

REGULATORY IMPACT ASSESSMENT

1. Title

1.1 The regulations are to be known as The Meat (Hazard Analysis and Critical Control Points) (England) Regulations 2002.

2. Purpose and Intended Effect of the Measure

2.1 The legislation amends meat hygiene regulations to implement Commission Decision 2001/471/EC. It requires the mandatory use of Hazard Analysis and Critical Control Point (HACCP) principles in licensed red meat and poultry meat plants in England and sets out standard procedures for carrying out certain microbiological tests.

2.2 **HACCP** is an internationally accepted management system that offers consumers the best guarantee of safe production of food. It provides a methodical, documented, but flexible approach that places responsibility on operators to prevent, eliminate or reduce physical, chemical and microbiological hazards in their food businesses. By applying the seven HACCP principles operators identify the hazards that need to be controlled, establish effective procedures that control the hazards, ensure that these procedures work and are being applied and can provide evidence of their control procedures.

2.3 Regular microbiological testing of carcasses can provide an objective method of demonstrating that the plant's HACCP-based Plan is achieving its aims. Microbiological testing of production surfaces provides a check on the effectiveness of cleaning procedures. The Decision sets requirements for testing carcasses in red meat slaughterhouses and for testing surfaces in red meat slaughterhouses and cutting plants. It also sets microbiological performance criteria for assessing the efficacy of plant procedures.

3. Risk Assessment

3.1 The legislation reflects the increased awareness of the risk to consumers from pathogenic micro-organisms that can contaminate meat at all stages from slaughter to consumption and cannot be detected visually. Procedures should focus on reducing contamination of raw meat by microbiological organisms and restricting their growth.

3.2 The CDSC¹ estimated total number of cases of Indigenous Foodborne Disease (IFD) in 2000 in England and Wales was 1,338,772. Of these 368,516 visited a GP and 970,256 did not. In a separate study of 1210 general food-borne outbreaks of Infectious Intestinal Disease (IID) reported by vehicle of infection between 1992 and 1999, poultry accounted for 22% and red meat for 19% of cases.

3.3 In 1999, 82,943 laboratory-confirmed individual cases of food poisoning contracted in the UK were attributed to the three most common bacterial pathogens – Campylobacter (61,713), Salmonella (19,801) and E.coli (1,429). All three can be carried in or on animals and can be transferred to raw meat during production, storage

¹ PHLS Communicable Disease Surveillance Centre

and transport. The greatest impact on meat-borne illness is likely to come from preventative measures on farm, but the implementation of documented HACCP-based systems by meat sector businesses is also important. Such a requirement has already been made mandatory in certain butcher's shops as part of the butchers' licensing scheme as recommended in the Pennington Report following the fatal E.coli O157 outbreak in Scotland in 1996.

4. Options

4.1 Three options have been considered:

Option 1 - No action

This option contradicts the Government's commitment to meeting its EU obligations and supports the HACCP approach to food safety, and has therefore been rejected.

Option 2 – Set extra requirements

Setting more specific requirements than in the Decision could benefit both industry and enforcement officers. However, since flexibility and operator responsibility are key concepts of the HACCP approach, it would be inappropriate to specify exactly how HACCP principles should be applied, and so this option has not been pursued.

Option 3 - Transposition of the Decision text into national legislation

This option meets EU obligations and implements the requirement for specified meat plant operators to apply HACCP principles in setting up permanent hygiene procedures in their premises without additional prescription. **This is the only option being recommended.**

The Decision offers a number of areas of flexibility, which have been taken full advantage of to minimise the burden on industry i.e.

- 12 month delay in implementing the Regulations in small /medium plants, the majority of the largest plants have already implemented HACCP voluntarily or because of customer demand;
- Non-destructive alternative to the excision method of sampling included as a Schedule to the Regulations;
- Reduced frequency of microbiological testing for low throughput plants and those operating less than full time to be established before June 2003;
- Data has been requested from manufacturers on rapid test methods with a view to enabling a potentially more economic method to be approved;
- A Pilot Plant Study has been launched to provide information on the effects on working practices and costs of implementing the legislation;
- Use of guides of good practice is encouraged and the FSA has provided draft guidance to industry and enforcement officers and further information and training material will be supplied particularly to assist the medium/small operators.

These points are discussed in the rest of this paper.

5. Issues of equity and fairness

5.1 The mandatory application of HACCP principles would apply to all meat plants licensed in accordance with the Fresh Meat and Poultry Meat Directives. The Commission Decision permits a 12-month extension to the implementation deadline for small plants. The Food Standards Agency believes it is in the consumer's interest to allow small and medium businesses the extra time so that practical assistance can be offered in 2002/3 to help achieve effective implementation of HACCP principles.

The Agency agreed throughput/capacity thresholds for premises, after discussions with stakeholders, which mean that over 75% of premises have an extra 12 months to implement the requirements, although they cover less than 30% of meat production.

5.2 The Decision does not provide for any reduction in official controls consequent upon the effective implementation of HACCP principles. The meat industry considers that, while robust enforcement action should be taken against operators who disregard hygiene procedures, operators who can prove that their procedures are effective in controlling hazards to public health (e.g. through satisfactory microbiological results) should benefit from reduced veterinary supervision. The Food Standards Agency supports a risk-based approach to determining the level of official control and will continue to press for changes in the negotiations on a new Commission proposal expected shortly.

5.3 The Decision allows reduced microbiological testing of carcasses to be set for low throughput red meat slaughterhouses and those operating less than full-time. The Agency will consider the options for reduced testing before the second implementation deadline of June 2003. Although no standard procedures have been set for poultry plants the Food Standards Agency and the British Poultry Council agree that poultry slaughterhouses and cutting plants should also conduct microbiological tests to check the effectiveness of HACCP and cleaning procedures. The Agency is funding trials on appropriate protocols for use by the industry and to inform any future Commission Decision on poultry testing.

6. Benefits

6.1 **Consumers of meat** should benefit from a safer product and decreased risk of illness. This should result from a greater emphasis by meat plant operators on control measures that reduce microbiological contamination, and from appreciation of their own responsibility for producing safe meat, rather than the mechanical implementation of legal requirements or reliance on enforcement officers' interventions.

6.2 **Operators of meat plants** should benefit from an increased awareness of the hazards that need to be addressed and the control procedures that will minimise the risk to consumers. Improved control and monitoring procedures may result in:

- Improved productivity through a reduction in reworking or disposal of visibly contaminated product;
- prevention of other problems, such as inadequate chill temperatures, before they become too serious and possibly lead to product recalls;
- increased customer satisfaction and reliance on the meat supplier's own checks.

Documentation of the control procedures and microbiological testing will provide evidence for customers and enforcement authorities that the operator is taking all reasonable measures to produce meat as safely as possible. It is hoped that under a future European risk-based enforcement regime it would be possible to reduce supervision costs in plants where HACCP is being implemented effectively.

6.3 **The national economy** should benefit from increased consumer confidence in the safety of home-produced meat and from reduced health/social service costs, as

well as from higher productivity and fewer working days lost to food borne illness, as a result of improvements in the microbiological safety of meat.

6.4 The estimated total cost of IFD in England and Wales is £1,290 million in the year 2000 (details at Annex 1), the sum of

(i) the estimated actual, out of pocket, cost of £164 million.

Costs 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. and

(ii) the monetary value of pain, grief and suffering due to such illness of £1,126 million.

Costs 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.

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

6.5 Adjusting the figures for England only, and assuming that 41% were attributable to poultry or red meat (see paragraph 3.2), the annual benefit of stopping 10% of the outbreaks attributed to red meat and poultry would be over £50 million annually. However cases cannot be attributed solely to the meat plants who will be required to implement HACCP principles, and the full and effective implementation of procedures based on those principles will not stop all microbiological contamination. Nevertheless the calculations at Annex 2 and summarised below show that benefits may be expected to outweigh costs even from a 1% reduction in the number of cases of food poisoning.

Summary of results

£, 2002 prices, discounted to 2002		PVB	PVC	NPV
Present Value of Benefits	at 10% reduction due to HACCP	423,131,591	22,449,908	400,681,684
	at 5%	211,565,796	22,449,908	189,115,888
	at 1%	42,313,159	22,449,908	19,863,252
	at .75%	31,734,869	22,449,908	9,284,962
	at .5%	21,156,580	22,449,908	- 1,293,328

7. Compliance Costs for Business, Charities and Voluntary Organisations

7.1 The legislation will apply to some 1000² licensed red meat and poultry meat slaughterhouses, cutting plants, cold stores, re-packaging and re-wrapping centres in England. It will not apply to charities or voluntary organisations. Additional costs may arise in two areas: (a) HACCP (b) Microbiological testing.

² 407 slaughterhouses, 411 cutting plants, 184 cold stores, 2 re-packaging and 0 re-wrapping centres licensed at 1 October 2001 (Slaughterhouse and cutting plant figures include standalone and combined premises).

(a) HACCP

7.2 Compliance costs will depend on the extent to which businesses need to enhance existing training, documentation and procedures to meet the requirements. The legislation contains **no** requirement for structural change or additional equipment, but some operators may decide to implement changes or update equipment as a consequence of a review of their hygiene controls.

7.3 According to a Meat Hygiene Service survey in 2000, 48.8% of red meat slaughterhouses and 59.2% of poultry meat slaughterhouses (i.e. 251 of 489 plants then licensed in England, Scotland and Wales) claimed to be applying some or all of the seven HACCP principles. No figures are available for other types of plants but as cutting plants are often co-located with slaughterhouses it is likely that if the slaughterhouse is implementing HACCP principles the cutting plant will be too.

7.4 **Training** - There is **no** specific requirement for training but where staff have no HACCP expertise, it is recommended that at least one or two should receive training in HACCP principles and planning so that they can form the HACCP team, or the nucleus of one in larger premises. An Agency-funded HACCP Manual is being produced for in-house or external training. Other plant staff may benefit from HACCP awareness and/or hygiene refresher training. Consultants may be used as part of the HACCP team. Large plants have been offered a two-day training course at £280 per person.

7.5 **Documentation** - Principle 7 of HACCP requires documentation to demonstrate effective application of the other principles and to facilitate official controls. Where none exists, time will need to be set aside to produce a HACCP Plan relevant to the business, as well as written hygiene policies, procedures and staff instructions. Records may need to be introduced or adapted to show that control is being exercised at critical points in the production process. The Manual will provide guidance and examples.

7.6 **Procedures** - Implementation of HACCP principles builds on existing good hygiene practices and control procedures. Responsible operators will already have many of the requirements in place without being aware that they are components of a HACCP system, but may need additional monitoring and corrective action procedures. Guidelines on the implementation of HACCP principles have been sent to operators.

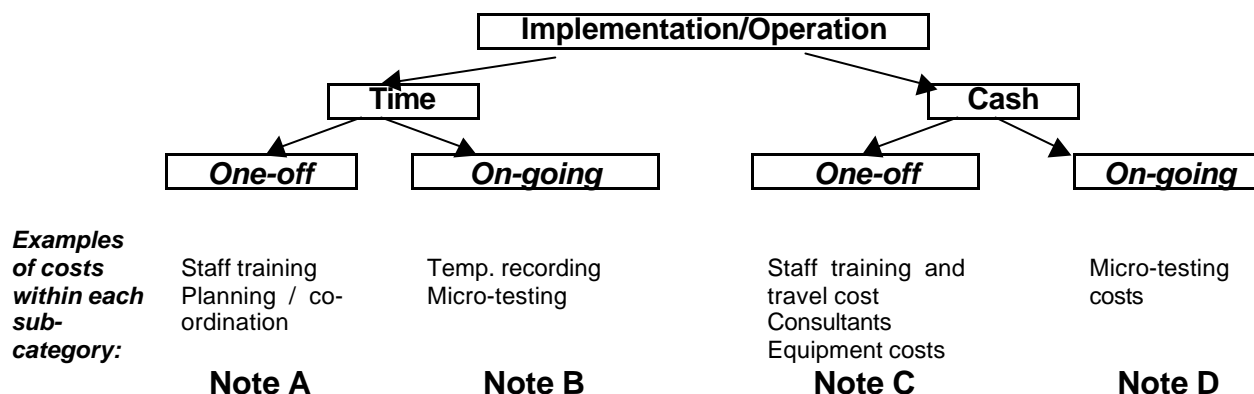
(b) Microbiological Testing

7.7 Compliance costs for red meat slaughterhouses and cutting plants that do not currently carry out microbiological testing will vary according to the laboratory chosen, transport costs, whether weekend testing is needed and whether testing frequency can be reduced after a period of satisfactory results and maintained at the lower level. If they already test the cost will depend on whether their procedures need to change to meet the requirements of the Decision Annex.

7.8 In the 2000 MHS survey, 94 (42%) full throughput red meat slaughterhouses in England, Scotland and Wales claimed to carry out microbiological testing of surfaces, while 85 (37.9%) carried out carcase testing. Some have in-house laboratories.

Pilot Plant Study

7.9 The Agency is conducting a Pilot Plant Study in seven plants to try to assess changes in working practices and resource costs of implementing the Commission Decision. In the period to March 2002 three plants had completed the implementation phase of the project. Plant costs have been divided into two categories, time and cash each sub-divided into one-off and on-going costs, as shown below.



Note A: One-off time costs of staff training and planning/co-ordination varied in the three plants from £577, £840 to £2,882 (average £1,433). Factors included the gross hourly pay and the effort (in terms of number of hours and employees) put into the training and planning process. This time may reflect the enthusiasm for the task rather than how advanced the plant was before they joined the Pilot Plant Study.

Note B: On-going time costs in the two plants that had begun micro-testing and additional record keeping in the period are reasonably similar, giving a weekly average time cost of £15 per week for additional recording, and £35 per week for micro-testing (= £2,600 for 52 weeks).

Note C: One-off cash costs were £107, £144 and £1,249 (average £500) depending on whether equipment was purchased (e.g. a fridge to keep samples), additional overtime was paid, etc. Training and consultancy costs of £2,500 per plant included, as part of the Study, two days off-site training for two staff, half day on-site awareness training for up to 12 staff and 3 consultancy visits.

Note D: The main on-going cash cost is the cost of micro testing. The average cost of micro-testing of carcasses and surfaces in the five pilot red meat slaughterhouses of £7,500 does not include any allowance for reduced frequency of testing after a period of satisfactory results.

Total Compliance Costs in red meat plants

7.10 The additional cost of implementing HACCP principles is estimated to range from £0 for the plants already applying all seven principles up to perhaps £4,500 for one-off training and implementation costs in plants with no HACCP experience. Time taken for additional procedures in these plants may be in the region of £2,600 a year.

7.11 **In slaughterhouses** implementing microbiological testing will cost from £0 for those already carrying out such tests of carcasses and surfaces. Estimates for laboratory services range from £2,505 if testing frequency can be reduced after a period of satisfactory results and maintained at the lower level, to £11,440 or more if the larger number of samples is taken and no reduction in testing frequency is justified, based on estimates from two laboratories excluding transport costs. The cost for **small slaughterhouses** that can benefit from the derogation for reduced testing

frequency (see 5.3) will depend on the sampling plan that is introduced. The annual cost of surface testing in **cutting plants** is estimated at £910 or less if testing frequency can be reduced, up to £3120 or more depending on laboratory charges.

ESTIMATE OF LABORATORY COST OF MICROBIOLOGICAL SAMPLE TESTING:

<p><u>Carcases #</u> (para. 7.5) <i>TVC + Enterobacteriaceae samples</i></p> <p>Minimum 5 x 2 samples a week x 6 weeks = 60 frequency reduced to: 5 x 2 samples a fortnight x 23 = 230 290 @ £5.50 = £ 1595 290 @ £8.00 = £ 2320</p> <p>Maximum 10 x 2 samples a week x 52 = 1040 1040 @ £5.50 = £ 5720 1040 @ £8.00 = £ 8320</p>	<p><u>Surfaces</u> (para. 7.8) <i>TVC samples</i></p> <p>Minimum 10 samples a fortnight x 26 = 260 (but frequency may be reduced by OVS) 260 @ £3.50 = £ 910 260 @ £4.00 = £ 1040</p> <p>Maximum 30 samples a fortnight x 26 = 780 780 @ £3.50 = £ 2730 780 @ £4.00 = £ 3120</p>
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Impact on Small Business

8.1 The Report of the Task Force on the Burdens of Food Regulations on Small Food Businesses³ concluded that there should be no relaxation of standards for small food businesses since consumers have the right to expect the same level of protection irrespective of the size of the business. It is nevertheless recognised that operators of small businesses, and particularly owner-managers, may face additional difficulties in implementing HACCP principles due to their lack of technical expertise and to time pressures both at the outset and for on-going record-keeping.

8.2 Bearing in mind the structure of the UK industry the Agency has proposed a definition of ‘small plants’ that is considerably wider than the low throughput definition proposed by some Member States. As a result over 70% of slaughterhouses and cutting plants have an extra twelve months to implement the requirements so that as much support as possible can be provided to achieve an effective outcome, such as the guidelines and HACCP Manual. The final part of the Pilot Plant Study is for open days to be held so that other operators can see what implementation will have involved.

8.3 As only three (2.2%) low throughput slaughterhouses carried out microbiological testing of surfaces and two (1.5%) tested carcasses in the MHS survey, this is an area where significant assistance will be need to achieve meaningful results. Smaller plants have fewer resources to call on and are less likely to have people with the know-how to take samples and interpret results. The Agency will seek to establish proportionate, science-based rules for those that can benefit from the derogation (see 5.3) and plans to issue guidance.

8.4 The Decision requires the establishment of documents and records commensurate with the size of the business. The HACCP Manual will provide advice and examples on what might be appropriate.

³ Task Force Report (*para 77*) published by the FSA in June 2001 (ISBN 1 904026 03 6).

Other Costs

9.1 The Agency will incur cost in producing training and guidance material for training of enforcement officers. Training in enforcement of the new regulations has been incorporated in the compulsory programme of continuing professional development for official veterinary surgeons in 2002/2003. Training for Meat Hygiene Inspectors is envisaged in the longer term.

Competition Assessment

10.1 From negative answers to most of the competition filter questions and the fact that HACCP principles will have to be applied by all EU licensed meat plants and will be the standard for EU imports from June 2003, we are satisfied that there will be no significant detrimental affect on competition resulting from these Regulations.

Results of Consultation

11.1 A Stakeholder Group of representatives of large, medium and small meat industry organisations and other bodies, established in July 2000, advises on the implementation of the Commission Decision. Sub-groups are formed as necessary to look at particular issues.

11.2 A 12-week public consultation was held from December 2001 to March 2002. Only a small number of respondents did not support HACCP and microbiological testing as a positive step for safeguarding public health. Some believed that the new arrangements have been progressed by the Commission with unreasonable haste and the fairness of allowing small businesses a 12-month extension was queried, but most felt that the twin track approach was appropriate in the circumstances. There was concern that implementation should be pragmatic and flexible, so that the impact on small businesses should be proportionate, and not threaten their financial viability. (Paragraph 5.1 above considers the timetable).

11.3 Consumer groups were in favour of the legislation, while emphasising that operator responsibility should not replace official controls. Industry respondents generally supported the HACCP concept, but were concerned about the additional regulatory burden and believed that the application of HACCP and microbiological testing by meat plants should lead to a reduction in official controls and an end to the HAS system. Consumer groups however support HAS as a means of providing assurance to the public. (Paragraph 5.2 above considers official controls).

11.4 UNISON and the Association of Meat Inspectors (AMI) doubted that HACCP would improve public health protection and the value of industry-monitored HACCP plans. In their view only strong independent regulatory enforcement could provide the necessary level of safe meat production. The AMI believed there was insufficient time to train enforcement staff and that there should be compulsory EU standardised HACCP training for industry.

11.5 The National Consumer Council particularly welcomed microbiological testing, while the Chartered Institute of Environmental Health felt that considerable training would be needed to provide accurate results, as well as guidance for operators and enforcement staff on interpretation. Industry queried the specific procedures laid

down in the Annex and the availability of an alternative swabbing method in order to avoid unnecessary duplication with current customer requirements. Industry groups strongly rejected any possibility of microbiological testing results being published.

Summary and Recommendations

12.1 The Agency believes that the application of HACCP principles in licensed red meat and poultry plants and the use of standard microbiological tests will improve the level of microbiological safety of meat for consumers, as well as being of benefit to operators. The HACCP approach is by its nature flexible and needs to be 'owned' by the operator but this legislation makes no changes to the level of official control. Enforcement training is being provided to officials. The Agency would have preferred a longer timetable for implementation but is committed to providing as much guidance as possible to industry, particularly smaller businesses so as to achieve the benefits as economically as possible. [An alternative swabbing method of microbiological testing has been approved, subject to review, and] consideration is to be given to a proportionate approach to the testing requirements for small plants for June 2003. **The implementation of the proposed amendments to meat hygiene legislation is recommended.**

Enforcement, Sanctions, Monitoring and Review

12.1 Enforcement of the implementation of HACCP principles and microbiological testing in licensed meat plants would be the responsibility of the Meat Hygiene Service under the existing regulations. Failure to comply with the new requirements would be dealt with by warnings and ultimately by legal action. Guidance on the enforcement of these Regulations have been produced for the Meat Hygiene Service and copied to the Stakeholder Group. They are being incorporated in the MHS Operations Manual.

12.2 A review of the impact of the implementation of HACCP principles and microbiological testing will be carried out in 2004/5. Data produced by the establishments carrying out microbiological testing will be used.

Declaration:

I have read the Regulatory Impact Assessment and I am fully satisfied that the benefits justify the costs.

Signed by the responsible Minister:.....

Date:.....

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ANNEX 1

EXTRACT FROM PAPER ON ECONOMIC COST OF INDIGENOUS FOODBOURNE DISEASE⁴

The CDSC paper estimated that 368,516 cases presented to a GP and 970,256 did not.

Total cost for those visiting a GP (£334.8 x 368,516) = £ 123 million

Total cost for those not visiting a GP(£42.55 x 970,256) = £ 41million

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

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 days. 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 days.

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;
£ 34.3 million	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.

The estimated total cost of IFD in England and Wales is the sum of

- the estimated actual, out of pocket, cost of **£164 m** and
- the monetary value of pain, grief and suffering due to such illness of **£1,126 m**
= a total of £1,290 million in the year 2000.

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

⁴ Report by Z. Hornstein, Economic Consultant to FSA.