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Precautionary Bans or Sacrificial Lambs?

Participative Risk Regulation and the Reform of the UK Food Safety Regime

Henry Rothstein

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Abstract

This paper explores contemporary trends towards participative risk regulation and considers the impacts of participative reform on policy processes and outcomes. Using the example of reform of the UK food safety regime, the paper examines whether participative reforms, in the form of stakeholder decision-making, are able to deliver their promised benefits and if not, why not. Empirically, the paper examines how UK's Food Standards Agency (FSA) used a stakeholder decision-making process to manage the potential risks from bovine spongiform encephalopathy (BSE) in sheep in 2002, and the initial rejection of those proposals by the European Commission. The paper finds that the potential benefits of the stakeholder process were mitigated by a number of institutional factors, including: considerable interpretative flexibility in how to represent consumer interests and the concept of precaution; restricted openness and exclusion of key stakeholders; and the impact of the supra-national regulatory context. The paper concludes that broadening participation per se does not necessarily produce more democratic or robust policy outcomes than closed processes, although it may have some limited value in improving public confidence in the regulatory regime.

Introduction

Broadening participation is undoubtedly the vogue prescription for many of today's regulatory ills. Widening participation in regulatory processes, so its proponents argue, can improve the quality of regulation and better serve the public interest by enhancing regulatory scrutiny, incorporating a wider set of views and interests, and improving public awareness of the issues (eg, see Dryzek 1990). Participative processes appear particularly attractive for risk regulation, because the traditional machinery of government too often appears ill-suited to cope with scientific uncertainties, conflicting demands for precautionary and resilient policy stances and implementation deficits. Indeed, in the wake of a number of risk regulation crises,

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both the UK government and the EU regard building greater transparency, consultation and independence into regulatory processes as important measures to restore public confidence in many failing domains of governance (eg, RCEP 1998; Cabinet Office 2002; EC 2002).

Whilst much hope is held out for broadening participation in risk regulation, less attention has been paid to the institutional operationalisation of participative processes and the consequent impact on regulatory outcomes. In practice, broadening participation can take many forms with consequently varying impacts on regulatory processes and outcomes. This paper, therefore, considers the factors that shape whether such reforms are able to deliver their promised benefits. In order to do so, the paper examines the factors that shape just one type of participative reform - that of stakeholder participation - and studies its consequences for policy processes and outcomes within the UK food safety domain.

At least three types of rationale can be identified for broadening participation in risk regulation (Perhac 1998; Owens 2000). Normative rationales hold that risk regulation is not a value-free enterprise and that, therefore, broadening participation within risk regulation is important for moral, democratic and enlightenment reasons (Munton 2003). Greater openness and participation, so it is argued, can help inform a wide range of social and ethical judgements throughout the regulatory process, confer democratic legitimacy to regulatory processes and outcomes, and strengthen general public knowledge about risk governance (eg, Shrader-Frechette 1991; Calman and Smith 2001).

Epistemic rationales, in contrast, hold that regulatory decision-makers are often hampered by uncertainties and information asymmetries, and that there is, therefore, a need to draw on sources of knowledge outside of traditional regulatory structures in order to reduce the chance of policy error (Majone 1989; Funtowitz and Ravetz 1996). Such compensating activities can take the form of consulting professional experts, interest groups or lay publics (eg, Irwin 1995; Irwin and Wynne, 1996).

Finally, instrumental rationales hold that broadening participation is a useful tool for ensuring the political viability of regulatory processes, particularly in the context of declining levels of trust in political institutions (Bloomfield et al 2001; Frewer and Salter 2002). Greater openness and participation is argued by many to increase public confidence in the legitimacy and integrity of risk regulation by offering opportunities to secure stakeholder buy-in, influence opinion-formers, and directly shape public opinion and behaviour.

Participative reforms, however, may promise more than they can deliver. First, the democratic and policy mandates of participative processes are often inversely related. As participation is widened to meet democratic goals, so such processes can become resource-intensive, unpredictable and hard to fit with the institutional and legal constraints of policy-making. Thus, participative reforms that come closest to meeting democratic ideals, for example, by directly involving the public in nationwide debates (eg, GM Public Debate 2003), tend to be the furthest away from actual policy-making. In contrast, reforms that have the closest links to policy-making, such as expanding the disciplinary composition of scientific advisory committees by including ethicists, tend to be the most timid in rectifying democratic deficits (eg, FSA 2002g). Models

that sit between these two extremes entail compromise trade-offs, such as stakeholder-style regulatory boards where public interest groups indirectly represent public interests within relatively well-structured policy processes.

Second, whilst some argue that widening participation can make for more robust policy, such processes can also present problems for decision-making. Such processes can be disproportionately resource-intensive. Extending participation can also be so time-consuming that society can miss out on potential benefits or be exposed to risks because of belated government action. As critics of US health and environmental policy in the 1980s have argued, greater transparency can fan, rather than extinguish, the flames of regulatory fire, by providing a platform for junk science, sowing public confusion and stimulating dysfunctional adversarialism in the policy process (eg, Jasanoff 1990). Moreover, outcomes of participative processes are likely to be highly dependent on who actually participates or is invited to participate, what they can add to often esoteric debates, and the way in which their contributions are structured within policy processes.

Finally, the institutional operationalisation of participative processes needs to be considered within the context of a regulatory regime as a whole. Reforms to national policy-making processes can be structurally limited if national processes are situated within EU regulatory frameworks. Even if national decisions are able to reflect broad constituencies of opinion, final decision-making at the supra-national level may reflect a different configuration of interests and pressures. Moreover, recent work on such complex regimes has shown how institutional responses to greater transparency can be heavily conditioned by blame-avoidance considerations and can have undesirable side-effects that mitigate the gains that openness brings (Hood et al 2001: Ch.9). Far from linear evolution from closed to open processes, regulatory institutions employ a repertoire of blame-shifting responses such as increased reliance on rule-driven decision-making, limited implementation of claimed reforms to preserve policy or institutional goals, or fudging accountability by diffusing responsibility, and hence blame, amongst multiple organisations.

Such arguments suggest that the implementation of participative reforms are unlikely to be straightforward and may have unanticipated consequences. There is, therefore, an empirical need to study participative processes in action, in order to examine whether such reforms can deliver their promised benefits, and if not, why not. By studying deviations between intention and practice, it may be possible to identify the critical factors that shape the implementation of participative reforms and their positive and negative impacts on regulatory processes and outcomes.

This paper examines one example of participative regulatory reform - that of the UK food safety regime, which was recently reformed with the creation of a stakeholder-style regulatory agency - the Food Standards Agency (FSA). The FSA has responded to a crisis of public confidence in food safety regulation by explicitly aligning itself with broadening participation in policy-making, and has established an appropriate set of guiding principles to help it fulfil its remit. Using those guiding principles as benchmarks by which to assess the stakeholder decision-making process and outcomes, the paper considers three questions. First, to what extent is decision-making in practice aligned with the FSA's own principles? Second, what factors can best explain divergences between principles and practice? And third, what impacts do

such factors have on the implementation of participative processes and regulatory outcomes?

Empirically, the paper presents a detailed analysis of a major regulatory problem that confronted the FSA in its early years - that of managing the potential risks from bovine spongiform encephalopathy (BSE) in sheep. The paper draws upon a range of documentary sources, attendance at FSA public meetings, and in-depth face-to-face and telephone interviews with state officials and scientific advisors at both the UK and EU level, and business and consumer representatives who have had to remain anonymous for confidentiality reasons.[2]

Reform of the UK Food Safety Regime

When the UK's Food Standards Agency (FSA) was established in 2000, it had a clear mandate to resolve the widely known problems that had plagued food safety regulation. In the preceding years, the previous regime had seemed unable or unwilling to deal with a litany of food safety problems, which culminated in the BSE crisis in the mid-1990s. There were at least three readily identifiable institutional problems with the old regime. First, the regime was marked by inherent conflicts of interest and regulatory capture, with the food safety responsibilities of the Ministry of Agriculture, Fisheries and Food (MAFF) dominated by its dual responsibility to promote food and agriculture business (eg, see Schofield and Shaoul 2000). Second, the regime was poorly linked-up. Horizontal relations between MAFF and its relatively weak policy partner - the Department of Health - were poor, whilst vertical relations between central government policy-making and local government enforcement were virtually non-existent - a problem that became a crucial component of the BSE story (Rothstein, 2003). And third, decision-making was opaque, giving little opportunity for external interests to expose regulatory capture, and which, together with regulatory failures, contributed to a decline in public confidence (eg, see Millstone and van Zwanenburg 2001).

The regime was reorganised and reformed in 2000, with the consolidation of food safety responsibilities in the FSA - established as a new, dedicated, non-departmental agency (Food Standards Act 1999). The creation of an agency, which reflected a common policy trend in many policy domains (Thatcher and Stone Sweet 2002), specifically addressed many of the problems that had afflicted the old regime. First, conflicts of interest were addressed by giving the FSA no formal role in food and agriculture business promotion and possibilities for direct political interference were restricted by enhancing the agency's independence by situating it at arms length from

[2] Research for this paper included attendance at numerous public meetings of the FSA Board, including the June 2002 Board meeting when the issue of BSE and sheep was discussed. Research also included in-depth face-to-face and telephone interviews with relevant FSA staff including the Deputy Chief Executive and acting Head of Food Safety Policy and an official responsible for BSE; selected members of the UK government's expert committee on BSE and related diseases - the Spongiform Encephalopathy Advisory Committee (SEAC); a member of the EU's Scientific Steering Committee; scientists contracted to provide scientific advice to the FSA on BSE and sheep; selected members of the FSA's stakeholder group on BSE and sheep including scientific, consumer and business representatives; and business representatives of the natural sausage casings industry. The FSA Deputy Chief Executive also provided a written response to an early draft of this paper. The FSA Board, however, declined requests for interviews.

government. Moreover, the agency was created as a stakeholder-style Board comprising up to 12 members to help prevent regulatory capture and provide a balance of skills and experience, such as in matters related to food safety and consumer interests. Second, institutional fragmentation was addressed by the consolidation of food safety standard-setting responsibilities within the FSA and by giving the agency extended monitoring powers over enforcement activities by local government and other agencies. And third, the transparency of the regime was enhanced to combat concealment of bias, improve decision-making and enhance public confidence.

The FSA was established with an accompanying set of policy targets, guidelines and ways of working to help the agency succeed where the previous regime had failed (FSA 2000a). In particular, the FSA's three guiding principles of 'putting consumers first', 'being open and accessible' and 'being an independent voice' provided a set of benchmarks to help the FSA improve the quality and effectiveness of food safety regulation (FSA 2000a).[3] The FSA has not been alone in setting such benchmarks. France's food safety agency, AFSSA, stresses the importance of 'excellence', 'transparency' and 'independence', and the EU's European Food Safety Authority (EFSA) emphasises the principles of 'excellence', 'integrity' and 'openness' (Byrne 2002). As core philosophies for new policy institutions, such guiding principles appear laudable. Like 'motherhood and apple pie', however, such principles are easy to sign up to, but harder to implement (cf. Hood et al 2000).

The FSA has undoubtedly gone to considerable lengths to reflect its guiding principles in policy-making. The agency, for example, has sponsored a consensus conference on genetically modified (GM) food, carries out extensive consultation with consumer groups and has set up a dedicated consumer committee. The FSA Board holds its meetings in public, publishes a considerable amount of material on which it bases its decisions, and has the right to publish its advice to Ministers. Indeed, the FSA has even proselytised its approach elsewhere, for example, by holding one of its monthly open Board meetings in Brussels in November 2002.

Many of these reforms have found a favourable response amongst the FSA's key constituents. For example, a recent report by the National Consumer Council was supportive of the FSA's consultation programmes (NCC 2002), food retailers are encouraged to see the FSA's focus on the food chain rather than just farmers, and recent survey work by the FSA found that overall consumer confidence in the agency had risen from 50 per cent in 2000 to 58 per cent in 2001 (FSA 2002a: 110). Such general support has been critically important to the FSA during its first few years of operation. As other commentators have argued, new agencies need support of critical constituencies to help them stay true to their central missions and confront the problems that proved fatal to previous regulatory arrangements (Sabatier 1975).

[3] In addition to its three guiding principles, the FSA set out six key priorities: '1) Reduce food borne illness by 20% by improving food safety right through the food chain; 2) Help people to improve their dietary health; 3) Promote honest and informative labelling to help consumers; 4) Promote best practice within the food industry; 5) Improve the enforcement of food law; 6) Earn people's trust by what we do and how we do it.' In addition, the FSA has set out five Working Practices: '1) Be accountable; 2) Be open and consultative; 3) Be consistent and proportionate; 4) Adopt best practice; 5) Apply the UK Cabinet Office principles of better regulation (which themselves include principles of Transparency; Accountability; Proportionality; Consistency; Targeting)' (FSA, 2000a).

When the FSA turned its attention to the issue of BSE in sheep in late 2001, however, its methods and decisions became the subject of some debate. In particular, its recommendation for a precautionary ban on natural sausage casings made from sheep intestines was controversially received. The FSA claimed that its recommendation had been appropriately arrived at and best reflected the public interest. That view was not universally accepted and, indeed, the recommendation was initially rebuffed by the European Commission. As one of the first conflicts to have arisen in the FSA's early life, BSE and sheep provides an important test case to assess the impact of participative reforms within the food safety domain and the impact of such reforms more generally on policy processes and outcomes.

The Natural Sausage Casings Ban

It is not currently known whether BSE is in the British sheep flock. No cases have yet been found. It is known, however, that sheep can be orally infected with BSE and that some sheep consumed the same feed that infected cattle during the 1980s. If BSE did get into the flock in the 1980s, it could have been passed through subsequent generations. Moreover, if BSE is present, then any infectivity is likely to be distributed throughout the carcass, presenting potentially serious public health risks, especially from older sheep (FSA 2002c: 3). In addition, physiological similarities between goats and sheep, suggest that goat herds may also be at risk.

The problem is that BSE is very difficult to distinguish from scrapie - a similar disease that is endemic in British and many other national flocks (FSA 2002c: 4). A recent government-funded sheep brain pool experiment to see if sheep had BSE, was abandoned after the discovery that samples had been contaminated by cattle brains (BBSRC 2001). Until such an experiment is completed, it will not be possible to know whether the sheep flock is free of BSE or if scrapie is masking BSE infection.

There are considerable uncertainties about the potential distribution of BSE infection in sheep meat and products. The FSA claims that current EU controls on sheep spleen, skull, spinal cord and tonsils, reduce potential infectivity by a third (FSA 2002d). The FSA, however, decided to review its controls in late 2001 through a participative process. In December 2001, the agency held an open stakeholder meeting on BSE and sheep, which was attended by over a hundred stakeholders. A smaller stakeholder group was then established to discuss the issue in greater depth in a series of three meetings.

The stakeholder group considered that the current risk reduction measures were inadequate and looked for ways in which the potential risks could be further reduced. In 2001, the French food safety agency, AFSSA, had found that processing intestines from scrapie–affected sheep into sausage casings could leave some residual infectivity and had recommended a ban on intestine. That recommendation was 'effectively kicked into touch' by the French food and farming lobbies and political sensitivities to French culinary traditions, as one European expert put it. There was, therefore, some reason to examine risks from natural casings.

The problem was that there was no quantitative information on how much processing reduced infectivity. The group was presented with two conflicting risk assessments. The FSA suggested that the first study by a team from Imperial College, which assumed a 10-fold reduction in infectivity during processing intestines into casings, showed that the use of intestines could contribute up to a third of the total exposure to potential BSE risks (FSA 2002c: ¶45; Ferguson et al 2002). The second study, by a scientific consultancy - DNV Consulting - took greater account of processing practices and estimated a 100-fold reduction in infectivity during processing intestines (DNV, 2001). DNV concluded that approximately 9 per cent of total potential exposure to humans would come from intestines used in natural casings for sausages, whilst more than 80 per cent would come from lymph nodes that are found throughout the carcass (DNV 2001: 24).

Confronted by these conflicting risk assessments, the group assumed the worst-case scenario for natural casings and recommended a precautionary ban on the use of intestines (FSA 2002c: R11). That recommendation went out to consultation and was then considered by the FSA Board during a public meeting in Northern Ireland in June 2002. The Board acknowledged the considerable scientific uncertainties, but agreed to recommend a precautionary ban within the European regulatory framework (FSA 2002e; ¶10).

The recommendation was forwarded to the European Commission's Scientific Steering Committee (SSC), which was holding a key meeting on BSE in sheep that month (Stewart 2003). The SSC is, in principle, a risk assessment rather than risk management body, but like many of the agencies discussed in this paper, the SSC similarly stresses the three principles of 'excellence', 'independence' and 'transparency'. 'Transparency' for the SSC, however, refers only to the publication of its opinions - SSC meetings are held *in camera*, in contrast to many of the scientific committees that advise the FSA (SSC 2000). The SSC reviewed the studies considered by the FSA, but also additional work sponsored by the natural sausage casings manufacturers, which suggested that processing practice could reduce the risk from casings up to a further order of magnitude lower than the DNV estimate (DNV Consulting 2002; Koolmees et al 2002). The SSC acknowledged the widely varying risk assessments for processing intestines, but contrary to the FSA position, chose to follow the studies that implied minimal risk from casings compared to other cuts of meat (SSC 2002a). Moreover, in an accompanying press release, the SSC made the risk management recommendation that no more action should be taken until what is a theoretically possible risk becomes a probable risk (SSC 2002b). After initially rebuffing the FSA, the Commission subsequently proposed a ban on the use of sheep ileum (or more technically, designated it Specified Risk Material), a particularly potentially infective part of the small intestine (Stewart 2003). At the time of writing, the ban was expected to come into force in late 2003. The ban went some way to meet the FSA's concerns, but fell short of a total ban on the use of sheep intestine.

The story so far could be argued to highlight the impact that reform can have on policy outcomes. From one point of view, it would appear that FSA's open and consultative process produced a more precautionary outcome than the more opaque European regime. It could be hypothesised that under the spotlight of public opinion, the FSA was more likely to take tough action than the EC's SSC, whose *in camera* decision-making, protected it from public pressures for precautionary action and

facilitated an organisational sleight of hand that enabled it to accompany the risk assessment with a strong risk management signal. When we benchmark the FSA's decision-making process and final recommendation against the agency's guiding principles, however, we find that the decision was less straightforward than presented.

Putting Guiding Principles to the Test

How does the FSA's natural casings decision fare when marked against the FSA's own guiding principles of putting consumers first, transparency and independence? Detailed analysis reveals a number of divergences between principles and practice and suggests a number of institutional factors that can shape the operationalisation of participative reforms and mitigate their potential benefits.

a) Putting Consumers First

It is not entirely clear what the FSA means by the principle of 'putting consumers first'. Putting consumers first might be conventionally interpreted as giving greater priority to consumer interests than business interests. Indeed, the FSA states in publicity material that, 'If there is uncertainty, we shall take a precautionary approach' (FSA 2001: 23). Precautionary action, however, has to be balanced against proportionality, which, in law, requires the maintenance of 'a proper balance' between the purposes of administrative action and the adverse effects of that action.[4] The FSA, however, does not elaborate on how to apply the principle of proportionality where the uncertainties of precautionary action make the calculations of costs and benefits difficult. Nor does the FSA explicitly make clear where the public interest lies in balancing paternalistic protection against choice - a contentious issue that arose when the UK government banned beef-on-the bone in 1997 (Hood et al 2001: 101). Moreover, the FSA's official Service Delivery Agreement, casts maintaining a strong consumer focus as improving consumer confidence in the food safety and standards arrangements, which is a more populist conception of serving the public interest (FSA 2000b). So in what way does the casings decision reflect 'putting consumers first'?

Public opinion is undoubtedly sensitive to BSE risks. According to the FSA's own research, BSE concerns affects 70 per cent of the UK public's eating habits (FSA 2002a: 61). Slack controls on BSE contributed to the final downfall of MAFF at the end of the 1990s and indeed the Conservative government in 1997. That point was emphasised by the Deputy Chair of the FSA Board during the public meeting in June 2002, who argued that a precautionary ban would be supported by both the public and scientists and that Board Members should remember the failing BSE years by which the FSA would be judged. Moreover, BSE and sheep gained a particular salience in 2001 following the release by the Department for Environment, Food and Rural Affairs (DEFRA) of a doomsday contingency plan for a mass cull when early indications from its flawed sheep brain pool experiment suggested that the flock was

[4] The principle of proportionality is enshrined in EU law and its application can be tested against three principles: balance, necessity and suitability (de Smith, Woolf and Jowell 1995: 593-8) The principle is also promulgated as a principle of good regulation by the UK Cabinet Office's Better Regulation Unit (BRTF 1998).

infected. According to some regulatory actors, BSE has such a political sensitivity that 'doing nothing was not an option' (eg, FSA 2002c: Annex 2, ¶9).

The question, however, was do what? Market failure analysis of the sheep problem suggests that the FSA could have recommended labelling and a public information campaign as the primary risk control measure rather than a ban.[5] Promoting 'honest and informative labelling' is one of the FSA's Key Priorities and the more general provision of information to consumers is regularly presented as a core philosophy of the agency (FSA 2000a; FSA 2001: 5). In line with that philosophy, the FSA issued general advice that consumers could significantly reduce their theoretical risk by avoiding mutton and sausages with natural casings, recommended voluntary country-of-origin labelling of baby food containing sheepmeat, and issued particular advice to Muslim and Afro-Caribbean groups where older (and hence more risky) goat and sheep play a particular dietary role (FSA 2002f; 2003a). The FSA, however, did not recommend other possible labelling measures, such as attaching health warnings to food labels or generalised country-of-origin labelling.[6] Importantly, despite the likely widespread distribution of infectivity throughout sheep carcasses if sheep are infected, the FSA explicitly stated that it did not advise against the consumption of sheepmeat (FSA 2002f).

So was the casings recommendation precautionary? The stakeholder group and FSA Board concluded that the most precautionary approach for sausage casings would be to follow the Imperial College study, which was interpreted to suggest that banning natural casings could reduce the theoretical risk to consumers by as much as a third. If, however, it was assumed that that there was a significant reduction in infectivity by processing intestines into casings, as assumed by the DNV study, then the greatest risk to consumers would not be from natural casings but from infective material such as lymph nodes that are endemically present in sheepmeat. On that basis, DNV calculated that potential infectivity in a leg of lamb could be five times greater than in a 250g meal of sausages (FSA 2002c: Annex 2). In that case, the most precautionary measure would be to ban normal carcass meat such as in joints and chops, not sausage casings.

Curiously, the Spongiform Encephalopathy Advisory Committee (SEAC), the UK scientific expert committee charged with advising government on BSE risks, was not asked to give a formal opinion on the relative risks of sheep meat and products. This is perhaps surprising given that a central recommendation of the Phillips Inquiry into

[5] Market failure analysis considers the need for the state to correct for potential failures in market or tort-law processes (Hood et al 2001: Ch. 5). From that perspective, regulatory intervention would be expected where the costs of individuals informing themselves about risks and/or opting out of risks through market or civil law processes are high. Avoidance of potential BSE risks from sheep could be argued to entail low opt-out costs because of the substitutability of sheepmeat with other meat (notwithstanding the lifestyle and cultural value of sheepmeat). Information costs could also be argued to be relatively low if all sheep meat and products were labelled with health warnings. Currently, all lamb and mutton is labelled as such if sold pre-packed or loose, but there is no requirement for caterers to label sausage skins or declare whether meat is lamb or mutton, nor are there any requirements for meat or product labels to include risk assessments or health warnings.

[6] Notwithstanding the baby-food recommendation, country-of-origin labelling is particularly problematic in the absence of good information about the relative global incidence of scrapie and past feeding practice, and might even enhance risks if labelling lamb as British led to patriotic purchasing behaviour.

BSE was to improve the use of expert committees and the FSA has itself published a set of best practice recommendations on using expert scientific advice (Phillips et al, 2000; FSA 2002g). Instead, scientific advice was provided by SEAC's chairman who sat on the stakeholder group, whilst members of SEAC were consulted afterwards as part of the public consultation on the stakeholder report. Whilst the FSA recommendation was publicly supported by at least one SEAC member (FSA 2002c: Annex 2), other SEAC members interviewed for this research gave more equivocal views, including one who would not have supported the FSA's interpretation of evidence. There was, therefore, no clear scientific view amongst the government's official advisors.

Given the equivocal scientific evidence, why then single out natural sausage casings? For some clues, we have to consider commercial factors. According to the FSA, a ban on meat from mature sheep could cost £115m in lost sales (FSA 2002c: 11) and could decimate the UK sheep industry - already crippled by low livestock prices and the previous year's foot-and-mouth epidemic. Removing lymph nodes and other infective material would require high surgical precision - making such a proposition unviable. But according to the FSA, a ban on natural sausage casings would affect only 15 per cent of the UK sausage market and would cost only £6.5m in lost casings sales. Moreover, whilst sheep farmers were uneasy about the ban they did not reject the proposal outright (FSA 2002c: Annex 2, ¶12). From the FSA's viewpoint, therefore, not only was the recommendation precautionary but also it was easy to implement and proportionate.

Others, however, disagreed with the FSA's analysis. The natural casings industry, for example, claimed that it followed a voluntary Code of Practice for processing, which, in line with the DNV estimate, significantly reduced potential infectivity compared to carcass meat. Indeed, best practice recommendations of the UK, European, North American and International Natural Sausage Casings Associations already resulted in the routine removal of the ileum before manufacture - prefiguring the later Commission proposal (Bradley 2002: 7). Industry also argued that the FSA had discounted costs that were germane to the regulatory impact assessment.[7] Industry, therefore, argued that the proposed ban was neither precautionary nor proportionate when judged against the weaker actions proposed by the FSA for other cuts of potentially riskier and more widely consumed sheepmeat.

From that point of view, the EC's SSC opinion appeared to be more consistent than the FSA's. The SSC concluded that there was currently no reason to single out sausage casings, but that if the presence of BSE in sheep became probable then the whole approach to sheep should be revised (SSC 2002b). In other words, if BSE was in sheep, then a ban on sausage casings would do little to protect the public when compared against the much greater risk and more widespread consumption of carcass meat. As a senior BSE scientist and ex-member of SEAC put it, 'If you want to reduce the risk by 50 per cent, it would be more consistent to cut every sheep in half and throw half away'. Given the equivocal scientific evidence, it could be argued that

[7] The FSA had discounted the £60m UK market for filled sausages with natural casings on the grounds that alternative casings could be used, and did not factor in the much greater European market, on the grounds that such concerns should be raised at the European level. According to casings manufacturers, the European market is worth £200m in casings sales and much more for sausages - Germans, for example, eat 11 million sausages with natural casings each day.

far from being a precautionary ban, sausage casings were picked on because the FSA needed to be seen to be doing something, they were easy to deal with and had only a limited impact on the UK sheep farming industry. From that viewpoint, the casings recommendation was not so much a precautionary ban, but rather more a sacrificial lamb.

b) Being Open and Accessible

In order to understand better how the FSA reached its recommendation, we need to examine the adherence of the FSA to its second guiding principle of openness and accessibility. As already observed, transparent practice is commonly promoted to enhance the legitimacy of government and guard against hidden bias. Indeed, the FSA itself claims that its aim is to ensure that any 'organisation and individual can make informed judgements' about the way FSA works and 'to ensure that we listen properly and establish productive dialogues' (FSA 2000a: 5). Such arguments underpin the concept of 'due process', which requires affected parties' interests to be respected (Baldwin 1995: 111). Close examination of the policy process, however, suggests some difficulty in operationalising such principles effectively.

First, although many stakeholders, including the casings manufacturers, attended the open stakeholder meeting in December 2001, the meeting was dominated by a discussion of the failed sheep brain pool experiment. Whilst the Chairman of SEAC identified removal of intestines as one potential risk reduction measure amongst several, the casings manufacturers claim that they were not given the impression that casings would be singled out for a specific ban. That conflict of views suggests that agencies and stakeholders may not equally see such forums as effective means for information dissemination.

Second, the core stakeholder group that was subsequently established was overwhelmed with FSA and other state-related personnel or advisors - some of them very senior (FSA 2002c: Annex 1 [Annexe E]). Out of twelve members, there were five FSA representatives including the Chief Executive, Board Chairman and Deputy Chair, two scientists that sit on government advisory committees, a representative of the Meat and Livestock Commission (MLC) - a non-departmental public body, a representative from the Welsh Assembly Government, a farmers representative and two consumer representatives. There were also twelve observers from the FSA and other government departments and two lay observers from the Human BSE Foundation. The group did not include key stakeholders, such as retailers, the abattoir industry or the natural sausage casings industry. The FSA claim that the casings industry had adequate opportunity to feed into the process through the farming and meat industry representatives, although the casings industry claim that they were not consulted. Whoever is correct, it seems clear that there was ambiguity over the role of stakeholders. One consumer representative, for example, saw her role as putting the consumer view whilst another non-FSA stakeholder group member explained that he sat on the group in a personal capacity rather than representing sectional interests.

Third, at least one non-FSA member of the stakeholder group found that the risk assessments and cost calculations were difficult to follow and had to take much on trust from expert members. Moreover, as risk estimates could only be presented very approximately within five categories from 'very low' to 'very high', it was not

possible to perform calculations that could help substantiate the proportionate nature of the various policy options. Indeed, many of the non-FSA group members interviewed for this research had some difficulty in elaborating what was meant by the concepts of precaution and, particularly, proportionality - points that were also highlighted in a study of the stakeholder process commissioned by the FSA (Rubery 2002: ¶51-2). For example, one senior member told the author during research for this paper, 'I don't understand what proportionate means', whilst another presented the concept of a proportionate decision as an 'appropriate' decision and referred the author to the FSA Chairman for clarification of 'appropriate'. This is not necessarily surprising as definitions of both precaution and proportionality vary, are difficult to apply and give considerable scope for discretion in their application (eg, de Smith, Woolf and Jowell 1995: 593ff; EC 2000). But what is perhaps surprising, is that there appeared to be little clarification of the use of these concepts during the stakeholder consultation process.

Fourth, the stakeholder report was issued just two weeks before the Board met to consider the issue: ten weeks short of the minimum 12-week period recommended as best practice (Cabinet Office 2000: 7). The FSA argued that the shortened consultation process was allowable under Cabinet Office guidelines because the EC's SSC were to consider BSE in sheep in June 2002 and there was a public interest argument in addressing the issue promptly (Stewart 2003). As a consequence, the natural casings manufacturers had only minimal time to respond to the recommendations. Moreover, FSA Board Members were given only a limited time to prepare for the Board meeting, receiving some crucial papers - in particular, the casings manufacturers' hurried response - only a day or two in advance of the meeting. There were, therefore, some tensions between the needs for prompt action and robust decision-making.

Finally, there was only limited time for discussion of the substantive issue during the Board meeting - under half an hour. Some Members expressed a degree of unease about the recommendation querying, for example, how much was understood about casings processing or the inconsistency of doing nothing about the lymph node route of exposure. Given the limited time that Board Members had to digest the response of the casings industry to the stakeholder report, however, it would have been difficult for Members to have expressed dissent given that the proposal was portrayed as an important public health measure. There was a strong steer towards a consensus view and the recommendation was passed. As the next section suggests, however, that strong steer was also consistent with in-built pressures within the Board on this particular topic.

The FSA robustly defended its stance arguing that the process had allowed for the inclusion of views from other groups with farming and meat interests (FSA 2002e). It could be argued, however, that openness and accessibility was institutionally limited and the consultation process tightly structured key inputs. In particular, key stakeholder representation was excluded from the consultation process and that was reflected in the final decision of the FSA Board. In contrast, when the SSC later reviewed the issue, it took greater account of processing practice and concluded that there was no reason to single out natural sausage casings. In general, therefore, the divergence observed between the rhetoric of consultation and consultation in action,

suggests that, as always, the devil is in the detail, with consultation per se being an insufficient guarantee of adequate interest representation within policy processes.

c) Being Independent

The FSA's third and final guiding principle is that of 'independence'. Independence is a key principle for legitimating decision-making and is of particular salience in the food safety domain, given past associations with business and farming capture. The FSA claims that its wide powers to publish information and advice guarantees its independence as an open, consultative, evidence-based policy institution (FSA 2001: 25). Moreover, the FSA robustly defended its casings recommendation against critics, by reaffirming that the agency was designed to 'insulate decisions on food issues from "special pleading"'(FSA 2002e).

Independence, like the FSA's other two principles, however, is a difficult concept to operationalise. For example, information asymmetries within risk regulation processes often create situations where expert advice to government is compromised by potential conflicts of interest, such as connections between scientific advisors and businesses that have a direct stake in regulatory outcomes (eg, Rothstein et al 1999). The casings decision illustrates a number of ways in which putting the principle of independence into practice has been problematic for the UK food safety regime.

First, there were potential conflicts of interest of senior Board Members – the stakeholder group was chaired by the FSA Board Chairman and the Deputy Chairman was also a stakeholder group member. During the Board meeting, the Chairman attempted to chair the meeting impartially by asking the FSA Chief Executive to present the position of the stakeholder group, of which he had also been a member (Stewart 2003). Nevertheless, that such senior figures were members of the stakeholder group presented a potential embarrassment if the Board had chosen to reject the groups' recommendations (see also Rubery 2002, ¶84-6; FSA 2002c; Annex 2, ¶20, 29). Moreover, the inclusion of the chair of SEAC in the stakeholder group created further potential conflicts of interest for SEAC, which, after the BSE debacle in the 1990s, had been at some pains to establish itself as an advisory body on risk assessment rather than risk management.

Second, the EU legal framework for food safety regulation restricts the ability of the FSA to act independently. Much of the FSA's work is closely tied into EU policy processes and so unilateral regulatory action could bring the FSA into political or legal conflict with the Commission and other member states. The FSA did manage to obtain a EU-wide ban on the use of the ileum, which might have some risk reduction value if current best practice recommendations are not followed by the casings industry or the ileum is used in other products. Certainly, lack of enforcement of BSE rules played an important part in the early years of the BSE story (Philips et al 2000; Rothstein 2003). Unlike the problems plaguing the removal of spinal cord from cows in the early 1990s, however, removal of the ileum is simple and there was no specific evidence to suggest non-compliance (Bradley 2002: 7; FSA 2003b). The risk reduction value of putting current voluntary practice of a broadly compliant industry on a statutory footing, therefore, remains to be estimated.

Finally, and relatedly, independence can be accompanied by the diffusion of political accountability. Whilst the FSA is set at arms length from government to give it some measure of independence, it also provides an effective blame conduit for government when dealing with difficult issues. Indeed, forwarding the Board recommendation direct to the Commission not only took UK ministers out of an uncomfortable loop, but also lessened the burden of accountability on the FSA by forcing the casings manufacturers to take their case to Europe. Indeed, one FSA Board Member explicitly claimed during the June public meeting that interested parties had ample time to make representations, since the Board were only making a recommendation to the EU. Independence, in this case, came with its own heavy dose of blame-shifting.

Assessing Reform of the Food Safety Regime

The plethora of guiding principles that have accompanied the launch of the new food safety agencies provide useful measures by which to assess institutional reform of these regimes. In the particular case of the FSA, study of the implementation of such principles also provides more general insights into the operation of stakeholder participation in regulatory decision-making. Of course, one case study can only provide limited insights into the workings of a regime which encompasses a wide range of issues and sectors with markedly different patterns of interest group pressures, public attitudes and policy histories. No evidence is offered in this paper as to how much can be read over into other food safety areas or other policy domains. Further case study work is required to assess how widely this paper's findings can be generalised. The casings controversy, however, does provide some insights into the institutional factors shaping decision-making within the reformed UK food safety regime, and within participative regulation more generally.

Assessing regulatory performance is not easy, particularly in areas of considerable scientific uncertainty where there are no obviously 'right answers'. The FSA has received considerable praise for its efforts in changing the way that food safety regulation is done in the UK. Nevertheless, analysis of the casings controversy suggests that a number of institutional factors have prevented the agency from fully fulfilling its remit in relation to each of its three guiding principles.

First, that the FSA 'did something' at all might itself suggest the agency has adopted a more precautionary orientation than the previous regime. The theoretical risk of BSE in sheep has been known about since at least the mid-1990s, yet it took the FSA to finally bring the issue to the forefront of the regulatory agenda. Precaution, however, is a famously difficult concept to operationalise, entailing multiple and difficult judgements about managing scientific and social conflicts, timing of action, and attribution of responsibilities to different regulatory actors (Calman and Smith 2001). Indeed, whilst precautionary action is often advocated in situations of scientific uncertainty, it is often difficult to judge the precautionary nature of proposed action precisely because of the presence of scientific uncertainty. The sheep and BSE case was one such classic case, in which alternative and conflicting policy options could be equally represented as precautionary and proportionate, depending on the framing of risk management questions and choice of evidence (cf. Jasanoff 1990).

In the absence of definitive evidence on the potential risks from sausage casings, it is hard to assess whether the FSA's recommendation represented consumer interests more or less than the SSC's since the two recommendations followed different risk assessments. Even if the agency was right to believe that natural casings could contribute to a substantial proportion of the theoretical risk, however, the recommended ban still appears inconsistent with the FSA's refusal to advise against the consumption of sheepmeat. That inconsistency increases if further scientific evidence suggesting lower risk from casings is taken into account. Such inconsistency casts doubt on whether, taken together, the recommendations on sheepmeat and products, including casings, were indeed precautionary and proportionate.

From that point of view, there is a strong argument that the FSA is operationalising the principle of 'putting consumers first' as a populist concept. The belief that the recommended ban would not produce a public backlash of the type that accompanied the 1997 beef-on-the-bone ban because of the smaller sausage market may have encouraged the agency to be seen to be doing something, whilst limiting the business risks to the UK sheep industry. The limited negative publicity in the media may have confirmed that view, although the agency received a rougher ride from more specialist critics (eg, Uhlig 2002; FSA 2002c: Annex 2, ¶8). The FSA regarded the eventual Commission proposal to ban the use of the ileum as 'quite significant' (Stewart 2003), but the potentially limited risk reduction value of the measure was suggestive of more populist concerns. That the FSA took this approach is not necessarily surprising. The agency was only a little over two years old when it took the decision, so it could be speculated that the agency needed an 'early win' to help establish itself as the consumer's champion, particularly on such a sensitive topic.

Second, the case suggests that the impact of greater openness and consultation is shaped by a number of institutional factors. From a pragmatic viewpoint, stakeholder consultation is not easy and always requires trade-offs between the plurality of potential inputs from stakeholders and the needs of the policy process for closure (eg, see Rubery 2002). Moreover, decisions characterised by high uncertainty are always likely to be contentious. Undoubtedly, formal openness and consultation has increased under the FSA. For example, the 1997 decision to ban beef-on-the-bone was taken entirely behind closed indoors. Indeed, the reconstruction of decision-making in this paper was partly reliant on the FSA's open procedures, such as the open Board Meetings. In that sense, the FSA goes some way to meeting its criterion that external observers can understand how the agency reaches its decisions.

Nevertheless, the differential inclusion and exclusion of key stakeholders appears to have had significant consequences for policy outcomes and policy credibility. Thus, the participative nature of the policy process was limited by not formally consulting SEAC - the government's expert committee on BSE; by excluding the natural sausage casings manufacturers from the stakeholder group; and, by limiting the consultation period to two weeks. Moreover, the case shows how the impacts of stakeholder consultation are highly dependent on the handling of information asymmetries, such as ensuring that stakeholders are given adequate and comprehensible information; that there is adequate time for deliberation of potential policy options; and, the ability of public interest representatives to determine how the public interests are best served when faced with complex and uncertain evidence. The case, therefore, provides only equivocal evidence to support the contention that broadening participation results in

more sustainable and robust decision-making. In the form that openness and consultation were operationalised, the extended peer review and greater policy inputs envisaged by some commentators simply failed to materialise.

Third, the case suggests that there are a number of ways in which the independence of an agency can be mitigated. Within more open and participative settings, there are trade-offs to be made between managing risks to the public and managing the institutional and personal risks of stakeholder representatives and regulatory officials. Thus, the cross-membership of FSA Board members with the stakeholder group created credibility risks if the Board rejected the recommendations of the stakeholder group.

Independence also needs to be considered within the wide regulatory context. The independence of national regimes that sit within supra-national settings is likely to be constrained by external pressures. Moreover, complex regimes provide considerable opportunities for blame-shifting responses that reduce the accountability of any one institutional actor for decision-making (see Hood et al 2001: ch.9). In general, the casings decision shows the difficulty of locating regulatory accountability, so that aggrieved parties can pursue remedial action. Those who wanted to contest the FSA decision had to go to Europe, and even the FSA, itself, was faced with a problem in contesting the European decision when the SSC extended its remit beyond risk assessment to send out a strong risk management signal.

Conclusions

The range of participative decision-making models adopted across policy domains suggests that there is considerable interpretative flexibility in notions of participative regulation (eg, see Spash 2001; Munton 2003). Study of just one particular model - in this case, elite stakeholder forums - can only provide limited insights into participative risk regulation more generally. Nevertheless, analysis of how the FSA dealt with the issue of BSE in sheep demonstrates the difficulty of implementing participative reforms and the factors that shape their impact on policy outcomes. In particular, the case reveals gaps between the conventional rationales for broadening participation and what such reforms can achieve in practice. Whilst broadening participation can go some way to meet normative, epistemic and instrumental rationales, as outlined at the beginning of the paper, there are a number of institutional factors that shape the operationalisation, and mitigate the benefits, of such reforms.

First, the paper suggests that achieving the normative goal of democratising risk regulation by expanding participation and rebalancing interest group representation within policy processes can be problematic. Broadening participation per se, is an insufficient criterion for rebalancing interest representation within policy processes. Instead, such rebalancing critically depends on the breadth of sectional interests represented, the capacity of stakeholder representatives to determine how their sectional interests are best served when faced with complex and uncertain evidence, and the institutional processes for factoring stakeholder views into the policy-making. In particular, information and power imbalances between stakeholders, means that participants with superior knowledge and resources, such as representatives of

regulatory agencies or dominant business groups, are well positioned to dominate the framing of issues and shaping of conclusions.

Developing and implementing principles of good regulation are also insufficient to ensure that normative goals are met (cf. Hood et al 2000). A simple scan of the range of principles enumerated by just a few food safety bodies suggests that there are no final agreed criteria for good food safety regulation. Moreover, adherence to principles can be difficult, for example if the contingencies of the regulatory problem means foregoing extended consultation, or because of inherent potential conflicts between principles. Most importantly, regulatory decisions are rarely straightforward choices between 'consumer' and 'other' interests. Regulatory decision-making often entails complex trade-offs between different interests such as consumer choice and consumer health, conflicting business interests, and the interests of regulatory professionals themselves. In many regulatory cases, therefore, consumer interests can be served in different ways and to different degrees, so that simple adherence to a predefined list of principles is insufficient guarantee that policy outcomes will be socially optimal.

Moreover, the impact of participative reforms can also be limited by the legal and institutional context of decision-making, particularly within complex regimes, where reforms to just one regime component may have limited impact on the overall regime. For example, conclusions reached within participative forums may have to be tempered by considerations of proportionality, policy processes may be constrained by supra-national contexts, or ultimate decision-making may not rest with those participative forums, but elsewhere such as within closed EU processes. In such cases, greater openness in decision-making can be accompanied by the dispersion of regulatory accountability within the regime thus mitigating the democratic gains of those reforms (cf. see Hood et al 2001: Ch.9).

Second, the paper provides little evidence to support an epistemic rationale for broadening participation, in so far as openness per se does not necessarily produce more robust policy outcomes than closed processes (cf. Pidgeon 1996). Instead, the case study suggests that the impact of broadening participation on policy robustness is highly dependent on which groups and individuals are consulted; the information made available to those participants; and, the ability of participants to handle what is often complex and uncertain information.

Taking policy decisions under uncertainty is undoubtedly a difficult task. The case suggests, however, that greater attention needs to be paid to policy decisions that are represented as precautionary and synonymous with serving consumer interests. In situations of scientific uncertainty, conflicting policy options can be equally constructed as precautionary and proportionate depending on the framing of risk management questions and the choice of evidence. This finding suggests considerable interpretative flexibility in the concept of precaution and presents an important challenge to the adoption of the precautionary principle within risk regulation (cf. CEC 2000).

Third, the paper provides limited evidence to support the contention that broadening participation can improve the legitimacy of regulatory decision-making and enhance public confidence in the policy process. Regulatory decision-making is difficult and

there is no reason to suppose that broadening participation will solve all the attendant problems: there will always be winners and losers however robust the regulatory decision. Broadening participation, however, offers a way of securing buy-in of key constituencies and opinion-formers, such as consumer groups, to avoid public controversy. Thus, whilst the FSA has received a rough ride from some specialist critics over the issue of BSE in sheep, survey evidence suggests that it is meeting its key priority of improving public confidence in the food safety regime (FSA 2000a). The evidence gathered in this paper, therefore, suggests that representations of policy processes and decisions as open, independent and consumer-focused may have rhetorical purchase, but meeting such objectives in practice can be more difficult.

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