively started around 1982. The reliance on small numbers of policy makers is seen as typical of Thatcher’s breech with broader consensus politics in Kavanagh, Thatcherism and British Politics.
89 See for example: National Rivers Authority, Annual R&D Review 1993. Thatcherite principles were also important here. The Conservative government found it improper that local water regulators worked as advisors to dischargers. Previously, informal advice had been part and parcel of the negotiated implementation of discharge regulations by field officers (Hawkins, Environment and Enforcement). This was the kind of service that should work through private consultants, not civil servants: this way the state would no longer pay for consultation. In addition, it was expected that a national concentration of regulatory policy for water would give government more grip on water policy, which was presented as allowing the NRA to ‘enforce tough standards’. Simultaneously, water companies were privatised. (Anonymous, This Common Inheritance, pp. 26-27, 139, 62-63; Murley, ed., 1993 NSCA Pollution Handbook, p. 253 et seq.) Indication of a tougher regulatory stance were at best ambivalent: NRA reported higher compliance rates and more successful prosecutions – although still representing a low number of legal cases (National Rivers Authority, Environmental Progress Made in a Businesslike Way; National Rivers Authority, Corporate Plan 1992/93; National Rivers Authority, Discharge Consents and Compliance; Financial Times,
became technical, while at WRc there seemed to be no concern over future funding from NRA and the Department of the Environment.\textsuperscript{90} It did appear that NRA developed an interest in university sources of reports, but WRc clearly continued to perform the key regulatory assessments, even some ten years after its privatisation.\textsuperscript{91}

2.3.2 Biological and ecological expertise for water pollution assessment

In contrast to the US, English biologists did not have to fight their way into a world dominated by engineers in the early seventies. Biological methods of water quality evaluation, monitoring, as well as eco/toxicity tests were already well established in the 1960s in the research circles that were part of the ‘court’ of water regulation. Although there seems to have been some stress on single species research and a focus on environmental toxicology at WRC,\textsuperscript{92} this did not mean that ecological knowledge was excluded. Water quality monitoring provides more insight in the patterns.

Water quality monitoring had been mostly a matter of chemical and physical parameters in the sixties, as in the US, although monitors involving a fish were used in England already.\textsuperscript{93} In 1976, the Department of the Environment and the National Water Council, the advisory body for water pollution control, established a Biological Water Monitoring Party. This party developed a scoring system for water quality based on the ‘Trent biotic index’, a species diversity index used by the former Trent River Board in the 1950s and early 1960s. Rather than counting species diversity as such, the

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\textsuperscript{90} By 1992/1993, NRA was by far the top client in pollution research in the UK. WRc ranked among the biggest consulting firms in this market, while universities’ share was in decline. (Foxon and Mayer, \textit{Environmental Consultation in Britain})

\textsuperscript{91} National Rivers Authority, \textit{Annual R&D Review 1993}, pp. 6-30.

\textsuperscript{92} WRc, \textit{Publications Catalogue}; Interview with Hedgecott, Medmenham, WRc, June 1994.

\textsuperscript{93} Lester and Woodward, “Water Quality Monitoring in the UK” of 1972 described fish in aquaria as monitors, used at Lea Marston, and monitoring of various chemical and physical parameters, e.g. dissolved oxygen, temperature, suspended solids, conductivity, Ph, ammonia, organic matter, oil, chloride, nitrate, some of which automated.
boundaries of regulatory science

index focused on macro-invertebrates and gave higher scores to biological families considered to be indicators of unpolluted, oxygen-rich water, and lower scores for families considered typical of oxygen-poor, polluted water. These scores were then used to classify rivers in 8 categories, which were used for biological evaluations of water quality. The Working Party's scoring system was used for an extensive survey of water quality based on biological sampling in 1980.94

The extensive biological monitoring data formed the basis for a project called RIVPACS, the River InVertebrate Prediction and Classification System. From around 1986, ecologists at the Institute for Freshwater Ecology tried to compare the results of monitoring data with baseline conditions in unpolluted natural waters (‘unstressed sites’), funded by the Department of the Environment, and later by the NRA. The central idea behind RIVPACS was that the model would predict a certain species variety, based on water type and physical properties of an equivalent stretch of unpolluted river. This predicted variety could then be a localised standard for the degree of overall stress on aquatic life, including pollution. For the prediction of the biotic score, the system used abiotic indicators, such as distance from the source of the river, altitude, mean water depth, alkalinity, etc. By the early nineties, the NRA had adopted RIVPACS as one of its central water quality monitoring tools.95 The tool fitted the English approach of localised water quality standards and fitted the idea of regulating with respect to the end result (overall water quality) rather than effluent standards. In comparison, regulatory interest in methods for systematic biological water quality monitoring in the US only took off around 1990-1992, but only as monitoring tools, not for direct regulatory application, such as in discharge licensing.96

96 Hart, “Building a Stronger Partnership between Ecological Research and Biological Monitoring”: with EPA’s Environmental Monitoring and Assessment programme, the National Water Quality Assessment Programme (US Geological Survey), and the Biomonitoring of Environmental Status and Trends project of the US Fish and Wildlife Service; with supporting biomonitoring tools developed by US EPA: Plafkin et al., *Rapid Biosassessment Protocols for Use in Streams and Rivers*. 


In contrast to the US, once again, these regulatory assessment devices did not go through extensive standardisation procedures or expert consensus building. Regulatory authorities would assign researchers to develop models and tools, and then assess their use for regulatory policy. In this sense, scientific validation was primarily a matter for the researchers involved. When more extensive expert review did take place, this took the form of evaluation by elite experts, typically under close supervision of the regulatory authorities.

One example of such a procedure was the committee on synthetic detergents, already established in 1957 by the Ministry of Housing and Local Government. The committee had been a platform for negotiation over methodology for assessing water pollution in the 1970s, for example of synthetic detergents in the first half of the seventies. At this point in time, experts were appointed by the Secretary of State and ‘in the case of members with industrial affiliations, after consultation with the Confederation of British Industry’, although members served in an individual capacity. The committee discussed methodology for testing the toxicity of surfactants to fish, including a European ring test. Another example was the later work of the Standing Committee of Analysts, which discussed the standardisation of methodology related to water analysis. Although mainly active in the development of water assessment techniques in analytic chemistry, the Committee also certified some eco/toxicity tests. Around 1980, the technical committee consisted of representatives of the Department of the Environment and the National Water Council. After the Council was abolished under Thatcher, the Standing Committee eventually was managed by the Drinking Water Inspectorate. Scientists from universities, government, and industrial laboratories were

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97 Largely based on OECD protocols, using OECD GLP, the Standing Committee produced protocols for tests such as acute toxicity (zebra fish, rainbow trout, *Daphnia magna*, and brown shrimp). (Standing Committee of Analysts, *Acute Toxicity Testing with Aquatic Organisms*) These protocols stressed the importance of expert judgement and expert competency in test performance and were less strict than OECD protocols in several aspects. For example, testing with rainbow trout according to OECD standards prescribe 15 degrees Celsius +/- 1 degree, whereas these protocols had +/- 2 degrees. The trout protocol was approximately 4 pages long.

98 Although the toxicity methods of the Standing Committee were referred to as acceptable methods for pesticide analysis or water quality standards, I have found no other toxicity testing methods from the Standing Committee. However, apart from these toxicity tests, it developed approximately six methods for biological sampling and assessment of water quality. (Standing Committee of Analysts, *Index of Methods for the Examination of Waters and Associated Materials 1976-1992*; Standing Committee of Analysts, *Cadmium, Chromium, Copper, Lead, Nickel and Zinc in Sewage Sludges by Nitric Acid/AAS.*
invited to write methodological guidelines, supervised by a group of the Standing Committee. This contrasts sharply with the development of methodology by, for example, the American Society for testing and Materials, where EPA kept much more distance; where the forum was open instead of based on expertise-by-invitation; and where the process of developing a methodology was targeted at building a broad consensus on all details of protocols.

In sum, we find the court structure in water regulation also: co-opted expertise, high degrees of secrecy, and a boundary between science and politics that takes the specific form of a boundary elite. Standardisation of toxicity testing and assessment procedures was generally low: although some tests were developed, the protocols and methodologies were less specific than those of other standard-setting organisations; negotiation over these protocols was limited and under close regulatory supervision; and their actual use left ample discretion for expert interpretation. Ecological assessment methodology was included in this regulatory regime, especially for monitoring, but also for setting water quality targets via reviews. The traditional court structure was undermined by the Thatcherite privatisation wave, but seemed more tenuous than one would expect: patterns of co-optation and preferred sources of expertise remained, although positions were slightly less exclusive than before.

2.4 Industrial chemicals

In June 1977, the Health and Safety Commission, formally a tripartite organisation with representatives of local government, labour and management, proposed a first notification scheme for industrial chemicals. Notification of new substances would be obligatory if produced over 1 tonne, after which ‘a dialogue’ would be started in case the Health and Safety Executive, the executive counterpart of the Health and Safety Commission who was to manage the scheme, thought it would need more data to perform an assessment. The main concern of the notification scheme was not environmental protection, but worker safety. The notification scheme was never implemented. Government decided to wait for the results of the negotiations in the EEC over notification of industrial chemicals (the ‘sixth amendment’ of 1979, see chapter 3). Nevertheless, the approach was indicative of English preferences for case-by-case pragmatic evaluations of substances, which conflicted with the uniform standards for substance evaluation that Europe was heading for, based on the French legislation. The government successfully tried to negotiate the approach of the 6th amendment Directive to resemble its own approach more, for example, stressing that the scheme was foremost a matter of notification (and not regulation or licensing), or that provisions should be made for dialogue with competent
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authorities, and even relaxing the conditions to require additional testing for large and very large quantities of chemicals to almost total discretion of national regulatory authorities.\(^9\) As a civil servant responsible for the policy matter at the of the Department of the Environment commented:

The UK has gone to great lengths to ensure that the Directive allows sufficient flexibility to enable professional judgement to be exercised. This has not been easy because some member nations argue that, if applied in the wrong way, this flexibility would re-instatethe elements of trade barriers, which the Directive is intended to remove.\(^{10}\)

Among UK industry, there were several concerns about these new regulations. For the major companies, there was the concern that testing requirements might be different from other industrial countries of the OECD – especially the US, where the Toxic Substances Control Act had been passed a few years earlier. However, there was also concern over the possibility of the export of the US regulatory system, with its higher degree of formality, litigation, and public accessibility of data.\(^{11}\)

In practice, the consequences of regulation were very minimal. The Health and Safety Commission published a brief consultation document on the new regulations in 1981,\(^{12}\) and some guidelines for testing in 1982.\(^{13}\) As far as toxicity testing was concerned, the guidelines consisted of some general requirements for testing and reporting, and mostly referred to OECD standard methods for eco/toxicity, single-species tests along with biodegradation and -accumulation tests, and chemical and physical parameters. The guidelines made it clear that these were only recommended:

In practice, competent authorities will be expected to maintain a certain degree of flexibility in this, and will accept results from other test

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\(^{10}\) King, “Regulations on Release of Chemicals into the Environment”, p. 62.

\(^{11}\) See discussion notes after King, “Regulations on Release of Chemicals into the Environment”.

\(^{12}\) Brickman, Jasanoff, and Ilgen, *Controlling Chemicals*, p. 35.

methods provided that their use instead of the approved methods is justified, and that they are demonstrated to be equivalent or superior to the approved methods.\textsuperscript{104}

In the notes and references several other methods manuals were suggested in addition to the OECD set.\textsuperscript{105}

As far as I was able to trace, implementation of eco/toxicological notification was minimal and evaluation of new substances on eco/toxicological grounds almost non-existent throughout the 1980s, although the official interpretation was different. The Health and Safety Commission reported in 1993 that, in the previous decade, only six notices were sent out to require data from notifiers that were ‘not previously forthcoming’, all six of which were complied with. According to the Health and Safety Commission, this meant that there was a high degree of compliance with the regulations and it suggested that ‘in practice, very few particularly hazardous new substances have been placed on the market’ after 1982.\textsuperscript{106}

Effective regulatory action was mostly limited to substances on the list of ‘old chemicals’, such as dioxins, PCBs, cadmium, and lead. Eco/toxicological evaluations only received more attention after a committee was formed by the Health and Safety Executive together with the Department of the Environment in 1990.\textsuperscript{107} The Department of the Environment set up a section to review substances from an eco/toxicological perspective, both old and new. Once again, the expert evaluations stressed flexibility and negotiation with notifiers. Hazard evaluations were based on literature reviews with expert evaluation of data, including safety factors based on expert judgement, in other words: much more based on human expertise than the highly formalised assessment procedures of the US EPA. In the case of some old chemicals, multispecies and field tests were considered in evaluation documents, even if no standard methods were used.\textsuperscript{108}

This strengthening of environmental evaluations was not just based on increased attention for environmental policies in England, but especially by

\textsuperscript{104} Health and Safety Commission, \textit{Approved Code of Practice: Methods for the Determination of Toxicity}, p. 6.

\textsuperscript{105} From the US EPA toxicity methods of 1975, to ISO methods, German DIN standards to French eco/toxicity tests. (Health and Safety Commission, \textit{Approved Code of Practice: Methods for the Determination of Toxicity}, pp. 13, 17.)


\textsuperscript{107} Anonymous, \textit{This Common Inheritance}, pp. 177-78.

\textsuperscript{108} For example: the Toxic Substances divisions reviewed trichloroethylene and accepted a field study with a natural pond, although in the end-evaluation, LC50 data were the crucial data for the evaluation. (Department of the Environment, \textit{Environmental Hazard Assessment: Trichloroethylene})
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efforts of the EU to further implement regulatory schemes for industrial chemicals, especially increased hazard evaluation after 1993. In the case of new substances, increased cooperation and data-exchange further implemented the possibility of notifying substances only in one country for the entire EU. The UK would become almost immediately the EU country with the largest number of notifications, with around a hundred per year almost a third of the annual number of European new substance notifications.

In the case of existing substances, priority substances divided over different ‘rapporteur countries’, each of which would perform a risk assessment that would be reported back to the Commission and other member countries. For the purpose of these assessments, the European Commission developed guidelines on how these risk assessments were to be performed, referring to its own standard methods, and Good Laboratory Practice. In preparation of, and in further refinement of, these guidelines, the UK formed a working group to write its own, more detailed guidelines on how handle these risk assessments. The working group involved various government departments (DoE, MAFF, the Department of Health and the Health and Safety Executive), as well as industry experts (Ciba, Exxon, Harcros, ICI, Shell, Unilever, and Zeneca), with a secretariat at the Chemical Industries Association.

Directives 93/793/EEC of 1993 attempted to step up evaluation of old chemicals with assessment procedures, while 92/32/EEC was an attempt to further harmonise notification of new substances, with increased attention for eco/toxicological parameters. (Department of the Environment and Health and Safety Executive, *How to Report Data on Existing Chemical Substances*; Interview with Rea, London, Department of the Environment, June 2 1994; European Commission, *The Directive on Dangerous Substances Website*)


For the details of the procedure, see: McCutcheon, “Risk Management of Chemical Substances in the European Union”, pp. 218-26. By 1994, 42 chemicals were on the priority list, with most assessments to be performed by the UK, Germany, and the Netherlands as ‘rapporteur countries’. (Environmental Data Services, “First EC Priority List of Chemicals for Risk Assessment”)

The development of these assessment guidelines was interesting for several reasons, especially when contrasted with risk assessment procedures used in the US. Firstly, these guidelines were more precise than the assessment principles used in England beforehand. For example, the 1993 UK assessment document gave a list of assessment factors to be used with various kinds of eco/toxicity data: a factor 1000 to be applied to the lowest LC50, 50 to the lowest chronic data, 10 for chronic data of the most sensitive species. These factors were different from the ones used in the US, where for example a factor 100 would be applied to acute data. However, there was also more room for expert assessment: factors could be varied based on assessment of whether there were grounds to assume that most sensitive species had been identified, indications of inter-species variation of toxicity, or 'any other information which would suggest that a lower assessment factor would be appropriate'. In the case of field data, the document recommended reviewing them on a case-by-case basis.\(^{113}\) As regards standards of eco/toxicity testing, the English regulations did not prescribe specific test protocols to be used, but suggested EU, OECD, or ISO standards, or to ask advise from the risk assessors.\(^{114}\) As the document put it: ‘Although the schemes require use of expert judgement, decision criteria are included to guide assessors.’\(^{115}\) This meant a formalisation of hazard assessment procedures compared to prior practices in England, but one that still reserved more room for expert evaluations compared to the US.

Secondly, these guidelines were developed explicitly by a working group of industry and government. Although the guidelines were presented as ‘proposed’, presumably for wider consultation, they were picked up immediately and used in assessments.\(^{116}\) Compare this with the development of similar guideline documents in the US: although there was similar consultation with industry, this was undertaken under the auspices of forums of science, remote from the US EPA, based on a wider audience for feed-back or consensus-building, and consequently published as a legal document. In England, this consultation with industry primarily followed the pattern of the court-like co-optation for the development of procedures. For the performance and evaluation of assessment data, a dialogue with industry experts was

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\(^{116}\) E.g. see the key decisions in the eco/toxicological evaluation in Willis *et al.*, *Environmental Hazard Assessment: Chlorinated Paraffins*. 
Contrasting patterns in regulatory regimes

considered essential, although these more formal guidelines and risk assessment principles could be used as resources in the negotiation. Or, as the risk assessment document put it for the establishment of the identification of potential hazards and the right safety factors:

Thus any review of the Initial Risk Characterisation will need close cooperation between the reviewers and industry. It is at this point that a discussion of the assessment factor can take place, but it must be clear that the onus will be on the manufacturer/supplier to justify a lower factor, and support this with the necessary data.  

Thirdly, the ‘regulatory court’ was now modified. New expert actors came into perspective. For example, a key role in the development of the guideline documents was player by Peter Calow, of the University of Sheffield, for example by chairing the workgroup on risk-benefit analysis. As far as I was able to trace, no other university department had ever been as structurally involved in aquatic eco/toxicological assessment in England. (In fact, several academic researchers I spoke to complained about their feeling of being excluded, of lack of funding, and of a certain degree of mistrust they experienced from those established participants in regulatory regimes.) Another new actor was the Building Research Establishment, a privatised government research facility that could perform the hazard assessments from human health point of view, in coordination with eco/toxicological experts from the Institute of Terrestrial Ecology. This combination performed twenty-seven evaluations of high-volume chemicals for the DoE’s Toxic Substances Division between 1991 and 1995, some for prioritisation under Existing Chemicals, but also in combination with assessments for water quality criteria, or priority listing for the North Sea conferences, hence integrating risk assessment procedures for regulatory regimes that had so far been largely separate.

From an environmental and political point of view, these were not the issues that were at the focus of attention for the regulation of existing chemicals. Much more important were problems like the enormous backlog of old chemicals that awaited review, the slow procedure of reviews, the fact that so-called ‘existing chemicals’ were actually chemicals on the market before

117 U.K. Government/Industry Working Group, Risk Assessment of Existing Substances, p. 37, italics in original; see also Department of the Environment and Health and Safety Executive, How to Report Data on Existing Chemical Substances.
118 BRE, BRE: The Whole Picture; Interview with Rea, London, Department of the Environment, June 2 1994; Willis et al., Environmental Hazard Assessment: Chlorinated Paraffins; Crookes and Howe, Environmental Hazard Assessment: Ethylbenzene.
1981 and screening of ‘new chemicals’ since that time had been very limited, continued problems of non-acceptance of risk assessment between countries, or ad-hoc reasoning and economical and political manoeuvring in Europe over specific substances. Nevertheless, from our perspective of comparing the construction of science/policy boundaries by diverging uses of different types of boundary devices and boundaries in eco/toxicology, these patterns provide sharp contrasts with similar regulatory regimes in the US.

2.5 Researchers’ perspectives

It would be wrong to suggest that university researchers were completely excluded from regulatory research prior to the nineties. However, compared to the US, the possibilities were much more restricted. The best research facilities in England for regulatory research were by far those of the WRC and industry, especially ICI. Universities did not manage to obtain enough foothold in regulatory funding from the DoE, NRA, or similar regulatory organisations to even begin to compete. Inversely, at least until in the nineties, there were no major strategic research initiatives such as the eco/toxicology research programmes in the Netherlands (see Chapter 4 and below). The resources of the Natural Environment Research Council (NERC) were comparatively small and steered away from regulatory issues, especially in the 1980s.

What that meant for an academic eco/toxicological research group can be nicely illustrated with the eco/toxicology group at the School of Pure and Applied Biology at the University of Wales College of Cardiff under David Pascoe (although strictly speaking on the wrong side of the Bristol Channel to be part of this research). In the seventies, Pascoe had done research on the effects of pollution on aquatic life with a small contribution of NERC funding, specifically looking at various forms of stress on freshwater fish. This research involved fish parasites, a classic topic of studies of fish physiology, but also pollution, such as the toxic mechanism of cadmium, using sticklebacks and rainbow trout as test organisms. The latter led to forays into the interaction between pollution and stress on fish from parasites, with complicating factors such as the toxicity of cadmium to the parasites, and the response of fish to cadmium pollution with the production of cadmium-

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119 For example, see Tukker, Frames in the Toxicity Controversy on risk debates over PVC.
120 Interview with Pascoe, Cardiff, University of Wales, June 1994.
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Some of this work was quite relevant to regulatory eco/toxicity testing, investigating complicating factors in toxicity effects. For example, the research raised questions about the validity of short-term tests for extrapolation to long-term pollution effects, questioned the realism of tests with unstressed, healthy fish, or the ‘inadequacy of standard toxicity tests in predicting the consequences of an episodic pollution incident’. (Reminiscent of – and referring to – the criticism of John Cairns of single species testing, but now from a physiological angle.) However, almost all of this research was funded from university money and grants to doctoral students. Throughout this period, the unit remained small, consisting of Pascoe and only a few research students.

When studies with fish became too expensive and there were problems getting licenses from the Home Office for studies with higher animals around 1985, Pascoe decided to shift to invertebrates. These were easier to keep and it was easier to get more replicates for experiments. Once again, this was research with potential regulatory importance, working on organisms that were being considered for regulatory testing for the very same reasons as Pascoe had decided to use them. For this research, substantial external funding was found, not from UK sources, but from the EEC. In the following years, Pascoe developed some practice of regulatory advice, not in the UK,

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123 Pascoe and Shazili, “Episodic Pollution. A Comparison of Brief and Continuous Exposure of Rainbow Trout to Cadmium”, p. 189. ‘Episodic pollution’ was of particular importance in the UK given its regulatory reliance on 95% compliance standards: statistics of monitoring of river discharges would measure compliance with standards 95% of the time. Details in: Royal Commission on Environmental Pollution, Sixteenth Report: Freshwater Quality.

124 Interview with Pascoe, Cardiff, University of Wales, June 1994; Williams, Green, and Pascoe, “Studies on the Acute Toxicity of Pollutants to Freshwater Macroinvertebrates”; Williams et al., “Effect of Cadmium on Oviposition and Egg Viability in Chironomus Riparius (Dipteria: Chironomidae)”; McCahon and Pascoe, “Cadmium Toxicity to the Freshwater Amphipod Gammarus Pulex (L.) During the Moul Cycle”.
but in Hungary. A smaller side-line of research studying acidification did receive some funding from the Department of the Environment, along with a contract from the Welsh Water Authorities. Pascoe and his students were clearly interested in the regulatory possibilities of their work in the UK. For example, in 1988, they performed a bit of ‘market research’. They identified the regulatory eco/toxicology laboratories in the UK that used invertebrates, finding that of 27 laboratories (government and industrial), only 14 used invertebrate tests, almost all of which involved Daphnia magna. Only one or two laboratories cultured non-Daphnia invertebrates. They continued to explain and document their own culture methods for three species of macroinvertebrates, successful laboratory culturing being precondition for stable testing. In addition, they introduced a new element in their tests: the three invertebrates that they had worked on could co-exist, raising the possibility of a microcosm design, possibly even extended with a predator (a hydra species).

From here on, Pascoe’s research went more and more into the direction of methods development, including another invertebrate detrivore used as fish food. The bulk of this research was funded by the European Commission, as part of a research programme on the ‘Development and Validation of Methods for Evaluating Chronic Toxicity to Freshwater Organisms’. From around 1988, some additional funding started to come from NERC, which expanded as NERC set up a modest research initiative in ecotoxicology. By 1991, some UK sources more involved in regulatory work appeared, such as WRc and NRA, but the bulk of the financing continued to come from the European Commission. The European funding was eventually used to

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125 Pascoe, “The Role of Aquatic Toxicity Tests in Predicting and Monitoring Pollution Effects”.
126 Ormerod et al., “Short-Term Experimental Acidification of a Welsh Stream”.
127 McCahon and Pascoe, “Culture Methods for Three Freshwater Macroinvertebrate Species and Their Use in Toxicity Tests”. The publication also gives an indication of the restricted scope of tests methods used in the UK, apparently relying almost entirely on fish toxicity and the standard OECD Daphnia test.
130 E.g. Taylor, Maund, and Pascoe, “Toxicity of Four Common Pollutants to the Freshwater Macroinvertebrate Chironomus Riparius Meigen”.

develop and validate a small invertebrate microcosm, as the European research programme was moving into validation of microcosms and mesocosm testing. The test development work for the European Commission seems to have led to some frustration, as these tests were not readily picked up in regulatory application in Europe. Nevertheless, the interesting phenomenon that occurred here was that European initiatives created new opportunities in regulatory science for UK eco/toxicologists, starting in the early nineties; opportunities that had been very limited before.

The Natural Environment Research Council did support eco/toxicological research throughout the period studied. Among its own institutes, the ecologists of the Institute of Terrestrial Ecology of Monks Wood continued research on pesticides. I have already described how NERC institutes like the Institutes of Freshwater and Terrestrial Ecology were funded by regulatory authorities to aid in eco/toxicological assessment and in the development of assessment tools such as RIVPACS. However, according to eco/toxicologists I interviewed, their chances of getting funding from NERC were very limited. There seem to be three explanations for this: in the period researched, NERC seems to have focused eco/toxicological research in its own research institutes; there were no major thematic research programmes in eco/toxicology; and success rates for non-thematic research were very low, especially after the budgetary restrictions of the early eighties.

The pattern was interrupted by a NERC 'special topic', a thematised research programme in the early nineties, followed by a funding programme that started just after the period I researched. This 'Environmental Diagnostics' programme supported research into biomonitoring involving the ecotoxicology group at Sheffield University; mesocosm studies performed by university researchers at WRc and co-financed by industry; as well as work on the determination by environmental quality standards with support of the Environment Agency and consisting of cooperation between university researchers and WRc. Still, with a total expenditure of 6 million pounds, this still was not comparable to the influence on eco/toxicological research that the US EPA had.

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131 Taylor et al., "A New Method for Measuring the Feeding Activity of Gammarus Pulex (L.)"; Interview with Pascoe, Cardiff, University of Wales, June 1994.
132 These centres were later conglomerated into NERC’s present Centre for Ecology and Hydrology. (Centre for Ecology and Hydrology, Welcome to CEH Web.)
133 Sheail, Natural Environment Research Council.
134 The project ran from around 1995 and was completed in 2001, for reports see: Centre for Ecology and Hydrology, Environmental Diagnostics. The 1988 interdepartmental toxicology programme in the Netherlands (see chapter 4) started
Nevertheless, these patterns of cooperation on regulatory science, with involvement of industry and regulatory authorities, do confirm the pattern of a weakening of the ‘court’ structure that had been so typical of older English regulatory regimes. On the one hand, research groups like the one in Sheffield managed to obtain positions in regulatory regimes, specifically after the new initiatives in the regulation of industrial chemicals, largely brought about by initiatives of the European Commission in the ‘7th amendment’. On the other hand, research groups like the one in Cardiff were able to use research funds from the European Commission to expand research and eventually also get UK regulatory work started.

2.6 England: the court, the boundaries
Until the late eighties, the development of eco/toxicological hazard assessment methodology in England followed a particular pattern: regulatory scientists at government research laboratories would develop methodology, normally in informal consultation with industry and approval of the ministries they worked for. A small number of methods were developed to assess effluents, to generate toxicity data for water quality objectives, and for use in pesticide evaluations. This methodology was never standardised to the same degree as in the US, nor did it go through lengthy negotiation procedures. The court structure determined who was to be consulted and the process ended with ministerial approval. The resulting assessment practice relied heavily on the intervention of people: the experts who adapted tests, assessment protocols and river water quality assessment to the needs of the situation at hand – not only from a scientific point of view, but also in light of regulatory policy requirements. Although expertise was transferred to objects and protocols, the boundary between science and politics was primarily guarded by the boundary elite of regulatory experts, almost exclusively from a very small group of government laboratories in consultation with industrial experts.

The regulatory regimes in England of this period were not as distinct as in the US in terms of experts involved. Although each regulatory authority did seem to have its own preferred source of expertise, expert sources were also shared. In addition, methodology was shared, although rules of thumb of assessment practices could differ. In general, regulation may have been informal, secretive, and negotiated, I have also shown that the precise form expertise took in different regulatory regimes varied, and so did the timing of changes in these regimes.

The boundary of the regime towards the rest of society and its (potential) stakeholders was sharply drawn and difficult to surpass. The

with an equivalent of approximately 8 million pounds, as input to a much smaller research structure. (Anonymous, “Het Stimuleringsplan Toxicologisch Onderzoek”)
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boundary defined and institutionalised people’s membership of the ‘court’, including experts and expert organisations. Once co-opted by the court, contact could be made with its members; to outsiders, doors were closed. With regard to texts, the boundary of the regime distributed which of the regimes’ texts were to be made public and which not. With regards to objects such as measuring apparatuses or toxicity tests, the boundary was not maintained through certification or an endorsement of certain apparatuses as such. Although regimes in England developed their own testing techniques just like in the other countries analysed, the selection of which tests were acceptable was left to the judgement of court’s experts. Important institutions that embodied and sustained this boundary were the Civil Service (including its Science Service variety) and its esprit de corps, the regime of secrecy and its legal embedding, and the discourse of reasonableness and pragmatism. Thus, the boundary of the regimes relied crucially on institutionalisation of personal membership and on secrecy.

Within these regimes, science/policy boundaries had a specific form. In court-like regulatory regimes, the boundary between science and policy is ambivalent. The ambivalence of the traditional English regulatory regimes consisted of a discrepancy between the public discourse that the members of the regime used and its actual pragmatic practice and diffuse expert/policy maker roles. The official discourse stressed, time and time again, the sharp distinction between ‘science’ and ‘politics’. In practice, the division of labour between experts and policy makers, between Ministries and laboratories, between government and industry, between expert and industrial representative, was far fuzzier. Career switches between a position as regulated and as a regulator were possible and in some cases, such as with Her Majesty’s Inspectorate of Pollution, even encouraged. Whereas, in public, the discourse of the sharp distinction between science and politics was maintained, the discourses within the court mingled and blurred the two under the motto of reasonableness.

Towards the end of the eighties, this state of affairs started to shift, but only very gradually. In the case of water regulation, some data on water quality and licenses was made publicly available very hesitantly. Stricter enforcement of environmental standards only started after the arrival of the NRA in the early nineties (with legal action and the very slow move towards statutory water quality objectives). In the case of pesticides, higher public availability of regulatory data gradually started after 1986, but, here too, practices of negotiation over the details of assessment remained informal and undisclosed. In terms of the format of expertise, the renewed regime for industrial chemicals that took shape after 1993 was the most diverging, using more formalised assessment methodologies, and involving non-traditional

\[135\] Cf. Wynne and Crouch, “United Kingdom”.
sources of expertise. Nevertheless, here too, negotiation with industry over methodology was a key element of the design of assessment procedures.

At least three major reasons can be indicated for these changes. Firstly, there was the continued pressure from the environmental movement, challenging regulatory decisions as well as trying to get structural access to regulatory information. Secondly, the neo-liberal conceptions of the conservative Thatcher governments had unexpected effects on the court structure of regimes. Especially in the second phase of Thatcherism, where emphasis was put on privatisation rather than the creation of a monetarist utopia, models of market competition undermined the exclusivity of regulatory expertise. This occurred in two ways. On the one hand, the traditional court laboratories were privatised and forced to look for other clients. Regulators were urged to go for the best bid, rather than the traditional court source of expertise. Nevertheless, the traditional ties proved strong and the preferred relations to a large extent survived, especially from the regulators' point of view – modest contractor differentiation did occur from the point of view of the laboratories.

The privatisation of former public agencies required the availability of regulatory information to potential buyers. However, as soon as the privatisation had taken place, information was quickly considered confidential again, now defined as commercially sensitive. Also, neo-liberal conceptions of government's role in markets abhorred the idea of informal consultation of regulated industries by inspectors, because that was seen as unfair competition to commercial consultants. The unexpected effects of Thatcherite changes on the court-like regulation therefore did not lead to its abolishment. After the changes, a new court elite took over, one with a similar code of secrecy: the client confidentiality of consulting firms.

A third major reason for the changes was the increasing importance of the European Union. The European Union and especially a number of Directives from the European Commission provided leverage for more delegitimation of English regulatory courts and even provided some very modest legal means to base it on. This was not because the regulatory approach of the European Commission in environmental affairs was so different from the English one. On the contrary, it too had strong court-like characteristics, but it did provide more formal modes of environmental standard setting. These more formal approaches were based on continental traditions that ultimately pushed English negotiated or voluntary schemes aside. Also, regulatory competition between EU members and the demand for mutual guarantees of harmonised assessment produced more formalisation. In terms of methodology, European regulatory initiatives, such as the new chemicals programme, tried to use the eco/toxicity methodology of the OECD, developed with a lot of American input. As regards research
perspectives, European research policies provided resources from which regulatory interests of scientists outside the court could be built.

The court-like regulatory regimes had a preference for expertise that was pragmatic, reasonable, flexible. In eco/toxicological this meant especially: attention for local environmental conditions, variability of the environment, its carrying capacity, as well as the peculiarities of individual chemicals. Highly standardised knowledge did not fit these regulatory regimes. They risked disrupting the pragmatic negotiation processes with their attention for contingencies. As these regimes became more formal in their regulatory decision making, they also started to support more formalised assessment methodology, although the attention for the local environment and environmental contingencies remained. Unlike in the US, there was no push for standardisation of eco/toxicity testing that pushed non-standardised forms of knowledge out. In addition, ecological knowledge was part of regulatory regimes already before the seventies and maintained its position there, especially with the ecological institutes of NERC. When assessment formalised, these ecologists showed that ecology was just as able to develop standardised assessment methodology, with RIVPACS as a prime example.

Although there were boundaries between environmental toxicology and ecology in research in England, they were not as pronounced as in the US. Handbooks and overviews of ecotoxicology, crossing the boundaries that seemed so sharp in the US, attempted to integrate both fields.\(^\text{136}\) Industry, regulatory decision makers, as well as scientists had more interest in ecological ways to assess pollution and in putting that knowledge to regulatory use. The more crucial boundary was the boundary between who could and could not participate in the regulatory regimes. Nevertheless, the influence of the sharper boundaries between ecology and environmental toxicology of the US had its effect, especially through the fact that more research from environmental toxicology was available, as well as through the more intense development of single species testing produced by investments of American regulatory regimes.

\(^{136}\) Moriarty, “Toxic Pollutants in Aquatic and Terrestrial Ecosystems”; Moriarty, Ecotoxicology; Calow, ed., Handbook of Ecotoxicology; and even Pascoe and Edwards, “Single Species Toxicity Testing”, in spite of its title also dealing with multispecies testing.
3 The Netherlands

3.1 A constrained consensus

As with England, a contrasting analysis of the boundaries of regulatory science in the Netherlands could start with a stereotype. We could call the typical format of Dutch regulatory regimes a ‘constrained consensus’. In Dutch regulatory regimes there is a stronger tradition to include a wider range of actors, both expert and lay, than in the English ‘court’. Access to the policy process is generally easier, more regulatory information is publicly available, and policy makers generally adhere more value to the generation of broad political support. This is the ‘consensus’ bit of the stereotype, the part that corresponds best to the self-image of Dutch regulatory politics. However, these elements of consensus politics are constrained: access to the policy process is not without threshold, extensive use is made of expertise to pre-structure the scope and definition of regulatory issues, regulatory expertise tends to be constrained by the discourses developed in expert advisory organisations, and there are also preferred positions of research institutes in policy advice.\(^{37}\) The stereotypical Dutch ‘consensus politics’ is thus not a general consensus, but a consensus built in a pre-structured arena, through the exclusion of outliers, following traditions of corporatist policy making. In contrast to the English ‘court’, participation in the construction of policy is often formally guaranteed, for example with statutory obligations to consult advisory bodies during policy making. Access to the policy process for a new actor relies less on co-optation by a core elite and more on the mobilisation of sufficient resources to actually claim a position at one of the many negotiation tables, possibly even with legal guarantees of consultation.

As with the ‘court’ stereotype of English regulatory regimes, this crude model of regulatory politics has its limitations. I will use it as a temporary tool to offset Dutch regulatory regimes against England and the US, and to show change in these regimes over time. I will focus on a few key examples of developments in regulatory regimes, once again while paying specific attention to the way boundaries are drawn and institutionalised. Hence these core questions: What were different patterns of integration of regulatory science and politics in the Netherlands? What specific boundary devices were used? How did these change over time and what was the relation with the developments of boundaries in eco/toxicology?

3.2 Pesticides

3.2.1 Before 1975

The legal basis for the regulatory regime for environmental hazards of pesticides in the Netherlands was created with the Pesticides Law (Bestrijdingsmiddelenwet) of 1962. Until a major revision of the law in 1975, it formed the legal cornerstone of the regime. At the heart of the law lay the principle that no pesticide should be sold or used without a product permit. For the first time, the hazards of pesticides as such were to be judged, not just their efficacy or the consequences of irresponsible use of pesticides. The hazards to the environment mentioned in the law were:

The damage of the production capacity of the soil, of plants or parts of plants, or of animals of which the protection is desirable, if this damage is out of proportion with respect to the intended goal of the use of the pesticide.138

Although the statement of hazardous impacts was rather vague and did not specify any criteria for judging what ‘out of proportion’ meant, it did form the basis for the first bans of pesticides considered hazardous to wildlife (rather than to the health of agricultural workers, consumers, or agricultural productivity). Between 1966 and 1970, permits for specific uses of a handful of organochlorine pesticides were withdrawn due to wildlife hazards. For example, uses of aldrin, dieldrin and heptachlor as seed dressing were restricted because of mortality among birds.139

A closer look at how the case for these early bans was put together reveals how environmental expertise was organised in this early phase of the regulatory regime. Although the law was passed in 1962, apparently systematic evaluation of pesticides only started in 1966. A small Pesticides Bureau (three scientists and four administrative personnel) was set up under the (then) Ministries of Agriculture and Fisheries and of Social Affairs and Health to handle applications and to provide executive assistance in pesticide policy. Actual licensing decisions were made by the department of agriculture for agricultural pesticides and the department of social affairs and health for others. The technical evaluation of applications was handled by the Plant Protection Service (Plantenziekttekundige Dienst) at the agricultural college of

138 Quoted in Vogelezang-Stoute et al., De Toelating van Bestrijdingsmiddelen, p. 19, see there for extended discussion of the law.

139 The bans were not complete: use of these pesticides for seeds of some crops, like beets, was still allowed. See Ministerie van Soziale Zaken en Volksgezondheid, Verslag van de Werkzaamheden van het Bureau Bestrijdingsmiddelen Gedurende de Periode 1 Januari 1966 - 1 Augustus 1970.
Wageningen, although other research institutes could be consulted if the Bureau considered it appropriate.\(^{140}\)

The screening of pesticides with respect to hazards to wildlife was minimal in this early phase. The screening in Wageningen focused on efficacy of the pesticide, which traditionally was the speciality of the Plant Protection Service: to treat and protect agricultural crops. Hazardous effects of organochlorine pesticides to wildlife were actually pointed out by an entirely different group of scientists. In 1965, the ‘Committee on Side-Effects of Pesticides’ (Commissie Nevenwerkingen Bestrijdingsmiddelen, CNB) was installed in TNO, the Dutch organisation for applied research. The committee had originated as a small group of concerned biologists, meeting to discuss books like *Silent Spring* and eventually to debate what they could do about pesticide hazards in their individual professional contexts. By the time the group became a TNO committee, its members were biologists working in government, universities, and industry. The status of a TNO committee provided more stature, as well as a way to administer the small budget for research that TNO provided to the group.\(^{141}\) It was this informal group of scientists that built up a dossier on organochlorine pesticides, eventually using members’ contacts in the ministry of agriculture to successfully argue for regulatory action, and to obtain partial voluntary withdrawal of a pesticide by its manufacturer.\(^{142}\)

The approach of these scientists was very similar to the approach of the researchers at the Nature Conservancy in England in the same time frame, both in terms of research methods and in terms of political action. Like the Monks Woods researchers, the CNB scientists focused on analysis of wildlife victims of pesticides and tried to establish causes of death, using the latest techniques of analytic chemistry. As with Monks Wood, the disciplinary composition of the CNB was varied. Although predominantly biologists, the CNB counted members of research institutes in public health, toxicology, as well as ecological research institutes, both from government and universities. Also similar to Monks Wood, the regulatory action was based on informal contacts and included voluntary cooperation with industry in exchanging information as well as in discussion of hazard reduction (although leading to a formal ban). As such, the CNB was not an exceptional structure for the regulation of pesticides at the time. A very similar informal committee operated with respect to human health effects, also organised on an informal

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\(^{142}\) Interview with Koeman, Wageningen, University of Wageningen 1991.
Contrasting patterns in regulatory regimes

basis, outside of pesticide legislation, and relying heavily on personal contacts in government. One major difference with the original English Pesticides Precaution Scheme was that ministries did have the authority to come to legal bans, but apparently negotiation with pesticide producers was extensive.\textsuperscript{143}

As in England, this type of advisory structure relied heavily on its status of ‘being scientific’ by guarding its personal boundaries: reasonable people, with the exclusion of ‘unscientific’, ‘over-zealous’ advocacy experts. Disciplinary boundaries between environmental toxicologists or ecologists did not affect membership, nor access to regulatory decision making. Different from the regulatory expertise in England, was that the sources of expertise were not restricted to a small circle of research institutes. Here we see the first sign of a tendency that will recur time and time again in the Netherlands: a stress on coordination of research, on cooperation between a wider range of research institutes.\textsuperscript{144}

3.2.2 A new law
Starting in 1970, there had been calls for new pesticides legislation that would pay more attention to environmental hazards of pesticides.\textsuperscript{145} In 1975 the Pesticide Law was modified, implementing more structured registration of pesticides, at the initiative of the Ministry of Agriculture and Fisheries. The Ministry wanted to keep the initiative in light of the growing importance of the department of the environment, at the time still part of the Ministry of Health and Environment.\textsuperscript{146} The law was presented as a better regulatory tool, specifically for the purpose of environmental protection. The environmental hazards to be considered for permitting pesticides were now defined slightly more precisely, as article 3 specified:

d. damage to the production capacity of the soil
e. damage to soil, water or air, animals, plants or parts of plants of which the protection is desirable, to a degree that is not acceptable.\textsuperscript{147}

\textsuperscript{143} The Commissie Phytofarmacie, see Groenewegen, “Attracting Audiences”, p. 311. There were close personal contacts and cooperation between both committees. (TNO, Milieuonderzoek in Nederland)

\textsuperscript{144} A full list of research institutes involved in Groenewegen, “Attracting Audiences”, p. 328 n.45. Groenewegen stressed the importance of the CNB for the later development of environmental toxicology in the Netherlands as a means of ‘attracting audiences’. Among eco/toxicologists, its research provided paradigmatic examples of organochlorine biomagnification. (E.g. Fuchs, Ma, and Smies, “Bioaccumulatie van Milieucontaminanten”, pp. 75-76)

\textsuperscript{145} Bal, Aquaplaning, p. 45.

\textsuperscript{146} I.e. the Directorate of Environmental Hygiene at that time, see: De Koning, In Dienst van het Milieu, pp. 60-62.

\textsuperscript{147} Voegelezang-Stoute et al., De Toelating van Bestrijdingsmiddelen, p. 21 et seq.
However, in spite of rhetoric, this definition of hazard barely added anything from the point of view of wildlife protection. Like its predecessor, the law did not specify what exactly was to be considered ‘damage’, nor what ‘a degree not acceptable’ meant. In fact, the early restrictions of organochlorine pesticides showed that regulatory action against pesticides specifically on the basis of wildlife effects was already possible before 1975.

The inclusion of wildlife effects in the old law had been confirmed by in an appeal case over acrolein, a pesticide used in cooling installations. Pesticide regulation had a particular appeals procedure: only directly interested parties (i.e. pesticide producers and users) could appeal against regulatory decisions on pesticides, similar to English pesticide regulations after it became statutory. Appeals were made to the appeals court for trade and industry (College van Beroep voor het Bedrijfsleven). In the acrolein appeal of 1975, just before the new law was passed, part of the appeals court’s ruling indicated that pesticide permits could indeed be withdrawn on the basis of hazardous effects to aquatic life, declining the appeal by its producer. Nevertheless, wildlife effects were not a major ground for regulatory action. Throughout the eighties, wildlife hazards remained a minor consideration in pesticide permitting. As regards the appeals procedure, between the first appeal of 1973 and the wave of accelerated environmental policy in 1988, there were only 13 cases.148 Apparently, users and producers of pesticides either did not have major qualms with regulatory action, or objections were addressed outside of the courtroom.

After 1975, a very slow formalisation process started, gradually defining environmental hazards more specifically. It is not easy to establish this, because of the high levels of secrecy around pesticide regulations. Some formalisation occurred in at least three ways. Firstly, we know that guidelines were developed for the evaluation procedure. For example, by 1981, with a delay of six or seven years, a new form was introduced for the registration of pesticides. The form, to be filed by the applicant registering a pesticide, now explicitly requested data on toxicity to birds, to aquatic life, and insects, on soil effects, mutagenicity, carcinogenicity, and bioaccumulation. However, only a limited set of acute aquatic data were formally required; the others were only required ‘if considered relevant’ or if the regulatory authority asked for such data.149 Although incomplete forms could be a reason to refuse registration, in practice incomplete forms were accepted for evaluation. In addition to the form, a handbook for pesticide evaluation was developed,

148 De Roo, Bestrijdingsmiddelen in Nederland; Vogelezang-Stoute et al., De Toelating van Bestrijdingsmiddelen, on acrolein see p.19-20, list of appeals in app.
149 Explained in the ‘clarification’ to the form that the CTB made available. (Könemann, “Ecotoxiciteitsonderzoek en Milieubeleid”)
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probably towards the end of the eighties. This handbook was somewhat mysterious, since, under the secrecy rules of pesticide regulation, the handbook was not made public at the time.\textsuperscript{150} In fact, not much was made public at all, as pesticide regulation was largely exempt from the legislation that otherwise grants Dutch citizens a high degree of access to government documents. The only information publicly available on individual pesticides were withdrawals of registrations.\textsuperscript{151}

Secondly, even though there were only few appeals from industry, some of these cases did serve to define what could and could not be considered adversary effects. In one case of appeal, the court ruled that the mere persistence of ICI's herbicide paraquat could not be a ground to withdraw the license, arguing that there was no proof of adverse effects, even in the long run.\textsuperscript{152} In spite of policy intentions, this blocked pesticide restriction on the grounds of persistence only, until formal criteria for persistence with legal power were issued in 1995.\textsuperscript{153}

\textsuperscript{150} Vogezezang-Stoute \textit{et al.}, \textit{De Toelating van Bestrijdingsmiddelen}, pp. 53 et seq., 230, form in its appendix.

\textsuperscript{151} Only final decisions on pesticides were published. The CTB only started publishing (very general) annual reports of its activities in 1990 (over the year 1988/1989). (Vogezezang-Stoute \textit{et al.}, \textit{De Toelating van Bestrijdingsmiddelen}, pp. 2, n.3)

\textsuperscript{152} College van Beroep Bedrijfsleven, 2 mei 1989, nr. 86/0172/60/029, zie Vogezezang-Stoute \textit{et al.}, \textit{De Toelating van Bestrijdingsmiddelen}, p. 23. Paraquat is a potent defoliant, used to clear weeds, but allegedly also used to spray drug plantations in Columbia and South Africa. It is highly toxic to mammals, but not very toxic to aquatic animals, since aquatic plants tend to absorb it. Because of its high toxicity, paraquat was on the Pesticide Action Network's 'dirty dozen' priority list. (Leikin and Paloucek, \textit{Poisoning & Toxicology Handbook}; Pesticide Action Network North America, \textit{PANNA Website}) In the background of this issue was resistance in industry over a specific sediment degradation test that had been developed at the Institute for Pesticide Research (IOB) in Wageningen: a test that was used for regulatory purposes only in the Netherlands. Industry objected on the grounds that the test was under-developed, requiring extra regulatory research costs for a test that was only used in the Netherlands. (Smies \textit{et al.}, "Milieutoxicologe in de Chemische Industrie", p. 89)

\textsuperscript{153} Persistence had criteria had been defined in the \textit{Persistentienota} of 1986, further defined in \textit{Nota Milieucriteria} of 1988, but these were only policy documents and lacked legal power, see Vogezezang-Stoute \textit{et al.}, \textit{De Toelating van Bestrijdingsmiddelen}, pp. 92-3; Tweede Kamer, \textit{Indicatief Meerjarenprogramma Milieubeheer}, 1987-1990, pp. 90-93. The deadlock was broken with the \textit{Besluit Milieutoelatingseisen Bestrijdingsmiddelen}, 23 January 1995. (Once again, delayed by about a year: this ministerial decision providing the legal power for the environmental standards was announced for early 1994.) (Tweede Kamer, \textit{Milieuprogramma 1994-1997}, p. 23)
Thirdly, the administrative procedure for pesticide assessment became more organised. After 1980, only civil servants were members of the Committee of Pesticide Permits (Commissie Toelating Bestrijdingsmiddelen, CTB) which prepared decisions on pesticides’ regulatory status. Although, theoretically, decisions were still made by the Minister, the CTB advice was normally followed. To reach its conclusion, the Committee relied on an advisory structure of committees and workgroups constituted of members of government research institutes. Prior to 1980, water companies had been represented. After 1981, the informal groups of environmental experts were replaced entirely by government scientists, although the CTB was not formally restricted to consult only these scientists. Once again, the secrecy of regulation at the time makes it difficult to reconstruct the details. By 1990, the advisory group preparing pesticide assessment dossiers from an environmental point of view, consisted of five members from three laboratories of the Ministry of Agriculture and Fisheries, one from a laboratory of the Ministry of Traffic and Water, and three from the RIVM, the institute closely associated with the department of the environment.\(^{154}\)

In addition to decisions on individual products, the CTB also gave instructions to their experts as to which data should be collected and how these should be evaluated. For example, after the introduction of the registration form, a set of ‘minimum required data’ was developed. Although this set was used informally in the workgroups, it was never officially implemented, because of opposition from the ministry of Social Affairs, represented in the CTB. Thus, even though there was some attempt to define what constituted a hazard and how it was to be evaluated, even the technical aspects of pesticides evaluation were not a matter of set procedures that were to implemented systematically, as with US pesticide regulation at the time. Procedures were a matter of negotiation, while the representation of the various points of view stretched to ministries mobilising ‘their’ research institutes. In this arrangement, there was no sharp demarcation of science and politics. As Vogelezang concludes:

The evaluations of the working groups can, given their composition, not be considered to be ‘expert judgement’, as some suggest. It would be better to speak of ‘government judgement’.\(^{155}\)

\(^{154}\) Research institutes represented were: Plantenziektekundige Dienst, Voedings-en Kwaliteitsaangelegenheden, Instituut voor Onderzoek van Bestrijdingsmiddelen, Centrum voor Agrobiologisch Onderzoek, Dienst Binnenwateren/RIZA, RIVM. (Vogelezang-Stout et al., De Toelating van Bestrijdingsmiddelen, p. 369, Appendix 8.4.2)

\(^{155}\) Vogelezang-Stoute et al., De Toelating van Bestrijdingsmiddelen, p. 55.
Thus, the formalisation of pesticide evaluation during the 1980s was only very gradual, resembling more the gradual shifts in pesticide regulation in England than in the US. Apparently, there was extensive negotiation between regulators and registrants over the acceptability of data, over the provision of data, and over the final regulatory status of pesticide products. This extended to the technical details of regulation. For example, although there was a system of GLP certification in the eighties, it was not entirely clear whether GLP certification was an effective prerequisite for submitted pesticide data.\(^{156}\)

This limited formalisation had consequences for how eco/toxicological knowledge could be included in the regime. According to one of the eco/toxicologists involved in the CNB, the formalisation of assessment criteria sometimes made it harder to evaluate environmental effects of pesticides, since effects that were not explicit criteria could not be used in the evaluations.\(^{157}\) The problems with the inability to regulate on the grounds of mere persistence are an example of this limitation.

We should not over-estimate the consequences for the possibility to include eco/toxicological knowledge. From an extensive study of pesticide licensing by Vogezezang et al. of 1990, we know that eco/toxicological effects of pesticides did not play a major role in assessment practice in the first place during the seventies and eighties. An analysis of six pesticides showed that such data were either very limited or that, when available, clear indications of environmental hazard had apparently not led to restrictions. In addition, information on higher-level ecological effects was practically absent.\(^{158}\)

Nevertheless, the limited formalisation of pesticide assessment during the eighties was not of such an extent that it caused systematic exclusion of multispecies data such as it occurred in the US. We do know from the previous chapters that for several pesticides of regulatory concern such data were available, since they were submitted to regulatory authorities in the US and England. We also know that there was an active interest in multispecies research in the Netherlands, including in laboratories of pesticide producers and at government agricultural research institutes involved in regulatory assessment. (Although mainly for the purpose of single species validation and research on the operation of pesticide effects: extrapolation of single species results was defended as an acceptable way to establish safe levels, even if accurate prediction of ecosystem level effects was problematic.)\(^{159}\)

\(^{156}\) De Roo, Bestrijdingsmiddelen in Nederland, p. 9; Vogezezang-Stoute et al., De Toelating van Bestrijdingsmiddelen, pp. 103 et seq., 85; versus Kônemann, "Ecotoxiciteitsonderzoek en Milieubeleid", p. 90.

\(^{157}\) Interview with Koeman, Wageningen, University of Wageningen 1991.

\(^{158}\) Vogezezang-Stoute et al., De Toelating van Bestrijdingsmiddelen.

\(^{159}\) E.g. the experimental streams at Renkum of SC-DLO, which were built specifically with the purpose of evaluating single species tests in for pesticide assessment. The streams were built in 1987 and research was partly funded by the
After 1990, the Ministry of Agriculture and Fisheries wanted to explore further the possibility of using multi-species tests in pesticide assessment and develop some guidelines for the performance of such tests. The efforts were met with opposition from other ministries, especially Environment (VROM). The sentiment among VROM civil servants was that multispecies test results would only be used in order to try to lower norms and that the 'straight-forward' results of single species tests were clear and strict, avoiding the risk of stalling tactics. However, by then, as we shall see below, European developments were beginning to take over.

On the whole, the CTB constituted a platform where interests of agriculture, health, social affairs, and environment were played out against each other, each represented by the ministries involved. Agriculture was represented more heavily in the CTB as well its advisory groups, at least until 1990 when each of the four participating ministries had only one representative on the Committee. As a consequence of this configuration, regulatory action was stalled frequently, with considerable implementation delays and recurrent use of exemptions and extensions of exemptions. Towards the end of the eighties, surface and drinking water regulatory authorities argued that pesticide regulation was too lax, based on water quality monitoring data provided by research institutes in their sector. Although reduction of pesticide use had been the official government policy since 1983, the licensing scheme did not seem suited to obtain such targets (and in fact even obstructed more ambitious environmental policy). Water pollution

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interdepartmental Stimulation Action Toxicological Research (see Chapter 4), with university researchers as well as institutes represented in the pesticide assessment scheme. (Leeuwangh, "Proefslotencomplex te Renkum"; Leeuwangh, "Het Voorspellen van Milieu-Effecten van Chemische Stoffen op Grond van Toxiciteitsonderzoek in het Laboratorium").


161 Vogelezang-Stoute et al., De Toelating van Bestrijdingsmiddelen, pp. 25, 67. In addition to this departmental representation, there was a formal obligation of consultation with a Pesticides Committee over changes in general pesticide regulation policy. In this committee, various interest groups were represented, including environmental organisations. However, the committee rarely met and rather than to come to one integrated advice, it tended to reproduce the positions of its members. In 1987, ministries involved in the pesticide regulation suggested to replace the committee with consultation with individual representatives at ministries' initiative. (Vogelezang-Stoute et al., De Toelating van Bestrijdingsmiddelen, p. 46) In 1992, its members were Nefyto (association of pesticide producers), the Landbouwschap (the corporatist organisation of the agricultural sector), and environmental group Natuur en Milieu. (De Roo, Bestrijdingsmiddelen in Nederland, p. 24)
control was faced with targets it could not meet through control of ‘point source’ discharges, as the ‘non-point sources’ of pesticide use were out of their control. In addition, from a legal point of view, the Pesticides Law had precedence over legislation on water pollution and industrial chemicals.\(^{162}\)

3.2.3 Increasing tensions

From 1987 onward, the department of the environment started to put more pressure on pesticide registration policy, attempting to withdraw registrations, end chronically extended exemptions, speed up re-evaluation of old pesticides, and implement stricter environmental criteria.\(^{163}\) Some result was noticeable in the appeals record: after 1988, the number of appeals rose, from approximately one per year up to five or six per year.\(^{164}\) The pressure resulted in various new policy plans that specified new targets for pesticide policy, as well as more detailed criteria. The most promising document was the multi-year pesticide reduction plan (*Meerjarenplan Gewasbeschermingsmiddelen*), which the department of agriculture had started to prepare in 1987.\(^{165}\) In 1989, the departments of agriculture and environment together proposed stricter criteria for pesticides in groundwater, as part of the more restrictive licensing policy of the multi-year plan, under the pressure of strict European drinking water criteria. The intentions resulted in major objections from the agricultural and pesticide sectors and an alerted Parliament.\(^{166}\) By the time the final multi-year plan was presented to Parliament in 1990, it included targets for reduction of pesticide use. Also, it suggested a stricter permitting policy based on more explicit eco/toxicity criteria, using lowest LC50 for fish, algae and daphnids with a safety factor 10. Since a safety factor for algae and

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\(^{162}\) For example: the analysis of pesticide bentazon in Amsterdam drinking water in 1988, caused by discharges by producer BASF in the Rhine (‘bentazon affair’), or high levels of pesticides in surface water in the Westland, with intensive greenhouse agriculture and horticulture. (Vogelezang-Stoute *et al.*, *De Toelating van Bestrijdingsmiddelen*, pp. 3, 7; Bal, *Aquaplanning*, pp. 13-14)


\(^{164}\) Vogelezang-Stoute *et al.*, *De Toelating van Bestrijdingsmiddelen*, pp. 377-79.

\(^{165}\) Ministerie van Landbouw en Visserij, *Naar een Taakstellend Meerjarenplan voor de Gewasbescherming*. This original version focused almost entirely on improved use of (less hazardous) pesticides, prevention of infections, and more research into increased research, rather than regulatory approaches. For an extensive analysis of the plan, see: Schreurs and Grin, *Gewasmiddelen en Beleid*.

\(^{166}\) When the criteria were proposed to Parliament, its members responded with 95 questions. (Centrale Raad voor de Milieuhygiëne, *Milieu van Jaar tot Jaar: 1989*, p. 99; Bal, *Aquaplanning*, pp. 54,55)
daphnids of 10 would rule out 40% of then permitted pesticides, introduction of this safety factor was postponed until 1995.167

The criteria in the plan were a political compromise. VROM had wanted to include sharper criteria, especially for persistence.168 However, even these compromise proposals met with considerable problems in the implementation phase of the policy plan. The inclusion of the strict European norm for pesticides in drinking water did not survive an appeal case over atrazine in 1992. The environmental movement argued that the multi-year plan was considerably watered down in its implementation, which was given form in a negotiated agreement with industry and agriculture.169

With the increased attention for environmental effects of pesticides also came a shift in the expert base used for pesticide assessment. While the evaluation of environmental effects had remained underdeveloped throughout the eighties, VROM had developed assessment methodology, especially via the RIVM. As environmental assessment was developed more, so also did the RIVM’s role in pesticide assessment increase. For example, in 1990, the RIVM set up a re-assessment project of already registered pesticides.170 The role of the RIVM would gradually expand until it eventually was the main address for the initial processing of the eco/toxicity data in the registration dossier.

As a result of increased tension, the regulatory regime for pesticides went through major changes after 1993. In attempts to break through the slow interdepartmental negotiations, the management of pesticide licensing was radically reorganised, in anticipation of another change of the Pesticides Law (passed in 1994) and as part of a government-wide attempt to improve administrative efficiency, at the initiative of Parliament.171 Instead of the Committee of civil servants, a new Board of Pesticide Permits was installed: a group of four independent experts, chaired by Jan Koeman (see Chapter 4). These experts would implement pesticide registration policy as developed by

167 Or half of approximately 300 registered active ingredients. (Tweede Kamer, Milieuprogramma 1993-1996, p. 19; Vogelezang-Stoute et al., De Toelating van Bestrijdingsmiddelen, p. 61). The environmental movement later claimed that the safety factors actually employed by the CTB were more lenient by a factor 100, see Reijnders et al., Zwartboek Toelating Bestrijdingsmiddelen.
168 De Roo, Bestrijdingsmiddelen in Nederland, p. 16.
169 De Roo, Bestrijdingsmiddelen in Nederland, pp. 17-20; Velders, “Dossier Landbouw: Toelatingsbeleid is Zeer Divers”.
170 Vogelezang-Stoute et al., De Toelating van Bestrijdingsmiddelen, p. 4.
171 Van Aartsen, Brief aan Tweede Kamer Inzake Evaluatie CTB; Projektgroep Evaluatie toelating Bestrijdingsmiddelen, Evaluatie van de Uitvoering van het Toelatingsbeleid.
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the ministries, with a mandate to license pesticides. In effect, this construction intended to delegate the implementation of pesticide registration to a committee of experts, assisted by the advisory structure of government research institutes. Meanwhile, the ministries continued to negotiate and define general pesticide registration policy. Although this now involved a clearer division of labour between the role of political institutions and experts, this division was not organised on the basis of science-versus-politics: as part of the implementation of policy, these experts were explicitly expected to balance agricultural and environmental interests, a role acknowledged by the new CTB’s chairman. This division was not the mobilisation of ‘science’ to constrain political conflict, but the mobilisation of scientists as part of an attempt to deport interdepartmental conflicts over regulatory implementation to a politically expedient distance.

By November 1993, the appeals procedure was altered, now to allow third parties to challenge regulatory decisions. Within a year and a half, environmental movements started procedures challenging the permits for sixteen pesticides. In addition, more information was made available about the pesticide evaluation procedures and about the activities of the CTB, although information on the details of evaluations of individual pesticides was still very limited. For its expertise, the CTB initially remained highly dependent on research institutes, but its in-house expert staff expanded gradually, until it could rely on its own risk assessors. This did not go without some tension, as the research centres previously involved in regulation complained about lack of consultation and in one case even of being avoided. Instead of the former more or less guaranteed position in evaluation, the new CTB now consulted these institutes on the basis of invitation.

Further formalisation of the assessment procedure occurred in the wake of the European ‘Uniform Principles’, an assessment procedure that was to harmonise pesticide evaluations in Europe. Legal implementation in the Netherlands occurred via the Pesticides Approval Decree of 1995, with more strict safety factors than had been proposed for the multi-year plan (but with

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173 Reijnders et al., Zwartboek Toelating Bestrijdingsmiddelen.
174 RIZA, the research institute that the department of water relied on, in the case of pesticides regulation especially for monitoring of pesticides in surface water. (Projektgroep Evaluatie toelating Bestrijdingsmiddelen, Evaluatie van de Uitvoering van het Toelatingsbeleid, p. 57; College voor de Toelating van Bestrijdingsmiddelen, Website CTB)
175 Hof, Hofman, and Gortzak, De Belissingsprocedure Rondom de Toelating van Bestrijdingsmiddelen.
exemptions in the application of these criteria until 2000). Following this scheme, the Dutch environmental hazard evaluation process was based on aquatic acute toxicity tests, with the option for registrants to defend their case with further research where acute norms would be exceeded (as compared to predicted environmental concentrations). As far as toxicity was concerned, this included multispecies tests that were to be evaluated case-by-case by expert judgement. More recent documents explain the procedure for this evaluation: protocols were to be based on the SETAC mesocosm protocol, but the experimental protocol was to be discussed with the CTB before tests were performed. Compared to American assessment documents, the EC guidelines relied more heavily on expert judgement. For example, several of the additional testing prescriptions were listed as ‘in as far as relevant’, or ‘after consultation of experts’. For acute toxicity tests, EC guidelines prescribed protocols of various sources, among which the OECD standard tests that were developed since the mid-eighties, or the EC’s own ecotoxicity methods, or even methods developed by SETAC. In the case of multispecies tests, the EC directive specified that prior consultation over the design of the test was required specifically to establish the precise purpose of the test. What is remarkable about these tests and test protocols, is that they operated successfully without the extensive expert consensus building required by, for example, the ASTM (see chapter 5). The SETAC mesocosm was developed at a SETAC workshop. OECD protocols were developed from the late seventies onward on the basis of national expert representatives.

Thus, through European directives, more specific guidelines for pesticide evaluation were introduced in the Netherlands, including the explicit possibility of using mesocosm data, in spite of continued objections from the Ministry of the Environment and the Ministry of Transport and Water. These Ministries wanted a stricter set of criteria for pesticide evaluation. They argued that multispecies tests went in the opposite direction and that there was ‘international discussion’ over their use. The new procedures were

176 Directive 91/414/EEC, with several modifications in the following years. (Tweede Kamer, Milieuprogramma 1995-1998, pp. 17-22; Projektgroep Evaluatie toelating Bestrijdingsmiddelen, Evaluatie van de Uitvoering van het Toelatingsbeleid; Reijnders et al., Zwartboek Toelating Bestrijdingsmiddelen, pp. 27-28. The European implementation of the Uniform principles was extremely problematic. They were later withdrawn after a court case at the initiative of the European Parliament, leading to an extended process of renegotiation.

177 European Community, “Directive 91/414/EEC”. One of the mesocosm guidelines suggested was taken over by the CTB: Crossland et al., European Workshop on Freshwater Field Tests.

178 Projektgroep Evaluatie toelating Bestrijdingsmiddelen, Evaluatie van de Uitvoering van het Toelatingsbeleid, p. 31) One of the major criticisms against the CTB at the evaluation of its position as a mandated regulatory authority, was its
documented in a new version of the pesticide evaluation handbook, as well as in instruction notes that were made available with the pesticide registration form, but this documentation was made publicly available only after 1998.\textsuperscript{179}

Throughout the nineties, pesticide regulation remained a conflict-ridden area of policy, with high levels of resistance against implementation of environmental standards from agriculture, expressed via the department of agriculture, the media, Parliament, and the appeals procedure. Opposition against stricter regulation continued to be accommodated with exemptions for restricted pesticide products, leading to more campaigning by environmental movements, especially around the first mid-term evaluation of the multi-year plan in 1995, as they argued that the targets of the plan were not met. In their opinion, the licensing policy continued to postpone strict regulation and failed to enforce the restrictions it had issued.\textsuperscript{180} Meanwhile, the CTB’s position as liberal use of its discretionary powers in designing evaluation procedures. Whereas the CTB, the department of agriculture, and industry seemed pleased with the independence and degree of informality, environmentalists and the left-of-centre fractions in Parliament had hesitations or outright criticism of its functioning. (E.g. Tweede Kamer, Commissie-Overleg LNV met Minister Van Aartsen)

\textsuperscript{179} In 1996, the CTB started a website, where evaluation procedures and annual reports can be consulted. It now also contains a 1999 version of the handbook for evaluations of pesticides, which, together with the guidelines that are issued with the registration form, specifies the role of multispecies tests. By the end of the nineties, one could even get hold of (very concise) overviews of risk evaluations of individual substances, similar to the documents that were issues by the English pesticide regulators towards the end of the eighties. The CTB asked research institutes to summarise data, which in the case of environmental toxicity was usually the RIVM (‘milieufiche’). This information could also be used in the new administrative appeals procedure, involving a member of the CTB and two external members, but the legal procedure remained available as second appeal. However, the summaries of the substantial data offered very few handles for such a challenge. For example, the environmental toxicity data on glyfosate were summarised in approximately one page. (College voor de Toelating van Bestrijdingsmiddelen, Website CTB; Koeman, Boleij, and Verkleij, “Toelatingsbeleid Bestrijdingsmiddelen”; Projektgroep Evaluatie toelating Bestrijdingsmiddelen, Evaluatie van de Uitvoering van het Toelatingsbeleid; Van Oijen, Roos, and Schouten, Glyfosaat in de Landbouw; Hof, Hofman, and Gortzak, De Belissingsprocedure Rondom de Toelating van Bestrijdingsmiddelen)

\textsuperscript{180} Reijnders et al., Zwartboek Toelating Bestrijdingsmiddelen; Muileman and Steekelenburg, eds., De Buik Vol van Gif. Apparently with some ground: continued use of long forbidden pesticides showed up in residue analyses of food, as well as surface water analysis. In 1995, research by RIZA for the Ministry of Transport and Water found organochlorine pesticides in surface water caused by illegal use of endosulfan. On the evaluation and the functioning of the CTB, see Van Aartsen,
an independent regulatory agency was made official in the summer of 1996. Almost immediately after this operation, government revoked some of its decisions to restrict pesticides, invoking the voluntary agreements made between government and industry in the implementation of the multi-year plan. In the summer of 2000, a similar conflict occurred over the ten-year-old plan to phase out the most hazardous pesticides. When the departments of agriculture and environment this time supported the CTB’s implementation of the old deadlines for exemptions, a small majority in Parliament overruled them, after a major political conflict. The majority decided that certain hazardous pesticides could not be missed in agricultural practice and should therefore be given new exemptions. However, we are now far beyond the time frame that was set out for this analysis.

3.2.4 The regime and its shifts

Between 1970 and 1995, the regulatory regime for pesticides in the Netherlands went through some troubled waters, as well as some interesting shifts in structure. Until about 1981, the regulatory regime resembled the regime for pesticides in England, with the major difference of the possibility of formal bans instead of the old voluntary scheme of the PSPS. However, even in the Netherlands, pesticide regulation relied heavily on voluntary cooperation, for example, in negotiations with producers over licensing geared at voluntary withdrawals, or through the recurrent use of exemptions. From the perspective of the use of expertise, the interesting feature is the use of informally organised expertise groups with elitist tendencies: boundaries of science were personalised, but there was little sign of a clear demarcation of

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Brief aan Tweede Kamer Inzake Evaluatie CTB; Schreurs and Grin, Gewasmiddelen en Beleid; Projekgroep Evaluatie toelating Bestrijdingsmiddelen, Evaluatie van de Uitvoering van het Toelatingsbeleid; Volkskrant, Milieubeweging Eist Strenger Beleid tegen Landbouwgif: Daling van Gebruik Bestrijdingsmiddelen is Volgens Organisaties Gezichtsbedrog, 20 May 1996; Volkskrant, Tussen Veel en Weinig Gif, 23 September 1995.

181 Staatscourant, College voor Toelating Bestrijdingsmiddelen op Eigen Benen, 8 July 1996; Volkskrant, Kabinet tegen Strenge Eisen voor Landbouwgif, 15 November 2000.

science and policy. Ecologists as well as pioneering environmental toxicologists participated in this.

In the eighties, pesticide regulation shifted towards a sort of ‘departmental corporatism’, in which departments mobilised expertise of their respective research institutes for decision making dominated by negotiation and strategising rather than development of coherent policy. The regulatory regime did not organise a strict boundary between science and politics, as experts, policy makers and their arguments were never clearly distinguished. The arrangement relied very little on legal action, an avenue only really available to pesticides producers. Once again, there are some parallels with English regulatory regimes in this respect. In both pesticides and water regulation the possibilities for environmental groups to participate in the formal regulatory process in England were also very minimal in the eighties. A key difference was that the balancing of interests of agriculture, protection of health of consumers and workers, and protection of the environment was to be guaranteed by a stronger representation of the respective departments in the Netherlands, bringing in their respective research institutes. Nevertheless, eco/toxicological effects apparently did not play a major role in assessments, but there was some degree of interest in multispecies tests and ecological forms of knowledge, especially from the part of the ministry of agriculture and its research institutes.

With the growing independence of the CTB that was started in 1993, pesticide regulation shifted away from the grip of the departments over the details of regulation. As appeal procedures, both administrative and legal, were opened up to environmental movements, some elements of a more adversarial style were introduced. Nevertheless, the regulatory evaluation was still not organised around a very strict separation of science and politics, as the CTB’s task conception was that of implementation of policy as formulated by the departments. In addition, where political requirements prevailed, the departments still changed the CTB’s decisions over individual pesticides. Later in the nineties, parts of scientific assessment were organised at more of a distance to policy, with initial processing of assessments by research institutes for the CTB and the expansion of the expert staff of the CTB. Some gradual formalisation of assessment procedures set in, making more use of standardised tests, in the wake of attempts to organise pesticide registration on a European level. However, the regulatory regime for pesticides continued to rely heavily on negotiation, both over the restrictions (e.g. the continued bargaining over exemptions) and over the details of testing requirements (e.g. the design of mesocosm tests).

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183 One of the main conclusions of a consultancy report of 1990, with suggestions for CTB reorganisation, see Vogelezang-Stoute et al., De Toelating van Bestrijdingsmiddelen, p. 163.
3.3 Water

3.3.1 The regulation of water pollution in the Netherlands

The management of water resources has a special position in Dutch policy making. Not only is there the obvious importance of water defence for the existence of large parts of the country, reflected in a prominent position of the department of water (Rijkswaterstaat) in the national policy arena, but also the historic process of reclaiming land has given rise to a peculiar system of parallel government in the local water boards (waterschappen). Throughout the twentieth century, these boards were local governmental structures that focused on coastal protection and water level management, organised around tax-based interest representation: those who paid taxes ruled the water boards and since taxes were based on land ownership, this meant that agriculture dominated the water boards. In response to the increasing scale of coastal works as well as the growing complexity of water policy through the arrival of environmental protection, water policy went through a process of concentration. On the one hand, the thousands of water boards in the country were reduced to only approximately one hundred in 1995, when the government of the water boards was expanded to include all its inhabitants with parallel elections. On the other hand, the role of provinces and national government gradually increased, creating a complex governmental array of regulatory actors.

After the implementation of the Surface Water Pollution Act had started in 1970, discharge licensing to local surface water became a responsibility of the provinces, but was gradually delegated to the water boards in most of the country. Water quality in the major rivers remained a national responsibility. Throughout the seventies, standards for discharge permits focused almost entirely on the classic parameters of pollution control, specifically oxygen depletion. This was closely related to the nature of regulatory control: with discharge permits based on a system of levies calculated via a standard measure of pollution of the discharge water, the assessment of the nature of a discharge would have to remain relatively simple, especially given the exclusivity of tools of analytic chemistry at the time.

184 Starting around 1992, elected positions in the water boards were created, usually via elections by municipality council members. In some cases, positions were even reserved for environmental groups. These developments led to a shift to more attention for environmental issues in water management, as environmentalists put forward their own candidates. (Anonymous, “Verkiezingen Vormen Waterschappen Om van Boerenrepublieken naar Moderne Waterbeheerders”; Volkskrant, Revolutie in de Polder, 21 February 2001)

185 See Tweede Kamer, Nationaal Milieubeleidsplan, pp. 258-62.
In the seventies, the range of monitoring data was limited also. The National Institute for Water Purification (Rijksinstituut voor Zuivering van Afvalwater, RIZA)\(^{186}\) had been given the legal task of research and advice on matters related to the Surface Water Pollution Act. In 1972, RIZA constructed two floating monitoring points in the Maas and Rhine, both at the point where the rivers enter the country. Measurement points where more than the most basic parameters could be measured remained limited to approximately a dozen throughout the seventies.

The system of levies was a successful instrument for general reduction of pollution levels caused by oxygen demand,\(^ {187}\) but required a counterpart in standards for a wider range of parameters of pollution. The search for standards by which the quality of surface water could be judged proceeded along two lines: water quality standards developed by national government, mainly in interaction between the department of water and the department of the environment; and policies developed via the water management boards, together with the Executive Committee for the implementation of the Surface Water Pollution Act (Commissie Uitvoering Wet Verontreiniging Oppervlaktewateren, CUWVO).

### 3.3.2 Ecologists and local water

Water quality management by water authorities provided a wide range of employment opportunities for aquatic ecologists, especially for aquatic ecologists interested in structural ecology. On the one hand academic education in ecology was developed to such a level in the Netherlands that it produced trained ecologists with knowledge of aquatic ecosystems. On the other hand aquatic ecologists discovered and defined some of the key problems in water pollution, especially with respect to eutrophication, which dominated the water pollution agenda in the seventies.\(^ {188}\) Based on an ecological frame of understanding of water pollution, water quality managers had started to develop means to assess water quality on the basis of indicators of community structure. Among these indicators were, for example, the ‘saprobic’ and ‘trophic’ indicators for excessive presence of biodegradable substances and nutrients. These indicators were based on ratios of abundance

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\(^{186}\) The meaning of the acronym changed to Rijksinstituut voor Integraal Zoutwaterbeheer en Afvalwaterbehandeling in 1990, as a consequence of reorganisations and policy changes in the department of water. (Rijksinstituut voor Integraal Zoutwaterbeheer en Afvalwaterbehandeling, RIZA Website)

\(^{187}\) And not as effective for heavy metals, see Bressers, Beleidseffectiviteit en Waterkwaliteitsbeleid.

of microflora. Other indicators used involved inventories of macrofauna and -flora, species richness, or indicator species for levels of pollution.189

These methods were produced by the Working Group for Biological Water Evaluation (Werkgroep Biologische Waterbeoordeling, WBW), a group of aquatic biologists and agricultural engineers that met for the first time at the National Institute for Nature Management (Rijksinstituut voor Natuurbeheer, RIN) in 1967. Among its members were academic researchers as well as biologists that worked for some of the large organisations in water quality management, at province level or at the larger water quality boards.190 The department of Hydrobiology of the RIN played a coordinating role. Until the end of the sixties, it had been the only sizeable governmental research institute for hydrobiology. During the seventies, it shifted its research focus from nature conservation to environmental management. Apart from use of field research for the development of ecological indicators of water quality, the department also used micro-ecosystems for experimental research on the effects of herbicides.191 Also member of the committee work biologists working at TNO in Delft (Instituut voor Milieuhygiëne en Gezondheids-techniek), an institute we will meet again soon in the standardisation of aquatic toxicity tests.

From 1972 to 1975, the group had been a member of the Foundation for Biological Research in the Netherlands (BION), as a subsection of aquatic ecology. Apparently, its position there was not a very happy one, as the group left BION altogether in the autumn of 1975. The group had not managed to receive funding for its research projects and experienced a ‘lack of cooperation’ and even ‘intolerance’. Not only did the group not correspond with the academic ambitions of Dutch aquatic ecology at the time, it also operated in a frame of structural ecology, while functional ecology was dominant in BION (see chapter 4).192

The manual the working group produced did not include just methods for establish species ratios, but also techniques for sampling, as well as chemical water analysis. Especially with respect to the ecological indicators, detailed knowledge of aquatic life was assumed. The principle of using species counts (and ratios based on them) was very similar to the counts suggested by John Cairns in the early seventies.193 Whereas John Cairns had tried to produce methods that could be used even by the engineers that

189 Werkgroep Biologische Waterbeoordeling, Biologische Waterbeoordeling.
190 Werkgroep Biologische Waterbeoordeling, Biologische Waterbeoordeling, pp. 1-5.
193 See chapter 4, Cairns and Dickson, “A Simple Method for the Biological Assessment of the Effects of Waste Discharges”.
dominated American water pollution control, these were methods clearly written for the ecologists that worked in Dutch water pollution control, along with the engineers.\textsuperscript{194} An alternative route of ecological involvement in water quality research of water boards was through internships of graduating academic biologists.\textsuperscript{195}

Basically, these methods of water quality evaluation used ecological effects as indicators of pollution, offering an avenue for ecologically defined targets for pollution control, e.g. the return of certain species or the creation of aquatic communities considered rare or valuable. Although these were methods used for assessing water quality, defining targets or standards was less evident. In this respect, the philosophy behind the methods was comparable to the one of the English RIVPACS model; the target was ‘a natural state’ of equivalent unpolluted water. As the manual for biological water quality indicators suggested:

The norm for good biological quality [of water] is the situation as it is supposed to be in this location without pollution or other disturbing influences. Fur this purpose older inventory data can be used or comparative (typological) research. These norms can vary considerably between regions.\textsuperscript{196}

Evidently, this did not resolve things, as the manual did not specify any further how this natural state should be determined. The problem would remain a key issue over the next two decades, as the Working Group

\textsuperscript{194} Nevertheless, the influence was not spectacular: a 1978 review of career opportunities for biologists in policy found forty biologists in policy positions in government. Biologists had started to enter policy positions between 1970 and 1975, and some had made it to high positions in national departments. Many of them had ecological backgrounds and found ecology important for their work. (Baerselman, \textit{Biologen in het Overheidsbeleid}.) Cramer was able to establish that, by 1984, approximately 30 to 40 small research units, in various layers of Dutch government, employed aquatic ecologists working on water quality control, environmental pollution, or physical planning. (Cramer, “The Scope of Mission-Orientiation in Dutch Freshwater Ecology”, p. 226)


\textsuperscript{196} My translation, original: ‘Als norm voor een goede biologische kwaliteit geldt de toestand zoals die ter plaatse zonder verontreiniging of andere verstorende invloed behoort te zijn. Hiervoor kan worden teruggestreept op invetarisatie-gegevens van vroeger of op vergelijkend (typologisch) onderzoek. Deze normen kunnen van streek tot streek aanzienlijk verschillen.’ (Werkgroep Biologische Waterbeoordeling, \textit{Biologische Waterbeoordeling}, pp. 10, see also p. 19-21)
continued to develop its methods, while the organisation developed into a society with approximately a hundred members in 1990.\textsuperscript{197} Other projects followed, for example, a typology of surface waters developed by the CUWVO in 1988 and attempts to develop detailed ecological standards for each of these types.\textsuperscript{198}

The possibilities for ecological criteria for water evaluation increased after an amendment to the Surface Water Pollution Act of 1981 required provinces to develop water quality plans. These plans were to indicate a framework of policy intentions and targets, for which there was a legal requirement to consult municipalities, water boards, national government, regional commercial and industrial representatives (\textit{Kamer van Koophandel}), as well as environmental groups. The plan for North-Holland of 1984, for example, included a framework for ecological evaluation of water quality, developed in cooperation with neighbouring provinces. It relied on a combination of physical/chemical parameters and parameters of structural ecology (saprobic index, total biomass, and diversity indexes) to define classes of water quality and targets for policy, specifically for areas where conservation policies were related to surface water quality. However, the system of ecological standards was related entirely to a very limited set of parameters: dissolved oxygen, biological oxygen demand, ammonia, total nitrogen and phosphor, and algal counts. In as far as other substances were concerned, measures and policy goals were based on national norms for water quality.\textsuperscript{199}

At the end of the eighties, this kind of regional planning for water quality received new impulses, with expansion of water plans to the national as well as local levels. Here too, ecological knowledge was used to define policy targets and assess water quality.\textsuperscript{200} A key feature of the ecological knowledge used in water quality management in this period was the tendency to develop indicators, e.g. indicators of eutrophication, of ecological quality, or of diversity. Based on a limited set of chemical indicators as well as more varied physical alterations of streams (fish traps, extra shadow on fast flowing streams, natural river banks, etc.), ecologists could provide planners with

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\textsuperscript{197} Higler, “Ecologische Normen Waterbeheer”, pp. 87-88.
\textsuperscript{199} Provinciaal Bestuur van Noord-Holland, \textit{Provinciaal Waterkwaliteitsplan Noord-Holland}.
\textsuperscript{200} Tweede Kamer, \textit{Derde Nota Waterhuishouding}.
\end{flushright}
indications of suitable policy measures, as well as likely results of policy alternatives expressed in terms of ecological indicators.

3.3.3 Ecology and national water quality policy
Parallel to these ecological parameters in (local) water quality management, national government also developed policy initiatives oriented at refining water quality standards. These involved both attempts to define chemical and physical parameters, as well as attempts to define ecological parameters. As regards chemical and physical standards, the Department of the Environment was an advocate of environmental norms that would not only include more parameters, but also set targets for discharge policies. The first set of Dutch targets for surface water quality were established in 1975 and found their way to local water boards as a means to measure performance of water quality management. They included indicative values for nearly forty physical and chemical parameters, almost half of them metals. One year later, the department of the environment came with its own policy document on environmental norms, trying to offer an integrated conceptual scheme for the status of norms and policy targets. The effect was not as far-reaching as the department had hoped: it was not yet at a point where could take the lead in setting norms and making them binding. National water planning was ‘indicative’, an indication for local water quality managers. In addition, the department of the environment was in a relatively weak position compared to the Department of Water, including when it came to negotiations over water quality standards in Europe. However, the implementation of these new norms aided the introduction of new levies for metals in discharged water, although with less success in reducing discharges. As with levies based on inhabitant equivalents, these levies were not meant to achieve strict regulation

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201 At this point only a department of the Ministry of Public Health and Environmental Hygiene. It only became an independent ministry in 1982, see chapter 3.

202 Lambers, Milieurecht, p. 112; Bressers, Beleidseffectiviteit en Waterkwaliteitsbeleid, p. 61. The limited range of chemicals of water regulation can be traced in some proposed contemporary standards and policy targets. In 1972, proposed standards by water quality managers were cadmium, copper, mercury (10 micrograms per litre) and chromium, nickel, lead, and zinc (100 micrograms per litre). Above these concentrations, levies would be charged. (Copius Peereboom, Chemie, Mens en Milieu, p. 298) The first indicative policy plan for water of 1975 formulated reduction targets for mercury, phenols, arsenic, lead, zinc, chromium, and tin (Indicatief Meerjarenprogramma Water, 1975-1979; see local use in: Provincie Groningen, Nota Milieunormen, pp. 32-33).

203 Tweede Kamer, Nota Milieuhygienische Normen.

204 De Koning, In Dienst van het Milieu, pp. 59, 71-75; Van Tatenhove, Milieubeleid Onder Dak?, p. 18.
aimed at water quality standards, but were meant to finance water treatment facilities as part of a policy of general reduction of pollution levels (see also chapter 3).\textsuperscript{205}

The surface water quality standards that were introduced were largely based on human health concerns, specifically involving drinking water, amenity values, and human consumption of fish. The standards made a distinction between 'general water quality', and function based water-quality: drinking and swimming water, for which chemical parameters had been negotiated in a European context.\textsuperscript{206} A more developed set of 'base quality' standards was introduced in 1981, involving thirty-six qualitative and quantitative parameters, ranging from visible pollution to physical parameters (e.g. maximum temperature of 25°C), and chemical parameters, some substance-specific (e.g. for specific heavy metals), some generic (e.g. all organochlorine pesticides). The general goal behind these norms was that they would guarantee a base quality for all Dutch surface water that would imply the absence of visible pollution and smell, as well as the presence of a healthy aquatic community and the protection of non-aquatic predators.\textsuperscript{207}

To the extent that non-human biota were considered for water quality norms, the framing expertise was once again ecological. The second indicative plan for water of 1981 even included a section with 'scientific background' of water quality management, involving an explanation of basic ecological notions largely based on functional ecology. In contrast, a chapter on ways to actually identify targets for the protection of aquatic life relied on structural ecology, referring to the methods of the Working Group on Biological Water Evaluation, and following the same approach: the ultimate target was the natural state. For water of ecological value this meant zero emission; for others the targets would depend on the 'desired structure of the ecological community'. Chemical and/or physical parameters for the latter were presented as a problem for local water management.\textsuperscript{208} Hence, in spite of the self-confident ecological language used to justify these norms, there was no clear eco/toxicological derivation scheme for them.

The regulatory regime also continued to struggle with the problem of how to create a meaningful correspondence between water quality criteria and effluent permits: even though water quality criteria were developed, including

\textsuperscript{205} Bressers, Beleidseffectiviteit en Waterkwaliteitsbeleid; see also: Cornet, “Kwaliteitsdoelstellingen en Normen in het Milieubeleid”, on the development of norm setting.

\textsuperscript{206} Tweede Kamer, Nota Milieuhygiënische Normen, pp. 53-61, including the bathing water Directive (76/160/EEC), the drinking water Directive (74/440/EEC).

\textsuperscript{207} Ministerie van Verkeer en Waterstaat, Indicatief Meerjarenprogramma Water 1980-1984.

\textsuperscript{208} Ministerie van Verkeer en Waterstaat, Indicatief Meerjarenprogramma Water 1980-1984, pp. 31 et seq., b7 et seq.
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various ecological standards in local practices, they failed to guide effluent permitting practice, with the exception of a few local conservation initiatives. To resolve these tensions, the 1989 Water Management Act (Wet op de Waterhuishouding) would create the possibility of planned water management, with a national framework plan cascading into local water management plans. These were to have water quality targets that could be used as legal basis for licensing policy, as well as for other pollution reduction measures (e.g. with respect to manure and pesticides). The first of these new-style national plans was the very voluminous Third Water Management Plan, which involved the construction of targets for water policy, grounded in ecological assessments of the condition of Dutch waters and water quality criteria (see below).

The problem of how to operationalise ecological water quality standards had the attention of national policy makers. Early 1979, the Temporary Advisory Council for Environmental Hygiene (Voorlopige Centrale Raad voor de Milieuhygiëne) suggested to the Minister of Public Health and Environmental Hygiene, L. Ginjaar at the time, that more attention for ecological norms was required. It pointed out that the norms for water suggested in the first indicative plan for water and the 1976 policy document on norms were 'general use' norms that lacked ecological foundation and diversity for different water types. The council suggested that a simple system was needed, identifying parameters for water quality evaluation, as well as normative values for those parameters. The minister did not share the assessment that water quality norms lacked scientific basis in ecology, but did agree that more could be one. For an advice on ecological water quality norms the minister turned to the Health Council of the Netherlands, of which he would later become the chairman.

This was to be the first major activity of the Health Council on protection of the non-human environment, after its original focus had always been human health. Ginjaar was to stimulate this role of the Health Council heavily in the mid-eighties. He envisaged a sharp division between the advisory representation of interests, in the Advisory Council for Environmental Hygiene, and science, which would have to be guaranteed by the presence of top experts in Health Council committees, typically organised on the basis of co-optation and with a format of organised peer review. An

209 Zuidhollandse Milieufederatie, Industriële Waterlozingen in Rijnmond: de Kloof Tussen Beleid en Praktijk
210 Tonnaer, Handboek van het Nederlands Milieurecht, pp. 168-70; Tweede Kamer, Derde Nota Waterhuishouding.
211 Correspondence in Gezondheidsraad, Advies Inzake een Begrippenlijst ten Behoeve van Ecologische Normen Waterbeheer.
212 The Council had been consulted earlier with respect to health aspects of environmental pollution, for example with respect to the drinking and bathing water
expert committee was composed for this task, consisting of aquatic ecologists and hydrobiologists from various government research institutes, in 1982 also university ecology groups and water quality managers, and one environmental toxicologist. Among the ecologists, there were structural and functional ecologists, but systems ecology, still dominant in academic aquatic ecology, was particularly well represented.

The committee deliberated its final report for almost ten years. It soon got entangled in theoretical issues and decided to first try and organise the confusion over terms and concepts with a list of definitions. In 1988, the committee reported a list of parameters of potential interest for ecological norm setting, followed by a detailed description of possible parameters a year later. The final report of over four hundred pages reads like a handbook of ecology, describing the aquatic systems of the Netherlands, environmental

norms (e.g. Gezondheidsraad, Verslag over het Jaar 1974) and at the time there were no alternative scientific advisory councils for the environment. The Health Council officially announced its move into environmental affairs in 1987 with: Gezondheidsraad, Het Sein op Groen. The report reconfirmed the sharp distinction between policy and science, for example relying on a risk assessment/risk management distinction to identify its role as assessor, or protesting the increasing reliance on the Council for policy implementation issues it considered the domain of policy, not science. In the same year, the Health Council claimed its new environmental terrain with two other reports, both on ecotoxicology: Gezondheidsraad, Ecotoxicologisch Onderzoek in Nederland; Murk, Ecotoxicologie: de Visie van 31 Betrokkenen.

W. Slooff, see below. For an overview of the contemporary viewpoints (as well as a sceptic position of the department of the environment), see Best and Haeck, "Ecologische Indicatoren".

The first intermediate report: Gezondheidsraad, Advies Inzake een Begrippenlijst ten Behoeve van Ecologische Normen Waterbeheer. It defined what was to be meant with terms such as ‘black box’, ‘norm’, ‘evaluation’, ‘system’ (‘a collection of objects forming a whole together with the relations between the objects and their properties’, p.25), ‘subsystem’, ‘ecological indicator’, ‘paradigm’ – indicative of the abstract level of its work, as well as the importance of systems ecology. The problem of defining ‘ecology’ provided an occasion for some boundary work: ‘The Committee has found that it is not possible to define the word “ecology” in such a way that other fields such as aetiology, physiology, etc. are excluded. There are also clear boundary cases, in which the research is both of aetiological and ecological nature and in which the choice of fields is determined by the context.’ (p.31) Either the Committee was trying to keep everybody on board, or this is a sign of a confident boundary strategy: ecology can expand and annex adjoining fields. See also the attempt at clarification by Kwa and Ringelberg, Algemene Ecologische Begrippen en hun Relatie met Ecologisch Beheer van Oppervlaktewater.

Gezondheidsraad, Ecologische Normen Waterbeheer: Keuze van Parameters.
chemistry of surface water, as well as a list of structural and functional indicators of water quality. At a symposium organised to present and discuss the report, ecologists involved in water quality management acknowledged the efforts of the committee in its attempts to create conceptual clarification, but also expressed their disappointment over the lack of concrete tools for water quality management. Ten years of deliberation had not produced the clearly defined and operational indicators for water quality management that policy makers had asked for.

Before the committee on ecological norms for water management was finished, the Health Council had already produced several other reports on environmental norm setting and eco/toxicology. For these purposes, it even installed a permanent ‘committee on ecotoxicology’ in 1992, consisting of a combination of researchers with toxicological and ecological orientations. The ecologists involved were now a different group, researchers who called themselves oeco- or ecotoxicologists and who had developed research practices in pollution assessment in closer relation to policy and environmental toxicologists during the eighties.

The causes of the failure of the committee on ecological norms were complex. There were the obvious divisions among ecologists, such as the tension between structural ecologists that dominated the practice of water quality management and the functional/systems ecologists that dominated fundamental research. Apart from personal idiosyncrasies among members of the Health Council committee, it was probably not the most suited forum for the problem. We can draw a parallel between this committee and the multispecies committee that was to select ecological tests for the US EPA (see chapter 5): this committee also did not come up with a clear selection of tests for further development, but limited itself to an review of available tests. Only insistence of the US EPA resulted in some selection, and even then the key decisions for further development were made by regulatory officers, not academics. The independence of the Health Council made a similar intervention impossible, and so policy makers turned to other sources for advice.

216 Gezondheidsraad, Ecologische Normen Waterbeheer: Deeladvies III, Beschrijving van de Parameters. The report referred to the CUWVO methods mentioned earlier as an example of how ecological targets could be operationalised (p.72), as well as the possibility of environmental toxicity tests (p.232-233), which by then already formed the backbone of environmental norm setting in the department of the environment. The report was followed by a summary in 1990: Gezondheidsraad, Ecologische Normen Waterbeheer: Hoofdlijnen....


218 See Gezondheidsraad, Ecotoxicologie op Koers, cf. Chapter 4.
The first ten years of structured water quality policy in the Netherlands had relied heavily on ecological notions, but had focused on pollution by nutrients and biodegradable substances. Eco/toxicological standards were mostly a matter for the local water boards, with an increasing role for (aquatic) ecologists during the seventies. The limited set of national water quality norms played a more modest role, in a position of minimum standards for local water quality management. When national government asked ecologists to improve the ecological derivation of water quality criteria, the ecologists did not produce operational criteria that could be used in policy. Although ecologists managed to construct a working division of labour in local water pollution regulation, they failed to do so in the national wing of the regulatory regime, which was steadily becoming more important.

3.3.4 The department of the environment, environmental toxicology, and risk assessment

Meanwhile, Dutch environmental policy makers had not waited for the results of the Health Council efforts. After 1981, the nature of the regulatory regime for water had started to shift and along with this shift came a change in the experts involved in water quality policy. A new development was the use of a ‘black list’ of chemicals that would have to be regulated more strictly, based on technological process standards. A European directive had created a legal framework for identifying a list of such substances in 1976, but the actual identification of such substances on a European level progressed only slowly.\(^{219}\) In addition, the international agreements over the Rhine operated with a black list of priority substances. The second national water plan of 1981 had announced the development of a system to derive candidate substances for such a list\(^ {220} \) and the secretary of the environment agreed to publishing a proposal for such a system shortly during the debate in Parliament. Not only could such a list be used in national policy, running ahead of international developments, but the proposal could also be used by the Dutch representation in the international negotiations. In 1982, a public draft proposal was published by a committee of civil servants from the

\(^{219}\) Directive 76/464/EEC designed a scheme for a black list of substances, with zero-emission as a target but quantitative standards for discharges or surface water quality as an intermediate goal, and a grey list, with general reduction targets. However, the Directive did not specify the contents of the list, which was to follow in ‘daughters directives’. Five years later, only mercury was on the European black list, the heavy metal involved in the Minimata disease.

\(^{220}\) Ministerie van Verkeer en Waterstaat, Indicatief Meerjarenprogramma Water 1980-1984, referred to Canton and Slooff, “A Proposal to Classify Compounds and to Establish Water Quality Criteria Based on Laboratory Data”. According to Slooff, Ecotoxicological Effect Assessment: Deriving Maximum Tolerable Concentrations (MTC) from Single-Species Toxicity Data, p. 7, the method was never used.
department of health and environment and the department of water, together with experts of government research institutes for drinking water (Rijksinstituut voor Drinkwatervoorziening), public health (Rijksinstituut voor Volksgezondheid), the Institute for Water Purification (RIZA), and the Netherlands Institute for Fisheries Research (Rijksinstituut voor Visserij Onderzoek, RIVO).\(^{221}\)

The committee was illustrative of the changes in water pollution regulation in several ways. The prioritisation system proposed, relied on a pre-selection of suspected substances and then proceeded to further refine the selection with basic exposure indicators (tonnage produced or emitted, or detection data), and, in the last phase, carcinogenicity, persistence, and acute and chronic environmental toxicity data. Bioaccumulation and biomagnification as criteria had been considered but removed because of lack of operationalisation. For those criteria, the committee suggested ‘further discussion, particularly in a broader context’.\(^{222}\) As with the regulation of pesticides in the eighties, this was an inter-departmental committee, where ministries designed policy together with experts from their respective research centres. However, one central player, the Ministry of Agriculture, was absent, even though the committee proposed several pesticides for the blacklist. In addition, the committee proposed a procedure that still relied extensively on expert judgement, but now included formal criteria, such as a maximum aquatic LC50.

Some of the key members of the committee were environmental toxicologists, early signs of a close cooperation between the department of the environment, the RIV(M) (which generally lacked ecologists),\(^{223}\) and the environmental toxicologists at the University of Utrecht. Over the next decades, there would be a strong alliance between these three, in terms of personal relations as well as approach to environmental assessment of chemicals. This connection developed into the context of an increasingly close formal cooperation between RIVM and VROM, a cooperation that would bring the RIVM into a position of planning bureau of the environment by the end of the eighties.\(^{224}\)

\(^{221}\) Ministerie van Volkshuisvesting, Systeem van Criteria voor Aanwijzing van Stoffen Uit de Zwarte Lijst.

\(^{222}\) Ministerie van Volkshuisvesting, Systeem van Criteria voor Aanwijzing van Stoffen Uit de Zwarte Lijst, p. 24.

\(^{223}\) Interview with Koeman, Wageningen, University of Wageningen 1991.

\(^{224}\) RIVM and VROM originally negotiated 4-year research programmes for the institute, in coordination with the department of the environment, thereby making sure research would be coordinated with the needs of VROM. Between RIVM and VROM in general, there was exchange of personnel, also in top positions. (For details see De Koning, In Dienst van het Milieu, pp. 47-52.) By 1992, RIVM discussed its research programme with VROM on an annual basis and VROM spent
Environmental toxicology in Utrecht had a strong physiological orientation. For example, one year after the black list proposal was published, in 1983, one of its members, Wilbert Slooff, defended his dissertation in Utrecht. The dissertation analysed effects of pollutants with laboratory tests (acute and chronic), physiological effects in surface water fish (e.g. lesions and deformities), and discussed the use of indicator organisms for water evaluation and biomonitoring. Slooff referred to the work of aquatic ecologists such as John Cairns and, like the Working Group Biological Water Evaluation, proposed to use an unpolluted environment as a standard. However, he also came to the conclusion that some of the ecologists' favourite pollution indicators, such as species diversity indexes, were of limited use:

In the presented approach it is assumed that a reduction in toxic stress can be described satisfactorily without the necessity of accurate estimations of total numbers or complete species lists, giving only attention to a limited number of species. (...) The reliability of using biological systems based on macrobenthos [i.e. bottom-dwelling organisms, wh] distribution to classify surface waters polluted with a variety of chemicals should be seriously doubted.225

The approach was typical of the kind of environmental toxicology that was to become dominant in the regulatory policy of the department of the environment, for which Slooff would become one of the key experts at the RIVM: ecologically informed, but operationalised through indicators on physiological (species or subspecies) level. As Slooff announced in 1982:

(...) whereas the 70s were characterised by the “single-species-in-a-tank-of-clean-water”, the 80s will be the years of “dirty-water-toxicology-comprising-ecological-elements” in an attempt to develop more realistic ecotoxicological criteria.226

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225 Slooff, Biological Effects of Chemcial Pollutants in the Aquatic Environment and Their Indicative Value, pp. 154,56.

226 Slooff, Biological Effects of Chemcial Pollutants in the Aquatic Environment and Their Indicative Value, p. 3, with reference to Koeman and Cairns. The first ‘statement’ (stelling) of his defence was: ‘The term ecotoxicology, as it is used nowadays, raises the unjustified expectation that the effects of toxic substances are studied on the integration level of the ecosystem.’ Perhaps his assessment was based on his experiences in the committee for ecological norms for water quality of the Health Council, of which he had been a member since 1982.
In the eighties, the development of more water quality criteria ran into continual delays, but in the circle of advisory councils and regulatory research, methodology for the derivation criteria was being suggested and developed. While advisory councils insisted on the importance of biological monitoring, attention for ecology and species diversity, the RIVM progressed rapidly with methodology to derive norms from acute and chronic toxicity tests.

As VROM manoeuvred to increase its role in environmental policy, reviews of substances became a matter of ‘integrated’ policy, as environmental policy was restructured around problem areas rather than environmental compartments. By 1985, the department of the environment would no longer wait for developments in other departments, but took the initiative with ‘base documents’, providing an assessment per substance, on the basis of which the department could propose environmental standards. These documents were to be prepared mainly by the RIVM through expert evaluation, reviewed by advisory councils such as the Health Council, and used as basis for consultation, especially concerning attainability of the new standards. Via this approach, VROM tried to build a consensus for regulatory policy, at least with respect to how hazards of substances should be evaluated. As a key element of the approach suggested, VROM proposed quantified risk levels for human health impact. However, risk for wildlife impact proved

227 The European water quality norms for drinking, bathing, and fishing water were legally implemented in the Netherlands in 1983, while the Council for Environmental Hygiene complained about the delayed national black list. (Centrale Raad voor de Milieuhygiène, Milieu van Jaar tot Jaar, pp. 60, 64-65).

228 Including environmentalist group Natuur&Milieu, the RMNO, CRMH, see Centrale Raad voor de Milieuhygiène, Milieu van Jaar tot Jaar, pp. 61-62, 40. The list was still only ‘temporary’ in 1985: Tweede Kamer, Indicatief Meerjarenprogramma Milieubeheer 1985-1989, pp. 60-61

229 ‘Integration’ started in 1983 and was reflected in the first indicative plan for the environment (rather than compartments) in 1986. (De Koning, In Dienst van het Milieu, p. 78; Van Tatenhove, Milieubeleid Onder Dak?, pp. 20-23; Tweede Kamer, Indicatief Meerjarenprogramma Milieubeheer 1985-1989) With the first Indicative Plan came the suggestion of a life cycle analysis of substances (as an alternative for risk-based norm setting), I will not go into that here, see: Tukker, Frames in the Toxicity Controversy. Also new was the direct approach of sectors in society by the Department of the Environment (doelgroepenbeleid), leading to bilateral negotiations and convenants.

230 Tweede Kamer, Indicatief Meerjarenprogramma Milieubeheer 1985-1989, pp. 111-12; Van Tatenhove has called this the policy of VROM of ‘breaking in’ on other departments, announcing stricter targets for both water and pesticides.(Van Tatenhove, Milieubeleid Onder Dak?)
harder to quantify as still no single endpoint was available. The problem of 'ecological norms for water quality' had now shifted to finding a quantifiable definition of eco/toxicological risk. Meanwhile, eco/toxicologists underlined the urgency of progress on this level. For example, in 1987, RIZA research showed that the 'base quality' of the multi-year plans for heavy metals was still toxic to *Daphnia magna*, referring to USEPA research and arguing for the ecological importance of daphnids as algal grazers.

### 3.3.5 95%

The breakthrough came in 1989. The simple norm, the one that ecologists had not been able to suggest or agree upon, was eventually suggested by environmental toxicologists: 95% protection of species would provide maximum risk levels, while 1% of this level would be considered a negligible level and hence a reduction target. The essential argument behind the criterion was that protection of 95% of species was a parameter of ecological structure, which would also provide protection of ecological functions. The criterion was proposed to Parliament in the policy document on risk policy that joined the first National Environmental Policy Plan in 1989, the same year the Health Council ecologists reported their list of complex ecological water quality parameters with potential. It seemed that political institutions provided the solution to a Gordian knot that scientists had not been able to cut, as Parliament endorsed the protection of 95% of species as a straight-forward criterion for all regulatory pollution policy. As Slooff commented, in an RIVM document two years later:

> There is no scientific basis for setting the maximum tolerable concentration at a 95% protection level, nor are there scientifically sound arguments to consider 1% of this level to have a negligible effect for the structure and functioning of ecosystems. However, the acceptability of these concentration levels [is] the result of continuous interaction between policy makers and scientists.

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231 Indicator species were suggested, but the conclusion in the multi-year environmental programme for 1986-1990 was that 'more research' was needed. (Tweede Kamer, *Indicatief Meerjarenprogramma Milieubeheer 1986-1990*, p. 24) Policy analysis of the base documents in: Biezeveld, "Milieubeleidsplanning", p. 99 et seq.


The 95% rule did not precede risk assessment. In fact, it was the development of statistical procedures to extrapolate single species test results to other species that created the possibility for the criterion. The bulk of this work was done by Dutch environmental toxicologists at the RIVM, RIZA, TNO, and the ecotoxicology group at the Free University, in discussion with US risk assessors, and reviewed by the new committee of the Health Council on ecotoxicological assessments in 1989.\(^{235}\)

Nor had the lack of a clear criterion prevented the development of new criteria: a new and stricter set of seventeen specific water quality criteria was adopted 1989, including parameters for some individual pesticides. In contrast to the 1981 standards, these parameters were now developed on the basis of extensive risk analyses by Dutch eco/toxicologists, based on literature reviews by experts, following the ‘base document’ approach.\(^{236}\) The 95% rule grew out of this practice and the regulatory research efforts that went with it (including for purposes of regulation of industrial chemicals, see below): it was a standard that was achievable in light of available methodology in environmental toxicology, developed in response to ecological considerations. It avoided the key conundrum of structural ecology: the problematic definition of the ‘natural state’ as a target for environmental protection. Slooff’s 1982 prediction of a development towards ecologically informed environmental toxicology was beginning to materialise.

With the establishment of this criterion and steady funding from the department of the environment, aquatic risk assessment at the RIVM accelerated. The convenience of the 95% protection rule was that it could be evaluated via acute and chronic single species toxicity tests which, by that time, had become the widely used tools in (international) environmental assessment of chemicals. The method used was a variation on the 1985 procedure used by the US EPA to derive quantitative water quality criteria: with toxicity results for five species and based on models of distribution of species sensitivity, extrapolations could be made to cover 95% of species. The statistic extrapolations could compensate for the fairly arbitrary ‘safety

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\(^{235}\) See background of the method in Slooff, Ecotoxicological Effect Assessment: Deriving Maximum Tolerable Concentrations (MTC) from Single-Species Toxicity Data, pp. 7-10; cf. Stortelder, Van der Gaag, and Van der Kooij, Kansen voor Waterorganismen; Van Straalen and Verkleij, eds., Leerboek Oecotoxicologie, pp. 351-55.

\(^{236}\) Prepared by the second Indicative Multi-year Pogramme for water (IMP-water), see Van Straalen and Verkleij, eds., Leerboek Oecotoxicologie, pp. 328, 59-62, they were presented as part of Tweede Kamer, Derde Nota Waterhuishouding. Dutch water quality parameters were made dependent on water usages, based on European classification, but expanded with a special category of water with ‘ecological targets’.
factors’ that traditionally compensated for a range of extrapolation uncertainties, among which the extrapolation to other species or extrapolation from laboratory single species tests to the field. As input for the procedure, chronic toxicity data were preferred, but in case such data were lacking, the RIVM used acute data with extrapolation factors.\textsuperscript{237} Where even acute toxicity data were absent, QSAR procedures could be used, although these would require additional safety factors.\textsuperscript{238}

Within a few years, extrapolation procedures for bioconcentration and biomagnification (\textit{doorvergiftiging}) were added, allowing the extrapolation to compensate for more and more aspects of the old safety factors. In other words: protection of ecological parameters (ecosystem functioning) was assumed from structural parameters (95% of species, biomagnification), which in turn were extrapolated from chronic toxicity data, which could be extrapolated from sets of acute data, which could in the worst case be substituted with quantitative parameters of chemical structure (QSAR). For purposes of regulatory risk assessment, ecological parameters were effectively reduced to physiological and chemical parameters of environmental toxicology/chemistry.

\textsuperscript{237} Tweede Kamer, \textit{Derde Nota Waterhuishouding}, p. 89. RIVM research built on attempts at the EPA Duluth laboratory to statistically extrapolate chronic from acute data, see: Slooff, Van Oers, and De Zwart, “Margins of Uncertainty in Ecotoxicological Hazard Assessment”, pp. 843-46. An example of statistical extrapolation procedures from acute to chronic for human toxicity, produced by the RIVM in 1995 is: Kramer et al., \textit{Derivation of Conversion Factors to Estimate Indicative Chronic NOAEL from Short-Term Toxicity Data}.

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This replacement of safety factors by statistical extrapolation procedures provides an interesting point of comparison with other regulatory regimes. Typically, regulatory regimes that relied mostly on (human) expert assessment at the most had safety factors based on practice and experience. In some cases, the experience-based safety factors would even be altered, depending on the case at hand. This allowed experts to compensate for idiosyncrasies of the case, whether based on research results of expediency in regulatory negotiations.\textsuperscript{239} The Dutch assessment of pesticides included provisions to that extent: safety factors could be changed on the basis of additional data or if there was reason to believe that they were too conservative. In American regulatory regimes for pesticides and industrial chemicals, safety factors were formalised in the detailed protocols of assessment procedures (see chapter 5). In this case, as in the case of American water quality criteria, a scientific/statistical procedure formalised assessment to a high degree, at least in the cases where sufficient eco/toxicity data were available.

With a highly formalised derivation procedure, multispecies test had little role to play. As Slooff explained:

Ideally, the effects of a substance should be tested in a natural system representative of the area to be protected, the results to be used in a comprehensive effect assessment. However, isomorphic testing is scarce and the (few) studies in various complex systems (including multi-species laboratory systems, microcosms, and field trials) are hard to evaluate (…). Therefore (…) the derivation of maximum tolerable concentrations from information on physico-chemical characteristics and single-species toxicity is presented only.\textsuperscript{240}

And in the words of the environmental toxicologist in charge of the chemical substances division of VROM at the time:

Field tests can only provide clear answers to clear questions, but very often the questions cannot be formulated clearly, because of the very limited standard physicochemical and ecotoxicological data available. At present [1995, wh] the OECD only has standardised ecotoxicity studies for bacteria, algae, daphnids, fish, earthworms, plants, birds and mammals. (…) From an extensive literature research on aquatic [multispecies] studies it appeared that very few reliable field

\textsuperscript{239} See Bal, \textit{Grenzenwerk} for examples from labour toxicology; Van Eijndhoven and Groenewegen, “The Construction of Expert Advice”.

\textsuperscript{240} Slooff, \textit{Ecotoxicological Effect Assessment: Deriving Maximum Tolerable Concentrations (MTC) from Single-Species Toxicity Data}, p. 11.
Boundaries of regulatory science

... experiments are available. (...) it appears that the view expressed by Crossland: "toxicity can be measured in the laboratory and the results of laboratory tests can be extrapolated to the field without great difficulty, provided that the exposure of the organism can be predicted" is correct. In fact, the debate surrounding [single species] tests versus [multispecies] tests is pointless. Both (...) have their own place in the process of deriving [predicted no-effect concentrations].

To the RIVM eco/toxicologists, the limited use of multispecies tests was not just a matter of whether data could be used for evaluations, but also a matter of cost. If statistical extrapolation methods were available, then, from regulatory point of view, acute toxicity tests were to be preferred:

(...) there is no solid evidence that predictions of ecosystem effect levels from acute tests are unreliable and so there is no reason to propose expensive and complex tests as additional or alternative research tools for routine hazard assessment. Time and money would be better spent in studying the acute toxicity to a variety of species that differ physiologically and in ecological function (...). Such data (...) may give a more sound estimate of a given substance when applied to proper mathematical risk models. However, at present, such risk models are still in development and are not yet available. It is in this respect that model ecosystem and field observations are urgently needed for the further development, calibration and verification of mathematical risk models.

Thus, multispecies tests were rhetorically manoeuvred into a supporting role. As in the regulatory regimes for water and environmental chemicals in the US, multispecies (field) tests were considered a tool for validation and further development of evaluations entirely organised around single species testing.243

The development of extrapolation methodology led to a sudden acceleration of the production of environmental quality norms, used in some cases as strict standards and in other cases as target values for water policy by the year 2000. During the nineties, approximately 200 substances passed

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243 Slooff, Ecotoxicological Effect Assessment: Deriving Maximum Tolerable Concentrations (MTC) from Single-Species Toxicity Data, p. 44; see also Gezondheidsraad, Ecotoxicologie op Koers, pp. 60-61.
through this scheme.\textsuperscript{244} In addition to such numerical standards for individual substances, policy makers were increasingly interested in water quality indicators to assess the effects of pollution control policies.\textsuperscript{245}

The introduction of this formalised expertise of environmental toxicology in the regulation of water pollution went hand in hand with the introduction of quantified risk definitions. It helped to quantify criteria for environmental risk and in turn benefited from their definition. With the parliamentary endorsement of the 95% rule, VROM could draw a boundary between science and politics more sharply.\textsuperscript{246} Scientific legitimation of protection targets had proven too problematic, but now a political legitimation was available and it became easier to ask the RIVM environmental toxicologists to ‘stick to the science’. National water quality standards further developed in a formalised regime, with an increasingly strict boundary between science and politics, relying heavily on environmental toxicology.

Five key processes stimulated this development: the strong reliance of VROM on RIVM and its environmental toxicologists for the development of environmental standards; the introduction of methodology that had been developed for the specific purposes of American regulatory regimes; the attempts of VROM to take a central role in environmental policy with ‘hard’ science and strict environmental standards (especially during the second half of the eighties); the corresponding development of the RIVM as an environmental version of the Central Planning Bureau;\textsuperscript{247} and the absence of a similarly successful national expert/policy coalition in Dutch ecology. There is also a sixth process, which environmental toxicologists will claim is actually the crucial one to explain their central role: ‘it works’. But then I am only a poor sociologist, gathering wood in the regulatory jungle, and that is something I really cannot judge.

3.3.6 And ecology?
Ecology did not disappear from water quality evaluation. The 1989 policy plan for water that acknowledged the importance of toxicity standards also suggested that the approach could not be developed for salt water. In this policy domain of the department of water, ecological standards and targets

\textsuperscript{244} Starting with the \textit{Notitie Milieukwaliteitsdoelstellingen Bodem en Water (MilBoWa)} in 1991. See also Ministerie van Sociale Zaken en Volksgezondheid, \textit{Verslag van de Werkzaamheden van het Bureau Bestrijdingsmiddelen Gedurende de Periode 1 Januari 1966 - 1 Augustus 1970}.

\textsuperscript{245} E.g. in Tweede Kamer, \textit{ Nationaal Milieubeleidsplan}.

\textsuperscript{246} This was explicitly communicated to the RIVM in the preparation of the MilBoWa criteria of 1991: Van de Meent \textit{et al.}, \textit{Streven naar Waarden}, p. 1.

\textsuperscript{247} Kwa, van den Bogaard, and Pastoors, “Het Groene Stempel van het RIVM”.
were defined via (sets of) indicator species. In addition, the language for local ‘integrated water management’, focusing on traditional pollution parameters of oxygen depletion or eutrophication, remained distinctly ecological. In the world of water boards, the attention for ecological evaluation methods continued. Especially as the representation of environmental issues in the water boards became stronger during the nineties, and ‘integrated water management’ a central motto, the domain of operation of the much more localised and ecosystem-specific tools of aquatic ecologists was expanded. The 1998 National Environmental Policy Plan acknowledged this:

The water boards have shifted their focus, in managing water quality, from the traditional physico-chemical quality parameters to an overall assessment of the quality of the aquatic system and its functioning as an ecosystem. In order to monitor this, the water boards make use of monitoring networks, which measure a general quality indicator and the quality for swimming, drinking and fishing purposes.

It appears that local practice of water regulation even preferred to derive local norms from ecological targets rather than to assimilate all the national water quality standards. By the mid-nineties, the division of labour between ecology and environmental toxicology in the regime for environmental protection of water can be summarised as such: national freshwater standards for toxic substances were based on derivation methods from environmental toxicology, ecologically informed and expanded on the basis of ecological objections; salt water targets were defined by ecological standards; local or ‘specific’ water quality standards relied on ecological approaches, including standards for the traditional pollution parameters such as oxygen depletion or nutrient load. However, as we will see, this is not the end of the story.

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248 Tweede Kamer, *Derde Nota Waterhuishouding*, pp. 90,91; the AMOEBA approach, see also Van der Windt, *En dan: Wat is Natuur nog in dit Land?*.
249 Tweede Kamer, *Derde Nota Waterhuishouding*, e.g. p. 44 et seq.
250 Ministerie van Volkshuisvesting, *National Environmental Policy Plan 3*, p. 239.
251 E.g. in North-Holland, some MilBoWa standards were seen as simply irrelevant because they did not correspond to ‘natural’ local conditions. Only a few of the national norms appeared in the North-Holland water management plans of the 1990s. (Provincie Noord-Holland, *Beleidsnota Stilstaan Bij Stromen*.)
252 And zero-emission standards of international agreements, which fall beyond the scope of this book.
253 Cf. De Haas, *Programmeringsstudie Gebiedsgericht Milieubeleid*. Simultaneously, soil eco/toxicology and, to a lesser extent, sediment eco/toxicology, had strong influences of ecology and micro/mesocosm approaches to testing, not least because of research of ecologically oriented research in the eighties. (e.g. Van
3.4 Industrial chemicals

3.4.1 The early notification regime

The regulatory regime for industrial chemicals in the Netherlands sheds more light on the regulatory origins of Dutch environmental toxicology as well as on the integrative developments in regulatory regimes in the nineties. I will briefly describe the development of early regulatory ecotoxicity testing, but then focus more on the ultimate attempt to formalise the regulatory assessment of chemicals: an automated model.

In the seventies, Dutch researchers had participated actively in the international preparation of assessment of industrial chemicals, especially early environmental toxicologists at TNO. The key contexts for this participation were the OECD chemicals programme and the European negotiations that prepared the harmonised scheme for regulation of chemicals prior to marketing, in which the Academy/Society for Ecotoxicology and Environmental Safety provided a forum for expert interactions. The key contribution of TNO concerned the development and especially selection of aquatic toxicity tests that could be used in regulatory assessment. This resulted in Dutch versions of the OECD protocols for aquatic toxicity testing by 1980, certified by the Dutch Normalisation Institute.

For the preparation of the screening of new chemicals, the Department of the Environment was particularly interested in what would constitute a suitable set of aquatic toxicity tests. Part of the debates over the introduction of new chemicals screening was whether a large or small set of tests should be available. For these purposes, a batch of available tests was performed with reference substances, leading to the conclusion that a limited set of tests could provide adequate information for aquatic risk assessment. The project was

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Straal en and Verkleij, eds., Leerboek Oecotoxicologie; Gezondheidsraad, Ecotoxicologie op Koers) The more ecologically oriented aquatic research was part of the research institutes of the department of water, especially RIZA. (see also Van Zon, Tachtig Tachtig Jaar RIVM, p. 392 et seq.)


255 Among them were tests with the waterflea Daphnia magna (acute and chronic, 1980), the guppy fish Poecilia reticulata, a popular aquarium fish (acute, 1980), and an algal test (1984), which were the Dutch environmental toxicity testing standards until 1991-1993. (Nederlands Normalisatie Instituut, Website NEN) The detailed description of the development of a Dutch standard for a biodegradability test (Van den Berg and Blok, “Bioafbreekbaarheid en de Invloed van de Ent op de Resultaten”) provides some insight on how these standards were developed via working groups with scientists from government research institutes and industry, with representation in similar groups of the EC.
performed in cooperation with the RIV(M) and reported in 1981. From there on, the role of RIVM as source of regulatory expertise would gradually expand, as new tasks tended to go to RIVM, where VROM had a say in research planning, rather than at TNO.

One of those new tasks was the planned evaluation of new industrial chemicals. The 1979 European ‘6th amendment’ Directive on industrial chemicals was implemented in the Netherlands on in 1986, with the Dangerous Substances Act (Wet Milieugevaarlijke Stoffen). Attempts to pass the legislation had started around 1981 and had met with considerable industrial opposition (see chapter 3). However, the delays meant that there had been ample time for the preparatory work designing an evaluation structure and procedures between VROM and the RIVM.257 A Bureau for the evaluation of chemical substances was installed at the RIVM in 1980, and was split up again in 1984: the policy sections (the Chemical Substances Bureau) moved to the ministry, while the scientific evaluation remained at the RIVM.258 With these shifts, the organisational basis for the Dutch regulatory regime for industrial chemicals was in place: science at the RIVM (evaluation of new substance notifications, as well as development of methodology in the ecotoxicology section), and policy at the directorate of the environment. Based on an interim arrangement, the first new substances were notified in the Netherlands already in 1983, although the legal framework of the Dangerous Substances Act was only implemented by January 1987, six years after the deadline of the European Directive and eight years after the Directive was accepted.259

256 Adema, “Toestoptimalisatie met Water- en Bodemorganismen”; see also Koenemann, “Ecotoxiciteitsonderzoek en Milieubeleid”; Smies et al., “Milieutoxicologie in de Chemische Industrie.”
257 On the contemporary planned Dutch testing requirements, the tiered approach of the EC dependent on production volume, reaching up to the suggested use of field tests, see: Koenemann, “Ecotoxiciteitsonderzoek en Milieubeleid”. Some background on negotiations over the Act in: De Koning, In Dienst van het Milieu, p. 171 et seq.
258 Leading to the Adviescentrum toxicologie in 1985 (Van Zon, Tachtig Jaar RIVM, pp. 292, 95, 387). The Bureau moved back to the RIVM after VROM decided to concentrate on ‘core tasks’ in 1996. (Bureau Milieugevaarlijke Stoffen, Website BMS)
259 The Dutch regulations differed slightly from the European Directive: they required premanufacture notifications (as in the US, and in contrast to the EU’s premarketing notifications), had provisions for existing substances (which were only addressed by the EU in 1993, discussed above under the ‘base document’ approach), had different requirements for substances under a tonne, and initially required only minimal ecotoxicity data (one of the compromises with industry). Such differences were gradually removed as new Directives were added, expanding on the 6th amendment, and I will not go into the details here. (See Vermeire et al.,
The number of notifications per year rose from a dozen in 1983 to approximately three dozen in the years after. Not all of these involved eco/toxicological risk assessment, as only production volumes larger than a tonne per year required eco/toxicological data; notifications could concern minor updates to earlier notifications; or could concern substances of which it could be assumed that they would not get into the environment, for example because they were used only in closed processes. The pressure on regulatory assessors was especially high for old chemicals. The Dutch 'base document' approach described earlier was in progress for approximately fifty substances by 1987, but the work proceeded slowly, partly due to the negotiations over the evaluations in every single document. The problem of evaluation of old chemicals was also to surface in European attempts to set up a procedure for old chemicals, and the Netherlands had committed itself to design methodology for old chemicals in the OECD.
3.4.2 Automating risk assessment

In 1988, the directorate of chemicals and risk management at the department of the environment initiated a policy programme that was to address these problems: the project Ecological Sustainability of the Use of Chemicals (*Project Ecologische Inpasbaarheid Stoffen*). The project had three parts or, as they were called, 'lines': the chemicals line for 'generic chemicals policy', the 'ecosystem line' for area-oriented chemicals policy, and the 'evaluation and perspective' line with monitoring and strategic research. The project was launched in January 1989 and formed a framework for development of ecotoxicological assessment for the department of the environment. I will focus here on the first line, the chemicals line, which is the part of the project most directly relevant for the regulation of industrial chemicals.²⁶³

The spearhead for the 'generic chemicals policy' line was the plan to develop an expert system for chemical risk assessment: a computer programme that could be used to scientifically evaluate the risk of chemicals to people as well as the environment, irrespective of policy domain. The same year, the plan received its legal basis. The first National Environment Action Plan of 1989 contained an 'action point' pertaining to the evaluation of industrial chemicals: the evaluations were to be accelerated. In order to achieve this, it announced the development of the expert system to relieve the overburdened experts: the Universal System for the Evaluation of Substances (USES).²⁶⁴ The development of USES offers interesting perspectives on the risk strategy of the department of the environment at the time, the way expertise was positioned in regulatory policy and science/policy boundaries were drawn, as well as the boundaries in eco/toxicology.

An expert system such as USES had become a conceivable and valued possibility as a consequence of several developments. Firstly, in light of the ongoing methodological developments, including effect modelling and formalisation of assessment procedures, the development of an integrated model seemed like a mere technical problem. Regulatory research at the RIVM was progressing rapidly with methodology oriented at routinised evaluation of chemicals. Where further development was hampered by uncertainties, the policy project assisted. For example, the definition of the target of protection of 95% of species in 1989 (see above) helped to provide an important standard for the evaluation of industrial chemicals also. The

evaluation of new chemicals could operate as an example of an expert system, as the automation of the assessment procedure was already on the way at the Chemicals Bureau. By 1989, Dutch regulatory assessments for new chemicals had a clearly defined protection target (the protection of 95% of species); a clear set of eco/toxicity endpoints (acute toxicity data, as specified in European data requirements for notification of new substances and based on standardised protocols); methodology to extrapolate to other species (possibly statistical, but at that point still mainly based on assessment factors); as well as increasingly refined methods for predicting exposure. The key elements of the hazard assessment procedure used for industrial chemicals were the same as the one we described for the US in chapter 5: determine expected concentrations in (various compartments of) the environment and compare them with effect concentrations in biota (i.e. the PEC/NEC comparison: predicted environmental concentration compared with assessed no effect concentration). Where data were lacking, techniques had been developed to infer parameters from chemical structure (QSAR), with considerable contributions from neighbouring Utrecht environmental toxicologists. The tools of highly formalised assessments developed for the purpose of US environmental regulatory regimes were readily available, as environmental toxicologists of the RIVM had very good contacts with US EPA regulatory laboratories, especially Duluth.

While the evaluation of environmental hazards of chemicals had focused on the definition of endpoints in acute toxicity tests, exposure assessment had remained a more uncertain part of hazard evaluation. In order to compare predicted effect concentrations with expected concentrations in the environment, regulatory assessors had to make an evaluation of where a chemical was likely to end up in the environment and in what concentrations. During the eighties, the RIVM had elaborated on some of the methods available, once again relying heavily on methodology that was already used for these purposes by the US EPA. The methods that looked particularly suited for modelling purposes, divided the environment into compartments, such as air, soil, surface and ground water, or biota, for example based on volatility, water solubility or bioconcentration factors of a compound. Based on chemical and physical parameters, such models predicted where chemicals

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265 The Beoordelingsysteem Nieuwe Stoffen (BNS) for new chemicals preceeded USES by approximately 2 years. (Hekstra, "Naar een Verdere Ecologische Onderbouwing van het Stoffenbeleid", p. 40)
were most likely to end up.\textsuperscript{266} Using such models, an evaluation system had already been developed for new substances.\textsuperscript{267}

Secondly, the idea of making a model, quantifying and formalising risk assessment, also fitted the risk philosophy in the Action Plan, and more in particular the strategy of VROM to use ‘hard science’ to make a case for reinvigorated environmental policy. The alarming ‘Caring for Tomorrow’ (\textit{Zorgen voor Morgen}) report of 1988,\textsuperscript{268} ordered by the RIVM and putting ‘the environment’ high on the political agenda, had paved the way for the Action Plan in exactly the same way. In addition, the ministry’s directorate dealing with chemical substances was also the one dealing with radiation, with an expert community that had a tradition of relying on quantified risk assessment.

Thirdly, industry supported the idea of an expert system, which could make regulatory assessment of chemicals more predictable and uniform. As USES was planned to provide one risk assessment procedure for industrial chemicals, pesticides, and water quality criteria (including ‘grey’ and ‘black’ lists), it could simplify risk management, especially for companies dealing with more than one of these policy areas.\textsuperscript{269}

Fourthly, the idea of a ‘universal’ method for the evaluation of environmental hazards of substances gave VROM a stronger position vis-à-vis other ministries involved in this policy domain, especially the department of agriculture with respect to pesticides and the department of water with respect to water quality policy. Since the department followed the line that risk assessment of chemicals was to be based on an ‘integrated’ approach, across media and even across policy domains, the goals went beyond industrial chemicals. The model was to include risk assessment of pesticides and was originally even planned for use by local governments in permitting schemes, specifically for water discharges, all based on the same PEC/NEC approach of state-of-the-art risk assessment methodology. In addition, the further development of risk assessment methodology could be used in international negotiations over harmonisation, in particular for industrial chemicals and pesticides, where European initiatives were on the way.

Fifthly, from the experts’ point of view, the idea of building a model for environmental risks of chemicals fitted well with the desire of the RIVM to become ‘the planning bureau of the environment’, mimicking the role of

\textsuperscript{266} For an example of RIVM research on exposure modelling in the mid-eighties, see: Minderhoud, “Beschrijving van Lotgevallen van Stoffen in het Milieu, met Behulp van Eenvoudige Modellen”.


\textsuperscript{268} Rijksinstituut voor Volksgezondheid en Milieu, \textit{Zorgen voor Morgen}.

the Central Planning Bureau for economic policy. The little ‘action point’ in the Environmental Action Plan was therefore the culmination of the development of formalised risk assessment methodology, a need for a tool that could evaluate many chemicals quickly (even with limited data) with higher predictability of the procedure for industry, the strategy of VROM to rely on formalised and quantified risk notions to get a grip on a policy field, as well as the strategic repositioning of RIVM as a planning bureau.

As a mere technical problem, the development of the expert system was contracted to a Delft engineering firm, which produced the first prototype, USES 1.0, by May 1990. The model contained a module to divide chemicals in groups of different hazard levels, and assessment module based on PEC/NEC procedures, as well as a prioritising scheme. Among the feedback on the prototype was a report by the Health Council, which had some major objections to the prototype. The Health Council indicated that the model did not sufficiently specify in what policy context it would be used. In being a ‘universal’ model, it had lost contact with the specific requirements of regulatory regimes. In addition, the Health Council suggested that only a preliminary screening would be possible with such a model, for example in drawing up a rough priority list. More detailed analysis would require human expertise. At best, such a model could be an expert support system. Given the cold reception, the problem of developing USES proved to be more than just a technical matter.

With an increased role for RIVM researchers, a second prototype was developed by December 1992. This second prototype of the USES model deserves some closer attention. The model was well documented in an extensive manual, as well as several publications in the scientific literature, and could be run on a simple desktop computer. This allows us to look specifically at the structure of the hazard evaluation that was presented, the

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270 The position of planning bureau of the environment was later embedded in the legal mission of the RIVM. On this development, see: Kwa, van den Bogaard, and Pastoors, “Het Groene Stempel van het RIVM”; Raad voor Milieu en Natuur-Onderzoek, Kennis voor Morgen; Raad voor Advies voor het Wetenschapsbeleid, Zorgen over het Milieuonderzoek, p. 12 et seq.; Rijksinstituut voor Volksgezondheid en Milieu, RIVM Website.
271 See preface Drs. C.J. Van Kuijen, then director of the department for Substances, Safety and Radiation at VROM in: Ministerie van Volkshuisvesting et al., Uniform Beoordelings systeem Stoffen (UBS): Tweede Prototype.
272 For the occasion, the Health Council had composed a committee with experts from industry, universities, government research institutes, as well as water companies. The department of the environment and RIVM had advisory positions. Gezondheidsraad, Stoffen Uniform Beoordelen?.
273 Ministerie van Volkshuisvesting et al., Uniform Beoordelings systeem Stoffen (UBS): Tweede Prototype.
eco/toxicological division of labour, as well as some aspects of the hazard evaluations for pesticides that were modelled in it. Compared to the first model, there were several striking differences. The claims of being an expert model were more modest: following the opinion of the Health Council, the model was now presented as a tool for screening and primary assessment, not for complete and detailed evaluations. Hence the role of USES for old chemicals was only one of screening and prioritising. Three years after USES was presented as the way to accelerate the backlog of evaluations, the main contribution that USES could have made to address this backlog had to be ceded.

In addition, the ambitions of a universal environmental evaluation of substances had now eroded somewhat. The expert hazard evaluation for pesticides and industrial chemicals was no longer the same. To be of regulatory use, the model was split in different modules and was in fact built by incorporating modules developed for separate regulatory domains. One of the modules followed the decision tree used by the CTB in pesticide hazard evaluation, one used the evaluation procedure for new chemicals, and one focused on prioritising old chemicals. In order to be of use in regulatory assessments, the model could not rely on what the RIVM considered state-of-the-art risk assessment methodology, but was bound to the legal frameworks that had been developed for such assessments. From a regulatory perspective, the model also had to give up some of its original range of regulatory ambitions: it no longer claimed to form a ground for discharge permits by local governments. On the one hand, this use could have undermined national water quality norms, and on the other hand USES was not built for a local, concrete environment. On the contrary: the implicit environment of USES was a highly abstract model of a very average environment, and to be more specific: an average Dutch environment.

The module for the assessment of new chemicals illustrates how exposure modelling related to legal requirements. The Dutch notification legislation for new chemicals indicated that assessment could not be undertaken for effects on one specific location, such as in the river near an effluent outlet, as this was covered in other legislation. Effects for new chemicals had to be assessed in the environment in general. However, an assumed distribution of chemicals over all of the Netherlands would not provide a realistic estimation of the localised nature of potential impacts. The exposure model was hence based on local effects in an abstract environment, in other words: a local assessment, but for a place that could be anywhere in

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the Netherlands (see figure 14). Another example was landfill leaching, covered by a different regulatory regime and a different law. Together with the limited data available on leaching, this meant that it was ‘(temporarily) assumed that no release to the environment will occur. In fact, landfill of potentially dangerous substances is controlled in the Netherlands so, according to the law, no leaching will occur’.275

![Diagram of exposure pathways in USES](image)

**figure 14**: Exposure pathways in USES (Vermeire, T. and P. Van der Zandt, “Procedures of hazard and risk assessment”).

Specific regulatory requirements could also be found in other aspects of the new chemicals module. In particular, its data input was designed to match data in notifications. If a chemical was produced in large quantities, leading to additional data requirements, then these could be used in the programme. Where such data were not available, they would automatically be replaced with extrapolation and estimation procedures. The model could not only be used to evaluate risks, but also to evaluate consequences of potential risk reduction measures. The Chemical Substances Bureau could discuss possible protective measures with notifiers in light of consequences of such measures

predicted by the model. The fact that the model was publicly available made the evaluation process more predictable for notifiers, both the assessment and the possible avenues for negotiations over protective measures.\textsuperscript{276}

The model did not only incorporate existing methodology. In order to achieve the integration of exposure models for such varied environmental processes as sewage treatment, precipitation, or soil chemistry, model makers did not only have to rely on a wide variety of sources, but also use expert estimations for some of the parameters. In order to compensate for such novel elements in the model, attempts were made to validate its results. In this early phase, validation studies were performed for the exposure modelling, comparing the predictions of the model with references for environmental distribution of twenty-five well-researched chemicals. Such validation proved very difficult, especially because concentrations measured in the environment varied more than in the abstract environment of the USES model.\textsuperscript{277} A few years later, the model developers would invert the validation: experts were asked to assess chemicals and their results compared with model output.

3.4.3 Accommodating the model
The development of USES did not end there. In fact, its further story provides interesting contrasts with other tools used in eco/toxicological assessment. The RIVPACS model in England was developed and refined by one research institute and then accepted by regulatory authorities after some informal consultation (see above). Assessment methodology in the new chemicals programme of the US went through extensive standardisation committees and/or publication in the \textit{Federal Register} and a formal public feedback procedure. But VROM organised the process differently. The development of USES itself had mainly been a matter of the RIVM, surrounded with committees of VROM and RIVM experts, with advisory positions for industry, other ministries, RIZA and TNO. In the following years, the further development of USES involved extensive consultation: with industry, with a broad range of eco/toxicologists and human toxicologists in expert meetings and workshops, and again with the Health Council. As VROM had wanted to create policy support by creating a maximum level of consensus over risk assessments in the base documents of the eighties, it now tried to build consensus around the USES model. If the model could be acceptable as an authoritative tool for chemical hazard evaluation, then it could both depoliticise elements of conflicts over chemical risk \textit{and} provide a framework for negotiations over reduction of risk. The policy of VROM with respect to

\textsuperscript{276} De Nijs \textit{et al.}, "Dutch Risk Assessment System for New Chemicals: DRANC".

\textsuperscript{277} Details of the exposure validation: Ministerie van Volkshuisvesting \textit{et al.}, \textit{Uniform Beoordelingsysteem Stoffen (UBS): Tweede Prototype}, pp. 53-54; De Nijs \textit{et al.}, "Dutch Risk Assessment System for New Chemicals: DRANC".
chemical regulation was not only oriented at highly quantified risk definitions, but also at direct negotiation with societal sectors over risk reduction, in order to come to ‘internalised’ environmental policy, i.e. carried by societal actors themselves even in absence of strict regulation. The highly formalised eco/toxicological methodology imported from the US, with its strong reliance on a strict boundary between risk assessment and risk management, had been embraced by the eco/toxicological expert community around the department of the environment and the RIVM. It was now being accommodated to the patterns drawn in these Dutch regulatory regimes.

In 1993, the Health Council committee that had commented on the first prototype, produced a report on the second prototype of USES that was much more positive. The committee wanted further clarification of the position in regulatory evaluation, insisting that it should only be used as expert support tool, not as a replacement of assessment. In support, it pointed at examples of where the specific nature of chemicals would make the model structure less applicable, for example in estimating biomagnification for heavy metals. Nevertheless, the committee disagreed with the consequences of the policy orientation that the model had taken. It recommended a stronger uniformity among the modules for new chemicals, old chemicals, and pesticides. If risk assessment was indeed to be separated from policy issues, then the Health Council committee saw no reason to have diverging procedures for the assessment of industrial chemicals (PEC/NEC based) and pesticides (based on the CTB decision tree).²⁷⁸ In a very roundabout way, the committee’s advice could be interpreted as saying: alter the assessment procedure for pesticides, allow VROM and RIVM to introduce their more formalised approaches.

The further development of USES led to the publication of the first official version in January 1994. Risk assessment procedures were now adapted to the latest European regulations and included the statistical extrapolation measures for protection of 95% of species in addition to the static assessment factors for small sets of data. With USES, the Netherlands could play a central role in the negotiations over the prioritisation of old chemicals in Europe and the OECD. By the time the model was published, the European Commission had accepted to use the model as a basis for further development for use in European industrial chemicals evaluation, in cooperation between the Netherlands, other member states, and European industry associations.²⁷⁹ The European version, EUSES, was completed by the end of 1996. The adaptation required an exposure model that could be extended beyond Dutch environmental conditions, such as different surface water types. In preparation, USES had already allowed alteration of effect

²⁷⁸ Gezondheidsraad, Stoffen Uniform Beoordelen? (2).
boundaries of regulatory science

estimations: assessment factors could be adapted to fit practices common in other countries. Compared to the former version, the model thus allowed for more expert intervention in control of parameters used for estimations. With such modifications, USES had become an expert support tool that both packaged large amounts of expertise and allowed for partial unpacking in the hands of expert users and risk assessors: a boundary object with a constrained flexibility for the science/policy boundary.

With respect to the boundaries in eco/toxicology, USES drew these more sharply. Given its degree of formalisation, USES could not deal with multispecies or field tests. Its makers justified this by presenting USES as an expert support tool limited to screening and intermediate level evaluations. For more comprehensive risk evaluation, assessment would still have to rely on experts that could integrate such data. Similarly, USES acknowledged its limitations with respect to the kinds of effects of chemicals that were considered in it, excluding climate change, eutrophication, acidification, or calamities.280 From the perspective of the ecologists that had attempted to develop methods to assess chemical hazards in the 1970s, with their multispecies tests and ecological indicators, one could say that USES provided a decomposed version of their concept of the environment. Based around key inputs of single species toxicity tests, the frame of environmental analysis developed by environmental toxicologists had reduced a number of typical processes presented by ecologists to sub-processes, such as biomagnification or toxicity to predators, for which USES had made provisions. The protection of ecological community structure had been translated to protection of 95% of species, also based on extrapolation from single species data. The integration of various exposure routes resembled the claim that such routes were modelled in a mesocosm. In fact, the schematic representation of the environment presented in USES bares some degree of resemblance with the images of early mesocosms, sketches of a stereotypical ‘environment’. Nevertheless, the accommodation of ecological critique of environmental toxicology in the Dutch context was not complete, as the exclusion of multispecies tests and classic ecological themes of eutrophication and acidification suggests.

With USES, the RIVM/VROM alliance in environmental toxicology had successfully advanced the formalised, quantified risk assessment schemes. With endpoints and assessment procedures defined in the models, as well as the structuring of data through the model’s input requirements, USES defined what risks were to be considered and how they were to be measured. While steering hazards of chemicals to a manageable problem, the development of USES and the policy field of industrial chemicals also

showed the limitations of this strategy. The ambitions of USES of a ‘universal’ and as an ‘expert system’, with a strict boundary between science and politics and hence presented as ‘risk assessment’ (i.e. ‘strictly scientific’), all had to be scaled down. To be of regulatory use, the model had to be brought closer to policy, allow for more expert manipulation, in correspondence with Dutch regulatory practices that relied more on expert judgement. Although the model makers had to acknowledge the mixture of what they considered science and politics in regulatory assessments, the model itself re-packaged this mixture. In some respects, the model clearly built on decisions that the scientists themselves ultimately considered political, such as the decision to protect 95% of species, but such decisions are now part of a ‘risk assessment’ model, wrapped up in equations and extrapolation procedures, and presented as an expert system. Covered in the complex structure of a computer programme, a decision of the Dutch Parliament, in turn pre-structured by RIVM and US experts, had now once again ended up on the science side of the boundary.

As for the development in the chemical regulation, USES, VROM, RIVM, as well as the European Commission have had some success in the harmonisation of evaluation of chemicals on the basis of the risk assessment methodology of environmental toxicologists. However, other tools have come to compete with risk assessment, such as life cycle analysis or the ‘precautionary principle’ (‘given lack of data, better to err on the safe side’, which proponents of risk typically abhor). In addition, old chemicals continued to present hard cases for quantified risk assessment. In this policy domain, risk assessment methodology has been far less effective in depoliticising regulatory policy. With extensive invested interests in the economy of these chemicals, especially in the ones that are of potential concern – typically produced in large volumes, with the readily mobilised counter-expertise as well as political and economic pressure involved in these chemicals, their assessment typically becomes complex and labour intensive. In some cases, such counter-expertise has involved ecologists. One example has been the case of zinc, where challenges of the risk assessment based on single species of the Dutch base document lead to a report by the Health Council that suggested shifts in community structure as the more relevant way to assess impact of chemicals on wildlife, at least in the case of essential elements (i.e. naturally occurring substances used in metabolism).

Risk assessment methods based on environmental toxicology stabilised in the assessment of new chemicals. A European evaluation of the new

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281 For a comparison of frames of risk assessment, the precautionary principle, and life cycle analysis, see: Tukker, Frames in the Toxicity Controversy; see also: Ministerie van Volkshuisvesting, National Environmental Policy Plan 3, p. 161 et seq.

282 Bal, Bijker, and Hendriks, Paradox van Wetenschappelijk Gezag, pp. 79-81.
substances procedures in 1998 nevertheless showed that differences continued to exist: the Netherlands would recommend risk reduction measures faster than England and in the Netherlands there was more conflict over labelling decisions than in England. Apart from different approaches of regulatory regimes, there were also some substantial issues, such as the problem of variation between national natural environments, potentially altering especially assessments of exposure between countries. (E.g. fast-flowing mountain streams lead to different dilution patterns than slow, tidal lowland rivers.) Several measures were taken to try and reduce these national differences in assessment practice. After the standardisation of ecotoxicity tests in the 1970s, the refinement of these tests in the eighties and early nineties, the development of assessment models such as EUSES in the early nineties, increased possibilities of exchange of data and notification decisions in the mid-nineties, the attention turned to the actual risk assessors. By means of increased contact between risk assessors, such as through workshops, the European Commission stimulated the development of a shared practice. The Commission also regularly invited risk assessors from the various regulatory authorities to come and discuss issues of interpretation of the Directive in closed meetings (closed, so commercially sensitive information in the applications could be discussed). Results of these interpretations were even recorded for reference in the Manual of Decisions. To allow industry to share this information and, once again, make the outcome of the procedure more predictable, a version of the manual was published from which all commercially sensitive data was removed. The public version of the manual is now a document of over 160 pages of detailed instructions on such issues as what substances are and are not subject to notification, how polymers should be notified, or how mixtures should be handled, produced from casuistic discussions as well as rule elaboration.

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283 In the questionnaire, regulatory assessors indicated that disagreements over labelling occurred in over 50% of all assessments in the Netherlands, while only in 10% of cases in the UK. Risk reduction measures were recommend in the UK in only a few percent of cases, while in the Netherlands in almost half the cases. (European Commission, Three Yearly Report on the Implementation of Directive 67/548/EEC, pp. 45, 46)

284 Started with the implementation of the database on notified substances that was prepared in meeting of the competent authorities in 1989 (European List of Notified Chemical Substances, ELINCS). (See European Commission, Manual of Decisions for Implementation of the Sixth and Seventh Amendment to Directive 67/548/EEC on Dangerous Substances (Directives 79/831/EEC and 92/32/EEC), Non-Confidential Version)

Contrasting patterns in regulatory regimes

Once again, we find the familiar trio: with a combination of texts, objects and people, European regulatory authorities have created a shared environment in which risk assessments for new chemicals became increasingly similar among the various national regulatory agencies. At least until the mid-nineties, subtle differences continued to exist between national regulatory authorities for new chemical notification, in spite of highly standardised testing methodology and risk assessment guidelines. In any case, the notification of new chemicals is, among the cases I studied, clearly the regulatory regime that had advanced the farthest in the direction of harmonisation.

And ecology? The project that had started the development of USES, the project Ecological Sustainability of the Use of Chemicals, not only had this ‘line’ for developing a generic chemicals policy. There was also the ‘ecosystem line’, in which there was closer cooperation with especially the department of water. Parallel to the generic approach, ultimately based on physiological and chemical/physical parameters expressing hazards in terms of effects on broad groups of species in an abstract environment, this ecological line focused on the development of standards for substances for specific areas and for nature conservation. In Dutch environmental policy, this was expressed as ‘special environmental quality standards’, as opposed to the generic ‘base quality’, in order to provide protection for vulnerable ecosystems. As mentioned above in the section on water, these standards included salt water, such as for the protection of the Wadden Sea. Here, targets were formulated with indicator species, for example plotted in the radar diagrams (AMOEBA). Whereas environmental toxicology in the Netherlands had developed in a direction to increasingly incorporate and accommodate objections of ecologists, this ecological research line assimilated more and more environmental toxicology: for a large set of indicator species attempts were made to define the toxicity of a small set of key pollutants. This would allow environmental quality standards and environmental protections measures concerning chemicals to achieve ecologically defined targets. In cases where the protection of biodiversity or rare species were involved, this could mean that 95% protection of species was extended to protection of ‘whole ecosystems’. The research projects typically involved cooperation of the RIVM, expanding its expertise on risk assessment to derivation for localised standards, with research institutes such as RIZA or research institutes of the department of agriculture (e.g. DLO).\(^{286}\)

\(^{286}\) Ministerie van Volkshuisvesting, Ecologische Inpasbaarheid van het Omgaan met Stoffen; Tweede Kamer, Milieuprogramma 1995-1998, p. 81; Tweede Kamer, Nationaal Milieubeleidsplan 2, pp. 204-05.
3.5 Eco/toxicology in the Netherlands

Although the regulatory regime for industrial chemicals drew sharp boundaries between environmental toxicology and ecology, particularly for the evaluation of new chemicals, the integrative tendencies of the regulation of environmental hazards in the Netherlands worked both ways. While VROM was able to expand ambitious environmental standards across policy domains along the ‘generic line’, the integration also worked in the other direction: the strong ecological presence in research institutes of other ministries remained present. Key processes by which these integrating tendencies continued to be expressed were (interdepartmental) research programmes. Although the various ministries carried out their own research programmes, at the occasion of major research efforts for more strategic policy research, these were generally set up as interdepartmental initiatives. As the project Ecological Sustainability of the Use of Chemicals ended, new initiatives strengthened these integrative tendencies. For example, in 1993, the advisory councils for agricultural and environmental research drew the lines for future developments in ecotoxicology, focusing on effects of pollutants on ecosystems, integrating research on population and ecosystem level with environmental toxicology. A year later, the Health Council insisted that effects on system and community level required more attention. Even if the RIVM-VROM alliance developed their approach to environmental assessment of chemicals from environmental toxicology, ecology kept being reintroduced through the representation of eco/toxicologists with more ecological orientations in such advisory bodies. Throughout the Dutch programming and review publications in Dutch eco/toxicology, whether policy documents or research publications, the triangle of relations between ecology, environmental toxicology, and environmental chemistry that Koeman had suggested in the early eighties continued to appear, in one form or another. It remained a stubborn reminder that the ‘eco-side of the problem’, as Cairns had once called it, was still there.

The tendency to integrate research via research policy contrasts with the England and the US, where individual ministries held the key position in their research programmes. The formation of closed regulatory regimes,

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287 Raad voor Milieu en NatuurOnderzoek and Nationale Raad voor Landbouwkundig Onderzoek, Hoofdlijnen Systeemgericht Ecotoxicologisch Onderzoek.
288 Gezondheidsraad, Ecotoxicologie op Koers.
relying on a handful of government research institutes, was particularly strong in England, leading to exclusion of a large part of the academic research world. In the US, the regulatory logic of highly formalised decision making meant that ecology lost out fairly early on in the development of regulatory regimes.

Nevertheless, in spite of these integrative tendencies, the formalisation of Dutch regulatory regimes and the continued lack of ecological tests that could compete with single species toxicity testing did also lead to a dominance of environmental toxicology. Whereas ecology had provided the dominant frame of knowledge in the seventies, it was environmental toxicology that dominated regulatory decision making in the eighties and received the largest stimulation of research. By this time, highly standard methodology for environmental assessment developed internationally, and especially in the US, was available and imported in the Netherlands. It resulted in an energetic alliance between VROM, the RIVM and Utrecht environmental toxicologists, producing powerful regulatory tools like USES that would find their way into the European efforts at harmonisation of environmental assessment of chemicals. The chances for development of testing based on ecology in the Dutch regulation of pesticides were minimal, largely due to conservative strategies with respect to the development of environmental regulation. Only in the nineties, by the time environmental toxicology was well established as the backbone of the ‘generic’ regulatory regimes, did the ecological side of pollution research receive more attention again.290 In addition, as much as research programmes contributed to blurred boundaries between ecology and environmental toxicology, they translated regulatory needs often formulated in terms of environmental toxicology and, by the very nature of programming, always had some selections in what research was to be considered relevant and what not.
