



**THE FOOD STANDARDS AGENCY'S APPROACH TO
REGULATORY DECISION-MAKING**

POLICY STATEMENT FOR CONSULTATION

March 2005

A. The objectives and principles of regulatory decision-making in the FSA

- 1. The primary objectives of the Food Standards Agency (FSA) are:**
 - a. to protect and improve public health, and
 - b. to protect consumers' other interests in relation to food and drink.
- 2. We use a range of classic regulatory and alternative approaches to help achieve these primary objectives.**
- 3. This policy statement:**
 - a. describes the range of means by which we seek to achieve our primary objectives; and
 - b. outlines the key principles that inform how we decide our approach in specific cases.
- 4. In our decision-making to achieve our primary objectives we aim to:**
 - a. be open and transparent;
 - b. be evidence-based, whilst acknowledging the acceptability to consumers of different risks
 - c. be independent of sectoral and political interests, whilst incorporating mechanisms for all stakeholders – particularly 'hard to hear' consumer groups – to make their voices heard from the earliest stages of policy development. This is centred on a statutory requirement for the FSA to consult¹;
 - d. be proportionate, by ensuring our decisions have considered the risks, cost and benefit of any action, where these can be quantified, and incorporate appropriate use of a precautionary approach, where the risks are unknown.;

¹ Food Safety Act 1990 (s48)

- e. meet our other statutory obligations² to take into account our Statement of General Objectives and Practices³, and any relevant advice from our advisory committees;
- f. focus on practicable and deliverable solutions within the (largely EU-based) legal framework within which we operate;
- g. support consistent and robust implementation, monitoring and enforcement;
- h. follow the principles of better regulation⁴; and
- i. deal fairly and equitably with businesses, and in particular to provide access to appropriate knowledge, information and guidance.

B. The Evidence Base

- 5. Often, the evidence underpinning any decision will be incomplete; different types of evidence may point in different directions; the data may be uncertain; or the underlying science may still be developing and the issues not yet fully understood. When scientific uncertainty is established, we are open about the uncertainty, and do not allow the absence of certainty to delay us from taking proportionate action. We also recognise that consumers can only benefit from advice if it is sufficiently meaningful to them and helps them make an informed choice.
- 6. For example, during the 2001 Foot and Mouth Disease outbreak burning carcasses on pyres posed a potential health risk of increasing the concentration of dioxins in the food chain. The risk assessment⁵ was based on the best science available on factors such as pyre combustion, atmospheric dispersion and food chain modelling, but contained significant inherent uncertainties. We decided to monitor levels of dioxins to better assess the risk. Since any dioxins would only be apparent in affected food after some time⁶ we issued precautionary advice to consumers. This explained the possible risk and suggested that consumers who consumed

² Food Standards Act 1999, sections 22 and 23.

³ <http://www.food.gov.uk/multimedia/pdfs/sgop.pdf>

⁴ Proportionality, accountability, consistency, transparency and targeting.

⁵ Carried out by the Department of Health and the Environment Agency

⁶ It would have been a period of weeks before dioxins deposited on grazing land would have been consumed and subsequently accumulated in the fat of the cattle and finally excreted in their milk.

milk and whole milk products exclusively from farms within 2km of the pyres might wish to vary their diet. When the subsequent tests concluded no increased risk of dioxins from pyres we lifted our precautionary advice.

7. The nature and magnitude of scientific uncertainty inform judgements on the most appropriate action:
 - a. where the magnitude of any scientific uncertainty can be assessed, the bounds inform regulatory decision-making, and the decision will be revisited periodically as new information enables the degree of uncertainty to be reduced; and
 - b. where an area of scientific uncertainty has been identified, but cannot be quantified, we engage with stakeholders to enable us to take into account the range of opinions on likely risks and appropriate actions.

C. Stakeholder Engagement

8. We will engage with a range of stakeholders from an early stage of policy development to help ensure that policy decisions take account of appropriate stakeholder views.
9. We use a range of mechanisms for engaging with stakeholders in the process of regulatory decision-making, including formal written consultation, questions from the floor at open Board meetings, closed and open meetings of stakeholder groups. This engagement provides both us and stakeholders with insights into the diversity of stakeholder views, allows us to assess and weigh stakeholder views in the process of reaching our judgements, and helps deliver transparency and accountability of regulatory decision-making.
10. We recognise that the formal consultation mechanisms relied on in the past are not always successful at reaching all stakeholders. In particular, many community-based and 'hard to hear' consumer groups may not be members of umbrella organisations and many food SMEs will not be members of trade associations. **We will develop more effective ways of ensuring we hear the views of those stakeholders.**

11. The following principles have been developed for engaging stakeholders and stakeholder groups in the policy-making process, informed by experience, including an independent review of how we had used stakeholder engagement⁷:
- a. **Openness:** stakeholder consultations, by whatever means, should be designed so as to permit openness, breadth and depth of consultation, and adequate identification and rigorous investigation of the key issues;
 - b. **Representation:** membership of stakeholder groups should as far as is practicable be truly representative of those with an interest, without becoming too unwieldy for their purpose;
 - c. **Diversity:** deliberative mechanisms used in stakeholder groups should recognise the complex series of beliefs, values and preferences that underlie judgements made by stakeholders; and
 - d. **Feedback:** there is a need for effective feedback to stakeholders on how their suggestions – whether made in response to formal written consultation or through other mechanisms – have influenced policy development.

D. Options for intervention

12. Our experience to date indicates that, for any given policy issue, the options for intervention range from doing nothing to direct, prescriptive regulation (see box 1 below).
13. Evaluation of interventions provides information on the effectiveness of different options. This enables us to learn from experience and to make judgements on whether the nature of the intervention should change over time, or even if any intervention is still necessary. For example, independent evaluations⁸ of butchers' licensing commissioned by the FSA

⁷ Dr Eileen Rubery (May 2002) *Review of the policy making process used by the Food Standards Agency in respect to BSE and sheep.*

<http://www.food.gov.uk/multimedia/pdfs/paperfsa020603annex.pdf>

⁸ R Gaze *et al*, Evaluation of the butchers' licensing initiative in England, Campden and Chorleywood Food Research Association, 28 July 2003. Food Research and Consultancy Unit, An evaluation of the butchers' licensing initiative in England, University of Wales Institute

show that the initiative has largely been successful in raising hygiene standards; arguably as a result butchers are better placed than many small retail and catering businesses to comply with forthcoming EU food hygiene regulations. Following a consultation with stakeholders, the Board of the FSA has decided that the requirement for butchers' licensing should not be extended beyond 31 December 2005. **We will develop processes for the further systematic evaluation of our interventions, based on appropriate measures of effectiveness, and incorporating the views of stakeholders.**

Cardiff, August 2003. J V Wheelock, Evaluation of butchers' shop licensing initiative in Scotland, 2002.

Box 1

OPTIONS FOR INTERVENTION⁹

- Doing nothing.
- Assembling and publishing the evidence, to inform public debate.
- Providing information to consumers, without advocating a particular course of action, so consumers may make informed choices.
- Providing advice to consumers.
- Providing and publishing our advice and recommendations to Ministers.
- Incentivisation by recognising or rewarding desirable behaviour by the private or voluntary sector.
- Encouraging self-regulation through voluntary codes of practice.
- Co-regulation through statutory or Government-backed codes of practice or action plans.
- Licensing of products, people, processes or premises.
- Direct regulation, and proportionate enforcement¹⁰, which might include penalties and reputational sanctions.
- Encouraging enforcement action taken by relevant enforcement bodies (usually local authorities or the Meat Hygiene Service).

14. We refer to the general principles established in the Statement of General Objectives and Practices¹¹ and in the FSA's Approach to Risk¹² when making judgements on the most appropriate regulatory approach to each policy issue. These principles are expanded in the following detailed operational guidance that we have published:

⁹ Whilst these options demonstrate the range of regulatory options available to us, it should not be taken to imply that we would consider each option in turn, in this order, for any specific issue.

¹⁰ See the Enforcement Concordat,
<http://www.cabinetoffice.gov.uk/regulation/docs/pst/pdf/concord.pdf>

¹¹ <http://www.food.gov.uk/multimedia/pdfs/sgop.pdf>

¹² <http://www.food.gov.uk/multimedia/pdfs/riskapproach.pdf>

- a. A Framework for measuring food risk management against Phillips' lessons¹³;
- b. Guidelines for FSA Technical Surveys¹⁴; and
- c. Guidelines for assessing and acting on information from food incidents and food surveys¹⁵.

15. We propose to bring together the key principles from these elements into a single, simple guide for stakeholders, in order to improve the transparency of our regulatory decision-making.

E. Deciding when to take action to protect public health

- 16.** In our work to protect consumers and their interests, we aim to select the right measure, at the right time. We do not aim to eliminate all risks, but to take action to reduce risks to the level that would be acceptable to the 'reasonable consumer'¹⁶. This is a challenging task as each consumer's acceptability of any given food risk will be based on that individual's values and beliefs.
- 17.** A range of factors influences our decisions on which approach to follow in each case:
- a. different approaches will be appropriate for different types of risk – where there is an immediate and acute threat to the health of vulnerable consumers (for example, children) such as konjac gel in jelly cup sweets, we will immediately issue public advice and Food Alerts to local authorities and, if needed, speedily bring forward emergency legislation;
 - b. different approaches may allow the achievement of policy objectives more quickly – for example, it may be quicker to propose and agree a voluntary approach with food manufacturers and retailers, rather than wait for the lengthy process of changing EU legislation to be completed.

¹³ <http://www.food.gov.uk/multimedia/pdfs/note020205.pdf>

¹⁴ <http://www.food.gov.uk/multimedia/pdfs/fsatechnicalsurveys.pdf>

¹⁵ <http://www.food.gov.uk/multimedia/pdfs/assessact.pdf>

¹⁶ In line with the findings of the BSE Inquiry Report (Vol.1) published in 2000.

An example of this approach is the voluntary provision by the food industry of information on labels about the salt content of foods;

- c. in some cases it may be judged appropriate to inform consumers as to where there are possible rather than actual risks, provide advice, and yet still allow the consumers to make their own choices. For example we are not advising against the consumption of sheep, but will continue to take a precautionary approach and recommend precautionary and proportionate measures to protect the public against the possible risk of BSE in sheep;

F. Deciding when to take action to protect consumers' *other interests* in relation to food and drink

18. Interpretation: The We also seek to take a consistent approach to issues outside the Government's traditional role in managing risk to food safety, but within our statutory duty, set out in the Food Standards Act 1999¹⁷, of *otherwise protecting the interests of consumers in relation to food* [and drink]. The Act does not define this term precisely, but states that it includes (*without prejudice to the generality of that expression*) *interests in relation to the labelling, marking, presenting or advertising of food, and the descriptions which may be applied to food.*

19. Within this wider remit the we have, to date, pursued a wide range of activities including:

- a. action to improve labelling to make it easier for consumers to make informed choices;
- b. carrying out surveys to assess whether food in the shops is correctly described;
- c. action to minimise pesticide residues in food, and provide those consumers who wish to avoid residues a wider choice of food products;
- d. working with local authorities on action to address fraudulent practices (which may or may not have safety implications); and

¹⁷ Food Standards Act 1999 (s7(1)(a))

e. action to protect consumers from practices which are legal but which are likely to mislead.

20. The above examples indicate the breadth of interpretation of *otherwise protecting the interests of consumers in relation to food*. There is unlikely to be a single methodology that could be used to identify and assess the consumer interest across this broad remit.

21. The tests that could be applied to determine scope might include:

a. **market failure** – where the ability of consumers to make informed choices is constrained by the high costs to consumers of either sourcing sufficient information on which to make a choice, or reducing their exposure to the product, ingredient or process they seek to avoid;

b. **expressions of societal concern** – particularly regarding protection of the most vulnerable consumers;

c. **the heterogeneity of consumer perceptions, beliefs and values** – acknowledging that none of us are “average consumers”. This could entail a need to consider a broader range of relevant evidence to inform any decision on what action, if any, may be necessary.

22. **Evidence:** In judging whether and how to act in each such case, we will also need to consider additional factors:

a. how to balance conflicting interests of different groups of consumers, particularly where changes sought by some consumers may impose costs on other consumers; and

b. when to intervene by seeking to influence the range of products available to the consumer, and the need to balance improving consumer protection in this way with the wish to maintain consumer choice.

G. Assessing the Costs and Benefits

23. We have a statutory responsibility to take into account the costs and benefits when considering whether and how to exercise any of our powers.

We will assess possible approaches not only in terms of improvements to public health and consumer protection but also in light of the effects on industry and other stakeholders.

Costs

24. The different kinds of costs could include:

- a. the **policy costs** to businesses of complying with a new regulation or meeting the requirements of other possible approaches such as self-regulation – for example, changes to products or packaging, purchasing new equipment, training for staff;
- b. the **administrative costs** to businesses – for example, time taken to understand the new requirements or guidance, generating appropriate information to support self-regulation, providing monitoring returns to enforcement agencies or others, accompanying inspectors or auditors around their premises;
- c. **costs to the public purse**, including both our costs (in developing and disseminating the policy and associated regulations, guidance or public information) and costs to the broader public sector (including advisory, educational and enforcement agents); and
- d. **wider indirect costs** – for example we are trialling the use of a Policy Assessment Framework¹⁸ covering environmental, social and economic aspects of sustainable development to prompt policy makers to consider these impacts in a methodical way.

25. We realise that the costs to the private and public sector can often be passed on to the consumer. Identifying and assessing the costs of any regulatory activity benefits all stakeholders.

Benefits

¹⁸ See Paper 04/10/02 *Sustainable development and the Food Standards Agency's policies* discussed by the Board at its 14 October 2004 Board meeting.

26. In assessing the benefits of possible options we consider both improvements to public health and consumer choice, and the effect of possible benefits to industry and other stakeholders.
27. For all significant new regulatory proposals we will capture these costs and benefits in a Regulatory Impact Assessment [RIA]¹⁹, that is published with our consultations, to allow stakeholders to comment on and contribute to the assessment.

H. Operating in a European Context

28. The FSA negotiates food law in the EU on behalf of the UK. In proposing a UK negotiating line to Ministers on proposals for EU law, we will take into account the same factors as for domestic legislation (see above). We use both formal negotiation and informal routes to influence the development of EU law.
29. We are working with other government departments to promote better regulation at EU level so that resultant legislation to protect public health and help consumers make informed choices has considered the resultant burdens on the private, public and voluntary sectors.
30. We work with stakeholders to review the practical implications of implementing and enforcing EU regulation. This then informs the UK's negotiating position on any new EU proposals.

I. Public accountability

31. A number of commentators have suggested an accountability gap in the operation of national regulators. Philip Hampton, in the interim report of his review of enforcement and inspection²⁰, notes that although regulators such as the FSA are accountable to Parliament, and that individual judgements of regulators should continue to be made independent of government

¹⁹ Called 'Regulatory Appraisals' in Wales,

²⁰ P Hampton. *Reducing administrative burdens: effective inspection and enforcement*. Publ. HM Treasury, December 2004

control, there is a gap in the accountability for the way in which regulators carry out their work. The House of Lords Select Committee on the Constitution has made the same point²¹, identifying the question as to how the performance of independent regulators is monitored to ensure that public interest is properly served.

32. We are accountable to the Westminster Parliament and the devolved administrations²² in a number of ways:

- a. we are accountable to Parliament and the devolved administrations through Health Ministers, who respond to any debates on issues within the our remit and answer any Parliamentary Questions relating to our activities;
- b. where we are seeking Ministerial agreement to a regulation, we are required to conduct a Regulatory Impact Assessment;
- c. we submit an Annual Report to Parliament, which Parliament may examine in committee;
- d. the Chief Executive, as Accounting Officer for the FSA, is answerable to Parliament through the Public Accounts Committee, advised by the National Audit Office, for the propriety and regularity of our spending;
- e. like all government departments (including non-ministerial departments), we are subject to periodic review by the National Audit Office of the economy, efficiency and effectiveness with which we discharge our functions and duties. Such reviews may result in a Public Accounts Committee inquiry.

33. We are also accountable for our actions in several ways:

- a. under our founding legislation²³, if it appears to Health Ministers that there has been a serious failure by us to perform our duties, or to comply with our obligations to take account of risks, the costs and benefits of our

²¹ House of Lords Select Committee on the Constitution. *The regulatory state: ensuring its accountability*. 6th Report of Session 2003-04, May 2004.

²² through mechanisms analogous to those quoted as examples

²³ Food Standards Act 1999, section 24.

actions, or of expert scientific advice, Ministers may issue directions to us to remedy that failure;

- b. our decisions may be challenged in the courts, for example through judicial review;
- c. if administrative procedures are not discharged correctly, a formal complaint may be made to us and, if not resolved, to the Ombudsman; and
- d. anyone attending an open meeting of the Board of the FSA, or viewing it via the internet, can submit a question to the Board on any aspect of our work.