ACM/584

ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD

THE MAKING OF HYGIENE LEGISLATION

1. This paper provides Committee members with an overview of hygiene law in the United Kingdom and the European Union. It discusses its justification, purpose, origins and intent, and considers the practical aspects of making, operating and enforcing hygiene legislation, as well as the constraints on amending it.

2. The paper, which attempts to address a complex area in a user-friendly way, is primarily for information.

3. The paper will be introduced by Catherine Bowles from the Hygiene Policy and Legislation Unit in Microbiological Safety Division of the Food Standards Agency.

Secretariat
June 2002

THE MAKING OF HYGIENE LEGISLATION

Background

1. The paramount purpose of hygiene legislation is the protection of public health. The vast majority of hygiene provisions in our national Regulations are based on Community law, although the Treaty of Rome does afford member states limited scope to supplement Community provisions, e.g. in the interests of public health, providing unjustified trade barriers do not result.

2. The making of hygiene law is subject to the same range of political influences and imperatives as any other legislation. Examples of this would include BSE at the international level, and the impact of the Lanarkshire *E.coli* O157 food poisoning outbreak, which became the driver for licensing certain butchers shops under UK national legislation. Hygiene legislation needs to take account of international obligations, not only in relation to public health protection, but also to the need to facilitate international trade so far as possible. In the development of hygiene proposals, proportionality is ever an issue, and due attention has to be paid to the balance between the benefits provided and the costs of compliance. The norm is that hygiene law should be soundly based in science. If, however, the available science is uncertain, and there is the possibility of harm to consumers, legislation may be made on a precautionary and temporary basis subject to review in the light of improvement or clarification of the science. Additionally, hygiene law should not unjustifiably constrain technological development.

3. This general background is developed further in the paragraphs below.

Justification for Hygiene Legislation

4. In broad terms, UK government policy is that regulation should be the last resort, only to be pursued where alternatives to statutory controls have been evaluated and considered to be inappropriate or unlikely to succeed. Food hygiene is one area where the government has generally accepted regulation to be the appropriate means to provide public health protection. This does not mean hygiene law can be made with impunity. Recent governments have had deregulation, better regulation or avoidance of over-regulation agendas, and government departments proposing new or amended laws are subject to close Whitehall scrutiny, for example through committees such as the Foreign Office's European Policy ('EP') Committee, and from the Cabinet Office Regulatory Impact Unit and the system of Regulatory Impact Assessment. UK regulation issues are discussed in paragraphs 18 to 22.

Purpose of Hygiene Legislation

5. The essential purpose, to protect public health, requires no further explanation. That said, any legislation can only be as good as its implementation, operation and enforcement, and it is these important elements that must be addressed if the legislation is to succeed in its purpose.

The law itself cannot 'ensure' or 'guarantee' food safety – it is there to provide the framework within which businesses must shoulder their own clear responsibility to produce food safely. There will always be those willing and able to comply, those willing but less able or unable to comply, and those unwilling. Because of this, effective enforcement is important component of good law. Enforcement aspects are considered further in paragraphs 29 to 32.

Origins, Intent and Nature of EU Hygiene Law

6. To all intents and purposes, the UK's present hygiene law originated in the European Union. Since 1964, some 17 different Council directives have been adopted and developed to provide the framework for food hygiene generally, official controls on products of animal origin, and the animal health aspects of placing food on the market. These Council directives have to be implemented at the level of national law, along with appropriate enforcement powers and offences and penalties to apply in the event of a breach of the provisions. In the UK, Council directives are generally implemented by Statutory Instruments (secondary legislation Regulations or Orders) following established Parliamentary procedures.

7. In establishing the primary framework of EU hygiene law at the political level, the Council directives have also invested powers in the European Commission to make certain implementing provisions of a more practical day-to-day nature. The scope for Commission action is delimited by the Council directives themselves. Examples would include the powers to set microbiological criteria and temperature control provisions under the General Food Hygiene Directive, and the powers to determine the extent of derogations from structural requirements for approved dairy establishments producing traditional dairy products. The Commission cannot exercise these powers in isolation. Although strongly invested with implementation responsibilities, the Commission is required to consult member states. This is known as 'comitology procedure.' In practice, the Commission submits its proposals for implementing provisions (usually in the form of a draft Commission Directive or draft Commission Decision[1]) to the Standing Committee on the Food Chain and Animal Health[2] (SCFCAH). This is a Committee of member state officials, usually experts in the particular aspect of hygiene under consideration, chaired by the Commission. SCFCAH discusses the proposals, and the Commission may entertain amendments. Eventually, the Commission tables a finalised proposal for a vote under qualified majority voting rules. The Commission does not vote. A positive opinion results when at least 63 of the 87 votes of the member states are in favour of the Commission's proposal. This allows the Commission to proceed to make its Directive or Decision. A negative opinion results when a qualified

[1] Community legal instruments are laid down in the Treaty. A regulation has general application. It is binding in its entirety and directly applicable in all member states. A directive is binding, as to the outcomes to be achieved, upon each member state to which it is addressed (usually all member states), but leaves national authorities the choice of form and method of implementation. A decision is binding in its entirety on those to whom it is addressed. Recommendations and opinions have no binding force.
[2] This Committee succeeded the Standing Committee for Foodstuffs and the Standing Veterinary Committee when the EU adopted its General Food Law regulation in January 2002.

majority is against the tabled proposal. Negative opinions are extremely rare. Where they occur, a complicated handling procedure is triggered[3]. Where there is no qualified majority, either for or against, no "opinion" has been delivered. This is often referred to as "non avis". On this middle ground the procedural rules of SCFCAH are the same as if a negative opinion had been delivered.

8. Commission decisions or directives are generally implemented by member states in the same way as a Council directive (see para 6), although in certain instances, for example where the new provisions create or affect rights for individuals, implementation may be by administrative means. An example of this might be where instructions to enforcement officials are provided in guidance rather than legislation; the administrative means would be to amend the guidance.

The European Commission as Custodians of EU Hygiene Law

9. The Commission, as the EU's civil servants, has the sole power to propose legislation based on the European Treaties. It executes decisions taken by the Council of Ministers[4] ('the Council'), and is responsible for ensuring that member states adequately implement, operate and enforce Community rules. Member states generally are required to submit copies of their (final) implementing regulatory instruments to the Commission to signal an implementation task is complete. Failure to implement by the due deadline, or failure to implement Community provisions faithfully, results in prompting by the Commission. This is followed, if necessary, by infraction proceedings under Article 226 of the Treaty of Rome, which can result in penalties imposed by the European Court of Justice. Issues about member state implementation can be raised with the European Commission by other member state governments or by individuals.

10. With regard to operation and enforcement, the Commission maintains an independent body of inspectors, known as the Food and Veterinary Office (FVO), to audit the competent authorities in member states. The FVO, based in County Meath, seeks to ensure consistency of operation and enforcement both within and between member states. Audit missions follow a strict procedure and timetable, and generally include an office-based investigation of relevant paperwork at both central and decentralised locations. Examples at the central level would include Statutory Instruments, Statutory Guidance to the enforcement authorities and guidance to industry, while at the local level the FVO would examine e.g. approval documents and inspection and enforcement action records. The FVO mission also observes member state

[3] Where a vote in SCFCAH results in a negative opinion, the Commission may withdraw its proposal, or it may submit it (with or without amendment) to the Council of Ministers for a decision, informing the European Parliament in the process. If the European Parliament wishes, it may express its view to the Council. The Council may act by qualified majority on the Commission's proposal. If the Council does not so decide within the stipulated timetable, and has not indicated its opposition, the Commission adopts the measure.

[4] The Council of Ministers (or Council of the European Union) is the final decision making body of the Community. It meets in several specialist formats, such as the Council of Internal Market Ministers, and is attended by the relevant national Ministers.

enforcement inspections in practice at a range of food production establishments. Mission reports critique the strong and weak aspects of member states' enforcement systems, and make recommendations for change or improvement. A member state Action Plan is produced in response, and the FVO can be expected to follow up on that plan to ensure it is put into effect.

11. The FVO is also responsible for hygiene audits at establishments in third countries authorised to export foodstuffs to the EU. These audits seek to ensure that EU consumers are adequately protected in relation to imported food supplies, through assessing the effectiveness of third country competent authority controls over production and exports, and the equivalence of their legislation with EU hygiene provisions, as envisaged by EU law.

Consolidation of EU Hygiene Law

12. The adoption and development of the 17 Council hygiene directives over time has resulted in a fragmented approach that lacks uniformity. While the present approach has, arguably, been fairly successful in protecting public health, its lack of consistency, and complex, sectoral, nature have in certain respects made it difficult to understand and, therefore, to operate and enforce efficiently. Existing hygiene law is only loosely associated with a hazard analysis and control-based approach to managing food safety, and is very prescriptive in nature.

13. The weaknesses of the present approach have been widely acknowledged, and the European Commission has tabled proposals to consolidate, simplify and update it. Negotiations are ongoing and progress reports may be found on the FSA website. The Commission proposes a package of hygiene provisions that will apply from farm to fork. It will become far clearer that food business operators are responsible for producing food safely. The new approach will take account of international developments in the Codex Alimentarius[5], and will focus on the need for food businesses to apply HACCP[6] principles fully throughout the food chain, other than in primary production. This should result in a consequential reduction in the prescriptions

[5] The Codex Alimentarius is a collection of internationally adopted food standards developed in Committees of the Codex Alimentarius Commission. The Codex Commission implements the Joint FAO/WHO Food Standards Programme, the purpose of which is to protect the health of consumers and to ensure fair practices in food trade. These Food Standards are of an advisory nature, and take the form of codes of (hygiene) practice, guidelines and other recommended measures to achieve the Codex purpose. The codes are often used as checklists for national food safety or standards requirements. Additionally, Codex Standards have a particular status under the World Trade Agreement in that the WTO may use them as reference documents in attempting to resolve any international trade disputes referred to it.

[6] Hazard Analysis and Critical Control Point (HACCP) is a structured food safety management system. It is based on the application of 7 principles. These provide a framework to identify food safety hazards and the stages in a food production process at which the control of those is critical to food safety. Critical control points are monitored so that appropriate and timely corrective action can be taken if established acceptable criteria are breached. Records are kept to underpin effective management and to show other parties, where necessary, that food safety controls are properly implemented and maintained.

of EU hygiene legislation, although that is not so far in evidence to a degree the UK would wish.

14. The new legislation should also result in official control (enforcement) inspections focusing on auditing the application of HACCP principles. The European Commission is shortly expected to introduce two proposals for updating the law on official controls. First, an overarching proposal on official controls on feed and food generally, and second, a proposal for sector specific official controls on products of animal origin, which will form part of the consolidation of hygiene legislation package.

15. With efficient and effective operation in mind, the new approach will also bring greater pressure on member states to encourage the development of Guides to Good Hygienic Practice. This system of voluntary stakeholder-developed and agreed guides to compliance has operated under the General Food Hygiene Directive since 1993 to the benefit of industry and enforcement alike. It will now be extended into areas presently covered by sector specific hygiene directives, such as those for fishery products, egg products etc. It will also be extended into the primary production sector, where it will assist with the identification of hazards occurring in primary production and the means to control them. Industry Guides will increase transparency of the controls to be effected, and represent an agreed approach to operating the consolidated hygiene legislation.

16. The timetable for the new legislation is uncertain. We may expect much of it to be adopted by the Council and European Parliament[7] in the next year or so. There will need to be a period between adoption and implementation in order to give both industry and the enforcement authorities time to take stock and adapt as necessary. The length of this "honeymoon period" will need to be considered towards the end of the negotiations, when it becomes clearer what the finally agreed requirements will actually be.

17. In contrast to the present raft of 17 Council directives, the consolidated approach is proposed in the form of 3 directly applicable regulations of the Council and European Parliament on hygiene and official controls, plus a Council regulation on animal health provisions, and a Council directive to repeal existing hygiene law. This approach reflects the Commission's belief that a directly applicable regulation, as distinct from a directive that requires implementing, provides a greater assurance of uniform application throughout the single market. It also means that member states do not have to take implementation steps nationally, other than to ensure appropriate enforcement provisions and offences and penalties for non-compliance are in place. The approach further reflects the enhanced rôle of the European Parliament in making food law, where they now share responsibility with the Council of Ministers under the Co-decision procedure.

[7] The European Parliament is directly elected every 5 years. It is responsible for the EU budget and has potential control over the activities of the European Commission. Its legislative responsibilities have been increased by successive European Treaties, and it is now jointly responsible with the Council of Ministers for food law.

Making Hygiene Legislation in the UK

18. The overall approach to hygiene legislation within the UK remains under the umbrella of the Food Safety Act 1990 in Great Britain, and parallel legislation in Northern Ireland (henceforth together referred to as 'The Acts'). Following Devolution, however, most detailed hygiene legislation is now made separately for England, Wales, Scotland and Northern Ireland, following respective Parliamentary or equivalent processes. Given the strong EU influence, much of it is essentially similar.

19. 'The Acts' provide a framework in primary legislation within which food safety can be managed. By way of illustration, they define the meaning of significant terms such as "food" and "sale". They also nominate and empower Ministers e.g. to make implementing (detailed) regulations, issue guidance and require information. 'The Acts' establish offences, appeals procedures, penalties and defences, and set down the enforcement systems including the establishment of food authorities, their powers of entry, the arrangements for sampling and analysis and the appointment of public analysts.

20. Detailed hygiene law is made by Statutory Instruments under 'the Acts' following the appropriate Parliamentary processes in each of the countries of the UK.

21. The scope for UK Ministers and the devolved administrations to act to introduce their own hygiene laws is strictly limited. The EU has competence in relation to food law, but it is possible to act where the EU has not acted, or where there is some prescribed leeway within the Treaty or more general EU texts. Where we do propose our own action, the European Commission and other member states must usually be notified in advance. This provides the opportunity for wider consideration of whether the proposed measures should be adopted at the Community level, or whether they can be approved as national provisions. Of course, proposals for national provisions may also be rejected by this process. For example if they are not scientifically justified, or proportionate. National provisions developed in this way may not generally be applied so as to prejudice trade with other member states. This concept is known as 'mutual recognition", and means in effect that a product legally marketable in one member state may lawfully be marketed in any other member state.

22. Examples of where the UK has had notified national provisions accepted by the EU include food temperature control and butchers licensing regulations, where the EU did not elect to follow suit. Other examples include the OTM, SRM[8] and beef bones legislation made during the BSE crisis, and in these cases much of our national provisions were overtaken by subsequent EU law. UK national provisions may vary, for example, raw cows' drinking milk is banned in Scotland.

[8] OTM: the 'Over Thirty Month' slaughter rule for beef animals entering the food chain.
SRM: 'Specified Risk Material' that has to be removed from carcases before they can be accepted for human consumption.

Parliamentary Scrutiny

23. All European Commission proposals for Council and European Parliament legislation are subject to scrutiny in both Houses of the Westminster Parliament. The nominated members of the Parliamentary Scrutiny Committees are responsible for developing Parliament's reactions to any given proposal on the basis of an Explanatory Memorandum[9] provided by the responsible Government Minister. The Clerks to the Committees generally recommend to the Members whether the proposal is of sufficient importance as to merit debate on the floor of the House (as was the case in the Commons with the General Food Law proposal), whether there should be a debate in Scrutiny Committee (as with the Hygiene Consolidation proposals), or whether the proposal is of such a nature that it can be recommended for Parliamentary agreement without debate. The latter two courses both result in a subsequent recommendation to the House on whether to agree or not.

24. Until Parliamentary Scrutiny is complete, responsible Government Ministers, (or officials on their behalf) are generally not in a position to adopt a definitive position on any given proposal, and have therefore to participate in Brussels negotiations under a Parliamentary Scrutiny reserve – which is later lifted once Parliament has completed scrutiny.

The Government's View

25. Hygiene policy in England is the responsibility of the Secretary of State for Health, advised by the Food Standards Agency. In Scotland, Wales and Northern Ireland responsibility for food hygiene is devolved, and the FSA advises the relevant responsible Ministers. The Secretary of State for Health has overall responsibility for negotiating hygiene proposals in the EU.

26. Most European Commission proposals will be of interest to several Government departments. They will also be of interest to the devolved administrations. Using hygiene consolidation as an example, DEFRA are interested because of their industry sponsorship rôle and their responsibility for animal health matters. The Small Business Service (part of DTI) has a remit to look after the interests of small businesses, while the Cabinet Office has a specific locus through the role of its Regulatory Impact Unit. HM Treasury oversees the financial implications of Commission proposals, while the Foreign and Commonwealth Office is responsible for co-ordinating the overall view of the Government on European Policy. No other Government department has expressed a particular interest in the consolidation proposals.

27. The Secretary of State for Health is responsible for securing the approval of Government Ministers to the proposed negotiating line (in practice, delegated to the Food Minister, Hazel Blears). This is achieved by

[9] An Explanatory Memorandum is a brief explanatory document, accompanying a proposal through Parliamentary Scrutiny. It summarises the proposal, its legal, policy and financial implications and the likely timetable for its consideration by the Council of Ministers. It is a formal communication to Parliament from the responsible government Minister, and it is carefully prepared with that status in mind.

writing to the Foreign Secretary, who chairs the European Policy Committee, copied to members of that Committee and to relevant Ministers in the devolved administrations. Agreement is generally achieved by consensus, and is heavily informed by the content of the Regulatory Impact Assessment on the proposals produced by the FSA for the Secretary of State for Health.

Regulatory Impact Assessment

28. It is Government policy that regulation must strike the right balance so that businesses, charities and the voluntary sector are not subjected to unnecessary burdens, and their growth is not stifled. In order to ensure that regulations are fair and effective, proposals for national and EU legislation have to be accompanied by a Regulatory Impact Assessment (RIA). The RIA is a short structured document which sets out the need for the legislation together with the risks, costs and benefits of the proposal both for industry and enforcement, and the options for implementing it. It also describes who is affected, discusses stakeholder views, and considers any non-regulatory options that have been considered by way of alternatives. RIAs are an integral part of the legislative process; they have to be agreed by the Cabinet Office Regulatory Impact Unit, and are signed by the accountable Minister before depositing in the House libraries when the legislation is presented to Parliament.

Enforcement of Hygiene Provisions in the UK

29. Enforcement has a crucial rôle to play in protecting public health and providing consumer protection. The Government recognises that the local approach to enforcement work depends on the prevailing circumstances, level of risk, political and stakeholder will, and other external influences, but expects local authority enforcers to adopt a balanced approach. The approach to be taken also needs to recognise that assisting compliance is every bit as important as detecting non-compliance.

30. The Food Standards Agency is the central administration with overall responsibility for hygiene enforcement across the UK. The Agency is committed to improving the enforcement of food law, e.g. by working with Food Authorities to develop and improve their enforcement services and by improving the transparency of enforcement arrangements for stakeholders. The Agency provides guidance and support for local enforcement officers, including through the provision of statutory codes of enforcement practice, and maintains an overseer's and audit profile. The Agency has established the 'Framework Agreement on Local Authority Food Law Enforcement' to provide a clear standard for local authority enforcement and a mechanism for the FSA to monitor and audit local authority enforcement arrangements.

31. The majority of day-to-day hygiene enforcement work is undertaken by Food Authorities, usually through environmental health officers. The Meat Hygiene Service, which is an Agency of the FSA, is responsible for enforcing hygiene legislation in fresh meat slaughterhouses, cutting plants and cold stores. There are also hygiene enforcement roles for the Dairy Hygiene

Inspectorate, the Egg Marketing Inspectorate and SOEEFD and DARD in Scotland and Northern Ireland respectively.

32. Statutory guidance to the enforcement authorities on hygiene inspections provides for food businesses to be assessed through a risk-based rating scheme. The rating takes account of the type of food manufactured, methods of handling and manufacture, type of consumer served, degree of compliance with food legislation, structure of premises, the degree of confidence in management practices and controls, and the risk of contamination by pathogens. A minimum frequency for inspections of businesses in each of 6 risk categories is established. For example, high risk premises in categories A or B will be visited at least twice a year. The present statutory guidance for enforcement officers is currently under review with a view to rationalisation and simplification. As a result, it is expected that all premises will be reviewed within a three-year programme – currently some premises are only scheduled to be inspected every five years – and all premises subject to approval under product specific food hygiene regulations would be inspected at least twice a year.

Microbiological Safety of Food Division
June 2002