

DRAFT INITIAL REGULATORY IMPACT ASSESSMENT

1. Title of the proposed provision:

Proposal for a Regulation 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.

2. Purpose and intended effect of the Regulation

The issue and objective:

Issue

2.1 The proposal is intended to replace current legislation relating to the organisation of official controls on products of animal origin intended for human consumption. The proposal would bring together official control rules governing a number of sectors into one Regulation. The proposal forms one part of a package of five linked proposals introduced by the European Commission intended to consolidate and simplify EU food hygiene legislation. It replaces the third (doc. COD (2000) 180) of the original package of five proposals (doc. COD (2000) 438). The new requirements must be made to accord with another proposal being prepared by the Commission laying down the overarching principles governing official feed and food controls.

2.2 Current food hygiene requirements in the European Union are contained in a raft of legislation, the earliest of which dates back over 35 years. It exhibits inconsistencies in approach and a degree of duplication that makes it difficult to interpret and to enforce. It has not kept up with change and innovation in food technology. These factors led the European Commission to come forward, in June 2000, with proposals to update and simplify this legislation. The Commission subsequently withdrew the original version of the proposal in the light of developments. In particular, the withdrawn proposal did not take account of the increasing role of Hazard Analysis and Critical Control Points (HACCP) principles in food safety management by meat plant operators. In addition, a new approach is envisaged for meat inspection. The revised proposal better reflects the importance of a risk-based and integrated, farm-to fork approach to food safety. It changes the present supervisory role of officials to one of audit of operators' HACCP-based programmes in meat plants. It also introduces inspection procedures that place more emphasis on the origin of the animals to be slaughtered and seeks to limit unnecessary post-mortem procedures, which may result in contamination of meat. The proposal has implications for the Meat Hygiene Service, Local Authorities, Environmental Health Officers and the Dairy Hygiene Inspectorate. The detailed official control rules contained in the annexes of the proposal will be operated in around 33,000 business premises in the UK.

The provisions governing approval of establishments may be more widely applicable depending on how those rules are applied in the UK. The proposal also holds implications for some of those businesses.

Objective

2.3 The primary objective of the package of proposals is to improve and modernise the existing EU legislative framework and optimise public health protection. Legislation needs to prescribe conditions under which food is produced to prevent, eliminate or acceptably control pathogen contamination of food. The proposals would introduce more risk based and flexible procedures better matched to the needs of enforcement of food safety management systems based on the application of HACCP principles. This proposal is an essential part of the whole package in setting out the role of competent authorities in auditing the systems operators are required to put in place. In most respects, the proposal would simply consolidate existing requirements. It does change current rules in some respects and there would be provision for some relaxation of the current requirements for veterinary supervision in licensed meat premises. The major part of the proposal covers the detailed rules for the conduct of meat inspections. In particular, it sets out:

- the tasks to be carried out by official veterinary surgeons and auxiliaries in slaughterhouses;
- the requirements for issues such as the qualifications of inspectors;
- the frequency of inspections;
- detailed rules for the conduct of both ante and post-mortem inspections; and
- record keeping and audit of HACCP procedures.

In addition, it sets out the rules for;

- the official controls to be conducted on the production of live bivalve molluscs;
 - official controls to be carried out on fishery products; and,
 - official controls on milk and milk products.
- It also includes rules for the approval of establishments.

Cost implications may be neutral overall, though some sectors will win and some will lose. How costs fall between industry and government will be dependent on the outcome of the negotiations on the proposed Regulation on official feed and food controls.

2.4 The wider package of proposals is the subject of a separate RIA that will require updating in the light of this re-issued proposal.

ii) Risk Assessment

2.5 The background against which this proposal should be viewed is the incidence of foodborne disease. In 2000, it is estimated that the total number of cases of foodborne disease (referred to hereafter as Indigenous Foodborne Disease (IFD)) in England and Wales was 1,338,772 of which, 368,516 visited a GP and 970,256 did not. It is estimated that 480 cases resulted in death. Similar figures for IFD in Scotland and Northern Ireland are not currently available. However, when these figures are increased pro rata to apply to the UK, the cost of IFD is estimated to be approximately £1.5 billion per year.

2.6 Bio-toxins in shellfish are responsible for a small number of food poisoning incidents in the UK each year. The present testing regime is effective in preventing outbreaks of toxic shellfish poisoning. This is one of the reasons the UK believes that the proposed increase in testing frequencies is not justified. It could not be viewed as a proportionate measure.

3. Options

3.1 As the proposal addresses an area already occupied by EU legislation, any option other than “do nothing” would mean changing the current EU legislative position. The three options therefore identified are:

Option 1 - do nothing.

Options 2 – to seek the removal or amendment of certain provisions in the proposal and inclusion of others not included in the proposal as issued.

Option 3 – to agree the proposal as issued.

Option 1

3.2 Maintaining the status quo would not achieve the desired modernisation and improvements to enforcement in the interests of public health protection. The European Commission’s proposal could only be removed at its own instigation or by Member States acting in unanimity in Council. The Commission is wedded to its proposals and other Member States are supportive. To do nothing would, therefore, be very difficult, even if it were desirable. In the event the proposals were to be withdrawn, there would be no costs or benefits as the status quo would be maintained.

Option 2

3.3 The proposal as issued brings together existing legislative requirements in a way that would make them easier to understand, interpret and enforce. It would be appropriate to negotiate for changes to some of the elements contained in the proposal because it does contain certain elements that would change rules not always with positive results. In particular, it would change the frequency of testing for biotoxins in live bivalve molluscs. It would introduce a weekly requirement for such tests and therefore increase testing in the UK, which is currently carried out monthly in winter and fortnightly in summer. This would more than double the costs of analysis and add about £3-5 million per year to the overall bill. Further evaluation is required for the total costs involved as there may also be increased costs involved in collecting samples. The UK considers that such an increase in testing rates has not been justified on risk based public health grounds and that it is unlikely to be necessary or desirable. The proposed change would increase burdens on competent authorities and possibly consequentially on business. It would be the intention of the FSA on behalf of the UK to argue against this part of the proposal.

3.4 The new proposal repeats existing EU law and would require licensing and attendance by the veterinary inspection team at all game meat plants. However, small quantities of meat supplied direct by the hunter to the final consumer or local retailers would be exempt. The costs of this will be identified in discussions with industry.

3.5 The proposal could also be changed to include certain elements that have been deleted from other proposals in the wider package in the process of negotiation. In particular, controls on the importation of foodstuffs to be carried out by the competent authority (in ensuring that the food comes from approved countries and establishments) should now be covered in this proposal. In the part of the proposal dealing with meat controls, the UK would also wish to clarify where responsibilities lie. For example, certain tasks assigned to the official inspection team would more appropriately sit with the plant operator.

Option 3

3.6 This would have the desired effect of consolidating and simplifying existing rules. It would not, however, deal with the problems identified in option (2) above. It would increase burdens and costs to the competent authority and possibly, to a lesser extent, certain of the sectors affected, principally, the live bivalve mollusc production sector.

3.7 For all options other than maintaining the status quo an important consideration is the need for realistic and practical implementation dates for the new requirements. They must allow for enforcement authorities and business to

put in place the necessary procedures. They must also allow time for authorities and industry to develop relevant guidance literature, training and advice. However, it is not possible to provide any realistic timetable for likely implementation as the subject has not been discussed in negotiations beyond a general recognition that adequate time will be needed. As the question arises in negotiations, the UK will pursue a practical implementation timetable, consistent with the assurance of public health. The proposal does currently indicate that the measures will not come into effect until 1 year after its adoption.

4. Benefits

4.1 The most significant benefit would be better enforcement of hygiene legislation. The role of enforcement authorities would change in the direction of greater auditing of operator procedures in place rather than simply checking the outcomes.

4.2 This proposal is part of a package the effects of which should be seen in the whole rather than piecemeal. Those effects are explored in a separate RIA. The precise effect the modernised approach would have on the level of food poisoning is difficult to predict or to measure, but work carried out on behalf of the FSA provides an indication. Work on IFD found that the estimated total cost in 2000 in the UK was £1,456 million. This comprised the basic costs to the health service, loss of earnings etc. Savings of £14.6 million would result per 1% reduction in illness per year. These benefits can be expected to build up over a number of years. It is impossible however to say what part of any improvement of the disease incidence situation would be due to an improved enforcement regime. The responsibility to produce safe food would, under the new regime, be placed more clearly on the food producer. Therefore, no particular claims are made for reduced disease incidence due to the changes to official control procedures contained in this proposal.

4.3 The benefits of focussed enforcement of hygiene legislation would be shared between the individuals affected, consumers, food businesses, business generally, the NHS and enforcers. Only options (2) and (3) above would deliver the benefits identified. Option (1) would maintain the status quo.

5. Compliance Costs for Business, Charities, and Voluntary Organisations

i) Overview

5.1 The sectors covered by this proposal include some 33,000 food businesses. However, as the proposal is exclusively limited to the role and duties

of the competent authorities, the effects on business should be relatively small and are still being estimated. The sectors in the UK affected would be slaughterhouse and meat cutting plant operators, fishery product establishments, live bivalve mollusc growers and producers and processors of milk and dairy products. The majority of these businesses will be affected by other proposals in the package to some extent, but that is explored in a separate RIA.

5.2 Any additional costs to businesses etc. related to this proposal on official controls will relate to the frequency of controls being applied and the attendance of the operator at those controls. However, in most sectors, those effects should be neutral in monetary terms. The proposal changes the focus of controls in meat plants. In fishery product establishments and milk and dairy establishments it simply consolidates existing requirements rather than adding or removing any burdens. The only exceptions would be if the proposed changes to the frequency of testing for biotoxins in live bivalve mollusc production were agreed or if EU law was implemented for wild game meat plants for the national market. That would increase burdens on competent authorities greatly and may have some minor consequential effect on operators in the sector.

Impact on Charities and Voluntary Organisations

5.3 As the requirements of this proposal relate only to enforcement authorities there would be no impact on charities and voluntary organisations.

ii) Costs and Benefits – Available Evidence

5.4 There may be costs involved for some businesses in the sectors affected if the proposals are introduced as drafted. However, if option (2) is agreed, the UK would negotiate proposals that would be proportionate in terms of effects.

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

5.6 Option (2) would be largely neutral in cost and benefit terms, as it would mainly re-organise existing enforcement tasks without greatly increasing or decreasing the overall burden.

5.7 Option (3) would increase the costs on enforcement authorities in certain respects. There would be very little in the way of offsetting benefits resulting.

5.8 The Commission's planned proposal on the principles governing official feed and food controls will, amongst other things, lay down provisions on how the controls in the third hygiene proposal will be financed. Depending on what is

included in the final proposal, it could have major implications for the meat industry and possibly other sectors.

6. Results of Consultation

6.1 Thorough consultation on the original package of proposals with stakeholders was initiated in July 2000. A summary of the comments received has been drafted and will be posted on the FSA web-site shortly. The results have been worked into the relevant RIA.

6.2 Further consultation on this re-issued and revised proposal with interested parties both internal and external will take place. It is intended to write to all those who responded to the original consultation and thereby indicated an interest and, additionally, to stakeholders identified as having an interest in the sector specific subjects covered. The consultation document will also be posted on the Food Standards Agency website for wider access. This draft Regulatory Impact Assessment will be amended in the light of the consultation.

7. Results of Consultation with Small Businesses “The Litmus Test”

7.1 The Small Business Service will be consulted about this proposal although the implications will be relatively small since the focus is on official controls.

8. Other Costs and Benefits - Enforcement

8.1 It is very difficult to estimate the precise costs and benefits of the proposal to enforcement agencies. However, from initial consultations, it is estimated that costs and benefits will be approximately neutral in the meat, fishery product, milk and dairy sectors. In the live bivalve mollusc sector however costs would increase by c. £3-5 million per year should the proposals be agreed as drafted. This should be seen against the background of an industry in the UK producing something in excess of 70,000 tonnes of live bivalve molluscs a year (2000 figures) valued at approximately £50 million.

8.2 The package of proposals as a whole will simplify and greatly reduce the volume of EU legislation that controls food hygiene, and do much to rectify anomalies that have made enforcement difficult. Because HACCP-based systems lend themselves to audit, and should not require constant supervision, enforcement resources could be targeted more effectively; e.g. certain enterprises may be identified as low-risk and visited less frequently. There will be a need for enforcers to undertake an educational role in this respect which it should be possible to accommodate by redirecting existing resources. There would be a benefit to enforcement authorities from any reduction in food

poisoning incidence leading to fewer post incident investigations. For these reasons, the FSA would expect any costs and benefits to be closely balanced. Enhanced guidance and further Agency training will be provided to help enforcers assess the effectiveness of HACCP based controls being put in place.

9. Summary and Recommendations

9.1 The proposals are likely to have financial implications for enforcement authorities, particularly in relation to testing for biotoxins in live bivalve molluscs. Financial implications for business are likely to be minimal.

9.2 The recommendation is to pursue option (2). It would consolidate the HACCP-based risk management approach to controls in the sectors covered in an effective, flexible and proportionate manner. Option (1) is considered to be unrealistic, and option (3) is considered to bring with it undue burdens with no demonstrable offsetting benefits.

10. Competition Filter

10.1 The competition filter requirements have been studied and the FSA consider that the proposals are unlikely to have a negative competitive impact. The new legislation will apply equally to all new and existing businesses and the major part of the requirements is already applied to industry. In theory, the proposals should not affect the competitive position of UK goods as against those from third countries as the proposals state that imports should be produced to the same or equivalent standards as those laid down for EU producers.

11. Monitoring and Evaluation

11.1 The intention is to develop this assessment in the light of developments. The draft Regulatory Impact Assessment will be updated on an ongoing basis in the light of the continuing consultations.

12. Timetable

12.1 The proposal was published by the European Commission on 15 July 2002. Negotiations are ongoing in Council Working Group and are expected to take another 1 – 2 years to negotiate. The question of implementation dates is yet to be considered and it will be important to ensure that all those affected by the proposals are given adequate time to adapt to new requirements. The proposal is yet to clear UK Parliamentary Scrutiny.