

INITIAL REGULATORY IMPACT ASSESSMENT

1. Title of proposal and timetable

This Regulatory Impact Assessment concerns the policy consideration to inform the content of national legislation and guidance necessary to apply a package of European food hygiene regulations adopted in April 2004. The new EU legislation will apply on 1 January 2006. The national legislation will need to apply from that date.

2. Purpose and intended effect of measure

(i) The objective

2.1 The three main regulations that make up the package¹ will be directly applicable and therefore constitute the law in each Member State of the EU. National legislation is not required, nor indeed allowed, to give effect to the EU Regulations, beyond providing for their enforcement in the UK. However, there are a number of areas in the Regulations that either require or allow Member States to adopt certain provisions as appropriate in their national law. This RIA represents an initial consideration of the potential implications should any of the policy options underlying the national legislation, and other related issues, be adopted. It should be seen in conjunction with the ongoing stakeholder consultation on these issues (see paragraph 3.2). The RIA will be developed further in the light of the consultation responses to the policy considerations outlined in the consultation documents.

(ii) Devolution

2.2 Separate national legislation will be introduced for each of the four countries of the UK. This initial RIA considers the situation in the UK, but when the consultation responses are received separate RIAs will be produced for England, Scotland, Wales and Northern Ireland.

(iii) The background

2.3 The recently adopted 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 EU legislation. The 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 proposals introduce a "farm to fork" approach to food safety, by including primary

¹ Regulation (EC) No 852/2004 – referred to as H1
Regulation (EC) No 853/2004 – referred to as H2
Regulation (EC) No 854/2004 – referred to as H3

production in food hygiene legislation for the first time in the majority of cases. A brief outline of the content of the new EU legislation is provided at Annex 1

2.4 A summary of the main areas covered in the policy consultation is set out below.

- the national rules to apply to certain categories of direct sale exempted from the EU Regulations (see paragraph 3.2 (i), (ii) and (iii) for options identified) ;
- the form that registration of food business operators should take (see paragraph 3.2 (iv) and (xvi) for options identified);
- the rules to apply to the supply of food of animal origin from one retail establishment to another (see paragraph 3.2 (v), for options identified);
- whether or not to use individual approval codes in addition to an approval number and whether secondary numbers for units of wholesale markets should be used (see paragraph 3.2 (vi) and (vii), for options identified);
- how to make lists of approved establishments available to other Member States and the public (see paragraph 3.2 (viii), for options identified);
- whether or not food chain information could accompany animals to the slaughterhouse rather than being provided in advance, in certain circumstances (see paragraph 3.2 (ix), for options identified);
- whether or not authorisation should be provided for some fish products not to be frozen and for these products to be transported over short distances (see paragraph 3.2 (xii) and (xii), for options identified); and
- questions specific to the primary production sector (see paragraph 3.2 (xvi), (xvii), (xviii) (xix) for options identified).

2.5 In addition to the national legislation referred to in paragraph 2.1 above, the ongoing stakeholder consultation considers two other elements as follows:

- The retention of national food hygiene legislation because they are not contained within the scope of the new European consolidated hygiene legislation; and,
- Repeal of national rules that are overtaken by the new EU legislation.

(iv) Risk Assessment

2.6 The policy decisions under consideration are intended primarily to meet an obligation under the new directly applicable EU law to introduce national law in certain cases. The major risk involved therefore is the failure to meet the obligations of a member state and risk the chance of action being taken against the UK.

2.7 A secondary risk is that the failure to act could 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.

It is for member states, under the principle of subsidiarity, to decide on the form and application of these national rules to best address national circumstances.

2.8 The views of stakeholders on any possible risks they might envisage from the approach being proposed would be most welcome.

3. Options

3.1 Options are limited in this area as the adoption of certain national law is a requirement of the EU law, which is directly applicable in all member states. To do nothing would leave the UK in breach of an EU obligation in some areas. Similarly, not to repeal existing UK national legislation overtaken by EU law would be a breach of a statutory obligation. The options identified in the consultation are explored below:

Proposals for the Adoption of National Legislation/Administrative Measures

3.2 For the areas in which it is proposed to adopt national legislation and/or other administrative measures, the options identified are set out below in the order in which they appear in the consultation documents. This section therefore needs to be read in conjunction with Annex 2 of the consultation documents, which provides a more detailed explanation of the measures. This can be found on the FSA website at

<http://www.food.gov.uk/foodindustry/Consultations/ukwideconsults/euhygieneleg>

The FSA preferred option is set out in more detail in Annex 2 of the consultation documents. Against each option below is an initial estimate of the resulting costs to business and/or competent authorities. The consultation document sets out a number of questions in relation to the FSA preferred policy option identified on which we would welcome the views of stakeholders.

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.

Cost Implications

If the FSA preferred option is applied, the measure is estimated to be cost neutral as it would, in effect, maintain the status quo. The introduction of new provisions could incur

costs for enforcement authorities in terms of enforcing whatever provisions were applied to 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.

Cost Implications

If the FSA preferred option is applied, the measure is estimated to be cost neutral as it would, in effect, maintain the status quo.

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.

Cost Implications

If the FSA preferred option is applied, the measure is estimated to be cost neutral as it would, in effect, maintain the status quo. The introduction of new provisions could incur

costs for enforcement authorities in terms of enforcing whatever provisions were applied to 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.

Cost Implications

If the FSA preferred option is applied, the measure is estimated to be cost neutral as it would, in effect, maintain the status quo.

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.

Cost Implications

If the FSA preferred option is applied, the effect of the measure 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. It refers to the application of food safety management procedures based on HACCP principles. Making new measures to extend the application of H2 to retail as envisaged in option 1 could lead to increased costs for retailers and enforcement authorities that would have to enforce the measures.

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.

Cost Implications

If the FSA preferred option is applied, and indeed any of these options, the measure is estimated to be cost neutral as it would, in effect, maintain the status quo.

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.

Cost Implications

These provisions should enable enforcement action to be more targeted. As a result there may be some resulting savings for individual market operators. However, this is difficult to estimate as any savings would depend on the number of infringements. The views of stakeholders on this aspect would be most welcome.

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.

Cost Implications

If the FSA preferred option is applied, the measure is estimated to be cost neutral. It would however require a change in the procedure by which competent authorities compile and maintain lists.

Sector-specific Issues

ix) Food Chain Information Accompanying Animals to the Slaughterhouse

Consultation reference: Annex2, 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.

Cost Implications

This provision recognises the practicality of animal movements and allows for animals moving through livestock markets etc. The views of stakeholders on any potential costs and benefits would be welcome.

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.

Cost Implications

If the FSA preferred option is applied, the measure is estimated to be cost neutral.

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.

Cost Implications

If it were deemed necessary, there would be a cost for auctions and wholesale markets in providing such facilities. However there is a question over whether such facilities are necessary and whether they would be required. Information from stakeholders on the possible cost implications would be welcome.

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.

Cost Implications

The FSA does not have a preferred policy option in this respect. If the case for exercising this flexibility can be made, we would be prepared to consider doing so. Is there a case to be made?

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.

Cost Implications

If the FSA preferred option is applied i.e maintain existing provisions, the measure is estimated to be cost neutral as it would, in effect, maintain the status quo. To exercise option 1 could impose a new burden on some operators. Information from stakeholders would be welcome.

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.

Cost Implications

There may be some additional burden on competent authorities as a result of the requirement, but this is alleviated by the flexibility negotiated. Views would be welcome.

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.

Cost Implications

In the case of England and Northern Ireland, the proposal would be to maintain the status quo and so the measure would hold no cost implications. In Scotland, the proposal to extend the ban was examined in an RIA in October 2000. At that time, the total additional compliance costs for business were estimated to be negligible. The requirement to heat treat drinking milk and cream from goats, sheep and buffaloes could cost small producers around £500 in purchasing pasteurisation equipment. At present, figures are not available on how many producers would have to purchase such equipment in Scotland and information from stakeholders on this aspect would be welcome. In Wales, the intention to change the labelling requirement will hold some cost implications for producers of raw drinking milk and cream. The costs are yet to be estimated precisely and further information will be provided in later versions of this RIA. Information from stakeholder would again be welcome. There are currently only 22 registered suppliers of raw drinking milk in Wales. On the basis of information already provided by one producer, the cost of a new plate for adding the warning onto glass bottles would result in a one-off cost in the region of £25. The cost of replacing the glass bottles themselves could be offset by producers replacing existing bottles that become lost or broken with those bearing the amended wording, in advance of this becoming a statutory requirement. However, we understand that the majority of producers use plastic bottles and affix computer generated labels. Therefore we would expect most producers to incur only minimal costs in amending the wording on their labels. The cost of replacing any stocks of existing computer generated labels is likely to be very low given the relatively small volume of sales of raw drinking milk and cream.

xvi) Registration of Primary Production Establishments²

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.

Cost Implications

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. However, setting up a completely new registration system as described in option 1 would be extremely costly particularly to enforcement authorities. The view of stakeholders on the cost of establishing a new system would be welcome.

It is possible that some primary producers may not be registered in any way at present with the competent authority. We would welcome information and views from stakeholders on this aspect.

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.

Cost Implications

None have been identified, but there may be some cost to industry if it chooses to become involved in the development of guidance. This may however be offset by the benefit to industry of guidance being more suitable to its needs. We would welcome the views of stakeholders in this area.

xviii) Enforcement at the level of primary production

Consultation reference: Annex 2, paragraphs 48 and 52

² This will not change the system of registration for dairy hygiene purposes as established under existing legislation.

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.

Cost Implications

It is not possible to determine the cost implications of an enforcement regime at primary production level until the form of the regime is determined. However, the views of stakeholders would be welcome. Option 1 would inevitably be far more cost effective.

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.

Cost Implications

It is not possible to determine the costs involved with the record keeping until information is received on what records are kept at present. However, from initial considerations, it would seem that most of what is required is already kept. Therefore cost implications should be minimal. The views of stakeholder on the costs and benefits would be welcome.

Retention of Existing National Legislation not Covered in the EU Regulations

3.3 In the main, what is being suggested in the consultation documents is maintenance of the status quo in relation to national hygiene legislation. The view of stakeholders is being sought on this approach. The legislation to be retained is set out in Annex 4 of the consultation documents. This would, in effect, maintain the status quo and have no cost implications.

Repeal of Existing National Legislation

3.4 There are no options in this respect as it is not legal to have two instruments occupying the same legislative space. The views of stakeholders are being sought in this regard simply in order to ensure that nothing is being missed from the list of legislation to be revoked as set out in Annex 3 of the consultation documents.

4. Benefits

4.1 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.

4.2 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.

4.3 The views of stakeholder on the likely benefits arising from these proposals would be most welcome.

Business sectors affected

4.4 There are approximately 600,000³ 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 these specific measures.

4.5 The specific measures described will have a greater effect upon some business sectors than others, but more information is needed before a realistic estimate of those effects can be made. The view of stakeholders is sought on the effects and is the subject of the consultation package. This section will be developed further in the light of the responses to the ongoing stakeholder consultation.

5. Costs

(i) Compliance costs

5.1 The policy proposals presented as the FSA preferred options do not substantially alter any requirements from the current legislation in most respects. The majority of the measures outlined in section 3 above will maintain the status quo and hold no cost implications.

5.2 Where the measures described in section 3.2 might hold cost and benefit implications, information from stakeholders is needed on which to make meaningful estimations. That information will be used to examine the cost implications more fully.

(ii) Other costs

Impact on Charities and Voluntary Organisations

³ The figure of 600,000 is based on estimates of registered food businesses gained from returns from local authorities.

5.3 The FSA believes that the measures outlined in the RIA will have no effect on charities and voluntary organisations. However, the views of stakeholder organisations are welcome on any possible costs or benefits identified.

(iii) Costs for a Typical Business

5.4 It is not possible to provide an estimate of the costs to a typical business at the present time. This element will be explored further in the light of stakeholder comments.

6. Issues of equity and fairness

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

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

7.1 The Small Business Service has been included in this consultation process. No comments have been received to date. Consultation will continue.

8. Competition Assessment

8.1 The new EU legislation will apply equally to all new and existing businesses and most of the requirements. Whilst businesses may incur some adjustment costs arising from changes to the hygiene requirements, we do not expect adoption of the proposals in line with the FSA preferred option to have an adverse effect on competition. Where costs to business are likely to result, they would be proportionate to the size of business and would not be sufficient to raise concerns for competition. As, for example, the new requirements would apply to all catering businesses, it would not apply a commercial disadvantage to any particular business. There is no evidence that there is likely to be any significant change in market concentration following the introduction of this legislation. Further work on the competition assessment on the specific measures proposed in this RIA will be carried out in the light of responses to the stakeholder consultation.

9. Enforcement and sanctions

9.1 It is very difficult to estimate the precise costs and benefits of the proposals to enforcement agencies. Local authorities and their representative organisations (LACORS and CIEH) are being consulted on the proposals. No comments have been received to date. Consultation will continue. A Public Services Threshold Test will be developed in the light of consideration and consultation as part of the partial RIA.

10. Monitoring and 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 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.

11. Consultation

(i) Within Government

11.1 Other Government Departments, including devolved administrations, have been included in the stakeholder consultation on the policy options. No comments have yet been received. Officials have had more detailed contacts with Agricultural Departments and Home Office on specific issues.

(ii) Public consultation

11.2 Consultation with stakeholders on the policy content of these measures is currently underway and is due to conclude on 9 June 2004. This RIA will be developed further in the light of the ongoing stakeholder consultation.

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.

13. Declaration

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

Signed.....

Date

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

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 proposal 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 establishes the voluntary use of either national or Community good practice guides. These are to be developed by the food business sectors concerned and are intended to assist food business operators to comply with the general high-level requirements and objectives of the regulation. The guides will be able to include more detailed requirements, specific to the sectors concerned, than would be necessary or appropriate in the simplified legislation.

4. The proposal 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 proposal does not require the application of HACCP procedures at this level. 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 proposal 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.

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 Proposal 1. 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. However, the extent to which further rationalisation and simplification might be possible will be dependent on the experience gained with the new legislation.

9. The proposal will require 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.

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 proposal also lays down rules for the approval of establishments.

11. The changes proposed to controls on meat hygiene are intended to take account of the introduction of HACCP-based procedures in slaughterhouses. It is also intended to 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 proposed system of meat inspection does 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.

H5

13. This directive 2004/41 would repeal the existing EU legislation and amend other related legislation.