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## REGULATORY SCIENCE, EUROPEANISATION AND THE CONTROL OF AGROCHEMICALS

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## ABSTRACT

This paper addresses issues of regulatory convergence and Europeanisation as they have developed within the agrochemicals sector. Taking the UK as a case study, the paper considers the continuing importance of local and national factors within systems that are ostensibly international and standardised. In particular, the paper shows how the embedded social relations of regulatory science in the UK, including institutional practices, judgements of expertise and established relationships of trust, result in a 'nation-centredness' and divergence of regulatory cultures despite the putative development of a harmonised European framework. It is argued that, as a consequence, the claimed universalism of scientific culture in this area is in tension with the local conditions of its practice and enactment.

## REGULATORY SCIENCE, EUROPEANISATION AND THE CONTROL OF AGROCHEMICALS

The agrochemical market is international in character. Companies wishing to operate across national boundaries have typically had to meet a diverse range of regulatory requirements even for the same product. The harmonisation of such requirements offers the opportunity of standardising these various systems so that approvals (including reviews of old agrochemicals) can be based on core sets of data that have wide validity. The twin objectives of these changes are to aid trade by creating a level-playing field of regulatory requirements across the EU and to provide a European-wide standard for the protection of public and occupational health, wildlife and the environment.

In seeking such objectives, the development of international regulatory frameworks places particular pressure upon scientific evidence and argumentation. Markets tend to favour standardisation for economic reasons. Nevertheless, the actual standards adopted are generally legitimated in scientific terms. Scientific evidence and evaluation is seen to offer not only a rational basis for harmonisation but also a policy foundation which applies across nations - and in that sense is 'universal'. However, such a generalised treatment of the relationship between science and regulation tends to ignore the local negotiations, institutional structures, social relationships and professional judgements that lie at the heart of contemporary regulatory science. As we argue here, the very notions of 'standardisation' and 'harmonisation' need to be critically examined in the light of arguments from the sociology of scientific knowledge - and especially its empirical analysis of modern scientific practice.

In this paper, therefore, we consider the emerging relationship between one national regulatory framework and moves towards the construction of a European structure. More particularly, we explore the relationship between an area of scientific and innovatory activity which we term 'regulatory science' and attempts to develop a harmonised system for the technical assessment and control of agrochemical products. We argue that an empirically-based understanding of the contemporary conditions of regulatory scientific production is necessary for the analysis of 'Europeanisation' as a political and scientific process. More particularly, we suggest that the conventional legitimation of regulatory harmonisation draws upon an idealised (and, indeed, ideological) account of regulatory science and its 'globalised' character.

The paper discusses the possible consequences of this empirical analysis for the concept of 'Europeanisation' and, by extension, 'globalisation'. Although 'Europeanisation' is often presented as a straightforward process of 'regulatory convergence', the pattern is also one of divergence, reinforcement of national self-identity and localism - and, as we suggest, for reasons especially linked to the contemporary character of scientific practice in this area. Accordingly, European regulatory structures cannot simply be imposed in a standardised fashion but must be negotiated and constructed within particular institutional settings.

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On that basis, our paper begins with a consideration of ‘regulatory science’ in the area of British agrochemical development. As we discuss below, regulatory science is contentious in terms of academic definition and analysis - not least in its portrayal of the inter-linkage between science, regulatory policy and industrial practice. However, we suggest that it does allow significant insight into the conditions of contemporary knowledge production.

Having discussed the character of British regulatory science with regard to the agrochemicals industry, we then consider the relationship between this and moves towards Europeanisation. In the case of agrochemicals, companies have been actively engaged in European regulatory processes over the last decade. Our findings suggest that the form of this practical engagement will be, and indeed already has been, strongly influenced by the institutional and cognitive organisation of regulatory science.

Previous academic studies have noted the difficulties of establishing policy (or ‘achieving closure’) within scientific domains that are often characterised by extreme uncertainty and indeterminacy (Wynne 1992; Jasanoff 1990; Irwin 1995). In such situations, the demands of certain national policy-makers for definitive and scientifically-robust risk assessments have often served only to exacerbate scientific disagreements. Regulatory science then emerges as a sometimes problematic meeting-ground between the institutional practices and professional expectations of science and of policy-making (for a fuller discussion of regulatory science, see Irwin *et al* 1997).

In general agreement with this conceptualisation, Shackley and Wynne (1995) have argued that regulatory science should be seen not just as a ‘sort of hybrid of science and policy’ but as part of a larger process of ‘mutual construction’. According to this perspective, ‘science’ and ‘policy’ do not simply interact on occasions but instead build upon one other so that political assumptions form a key but unacknowledged element within scientific risk assessment, and scientific assessment in turn serves to frame policy. Thus, the relationship between science and policy is presented by Shackley and Wynne as a ‘material institutional and cultural enterprise’ within which ‘common cultural and epistemic commitments may unite policy bodies, scientific researchers and the hybrid area in between them’. Rather than simply defining regulatory science by its purpose, we see that it can represent a specific set of assumptions and practices. The implication is that - far from offering a universal and objectively-determined basis for common standards - regulatory science can vary substantially across policy settings and decision-making processes.

In this paper, and broadly in line with Shackley and Wynne’s portrayal, we wish to consider the cognitive and organisational characteristics of regulatory science as it has emerged in the area of agrochemicals. In order to conduct this analysis, we will approach issues of regulatory science and European harmonisation from the perspective of one nation - the United Kingdom (and especially industry with a base in the UK). Rather than presenting an international comparative survey, our empirical analysis will draw upon one national context as it faces up to the challenges of harmonisation. In this way, whilst the paper might serve as a precursor to a more internationally-based study of regulatory standardisation, it also allows a more specific exploration of the locally-negotiated conditions of regulatory science.

Our research is based upon an extended series of interviews with industrialists holding special responsibility in this area (including toxicology, R&D and regulatory affairs managers) within R&D-intensive agrochemical corporations with a base in the UK. As all the major R&D agrochemical corporations are multi-nationals, and the agrochemical market is itself international in character, these representatives have considerable experience of regulatory systems in Europe and the rest of the world. In addition, we have interviewed government officials from the relevant

departments and agencies (including the Pesticides Safety Directorate, PSD), officials of the European Commission and scientists (working in university and industrial contract laboratories). We have also made full use of documentary sources - and especially evidence compiled by the House of Commons Agriculture Committee. In order to establish the regulatory background to this research, we will now briefly consider the UK structure of the regulation of agrochemicals and of regulatory science as these existed prior to the 'European' initiatives of the 1990s.

## REGULATORY SCIENCE IN THE UK

In the last decade, pesticide regulation in the UK has changed considerably. Until 1986, the UK had no statutory regulations for the approval and registration of pesticides. Instead, 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 an independent advisory body, the Advisory Committee on Pesticides (ACP), would be supplied.

In 1986, under pressure from the European Community to introduce a statutory scheme, the UK replaced PSPS by the Control of Pesticides Regulations (COPR) which legally obliged manufacturers to submit data on pesticides to MAFF for expert review. Under this statutory scheme, MAFF's Pesticide Safety Directorate (PSD) administers pesticide registration, the ACP makes recommendations on the approval of pesticides, and Ministers formally take approval decisions. As will be discussed below, the introduction of statutory regulation stimulated and professionalised regulatory compliance activities undertaken by industry and necessitated a concomitant expansion of government facilities for reviewing submissions. For example, between 1986 and 1992, the UK's Pesticide Safety Directorate (PSD) increased its scientific staff from 25 to just over 100 (House of Commons Agriculture Committee 1995, 210). These changes have put the UK in a strong position both to accommodate and influence current changes at the European level.

It is in this context that we consider the evolution and character of scientific activity relating to the British regulation of agrochemicals. Previous discussions have tended to characterise regulatory science either in terms of its social function (informing the regulatory process) or its applied content (often in contrast to 'basic' or 'academic' research).<sup>1</sup> Our empirically-based approach, using in-depth interviews and associated literature searches, permitted an exploration of the relationship between 'science' and 'regulation' in the specific context of changes in policy-making.

Our research suggests that previous characterisations of regulatory science are too generalised. Instead we have identified a diverse range of activities which comprise 'regulatory science in action' (for a fuller discussion see Irwin *et al.*, 1997). These activities cross the conventional boundaries between 'science', 'regulation' and 'industrial innovation', suggesting just how mutually embedded they have become within the national context studied here. Thus our notion of regulatory science does not simply encompass what might be conventionally defined as 'science' but also a multifarious range of technical, innovative, legal and administrative activities which relate to the development and innovation of agrochemicals.

This is not to deny, however, that there is a 'scientific' component to this area - often involving what might be conventionally termed as 'basic' science but always with a practical application ultimately in mind. In this, of course, regulatory science may not be atypical of the wider conditions of contemporary knowledge production as supported by industry, government and academia.<sup>2</sup> Certainly, we would not accept the assertion that regulatory science simply represents some 'applied' form of basic or academic science - not least since such a dichotomy depends upon a Mertonian (or at least pre-Kuhnian) conception of the scientific enterprise.

In order to illustrate these points - and also to indicate the range of scientific disciplines and specialties, and institutional activities involved - we set out below a number of diverse types of regulatory scientific activity as described to us by industrial and governmental representatives. Our research especially emphasised the regulatory scientific activities of British companies prior to regulatory review. Of course, in public terms this might be only the beginning of a wider scrutiny of the technical evidence regarding the safety of a specific agrochemical.

For example, speculative research on subjects that may have regulatory significance (such as questions of chemical toxicity or environmental hazard) may seem to be the most 'academic' form of regulatory science - and certainly university laboratories are involved. However, it is worth noting that some research in this area is undertaken by the larger R&D-active agrochemical firms. The development and validation of tests for screening chemicals, meanwhile, draws upon more diverse institutional bases of government and a small number of academic laboratories, as well as the agrochemical industry, contract laboratories and consultancies (in these cases often through their involvement in professional associations).

In contrast to such development work, regulatory compliance testing to screen chemicals for hazard, is generally repetitive and highly-standardised (with fixed protocols and test procedures which must be conducted in accordance with the requirements of Good Laboratory Practice). This form of regulatory science is the domain of the agrochemical company developing the pesticide and associated contract laboratories, with British university laboratories seldom getting involved. However, investigative research, exploring whether positive results from regulatory compliance testing are 'false positives' or whether special circumstances suggest that results are irrelevant to risk assessment, is organised on a more case-by-case basis. This work by its nature tends to be rather more research intensive, although it is still largely undertaken in industrial facilities.

Finally, regulatory submission, comprising the completion of the in-house risk assessment and the compilation of the dossier of information for regulatory review, is a highly multi-disciplinary process combining both technical, regulatory and managerial inputs. Whilst regulatory submission is generally a matter for the agrochemical companies themselves - often working closely with consultancies and contract laboratories- the relevant British government agency (PSD) may also play a role in offering constructive advice and general guidance.

This thumbnail sketch suggests the variety of scientific disciplines and specialties, bureaucratic practices and institutions that comprise regulatory science. In institutional terms, it is important to note that regulatory scientific activities draw upon a national - but also international - patchwork of organisational forms. As we discuss below, this patchwork has developed particularly over the last decade or so in response to the changing regulatory framework. In order to explore this patchwork, we will focus on regulatory scientific activities from the perspectives of industry, contract laboratories and governmental agencies.

For industry, there has over the last decade or so been a move towards taking greater account of regulatory demands within the development of new agrochemicals. According to one regulatory affairs manager, prior to the introduction of statutory approval requirements registration "was almost a part-time occupation of a [field] trials officer." However, the introduction of statutory registration in 1986 forced companies to strengthen and professionalise their regulatory compliance activities. As another company representative put it to us, "we found a successful family of Active Ingredients and invested quite heavily, but we then came up against a problem which killed it. We realised we could no longer afford to do safety tests at the end - so now we run the tests in parallel." Whereas previously testing could be 'bolted-on' at the end of the innovation process, the possibility

of costly registration failures necessitated a general move by agrochemical companies to integrate regulatory compliance testing into the innovation process.

Increasing innovation costs and lead-times to market have become critical in determining the eventual profitability of a pesticide. Screening-out potentially efficacious but unregistrable Active Ingredients (AIs) by routinely testing them at well-defined stages in their development has, therefore, become an integral part of the agrochemical innovation process. Termed 'process orientation' by industry, this organisation of regulatory scientific activities appears to represent a new stance in industrial scientific work.

The process orientation of regulatory compliance work generally involves a multi-disciplinary team 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 responsibilities for decision-making over the continuance or termination of projects. Innovation and regulation are indeed becoming more closely related in this sector - and mainly through the changing role and organisational location of regulatory expertise within companies.

According to our interviews, such innovation processes rely on an extended network of relationships between industry, contract laboratories and agency staff. For example, external contract laboratories, which are primarily used for regulatory compliance testing, have to be trusted to provide reliable scientific services. Indeed, one industrial expert referred to such laboratories as "extensions" of their own industrial facilities. For contract laboratories to gain such trust, both technical competence and in-depth knowledge of regulatory requirements are required. Where the contract laboratories undertake work close to regulatory submission, it can also require informal knowledge in terms of judging how regulations will be interpreted and applied. Thus, considerable value is placed upon good relationships between industry, contract laboratories and the PSD. Furthermore, several interviewees from industry and contract laboratories observed that regular dialogue with the government agency was critical in negotiating the fulfilment of regulatory requirements.

This institutional network is reinforced by its relatively small and informal character - so that the key regulatory science actors know each other by name. In Britain, for example, a number of people have moved from government positions to industry. Equally, there are fewer than ten R&D-active companies with a base in Britain, an equivalent number of larger contract laboratories and, in PSD, a high-profile government agency. Given the intensity of discussions within this small world and the perceived unity of purpose, it is hardly surprising that close personal links should have developed over time. Indeed, as one representative of a contract organisation with prior government experience observed, "industry uses us because they know if a problem develops we can get on the phone... it's about trust building."

It is also a noteworthy feature of the British regulatory system that the relevant governmental agency has a role in regulatory submission. This is not to suggest that civil servants are bureaucratically involved in making submissions. However, they can be involved in an informal way, advising on the form, and perhaps even the content, of regulatory submissions - for example, by discussing the suitability of applications with agrochemical companies prior to review. Indeed, one PSD official put it to us that the agency sees its relationship with industry as co-operative and inter-dependent in character: as "two sides of same coin." He considered that the relationship between the agency and industry has been helped by industry's recognition of the "need for their registration officers to be far more professionally orientated." The PSD, for example, is "happy to talk to people who are new to regulatory departments in industry and tell them what we are about



and how we go about things, what we expect of them, and hopefully get a better idea of what they expect of us.” Similarly, industry has viewed positively the way that the PSD has evolved in its implementation of the statutory regime.

Within British industry, the ‘hands-on’ style of the PSD is positively contrasted with the ‘hands-off’ approach of certain other countries. One European regulatory affairs manager we interviewed was particularly struck by what he described as PSD’s “willingness to register compounds rather than stop them” - a point expressed in terms of a direct contrast with the Scandinavian and US systems.

This does not imply that the relationship between industry and PSD has always been easy. In particular, the introduction of statutory regulation in 1986 inevitably changed the relationship between government and industry introducing less flexibility and more bureaucracy. As one consultant to the agrochemical industry put it, “I can think of instances where [pre-statutory regulation] we put in for limited approval for a thousand acres and the Ministry guy would say we can’t possibly allow this, will you accept a tenth of that?... and we couldn’t possibly do that so he would offer us twenty per cent. It was this sort of thing which now just wouldn’t happen.” Particularly problematic for industry were the delays introduced into the approval system as the Ministry struggled to cope with the massively increased and accumulating backlog of work (House of Commons Agriculture Committee 1995, 77). This was only overcome by the rapid expansion of PSD over the following years, culminating in the establishment of PSD as an agency in 1993. This intensification of governmental activity has effectively transformed the PSD 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 (House of Commons Agriculture Committee 1995, 211). Even so, the heavy workload has placed such pressure on the PSD that it has been unable to cope fully with the review of dossier submissions. In order to meet this demand, it has contracted out some reviews to external organisations, representing a partial privatisation of regulatory functions (House of Commons Agriculture Committee 1995, 46). This could be seen as further tying PSD and external contract organisations into a close institutional network.

Whilst the focus of this discussion has been on the relationship between PSD and industry, it should be noted that recommendations on the registration of a novel AI are made by the Advisory Committee on Pesticides. From the perspective of industry this can cause uncertainty, for as one senior industrial regulatory affairs manager put it to us, “I think largely that they [the PSD] will know how the ACP is likely to react..., but it’s still never a cut and dried case. You know the ACP still have the independence to say ‘No I’m sorry, we don’t agree with that’, and it still does happen.” However, his perception was that over the last ten years or so “there is a better understanding and a better working relationship” between the PSD and ACP.

In institutional terms, therefore, regulatory science in the area of agrochemicals represents a patchwork of activities which are generally - at least in the British context - tied together by relations of expert knowledge, trust and mutual understanding. This seems especially true of the linkage between industry officials, government representatives and contract laboratories. In scientific and technical terms, these institutional arrangements are frequently legitimated by the expressed need to proceed rationally and sensibly through an area of some complexity and indeterminacy. The particularly hybrid and interdisciplinary nature of regulatory scientific activities reinforces this sense of collegiality.

However, and very importantly, it is in the character of such an overlapping patchwork that not all possible participants are included. In particular, the position of NGOs deserves some attention in this regard. The scope for UK NGOs to participate in the development of regulatory science was widely considered by industry and government officials to be limited. This position was defended on the grounds that NGOs were not seen as possessing the resources to undertake regulatory scientific work of their own nor to develop the very specialised expertise needed to shape debate. Their activity was seen to be most appropriately confined to lobbying around the general goals of the new regulatory regime and the resolution of certain specific regulatory issues. The contrast with the position of industry in terms of the possibilities both for overt and more subtle influence seems quite clear. Thus, the character of regulatory science has major implications for discussion over the possible extent of 'public participation'.

In summary, alongside the growth of regulatory science have come changes in the management of intramural research and the development of specialised contracting and consultancy facilities. Moreover, the particular character of this national setting has encouraged the growth of cross-institutional links and informal relations. Yet whilst regulatory evolution in the UK has resulted in a close professionalised network between industry and government with an emphasis on mutual understanding, moves towards European harmonisation present new uncertainties. As one senior regulatory affairs manager put it to us in 1996, there are "not usually now too many surprises" in submitting a pesticide for approval in the UK, but "what is a complete unknown quantity at the moment is what happens when you take 15 PSDs, bolt them together and give them score cards. I mean to me that is a big worry."

The question raised by regulatory moves towards Europeanisation, and which we can now address directly, concerns the relationship between this local and national network, and newly-emerging trans-national systems. How flexible is this national system likely to be in the face of such moves towards harmonisation? In particular, what will regulatory change mean for the institutional patchwork described here? Put differently, are the local conditions of scientific and institutional practice likely to be simply swept aside by such 'globalised' initiatives - or will localism maintain significance within this new setting?

## EUROPEAN HARMONISATION AND UK REGULATORY SCIENCE

An enormous variety of agrochemical products is marketed across Europe. Harmonising these diverse authorisations is complex as agrochemicals vary in their efficacy, safety and environmental impact dependent upon regional agricultural, ecological and plant health conditions. In order to deal with this diversity, the new European regulatory regime retains national dimensions of approval that, according to the Commission, strike a balance between the need of the Single Market for 'central judgement and control' and for 'local decisions' to meet regional conditions (Scharpe 1992, 97).

Accordingly, the European Union's Plant Protection Product Directive 91/414/EEC (Council of the European Communities, 1991) has been designed as a two-tier approval system. Whilst Active Ingredients (AIs) - the molecules responsible for the action of pesticides - will be authorised at the European level (using a rapporteur system), particular agrochemical products will be authorised at the level of Member States. However, data requirements and evaluation guidelines will be common throughout the EU, subject to modification on the basis of regional ecological variation. Given this proviso, Member States will be expected to abide by centralised and commonly-agreed approvals of Active Ingredients, and to mutually recognise each other's approval of agrochemical products.

The new European system, therefore, is an attempt at standardising practice across Europe. Common data requirements and common standards of production, evaluation and interpretation of data are crucial to the success of the regime. By harmonising Member States' regulatory traditions and requirements, pesticide companies will no longer have to apply to each individual country for approval. This is attractive to business as less repetitious testing will be required to satisfy each national market. However, the standardisation of testing has also created a more rigorous European regime: there has been an expansion of the range of testing, particularly in the increasingly politically-sensitive fields of ecotoxicity and environmental fate.

From the point of view of the UK, and indeed of other Member States, there will be a long transition from national systems to a fully European system (see, for example, the evidence of the British Agrochemicals Association to the House of Commons Agriculture Committee 1995, 82). The extent to which the implementation of this regime impacts on Member States will also depend at least in part upon the state of existing regimes. For some European countries, in particular those in Southern Europe, the new regime will represent a considerable change in policy and procedure. For others with longer-established regulatory systems, predominantly in Northern Europe, the transition is likely to be less radical in character. This paper now considers this transition from the perspective of the UK - and, especially, how this transition is being conceptualised from the perspective of key regulatory scientific actors as they consider the new regime.

Based on the brief discussion so far of agrochemicals, steps towards European harmonisation appear to be founded on two premises. The first is that scientific principles are common - transcendent even - and therefore valid throughout Europe. In similar environmental conditions, what is safe for Germans will be safe for the Portuguese, and so on. Second, the technical reliability of scientific producers means that a test or trial competently carried out in one Member State should have validity elsewhere. The universality of science is the basis on which tests performed in a French toxicological laboratory can satisfy the regulatory authorities in Athens and Copenhagen.

As described so far, however, our research suggests that regulatory science - at least in the UK context - is an activity institutionally and organisationally embedded within national regulatory and industrial systems. Within our interviews, we especially focused upon the issues for UK regulatory science raised by the development of European systems. In this context, a number of characteristics of the UK system were seen as especially valuable to participants but also as potentially in tension with the globalised ethos of Europeanisation.

Our interviews, for example, highlight the current dependence of regulatory science on a relatively-small number of participants drawn especially from industry and the regulatory authorities. One recurrent theme within our interviews was that key respondents from different companies, contract research laboratories and the regulatory authority generally knew each other personally, had often sat together on various committees or may even have worked at some point for the same organisation. None of this is too surprising within such a small and highly-specialised world. The value of maintaining established personal links was emphasised by one regulatory affairs manager who observed that, "we know pretty well now what to expect... But then you end up with someone new at PSD who suddenly starts wanting to know things that you previously took for granted because of the relationship you had with the predecessor who accepted and understood." In the wider European context, industrial respondents saw such problems as being inevitably exacerbated.

Relationships between these participants have developed over time - often being based on a sense of trust and locally-negotiated understanding. Whilst it was, for example, considered to be important to get routine testing work done in a cost-effective manner, it was essential also that contractors could deliver high-quality research and offer associated advice and support. From the

perspective of contract laboratories, reputation within the industry was seen to be crucial - a point made all the more important by the publicly-sensitive nature of the animal testing involved (a sensitivity which tended to bring the key participants together in mutual defence).<sup>3</sup> Once again, even among companies with a strong international orientation, there was concern about the maintenance of such trust relationships within an apparently 'impersonal' regulatory system.

Indeed, the well-established nature of these embedded institutional relations of regulatory science suggests a definite limit to harmonisation. In addition to the previously-discussed case of NGOs, a number of interviewees considered that this close institutional network meant that organisations less-well connected to the agency, in particular little-known (within the UK) foreign laboratories, will be less attractive both to industry and regulator. Without the 'insider' knowledge of institutions already keyed into the industrial-governmental networks described above, overseas laboratories were considered to have greater problems in negotiating and meeting regulatory requirements as perceived by the UK, than UK-based or well-renowned organisations.

Also important is the relationship between the particular British policy style and the development of knowledge in this area. The UK approach has characteristically been built on shared learning (constrained, of course, by commercial secrecy). Trade organisations (such as the British Agrochemicals Association, BAA) have worked particularly to this purpose. Whilst it would be an exaggeration to suggest that this leads to total agreement across the industry about key technical principles, our discussion with one important cross-industry committee (within the BAA structure) did suggest an agreement at least on the regulatory agenda and on the issues which required resolution. This sense of common purpose extends to the characteristic British pragmatic acceptance of the need for all parties (including regulators) to 'learn by doing'. Regulatory scientists in industry praised the PSD's preparedness to draw lessons and adapt practice in the light of experience - a process which crucially, included the experience of industry.

In contrast, there is much discussion of other countries' perceived 'regulatory styles'. For example, although other national agencies might consider that they are implementing the legislation effectively, our industrial respondents were concerned that problems were arising due to the more 'hands-off' or even disorganised approach of some Member States. As one put it, "The Germans have said effectively don't bother us for the time being until we have our house in order... [and] we talked to the French who said they hadn't a clue how to handle it at the Euro level."

Closely allied to these contextually-related points, is the importance of professional judgement within the conduct of regulatory science. As was pointed out to us on various occasions, regulatory science has to operate in the 'real world' of commercial development and the specific conditions of pesticide usage. The technical culture was, therefore, one that emphasised practicality and pragmatism over hypothetical scenarios and unrealistic expectations. The Directive makes provision for some flexibility in data requirements and the British participants prided themselves on implementing a suitably pragmatic and workable system. This was contrasted, for example, with observations about the German approach. One regulatory affairs manager who had worked with a German-based agrochemical company described the German tradition as "essentially box-ticking... quite often you'd do studies which were totally irrelevant for the regulatory decision because you just had to fill that box. ...German companies do not feel too comfortable if there are big areas of the package left to expert judgement."

The inter-disciplinary and 'hybrid' nature of the field both in terms of the complex ecological pathways being considered (covering a whole range of human, animal and environmental effects) and the range of disciplines being drawn upon, also creates some problems for moves towards supra-national regulatory frameworks. The somewhat distant relationship with academic

departments suggested that expertise in regulatory science was largely constrained to the small group of actors within the regulatory patchwork and has not generally been institutionalised within an established teaching programme or academic research centre which covers all of these questions. This absence of institutionalisation makes the call for standardisation especially problematic.

Inextricably linked with these institutional points, respondents raised a number of specific and explicit scientific concerns about the new regime. These concerns related particularly to the perception that the new European system would deny the importance of contextual variability but instead impose a 'rule-book' form of standardisation. Such an approach to standardisation was seen as the very antithesis of good regulatory scientific practice. These concerns covered a range of issues.

For example, concerns were expressed that the tiered approach towards testing in the case of beneficial insects was overly cautious. The tiered approach sets out a number of levels of testing, but an AI only progresses onto the next level if it fails to pass a previous one. However, as one industry representative commented, "Some of the triggers seem too conservative so that the tiered approach is never an option - you will always go from one tier to the next. We might have situations where we say why on earth do we have to do this? We are developing insecticides which kill insects!"

In another case, a regulatory affairs manager described how the German authorities brought in a new requirement to study volatilisation of a pesticide. "Effectively you had to spray a load of dwarf French beans and then take them down a wind tunnel and blast air at them, I mean it was so crazy, the whole concept, but it had never been discussed with industry. Unfortunately that data requirement has now been sort of copied into the European legislation so in a sense we are all caught up in that."

Nevertheless, and whilst British-based respondents expressed concerns over the attempted standardisation of technical requirements within the new European regime, the perception of both industrial and governmental respondents was that the UK had played a leading role in the development of the European regime. Indeed, our research suggests that issues of national regulatory science are not simply important in terms of responding to European regulatory systems but also represent a subtle influence over the design of regulatory requirements.

Having gone through its own regulatory upheavals in the 1980s, the UK has been well-placed to understand and influence the European regulatory agenda. According to a PSD representative, the PSD has been "playing a major role in the development of the procedures and ideas with Europe, based very much on our own experience in the UK following the implementation of legislation." This influence has been reinforced by the involvement of the UK in a series of pilot registrations designed to resolve uncertainties about how some of the scientific and, in particular, ecotoxicological issues were to be addressed. The establishment of some of the regime's operating principles in this way suggests again that regulation cannot just be formally set but must also be defined and interpreted within the processes of its implementation. Industry's perception of this process was that PSD's 'hands-on' approach made the UK an especially-strong player within the eventual regime. In that way, it was not considered to be a case of locally-established networks 'reacting' to a European regime but also of these networks influencing the character of 'universal' regulatory systems.

Furthermore, our research revealed the subtle role of industry in influencing the European regime. Critics of the agrochemical and (using parallel arguments) the pharmaceutical industry have in the past highlighted the extent to which firms seek to manipulate regulatory environments to favour

their particular products. However, our findings suggest the ethos of reasonable and practicable regulation may feed forward from agrochemical companies into the design of regulations through the advice and activities of professional organisations within which companies are well-represented.

For example, one industrial toxicologist explained to us how his large multi-national corporation neither organised their research to respond to nor anticipate regulations since they were “actively involved in the development of regulations.” This was primarily through the European Crop Protection Association expert committees that have helped develop various testing strategies. Even in the case of the toxicology guidelines, the perception of industry was that, whilst not all of industry’s comments were taken on board, “most of them were.”

Of course, the boundary between this ‘feeding forward’ process and lobbying can be extremely fine. For example, in the absence of established test guidelines on beneficial arthropods, industry was concerned that the Commission might adopt the German system which it saw as complex and excessively cautious. Industry therefore set up the Beneficial Arthropods in Registration Testing group (BART) in order to produce a new set of guidelines. BART co-organised a conference (with EC funding) which involved experts from a range of backgrounds. The test guidelines produced are now utilised by the EC (Barrett *et al* 1994). The point here is that established organisations can play a leading role in the development of the regime through the *de facto* provision of expertise.

In all of these areas, the development of standardised procedures was seen by industry as commercially advantageous but also problematic for the conduct of regulatory science. On the one hand, the established and locally-negotiated conditions and practices of regulatory science in the UK were seen as being threatened by the creation of a standardised regime, and as presenting barriers to its implementation. On the other hand, the perception of the UK’s influence over the character of the regime mitigated some of the concerns of our UK-based industrial respondents, as indeed did their perception that industry itself had played, and will continue to play, its own influential role. The character of the European regime was therefore perceived by our industrial and governmental respondents to be influenced by a variety of nationally- and organisationally-based practices, capabilities and agendas. As discussed below, our research suggests that these perceptions can have practical consequences for the way the regime is evolving and for the changing character of regulatory science in this area.

## REGULATORY SCIENCE, UNIVERSALITY AND MUTUAL RECOGNITION

The general differentiations that our industrial respondents perceived regarding the respective roles and merits of different Member States present industry with a number of dilemmas concerning future regulatory submissions. For example, issues of universality across Europe are highlighted in the choice of country for the approval of Active Ingredients. Whilst the regime presupposes that the choice of Member State to act as rapporteur is essentially an irrelevance (since all are assumed to be working to the same set of technical requirements), there is some evidence that a number of technical and institutional factors may influence the choice of rapporteur country. The UK was seen as attractive to our UK-based industrial respondents, both because of their familiarity with the regulators and also because of the perception that the UK had sufficient capabilities. As one senior regulatory affairs manager observed, “The UK has probably got the best understanding of what the new process will look like in the future... because their system is closest to the new system. They are the leaders at the moment on the process.”

Connected to this point, our industrial respondents were also concerned about the quality of review. Choice of country may, for example, bestow a certain status and integrity upon the AI (with certain

nations being seen to carry more regulatory weight than others). Equally, some industrial interviewees were concerned that their submissions might be sent to less well-equipped (particularly Southern European) Member States for review - as one respondent put it, they are “not tooled up to do the job.”

In considering the choice of Member States for reviewing a submission, industrial respondents were also concerned about differing Member States’ views on pesticide usage. In particular they were concerned about submitting applications to Member States less favourably disposed to pesticide usage. One senior regulatory affairs manager, for example, commented that, “Germany, Denmark, Sweden and the Netherlands have a lot of young and not so young scientists who believe that crop protection products are, well, not the best things to have around, or at least when they are necessary they must be reduced to a minimum.”

At the same time, our industrial respondents also pointed out a number of issues that will directly influence the process of mutual recognition. For example, from a practical point of view there was seen to be little point in submitting an AI for review to a Member State where it had no uses. However, there was considerable concern that in other cases where pesticide products would have wider applicability, Member States may not choose to mutually recognise each other’s approvals of products. It was regularly pointed out to us that there was considerable scope for a Member State to use ecological variation as grounds for objecting to the approval of a pesticide product that had been approved by another Member State. The calculation for agrochemical companies was made more complex by the perception that Northern European Member States were less likely to accept the evaluations of Southern European Member States than vice versa. As one industrial expert has described it, mutual recognition ‘takes you beyond the science of regulatory affairs. It takes you into an area of trust: one Member State has to trust the decision of another Member State’ (House of Commons Agriculture Committee 1995, 90).

These dilemmas for industry have been exacerbated by what our respondents saw as attempts by Member States to manipulate the system so as to support their own indigenous regulatory scientific infrastructure (or at least to ensure that other countries do not receive ‘undue’ support). Several industrial interviewees, for example, suggested that the French authorities were exploiting the size of the French Market by informally attempting to insist that they be chosen as rapporteur for the approval of AIs with a potential use in France. Furthermore, the French authorities were informally suggesting that efficacy data be generated in France according to their own methods. As one field trials expert put it candidly, it was a case of ‘jobs for the boys’.

The choice of country to evaluate an AI is further complicated by the move across Europe towards the devolvement of governmental agencies such as the UK’s Pesticide Safety Directorate (PSD). As there is no harmonised fee structure for approvals, there is considerable variability in charges across the European Union: from the PSD which operates full cost recovery, to other agencies which may charge no fee. For new AIs this may only be a very minor part of the total costs of innovating a new AI, but for old AIs in review this can be a more substantial cost (House of Commons Agriculture Committee 1995, 92-93).

These considerations raise the interesting possibility of the development of a market in approvals, with the PSD adopting an entrepreneurial stance, looking for regulatory business within a European context. Whilst fees charged and ‘customer service’ (e.g. efficiency, accessibility) would provide one element within this ‘market’, another would be the perceived status and credibility of national agencies (as viewed, for example, by non-European authorities). Clearly the PSD considers itself well-placed in this regard given its involvement in the development of the European regime.

Issues such as these have been implicitly recognised by the Commission. For example, it has taken on the power to reallocate the rapporteur country if one Member State appears to be taking on a disproportionate number of reviews. It has also instituted a system of co-rapporteurs whereby less established authorities can call upon their more experienced counterparts in evaluating AIs (House of Commons Agriculture Committee 1995, 57). The extent to which these moves will be able to resolve both the concerns of Member States and industry, however, is unclear.

In part, therefore, a European political economy of generating regulatory requirements, producing data and undertaking evaluations can be identified as evolving in the harmonised regime. This tendency is further reinforced by established national relations of familiarity and trust. The argument here is that the production of regulatory science is not a universalistic practice but is heavily contextualised within the institutional social-relations resulting from (and helping create) regulation.

What should also be very apparent from the previous discussion is that, whilst scientific universality is presented as a powerful legitimation for mutual recognition and for ‘globalised’ regulatory systems, scientific requirements are actually interpreted and actively made sense of within these social, political and institutional settings. Here, we have highlighted such processes from the particular perspective of one nation. Of course, it seems reasonable to speculate that other nations will follow similar forms of interpretation and ‘sense-making’ as they also try to anticipate, interpret and shape new regulatory regimes. Our point is not to present the UK case as either unique or typical. Instead, we wish to suggest them generally-unacknowledged cultural and institutional dynamics at work within what are often presented by policy-makers as ‘global’ and centrally-driven processes.

In the UK case, one illustration of such interpretative processes is provided by the continued significance of national regulatory committees such as those within the British Agrochemicals Association structure. Indeed, the government agency may in fact now have an augmented rather than diminished role as a consequence of European changes. In such ways, standardisation may actually reinforce local and national negotiations rather than rendering them meaningless. At the same time, and despite the universal claims of science, the character of regulatory science continues to demand contextual interpretation and situation-specific modifications - and for reasons which go beyond the obvious requirements of ecological variation across Member States. Whilst ecological variation is conventionally framed as a ‘technical’ issue, our research suggests the inseparability of ‘technical’ from social and institutional factors (as when ecological variation is used as grounds for blocking products already approved elsewhere). Contextual variation is, therefore, as much a ‘social’ as a ‘scientific’ phenomenon.

In policy terms, we encounter a question of balance between ‘centralised’ and ‘localised’ systems and the most effective relationship between these. However, this is not just a matter of institutional relations but also of the scientific assumptions which underpin these. Whilst European initiatives draw upon a ‘universal’ account of science, British regulatory scientists typically emphasise the judgemental, case-by-case and pragmatic application of science - indeed, a requirement for local flexibility and interpretation seems central to the whole ethos of UK regulatory science. Each approach claims to be ‘scientific’ - but actually interprets this in very different ways. At the heart of this standardised system, therefore, there is an active set of negotiations over the desirability, practicability and scientific legitimacy of ‘universal’ requirements. At this point, Waterton and Wynne’s discussion of the scientific and cultural dimensions of European environmental policy becomes highly-relevant:



'Perhaps the key question is whether what is lacking is skill in finding a supposedly 'correct' level of standardisation in such information and data, or whether the very idea of a singular optimal point, on a range from complete standardisation to complete localisation, is itself illusory. Instead, perhaps, one might look for a policy culture and institutions in which discourses of 'natural' universality or standardisation can coexist and interleave constructively with discourses of 'natural' local variety' (Waterton and Wynne 1996, 436).

In the case of agrochemical regulation, it is still premature to conclude how this balance will operate. It seems likely, however, that the kinds of negotiation and intervention which have already taken place between British industry and 'Brussels' will produce a less stark dichotomy than was the case with the CORINE environmental information system discussed by Waterton and Wynne. Nevertheless, our study has highlighted the potential points of conflict which lie ahead and also the underlying tensions between the stated rationale for policy-making and its local re-negotiation and re-construction. It seems safe to conclude even from this single-nation case-study that 'standardisation' is not simply a question of agreeing upon the 'rules of the game'. It also represents a more complex institutional and scientific challenge to the flexibility and responsiveness of existing processes. Whilst UK-based industry and governmental officials are willing to undertake this challenge (and indeed consider themselves to have little choice), the consequences of this are unlikely to be as straightforward as would be indicated by the simple metaphor of a 'level playing-field'.

#### CONCLUSION: SCIENCE, LOCALISM AND UNIVERSALISM

One possible response to the discussion so far is that it suggests only the predictable teething troubles of a move from national to international systems. Equally, it can be argued that such a transition raises institutional and political problems but will have no consequences for the character of scientific evidence and argumentation. Based on our interviews with key governmental and industrial officials, however, it seems clear that British networks will not be swept aside by centralised initiatives towards Europeanisation. Instead, we would predict that local institutional arrangements will continue to play an important role. In this, our case-study suggests the continuing significance of local social and technical relations within globalised regulatory systems. Talk of 'Europeanisation' consistently fails to recognise these points of tension and their scientific implications. From our perspective, globalisation cannot ignore the local conditions of application and implementation - and for cultural reasons which appear unlikely to be eradicated or swept aside. At the same time, we would suggest that the issues raised in this paper are not 'merely' matters of institutional politics or national prejudices - instead they play a constitutive role within the interpretation, negotiation and reconstruction of scientific evidence.

Accordingly, a number of immediate and empirically-based conclusions can be drawn from our discussion of the European framework for the regulation of agrochemicals. Firstly, Europeanisation goes along with difference (Yearley 1996; Abraham and Charlton 1995). Moves towards standardisation can serve to re-emphasise the significance of local mechanisms for interpretation and implementation. Far from the system simply becoming more impersonal and, in that sense, 'bureaucratised' (or even 'globalised') as a result of Europeanisation, the increased complexity appears also to be re-emphasising existing relations of trust and familiarity.

Secondly, the importance of these local negotiations is downplayed by academic and policy approaches that simply focus on the business of standard-setting rather than standard-enactment. Our empirical evidence suggests a subtle and diverse series of negotiations (notably, between the British agency and the industry) concerning 'what regulatory requirements really mean'. Rather than simply assuming that regulatory standards are readily 'exportable' across institutional and

national boundaries, our research suggests the active processes of ‘sense-making’ that are necessarily involved.

Thirdly, and closely linked to this point, it is generally claimed by regulatory institutions that science is universalistic in such contexts but, as we have seen, it is subject to various local negotiations and expressions of professional judgement. Test results do not simply ‘speak for themselves’ but must instead be interpreted and contextualised. Within our study, for example, this leads to regular discussions of the ‘significance’ of test data but also the claim from industry that what is required is scientific discretion rather than bureaucratic ‘box-ticking’.

Fourthly, and most specifically, regulatory science represents not just an area of partial (or temporary) overlap between ‘science’ and ‘policy’ but has its own - albeit heterogeneous - institutional and technical practices. These in turn have a major impact on the conduct of harmonisation and standardisation processes across a range of national contexts. We have noted especially the significance of existing ‘patchworks’ of regulatory science for the enactment of the UK approach to European regulations. We have also suggested that such local processes can influence the shape of ‘universal’ regulatory systems (especially, as in the British case, when these local conditions have already reached a reasonable stage of development).

In sum, though ‘Europeanisation’ is commonly presented as a story of harmonisation, this research project suggests that Europeanisation is accompanied by divergence and differentiation. Our working hypothesis based on this UK evidence is that common European regulations are configured differently in different national contexts and that attempts to produce uniformity ironically bring new differences to the fore. While science appears to offer a universal language (and is presented as such to support ‘harmonised’ policy initiatives), it also reinforces the significance of existing local arrangements and institutional relations.

Considering this empirical evidence in more general terms, it would appear to follow that both analysts and policy-makers need to deal cautiously with the concept of ‘Europeanisation’. This is not, of course, to deny the potential practical significance of European moves in this area - these are clearly being taken seriously by industry and the regulatory authorities. Instead, we have drawn attention to the distinction between what may be claimed for this form of Europeanisation and what may be achieved in the short term - an issue which, at least in the regulatory context, has been insufficiently explored but which may be crucial.

These issues of localism and universalism, and of sameness and difference, have a potentially wider significance for the analysis of modern scientific practice - especially when taken alongside the heterogeneous network of ‘knowledge producers’ encountered within regulatory science. Rather than being specific to discussions of chemical regulation, these themes and issues may suggest one part of a larger process of knowledge development, accreditation and implementation as it is taking place across new institutional forms and changing contexts. In that way, standardisation represents an important form not simply of ‘technology transfer’ but of a broader ‘knowledge transfer’ (of a kind which involves not just specific technologies and bodies of scientific knowledge but also technical practices, legal interpretations, social assumptions and professional/institutional understandings).

Thus, regulatory science may not represent a deviation from the established worlds of ‘science’ and ‘policy’ (as it is still often presented) but instead one example of changing knowledge relations and the emergence of new networks of knowledge users and producers (Gibbons *et al* 1994). This final conclusion leads into a wider consideration of standardisation as an important case-study for the ‘sociology of knowledge transfer’. Whilst the sociology of scientific knowledge has long

considered the social and technical negotiations which relate to the replicability of, for example, scientific experiments (see, for example, Collins 1985), the international standardisation of regulatory science potentially opens up more complex issues for the 'exportability' of technical practices across social and institutional contexts. The study of agrochemicals offered here represents one contribution to this emerging area of sociological and STS-based inquiry.

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## NOTES

- <sup>1</sup> For a general review of regulatory science, see Irwin et al, 1997.
- <sup>2</sup> A point discussed, for example, by Ravetz some 25 years ago in his discussion of 'industrialised science'. See Ravetz 1973.
- <sup>3</sup> This point was emphasised towards the end of our research by a TV documentary that included contentious footage of dog testing smuggled out of one of the major contract laboratories. Such incidents are seen to bring adverse public attention to the industry as a whole.