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REGULATORY SCIENCE—TOWARDS A SOCIOLOGICAL FRAMEWORK[1]

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The close relationship between scientific expertise and regulatory policy in certain controversial and public areas has prompted commentators to suggest the concept of 'regulatory science'. However, definition is generally constrained either to the concerns of regulatory science or to its context. This paper proposes an approach to regulatory science which is both empirically-based and allows a more theoretical treatment of the new conditions of scientific and regulatory activity. A particular case-study of the British agrochemicals sector is presented in terms of a five-way analytical framework for regulatory science. The paper concludes by considering the wider relevance of regulatory science for future sociological and policy research. © 1997 Elsevier Science Ltd

One way to deal with these assaults on scientists and scientific truth would be to define a new branch of science, called regulatory science, in which the norms of scientific proof are less demanding than the norms in ordinary science.[2]

There is no such thing as a regulatory science. [It] is an art and a very difficult one....[3]

This paper considers the concept of 'regulatory science' and its practical and theoretical significance within contemporary debates concerning science and regulatory policy. An expanding policy and sociological literature has examined the relationship between scientific evidence and the making of policy decisions—both at the level of government[4] and the judiciary.[5] This literature has regularly focused on scientific controversies and

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the relationship between 'facts' and matters of 'politics' or 'values'. Such work has also identified the uncertainties, and indeed indeterminacies,[6] which characterise much scientific evidence within a policy context when dealing with issues of risk and environmental hazard.

Potentially, the study of 'regulatory science' can provide an insight into the changing conditions of scientific practice—and especially the operation of science within an area of industry–governmental–academic relations which is also pressured by the need to make potentially far-reaching decisions (in terms of both public health and economic costs) on a regular basis. The possibility arises that scientific practice in such an area may become bureaucratised and/or standardised to the extent that it loses contact either with more fundamental research (eg regarding underlying mechanisms of causation) or indeed 'real world' circumstances of application. Equally, the commercial secrecy which is fundamental to industrial innovation may hinder the processes of peer review. The high levels of uncertainty which characterise regulatory judgement further serve to increase these concerns. For all these reasons, we argue that careful empirical and conceptual analysis of regulatory science is required.

This discussion will consider especially the possible emergence of regulatory science in the area of toxic chemical control in the European Union—with emphasis on activities in the British agrochemicals sector. Over the last decade in particular, this area has expanded into a series of procedures for the review and official clearance of new agrochemicals.

Some sense of the range of scientific research which might be necessitated by such procedures can be gathered from the variety of *institutional contexts* within which it is conducted:

- University-based research of a fundamental nature (eg concerning mechanisms of carcinogenesis or investigating toxic and environmental hazard).
- University-based research centres that depend on external funding and may conduct relevant research of a more applied nature.
- Private laboratories conducting large-scale regulatory compliance tests to assess hazard and efficacy.
- Industrial scientists assessing the health and environmental hazards of a possible product.
- Government institutions that must assess the evidence submitted by industry and make regulatory decisions.

Whilst we can establish an institutional range of 'regulatory scientists', it must also be emphasised that in the case of agrochemicals this is an *international* (and indeed global) area of activity so that research is spread across various national centres. This international element is also reflected within, for example, the European Union where harmonisation of national systems has become an important policy goal.

Equally, the range of *academic disciplines* involved can be very great since the assessment of, for example, a pesticide for regulatory purposes is likely to draw upon a number of scientific specialties. Thus, a private laboratory wishing to offer a full 'regulatory service' to industrial clients would need to cover a number of disciplines (eg pathology, biochemistry, microbiology, toxicology, chemistry, veterinary medicine) and a number of specific areas of expertise (including efficacy testing, metabolism, residues, wildlife and environmental fate).

It is immediately apparent that regulatory science is likely to be very heterogeneous in character—in institutional, geographical and specialty terms. In this paper, we argue that it is possible nevertheless to identify certain common characteristics. In order to make this case, we will first briefly examine previous academic and policy discussions of regulatory science.

Defining regulatory science

Within the literature, various labels such as 'trans-science',[7] 'regulatory science'[8] and 'mandated science'[9] have been employed in order to distinguish this area from 'academic science' as conventionally practised in universities. Two characterisations of science in the regulatory context illustrate the disparate nature of these discussions. The first focuses on the *concerns* of regulatory science, the second on its *social context.*

The concerns of regulatory science

A conventional (and perhaps hopeful) approach to this subject has been to regard science conducted for government and commerce as unproblematic as long as a separation between matters of science and policy is maintained. Wood, for example, considered that scientists could be part of an...

> ...apolitical elite triumphing in the political arena to the extent to which it disavows political objectives and refuses to behave according to conventional political practices.[10]

The last decades, however, have seen science confronted with problematic questions arising from policy issues (such as the release of GMOs[11]) in which the validity of the science is called into question, and claims and counter-claims are made for the 'correct' scientific interpretation of issues. This lack of consensus appears to contradict the scientistic and separatist view of science in the policy process.

One resolution of this apparent contradiction has been to suggest that regulatory science is concerned with different types of issue than 'academic science'. In particular, the focus on the predictive aspects of science (as typically required for regulation) concentrates attention on the uncertainties involved in a considerable number of policy-questions, which science is not in a sufficiently advanced state to answer. This in turn presents particular problems for policy-making. Weinberg has suggested that in such cases methods and concepts at the margins of science are employed and that such 'regulatory science' should be treated as 'a new branch of science... in which the norms of proof are less demanding than are the norms in ordinary science'.[12]

Analytically, therefore, this concept of regulatory science is concerned with how science can make predictions on the basis of uncertainties. The suggestion is that science in meeting the demands of policy has to transgress its own cognitive boundaries and limitations. It is the manner in which regulatory science approaches these challenges that supposedly lends it a different character to 'academic science'.

From a normative perspective, however, it would appear that a definition of regulatory science as a poor imitation of conventional science undermines precisely what it seeks to preserve. The reification of regulatory science as non-science made more scientific, leaves the methods and results of regulatory science open to challenge on the grounds that they are just policy strategies disguised in scientific language.

The context of regulatory science

In contrast to the above analysis, studies within the sociology of scientific knowledge tradition[13] have portrayed the intimate relation between social commitments and scientific practice as implicit in the construction of scientific knowledge—and not simply as a deviation from proper standards of scientific objectivity. From this perspective, the conventional scientific approach to regulatory science appears inadequate as an understanding of the causes of scientific uncertainty and how that uncertainty is negotiated. Moreover, it is also inadequately expressive of the problematic treatment of regulatory science as a discrete field of activity.

Such sociological studies have portrayed uncertainties in regulation not just as technical uncertainties which can be reduced by further investigation and rational discussion, but also as the result of deeper underlying structural indeterminacies and conflicts in the policy-process resulting from the differing perspectives, interests and rationalities of different groups involved in regulation.[14] From this perspective, the institutional and cultural context of the practice of science has been identified as a more important defining characteristic than its objects of inquiry.

A number of studies, for example, have shown how the production and presentation of scientific evidence may be significantly affected by institutional affiliation. The ways in which industrial scientists may decide, for example, what scientific evidence is significant and what can be ignored and how such evidence should be interpreted, is not solely dependent upon some objective criterion, but is intimately related to their institutional and cultural environment.[15]

In relation to policy-making, it has been argued that it is the institutional environment of science in a regulatory context which affects the practice of that science and lends it a distinct character. Such issues as the audience to which the outcome of scientific review is addressed and the goals of that audience, are likely to influence the design and scope of the science undertaken and reviewed. In particular, the domination of such science by industry and government in producing and certifying knowledge has been identified as having a significant effect on how scientists review and interpret evidence.[16]

The cultural and institutional differences between regulatory science and academic science have led some authors to posit a set of contrasts between the two areas. Jasanoff, for example, has characterised academic science as amongst other things open-ended, innovative, subject to peer review, and undertaken with the aim of advancing knowledge. Regulatory science, on the other hand, is characterised as bounded by external pressures of time and politics, directed towards closure, proprietary, subject to a variety of types of review and undertaken with the aim of aiding policy-making.[17]

Two problems arise from such a characterisation. Firstly, it appears to rely on a rather idealised view of academic science—of the kind that has been convincingly criticised elsewhere by sociologists of scientific knowledge. Secondly, the literature on science and policy-making suggests that the institutional culture of regulatory science changes from country to country so that cross-national comparison suggests significant variation. Thus, it can be implied from the work of several authors that in Europe regulatory science shows greater similarities to academic science than is the case in the USA.[18]

A framework for regulatory science—the regulatory pentangle

It would seem to follow from the discussion so far that attempts to distinguish regulatory science either in terms of its content or context are fraught with difficulty—partly because of the problematic distinction between 'academic' and 'regulatory' science but also due to the very heterogeneous nature of what is being discussed. Despite this interim conclusion, we would argue that the term can nevertheless indicate a useful heuristic category for empirical and theoretical analysis. As a foundation for this, we propose a rather different and non-essentialist set of categories for the discussion of regulatory science.

Our research has so far identified a framework within which regulatory science can be explored in both theoretical and empirical terms. This takes the form of five separate (but closely connected and certainly dynamic) categories that have so far been developed in the context of the British regulation of agrochemicals. These categories suggest the diverse activities which can be grouped within regulatory science. For the purposes of this paper, we have focused on the kinds of science (and scientifically-related activities) which might be employed and developed prior to the innovation of a chemical substance—and hence we have taken an industrial/governmental view of the processes involved (for a discussion of public responses to such issues see Irwin, 1995).[19]

It is apparent within these categories that they transgress the content/context distinction. Instead, they combine elements of both (ie there is a tight relationship between the cognitive dimensions of the following categories and the social and institutional contexts within which they are developed).[20]

1. Speculative research

Speculative research is taken to embrace basic academic research on subjects that may have regulatory relevance such as chemical toxicity or environmental hazard.

2. Development and validation of regulatory tests

Whilst hazards associated with the use of certain chemicals may be identified as a result of basic speculative research, specific tests have to be developed and validated so that chemicals can be screened for potential hazards.

3. Regulatory compliance testing

This refers to the undertaking of screening tests by industry—although often in collaboration with various scientific services—as specified by regulatory authorities.

4. Investigative problem-solving

Whilst positive results from regulatory compliance testing may result in regulatory failure, further investigation may be pursued in order to identify whether results are false positives, or whether special circumstances suggest that the result is irrelevant to risk assessment.

5. Regulatory submission

The final stage of the production of regulatory science is concerned with compiling the dossier of information for regulatory review and completing the in-house risk assessment.

These five categories indicate the diversity of activities involved in regulatory science within one sector. These range from fundamental research, through more narrowly 'technical' exercises, to bureaucratic administration (which sometimes may be no more than 'box-ticking' but can also be technically-complex and demanding of expert judgement). In addition, the categories are neither linear (ie they do not necessarily fall in the above order) nor are they self-contained. Certainly, there is likely to be substantial cross-over between the categories. Thus, investigative problem-solving may necessitate what could also be described as fundamental research. Equally, work in this category may involve further regulatory compliance tests or negotiation with regulatory authorities over the applicability of certain requirements.

The above categories are also likely to be variable in terms of the institutional location of the regulatory scientific activities. Whilst, for example, it might be anticipated that fundamental research on health and environmental hazard would be primarily located within the academic sector, larger or specialised industrial laboratories may also serve as 'universities' for this purpose. However, regulatory compliance testing is more likely to be undertaken in the private sector (including in-house laboratories) which often specialises in performing standard assays in conformity with regulatory requirements such as Good Laboratory Practice (GLP).

It can already be seen from the above categorisation and brief discussion that regulatory science crosses a number of scientific and institutional boundaries. In contrast to previous attempts at classifying this area in one-dimensional terms of either its content or context, our proposed framework emphasises the *heterogeneous and hybrid* character of regulatory science. This plurality brings together:

- Scientific activity as located within academic, industrial and governmental settings (ie a variety of *institutional locations*).
- Activities which bring together a range of *specialty and disciplinary orientations* and which embrace varying *levels of scientific uncertainty/indeterminacy* (from complex and innovative work on mechanisms through to routine testing).
- Intellectual and practical activities which—to varying degrees—span the *technical* and the *bureaucratic.*
- Concerns which are inevitably *scientific, economic and political* in character (from basic research through to regulatory lobbying and the taking of key industrial decisions).
- Activities that encompass both *regulation* and *innovation* since in our chosen sector regulatory concerns start at the very earliest stage of the innovation process.

In order to test out the validity of the above five-way categorisation and the general categorisation of regulatory science, we will focus for the rest of this paper on one area of regulatory scientific activity.

The case of agrochemicals

The highly-regulated and research-intensive nature of this sector makes it especially appropriate for examining the consequences of the evolving European regulatory framework for both innovative and safety-related activities within firms located in the UK, research laboratories and universities. The agrochemical industry is one of the most research and development (R&D) intensive industrial sectors, with (based on industry sources) the top 20 companies world-wide committing on average around 11% of total sales to R&D. An agrochemical company might screen up to 40,000 chemicals to find one suitable ingredient—the 'active' molecule used in a pesticide formulation. This can cost many tens of millions of pounds.

Agrochemicals now represents a very mature industry with new products emerging at a relatively slow rate. Tait has argued that this, coupled with the scale of investment required over a long development period, has put the innovation of novel agrochemicals out of the reach of all but a handful of corporations.[21] It is expected that in about 15 years time there will only be seven corporations world-wide in a position to innovate new agrochemicals. This has led to a growing emphasis on 'me-too' and 'generic' products.

Industry has often argued that the emergence of strict regulatory regimes has had a generally detrimental effect on innovation. Certainly, regulatory requirements have increased substantially over the last few decades in the agrochemical sector. It has been estimated that to comply with data requirements world-wide, a new pesticide requires approximately three-quarters of a tonne of documentation!

The UK had no statutory regulations for the approval and registration of pesticides until 1986. Prior to this, a voluntary scheme known as the Pesticides Safety Precautions Scheme (PSPS) operated between government, manufacturers and suppliers. Although there was no enforcement, PSPS operated on the principle that only pesticides approved by the government expert Advisory Committee on Pesticides (ACP) would be supplied.

In 1986 the Control of Pesticides Regulations (COPR) were introduced, which legally obliged manufacturers to submit data on active ingredients to be used in pesticides to MAFF for expert review. More recently, the European Plant Protection Product Directive 91/414/EEC[22] has been implemented and submissions of new active ingredients and the review of old active ingredients are under way. The regime is not fully completed and it is expected that the first registrations will establish some of the principles for the operation of the regime.

One expected result of the new European regime is that less testing overall will be required since a core set of data can then be modified as appropriate for each country within the EU. On the other hand, the range of testing is expanding so that a recent emphasis on environmental impact has increased the number of types of test required to meet regulatory requirements.

Overall then, and based on our company interviews, the perception within the British agrochemical industry is of regulatory change and of an increasing regulatory burden—a burden that many in the industry see as greater, for example, than that experienced within the pharmaceuticals sector since standards are at least as strict but cover a wider variety of possible hazards and pathways. In particular, the new regulatory regime requires detailed scientific testing and a concern with hazard which runs throughout the innovation process.

Regulatory science and the agrochemical industry

The discussion that follows is based on an extensive series of interviews in Britain and the European Commission with government officials, non-governmental organisations (NGOs), industrial representatives from multinational agrochemical companies undertaking R&D in the UK, and major academic laboratories operating in this area. How then does the 'regulatory pentangle' apply in this area?

Speculative research

Within agrochemicals, research in this category is primarily located within the academic sector and is likely to derive funding from research councils and other government sources but, significantly, may also be supported, directly or indirectly, by industrial funding. Some of the more sophisticated industrial laboratories, independent and private sector laboratories also claim to be increasingly undertaking basic research. With regard to agrochemicals, speculative research raises particular questions about industry–university cooperation—which many in the industry feel is less than sufficient. Instead, there would appear to be a lack of communication between speculative research funded by the private and public sectors.

Basic research on hazard may simply be of relevance to pesticides or may have cross-sectoral implications for other chemical hazards. For example, whilst work on environmental fate may be directly concerned with agrochemicals, research on hormonal disrupters may apply across the chemical sector. In that sense then, this is likely to be the least 'sector specific' area within regulatory science.

Closely linked to this is 'blue sky' basic research, which might lead to new products or processes. This may similarly be undertaken within academic or industrial research laboratories and have a variety of funding sources. Whilst a major part of the rationale for such research does relate to putative regulatory and innovatory developments, the research may well not have immediate applications but may be part of a longer-term industrial strategy of keeping a 'watching brief' on significant areas of change.

Whilst speculative research on products may not be of immediate relevance to regulatory agencies, there is clearly a bureaucratic interest in this area. Without at least an understanding of scientific developments, governments will be disadvantaged in terms of responding to new technical understandings, regulatory pressures from outside Britain or industrial lobbying to remove 'irrelevant' tests. A similar point applies to industry—one large private sector association claims that 98% of such research is funded by industry. Thus, speculative research can appear to be removed from specific regulatory matters but is nevertheless an important domain for regulatory science.

Development and validation of regulatory tests

The development and setting of tests in order to establish whether a chemical presents a health or environmental hazard interlinks social, bureaucratic and scientific demands. Such considerations as achievable levels of sensitivity, generally available equipment, acceptable margins of error, acceptable grounds for modelling, and the interpretation of results from model systems present opportunities for a number of social assumptions to pervade the development of a technical regulatory regime.

Whilst scientific judgement underlies the development of such tests, decisions concerning which tests to utilise may involve a variety of political and commercial considerations. A political climate which emphasises environmental protection, for example, may result in further incorporation of tests to screen for environmental hazard, or the setting of precautionary limits. On the other hand, commercial pressures to minimise cost in a testing regime may have a countervailing influence.

This issue has been illuminated by the difficulties of reaching agreement on an ecotoxicity testing regime for harmonised regulations. Considerable problems have been encountered in devising an ecotoxicity testing regime both because of scientific uncertainties and political sensitivities. In setting the testing regime, the Commission has, for example, had to balance the incorporation of the widest range of target species against the demands of a practical regime. For its part, industry, conscious of potentially spiralling costs, is concerned that the 'nice-to-know' is not confused with the 'need-to-know'.

Institutionally, the development of test requirements for the harmonised regime is a relatively informal process involving considerations of current law in the EU, the *ad hoc* consultation of international organisations such as the Organisation for Economic Cooperation and Development (OECD) and the European Plant Protection Organisation, and industrial experts (who are thus well-placed to influence the shape of regulations). The tests are then finalised in inter-governmental working groups consisting of government and specialist expertise, though some Member States may be more enthusiastic participants than others.

In practice the Commission does not develop its own guidelines if none pre-exist, partly because of the resources required and partly because once set, further agreement would still be required with countries outside the EU, such as the USA, Canada and Japan. Instead, where pre-existing guidelines are not available, arrangements are made for the OECD to investigate urgent items whilst leaving applicants to negotiate with individual Member States pending the implementation of an agreed guideline. Once again, this implies the importance of informal governmental–industrial settings in negotiating this dimension of regulatory science.

Regulatory compliance testing

Regulatory compliance testing brings together a variety of institutional, professional and technical issues. Technical activities in this area are defined by standardised protocols, methodologies and practices either through regulatory requirements or best professional practice. As such, testing combines both bureaucratic and technical elements.

Commonly in this sector, such activities are regarded as concerned primarily with *technique* rather than *research.* Undoubtedly, such testing encompasses a wide range of activities some of which are standardised and repetitive (ie so-called 'handle-turning'). Other activities such as metabolic studies will involve a considerable research element. As such, testing encompasses a wide range of disciplinary activities and specialties. Thus whilst the production of chemical and toxicological data may be obtained from standardised and widely used protocols, some assays, particularly in the area of ecotoxicology, may be less well developed and require a more investigative approach.

The bureaucratic element of regulatory compliance testing may be best exemplified through the necessity of working to standards of Good Laboratory Practice. GLP is a requirement aimed at ensuring the integrity of data. This was introduced in an attempt to reduce fraudulent practice following a number of high-profile cases in the USA.[23] Whilst GLP sets a range of principles for the design, performance and recording of tests, it has no direct influence on the quality of the science—and indeed it is quite possible to do 'bad' science (especially when viewed in traditional academic terms) to 'good' GLP principles.

The choice for an agrochemical company to use commercial or in-house facilities will vary depending upon the availability of in-house facilities and strategies for maximising their efficient usage. Whilst some companies have their own facilities, others entirely rely on contract facilities. Within the private sector, there are a number of commercial laboratories which specialise in regulatory compliance testing and which have achieved a high level of efficiency. The range of activities performed by such laboratories may vary from highly specialised but limited facilities to those which, in principle, can undertake the whole range of testing.

Whilst costs are inevitably an issue, a high premium is placed on quality, security and confidentiality in laboratory selection. Thus, in company-contract laboratory relations a considerable value is placed on building relationships of trust, which is reflected in sometimes local arrangements, but also through the relatively small and close professional–social nexus of personnel in companies and contract laboratories. However, the farming-out of research can diminish industry's capacity to accumulate tacit knowledge that might aid with future development of the product.

The necessity of working to GLP can present problems for laboratories in the university sector. University facilities and research cultures do not fit easily with the GLP requirements of dedicated facilities and quality assurance practices. A few laboratories attached to British universities have become GLP-compliant and dedicated to specialised testing work for the agrochemical industry. However, a mutual reluctance to engage jointly in these activities on the parts of both industry and academia can be discerned in industry's suspicion of a capricious academic research culture, and general reluctance to undertake repetitive technical exercises. Furthermore, such work also raises problems for universities, because of its potentially erratic nature, the limited market, and the lack of contribution of such work to research assessment exercises such as those carried out in Britain (which typically reward more academic and published output).

The organisation of testing also illuminates the evolving relationships between innovation and regulation. As regulatory frameworks have developed nationally and internationally, reactive strategies of regulatory compliance testing at the end of the innovation process have become replaced by more anticipatory strategies of integrating testing fully into the innovation process. The adaptation of the innovation process to take account of actual and potential future regulatory developments has explicitly been orientated towards addressing past problems of dislocation between innovation and regulation.

As the costs of innovating a new agrochemical increase, potentially efficacious but unregisterable active ingredients (AIs) are screened out by routinely putting chemicals through a standard series of regulatory compliance tests at well-defined stages of their development. This both reduces wasted time and costs, and speeds the collation of dossiers for regulatory submission. This is commonly termed a 'process orientation' within industry and would appear to represent a new stance in industrial scientific work.

Process orientation of regulatory compliance work involves a multi-disciplinary team approach which integrates scientists with other sections of companies, such as marketing, throughout the innovation process. This has resulted in scientists, pre-eminently toxicologists—although increasingly also ecotoxicologists as environmental issues rise up the regulatory agenda—having enhanced repsonsibilities for decision-making on the continuance or termination of projects. Yet, at the same time, such decisions must balance the risks (and opportunities) of pursuing development against registration failure and thus involve expertise from various parts of the company.

Investigative problem-solving

If early toxicological screens indicate potential problems, tests may be repeated or further investigative work may follow. Of course, decisions over this have to take into account the regulatory agency to which the agrochemical is being submitted. Within the EU regime, further investigative work is laid down within the regulations, should a product fail a first round of conservative tests. If a result is thought to be a false-positive or in some way anomalous or atypical, further investigative research may reveal a reason for a false-positive or a mechanism for the anomaly, which might imply that the anomaly is irrelevant for risk assessment purposes. In such a case, regulatory approval might subsequently be secured.

A decision to pursue such a sometimes-costly option, however, will be ultimately dependent upon the expected gains from marketing the product: clearly the greater the expected gains, the greater the incentive. Such a situation can also enhance the responsibility given to industry scientists—but also place them in close interaction with marketing, regulatory affairs, corporate strategists and senior management.

Private sector organisations can undertake certain aspects of investigative problem-solving in addition to in-house work, particularly if the work has to be conducted to GLP standards. Where more basic research is required, this may have to be contracted out to academic experts within universities and other public institutions. Such work can make valuable contributions to academic research and could offer new forms of funding.

Regulatory submission

The final area of activity concerns the compilation and submission of dossiers of information for regulatory review. Regulatory submission has to meet both bureaucratic criteria and the technical requirements of expert review and risk assessment. There is a tension between these elements, highlighted for example by the short period following submission permitted for clarification of requirements for further data by agency staff. For example, it is common for industry to perceive additional requests for data as unnecessary 'box-ticking' (ie as trivial details designed only to satisfy an arbitrary bureaucratic demand), whilst the agency regards such requests as scientifically-important.

The process of regulatory submission has become intricately entwined with the innovation process as delays in submission and review can critically affect the eventual profitability of the product. Thus, as the complexity of the submitted dossier has increased, advance planning for regulatory submission has become increasingly important.

According to our interviews, under the voluntary arrangements of the UK PSPS scheme, this activity was given low priority for companies, and could be typified as the responsibility of ex-field trials officers with relatively limited promotional prospects. The small network of professional and social contacts, and the informal nature of the scheme, was described by one intervieweee as making it possible to 'take out the MAFF representative for a couple of beers and everything would be all right. You laugh, but it was very nearly like that'.

With the increasing demands of regulatory frameworks, the crucial importance of regulatory submission has been reflected in the professionalisation and growth of regulatory affairs departments within companies, responsible for preparing regulatory submissions, ensuring the adequacy of the information and liaising with regulatory authorities. Personnel may have agency backgrounds, valued both for their scientific and regulatory skills as well as for their familiarity with regulatory institutions and personnel. Thus even in the increasingly formal regulatory process, a high value is placed on developing and maintaining a trust-based relationship with the regulators. Regulatory affairs have also become an important area for contract laboratories, similarly employing professional expertise with regulatory or industry backgrounds.

In response to the increased workload brought about by statutory regulations, MAFF's Pesticide Safety Directorate (PSD) has increased its scientific staff from 25 in 1986 to just over 100 in 1992[24] and has evolved into what might be termed a 'regulatory science institution'. Staff training has been critical in this expansion, with the PSD considering that it takes around 18 months to turn a graduate (usually recent) into a 'regulatory scientist' acquainted with a number of fields of science, law and agriculture.[25] Thus, for the PSD, a regulatory scientist has multiple, cross-disciplinary skills.

Despite the expansion of PSD, the agency—due to the heavy workload—contracts out reviews of dossier submissions. This extension of the peer review process further blurs boundaries between contract laboratories and the regulatory agency.

Conclusion

The previous section has indicated the diversity of regulatory science, what we termed earlier its 'heterogeneous and hybrid character', even within one sector. Furthermore, our treatment here has not considered other possible dimensions of regulatory science—for example, the kinds of expertise deployed by environmentalist groups or the US judiciary within public debate. Instead, we have deliberately focused on the 'private' face of government–industry–academic relations.

The close relationship between conventionally 'scientific' activities and those concerned with economic, social and political factors has been apparent throughout. Indeed, the assessment of various forms of scientific evidence is so thoroughly contextualised that such distinctions make little sense. Thus, even the most academic questions of mechanism will be considered in practical and market-oriented terms: how will product ranges be affected by this finding? what kinds of innovation strategies make sense in the face of potential uncertainties? should regulatory agencies force the pace or await industrial developments? Given the complexities of the science under discussion, the negotiation of technical uncertainty becomes crucial to regulatory science.

There are, therefore, a number of possible conclusions and lines of argument which could be drawn from this treatment of regulatory science. Certainly, the implications of the above for environmentalist and 'public interest' groups deserve serious attention: it seems possible that regulatory science effectively disenfranchises groups which cannot play an intimate role in the largely confidential negotiations discussed so far. A second line of discussion would consider the relationship between regulatory science and the emerging conditions for the production of science in other areas: does regulatory science represent part of a wider phenomenon of 'industrial science' where, for example, 'process orientation' and multidisciplinarity have become a fact of life? Thirdly, it is important to consider the nature of peer review in this area: the possibility is that the institutional context of regulatory science will hinder external scrutiny and hence diminish the quality of scientific work.

It would appear, therefore, that the concept of regulatory science suggests a number of important areas for critical debate and further empirical research. In terms of the latter, it would be especially helpful to explore the overlap between the analysis here of agrochemicals and other sectors—with pharmaceuticals as an especially-strong candidate for comparative analysis. Such research could also look outside the British context in order to assess whether this alters the substance of our framework.

The very emergence of such important research and policy issues suggests for us one significant strength of our framework and focus. However, rather than pursue empirical matters further, discussion in this final section will return to the conceptual level. In particular, and throughout the previous discussion, an analytical tension has existed between, on the one hand, the 'heterogeneous and hybrid' nature of regulatory science, which for us overwhelms attempts to classify it in simple one-dimensional terms such as 'content' or 'context', and the very coherence of the concept itself. Put bluntly, if the term refers to such a diverse range of activities is there any merit in its usage?

This paper suggests that there are several basic justifications for the deployment of 'regulatory science'. First of all, and as already exemplified by this conclusion, consideration of regulatory science suggests further empirical and policy issues which might be neglected by a less systematic approach. In particular, the focus here on the more private face of regulatory science allows a set of strategic and public questions to emerge which might otherwise be neglected. Certainly, the area of regulatory science seems to be ignored within most policy discussions of the national and international science base—a tendency which may have been encouraged by previous disparaging treatments of regulatory science as a poor relation of 'academic science'.

Secondly, although regulatory science may not necessarily be unique in this regard, the treatment here allows a sense of the emerging scientific and regulatory context within which key innovatory and environmentally-related decisions are being made. The industrial distinction between 'need-to-know' and 'nice-to-know', for example, conveys some sense of the practical pressures on technical matters which may be highly indeterminate in character. Our treatment of these concerns suggests that this is a rich site for sociological analysis which takes us beyond the more traditional focus on 'laboratory science'.

Thirdly, and at a very different level, regulatory science gains a validity from its currency as a term among practitioners in this field—we would hypothesise that this is a growing tendency which reflects the professionalisation and enhanced status of activities in this area. Of course, and in the constructivist tradition, it is important that we critically evaluate such everyday terminology rather than merely accepting its validity. However, the concept seems to be a reflection of the kinds of institutional and scientific change taking place with regard to the internationalisation of regulation.

Finally, regulatory science draws attention to the social and regulatory pressures on industry and government which are currently being generated. Put in more theoretical terms, regulatory science represents a major test case for the flexibility of modernistic institutions, including those of science and industry, in incorporating environmental values whilst operating within major constraints (most notably, the market-place itself). The tension within regulatory science between rule-based standardisation (as required by international governmental and industrial institutions) and flexible patterns of innovation and scientific investigation (as the same institutions also claim to value) represents a major challenge for regulatory scientific bodies such as the PSD and its European equivalents. In particular, can scientific and commercial credibility be maintained or will rule-making ultimately undermine the scientific, governmental and industrial institutions it currently aims to support?

Regulatory science, therefore, suggests some of the key scientific and institutional challenges of our age. Its hybrid and heterogeneous nature should not disqualify it from academic treatment but rather serve to reinforce its significance for future research and policy-making.

Notes and references

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