5. Risk analysis: an analytical approach to policy-making

Introduction

5.1 Government usually involves choosing between different policy options, programmes and projects. Alternative options will have varying merits and costs and the ‘right’ course may not be popular. The process of choice has to be robust and transparent if the resulting decisions are to be acceptable to the public. This means using objective and widely accepted criteria that can be assessed analytically.

5.2 Governments have for many years used techniques such as risk assessment, cost-benefit analysis, and sensitivity analysis as a basis and justification for their decisions. These techniques have been developed and refined in the light of experience, a process which continued throughout the 1980s and 1990s (as the Risk Analysis Timeline in Annex 2 shows).

5.3 Practically every decision on BSE had to be made when much was uncertain – for example, whether or not to introduce a slaughter and compensation policy without knowing whether or to what extent BSE-infected cattle might be a risk to human health; and what to do about the possible risk from subclinically infected cattle without knowing which tissues, if any, were infective to humans. Doing nothing until firm information was available was itself risky, because answers to such questions might not become available for years.

5.4 Officials and Ministers had to assess the risks and the options for managing them, and to decide how to inform the public – and groups such as farmers, pharmaceutical manufacturers and vets – of the risks. How they did this is considered in the parts of this Report that tell the BSE story (volumes 3–11). This chapter gives the background on how the tools available to policy-makers developed between 1986 and 1996.

5.5 Three questions are addressed here:

i. What analytical concepts and techniques were available to government policy-makers, and when? (A timeline of concepts and publications is at Annex 2.)

ii. What did Departments use these techniques for?

iii. What efforts were made to disseminate ideas and approaches as they developed?
Basic definitions

5.6 Risk assessment, the term most often used in the BSE documents, is one part of a joint FAO/WHO definition of risk analysis, which comprises

i. risk assessment – (a) hazard identification; (b) hazard characterisation; (c) exposure assessment; and (d) risk characterisation;

ii. risk management – (a) risk evaluation; (b) option assessment; (c) implementation of management decision; and (d) monitoring and evaluation; and

iii. risk communication – an interactive exchange of views with those involved or affected covering the whole process. 190

5.7 There is a key distinction between a hazard and risk:

... hazard is an intrinsic property of, for example, a food chemical, whereas risk is a measure of the probability that the food chemical will produce adverse effects through the circumstances of human contact with it. 191

The same hazard may pose different risks – for example, the same dose of a particular poison may cause more virulent reactions in some groups of people than in others, because the former are more susceptible to it (for example, because of their age or for genetic reasons). Also, the nature of a hazard and the extent of the risks that it poses may only become known over time, as more is learned about its properties and potential pathways of infection.

5.8 Risk assessment and management involved the use of a number of concepts for which acronyms were often used. The following examples were particularly relevant to the BSE story.

5.9 ALARP (As Low As Reasonably Practicable) was ‘inherent in the general duties of the Health and Safety at Work etc Act 1974’. 192 This Act placed legal responsibility for the safety of workers and the public on the employer who controlled an industrial plant.

The injunction laid down in safety law is that any risk must be reduced so far as reasonably practicable, or to a level which is ‘as low as is reasonably practicable’. 193

The Courts had expressed the view that the term ‘reasonably practicable’ was narrower than ‘physically possible’ and involved a degree of proportionality (see below) – ie, the benefit in terms of risk reduction had to be proportionate to the cost imposed (in terms of money, time, etc) by the measures needed to achieve it. 194

Also:

190 Application of risk analysis to food standards issues: report of the Joint Food and Agriculture Organisation/World Health Organisation Expert Consultation 13–17, March 1995 – the FAO/WHO Risk Analysis Scheme (M65 tab 1 p. 6)
191 PH (90) 12, InterDepartmental Group on Public Health: Risk Assessment and Risk Management in MAFF, October 1990 (M66 tab 1), p. 2. The Group (IDGP/H) comprised Grade 2 officials from a number of Departments, chaired by the Chief Medical Officer
193 The Tolerability of Risk from Nuclear Power Stations, Health and Safety Executive (HSE), December 1987, p. 4, para. 17(c)
194 Edwards v National Coal Board (1949 1 KB 704; 1949 1 All ER 743)
The ALARP principle may be taken for all practical purposes as indistinguishable from ALARA (so far as is reasonably achievable).195

5.10 **Hazard Analysis Critical Control Point (HACCP)** was a three-stage system of control applicable to ‘all stages of food manufacturing from raw material acquisition to product sale and consumption’196 which:

i. described and assessed the hazards associated with all stages of the process;

ii. identified Critical Control Points at which it was necessary to control these hazards; and

iii. established procedures through which Critical Control Points could be effectively monitored.

The HACCP approach:

. . . shifts the emphasis from final product testing to process and raw material control . . . [it] has the potential to identify areas of concern where failure has not yet been experienced, making it particularly useful for new operations.197

It was endorsed in 1990 by the Committee on the Microbiological Safety of Food (the Richmond Committee), firstly in connection with food manufacturing ‘if properly carried out’198 and later in relation to slaughterhouses.199

5.11 The **precautionary principle** was defined in a number of ways. For example:

. . . it is better to be safe than sorry.200

. . . where the analytical basis for assessment of risk is weak, the lack of full scientific certainty should not be used as a reason for postponing cost effective measures particularly where there are threats of serious or irreversible damage.201

. . . acting to reduce risk in advance of a complete scientific understanding, by extension of evidence and in the exercise of reasonable foresight.202

5.12 The idea of *proportionality*, ‘a European law concept’,203 was associated with the Government’s Deregulation Initiative, described in Chapter 7. Regulation was to be ‘aimed at the right target and [was to be] no more than is needed to achieve the objective’, while ‘risk management techniques are used when there is doubt about the level of risk and the type of regulation needed to deal with a problem’.204
5.13 NOAEL (No Observable Adverse Effects Level) was used when licensing medicines or assessing risks in food from additives or residues. Other concepts were used when assessing certain kinds of risks:

i. ADI and TDI (Acceptable or Tolerable Daily Intakes) – in connection with the risks of additives or contaminants in food;

ii. AOEL (Acceptable Operator Exposure Level) – in connection with the risks from pesticides; and

iii. MRL (Maximum Residue Limits) – in connection with the persistence of chemicals in the soil, in water, or in food.

5.14 Risk perceptions were shaped by psychological and cultural factors, and might vary among different groups in society. Scientists tended to compare and rank different risks according to probabilities. The ‘lay’ public view might be more subjective, taking account of the novelty of the risks, the extent to which exposure to these risks was within their control, and whether the hazards were man-made or ‘natural’. These varying views had to be reconciled, and risk communication was an important part of that process:

The best way of ensuring that the public and the experts understand each other is to explain the scientific issues and to give people the opportunity to make their views known.205

5.15 Cost-benefit analysis (CBA) was a system of financial appraisal that also took account of external and non-monetary costs and benefits to individuals, organisations and society as a whole. It involved adding up the costs (in the wider sense just mentioned) of construction, operation, maintenance, etc, throughout the lifetime of a project or programme, converting them to present-day values by applying a discount rate, and treating the likely benefits likewise. If benefits exceeded costs, the project was worthwhile. CBA was traditionally associated with the appraisal of large capital projects (roads, airports, power stations, etc), but it could also be used to assess options for regulation or for managing risk, thereby forming part of the process of risk management.

5.16 In practice, it was not straightforward to apply the CBA approach. It was difficult to maximise benefits and to evaluate non-monetary factors or uncertainties. Moreover, seeking to attach monetary or other comparative values to human life, health and preferences was controversial and subjective, although it was necessary to attempt this if the costs and benefits of precautionary regulations and procedures were to be assessed. In doing so, the aim was not to calculate ‘compensation’ for the loss of a life (which would be impossible), but to assess:

... the value to be attached to a small reduction in risk that would result in the saving of a life as it relates to an unknown individual.206

5.17 Sensitivity analysis was the process of assessing the effects of different assumptions about the future and their likelihood.207 It provided a means of testing

206 The ILGRA Report (M66 tab 5), p. 12, para. 42
the robustness of a chosen course of action and identifying ways of proceeding if things went wrong.

The development of risk analysis in government

5.18 Government was interested in risk for a number of reasons:

i. traditional investment appraisal (for example, of new transport schemes and industrial sites);

ii. assessing the need for regulation (for example, in respect of workplace safety, air and water quality, the handling of solid wastes and toxic substances, and food safety); and

iii. assessing the effectiveness of enforcement.

5.19 The Risk Analysis Timeline in Annex 2 gives an idea of how thinking developed from the mid-1980s, and what guidance was available to policy-makers if they looked for it. There were two broad trends:

i. A growing recognition that the principles behind quantitative techniques for comparing costed projects could also provide a useful framework for thinking about options and problems that could not be costed or in which there were uncertainties. Successive editions of the Treasury Green Book increasingly addressed the issues of risk, uncertainty, elements that could not be valued in money terms, and equity. Guidance issued in 1991 by the then Department of the Environment was explicitly about appraising policy rather than capital investment proposals. However, in 1987, when MAFF officials were first considering the implications of BSE, such guidance was not readily available.

ii. A move away from an approach based on trying to persuade the public that they should accept the ‘scientific’ or ‘correct’ answer, and towards trying to understand the values which individuals brought to decisions about risk. By 1996, Treasury advice on The Setting of Safety Standards explicitly recognised the place of ethical assumptions about the distribution of risks and benefits, and the importance of how the public perceived the ‘quality’ (nature) of risks. But the fact that public perception of risks was often at variance with the scientific evidence was familiar within Whitehall long before then. For example, this discrepancy was discussed in a Health and Safety Executive (HSE) document in 1987, and in the 1990 MAFF paper on risk assessment quoted earlier.

210 The Setting of Safety Standards: a report by an inter-departmental group and external advisers, HM Treasury, June 1996.
211 The Tolerability of Risk from Nuclear Power Stations, HSE, December 1987, p. 2, para. 11
212 M66 tab 1 pp. 2–3 para. 5 (see paragraph 5.7)
The dissemination of ideas

5.20 Until the early 1990s, Departments pursued their own individual approaches to risk analysis. Then two separate policy developments prompted efforts to disseminate ideas and best practice across Whitehall. Firstly, the Deregulation Initiative (questioning the complexity of or need for regulations that impacted on business) prompted the establishment in April 1991 of an official group to produce guidance on risk assessment in that context, with a view to achieving greater consistency in decision-making. Secondly, ‘a growing interest in the use of formal risk assessment techniques’ in developing controls on (in particular) chemicals and genetically modified organisms resulted in a commitment to identify best practice and disseminate it across government.213 This led to the formation of the Inter-Departmental Liaison Group on Risk Assessment (ILGRA), of which the chair and secretariat were provided by the HSE. ILGRA first met in April 1992.

5.21 When revised in April 1993, ILGRA’s terms of reference envisaged that it would report by September 1994. In the event, it reported in January 1996, giving an overview of risk assessment in government, describing the basic concepts and techniques, and outlining how various Departments used them. The Report recorded general agreement on issues such as how to handle uncertainty, the difficulty of quantifying risks, the unreliability of CBA and the need to use equity-based criteria as well, and the importance of taking account of public perceptions of risk. It identified a need for greater consistency in carrying out risk assessments and adopting new techniques, and for a common terminology.214

Risk analysis in MAFF – general approach

5.22 The description in the ILGRA Report of MAFF’s approach to risk assessment noted that the Ministry used both quantitative and qualitative methods. Food safety standards, mostly determined internationally, generally involved tolerability limits based on scientific judgement. Microbiological organisms were mainly controlled by ALARP-based risk assessments. Regulation of animal diseases that might pose public health risks depended on whether the risk was well known. If it was, risk management was adopted (eg, quarantine). Where scientific knowledge was insufficient to quantify the risk – the Report cited BSE as an example – a precautionary regime was adopted and a ‘decision framework’ was developed, which analysed objectives as well as direct and indirect effects, and took full account of the multifaceted and complex nature of food safety.215

5.23 The Report recorded MAFF’s view that:

i. safety-related Regulations had to balance protecting human health with the need to avoid imposing excessive costs on industry,216 and take account of public expectations, confidence and reputation, consumers’ perceptions, uncertainty, and other qualitative factors as well as experts’ judgement;

214 The ILGRA Report (M66 tab 5)
215 The ILGRA Report (M66 tab 5), paras 88–90
216 That is, be proportional

ii. safety, although the prime objective, might have to be balanced with objectives such as ensuring fair competition;

iii. safety benefits from regulation were often difficult to quantify; and

iv. current regulatory regimes were complex and interacted with each other and with non-regulatory approaches such as industry codes of practice and information for the public. 217

5.24 As the Report also noted, MAFF used cost-benefit analysis (CBA), 218 but considered that while some risk assessments (eg, environmental risks) needed to include costs and benefits, this was not possible in other areas (eg, the release of genetically modified organisms).

5.25 Mr Brian Dickinson (MAFF, Food Safety) and Dr William Denner (MAFF, Food Science) told the Inquiry that, by 1988, MAFF had a ‘well-ordered system for food chemical risk assessment’: 219

For chemical risks in food (additives, contaminants and residues) there were well-established methods for assessing any toxicological risks and determining No Observed Adverse Effect Levels (NOAEL); after applying a suitable safety factor (often 100) the NOAEL was used to derive Acceptable or Tolerable Daily Intakes (used for additives and contaminants) and Maximum Residue Limits (for pesticides and veterinary medicines) . . . The broad thrust was thus to prevent any unnecessary risk in food. 220

5.26 However:

Microbiological contamination was approached in a very different way. The main problems were to identify the main organisms which might cause food poisoning, the foods which acted as vehicles for the organisms and the sources of contamination, the behaviour of the organisms in food and the factors which encouraged their growth or death . . . The emphasis was upon risk control rather than complete prevention (except for especially serious hazards such as botulimum toxin). Much more than for chemical risks, the emphasis was upon bringing businesses to assess and manage risks for themselves (and on reminding consumers what they should do). 221

5.27 Dr Denner indicated that the distinction arose from historical circumstances:

Prior to the onset of ‘Listeria hysteria’ and the salmonella in eggs incident, MAFF had largely left the whole area of microbiological food safety to DH. Although there were food scientists in the Food Science Group with extensive knowledge of the practical application of hygiene controls in various aspects of food manufacture, we did not have any mainstream microbiologists among the advisory staff in headquarters. There were however a limited number of microbiologists in our laboratories working on microbiological methods including a significant source of expertise on botulism in our Aberdeen laboratory.

217 The ILGRA Report (M66 tab 5), para. 90
218 Applying this to the more readily estimated risks of floods’ (The Setting of Safety Standards: a report by an inter-departmental group and external advisers, HM Treasury, June 1996, p. 4)
219 S435 Denner para. 19
220 S97B Dickinson B para. 11
221 S97B Dickinson B para. 13
As the political importance of microbiological food safety increased, a new Microbiology Branch was set up in my Division in 1989. It became necessary to second temporary staff from other parts of MAFF and the AFRC [Agriculture and Food Research Council] because the immediate need for staff in post outstripped the pace of recruitment of permanent staff from outside the Civil Service.

There was a marked contrast between the well-ordered system for food chemical risk assessment and that for microbiological risk assessment. There were no DH independent committees to which problems could be referred for advice. There was no co-ordinated system of surveillance as had been put in place on the chemical side by MAFF almost 20 years previously. Any microbiological surveillance carried out with Government funding was carried out by the Public Health Laboratory Service.

5.28 On the other hand, Mr Cruickshank (of MAFF) told the Inquiry that during the period 1986–89:

I do not think . . . we discussed risk assessment quite in those terms. More recently it has become a well-recognised term and the expression is well known and understood. I do not think at that point it was so well understood, and it was certainly rarely used.

He continued:

I think we tended to use another couple of legal concepts . . . in dealing with any risk, one would apply the concept of reasonableness . . . in some cases it was explicitly stated in legislation. In other cases the advice we got from our own lawyers was that anything we did had to be reasonable. That tended to mean it had to be based on scientific advice. If we were purporting to ban something, or restrict its use, we had to have pretty good scientific advice to suggest it should be banned or restricted, or whatever.

The other concept that came in [w]as a European law concept, the concept of proportionality which, as I understand it, basically means you do not use a sledgehammer to crack a nut.

5.29 In response to the question ‘What happens if the scientific advisers say: “This is possible, but we have not got any evidence that it actually happens”?’, Mr Cruickshank said:

Well, that is really what was happening with BSE of course. And it put us in a very difficult situation . . . nobody was saying to us: ‘This disease is likely to be transmissible.’ Therefore, we paused a long time before we classified BSE as a zoonosis. On the other hand, it did not stop us doing anything, of course. The fact that one does not have scientific advice does not mean one does nothing. One can try to avoid problems arising; but it does mean that one has great difficulty in banning the sale or use of a product.
He agreed with the proposition ‘the scientific advice must be that there is evidence that such and such occurs before the Government can act to stop it’, commenting: ‘Yes, that was the policy.’

**Risk analysis in MAFF – risk communication**

5.30 The quality and timeliness of guidance to the public were among the aspects of the handling by MAFF and DH of earlier food scares criticised in reports by two House of Commons Select Committees, as well as by the media. MAFF responded by setting up a Risk Assessment and Management Strategy Branch in its Food Science Division. Between 1989 and 1994, it did a lot of work on how the level of public understanding might be raised and on opening up public debate about relative risks, the relationship between individuals’ views and scientific evidence, and how individuals rank risk. In 1991 the Chief Scientific Adviser welcomed plans by the Economic and Social Research Council for research on consumer perceptions relating to food safety.

5.31 Discussions within MAFF were supplemented by seminars involving invited speakers from inside and outside government, and research by external consultants into the views and approaches adopted in various parts of MAFF. There was an attempt to develop an IT system that could be used by members of the public to record the values they placed on the risks and benefits of different food-related hazards (this was called ‘a risk prioritisation tool kit’).

5.32 Dr Christopher Fisher (MAFF, Food Science), a key figure in this work, told the Inquiry that initially ‘the importance of taking outside views into account in policy-making was not yet fully understood’. There was soon an attempt to remedy this and to mend damaged fences by establishing a discussion forum, the Consumer Panel. This first met in April 1990 and brought together MAFF Ministers, key MAFF and DH officials, and representatives of consumer groups.

5.33 Considerable hopes rested on these initiatives, but their outcome was rather disappointing. The consultants’ report identified some doubts about MAFF’s effectiveness in communicating with the public on food safety issues, and a follow-up paper, *Towards a Risk Communication Strategy*, which was not circulated to MAFF officials for consultation until September 1994, met with a lukewarm reception, and ‘in the end there was no further action taken’. The ‘tool kit’ IT system for recording public views was developed and extensively tested both within and outside MAFF, but was considered to be too slow and not sufficiently cost-effective to justify further work. The Consumer Panel facilitated discussion, but as representative and campaigning organisations, the consumer groups could not be expected to convey messages on the Government’s behalf. Nor did they have any

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226 T32 p. 70
228 YB91/6.21/1.4
229 Paper by Dr C Fisher: *Risk assessment and management strategy – progress to date*, August 1991 (YB91/08.00/1.1–1.10), p. 6
230 S307 Fisher para. 19
231 Professor G M Breakwell and Dr C Purkhardt, Department of Psychology, University of Surrey, *Risk Perception and Communication Audit Final Report* (MS2 tab 10)
232 YB94/09.27/2.1–2.12
233 S307 Fisher para. 31
234 *The Toolkit for Managing Food Related Risks – Memorandum for the BSE Inquiry from MAFF*, 22 July 1999 (M66 tab 10)
means of communicating with the wider public beyond their own membership. At best, they could only enlarge at the meetings on current consumer concerns.

5.34 The evidence suggests that the food scientists’ efforts were regarded as interesting but academic by their administrative colleagues:

We have made considerable efforts to make others aware of the R&D work on risk management, as you know, but even where we have had high quality work it has been something of an uphill struggle to get others to take notice.235

Dialogue with consumers was accepted in principle, but was considered likely to be undermined by the media and by pressure groups with their own agendas.236 ‘The step from ‘a purely academic context’ to practical usefulness was difficult to take.’237

5.35 In the case of BSE, there were two main dialogues: between the MAFF administrators and the veterinarians, doctors and other scientists who advised them; and between the Government and the public. The media (the press, radio and television) played an important role, as they were the main means of communication with the public.

Risk analysis in the Department of Health

5.36 The ILGRA Report noted that DH used risk assessment when setting safety standards for medicines and foods, environmental hazards and medical equipment, and in addressing possible public health consequences. The approach was to examine end points such as mortality, morbidity, and societal costs, and to determine key areas for action on the basis of the scope for effective intervention and the possibility of setting objectives and targets. This was an equity-based approach, giving weight to the rights of the individual and the need to protect the weakest in society. Uncertainty was addressed by introducing safety factors (explained below) plus, where appropriate, the precautionary principle.238

5.37 DH also had methodologies for assessing exposure to certain hazards and its consequences. For example, an ADI or a TDI (see paragraph 5.13 above) could be obtained for a particular food chemical by dividing its NOAEL (paragraph 5.13) by a standard safety factor of 100 – a factor of 10 to account for uncertainties in extrapolating from animals to man, and a further factor of 10 to account for differences in susceptibility among the human population.239 Where an NOAEL was considered to be inappropriate, exposure was reduced until it was as low as reasonably practicable (ALARP).240

5.38 Other evidence makes more explicit DH’s caution about using quantitative methods in making microbiological risk assessments (MRAs). This was because:

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235 Minute of 3 February 1995 from Dr Fisher to Mr Dickinson (YB95/02.03/8.1–8.2)
236 Minute of 10 October 1994 from Mr Laweson to Dr Fisher (YB94/10.10/1.1)
237 S97B Dickinson B para. 57
238 The ILGRA Report (M66 tab 5), paras 78–80
239 Hazard assessment in the Department of Health: paper prepared by the Department of Health for ILGRA, March 1996 (M66 tab 6), Annex C, para. 3
240 The ILGRA Report (M66 tab 5) para. 81
i. for ethical reasons, effective dose response trials on humans (ie, trying out different levels of contamination and monitoring the reactions) were not possible;

ii. most epidemiological studies would not provide appropriate dose response data;

iii. the hazard associated with a pathogen and the extent of any consequential risk could vary between groups of people and according to physical conditions; and

iv. experimental results might not accurately reflect what happened under natural conditions because pathogens could vary significantly in response to different environments. 241

Risk assessment of medicines

5.39 Veterinary and human medicines were regulated by licensing their manufacture and sale. The statutory position is described in vol. 14: Responsibilities for Human and Animal Health and the licensing system is described in vol. 7: Medicines and Cosmetics.

5.40 A manufacturer’s licence was granted if the relevant premises were deemed to be suitable, the staff involved were considered competent, and the process was of an appropriate quality. Applications for product licences were assessed in terms of the safety, quality and efficacy of the product. Applicants had to submit supporting information about the ingredients, the process of manufacture and control, and how the product would be administered, and also the results of tests and clinical trials, together with pre-clinical and clinical data. 242

5.41 Veterinary medicines were licensed on behalf of the Minister of Agriculture, Fisheries and Food by the Veterinary Medicines Directorate (VMD), which became an Agency of MAFF in April 1990 (the development of such Agencies is described in Chapter 6). The required supporting information had to cover potential risks to human health from exposure to the medicines and potential risks to the environment. Applications were assessed by VMD officials advised by the Veterinary Products Committee (VPC), a committee of independent experts. Products had to be re-authorised every five years, by means of a Periodic Safety Update Report, which included details of all suspected adverse reactions.

5.42 Human medicines were licensed on behalf of the Secretary of State for Health by the Medicines Control Agency (MCA), 243 advised by the Committee on Safety of Medicines (CSM), the Committee on Dental and Surgical Materials (CDSM) and the Committee on Review of Medicines (CRM). The assessment process involved risk-to-benefit considerations, identifying potential hazards and taking account in particular of the nature of all constituents; the product’s therapeutic and side effects, dosage, pharmaceutical form, method and route of administration, and expected shelf life; and the data and results of all tests and clinical trials. The MCA was also responsible for monitoring and responding to adverse reactions.

241 ‘Microbiological Risk Assessment and Public Health’: a paper read to the October 1992 International Conference on Risk Assessment by Dr Roger Skinner of DH – conference proceedings (M66 tab 11)
242 DH01 tab 6 paras 14 and 15
243 Prior to its launch as an Agency in April 1989, this was the DH Medicines Division
5.43 The Medical Devices Agency (MDA)\textsuperscript{244} was involved in the development of European standards for risk analysis of medical devices and animal tissues used in them. One of its functions was to consider reports of incidents, involving medical devices, which had the potential to affect the safety of patients or users, and to investigate serious ones. On receiving such a report, risks to patients and users were assessed ‘with the aim of formalising these’ so that investigations would start only if they were ‘likely to improve device safety’.\textsuperscript{245} One of the Agency’s ‘Key Activities’ was to ‘scrutinise applications from manufacturers for clinical investigations to establish whether the risks to patients outweigh the possible benefits’, while among its ‘Operating Principles’ was that of ensuring ‘that levels of regulation are not excessive’.\textsuperscript{246}

\begin{footnotesize}
\textsuperscript{244} Prior to its launch as an Executive Agency in September 1994, this was the Medical Devices Directorate of DH, and before that the Supplies Technology Division of the DH NHS Procurement Directorate
\textsuperscript{245} MDA Annual Report and Accounts for 1994–95, p. 14
\textsuperscript{246} MDA Framework Document (M39 tab 22), pp. 5–6
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