

**UPDATED PARTIAL REGULATORY IMPACT ASSESSMENT
PROPOSALS TO CONSOLIDATE EU FOOD HYGIENE LEGISLATION**

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UPDATED PARTIAL REGULATORY IMPACT ASSESSMENT

1. Title of proposal

The draft instrument contains five linked proposals covering food hygiene requirements in the European Union. Details of the proposals are at **Annex A**.

A list of the current legislation to be replaced by the proposals is at **Annex B**.

2. Purpose and intended effect of measure

(i) The objective

2.1 The primary objective of the package of EU food hygiene proposals is to optimise public health protection by improving and modernising the existing EU legislation. Legislation needs to establish conditions under which food is produced to prevent, eliminate or acceptably control pathogen contamination of food. The proposals would introduce more risk based and flexible procedures better matched to the needs of individual businesses. This would be facilitated by the introduction of food safety management procedures based on the application of Hazard Analysis and Critical Control Points (HACCP) principles. The application of HACCP-based principles in food manufacturing and preparation is widely regarded as crucial to the management of food safety and, in turn, consumer protection. (Information on HACCP, its current status in the UK and a short explanation of the 7 principles is at **Annex C**.) The proposals would introduce a “farm to fork” approach to food safety, by including primary production in food hygiene legislation in the majority of cases for the first time, and more clearly place responsibility for safe production of food on food producers, not enforcement authorities.

Devolution

2.2 The proposals will be directly applicable throughout the UK.

(ii) The background

2.3 The need for food hygiene legislation is generated by the risk to consumers of illness or death from pathogenic microorganisms, which can occur in or cross-contaminate food at all stages from production to consumption. Current food hygiene requirements in the European Union are contained in a raft of legislation, the earliest of which is almost 40 years old. It exhibits inconsistencies in approach and a degree of duplication that makes it difficult to interpret and to enforce. It has not kept up with change and innovation in food technology. These factors led the European Commission to come forward, in June 2000, with five linked proposals to update and simplify this legislation. The proposals as issued would hold implications for around 800,000¹ businesses in the UK.

¹ The figure of 800,000 includes 200,000 businesses at primary production level (farms, fishing vessels etc) (see **Appendix I**) and 600,000 food businesses (caterers, retailers, manufacturers etc) (see **Appendix E**). As the method of collecting the figures varies according to business sector, the overall figure is a reasonable estimate.

2.4 Four of the proposals are the responsibility of the Food Standards Agency. The fourth proposal (now adopted), relating to animal health rules, is the responsibility of Defra and is not the subject of this RIA. The third proposal, on specific rules for the organisation of official controls on products of animal origin intended for human consumption, is the subject of a separate RIA as the original proposal was withdrawn by the Commission and replaced by a substantially revised version issued in July 2002.

2.5 The current legislative requirements have very uneven coverage. At present, primary producers are not generally covered by food hygiene legislation. Retail and catering businesses are covered by the general food hygiene directive (93/43) which requires businesses to comply with requirements corresponding to the first five HACCP principles, namely to identify and control hazards. Producers of products of animal origin are covered by specific directives most of which require the identification and control of hazards (involving in most cases highly prescriptive detail, e.g. tiling of walls to 2 metres height). In some cases (producers of meat, fish and milk products), "own checks" additionally require verification and recording of procedures in place, effectively applying the final two HACCP principles.

(iii) Risk Assessment

2.6 The background against which the package of proposals should be viewed is the incidence of foodborne disease. In 2000, it is estimated that the total number of cases of foodborne disease (referred to hereafter as Indigenous Foodborne Disease (IFD)) in England and Wales was 1,338,772 of which, 368,516 visited a GP and 970,256 did not. It is estimated that 480 cases resulted in death. Similar figures for IFD in Scotland and Northern Ireland are not available, but when the England and Wales figures are increased pro rata to apply to the UK, the cost of IFD is estimated to be in excess of £1.5 billion per year. Evidence on the origin of disease is limited, but data on general outbreaks shows that the majority (80-90%) originate in catering or retail outlets of various types. Even cases thought to originate in the home may be the result of that food containing pathogenic microorganisms when purchased. It is not possible or desirable therefore to eliminate these cases from consideration here. Information on food poisoning incidence in the UK is outlined at **Annex D**.

3. Options

3.1 Officials have pursued a negotiating line based on option 4 outlined in previous versions of the RIA as agreed by the Ministerial Sub-Committee on European Issues (EP). **Annex L** contains the information on the options identified.

Changes to the original text made during the course of the negotiations

3.2 The negotiation up to and including the time of political agreement at first reading in Agriculture Council has seen the texts develop in a number of areas. The changes reflect, to a significant degree, success by the UK in achieving its negotiating objectives. Detailed changes have made the meaning clearer and the eventual application more straightforward. In addition, the UK has been successful in attaining a number of significant changes that will make the proposals more practicable for businesses and make enforcement more achievable. The most

significant of the changes are set out below in order of the relative priority attached to them by the UK:

First Proposal

- Agreement that, other than in primary production (where HACCP-based procedures will not be applied) food safety management procedures should be based on the principles of HACCP, not the strict interpretation of the Codex system;
- Additional flexibility has been secured by providing for food business operators to provide evidence of compliance in the manner the competent authority requires, taking account of the nature and size of the food business. This application of subsidiarity will allow the competent authority to tailor the requirement in a flexible way to meet the needs of individual businesses and sectors (e.g. what might be required in a manufacturing plant need not be the same as in a newsagents. This improves on the original text that implied that the same approach should be taken in all establishments.
- The proposal now allows for the adoption of more detailed arrangements in relation to HACCP-based procedures. It suggests that implementation of the procedures may be facilitated by the use of guides. Those guides will be a crucial aid to business, particularly SMEs, and could include information on record keeping etc. appropriate to the business sector concerned.
- The UK has successfully clarified that the guides are to be voluntary in nature. Success was also achieved in advocating that guides are the place to lay down detailed requirements for individual industry sectors in order to help clarify conformity with the general requirements of the regulation. This has resulted in the proposals being both clearer and shorter. They now set high-level objectives and much of the repetitive and unnecessary detail has been removed and would, as necessary, be accommodated within the guidance. The involvement of industry will be crucial to the production of guides (a number of stakeholders, including the FDF and NFU, have already expressed a strong wish to be involved). This will provide scope for generic systems to be developed by the industry sectors to meet particular needs.
- Prescriptive time limits for the retention of documentation have been dropped. The original would have required records to be kept for the shelf-life of a product, but the most recent text refers to keeping records for an appropriate period. This is far more flexible and practical and allows for greatly varying circumstances. For example, the requirements placed on a restaurant would, of necessity, be very different from those applying to a malt whisky producer.
- The registration of premises has been clarified so that existing registrations can be used - it will be for the Member State and its competent authorities to determine the form the registration takes. The specific requirement to identify food produced with the registration number of the food business has been dropped in favour of the traceability requirements flowing from the General Food Law Regulation. This has removed one of the burdens envisaged for

business in the original proposal. In addition, the requirement for withdrawal and traceability of products has now been removed from the latest texts to be dealt with under General Food Law.

- Throughout the negotiations the UK maintained the line that the requirement for certain premises to be approved should relate to risk. The resultant texts require that food businesses be registered with the competent authority, in a manner that the competent authority determines, so that their existence is known and they can be factored into official control. At Community level, it has been decided to continue to require that premises handling products of animal origin for which the second proposal lays down conditions shall be approved. This is much as the current position in the UK. Member States are able to require in addition that other premises also be approved subject to notification of the other Member States and the Commission.
- There is greater clarity and consistency to the rules for primary production. This has clarified that certain associated operations (for example transport at the place of production) are also considered to be primary production and subject to the same requirements. It is also now clear that guides to good practice can deal with the hazards and the means of controlling them in a generic way, which will make the requirements easier to apply.
- The possibility is introduced for Member States to adapt certain of the requirements of the legislation providing that does not compromise its objectives. This is included so as to take account of certain traditional practices and the needs of businesses in areas of special geographical constraints. Any such measures would have to be agreed under comitology and so provide for other Member States and the Commission to examine them and ensure a level playing field.
- The scope of the proposal has been amended to reflect the practicalities of certain primary production practices. It exempts from the requirements of the legislation the supply of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer. This allows the current practice of selling small quantities from the farm gate etc. to continue. The terms “small” and “local” are not defined so providing flexibility to apply the exemption in the form of national rules.
- In the Annex applying to all food businesses other than primary producers, and in the second proposal, the UK has been successful in arguing for requirements that are expressed at a high/generic risk-based level.. As such, Member States will be able to be more flexible in implementation.
- The text has been improved to clarify the role of, and overlap with, other existing legislation, e.g. the EU zoonoses legislation and so duplication is avoided.

Second proposal

- The rules governing composite products (those containing both processed products of animal origin and products of plant origin) have been simplified (both in terms of the original text and the current legislation). Currently an aggregation of the legislation on products of animal origin applies to composite products. It complicates the legislative position for a variety of businesses e.g. a business producing pizza containing cheese and ham has to comply with the separate pieces of legislation covering dairy and meat products. Now, only the requirements of the first proposal would apply which represents a major move to deregulation of particular significance to manufacturers (individual products of animal origin going to make up the composite products would still have to be produced under the requirements of the second proposal).
- In line with the first proposal, an exemption is introduced from the requirements of the legislation for the direct supply by the producer of small quantities of primary products, meat from poultry and lagomorphs slaughtered on the farm, to the final consumer or local retailer supplying the final consumer. The exemption will also apply to hunters supplying small quantities of wild game or wild game meat. This latter was a particular concern for wild game stakeholders in the UK.
- The proposal allows for flexibility to be applied to retail-to-retail transactions. It provides Member States flexibility to determine what are “marginal”, “localised” and “restricted” activities and then, should it wish, to exclude those activities from the requirements of the regulation. The outcome is proportionate and applicable to particular circumstances, when some other member states argued for much more specific criteria. The UK considered that national law was appropriate to determine these issues.
- The UK secured an amendment, despite strong opposition, to the definition of Mechanically Separated Meat that allows for the continuation of current UK practice that would otherwise have been under threat. This was welcomed by several organisations in the UK meat product manufacturing sector.
- A good deal of prescription was removed from the requirements placed on meat cutting plants and in the cutting and boning process.
- Significant improvements were also secured in the requirements placed on wild game and the expectations of hunters are now far more realistic than originally proposed.
- The requirements for food chain information have been improved in the course of the negotiations. It now clarifies the linked requirements of the first three proposals in a logical manner and places the responsibilities for the provision of information appropriately. This information is of great significance to the controls applied at the point of slaughter. By laying down high level objectives it leaves the detailed arrangements to be determined by comitology procedure.

- On meat preparations, the text has been clarified to better meet the needs of the industry.
- In the case of live bivalve molluscs, the text now clarifies which activities are classed as primary production and which go beyond that and so need to apply HACCP procedures. This is a most important improvement for the industry which needs to know what procedures to adopt.
- Similarly, in the case of fishery products, the text was clarified in relation to HACCP procedures and when to apply them.

3.3 Although the precise financial consequences of these changes are almost impossible to quantify, as a whole they will have the result of minimising any additional burdens arising from the new legislation for both industry and enforcement agencies. The consequences are largely accounted for in the cost information detailed in section 5.

4. Benefits

4.1 The most significant benefit from adopting the proposals as negotiated would be the simplification of hygiene legislation in a way that would lead to its better application and enforcement. Improved understanding of hazard-analysis based requirements would be expected to result in greater public health assurances, reduction in the incidence of food poisoning, and, in turn, greater consumer confidence. Documentation on the controls in place will help food business operators demonstrate to the enforcement authorities that controls are effective. The precise effect the modernised approach would have on the level of food poisoning is difficult to predict or to measure, but two related pieces of work carried out on behalf of the FSA provide information. Work on IFD (see report at **Annex D**) in England and Wales found that the estimated total cost in 2000 was £1,366 million. This comprised the basic costs to the health service, loss of earnings etc. £164 million and the costs of pain grief and suffering £1,202 million. When applied to the UK as a whole these figures indicate costs of £1,508 million per year. Therefore, a reduction in the incidence of foodborne illness of between 1% and 5% (an estimated outcome foreseen by enforcement experts consulted) resulting in benefits in the region of £15.1 to £75.4 million. Research undertaken by a consultant economist has indicated that benefits are likely to build up over a number of years as both business and enforcement authorities improve the way in which the regulations are applied and checked. It is impossible to say what precise reduction in foodborne illness will result from application of the new requirements, but any improvement will produce a stream of benefits. **Annex E** considers a scenario of a reduction in IFD of 3% and 5% over the first five years. In both cases, the benefits outweigh the costs in less than 10 years. On a 3% scenario, the break even point, when costs are equal to benefits, is after about eight years.

4.2 A second study looked at the concept of “willingness to pay” by consumers (see Executive Summary report at **Annex F**). It was based on two earlier studies and found that consumers state that they are willing to pay a premium for greater assurance that the food they buy has been subject to improved food safety procedures (it was assumed that this premium would be in the region of 1%). The

potential benefits were found to be in the region of £500 to £1000 million per year. Benefits could be even greater if the risk of food poisoning were reduced to the lowest possible level. However, the benefits identified overlap to such a degree with those identified at paragraph 4.1 above that they have not been included in the summary of costs and benefits.

4.3 Benefits would be shared between all the individuals affected- consumers, food businesses, business generally, the NHS and enforcers. Other real benefits would result for both consumers and food businesses which are difficult to quantify in pure monetary terms. They are set out in **Annex G**. For food businesses, one of the major benefits is the implementation of measures that would be more likely to enable them to avoid the possible consequences of a food poisoning incident being attributed to their business. Business is increasingly aware of the dire consequences of direct litigation, cancellation of orders and the harm to reputation that can result from association with an outbreak of foodborne illness. In addition, the operation of the new requirements may open up markets that would otherwise be closed to them. For example, Saudi Arabia require that dairy products exported from the UK come from establishments operating a HACCP system which they do not necessarily do at the moment. The benefits arising from the options identified in previous versions of the RIA are set out in the **Annex L**.

Business sectors affected

4.4 There are approximately 600,000² food business establishments in the United Kingdom, covering catering, retail, manufacturing and distribution. In addition, there are in the region of 200,000 primary producers, including farms, aquaculture establishments and fishing vessels. The majority of the businesses will be affected by the proposals to some extent, although many will have procedures in place that comply with the requirements of the proposals, e.g. major manufacturers, major retailers and their suppliers. The businesses affected range from low-risk one-person businesses selling wrapped confectionery, through to major businesses manufacturing high-risk products and employing hundreds of people.

Issues of equity and fairness

4.5 This proposal does not introduce any new questions of equity or fairness.

5. Costs

(i) Compliance costs

5.1 The costs resulting from the options identified in earlier versions of the RIA are set out in **Annex L**. However, if the proposal is adopted in line with the most recent text, the major cost changes should be as set out below.

5.2 The main additional cost to business will be associated with the introduction of verification and documentation of HACCP-based procedures. Implementation of

² The figure of 600,000 is based on estimates of registered food businesses gained from returns from local authorities.

the hazard analysis requirements of the existing regulations is variable throughout the UK. Data are limited, but best available information indicates that about 20 per cent of food businesses (excluding primary producers) operate a documented HACCP-based system and a further 45 per cent operate an undocumented one. This equates to approximately 390,000 (of the total 600,000) food businesses. Results of the survey used to gain this information are summarised in **Annex H**.

5.3 If the retail and catering sectors were complying with current legislative requirements for hazard analysis, in excess of 565,000 premises would be complying with the major part of the new requirements (See **Annex I** for information on the current legislative requirement by sector). Non-compliance is a concern for the FSA, and is currently being addressed by a major food hygiene campaign. This aims to raise awareness and, in turn, compliance levels. In addition, the FSA's HACCP strategy, aiming to ensure that 30% of businesses have documented HACCP-based systems in place by 2004, is also addressing non-compliance with current legislative requirements. Implementation of this strategy will provide training and guidance for food businesses and will go a long way to preparing UK business for the new requirements. Indeed, it should reduce the costs to business estimated in this RIA as those estimates have not been adjusted to account for the raising of standards that the strategy will bring about.

5.3 Costs will vary greatly dependent on the nature and sector of the business and existing food safety systems. Most major retailers and large food manufacturers have HACCP-based systems in place, while smaller food businesses may have much reduced awareness. Even so, for the vast majority of small businesses new record keeping requirements will be minimal, and implementation guidance will ensure these are proportionate to the nature and size of individual businesses. Many businesses will already be doing at least some of what is necessary, such as recording temperature monitoring. The additional burdens and costs will, in the main, fall to the retail and catering sectors.

5.4 For the food manufacturing, production and processing sectors any additional burdens should be minimal. Most operators (90%+) should already be implementing systems based on at least the first five HACCP principles. Most sectors covered by specific Directives are required to carry out 'own check' systems that need some form of record keeping already. Even so, there may be additional requirements around record keeping and it is possible to estimate the costs involved by applying the average costs for the catering and retail sectors to the remaining sectors. Excluding retail and catering businesses and slaughterhouses (already required to implement HACCP principles under Commission Decision 2001/471/EC) there remain approximately 33,500 food businesses. Under this assumption the costs per business would be in the region of £300 per year and the total cost would be approximately £10 million. However, work carried out on behalf of the FSA (**Annex J**) estimates the additional costs in the processing sector at approximately £1 million per year. Therefore a mid-range estimate of £5 million per year has been included in the summary and the costs of HACCP training for food businesses have been factored into the estimates.

Impact on Primary Producers

5.5 Primary producers will not be required to apply HACCP-based procedures. Instead, the control of possible hazards will be addressed in codes of practice. Primary producers will need to follow good practice and manage their operations in such a way that hazards are acceptably controlled. As with other food businesses, primary producers would have to be registered with Competent Authorities. In practice, the requirements are expected to entail relatively modest change to current practice. Certain current legislation requires primary producers to identify and control hazards, e.g. under veterinary and pesticides residues and zoonoses legislation. Various assurance schemes cover the majority of primary production in the UK. Some of the schemes identify hazards and require action to be put in place to address them. Relatively minor change would therefore seem needed in order to make them compatible with the proposals. Adoption of any new requirements in respect of primary producers will need to be fully aligned to other government initiatives to take account of the particular circumstances facing farmers.

5.6 Research (**Annex J**) estimates the total additional costs to primary producers as approximately £27 million per year. The costs were calculated on the basis of costs shared between in excess of 146,000 farm businesses³ in the UK. A range of business types and sizes was considered, but not the fishing or the game/hunting industries. The cost of adopting hazard analysis ranged from £94 for a very small beef or sheep farm to £620 per year for a large horticultural producer (the total figure included an element for traceability measures now removed). Costs for the UK fishing sector have been estimated by attributing to the number of fishing vessels and fish farms the average costs to other primary producers. The result is an estimate of costs for the fishing sector of £1.5 million, although this is likely to be an overestimate as the number of vessels will certainly exceed the number of businesses. It is possible to attribute costs in a similar way for the c.200 game farms in the UK resulting in costs in the region of £40,000.

Registration of Food Businesses and Traceability Requirements

5.7 All food businesses will have to be registered with the competent authorities, but a new unified registration system is not being proposed. For most businesses, this will not impose a new burden as use of existing forms of registration will be allowed where feasible (the Council Secretariat indicate that tax registration would suffice). In any case, existing Food Premises legislation requires premises used as food businesses to be registered with local authorities if they are not otherwise registered or approved. This applies with only limited exemptions including most primary producers and premises controlled by voluntary organisations or charities. In the case of agricultural primary production, registration systems already in place could be used, such as the Integrated Administration and Control System or the newly introduced registration of laying hens legislation. The traceability elements contained in the original proposals have been removed from the latest texts following the introduction of requirements in the General Principles of Food Law Regulation. No additional costs, in relation to traceability, will therefore arise from this measure.

³ 146,430 farm businesses derived from VAT registrations. It does not include fishing, fish farming or game business numbers.

(ii) Other costs

Impact on Charities and Voluntary Organisations

5.8 Charities and voluntary organisations should already be complying with the requirements of the General Food Hygiene Regulations 1995, which require, in effect, implementation of the first five HACCP principles. These organisations will be affected by the proposals to some extent as will organisations that give out food, e.g. Shelter and Crisis at Christmas. However additional burdens should not be great. Such organisations would need to be registered as food businesses and would have to verify and record procedures, but many may be doing so at present. A number of charitable organisations were included in the original consultation, including the National Federation of Women's Institutes and the Townswomen's Guild, but no comments were received from them.

(iii) Costs for a typical business

5.9 Some 800,000 businesses in total are affected by this proposal and on the basis of the foregoing estimates, total compliance costs are put at around £200 million per year, with an additional £5 million one-off costs. However, for the reasons stated earlier, we consider that the estimated costs may be overstated. Further consultations have suggested that the balance between ongoing and one-off costs may be somewhat unrealistic. There are likely to be costs involved in putting record keeping and verification systems in place that will fall away once systems are up and running. For this reason, the summary of costs and benefits indicates costs in the first year of £200 million reducing to £150 million thereafter. (See paragraph 5.14 and Annex E for more detailed information on the costs estimated in the retail and catering sectors). The ongoing costs would be borne by industry sectors as follows (£million):

Retail	46
Catering	69
Primary production	29
Production and Processing	5
Total	149

5.10 Averaged out over the entire industry the costs of complying with the additional requirements are estimated at around £300 per business annually. Research has looked at a number of examples in the retail and catering sectors. It indicates that for a provincial good class restaurant costs would increase by 0.5% of net turnover, 0.9% of net turnover for a small estate supermarket and for a small delicatessen 1.6% of net turnover. In no instance is it believed that increased burdens will be of the magnitude to deter new entry into the industry or to bring about the closure of businesses. Neither would any particular foodstuffs be affected more than others by the proposals. **Annex K** has further information on costs and benefits.

6. Consultation with small business: the Small Firms' Impact Test

6.1 The Small Business Service has been consulted about this proposal.

6.2 Currently, the requirements of food hygiene legislation in general do not necessarily reflect the situation in smaller businesses. Prescriptive requirements have been included that reflect the position in larger business and this has led to attempts to deal with this situation through the application of derogations against the requirements. The approach of this proposal however, by removing prescription, means that rules can be applied to all business sizes appropriately. Controls will be more reflective of risk and targeted on critical points, moving away from mechanistic compliance.

6.3 A number of small and medium-sized businesses (SMEs), or their representative organisations responded to the consultation. In addition, in conjunction with the Small Business Service (SBS), the FSA are visiting and talking to SMEs. At the end of March 2002, four small retail businesses which sold fresh, chilled and preserved foods were visited. These visits were arranged with the Rural Shops Alliance. All were registered with the Local Authority (LA), or the LA was aware that they were operating. All received visits by Environmental Health Officers which they found a useful source of information and advice. Although the businesses lacked knowledge of HACCP principles, they were identifying hazards and taking action to control them. Temperatures were controlled, checked and, in most cases, records kept. The businesses regarded the proposals as reasonable and proportionate, and did not consider that the proposals carried undue cost implications. The most common response was that the new requirements reflect measures businesses already undertake as part of normal operations. All accepted that the financial consequences of a food poisoning incident being attributed to a business could be very serious, and threaten its existence. The businesses encouraged the FSA to provide simple, straightforward and easy to access information. Such information is a major part of the FSA HACCP strategy independent of these proposals. It is intended to continue with further consultation and visits to SMEs.

6.4 Most other concerns expressed by representatives of small businesses can be accommodated through the appropriate interpretation of "small" and "local" in the proposals. This is particularly important in relation to sales of small quantities of game meat to the final consumer or local retail outlets.

7. Competition Assessment

7.1 We do not expect adoption of the proposals in line with the UK negotiating objectives to have an adverse effect on competition.

7.2 The new legislation will apply equally to all new and existing businesses and most of the requirements relating to production controls and monitoring are already likely to be used as the industry standard. Whilst businesses may incur some adjustment costs arising from changes to the hygiene requirements, these are not expected to have implications for competition. Where substantial costs to business are likely to result, they would be proportionate to the size of business and would not

be sufficient to raise concerns for competition. There is no evidence that there is likely to be any significant change in market concentration following the introduction of this legislation.

8. Enforcement and sanctions

8.1 It is very difficult to estimate the precise costs and benefits of the proposals to enforcement agencies. The proposals will simplify and greatly reduce the volume of EU legislation that controls food hygiene, and do much to rectify anomalies that have made enforcement difficult. Because HACCP-based procedures lend themselves to audit, and should not require constant supervision, enforcement resources could be targeted more effectively; e.g. certain enterprises may be identified as low-risk and visited less frequently. There would be a benefit to enforcement authorities from any reduction in food poisoning incidence leading to fewer post-incident investigations. For these reasons, there may be a reduced burden on local authorities in the longer term, although it is not possible to rule out the possibility that there may be some additional start-up resource implications.

8.2 Research has provided widely varying results on the costs to enforcement agencies. In one case (**Annex F**) it estimated minimal increased training costs for enforcers of £118,000 whereas a second project (**Annex J**) indicated costs in the region of £32.5 million. The second project recognised that the estimate was based on information from less than 1% of local authorities and was unlikely to be at all accurate. The revised third proposal contains implications for enforcement authorities that are explored in a separate RIA.

8.3 Through the FSA's strategy for wider implementation of HACCP-based procedures, it is planned to maximise the role of local authorities in helping businesses apply centrally developed guidance in a practical way. Enhanced guidance and further Agency training will be provided to help enforcers assess the effectiveness of HACCP-based controls. This work should go a long way to smoothing the transition in the duties of enforcement authorities demanded by the proposals. Although the HACCP strategy will greatly help, implementation is not dependent upon the outcome of the strategy. It is accepted that there may be some additional costs in terms of training enforcement officers as envisaged in **Annex F** and a cost has been indicated in the summary of £0.2 million.

9. Monitoring and review

The intention is to develop this assessment in the light of developments and, in particular, the ongoing EU negotiations. The Regulatory Impact Assessment will be updated on an ongoing basis in the light of the continuing consultations and further research. The proposals include a revision clause under which the Commission will report to the European Parliament and the Council on the implementation of the Regulation after five years of its implementation. This is a worthwhile exercise where the lessons of experience can be learned and, if appropriate, amendments can be proposed. UK stakeholders will be consulted on the review process.

10. Consultation

(i) Within Government

10.1 Other Government Departments were consulted on the proposal through the Ministerial Sub-Committee on European Issues (EP). The Committee cleared the proposed UK negotiating lines and are being kept up-to-date with developments. Officials have had more detailed contacts with Defra and Home Office on specific issues.

(ii) Public consultation

10.2 Thorough consultation with stakeholders was initiated in July 2000. This included issuing approximately 2000 consultation packs, supported by an initial draft RIA, and posting the documents on the FSA web-site. Some 150 responses were received. A summary of the comments received was posted on the FSA web-site. Consumer groups have generally welcomed the strategic direction of the proposals, especially with regard to a farm to fork approach, a HACCP-based food safety management approach and simplified legislation. The food manufacturing and retailing industries represent the most diverse group of stakeholders. There is widespread support for the concept of simplifying the legislation and removing the inconsistencies that have developed in the different sectors. There is a general belief in these sectors that the proposals do not go far enough to simplify the legislation, the argument being that, if a HACCP-based approach is adopted, more of the prescription could be removed. The multi-national based companies, in particular, welcome the legislation taking the form of a Regulation rather than a Directive on the basis that a Regulation would promote more consistent legislation throughout the Community. Many respondents expressed concerns about how the proposals might impact on smaller businesses, particularly how the application of HACCP-based food safety management procedures can be effective and proportionate in these circumstances. The results have been used to develop the UK negotiating strategy and the majority of the major concerns have been successfully addressed.

10.3 Separate consultation on the re-issued and revised third proposal was undertaken, with interested parties both internal and external, in August 2002. All of the stakeholders who responded to the original consultation and thereby indicated an interest and, additionally, to stakeholders identified as having an interest in the sector specific subjects covered were contacted and asked for their views. The consultation document was also posted on the Food Standards Agency website for wider access. This draft Regulatory Impact Assessment has been amended in the light of the consultation.

11. Summary and Recommendation

11.1 The proposals are likely to have some financial implications for most sectors of the food chain. As initially assessed, costs to business across all of the sectors affected (c.800,000 businesses) are likely to be in the region of £200 million in the first year and £150 million per year thereafter. This includes one-off costs in the

retail and catering sectors of approximately £5 million for start-up and training requirements indicated in one piece of research. Additional costs to enforcement authorities, in terms of additional training, are likely to amount to approximately £0.2 million per year. The costs identified, however, should be reduced significantly by the changes negotiated to the proposals by the UK as set out in paragraph 3.2 above.

11.2 The monetary benefits, in basic foodborne disease reduction terms, are thought to be in the region of £15.1 to £75.4 million per year assuming that the new requirements result in a 1% to 5% reduction in food poisoning incidents. Those benefits are likely to build up over a number of years and will outweigh costs in less than a 10 year period in the case of either a 3% or 5% reduction scenario (See **Annex E**). The 3% scenario developed in **Annex E** has been used for indicative purposes in producing the summary in TABLE 1.

11.3 The recommendation is to continue to pursue agreement of the proposals in line with the negotiating line agreed by EP Committee (as Option (4) in the earlier versions of the RIA). It would introduce a hazard-based approach at primary production and consolidate HACCP-based food safety management procedures throughout the remainder of the food chain in a flexible and pragmatic manner.

11.4 Although the summary (TABLE 1) below indicates that the total benefits identified are greater than costs over a 10 year period, the major part of the costs fall to business, whereas benefits are more widespread across society. However, the UK line is justified on the basis of the paramount importance of protecting public health by the full but flexible and proportionate application of HACCP-based procedures. The proposals, introduced in a flexible and pragmatic manner, provide the opportunity to improve food safety management. Food safety management based on HACCP-based procedures has been promoted by the FSA (earlier by DH and MAFF) independent of the EU proposals. The costs outlined in this RIA could be significantly reduced depending upon how implementation the FSA HACCP strategy can be funded, although implementation is not dependent upon it. TABLE 2 provides information on the major elements of the evidence on costs and benefits used to produce TABLE 1 in relation to the UK negotiating position.

TABLE 1 - Food Hygiene Legislation – Summary of Evidence on Costs and Benefits

Col. 2 - Costs are higher in the first year and lower in subsequent years;
 Col. 3 - Benefits are a reduction of 3% in indigenous foodborne illness in the first five years and constant thereafter.

Year	Cost £ million	Benefits (3% p.a.) £million
1	200	45
2	150	90
3	150	136
4	150	181
5	150	226

6 to 10	150	226
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The year one value over 10 year deflated by 3.5% p.a. of the stream of costs is £1341 million and the value of the stream of benefits is £1510 million. Over ten years benefits outweigh the costs by some 13%. The break-even point, when costs are equal to benefits is after about eight years.

TABLE 2 - Food Hygiene Legislation – Summary of Evidence on Annual Costs and Benefits

(£million)		Agreed UK Negotiating Position
Costs	Primary production	29
Year one	Retail	67
	Catering	103
Year 2 and after	Retail	46
	Catering	69
	Production and processing	5
	Enforcement	0.2
Benefits	Disease reduction	15.1 – 75.4 1% - 5%

12. Timetable

The proposals were presented by the European Commission to the Agriculture Council on 17th July 2000. Political agreement to a Common Position on First Reading for the first and second proposals has been reached. The prospect is that this will be achieved for the remaining elements of the package at Agriculture Council on 22-23 July. The date of application is the main outstanding UK issue to be resolved. Officials have taken opportunities throughout the negotiations to stress the importance of this. The UK will pursue a practical implementation timetable, consistent with the assurance of public health protection. It will be necessary for authorities and industry to develop relevant guidance literature, training and advice. The proposals currently indicate that the measures will not come into effect until 1 year after its adoption, but the UK would intend to argue for a minimum period of 2 years. The proposals have cleared UK Parliamentary Scrutiny.

PROPOSALS TO SIMPLIFY AND CONSOLIDATE EU FOOD HYGIENE LEGISLATION - Draft instruments concerning 5 linked proposals.

PROPOSAL 1 for a Regulation of the European Parliament and of the Council on the hygiene of foodstuffs (2000/0178 (COD))

1. This proposal applies to the production of all foodstuffs (including products of animal origin). It would extend the existing principles embodied in Council Directive 93/43/EEC, namely:

- the paramount concern to protect human health,
- the use of procedures based on HACCP principles (but not necessarily HACCP *per se*) to identify, control and monitor critical food safety points in food businesses,
- the possibility of adopting microbiological criteria and temperature control measures in accordance with scientifically accepted principles,
- the development of codes of good hygiene practice,
- the monitoring of food hygiene by the competent authorities of the Member States,
- the obligation on food business operators to ensure that only foodstuffs not harmful to human health are placed on the market.

2. The proposal would introduce a requirement for all food business operators (other than primary producers) to operate fully documented food safety management procedures based on HACCP principles.

3. The proposal seeks to ensure good hygiene practice throughout the food chain, starting with primary production in order to provide a farm to fork approach to food safety. Primary producers, while not subject to the requirement to operate procedures based on HACCP principles, would be required to control hazards in the interests of public health protection, and to retain records relating to those controls. The proposal provides that methods of doing so should be addressed in guides to good practice in combination with those already required under existing relevant legislation.

4. The proposal would require:

- the registration of food businesses by the competent authority. In certain cases, where the competent authority wished to have assurances about compliance of food businesses with the hygiene rules prior to starting-up such business, the prior approval of the food business concerned would be required; and
- that food businesses must keep adequate records.

The definition of “food business” in the proposal would mean that these requirements applied as appropriate to primary producers.

5. The proposals would allow a certain flexibility in applying controls to small to medium sized enterprises (SMEs), especially those situated in regions with special

geographical constraints (mountains, remote islands etc), and for the manufacture of traditional products. This proposal would allow Member States to grant certain derogations for SMEs, subject to European Commission “approval”, as long as the overall objective of food hygiene were not compromised.

6. The proposal would require that imports into the EU would need to adhere to (at least) equivalent standards.

PROPOSAL 2 for a Regulation of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin (2000/0179 (COD))

7. The legislation laying down public health controls in this area is currently embodied in food-sector specific Directives. These date back over almost 40 years and naturally reflect the understanding of, and approach to, public health issues at the time they were made. In general this has meant the adoption of a detailed, prescriptive approach with specific standards laid down for e.g. the construction of premises, hygiene measures and production processes. Whilst these specific rules have proved reasonably successful in protecting public health, it is now recognised by the European Commission that they are unnecessarily burdensome, inconsistent, complicated and contain repetitions of similar or identical requirements.

8. The proposal aims to reduce and rationalise the detailed prescriptive requirements applying to products of animal origin. Certain derogations for SMEs serving the local market or those situated in regions with particular supply constraints are proposed, subject to the need to ensure food safety.

PROPOSAL 3 for a Regulation of the European Parliament and of the Council laying down detailed rules for the organisation of official controls on products of animal origin intended for human consumption (2000/0180 (COD))

9. The detailed proposals for official controls on products of animal origin covers such issues as qualifications of inspectors, frequency of inspections, detailed procedures for both ante and post-mortem meat inspection and record keeping. There would be provision for some relaxation of the current requirements for veterinary supervision in licensed meat premises.

PROPOSAL 4 for a Council Regulation laying down the animal-health rules governing the production, placing on the market and importation of products of animal origin intended for human consumption (2000/0181 (CNS))

10. This proposal deals with animal-health rules and is the responsibility of DEFRA.

PROPOSAL 5 for a Directive of the European Parliament and of the Council repealing certain Directives on the hygiene of foodstuffs and the health conditions for the production and placing on the market of certain products of animal origin intended for human consumption, and amending Directives 89/662/EEC and 91/67/EEC. (2000/0182 (COD))

11. This measure would repeal the existing EU legislation and amend other related legislation.

EXISTING EU FOOD HYGIENE LEGISLATION

Council Directive 64/433/EEC of 26 June 1964, on health conditions for the production and marketing of fresh meat, as last amended by Directive 95/23/EC.

Council Directive 71/118/EEC of 15 February 1971, on health problems affecting the production and placing on the market of fresh poultry meat, as last amended by Directive 97/79/EC.

Council Directive 77/96/EEC of 21 December 1976 on the examination for trichinae (*trichinella spiralis*) upon importation from third countries of fresh meat derived from domestic swine, as last amended by Directive 94/59/EC.

Council Directive 77/99/EEC of 21 December 1976 on health problems affecting the production and marketing of meat products and certain other products of animal origin, as last amended by Directive 97/76/EC.

Commission Directive 89/362/EEC of 26 May 1989 on general conditions of hygiene in milk production holdings.

Council Directive 89/437/EEC of 20 June 1989 on hygiene and health problems affecting the production and the placing on the market of egg products as last amended by Directive 96/23/EC.

Council Directive 91/492/EEC of 15 July 1991, laying down the health conditions for the production and the placing on the market of live bivalve molluscs, as last amended by Directive 97/79/EC.

Council Directive 91/493/EEC of 22 July 1991, laying down the health conditions for the production and placing on the market of fishery products, as last amended by Directive 97/79/EC.

Council Directive 91/495/EEC of 27 November 1990, concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat, as last amended by the act of accession of Austria, Finland and Sweden.

Council Directive 92/45/EEC of 16 June 1992 on public health and animal health problems relating to the killing of wild game and the placing on the market of wild game meat, as last amended by Directive 97/79/EC.

Council Directive 92/46/EEC of 16 June 1992, laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products, as last amended by Directive 96/23/EC.

Council Directive 92/48/EEC of 16 June 1992 laying down the minimum hygiene rules applicable to fishery products caught on board certain vessels in accordance with Article 3(1)(a)(i) of Directive 91/493/EEC.

Council Directive 92/118/EEC laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/445/EEC, as last amended by Directive 97/79/EC.

Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs.

Council Directive 94/65/EC of 14 December 1994 laying down the requirements for the production and placing on the market of minced meat and meat preparations.

Hazard Analysis and Critical Control Points (HACCP)

Background to HACCP

1. HACCP is a system of food safety management based on the prevention of food safety problems. HACCP is internationally accepted by governments and the food industry alike as the system of choice in the management of food safety in food businesses. It provides a documented, structured approach to ensuring food safety and places a requirement on food businesses to identify, manage and control hazards inherent in their food handling and production process. It is proportionate and flexible and offers the best protection to consumers when implemented effectively. In line with modern thinking on a wide variety of matters, it is a risk-based system. Wider application of effective HACCP based controls is considered as key to the FSA achieving its wider food borne disease targets. The UK has been one of the leading advocates of HACCP in the EU.

2. Increasing uptake of HACCP was confirmed as Government policy when accepting the recommendations of the Pennington Report into the 1997 *E.coli* O157 outbreak in Scotland. Indeed, the need to overhaul European hygiene legislation was a specific recommendation of the Pennington Report that was accepted by Government. In addition, HACCP is promoted by the main international bodies with an interest in this field, e.g. the WHO and the Codex Alimentarius Commission. In recent years a clear international trend has developed to adopt a HACCP approach to food safety.

3. The FSA has a publicly declared Service Delivery Agreement target for 30 per cent of food businesses to be operating documented HACCP based controls by April 2004. The target is aimed at complementing and assisting wider Agency action to reduce food-borne disease by 20 per cent by April 2006. The FSA has a strategy in place to achieve this target.

The Proposal

4. The proposal will require food business operators to put in place, implement and maintain a permanent procedure, or procedures, based on the HACCP principles. The HACCP principles are set out in paragraph 6 below. It is important to recognise that the requirement is not for full HACCP systems. Food businesses will need to operate procedures based on the principles. The legislation is to be structured this way so that it can be applied pragmatically in all food businesses regardless of their type or size. The FSA is working on a compliance statement as part of its HACCP strategy and this will provide the basis for further guidance on compliance in individual food business sectors.

Current Status of HACCP and Hazard Analysis in the UK

5. For the vast majority of the businesses affected by the proposals, the application of procedures based on HACCP principles is not a new requirement. In most areas of food production the law requires that the main elements of HACCP should be being applied already. Since the implementation of the General Food

Hygiene Directive in 1995, food businesses including retail and catering businesses (by far the biggest two sectors in terms of numbers of businesses affected), have been required to analyse and control hazards on the basis of applying five of the seven HACCP principles. In addition, many of the sector specific hygiene directives require manufacturers to operate 'own checks', based on HACCP principles. What is new in the proposals as they apply to all food businesses is the requirement to verify that the procedures in place actually work. Businesses operating under General Food Hygiene law, and some sector specific law, will also have to keep documentary records of the procedures in place. Regardless of the present legal requirements, many businesses that are applying the five principles of HACCP will actually be keeping documentary records for their own purposes. The proposals will remove a degree of prescriptive detail contained in the current legislation and so will mean a reduced compliance burden for some sectors of the industry. For example, in the case of slaughterhouses, the proposals make no additional requirements of operators, but do clarify what is required of all food businesses as opposed to what is specific to slaughterhouses. **Annex H** provides an overview of HACCP uptake by the main sectors. **Annex I** provides an overview of the current legislative requirement to have hazard analysis systems in place.

6. The HACCP principles are:
 - a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;
 - b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;
 - c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
 - d) establishing and implementing effective monitoring procedures at critical control points;
 - e) establishing corrective actions when monitoring indicates that a critical control point is not under control;
 - f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and
 - g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.

THE COST OF INDIGENOUS FOODBORNE DISEASE (England and Wales)

Introduction

The aim of food safety regulations is to ensure the production of safe food and reduce the incidence of foodborne disease. The benefits of any new food safety regulation are mainly any consequent reduction in indigenous foodborne illness, i.e. illness due to food consumed within the country. The economic savings due to the reduction in indigenous foodborne illness therefore measures the benefits of the new regulation.

This note provides an estimate of the total economic cost of foodborne illness at a baseline year, the year 2000. Any proportionate reduction in foodborne illness attributed to the new regulations can then be estimated using this benchmark.

The amount of indigenous foodborne disease

In a recently published paper researchers at PHLS Communicable Disease Surveillance Centre (CDSC)⁴ estimate the number of cases of Indigenous Foodborne Disease (IFD) in England and Wales in 1992, 1995 and 2000. This information is available classified by foodborne pathogen (16 bacteria, 3 parasites, 3 viruses and those of unknown origin) and for each pathogen there are estimates of the total number of cases, cases presented to a GP, hospital admissions, hospital bed days and deaths (data in table1, Appendix 2).

The CDSC estimates are based on data from routinely available surveillance data, special survey data (including the IID Study discussed below), hospital episode statistics and National Statistics mortality data. Adjustments to the data were made to reflect available estimates on the proportion of total disease, by pathogen, confirmed in laboratory tests and included in the surveillance data. A further adjustment was made to deduct foodborne disease imported through foreign travel.

For the purpose of costing the effectiveness of any change in UK food safety legislation the relevant measure is the indigenous foodborne disease level and not all foodborne illness. In estimating the cost of indigenous foodborne disease the CDSC estimates will be used as a base for the quantity and outcome of foodborne illness in the year 2000 and these quantities will be matched by a price vector based on available estimates on the cost of such disease, taking into account the outcomes of such illness.

The cost of foodborne disease

The cost of illness, including foodborne disease, can be assumed to comprise two main components: (i) the actual, out of pocket, costs of the illness to individuals, employers and the NHS and (ii) the additional monetary value to individuals of the pain, grief and suffering due to the disease. Information on actual costs is based on data collected from individuals and includes expenses of ill individuals and their carers, lost output and the costs to the NHS. Estimates of the monetary value individuals attribute to the pain, suffering and grief due to

⁴ Adak G.K., Long S.M., O'Brien S.J. Trends in Indigenous Foodborne Disease and Deaths, England and Wales - 1992 to 2000 (*Gut* 2002; 51: 832 - 841).

illness are based on studies of individuals' willingness to pay (WTP) to reduce the risk of death or of getting ill.

(i) Actual price/cost of illness

A source of information on the actual cost of all intestinal illness is available from the relatively recent **Report of The Study of Infectious Intestinal Disease in England** (IID study)⁵. This comprehensive study includes survey data collected between August 1993 and January 1996 (centred in 1994/5). The study includes estimates of the actual costs of all IID for a long but not complete list of intestinal diseases, for example Listeria is missing and though the number of cases of Listeria is small, 194 cases estimated in 2000, the mortality rate is high, 68 deaths in 2000⁶. The costs are for all IID, including both foodborne diseases and those transmitted in other ways. To utilise these estimates in the RIA, an assumption is made that the average cost of foodborne disease is similar to that of all IID.

The design of the IID Study was complex and aimed to answer a range of questions including estimates of the total number and proportion in the population suffering from IID, the proportion that present to GP and the proportion where the infectious organism is identified. Costs of IID were estimated from samples of individuals and provide details on the financial burdens incurred by the NHS, individuals and employers.

The IID study collected information on individual for a period of 6 months and does not include information on long-term consequences of IID. The study does not provide information on cases of permanent incapacity due to the illness nor does it include any cases of death. Estimates of the actual costs based on this data are therefore likely to be biased downward.

For the RIA we would ideally want an estimate of the total cost of illness at some base date and a breakdown of the costs by foodborne organism. Such a breakdown would allow monitoring or estimating the cost of reducing specific sources of foodborne disease due to the introduction of the new legislation. However, such detailed estimates are not available. The IID study only includes details of costs for a few pathogens⁷ and it is not possible to estimate the cost of total IFD by adding up the costs of illness attributed to each of the pathogens. The estimates below are, by necessity, based on the average cost estimates for all IID for two groups, patients who visit a GP and patients who do not visit a GP.

The costs in the IID study were centred in 1994/5 and to apply them to estimate the costs of IFD in the year 2000 the costs are uprated using appropriate price indices.

Estimate of actual cost of IFD, England and Wales 2000

Table 1 in Annex 1 presents the CDSC estimates of Indigenous Foodborne Disease in 1995 and 2000. The estimated total number of cases of IFD in 2000 was 1,338,772 of these 368,516 visited a GP and 970,256 did not.

For the 368,516 cases who visited a GP the actual cost of illness is based on the GP control component in the IID Study. This component is a sample of 1652 individuals with intestinal disease who visited their doctor and is considered to be the more accurate source of information in the IID Study for this group⁸.

For the 970,256 individuals who suffered from IFD in 2000 and did not visit their doctor the only source of information on costs is from the population or community component in the IID Study. This component is a smaller sample of 397.

Costs in the IID Study were classified into three categories: costs to the NHS including GP, laboratory and hospital costs, direct personal cost and costs of lost output which were estimated by lost earnings. For our purpose, of estimating the cost of illness in 2000, each of these components has to be uprated by a suitable price index from 1994/5, taken as Q4 1994, to mid 2000.

For the NHS cost the price index used is the NHS Composite Inflation Index (see Annex 3 for information on uprating factors) produced by DOH. This index includes the prices of both primary and secondary NHS care and is considered to be the most appropriate of available health care price indices. The direct personal costs borne by the ill person and their carers are uprated by the RPI index excluding housing costs between Q4 1994 and Q2 2000. Lost earnings are uprated by the rise in the Average Earnings Index between Q4 1994 and Q2 2000.

The estimated total actual costs in 2000 of those who suffered IFD and visited a doctor are estimated as £123 million in 2000 prices and for those who did not visit a doctor the total cost are estimated as £41 million (detailed calculations are in Annex 1). The estimated **overall total actual cost is £164million in 2000**. As explained above, the estimate of total actual costs is based on a study that followed individuals for a period of six months and do not include the cost of cases of long term illness. The total estimate of actual cost is therefore likely to be biased downward.

The actual, out of pocket, costs do not include the monetary value of pain, grief and suffering due to illness, injury and death. Such costs are usually included in Cost/Benefit analysis and RIAs of government policy, and to these we turn next.

(ii) Monetary value of pain, grief and suffering due to IFD, England and Wales 2000

Monetary value for pain, grief and suffering are included in RIAs produced by Department for Transport Local Government and the Regions (DTLR) and the Health and Safety Executive (HSE). Such values are part of the estimates of the cost of road accidents and illness due to work. The basis for estimates of the cost of pain grief and suffering is the measurement of individuals' willingness to pay (WTP) to reduce the risk of premature death due to road accidents.

For example⁹, consider a safety improvement expected to reduce the number of premature deaths in a year by one in a population of 100,000. Each person's risk of dying is thus reduced by an average of 1 in 100,000. Assume people are prepared to pay (on average) £50 extra a year to effect the safety improvement. For each death prevented there are a 100,000 people willing to pay £50, or a total of £5 million: the Value of Fatality Prevention (VFP) is

There are practical difficulties involved in determining appropriate values and the value used here is the one formally adopted by DTLR (formerly DETR) and also used, with some modifications, by HSE¹⁰. This VFP is based on a major empirical study and was subjected to public consultation. The final figure chosen by DTLR is towards the bottom end of the potential range suggested by the research¹¹.

The VPF, and related values for preventing casualties of varying severity, are updated annually and published by DTLR. The latest one is for 2000 (HEN 2000)¹² where the estimate of the VPF is £1,144,890 in June 2000 prices. This is the sum of lost output (£393.580) medical and ambulance cost (£670) and human cost (£750, 640).

The HSE uses the WTP element of the DTLR estimates of the VPF to derive an estimate of the monetary value of pain, grief and suffering in the case of death. This is calculated as the human cost component of the VPF plus 80% of the lost output component and yields (detailed calculations in Appendix 1) an estimate for the monetary value of pain, grief and suffering in a case of death in 2000 of £1,065,504 (June 2000 prices). HSE add this cost to independent estimates of actual, out of pocket, costs to individuals, employers, the NHS and other costs central and local government to estimate the total cost of a fatality due to work accident or illness.¹³

HSE also produces estimates of the cost of pain, grief and suffering for ‘minor cases of ill health’, defined as those ill for up to 7 days, for ‘other cases of ill health’, defined as those ill for more than 7 days, and for ‘permanently incapacitating ill health’. The costs for minor and other illness is derived using the ‘standard gamble’ approach, a variant of the WTP approach, where individuals are asked what they are willing to pay to reduce the risk of varying severity of illness or injury¹⁴. The latest published estimates are for Q3 1999¹⁵ and these are uprated to Q2 2000 by the rate of increase of nominal GDP per capita between the two periods¹⁶ (see appendix 1 for detailed calculations).

The estimated monetary values of pain, grief and suffering for the four levels of severity of illness, uprated to mid 2000 are:

- | | |
|--|------------|
| 1. Minor illness of up to 7 days | £155 |
| 2. Illness lasting more than 7 days | £1,960 |
| 3. Permanently incapacitating ill health | £188,870 |
| 4. Death | £1,065,504 |

Matching quantities on the number of cases of IFD occurring at each level of severity of illness utilises the estimates by PHLS/CDSC, information from the IID Study on the duration of intestinal illness and a few additional assumptions.

The CDSC paper provides information on the total number of IFD cases and a breakdown into those cases presenting to a GP (368,516) and those not visiting a GP (970,256). The IID Study estimates that 97% of those not seeing a GP are ill for up to 7 days and 3 % for longer than 7 days¹⁷. For those who do see a GP it is estimated that close to 60% are ill for up to 7 days while 40% are ill for longer than 7 days¹⁸.

There is no information on the number of cases that become permanently disabled due to IFD but CDSC estimate that there were 480 cases of deaths due to IFD in the year 2000. A conservative assumption is added that the number of cases of permanent disablement is the same, 480.

In the calculations of costs it is also reasonably assumed that all cases resulting in permanent disability or death consulted a GP.

The monetary value of pain, grief and suffering from IFD is estimated at a total of £1,126 million, the (rounded) sum of:

£145.9 million	for cases that do not see a GP and ill for up to 7 days;
£ 57.1 million	for cases that do not see a GP and ill for more than 7 days;
	for cases that see a GP and ill for up to 7 days;
£287.9 million	for cases that see a GP and ill for more than 7 days;
£ 90.7 million	for cases of permanent disability;
£511.4 million	for cases of death;

(Detailed calculations of the above estimates are provided in Appendix 1.)

The estimated total cost of IFD in England and Wales is the sum of (i) the estimated actual, out of pocket, cost of £164 million and (ii) the monetary value of pain, grief and suffering due to such illness of £1,126 million, a total of £1,290 million in the year 2000.

The average cost per case is £1,290 / 1,338,772 = £964 per case.

Assuming that the incidence and outcome of IFD is the same in Scotland and Northern Ireland as in England and Wales, the estimated total cost of IFD can be scaled up to UK level, by the ratio of the population in UK to that in England and Wales. The estimated total cost of IFD in the UK in 2000 is £1,456 million.

¹ Adak G.K., Long S.M., O'Brien S.J. Trends in Indigenous Foodborne Disease and Deaths, England and *Gut* 2002; 51: 832 - 841).

² *A Report of the Study of Infectious Intestinal Disease in England* (2000) Food Standards Agency, HMSO.

³ Source of information see (i) above.

⁴ There are estimates of the average costs of cases of Salmonella (£606), Campylobacter (£315), Enterovir E. coli (£214), C. difficile (£287), Rotavirus (£164) and SRSV (£177) in 1994/5 prices.

⁵ Advise by Dr J Roberts, the economist on the IID study team.

⁶ Quoted from HSE document *GAP 23: Regulatory Impact Assessment – Policy Appraisal and Evaluation. Version: 3rd version, January 2001.*

⁷ Though the HSE has not formally endorses any single VPF figure.

⁸ For further details refer to GAP 23 above and to HSE Book published by HMSO (1999), *The Costs to Britain of workplace accidents and work-related ill health in 1995/6.*

⁹ DTLR Highways Economic Notes No1: 2000.

¹⁰ It is relevant to note that while the HSE uses this statistical value of life for most death cases, for death due to work related cancer a value double this estimate is used to reflect the particular aversion of people (the dread factor) to this illness.

¹¹ See HSE *The cost to Britain of workplace accidents* (reference in viii above) pages 32 & 33 and Appendix 4 pages 77 & 78.

¹² Source *GAP 23, January 2001*, reference iii above.

¹³ See paragraph 10 in HEN2000, reference vi above for method of uprating WTP estimates.

¹⁴ Data from the Population Component of the IID Study matching diagram A4.48, provided by Dr J Roberts.

¹⁵ Same as xiv to match diagram A4.44.

Lost earnings of ill person and carers £139.97 +£35.98 = £175.95 * 1.253 (Average Earnings Index 1994Q4 to 2000Q2) = £220.5

Average actual cost for those visiting a GP = £334.8

Total cost for those visiting a GP £334.8 * 368,516 = £ 123 million.

[Note that these costs do not include any estimate of direct cost for cases of fatality and those ill for more than six months since the IID Study, on which the above costs are based did not include such cases. Some, partial, correction for these missing costs is provided at the end of the calculations in this appendix.]

*{Due to rounding, the total actual cost of those visiting a GP is £123 million, even if the lost earning of those dying or permanently disabled (2*480) are deducted from the calculation above – see correction at end}*

For those not visiting a GP the average cost of illness is based on the cost in the Population/community component in the IID Study (see Table 8.7). The average cost comprise of:

Direct cost £3.72 * 1.1355 (RPI) = £4.22

Lost earnings £17.21 + £13.38 = £30.59 * 1.253 (AEI) = £38.33

Average cost for those not visiting a GP = £42.55

Total actual cost for those not visiting a GP $£42.55 * 970,256$ =£41million

Total actual cost for all cases of IFD £123 + £41 =£164million

(ii) Additional monetary value of pain, grief and suffering based on estimates of values by DTLR as used by HSE to add monetary value for pain, grief and suffering to actual cost of work related illness and death.

HSE uses four classifications of the severity of illness: minor illness lasting up to 7 days, other illness lasting more than 7 days, permanent disability and death.

For death the estimates of the monetary value of pain, grief and suffering used in this paper are taken from components of the cost of fatality for June 2000 published by DTLR in the Highways Economic Notes No1: 2000. The components of Human costs and Lost output are combined, using the formulae used by HSE:

Value of pain etc. in case of death = Human cost + 0.8 * Lost output = £750,640 + 0.8* £393,580 =

The monetary value of pain grief and suffering of permanent disability, other ill health and minor illness are taken from the latest published estimates for the third quarter of 1999 by HSE (GAP23: Regulatory Impact Assessment – Policy Appraisal and Evaluation, 3rd Version, January 2001). These estimates are uprated from Q3 1999 to Q2 2000 by the nominal growth of GDP between the two periods, an addition of 3.15%. (No correction is made for change in population since the period is short.)

The monetary values of pain grief a suffering for various severity of illness are:

Minor illness in Q3, 1999 £150 * 1.0315 = £155 in Q2, 2000;

Other illness in Q3, 1999 £1,900 *1.0315 = £1,960 in Q2, 2000;

Permanent incapacitating ill health Q3, 1999 £183,100 * 1.0315= £ 188,870 in Q2, 2000.

Quantities of illness of various severities have to be matched to the above estimates of costs per case. Quantities estimates are based on the CDSC estimates of the total number of IFD in the year 2000 (data in Appendix 2).

The CDSC researchers estimate that there were 480 cases of death from IFD in 2000.

There is no information on the number of cases of permanent incapacity. An assumption is made that the number of cases of permanent incapacitating IFD is of a similar scale to that of fatality, 480 cases in 2000. There is some evidence from the US for a few pathogens on the level of very long-term illness and this suggests that our assumption is reasonable and may be conservative.

There are in total 1,338,772 of cases of IFD in 2000 (CDSC estimates).
Of this total 368,516 see a GP and 970,256 don't see a GP.

Using information collected in the IID Study, these totals are divided into cases that are ill for up to 7 days and those that are ill for longer than 7 days:

For those not seeing a GP 97% are ill for up to 7 days and 3% for longer (population component, diagram A4.48, data provided by authors).

For those presenting to a GP some 60% are ill for up to 7 days and 40% are ill for longer (GP component, diagram A4.44, data provided by authors).

Applying these proportions we get:

Cases not seeing a GP and ill for up to 7 days	$970,256 * 0.97 = 941,148$
Cases not seeing a GP ill for longer than 7 days	$970,256 * 0.03 = 29,108$
Cases seeing a GP and ill for up to 7 days	$368,516 * 0.6 = 221,110$
Case seeing a GP and ill for longer than 7 days	$368,516 * 0.4 = 147,406$

Assuming that all cases of death and permanent incapacity see a GP and are ill for longer than 7 days, we deduct 960 (=480+ 480) from the last category to yield:
Cases seeing a GP and ill for longer than 7 days, net $147,406 - 960 = 146,446$.

Multiplying quantities by prices, costs, we get the following monetary values in year 2000 for pain, grief and suffering for the various categories of IFD illness:

Mortality	480 cases * £1,065,504	= £511.4 million
Permanent disability	480 cases * £188,870	= £90.7 million
Not presenting to GP, up to 7 days illness	941,148 cases * £155	= £145.9 million
Not presenting to GP, more than 7 days illness	29,108 cases * £1,960	= £57.1 million
Presenting to GP, up to 7 days illness	221,110 cases * £155	= £34.3 million
<u>Presenting to GP, more than 7 days illness</u>	<u>146,446 * £1,960</u>	<u>= £287.0 million</u>
Total		= £1,126.4 million

[**Correction** for missing estimates of output, or expected income, of those suffering permanent disability and cases of fatality.

In the estimated direct cost there is no allowance for the lost output in cases where foodborne illness causes permanent incapacity or death. A minimal correction for cases of fatality is to add the 20% of estimated lost output not included already in the estimate of pain, grief and suffering in section (ii) above. This adds £37.8 million (=£78,716 *480 cases) to the total cost. There is no obvious source for an estimate of lost output in cases of permanent incapacity but since, by definition, those suffering

from permanent incapacity will not work again, a correction of similar order of magnitude to cases of mortality is used adding another £37.8 million to total cost.

The total correction for lost output for these two small groups is conservatively estimated at £75.6.]

The estimated total cost of IFD in England and Wales is the sum of (i) the estimated actual, out of pocket, cost of £164 million and (ii) the monetary value of pain, grief and suffering due to such illness of (rounded) £1,126.4 million, a total of £1,290.4 million in the year 2000. [Adding the correction for lost output of £75.6 brings this total to £1,366 million.]

The average cost per case is $\text{£}1,336 / 1,338,772 = \text{£}979$ per case.

To scale the estimates of total cost of indigenous foodborne disease in England and Wales to the UK level an assumption is added that the number and outcome of cases of IFD in Scotland and Northern Ireland is similar to that in England and Wales. The UK costs can then be calculated scaling up the costs in England and Wales by the ratio of their population to the UK population. The population ratio in 1999, the latest available data, was 59,501/52,690 thousand = 1.129 (source: Social Trends 2001 Table 1.1)

The estimates total cost of IFD in the UK in 2000 is:

1,336 million * 1.129 =1,508 million

Appendix 2

Estimates of Infectious Foodborne Disease*

TABLE 1

Infectious Foodborne Disease 2000

	Cases	GP Presentation	Hospital admission	Hospital day beds	Deaths
Bacteria					
Bacillus spp.	11,144	4,458	27	70	0
campylobacter spp.	359,466	171,174	16,946	62,701	86
C. perfringens	84,081	44,253	354	5,240	89
VETC 0157	995	995	377	2,149	22
Non VETC 0157	111	111	42	240	2
Other Escherichia coli	62,050	13,850	319	1,561	6
Listeria monocytogenes	194	194	194	3,473	68
Salmonellas	41,616	29,726	1,516	8,793	119
S. paratyphi	85	85	27	170	0
S.typhi	96	96	39	267	0
Shingella spp.	202	202	5	24	0
Staphylococcus aureus	2,276	910	57	69	0
Vibrio cholerae non 01/0139	126	63	5	19	0
Other vibrios	364	182	5	21	2
Yersinia spp.	45,144	3,858	216	1,901	1
Parasites					
Cryptosporidium parvum	2,063	1,086	39	145	3
Cyclospora cayatenensis	992	522	3	10	0
Giardia duodenalis	1,673	881	5	18	0
Viruses					
Astrovirus	17,291	3,930	12	46	4
NLV	57,781	9,172	37	143	9
Rotavirus	8,979	1,497	46	121	4
Unknown	642,043	81,271	488	1,365	65
<hr/>					
Total					

*Includes only pathogens
with foodborne disease
cases

Source: CDSC paper⁴

Appendix 3: Data and uprating factors

NHS Composite Inflation

Estimates of annual inflation increase of NHS total costs, percentages. Source: DOH

Increase from 1994/5, when data from the IID Study is centred to the latest available year 1999/00 and an assumed addition of 2% from the middle of 1999/00 (September/October) to mid 2000.

Base year 1994/5	% increase	Index (1994/5=100)
1995/6	3.7	103.7
1996/7	2.9	106.7
1997/8	2.1	108.9
1998/9	3.9	113.2
1999/00	4.5	118.3

Adding 2% for the period mid 1999/00 to mid 2000 the index is 120.6.

The uprating factor between 1994/5 and mid 2000 is 1.206.

Retail Price Index excluding housing

Source: National Statistics StatBase. Dataset Name:rpi1 Index of all items excluding housing (CHAZ), Quarterly series (update 12/2/02).

Index in 1994 4	142.4
Index in 2000 2	161.7

Uprating factor between the two periods $161.7/142.4 = 1.1355$.

Average Earnings Index

Source: National Statistics StatBase. Dataset Name: aei. Average Earnings Index for the Whole Economy, s.a. (LNMQ), Quarterly series (update 13/2/02).

Index in 1994 Q4	98.3
Index in 2000 Q2	123.2

Uprating factor between the two periods $123.2/98.3 = 1.253$.

Gross domestic product (GDP) at market prices

Source: National Accounts Table A1. GDP at market prices, s.a. £ million.

1999 Q3	224,686
2000 Q2	231,773

Uprating factor between the two periods $231,773/224,686 = 1.0315$.

BALANCE OF COSTS AND BENEFITS

Benefits

The benefits of the new regulations will mostly be due to the extension of full HACCP to all food businesses, that is the addition of verification and documentation of HACCP in those businesses currently required to apply only the first five principles of HACCP.⁵

Benefits from improved food safety will manifest themselves in a reduction of indigenous foodborne illness and the consequent savings in costs.

A way of getting a handle on the likely scale of benefits from the introduction of the new regulations is to examine the reduction in indigenous foodborne disease (IFD) over the last decade and consider how much of this reduction is likely to be due to the introduction of partial HACCP in 1995.

Estimates by CDSC of indigenous foodborne illness are of a total 2,869,753 in 1992, 2,365,909 in 1995 and 1,338,772 in 2000. The reduction between 1992 and 1995 was of 17.5% and between 1995 and 2000 of 43.5%. Though these estimates are approximate and annual variations in IFD from year to year can be expected, these reductions do indicate the likely scale of reduction in foodborne illness due to tightening food safety regulations.

The effect of introducing the new regulations can be expected to build up over a number of years as both businesses and the enforcement authorities improve the way in which the regulations are applied and checked. We assume that the full effect of the implementation of the new regulations will build up over five years and that a reduction of 5% a year will be achieved in this period with an overall effect of 25% reduction in IDF.

The benefits implications will be the following **savings** in costs in the UK (based on estimates in The Cost of IFD paper costing illness in 2000):

First year	£ 72.8 million
Second year	£ 145.6 million
Third year	£ 218.4 million
Fourth year	£ 288.3 million
Fifth year	£ 364.0 million
Every year thereafter	£ 364.0 million.

One important reason why the extension of HACCP to include the last two principles can be expected to bring about a significant improvement in foodborne illness is that the legal requirement for documentation should make the enforcement of all seven HACCP principles more effective.

⁵ Current requirements are the Food Safety (General Food Hygiene) Regulations 1995.

Costs

The main costs of the new regulations will be due to the extension of the last two principles of HACCP, verification and documentation, in catering and retail industry. Currently these businesses are only required to implement the first five principles of HACCP including identifying potential hazards and measures for their control, determining critical control points (CCP), establishing critical limits for each CCP, establishing a monitoring system and establishing corrective actions when monitoring indicated any CCP is not controlled.

A commissioned study of the cost of implementing the last two principles of HACCP in the retail and catering sectors estimates that the set up costs are very small. The **running costs** of verification and documentation are estimated at £170 million each year.

Costs and benefits

Comparing the costs and benefits the schedules look as follows (benefits in 2000 prices, costs in 2000 prices):

5% Scenario

Year	Cost £ million	Benefits (5% p.a.) £ million
1	170	73
2	170	146
3	170	218
4	170	291
5	170	364
Every year thereafter	170	364

To compare the two streams of costs and benefits a decision has to be made on the length of period and the rate of discount. The rate of discount given in the Green Book for use in evaluating Government policy is 3.5%. The length of time considered in evaluating policy depends on the nature of the policy. Large investment with a long period of pay off will indicate a longer horizon. Another indicator of a longer period is a situation with high labour turnover and a continual need for retraining. On balance a period of about 10 years seems appropriate for the policy introduced by the new regulations.

The year one value over 10 year deflated by 3.5% p.a. of the stream of costs is £1463 million and the value of the stream of benefits is £2429 million. Over ten years benefits outweigh the costs by some 66%. The break-even point, when costs are equal to benefits is after about four years.

3% Scenario

Col. 2 - Cost are higher in the first year and lower in subsequent years;

Col. 3 - Benefits are a reduction of 3% in indigenous foodborne illness in the first five years and constant thereafter.

Year	Cost £ million	Benefits (3% p.a.) £ million
1	200	45
2	150	90
3	150	136
4	150	181
5	150	226
6 to 10	150	226

The year one value over 10 year deflated by 3.5% p.a. of the stream of costs is £1341 million and the value of the stream of benefits is £1510 million. Over ten years benefits outweigh the costs by some 13%. The break-even point, when costs are equal to benefits is after about eight years.

This more conservative scenario has been used in the main assessment shown in Table 1 on page 16

**Work to inform the preparation of a Regulatory Impact Assessment
Verification and documentation of HACCP – Catering and Retail Sectors**

Drew Associates. Project B13, C, D, E Short Report. Project Code B 18005.

Executive Summary

This project examines the financial impact of the EU proposal to apply from 2004, verification and documentation procedures related to HACCP, in catering and retail businesses.

Methodology:

- a telephone survey of trade, enforcement, educational and other interests, to assess the response, level of support or opposition to the proposal;
- an assessment of food business costs in terms of time required for training, verification and documentation, using three businesses on which hypothetical calculations were based; and
- an estimate of the benefits of improved food safety.

The cost assessment is subject to uncertainty. Annual expenditure requirements of £103 million in the catering sector and £67 million in the retail sector have been estimated. A one-off training-time expenditure of £118,000 for local authority EHO's, is also estimated.

The food safety benefits are potentially large: in the region of £500 to £1000 million, or even more on some assumptions. These figures are based on what consumers would be willing to pay and are much larger than implied by DOH estimates of cost savings from reduced infectious intestinal disease (IID): about £2 to £5 million for each 1% reduction.

1. INTRODUCTION

The project remit was to examine the implications for the catering and retail food sectors of verification and documentation of the HACCP proposals. The Food Safety (General Food Hygiene) Regulations 1995 imposed the first five principles of HACCP on food businesses in the UK. Therefore the extra, anticipated costs, involves the necessity for verification and documentation procedures and enforcement by EHO's.

2. THE FSA STRATEGY

The FSA strategy for the wider implementation of HACCP and the FSA action plan, aims to achieve documented HACCP implementation in 30% of UK food businesses by April 2004. The extra cost implications arising from this have also been considered.

3. ASSESSING HACCP APPLICATION – CATERING/RETAIL SECTORS

3.1 Views of trade associations, local authority organisations, academic, professional bodies and individuals were sought on the EU proposal. Although in general there were no specific or strongly expressed views opposing the future increased HACCP requirements, there were concerns regarding documentation.

3.2 Overall, there was no serious criticism of the proposal to require verification and documentation procedures, but emphasis was placed on the need to balance the requirements and enforcement aspects with the scale of business operations.

3.3 Calculations were made of notional and relative costs of applying verification and documentation requirements in three SME's. The figures used were hypothetical, but based on actual businesses from examination of research projects in the earlier BO2 Programme, and after discussion with catering and professional experts situated in the area of the three businesses. They considered figures after payment of VAT and NI. The calculations were also examined by independent HACCP and training experts, who judged them as reasonable.

4. VERIFICATION AND DOCUMENTATION ESSENTIALS

4.1 It is presumed that if future legislation requires application of HACCP as defined by Codex, a HACCP Plan or similar document will be required for each business. Flow and decision tree charts will most likely need to be optional, depending on each food producing operation.

4.2 The Department of Health publication "Assured Safe Catering" identifies in Appendix 4, the critical points in SME's where daily monitoring, verification checks and the record of such checks, are necessary. This guidance will likely be enhanced by initiatives in the FSA strategy for HACCP.

5. ASSESSMENT OF THE COST OF THE LEGISLATION CHANGE

5.1 Local authority EHO time costs

Looking ahead to 2006, an estimated provision is required for the training time necessary for one officer from each authority to acquire the necessary expertise of a HACCP specialist. An estimate of £118,000 is made in this respect. No extra enforcement costs are anticipated.

5.2 Costs for the Catering and Retail sectors

The cost assessment required relates to 380,198 catering and 187,147 retail businesses, the application of verification and documentation requirements of HACCP from 2004, and the time needs for staff training.

5.3 The estimates of costs are based on figures for 3 SME's in the catering and retail sectors, referred to in paragraph 3.3, although some adjustments have been made to make them more typical of the average business. The costs are the ongoing daily costs and the start up costs of training and putting system in place. The latter element is very small.

5.4 The ongoing costs are more substantial, but even so for some businesses are likely to be modest. Most food retailing SME's sell only pre-prepared food for which the only checking required relates to temperatures of storage and display. Also for some caterers, the time costs will be small. For the smaller less complicated catering business and retailers it is assumed that 15 minutes each day is required and for the larger catering business, a little over 30 minutes, at around £10 per hour.

5.5 The total calculated costs to the catering and retail sectors of verification and documentation of HACCP is estimated at £170 million annually, equivalent to 0.4% of turnover.

6. BENEFITS

6.1 In the Department of Health's study of IID, the average cost per case was put at £79 in 1994/95 prices (say £100 at present prices) and the total cost of food borne IID was estimated at between £190 million and £550 million. On this basis, each 1% reduction in IID would save costs of £1.9 to £5.5 million.

6.2 These estimates of costs per case of IID were extremely narrowly based. They counted only the very direct costs of each incident in isolation: costs to the NHS, costs to employers in lost production and the small amount of expenses incurred by the individuals concerned. They did not make any allowance for suffering and inconvenience borne by IID victims or their close relatives, or for the risk adversity of consumers.

6.3 Benefits of avoiding the risk of IID are shown, and can be measured by willingness to pay (WTP) studies. These indicate that the benefits to consumers of reduced risk of IID could be very large: in the region of £500 to £1,000 million, or possibly much more if the risk of food poisoning was reduced to the lowest possible level.

Benefits to Consumers and Food Businesses

To Consumers:

1. Consumers of food will benefit from increased food safety as a result of enhanced hygiene controls. Notably, the WHO has stated that the main benefit of the implementation of HACCP will be the reduction of the risk of food-borne disease.
2. A second benefit to the consumer will be increased confidence in the food supply, reflected in perceived benefits from “willingness to pay”. Improved food safety standards should reduce the potential for consumer complaints and wastage.
3. The WHO argues that application of HACCP can improve the quality of life for consumers, in terms of both health and socio-economic factors. The Consumers’ Association has welcomed the proposals and argue that HACCP should ensure a higher level of food safety. HACCP should be viewed as a tool for food producers to use to ensure that they are providing safer food.

To Food Business Operators:

4. The proposal should remove much of the outdated and unnecessary controls on production processes thereby allowing some cost savings. The benefits include:
 - a single, systematic risk-based approach to all aspects of food safety from raw materials through to final product use;
 - movement from solely retrospective end product testing towards a preventative approach, in turn leading to reduced product losses;
 - capacity to identify areas of concern where failure has not yet been experienced, making it particularly useful for new operations and products;
 - a business focussed, flexible approach aimed at preventing problems occurring and therefore protecting reputations of businesses;
 - focusing technical resources into critical parts of the food production process;
 - application of HACCP techniques can also bring direct benefits in terms of new and additional orders for the business (as demonstrated in the Cardiff study);
 - in requiring that third countries exporting food to the EU conforms to the same or equivalent standards, the proposals may aid business by helping to create a level playing field and driving out substandard competition;
 - food businesses will also benefit directly, as all other members of the population, by reduced foodborne illness among the staff working in those businesses; and

- the potential to reduce the costs of official supervision and inspection in fresh meat plants as HACCP procedures lend themselves to audit and therefore do not require constant supervision.

-

HACCP and Hazard Analysis Uptake by Food Business Sector in the UK

Food Industry Sector	% businesses with HACCP in place (1)	No. businesses with HACCP in place	% businesses with hazard analysis in place	No. businesses with hazard analysis in place	No. businesses in sector
Restaurants & other caterers	19%	72,000	51%	194,000	380,000
Retailers	16%	30,000	42%	78,000	185,000
Manufacturers	59%	11,000	27%	5,000	18,000
Other	27%	5,000	38%	6,000	17,000
Total	20%	120,000	45%	270,000	600,000

N.B. This information was drawn from the results of a questionnaire sent to UK food authorities in September 2001 seeking local information on the number of businesses operating HACCP based controls. The above estimates must be indicative only, as they are more based on local authorities' perceptions than objective assessments and records.

(1) Having HACCP in place means applying all 7 principles, including the 6th and 7th, which require establishing procedures to verify that the system is working effectively and documentation of all procedures and records.

Current Legislative Requirement to have a HACCP or Hazard Analysis System in Place by Sector in the UK

Sector	Current Legislative Requirement		No. businesses in sector
	Full HACCP	Hazard Analysis or 1 st 5 principles of HACCP	
Primary Producers	No	No	265,000
Approved Manufacturers Of which:			
Meat products	Yes	Yes	1,293
Minced meat and Meat preparations	Yes	Yes	231
Fish products	Yes	Yes	2,273 (includes LBM's)
Milk products	Yes	Yes	1,410
Other animal origin products	Yes	Yes	
Egg products	No	No	99
Fresh meat *	Yes	Yes	1,149 (red) 307 (poultry)
Wild Game	No	No	37
Fresh dairy	No	Yes	27684
Non-approved Manufacturers Of which:			
Non-animal origin products	No	Yes	
Distributor/ transporter	No	Yes	11,270
Retailers	No	Yes	185,000
Caterer/Restaurants	No	Yes	380,000

* Commission Decision 201/471/EC requires the implementation of HACCP principles and microbiological testing in fresh meat and poultry meat slaughterhouses, cutting plants and cold stores by June 2002, and for smaller plants, June 2003.

N.B. The requirements outlined above refer to the legislative position flowing from the current EU Directives. Those Directives will be repealed (detailed in Annex A) and replaced by the implementation of the legislation that is the subject of the proposals under consideration.

ADAS CONSULTING LTD

FSA Project Code: B18004

**PROPOSALS TO CONSOLIDATE AND SIMPLIFY EU FOOD HYGIENE
LEGISLATION: WORK TO INFORM THE PREPARATION OF A REGULATORY
IMPACT ASSESSMENT**

**SUMMARY OF COST BENEFIT ANALYSIS FOR REGULATORY IMPACT
ASSESSMENT**

Costs and Benefits: Available Evidence

The main costs will be additional compliance by firms operating in the food chain from primary producer to final consumer. The main benefit will be less illness among consumers caused by food.

The cost benefit analysis (CBA) seeks to estimate the total of society's additional costs and benefits arising from the proposed new EU regulations. As is convention in CBA, transfer costs have been ignored. For example, if enforcement bodies raised charges for their work, this would be a transfer from businesses in the food chain to enforcers. The total costs and benefits to society as a whole would not change. Hence our calculations do not investigate the distribution of costs and benefits between the different economic agents. In practice the market would be likely to transfer much of the additional costs borne by businesses to consumers through higher food prices.

The following page shows a simple diagram (Table 1) that summarises the possible costs and benefits of food safety regulation. An important notion when identifying costs and benefits is causality. In the diagram below causality runs from left to right. It is only changes in costs and benefits caused by the new EU Regulation which should be costed.

The impact of the new regulations on businesses in the food chain are now considered in turn, and then the impact on consumers. The food businesses considered in this study were farmers and growers, and food processors. Other studies have considered the impact on other primary producers (e.g. fishing) and caterers/retailers. In addition the new regulations will affect regulators and enforcers. The FSA and Local Authorities are the institutions with the regulation and enforcement functions.

Table 1. Simple Model of Potential Costs and Benefits of New EU Food Safety Regulations

Processes and Changes	Costs	Potential Benefits
<p>1. Registration of food businesses</p> <p>2. Traceability systems</p> <p>3. Move from prescriptive legislation to hazard analysis-based approach</p>	<p><i>Businesses in the Food Chain</i></p> <p><u>One-off Costs</u></p> <p>Consultancy</p> <p>Investments in recording systems etc.</p> <p>Staff training</p> <p>Management time</p> <p><u>Recurring Costs</u></p> <p>Management time</p> <p>Documentation and record keeping</p> <p>Staff training</p> <p>Microbiological testing</p> <p>Operational changes</p> <p><i>Consumers</i></p> <p><u>One-off Cost</u></p> <p>Nil?</p> <p><u>Recurring Costs</u></p> <p>Food prices if cost increases passed are on by producers</p> <p><i>Regulators/Enforcers</i></p> <p><u>One-off Costs</u></p> <p>Training of staff</p> <p>Advice to businesses</p> <p><u>Recurring Costs</u></p> <p>More registered businesses</p> <p>More detailed inspections</p>	<p><i>Consumers</i></p> <p>Decrease in food poisoning</p> <p>Greater buying confidence</p> <p>More choice of safe foods</p> <p><i>Businesses in the Food Chain</i></p> <p>Savings in cost from removal of unnecessary regulations</p> <p><i>Regulators/Enforcers</i></p> <p>Saving in regulatory and enforcement costs</p>

Primary Producers (Farmers and Growers)

The estimate of the cost to farmers is calculated on an assumption of 146,430 farm businesses in the UK derived from data on VAT registrations. The mix of farm types and sizes have been based on statistics from the Agriculture Departments of the UK based on the annual agricultural census returns.

About 65,000 farms, mainly the larger ones, were in Produce Assurance schemes and these produce the largest volumes of products. A key assumption in calculating the cost to farms of the new EU regulation is whether farm assurance schemes will satisfy their new obligations under the proposed EU regulation. It is assumed that farm assurance schemes will meet nearly all the requirements of the new EU regulation leaving assured farms to make an expenditure of a balance of only 5% of the cost which will be incurred by non-assured farms. For the remaining 71,000 farms the costs of compliance have been estimated by ADAS specialists for a farm business with two full time persons. Very small farm business are assumed to incur a cost of 50% of the two man business, small farms to incur a cost of 75% of two man businesses, large farms to incur a cost of 150% of two man businesses.

In this study the costs of meeting the expected requirements for traceability and for the adoption of hazard analysis principles for food safety were estimated separately and these are shown in Table A4.5.(a) - (c). Costs of adopting hazard analysis ranged from £94 for a very small beef and sheep farm to £620 per year for a large horticultural producer. The details are shown in Table 4. The cost of £20.69 million per year is composed of £0.94 million for assured farms and £19.74 million for non-assured farms. The costs of including traceability are shown in Table A6.1, Appendix 6.

Food Processors

There are calculated to be about 14,000 food processors. After excluding those in sectors where the new EU regulation will not add to the legislative requirements there were about 6,500 small processors employing less than 50 employees. Larger businesses were generally considered to be already complying with the new proposals, due to customer pressure. ADAS specialists estimate the compliance cost per business at £120 per year for adopting traceability measures and £504 per year for adopting full HACCP, totalling £624 per year. The compliance cost for HACCP is calculated at £0.99m. per year. The costs of including traceability are shown in Table A6.1, Appendix 6.

Regulators/Enforcers

The quantitative evidence of the cost of enforcement of the new regulation is not substantial because at the time of completion of this draft report replies had only been received from four local authorities, one in Wales and three in England.

There are no data sources on the total manpower or cost of food hygiene work carried out local authorities in the UK. The FSA is now receiving information on Food Service plans from each Local Authority but this only becomes available as audits are carried out and this is not yet complete.

In the ADAS consultation, four local authorities covering a population of 1.195 million people devoted 6,900 person days to food hygiene. Raising this figure to the total population of the UK (which takes no account of differences between the nature of work in different types of authority) gives an estimate of 1,500 person years per year engaged in food hygiene work. The grades of staff employed in this work will vary from relatively junior technical staff to senior managers. ADAS has used a total cost per person year (to cover salary, employer's national insurance, pension costs, office accommodation, expenses and any support staff not included in the 1,500 man years) of £35,000 as the average cost across all grades. The implied expenditure on food hygiene enforcement is therefore £53 million per year.

In the responses from the four local authorities their expectations were for very little change in non-staff cash expenditure, but for one-off cost of implementation of 50% of current staff time, and ongoing costs of 50% of staff time to enforce the new regulation. Annualising the one-off cost by the method used for primary producers and processors, plus the recurrent costs, gives an additional total annualised cost of £32.5 million per year.

The cost estimate reported above clearly needs to be made more robust by getting more responses from Local Authorities. Account also needs to be taken of any incentive for Local Authorities to generously estimate the size of additional costs. These estimates probably reflect a worst case scenario as viewed from the Enforcement Officers' perspective. It has not been possible to accurately estimate the split in costs between the enforcement of traceability and of HACCP, but the bulk of costs would be associated with the latter.

Consumers

It has been claimed that consumers would benefit from having more confidence in buying food if there were greater assurances about food safety and less cause for 'media scares'. Whilst these claims may be true it would be necessary to use a willingness to pay methodology to estimate these benefits and this has not been done in the CBA presented here.

Consumers would be the main beneficiaries of a reduction in the incidence of Infectious Intestinal Disease (IID). The cost of IID was £676.9 million in England in 1995. To adjust this to 2002 prices and for the UK, based on population, the total becomes £975.3 million. These costs are based on the resource costs of IID, not willingness to pay.

The cost calculated in the report (1994/95 figures) per organism was:

Table 2. Cost per organism (IID Report)

	£ million/year
<i>Salmonella spp</i>	46.4
<i>Campylobacter spp</i>	69.5
<i>E. coli</i>	69.3
<i>C. difficile</i>	5.6
Rotavirus	16.5
SRSV	24.4
No target organism	318.5

The IID report includes organisms (e.g. viruses) where person to person transmission is common. If one assumes 90% of the *Salmonella*, *Campylobacter* and *E. coli* costs were attributable to foodborne transmission, and 50% of the remaining cases to foodborne transmission, the total cost of foodborne disease in the UK in 2002 is estimated as £594 million per year

The reduction in foodborne disease which the new regulation might assist is very uncertain, but an estimate of 5% is used in this document which would generate a benefit of £29.72 million per year.

The benefits of avoiding the costs of deaths from food poisoning have not been included in this calculation since these were excluded from the IID costing. However these should in principle be added to the FSA's final RIA. An alternative means of calculating benefits would be to cost the willingness of consumers to pay higher costs for 'safer' food, and in the consultants' opinion this is likely to increase value of benefits.

SUMMARY OF COSTS AND BENEFITS

The costs and benefits described above are summarised in Table 3.

Table 3. Summary of Costs of Adopting Hazard Analysis/HACCP and Benefits

Businesses and People Affected	Costs £ million per year	Benefits £ million per year
Primary Producers (Farmers) Hazard analysis	20.69	
Food Processors HACCP	0.99	0
Caterers	?	?
Retailers	?	?
Regulators/Enforcers	32.50	0
Consumers	0	29.72
Total	54.18	29.72
Overall Benefit: Cost Ratio	0.55	

The costs exceed the benefits with total costs of £54.18 million per year (excluding caterers and retailers) and total benefits of £29.72 million per year.

Costs and benefits – Further Background Evidence

1. There will be compliance costs for implementation of this proposal for SMEs (Small and Medium Enterprises). However, evidence gathered to date suggests that the costs of complying with the additional HACCP requirements would not be that great or overly burdensome. Notably, the report of the “Task Force on the burdens of food regulations on small food business” (paragraph 16) found that “the HACCP approach should be an important way for businesses to minimise regulatory burdens and costs”. In no instance is it believed that increased burdens will be of the magnitude to deter new entry into the industry or to bring about the closure of businesses. Neither would any particular foodstuffs be affected more than others by the proposals.

2. Of the 30 businesses interviewed for the Task Force study, 29 were small businesses. Coverage was wide in terms of activity and location. A HACCP plan was in place in 25 of the businesses while the remaining 5 had a HACCP approach to food safety, identifying and controlling hazards but without a documented plan. Seven of the businesses had a documented HACCP plan without a legal obligation to do so. Costs were identified on the basis of the additional costs to the business of HACCP and/or other food safety regulations other than what the business would do if the regulations did not exist. It emerged that the costs of HACCP are, in most cases, negligible or small and in no business were the costs considered by the business to endanger its viability. In only four businesses with a HACCP plan were the costs significant, three in the meat trade and one where there were serious problems with food safety generally. In this context it is useful to note that one of the Task Force conclusions was that reviewing and simplifying existing HACCP plans could in some cases reduce existing running costs of HACCP.

3. University of Wales Institute research on the “Evaluation of barriers to the use of food hygiene management systems throughout the UK food industry” included a postal survey of 254 SME’s in food manufacturing, catering and retail and a detailed case study of eight businesses with data on costs and benefits. The eight businesses comprised five independent small businesses, one of medium size and part of a multinational and two small plants part of a bigger group. It found that the non-recurring total value of time and money spent on HACCP implementation, with one exception was between 3% and 17% of one-week turnover of the business. The changes in direct costs of ongoing hygiene management as a direct result of HACCP implementation, as a percentage of weekly turnover, amounted to substantially less than 1 per cent in five of the businesses and 2.3% in one business. In one case there was not sufficient data to calculate the percentage of running costs and in another the researchers calculated a decrease of 28% in costs as weekly turnover was substantially

increased as a result of introducing HACCP. The study also found that even where businesses were not applying a full HACCP system, most did apply some of its principles. The system could not therefore be called a totally new requirement nor were all the costs additional and due to new regulations. For example, caterers did apply hazard analysis in 37% of cases, identified critical control points in 43%, had documentation in 63% and verification in 65% of cases without being legally obliged to do so.

4. A Regulatory Impact Assessment was produced on “The Food Safety (General Food Hygiene) (Butchers’ Shops) Amendment Regulations 2000”. It found that the costs of implementation of HACCP in butchers’ shops varied from £0 to £500 for those just selling raw meat, to £1,000 to £5,000 for premises manufacturing and selling a range of cooked meats alongside raw meat. This provides an indication of the costs involved for one industry sector. However, these figures are likely to be higher than for many sectors affected given the relatively higher risks involved in the meat sector (see results of Task Force in paragraph 6.2 where higher costs were almost exclusively in the meat trade). It is also probable that in a number of cases examined the business was starting from having no hazard analysis in place, whereas most businesses should be applying the first five principles of HACCP already.

5. It should be borne in mind that, for the studies above, the costs identified were in the main relating to one-off start up costs, and not ongoing running costs. It is also true that, in some cases, costs were included for equipment purchase, such as freezers, which do not, in fact relate to the costs of HACCP, but rather to the proper running of the business as required under existing legislation.

Annex L

Options Agreed in the Previous Versions of the RIA – Option 4 was agreed as the basis of the UK Negotiating Line by the Ministerial Sub-Committee on European Issues (EP)

1. As the proposal addresses an area already occupied by EU legislation, any option other than “do nothing” would mean changing the current EU legislative position. There are options in relation to the manner in which the provisions would be implemented, particularly with regard to the application of procedures based on the HACCP principles. The five options therefore identified are:

Option 1 - do nothing.

Options 2 –remove one or more of the proposals.

Option 3 –rigid implementation of a full HACCP system as laid down in some formal literature.

Option 4 –negotiate legislation, the application of which would be flexible and pragmatic.

Option 5 - pursue proposals limited in application, to higher risk operations, or exempting smaller businesses.

Option 1

2. Maintaining the status quo would not achieve the desired modernisation and improvements to public health protection. The European Commission's proposals could only be removed at its own instigation or by Member States acting in unanimity in Council. The Commission is wedded to its proposals and other Member States are supportive. All Member States other than Greece and Italy have welcomed the proposals, and Italy and Greece have not objected in principle. In the event the proposals were to be withdrawn, there would be no costs or benefits. In addition, should the UK fail to apply the legislation eventually adopted by the EU, it would most likely face infraction proceedings in time.

Option 2

3. This would unbalance the proposals and leave incomplete coverage because the package stands together to consolidate and simplify existing legislation. The first proposal contains most of what is new in the proposals, primarily by extending the scope of coverage of hygiene legislation to the

majority of primary production for the first time and by requiring catering and retail sectors to verify and document their hazard control procedures. Hygiene rules already apply to the primary production of milk and live bivalve molluscs. The second proposal contains the essential detailed legislation on products of animal origin currently contained in 15 separate directives and is, in the main, a consolidation exercise. The third proposal contains the rules governing the control measures necessary to ensure compliance in businesses covered by the second proposal. The fifth proposal simply repeals existing legislation. Commission action or unanimity among Member States would also be required to remove any one of the proposals.

Option 3

4. This would require every food business to assemble a HACCP team of various experts to identify the hazards in the business operations, to determine the critical control points and the controls to be applied and monitored. While appropriate for some businesses, particularly large manufacturing enterprises (we have been speaking to a number of large companies that operate systems at least to these standards) with in-house technical expertise, it would impose a disproportionate burden on many smaller businesses or those dealing with food of lower risk. The benefits arising from rigid implementation of a HACCP system would be most unlikely to be justified in terms of further reduction in disease incidence or consumers' willingness to pay for improved food safety.

Option 4

5. This would allow full application of HACCP systems where appropriate (e.g. the large manufacturing enterprise), but would also allow for the development of generic HACCP-based food safety management procedures on a pragmatic and proportionate basis. For example, guides could be developed for convenience stores just dealing in ready wrapped foods for display in a chiller cabinet where the record keeping requirement may consist of simply recording temperature control information. This proportionate approach would be to the advantage of many small businesses by avoiding unnecessary burdensome application. Such an approach is consistent with the findings of the FSA's Task Force report on the "burdens of food regulations on small food business". A particular system would not be imposed on business as this option respects the principle of operator responsibility – one of the main principles behind the proposals. A flexible approach should be based on risk providing the possibility to take account of exceptional circumstances without compromising food safety.

Option 5

6. An exemption for a particular size of business, or those employing fewer than a set number of employees, would be arbitrary and ignore the fact that smaller businesses may be involved in operations that may pose significant health risks. This option may improve the situation in some sections of the industry, but fails to provide the complete coverage sought. Concentration on perceived higher risk businesses would create difficulties for enforcement as operations within individual businesses may change frequently and without notice and authorities may be unaware that a business has changed from one risk category to another. It is dangerous, as it does not allow for the prevention of, or reaction to, new and emerging threats. This is, in effect, the way food hygiene legislation has built up over the years with numerous sector specific directives. This approach is unlikely to produce any cost benefits, and may indeed increase costs, as such an approach is very time consuming to competent authorities. In addition, it would be most unlikely to produce any significant benefits in terms of reduction in disease incidence.

Benefits

7. Only options (3) and (4) above would deliver the benefits identified. Option (1) would maintain the status quo, and options (2) and (5) would not change current practice sufficiently to improve significantly the present situation.

Compliance Costs

Option (1) would be neutral in terms of costs and benefits, as it would perpetuate the status quo.

8. Option (2) would be neutral in terms of costs and benefits, as it would perpetuate the status quo.

9. Option (3) would likely double, at least, the compliance costs for most sectors, with the exception of primary production, and would be particularly burdensome on SEM's. It could, as a rough estimate, increase the total compliance costs to in excess of £350 million per year, and substantially increase the one-off costs to business in setting up HACCP procedures. No specific research has been undertaken to cost this scenario, however all the researchers involved in costing these proposals agree the cost effect outlined above.

10. Option (4) is the preferred option and is examined in more detail below.

11. Option (5) would involve continuing and developing concentration on areas of perceived higher risk in the food chain. It is extremely difficult to predict what may emerge as "new" risks in the future. However, the likelihood is that the costs of enforcement under such an approach would increase as time passes as

experience shows that increased effort on controlling new risks does not replace existing ones, but rather increases the burdens on competent authorities. A nominal figure has been included to reflect this tendency of £5 million per year.

TABLE 2 - Food Hygiene Legislation – Summary of Evidence on Annual Costs and Benefits

(£million)		Option a	Option b	Option c	Option d	Option e
Costs	Primary production	0	0	29	29	0
Year one	Retail	0	0	134	67	0
	Catering	0	0	206	103	0
Year 2 and after	Retail	0	0	92	46	0
	Catering	0	0	138	69	0
	Production and processing	0	0	10	5	0
	Enforcement	0	0	0.2	0.2	5
Benefits	Disease reduction	0	0	15.1 – 75.4 1% - 5%	15.1 – 75.4 1% - 5%	0