

EXPLANATORY MEMORANDUM TO THE FOOD HYGIENE (ENGLAND) REGULATIONS 2006

2006 No.14

1.1 This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1 This instrument provides enforcement powers in respect of the EU Food Hygiene Regulations and associated pieces of implementing and transitional legislation. In particular, it designates competent authorities and enforcement authorities and makes provision for offences and penalties. It also addresses aspects where the EU Regulations either require or allow Member States to adopt certain provisions in their national law.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The instrument will breach the 21 day rule. This has been caused by late publication by the European Commission of Commission Regulations (laying down implementing and transitional rules) to which this SI gives effect and as such has been unavoidable. The last three of the five relevant Commission Regulations were adopted formally on 5 December 2005 and four out of the five Commission Regulations were not published in the Official Journal of the European Communities until 22 December and apply from 11 January 2006. Inevitably, therefore, the delay has been compounded by the intervening holiday period.

4. Legislative Background

4.1 The new EU legislation has as its primary objective the optimisation of public health protection by improving and modernising the previous sector specific EU legislation. The new EU legislation establishes the conditions under which food is produced to prevent, eliminate or acceptably control pathogen contamination of food. More risk based and flexible procedures are introduced that are better matched to the needs of individual businesses and to enforcement. The legislation introduces a "farm to fork" approach to food safety, by including primary production in food hygiene legislation for the first time in the majority of cases.

4.2 The EU Food Hygiene Regulations will be directly applicable in each Member State of the EU. National legislation is neither required nor allowed, to give effect to the EU Regulations, beyond providing for their

enforcement in England. However, there are a number of areas where the EU Regulations either require or allow member states to adopt certain provisions in their national law and these Regulations address those aspects too.

4.3 This SI is made under the powers given by section 2 (2) of the European Communities Act 1972. As the subject matter of the SI is food hygiene it has been developed to mirror the provisions of the Food Safety Act 1990. It creates penalties and offences, powers of entry and other administrative measures based in the main on existing requirements. Where the EU Regulations do not apply and no more specific national provisions have been made, the general legal requirements relating to placing unsafe food on the market contained in Article 14 of Regulation (EC) 178/2002 as implemented by the General Food Regulations 2004 will apply to ensure the supply of food in such circumstances is fit for human consumption.

4.4 It revokes and replaces the Food Hygiene (England) Regulations 2005 (SI 2005/2059).

5. Extent

5.1. This instrument applies to England. Parallel legislation is being developed in Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy Background

7.1 The Regulations designate the Food Standards Agency as the competent authority and designate food authorities and the Food Standards Agency as enforcement authorities. The division of responsibility is set out in regulation 5.

7.2 There are a number of areas where the EU Regulations either require or allow Member States to adopt certain provisions in their national law. These areas cover the bulk transport in sea-going vessels of liquid oils or fats and the bulk transport by sea of raw sugar, temperature control requirements for foodstuffs, the direct supply of small quantities of meat from poultry and lagomorphs (rabbits and hares) slaughtered on-farm, and restrictions on the sale of raw milk intended for human consumption.

7.3 SI 2005/2059 introduced new enforcement powers in relation to the requirements of the EU Regulations that apply on 1 January 2006. It applied the required penalties and offences, powers of entry and other administrative measures. This new SI consolidates with amendments SI 2005/2059. The new SI provides for the application of the European Commission transitional and implementation measures which are directly applicable in Member States from 11 January 2006. It also makes changes to certain enforcement provisions. These include enforcement responsibilities at the level of primary production

and providing for food authorities to take enforcement action in non-approved meat plants.

- 7.4 A full consultation and RIA were completed for the EU Regulations and the Food Hygiene (England) Regulations 2005. A full consultation and RIA have been completed for the EU implementing and transitional legislation and the Food Hygiene (England) Regulations 2006.
- 7.5 An initial consultation with stakeholders on the policy content of these measures was undertaken and concluded on 9 June 2004. A full consultation was carried out on the Food Hygiene (England) Regulations 2005 and associated guidance giving effect to the EU legislation which concluded on 31 January 2005. The responses of stakeholders to the initial policy consultation were generally in favour of the FSA preferred options. Stakeholders overwhelmingly called for practical and flexible application of the EU legislation in the UK and for national measures that respected existing practice and did not add to the burden on business. This approach has been respected in SI 2005/2059 and associated guidance to give effect to the legislation. The FSA Board reviewed the results of the consultation at its open meeting in March 2005 and endorsed the approach being taken.
- 7.6 A further consultation on the new Food Hygiene (England) Regulations ran for 12 weeks and ended on 13 December 2005.
- 7.7 The most significant issue for respondents was the FSA's proposal to extend to all food businesses the use of Remedial Action Notices (RANs) as an enforcement mechanism to secure compliance with the legislation. Under the terms of SI 2005/2059, RANs, (which have been available for enforcement action in fresh meat plants for a number of years) have been extended to all approved products of animal origin premises. Opinions were sharply polarised on the suggestion of extending this further. Local authority enforcement representatives strongly supported the proposal, whereas many industry representatives (and associated government sponsors) expressed reservations and concerns about its impact, to varying degrees.
- 7.8 Given the divergence of respondents' views the FSA has withdrawn this provision from the SI for the time being. The FSA remains minded to pursue this further, since it thinks it provides a less bureaucratic mechanism for securing compliance than is already in use, and one more in line with the recommendations of the Hampton review of regulatory inspection and enforcement. The FSA acknowledges the need to evaluate fully the range of opinions expressed and the need for further stakeholder engagement. This cannot be adequately undertaken in the time available, dictated by the EU timetable. The FSA will therefore pursue this course separately with stakeholders and will inform them accordingly.

8. **Impact**

8.1 A Regulatory Impact Assessment (RIA) has been prepared for this instrument and is attached at Annex C.

9. **Contact**

Catherine Bowles at the Food Standards Agency (Tel: 020 7276 8952 or e-mail: catherine.bowles@foodstandards.gsi.gov.uk) can answer any queries regarding the instrument.

FULL REGULATORY IMPACT ASSESSMENT

1. Title of proposal

The Food Hygiene (England) Regulations 2006. The proposal consolidates with amendments the Food Hygiene (England) Regulations 2005 (SI 2005/2059) and would replace SI 2005/2059 in its entirety.

2. Purpose and intended effect

2.1 Objective

To optimise public health protection and otherwise secure the benefits to consumers, the food industry and the enforcement community of improved, flexible, risk-based food hygiene legislation. In particular:

2.1.1 To provide for the application of a number of Commission Regulations which implement or provide for a period of transition to apply the EU Food Hygiene Regulations. (Listed in **Annex D**).

2.1.2 To make various changes to the regulations establishing responsibility for enforcing and executing the hygiene regulations.

2.2 Background and timing

2.2.1 SI 2005/2059 was made on 21 July 2005. The Final RIA for that SI is at **Appendix 1** and gives background to its form and content. This RIA relates only to the changes being proposed to the SI.

2.2.2 The Commission implementing and transitional measures listed in the Annex are subject to a separate RIA (**Annex D**). The main EU Food Hygiene Regulations were also subject to a separate RIA. This can be accessed from the following weblink:

<http://www.food.gov.uk/multimedia/pdfs/euhygiene2004riafull.pdf>

2.2.3 The Commission implementing and transitional measures listed in **Annex D** were formally adopted by the Commission on 5 December 2005. They were published in the Official Journal on 22 December 2005. The RIAs have been subject to a consultation with stakeholders which finished on 13 December.

2.2.4 The EU Food Hygiene Regulations, the Commission implementing and transitional measures and the Food Hygiene (England) Regulations 2006 will apply from 11 January. Parallel national legislation will be made in Scotland, Wales and Northern Ireland.

2.3 Changes proposed to SI 2005/2059

Amendments to apply the Commission implementing and transitional measures

2.3.1 For the most part, the only change necessary to apply the measures (which will be directly applicable Commission Regulations) is to include reference to them in the definitions which refer to the EU food hygiene regulations. Changes have therefore been made to the definitions of “the Community Regulations” and to the list of Community legislation cited in Regulation 2(1) and to Schedule 1.

2.3.2 In order to apply fully the proposed Commission Regulation on microbiological criteria, it is necessary to create an offence where food business operators fail to take the actions set out in the Annex to that Regulation, as required by Article 7 of the proposal. This has been done by adding an appropriate entry in Schedule 2. An offence has also been created to apply Article 9 of the proposed Commission Regulation on *Trichinella* in meat.

Other amendments

2.3.3 We are taking the opportunity to amend the definition of “food authority” in Regulation 2(1). This will bring it into line with other legislation, but does not alter the scope of the definition. We are proposing a change to the responsibility for enforcing the EU food hygiene regulations at the level of primary production, as described in Regulation 5(1)(a). Currently, this responsibility lies with the Food Standards Agency alone. We are proposing that this responsibility may be exercised by either the Agency or by a food authority. This change reflects the fact that decisions have yet to be taken on who will be responsible for undertaking this enforcement responsibility. The formula proposed in Regulation 5(1)(a) is one used elsewhere in the Regulation and provides for responsibilities to be described more fully in, for example, the Code of Practice and Practice Guidance (in the case of food authorities) or in Service Level Agreements that the Agency may make with other enforcement bodies. As such, this change broadens the scope of which enforcement authority might undertake this work. Separately, work is ongoing to consider the form of enforcement of the hygiene legislation and which body should undertake this.

2.3.4 The Commission has recently clarified that activities undertaken at egg packing stations are not primary production. Egg packing stations would therefore be subject to the general hygiene requirements of Annex II to Regulation 852/2004 and any specific requirements for shell eggs in Regulation 853/2004. It would also be necessary for them to comply with the requirement to have in place food safety management systems based on HACCP principles (Article 5 of Regulation 852/2004). Enforcing and executing these requirements would be more appropriately undertaken by food authorities than by (in the case of England) Defra’s Egg Marketing Inspectorate. The precise extent of the enforcement responsibility and how it is to be carried out still needs to be determined. In order to allow this to be developed, it will be necessary to make the activities described in Regulation 5(2)(a)(iv) of SI 2005/2059 subject instead to Regulation 5(2)(b). This has been achieved in the draft SI by deleting Regulation 5(2)(a)(iv).

2.3.5 We are proposing to limit the role for the Agency in respect of premises described in Regulation 5(2)(a)(i) to (iii) of SI 2005/2059 to those premises which are approved, or conditionally approved, or licensed under current legislation. These are premises which handle products of animal origin, with some exceptions. These exceptions are “non-approved” premises are to be subject to enforcement action by the food authority. This retains the current arrangements for enforcement in respect of certain meat plants. This has been achieved in Regulation 5(2)(a) and (6) of the draft SI.

2.3.6 We are proposing to amend Regulation 13 to provide that samples taken in accordance with the Regulations are subject to the Food Safety (Sampling and Qualifications) Regulations 1990 in the same way as samples taken under the Food Safety Act 1990.

2.3.7 Schedule 7 contains consequential amendments which are necessary to *other* existing legislation when the Food Hygiene (England) Regulations apply. These amendments are of a technical nature and require no changes in practice and so have no impact upon the sector.

2.4 Rationale for government intervention

2.4.1 Failure to intervene would result in the food hygiene legislation not being fully and effectively applied in England, with the resultant risk of failing to improve the overall public health position in the UK with regard to the level of food-borne illness.

2.4.2 The background against which food hygiene legislation should be viewed is the incidence of foodborne disease. In 2003, it was estimated that the total number of cases of Indigenous Foodborne Disease (IFD) in England and Wales was 843,049 of which 253,382 visited a GP and 17,230 cases were admitted to hospital. It is estimated that 443 cases resulted in death. Similar figures for Scotland and Northern Ireland are not available. However, based on evidence from laboratory reports for 2002, foodborne disease in Scotland is estimated to account for 11% of all cases in the UK and Northern Ireland for 2%. The cost of IFD, therefore, is estimated to be in excess of £1.5 billion per year¹. Evidence regarding 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. Additionally, most cases arising in the home are thought to originate from food containing pathogenic microorganisms at the time of purchase. It is possible that a small proportion of cases reported might be due to organisms present in the domestic environment, but it is not possible to eliminate these cases from consideration here.

2.4.3 A secondary risk is the chance of action being taken against the UK as a result of its failure to discharge EU Treaty obligations.

2.4.4 In particular, failure to implement the changes provided for in the Food

¹ Information on food poisoning incidence in the UK is outlined at Annex D of the Full regulatory impact assessment: Proposals to Consolidate EU Food Hygiene Legislation (<http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/>)

Hygiene (England) Regulations 2006 would result in our not having the enforcement measures in place to fully implement the EU hygiene regulations and we would not have provided for a change in the responsibility for enforcing EU hygiene regulations at the level of primary production.

3. Consultation

Within Government

3.1 Other Government Departments have been included in the consultation on the draft SI. Both DEFRA and SMS were opposed to the extension of remedial action notices to all food businesses, however this proposal has not now been included in the final SI.

Public consultation

3.2 The draft SI was subject to public written consultation for 12 weeks. The Commission implementing and transitional measures were subject to the same consultation as they were included in the SI.

3.3 The consultation on the measures contained in the Food Hygiene (England) Regulations 2006 attracted 94 responses. 67 were from enforcement authorities, 20 from industry, 6 from others including OGDs and 1 from consumers.

3.4 We had proposed in the consultation to extend the use of remedial action notices and detention notices to all food businesses to which the legislation applies, including those at the level of primary production. They are currently only available in respect of premises subject to approval under Article 4 (2) of Regulation 853/2004.

3.5 While local authority enforcement officers were in favour of this extension, the proposal met with strong objections from many food industry bodies, DEFRA and SBS on behalf of industry. We also felt we could be subject to accusations of procedural infringement if we introduced such a significant change at this time so soon after the end of consultation. Given the divergence of respondents views we have withdrawn this provision from the SI and may consider an amendment at a later date dependent on a further evaluation of the arguments for and against and a full cost benefit analysis. The provision will therefore remain as provided for in SI 2005/2059.

3.6 Otherwise the other changes proposed during the consultation on the Food Hygiene (England) Regulations were not contentious and attracted no major opposition.

4. Options

4.1 Options are limited in this area as the adoption of national law is necessary in order to apply the Commission implementing and transitional measures, therefore alternatives to regulations are not feasible. To do nothing would leave the UK in

breach of an EU obligation. Where changes are proposed to the measures concerning enforcement, these too derive from the need to provide for the effective application of the EU legislation.

4.2 Options in relation to SI 2005/2059 were identified at **Section 4 of Appendix 1**.

5. Costs and benefits

Sectors and groups affected

5.1 Generally speaking, 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 160,000³ primary producers, including farms, aquaculture establishments and fishing vessels. The majority of the businesses will be affected by the EU legislation to some extent. The businesses affected range from low-risk one-person businesses e.g. selling wrapped confectionery, through to major businesses manufacturing high-risk products and employing hundreds of people.

5.2 The amendments within the Food Hygiene (England) Regulations 2006 relate particularly to enforcement (sanctions and penalties and a change in responsibility for enforcement at the level of primary production) and so affect these businesses and the authorities responsible for the enforcement of food hygiene legislation.

5.2 The Food Standards Agency does not consider that the provisions within the Food Hygiene (England) Regulations 2006 will have any impact on racial equality issues. No economic, social or environmental impact from the proposal has been identified.

Benefits

5.3 The most significant benefit identified in respect of SI 2005/2059 was the practical and effective application of the new simplified EU food hygiene legislation, thus supporting the overall objective of improving public health by reducing the levels of foodborne illness in the UK. Benefits would be shared between all the individuals affected: consumers, food businesses, business generally and enforcers.

5.4 The changes set out in the new SI would, through application of the Commission implementing and transitional measures, provide for the benefits identified in respect of those measures to be realised. Changes proposed in respect of the enforcement provisions would contribute to realising the benefit of practical and effective application of the simplified food hygiene legislation.

Costs

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

³ Based on agricultural census information.

5.5 Costs associated with SI 2005/2059 were identified in Appendix 1. No additional costs to businesses are identified as a consequence of changes being made in the draft Food Hygiene (England) Regulations 2006.

5.6 Costs associated with the Commission implementing and transitional measures are identified in a separate RIA attached at **Annex D**.

6. Small Firms Impact Test

6.1 In respect of SI 2005/2059, refer to the RIA submitted with that instrument (**Appendix 1, section 6**) for an assessment of the impact on small businesses of the hygiene legislation as a whole.

6.5 The changes contained in the proposed regulations to replace SI 2005/2059 are not likely to impact disproportionately on small businesses. We will continue to develop and consult on material concerning the application of the food hygiene regulations as a whole which address the particular needs of small businesses throughout the food chain. Particular emphasis will be given to continuing to work with businesses and enforcers to equip them to comply with the requirement for food safety management procedures based on HACCP (Hazard Analysis and Critical Control Point) principles.

7. Competition Assessment

7.1 In respect of SI 2005/2059, the competition filter revealed that the requirements of the proposed legislation are unlikely to have a significant impact on competition. The legislation applies equally to all new and existing businesses across the food industry and is unlikely to fall disproportionately on any individual firm. Given that the proposals focus on the administrative processes carried out by businesses, these are not anticipated to be very costly or impact significantly on the administrative capacity of firms. As a result, there are unlikely to be any significantly increased barriers to entry or impacts on the structure or dynamics of this sector. Furthermore, the proposed changes are likely to increase the transparency and consistency of legislation across the food industry and this may act to support a competitive environment.

7.2 It is not envisaged that the changes contained in the Food Hygiene (England) Regulations 2006 will present any further competition issues.

8. Enforcement, sanctions and monitoring

8.1 The purpose of the national legislation is to attribute responsibility for the enforcement of the directly applicable Community legislation and to provide enforcers with the relevant powers of entry, and other mechanisms to provide for enforcement. It also creates sanctions in relation to offences. The approach taken was to mirror the provisions of the Food Safety Act 1990.

8.2 For food authorities, the Code of Practice and associated Practice Guidance will be re-issued under Section 40 of the Food Safety Act 1990 and Regulation 24 of the Food Hygiene (England) Regulations 2005 and eventually of this SI to reflect the

provisions of the new hygiene legislation. This revision was subject to public written consultation. This will facilitate effective and consistent enforcement by the enforcement authorities.

8.3 The Code requires that food authorities should ensure that enforcement action taken by their authorised officers is reasonable, proportionate and consistent with good practice. Authorised officers should take account of the full range of enforcement options. This includes educating proprietors, giving advice, informal action, sampling, detaining and seizing food, serving improvement notices, prohibition procedures and prosecution procedures. Except where circumstances indicate a significant risk, officers should operate a graduated and educative approach starting at the bottom of the pyramid i.e. advice/education and informal action and only move to more formal action where the informal does not achieve the desired effect.

8.4 The new SI provides for a change in responsibility for the enforcement of food hygiene at the level of primary production. A decision still has to be made as to which body will be responsible for this.

9. Implementation and delivery plan

9.1 Throughout the development of this legislation stakeholders have been fully consulted. The FSA has produced generic and sector specific guidance and the Code of Practice under the Food Safety Act has been revised to reflect the changes for enforcement authorities from 1 January 2006.

9.2 Decisions still need to be made on which body should undertake enforcement at the level of primary production. We will continue to consult stakeholders as these discussions develop.

10. Post-implementation review

10.1 The EU legislation includes a revision clause under which the Commission will report to the European Parliament and the Council on the implementation of the Regulation in May 2009. At this stage, depending on lessons of experience, further amendments may be proposed. UK stakeholders will be consulted on the review process.

11. Summary and recommendation

11.1 In summary, the proposals that are the subject of this RIA will have limited effect on stakeholders other than those already identified in the RIA submitted with 2005/2059 (**Appendix 1 below**)

11.2 The FSA intend to apply the proposals as set out in this RIA, having discounted at present extending the use of remedial notices due to strong opposition from industry.

12.1 Declaration and publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

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Date: 9th January 2006

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FULL REGULATORY IMPACT ASSESSMENT (Food Hygiene (England) Regulations)

1. Title of proposal and timetable

The Food Hygiene (England) Regulations 2005. The Regulations are necessary to apply a package of three EU food hygiene regulations that entered into force in May 2004. The new legislation will apply on 1 January 2006.

2. Purpose and intended effect of measure

(i) The objective

2.1 The three EU regulations will be directly applicable in each Member State of the EU. The new EU legislation has as its primary objective the optimisation of public health protection by improving and modernising the previous sector specific EU legislation. National legislation is neither required nor allowed, to give effect to the EU Regulations, beyond providing for their enforcement in England. However, there are a number of areas where the EU Regulations either require or allow Member States to adopt certain provisions in their national law and these Regulations address those aspects too.

(ii) Devolution

2.2 Separate national legislation (Statutory Instruments) will be introduced for each of the four countries of the UK.

(iii) The background

2.3 The new EU legislation (which is the subject of a separate RIA) has as its primary objective the optimisation of public health protection by improving and modernising the previous sector specific EU legislation. The new EU legislation establishes the conditions under which food is produced to prevent, eliminate or acceptably control pathogen contamination of food. More risk based and flexible procedures are introduced that are better matched to the needs of individual businesses and to enforcement. This is facilitated by the introduction of food safety management procedures based on the application of Hazard Analysis and Critical Control Points (HACCP) principles. The legislation introduces a "farm to fork" approach to food safety, by including primary production in food hygiene legislation for the first time in the majority of cases. The separate RIA considers the costs and implications of these issues. A brief outline of the content of the new EU legislation is provided at Annex 1. The adopted EU legislation contain five linked proposals covering food hygiene requirements in the European Union. These include 3 main Regulations¹ and Directive 2004/41/EC that repeals existing food hygiene legislation. The fourth proposal (now adopted), relating to animal health rules, is the responsibility of Defra and is not the subject of this RIA. This RIA should to be considered with the RIA on the EU Hygiene Regulations themselves.

The Statutory Instrument (SI)

2.5 The SI is made under the powers given by section 2 (2) of the European Communities Act (ECA) 1972. As the subject matter of the SI is food hygiene it has been developed to mirror the provisions of the Food Safety Act 1990. It creates penalties and offences, powers of entry and other administrative measures based in the main on existing requirements. Where the EU Regulations do not apply and no more specific national provisions have been made, the provisions of the Food Safety Act 1990 will apply to ensure the supply of food in such circumstances is fit for human consumption.

(iv) Rationale for Government Intervention

2.6 Failure to intervene would result in the new legislation not being fully and effectively applied in the UK with the resultant risk of failing to improve the overall public health position in the UK with regard to the level of food-borne illness. The background against which the new legislation should be viewed is the incidence of foodborne disease, the cost of which is estimated to be in excess of £1.5 billion per year (see RIA on the EU Regulations themselves).

2.7 A secondary risk is the chance of action being taken against the UK as a result of its failure to discharge EU Treaty obligations. The proposals are intended to meet the obligation to introduce national law in certain cases.

3. Consultation

Within Government

3.1 Other government departments were included in the stakeholder consultation on the policy options. Defra supplied comments that have been taken into account in developing the policy proposals. Officials have had more detailed contacts with Defra and Home Office on specific issues.

Public consultation

3.2 A stakeholder consultation (ended in June 2004) elicited views on the policy underlying the development of national legislation and other related issues. A further stakeholder consultation (ended in January 2005) sought views on the statutory instrument and associated guidance developed to apply these rules. A summary of the replies received to the first consultation and an FSA response are available on the FSA website at http://www.food.gov.uk/foodindustry/Consultations/completed_consultations/completed_euhygieneleg. Summaries and responses to the second consultation will be published next month. The results of both consultations have been used to further develop the policy options, the SI and the content of guidance on the approach to applying the legislation. The FSA Board reviewed the results of the consultation at its open meeting in March 2005 and endorsed the approach being taken.

3.3 The responses of stakeholders to the initial policy consultation were generally in favour of the FSA preferred options. Consultees overwhelmingly called for practical and flexible application of the EU legislation in the UK and for national measures that respected existing practice and did not add to the burden on business. This approach has been respected in developing the SI and associated guidance to give effect to the legislation. A large proportion of comments concerned the interpretation of certain definitions contained in the EU Regulations e.g. ‘small quantities’, ‘marginal’ and ‘restricted’. Stakeholders, understandably, want clarity on what these terms mean in practice. Where there were differences of opinion on questions of detail, e.g. the interpretation of what constitutes “local”, a practical middle ground solution that should be acceptable to all has been sought.

4. Options

4.1 Options are limited in this area as the adoption of certain national law is a requirement of the EU legislation. To do nothing would leave the UK in breach of an EU obligation. Similarly, not to repeal existing UK national legislation overtaken by EU law would be a breach of a statutory obligation. Where the application of the EU hygiene legislation is not given effect to in the Statutory Instrument, it will be provided for in guidance material.

Proposals for the Adoption of National Legislation/Administrative Measures

4.2 A principal objective of the proposed national rules and administrative measures is not to ‘gold plate’ the EU legislation. The majority of the FSA options, should they be adopted, would result in either the retention of the status quo or nothing additional to the requirements of the EU legislation. In both cases the result will be no identifiable new costs or benefits over and above those identified in the RIA covering the EU regulations. Some, albeit minor, costs and benefits may arise where the status quo may change and these are explored further below. Options other than those now set out as the FSA proposals were included in the initial RIA and previous consultation which concluded in June last year. These options are set out in Annex 2. In most cases, those are excluded from consideration now, as there was no support for the alternative in the replies to the consultation or initial RIA. For this reason the individual FSA preferred policy options identified in the initial RIA are brigaded here as FSA proposals (amended as necessary to take account of the views expressed in the previous stakeholder consultation). These have been grouped as follows:

- a) Measures where the status quo will be retained;
- b) Measures where the EU legislation will be relied upon;
- c) Measures where changes to the status quo would occur.

In addition, there is a fourth group to cover;

- d) consideration of primary production issues where definite policy decisions have yet to be taken.

a) Measures Where the Status Quo Will be Retained

i) Rules to Govern the Direct Supply of Small Quantities of Primary Products to the Final Consumer or to Local Retail Establishments supplying the Final Consumer

The FSA option is to rely on the general provisions of the Food Safety Act 1990 (Section 8: Selling food not complying with food safety requirements and Section 14: Selling food not of the nature or substance or quality demanded) to implement rules in this area. The FSA view is that specific new provisions are not justified. (The intention would be to include under this exemption the direct sale of small quantities of primary products to the final consumer by mail order/internet sale.

It is proposed to provide information on what constitutes “small quantities” in industry and enforcement guidance. A meaningful interpretation of what constitutes a small quantity of various primary products will vary enormously from product to product, e.g. potatoes, strawberries, fish etc.

It is proposed that “local” and “localised” be interpreted in guidance as ‘sales within the supplying establishment’s own county plus the greater of either the neighbouring county or counties or 30 miles/50 kilometres from the boundary of the supplying establishment’s county’. “County” would be interpreted here as meaning metropolitan or non-metropolitan counties in England and Wales as defined in the Local Government Act 1972 and London Government Act 1963 (e.g. Greater London, North Yorkshire, Leicestershire, Powys), a local authority in Scotland, or an administrative county in Northern Ireland (e.g. Co. Fermanagh). This makes allowance for the imbalance between closely spaced urban authorities and widely spaced remote populations, as well as those on the boundaries or bordered by the sea. This interpretation would also apply in the case of supplies of poultry and lagomorphs below. The FSA intention is to review this interpretation in two or three years in the light of experience.

ii) Rules to Govern the Direct Supply by the Producer of Small Quantities of Meat from Poultry and Lagomorphs Slaughtered on the Farm to the Final Consumer or to Local Retail Establishments directly supplying such Meat to the Final Consumer as Fresh Meat

The FSA option is to maintain the status quo by retaining the equivalent of current controls as set out in the Poultry Meat Regulations. This would exempt producers from the detailed rules contained in regulations 853/2004 and 854/2004. The exemption limit would be set at under 10,000 poultry or lagomorphs per year reared and slaughtered on the farm as at present. The current rules for labelling and record keeping would also be retained. ‘Local’ would be considered as in (i) above. Such supplies would be subject to the general rules contained in Regulation 852/2004.

A separate EU Regulation on microbiological testing requirements is under discussion and so the possibility of the testing of carcasses would be the subject of that regulation and the accompanying RIA. It is not considered here.

iii) Approval Codes – Individual Product Codes

The FSA option is not to make use of product codes a requirement of national law as it could only be used in certain sectors. Instead the use of such codes should be addressed in guidance, both for industry and enforcement so as to ensure consistency of interpretation. Guidance is being prepared in order to minimise inconsistencies as far as possible.

iv) Fish Products – Authorisation to Transport frozen fish

The FSA option is to set criteria, in line with existing rules, to exempt food business operators from maintaining fishery products at an even temperature of not more than -18°C in all parts of the product if the transport is under 30 miles/50 kilometres or the journey is less than 1 hour. The criteria would be laid down in Statutory Codes of Practice and Practice guidance under the Food Safety Act.

v) Rules relating to raw milk or raw cream for direct human consumption

The FSA option is to maintain existing rules as follows.

In England and Northern Ireland we propose to retain the current restrictions on the sale of raw milk intended for direct human consumption.

In Wales we propose to maintain the current restrictions on the direct sale of raw milk and cream for human consumption but expand the existing labelling requirements.

In Scotland, we propose to extend the current ban on the sale of raw milk intended for human consumption to include milk from all farmed animals.

Vi) Fish Products – Lockable Facilities for Competent Authority Use

FSA Proposal - Not to make adequately equipped lockable facilities to be available exclusively for the use of the competent authority mandatory in national law. Instead, on the basis that the provision will not always be needed or practical, the proposal is to allow discretion for an enforcement authority to apply the provision through Statutory Codes of Practice and guidance.

vii) Fish Products – Competent Authority Authorisation not to Carry out Freezing

FSA Proposal – To allow for the producer not to freeze certain fish products. The intention is that both practices and enforcement would be addressed through the provision of Statutory Codes of Practice and guidance. In each case, enforcement authorities would be required to carry out a risk assessment and the producer would require approval for this activity.

viii) Fishing Vessel – Conditional Approval

FSA Proposal – To provide the competent authority with power to refuse product from any factory or freezer vessels which have not received full approval within the

12 month period. The intention is that both practices and enforcement is being addressed through the provision of Statutory Codes of Practice and guidance.

b) Measures where the EU Legislation will be Relied Upon

ix) Rules to Govern Hunters who supply Small Quantities of Wild Game or Wild Game Meat Directly to the Final Consumer or to Local Retail Establishments Directly Supplying the Final Consumer

FSA proposal – Subject such supply to the general provisions of Regulation 852/2004 and not apply more specific rules. The quantitative limit applied to such supplies would be under 10,000 small wild game and under 300 large wild game per year. These limits would ensure that small producers are not subject to the detailed provisions of Regulations 853/2004 and 854/2004. The under 10,000 small wild game bird limit would also be consistent with rules for poultry and lagomorphs. Guidance has been produced to provide a meaningful interpretation of small quantities. ‘Local’ would be considered as in (i) above.

x) Registration of Food Business Establishments

FSA Proposal - The requirements currently contained in the Food Premises (Registration) Regulations 1991 will be replaced by the requirements of Article 6(2) of Regulation 852/2004. It is intended that these existing requirements will, where possible, form the basis of new requirements, mainly through the registration of establishments with the local authority. Existing registered premises will not have to re-register.

xi) Supply of Food of Animal Origin from One Retail Establishment to Another

FSA Proposal – The FSA consider that, in general, the rules contained in Regulation 852/2004 represent proportionate and effective control for retail activities. The proposal therefore is to rely on those rules and not to take up the option to apply the more detailed rules contained in Regulation 853/2004 generally to retail activities.

This will require guidance on the interpretation of the terms in Recital 13 of Regulation 853/2004 under which the exemption can be applied as follows:

- “localised”, will be as described for local direct supplies as in (i) above;
- “marginal”, will be up to a quarter of the business’ turnover in terms of food; and,
- “restricted”, will be specified product categories as referenced in Regulation 853/2004 (e.g. dairy products, collagen, minced meat) and establishment types (e.g. a butcher’s shop, distribution centre).

xii) Food Chain Information Accompanying Animals to the Slaughterhouse

FSA Proposal – To allow food chain information to accompany animals to the slaughterhouse in all the circumstances permitted by the Regulations. Not to allow for this flexibility, and insist that the information precede the animals in all circumstances, would be impractical. This flexibility would avoid the need for

individual judgement by the Official Veterinary Surgeon present in the slaughterhouse.

c) Measures Where Changes to the Status Quo Would Occur

xiii) Approval – and Withdrawal/Suspension of Approval for the Unit/s of Wholesale Markets

FSA Proposal – The FSA propose to make full use of this flexibility so that in the event of an infringement, action could be taken against a single unit rather than seeking the closure of an entire market operation.

xiv) Approval – Making Lists of Approved Establishments Available

This issue is now part of the EU Regulation on Official Feed and Food Controls (Regulation No. EC 882/2004) and so is not considered here. However, the Commissions' proposal for implementing and transitional measures lays down a format for standardising this process. Any impact will be considered in the RIA developed for these measures later in the year.

xv) Live Bivalve Molluscs (LBMs) – Registration Documents not Required Where the Gatherer is also Dispatch Centre etc.

FSA Proposal – Not to require registration documents for each batch unless the operator of the dispatch, purification, relaying and processing operations are different. This is for reasons of practicality and ease of inspection and because it does not give rise to food safety concerns. These provisions have been included in Statutory Codes of Practice and guidance.

d) Primary Production Issues

xvi) Registration of Primary Production Establishments

FSA Proposal - rely on existing registration arrangements as far as possible except where a primary production establishment would not otherwise be registered. Information already held by Agriculture Departments for other purposes would be used to meet this requirement.

xvii) Guides to good practice at the level of Primary Production

FSA Proposal – Where appropriate to encourage industry to develop voluntary guides to good hygiene practice for primary production activities to aid compliance with the regulations.

4.3 The Statutory Instrument includes provisions to retain existing national measures for the control of bulk transport of liquid oils, fats and raw sugar by sea and for temperature control requirements. These simply repeat existing requirements and hold no new cost or benefit implications.

5. Costs and benefits

Sectors and groups affected

5.1 There are approximately 600,000 food business establishments in the United Kingdom, covering catering, retail, manufacturing and distribution. In addition, there are in the region of 160,000 primary producers, including farms, aquaculture establishments and fishing vessels. The majority of the businesses will be affected by the EU legislation to some extent. The businesses affected range from low-risk one-person businesses selling e.g. wrapped confectionery, through to major businesses manufacturing high-risk products and employing hundreds of people. However, most of these businesses will notice little effect from the specific national measures.

5.2 The specific measures described may have a greater effect upon some business sectors than others in particular in the primary production sector where the policy approach is yet to be determined. Stakeholders views are that there should be a single enforcement authority for this area and enforcement should be consistent across all sectors with clear guidelines on interpretation. The FSA are taking these points on board whilst developing the arrangements to apply the legislation at the level of primary production.

Benefits

5.3 The most significant benefit from adopting the proposed national rules as suggested above would be the practical and effective application of the new simplified legislation thus supporting the overall objective of improving public health by reducing the levels of foodborne illness in the UK.

5.4 Benefits would be shared between all the individuals affected; consumers, food businesses, business generally and enforcers.

5.5 The move to the withdrawal and suspension of approval for individual market units (3.2 c) xiii) will be a benefit to market operators and this has been appreciated by stakeholders in response to the initial consultation. It could result in some minimal savings for individual market operators dependent on the number of infringements that occur.

Sustainable Development

5.6 Other than the costs and benefits identified elsewhere, the proposed legislation holds little in terms of social, economic and environmental impacts. In social and economic terms a contribution to the overall objective of improving public health may result. There are no identified environmental impacts arising from the proposals.

Costs

(i) Compliance costs

5.7 The policy proposals presented do not substantially affect the compliance costs identified in the RIA on the package of EU legislation. The majority of the measures outlined in section 3 above will maintain the status quo or simply apply the requirements of the EU legislation. As such of themselves they hold no additional cost implications. Potential costs were identified by stakeholders in the primary production sector associated with keeping records and reading guidance, however, many of these costs are covered by the RIA on the EU legislation itself. Outstanding costs will be further explored in the RIA covering the Commission's implementing and transitional measures later in the year.

5.8 The cost implications of the proposals set out in section 3.2 are as follows:

a) Measures Where the Status Quo Will be Retained

Cost Implications

The assumption, based on the evidence available, is that if the FSA proposals are applied in all of the cases above, the measures are not likely to impose any additional costs, as they would, in effect, maintain the status quo.

b) Measures Where the EU Legislation Will be Relied Upon

Cost Implications

If the FSA proposals are applied, the effect of the measures would be catered for in the EU legislation and so there would be no additional cost over and above that described in the RIA on the package of EU legislation.

c) Measures Where Changes to the Status Quo Would Occur

Cost Implications

If the FSA proposals are applied, the measures are not estimated to have significant cost implications. These provisions should enable enforcement action to be more targeted. The standardisation of lists of approved establishments (3.2 c) xiv) would require a minor change to the procedure by which competent authorities compile and maintain lists. This is unlikely to impose additional costs on competent authorities and could even result in a small saving in administrative costs, but this is unlikely to be significant. Any such costs will be further explored in the RIA covering the Commission's implementing and transitional measures later in the year.

d) Primary Production Issues

Cost Implications for 3.2 c) xvi)

As described in the RIA on the package of EU legislation, there will be no change to the registration arrangements covering most primary producers. There are no plans to

introduce a new wholesale registration requirement. To this extent the status quo would be maintained and there would be no new cost implications.

It is possible that some primary producers may not be registered in any way at present with the competent authority and the previous consultation produced ideas on operators who may not be covered at present. However the areas identified, namely hand rakers of shellfish are thought to be so small as to represent a de minimis additional requirement and cost other than those identified in paragraph 5.1. Any such costs will be further explored in the RIA covering the Commission's implementing and transitional measures later in the year.

Cost Implications for 3.2 c) xvii)

There are no direct industry compliance costs associated with the development or use of voluntary guides to good hygiene practice. There may, however, be some cost to industry if individual business operators choose to become involved in the development of guidance for the first time. This may however be offset by the benefit to industry of guidance being more suitable to its needs.

5.9 A Public Services Threshold Test has been completed and the proposals being considered contain no significant issues for public services.

(ii) Other costs

Impact on Charities and Voluntary Organisations

5.10 The FSA believes that the measures outlined in the RIA will have no effect on charities and voluntary organisations.

5.11 The Food Standards Agency does not consider that implementing these Regulations will have any impact on racial equality issues.

(iii) Costs for a Typical Business

5.12 The policy proposals set out above do not suggest any particular additional costs for particular business types other than the possible costs to primary producers in paragraph 5.7.

Issues of equity and fairness

5.13 These proposals do not introduce any new questions of equity or fairness.

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

6.1 The Small Business Service has been included in this consultation process and the previous stakeholder consultation, however, no comments were received to date.

6.2 A number of bodies representing small businesses were included in the initial stakeholder consultation. The organisations that responded to the consultation were the British Hospitality Association, the Family Farmers' Association, the Forum of Private Business, the National Association of Master Bakers, the National Association of Tripedressers, the National Farmers Union, the Royal Association of British Dairy Farmers, the Specialist Cheesemakers Association, Welsh Lamb and Beef Promotions, FACE UK and the Women's Food and Farming Union. A large number of other bodies and individual companies did not respond. In addition, visits have been made to a number of individual farm businesses in order to gain an understanding of the present stage of preparedness for the new requirements at primary production level and the immediate reaction of farmers. The overriding concern for small business is the desire to avoid further burden and bureaucracy. In relation to the majority of the individual policy options identified the stakeholder supported the preferred option proposed. No significant new burdens on small business were revealed.

7. Competition Assessment

The competition filter revealed that the requirements of the proposed legislation are unlikely to have a significant impact on competition. The legislation applies equally to all new and existing businesses across the food industry and is unlikely to fall disproportionately on any individual firm. Given that the proposals focus on the administrative processes carried out by businesses, these are not anticipated to be very costly or impact significantly on the administrative capacity of firms. As a result, there are unlikely to be any significantly increased barriers to entry or impacts on the structure or dynamics of this sector. Furthermore, the proposed changes are likely to increase the transparency and consistency of legislation across the food industry and this may act to support a competitive environment.

8. Enforcement and sanctions

8.1 It is very difficult to estimate the precise costs and benefits of the proposals to enforcement agencies. Local authorities and their representative organisations (e.g. LACORS and CIEH) have been consulted on the proposals. Some potential costs were identified by enforcement authorities associated with registering new businesses, implementing new guidance and updating procedures and paperwork. However, no cost estimates were provided. A number of these costs will also be subsumed by the RIA on the main EU Regulations. Costs associated with enforcement at the level of primary production will be further explored in the RIA covering the Commission's implementing and transitional measures later in the year if necessary.

8.2 The Code of Practice and associated Practice Guidance will be re-issued under Section 40 of the Food Safety Act 1990 and Regulation 24 of the Food Hygiene (England) Regulations 2005 to reflect the provisions of the new EU hygiene legislation. This will facilitate effective and consistent enforcement by the enforcement authorities.

9. Monitoring and review

9.1 The EU legislation includes a revision clause under which the Commission will report to the European Parliament and the Council on the implementation of the Regulation five years after 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 and on the accompanying national measures outlined in the RIA. The European Commission are also bringing forward legislation on implementing and transitional measures for the main EU Regulations. Any further costs and burdens associated with these measures will be covered by a separate RIA later in the year.

10. Implementation and Delivery Plan

Throughout the negotiations on the EU proposals, all stakeholders have been fully consulted on the legislation regarding their responsibilities under the new legislation. This has involved FSA public written consultations, meetings and attendance at conferences and other events. The FSA has also produced guidance on the requirements of food business operators under the new legislation based upon their activities. Summary guidance has also been produced for small businesses. Guidance is also being issued to enforcement authorities in the form of a revision to the Code of Practice and practice guidance under the Food Safety Act. Training on the requirements of the new legislation for local authorities is also being organised, commencing later this year. We are discussing how to communicate information about the legislation more widely for stakeholders.

Post implementation, we will continue engaging with stakeholders and consider any further training of local authorities required. We will also develop any FSA guidance as appropriate.

11. Post Implementation review

The EU legislation includes a revision clause under which the Commission will report to the European Parliament and the Council on the implementation of the Regulation in May 2009. This is a worthwhile exercise where the lessons of experience can be learned and, if appropriate, amendments can be proposed. These national measures will be included in this review. UK stakeholders will be consulted on the review process and on the accompanying national measures outlined in the RIA.

12. Summary and Recommendation

12.1 In summary, the proposals that are the subject of this RIA will have limited effect on stakeholders and cause little change to the existing legislation.

12.2 The FSA intend to apply the proposals as set out in this RIA taking account of any further views received.

13. Declaration

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs.

Signed...N/A –**SI already made and to be revoked by the Food Hygiene (No 2) (England) Regulations**

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ANNEX 1

NEW EU FOOD HYGIENE LEGISLATION – The new instruments concerning 5 linked pieces of legislation.

Regulation 852/2004 (H1)

1. This regulation 852/2004 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 good practice guides to aid compliance,
- 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. This is the cornerstone of the package. It applies to all stages of production, processing and distribution of food (including primary production) other than:

- primary production for private domestic use
- domestic preparation, handling or storage of food for private domestic consumption

and

the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments supplying the final consumer. (This is to be controlled nationally).

3. The Regulation contains "horizontal" rules which are those which will apply across all food sectors. The proposal describes the duties of food business operators (as opposed to describing how control is to be exercised by enforcement authorities). It introduces for all food sectors, other than for primary production, a requirement for food safety management procedures based on HACCP principles. It provides for the development and voluntary use of national or Community good practice hygiene guides to assist food business operators comply with the legal requirements.

4. The Regulation establishes the idea that food businesses need to be registered with the competent authority so that enforcers know where food businesses are and may factor them into official control programmes. This proposal also lays down basic hygiene requirements for premises, staff, packaging, storage, transport, and handling of foodstuffs.

5. With regard to primary production, the Regulation does not require the application of HACCP procedures. It does however require that primary producers control the hazards associated with their operations. As with other food sectors, good practice guides may need to be produced.

6. The Regulation will require that food imported into the Community complies with same or equivalent standards. It also contains the capacity for Member States to adapt certain of the provisions (without compromising the objectives of the Regulation) in certain circumstances, subject to Commission "approval" under comitology.

Regulation 853/2004 (H2)

7. This regulation 853/2004 reflects the fact that products of animal origin tend to represent the highest risk, so that additional controls are needed. It lays down specific controls which apply additional to those in Regulation 852/2004. They do not (in general) apply at the level of retail sale, nor do they apply to food containing both products of plant origin and processed products of animal origin.

8. In bringing all the existing controls together, it has been possible for the Commission to remove some repetition and inconsistency that existed in the current legislation.

9. The Regulation requires the approval by enforcement authorities of premises handling products of animal origin. Products of animal origin will have to bear an identification mark displaying information about where the product was produced or handled. Fresh red meat and game meat will have to bear a health mark, applied under the supervision of the Official Veterinarian (OV). As with the first proposal, the same, or equivalent, standards are to be applied to imported products.

Regulation 854/2004 (H3)

10. The majority of this regulation 854/2004 concerns detailed rules for the conduct of meat hygiene controls, although rules are also laid down for controls on live bivalve molluscs and the areas from which they may be gathered, fishery products and raw milk and dairy products. The Regulation also lays down rules for the approval of establishments.

11. The changes to controls on meat hygiene will take account of the introduction of HACCP-based procedures in slaughterhouses. These changes will also take account of the fact that the traditional meat inspection regime is not equipped to cope with the presence of pathogenic micro-organisms which now account for most meat-related foodborne disease incidents.

12. The system of meat inspection will not affect current TSE or animal welfare controls but introduces a number of other changes:

Although ante-mortem inspection will still be carried out by the OV and post-mortem inspection will remain his or her responsibility, operators are given clear responsibility for the hygienic production of meat, with the role of officials changing from supervision to audit.

All animals will have to be accompanied to slaughter by “chain information” supplied by the farmer. This will contain information relevant to food safety. If this information is not available the animals will be slaughtered, but their meat will not be allowed into the food chain.

Unnecessary post-mortem inspections for some conditions may not have to be carried out, where area or herd guarantees of disease freedom can be provided.

Post-mortem handling of the carcasses and offal will be progressively minimised, following advice from the European Food Safety Authority (EFSA) on procedures for individual types of animal.

Ante and post-mortem inspection findings of significance for public health or animal health and welfare will be required to be included on relevant databases and communicated to public and animal health officials as appropriate, as well as to the farmer of origin and his/her veterinary surgeon.

The strict requirement for the full time presence of an OV is removed allowing OAs to take on more of the OV duties.

Directive 2004/41 (H5)

13. This directive 2004/41 will repeal the existing EU legislation and amend other related legislation with effect from 1 January 2006.

ANNEX 2

OPTIONS SET OUT IN THE INITIAL RIA

i) Rules to Govern the Direct Supply of Small Quantities of Primary Products to the Final Consumer or to Local Retail Establishments supplying the Final Consumer
Consultation reference: Annex 2, paragraph 6

Option 1 : Introduce specific new provisions to regulate the direct supply of small quantities of primary products to the final consumer into national law.

Option 2 : (FSA preferred option) Rely on the general provisions of the food Safety Act 1990 (Section 8: Selling food not complying with food safety requirements and Section 14: Selling food not of the nature or substance or quality demanded) to implement rules in this area.

ii) Rules to Govern the Direct Supply by the Producer of Small Quantities of Meat from Poultry and Lagomorphs Slaughtered on the Farm to the Final Consumer or to Local Retail Establishments directly supplying such Meat to the Final Consumer as Fresh Meat

Consultation reference: Annex 2, paragraphs 7 to 11

Option 1 : Rely on the application of general rules envisaged under H1 for the implementation of these measures.

Option 2 : Apply an extensive range of provisions under H2 for products of animal origin.

Option 3: (FSA Preferred Policy Option) Apply the microbiological criteria currently being proposed by the Commission (see Annex 2, paragraph 11) and retain existing rules intended to provide both consumer choice and traceability consisting of:

- (a) the Food Safety (General Food Hygiene) Regulations, the provisions of which will be replaced by H1,
- (b) a requirement that each carcass bear a label with the name and address of the farm of origin, and
- (c) a requirement to keep records of the number of birds processed and amount of meat despatched each week.

iii) Rules to Govern Hunters who supply Small Quantities of Wild Game or Wild Game Meat Directly to the Final Consumer or to Local Retail Establishments Directly Supplying the Final Consumer

Consultation reference: Annex 3, paragraphs 12 and 13

Option 1 : Introduce specific new provisions to regulate the direct supply of small quantities of primary products to the final consumer into national law.

Option 2 : (FSA preferred option) Rely on the general provisions of the food Safety Act 1990 (Section 8: Selling food not complying with food safety requirements and Section 14: Selling food not of the nature or substance or quality demanded) to implement rules in this area.

iv) Registration of Food Business Establishments

Consultation reference: Annex 2, paragraph 14 to 16

Option 1 (FSA Preferred Policy Option) : The requirements currently contained in the Food Premises (Registration) Regulations 1991, as amended (and equivalent legislation in Northern Ireland) and the associated guidance will be reviewed for their compatibility with the requirements of Article 6(2) of H1. It is intended that these existing requirements will, where possible, form the basis of new requirements.

No other options have been identified in this area. However we would welcome comments from stakeholders on other options if relevant that can be developed for the partial RIA.

v) Supply of Food of Animal Origin from One Retail Establishment to Another

Consultation reference: Annex 2, paragraph 17 to 23

Option 1 : make national measures to extend the application of H2 to retail establishments which are exempt by virtue of Article 1(5)(b) owing to the fact that they are considered to be a marginal, localised or restricted activity.

Option 2 : (FSA Preferred Policy Option) rely on the exemption under Article 1(5)(b) without taking up the option of making national rules in order for the controls of H1 to apply to as broad a range of retail activities as possible.

vi) Approval Codes – Individual Product Codes

Consultation reference: Annex 2, paragraphs 24 and 25

Option 1 : Do nothing.

Option 2 : To make provisions in national law for food business operators to have the option of using product codes.

Option 3 : (FSA Preferred Policy Option) Not to make use of product codes in national law. Instead the use of such codes should be addressed in guidance, both for industry and enforcement so as to ensure consistency of interpretation.

vii) Approval –and Withdrawal/Suspension of Approval for the Unit/s

Proposal reference: H3 Art. 3.3 & 3.4

Option 1 : Do nothing. This would risk the possibility of an entire wholesale operation being closed as a result of an infringement by a single unit operator and an unjustified burden on all operators.

Option 2 : (FSA Preferred Policy Option) To make provisions in national law for food business operators to have the option of using Secondary Numbers for Units of Wholesale Markets.

viii) Approval – Making Lists of Approved Establishments Available

Consultation reference: Annex 2, paragraphs 28 and 9

Option 1 : maintain current arrangements whereby different approaches are adopted in different product sectors.

Option 2 : (FSA Preferred Policy Option) Standardise the way in which lists of approved establishments are communicated to the competent Authority in a way which meets data protection concerns.

Sector-specific Issues

ix) Food Chain Information Accompanying Animals to the Slaughterhouse

Consultation reference: Annex 2, paragraphs 30 and 31

Option 1 : (FSA Preferred Policy Option) Allow food chain information to accompany animals to the slaughterhouse rather than being provided in advance in all circumstances permitted by the Regulations.

Option 2 : Only allow food chain information to accompany animals to the slaughterhouse in a limited number of specified circumstances permitted by the Regulations.

Option 3 : Make provisions to only allow food chain information to accompany animals to the slaughterhouse under the agreement/professional judgement of the Official Veterinarian.

x) Live Bivalve Molluscs (LBMs) – Registration Documents not Required Where the Gatherer is also Dispatch Centre etc.

Consultation reference: Annex 2, paragraphs 32 and 33

Option 1 : Do nothing – this would leave the requirement at the discretion of local authorities.

Option 2 : (FSA Preferred Policy Option) make national provisions so that registration documents may not be needed for each batch, unless the operators of the dispatch, purification, relaying and processing operations are different.

xi) Fish Products – Lockable Facilities for Competent Authority Use

Consultation reference: Annex 2, paragraphs 34 and 35

Option 1 : Do nothing and make to requirement for the provisions of lockable facilities.

Option 2 : To make provisions in national law for adequately equipped lockable facilities to be available exclusively for the use of the competent authority.

Option 3 : (FSA Preferred Policy Option) Not to make adequately equipped lockable facilities to be available exclusively for the use of the competent authority mandatory in national law. Instead this issue should be addressed in guidance.

xii) Fish Products – Competent Authority Authorisation not to Carry out Freezing
Consultation reference: Annex 2, paragraphs 36 and 37

Option 1 : Do nothing and not exercise this flexibility. All specified fish products would have to be frozen.

Option 2 : Make provisions in national legislation to exempt food business operators from carrying out freezing of certain fish products.

xiii) Fish Products – Authorisation to Transport frozen fish
Consultation reference: Annex 2, paragraphs 38 and 39

Option 1 : Do nothing and not allow any exemptions to transporting fish in a frozen state.

Option 2 : (FSA Preferred Policy Option) Set criteria to exempt food business operators from maintaining fishery products at an even temperature of not more than -18°C in all parts of the product if the transport is under 50 kilometres or the journey is less than 1 hour.

xiv) Fishing Vessel – Conditional Approval
Consultation reference: Annex 2, paragraphs 40 and 41

Option 1 : Do nothing – there is currently no provision for conditional approval.

Option 2 : (FSA Preferred Policy Option) make national provisions to ensure that as part of its vessel approval responsibilities the competent authority should have power to refuse product from any factory or freezer vessels which have not received full approval within the 12 month period.

xv) Rules relating to raw milk or raw cream for direct human consumption
Consultation reference: Annex 2, paragraph 42

Option 1 : Do nothing.

Option 2 : (FSA preferred policy option):
in England and Northern Ireland do nothing and maintain existing national rules.

in Scotland prohibit the placing on the market of raw milk and raw cream intended for direct human consumption.

for Wales) expand the current labelling requirements for the placing on the market of raw milk and raw cream intended for direct human consumption.

xvi) Registration of Primary Production Establishments

Consultation reference: Annex 2, paragraphs 43 to 45

Option 1 : set up a completely new registration system for food business operators operating at the level of primary production specifically for the requirements of this legislation.

Option 2 : (FSA Preferred Policy Option) rely on existing “registration” arrangements as far as possible except where a primary production establishment would not otherwise be registered.

xvii) Guides to good practice at the level of Primary Production?

Consultation reference: Annex 2, paragraphs 46 and 47

Option 1 : Do nothing and leave industry to consider the requirement for guides.

Option 2: (FSA Preferred Policy Option) To encourage industry to develop guides to good hygiene practice for primary production activities, where this would be beneficial, and to facilitate that process.

xviii) Enforcement at the level of primary production

Consultation reference: Annex 2, paragraphs 48 and 52

Option 1 : (FSA Preferred Policy Option) To use existing official presence on-farm (and in other sectors) to carry out hygiene enforcement that is proportionate, risk-based and effective.

Option 2 : To set up a new enforcement body for this purpose.

xix) Record keeping at the level of primary production

Proposal reference: Annex 2, paragraphs 53 to 56

Option 1 : To make provisions in national law to stipulate what records should be kept and for how long.

Option 2 : (FSA Preferred Policy Option) Not to make national law to stipulate what records should be kept and for how long. Instead this issue should be addressed in guidance, codes to good practice or through assurance schemes, emphasising a proportionate approach.

(PART 1)

Full Regulatory Impact Assessment

1. Title of proposal and timetable

- A. Commission Regulation (EC) No 1688/2005 implementing Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards special guarantees concerning salmonella for consignments to Finland and Sweden of certain meat and eggs
- B. Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
- C. Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for *Trichinella* in meat.
- D. Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) Nos 854/2004 and 882/2004 of the European Parliament and of the Council and amending Regulations (EC) Nos 853/2004 and 854/2004.

The first measure applies from 1 January 2006. Due to delayed publication of the other adopted measures in the Official Journal, the remainder will apply from 11 January 2006.

A Commission Regulation on microbiological criteria for foodstuffs is the subject of a separate RIA (**ANNEX D, PART 2**)

2. Purpose and intended effect

2.1. The Commission implementing and transitional measures are intended to provide transitional measures to assist food businesses and enforcers making the change to the new regulatory framework. They also establish detailed implementing provisions as provided for in the EU Regulations.

2.2 Background

2.2.1 New EU Food Hygiene Regulations entered into force in May 2004 and will apply in the UK from 1st January 2006. They are subject to two separate RIAs on the

EU Regulations themselves and their application in the UK. The RIAs can be accessed from the following weblinks :

<http://www.food.gov.uk/multimedia/pdfs/euhygiene2004riafull.pdf>

<http://www.food.gov.uk/multimedia/pdfs/hyg2005riaeng.pdf>

2.2.2 Regulation 882/2004 on official controls also came into force in May 2004 and will apply in the UK from 1 January 2006. Again, the EU Regulation and associated domestic legislation are subject to separate RIAs. These RIAs can be accessed from the following weblinks :

<http://www.food.gov.uk/foodindustry/regulation/ria/ria2004/officalfoodandfeedcontrols>

to the RIA for Regulation 882/2004, and

<http://www.food.gov.uk/foodindustry/regulation/ria/ria2005/offc2005ria>

to the RIA for the OFFC (E) Regs 2005. Similar regulations apply in all UK countries.

Implementing Measures

2.2.3 The Commission Regulation (EC) No 2074/2005 covers, with details in various annex, the following implementing measures relevant to the UK:

Visual inspection of Fishery products (Annex II): lays down obligations on Member States for the visual detection of parasites in fishery products and limits of volatile nitrogen in fishery products according to Article 11(9) of Regulation 853/2004.

Analytical methods for detection of marine biotoxins (Annex III): lays down analytical methods for the detection of marine biotoxins.

Mechanically separated meat (Annex IV): lays down provisions for the calcium content of MSM.

Lists of approved establishments (Annex V): lays down provisions for standardising the format for producing lists of approved establishments in the EC under Article 31 of Regulation 882/2004 on official controls which requires that lists of approved establishments are made available to other Member States and to the public.

Certificates for Importation of frogs' legs and snails, gelatine and collagen (Annex VI): lays down import certificate requirements updated to reflect the new EU Food Hygiene legislation.

Specifications for certain heat treatments used to process raw milk or dairy products (Annex VII): This Annex establishes standards and definitions for pasteurisation and ultra heat treatment of milk.

Other transitional measures

2.2.4 The Commission Regulation (EC) No 2076/2005 covers the following transitional arrangements:

Poultry and lagomorph meat supplied directly to the final consumer (Article 3): this allows Member States to maintain arrangements to supply small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat.

Requirements concerning stocks of products before January 2006 (Article 6): provides for Member States to continue marketing products only approved nationally under product specific hygiene legislation until their first inspection for approval under the new EU Food Hygiene legislation. Article 4 of the Commission Regulation also provides for the continued use of equipment that they ordered before the date of application of this Regulation until 31 December 2007.

Food Chain information accompanying animals to the slaughterhouse (Article 8): this Annex provides for obligations on food business operators at various stages in the food chain.

Use of clean water on fishery products (Article 11): lays down requirements for the use of clean water for on-land establishments for certain operations on fishery products until 31 December 2009.

Raw milk and dairy products (Article 12): maintains current plate count levels for raw milk until 1st December 2009.

Slaughterhouse staff assisting with official controls (Article 14): lays down provisions for slaughterhouse operators to have a 4 year period in which plant staff currently carrying out certain post mortem procedures could be trained to the same standards as official assistants.

Accreditation of laboratories (Article 18): this provides a four year transitional period for meeting accreditation requirements set out in Regulation 882/2004 on official controls for official laboratories that are not already required to be accredited under existing Community legislation.

Obligations on Member States regarding Trichinella: Annex II of Commission Regulation (EC) No 2075/2005 lays down requirements for the cold treatment of meat in relation to Trichinosis and associated inspection and sampling requirements according to Article 18(9) of Regulation 854/2004. The Regulation includes clarification of terms requested previously by UK industry.

2.3 Rationale for government intervention

2.3.1 The Commission's implementing and transitional measures are directly applicable in the UK and so failure to give these effect could result in failure to discharge EU Treaty obligations.

2.3.2 The transitional measures allow for a phased period of adjustment before the end of the transition period in 2009, without which business, or in the case of the measures relating to Regulation 882/2004, the competent authorities, may experience difficulties in becoming compliant.

2.3.3 The background against which food hygiene legislation should be viewed is the incidence of foodborne disease. In 2003, it was estimated that the total number of cases of Indigenous Foodborne Disease (IFD) in England and Wales was 843,049 of which 253,382 visited a GP and 17,230 cases were admitted to hospital. It is estimated that 443 cases resulted in death. Similar figures for Scotland and Northern Ireland are not available. However, based on evidence from laboratory reports for 2002, foodborne disease in Scotland is estimated to account for 11% of all cases in the UK and Northern Ireland for 2%. The cost of IFD, therefore, is estimated to be in excess of £1.5 billion per year⁴. Evidence regarding 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. Additionally, most cases arising in the home are thought to originate from food containing pathogenic microorganisms at the time of purchase. It is possible that a small proportion of cases reported might be due to organisms present in the domestic environment, but it is not possible to eliminate these cases from consideration here.

3. Consultation

Within government

3.1 Other Government departments, in particular DEFRA and the Home Office were included in the stakeholder consultation on policy options. OGDs contributed to discussions to agree on the UK negotiating position on the proposals.

Public consultation

3.2 Stakeholders were updated on progress throughout the negotiation of the measures and given opportunity to comment. In addition a separate written consultation with stakeholders was undertaken which ended on 13th September 2005 (21 responses). There were some concerns expressed over the requirement to provide food chain information in advance of animals sent to the slaughterhouse, in particular in relation to animals selected for slaughter, or purchased at auction on the day of transport. The transitional arrangements have since relaxed this requirement. Otherwise, there were no major areas of contention.

3.3 No further costs were identified in association with the implementation and transitional measures other than those already identified in association with trichinella testing. However, representatives of the pig industry (NPA) have acknowledged FSA's efforts to secure a derogation from the requirement to more truly reflect the low risk from trichinella in the UK. Meanwhile the cost of testing will pass to industry to Government. A case has been prepared to allow the UK to continue its current position as regards trichinella testing. The derogations and transitional arrangements were welcomed as an easement to full immediate compliance.

4. Options

4.1 Option 1: Do Nothing

This option would mean that the UK would not have contributed to the discussions on the proposals and would not have had the opportunity to influence negotiations on behalf of the UK. Not to apply the Regulations would leave the UK in breach of an EU obligation.

4.2 Option 2: Contribute to the negotiations and take steps to enforce the Commission Regulation in the UK.

This was the FSA's preferred policy option. This allowed the UK to influence negotiations and subsequently give effect to the Commission proposed Regulations appropriately within the UK principally by way of the Food Hygiene Regulations 2006.

5. Costs and benefits

Sectors and groups affected

5.1 There are approximately 600,000⁵ food business establishments in the United Kingdom, covering catering, retail, manufacturing and distribution. In addition, there are in the region of 160,000⁶ primary producers, including farms, aquaculture establishments and fishing vessels. The majority of the businesses will be affected by the EU legislation to some extent. The businesses affected range from low-risk one-person businesses e.g. selling wrapped confectionery, through to major businesses manufacturing high-risk products and employing hundreds of people.

5.2 The main sector affected by the Commission's new measures is the meat sector. Some provisions such as establishing a list of approved establishments and the

⁵ The figure of 600,000 is based on estimates of registered food businesses gained from returns from local authorities.

⁶ Based on agricultural census information.

use of substances to remove surface contamination will apply to the whole of the meat sector. Other provisions are specific to certain sectors such as fish (e.g. visual inspection of fishery products and use of clean seawater), red meat (e.g. food chain information) and the pig industry (*Trichinella*). The cost estimates included in this RIA are the result of initial informal contacts with industry and enforcement bodies

5.3 The Food Standards Agency does not consider that the EC Regulations will have any impact on racial equality issues. No economic, social or environmental impact from the Regulations has been identified.

Benefits

5.4 Benefits would be shared between all the individuals affected: consumers, food businesses, business generally and enforcers.

5.5 The changes being proposed in the draft SI would, through application of the Commission implementing and transitional measures, provide for the benefits identified in respect of those measures to be realised. The transitional measures are particularly useful, and have been welcomed as such, in enabling food businesses to work towards full compliance over a period of time (in most cases until 2009). Immediate compliance following the application of the new legislation would present an unrealistic challenge to some food businesses.

Costs

Microbiological criteria – see separate RIA (ANNEX D, PART 2)

Trichinella testing

5.6 The Food standard's Agency estimates that the additional costs to the UK government for Obligations on Member States regarding *Trichinella* testing would amount to £1.5 million. There would also be an anticipated cost saving for industry in the region of £1 million on the basis that the cost for sampling and testing would transfer from industry to UK government.

5.7 The UK is currently developing a case to put to SCoFCAH for recognition of the negligible risk of *trichinella* in the UK. Such a derogation would allow fattening pigs to go through untested but sows, boars, wild boar and horses would have to be tested. However, the case will take some time to go through until when UK pigs will be subject to the *trichinella* testing requirements as set out.

Exports to Sweden and Finland

5.8 The volume of UK exports to Sweden and Finland of the fresh products affected are minimal. In any case, the salmonella guarantees in the transitional

measures are simply a rolling forward of existing measures and thus should entail no change in costs.

.....

5.9 The majority of the EC Regulations affect food businesses concerned with products of animal origin. FSA do not anticipate significant extra costs for businesses or competent authorities to be associated with these proposals (other than for Trichinella as mentioned above) beyond costs already identified in the RIA submitted with SI 2005/2059.

5.10 For the proposals which relate to Regulation 882/2004 (publication of lists of approved establishments and accreditation of laboratories, the effect is on the competent authorities and official laboratories. FSA do not anticipate significant extra costs beyond those already identified in the RIA for Regulation 882/2004.

5.11 Where these measures provide a derogation from the EU hygiene regulations allowing for a transitional period over which to apply the new regulations, they will not result in costs over and above those already identified in the relevant RIA.

6. Small Firms Impact Test

6.1 The changes contained in the implementing and transitional regulations are not likely to impact on small businesses.

6.2 In relation to the main EU food hygiene regulations, 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 have been visiting and talking to SMEs in relation to the HACCP strategy, particularly as it impacts on caterers. The new legislation requires all food businesses to operate a food safety management system based on the HACCP principles. In order to help caterers comply with the regulations from January 2006, the FSA has developed a range of guidance materials. These are 'Safer Food Better Business' (SFBB) in England, 'Safe catering – your guide to HACCP' in Northern Ireland and 'Cooksafe' in Scotland. FSA Wales are providing support and funding to enable Welsh authorities to develop their own guidance packs.

6.3 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 even 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.

6.4 Other concerns expressed by representatives of small businesses can be accommodated through the appropriate interpretation of ‘small’ and ‘local’ in the proposals. EC Regulation 853/2004 allows for the provision of *national* law where small quantities of primary products and certain types of meat are supplied directly by the food business to the final consumer or another local retail establishment. This is particularly important in relation to sales of small quantities of game meat to the final consumer or local retail outlets.

6.5 Consultation respondents included the Family Farmers Association and the Forum of Private Business and did not associate extra costs with the transitional and implementation measures. We will continue to develop and consult on material concerning the application of the food hygiene regulations as a whole which address the particular needs of small businesses throughout the food chain. Particular emphasis will be given to continuing to work with businesses and enforcers to equip them to comply with the requirement for food safety management procedures based on HACCP (Hazard Analysis and Critical Control Point) principles.

7. Competition assessment

7.1 Given our current knowledge, the results from the competition filter indicate that the proposed Regulation will have no significant impact on the competitive structure within the meat sector. With the notable exception of Trichinella testing, the proposed measures are not expected to result in any new industry or government burden or cost. A benefit will result to businesses from the transfer of testing costs from industry to Government. The Regulation applies equally to all new and existing businesses across the meat sector and is unlikely to fall disproportionately on any individual firm. Furthermore, there are no effects on entry barriers to this sector.

8. Enforcement, sanctions and monitoring

8.1 Enforcement and execution of the proposed Commission Regulations will be via the Food Hygiene Regulations 2006. It is very difficult to estimate the precise costs and benefits of the proposals to enforcement agencies. However, costs are anticipated for enforcing new requirements for Trichinella, however these are subsumed in the costs identified above. Responses to the consultation provided no further views on the costs of trichinella testing, however respondents welcomed the FSAs efforts to present a case for a derogation allowing the UK country-free status and that meanwhile costs will be assumed by Government rather than industry. Discussions have been ongoing between the FSA and enforcement authorities regarding specific responsibilities for enforcing the new EU hygiene legislation. This proposed Regulation is thought not to change the overall nature of enforcement of hygiene legislation or the bodies that currently enforce the legislation.

9. Implementation and delivery plan

9.1 Throughout the development of this legislation stakeholders have been fully consulted. The FSA has produced generic and sector specific guidance and the Code of Practice under the Food Safety Act has been revised to reflect the changes for enforcement authorities from 1 January 2006.

9.2 Training has been made available to EHOs and Lead Officers in both HACCP training and Safer Food, Better Business. 12 training courses in Safer Food, Better Business have already been held and a further 24 are planned for 2006. Similar initiatives have been run in each of the other UK countries.

10. Post-implementation review

10.1 The EU legislation includes a revision clause under which the Commission will report to the European Parliament and the Council on the implementation of the Regulation in May 2009. At this stage, depending on lessons of experience, further amendments may be proposed. UK stakeholders will be consulted on the review process.

11. Summary and recommendation

11.1 The only provisions in the proposed Commission Regulation where costs are envisaged are the obligations on Member States regarding Trichinella (see paragraph 5.6). There are some provisions where the FSA anticipate a benefit (e.g. the continued use of stocks and labels and a benefit will result to businesses from the transfer of trichinella testing costs from industry to Government).

11.2 We therefore recommend that you sign this RIA.

12. Declaration and publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed: Caroline Flint

Date: 9th January 2006

Parliamentary Under Secretary of State, Department for Health.

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FULL REGULATORY IMPACT ASSESSMENT

**Commission Regulation (EC) No 2073/2005 on
Microbiological Criteria for Foodstuffs**

FULL REGULATORY IMPACT ASSESSMENT

1. TITLE OF PROPOSAL

Commission Regulation (EC) 2073/2005 on Microbiological Criteria for Foodstuffs

2. PURPOSE AND INTENDED EFFECT

Objective

- 2.1 To review and harmonise European Community microbiological standards and to protect consumer health by the reduction of foodborne disease.

Devolution

- 2.2 The Regulation will be directly applicable throughout the UK.

Background

Overview

- 2.3 This European Commission (EC) *Regulation 2073/2005 on Microbiological Criteria for Foodstuffs* seeks to modernise and revise existing criteria and ensure that they are consistent and relevant to consumer health protection. The Regulation was formally adopted in September 2005 and was published in the Official Journal of the European Community on 22 December 2005 (see paragraph 2.22). The Regulation applies to all food businesses involved in the production and handling of food. To demonstrate compliance with the microbiological criteria food businesses will need to have sampling and testing plans as part of their risk-based food safety management plan that are proportionate to the nature and size of their business.
- 2.2 In addition, the Competent Authority will be required to verify that the food business operator complies with the Regulation. The Competent Authority may also use microbiological criteria for official control purposes in line with the requirements in the Official Feed and Food Regulation ((EC) No 882/2004) when undertaking sampling and analysis for a variety of purposes. These are when monitoring for micro-organisms, including those specified in the Regulation, verifying the food safety management plan, identifying where food is suspected of being unsafe, or in the context of a risk analysis.

Introduction

- 2.3 The Regulation on the Hygiene of Foodstuffs (EC) No 852/2004, published in the *Official Journal of the European Communities* on 30 April 2004, provides the legal basis for the microbiological criteria. Article 4(3)(a) requires food business operators to comply with microbiological criteria for foodstuffs and Article 4(4) stipulates how the criteria are to be adopted. This is part of the package of linked measures⁷, which

⁷ The package of linked food hygiene regulations and directives are:

- Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs;

aim to optimise public health protection by improving and modernising existing European food hygiene legislation.

- 2.4 The food hygiene legislation establishes the conditions under which food is produced to prevent, eliminate or acceptably control pathogens in food. The package of EU food hygiene legislation sets out the duty of the food business to produce food safely, ensured by a preventative approach through the implementation of Good Hygiene Practices (GHP) and application of procedures based on Hazard Analysis and Critical Control Points (HACCP) principles. The criteria should be applied within the framework of a risk-based food safety management system that is proportionate to the nature and size of the business. The safety of food is neither guaranteed nor controlled by microbiological testing. Microbiological criteria can be used in validation and verification of HACCP procedures and other hygiene control measures. It is therefore appropriate to set microbiological criteria for this purpose.
- 2.5 There is a great need for harmonised criteria for the trade of foodstuffs. Criteria in previous Community legislation were applicable at the site of food production and used for import control and intra-community trade, but not at retail level, with the exception of the criteria set for natural mineral waters. In addition, there are no criteria for food of non-animal origin in current Community legislation.
- 2.6 As part of the consolidation of the food hygiene legislation, the Commission addressed a question concerning microbiological criteria to the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH). The Committee gave its opinion on the evaluation of microbiological criteria for food products of animal origin for human consumption on 23 September 1999. The Committee concluded that the current criteria were not based on risk assessment or on internationally approved principles. The Committee recommended that microbiological criteria should be relevant and effective in relation to consumer health protection, should consider regional differences in the prevalence of pathogens and changes in food production practices. It also recommended that microbiological criteria should be harmonised, and that existing problems regarding emerging foodborne pathogens should be considered as part of a horizontal approach.
- 2.7 The Commission therefore produced a discussion paper on the *Strategy for Setting Microbiological Criteria for Foodstuffs in Community Legislation* (SANCO1252/2001.Rev. 11) that laid out the principles for the development of the

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- Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin;
 - Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. (As amended by Regulation (EC) 882/2004 of the European Parliament and of the Council on official controls to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.)
 - Directive 2002/99 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption; and
 - Directive 2004/41 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662 and 92/118 and amending Decision 95/408.

microbiological criteria. The principles of Codex Alimentarius and the recommendations from the Scientific Committees of the EU, including the European Food Safety Authority (EFSA), should be followed if the current microbiological criteria were to be revised or new criteria set.

- 2.8 The Commission Regulation applies to all food business operators involved in the production and handling of food, i.e. primary producers, manufacturers, processors, distributors, retailers and caterers are all affected. The Regulation continues the theme of the food hygiene legislation by placing responsibility for food safety with the food business operator, although the actual day to day effect will be proportionate to the nature and size of the business.
- 2.9 The introduction of harmonised Community criteria will mean that from 11 January 2006, national criteria which result in a product withdrawal will no longer apply to imports and goods from other Member States. However, Member States have retained the right to establish national food safety criteria if there are specific circumstances, such as an outbreak of foodborne disease associated with a specific product. The Commission has collected data on national criteria which Member States wish to maintain from 11 January 2006. Based on this data and opinions provided by the EFSA Biohazard Panel, the harmonisation of microbiological criteria will be continued by introducing new criteria after 11 January 2006. Discussions on the approach for handling national criteria are continuing at the next Working Group planned for 9 January 2006.

Microbiological Criteria

- 2.10 A microbiological criterion is defined in the Commission Regulation as meaning the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch. There are two types of criterion, those that define the safety of a product or batch of foodstuffs (a food safety criterion) and those that indicate the acceptable functioning of a production process (a process criterion). The actions to be taken when criteria are not met are different for the two types.
- 2.11 The adoption of such criteria does not impose a general requirement for increased end product microbiological testing or positive release. The criteria should be applied within the framework of a risk-based food safety management system based on GHP and procedures based on HACCP principles, that is proportionate to the nature and size of the business. The criteria can be used when validating and verifying these procedures, and when assessing the acceptability of foodstuffs and their manufacturing, handling and distribution processes.
- 2.12 Within the Regulation there is flexibility with regard to the actions that may be taken to demonstrate compliance with the criteria. These should be determined by a risk-based approach, which takes into consideration the specific circumstances. The flexibility provided permits food businesses to set sampling and testing plans according to the risk and within the framework of their food safety management procedures, apart from where specified sampling frequencies are provided for in Annex I of the Regulation. Equally it allows the food business operator to apply the criteria within their own controls, and allows for alternative indicators to be

monitored to ensure the process hygiene criteria are being met. For example, instead of testing as laid down in the Regulation, the food business operator might equally monitor time/temperature profiles for a heat treatment process as a means of showing that the process criteria are being met.

- 2.13 Where a foodstuff tested exceeds the food safety criterion, food business operators have an obligation not to place on, or to withdraw/recall, unsafe food from the market, as provided in Regulation (EC) No 178/2002⁸ which lays down general food safety requirements. In addition, corrective actions must be undertaken to ensure the criterion is likely to be met with future production. On the other hand, where a process hygiene criterion is exceeded, there is no requirement not to place the unsatisfactory batch on the market or to withdraw or recall it from the market. The corrective actions taken should form part of a food business operator's risk-based management system that includes the corrective actions specified in Annex I chapter 2 of the Regulation.

Official Controls

- 2.14 It was envisaged that a separate working document to address microbiological criteria for official control purposes would be produced. However, in December 2004 the Commission extended the scope of the proposal to cover official controls. This was in response to comments received as part of an EU-wide consultation and concerns expressed by some Member States that if there were two documents, it would have been unlikely that the official controls would have been agreed by January 2006.
- 2.15 As part of the official controls of foodstuffs, the Competent Authority is required to verify the compliance of foods with the microbiological criteria. The Commission Regulation devolves competence to the Member States and allows them to decide how they will implement the checks in accordance with the Official Feed and Food Regulations (EC) No 882/2004⁹ when undertaking sampling and analysis for a variety of purposes. In practice, this will not necessarily mean that the Competent Authority will take duplicate samples to verify results obtained by the food business operator. It is envisaged that samples may be taken when monitoring for micro-organisms including those specified in the food safety management plan, where food is suspected of being unsafe, or in the context of a risk analysis.
- 2.16 The food safety criteria are also applicable to trade within the European Community and to imported products at Border Inspection Posts, whilst the process hygiene criteria would only apply at production establishments where they would be verified by audit by the relevant national Competent Authority.

Enforcement Authorities

- 2.17 Enforcement authorities will require sufficient evidence that criteria are being met at whatever level the food safety management procedures are designed to operate. As such, the microbiological criteria set out in this Regulation are intended to assist food business operators with validation and verification of procedures based on HACCP principles and GHP. Like the application of the EU food hygiene legislation, the

⁸ General Food Law (Regulation (EC) No. 178/2002)

⁹ Further information on the OFFC Regulation is provided through the Commissions website at: http://europa.eu.int/servlet/portail/RenderServlet?search=DocNumber&lg=en&nb_docs=25&domain=Legislation&coll=&in_force=NO&an_doc=2004&nu_doc=882&type_doc=Regulation

responsibility for setting the sampling and testing frequency rests with food business operators, who should determine this based on their assessment of the risk, unless Annex I of the Regulation provides specified sampling frequencies. When demonstrating compliance with the criteria, food business operators may also use alternative methods to the reference methods in the Annex to the Regulation, if these have been approved by the relevant national Competent Authority to achieve the same end result.

- 2.18 The Regulation also sets out what additional measures are to be taken in the case of an unsatisfactory result, apart from the appropriate corrective actions defined in food business operators' food safety management procedures. Enforcement authorities will require sufficient evidence that the food business operator has taken the appropriate corrective action in the case of an unsatisfactory result.

Scientific Consultation

- 2.19 The existing Community criteria have been revised and other foodborne pathogens have been considered. Based on scientific opinions issued by the scientific committees and EFSA, criteria for micro-organisms and certain food groups not previously included in Community legislation have been proposed, i.e. criteria for pre-cut fruit and vegetables, powdered infant formulae, *Salmonella* on meat carcasses and *Listeria monocytogenes* in ready-to-eat products.
- 2.20 In addition, the working document also requires food business operators to consider conducting a durability study with respect to *Listeria monocytogenes* in ready-to-eat foods. Whether a business chooses to conduct a durability study is likely to reflect the fact that there are two sets of *L. monocytogenes* criteria, one for those who have undertaken durability studies and one for those who have not or where growth is found to exceed the maximum limit during the given shelf-life. This is the first time such a requirement has been set in Community legislation and provisions for carrying out such studies are also given in Annex II of the Regulation. The Commission has included a provision to permit food business operators to collaborate when conducting these studies to assist in particular, small and medium sized businesses.

Progress of the Negotiation

- 2.21 Negotiations on the Commission Regulation are complete. The Commission working group met over 25 times and during the negotiation process expert working groups discussed specific issues relating to shellfish, fishery products, fruit and vegetables, durability studies, *Salmonella* sampling for meat carcasses, the measurement of microbiological uncertainty and the development of guidance for official controls.
- 2.22 This Regulatory Impact Assessment was prepared for Revision 19 of the proposed Regulation (SANCO4198/2001rev19). Following intense negotiations, the Regulation was accepted by a qualified majority vote at the 21-22 June meeting of the Standing Committee (SCoFCAH) and was referred to the World Trade Organisation (WTO) for consultation under the Sanitary and Phytosanitary procedures of the WTO. Member countries were allowed 60 days, in which to comment on issues that may affect trade with the European Union. Very few comments were received and there were no substantial changes to the proposal, though a few minor technical changes and

corrections produced Revision 20, which was formally adopted by SCoFCAH on 21-22 September 2005. The Commission has since produced Revision 21, which contains a minor correction. Although the RIA was developed for Revision 19 there have been no substantial changes between Revision 19 and 21, and so the RIA applies equally. Revision 21 was published in the Official Journal of the European Community on 22 December 05.

Rationale for Government Intervention

- 2.23 This European Regulation will be directly applicable in the UK. The UK would be in breach of its obligations under the EC treaty (Article 10 – Co-operation) if it failed to provide for the proper enforcement of the provisions within this Regulation. The Regulation will both benefit UK consumers by the production of safer food and assist UK food businesses to manufacture and trade within Europe.
- 2.24 Where criteria have not been set, Member States have established their own national criteria. At present a variety of non-uniform microbiological criteria are being used. The lack of Community criteria has led to different interpretations concerning the acceptance/rejection of batches of food produced in the Community or imported, and it has caused problems for border control as well as for intra-Community trade. This causes not only a problem for third countries but UK businesses that may produce products in one Member State and retail in another, where the same product must comply with different criteria.
- 2.25 The background against which the package of food hygiene legislation and, in turn, the microbiological criteria proposals, should be viewed is the incidence of foodborne disease. In 2003, it was estimated that the total number of cases of Indigenous Foodborne Disease (IFD) in England and Wales was 843,049 of which 253,382 visited a GP and 17,230 cases were admitted to hospital. It is estimated that 443 cases resulted in death. Similar figures for Scotland and Northern Ireland are not available; however, based on evidence from laboratory reports for 2002, foodborne disease in Scotland is estimated to account for 11% of all cases in the UK and Northern Ireland for 2%. The cost of IFD, therefore, is estimated to be in excess of £1.5 billion per year¹⁰. Evidence regarding 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. Additionally, most cases arising in the home are thought to originate from food containing pathogenic micro-organisms at the time of purchase. It is possible that a small proportion of cases reported might be due to organisms present in the domestic environment, but it is not possible to eliminate these cases from consideration here.
- 2.26 In a separate study by the Health Protection Agency (HPA) of disease risks from foods in England and Wales between 1996 and 2000, poultry accounted for 29% and red meat 17% of cases. In the same study, fish and shellfish were found to account for 7% of cases, milk for 6% and dairy products accounted for less than 1% of cases.

¹⁰ Information on food poisoning incidence in the UK is outlined at Annex D of the Full regulatory impact assessment: Proposals to Consolidate EU Food Hygiene Legislation (<http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/>)

However, given the seriousness of the pathogens that may be involved in illness associated with milk and dairy products (e.g. *Escherichia coli* O157, *Listeria* and *Salmonella*) it is important to ensure appropriate controls are in place.

Business sectors and charities affected

- 2.27 The Regulation affects all food businesses concerned with the production or marketing of foodstuffs. For a food business operator the microbiological criteria are intended to apply within the framework of a risk-based food safety management system based on HACCP and GHP. It allows food business operators to apply the criteria within their own controls, and allows for alternative indicators to be monitored to ensure the process criteria are being met. This may include monitoring other micro-organisms, using alternative testing methods approved by the Competent Authority, ensuring that foodstuffs are chilled appropriately, raw foods are kept separate from cooked foods to avoid cross contamination, foods are cooked thoroughly, effective cleaning measures are observed and that raw products are bought from a reputable source. The degree to which businesses will be affected will depend on the procedures that the food business operator currently has in place, the type and size of food business and the nature of the foodstuff being handled.
- 2.28 There are approximately 600,000¹¹ food business establishments in the UK, covering catering, retail, manufacturing and distribution. In addition, there are in the region of 160,000 primary producers, including farms, aquaculture establishments and fishing vessels. The majority of businesses will be affected by the Regulation to some extent. From 1 January 2006 the food hygiene legislation will require all 600,000 food businesses to have a food safety management plan. The frequency of sampling and testing required to demonstrate compliance with the microbiological criteria should be proportionate to the nature and size of the business. For example, low-risk microbusinesses or small caterers, small retailers, small slaughterhouses and minced meat and meat preparation establishments producing small quantities may not conduct any, or may undertake microbiological testing at a reduced frequency. They will however need to provide evidence that they comply with their food safety management plan, such as, by behaving responsibly by following existing Regulations and/or guidelines and handling foodstuffs within the required hygiene standards. Whereas major businesses manufacturing high-risk products and employing hundreds of people may already have established sampling and testing procedures in place to verify their procedures based on HACCP principles.
- 2.29 The microbiological criteria will apply to all food businesses involved in the production and handling of food, including primary production and retail. At present this Regulation is unlikely to greatly affect producers of unprocessed fruit and vegetables (with the exception of sprouted seeds), as the majority of the criteria are applicable to prepared ready-to-eat products. However, growers and suppliers of fresh produce may be affected by controls on raw materials and the corrective actions stated in a customer's HACCP plan in the event of an unsatisfactory result, e.g. improvements in production hygiene and selection of raw materials.

¹¹ The figure of 600,000 is based on estimates of registered food businesses gained from returns from local authorities.

3. CONSULTATION

Within government and public sector bodies

- 3.1 The Agency has to date, sought opinions from Department for the Environment, Food and Rural Affairs (Defra), Department of Health, Department for Trade and Industry, Department for International Development, the Cabinet Office, devolved administrations, the Health Protection Agency, Local Authorities Co-ordinators of Regulatory Services (LACORS), the Small Business Service and the Improving Regulation in Scotland (IRIS) unit to help inform and develop the agreed UK negotiating line. The results of this consultation are included below.

Public Consultation

- 3.2 The Agency issued an 8-week formal consultation on the Regulation and the partial RIA on 12 September 2005, which covered all key stakeholders and interested parties. This short consultation period was due to time constraints dictated by the Commission's timetable. Responses received have been used to finalise the RIA. This followed a previous formal consultation issued in January 2003, the responses from which were collated and returned to the Commission as part of an EU-wide consultation and used to inform the Agency's negotiating position. There has also been informal consultation with interested parties throughout the period of the negotiations. The Agency has informed and consulted stakeholders in the UK on an informal basis throughout the four years of negotiations. Where appropriate, the Agency has met with interested parties as part of bilateral meetings with individual sectors such as at the Agency's Meat Hygiene Policy Forum (MHPF) or at stakeholder meetings such as those hosted by Campden and Chorleywood Food Research Association (CCFRA) in December 2004. UK stakeholders have also assisted the Agency by contributing expert advice or attending EU expert working groups covering specific topics. Discussions with stakeholders are still continuing on the practical implementation of the Regulation, particularly on the meat criteria and we would expect these to continue for some time after the Regulation comes into force.
- 3.3 The European Commission has conducted three EU-wide consultations with their main European stakeholders in January 2003, March 2004 and December 2004. The Agency has responded to these consultations.
- 3.4 The most recent UK formal consultation provided 18 substantial responses from: 1 consumer group, 6 industry trades associations, 5 enforcement bodies, 1 professional body, 2 public bodies, 1 Government Department, 1 consultant and 1 Executive Agency.
- 3.5 Many of the responses welcomed the harmonisation of the existing microbiological criteria into a single Regulation, with some acknowledging the Agency's efforts to reach a more positive outcome. One response did suggest the Regulation itself was not warranted and some asked whether the food safety criterion for minced meat and

meat products to be eaten cooked was achievable or necessary. Two respondents would have liked the criteria for raw milk cheeses to remain in the Regulation. Most responses suggested the need for guidance on the legislation and areas such as sampling frequency, the definition of food categories, the use of flexibilities within the legislation, the withdrawals of product intended to be cooked before being eaten, shelf life testing, primary production and on farm processors were mentioned specifically. Guidance for small businesses was also requested.

- 3.6 Many stakeholders have already supplied data and information during the negotiating process so it was not unexpected that the consultation yielded little extra detail that could be included in the impact assessment. The areas of most concern seemed to be the extra cost of withdrawing product that failed to meet the criteria, particularly minced meat and meat products, the training needs of enforcers and the extra burden on enforcers as they explained the new requirements to food businesses. Several responses commented on the application of the exemption for small slaughterhouses and minced meat and meat preparation establishments producing small quantities, with some supporting the use of the exemption and others preferring a requirement for sampling proportionate to the size of the business.

4. OPTIONS

- 4.1 The following discussion addresses the UK's options prior to the adoption of the proposed Regulation (Revision 20) at the Standing Committee on the Food Chain and Animal Health (SCoFCAH) meeting in September 05.

Option 1: do nothing.

- 4.2 This was not a credible option, because this is an EU Regulation, and as such, is directly applicable. The UK would have been in breach of its obligations under the EC treaty (Article 10 – Co-operation) if it failed to provide for the proper enforcement of the provisions of the Regulation. This Regulation supports the EU food hygiene legislation, which states that food business operators must comply with microbiological criteria. The combined objective of these regulations is to ensure a high level of human health protection in respect of foodborne disease. If the UK had failed to accept the Regulation this may have had a detrimental effect on the competitiveness of UK businesses trading within the EU, in turn resulting in a lack of confidence in UK foodstuffs and the Competent Authority.
- 4.3 The Regulation has been designed to complement a simplified, risk based and proportionate approach to food safety, which protects public health. In general, when we considered the benefits of the proposed microbiological criteria, it was important to consider them in combination with the package of recently adopted EU food hygiene legislation. Improved understanding and operation 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.

Option 2: accept the proposal as it stands.

- 4.4 To support the Commission's proposal for the amendment and consolidation of existing microbiological criteria. The UK had a significant input into the negotiations and has secured more proportionate controls for industry whilst maintaining public health protection. Through co-operating in and influencing the negotiations we have minimised any potential negative impacts of the Regulation and have prevented a situation that would have been less advantageous to UK consumers and to UK food businesses. Replacing the un-harmonised microbiological criteria with a single set of risk based measures, was the best option.

Option 3: seek further amendments.

- 4.5 The proposal has been accepted by a qualified majority and was adopted in September 05; therefore, there will be no further opportunities to introduce further amendments. The main UK focus will be working to ensure that the Regulation is implemented in the spirit intended during the negotiations, to reflect the envisaged flexibility by all Member States through the production of guidance and continued influence. The UK has had a significant input to the negotiations to secure more proportionate controls and accepted the proposal in UK interests. The UK will continue to press the Commission to revise the criteria as and when more scientific evidence is available.
- 4.6 The following considers specific elements of the UK negotiating strategy to achieve this goal.

Context and Food Standards Agency Position

General

- 4.7 There is no doubt that existing microbiological criteria in EU legislation need to be reviewed and revised, as those contained in Community legislation tend to be numerous, inconsistent, non-risk based and restrictive. Setting microbiological criteria at the EU level is the responsibility of the European Commission, under powers vested in it by the Regulation on the Hygiene of Foodstuffs (EC) No 852/2004.
- 4.8 The Agency's negotiating line has been to promote a preventative (HACCP-based) approach to food safety management, rather than relying on the proliferation of microbiological criteria in legislation and end product testing, unless particular circumstances dictate. The emphasis should be on the implementation of procedures based on HACCP principles to assure food safety, and the use of microbiological criteria should complement that. We welcome the greater transparency in the Commission's papers between the role of HACCP and microbiological criteria, and have been pursuing this in the discussions at the working group level.
- 4.9 We agree with the whole chain approach, but the approach must be proportionate to risk and, where microbiological criteria are set, the actions to be taken when they are not met must clearly be shown to benefit public health.

Specific Points

- 4.10 The Agency position is that the Commission Regulation should, where appropriate, follow the internationally agreed Codex Alimentarius.

- 4.11 The Agency is generally content with the Commission's views on *Listeria monocytogenes* criteria for ready-to-eat foods. We are keen to promote the view that the presence of the organism at low levels should not be considered as acceptable and that, whilst not necessarily leading to enforcement action, this should be a cause for concern and corrective intervention by a food business.
- 4.12 The Agency supported the conclusions from the shellfish expert working group meeting in June 2004, including the proposed criteria in Revision 19 of the Regulation, i.e. *Salmonella* (absence in 25g), *E. coli* (<230 colony forming units (cfu)/100g). We agree with the scientific experts who have stated that the use of a bacteriophage criterion as a surrogate for the absence of foodborne viruses would mean using depuration temperature and time combinations that would be likely to make the shellfish inedible. We would support any future proposal by the Commission to introduce greater controls for *E. coli*, such as time controls for depuration (e.g. at least 42 hours), provided that it was based on scientific evidence.
- 4.13 The Agency supports the Regulation in relation to criteria for powdered infant formulae. This follows a proposal from the UK and proposes a 2-tier approach, where a positive *Enterobacteriaceae* result would trigger testing for *E. sakazakii* and *Salmonella*. The presence of either of these organisms would trigger action not to place the product on the market or to withdrawal/recall the product if it is already on the market.
- 4.14 The Agency supported the proposals for minced meat and meat preparations which were the result of intense negotiations at the Standing Committee meeting on 21-22 June 2005. This establishes a criterion of the absence of *Salmonella* in 5 x 10g for those products intended to be cooked, and absence in 5 x 25g for products that may be consumed raw or undercooked. A transitional national derogation until 2009 for minced meat and meat preparations intended to be cooked is provided for in Article 8. This permits these products to remain on the market when one out of the five samples is positive for *Salmonella*, provided they are only placed on the home market and carry a special mark clearly identifying them. In addition, all minced meat and meat preparations intended to be eaten cooked must be labelled with information that the meat requires cooking (Article 6 (1)). Following the request by the UK the Commission has also agreed to seek from EFSA, a (quantitative) risk assessment on *Salmonella* in minced meat and meat preparations based on data provided by Member States, by December 2008. This will enable the criterion to be reviewed in light of a scientific risk assessment.

Risks

Compliance and enforcement

- 4.15 The Agency aims to maximise compliance and enforcement of the Regulation through the provision of guidance material to explain the requirements for food businesses and enforcement officials. A consultation on guidance for food businesses was issued on 4 November and the Agency plans to make this guidance available when the Regulation comes into force. The Commission is also working with several Member States (including the UK) to produce guidelines for the sampling and testing for microbiological criteria for official control purposes.

- 4.16 The view of the Agency is that the obligations on food business operators, as set out in Article 7 of the Regulation, are such that failure to comply with the responsibility to protect the health of consumers by taking the measures indicated in the last column of the relevant criterion, together with the actions defined in their respective HACCP plans should constitute an offence, which should be subject to a penalty, and that there should be appropriate enforcement powers. The Food Hygiene No 2 Regulations will provide the necessary powers.
- 4.17 The Regulation has also been included in an amended version of the UK Food Law Practice Guidance¹² that is currently being prepared.
- 4.18 Enforcement officials will ensure that food businesses comply with the criteria through the audit of food safety management plans, such as, procedures based on HACCP principles and GHP, as referred to in Regulation (EC) No 852/2004. Further increased testing is not expected to occur.

Unintended consequences

- 4.19 The preferred option has been to negotiate for the adoption of a proportionate Regulation which delivers consumer and trade benefits. This approach minimises any negative impact of the Regulation and reflects the best interests of UK consumers and food businesses. Every effort has been made to remove any potential loopholes. The Regulation will apply within the framework provided by (EC) No 852/2004, (EC) No 178/2002 and (EC) No 882/2004. As the Regulation is directly applicable throughout Europe and will apply to all food businesses it is unlikely to affect competition.
- 4.20 Apart from when the Annex to the Regulation provides specified sampling frequencies, the frequency of sampling and testing should be included in the food safety management plan determined by the local risk, and proportionate to the size and nature of the food business. If there is a lack of understanding of this concept of flexibility by food businesses and enforcement authorities, then an unintended consequence of the Regulation could be a reliance on end product testing and an increased amount of microbiological testing by food business operators. The Agency will address this concept of flexibility in the guidance produced for enforcers and food businesses.

5. COSTS AND BENEFITS

- 5.1 The Regulation consolidates existing microbiological criteria in force in European legislation based on the assessment of new scientific evidence. The proposal has been designed to complement a simplified, risk based and proportionate approach to food safety, which protects public health. In general, when considering the benefits of the proposed microbiological criteria, it was important to consider them in combination with the package of recently adopted EU food hygiene legislation. Improved understanding and operation 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 of the controls in place will help food business operators demonstrate to the enforcement authorities that the controls are effective, for example, by using the microbiological criteria to

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

validate and verify their procedures based on HACCP principles. As such, the benefits from the changes will help reassure consumers by providing a standard for food businesses and enforcement authorities. The main benefit of microbiological criteria is that they will allow food business operators to proportionately validate and verify their risk-based approaches, including their procedures based on HACCP principles. They will also create a consistency of standards across the EU.

Sectors and groups affected

Consumers

- 5.2 Consumers of food will benefit from safer food as a result of enhanced hygiene controls which will apply throughout the food chain and which are responsive to the risks that food may present. Greater protection will be afforded by more clearly placing responsibility for producing and selling safe food on producers, caterers and retailers, rather than relying on enforcement authorities to police these activities. Improved understanding and operation 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.
- 5.3 If the microbiological criteria are considered as an integral part of a HACCP based system, then it is possible to equate the benefit of the Microbiological Criteria Regulation with that of the food hygiene legislation. This work has shown that the precise effect the new proposals, including the food hygiene legislation, would have on the level of food poisoning is difficult to predict or to measure, but work carried out on behalf of the Agency provides some information. Work undertaken by a consultant economist on Indigenous Foodborne Disease (IFD) 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. of £164 million, and costs of pain, grief and suffering of £1,202 million. When applied to the UK as a whole, these figures indicated costs of £1,534 million per year. Therefore, even a further minimal incremental reduction in the incidence of foodborne illness of between 1% and 5% would result in further benefits in the region of £15.3 million to £76.5 million per year. This work indicates that benefits are likely to build up cumulatively over a number of years as both business and enforcement authorities improve the way in which the regulations are applied and checked. Any resulting improvement in food safety management will mean that the overall food hygiene position would be improved and the incidence of disease should improve as a consequence of this. An indicative figure of 3% was included in the regulatory impact assessment¹³ for the purpose of the cost/benefit analysis. This figure would seem reasonable set against the confirmed reduction (in the number of laboratory-reported cases of the five foodborne disease pathogens monitored) of 15% seen in the first three years of the Agency's Foodborne Disease Strategy, (2000-2003).

Food businesses

- 5.4 The benefits of applying microbiological criteria as part of a risk-based approach to food safety management will include:

¹³ Full regulatory impact assessment: Proposals to Consolidate EU Food Hygiene Legislation (<http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/>)

- capacity to identify areas of concern, where failure has not yet been experienced, through the analysis of trends, and to allow prospective remedial actions to be taken;
- it can support a defence of ‘due diligence’ under UK food safety legislation
- a potential reduction in costs for microbiological testing, through movement from end product testing to a risk based approach using procedures based on HACCP principles and GHP. A preventative approach will reduce product losses. However, there may be greater costs if the requirements of applying the microbiological criteria are over and above the food safety management systems that food businesses may currently have in place.

5.5 The Microbiological Criteria Regulation will reduce the legislative burden in place on food businesses, by replacing existing criteria contained in commodity based EC directives with a single Regulation that seeks to modernise and harmonise in order to remove inconsistencies between micro-organisms and food products.

Voluntary Organisations and Charities

5.6 This Regulation is not expected to have any impact on voluntary organisations or charities.

Social Groups

5.7 The Regulation is not expected to have any effect on human rights, gender equality, disabled people, children and young people, older people, devolved countries or any region of the UK. Whilst there may be a larger proportion of small businesses within rural communities, the Regulation is not expected to have any effect on these communities given the flexibility that exists within the Regulation to demonstrate compliance by providing sufficient evidence that foodstuffs are handled using good hygienic practices. The Agency will provide supporting guidance for food businesses and enforcement authorities on which we are consulting on.

Race Equality

5.8 It is not envisaged that the Commission Regulation on the Microbiological Criteria for Foodstuffs will have any race equality impacts.

Public Sector

5.9 There is not expected to be any additional costs to Government beyond the initial implementation, including training.

Enforcement Authorities

5.10 The implementation of the EU food hygiene legislation in January 2006, and in turn the Microbiological Criteria Regulation, will reduce the amount of EC legislation that currently contains microbiological criteria and will do much to remove inconsistencies. It provides for a potential reduction in the costs of official supervision and inspection, as HACCP-based systems lend themselves to audit, and should not require constant supervision to safeguard public health.

5.11 It is not envisaged that the setting or operation of microbiological criteria within the food business operators’ food safety management plan should cause Enforcement Authorities to incur significant additional costs over and above the routine audit of HACCP plans. However, information supplied by LACORS suggests that there may

be additional costs to enforcement authorities during the first year operating the Regulation, to cover training and additional audits. The Agency sought further information through the consultation to inform the regulatory impact assessment. Responses from enforcement bodies indicated there was likely to be an increased burden on enforcement officials as they worked to understand the Regulation themselves and explained the requirements to food businesses. No specific details of cost were provided; however, an estimate has been included as part of the Regulatory Impact Assessment for the new food hygiene regulations (paragraph 67)¹⁴.

Environmental

- 5.12 We do not envisage any significant additional costs in relation to environmental aspects, although some respondents to the consultation noted the potential costs for disposing of product taken off the market.

Sustainable Development

- 5.13 Other than the costs and benefits identified elsewhere, the legislation holds little in terms of social, economic and environmental impacts. In social and economic terms a contribution to the overall objective of improving public health may result. The Microbiological Criteria Regulation is not expected to have any undue consequences for sustainable development.

Overall

- 5.14 Benefits would be shared between all the individuals affected (consumers, food businesses, business generally, the NHS and enforcers); however, these are difficult to quantify in pure monetary terms. Food businesses will benefit through the implementation of measures that could possibly enable them to avoid the 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 the association with an outbreak of foodborne illness.

Analysis of costs and benefits

Administrative burden

Food businesses

- 5.15 Microbiological criteria are required to verify or validate the system; by facilitating the move from end product testing to a preventative approach, it is possible that the requirement for microbiological testing will decrease. Many businesses are already testing products as part of current EU legislation, because of specifications from customers or as part of industry specific guidelines and standards. For example, most food businesses that supply the major UK retailers may already have procedures based on HACCP principles in place which include sampling and testing schedules, and may also seek additional certification such as that provided by the British Retail Consortium (BRC), Nature's Choice, Assured Produce, Linking Environment and

¹⁴ Full Regulatory impact assessment: Proposals to Consolidate EU Food Hygiene Legislation (<http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/>)

Farming (LEAF) etc. The Regulation provides a number of flexibilities in terms of the sampling and testing frequency, permitting alternative methods and means of demonstrating compliance. As stated previously this may not be through microbiological testing but by ensuring that food is cooked thoroughly, the cold chain maintained, separation of raw foods from cooked to avoid cross contamination, good hygiene practices employed throughout and an efficient cleaning system.

- 5.16 The Agency is running a series of initiatives throughout the UK designed to assist small businesses in complying with Regulation (EC) No 852/2004. These include:
- “*Safer Food, Better Business*” (SFBB) in England;
 - “Cooksafe” in Scotland;
 - “Safe Catering” in Northern Ireland which has been established over a number of years in the catering sector; and
 - In Wales, several local authorities have developed their own guidance packs over the years and FSA Wales has encouraged sharing of these packs throughout Welsh local authorities. A guidance pack written in English/Welsh; English/Bengali; English/Chinese and English/Turkish is available from Welsh local authorities.
- 5.17 These schemes have been developed to allow businesses to manage food safety and protect consumers through simple and practical guidance, whilst at the same time avoiding unnecessary burdens on business. Further information on these initiatives is available in a paper presented at the March 2005 Food Standards Agency board meeting¹⁵. The guidance is being further developed for different business sectors and will be available during 2006.
- 5.18 We envisage that the greatest additional administrative costs to food businesses will be associated with the introduction and implementation of a risk based approach to food safety management, e.g. procedures based on HACCP principles and GHP as required by the new EU food hygiene legislation, which was considered in the corresponding regulatory impact assessment,¹⁶ this estimates the cost of implementing a HACCP based system as being £132 million in the first year and £96.1 million per year thereafter. These are the costs applied to all sectors, approximately 760,000 businesses, including primary producers and include the one-off cost of introducing Agency initiatives (e.g. Safer Food Better Business in England).
- 5.19 In terms of the Microbiological Criteria Regulation, the Agency does not envisage any change in practice in the majority of sectors, with the exception of criteria for meats where there are specific requirements. Therefore, for these businesses, the Agency envisages that where they are currently conducting microbiological testing e.g. the dairy sector, they check whether there are any additional criteria or amendments to the limits. Secondly, where businesses have established procedures based on HACCP principles they check the limits for verification and validation. Other businesses may wish to ensure that they have sufficient controls in place to be able to demonstrate compliance with the Regulation. Therefore, there will be a one-off ‘setting-up’ cost required for food businesses to assimilate the guidance and

¹⁵ March 2005 board paper: <http://www.food.gov.uk/multimedia/pdfs/fsa050302.pdf>

¹⁶ Full regulatory impact assessment: Proposals to Consolidate EU Food Hygiene Legislation (<http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/>)

determine how their respective business will demonstrate compliance with the Regulation, this will vary depending on the size and nature of the business. The Agency estimates that this would take an average of 15 minutes to 30 minutes of a manager's time (£15 per hour). In this case the overall cost to the 760,000 food businesses in the UK would be £2,850,000 to a maximum value of £5,700,000, given the current food safety management practices and the other Agency initiatives in place, to introduce procedures based on HACCP principles.

- 5.20 Although implementation is likely to have a greater impact on small and medium sized businesses across the whole of the food chain, the actual financial cost will vary depending on the risk associated with the individual business. We expect that compliance costs will vary greatly depending on existing food safety management systems and present levels of compliance, for which we have no readily available or reliable statistics and nothing specific was provided as a result of the consultation.

Enforcement Authorities

- 5.21 It is not envisaged that the setting or operation of microbiological criteria should cause Enforcement Authorities (Local Health Authorities, Port Health Authorities, Meat Hygiene Service and Trading Standards Officers) to incur significant additional costs over and above the routine audit of food safety management plans. The Microbiological Criteria Regulation will reduce the number of EC directives that currently contain microbiological criteria and seeks to remove inconsistencies with food products; therefore, there will be less legislative burden on enforcement officials.
- 5.22 The regulatory impact assessment produced in support of the EU food hygiene legislation estimated that additional costs to enforcement authorities, in terms of additional training are likely to amount to approximately £0.2 million per year. In addition to the requirements of the EU food hygiene legislation, enforcement officers are likely to require time to advise businesses of the requirements in the Microbiological Criteria Regulation. This may have an adverse impact upon the local authority inspection program.

Policy cost

- 5.23 The policy cost considers the costs of monitoring compliance with the microbiological criteria. The Regulation is intended to be flexible in nature and does not have a one-size fits all approach, the frequency of any testing and sampling plan will depend on the local risk associated with a particular food business and foodstuff. The Regulation is not a requirement for increased end product testing and should therefore not lead to an increase in testing costs, or undermine the current high standards and practices employed across the industry; the microbiological criteria should apply within a food business's food management plan based on risk assessment.
- 5.24 The Agency will be issuing guidance both to food businesses and enforcement officials as part of the implementation process, to clarify what would constitute compliance. All food businesses will be required to have a HACCP based management system in place after 1 January 2006, which if correctly implemented

will eliminate the need for excessive product testing through effective process controls.

- 5.25 The criteria will apply to all food businesses including retailers with in store delicatessens, bakeries, rotisseries, pizza ovens, cream cakes etc. The Agency has been informed that the safety of the food counter is controlled using a HACCP based food management approach with staff training and that, in the larger retailers, the HACCP plan is verified using random microbiological testing. Effective controls should ensure products comply with the microbiological criteria in the Regulation and that the microbiological testing specified in the HACCP plan helps demonstrate this.
- 5.26 The Regulation allows food business operators to set sampling frequencies for most commodities, except for carcasses, minced meat, meat preparations and mechanically separated meat, where harmonised sampling frequencies have been laid down. However, the Regulation allows some flexibility to derogate from the proposed sampling frequency. Article 4 says that the frequency of sampling may be adapted to the nature and size of the food business, provided that food safety is not endangered. In addition Annex I Chapter 3.2 allows small slaughterhouses and establishments producing minced meat and meat preparations to be exempt from the sampling frequencies. Several responses to the consultation supported the full use of the flexibilities in the Regulation; however, some did note that small slaughterhouses and establishments producing minced meat and meat preparations should not be exempt from sampling, but a level of sampling and testing should be established that was proportionate to the size of the business.
- 5.27 The Agency understands that the cost resulting from a withdrawal or recall of a product following non-compliance with a food safety criterion in the Regulation, to an individual food business supplying one of the major retailers, is in the region of £100,000 to £125,000. This includes the costs of issuing a press notice, withdrawing and destroying the product and any fine imposed by the retailers. However, we are unable to provide representative costs for a business for a year resulting from non-compliance with the Regulation. The number of recalls or withdrawals undertaken by a business will depend on a number of different factors, including the effectiveness of its food safety management plan and, for certain foodstuffs, the prevalence of the micro-organism e.g. *L. monocytogenes* or *Salmonella* present in foodstuffs. Responses to the consultation did not provide any more indication of the costs associated with any withdrawal, but some did suggest that they would expect the Regulation to lead to an increased number of recalls and withdrawals, with those associated with *Salmonella* in minced meat and meat preparations being of particular note.
- 5.28 The costs of corrective actions in terms of non-compliance with the process hygiene criteria have not been considered. The actions that a food business operator must take in the case of an unsatisfactory result are, for example, improvements to production (slaughter) hygiene and improvements in selection and/or origin of raw materials, as well as any actions specified in the food safety management plan.
- 5.29 UK stakeholders, including individual food businesses, replied to the Agency as part of a stock take exercise in November 2004 and in response to a Commission led European Consultation exercise in January 2005, with examples of indicative costs

associated with the implementation of the Regulation. The most recent consultation did not provide further details or particular examples for inclusion in the regulatory impact assessment.

***Listeria* criteria for ready-to-eat products and durability studies**

- 5.30 The Microbiological Criteria Regulation, for the first time places a legal requirement on food businesses to consider conducting durability studies on all ready-to-eat products in relation to *Listeria monocytogenes*, in accordance with the procedures at Annex II of the Regulation.
- 5.31 The Regulation provides food safety criteria for *Listeria monocytogenes* in ready-to-eat foods, where an unacceptable result would lead to a withdrawal or recall of the food product. The limits vary depending on the intended end consumer of the foods, e.g. stricter requirements for food for infants and for special medical purposes, whether or not a durability test has been conducted and the outcome where conducted. The Regulation proposes a step-wise approach to evaluating durability, from the initial stage of determining the properties of the food to ascertain whether it would support the growth of *Listeria*, through to an actual challenge test if required. We expect that most food businesses will conduct durability studies where appropriate in the course of their normal business and product development. However, a full assessment through to a challenge test may not be required for each product line or recipe change, food business operators may be able to draw comparisons with similar products, or representative worst case products, e.g. low salt ham, to define the maximum shelf-life for all hams, historical end of life testing data or previous durability studies to demonstrate that where present, *Listeria* has not been able to grow to 100 cfu/g provided that the physico-chemical properties of each foodstuff are known. In addition, a provision has been included in the Regulation that permits food businesses to collaborate when conducting these studies, in order to assist small and medium sized establishments in particular. This would mean that businesses would be able to collaborate with each other, to approach various food research associations for assistance to carry out the testing or share the cost with other businesses.
- 5.32 In order to assist in assessing any additional costs that may be incurred, interested parties were asked to provide the Agency with an approximate figure (£) for:
- (a) the consideration of the physico-chemical characteristics of the product and consultation of available scientific literature and research data for the growth and survival characteristics, and
 - (b) the studies conducted under (a) plus
 - (i) predictive mathematical modelling;
 - (ii) tests to investigate the ability of the micro-organism of concern to grow or survive in the product under expected storage conditions; and
 - (iii) studies to evaluate the growth or survival of micro-organisms of concern that may be present in the product during the shelf-life under reasonably foreseeable conditions of distribution, storage and use.
- 5.33 Responses were received from trade associations, (BRC, Chilled Food Association (CFA) and National Association of Master Bakers (NAMB)) and individual food businesses, including suppliers, manufacturers and retailers. The maximum cost of complying with these studies if a challenge test was required for all products and lines. As detailed above, the Agency's understanding is that challenge tests would not

be required for every product produced, the decision should be taken within the framework of the food safety management plan based on the individual assessment of the risk. Therefore, where the local risk indicates that a challenge test would be required, this would cost £1,000 per product type.

- 5.34 Whilst this is the first time that there has been a legal requirement to consider conducting durability studies, the Agency expects that any reputable and responsible business will already undertake durability studies as part of their product development and will consider whether these are required as part of any reformulation. The Agency also considers that the requirements specified in the Regulation do not exceed those that would be in operation commercially; therefore, for major retailers and manufacturers the requirement to consider conducting durability studies would be cost neutral. We expect that small retailers and caterers would be unlikely to be required to conduct durability studies as part of their day to day activities, as they would have been conducted by the manufacturers during the product development phase; therefore, for these businesses the requirement is likely to be cost neutral.
- 5.35 However, there may be additional costs for small manufacturers who may not currently consider the need to undertake durability studies. As a worst case scenario, if these studies were required for all their products there would be a maximum cost of £15,000 assuming 15 product lines.

Manufacturing

Small manufacturer (assuming 10 to 15 product lines)

Initial costs ~ £10,000 to £15,000

Listeria monocytogenes criteria for ready-to-eat products

- 5.36 This is the first time that there is a legal requirement to comply with *Listeria monocytogenes* criteria for all ready-to-eat products. However, given the seriousness of foodborne disease caused by *Listeria*, the Agency expects that reputable businesses would already sample and test the production environment and foodstuffs for this micro-organism. Therefore, for the major retailers and manufacturers the cost of complying with the requirement will be cost neutral. Extra costs may be expected to occur where criteria for *L. monocytogenes* are not already considered as part of a food safety management system or perhaps associated with an increased number of product withdrawals. Whilst small retailers and caterers will be expected to provide sufficient evidence to show that they are complying with this criteria, it is not expected that the HACCP would be verified by microbiological testing. These food businesses may be able to demonstrate compliance by providing evidence of the safe and hygienic handling of foodstuffs.
- 5.37 With the exception of milk and dairy products, the Regulation requires that all ready-to-eat foods meet food safety criteria for *L. monocytogenes* (criteria 1.1, 1.2 and 1.3) and proposes that businesses should also conduct environmental sampling. For the criterion 1.2 (ready-to-eat products able to support the growth of *L. monocytogenes*) there are 2 criteria: 100 cfu/g for products where a durability study is conducted and shows that any growth will not exceed this limit during the shelf-life, and absence in 25g for any foodstuff when a durability study is unable to be conducted or where the durability study shows that *L. monocytogenes* growth exceeds the 100cfu/g limit.

- 5.38 It is expected that there may be additional burdens on smaller manufacturers who may not have previously considered *L. monocytogenes* within their food safety management plan. An important first step will be for businesses to know the physico-chemical properties of their foodstuffs and hence determine whether *L. monocytogenes* will either grow or survive, whilst considering the shelf-life and intended use of the product, e.g. breads that are baked on the day of purchase are unlikely to pose a problem for consumer health, whereas raw milk/mould ripened soft cheeses have a known association with Listeriosis. Therefore, there may be certain situations where sampling and testing foodstuffs for *L. monocytogenes* would not be useful.
- 5.39 Any additional impact of complying with the *Listeria monocytogenes* criteria (1.1, 1.2 and 1.3) for ready-to-eat products is considered individually under each sector, e.g. fresh produce, fishery products etc.

Fresh fruit and vegetables (including sprouted seeds and unpasteurised juices)

- 5.40 The requirement for ready-to-eat pre-cut fruit and vegetables to meet a *L. monocytogenes* criterion is new. The fresh produce sector has indicated that the cost of *Listeria* testing could equate to 1% of any businesses total turnover.
- 5.41 The Regulation introduces a requirement for ready to eat pre-cut fruit and vegetables to comply with a *Salmonella* criterion of absence in 25g sample. Food businesses have provided data to the Commission and Agency on the potential costs of testing. These figures assume that testing will be required on all lines produced each day and does not consider alternative approaches, or the testing requirements and controls that are already in place to satisfy the retailers. The Agency would expect those responsible manufacturing businesses supplying pre-prepared fruit and vegetables to already consider microbiological testing for the specified micro-organism. The necessary sampling and testing frequencies would be determined by the food business operator, in the context of their food safety management plan according to the local risk. The exception may be small businesses selling prepared salads, however in these situations the risk should be assessed by taking account of the nature, turnover of the product and the hygienic preparation of the foodstuffs. Therefore, the Agency considers that the costs provided below would be the maximum expenditure and that the actual costs would be significantly lower, approaching cost neutral.
- 5.42 The Regulation introduces a *Salmonella* criterion (criterion 1.20) for unpasteurised fruit and vegetable juices (ready-to-eat). Whilst this is a new requirement it is expected that the impact will be cost neutral. Most producers may already be testing for *Salmonella* as part of their food safety management plan, the frequency of the sampling and testing will be determined by the local risk and will be proportionate to the scale of the business.
- 5.43 A *Salmonella* criterion for sprouted seeds (ready-to-eat), absence in 25g, is included in the Regulation. Whilst this is a new requirement it is expected that the impact will be cost neutral. Most producers may already be testing for *Salmonella* as part of their food safety management plan, the frequency of the sampling and testing will be determined by the local risk and will be proportionate to the scale of the business.

Criteria for milk and dairy products

5.44 Microbiological criteria for milk and dairy products are included in the England and Wales Dairy Products (Hygiene) Regulations (DPHR) 1995. Similar national legislation applies in Scotland and Northern Ireland. A general assessment has been made of the requirements in the Regulation, comparative to the current requirements in the DPHRs in terms of additional burdens to food business operators. Table 1 summarises this assessment.

Table 1: Comparison of requirements in the Microbiological Criteria Regulation (MCR) for dairy products to those in the DPHRs & assessment of impact on Food Business Operators (FBO)

Requirements in Annex 1 of MCR		Micro-organism	Change to those in the DPHR Yes/No	Extra burden on FBO
	Food Category			
1.2	Ready-to-eat foods able to support the growth of <i>L. monocytogenes</i>	<i>L. monocytogenes</i>	Yes	Possible. Although the requirements in the DPHRs for absence in 25g sample are present in the MCR
1.3	Ready-to-eat foods unable to support the growth of <i>L. monocytogenes</i>	<i>L. monocytogenes</i>	Yes	None expected. DPHR requires absence in 1g whereas up to 100cfu/g allowed in the MCR
1.11	Cheese, butter and cream made from raw milk that has undergone a heat treatment lower than pasteurisation	<i>Salmonella</i>	No	None, the criteria remain the same
1.12	Milk & whey powder	<i>Salmonella</i>	Yes	There is a reduction in the number of samples specified from 10 to 5.
1.13	Ice cream excluding products where the manufacturing process or the composition will exclude the <i>Salmonella</i> risk	<i>Salmonella</i>	No	None
1.2.1	Cheeses, milk powder & whey powder	Staphylococcal enterotoxins	Yes	Yes. Required to test for Staphylococcal enterotoxin if levels of coagulase-positive staphylococci exceed 10^5 cfu/g

2.2.1	Pasteurised milk and other pasteurised dairy products	Enterobacteriaceae	Yes	No. Replaces test for <i>S. aureus</i> for dairy products, and tests for pathogenic microorganisms, coliforms and plate count for heat-treated milk.
2.2.2	Cheeses made from milk or whey that has undergone heat treatment	<i>E. coli</i>	No	None.
2.2.3	Cheeses made from raw milk	Coagulase-positive staphylococci	Yes	No. Replaces test for <i>S.aureus</i> and <i>E.coli</i> .
2.2.4	Cheeses made from milk that has undergone a lower heat treatment than pasteurisation & ripened cheeses made from milk that has undergone pasteurisation or a stronger heat treatment	Coagulase-positive staphylococci	Yes	No. Replaces test for <i>S.aureus</i> and <i>E.coli</i> .
2.2.5	Unripened soft cheeses (fresh cheeses) made from milk or whey that has undergone pasteurisation or a stronger heat treatment	Coagulase-positive staphylococci	Yes	No. Replaces test for <i>E.coli</i> .
2.2.6	Butter and cream made from raw milk or milk that has undergone a lower heat treatment	<i>E. coli</i>	Yes	Yes
2.2.7	Milk & whey powder	Enterobacteriaceae	Yes.	Yes.
		Coagulase-positive staphylococci	Yes.	No. Replaces test for <i>S.aureus</i> .
2.2.8	Ice cream & frozen dairy desserts	Enterobacteriaceae	Yes.	No. Replaces test for <i>S.aureus</i> .

5.45 In terms of additional financial burden, it is hard for the Agency to make an assessment at this time, as we have no figures for the costs of the specific tests and different sectors of the dairy industry will be affected to different degrees. In broad terms, the overall effect of the new requirements across the dairy industry would seem to be cost neutral as the sampling and testing is a requirement of existing legislation and should be established through the business' food safety management plan. The consultation did not provide any additional data which would allow the Agency to assess whether the Regulation would be an additional burden.

Criteria for shellfish and fishery products

- 5.46 Information supplied by the industry (suppliers of fishery products) indicates that 0.2% of the annual turnover is currently spent on testing for *Listeria monocytogenes*, primarily in the finished end product and also within the environment, to ensure appropriate measures are put in place to minimise *Listeria* growth. Indicative costs from the frozen and chilled fish, and seafood industry are that the extra testing that might be required for *Listeria* and *Salmonella*, is likely to add an extra £60 to each production run, equating to up to £15,500 per annum. However, this does not include shelf life studies or ongoing verification costs. Most responsible and reputable producers may already have considered sampling and testing for *Salmonella* and *Listeria* as part of their food safety management plan. The frequency of the sampling and testing will be determined by the local risk and will be proportionate to the scale of the business.
- 5.47 There is also a slight change to the testing regime for live bivalve molluscs. For larger animals the current National Reference Laboratory protocol recommends a minimum of 6 animals for larger species, such as, scallops. The Regulation indicates a sample should consist of 10 animals. The main implication will be an increase in sampling which could cost in the region of £50 per site as the shellfish will be collected by dredging or diving. The impact is however, likely to be relatively minimal as there are currently only 3 harvesting areas classified for these species.
- 5.48 The criteria in current EU Directives applicable to shellfish and fishery products remain largely unchanged in the Regulation. The only differences are the indicator organism (process hygiene) mesophilic aerobic bacteria from Directive 93/51 has not been retained and there are changes to the process criteria for shelled or shucked cooked crustacea and bivalves. The latter is likely to have a more significant effect than the former, but the exact impact cannot be determined at this stage. However, it should be noted these process hygiene criteria will be used by food business operators to assess whether their plants are operating satisfactorily and to assist them in implementing production monitoring procedures. Therefore, the likely impact of the criteria on these products is likely to be cost neutral or reduced costs, as the frequency of sampling and testing is to be determined by the food business within the context of their food safety management plans.

Criteria for powdered infant formulae

- 5.49 Following the 2004 EFSA opinion on powdered infant formulae, the Commission has included microbiological criteria for this proposal. This is a 2-step approach whereby the detection of Enterobacteriaceae (criterion 2.2.9) would trigger further testing of the positive samples for *Enterobacter sakazakii* (1.23) and *Salmonella* (1.22). The presence of either of these pathogens would require product withdrawal. The Agency has sought economic data from the infant formulae industry on the estimated burden of implementing the Regulation resulting in changes to testing and subsequent product rejections. The respondents suggested that costs would be less than £250,000 per firm, with one company suggesting a cost of £100,000. These figures would apply to the detection of *E. sakazakii*, *Salmonella* and/or Enterobacteriaceae in the product. The Agency does not expect that there would be an actual increase in the frequency of sampling or testing given the rigorous testing regimes already set in place by the manufacturers; however, the actions to be taken in the case of non-compliance with the Enterobacteriaceae process hygiene criterion may differ.

Criteria for meat carcasses

Current requirements

- 5.50 Operators of full throughput red meat slaughterhouses have been required to arrange for microbiological testing of cattle, sheep, pigs, and other species killed for human consumption for Enterobacteriaceae and TVCs¹⁷, under the Meat (HACCP) Regulations since June 2002. The requirement has applied to operators of low throughput slaughterhouses since June 2003. Fortnightly testing for TVCs, of a minimum of 10 surfaces of production equipment in red meat slaughterhouse and cutting plants was also a requirement. Guidance on sampling and test methods, and on reduced levels of sample numbers was provided by the Agency. There is no current requirement for microbiological testing of poultry meat carcasses.

¹⁷ Total Viable Count

Legislative changes and impact

- 5.51 The Meat (HACCP) Regulations 2002 will be revoked on 31 December 2005. The Microbiological Criteria for Foodstuffs Regulation continues the requirements for weekly testing in slaughterhouses of five red meat carcasses for Enterobacteriaceae, aerobic colony counts and introduces the requirement for testing red and white meat carcasses for *Salmonella*. The Regulation provides for the use of alternative procedures and reduced frequency of testing in certain circumstances. The Agency has reviewed its current guidance to operators, with the aim of maintaining a proportionate approach to the frequency of testing, consistent with the legislation. There should be no overall increase in cost for red meat slaughterhouses, as there is no longer a legal requirement to test production equipment surfaces, although all food business operators are recommended to periodically carry out such testing to demonstrate the effectiveness of their cleaning and disinfecting procedures. The Meat (HACCP) Regulations 2002 recommend that *Salmonella* testing of poultry is part of the requirement to verify the implementation of a plant's procedures based on HACCP, so it is likely that some plants will already have a relevant testing programme in place. The new requirement for sampling and testing poultry meat carcasses for *Salmonella* will add to operators' costs if they do not test currently, or do not use the specified sampling procedure, or test at the required frequency.

Salmonella sampling and testing of red meat carcasses

- 5.52 The requirement is to test samples taken from carcasses of cattle, sheep, goats, horses and pigs for *Salmonella*. Five carcasses a week should be sampled using an abrasive sponge and tested using the ISO (International Standards Organisation) test method. It is possible to test the sponge sample for Enterobacteriaceae and aerobic colony counts, which would minimise the cost of taking samples and the revised guidance currently in preparation details a method to use a sponge sample for all the tests required.

Salmonella sampling and testing of white meat carcasses

- 5.53 The requirement is to test samples taken from poultry carcasses (broilers and turkeys) for *Salmonella*. Five samples a week should be tested using the ISO method, each sample should be composed of 3 neck skins.

Sampling and testing costs

- 5.54 Microbiological sampling and testing costs for slaughterhouses will vary according to the time taken to collect samples, the choice and location of the laboratory (some operators have their own facilities), transport costs, whether weekend testing of samples is needed and whether testing frequency can be reduced after a period of satisfactory results and maintained at the lower level. In a small 2001/02 pilot plant study the weekly average time costs for collecting and handling samples in seven small red meat plants were £21.10 per week for each plant. This figure comprised the cost of taking the sample (swabbing) £12.16, recording £7.66, audit £0.18 and training £1.54¹⁸. A feasibility study has shown that the method for taking *Salmonella* samples from red meat carcasses (an abrasive sponge) is also suitable for taking samples for Enterobacteriaceae and aerobic colony count testing. As this method is easier and quicker to use than the current method, these costs could fall. If an operator chooses not to use the combined method there would be an increase in costs due to

¹⁸ HACCP in meat plants, Report of the 2001/02 pilot plant study and 2002/03 review: <http://www.food.gov.uk/multimedia/pdfs/haccpstudy2003.pdf>

taking a sponge sample in addition to the swab or excision samples taken for Enterobacteriaceae and aerobic colony count tests. There will be an additional cost for poultry meat slaughterhouses due to sampling and handling neck skin samples.

The laboratory cost of testing a sample for *Salmonella* is estimated to be between £5-10.

As the Microbiological Criteria Regulation continues the requirement for carcass testing for aerobic colony count and Enterobacteriaceae (current costs detailed in Table 2 and the requirements in the Microbiological Criteria Regulation in Table 3), this is cost neutral. The laboratory cost of testing five samples a week for *Salmonella* for a slaughterhouse for one year would be £1,300 to £2,600.

5 samples x 52 weeks x £5-10 cost of *Salmonella* test = £1,300 – 2,600.

There are currently 345 licensed red meat slaughterhouses in the UK, so the upper cost detailed in Table 3 would be an additional £448,500 - £897,000.

5 samples x 345 licensed red meat plants x 52 weeks x £5-10 cost of *Salmonella* testing = £448,500 - £897,000.

5.55 In the UK there are 76 full throughput poultry producers and 58 low throughput producers, but not all of these slaughter broilers or turkeys.

5.56 The testing frequency for red and white slaughterhouses can be reduced from weekly to fortnightly if satisfactory results have been obtained for 30 consecutive weeks, so potentially the costs given in Table 4 could be reduced by up to 50% after 30 weeks.

Estimate of Laboratory Cost of Microbiological Sample Testing:

Table 2: Current costs for red meat carcasses

<u>Carcasses</u> Current and continuing costs	<u>Surfaces</u> Current cost with potential for reduced costs
2 tests per sample (ACC + Enterobacteriaceae)	1 test per sample (ACC)
<i>Minimum requirement</i>	<i>Minimum requirement</i>
5 x 2 tests a week x 6 weeks = 60	10 tests a fortnight x 26 weeks = 260
frequency reduced to:	260 @ £3.50 = £ 910
5 x 2 tests a fortnight x 23 = 230	260 @ £4.00 = £ 1,040
290 @ £5.50 = £ 1,595	
290 @ £8.00 = £ 2,320	
<i>Maximum requirement</i>	<i>Maximum requirement</i>
10 x 2 samples a week x 52 weeks = 1040	30 samples a fortnight x 26 weeks = 780
1040 @ £5.50 = £ 5,720	780 @ £3.50 = £ 2,730

1040 @ £8.00 = £ 8,320	780 @ £4.00 = £ 3,120
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Table 3: New costs and reduced costs for red meat carcasses

<u>Carcasses</u> Additional costs	<u>Surfaces</u> Reduced costs
1 additional test per sample (<i>Salmonella</i>)*	1 test per sample (ACC) no longer required. Periodical testing only.
<i>Minimum requirement</i>	<i>Maximum saving</i>
5 x 1 test a week x 30 weeks = 150 frequency reduced to:	10 tests a fortnight x 26 per year = 260
5 x 1 test a fortnight x 11 weeks = 55	260 @ £3.50 = £ 910
205 @ £5.00 = £ 1025	260 @ £4.00 = £ 1040
205 @ £10.00 = £ 2050	
<i>Maximum requirement</i>	<i>Minimum saving</i>
5 x 1 test a week x 52 weeks = 260	30 samples a fortnight x 26 weeks = 780
260 @ £5.00 = £ 1,300	780 @ £3.50 = £ 2,730
260 @ £10.00 = £ 2,600	780 @ £4.00 = £ 3,120

* The cost of testing a sample for *Salmonella* is estimated to be between £5-10

5.57 The possible reduced costs are because there is no longer a requirement for weekly surface tests, this has a greater cost than the new costs for *Salmonella* testing. It is expected however that the operators will include some surface testing as part of the verification of their cleaning procedures.

Table 4: New costs for poultry meat carcasses

<u>Broiler and Turkey carcasses</u> New cost
1 test per sample (<i>Salmonella</i>)*
<i>Minimum requirement</i>
5 x 1 test a week x 30 weeks = 150 frequency reduced to:
5 x 1 tests a fortnight x 11 = 55
205 @ £5.00 = £ 1025
205 @ £10.00 = £ 2050
<i>Maximum requirement</i>
5 x 1 test a week x 52 weeks = 260
260 @ £5.00 = £ 1300
260 @ £10.00 = £ 2600

* The cost of testing a sample for *Salmonella* is estimated to be between £5-10

- 5.58 Sampling frequency may be reduced further if there is a national or regional *Salmonella* control programme in place, and if this programme includes testing that replaces the sampling frequency of the Regulation. The sampling frequency may be reduced further if the national or regional *Salmonella* control programme demonstrates that the *Salmonella* prevalence is low in animals purchased by the slaughterhouse. The national control plans required for pigs and poultry specified in the Zoonoses Regulation 2160/2003 would be acceptable control programmes.
- 5.59 Additionally, when justified on the basis of a risk analysis and consequently if authorised by the competent authority, small slaughterhouses may be exempt from these sampling frequencies. The Agency has reviewed its policy in this area and proposed a proportionate approach. Following the generation of data the intention is to further review these frequencies early in 2007.

Zoonoses Action Plan (ZAP) as a national control plan

- 5.60 In Great Britain (GB) and Northern Ireland (NI) industry Zoonoses Action Plans (ZAP) have been introduced with the aim of reducing the carriage of *Salmonella* in pigs. The plans cover assured pig production in GB, which includes 92% of pig production and all pig production in NI. 136 slaughterhouses are licensed to handle pigs in the UK, including 3 in NI. Currently there are 22 slaughterhouses in the UK in the ZAP scheme and to date the cost of testing samples has been part funded by the Agency at a cost of £200,000 per year. The cost of testing five carcass sponge samples a week for *Salmonella* for the 22 slaughterhouses would be £28,600 to £57,200.

5 samples x 22 slaughterhouses x 52 weeks x £5-10 cost per *Salmonella* test = £28,600 - £57,200.

- 5.61 A feasibility study has been commissioned to look at whether ZAP control plans could fulfil the requirements of national control plans and whether the testing could be a substitute for carcass testing. The study has concluded that the ZAP study should continue to function as present and that carcass testing should be undertaken as specified. If and when the prevalence of *Salmonella* in pigs has fallen then the frequency of carcass testing can be reviewed.

Corrective actions for unsatisfactory results

- 5.62 All criteria proposed for meat carcasses are process criteria not food safety criteria, so do not result in unsatisfactory meat. The action the food business operator must take in the case of unsatisfactory results are improvements in slaughter hygiene, review of HACCP controls, origin of animals and biosecurity measures on the farms. These actions will result in some extra cost, but at least some of the proposed actions will currently be in place in plant procedures based on HACCP principles.

Criteria for testing minced meat, meat preparations, meat products, mechanically separated meat, gelatine and collagen

Salmonella sampling and testing of meat products

- 5.63 *Salmonella* testing is a new requirement for meat products intended to be eaten raw (unless the production process eliminates the risk of *Salmonella*) and for meat products made from poultry meat intended to be eaten cooked. The Regulation

proposes that food business operators' determine the frequency of such testing calculated on a risk basis with the option to reduce the frequency of testing where, over a period of time, the results have been satisfactory. The Competent Authority will verify and audit the food business operator's results and sampling frequency decisions. Guidance produced between industry and the Agency covers how sampling frequency should be decided.

- 5.64 National records indicate that there are 1441 listed, approved meat products plants in England. However, under the new legislation, the definition of a meat product will change and many of these food businesses will no longer be considered to be manufacturing meat products (Article 1(2) of the Regulation (EC) No. 853/2004, refers). The records do not indicate the number of plants that would fall into this category and we have no information on the number of products to which the criteria apply, although the general view is that the number is quite small. When necessary, *Salmonella* testing should be undertaken on 5 x 25g samples from a batch. Using an average cost of testing would be: £5-10 x 5 = £25-50 per sampled batch. There would be a small cost associated with collecting samples and dispatching them to the laboratory for testing.

Minced meat and meat preparations

- 5.65 The current legislation requires microbiological sampling and testing (for *Salmonella*, *E. coli*, aerobic mesophile bacteria and *Staphylococcus aureus*) to be undertaken. The frequency varies depending on whether the product is for the national market (1 representative sample per week for minced meat and meat preparations) or for trade (1 representative sample per day for minced meat and 1 representative sample per week for meat preparations). The Regulation specifies weekly *Salmonella*, *E. coli* and aerobic colony count testing of five samples of minced meat and meat preparations intended to be eaten raw or fully cooked. If *Salmonella* is found, the batch is unsatisfactory and cannot be placed on the market or, if on the market, it must be withdrawn from the market. This will result in additional costs for the producer. The batch in question may be used by the food business operator (but not at retail) for other purposes, including processing, that will eliminate the *Salmonella* risk. In practice however, this is not thought to be practical, as most product will be in final packaging. There is a provision in the Regulation for Member States to apply a transitional derogation until the end of 2009 where minced meat and meat preparations intended to be eaten fully cooked can remain on the home market if one of the five samples is positive for *Salmonella*. If a Member State wishes to apply the derogation, it must notify the Commission of this decision and products for the home market produced under the derogation must bear a special mark. If the derogation is applied there will be costs involved in the marking of product, but the costs associated with not placing the product on the market and/or product withdrawal will be reduced as less batches will have two or more positives, compared to one or more positives. Some stakeholders are concerned that the application of a special mark may affect consumer confidence in the product. This will be a factor for each company to take into consideration when deciding whether or not to apply the derogation.
- 5.66 Costs per batch of product recall are estimated as 200,000 Euro (average figure produced by 3 trade associations). In addition, industry has commented that those producers supplying the major retailers would be fined £75,000 for non-compliance. Costs for products not able to proceed to retail would be considerably less. The

Northern Ireland Association of Meat Exporters estimated recall costs at £3000 per tonne of product and that the retailer fine for failure to comply with the criteria could be as much as £200K. A major European trade association (UECVB) has used a figure of 10 Euro per kilogram as a direct cost of withdrawing product. It is likely that most minced meat and meat preparation producers would operate a sampling procedure where the batch tested is isolated and/or frozen and would be in effect “positively released”. In this case, the costs for a batch with unsatisfactory results would include the value of the product and the cost of disposal. Although the Regulation does allow unsatisfactory batches to be heat-treated in reality this may not always be possible, as much of the product will be pre-packed for sale in retail packs. In addition, some product has a short shelf life and the results of testing will not be available until the product has reached the end of this, in these cases an unsatisfactory results will not have any additional costs.

- 5.67 The number of unsatisfactory batches will depend on the prevalence of *Salmonella*.
- 5.68 Data provided from UK industry for 25g samples of minced meat suggest a 3 percent prevalence for *Salmonella*. Data provided to the European Commission suggest an average *Salmonella* prevalence across Member States of 1%. A UK raw meat (not including minced meat) survey of in excess of 5,000 samples, undertaken at retail by the Health Protection Agency from March 2003 to March 2005, has provisionally recorded a prevalence of *Salmonella* of 5% in 25g samples of raw meat.
- 5.69 As the prevalence in minced meat and meat preparations is not clearly established (particularly in 10g samples as specified in the Regulation), the following data is provided to demonstrate the expected number of batches where all 5 samples will test negative for *Salmonella* compared to 1 in 5 positive and more than 1 in 5 positive, at 3 different (1, 3 and 5 percent) assumed prevalence of *Salmonella*.

Example data

A. Prevalence of 5 percent:

- the chance of accepting a batch is
- 97.74% when $n=5$ $c=1$ (2.26% batches tested will require action) and changes to
- 77.4% when $n=5$ $c=0$ (22.6% batches tested will require action)
- The number of batches requiring action increases 10 fold in $c=0$ compared to $c=1$

B. Prevalence of 3 percent:

- the chance of accepting a batch is
- 99.15% when $n=5$ $c=1$ (0.85% batches tested will require action) and changes to
- 85.9% when $n=5$ and $c=0$ (14.1% batches tested will require action)
- The number of batches requiring action increases 16 fold from $c=0$ to $c=1$

C. Prevalence of 1 per cent:

- the chance of accepting a batch is
- 99.9% when $n=5$ and $c=1$ (0.1% batches tested will require action) and changes to

- 95.1% when n=5 and c=0 (4.95% batches tested will require action)
- The number of batches requiring action increases 50 fold from c=0 to c=1

5.70 The **action required** associated with an unsatisfactory batch will include:

- Product withdrawal if the product is available at retail.
- Product diversion if the product is not at retail this could be
 - Heat treatment
 - Product disposal
- Revision of procedures based on HACCP that should include
 - Supply of raw material
 - Production process for the raw material

5.71 The batch size in UK production is 500 to 5,000kg. The Northern Ireland Association of Meat Exporters suggest that this is an underestimate and batch size can vary from 500 to 20,000 kg.

- Minced meat yearly production is 140,000 tonnes (estimated as 28,000 to 280,000 batches)
- The number of batches produced per week by a typical producer is 100 to 500.

5.72 The percentage of batches to be tested is estimated to be 0.5 to 1%. We do not however have an accurate estimate of how many of the tested batches will be on the market and or if product diversion is possible so are unable to provide the costs associated with unsatisfactory results. As an example, if we assume 1% of 280,000 batches are tested at a prevalence of 1% then 5% could give unsatisfactory results. This would be 140 batches of 500 kg at a cost of 10 Euro per kg giving an upper cost of 700,000 Euro if all the product were available. If the derogation was applied then 0.1 per cent could give unsatisfactory results. This would be 3 batches of 500 kg giving an upper cost of 15,000 Euro if all the product was available. As we do not have the figures for meat preparations we have assumed a similar figure of 700,000 Euro, including the possibility of 6 full recalls a year to give an estimated figure of £2,000,000. This is based on the data provided from Member States to the Commission who currently operate a strict withdrawal policy.

5.73 If the derogation was applied the cost could be reduced by a factor of 50, but would be offset by the potential cost of applying the special mark to new packaging.

5.74 The proposal in the new Regulation would give a reduction (from daily to weekly) in the frequency for microbiological testing for producers of minced meat for trade (i.e. for export) but as the requirement is for five samples a week in comparison to one sample a day, the effect will be cost neutral. The Regulation does not contain a requirement to test for *Staphylococcus aureus* so this would be a cost reduction. For producers of meat preparations for trade (i.e. export) the proposal would probably be cost neutral as there would no longer be a requirement to test for *Staphylococcus aureus* but there would be a requirement to test the aerobic colony count. For the same reasons, the cost of microbiological testing for those producers of minced meat and meat preparations for the national market only, is expected to be cost neutral. When justified on the basis of a risk analysis and authorised by the competent authority, establishments producing minced meat and meat preparations in small quantities may be exempt from these sampling frequencies. Producers of small quantities of minced meat and meat preparations would see a further reduction in their

overall costs, if they were exempt from the sampling frequencies. The Agency is currently considering what quantity of production might qualify as 'small'.

- 5.75 There is no requirement in the current legislation for minced meat and meat preparations to be labelled to indicate the need for thorough cooking. The new food hygiene legislation requires (in paragraph 2, Chapter IV, Section V, Annex III of Regulation 853/2004) that 'Packages intended for supply to the final consumer containing minced meat from poultry or solipeds or meat preparations containing MSM must bear a notice indicating that such products should be cooked before consumption.' This labelling is in addition to that required by Council Directive 2003/13/EC on the labelling of foodstuffs (This legislation includes, at Article 3.1(6) the conditions of use and at Article 11 that instructions for the use of the foodstuff should be indicated). Whilst the Agency's partial regulatory impact assessment for The Food Labelling (Amendment) (England) (No. 2) Regulation 2005 estimated that the cost of changing food labels as £1,000 per product, the Advisory Committee on the Microbiological Safety of Food (ACMSF) Report on Verocytotoxin-Producing *Escherichia coli* (1995) recommended that the industry should label raw minced beef and minced beef products with appropriate handling and cooking instructions. We believe many producers already label their products as a result of this recommendation and there are unlikely to be additional costs for producers resulting from this requirement. However, if the national derogation is to be applied there will be labelling costs associated with applying the special mark to the package. The Northern Ireland Association of Meat Exporters suggested changes to the label would cost approximately £250 per design and as companies currently hold an active stock of 20 label designs, this would cost a business around £5,000.
- 5.76 There are 384 approved minced meat and meat preparations plants in UK (278 in England, 15 in Wales, 41 in Scotland and 50 in Northern Ireland) that are eligible to trade. There is no national record of the number of plants that produce minced meat and meat preparations for the national market only, these records are held by the individual local authorities.

Mechanically separated meat (MSM)

- 5.77 There is currently no legislative requirement to perform microbiological sampling and testing on MSM, although some producers may be doing so in verification of their procedures based on HACCP principles. The Microbiological Criteria Regulation includes a requirement for weekly microbiological testing of five samples for *Salmonella*, *E. coli* and aerobic colony count which will represent an increase in costs for the producer. It is not known how many producers of MSM there are in the UK.
- 5.78 The average cost of *Salmonella*, *E.coli* and aerobic colony count tests is £15-25. Therefore the weekly cost of microbiological testing for producers of MSM would be £75 to £125.
- 5 x *Salmonella*, *E. coli* and aerobic colony count tests £15-25 = £75 - £125.
- 5.79 In addition, there would be an additional cost for taking the samples and dispatching them to the laboratory. If *Salmonella* is found in any of the five samples the batch is regarded as unsatisfactory and can only be used for producing heat-treated meat

products in approved premises. This is also likely to result in costs for the producer. There is no scope in the Regulation to allow a reduction of the weekly sampling.

Gelatine and collagen

- 5.80 Current requirements are for microbiological testing to be carried out on each production batch for a range of 'bacteria'. The Commission proposal is for testing of five samples a batch for *Salmonella* only with sampling frequency to be determined by the food business operators within the context of their HACCP based procedures. If one or more samples are positive the batch may not be placed on the market or must be withdrawn or recalled from the market. This may result in costs for the producer; however, overall this is likely to result in a reduction in costs for these businesses.
- 5.81 We are not aware of any manufacturer of gelatine for human consumption in the UK. We are, however, aware of at least one producer of collagen for human consumption in Scotland.

Environmental

- 5.82 We do not envisage significant additional costs in relation to any environmental aspects, although some respondees to the consultation noted that there may be increased costs associated with the disposal of withdrawn/recalled product.
- 5.83 A summary of the costs and benefits are given in Table 5 on page 39.

6. SMALL FIRMS IMPACT TEST

- 6.1 The Small Business Service has been kept informed and consulted about this proposal, as has the Improving Regulation in Scotland (IRIS) unit.
- 6.2 Initial soundings with small firms indicated that there might be some possibility of significant cost impact on small firms. We therefore carried out stage two of the small firms impact test and invited a number of small firms to attend a focus group to further explore the possible impact of the proposals on small business.
- 6.3 We were able to address the main concern, which was that small firms would have to introduce new testing procedures that may prove costly. We explained that small firms in most sectors (there might be a rare exception in a high risk area, but such firms are likely to already be undertaking testing) could provide evidence of compliance simply by continuing to do as they already do, that is by complying with current food hygiene regulations and following good practice. For example, buying from reputable sources, storing products at the appropriate temperature and conditions, ensuring foodstuffs are cooked properly, hygienic handling food, avoiding cross contamination between cooked and raw products and a considering the shelf life and turnover of foodstuffs. We have worked with the Small Business Service throughout the process, who is happy with our approach.

Equity and Fairness

- 6.4 Any new legislation specifying microbiological criteria for use by food businesses would be equally applicable to all relevant businesses involved in the production, manufacture, distribution, retail and catering sectors. In addition, all food businesses should be able to produce safe food. Therefore, the microbiological criteria will apply to all businesses.
- 6.5 We expect that small and medium sized businesses, especially those in the retail or distribution sectors, may proportionately be affected more than larger operators. However, most businesses will be conducting some form of microbiological testing as laid down in the existing vertical directives, industry specific guides or as specific customer requirements. In addition, it is important to remember that this Regulation places a requirement for the food business operator to demonstrate compliance as part of a risk based food management system. As such, the majority of the burden will be in establishing risk based procedures in food businesses where there were previously none and this has been covered in the RIA that complements the EU food hygiene legislation. Microbiological criteria should be used to verify and validate the procedures in place. However, the Agency considers that this will be a very small proportion of relevant businesses.

7. COMPETITION ASSESSMENT

Competition Filter Test

- 7.1 The new legislation applies to all businesses involved in the production or handling of food (“farm to fork” coverage) and will apply to all sectors including retail, catering, manufacturing and distribution and primary production, some 760,000 businesses in total. Given the number of different sectors affected within the UK no single business or number of businesses have a significantly large share of the market (50%).
- 7.2 It is anticipated that the greatest additional costs to food businesses will be associated with the introduction and implementation of a risk based approach to food safety management, e.g. procedures based on HACCP principles or GHP as required by the EU food hygiene legislation. Many businesses are already testing products as part of current EU legislation, because of specifications from customers or as part of industry specific guidelines and standards. It is expected that the new legislation will have a greater financial burden on small and medium sized businesses that might not have an established food safety management plan. However, the Regulation is flexible in its approach in terms of the sampling and testing frequency, permitting alternative methods and means to demonstrate compliance depending upon the local risk. The introduction of the Regulation will also complement other Agency initiatives such as those designed to assist small businesses in complying with Regulation (EC) No 852/2004 through the production of Agency guidance. These initiatives have been developed to allow businesses to manage food safety and protect consumers whilst at the same time avoiding unnecessary burdens on business. Whilst assistance is planned for these businesses, there remain additional financial implications to ensure understanding and compliance.
- 7.3 The Microbiological Criteria Regulation is not expected to affect the market structure, as the legislation will apply equally to all food businesses and adverse affects have

been avoided through the various options available to businesses, to demonstrate compliance with the criteria.

- 7.4 Higher set-up and ongoing costs are not expected for new or potential food businesses, as the Regulation will affect all businesses equally at the same time. Existing and new businesses will all need to comply with the legislation from 11 January 2006.
- 7.5 This is a fast moving area and new products are constantly being developed (BRC has estimated that during a year 30% of products will be subject to recipe changes). Where these are ready-to-eat products durability studies may need to be undertaken in respect of *Listeria monocytogenes*. This does not mean that food business operators would be required to undertake a full assessment each time; they may be able to draw comparisons with similar products, historical data or previous durability studies.
- 7.6 The new legislation is not expected to restrict the ability of food businesses to determine the price, quality, range or location of their products. The key objective of the Regulation is to ensure a high level of human health protection in respect of foodborne disease whilst removing obstacles to trade within the EU. Therefore this Regulation seeks to improve food safety and standards throughout.
- 7.7 The new legislation will apply equally to all new and existing businesses. The Regulation will have the potential to aid business, by helping to create a level playing field and possibly drive out substandard competition. This is particularly true for intra-Community trade and for imported food that will have to be produced to the same or equivalent standards as that produced within the UK and EU. Whilst businesses may incur some adjustment costs arising from the implementation of a risk based approach to food safety management specified in the new hygiene legislation, we do not expect that adoption of the Regulation will have an appreciable impact on competition, as it applies equally to all food businesses.

8. ENFORCEMENT, SANCTIONS AND MONITORING

Enforcement

- 8.1 It is very difficult to estimate the precise costs and benefits of the Regulation to enforcement agencies. LACORS, CIEH (Chartered Institute of Environmental Health) and Royal Environmental Health Institute of Scotland have been included in all informal consultations with stakeholders. LACORS expressed concern that there would be extra costs to Authorities in spending time explaining the new requirements to proprietors and in clarifying how they are to be applied, particularly if the guidance to industry (or enforcers) is not clear and easy to understand. There will also be training implications for the enforcement agencies whose officers will need training on the new requirements. Further resources may be required to explain that the new requirements to businesses and this will add to the time spent on inspections. As a result there could be implications for the completion of the local authority inspection programme.

- 8.2 To enable the consistent enforcement of the Microbiological Criteria Regulation for official control purposes in line with the requirements in Regulation (EC) No 882/2004, the Commission is developing guidelines with a number of Member States including the UK. It is the Agency's intention that these guidelines should extend the flexibility that exists in the Regulation to the enforcement authorities, whilst also providing a framework to assist harmonisation throughout Europe. The Agency has engaged with a group of interested UK stakeholders to discuss the various options available for the development of the guidelines.

Sanctions

- 8.3 Much of the Microbiological Criteria Regulation can be regarded as setting the criteria specified in Article 4(3)(a) of the Food Hygiene Regulation (EC) No 852/2004 and, as such, will be covered by legislation implementing that Regulation. However, there is a requirement in Article 7, that food business operators take certain steps where there has been a failure to comply with the obligations set down, i.e. where non-compliance is not a failure to meet the microbiological criterion but failure to carry out the actions specified in Annex I of the Regulation and in the food businesses' food safety management plan. A person who fails to do this is guilty of an offence and it is necessary to provide in domestic law certain enforcement powers for breach of these requirements.
- 8.4 The issue of sanctions is covered by the Regulation on Official Feed and Food Controls. However, the UK will have to apply penalties specific to this Regulation through national implementing legislation. The Agency has begun the formal process of implementing the Regulation. The Food Hygiene (England) Regulations 2005, which give effect to the EU food hygiene legislation, have been revised to give effect to the Microbiological Criteria Regulation. An Agency consultation has been issued on the draft Statutory Instrument.

Monitoring

- 8.5 The microbiological criteria contained in the Regulation are subject to continuous review via the Standing Committee procedure based on the latest scientific evidence, including opinions from EFSA, new technology, and emerging pathogenic micro-organisms in foodstuffs.
- 8.6 Microbiological criteria would be revised in accordance with the procedure referred to in Article 14(2) in Regulation (EC) No 852/2004, that the impact and effectiveness of the Regulation after 5 years following its implementation. This is a worthwhile exercise where lessons can be learnt and, if appropriate, amendments made. The UK will consult stakeholders when this procedure is initiated.

9. IMPLEMENTATION AND DELIVERY PLAN

- 9.1 The Agency has begun the formal process of implementing the Regulation. The key project objectives were to put in place any legislation required to apply the Regulation and to provide appropriate guidance material (including training) on the requirements of the Regulation on Microbiological Criteria for Foodstuffs for enforcement authorities and businesses.
- 9.2 The Statutory Instrument being prepared to give effect to the EU food hygiene legislation, will also include the necessary provisions to give effect to the Microbiological Criteria Regulation. This should simplify the application of the legislation for stakeholders as only one SI implements two sets of legislation. The Agency has prepared guidance for businesses and issued this for consultation on 4 November 2005. The guidance should be available when the Regulation comes into force on 11 January 2006.
- 9.3 Approximately £10m over 3 years has been allocated to achieve a step-change in small businesses to improve public health and reduce food poisoning. The money is being allocated as grants to Local Authorities to assist small businesses in complying with new hygiene legislation, using the Safe Food Better Business (SFBB) approach. The first tranche of successful awards was announced in September. 111 applications were received, and £5.5m was awarded to 54 projects involving 158 Local Authorities.
- 9.4 Due to changes to the proposals at late stages of the negotiations, discussions are continuing with stakeholders on the practical application of the Regulation, particularly with the special mark required if the transitional derogation is used for minced meat, meat preparations and meat products. The Agency will be providing guidance on these issues when a decision has been reached and stakeholders will be fully consulted on the development of this.

10. POST-IMPLEMENTATION REVIEW

- 10.1 The Agency will keep the Regulation under review and will seek amendments should evidence become available to support the amendment of existing criteria or inclusion of new criteria. It will also seek feedback from stakeholders on the effectiveness of the Regulation as part of the ongoing policy process over the next three years. The

Commission has indicated it will review the recent European Food Safety Authority opinions and identify additional areas where criteria could be proposed, for example, *Campylobacter*, *Bacillus Sp.* and *Clostridium Sp.* The UK also secured a commitment from the Commission that by the end of 2008 it would seek a quantitative risk assessment from EFSA in relation to the presence of *Salmonella* in minced meat and meat preparations based on data provided member states. The Agency will seek stakeholder views and contribute to the negotiations in line with the Commission's review process.

10.2 Guidance on the Regulation should be available when the Regulation comes into force. This document provides general information that will help businesses understand the requirements of the Regulation. The consultation has already indicated some areas where specific guidance may be required and it is likely practical application of the Regulation will highlight further areas. The Agency will discuss the need for additional guidance and the appropriate format for providing such guidance with stakeholders, with particular attention to the needs of small businesses.

11 SUMMARY AND RECOMMENDATION

11.1 The Regulation modernises and harmonises existing microbiological criteria to ensure they contribute to the protection of public health. The Regulation has been developed to support the new food hygiene legislation which will come into force on 1 January 2006. The criteria should be applied to help validate and verify the food safety management systems implemented by food businesses. The Regulation will benefit UK consumers by contributing to the production of safer food and assist UK food businesses to manufacture and trade within Europe.

Summary costs and benefits table

One-off setting up costs

	Costs in the first year
One off 'setting-up' costs for UK food businesses (760,000)	£2,850,000 to £5,700,000
Training for enforcement officers and additional time to explain requirements of the Regulation to food businesses	Consultation indicated this would be significant cost but no costs provided
	£2,850,000 to >£5,700,000

Benefits per annum

	Annual benefit
Benefits to the health service resulting from an incremental 1-5% reduction in foodborne illness	£15.3 to £76.5 million
Saving resulting from surface testing for aerobic colony counts for read meat carcasses no longer being required	£313,950 to £1,076,400
Maximum saving per annum	£15.6 to £77.6 million

Costs per annum

	Costs per annum
Charges for implementing the criteria for powdered infant formulae resulting from additional testing and cost of product unable to be placed on the market or withdrawal / recall (maximum £250,000 per firm per annum)	£1,500,000
Additional <i>Salmonella</i> test for red meat carcasses	£448,500 to £897,000
Broiler and turkey carcasses	£77,900 to £197,600
Costs for non-compliance with <i>Salmonella</i> criteria for minced meat and meat preparations intended to be eaten cooked without applying the transitional derogation	£2,000,000
<i>Salmonella</i> testing for mechanically separated meat (MSM)	Number of plants in the UK unknown. Cost per plant per week is £75 to £125
On-going cost to enforcement authorities	Costs unknown
Cost per annum	£4,026,400 to >£4,594,600

- 11.2 Option 1 (to do nothing) and Option 3 (seek further amendments) are no longer credible options as the Regulation has been adopted by the Standing Committee. The UK must implement the Regulation to meet its European obligations. The UK has had significant influence during the negotiations and the final proposal represents the most positive outcome that could be achieved. The Agency will keep the Regulation under review but it is not appropriate to seek further amendments at this stage.
- 11.3 The Food Standards Agency therefore recommends Option 2 – accept the proposal and implement the Regulation in the UK.

DECLARATION AND PUBLICATION

I have read the regulatory impact assessment and I am satisfied the benefits justify the costs.

Signed: Caroline Flint

Date: 9th January 2006

Parliamentary Under Secretary of State, Department of Health.

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