
REGULATORY IMPACT ASSESSMENT

1. Title of proposal

1.1 Proposal for a Regulation of the European Parliament and of the Council on official feed and food controls (COM (2003) 52 Final).

2. Purpose and intended effect of measure

(i) Objective

2.1 The primary objective of the proposal is to improve the consistency and effectiveness of official controls across the European Community and, consequently, to raise standards of food safety and consumer protection, and to facilitate the functioning of the internal market for feed and food. A framework Regulation is proposed which will consolidate and extend the approach set out in existing EU horizontal and sector specific legislation on official feed and food controls. In so doing, it will create a more comprehensive, consistent and integrated 'farm to table' system. In achieving its objectives, the proposal will contribute to the reduction of serious illness and death that results from food-borne disease, reduce feed and food contamination incidents, and improve the quality and labelling of feed and food, thereby promoting the interests of consumers and businesses throughout the Community.

2.2 The proposal addresses the approach that the enforcement authorities in the Member States should adopt for checking that relevant businesses are complying, where appropriate, with feed and food law and EU animal health and welfare rules. Further, it covers how the European Commission will, in turn, check that the enforcement authorities in the Member States and in third countries are meeting the requirements of the current proposal. Checking compliance in this context is achieved using 'official controls'. Examples of official controls that are undertaken by enforcement bodies in the Member States to verify whether businesses are complying with legal requirements include, inspections, audits, surveillance, sampling and analysis etc. Official controls carried out by the European Commission are generally undertaken by the Food and Veterinary Office (FVO) and are designed to evaluate the performance of national enforcement bodies in the Member States and in third countries.

2.3 The proposal itself does not set out any requirements for businesses. Such requirements are contained within the feed and food legislation that exists or is being developed (e.g. feed and food hygiene legislation, food labelling laws,

food additives and contaminants legislation etc) and within EU animal health and welfare regulations and directives etc.

(ii) Devolution

2.4 The Regulation will be directly applicable throughout the UK.

(iii) Background

Need for the proposal

2.5 The origins of the proposal go back to the EU White Paper on Food Safety (COM (1999) 719 of 12 January 2000) which highlighted a clear need for a new Community framework of national control systems which would streamline and reinforce the existing system. The existing rules were developed over a period of several decades and are sector specific i.e. separate rules were developed for the feed, food and veterinary sectors. This fragmented approach led to repetition and inconsistency and in some areas to loopholes in legislation. This includes, for example, a lack of harmonised Community rules on import controls (official controls of products imported into the Community from third countries) by Member States on products of non-animal origin (non-POAO). In addition to this, the range of control responsibilities at both national and Community level is becoming wider as the food production chain becomes more complex and sophisticated and covers an increasing number of products and sectors and also imports from over 200 countries. Control systems need to be adapted to take account of these developments.

2.6 With regard to animal health and welfare, it is clear that some aspects will have a direct or indirect impact on the feed or food chains whilst others will not. However, the Commission believed that there was a need for a framework that would ensure coherence and consistency in the controls carried out in respect of all animal health and welfare rules.

2.7 The EU White Paper also identified the need to properly define the role of the Commission's own control services to ensure that the most efficient use is made of available resources.

Scope of the proposal

2.8 The proposal describes in detail how the basic principles relating to monitoring and enforcing feed and food law that are contained in the General Food Law Regulation must be interpreted and implemented. These are that Member States shall:

- enforce feed and food law and monitor and verify that the relevant requirements of food law are fulfilled by feed and food businesses;
- maintain a system of official controls covering all stages in the feed and food chain of production, processing and distribution; and
- lay down the rules on measures and penalties applicable to infringements of feed and food law which shall be effective, proportionate and dissuasive.

2.9 The Proposal sets out the approach to official controls at all critical points, i.e. at Community, national, regional, local and individual enterprise level.

2.10 It defines the role of the Member States and their designated enforcement bodies (known as the competent authorities) in checking that relevant businesses are complying with legal requirements set out in feed and food law and in animal health and animal welfare legislation. This represents a wide range of feed and food safety measures but also feed and food composition and labelling rules etc. Existing specific rules for controls established to deal with particular areas of concern (e.g. BSE, pesticides) will continue to apply without prejudice to the new overarching Regulation and new specific rules may also be established (e.g. the Commission's proposal for a regulation laying down detailed rules for official controls on products of animal origin intended for human consumption). The framework proposal covers controls at all stages of production, processing and distribution. It relates to products produced within the EU and in free circulation in the internal market, and those exported to or imported from third countries.

2.11 The proposal does not cover monitoring and enforcing compliance with legislation for the marketing of agricultural products such as wine, olive oil, fruit and vegetables, hops, milk and milk products, etc. for which well-established control systems are already in place.

2.12 The proposal also defines the role of the Commission with regard to ensuring the effectiveness of control systems in Member States and in third countries.

2.13 The proposal is for a framework Regulation and sets down general principles and enabling powers in respect of carrying out official controls rather than prescriptive and detailed measures. It does not require that 'new' (additional) controls be carried out but rather is concerned with the approach to controls, the need for which arises from the requirements in specific feed and food legislation and in EU animal health and welfare rules.

Main elements of the proposal

2.14 The proposal sets out the responsibilities of the competent authorities including operational criteria with which they must comply, training requirements for enforcement officers, rules for delegating certain tasks to independent bodies, rules for dealing with emergencies and rules for undertaking import controls. It includes information on the type of controls that should be carried out. In particular, it contains rules on methods of sampling and analysis that should be used and requires that the laboratories undertaking analysis meet certain standards. Provisions on the financing of controls are also included as are enforcement measures (i.e. action that should be taken when businesses are found to be in contravention of feed and food legislation or EU animal health and welfare rules, and the sanctions that should be applied). At Community level, there are rules on administrative assistance and co-operation between Member States and with the Commission where issues arise that have implications in more than one country. It sets out how the FVO will monitor and assess the performance of control systems in the Member States and in third countries from which feed or food is imported. Additionally, the responsibilities of the Community reference laboratories (and corresponding national reference laboratories) are set out.

Existing rules and new elements

2.15 In many respects, the new proposal simply consolidates existing requirements for the Member States and their designated enforcement bodies. The approach to checks on feed and food businesses remains essentially the same but aims to place greater emphasis on proportionality and risk such that resources may be targeted where they can be most effective in monitoring and promoting feed/food safety and quality. The proposal, however, also introduces new provisions or requirements for competent authorities and a new system of checks by the Commission on Member States and third countries. These are outlined below:

- *Auditing requirements for competent authorities* – competent authorities are required to undertake internal audits or have external audits carried out. In the UK, auditing of competent authorities is already undertaken so no new costs are anticipated as a result of this requirement.
- *Requirements for ‘control bodies’* – the competent authorities may continue to delegate certain control tasks to independent bodies as now, but such bodies will now be required to meet certain specified criteria and must be audited or inspected by the competent authority. In the UK, these control bodies include the Animal Medicines Inspectorate (AMI) of the Royal Pharmaceutical Society of Great Britain (RPSGB) which has responsibility

for controls on zootechnical feeds) and independent laboratories carrying out analytical work for the competent authorities, including commercially run public analyst laboratories. Although these bodies already have to meet appropriate standards, they are not currently audited or inspected formally by the competent authority.

- *Training for staff carrying out official controls* – staff undertaking official controls are required to have training for their area of competence. This is already required under existing legislation. Training on implementation of HACCP-based procedures is specifically mentioned in the proposal. The need for this training and any associated cost implications for enforcement bodies is, however, a consequence of the introduction of new requirements under the revised food hygiene legislation and the new feed hygiene proposal (these are both subject to separate RIAs). The Commission also plan to introduce a programme of Community-wide training courses which enforcement officers from the Member States may attend.
- *Accreditation of official laboratories for feed analysis* – official laboratories undertaking analysis of feed will have to be accredited (this is in line with current requirements for food laboratories). In the UK, food laboratories (public analysts) are effectively also feed laboratories (Agricultural Analysts) so this requirement will simply mean that accreditation will have to be extended to cover feed methods. Clearly, however, this will have cost implications.
- *Import controls for feed and food of non-animal origin from third countries* - the proposal supplements existing rules for official controls on imports of feed and food products of animal origin (POAO). It also introduces harmonised Community rules for import controls on non-POAO feed and food. It requires that non-POAO known to present a ‘high risk’ to human or animal health undergo more intensive controls at the external borders of the Community. Where there is no evidence of an increased risk, random checks at any place in the feed and food distribution chain after importation are considered sufficient. With regard to the ‘high risk’ products, the proposal contains an enabling power whereby the Commission, in consultation with the Member States, will identify these (through comitology) and at the same time will determine the nature and frequency of controls. These are likely to include for example, peanuts and pistachio nuts from certain areas where there have been problems with aflatoxin contamination. This continues and existing safeguards for products of known risk and will extend the arrangements to new and emerging risks.. During the negotiations it has been agreed that Member States must require importers to provide prior notification of imports of ‘high risk’ non-POAO and must carry out the controls on these products at designated points of entry. Potential cost

implications are considered in section 5. It has also been agreed that for other (i.e. 'low risk') non-POAO feed, Member States *may* require prior notification and may designate specified ports for carrying out checks. This continues optional provisions in existing feed legislation. The UK has not made use of these to date and any future consideration of implementing them would be subject to a separate RIA.

- *Penalties* - provisions are included which require Member States to lay down rules on penalties that should be applied where businesses are found to be infringing relevant feed and food law and animal health and welfare rules. The Commission originally proposed a provision that required that these rules specified criminal sanctions for offences where these are committed intentionally or through serious negligence. This was unacceptable to the Member States and also to the European Parliament (EP). A compromise has been agreed that requires simply that Member States have a system of effective, proportionate and dissuasive sanctions in place (as already required under the General Food Law Regulation – EC/178/2002).
- *Reference laboratories* – The proposal covers requirements for Community Reference laboratories for which Member States must have designated corresponding national reference laboratories. These laboratories provide scientific and technical expertise and advice mainly in the veterinary sector. These have been established under existing legislation that is simply consolidated in the new proposal. There is, however, also provision to establish new Community Reference Laboratories (Community funding is available for six) which would provide specialised expertise in new areas, e.g. feed and food additives, feed and food contaminants, microbiological risks/zoonotic agents etc. Member States will then be required to designate corresponding national reference laboratories for which there will be associated costs for the competent authorities.
- *National control plans* - Member States will be required to submit and annually update a high-level general control plan for the enforcement of feed and food legislation and animal health and welfare rules and to report annually on the implementation of that plan. These control plans will form the basis of Commission controls in Member States. The requirement to have an annual enforcement programme and for Member States to make a report on enforcement activity is already a feature of EC feed enforcement legislation. Similarly, annual returns on food law enforcement activity are required under existing European rules. Nonetheless, preparation of the initial national plan, the updates of the plans and the annual reports will have resource implications for the central competent authorities in terms of co-ordinating the exercises and also potentially for local competent authorities in terms of data returns etc.

- *Liaison body arrangements* – to ensure effective co-operation and assistance between competent authorities, each Member State will be required to establish a one or more liaison bodies to act as the central contact and communication point. This will require Member States to extend an existing requirement in the food sector to the feed and veterinary sectors so will have associated cost implications.
- *Commission controls in Member States and third countries* – Member States will be required to produce control plans and third countries will be required, when requested, to provide information on the general organisation and management of control systems. Member States will be required to report annually on implementation whilst third countries will be required to have written records of implementation of controls. The plans and reports/records will form the basis of Commission controls or audits. These will consist of a general audit of enforcement activities which may be supplemented by further audits of specific sectors or particular critical control points. The aim is to allow the Commission to target available resources more effectively.

2.16 As well as the approach to official controls, the proposal addresses the issue of funding of controls. The relevant provisions have been the most contentious during negotiations. The Commission's original proposal was that, in general, financing should be a matter of subsidiarity. The exceptions were twofold: firstly, businesses were to be charged for costs of controls which represent activity in excess of that normally undertaken and which follow detection of non-compliance ('excess controls'); secondly, costs were also to be recovered from businesses for import controls. In respect of the latter, and after some initial confusion, it was confirmed that this included checks on imports of both POAO and non-POAO. As no additional controls are required under the proposal, it was not anticipated that total costs for official controls in the UK would increase. However, these provisions would have necessitated a transfer of costs from the competent authorities to businesses in some sectors by means of charging for 'excess controls' and for import controls of non-POAO.

2.17 The views of the Member States on the Commission's proposals varied widely, reflecting differences in current national arrangements, and ranged from those wanting all funding by means of general taxation to those that wanted businesses to cover all costs. The EP (which also considered the proposal – see para 2.19) favoured compulsory charging of businesses for all controls, including all import controls. In view of the divergent positions, a compromise was developed on which there is now consensus among the Member States and agreement of the EP. The main elements of this are as follows.

- Mandatory fees for veterinary checks on products of animal origin, including import controls, where this is already required under existing EU legislation. Flat rate minimum fees are specified. These rates will be updated every two years to take account of inflationary increases in the costs incurred by the enforcement bodies. In the case of intra-Community checks, transitional arrangements are included such that minimum charges under the current legislation may be applied until 1 January 2008. Notwithstanding the flat rates, Member States may recover up to and including full costs or may reduce fees below the minimum rates where actual costs are less.
- Mandatory fees for approvals of feed establishments (as is currently the requirement and will continue to apply to establishments approved under the proposed feed hygiene regulation). A flat rate minimum fee is not specified in this case;
- In other sectors, Member States have flexibility to impose fees if they wish. Any consideration of implementing this option in the UK would be subject to a separate RIA.
- Where fees are imposed (either mandatory or optional), certain expenses only are eligible for calculation of the fee and Member States must take account of a number of factors including, for example, the interests of small businesses.
- Member States must recover from businesses the costs for ‘excess’ controls required following detection of non-compliance. This will apply only in the case of significant issues which are not foreseen in national control plans (e.g. major dioxin incidents). Implementing rules will be established to clarify this.
- Fees *may* be established for import controls on ‘high risk’ products of non-animal origin (non-POAO), including ‘high risk’ non-POAO feed, when such products are identified through the EU comitology procedure and when the specific checks that must be undertaken are laid down.
- The Commission will review the charging arrangements within three years of the proposal coming into force with a view to extending the range of sectors subject to mandatory fees.

The implications of the financing provisions for businesses are considered in Section 5.

Primary production sector

2.18 New EU food hygiene legislation which is currently being negotiated will require primary producers to follow good practice and manage their operations in such a way that hazards are acceptably controlled. This requirement will need to be verified by the relevant competent authorities, to the extent that the requirements are not already covered by existing legislation. Any impact on these authorities arises from the hygiene legislation and not the current proposal. The current proposal is about the approach that should be taken generally for enforcement of all feed/food legislation and animal health/welfare rules.

Current status of the proposal

2.19 The proposal was presented formally to the Agriculture Council on 20 February 2003 and was referred to Council Working Group (CWG) for detailed consideration. Negotiations began under the Greek Presidency and then progressed rapidly under the Italian and Irish Presidencies. The proposal was also referred to the EP and, in particular, to its Environment Committee. Negotiations in the EP also progressed rapidly and following close co-operation between the various institutions, the Irish Presidency is expected to seek agreement at first reading at the April 2004 Agriculture Council.

2.20 If adopted, the Regulation will apply from 1 January 2006 with the exception of the provisions on financing which will apply from 1 January 2007.

2.21 Three key issues emerged in the negotiations:

- **Scope** - The Commission's proposal was for a broad scope covering controls in respect of all feed and food law and EU animal health and welfare rules. Some Member States, however, believed that the scope should be restricted to those aspects of animal health and welfare that impact on the food chain. The majority of Member States (including the UK) and the EP, on the other hand, took the view that it would be difficult, in practical terms, to separate those aspects which impact on the feed and food chains from those that do not. Consequently, the broad coverage has been accepted.
- **Sanctions** – The Member States did not agree that the Commission has the competence to require them to criminalise certain activities breaching feed and food law. The EP shared this view and a compromise was agreed such that Member States must simply have a system of effective, proportionate and dissuasive sanctions in place (as already required under the General Food Law Regulation – EC/178/2002).

- **Financing** - As mentioned previously, the views of the Member States varied widely on the original proposals and the EP preference was for funding all controls through levying of charges to businesses. A compromise has, therefore, been agreed and is outlined in para 2.17.

(iv) Risk assessment

2.22 The risk in the context of the proposal is the threat to consumers of unsafe food and poor quality food which is not identified by enforcement authorities in the different Member States because of ineffective and inconsistent monitoring and enforcement arrangements. In the UK, there is already an extensive control system involving both central and local government but a framework of principles for all national control systems will improve the quality of monitoring and enforcement at Community level and consequently raise food safety standards across the whole of the EU. It will deliver a better and more equal protection of consumers all around Europe and a smoother functioning of the internal market.

2.23 The provisions on imports of products of non-animal origin from third countries, by filling a gap in the current legislation, will help to achieve a greater degree of consumer protection. There has been considerable consumer concern about UK controls generally on food imports at ports and airports, and whether or not these are sufficient to ensure the safety of imported food in terms of public, animal and plant health. The concern was generated by the recent outbreak of Foot and Mouth Disease and the view that this may have been caused by an illegally imported animal product. The provisions requiring mandatory pre-notification of imports of 'high risk' non-POAO and checks at specified ports will help to safeguard public health by ensuring better targeting of controls and more effective management of risks. The new proposal does not alter the regime for veterinary checks for legal imports of animal products nor the responsibilities of HM Customs and Excise for controls on illegal meat imports. Nevertheless, the new rules on import controls for non-animal products will help to minimise illegal imports of this category of product.

2.24 Requirements for all Member States to have contingency plans in the food sector will increase public health protection, as they will help ensure that food emergencies within Europe are dealt with quickly and effectively.

2.25 Reduction in food-borne illness - The proposal may be viewed, in part, against the background of the incidence of foodborne disease. In 2000, it is estimated that the total number of cases of food-borne disease (Indigenous Foodborne Disease - IFD) in England and Wales was 1,338,772 of which 368,516 cases were reported by a GP. It is estimated that 480 cases resulted in death. A further 9,326 cases of IFD were recorded in Scotland and Northern

Ireland over the same period. This brings the total estimated economic cost of IFD to the UK of £1.61 billion per annum (September 2003 prices). These costs are considered further in section 4.5.

2.26 Reduction in chemical contamination incidents - Although more effective enforcement clearly has a role in reducing food poisoning, there will be other benefits in terms of protection of public health, such as reducing the incidence and level of chemical contamination of feed and food. Feed contamination incidents are currently estimated to have an annual cost to the UK of £0.88 million. A figure for the cost of food contamination incidents is currently not available but is potentially significant.

2.27 Increased consumer protection – Consumers also have a right to expect high levels of protection in terms of food quality and choice. This includes, for example, accurately and reliably labelled food. A figure for the cost to the UK resulting from mislabelling of food and other fraudulent practices is not available.

2.28 More effective monitoring and enforcement of feed and food legislation will contribute towards a reduction in food-borne disease, a reduction in contamination incidents and to increased consumer protection and to a reduction in the costs associated with these. It will also lead, in turn, to increased consumer confidence in food produced within the Community and in imported food.

(v) Sectors affected

Business sectors affected

2.29 As mentioned, the proposal itself does not set out any requirements for businesses but rather addresses how the enforcement authorities will check that these businesses are complying with relevant legal requirements. Notwithstanding this, however, businesses may be affected in terms of covering the costs incurred by the enforcement authorities in carrying out ‘excess controls’ and possibly for import controls on non-POAO. These potential costs are explored in detail in section 5 of this RIA. In addition to this, the provisions on prior notification and designated ports for ‘high risk’ non-POAO are new for importers. Again, this is explored in section 5. As this is a general framework Regulation covering the feed and food chains from ‘farm to table’ the full range of feed and food businesses are potentially affected. Monitoring data obtained by the Food Standards Agency from local authority food law enforcement services indicates that there are a total of 577,893 registered feed and food businesses in the UK. Of this total, approximately 2,800 are feed businesses. In addition there are some 146,000 VAT registered farms in the UK.

Enforcement bodies affected

2.30 This proposal is principally concerned with the roles and responsibilities of the enforcement bodies carrying out official controls (competent authorities). In the UK, responsibility for official controls is held centrally. In practice, execution of the responsibilities is divided between centralised and decentralised authorities. The central competent authorities are:

- Food Standards Agency – oversees feed/food law enforcement by local authorities.
 - ❖ Meat Hygiene Service – is an executive agency of the FSA, responsible for enforcing legislation in licensed slaughterhouses; cutting plants and cold stores in Great Britain. DARD veterinary services provide this function in Northern Ireland on behalf of the FSA.
- Department for Environment, Food and Rural Affairs (DEFRA) and its agencies and inspectorates (see below), and devolved Agriculture Departments in Scotland and Wales
 - ❖ Pesticide Safety Directorate – responsible for the national surveillance and monitoring of pesticide residues in food.
 - ❖ Veterinary Medicines Directorate - responsible for the National Surveillance Scheme for residues of veterinary medicines and certain other substances to fulfil the UK's obligations under EU legislation. It also oversees feed law enforcement for medicated feedingstuffs and zootechnical feed additives by the AMI of the RPSGB.
 - ❖ Dairy Hygiene Inspectorate - responsible for checking standards at milk production holdings in England and Wales;
 - ❖ Egg Marketing Inspectorate - responsible for checking standards in egg production, packing and distribution centres;
 - ❖ Plant Health and Seed Inspectorate - responsible for the plant health aspects of import and export arrangements for living plant material, and growing medium in England and Wales. It should be noted that the impact of the official control proposal on plant health is limited to a minor consequential amendment to the Plant Health Directive in respect of national control plans.
 - ❖ Horticultural Marketing Inspectorate - responsible for checking the quality of fruit and vegetables sold in the UK.
 - ❖ State Veterinary Service - carry out on-farm sampling and follow-up investigations on farms for the National Surveillance Scheme for residues of veterinary medicines. SVS also has responsibility for implementation of animal health and welfare controls in GB (DARD – see below – carries

out this function in Northern Ireland) with, in general, local authorities being the enforcement bodies.

- Department of Agriculture and Rural Development for Northern Ireland (DARD) - day to day enforcement of legislation relating to licensed slaughterhouses, cutting plants and cold stores, horticultural standards, egg marketing standards, dairy hygiene and residue testing.
- HM Customs and Excise – processing imports and collecting import revenue and the application of illegal import controls.

2.31 Much of the enforcement of feed and food law is carried out by Environmental Health and Trading Standards Services in the 468 UK local authorities. Local authorities at sea and airports are responsible for checking food imports at borders. This includes 35 authorised Border Inspection Posts (BIPs) with responsibility for controls on products of animal origin entering the UK from third countries.

2.32 Many of the requirements in the proposal consolidate and update existing rules for the enforcement authorities but, as set out in para 2.15, there are some new elements and some of these may have a financial impact. Again, the potential costs are explored in detail in section 5 of this RIA. The proposal does not require that ‘new’ (additional) controls be carried out but rather is concerned with the approach to controls, the need for which arises from the requirements in specific feed or food legislation. Therefore, it is not envisaged that the proposal will result in the need for an increased number of enforcement officers.

(vi) Issues of equity and fairness

2.33 The proposal aims to update and harmonise control requirements across the Community, within the Member States, at borders and in third countries in order to ensure a greater consistency in terms of consumer protection and a more level playing field in terms of fair trade within the internal market. In particular, with regard to imposing inspection costs in sectors where a Member State decides to take up the option to do so, specific account has been taken of the interests of businesses with a small turnover and also of businesses which themselves carry out significant checks.

3. Options

3.1 Three options were identified when the proposal was issued and have been considered during the course of the negotiations.

Option 1 – No action

3.2 Retain the *status quo* in terms of the UK's national control system and the role and responsibilities of the competent authorities, and in terms of the current financing and charging arrangements for official controls. This will leave the UK liable to infraction proceedings as the Regulation will be directly applicable in all Member States.

Option 2 – Adopt new requirements in part

3.3 The second option, as identified in the original RIA, was to implement the majority of the additional requirements for competent authorities contained in the proposal with the exception of the rules for penalties and sanctions. The UK believe that the Community has no competence to require that certain behaviour be criminalised and that sanctions for breaches of Community law are a matter for Member States.

3.4 This option, however, is now void as a compromise on sanctions has been accepted as outlined in para 2.15, sixth bullet point.

Option 3 – Adopt new requirements in full

3.5 All of the requirements for competent authorities contained in the proposal would be implemented (including rules on sanctions).

3.6 The proposal is for a Council and European Parliament Regulation and, as such, its provisions will be directly applicable in all Member States. Any under-implementation by the UK will, therefore, result in infraction proceedings being brought by the Commission. Consequently this option is the only feasible one.

3.7 In view of the successful negotiations on the sanctions issue (see para 2.15, sixth bullet point), option 2 effectively becomes identical to option 3.

4. Benefits

Option 1 – No action

4.1 This option affords no benefits.

Option 2 – Adopt new requirements in part

4.2 As noted above, this option, although originally considered, is now void as a compromise on sanctions was accepted.

Option 3 – Adopt new requirements in full

4.3 This option accords with UK policy objectives for feed and food safety i.e. the protection of public and animal health in relation to feed and food, ensuring coherent legislation throughout the food chain, and the introduction of proportionate controls. It also accords with the strategic objectives of the Food Standards Agency in relation to enforcement, i.e. to improve the effectiveness of local authority and Meat Hygiene Service enforcement, to ensure proportionate and more consistent enforcement, to improve the transparency of enforcement arrangements for stakeholders, and to promote the wider implementation of risk-based systems for improving safety standards across the food chain. Although much of the proposal consolidates existing requirements, the new general rules will harmonise further the approach to national control systems, particularly with regard to imports of non-POAO. This will increase consistency and effectiveness of enforcement across the Community for businesses.

4.4 Better enforcement will contribute to a reduction in food-borne disease, a reduction in the direct and wider economic costs of food-borne disease, a reduction in contamination incidents and to increased consumer protection as outlined in paras 2.25 to 2.27. It is difficult to quantify the benefits but estimates have been made in two areas:

- Food-borne disease – The economic costs relating to this have been estimated at £1.61 billion per annum (September 2003 prices). These estimates comprise of two main components: (i) the actual, out of pocket, costs of the illness to individuals, employers and the NHS and (ii) the additional monetary value to individuals of the pain, grief and suffering due to the disease. If it is assumed that only 0.5% of these costs can be avoided as a result of this proposal an annual benefit (saving) of £8 million would be generated¹.
- Chemical contamination incidents – In the feed area alone, chemical contamination incidents are currently estimated to have an annual cost to the UK of £0.88 million. The cost-benefit calculations have assumed that this proposal could lead to the avoidance of 10% of current incidents through more effective enforcement and thus an annual saving of £88,000. No figures are currently available for the cost of food contamination incidents to

¹ These calculations are based on the estimates used in the Food Hygiene Consolidation proposal adjusted to September 2003 prices. In order to reach break-even point (benefits=costs) using the quantified estimates, 0.21% of the economic costs of IFD need to be avoided. However this figure is bound to be lower than this proportion as not all the benefits can be estimated and have therefore being omitted from the calculations.

the UK, but again, more effective enforcement will contribute to a reduction in costs.

4.5 There are other benefits associated with this regulation which, because of lack of available information, cannot be quantified. These include general trade harmonisation benefits and the avoidance of infraction proceedings if not implemented in full. Further to this, increased consumer protection, will also result from more effective monitoring and enforcement and will consequently reduce losses arising from mislabelling and fraudulent practices.

4.6 In terms of the provisions on penalties and sanctions, it has until now been the case that it is the sovereign responsibility of Member States to do what is necessary to enforce Community legislation in their territory and to determine the sanctions to be applied. The UK Government position is that this a matter of subsidiarity and that the Community does not have competence to insist that certain behaviour be criminalised. There are already criminal sanctions in place in the UK for serious breaches of feed and food law in line with requirements in the General Food Law Regulation (EC/178/2002). As previously mentioned, during the negotiations it was clear that the majority of Member States and the EP shared the UK analysis of the Commission proposal. A compromise was agreed that requires Member States simply to have in place a system of effective, proportionate and dissuasive sanctions.

4.7 In terms of the financing, it should also be noted that the provisions that were negotiated represented the best that were likely to be achieved. Legal analysis of the compromise framework indicates that it allows the UK to maintain the *status quo* in respect of financing of official controls for now.

5. Costs for business, charities and voluntary organisations

(i) Compliance costs for businesses

Option 1

5.1 There would be no compliance costs but this option could potentially lead to trade barriers and unquantifiable cost to industry through lost business.

Option 2

5.2 As noted above, this option, although originally considered, is no longer relevant as a compromise on sanctions has been agreed. At any rate, the costs were essentially the same as those for option 3.

Option 3

5.3 Compliance costs will arise in the following areas:

Financing of official controls

5.4 In the UK, the means of funding official controls varies from sector to sector. Feed and food controls carried out by local authorities are funded through the revenue support grant and local taxation. On-farm milk hygiene inspections are also funded centrally through the Food Standards Agency. There is partial cost recovery for meat hygiene inspections. Defra's programme for pesticide residue surveillance is funded by a levy on industry and a contribution from the Treasury. For veterinary medicine residue surveillance, there is full cost recovery from industry and feed controls carried out by the AMI are funded from full cost recovery from industry. Further details are given at Annex A.

5.5 The requirements in the original proposal are outlined in para 2.16. However, as highlighted in para 2.17, views of the Member States on these provisions varied widely and compromise provisions were developed on which there is now consensus. Legal analysis of these proposals indicates that they include sufficient flexibility to permit the UK, for the most part, to retain the *status quo* for now.

5.6 Notwithstanding the above, mandatory fees for veterinary inspections, will be updated regularly to take account of inflationary increases in the costs incurred by the competent authority in undertaking official controls.

5.7 There will also be some transfer of costs from the competent authorities to businesses as Member States will be required to impose fees for 'excess controls'. The Commission has confirmed that this will apply only for significant problems which are not foreseen in the national control plan, e.g. a major dioxin incident. Commission decisions may be issued to clarify this. As incidents of this nature occur only infrequently or uniquely, it is not possible to quantify what the costs may be.

5.8 With regard to import controls for non-POAO (i.e. from third countries), Member States *may* be required to impose fees to cover costs of import checks on 'high-risk' products. This will be decided when such products are identified through comitology (see para. 2.15, fifth bullet point). In view of this, it is not possible to estimate costs at this stage. Even if fees are established on a mandatory basis for all products designated as 'high risk', the total costs will depend on the number and type of products involved. To date, there has been no indication from the Commission of potential product numbers. However, the expectation is that the Commission will designate more products as 'high risk'

than are currently subject to specific EU Emergency Control Procedures (Annex B). The current annual cost of carrying out these current controls is estimated to be around £1 million. Thus if the number of products is doubled, costs may be estimated at £2 million per annum. At present, costs are covered by centrally funded competent authorities but, under the proposal, importers *may* be charged to cover this.

5.9 The compromise framework also provides a legal basis for Member States to recover costs from businesses in other sectors. If the UK decides to consider implementing this option in the future, any proposals will be the subject of a separate RIA.

5.10 Where fees are imposed, either on a mandatory or optional basis, these must be calculated on the basis of a specified and exhaustive list of expenses. This includes salary costs and costs of facilities etc. and is interpreted to include overheads etc.

5.11 It should be noted that the proposed Regulation includes provisions to review the requirements for fees and the level fees set within three years of the Regulation coming into force. This will be undertaken with a view to increasing the sectors in which fees will be mandatory across the EU. The approval of establishments, which is required under new food hygiene proposals, is for example, likely to be subject to mandatory fees in the future. Once the review has been completed, any resulting proposals will be subject to the co-decision procedure and will therefore be subject to full consultation within the UK.

Prior notification and designated points of entry

5.12 Provisions are included for Member States to require importers to provide prior notification of 'high risk' non-POAO feed and food and to undertake official controls on these products at designated points of entry. There is also an option for Member States to implement such provisions for feed other than 'high-risk' non-POAO feed but this is not new as there is an enabling power in current EU feed legislation permitting this (the UK has not taken it up). At the majority of UK seaports, there is already a well established system of prior notification of POAO and non-POAO subject to mandatory controls under Emergency Control Arrangements. This is achieved by means of physical or electronic transfer of information between the importer or clearing agent and the enforcement body. It is, therefore, not anticipated that there will be any increase in costs to businesses operating through seaports. However, a more limited system of prior notification exists at Airports so some additional costs will be incurred in establishing appropriate systems. It should be noted that the Association of Port Health Authorities (APHA) report that the number of 'high

risk' non-POAO arriving through UK airports forms only a small proportion of the total trade.

5.13 It is not envisaged that the designation of specific ports for 'high risk' non-POAO will impose additional costs on businesses. The requirement for importers to clear non-POAO subject to current mandatory checks through designated ports (with adequate examination facilities) is already established, and there is a good geographical spread of seaports in the UK. For example 29 points of entry (including four airports) are currently designated for importation of certain nut products.² It seems likely that the existing designated points of entry will be appropriate for those non-POAO deemed to be 'high-risk' and there should be no need for shippers to re-route consignments.

(ii) Costs for a typical business

5.14 With regard to national controls, a 'typical business' may be defined as one that complies with feed and food law requirements. The cost to existing businesses if the proposal is adopted as drafted should therefore be neutral, as any additional costs will only result from 'excess controls' carried out when serious non-compliances have been detected.

5.15 With regard to importers of 'high risk' non-POAO, until fees are set through comitology, it is not possible to provide an accurate estimate of the average cost to a typical business.

(iii) Compliance costs for the enforcement sector

5.16 The proposal sets out the principles and approach that national enforcement bodies should take to checking that feed and food businesses are complying with all relevant feed and food legislation. Much of the proposal consolidates existing requirements or practices but some elements are new (see para 2.15). Where there are financial implications, estimated costs are set out below:

- *Auditing control bodies* - It is estimated that the cost for the competent authorities in auditing these will be £5,000 per control body. Currently, it is believed that 10 control bodies are employed by UK competent authorities (this can vary at any time). If these are audited annually, the estimated total cost would be approximately £50,000 per annum.

² Specified points of entry – Commission Decision (2003/43/EC)

- *Sampling procedures* – bringing current sampling procedures in line with the requirements of the proposal is estimated to have an annual cost of approximately £100,000.
- *Accreditation of feed laboratories* - initial start up cost for this is estimated to be £30,000 per laboratory and on-going annual costs are estimated to be £7,000 per laboratory, for up to 25 laboratories. Thus, total additional costs may amount to a maximum of approximately £750,000 for initial outlay with an additional annual cost of up to approximately £175,000. These costs would be borne by the laboratories.
- *Designation of national reference laboratories* - estimated costs are £20,000 for start up with on-going costs for accreditation of approximately £4,000 per annum for up to six laboratories. Thus, maximum costs are estimated to be £120,000 for initial outlay and £24,000 annually thereafter. However, it is anticipated that the laboratories which will be designated for new areas will already be national reference laboratories for other areas, so costs may be significantly less.³
- *Import controls* (implementing a system of prior approval and facilities at designated ports) – as highlighted in paras 5.6 and 5.7, there may be some additional costs at airports for establishing prior notification procedures but these are not anticipated to be significant. Linked to this, there may be a requirement for additional HM Customs & Excise staff resources should Customs be required to withhold Customs clearance of high risk goods until appropriate health checks have been concluded. It is not possible to quantify these costs at this time."
- *Liaison body arrangements* - costs for the UK liaison body for food issues (LACORS – Local Authority Co-ordinators of Regulatory Services) are currently £30,000 per annum. The proposal requires that there are similar arrangements for the feed and veterinary sectors. Total costs of £60,000 per annum are estimated.

³ For the purposes of calculating the full cost-benefits of the proposal, a mid-value of 3 laboratories has been used.

- *National control plans* - It is difficult to assess accurately the costs of this before the Commission establishes the guidelines which these plans and annual reports should follow. However, total estimated cost for the first year is £200,000. This includes costs for the FSA, which will co-ordinate the exercise, and costs for the other main central authorities involved in contributing to the plan. There may be scope to reduce costs in subsequent years.

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

6.1 This proposal does not set out any requirements for small businesses. However, such businesses (as with all other relevant businesses) may be affected in terms of covering the costs, in full or in part, incurred by the enforcement authorities in carrying out official controls. Until the requirements on financing are finalised, it will be unclear exactly what the extent of the impact of the proposal might be. However, the compromise provisions do take account of the interests of small businesses where charges for controls are to be made.

6.2 With regard to importers, including small importers, there may be an additional financial impact for establishing systems for pre-notifying the competent authorities of ‘high risk’ non-POAO consignments going through ports. Details of the percentage of importers that would be defined as ‘small businesses’ have been sought through the Association of Port Health Authorities but it has not been possible to establish a figure.

6.3 The Small Business Service (SBS) has been consulted about this proposal and has been involved in the development of the RIA. The SBS agreed to distribute to small businesses a letter prepared by the Food Standards Agency. This asked for views on the proposal generally but in particular on the financing provisions and the potential effects that this may have for them. To date, no responses have been received. Similarly, a number of trade associations representing small businesses were contacted but again no quantitative information on financial impacts has been received.

7. Competition assessment

7.1 The proposal provides a framework regulation to consolidate the approach taken by the enforcement authorities in the Member States for checking that relevant businesses are complying with feed and food law and animal health and animal welfare legislation. Consequently, it does not set out any new requirements for businesses and negative competition effects are therefore unlikely.

7.2 Option 1 represents the *status quo* and will not have any competition effect. Option 2 is now void. Any impact on competition of Option 3 is expected to be very small as new requirements in this proposal fall to enforcement agencies rather than business. However, there is an element of potential new fees which may be levied on business (instead of being absorbed by enforcement agencies i.e. this represents a transfer of costs from enforcement bodies to businesses for the controls undertaken). In addition, the proposal includes provision to review and then regularly update the level of fees to take account of inflationary increases. It is not possible at this stage to assess the effects on competition.

7.3 Charging for import controls on 'high risk' non-POAO, is new and may have some potential effects on competition with a disproportionate impact on smaller businesses (because of lower import volumes). However, the level of fees for controls on such products will not be set under the current proposal but rather through comitology. In doing so the principles set out under the compromise proposals on financing are likely to be followed and these take into account the interests of small businesses. Consequently, overall, these effects are expected to be very small.

8. Enforcement and sanctions

8.1 This proposal details the role and duties of the competent authorities in the Member States. These requirements will be enforced through controls conducted by the Commission and in particular by the Food and Veterinary Office.

8.2 The proposal also contains provisions on enforcement measures that the competent authorities in Member States should take when infringements of feed and food law are detected.

9. Monitoring and review

9.1 The proposal requires that Member States develop a comprehensive control plan and report annually on implementation of this. The plan and annual reports will be used by the Commission's Food and Veterinary Office to assess the effectiveness of the national control system and the measures in place under the proposed Regulation.

10. Consultation

i) **Within Government**

10.1 Consultation at official level has been ongoing since the proposal was issued continuing throughout the negotiations. Other Government Departments have also been consulted on the proposal through the Ministerial Sub-Committee on European Issues.

ii) **Public Consultation**

10.2 A full consultation took place between March and June 2003. The response generally was disappointing and no information was provided to include in the RIA. Following this, three updates were published on the FSA website– September and November 2003 and February 2004. These updated stakeholders on the progress of the negotiations and sought further comments on the developing proposal and, in particular, on the emerging compromise proposals on financing. The partial RIA was also included in the latter two updates and requested comments on this. Again, the response generally was poor and no further information on the financial impact on affected businesses was provided.

11. Summary and recommendation

A summary of the costs and benefits is given in the table on the next page. Option 1 of non-implementation has no associated costs but equally provides no associated benefits. Option 2 has is now void given that a compromise has been agreed on penalties and sanctions. Option 3 , compared with Option 1, provides positive net present value. **Hence option 3 is the recommended choice.**

Summary of Economic Costs and Benefits (£ millions)

Option	Discounted Costs £m	Discounted Benefits £m	Net Present Value £m
1 - Do nothing; non-implementation	0	0	0
2 - Adopt new requirements in part (excluding rules for penalties and sanctions)	£14.1	£67.9	£53.8
3 - Full implementation	£14.1	£67.9	£53.8

Current (September 2003) prices; 3.5% discount rate over 10-year authorisation period.

The costs identified above represent additional costs (rather than transfer costs) that arise as a result of the provisions in the proposal and that, for the most part, are compliance costs for the enforcement sector. These estimates are based on the assumptions outlined in sections 4 and 5.

12. Declaration

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

Signed

Date

Minister's name, Title , Department

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Annex A

Funding of official controls in the UK

- Local authorities - are resourced by Council taxes and through the Revenue Support Grant mechanism (RSG). The RSG is the principal method by which central government provides funding to local government and is administered via the Office of the Deputy Prime Minister (ODPM). The RSG is calculated using Standard Spending Assessments (SSAs) for different local authorities. SSAs are based, amongst other things, on population data (commuters and visitors, resident population, density, social and economic conditions) and differences in the costs of the provision of services between areas. The SSA for each local authority type includes funding for services provided under the broad heading of Environmental, Protective and Cultural Services (EPCS) and this includes feed (and food) law enforcement. Funding is not ring fenced or separately identified within the EPCS. In addition, those local authorities with Border Inspection Posts generate limited revenue from charging for import controls on POAO.
- Local Authorities in Scotland - The mechanism for funding in Scotland is basically the same as above for England, Wales and Northern Ireland but the bodies involved are slightly different as there is a role for CoSLA [DN – need to include in full] and Scottish Executive in providing and administering funding.
- Meat inspection - General meat Hygiene and Transmissible Spongiform Encephalopathies (TSE) controls are funded by both industry and Government. Industry in Great Britain pays for part of the costs of meat inspection and official supervision of licensed meat plants (approximately £21m in 2002/03), in line with the EU Charges Directive (85/73 as amended), the FSA pays the balance of this cost (circa £25m in 2002/03). In addition, the FSA also meets the costs of enforcing the EU TSE legislation in Great Britain licensed meat plants (£16 –17m per annum). Meat Hygiene controls are funded separately in Northern Ireland.
- Pesticide residue monitoring - the programme to monitor pesticide residues in food costs £2 million per annum. Currently, the costs of the programme are met by pesticide manufacturers (60%) and the Exchequer (40%).
- Veterinary medicines surveillance - Defra's programme to monitor residues of veterinary medicines and certain other substances in food costs approximately £4 million per annum. Currently all of the costs of the programme are met by charges on the livestock industry as required by EU law

- Medicated feedingstuffs and zootechnical feeds – costs for 2004/05 for controls undertaken by the Animal Medicines Inspectorate of the Royal Pharmaceutical Society of Great Britain on behalf of the Veterinary Medicines Inspectorate are estimated to be £284,000. These costs will be recovered in full from industry as required by current EU legislation.
- Dairy Hygiene Inspectorate. - is part of core Defra but works for the FSA through a Service Level Agreement (SLA) to carry out on-farm inspections. The SLA for 2003-04 is valued at £1.554m (£1.342m for England and £211k for Wales. This is largely based on the cost which Defra charge per inspection of £96. Dairy farmers were charged for inspection (at that time £ 94) until 2000 when charges were removed as part of the Prime Minister's Action Plan for Farming. Most dairy farmers would be considered as small businesses.
- Egg Marketing Inspectorate – is part of Defra. The inspectorate is centrally funded and does not raise any revenue from its activities.
- The Plant Health and Seed Inspectorate – is part of Defra. It imposes charges for: inspection of seed potato crops, agricultural seed crops and certain horticultural planting material to ensure certain standards of species, varietal purity and health are met; certification for export of plants, plant material and produce; inspections for the purposes of conferring authority to issue plant passports and subsequent monitoring under the Single Market regime for plant health where intra-community trade is based on grower self-certification. A harmonised regime of charges for the inspection of imported plants, planting material and produce from non-EU countries is to be introduced across the EU from 1 January 2005
- The Horticultural Marketing Inspectorate – is part of Defra and inspection and certification activities are centrally funded. The inspectorate does have a SLA with the Pesticide Safety Directorate to collect samples of fruit and vegetables for pesticide residue monitoring and surveillance.

Annex B

Current list of high – risk non-POAO subject to EU emergency control arrangements

Product	Origin
Fruits of the Forest (genus Vaccinium e.g. cranberries, blackberries etc Wild mushrooms (uncultivated)	Albania Belarus Bosnia and Herzegovina Bulgaria Croatia Czech Republic Estonia Hungary Latvia Liechtenstein Lithuania Fmr. Yugoslav Republic of Macedonia Moldova Norway Poland Romania Russia Slovak Republic Slovenia Switzerland Turkey Ukraine Federal Republic of Yugoslavia
Pistachio nuts and derived products	Iran
Groundnuts (peanuts) and derived products	Egypt China
Figs, hazelnuts, pistachio nuts and derived products (fruits falling containing figs, hazelnuts or pistachios) (hazelnuts, figs and pistachios, prepared or preserved, including mixtures)	Turkey
In shell Brazil nuts	Brazil
Hot Chilli & Hot Chilli products intended for human consumption. These are fruits of genus Capsicum, dried <u>and</u> crushed or ground.	All