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Emergence of a techno-legal specialty: Animal tests to assess chemical safety in the UK, 1945–1960

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ABSTRACT

It has been suggested that knowledge domains which emerge within regulatory science represent a compromise between technical knowledge and policy priorities. This article investigates the claim through consideration of the emergence of animal tests to evaluate chemical safety in the UK between 1945 and 1960. During this period there was a proliferation of new chemical-based innovations in consumer products. The situation gave rise to concerns about the potential impact on public health. Solutions required development of a knowledge domain that would fulfil policy requirements, outside the remit of academic science. Lack of consensus in the scientific field gave rise to debate over the best means to collect accurate data. This resulted in emergence of the new specialty of safety testing, in response to political and industrial needs. The socio-political context of this case illustrates the impact that organisational setting can have on shaping knowledge claims.

1. Introduction

This article considers the emergence of animal tests for assessing safety of chemicals used in consumer products in the UK. It considers the specific context that framed both early policy discourses and development of routine toxicity testing as a means for safety evaluation. In the academic literature, it has been suggested that such policy-based knowledge domains are located within a wider paradigm of regulatory science. Many studies in this area have investigated public controversies relating to specific chemicals (see for example Abraham and Reed, 2002; Bal and Halffman, 1998; Brickman et al., 1985; Gillespie et al., 1979; Jasanoff, 1990; MacGillivray et al., 2011; Murphy et al., 2006; Rosner and Markowitz, 2007; Turner 2001). In contrast, this article highlights conditions which influenced the development of a new speciality within regulatory science. Initially, literature is reviewed on the emergence of new scientific domains, specifically focusing on risk evaluation. The paper then considers debates that were articulated in the UK between 1945 and 1960 in relation to the safe use of new chemicals in consumer products. Examining discursive arguments that were published at the time demonstrates how scientific debate was influenced by the requirements of policy goals. The result was a specifically configured system of routine animal tests to answer policy needs. This new knowledge domain can be considered a hybrid, techno-legal specialty within the paradigm of regulatory science.

2. Institutional context and new scientific specialties

There is a wide literature on the emergence of scientific specialties although attention has been mainly on new domains within an academic context (Edge and Mulkay, 1976; Geison, 1981; Guntau and Laitko, 1991; Keith and Hoch, 1986; Law, 1973; Lemaine et al., 1976; Mullins, 1972). Scientific activities leading to novel specialties which are subject to non-scientific pressures have been studied to a lesser extent. Within the studies of academic science, Wray (2005) divides accounts into two phases, initially focusing on social organisation and cohesion (Ben David and Collins, 1966; Crane, 1969; de Solla Price, 1963; Mulkay, 1975; see also Van den Besselaar and Leydesdorff, 1996). The second phase, Wray notes, considers the emergence of new specialties as a process of co-creation between conceptual, technical and social reconfiguration of a scientific field (see also Boyack et al., 2014; Golinski 2012; Nye, 1994; Stichweh, 1992). Others have noted that, even within the academic sphere, different institutional forms have an impact on the process and direction of knowledge development (Heidler, 2011; Youtie et al., 2006). In the case of biochemistry, Kohler (1982) demonstrates how scientists navigate institutional opportunities and constraints, while Rheinberger (1997) demonstrates the role of laboratory-based experimental practices in creating knowledge for emerging disciplines (see also Frickel and Hess, 2014).

Traditional studies of new scientific specialties focus on social and cognitive organisation, but do not consider the specificity of

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organisational context. As Johnston and Robbins (1977) point out scientists work in different types of institutions, most of which have specific requirements for knowledge, which are constrained and directed by non-scientific factors. Thus, study of institutional settings should be considered as they intervene in the ability of scientists to set goals, communicate results, and develop a technical community with shared norms and values. Souren et al. (2007), for example, illustrate the difficulty of communicating new knowledge between scientists, environmental organisations and policy makers in Dutch soil policy. Johnston and Robbins point out that lack of shared understanding can lead to expert disagreements. The industrial base is more likely to promote differentiation, secrecy and fragmentation of knowledge in contrast to academic expectations of coherence, collaboration and open debate. Johnston (2009) identifies such factors in the emergence of nuclear engineering. Both Linthorst (2010) and Frickel and Moore (2006) note that these factors affect the activities of technical domains in the policy field which find it difficult to develop a shared paradigm and have an impact on scientists' autonomy (see also Lave, 2014; Lave and Doyle, 2010).

This work has opened out traditional approaches to the study of new scientific domains and indicates how a much wider set of factors are involved. It questions the assumption that knowledge is independent of its socio-institutional context, as Jones (2007) points out in a review of different types of relationship that exist between production of environmental knowledge and environmental policy. It postulates scientific knowledge is deeply configured within specific social contexts, influenced by institutional, political and economic priorities. Kleinman and Suryanarayanan (2013, 2016) emphasise this point in their analysis of different scientific explanations given by dominant institutions in agricultural research in relation to the collapse of honey bee colonies. Contributors have analysed emergent domains reconstructively to fully appreciate how locational and cultural contingency affect knowledge outcomes. Lenior, (1997), for example, identifies how institutional and cultural contingencies affected the development of a range of scientific disciplines, while Livingstone (2003) and Powell (2007) consider the role of geography and place. Other have extended these insights to explain international differences in science-based policy regimes (Boudia and Jas, 2013; Sellers and Melling, 2012). Key issues arising for regulatory science are specificity of context, processes of institutional adaptation, and responses to policy initiatives. In terms of studying the emergence of animal testing regimes within regulatory science, these factors interact, and can result in different standards applied in different regulatory contexts.

2.1. *Regulatory science as a knowledge domain*

Rushefsky (1986:6) considers regulatory science as knowledge designed to further political goals, enabling decisions to be made under uncertain conditions, 'mixing fact and values, science and politics'. Others have supported this general definition, while adding other issues such as national context, lack of standardisation and decision-making processes (Abraham and Davis, 2007; Boudia and Jas, 2014; Hansson and Aven, 2014; Jasanoff, 1993). The general separation of scientific results from the value-based activities of risk assessment is felt to be responsible for variations in control of the same substances between different regulatory systems. (Carr and Levidov, 2000; Koch and Ashford, 2006; Krings, 2016; Longino, 1990; Murphy et al., 2006). From this discussion, regulatory science is characterised by situated scientific, regulatory and evaluative procedures, which can differ between contexts and over time. Also, the unstable nature of policy setting can destabilise agreed standards (Howarth, 2010; Raymond and Olive, 2009). For Steel (2011), there is no universal, objectively determined basis for communality between regulatory settings, resulting in *ad hoc* standards. Established processes ensure that access to knowledge is restricted to certain stakeholders, typically excluding public scrutiny (see Myhr, 2010; Ricci and Sammis, 2012). These considerations have led Abraham and Davis (2007) to conceptualise regulatory science as an epistemological paradigm influenced by both scientific and social goals, a heterogeneous knowledge area incorporating a range of risk evaluation practices. The authors argue for research into the cognitive content of regulatory science, to establish the technical activities which comprise the area.

Existing studies of regulatory science highlight both its difference from traditional science and its hybrid nature. Rothstein et al. (1999) contend that regulatory science is fundamentally different from academic science both methodologically and in interpretation (see also Todt et al., 2010). In particular, safety assessments are made from limited test data produced under legal, temporal and budgetary constraints. Cranor (1993, 1997) points out that the epistemic approach is not concerned with discovery of universal truths but with minimising health concerns, environmental impacts and socio-economic costs. Moghissi et al. (2014) note, more specifically, that regulatory science achieves these objectives through incorporating policy aims into the development of appropriate assessment tools. Shackley and Wynne (1995) go further, as they contend that regulatory science is not only modified by national context, but that policy objectives and scientific techniques co-construct the knowledge domain (see also Anderson and Felici, 2009; Assmuth, 2011; Koch and Ashford, 2006; Flüeler and Scholz, 2004; Van Overveld et al., 2010). Irwin et al. (1997) conclude that the relationship between regulatory and academic science is complicated, interactive, crossing cognitive and institutional boundaries. The result is a heterogeneous and hybrid knowledge area, affected by differences in institutionalisation of these different knowledge domains (see Christian, 2004 for a discussion of the situation in the USA).

Knowledge domains within regulatory science are not only influenced by institutional or organisational priorities, but also by policy requirements which become intertwined with knowledge production processes (Davis, 1988; McPartland et al., 2015). Both deliberative policy processes and contributing scientific areas co-create regulatory standards, and determine how external goals are incorporated into technical activity.[1] Historical analysis can identify how social and cultural considerations shaped situated policies and can highlight issues that were decisive in articulating solutions (Hirsh and Jones 2014). In the UK, animal tests for chemical safety had been trialled by 1945 but were not proven as suitable for policy recommendations. However, in the ensuing 15 years the situation changed in response to the increasing use of new organic chemicals by industry. The solutions adopted were contextually specific and informed by prior experience of regulating for public safety.

3. The UK regulatory context pre-1945

By the end of the 1930s there were specific Acts of Parliament that directly controlled public exposure to poisons. Both the 1933 Pharmacy and Poisons Act and the 1938 Food and Drugs Act, however, were backward looking and enshrined issues that were mainly of concern to a previous generation. Poisons legislation restricted public exposure to a regulated list of acute poisons, which were understood by the medical profession. The possibility of chronic toxicity, deleterious effects that would result from cumulative small exposures, was not widely accepted (Anon a, 1897). This attitude, in part, was due to an interpretation of the new science of immunology to mean that the human body could adapt to small doses of potentially harmful substances (Lancaster, 1895). The 1938 Food and Drugs Act was drafted in response to concerns about food adulteration using non-nutritious substances. Legislation required the whole food product to be safe rather than specific ingredients. This would later cause a problem in relation to specific food additives. A new departure for both Acts was the establishment of scientific advisory committees – a Poisons Board and the Food Standards Committee (FSC), set up in 1933 and 1938 respectively.

[1] This is explicitly illustrated by the reported 'paradigm' change for risk assessment procedures in the European Union with implementation of the REACH procedures (Führ and Bizer, 2007)

Before the 1920s there had been some experiments using animals to ascertain the safety of food additives, but these were sporadic and inconclusive. However, in 1927, J W Trevan, a pharmacologist at the Wellcome Physiological Research Laboratories, published a paper promoting the use of statistical techniques to evaluate levels of acute toxicity from animal tests. Trevan was concerned with drug standardisation, as some compounds were contaminated with impurities while others had a small safety margin between therapeutic and toxic doses. His suggestion, to ascertain the Median Lethal Dose (LD50) on a large sample of animals (50–100) would become a standard indication of acute toxicity (Trevan, 1927).

There were therefore pre-existing scientific and policy issues that would require changes to adapt to post-war experimentation with new organic chemicals. Emerging questions for policy makers were whether prolonged exposure to any novel substance would be injurious to health, and what sort of pre-market testing should be undertaken to evaluate the situation.

4. Processes of institutionalisation, post-1945

The immediate post-war years saw an increase in requests from industry for information on the safety of new chemicals. Some of the large chemical manufacturers invested in their own facilities. In 1948 the Imperial Chemical Industries (ICI) opened the Industrial Hygiene Research Laboratory in Alderley Park, Cheshire, one of the first industrial laboratories of its kind in the UK. A past director, A A B Swan, explained the objective was to 'provide … information and advice … on the toxic properties of chemicals to help ensure ….the safe use of the companies' products by other industries and the general public' (Swan, 1975). Other firms looked to government for advice, until the Medical Research Council (MRC) felt under pressure to respond (TRUa, n.d.). The Council initially established its Toxicology Committee in 1947 to advise on the need for experimental work on chemical safety, followed by establishment of the Toxicology Research Unit (TRU) in the same year. Research at the TRU was intended primarily to help the Committee answer scientific queries (Anon b, 1947, Anon c, 1947).

Early attempts at institutionalisation straddled the industry-government divide. There were also moves to establish a collaborative venture in the form of a national laboratory. The Department of Scientific and Industrial Research (DSIR) wanted to set up a Research Association jointly funded by government and industry but there were divisions within industries, some firms claiming that government should take full responsibility for safety testing. The Confectionary and Chemical industries, however, were determined to see the plan through as a research association would deal with both short term practical problems and more in-depth research (Coles, 1978). The situation was not resolved until 1961 when the DSIR opened the British Industrial Biological Research Association (BIBRA) which would carry out both basic biological studies and routine testing. The idea was that problems encountered from animal feeding tests could be referred for in-depth scientific analysis. Thus, both manufactures, and the public would benefit from the organisation (Goldberg, 1963).

During the 1950s, however, the TRU was the main national toxicology laboratory. The first Head, a young researcher, John Morrison Barnes, who had been employed in military research on toxicology, emerged as a vocal proponent of basic research. Barnes was, then, well placed to act as a leader around whom a new scientific specialty of toxicology could coalesce. The fact that this did not appear over the following years was due to two main issues. Scientists at the TRU were educated in a range of bio-medical disciplines, all of which were still in the process of making scientific discoveries. In particular, Barnes, a medical pathologist, did not regard himself as a 'toxicologist', but as a biologist using toxicity research to extend bio-chemical knowledge. He argued consistently for the superior knowledge that would be provided by academic research, arguing

> 'toxicology as a practical problem involves the effect of poisonous materials on the whole animal …. toxicology is not a discipline in itself; it is or should be, the application of recent advances in the basic sciences to the study of practical problems'. (TRUb, 1955, n.d.).

For Barnes, TRU research should examine mechanisms of toxicity on human physiology. The work would be scientific in nature and the TRU would not become synonymous with routine testing in service to either industrial research, or policy procedure (TRUc, n.d.). Barnes was supported by more senior scientists, and reported, that his former supervisor, Gordon Roy Cameron, 'was a great help in ensuring the new unit was not turned into a testing laboratory, but was allowed to grow along the lines we both thought to be the right ones' (Oakley,1968). Despite concern over public health risks arising from use of novel chemicals, knowledge conditions within the academic community were not conducive for toxicology to emerge as a new specialty. Scientists had become defensive, protecting their interest in basic research against a perceived pressure to carry out routine tests.

5. Policy deliberations – the Committee on Toxic Substances in Consumer Goods

During the Second World War, industrial scientists had been encouraged to exploit capabilities of the new science of organic chemistry. This resulted in a situation where novel chemicals were being incorporated into a range of consumer goods without regard to their toxicity, or risk to public health (Ministry of Food, 1949). After the war industry wanted to continue these practices, and the situation regarding use of chemicals in consumer goods had changed significantly. Not only had war time shortages led to substitutions but new substances were continually being developed. Existing regulations, relying on traditional knowledge about toxicity, supported by limited chemical assessments by the Public Analyst were becoming outdated (Cobbold, 2016; Coles, 1983). The question of introducing pre-market testing for new chemicals was quickly raised as a policy issue (Zuckerman, 1949). Three factors contributed to this situation: slow development of commercial testing facilities; existing regulations, which provided only *post hoc* powers to ban the use of chemicals; and lack of scientific knowledge. The situation in Britain in 1945 with regard to assessment of potential toxicity was not encouraging.

Concerns were raised by a number of different groups. The Association of Scientific Workers lobbied the government's Advisory Council for Scientific Policy (ACSP) seeking assurances about the safety-in-use of chemical substances (TSCGa, 1949). Representatives from both the Ministries of Health and Food had also raised concerns. The Ministries questioned the lack of national facilities to provide scientific data for government (TSCGb, 1948). The ACSP responded by establishing a committee to review policy arrangements to control the addition of potentially harmful substances to consumer goods. The Committee on Toxic Substances in Consumer Goods (TSCG) was appointed on July 6, 1949. Solly Zuckerman, professor of anatomy at Birmingham University, was appointed chairman, while committee members consisted of representatives from concerned government departments (TSCGc, 1949). This committee was of major importance in highlighting areas where legislation on this issue was lacking. In addition, it made recommendations that would help to clarify the policy issues. The remit was,

> to examine existing arrangements for regulating ingredients or processes potentially injurious to health used in the preparation of foods, beverages, drugs, cosmetics, insecticides and other substances intended for use in contact with the human body: and if desirable to make recommendations for the better control of these substances and processes (Zuckerman, 1949).

Between the time of their first meeting on November 4, 1948 and the final report in 1950 the committee took evidence from the Ministry of Food, Ministry of Health, Department of the Government Chemist,

Medical and Agricultural Research Councils, the Department of Health for Scotland and the Board of Trade (ACSP, 1950). The committee had reviewed existing departmental arrangements for the control of ingredients in food, drugs, cosmetics, detergents, fertilisers and insecticides. The main point was to discover whether Departments had sufficient powers to obtain information about substances used in consumer goods. The committee had also endeavoured to ascertain if there was sufficient knowledge available to protect public health. Finally, to assess whether existing facilities were adequate for testing suspect products.

The answers were generally negative, exposing a lack of governmental powers to obtain information on the use of new chemicals or to investigate long-term effects on health (TSCGc, 1949). The committee recommended that new legal powers rather than voluntary agreements between government and industry would be most effective in ensuring firms would comply with the need to demonstrate safety. It also noted the absence in the UK of an independent, centralised, well-equipped laboratory that could undertake safety evaluations. One recommendation was that 'there is an urgent and vital need for a central scientific advisory organisation … which could serve as the focus for scientific advice …. handing out fundamental research problems … and co-originating routine testing' (ibid.). This recommendation was based on information gathered from visits made to the Food and Drug Administration (FDA) in the USA, and the stated desire to exchange information with this organisation. However, the recommendation was withdrawn at the last minute, due to limits of available finance and scientific personnel. The committee finally suggested that government and industry should jointly bear the cost of safety evaluations (TSCGd, 1950). The outcome was that toxicity would be dealt with, in policy terms, along the lines of existing departmental responsibility. The MRC, however, also considered the evidence, and came to the conclusion that the public was exposed to the danger of chronic toxicity[2] (TSCGe, 1950).

The TSCG represented a period of review of British policy towards chemical safety. However, discussions were entirely internal to the government, as reports were not made public. Evidence was taken solely from governmental organisations, and the remit was to support and encourage innovation in synthetic chemicals, not to subdue it. The TSCG had examined the need for pre-market testing of chemicals used in consumer goods but had not provided concrete guidelines on how this could be achieved in a manner acceptable to both government and industry. Over the next decade the first set of policy guidelines would be published.

6. The role of legislation

After the TSCG report, concerns about safety persisted in two area, agricultural chemicals and food additives. Zuckerman was almost immediately drafted to become chairman of the Working Party on Precautionary Measures against Toxic Substances Used in Agriculture set up in 1951 (WPTSA, 1951). The remit here was to make recommendations for safety in use of acutely poisonous substances that had claimed the deaths of agricultural workers. The Agriculture (Poisonous Substances) Act 1952 was a result of these deliberations, restricting agricultural workers exposure to deleterious substances. The final report from the Working Party highlighted the general lack of testing facilities in industry and government and reiterated the need for a central co-ordinating body to collect information on the use of chemicals in agriculture (WPTSA, 1953). However, not everyone was convinced. The British Medical Journal (BMJ), speaking for the medical profession, reported that, regarding pesticides, 'the risks of consuming very small quantities that could find their way into food are difficult, if not impossible to measure' (Anon d, 1954: 446). The journal also criticised the idea of using animal tests to assess chronic toxicity, claiming these would be difficult to interpret (ibid: 447). The situation was resolved through establishment of a voluntary scheme, the Pesticide Notification Scheme (PNS), which relied on close relationship between the Department of Agriculture and Fisheries and manufacturers of agricultural chemicals (Anon e, 1954). Responsibility for safety testing would lie with industry and a new governmental scientific advisory committee was set up to review all risks arising from use of chemicals in agriculture. Manufacturers would notify the committee of new substances, voluntarily avoiding the need for new legislation.

In the area of food additives, in 1951 a sub-committee was set up to specifically to review the regulations relating to safe use, under the chair of Professor E C Dodds a prominent biochemist (Anon f, 1951). Questions had been raised in the House of Commons relating to the increasing use of chemicals in food manufacturing (HoC, 1954). The government response was to insist there was no evidence of harm from their use, and that they were indispensable to industry. However, in the House of Commons, Dr A D Broughton stated that there were at least 400 chemicals in use in the UK about which there was no information on their long-term effect on the human body. (Anon g, 1951). The issue was resolved by the passage of the 1955 Food and Drugs Act. This legislation explicitly required manufacturers to ensure that chemicals added to food were not 'injurious to health' and gave statutory powers to the Minister of Food to obtain information about new chemicals used in the preparation of food. The Act attempted to build a bridge between 'excessive enthusiasm for the protection of public health' and 'assuming there is no danger' (HoC b, 1954). It established a permitted list of food additives that were deemed to be safe in use. Industry would be responsible for pre-market testing and the Food Standards Committee would provide scientific evaluation of results. In fact, as Weedon (1970:243) notes, development of the food additive permitted list 'was closely accompanied by the consolidation of an advisory mechanism'.

7. Testing chemicals for safety

The question of how best to evaluate safety was not yet settled as the use of animal tests was not fully supported. The BMJ, for example, reported that it would be a waste to use scientific training for routine safety testing. In addition, the utility of such tests was unproven, 'much of the work consists of long term feeding tests on the experimental animals, but the results can be strictly applied only to those animals' (Anon h, 1951:896). The BMJ also suggested that findings of the Delaney Committee in the USA demonstrated a lack of progress in understanding toxic effects (Anon i, 1952). In contrast, in the USA, the Food and Drug Administration had its own Division of Pharmacology, with access to a publicly funded laboratory. The Division pioneered the development of animal feeding tests and published their suggested procedure in 1949 (Coles, 1989; Lehman et al., 1949). Other European countries followed but differed in speed of implementation. In France, for example, industrial interests held sway over regulation for public health during the 1950s (Jas, 2007). In the UK academic scientists promoted the idea of routine testing, which led to published disagreements on the best course of action. A pragmatic compromise was championed by Alastair Frazer, Professor of Medical Biochemistry and Pharmacology at Birmingham University. Frazer was motivated by the post-war food shortages and felt that technology should be used to improve the situation, stating that,

> 'it is the duty of all who have knowledge of food, whether they be nutritional experts or industrialists, to advise and help less informed sections of the population. If synthetic chemicals are to be introduced into foods for purposes of improvement, or for other legitimate reasons, full responsibility lies with those concerned with the use and distribution of the materials, and adequate safeguards for the health of the public must be taken before any responsible body can agree to the use of such materials' (Frazer, 1951: 1).

[2] Concern about chronic toxicity, where long-term exposure to small doses would result in harm to a specific part of the body had been raised by research in the USA on lead poisoning (Sollman, 1922).

Frazer was not in opposition to scientists who favoured scientific research, but was an advocate for changing policy towards pre-market safety evaluation, because,

> 'there was no need to suggest that the use of all chemicals in food manufacture should be forbidden, even if such extremist action were a practical solution, since the problems raised by the use of chemicals in food can be solved along more rational lines' (Frazer, 1952a: 1)

He was the first in the UK to suggest a programme of routine tests, publishing his own recommendations for a test schedule (Frazer, 1952b). Frazer felt that chemical safety could be inferred from biochemical and pharmacological assessment, and suggested both short and long-term animal feeding tests through several generations. More than one species should be used as well as tests on human volunteers. Other investigations would assess possible indirect effects, due to interaction with other food constituents or from interference with nutritional properties. Frazer admitted that routine testing could not ensure safety to the standard offered by academic research, but it would minimise public health risks,

> 'there are those who say that these investigations do not provide a 100% guarantee of safety. Of course, this is true - there is practically nothing we do in our lives that carries a 100% guarantee of safety. It is contrary to the whole basis of biological research to expect such absolute results' (Frazer, 1952b: 457).

Fraser also felt uncertainties would be progressively reduced by advances in bio-medical science, so that, 'the greater and more accurate this basic knowledge, the more complete and more reliable is the safeguard derived from its application' (ibid: 457).

Frazer understood the limitations of chronic toxicity tests, but supported their use on pragmatic grounds, stating, 'I do not consider, however, that one can altogether dispense with acute, sub-acute, and chronic tests that are intended to pick up and predict effects' (Frazer, 1955, p. 686). He felt a variety of tests could be used to satisfy policy requirements, which could be adapted in response to new knowledge (Frazer, 1956). Frazer felt that testing chemicals for regulatory complicity was a distinct knowledge area, worthy of recognition and critical evaluation. He expected such tests to be extensive to provide adequate basis for risk assessment decisions, with evaluations supported by continual developments in basic science and was clear about the pragmatic nature of knowledge for policy. The interrelation between testing for safety assessment and the development of a more traditional academic specialty, initially identified by the TSCG, was reinforced by Frazer's published deliberations.

7.1. The academic critics

Frazer was advocating a wide range of routine animal feeding tests to give a quick evaluation of safety-in-use. However, this approach was not accepted without some scientific debate. An extensive critical review which highlighted uncertainties in the data from animal tests was published in 1954 by two scientists from the TRU, Barnes and his colleague Frank Anton Denz (Barnes and Denz, 1954). They acknowledged the number of novel chemicals entering the human environment had created a policy problem, and that scientists had been asked by government, to suggest means of assessment. The authors noted 'absolute proof of the safety of a chemical will not be demonstrated by experimentation on animals, but equally it is clear that some observations on animals must be made' (ibid: 192). However, these tests would be a poor substitute for developing bio-medical knowledge. Standardised testing regimes did not represent variations in human populations due to factors such as age, gender or nutritional state. Tests could only deliver temporary knowledge,

> 'always a makeshift affair to be replaced as soon as possible by a more permanent structure of knowledge built on the foundations of physiology, biochemistry and other fundamental sciences' (Ibid: 196).

The review criticised all the techniques that had been suggested for use in chronic toxicity tests. On the choice of test animals they noted, that rats were chosen for convenience, cost and time, but the choice of a second species was problematic as there was little evidence to show that species differences would be observed. In addition, there was rarely enough evidence to compare animal results with those in humans. A persistent problem was the presence of impurities in the test substance, which could differ between manufacturers and could affect the end results. Other factors that were noted that could affect the outcome were dose levels and method of administration. Substances mixed with feed would alter both the toxicity and the dose ingested. They raised problems with the duration of testing programmes which raised the inability to separate toxicity from the effect of aging. These shortcomings, the authors stated, demonstrated 'the difficulty of finding acceptable criteria of poisoning or abnormality attributable to the toxic agent' (ibid: 221). At best a negative result could strengthen confidence that the substance could be used safely without giving certainty. However, they noted that both very rare reactions as well as reproductive effects that passed through subsequent generations were possible but would be undetected with the current testing practices.

Barnes and Denz forcefully argued that such tests could not be considered the best means of assessing the safety of new chemicals. They reiterated their favoured solution of stepping up academic investigations, particularly in the metabolic processes of test substances, even though these investigations would be time consuming. The advantages would be incontestable, they argued, 'this approach would be scientific in contrast to the empirical method of chronic toxicity tests … The use of such an experimental approach should not be confused with a scientific attack on a difficult problem' (ibid: 232). The authors of this review were consistent in their advocacy for the superiority of in-depth scientific research over routine tests in generating more certain knowledge. However, the more pragmatic policy discussions had forced them to engage with issues relating to efficacy of potential animal tests, as it was clear that routine testing would became enshrined in law.

7.2. Development of animal testing regimes

The 1950s was a decade where it was generally agreed that the use of chemicals by industry was increasing faster than knowledge of their potential effect on health. For some prominent scientists in the biochemical field, this situation posed risks of long term or chronic harm, while others were less convinced. Both pesticides and food additives had shown that concerns by government could result in legislation that compelled disclosure of findings from safety tests. The official position was that government would not fund a centralised laboratory for routine testing. The FDA's Pharmacology Unit in the USA had published extensive animal test guidelines (Lehman et al., 1949), but for UK scientists the question of advising on the assessment of safety was difficult to answer. Towards the end of the decade, the MRC Toxicology Committee was under increasing pressure to give advice on suitable animal tests but backtracked, claiming its role was to 'interpret the available information about safety' not to define 'conditions of safe use or the setting of permitted concentrations in foods or other consumer goods' (MRC, 1957). By 1958 three testing schedules had been suggested, one from Professor Frazer, published in a technical journal, and two from government committees. The testing regimes suggested by each schedule are compared in Table 1.

This table indicates the extent of both agreement and disagreement between the three schedules. Notably, Frazer's suggestions were specifically directed towards assessing the safety of food additives, and he was the only one to include human trials. The PNS tests were tailored towards assessment of pesticides, while the MRC Toxicology Committee were suggesting a more general testing regime. There is clear agreement on the necessity of measuring acute toxicity by oral administration in three species including rats and mice, and on carrying out

Table 1
Comparison of suggested UK testing regimes (compiled from Frazer 1952a,b; MRC Toxicology Committee, 1957 and Pesticide Notification Scheme, 1958).

Suggested animal tests	(Frazer, 1952b)	MRC (1957)	PNS (1958)
Chemical and physical examination	x	–	x
Acute toxicity (LD50)	x	x	x
Oral	x	–	x
Parenteral			
LD50 animal species	x	x	x
Mice	x	x	x
Rats	x	x	x (non-rodent)
Other			
Biochemical studies	x	x	x
Cumulative toxicity, largest non-toxic dose; 2–4 weeks	–	–	x
Chronic toxicity: Duration	x	–	x
12-24 months	x	–	–
Life span	x	–	–
Several generations	–	x	x
Dose			
2 levels + control			
Largest non-toxic			
Skin toxicity	–	x	x
Potentiation	–	–	x
Delayed effects	–	–	x
Diagnostic information	–	–	x
Inhalation	–	x	–
Maximum concentration administered during rapid growth	–	x	–
Investigate toxic effects with non-fatal dose	–	x	–
Opinion on general mode of action	–	x	–
Human trials	x	–	–

biochemical studies, although the extent and type of these was not specified by any of the schedules. Also the proposed tests show agreement on the necessity of testing for chronic toxicity but not on the specific tests, as the guidelines differ in their suggestions for duration and dosage. Both the PNS and the MRC recommend extra tests but these are directed at their specific concerns. The PNS wanted to know about skin toxicity, potentiation, delayed effects and diagnostic information, all issues that had been observed as affecting agricultural workers using chemical products. The MRC wanted more general information about toxicity to be recorded, including inhalation study, and dosage issues – investigating effects of a non-toxic dose and increasing dosage levels during growth spurts. Finally, the MRC required an expert opinion on the mode of action of the chemical under test. In practice, however, only the PNS tests were officially recommended by the ministry of Agriculture and Fisheries as the schedule had been devised by their own Plant Pathology Laboratory and were necessary to the operation of the Pesticide Notification Scheme.

However, Barnes still had concerns and separately published an article in 1957 outlining problems with the routine assessment of toxicity. While he finally admitted that, in his opinion, ingesting repeated small doses of most chemicals would not be hazardous, he reiterated that the toxicity test was not an appropriate substitute for scientific investigation,

> 'the toxicity test by itself is not a satisfactory basis for decisions on safe use. Everything else must be taken into consideration and the more this is done the greater are the opportunities for individual's opinion –prejudices if you like – to sway the balance of judgement of the problem as a whole' (Barnes, 1957).

In the policy arena, pragmatism was selected over basic research and as Barnes, the principal defender of basic science, admitted compromise in the routine assessment of chemical safety had been reached. However, the first published government guidelines in the UK had been written eight years after those published and adopted in the USA, illustrating how a measure of delay could be introduced from prolonged scientific disagreement.[3]

8. Discussion

This article has traced the deliberations that culminated in the first published animal testing schedules in the UK. These documents represent emergence of a new area of regulatory science which was institutionalised outside the arena of academic science. Animal testing for chemical safety has roots in both industrial and governmental laboratories. Thus, this example of an area of regulatory science demonstrates that knowledge for policy can be more independent from institutional bases than academic science. However, the FDA's Division of Pharmacology, with a dedicated scientific team and centralised resources was a model which UK scientific advisors sought to copy for a period. Eventually, it was accepted that the UK did not have resources or inclination to fund a similar laboratory and the shared responsibility of BIBRA was more suitable to needs and priorities. With regard to the test schedules, the UK had a specific response, dividing responsibility between different government departments. This gave rise to the two alternative schedules tailored to different chemical types, with the Plant Pathology Laboratory suggesting specific tests for agricultural chemicals and the Toxicology Committee giving more general directives to a wider range of industries. It is worth noting that both government schedules agreed on tests for chronic harm resolving a long held scepticism that this was an issue worthy of investigation. In addition, the adoption of animal tests put to rest lingering doubts over this approach to safety evaluation.

In the immediate post-war period, it became clear that the increasing number of synthetic chemicals was creating a new policy problem. Scientific debate focused on identifying optimal responses to the problem of evaluating their safety in use. Although a full controversy did not develop, there was a vigorous debate over reliability of knowledge from different sources. Frazer expressed the opinions of those who prioritised the need for relatively fast decisions while Barnes felt that the superiority of knowledge from basic science overrode other arguments. However, government was not disposed to provide resources either for an increased level of scientific research or for routine animal testing. The MRC Toxicology Unit, although small, remained the major laboratory for academic research for thirteen years while the emergence of more prescriptive policy schedules forced industry to invest in their own laboratories. There were, then, differences of opinion about the scientific nature of routine testing to establish safety and the best means to optimise the balance between basic research and safety testing. There was some scientific agreement about uncertainty in the test results, and the importance of improving their predictive value through the support of basic research. Pragmatism was to win over academic science, resulting in pressure on commercially-based scientists to undertake animal tests. These tests were eventually both recommended and criticised by academic scientists.

Routine assessments on animals were adopted as the basis for UK policy over the claimed superiority of more certain outcomes from academic science. There were a number of reasons, not least the lack of predictive models that could be offered by scientific knowledge. The adoption of nationally agreed test standards enabled other issues to be resolved, including the fact that industry would bear the cost of testing. The solution institutionalised a technocratic evaluation and approval system as data would be submitted to committees of expert scientists for review and evaluation. The policy regime adopted was essentially a compromise between available knowledge, expertise, cost and responsibility. The solution gained a certain extent of expert agreement, but for technical expediency rather than scientific authenticity. The test

[3] Brown and Lyon (1992) discuss the effect of controversy between different scientific disciplines in slowing global reaction to the problems of ozone in the upper atmosphere.

findings would be confidential and owned by industry, not open and available for general use. The data would be specific to the particular compound under test and contingent on the needs of the testing regime, not general or universal scientific statements. The policy framework had to take account of existing bio-chemical knowledge which contained a high level of uncertainty and lack of predictability in regard to the impact of chemical action on the human body. To compensate the testing regime was functional and practice based (Todt et al., 2010). Finally, lack of openness of the data and the exclusion of a wider stakeholder group from the risk management decisions have been persistent criticisms (Flüeler and Scholz, 2004; Stilgoe, 2007; Van Overveld et al., 2010).

The discussion presented here relates to factors within the UK context that influenced acceptance of animal safety tests. It is suggested that test schedules published during the 1950s represent the articulation of a specific scientific area within regulatory science. The academic literature on emergence of new scientific specialties provides guidance on interpreting the dynamics of change, and can help to understand the tensions between academic scientist and pragmatic requirements of policy. Studies of new scientific areas put emphasis on cognitive coherence and social organisation, including the position of intellectual leaders. For knowledge domains located in non-academic institutions, other aspects such as institutional goals, knowledge fragmentation, isolation of research activities will impact on the area. In addition, work on regulatory science indicates a number of issues are involved in knowledge development. The role of specific context, setting values, the relationship between science and politics, the nature of policy setting and systematisation of evaluative procedures should be considered. Other issues include openness of knowledge, constraints in terms of time, budget, and the limits to existing assessment techniques.

The emergence of animal test schedules in the UK draws on all these insights. It is clear that the norms and values of academic science were being clearly expressed by the practitioners involved with developing the research agenda of the TRU. In particular, the views held by Barnes with respect to animal testing were the main factors responsible for preventing the Unit becoming a central government scientific laboratory similar to the Pharmacology Division in the United States. However, other academic scientists were more conciliatory. Zuckerman, for example, had a clear focus on the need to assess safety of small amounts of chemicals regularly used in consumer goods. He continued to be a proponent of the need for a centralised laboratory as a knowledge repository. Frazer, also took it upon himself to support the idea of animal tests and published a schedule of test to help industrial scientists in their evaluations. Early institutionalisation took place both in government run and industrial laboratories. While the TRU as the government facility defined itself as academically oriented, the ICI laboratory exhibited characteristics of industrial science, identified by Johnston and Robbins being focused on internally set goals.

Policy requirements and social values have been identified as playing a key role in regulatory science. This case illustrates different factors that contribute to the policy input. On one hand legislation enshrined certain responsibilities in law. However the extensive deliberations of the TSCG illustrate the process of review and revision in the light of what was perceived to be a changing situation. It also took the responsibility for articulating the new social values that would lie behind all future deliberations - that government should put into place procedures to protect the public health. The fact that the preferred option of a centrally funded laboratory was rejected demonstrates how solutions were negotiated. However, core issues highlighted by the committee, that of pre-market testing and potential for chronic toxicity were influential in considering legal changes both for agricultural chemicals and food additives. The difference between controls in these areas demonstrates that development of policies towards chemical safety resulting in compulsion through an Act of Parliament was not necessarily the favoured solution. The PNS, with voluntary participation was felt to be sufficient. For food additives, however, it became compulsory for industry to submit safety data for addition to the permitted list.[4] Although these were different approaches, the review systems established to enable government departments to evaluate data was similar. They both utilised scientific advisory committees to evaluate and give recommendations on submitted test data.

The final question related to the test schedules themselves. As Shackley and Wynne (1995) attest, knowledge domains in regulatory science are co-created by policy and scientific priorities. The two government test guidelines that were published by the Toxicology Committee and the PNS were notable in this sense. In fact, neither set of suggested tests pushed knowledge boundaries in the area of safety testing in the same way as the FDA Division of Pharmacy whose guidelines were far more scientifically detailed (Coles, 1989). However, they both agreed on the fact that acute and chronic toxicity should be investigated, the latter over the lifetime of the test animals. In addition, the pesticide recommendations included specific tests relating to the use of agricultural chemicals. This illustrates how knowledge is tailored to specific policy goals in regulatory science.

While safety testing displays some of the characteristics of an industrial science as described by Johnston and Robbins, its status as a knowledge domain incorporates additional characteristics. Tests are carried out to comply with legislation but are a cost to firms, in contrast to other types of industrial research concerned with economic gain. Firms also carry out tests that have been externally defined and are constant not only between firms but also between classes of chemical. In addition knowledge outputs are not held in confidence by the firm but must be submitted to government appointed committees for evaluation in the light of policy. Thus the operational aspects of safety testing as a knowledge domain split between knowledge production and knowledge evaluation, was initially adopted for political expediency.

Animal tests for chemical safety in the UK therefore displayed characteristics additional to those of an institutionalised industrial specialty:

1. Test schedules were tailored to achieve public policy goals
2. Technical knowledge was supplied specifically to enact the goals of public policy, not to further knowledge.
3. Production and evaluation of knowledge was fragmented and secrecy of results inhibited generalisations that might be drawn from different firms' results.
4. Uncertainty was accepted as an integral part of the evaluation procedure, but attempts to counteract such risks would be enshrined in the range of tests adopted.

In this sense the regime of animal tests can be thought of as an early example of the cross boundary knowledge fields postulated by Frickel and Hess (2014). However, given the specific socio-economic context it is not surprising that this type of safety evaluation has subsequently come under criticism, not only for creating a knowledge deficit in regard to chemical risk but also for ease of capture by dominant industrial interests (Frickel and Moore, 2006; Lave, 2014). Animal testing for safety evaluation, then, is a knowledge domain directed by both political and technical rather than purely scientific requirements, utilising routine testing rather than scientific experimentation, carried out in commercial rather than academic institutions.

Abraham and Davis (2007) conceptualise regulatory science as an epistemological paradigm influenced by both scientific and social goals, a heterogeneous knowledge area incorporating a wide range of different risk evaluation practices. This article has investigated the emergence of a system of animal tests to evaluate chemical safety for use in consumer goods. It has considered policy deliberations that set requirements for

[4] A permitted list of food additives was also introduced in the USA in the 1958 Food Additive Amendment to the 1938 Food, Drug and Cosmetic Act. This was the first time the Delaney Clause, which prohibited the use of chemicals shown to be cancerous at any dose, was incorporated into legislation (Wargo, 2010).

empirical investigations, debates concerning the optimum knowledge required to demonstrate safe use and the final institutional arrangements. This case supports claims made by Shackley and Wynne (1995) that regulatory science is co-created by both scientific and political goals and demonstrates how non-scientific policy requirements are deeply configured with the cognitive system of knowledge generation. This interrelationship demonstrates that animal tests for chemical safety evaluation should be considered a specific techno-legal specialty within the broader regulatory science paradigm. It is fundamentally configured as a hybrid knowledge domain defined by interaction between policy goals and scientific technique, designed to generate data with speed rather than accuracy. Finally, this specialty is geographically and contextually located, a specific outcome of the particular deliberations that took place in the UK in the immediate post-war period which influenced its emergent structure and mode of operation.

9. Conclusion

This article has considered the factors that influenced emergence of animal testing as an institutionalised system for evaluating chemicals used in consumer products in the UK. It is suggested that this knowledge domain can be conceptualised as a hybrid, techno-legal specialty, within the wider paradigm of regulatory science, as testing regimes are selected to achieve specific policy goals. This example raises questions regarding the influence of context and process in constructing priorities for emerging domains within regulatory science. Additional in-depth case studies of similar fields are required to further investigate these issues.

Author statement

I confirm that this article is my original work and has not been published elsewhere.

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Appendix A. Supplementary data

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