



COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on official feed and food controls**

(presented by the Commission)

## EXPLANATORY MEMORANDUM

### I. SUMMARY

1. This proposal is a follow-up of the Commission's announcement in the White Paper on Food Safety<sup>1</sup> that it would submit to the European Parliament and the Council a proposal for a Regulation on official feed and food safety controls. It lays down the rules to be respected by the competent authorities responsible for carrying out official controls as well as the tasks of the Commission with regard to the organisation of those controls. It is the result of a review of the existing Community rules on the subject, which were adopted separately for the animal feed sector, the food sector and the veterinary sector. It covers the entire range of activities covered by feed and food law, which includes feed and food safety but also other aspects that relate to consumer protection, such as feed and food labelling.

Special attention is paid to enforcement measures and in particular the imposition of sanctions at national and Community level. For that purpose, the proposal contains minimum requirements on criminal sanctions to be imposed by the Member States with regard to serious offences that are committed intentionally or through serious negligence. The proposal also contains new tools for the Commission to enforce the implementation of Community feed and food law by the Member States.

### II. INTRODUCTION

2. The motives for the Commission to present this proposal can be summarised as follows:
  - The existing sectoral approach has led to repetition or to situations whereby requirements of a similar nature are covered in a different way for the different sectors concerned. For certain sectors, some control aspects are lacking, thus leaving loopholes in legislation.
  - Recent feed and food emergencies have highlighted deficiencies in national control systems. At the heart of the problem is the lack of a harmonised Community approach to the design and development of national control systems.
  - There is a need to properly define the role of the Commission's own control services so as to ensure the most efficient use of available resources.

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<sup>1</sup> Document COM (1999) 719.

3. As stated in the White Paper on Food Safety it follows that:

*"There is therefore a clear need for a **Community framework of national control systems**, which will improve the quality of controls at Community level and consequently raise food safety standards across the European Union. The operation of such control systems would remain a national responsibility. This Community framework would have three core elements.*

- *The first element would be **operational criteria** set up at Community level, which national authorities would be expected to meet. These criteria would form the key reference points against which the competent authorities would be audited by the FVO, thereby allowing it to develop a consistent, complete approach to the audit of national systems.*
- *The second element would be the development of **Community control guidelines**. These would promote coherent national strategies, and identify risk-based priorities and the most effective control procedures. A Community strategy would take a comprehensive, integrated approach to the operation of controls. These guidelines would also provide advice on the development of systems to record the performance and results of control actions, as well as setting Community indicators of performance.*
- *The third element of the framework would be enhanced **administrative co-operation** in the development and operation of control systems. There would be a reinforced Community dimension to the exchange of best practice between national authorities. This would also include promoting mutual assistance between the Member States by integrating and completing the existing legal framework."*

The present proposal aims to create such Community framework of national control systems by merging and completing existing rules for national and Community controls within the EU, at the borders and in third countries.

4. The proposal takes into account the principles of food safety that are spelled out in the Commission's White Paper on Food Safety, and in particular that:

- Food safety policy must be based on a **comprehensive, integrated approach**,
- Feed and food businesses operators have the prime responsibility for feed and food safety, whilst the competent authorities **monitor and enforce** this responsibility through the operation of national surveillance and control systems; the Commission's control services concentrate on evaluating the ability of competent authorities to deliver these systems through audits and inspections,
- Feed and food safety policy must be **risk-based**,
- The **farm to table** policy, covering all sectors of the food chain, including feed production and animal feeding, primary production, food processing, storage and distribution, animal health and animal welfare, needs to be systematically implemented.

5. Based on the above observations, the proposal contains the following main elements:
- The official controls by Member States shall enable them to verify and enforce compliance with national and Community feed and food law; for that purpose, official controls shall be carried out regularly and must be defined on the basis of risk.
  - The authorities in the Member States that are competent for performing official controls shall meet operational criteria that guarantee their efficiency, effectiveness and impartiality.
  - Staff performing official controls shall have received adequate training in order for them to undertake their duties competently.
  - Specific control tasks may be delegated to an independent body only under strict conditions.
  - Methods of sampling and analysis shall be validated in accordance with internationally accepted protocols, including those based on performance criteria, and be carried out by laboratories accredited for that purpose.
  - Where non-compliance is identified during official controls, appropriate measures shall be taken, including administrative measures and criminal sanctions. These measures and sanctions shall be effective, dissuasive and proportionate.
  - Contingency plans shall be drawn up setting out measures to be implemented in case of feed and food emergencies.
  - Member States shall proceed to regular controls of feed and food imports.
  - Where official controls require action by more than one Member State, the competent authorities of the Member States concerned shall afford each other administrative assistance. This assistance may be extended to active co-operation including on-the-spot controls of Member State experts in another Member State.
  - In co-operation with the Member States, a Community framework for the development and operation of national control systems shall be developed taking account of existing best practices and of the experience of the Commission's control services. It will be based on agreed criteria for the performance of these systems, and lead to clear guidelines on their operation. Community guidelines will be developed for that purpose.
  - Inspections and audits by the Commission's Food and Veterinary Office (FVO) shall be organised to verify the effectiveness of national control systems.

- Additional tools for the Commission to enforce implementation of Community feed and food law by Member States must be made available.
  - There must be a Community framework for the training of control staff in the Member States in order to ensure a uniform level of decision taken by such staff.
  - There is a need to take special account of the needs of developing countries.
6. The basic principles related to responsibilities of the Member States authorities are already laid down in the Regulation (EC) No 178/2002 laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>2</sup>. This Regulation stipulates in particular that "Member States shall enforce food law and monitor and verify that the relevant requirements of food law are fulfilled by feed and food business operators at all stages of production, processing and distribution. For that purpose they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on feed and food safety and risk, feed and food safety surveillance and other monitoring activities covering all stages of production, processing and distribution. Member States shall also lay down the rules on measures and penalties applicable to infringements of feed and food law. The measures and penalties provided for shall be effective, proportionate and dissuasive".

The present proposal describes in more detail how these basic principles must be interpreted and implemented.

### III. GENERAL ANALYSIS OF EXISTING COMMUNITY LEGISLATION

7. Community legislation on official controls in the areas of feed and food safety has been developed over a period of several decades and on a sectoral basis. As a result, it is contained in several Directives and Decisions. The situation can be summarised as follows:

#### *Feed*

8. Council Directive 95/53/EC of 25 October 1995<sup>3</sup> fixes the principles governing the organisation of official controls in the field of animal nutrition.

The main purpose of this Directive is to harmonise official controls carried out by the Member States' competent authorities as regards both imports and trade within the Community.

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<sup>2</sup> OJ L 31, 1.2.2002, p. 1.

<sup>3</sup> OJ L 265, 8.11.1995, p. 17.

The Directive covers all products and substances used in animal nutrition. The following elements constitute the basic provisions:

- (a) Uniform principles for the organisation of checks.
  - (b) Reinforcement of checks at source and organisation of checks at the place of destination in the context of the single market.
  - (c) Systematic documentary checks and random identity and physical checks on feed imports and a procedure for improving the harmonisation of these checks.
  - (d) Procedures for the co-operation between Member States when infringements are detected.
  - (e) A requirement for the Member States to set up national annual control programs.
  - (f) A requirement for the Member States to transmit a report on the implementation of the national programs to the Commission commencing in April 2000.
  - (g) Based on the above information, a requirement for the Commission to present each year an overall summary report and a proposal for a recommendation concerning a co-ordinated Community control program.
  - (h) A procedure for carrying out Commission on-the-spot controls both in the Member States and in third countries.
  - (i) The possibility for the Commission, when confronted by a serious risk, to adopt safeguard measures on products originating in third countries.
  - (j) Provisions to set up specific control plans when appropriate in addition to the annual and general control plan.
  - (k) A requirement for Member States to have adequate contingency plans to deal with serious feed risks.
  - (l) A requirement for Member States to inform the Commission as soon as a serious contamination or risk is detected and has spread.
9. The financing of official controls in the animal feed sector is organised by Council Decision 98/728/EC<sup>4</sup>. This Decision provides for a Community system for fees to be levied for the examination of dossiers of specified additives and for the approval of certain establishments and intermediaries. The Decision fixes an exclusive list of costs that can be taken into account when calculating control fees. This includes staff costs, administrative costs and technical costs. Based on these criteria, Member States may apply flat-rate amounts for financing expenses for official controls in specific areas. The direct or indirect refund of the fees to the feed or food business operators is not allowed.

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<sup>4</sup> OJ L 346 , 22.12.1998, p. 51.

Although this Decision has only recently become applicable, it seems to function properly. Contrary to the system that is applied in the veterinary sector, no difficulties in implementing it have been notified to the Commission.

10. Community methods of sampling and analysis for the official control of feedingstuffs are laid down in Council Directive 70/373/EEC<sup>5</sup>. This Directive empowers the Commission to establish such methods for the purpose of checking compliance with quality and compositional requirements, taking into account current scientific and technical knowledge.

That has allowed to establish a number of analytical methods, such as Commission Directive 98/88/EC of 13 November 1998 establishing guidelines for the microscopic identification and estimation of constituents of animal origin for the official control of feedingstuffs<sup>6</sup>. Directive 70/373/EEC does however not lay down criteria with which methods of analysis shall comply, as it is the case for foodstuffs (Council Directive 85/591/EEC). There is a need to harmonise both areas.

### ***Food***

11. Two Directives apply to official controls in the food area:
  - Council Directive 89/397/EEC on the official control of foodstuffs<sup>7</sup>,
  - Council Directive 93/99/EEC on the subject of additional measures concerning the official controls of foodstuffs<sup>8</sup>.

The scope of these Directives covers all food, without prejudice to the application of requirements in veterinary legislation described below. They lay down, in a general way, the general principles that must be applied by the control services in the Member States to ensure compliance of foodstuffs, food additives, vitamins, mineral salts, trace elements and other additives as well as materials and articles intended to come into contact with foodstuffs. These include in particular rules on the organisation of the official controls in the Member States, sampling and analysis, the right of appeal against measures taken by the competent authority, the organisation of controls in accordance with in advance established plans, Community controls in the Member States and mutual assistance.

These Directives do not include however common rules on the control of foodstuffs imported into the Community nor on the organisation of Community controls in third countries. Neither do they include procedures to be implemented in case of food emergencies or on the financing of official controls. They do not specify the measures to be taken when the official controls disclose irregularities.

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<sup>5</sup> OJ L 170 , 3.8.1970, p. 2.

<sup>6</sup> OJ L 318, 27.11.1998, p. 45.

<sup>7</sup> OJ L 186, 30.6.1989, p. 23.

<sup>8</sup> OJ L 290, 24.11.1993, p. 14.

### *Veterinary checks*

12. There is a comprehensive set of rules to be applied by the controlling authorities in the Member States to checks on products of animal origin and for verifying their compliance with Community veterinary rules. These include the following Directives that are of a general nature and thus applicable to all food of animal origin:
  - Council Directive 89/662/EEC concerning veterinary checks in intra-Community trade with a view to the completion of the internal market<sup>9</sup>,
  - Council Directive 97/78/EC laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries<sup>10</sup>.
13. The first Directive was adopted at the time of the establishment of the single market. It aims to ensure that veterinary checks on goods that are intended for the EU market are carried out at the place of dispatch and no longer at the internal borders of the Community. It contains elements on the organisation of the controlling services in the Member States, the measures to be taken in case of food emergencies and the establishment of control plans.
14. The second Directive fixes in detail all the checks that must be carried out on goods coming from third countries. It lays down in particular that such goods must be cleared in advance through a border inspection post, which must be included on the list of Commission approved Border Inspection Posts, and that they must be submitted to a documentary, identity and physical check. It describes the procedures that must be followed in case of non-compliance of the goods with Community veterinary rules.
15. In addition to these two Directives, a number of product specific Directives exist. Each of these Directives contains obligations for the competent authorities to perform controls on the products concerned. They include meat, meat products, egg products, fishery products, milk and dairy products etc.
16. Two other Directives in the veterinary sector are of major importance with regard to the organisation of official controls:
  - Directive 89/608/EEC contains detailed rules on mutual assistance between the administrative authorities of the Member States and co-operation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters<sup>11</sup>,

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<sup>9</sup> OJ L 395, 30.12.1989, p. 13.

<sup>10</sup> OJ L 24, 30.1.1998, p. 9.

<sup>11</sup> OJ L 351, 2.12.1989, p. 34.



- Directive 96/43/EC amending and consolidating Directive 85/73/EEC in order to ensure financing of veterinary inspections and controls on live animals and certain animal products<sup>12</sup>. It covers, for products of animal origin and for live animals, the financing of veterinary controls.
17. Finally, Regulation (EC) N° 999/2001 of the European Parliament and the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies is of major importance for the organisation of official controls in veterinary sector, as well as the recently adopted Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down the health rules concerning animal by-products not intended for human consumption<sup>13</sup>.
  18. The veterinary legislation lays down, for food of animal origin, common rules on the organisation of official controls, the control of foodstuffs imported into the Community, procedures to be implemented in case of food emergencies, specific measures to be taken when the official controls disclose irregularities, detailed rules on mutual assistance and on the financing of veterinary inspections and controls on live animals and certain animal products. It also covers the organisation of Community controls in Member States and third countries. An issue that is not covered in a comprehensive way under veterinary legislation is the question of official sampling and analysis of food.

***Other sectors***

19. In the areas of animal health and animal welfare, official control requirements proper to these sectors have been developed. However, bearing in mind its horizontal character and general nature, the proposal on official feed and food controls can be fully applied to these sectors. This is in line with the White Paper on Food Safety stating that animal health and animal welfare are important factors that contribute to feed and food safety.

**IV. COMMISSION CONTROL RESPONSIBILITIES UNDER CURRENT LEGISLATION**

***Commission powers and obligations in relation to activities in Member States***

20. Controls fall within the wider guardianship role of the Commission to ensure that Community legislation is effectively applied and enforced within the Community as laid down in Article 211 of the EC Treaty. There is also the requirement in Article 152 that “Community action ... shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health”. Control obligations contained in legislative texts are subject to these broader duties to ensure that legislation is effectively enforced and that dangers to health are obviated.

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<sup>12</sup> OJ L 162, 1.7.1996, p. 1.

<sup>13</sup> OJ L 273, 10.10.2002, p. 1.

21. There are only a few instances where Community legislation requires the Commission to carry out controls in the Member States. In the vast majority of cases the legislation provides an authorisation to inspect without imposing an obligation to do so. Thus the Commission has discretion as to whether to carry out controls or to use other means of securing enforcement of the legislation. Currently there are two exceptions to this:
- (a) Commission Decision 97/778/EC requires the Commission to inspect border inspection posts normally on an annual basis (there are about 290 posts in the Community);
  - (b) Several Commission Decisions in recent years relating to BSE have specifically called for controls by the Commission to verify compliance.

The obligation under (a) has never been fully met due to resource constraints. Moreover, the frequency of inspections currently prescribed is not essential to ensure a high level of protection. Ensuring the proper functioning of these facilities should be primarily the responsibility of the Member States' controlling services, whilst the Commission's control services should integrate their control element into their general audits of the Member States' control systems in line with the ideas expressed in this memorandum. The Commission considers that the existing rules should therefore be reviewed and adapted accordingly. This will be subject of separate proposals.

#### ***Commission powers and obligations in relation to third countries***

22. As regards third countries, Community legislation generally imposes major obligations to inspect only in the veterinary sector, where the vertical hygiene Directives provide that Community controls "shall" be carried out with a view to verifying whether the standards applied by the relevant third country comply or offer an equivalent level of protection to that applied within the Community. In so far as the hygiene Directives include an obligation to inspect, a derogation from this obligation was introduced by Council Decision 95/408 for all animals and products, except cattle, sheep, pigs and goats and their products. In relation to the latter, Commission Decision 86/474/EEC requires the Commission to carry out controls in a large number of countries and establishments annually. Due to resource constraints, only a small fraction of these countries and establishments are in fact visited each year in relation to the products concerned. It is clear that the rules as existing at present must be adapted so as to take account of these constraints and apply an audit approach to third countries as soon as practicable.

## V. THE ROLE OF THE COMMUNITY

### *The changing context*

23. The context for the Commission's control activities has changed in a number of important respects in recent years.

Food safety has moved to and remains at the top of the Community's agenda. Part of the present Commission's response to the continuing concerns of European consumers about food safety was to bring together in 1999, within the Directorate General for Health and Consumer Protection, all the services responsible for feed and food safety issues. In this way it aims to focus all its available resources, in a concerted and efficient manner, on the main priorities for ensuring food safety at Community level. Thus, the control and legislative services of the Commission work in close co-operation to ensure that food safety legislation is up-to-date, comprehensive and practicable, and that it is being properly implemented and enforced.

24. In Member States too, new institutional arrangements are being put in place. Food safety agencies have been or are being set up in a number of Member States to help meet consumers' food safety concerns. Some of these new bodies have major control responsibilities.

25. The range of control responsibilities at both national and Community level is becoming wider. Community controls have tended in the past to concentrate on the initial stages of food processing, especially of food of animal origin. Much of the existing detailed legislation on food safety relates to controls in these areas. However, control authorities must cover the whole food chain for an ever-expanding number of products and sectors. The food production chain is also becoming more complex and sophisticated, with foods being manufactured by new processes not foreseen in existing legislation. Control systems need to adapt accordingly. They need to be based upon an approach that is targeted at critical points at each level of control: Community, national, regional, local and at the level of the individual enterprise.

26. The Commission has also an ever growing responsibility to ensure that Community requirements are met in relation to all imports of food, animals, plants and their products from third countries. The EU now imports such products from over 200 countries around the world. These countries range from the highly developed to the poorest countries in the world. They have very different control methods and standards. Balancing the demands of Community legislation on food safety, animal health, animal welfare and plant health issues against the Community's trade and humanitarian obligations concerning so many countries is complex and delicate.

The future enlargement of the Union will also add a new dimension to the Commission's responsibilities. It is clear that many of the applicant countries face a serious challenge in bringing their control systems up to the standards required within the Community. The Commission will have to play its part in helping them to achieve this goal.

### *Community framework for national control systems*

27. The White Paper on Food Safety identified the need for a more harmonised approach to the operation of the systems in Member States to monitor and enforce Community legislation. It therefore proposed the development of a Community framework for national control systems in order to raise standards of food safety across the EU.
28. In this Regulation the Commission proposes the introduction of a new approach under which the three aspects of control – verifying transposition, receiving reports from Member States, and carrying out on-the-spot controls – will be combined into one integrated control process for all feed and food. The control cycle under this new approach will involve four main stages.

#### Stage 1:

Broad guidelines will be drawn up by the Commission, in consultation with the Member States and taking into account the principle of subsidiarity, on the structure and organisation of integrated national control systems, and on the scope, content and operation of national control plans. These guidelines will aim to promote a harmonised approach to controls, covering the full range of Community legislation, and embracing all product sectors and all stages of the feed and food chain. They will encourage the adoption of best practices in respect of the key principles outlined above at all levels of the control system in each Member State and will indicate the main performance indicators to be applied in assessing and auditing national control plans.

#### Stage 2:

Member States will be required, within six months of the entry into force of the Regulation, to prepare an integrated multi-annual national control plan, to maintain this plan and to present it to the Commission upon request. The plans shall be implemented for the first time one year after the entry into force of the Regulation.

#### Stage 3:

On the basis of the multi-annual national control plan the Commission will conduct, on a regular basis, a general audit of the control activities of each Member State which may include selected controls at regional, local/district and establishment level to verify aspects of the control system. This general audit may be supplemented by further audits of specific sectors or particular critical control points, including the investigation of emergencies or new developments, as considered appropriate.

#### Stage 4:

One year after the implementation of the control plans and annually thereafter, Member States will be required to present a report to the Commission which will, where necessary, update their initial plan in relation to (a) what new legislation has been introduced or modified to meet Community requirements, (b) what important changes have been made to the structure and functioning of control systems, and (c) adjustments made to their control plans. Subsequent Commission audits of the Member States will be based on their updated plans.

A general report on the overall operation of national control systems in the Member States, based on the Member States reports, the outcome of Commission audits and other relevant information, will be prepared by the Commission and submitted to the European Parliament and Council and published.

29. This new approach to controls will have a number of important advantages. For Member States it will enable them to plan and implement their control activities with a clear understanding of what is expected at Community level and within an overall, integrated Community framework. Existing Community legislation on food safety, animal nutrition, animal health, animal welfare and plant health sets out a very broad and diverse range of requirements. Member States sometimes express concerns that the criteria and benchmarks by which their control systems are checked and assessed by the Commission are not always clear and consistently applied. The new approach will respond to these concerns.

For the Commission, it will be able to apply its available resources more effectively by combining its various existing control activities into one overall integrated process. This approach will also ensure that all the main requirements set down in Community legislation are regularly checked and that no important gaps are left in the control process.

For consumers, the new approach will be more transparent and understandable. The publication of reports on the overall operation of national control plans in the Member States and the results of audits by experts from the Commission will provide a very clear view of how Community legislation on food safety is being implemented and what the Commission and Member States are doing to ensure adequate consumer protection and to improve feed and food safety, animal health, animal welfare and plant health.

#### ***Community controls in third countries***

30. The European Union imports feed, food, plants and animals from over 200 countries around the world. Under current legislation, the Commission is required
- (a) to verify that the competent authorities in these countries are capable of ensuring that Community requirements are met in respect of all products exported to the EU,

- (b) in the case of certain products, to inspect individual production establishments, of which there are currently around 13.500 approved for export to the Community,
  - (c) to monitor on a regular basis the operation of around 290 existing inspection posts that carry out specified checks on all imports of animals, animal products and food of animal origin at their point of entry into the EU, and to inspect new inspection posts for their individual approval.
31. This represents an enormous range of responsibilities for the Commission. Given the limits on its resources, a major effort of prioritisation is needed. It is considered that adopting a more integrated approach to controls whereby third countries would be audited on the basis of control plans similar to those foreseen for the Member States, would facilitate this process. For this purpose, third countries can be classified into four broad categories:
- the applicant countries currently negotiating to join the European Union,
  - the countries that have negotiated veterinary and phytosanitary agreements with the EU (Canada, USA, New Zealand, Chile and Switzerland). Under these agreements the contracting parties have accepted that certain legislative requirements on food safety and animal health provide an equivalent level of consumer and animal health protection,
  - the three countries that have special agreements with the EU (Norway, Iceland and the Faroe Islands) which provide that imports of all or specified products (e.g. fishery products from Iceland) will be treated in accordance with the relevant agreement,
  - all other third countries, many of which have only a very small volume of exports to the EU.

32. Applicant countries

The Commission has intensified its control activities in applicant countries in anticipation of enlargement. At present its control responsibilities relate only to those sectors and establishments approved for export to the EU, which are generally small relative to the national sectors as a whole. However, agreement has been reached with most applicant countries that controls of the FVO should now extend to all areas of feed, food, animal and plant production. The Commission's role in relation to the applicant countries has therefore already changed substantially in recent years, requiring it to take on major additional responsibilities, and to extend its controls to cover the whole production chain in these countries in the same way as in Member States.

The applicant countries already account for a large proportion of the feed, food, plants and animals currently imported from outside the Community, in particular the higher risk products of animal origin and live animals.

### 33. Countries with a bilateral agreement

Veterinary agreements have been concluded with the USA, Canada, New Zealand, Chile and Switzerland. These agreements provide a framework under which the parties to each agreement may agree that for certain animals and products their respective legislation offers an equivalent level of protection for trade purposes.

With respect to Mercosur, it was agreed at the recent EU-Mercosur Summit held in Madrid on 17 May 2002, to start negotiations on sanitary and phytosanitary measures between the EU and the Mercosur countries. These negotiations will be part of the single undertaking of the future bi-regional association agreement.

At present, each agreement covers sanitary measures applied to most live animals and commodities containing products of animal origin, with the exception of certain issues specified in the agreements (e.g. certain residues, additives, labelling). Currently limitations exist with regard to the number of items for which full equivalency has been agreed. Thus the Commission is required to apply two different standards when verifying the operation of control systems in relation to trade with these countries. For the products for which full equivalence has been agreed, the Commission must verify that the control systems in these countries are operated in accordance with and deliver the standards laid down in their own domestic legislation. For other products, it carries out inspections to verify whether control systems in place can ensure that the requirements of Community legislation are met in relation to those aspects where equivalency has not yet been agreed. The increasing demands arising from this dual system of control needs to be addressed.

It seems appropriate therefore to conduct one general, comprehensive audit of each of these countries which would cover all the main sectors which export products to the EU. As with the Member States, the authorities in countries that are party to the agreements would have available a plan setting out the structure, organisation and functioning of control systems in relation to the main products they export to the EU. The audits would then be carried out against this background. If particular issues emerge from these general audits, they may subsequently be the subject of additional more specific audits as appropriate.

Broadly the same approach will apply to the three other countries with which the Community has special agreements.

### 34. Other Third Countries

Around 190 other third countries export feed, food, plants or animals to the EU. With the limits on its resources, the Commission cannot meet all its current obligations in relation to the evaluation of competent authorities and the checking of establishments in these countries.

It seems appropriate therefore to organise audits in these countries on the basis of control plans similar to those foreseen for Member States, in respect of the products they export to the EU.

Currently the Commission verifies the guarantees given by third countries through exchanges of correspondence, questionnaires, reports on the implementation of controls and on-the-spot inspections in respect of each commodity sector for which the third country is approved to export to the Community. This exchange of information corresponds with the actions provided for in Articles 4 and 7 and point 3 of Annex B of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Code) adopted in the framework of the World Trade Organisation.

Under the new arrangement, exporting third countries shall be required to maintain a control plan which provides accurate and up-to-date information on the general organisation and management of the relevant control systems, and to maintain up-to-date records on the implementation of these systems, all of which shall be made available to the Commission on request. The control plan and records will replace the system of pre-mission questionnaires except in specific instances where supplementary information, not covered by the standard plan or records, is required. The control plan shall be proportionate and technically and economically feasible taking account of specific situation of the third country and the nature of the products exported to the Community. Guidelines will be established specifying how these control plans and records should be drawn up and presented to facilitate third countries in complying with this requirement. Commission audits will then be carried out against these plans by a multidisciplinary team covering the main sectors exporting to the EU. The frequency of these controls should be determined on the basis of risk: where, on the basis of an assessment involving the nature of the products, the guarantees given by a third country and possible records on compliance history, a higher risk is perceived, the frequency of the audits shall be higher. If particular issues emerge from these general audits, they may be the subject of subsequent more specific audits as appropriate.

Experience has shown that competent authorities in some of the less developed countries can have major difficulties in organising their control systems in a manner that is required to meet Community standards. The Commission is often presented with a dilemma in these circumstances. To follow the letter of the law requires the Commission to propose closing down imports from these countries in accordance with the precautionary approach. But the products in question may often be one of the few sources of foreign revenue available to them and an import ban often has very serious economic consequences, not just for the establishments in question, but for the whole country.

The Commission will seek to identify means of helping countries in these circumstances while ensuring that consumer health protection will not be compromised. For example, additional assistance could be given through Community aid and training programmes to third countries in order to provide guidance on the best methods of achieving Community standards and to identify particular control solutions that more precisely reflect the level of risk posed by particular products.



## VI. ANALYSIS OF THE PROPOSAL

35. The proposal attached herewith aims to review the existing Community rules on official controls. Such a review will eliminate discrepancies between the different parts of existing Community legislation and to fill loopholes in feed and food law in certain areas. The resulting harmonisation across all sectors of feed and food law will increase transparency.
36. With the adoption of Regulation (EC) No 178/2002 laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, a number of issues have now been resolved for all areas of feed and food law. These do not therefore need further attention in the present proposal. This is the case for:
- The basic definitions of feed and food law.
  - The basic responsibility of the Member States with regard to official feed and food controls.
  - Procedures for the implementation of emergency measures.
  - Information to be made available to the Commission and the other Member States in the event of feed and food posing a serious threat to health.

### *Official controls by the Member States*

37. Objectives and general obligations

The objective of official controls carried out by the Member States shall be to enforce feed and food law and to reveal whether feed and food business operators at all stages of production, processing and distribution fulfil the relevant requirements of such law. For these purposes, the different control techniques that are available such as inspections, monitoring, verification, audits, sampling and the analysis of samples must be implemented. The intensity of these controls depends on many factors: in addition to a basic routine monitoring programme, account must be taken of identified risks associated with particular feed and food commodities or businesses, the performance of feed and food businesses with regard to in-house controls, the suspicion of non-compliance and possible fraudulent practices.

38. Competent authorities

Member States shall designate the authorities that are competent for carrying out official controls. These competent authorities shall meet a number of operational criteria that must guarantee their efficiency, effectiveness and impartiality. They shall in particular have or have access to a sufficient number of suitably qualified staff. It must be ensured that these staff can function properly also in extreme conditions of possible feed and food emergencies. This requires contingency plans to be established and staff to be properly trained to implement these plans. Audits subject to independent scrutiny shall be carried out to ensure that competent authorities achieve the objective of this regulation.

Suitable co-ordination procedures shall also be established in order to ensure that different departments involved in official controls are acting effectively together. This is particularly important in Member States with a decentralised structure, where it is essential that there is effective and efficient co-ordination between the central competent authority and the authority or authorities to which the competence for performing official controls has been delegated.

39. The delegation of control tasks to non-governmental control bodies

Several Member States have delegated certain control tasks to non-governmental bodies. This is in particular the case for the laboratory examination of official samples. It does not exclude however that other tasks are delegated to such bodies. Where Member States practice such delegation of competence, it must be ensured that a high level of consumer protection is maintained. For that purpose, the proposal lays down that bodies to which competence for performing official controls is delegated must operate in accordance with strictly defined conditions and in accordance with internationally recognised rules that must ensure their competence and independence.

It must also be envisaged that certain control tasks cannot be delegated to non-governmental bodies. A procedure is therefore provided to define at Community level the tasks that can (or cannot) be delegated to such bodies.

#### 40. Sampling and analysis

There is an urgent need to ensure that results following official sampling and sample analysis are obtained on the basis of common principles. This is not always ensured in the Community legislation in force. Although ideally all methods of sampling and analysis should be harmonised, it is not feasible to reach this goal in the short term. The proposal instead introduces requirements for laboratories to implement, where they are available, methods of analysis that are validated in accordance with international protocols, including those based on performance criteria, such as those accepted by the European Committee for Standardisation (CEN), the International Organisation for Standardisation (ISO) and the International Union of Pure and Applied Chemistry (IUPAC). There should also be a procedure that allows the Commission to establish methods of sampling and analysis. The laboratories that are designated to analyse official samples shall be accredited in accordance with the relevant international standards established for that purpose.

In developing, harmonising and validating methods of sampling and analysis or for establishing performance criteria for such methods, the Commission's Framework programme and Joint Research Centre (JRC) play already a prominent role and their capacities could even better be exploited in the future, whether or not in co-operation with the international bodies referred to above.

For ensuring a high standard of sampling and analysis, the proposal relies to a certain extent on the work of the CEN. This standardisation body has developed activities in the food sector. This involvement has so far been restricted to the development of analytical methods, a number of which emanate from ISO. A number of EN Standards developed by CEN relate to the organisation of controls. This is in particular the case for the validation of methods of analysis and to the operation and accreditation of control bodies. These standards have a recognised international status fully justifying their use in this context.

#### 41. Contingency plans

Experience has shown that the prompt handling and management of emergency situations requires the availability of infrastructures, material and human resources that can be mobilised in the short term and for a certain period in time. It also requires a high degree of co-ordination where responsibilities are shared between different services or departments. The present proposal introduces an obligation to ensure effective emergency management of feed and food emergencies through the establishment of contingency plans.

#### 42. Feed and food imports

Certain sectors, and in particular the veterinary sector, already implement detailed rules to ensure that imported products are effectively controlled. The products covered by that sector (products of animal origin) must be presented at an approved EU border inspection post and be submitted to a documentary check as well as to an identity and physical check in accordance with a scheme the principles of which are laid down at EU level. There are also requirements for products in transit and for products that are temporarily stored on the territory of the Community. It functions properly, and there is no reason to amend the system.

For feed and food other than that of animal origin, there is no harmonised Community approach towards import controls. The present proposal aims to introduce a control system for these products based on the following principles:

- (a) The Member States shall proceed to regular controls of feed and food that will be released for free circulation in the Community. These controls shall be organised using a statistically based sampling plan. They can take place at any point of the distribution of the goods: before release for free circulation or afterwards, e.g. at the importer's premises, during processing or at the point of retail sale. There shall in any way be a close co-operation between the customs services and the authority that is competent for controlling feed and food imports.
- (b) In addition it is proposed to establish at Community level a list of priority feed and foodstuffs for which experience has shown that hazards may occur (e.g. aflatoxins in certain foods). Such feed and food shall be presented at specially designated and equipped inspection posts for the carrying out of the necessary checks. These controls must be carried out before the goods are released for free circulation.

Additionally and in order to allow for the possibility of controls on feed and food from third countries that enters into free zones and free warehouses or is placed in transit, customs warehousing, inward processing, processing under customs control or temporary admission, the proposal foresees a possibility for performing official controls of feed and food kept under these different customs approved treatments or uses.

The present proposal aims also to better define the essential controls that are needed to ensure feed safety along the same lines as those that are developed for food.

#### 43. Financing of official controls

A system of control fees is applied at present in two sectors: the veterinary sector and the feed sector. The system in the veterinary sector relies on a flat rate from which departures can be made in order to take account of local differences with regard to the elements that have been taken into account to calculate the flat rate (wages, transport costs etc.) Although the fees in the veterinary sector have been introduced to avoid differences between Member States that may lead to distortions, experience has shown that important differences between and in certain cases within Member States continue to exist. The system has not always attained the desired objective.

In the feed sector, fees can be levied for particular well-specified control tasks. The Directive that governs this sector does not fix a Community flat rate, but leaves this to the Member States who must observe certain criteria in fixing flat rates. The rules that fix these principles have been adopted relatively recently (Council Decision 98/728 of 14 December 1998 concerning a Community system of fees in the animal feed sector).

Taking into account the experience gained so far, it is proposed to lay down the principles that underlie the financing of official controls and in particular that:

- Member States must ensure that adequate financial resources are available for organising official controls;
- if inspection fees are imposed to feed and food business operators, common principles must be observed for setting the level of such fees,
- where official controls reveal non-compliance with feed and food law, the extra costs that result from more intensive controls possibly linked to such non-compliance be borne by the feed and food business operator concerned,
- there is a need for flexibility in order to take into account the interests of small businesses.

#### 44. Official certification

Within the EU, where there is free circulation of goods, there is no need to provide for consignments of feed and food to be systematically accompanied by official certificates issued by the competent authority.

Two areas can be identified however where official certification can be envisaged: (a) in exceptional circumstances when a feed or food emergency occurs within the EU, and (b) in order to obtain confirmation from the authorities in exporting third countries that the goods comply with the EU standards or with standards equivalent thereto.

In order to cover these areas the proposal provides for a procedure for specifying the cases and conditions under which official certification must be ensured.

### ***Reference laboratories***

45. A number of Community Reference Laboratories (CRLs) have been established under Community legislation in force. They are operating with Community financial support. These laboratories have an important role in ensuring a high level of consumer protection. They must provide the national reference laboratories, for example, with details of analytical methods, organise comparative testing, co-ordinate within their area of competence the practical and scientific activities needed to obtain new analytical methods, conduct training courses and provide technical assistance to the Commission. CRLs exist at present for residue testing (four laboratories), milk testing, the quantification of biotoxins in molluscs, for testing molluscan shellfish for the absence of harmful viruses, for the control of zoonoses (salmonella) and for transmissible spongiform encephalopathies (TSEs).

The present proposals lays down procedures to ensure that these laboratories can continue their work and for establishing new laboratories should the need arise.

For each CRL, a national reference laboratory must be established in each Member State. Such laboratories function as the point of communication between the CRL and all the official laboratories in the Member States. The national reference laboratories play therefore an important role in ensuring that a uniform level with regard to analytical results of official samples is achieved.

### ***Mutual assistance***

46. Mutual assistance between the controlling authorities of the Member States is an essential element of Community legislation. It must ensure effective co-ordination where action is required by more than one Member State (e.g. feed and food emergencies or non-compliance that affect two or more Member States).

Although this aspect is covered in the legislation affecting the different sectors concerned, it is conceived in different ways resulting in unnecessary differences. The present proposal fixes a uniform system based on the following principles:

- (a) Member States shall designate a liaison body the role of which shall be to assist and co-ordinate communication, transmission and reception of requests for assistance.
- (b) Upon receiving a reasoned request, the liaison body shall contact the relevant authorities who shall ensure that the requesting party is provided with all necessary information and documents enabling it to verify compliance with feed and food law.
- (c) If necessary, the different parties shall seek together ways and means of remedying the situation.

The procedure applies to the exchange of all information, except that which cannot be released because of it being the subject of legal proceedings.

### ***National control plans***

47. As set out above, the proposal provides for the establishment of national control plans that set out the national control system and activities in a global and comprehensive way. These plans will have to be developed along the lines that are contained in guidelines to be established by the Commission in consultation with the Member States.
48. The Member States are requested to report annually on the results of the controls that have been carried out the previous year. If necessary, the control plans must be adapted in function of these results. The Commission will then, on a regular basis, audit the Member States on the basis of their updated plans.

### ***Community activities***

49. Community controls in the Member States

Until now, Community controls in the Member States were organised in function of the mandates the Commission has in the different sectoral Directives. This system has not always permitted to evaluate Member State control systems in a global way.

The creation of a single legal basis with the present proposal and the establishment of control plans will allow the Community control services to perform a general audit of the Member States' control systems globally. These audits will be carried out globally in order to verify the continuous achievement of the required level of control by the competent services in the Member States. If needed, these can be supplemented by more specific audits and inspections for a particular sector or problem.

50. Community controls in third countries

The volume of imported feed and food is substantial. Given the available resources, it is excluded that all of the operators in third countries involved in feed and food exports are individually controlled in a systematic way by FVO inspectors. The proposal therefore establishes a system that obliges the controlling authorities in third countries to guarantee that feed and food that is exported to the EU complies with EU feed and food law or with requirements that are judged equivalent to those.

For that purpose, the proposal requires third countries to have a control plan available, similar to those foreseen for Member States, in respect of the products they export to the EU. These plans will form the basis for subsequent Commission audits and inspections that will be carried out within a multidisciplinary framework covering the main sectors exporting to the EU. Where necessary more specific inspections and audits of particular sectors can be carried by the Community control teams. The same principles shall apply to live animals and plants.

51. Third country controls in the Community

In the same way as the FVO is entitled to perform controls in third countries to verify compliance or equivalence of the third requirements with EU feed and food law, third country authorities are entitled to organise controls in the Member States. Experience has shown that it is beneficial in some cases to ensure that representatives of the FVO accompany the third country teams that visit Member States. These representatives can assist Member States by providing information and data that are available at Community level and that may be useful in the context of the third country control carried out. The present proposal provides for a procedure to ensure such assistance.

*The training of control officials*

52. The integrated and global approach towards feed and food safety requires high levels of competence and expertise from the controlling authorities: they need to have a broad knowledge of different hazards (chemical, biological and physical) that can occur along the feed and food chain. They must also understand the mechanisms of the market in which ingredients for composite products can be obtained from different sources. At the same time, they need to be informed about very specific problems that are inherent to specific production methods. They must be able to identify non-compliance with feed and food safety requirements and to detect fraudulent practices.

Modern control techniques require feed and food control officials to be highly skilled so that controls are efficient, objective and adequate. This is in particular the case where the performance of hazard analysis and control techniques applied by food operators must be assessed.

Control of feed and food production and marketing requires therefore a multidisciplinary approach. Feed and food inspectors will need continuing training and updating of their knowledge. It is essential that the necessary legal provisions are made to facilitate such training. The present proposal therefore requires the establishment of proper training programmes both at national and Community level.

In this context, special attention has been paid to the organisation of training programmes at Community level and provision is made for organising such training. It must be ensured for example that the assessment of the implementation of the HACCP principles and the decisions that are subsequently taken by the assessor reflect an approach that is based on a standard procedure that applies in a uniform way in all Member States. The organisation of training courses is left to a future decision, but a possibility could be the establishment of a training centre under the aegis of the Commission, within the limits of the human and financial resources available to it. Leading experts in the area of feed and food controls and the different control techniques could be invited. Control officials from the Member States, but also from third countries and in particular from developing countries could be invited to follow the courses.



## ***Enforcement of feed and food law***

### 53. National enforcement measures

In order to guarantee and maintain a high level of public health and consumer protection, adequate enforcement measures must be available to the competent authorities and effectively used by them in order to tackle non-compliance with feed and food law.

The responsibility for implementing and enforcing community legislation lies primarily with the Member States. According to Article 10 of the EC Treaty, Member States must take all measures necessary to guarantee the application and effectiveness of Community law. Such measures include, in any event, effective proportionate and dissuasive penalties (judgement of the Court of 10 July 1990 in case C-326/88). Such measures may consist of administrative measures or criminal sanctions to be imposed by the competent authorities in the Member States.

### 54. Administrative enforcement measures

Administrative enforcement measures are to a greater or lesser extent spelled out in certain Community acts such as the veterinary legislation (Directives 89/662/EEC and 97/78/EEC), the feedingstuffs legislation (Article 13 of Directive 95/53/EEC) and the food legislation (Article 10 of Directive 89/397/EEC). In these Community acts, these measures extend from a simple requirement “to take the requisite measures” (Article 10 of Directive 89/397/EEC) to take action at the level of the products (withdrawal from the market, destruction, product sanitation etc.) or of the food business concerned (taking of corrective action, temporary or permanent closure of a food business). National legislation may also, of course, provide for further, different administrative sanctions.

Such administrative measures, having direct effect on operators, are a powerful tool and, if properly used, also have an important dissuasive effect. The present proposal therefore re-confirms the need for the Member States to take administrative enforcement measures. It also aims to ensure that a requirement to that effect applies to all feed and food businesses at all levels of the feed and food chain.

### 55. Criminal sanctions

There is a lack of certainty in Community law with regard to the Member States’ obligation to provide criminal penalties. In addition, there is no minimum standard with regard to the constituent elements of offences to the detriment of feed and food safety.

In many cases, only criminal penalties will provide a strong dissuasive effect. The provision for such sanctions demonstrates social disapproval of a qualitatively different nature compared to administrative enforcement measures. There is also an additional guarantee of impartiality of investigating authorities, because other authorities than those who have granted exploitation licences will be involved in a criminal investigation.

Therefore, a common minimum set of serious offences under EU feed and food law, or under rules adopted by the Member States in order to comply with such law, for which Member States are required to impose criminal penalties, must be established. This takes the form of a list of serious offences against Community feed and food law committed intentionally or through serious negligence, for which Member States must provide for criminal sanctions. These are the offences that could threaten most feed and food safety and therefore public health.

The proposal aims to set a minimum standard of feed and food safety protection, including animal health and animals welfare, through criminal law. It does not cover all activities regulated by Community feed and food law, but only important offences that may lead to the placing on the market of feed or food that are unsafe in the sense of Articles 14 and 15 of Regulation (EC) No 178/2002.

The offences listed in the present proposal are offences that may eventually lead to the placing on the market of unsafe feed or food. Considering the seriousness of the threat they pose to public health, it is important that these offences are made punishable "per se", whether they eventually lead or not to the placing on the market of unsafe feed or food.

Member States may, of course, establish additional offences and/or provide for different additional types of enforcement measures and penalties. For instance, they may consider to provide for disqualification of natural persons from engaging in an activity of founding or directing a company or other form of enterprise.

The nature of the sanctions can only be determined under national law by the Member States. For the same reason, the Regulation does not regulate questions of criminal investigations and prosecutions, nor questions of criminal procedure. It is up to the authorities in the Member States to decide whether the offences listed in the Regulation must be prosecuted in any case or whether the competent authority may refrain from providing for criminal penalties in minor cases where the impact on feed and food safety is insignificant.

As to natural persons, the proposal would oblige Member States to provide for effective, dissuasive and proportionate criminal penalties against the defined breaches of Community law. In order to ensure a high level of feed and food safety, it is important also to include sanctions against complicity (participation and instigation) in the offences that are listed. In serious cases, Member States would have to provide for the possibility of imprisonment but would have a broad discretion in defining such serious cases.

As to legal persons, it is essential for effective enforcement of Community feed and food law that they can be held liable and that sanctions against legal persons are taken. However, for some Member States it might be difficult to provide for criminal sanctions against legal persons without changing fundamental principles of their national legal systems. Therefore, Member States would be able to foresee sanctions other than those of a criminal nature as long as they are effective, proportionate and dissuasive. For instance, they could provide for non-criminal fines, judicial supervision, judicial winding-up orders or exclusion from entitlement to public benefits or aid.

The Commission believes that such a measure is justified in order to ensure that feed and food safety rules are respected throughout the EU by means of a harmonised approach in all Member States. This objective is best achieved by a Community approach in accordance with Article 5, paragraph 2 of the EC Treaty.

56. Community safeguard measures

The procedure referred to in Article 226 of the Treaty (infraction procedure) offers a tool for the Commission to proceed against Member States that fail to implement Community law.

Although this procedure is a powerful instrument, the time constraints imposed on it render it impractical where a failure to implement Community law requires prompt action to safeguard feed and food safety. The safeguard measure adopted under Regulation (EC) No 178/2002 allows the taking of measures only where there is evidence that feed or food that is placed on the market is likely to constitute a serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned. This measure does not allow the Commission to take action when there is clear evidence that a Member State's control system shows serious shortcomings and is inadequate to implement Community law properly thus possibly compromising feed and food safety in a more general way.

The present proposal adds a new dimension to the existing safeguard measure in Regulation (EC) No 178/2002. It introduces a tool that would allow the Commission to take measures when there is proof that a Member State's control system is inadequate. These may include the suspension, for the Member State in question, of the placing on the market of certain feed or foodstuffs, laying down special conditions for certain feed or foodstuffs or the taking of any other interim measure required to ensure protection of human health, animal health and animal welfare.

***Special and Differential treatment***

57. Article 10 of the agreement on the application of Sanitary and Phytosanitary Measures (SPS Code) adopted by the World Trade Organisation lays down that, in the preparation of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members.

The EU imports large quantities of feed and food from developing countries. These countries fall within the same general requirements laid down in Regulation (EC) No 178/2002 that third countries must ensure that feed or food exported towards the EU complies with the relevant requirements of feed and food law, or with conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with the requirements contained therein.

Whilst it is not possible to grant derogations on the health standards that are established under Community feed and food law, it is possible to consider a number of activities to assist developing countries to provide the requisite guarantees. The proposal therefore introduces procedures to that effect. These concern, for example, a phased introduction of the requirement to present a control programme, assistance with the establishment of a control programme, the promotion of twinning projects between developing countries and Member States, sending Community experts on the spot so as to assist in the organisation of official controls.

### ***Financial support***

58. The proposal includes a number of activities that require a financial input from the Community. These are in particular:

- the designation of new reference laboratories;
- the creation of a database on country profiles;
- the participation of national experts in FVO missions;
- the standardisation of methods of analysis and sampling, in particular by the establishment of criteria based performance standards;
- the support for developing countries;
- the creation of training facilities for control staff of the Member State and third countries;
- feed and food safety studies, conferences and publications.

At the moment, feed and food safety controls account for about € 3 Mio in the annual Community budget. Implementing all of the above proposed measures would increase this amount to approximately € 16 Mio annually or € 95 Mio over six years. € 7.5 Mio out of those € 16 Mio are foreseen for training of control officials from Member States, Candidate Countries and third countries on the (new) EU feed and food control measures.

This action must be considered as **the completion of action 79 of the White Paper on Food Safety** which aims to provide for a legal basis to ensure adequate Community financial support of actions necessary to enhance food safety.

### ***Implementing measures***

59. The proposed rules cover an extensive area including official controls of all feed and food at all stages of the food chain within the Community or presented at the Community border for import. These rules cannot cover all the details that characterise official controls. They must therefore be considered as a framework containing the essential requirements on the basis of which more detailed rules to ensure uniform implementation by the Member States can be developed if necessary. It is for that reason that provision is made for the development of such implementing rules in accordance with the procedure provided for in Article 5 of Council Decision 1999/468/EC.

### ***Scope of the proposed Regulation***

60. The principles set out in this proposal are generally applicable to all feed and food law, and to animal health and animal welfare legislation. However, bearing in mind that for certain areas of food law there are already comprehensive and specific control measures in place, the proposed Regulation should therefore take account of this *acquis*.

The scope of the proposal does therefore not extend to the verification of compliance with the rules on the common organisation of the markets of agricultural products (arable crops, wine, olive oil, fruit and vegetables, hops, milk and milk products, beef and veal, sheepmeat and goatmeat and honey) for which a well established and specific control system is already in place. In addition, the purpose and objectives of the proposal are different from the purpose and objectives of the controls that apply to the common organisation of the agricultural markets.

The following contain specific measures for the verification of compliance with the requirements contained therein:

- Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community<sup>14</sup>,
- Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs<sup>15</sup>,
- Council Regulation (EC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs<sup>16</sup>, and
- Council Regulation (EC) No 2082/92 of 14 July 1992 on certificates of specific character for agricultural products and foodstuffs<sup>17</sup>.

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<sup>14</sup> OJ L 169, 10.7.2000, p. 1.

<sup>15</sup> OJ L 198, 22.7.1991, p. 1.

<sup>16</sup> OJ L 208, 24.7.1992, p. 1.

<sup>17</sup> OJ L 208, 24.7.0992, p. 9.

This proposal should be flexible enough so as to take account of the specificity of these areas.

### *The structure of future Community rules on feed and food controls*

61. The proposal joined herewith provides for the general rules applicable to the official controls of all feed and food at any stage of production, processing and distribution, whether produced within the EU, exported to or imported from third countries. In addition to these general rules, it must be envisaged that particular problems need particular solutions. There must therefore be room for more specific control measures in order to maintain a high level of protection. Within this context it is clear that existing more specific control rules must be kept in place. These are for example:
- Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC<sup>18</sup>,
  - Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC<sup>19</sup>,
  - Regulation (EC) N° .../... 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<sup>20</sup>,
  - Regulation (EC) N° 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies<sup>21</sup>,
  - Regulation (EC) N° .../... of the European Parliament and of the Council on the control of salmonella and other food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC<sup>22</sup>,
  - Council Directives 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals<sup>23</sup> and 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables<sup>24</sup> and the implementing rules resulting therefrom,

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<sup>18</sup> OJ L 125, 23.5.1996, p. 3.

<sup>19</sup> OJ L 125, 23.5.1996, p. 10.

<sup>20</sup> COM (2000) 438, doc. 2000/0180 (COD).

<sup>21</sup> OJ L 147, 31.5.2001, p. 1.

<sup>22</sup> COM (2001).

<sup>23</sup> OJ L 221, 7.8.1986, p. 37.

<sup>24</sup> OJ L 350, 14.12.1990, p. 71.

- Commission Directives 92/1 of 13 January 1992 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption<sup>25</sup> and 92/2 of 13 January 1992 laying down the sampling procedure and the Community method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption<sup>26</sup>.

Likewise, it is not excluded that in future new rules must be developed where special problems arise. In that event, proposals will be made to that effect.

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<sup>25</sup> OJ L 34, 11.2.1992, p. 29.

<sup>26</sup> OJ L 34, 11.2.1992, p. 30.

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of**

**on official feed and food controls**

**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37, 95 and 152(4)(b) thereof,

Having regard to the proposal from the Commission<sup>1</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>2</sup>,

Having regard to the opinion of the Committee of the Regions<sup>3</sup>

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

- (1) Feed and Food should be safe and wholesome. Community legislation comprises a set of rules to ensure that this objective is attained. These rules extend to the production and the placing on the market of both feed and food.
- (2) The basic rules with regard to feed and food law are laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety<sup>4</sup>.
- (3) In addition to those basic rules, more specific feed law and food law cover different areas such as animal nutrition including medicated feedingstuffs, feed and food hygiene, zoonoses, animal by-products, residues and contaminants, control and eradication of animal diseases with a public health impact, feed and food labelling, pesticides, feed and food additives, vitamins, mineral salts, trace elements and other additives, materials in contact with food, quality and compositional requirements, drinking water, ionisation, novel foods and genetically modified organisms (GMOs).

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<sup>1</sup> OJ C , , p. .

<sup>2</sup> OJ C , , p. .

<sup>3</sup> OJ C [...], [...], p. [...].

<sup>4</sup> OJ L 31, 1.2.2002, p. 1.



- (4) Animal health and animal welfare are also important factors that contribute to the quality and safety of food.
- (5) Community feed and food law is based on the principle that feed and food business operators at all stages of production, processing and distribution within the businesses under their control are responsible for ensuring that feed and food satisfy the requirements of feed and food law which are relevant to their activities.
- (6) The Member States should enforce feed and food law and monitor and verify that the relevant requirements of food law are fulfilled by feed and food business operators at all stages of production, processing and distribution. Official controls should be organised for that purpose.
- (7) A Community framework should be established for the organisation of official controls covering all the areas of feed and food law, including animal health and welfare.
- (8) As a general rule this Community framework should not include official controls with regard to organisms harmful to plants and plant products since these controls are already adequately covered by Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community<sup>5</sup>. Certain aspects of this Regulation should however also apply to the plant health sector and in particular those concerning the establishment of national control plans and Community inspections within the Member States and in third countries. It is therefore appropriate to amend Directive 2000/29/EC accordingly.
- (9) Council Regulations (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs<sup>6</sup>, (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs<sup>7</sup>, and (EEC) No 2082/92 of 14 July 1992 on certificates of specific character for agricultural products and foodstuffs<sup>8</sup> contain specific measures for the verification of compliance with the requirements contained therein. These requirements of this Regulation should be flexible enough so as to take account of the specificity of these areas.
- (10) For the verification of compliance with the rules on the common organisation of the markets of agricultural products (arable crops, wine, olive oil, fruit and vegetables, hops, milk and milk products, beef and veal, sheepmeat and goatmeat and honey) a well established and specific control system is already in place. This Regulation should therefore not apply to these areas, all the more since the objectives of this Regulation differ from the objectives pursued by the control mechanisms for the common organisation of the markets of agricultural products.

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<sup>5</sup> OJ L 169, 10.7.2000, p. 1. Directive as last amended by Commission Directive 2002/36/EC (OJ L 116, 3.5.2002, p. 16).

<sup>6</sup> OJ, L 198, 22.7.1991, p. 1. Regulation as last amended by Commission Regulation (EC) No 436/2001 (OJ L 63, 3.3.2001, p. 16).

<sup>7</sup> OJ L 208, 24.7.1992, p. 1. Regulation as last amended by Commission Regulation (EC) No 2796/2000 (OJ L 324, 21.12.2000, p. 26).

<sup>8</sup> OJ L 208, 24.7.1992, p. 9. Regulation as last amended by the Act of accession of Austria, Finland and Sweden.

- (11) The competent authorities for performing official controls should meet a number of operational criteria so as to ensure their impartiality and effectiveness. They should have a sufficient number of suitably qualified and experienced staff and possess adequate facilities and equipment to carry out their duties properly.
- (12) The official controls should be carried out using appropriate techniques developed for that purpose, including routine surveillance checks and more intensive controls such as inspections, verifications, audits, sampling and the testing of samples. The correct implementation of those techniques requires appropriate training of the staff performing official controls. Training is also required in order to ensure that the competent authorities take decisions in a uniform way, in particular with regard to the implementation of the Hazard Analysis and Critical Control Points (HACCP) principles.
- (13) The frequency of official controls should be regular and proportionate to the risk, taking into account the results of the checks carried out by feed and food business operators under HACCP based control programmes or Quality Assurance Programmes, where these are designed to meet requirements of feed and food law. Where necessary, ad hoc controls must be carried out in case of suspicion of non-compliance with feed and food law.
- (14) Official controls should take place on the basis of documented procedures so as to ensure that these controls are carried out uniformly and are of consistent high quality.
- (15) The competent authorities should ensure that where different control units are involved in carrying out official controls, appropriate co-ordination procedures are in place and effectively implemented.
- (16) The competent authorities should also ensure that, where the competence to carry out official controls has been delegated from the central level to a regional or local level, there is effective and efficient co-ordination between the central level and that regional or local level.
- (17) Laboratories involved in the analysis of official samples should work in accordance with internationally approved procedures or criteria based performance standards and use methods of analysis that have as far as possible been validated.
- (18) The designation of Community and national reference laboratories should contribute to a high quality and uniformity of analytical results. This objective can be achieved by activities such as the application of validated analytical methods, ensuring that reference materials are available, the organisation of comparative testing and the training of staff from laboratories.
- (19) The activities of reference laboratories should cover all the areas of feed and food law, in particular those areas where there is a need for precise analytical and diagnostic results. This includes animal health given the importance of this sector with regard to feed and food law.

- (20) For a number of activities related to official controls, the European Committee for Standardisation (CEN) has developed European Standards (EN Standards) appropriate for the purpose of this Regulation. These EN Standards relate in particular to the operation and assessment of testing laboratories and to the operation and accreditation of control bodies. International standards have also been elaborated by the International Organisation for Standardisation (ISO) and the International Union of Pure and Applied Chemistry (IUPAC). These Standards might, in certain well defined cases, be appropriate for the purposes of this Regulation, taking into account that performance criteria are laid down in feed and food law in order to ensure flexibility and cost effectiveness.
- (21) Provision should be made for delegating competence for performing specific control tasks from the competent authority to a non-governmental body, and for the conditions under which such delegation can take place.
- (22) Appropriate procedures should be available for the co-operation of the competent authorities in and between the Member States, in particular when official controls reveal that feed and food problems extend to more than one Member State. In order to facilitate such co-operation, Member States should designate one or more liaison bodies with the role of co-ordinating the transmission and reception of requests for assistance.
- (23) In accordance with Article 50 of Regulation 178/2002, the Member States shall inform the Commission where information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed is available.
- (24) It is important to create uniform procedures for the control of feed and food from third countries introduced into the territory of the Community, taking into account that harmonised import procedures are already established for:
- food of animal origin by virtue of Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries<sup>9</sup>;
  - for live animals by virtue of Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675<sup>10</sup>.

These procedures function properly and should be maintained.

- (25) The checks on feed and food from third countries referred to in Directive 97/78/EEC are limited to veterinary aspects. It is necessary to supplement these checks with official controls on aspects that are not covered by veterinary checks, such as those on additives, labelling, traceability, irradiation of food and materials in contact with food.

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<sup>9</sup> OJ L 24, 30.1.1998, p. 9.

<sup>10</sup> OJ L 268, 24.9.1991, p. 56. Directive as last amended by Directive 96/43/EC (OJ L 162, 1.7.1996, p. 1).

- (26) Community legislation also provides for procedures for the control of imported feed by virtue of Council Directive 95/53/EC of 25 October 1995 fixing the principles governing the organisation of official inspections in the field of animal nutrition<sup>11</sup>. That Directive contains principles and procedures that must be applied by the Member States when releasing imported feed for free circulation.
- (27) It is appropriate to establish Community rules in order to ensure that feed and food from third countries is submitted to official controls before release for free circulation in the Community. Special attention should be paid to import controls of feed and food for which there may be an increased risk of contamination.
- (28) Provision should also be made for the organisation of official controls of feed and food that is introduced into the territory of the Community under customs procedures other than free circulation, and in particular those introduced under the customs procedures referred to in points (b) to (f) of article 4(16) of Regulation (EC) No 2913/92 of 12 October 1992 establishing the Community Customs Code<sup>12</sup>, as well as their entry into a free zone or free warehouse. This includes the introduction of feed and food from third countries by passengers of international means of transport and through parcels sent by mail.
- (29) For the purpose of official controls on feed and food, it is necessary to define the territory of the Community in which the rules apply in order to ensure that feed and food that is introduced in this territory is submitted to the controls prescribed by this Regulation. This territory is not necessarily the same as provided for in Article 299 of the Treaty, or as defined in Article 3 of Council Regulation (EEC) No 2913/92.
- (30) In order to ensure a more efficient organisation of the official controls on feed and food from third countries and in order to facilitate commercial flows, it may be necessary to designate specific points of entry for feed and food from third countries into the territory of the Community. Likewise, it may be necessary to require advance notice of the arrival of goods at the territory of the Community.
- (31) In establishing rules on the official controls of feed and food from third countries, it should be ensured that the competent authorities and the customs services work together, taking into account that rules to that effect already exist in Council Regulation (EEC) No 339/93 of 18 February 1993 on checks for conformity with the rules on product safety in the case of products from third countries<sup>13</sup>.
- (32) Adequate financial resources should be available for organising official controls. Where for that purpose fees are imposed on feed and food business operators, common principles should apply. It is appropriate therefore to lay down the criteria for setting the level of inspection fees. With regard to fees applicable for import controls, it is appropriate to establish directly the rates for main import items with a view to ensure their uniform application and to avoid trade distortions.

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<sup>11</sup> OJ L 265, 8.11.1995, p. 17. Directive as last amended by Directive 2001/46/EC (OJ L 234, 1.9.2001, p. 55).

<sup>12</sup> OJ L 311, 12.12.2000, p. 17.

<sup>13</sup> OJ L 40, 17.2.1993, p. 1.

- (33) Community food law and feed law provide for the registration or approval of certain feed and food businesses by the competent authority. This is in particular the case in:
- Regulation (EC) No .../... of the European Parliament and of the Council on the hygiene of foodstuffs<sup>14</sup>;
  - Regulation (EC) No .../... of the European Parliament and of the Council on the laying down specific hygiene rules for food of animal origin<sup>15</sup>;
  - Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector and amending Directives 70/524/EEC, 74/63/EEC, 79/373/EEC and 82/471/EEC<sup>16</sup>.

Procedures should be put in place in order to ensure that registration and approval of feed and food businesses are carried out in an efficient and transparent way.

- (34) In order to have a global and uniform approach with regard to official feed and food controls, Member States should establish and implement national control plans in accordance with broad guidelines elaborated at Community level. These guidelines should promote coherent national strategies, and identify risk-based priorities and the most effective control procedures. A Community strategy should take a comprehensive, integrated approach to the operation of controls.
- (35) The national control plans should cover food law and feed law, and the legislation on animal health and animal welfare.
- (36) The national control plans should establish a solid basis for the Commission inspection services to carry out controls in the Member States. The control plans should enable the Commission inspection services to verify whether the official controls in the Member States are organised in accordance with the criteria laid down in the this Regulation. Where appropriate and in particular where the audit of the Member States against the national control plans shows weaknesses or failures, detailed inspections and audits should be carried out.
- (37) Member States should be required to present an annual report to the Commission with information on the implementation of the national control plans. This report should provide the results of the official controls and audits carried out during the previous year and, where necessary, an update of the initial control plan in response to these results.
- (38) Community controls in the Member States should allow the Commission control services to verify whether feed and food law, and the legislation on animal health and animal welfare are implemented in a uniform and correct way throughout the Community.

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<sup>14</sup> OJ L

<sup>15</sup> OJ L

<sup>16</sup> OJ L 332, 30.12.1995, p. 5. Directive as last amended by Directive 1999/20/EC (OJ L 80, 25.3.1999, p. 20).

- (39) Community controls in third countries are required in order to verify compliance or equivalence with Community feed and food law as well as with the legislation on animal health. Third countries may also be requested to establish control plans similar to those intended for Member States, in respect of the feed and food exported by them. These plans, which should be established on the basis of Community guidelines, should form the basis for subsequent Commission controls, which should be carried out within a multidisciplinary framework covering the main sectors exporting to the Community. This evolution should allow a simplification of the current regime, enhance effective control co-operation, and consequently facilitate trade flows.
- (40) In order to ensure that imported feed and food comply with or are equivalent to Community food law and feed law, it is necessary to establish procedures that allow the definition of import conditions and certification requirements as appropriate.
- (41) Breaches of feed and food law may constitute a threat to human health, animal health, and animal welfare. Such breaches should therefore be subject to effective, dissuasive and proportionate measures at national level throughout the Community.
- (42) Such measures should include administrative action by the competent authorities in the Member States who should have procedures in place for that purpose. The advantage of such procedures is that quick action can be undertaken in order to restore the situation.
- (43) Experience has shown that the existing systems of sanctions have not always been sufficient to achieve compliance with Community law. Such compliance can and should be strengthened by the application of criminal penalties, which demonstrate a social disapproval of a qualitatively different nature compared to administrative measures or a compensation mechanism under civil law.
- (44) Entrusting to judicial authorities, rather than to administrative authorities the task of imposing penalties, entails giving responsibility for investigating and enforcing the respect of animal health rules and feed and food law to authorities which are independent of those which grant exploitation licences.
- (45) Certain offences should therefore be considered criminal offences when they are committed intentionally or through negligence, and should be subject to criminal penalties, involving in serious cases deprivation of liberty.
- (46) Legal persons should also be subject to effective, dissuasive and proportionate penalties, because breaches of Community law to a large extent are committed in the interest of legal persons or for their benefit.
- (47) Feed and food business operators should have a right to appeal against the decisions taken by the competent authority as a result of the official controls, and be informed about such right.
- (48) It is appropriate to take account of the special needs of developing countries, and in particular of the least-developed countries, and to introduce measures to that effect.

(49) The rules contained in this Regulation underpin the integrated and horizontal approach necessary to implement a coherent control policy on feed and food safety. There must be room however to develop specific control rules where required. Likewise, more specific rules existing in the area of feed and food controls should be kept in place. These include in particular the following acts:

- Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC<sup>17</sup>,
- Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC<sup>18</sup>,
- Regulation (EC) No .../... of the European Parliament and of the Council of [...] laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption<sup>19</sup>,
- Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies<sup>20</sup>,
- Regulation (EC) No.../... of the European Parliament and of the Council of [...] on the control of salmonella and other food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC<sup>21</sup>,
- Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals<sup>22</sup>,
- Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables<sup>23</sup> and the implementing rules resulting therefrom,
- Commission Directive 92/1/EEC of 13 January 1992 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption<sup>24</sup>,

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<sup>17</sup> OJ L 125, 23.5.1996, p. 3.

<sup>18</sup> OJ L 125, 23.5.1996, p. 10.

<sup>19</sup> COM (2000) 438, doc. 2000/0180 (COD).

<sup>20</sup> OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 270/2002 (OJ L 45, 15.2.2002, p. 24).

<sup>21</sup> COM (2001)452 final-2001/0177 (COD).

<sup>22</sup> OJ L 221, 7.8.1986, p. 37. Directive as last amended by Commission Directive 2002/42/EC (OJ L 134, 22.3.2002, p. 29).

<sup>23</sup> OJ L 350, 14.12.1990, p. 71. Directive as last amended by Directive 2002/42/EC.

<sup>24</sup> OJ L 34, 11.2.1992, p. 28.

- Commission Directive 92/2/EEC of 13 January 1992 laying down the sampling procedure and the Community method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption<sup>25</sup>.
- (50) This Regulation covers areas that are already covered in certain Directives in force at present. It is appropriate therefore to repeal in particular the following acts on feed and food controls and to replace them by the rules of this Regulation:
- Council Directive 70/373/EEC of 20 July 1970 on the introduction of Community methods of sampling and analysis for the official control of feedingstuffs<sup>26</sup>;
  - Council Directive 85/591/EEC of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption<sup>27</sup>;
  - Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs<sup>28</sup>;
  - Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs<sup>29</sup>;
  - Council Directive 95/53/EC of 25 October 1995 fixing the principles governing the organisation of official inspections in the field of animal nutrition<sup>30</sup>;
  - Council Directive 96/43/EC of 26 June 1996 amending and consolidating Directive 85/73/EEC in order to ensure financing of veterinary inspections and controls on live animals and certain animal products and amending Directives 90/675/EEC and 91/496/EEC<sup>31</sup>;
  - Council Decision 98/728/EC of 14 December 1998 concerning a Community system for fees in the animal feed sector<sup>32</sup>;

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<sup>25</sup> OJ L 34, 11.2.1992, p. 30.

<sup>26</sup> OJ L 170, 3.8.1970, p. 2. Directive as last amended by Regulation (EEC) No 3768/85 (OJ L 362, 31.12.1985, p. 8).

<sup>27</sup> OJ L 372, 31.12.1985, p. 50.

<sup>28</sup> OJ L 186, 30.6.1989, p. 23.

<sup>29</sup> OJ L 290, 24.11.1993, p. 14.

<sup>30</sup> OJ L 265, 8.11.1995, p. 17. Directive as last amended by Directive 2001/46/EC of the European Parliament and of the Council (OJ L 234, 1.9.2001, p. 55).

<sup>31</sup> OJ L 162, 1.7.1996, p. 1.

<sup>32</sup> OJ L 346, 22.12.1998, p. 51.



- (51) The following rules should be amended in the light of this Regulation:
- Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market<sup>33</sup>;
  - Directive 96/23/EC;
  - Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries<sup>34</sup>;
  - Directive 2000/29/EC.
- (52) In accordance with the principles of subsidiarity and proportionality as set out in Article 5 of the Treaty, the objectives of the proposed action to ensure a harmonised approach with regard to official feed and food controls, cannot be sufficiently achieved by the Member States since such harmonisation requires a Community approach, and can therefore, by reason of its complexity, its trans-border character and, with regard to feed and food imports, its international character, be better achieved by the Community. This Regulation confines itself to the minimum required in order to achieve those objectives and does not go beyond what is necessary for that purpose.
- (53) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>35</sup>,

HAVE ADOPTED THIS REGULATION:

## **TITLE I**

### **SUBJECT MATTER, SCOPE AND DEFINITIONS**

#### *Article 1*

##### *Subject matter and scope*

1. The purpose of this Regulation is to lay down the general rules for the performance of official controls as defined in Article 2(1). This Regulation aims to:
  - (a) prevent risks to humans and animals, either directly or through the environment;
  - (b) protect consumer interests, including those with regard to consumer information.

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<sup>33</sup> OJ L 395, 30.12.1989, p. 13. Directive as last amended by Directive 96/23/EC (OJ L 13, 16.1.1997, p. 28).

<sup>34</sup> OJ L 24, 30.1.1998, p. 9.

<sup>35</sup> OJ L 184, 17.7.1999, p. 23.

2. This Regulation shall not apply to official controls for the verification of compliance with the rules on common market organisations of agricultural products.

*Article 2*  
*Definitions*

For the purposes of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 shall apply.

The following definitions shall also apply:

1. "official control" means any form of control performed by the competent authority or by the Community for the verification of compliance with feed and food law, including animal health and animal welfare rules;
2. "verification" means the confirmation by examination and provision of objective evidence that specified requirements have been fulfilled;
3. "feed law" means the laws, regulations and administrative provisions governing feed in general and feed safety in particular; it covers any stage of production, processing, distribution and use of feed;
4. "competent authority" means the authority of a Member State or a third country designated to carry out official controls;
5. "control body" means a non-governmental body to which the competent authority has delegated certain control tasks;
6. "audit" means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives;
7. "inspection" means the examination of plants, animals, feed and food, of their processing, of feed and food businesses, of their management and production systems including finished product testing and feeding practices, and of the origin and destination of production inputs and outputs, in order to verify that all these items conform to legal requirements;
8. "official certification" means the procedure by which the competent authority or control bodies provide written or equivalent assurance that feed and food or feed and food businesses conform to requirements;
9. "import" means the release for free circulation of feed and food and the intention to release feed or food for free circulation within the meaning of Article 79 of Regulation (EEC) No 2913/92 in one of the territories referred to in Annex I;
10. "introduction" means import as defined in point 9 above, and the placing of goods under the customs procedures referred to in points (b) to (f) of article 4(16) of Regulation (EEC) No 2913/92, as well as their entry into a free zone or free warehouse;

11. "documentary check" means the examination of the commercial documents and where appropriate the documents required under feed and food law that are accompanying the consignment;
12. "identity check" means a check by visual inspection to ensure that the documents accompanying the consignment tally with the labelling and the content of the consignment;
13. "physical check" means a check on the feed or food itself;
14. "control plan" means a plan established by the competent authority containing general information on the structure and organisation of the feed and food control systems operated by it.

## **TITLE II**

### **OFFICIAL CONTROLS BY MEMBER STATES**

#### **Chapter I: General obligations**

##### *Article 3*

##### *General obligations with regard to the organisation of official controls*

1. Member States shall organise official controls on a regular basis and with a frequency appropriate to achieve the objectives of the present Regulation, taking into account:
  - (a) identified risks associated with feed and food, feed and food businesses, the use of feed or food or any process, material, substance, activity or operation that may influence feed and food safety;
  - (b) the experience and knowledge gained from previous controls;
  - (c) the reliability of the controls already carried out by feed and food business operators;
  - (d) suspicion of possible non-compliance.
2. As a general rule, official controls shall be carried out without prior warning.
3. Official controls shall be carried out at any stage of production, processing and distribution of feed and food. They shall include controls on feed and food businesses, on the use of feed or food, on any process, material, substance, activity or operation applied to feed and food and, where relevant for achieving the objectives of this Regulation, on live animals and plants.
4. Feed and food intended for export outside the Community shall be controlled with the same care as feed and food intended for the Community market.

## Chapter II: The competent authorities

### *Article 4*

#### *Designation of competent authorities and operational criteria*

1. Member States shall designate the competent authorities responsible for the purposes and official controls set out in this Regulation.
2. The competent authorities shall meet the following criteria:
  - (a) they must be impartial and free from any conflict of interest;
  - (b) they must ensure the effectiveness and appropriateness of the official controls at all stages of feed and food production, processing and distribution;
  - (c) they must have, or have access to, an adequate laboratory capacity for testing and to a sufficient number of suitably qualified and experienced staff so that the official controls and control duties can be carried out efficiently and effectively;
  - (d) they must have appropriate and properly maintained facilities and equipment to ensure that staff can perform their control duties efficiently and effectively;
  - (e) they must have the legal powers to carry out official controls and to take the measures prescribed by this Regulation;
  - (f) they must have contingency plans in place and be prepared to operate such plans in case of emergencies.
3. Where a central competent authority has conferred the competence to carry out official controls to another authority or authorities, in particular those at regional or local level, there shall be effective and efficient co-ordination between or among the central competent authority and the authority or authorities to which that competence has been conferred.

The quality and uniformity of the controls shall be ensured at all levels at which the competent authorities are operating.
4. Where within a competent authority official control duties are given to different control units, efficient co-ordination and co-operation between these different units shall be ensured.
5. Audits shall be carried out to ensure that the competent authorities achieve the objectives of this Regulation. These audits shall be subject to independent scrutiny and shall be carried out in a transparent manner.
6. Detailed rules for the implementation of this Article may be adopted in accordance with the procedure referred to in Article 62(3), including for the accreditation of the competent authorities referred to in paragraph 1.

*Article 5*  
*Delegation of specific control tasks*

1. The competent authority may delegate specific control tasks to one or more control bodies. However, the activities referred to in Article 54 shall not be the subject of such a delegation.

A list of tasks that may or may not be delegated may be established in accordance with the procedure referred to in Article 62(3).

2. The competence for performing specific control tasks shall not be delegated unless the following criteria are met:
  - (a) there must be an accurate description of the tasks that can be carried out by the control body and of the conditions under which the delegated competence can be exercised;
  - (b) there must be proof that the control bodies :
    - (i) have the expertise, equipment and infrastructures required to carry out the tasks that have been assigned to them;
    - (ii) have a sufficient number of suitably qualified and experienced staff;
    - (iii) are impartial and free from any conflict of interest;
  - (c) it must be ensured that the control bodies work and are accredited in accordance with the European Standard EN 45004 "General criteria for the operation of various types of bodies performing inspection";
  - (d) the results of the controls carried out by control bodies shall be communicated to the competent authority on a regular basis and upon request of the latter; where the results of the controls show non-compliance or a suspicion thereof, the competent authority shall be informed immediately by the control bodies;
  - (e) the control bodies must regularly carry out internal audits in order to ensure their capacity to perform efficiently the tasks that have been assigned to them;
  - (f) there must be efficient co-ordination between the delegating competent authority and the control bodies;
3. The control bodies shall be subject to audits as necessary organised by the delegating competent authority. If as a result of an audit it appears that such bodies fail to perform the tasks that have been delegated to them, the delegation of competence may be withdrawn, and shall be withdrawn without delay in the absence of appropriate and timely remedies.

4. Any Member State wishing to delegate a specific control task to a control body shall notify the Commission and the other Member States. This notification shall provide detailed description of:
  - (a) the task to be delegated;
  - (b) the body to which the task will be delegated.

Member States shall have three months from the receipt of a notification to send written comments to the Commission. The Commission may – and, when it receives written comments from one or more Member States, shall – consult Member States within the committee referred to in Article 62(1). The Commission may decide, in accordance with the procedure referred to in Article 62(3), whether the measure may be implemented subject to, if necessary, appropriate amendments.

*Article 6*  
*Staff performing official controls*

1. Staff of the competent authority performing official controls shall have, for their area of competence, received appropriate training in order to undertake their duties competently and to ensure that official controls are carried out in a uniform way. This training shall cover as appropriate the areas referred to in Annex II, Chapter I.
2. Staff performing official controls shall be regularly kept up-to-date on all issues in their area of competence and shall receive additional training as necessary.

*Article 7*  
*Confidentiality*

Without prejudice to the need to protect public health, staff of the competent authority shall respect rules of confidentiality on information acquired when undertaking their duties and shall be bound by rules on professional secrecy laid down in national legislation.

*Article 8*  
*Control procedures and guidelines*

1. Official controls by the competent authority shall be carried out in accordance with documented procedures. This documentation shall contain information and instructions for staff performing official controls including *inter alia* the areas referred to in Annex II, Chapter II.
2. Specific control procedures and guidelines for controls may be determined in accordance with the procedure referred to in Article 62(2). These may include procedures for official controls on the implementation of the HACCP principles or of management systems operated by the feed and food businesses where these systems are designed to meet feed and food law requirements.

*Article 9*  
*Verification procedures and reports*

1. The competent authority shall have procedures in place for the verification of the efficiency and efficacy of its control system and for taking corrective action when needed.
2. The competent authority shall establish reports of the official controls that have been carried out. These reports shall at least include a description of the purpose of the official control, the control methods that have been applied, the results of the official controls and where appropriate the corrective action to be taken by the feed or food business concerned. These reports shall be submitted to those who have been the subject of the controls.

*Article 10*  
*Control activities, methods and techniques*

Official controls shall include the following activities:

- (a) The verification of the efficacy of the control systems put in place by feed and food business operators.
- (b) Inspection of feed and food businesses and their surroundings, premises, offices, equipment, installations, machinery as well as of feed and food.
- (c) Checks on the hygiene conditions in feed and food businesses.
- (d) Assessment of the procedures on good manufacturing practices (GMP), good hygiene practices (GHP) and HACCP, taking into account the use of guides established for that purpose.
- (e) Examination of written, documentary material and other records which may be relevant to the assessment of compliance with feed or food law.
- (f) Examination of any control and verification system set up by the undertaking and of the results obtained.
- (g) Interviews with the feed and food business operators and with the staff employed by feed and food businesses.
- (h) The reading of values recorded by measuring instruments installed by the undertaking.
- (i) Controls carried out with the competent authority's own instruments in order to verify the measurements made by the feed or food business.
- (j) Any other activity used to verify compliance with feed and food law.

Official controls shall be carried out using appropriate control methods and techniques such as monitoring, surveillance, verification, audit, inspection, sampling and analysis.

## Chapter III: Sampling and analysis

### *Article 11*

#### *Methods of sampling and analysis*

1. In the context of official controls methods of sampling recognised by international organisations shall be used, where available.
2. The methods of analysis used within the context of official controls shall be fully validated in accordance with Community legislation or with internationally accepted protocols, in particular those methods that have been accepted by the European Committee for standardisation (CEN). If these are not available, methods accepted by other international organisations or by national bodies may be used.

Where such methods of analysis are not available, other methods fit for the intended purpose or developed in accordance with scientific protocols may be used.

When justified by the circumstances the methods of analysis may be validated within a single laboratory according to an internationally accepted protocol.

3. The methods of analysis shall comply whenever possible with all or with the appropriate criteria set out in Annex III.
4. The methods of sampling and analysis to be applied for ensuring compliance with feed and food law, including the reference methods to be used in the case of dispute and the acceptance criteria for such methods, may be laid down in accordance with the procedure referred to in Article 62(3).
5. Feed and food business operators, whose products are subject to sampling and analysis, may apply for a second opinion. This implies that a sufficient number of samples, taken under identical conditions, are taken so as to provide feed and food business operators with a counter sample. However, this right shall not prejudice the obligation of the competent authorities to take prompt action in case of emergencies.

### *Article 12*

#### *Official laboratories*

1. The analysis of samples taken during official controls shall be carried out by laboratories designated for that purpose by the competent authority. Any laboratory that fulfils the criteria laid down in paragraph 2 shall be eligible for designation as an official laboratory.
2. The laboratories referred to in paragraph 1 shall operate, be assessed and be accredited in accordance with the following European Standards developed by CEN:
  - (a) EN ISO/IEC 17025 on "General requirements for the competence of testing and calibration laboratories";
  - (b) EN 45002 on "General criteria for the assessment of testing laboratories";



- (c) EN 45003 on "Calibration and testing laboratory accreditation system-General requirements for operation and recognition",

taking into account criteria for different testing methods laid down in Community feed and food law.

3. The accreditation and assessment of testing laboratories referred to in paragraph 2 may relate to individual tests or groups of tests.
4. Any deviation in the way in which the standards referred to in paragraph 2 are applied shall be adopted in accordance with the procedure referred to in Article 62(3).

## **Chapter IV: Crisis management**

### *Article 13*

#### *Contingency plans*

1. For the implementation of the general plan for crisis management referred to in Article 55 of Regulation (EC) No 178/2002, Member States shall draw up contingency operational plans setting out measures to be implemented without delay where feed or food have been found to pose a serious risk to humans or animals either directly or through the environment, and specifying the administrative authorities to be engaged together with their powers and responsibilities, as well as channels and procedures for transmitting information among the relevant actors.

Member States shall review these contingency plans as appropriate, particularly in the light of changes in the organisation of the control services and of experience, including experience gained in simulation exercises.

2. Where necessary, guidelines may be issued to harmonise those contingency plans in accordance with the procedure referred to in Article 62(3), ensuring that such contingency plans are compatible with the general plan for crisis management referred to in Article 55 of Regulation (EC) No 178/2002. These guidelines shall also indicate the role of stakeholders in the establishment and operation of the contingency plans.

## **Chapter V: Controls on the introduction of feed and food from third countries**

### *Article 14*

#### *Controls on feed and food of animal origin*

The checks on feed and food of animal origin provided for in Council Directive 97/78/EC shall, as appropriate, be supplemented with official controls on the verification of compliance with aspects of feed law and food law that are not covered by that Directive, including those aspects referred to in Articles 47 to 49 of this Regulation.

*Article 15*  
*Controls on feed and food of non-animal origin*

1. The competent authorities shall proceed to regular official controls of feed and food of non-animal origin not covered by Directive 97/78/EC, imported into the territories referred to in Annex I. These controls shall be organised using a plan established on the basis of potential risks and shall include any aspect of feed and food law.

These controls shall take place at an appropriate place, including the point of entry of the goods into one of the territories referred to in Annex I, the point of release for free circulation, warehouses, the premises of the importing feed and food business operator, or other points of the feed and food chain.

These controls may also include checks on goods that are placed under one of the customs procedures referred to in points (b) to (f) of Article 4(16) of Regulation (EEC) No 2913/92, or to be handled in free zones or free warehouses. Satisfactory results of these checks do not preclude feed and food from compliance with feed and food law at the moment of release for free circulation, and from renewed controls.

2. The controls referred to in paragraph 1 shall include at least a documentary check and, as appropriate, an identity check and a physical check.

Physical checks shall be conducted in accordance with a frequency taking into account:

- (a) possible risks that may be associated with the different feed and food commodities;
- (b) the history of compliance with the requirements of a product, establishment of origin, importing feed or food business operator, exporting feed or food business operator, or third country;
- (c) the controls carried out by the importer;
- (d) the guarantees given by the exporting third country's competent authority.

Physical checks may include:

- (a) checks of the means of transport;
- (b) checks on the packaging;
- (c) checks of the temperature of the products;
- (d) sampling and laboratory testing; or
- (e) any other check necessary to check compliance with feed or food law.

Physical checks shall be carried out under satisfactory conditions and at a place, which allows investigations to be conducted correctly, representative samples to be taken, and the feed and food to be handled hygienically. Samples must be handled in such a way as to avoid altering the validity of the sample.

3. In accordance with the procedure referred to in Article 62(3), a list shall be drawn up of feed and food of non-animal origin, that on the basis of known risks shall be subject to an increased level of official controls at the point of entry into territories referred to in Annex I. The frequency and the nature of these controls shall also be laid down in accordance with the procedure referred to in Article 62(3).

#### *Article 16*

##### *Points of entry and in-advance information*

To the extent strictly necessary for the organisation of the controls referred to in Article 15(3) and for the controls of feedingstuffs, the Member States may designate particular points of entry in their territory for the various types of feed and food products. They shall inform the Commission and the other Member States thereof. These measures shall be designed in such a way as to avoid unnecessary disruption of trade.

For the same purpose and subject to the same conditions, Member States may require feed and food business operators responsible for the consignments to forward to them in-advance information concerning the arrival and the nature of a consignment.

#### *Article 17*

##### *Action in case of suspicion*

Where it is suspected that feed law or food law have not been complied with or where there is doubt as to the identity or the actual destination of the consignment, the competent authority shall carry out any control that it deems appropriate in order to confirm or rule out the suspicion.

The products checked shall then remain under supervision of the competent authority until the results of the checks are obtained.

#### *Article 18*

##### *Action following controls of feed and food from third countries*

Feed or food from third countries not complying with feed and food law may be seized or confiscated, and shall be destroyed, submitted to a special treatment in accordance with Article 20, or re-dispatched outside the Community in accordance with Article 21. Where necessary, products shall be recalled following importation.

Feed and food to be destroyed, submitted to a special treatment, or used for other purposes shall not give rise to any adverse effects on human and animal health either directly or through the environment.

#### *Article 19*

##### *Decisions on consignments*

Where a consignment of feed or food is not complying with feed or food law, the competent authority in consultation with the feed or food business operators responsible for the consignment shall take a decision on its destination. Such decisions shall be taken without unnecessary delay.

If the official controls provided for in Articles 14 and 15 indicate that a consignment is likely to have adverse effects on human or animal health, the competent authority shall seize and destroy the consignment in question, or take any other appropriate measure necessary to protect human and animal health.

Feed or food of non-animal origin which is subject to an increased level of controls in accordance with Article 15(3) without being presented for official controls, shall be recalled and seized without delay, and the competent authority shall decide either to destroy the feed or food or to re-dispatch it in accordance with Article 21.

Where feed and food are denied introduction, the competent authority shall inform the other Member States and the Commission of the findings and of the identification of the products and notify its decisions to the customs services. Such decision shall be subject to the right of appeal referred to in Article 54(3).

#### *Article 20* *Special treatments*

The special treatment provided for in Article 18 may include:

- (a) bringing the products into line with the requirements of Community law, or with the requirements of a third country of re-dispatch, including decontamination where appropriate;
- (b) processing in any other suitable manner for purposes other than animal or human consumption.

The competent authority shall ensure that the special treatments are carried out under its control and in accordance with the procedures prescribed by it.

#### *Article 21* *Re-dispatch of consignments*

In the case of re-dispatch of consignments of feed and food outside the territories of the Community, the destination of the consignments shall be agreed with the person responsible for the load. However, a consignment shall not be re-dispatched to the third country of origin or to another third country unless the competent authorities of the third country of destination have expressly agreed to receive the consignment, after having been fully informed of the reasons for which and the circumstances under which the feed or food concerned could not be placed on the market in the Community.

Re-dispatch shall take place within a maximum time limit of 60 days from the day the decision has been submitted to the feed or food business operator, where this is not precluded by the results of the control. If and when the person responsible for the load gives his agreement, or if re-dispatch is found impossible after 60 days on the basis of the control results, the consignment shall be destroyed.

Pending re-dispatch of consignments or confirmation of the reasons for rejection, the competent authorities shall keep the consignments in question under their supervision.

The controlling competent authority shall activate the notification procedure provided for in Article 50(3) of Regulation (EC) 178/2002, and further measures shall be taken as necessary by the competent authorities co-operating in accordance with Title IV, so as to ensure that it is not possible to reintroduce the rejected consignments into the Community.

#### *Article 22*

##### *Costs*

The feed or food business operator responsible for the consignments or his representative, shall be liable for the costs incurred in the process of a special treatment, re-dispatch, destruction or storage under supervision of the competent authority of the consignment.

#### *Article 23*

##### *Approval of pre-export checks by third countries*

1. Specific pre-export checks performed by a third country on feed and food immediately prior to export to the Community with a view to verify that the exported products satisfy the requirements of the Community may be approved in accordance with the procedure referred to in Article 62(3). The approval may only apply to feed and food originating in the third country concerned, and may be granted for one or more products.

Where such approval has been granted the frequency of import controls for feed or food established under the plan provided for in Article 15(1), or under Directive 97/78/EC for feed and food of animal origin, may be adapted. However, Member States shall conduct controls of feed and food imported in accordance with the approval referred to in the first subparagraph on a significant proportion of the consignments. Such proportions shall be sufficient to ensure that the pre-export checks conducted by the competent authority or control bodies of the third country remain effective and efficient.

2. The approval referred to in paragraph 1 may only be granted to third countries if:
  - (a) it has been shown after a Community audit that the Community requirements, or requirements that are at least equivalent, are met;
  - (b) the controls carried out by the third country prior to dispatch are considered effective and efficient so as to replace or reduce the documentary, identity and physical checks prescribed in Community law.
3. The approval referred to in paragraph 1 shall specify the competent authority in the third country under whose responsibility the pre-export checks are performed and as necessary the control body to which such controls may have been delegated by the central competent authority. Such delegation may only be approved when the criteria referred to in Article 5, or equivalent conditions, are fulfilled.

The competent authority and control body specified in the approval shall be responsible for contacts with the Community.

4. The competent authority or control bodies of the third country shall draw up, for each consignment checked prior to its entry into one of the territories referred to in Annex I, an official certificate the model of which shall be specified in the approval referred to in paragraph 1.
5. Where border controls reveal significant irregularities, Member States shall immediately inform the Commission and the other Member States, increase the number of consignments checked in accordance with this Article and where necessary to allow a proper analytical examination of the situation, keep an appropriate number of samples under appropriate storage conditions.
6. In accordance with the procedure referred to in Article 62(3), the approval referred to in paragraph 1 shall be either suspended or revoked if it is found that, in a significant number of consignments, the goods do not correspond to the information in the certificates issued by the competent authority or control bodies of the third country.

#### *Article 24*

##### *Competent authorities and customs services*

For the organisation of the controls referred to in this Chapter, the competent authorities and the customs services shall work together.

With regard to consignments of feed and food of animal origin and of feed and food referred to in Article 15(3), the customs authorities shall not allow the introduction or the handling in free zones or free warehouses, unless proof has been supplied that controls have been carried out with satisfactory results.

Where samples are taken, the competent authority shall inform the customs services and indicate whether or not the goods can be released prior to the results of the analysis of the samples being available.

In the case of release for free circulation they shall work together in accordance with the requirements laid down in Articles 2 to 6 of Regulation (EEC) No 339/93.

#### *Article 25*

##### *Implementing measures*

1. Where necessary to ensure the uniform implementation of controls on the introduction of feed and food, measures to that effect shall be laid down in accordance with the procedure referred to in Article 62(3).
2. In particular, detailed rules may be laid down for:
  - (a) feed and food imported or placed under one of the customs procedures referred to in Article 4(16)(b) to (f) of Regulation (EEC) No 2913/92 or that are to be handled in free zones or free warehouses;
  - (b) food for the supply of the crew and passengers of international means of transport where such food does not comply with food law;

- (c) food ordered and sent by mail or carried by passengers and crew of international means of transport;
- (d) specific conditions or exemptions concerning certain territories referred to in Article 3 of Regulation (EEC) No 2913/92, so as to take account of the natural constraints specific to these territories;
- (e) ensuring uniformity of the decisions taken by the competent authority as referred to in Article 19.

## **Chapter VI: Financing of official controls**

### *Article 26 General principle*

Member States shall ensure that adequate financial resources are made available for official controls.

### *Article 27 Activities subject to fees*

Where the detection of non-compliance with feed and food law leads to control activities that exceed the normal monitoring activity of the competent authority, the expenses caused by these activities shall be charged to the feed and food business operators concerned by these additional controls. The normal monitoring activity is that required by Community or national law and in particular that described in the plan provided for in Article 42. Activities that exceed the normal monitoring activities include the taking and analysis of samples as well as other controls that are required to check the extent of the problem and to verify whether corrective action has been taken.

In setting the level of these expenses, account shall be taken of the principles set out in Article 28. In addition to the publication of the method and data used for calculating the expenses, Member States shall adopt and publish in advance the criteria for defining control activities that exceed normal monitoring and for identifying the operators concerned by the expenses linked thereto.

### *Article 28 Level of fees*

Where for the purpose of Article 26 fees are imposed to feed and food business operators, the following principles shall apply:

- (a) the following expenses are eligible for calculating the fees:
  - (i) staff salaries;
  - (ii) travel and associated costs;
  - (iii) laboratory and sampling costs;

- (b) account shall be taken of:
  - (i) the interests of feed and food businesses with a small turnover;
  - (ii) the level of official controls required, in relation to the quality and intensity of the own checks already carried out by feed and food businesses;
- (c) where in an establishment several official control activities are carried out, these activities must be considered as a single activity and shall not therefore account for multiple fees;
- (d) the methods and data used for the calculation of the fees shall be published or otherwise made available to the public;
- (e) the direct or indirect refund of fees regularly collected by Member States shall be prohibited; however, the application of average fees shall not be regarded as an indirect refund.
- (f) without prejudice to charging the expenses referred to in Article 27, the fees shall replace all other charges or fees levied by the competent authorities of Member States for the controls covered by this Regulation;
- (g) feed and food business operators shall receive proof of payment of the fees.

*Article 29*  
*Fees for import controls*

1. Member States shall collect fees for the costs incurred by the competent authority for performing controls on imported feed, food and animals.
2. The fees are to be paid by the importer or his customs agent and charged at the customs office responsible for the border inspection post, directly at the border inspection post or at the competent authority in charge of the import controls.
3. The amount of the fees for the activities covered by Directive 97/78/EC, and Directive 91/496/EEC is set out in Annex IV.
4. Other activities for which fees shall be levied and the amount thereof may be established in accordance with the procedure referred to in Article 62(3).

## **Chapter VII: Other provisions**

*Article 30*  
*Official certification*

1. Without prejudice to certification requirements adopted for animal health or phytosanitary purposes, certification requirements may be adopted in accordance with the procedure referred to in Article 62(3), concerning:
  - (a) the models of the certificates;



- (b) the qualifications of the certifying officers;
  - (c) the principles that are to be respected for ensuring reliable certification, including electronic certification;
  - (d) the procedures to be followed in case of the withdrawal of certificates and for replacement certificates;
  - (e) consignments that are split into smaller consignments or that are mixed with other consignments.
  - (f) the documents that must follow the goods after the official controls have been carried out.
2. Where official certification is required, it shall be ensured that:
    - (a) a link exists between the certificate and the consignment;
    - (b) the information in the certificate is accurate and authentic.
  3. Feed and food certification requirements shall be combined where appropriate with other certification requirements in a single model of certificate.

#### *Article 31*

#### *Registration/approval of feed and food business establishments*

1. The competent authorities shall establish the procedures to be followed by feed and food business operators who apply for the registration of their establishments in accordance with Regulation (EC) No .../... (on the hygiene of foodstuffs), Regulation (EC) No .../... (laying down specific hygiene rules for food of animal origin), or Directive 95/69/EC.

The competent authorities shall keep up-to-date the list of the establishments that have applied for registration. Where such a list already exists for other purposes, it may also be used for the purposes of this Regulation.

2. The competent authorities shall establish procedures to be followed by feed and food business operators who apply for the approval of their establishments in accordance with Regulation (EC) No .../... (on the hygiene of foodstuffs), Regulation (EC) No .../... (laying down specific hygiene rules for food of animal origin), or Directive 95/69/EC.

When receiving an application for approval from a feed or food business operator, the competent authorities shall make an on-the-spot control.

The competent authority shall approve establishments only if it has been demonstrated that they meet the relevant requirements of feed or food law. The approval shall be withdrawn if the approval conditions are no longer fulfilled. In that event, it must be ensured that feed and food business operators cease their operations.

In establishments starting up their activities, the competent authority shall grant an initial approval if it appears from an on-the-spot control that all of the infrastructure and equipment requirements are adhered to and that operational procedures such as the HACCP system are in place.

A final approval can only be granted if it appears from a new on-the-spot control carried out within three months after the initial approval has been given that all requirements of relevant feed and food law are complied with.

The competent authorities shall keep up-to-date the list of the establishments that are approved and make it available for the other Member States.

## **TITLE III**

### **REFERENCE LABORATORIES**

#### *Article 32*

#### *Community reference laboratories*

1. The Community reference laboratories referred to in Annex V shall be responsible for:
  - (a) providing national reference laboratories with details of analytical methods, including reference methods;
  - (b) co-ordinating the application, by national reference laboratories, of the methods referred to in (a), in particular by organising comparative testing and by assuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols, when available;
  - (c) co-ordinating within their area of competence, the practical arrangements needed to apply new analytical methods and informing national reference laboratories of advances in this field;
  - (d) conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries;
  - (e) providing scientific and technical assistance to the Commission, especially in cases where the results of analyses are contested between Member States;
  - (f) collaborating with laboratories responsible for analysing feed and food in third countries.
2. Article 12(2) and (3) shall apply to the Community reference laboratories.
3. The Community reference laboratories shall comply with the following conditions:
  - (a) they must have suitably qualified staff with adequate training in the techniques applied to the analysis and testing of feed and food;

- (b) they must possess the equipment and substances needed to carry out the tasks assigned to them;
  - (c) they must have an appropriate administrative infrastructure;
  - (d) they must ensure that its staff respect the confidential nature of certain subjects, results or communications;
  - (e) they must have sufficient knowledge of international standards and practices;
  - (f) they must have available, if appropriate, an updated list of available reference substances and reagents and an updated list of the manufacturers and suppliers of such substances and reagents;
  - (g) they must take into account the research activities at national and Community level.
4. Other Community reference laboratories relevant to the areas referred to in Article 1 may be included in Annex V in accordance with the procedure referred to in Article 62(3);
  5. Additional responsibilities and tasks for Community reference laboratories may be laid down in accordance with the procedure referred to in Article 62(3).
  6. The Community reference laboratories may be granted a Community financial contribution in accordance with Article 28 of Council Decision 90/424/EEC<sup>36</sup>.
  7. The Community reference laboratories may be subject to Community inspections in order to verify whether the requirements laid down in this Regulation are being complied with.
  8. Paragraphs 1 to 7 shall apply without prejudice to more specific rules, and in particular Chapter VI of Regulation (EC) No 999/2001 and Article 14 of Directive 96/23/EC.

*Article 33*  
*National reference laboratories*

1. Member States shall ensure that one or more national reference laboratories are designated for each Community reference laboratory referred to in Article 32.

These national reference laboratories shall:

- (a) collaborate with the Community reference laboratory in their area of competence;
- (b) co-ordinate, within their area of competence, the activities of the official laboratories responsible for the analysis of samples in accordance with Article 11;

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<sup>36</sup> OJ L 224, 18.8.1990, p. 19.

- (c) where appropriate organise comparative tests between the official national laboratories;
  - (d) ensure that the information supplied by the Community reference laboratory is disseminated to the competent authority and to the official national laboratories;
  - (e) assist with the implementation of the co-ordinated control plans adopted in accordance with Article 53;
  - (f) be responsible for carrying out other specific duties provided for in accordance with the procedure referred to in Article 62(3).
2. Article 12(2) and (3) shall apply to the national reference laboratories.
  3. Member States shall communicate the name and address of each national reference laboratory to the Commission, the relevant Community reference laboratory and the other Member States.
  4. Where more than one national reference laboratory is designated per Community reference laboratory, it must be ensured that these laboratories work closely together so as to ensure efficient co-ordination between them, with the other national laboratories and with the Community reference laboratory.
  5. Additional responsibilities and tasks for national reference laboratories may be laid down in accordance with the procedure referred to in Article 62(3).
  6. Paragraphs 1 to 4 shall apply without prejudice to more specific rules and in particular Chapter VI of Regulation (EC) No 999/2001 and Article 14 of Directive 96/23/EC.

## **TITLE IV**

### **ADMINISTRATIVE ASSISTANCE AND CO-OPERATION**

#### *Article 34* *General principles*

1. Where the outcome of official controls requires action by more than one Member State, the competent authorities of Member States shall afford each other administrative assistance.
2. The administrative assistance shall be granted upon request, or spontaneously where required by the course of investigations. Administrative assistance may include, where appropriate, participation to on-the-spot controls carried out by the competent authority of another member State.
3. Articles 35 to 41 shall not prejudice national rules applicable to the release of documents which are the object of, or are related to, court proceedings, nor rules aimed at the protection of commercial interests of natural or legal persons.

*Article 35*  
*Liaison body*

1. Each Member State shall designate a single liaison body to liaise as appropriate with the liaison bodies of other Member States. The role of the liaison bodies shall be to assist and co-ordinate communication and, in particular, the transmission and reception of requests for assistance.
2. Member States shall inform the Commission and the other Member States of all the relevant details of their designated liaison body, and of any change that are made to it.
3. The designation of liaison bodies shall not preclude direct contacts, exchange of information or co-operation between Member States' officials. Where an official of a Member State contacts an official of another Member State on one of the matters referred to in this title, he shall inform at the same time the liaison bodies of both Member States concerned about the nature of the contact. He shall also forward to the liaison bodies concerned all information that is the subject of the contact.
4. Where a liaison body receives information on the existence of a serious direct or indirect risk to human health deriving from feed or food, this information shall be immediately notified to the national contact point for the rapid alert system referred to in Article 50 of Regulation (EC) No 178/2002.

*Article 36*  
*Assistance on request*

1. Upon receiving a reasoned request, the requested competent authority shall ensure that the requesting competent authority is provided with all necessary information and documents enabling the latter to verify compliance with feed and food law within its jurisdiction.

For that purpose, the competent authority of the requested Member State shall arrange for the conduct of any administrative enquiries necessary to obtain such information and documents.

2. The information and documents provided pursuant to paragraph 1 shall be forwarded without delay. Documents may be transmitted in their original form or copies may be provided.
3. By agreement between the requesting authority and the requested authority, officials designated by the requesting authority may be present during administrative enquiries.

Such enquiries shall at all times be carried out by the officials of the requested authority. The requesting authority's officials may not, on their own initiative, exercise the powers of enquiry conferred on officials of the requested authority.

They shall, however, have access to the same premises and documents as the latter, through their intermediary, and for the sole purpose of the administrative enquiry being carried out.

4. The officials of the requesting authority present in another Member State in accordance with paragraph 3 shall at all times be able to produce written authority stating their identity and their official capacity.

#### *Article 37*

##### *Assistance without request*

1. Where a competent authority becomes aware of non-compliance with feed or food law, and such non-compliance may have implications for another Member State or Member States, it shall pass such information to the other Member State(s) without prior request and without delay.
2. The Member States receiving such information shall investigate the matter and inform the first Member State of the results of this investigation and where appropriate of the measures taken.

#### *Article 38*

##### *Assistance in case of risks and non-compliance*

1. If during an official control carried out at the place of destination of the goods or during their transport the competent authority of the Member State of destination establishes that the goods do not meet feed or food law requirements in such a way as to create a risk to human or animal health or constitute a serious infringement of feed or food law, it shall contact the competent authorities of the Member State of dispatch without delay.
2. The competent authorities of the Member State of dispatch shall investigate the matter, take all necessary measures and notify the competent authority of the member State of destination of the nature of the investigations and official controls carried out, the decisions taken and the reasons for such decisions.
3. If the competent authority of the Member State of destination has reason to believe that such measures are inadequate, the competent authorities of the two Member States shall together seek ways and means of remedying the situation including, if appropriate, an on-the-spot joint inspection.

#### *Article 39*

##### *Relations with third countries*

1. When the competent authority of a Member State receives information from a third country, that authority shall pass that information on to the competent authorities of the Member States which might be interested in it and in any event to all those Member States which request it.

Such information shall also be communicated to the Commission whenever it is of relevance at Community level.

2. Provided the third country has given a legal undertaking to provide the assistance required to gather evidence of the irregular nature of transactions that are or appear to be contrary to the relevant feed and food law, information obtained under this Regulation may be communicated to that third country, with the consent of the competent authorities which supplied the information, in accordance with laws applying to the communication of personal data to third countries.

#### *Article 40*

##### *Co-ordinated assistance and follow up by the Commission*

1. The Commission shall as quickly as possible co-ordinate the action undertaken by the Member States when it, further to information received from the Member States or from other sources, becomes aware of activities which are, or appear to be, contrary to the food law or feed law and which are of particular interest at Community level, and in particular:
  - (a) where such activities have, or might have, ramifications in several Member States, or
  - (b) where it appears that similar activities have been carried out in several Member States.
2. Where official controls at destination show repeated non-compliance or other risks to humans or animals from feed or food, either directly or through the environment, the competent authority of the Member State of destination shall inform the Commission and the competent authorities of the other Member States without delay.
3. The Commission may:
  - (a) send an inspection team for making an on-the-spot control:
  - (b) request the competent authority of the Member State of dispatch to intensify its official controls on the matter and to report on the action and measures taken.
4. Where the measures provided for in paragraphs 2 and 3 are taken to deal with repeated irregularities by a feed or food business, the competent authority shall charge any expenses due by such measures to the business in question, including the costs established by the Commission for its inspection. In the latter case, the amounts collected by the Member State shall be remitted to the Commission following a procedure to be established in accordance with the procedure provided for in Article 62(3).

#### *Article 41*

##### *Disclosure of information*

1. In criminal proceedings, the information forwarded under this Chapter can be used only with the prior consent of the sending Member State in accordance with, for those Member States who are parties to them, the international conventions and agreements in force on mutual assistance in criminal affairs.

2. If the sending Member State indicates that the information contains data whose disclosure could undermine the protection of commercial interests of a natural or legal person, the receiving Member State shall undertake not to disclose the information without the prior consent of the sending Member State. If it is not possible for the receiving Member State to give such undertaking, it shall not be contrary to the terms of this Regulation for the sending Member State to withhold it.
3. Any refusal to provide information according to the provisions of this Article shall give reasons.

## **TITLE V**

### **CONTROL PLANS**

#### *Article 42*

#### *Multi-annual national control plans*

1. For the implementation of Article 17(2) of Regulation (EC) No 178/2002 and of Article 45 of this Regulation, Member States shall within six months after the entry into force of this Regulation prepare an integrated multi-annual national control plan. National control plans shall:
  - (a) be maintained by the Member States and presented to the Commission upon request; and
  - (b) be implemented for the first time one year after the entry into force of this Regulation at the latest.
2. National control plans shall contain general information on the structure and organisation of the feed and food control, animal health and animal welfare systems in the Member States and in particular on:
  - (a) the strategic objectives of the plan and how these are reflected in the prioritisation of controls and allocation of resources;
  - (b) the designation of competent authorities and their tasks at central, regional and local level, and on the resources available to these authorities;
  - (c) the general organisation and management of official control systems at national, regional and local level, including official controls in individual establishments;
  - (d) the control systems applied to the different sectors and the co-ordination between the different services of the competent authorities in charge of controlling these sectors;
  - (e) where appropriate, the delegation of competence to control bodies;
  - (f) the methods to ensure that operational criteria referred to in Article 4(2) are met;



- (g) the training of control officials referred to in Article 6;
  - (h) the documented procedures referred to in Articles 8 and 9;
  - (i) the organisation and operation of contingency plans for disease emergencies, food contamination incidents and other human health risks;
  - (j) the organisation of co-operation and mutual assistance.
3. National control plans may be adjusted during their implementation. Amendments may be made in the light of, or in order to take account of, factors including:
- (a) new legislation;
  - (b) the emergence of new diseases or other health risks;
  - (c) significant changes to the structure, management or operation of the competent national authorities;
  - (d) the results of controls carried out by the Member States;
  - (e) the results of controls carried out by the Commission in accordance with Article 45;
  - (f) an amendment of the guidelines referred to in Article 43;
  - (g) scientific findings;
  - (h) the outcome of audits carried out by a third country.

*Article 43*  
*Guidelines for multi-annual national control plans*

1. The national control plans referred to in Article 42(1) shall be drawn up in accordance with broad guidelines to be established in accordance with the procedure referred to in Article 62(2). They shall in particular:
- (a) promote a uniform, comprehensive and integrated approach to official controls of feed and food, animal health and animal welfare legislation, and embrace all sectors and all stages of the food chain;
  - (b) identify risk based priorities and the most effective control procedures;
  - (c) identify other priorities and the most effective control procedures;
  - (d) identify the points in the production, processing and distribution of feed and food which will provide the most reliable and indicative information about compliance with feed and food law;
  - (e) encourage the adoption of best practices at all levels of the control system;
  - (f) encourage the development of effective traceability systems;

- (g) provide advice on the development of systems to record the performance and results of control actions;
  - (h) reflect standards and recommendations made by the relevant international bodies regarding the organisation and operation of official services;
  - (i) lay down criteria for the conduct of the audits referred to in Article 4(5);
  - (j) lay down the structure of, and information to be included in, the annual reports required in Article 44;
  - (k) indicate the main performance indicators to be applied in assessing national control plans.
2. Where necessary, the guidelines shall be adapted in the light of the analysis of the annual reports submitted by the Member States as referred to in Article 44, or the audits and controls carried out by the Commission.

*Article 44*  
*Annual reports*

1. One year after starting the implementation of the national control plans, and subsequently every year, the Member States shall submit to the Commission a report indicating:
- (a) an update of the initial national control plan in relation to the factors referred to in Article 42(3);
  - (b) results of controls and audits conducted in the previous year under the provisions of the national control plan;
  - (c) the type and number of infringements that have been established;
  - (d) the actions to ensure the effective operation of the national control plans, including enforcement actions and their results.

In order to ensure a uniform presentation of this report and in particular of the results of official controls, this information shall be drawn up in accordance with guidelines to be adopted in accordance with the procedure referred to in Article 62(2).

This report shall be established within four months of the end of the year to which the report relates and shall be sent to the Commission.

2. In the light of the reports referred to in paragraph 1, the outcome of Commission controls in the Member States and any other relevant information, the Commission shall establish a report on the overall operation of the official control systems in the Member States. It may, where appropriate, include recommendations on:
- (a) possible improvements to the official control and audit systems in the Member States, including their scope, management and implementation,

- (b) specific control actions concerning sectors or activities either covered or not covered by the national control plan,
- (c) co-ordinated plans aiming at addressing issues of particular interest.

On the basis of the conclusions and recommendations contained in this report, the national control plans and the guidelines shall, where appropriate, be adapted.

This report shall be submitted to the European Parliament and the Council.

## **TITLE VI**

### **COMMUNITY ACTIVITIES**

#### **Chapter I: Community controls**

##### *Article 45*

##### *Community controls in the Member States*

1. Experts of the Commission, who may be assisted by experts of the Member States appointed by the Commission, shall carry out general and specific audits in the Member States. The general audits shall be organised on a regular basis in co-operation with the competent authorities in the Member States. Their main purpose shall be to verify that the overall official control activities in the Member States are in accordance with the national control plans referred to in Article 42 and in compliance with Community law. For this purpose Member States shall, upon request, immediately make available up-to-date copies of the national control plans to the Commission.
2. The general audits may be supplemented by specific audits and inspections covering one or more specific areas. These specific audits and inspections shall in particular serve to:
  - (a) verify the implementation of the national control plan, feed and food law and the animal health and animal welfare legislation and may include, as appropriate, on the spot inspections of the official services and of the facilities associated with the sector being audited;
  - (b) verify the functioning and organisation of the competent authorities;
  - (c) investigate important or recurring problems in the Member States;
  - (d) investigate emergency situations, emerging problems or new developments in the Member States.
3. The Commission shall establish, for each control carried out, a report on its findings. This report shall, if appropriate, contain recommendations for the Member States on the improvement of compliance with feed and food law. These reports shall be made publicly available.

4. The Commission shall establish an annual control programme, communicate it to the Member States in advance, and report on the results thereof. This programme may be amended to take account of developments in the feed and food safety, animal health and plant health situation.
5. Member States shall:
  - (a) ensure an appropriate follow-up of the recommendations resulting from the Community controls;
  - (b) give all necessary assistance and provide all documentation and other technical support requested by Commission experts to enable controls to be carried out efficiently;
  - (c) ensure that the experts of the Commission have access to all premises or parts of premises and information, including informatics systems, relevant to the execution of their duties.
6. Detailed rules concerning Community controls in the Member States may be determined or amended in accordance with the procedure referred to in Article 62(3).

*Article 46*  
*Community controls in third countries*

1. Experts of the Commission, who may be assisted by experts of the Member States appointed by the Commission, may carry out controls in third countries in order to verify, on the basis of the control plans referred to in Article 47(1), either compliance or equivalence of third country legislation and systems with Community feed law and food law, and Community animal health legislation. In doing so, account shall in particular be taken of:
  - (a) the legislation of the third country;
  - (b) the organisation of the competent authority/authorities of the third country and of its control services, of the powers and independence of these services and the supervision to which they are subject, as well as the authority that these services have to enforce effectively their legislation;
  - (c) the training of staff in the performance of control functions;
  - (d) the resources including diagnostic facilities available to the control services;
  - (e) the existence and operation of documented control procedures and control systems based on priorities;
  - (f) where applicable, the situation regarding animal health, zoonoses and plant health, and the procedures for notification to the Commission services and relevant international bodies of outbreaks of animal and plant diseases;
  - (g) the extent and operation of controls over imports of animals, plants and their products;

- (h) the assurances which the third country can give regarding compliance or equivalence with Community requirements.
2. In order to facilitate the efficiency and effectiveness of the controls in a third country, the Commission may, in advance of carrying out such controls, request that third country to submit a control plan referred to in Article 47(1) and where appropriate written records on its implementation referred to in Article 47(3).
  3. The frequency of the controls carried out by the Commission in third countries shall be determined on the basis of:
    - (a) a risk assessment of the products exported to the Community;
    - (b) the provisions of Community legislation;
    - (c) the volume and nature of imports from the country concerned;
    - (d) the results of controls already carried out by the Commission services or other inspection bodies;
    - (e) the results of import controls and of any other controls performed by the Member States;
    - (f) information received from the European Food Safety Authority or similar bodies;
    - (g) information received from internationally recognised bodies such as WHO, Codex Alimentarius and the *Office International des Epizooties* (OIE), or from other sources;
    - (h) evidence of emerging disease situations or other health risks that might have consequences for imports of live animals, live plants or their products;
    - (i) the need to investigate or respond to emergency situations in individual third countries.

The criteria for determining the risk for the purpose of the risk assessment referred to in point (a) shall be decided in accordance with the procedure referred to in Article 62(3).

4. The procedure and guidelines for controls in third countries may be determined or amended in accordance with the procedure referred to in Article 62(3).

These shall include, in particular, procedures for and guidelines on:

- (a) controls in third countries in the context of a bilateral agreement;
  - (b) controls in other third countries.
5. If during a Community control a serious risk to humans or animals is identified, the Commission shall immediately take the emergency measures deemed necessary and inform the Member States thereof.

6. The Commission shall communicate its programme of controls in third countries to the Member States in advance and report on the results thereof. This programme may be amended to take account of developments in the feed and food safety, animal health and plant health situation.

## **Chapter II**

### **Import conditions**

#### *Article 47*

#### *General import conditions*

1. Imports of feed and food, animals or animal products from a third country into one of the territories referred to in Annex I shall be subject to the notification to the Commission by the third country that it has in place a control plan accessible upon request, which provides the following accurate and up-to-date information on the general organisation and management of sanitary control systems operated by the competent authority of the third country:
  - (a) any sanitary or phyto-sanitary regulations adopted or proposed within its territory;
  - (b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;
  - (c) risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;
  - (d) where appropriate, the follow-up given to the recommendations made pursuant to controls referred to in Article 46.
2. A control plan referred to in paragraph 1 shall be proportionate and technically and economically feasible taking into account the specific situation and structure in the third country and the nature of the products exported. Its scope shall cover at least the products intended to be exported to the Community.
3. Imports of feed and food, animals or animal products from a third country into the Community shall be subject to the maintenance by the third country of written records on the implementation of the control plan referred to in paragraph 1.

The records on the implementation of the control plan shall indicate:

- (a) results of the domestic controls carried out under the control plan;
- (b) important changes which have been made to the original plan or to the structure and functioning of the relevant control systems, in particular to meet Community requirements or recommendations;

4. Guidelines specifying how the control plan and the records referred to in paragraph 3 shall be drawn up and presented to the Commission, as well as transitional measures to allow third countries time to prepare and implement the control plan shall be established in accordance with the procedure referred to in Article 62(2).

*Article 48*  
*Specific import conditions*

1. The conditions and detailed procedures to be respected when importing feed and food from third countries or regions thereof shall be established where necessary in accordance with the procedure referred to in Article 62(3).
2. The conditions and detailed procedures referred to in paragraph 1 may include:
  - (a) the establishment of a list of third countries from which feed and food may be imported in one of the territories referred to in Annex I;
  - (b) the establishment of models of certificates accompanying consignments;
  - (c) special import conditions, depending on the type of product and the possible risks associated therewith.
3. Third countries shall appear on a list referred to in point (a) of paragraph 2 only if their competent authorities provide appropriate guarantees as regards compliance or equivalence with Community feed and food law.

When drawing up or updating lists particular account shall be taken of:

- (a) the third country's legislation in the sector concerned;
- (b) the structure and organisation of the competent authority of the third country and its control services, as well as the powers available to it/them and the guarantees that can be provided with regard to the implementation of the legislation concerned;
- (c) the existence of adequate feed and food controls;
- (d) the regularity and rapidity of information supplied by the third country on the presence of hazards in feed and food;
- (e) the guarantees given by a third country that:
  - (i) conditions applied to the establishments from which feed and food may be imported in the Community comply with or are equivalent to the requirements in Community feed and food law;
  - (ii) a list of such establishments is established and kept up-to-date;
  - (iii) the list of establishments and its updated versions are communicated to the Commission without delay;

(iv) the establishments are the subject of regular and effective controls by the competent authority of the third country.

4. In deciding the import conditions referred to in point (c) of paragraph 1, account shall be taken of the information submitted by third countries and where necessary the results of Community controls carried out in third countries.

These import conditions may be established for each commodity or group of commodities and per third country or regions thereof, or for a group of third countries.

*Article 49*  
*Equivalence*

1. Pursuant to the implementation of an equivalence agreement, or to a satisfactory audit, a decision may be taken, in accordance with the procedure referred to in Article 62(3), recognising that measures in areas of feed and food law applied by a third country or a region thereof, offer guarantees equivalent to those applied in the Community, if the third country supplies objective proof in this respect.
2. The decision referred to in paragraph 1 shall set out the conditions governing the importation of feed and food from that third country or region of a third country.

Those conditions may include:

- (a) the nature and content of the certificates that must accompany the products;
  - (b) specific requirements applicable to importation into the Community;
  - (c) where necessary, procedures for drawing up and amending lists of regions or establishments from which imports are permitted.
3. The decision referred to in paragraph 1 shall be repealed in accordance with the same procedure and without delay where any of the conditions for recognition of equivalence established at the time of its adoption cease to be fulfilled.

*Article 50*  
*Support for developing countries*

In accordance with the procedure referred to in Article 62(3) the following measures may be adopted for ensuring that developing countries are able to comply with the provisions of this Regulation:

- (a) a phased introduction of the requirement to present a control plan for the products that are exported to the Community, and a report on the results of such plan;
- (b) assistance on the establishment of a control plan, if necessary by Community experts;
- (c) the promotion of twin projects between a developing country and a Member State;



- (d) the development of guidelines to assist developing countries in organising official controls on the products exported to the Community;
- (e) the sending of Community experts to developing countries so as to assist in the organisation of official controls;
- (f) the participation by control staff of developing countries in the training courses referred to in Article 51.

### **Chapter III**

#### **Training of control staff**

*Article 51*  
*Training of control staff*

1. The Commission may organise training courses for the staff of the competent authorities in the Member States responsible for the controls referred to in this Regulation. These training courses shall serve to develop a harmonised approach towards official controls in the Member States. They may include in particular training on:
  - (a) Community feed and food law;
  - (b) control methods and techniques such as the auditing of systems designed by feed and food business operators to meet feed and food law requirements;
  - (c) controls to be carried out on feed and food imported into the Community;
  - (d) feed and food production, processing and marketing methods and techniques.
2. The training courses referred to in paragraph 1 may be open to participants from third countries, in particular from developing countries.
3. Detailed rules for the organisation of training courses may be laid down in accordance with the procedure referred to in Article 62(3).

### **Chapter IV**

#### **Other Community activities**

*Article 52*  
*Third country controls in the Member States*

1. Experts from the Commission may assist the Member States during controls carried out by third countries, upon request and in co-operation with the authorities of the Member States.

2. Member States in whose territory a control as referred to in paragraph 1 is undertaken by a third country shall inform the Commission about the planning, scope, documentation and any other relevant information enabling the Commission to take part efficiently in the control.
3. The assistance by the Commission shall serve in particular to:
  - (a) clarify Community feed and food law;
  - (b) provide information and data available at Community level that may be useful for the control carried out by the third country;
  - (c) ensure uniformity with regard to controls carried out by third countries.

*Article 53*  
*Co-ordinated control activities*

Community co-ordinated plans may be established in accordance with the procedure referred to in Article 62(2). These plans shall be:

- (a) organised annually in accordance with a programme; and
- (b) where considered necessary, organised on an ad-hoc basis in particular with a view to establish the prevalence of hazards in feed or food.

## **TITLE VII**

### **ENFORCEMENT MEASURES**

#### **Chapter I: National enforcement measures**

*Article 54*  
*Action in case of non-compliance*

1. Where non-compliance with feed law or food law is identified and depending on the nature of the non-compliance, the competent authority shall take action to ensure that the feed or food business operator remedies the situation.
2. Such action shall include, where appropriate, the following measures:
  - (a) the imposition of sanitation procedures or any other corrective action deemed necessary to ensure the safety of feed and food or compliance with feed law and food law;
  - (b) the restriction or prohibition of the placing on the market, importation or exportation of feed and food;
  - (c) the recall, withdrawal and/or destruction of feed and food;

- (d) the authorisation to use feed or food for other purposes;
- (e) the suspension of operation or closure of all or part of the business concerned for an appropriate period of time;
- (f) the suspension or withdrawal of the approved status of establishments;
- (g) the measures referred to in Article 19 on consignments from third countries;
- (h) other measures deemed appropriate by the competent authority.

In deciding which action to take in accordance with the first subparagraph, account shall be taken of the record of the feed or food business operator with regard to non-compliance with feed or food law.

3. The decisions concerning the action taken by the competent authority in accordance with paragraph 1 together with the reasons thereof, shall be notified in writing to the feed or food business operator concerned or his representative and where appropriate to the competent authority of the Member State of dispatch. The feed or food business operator shall be informed of his rights of appeal against such decisions and of the procedure and time limits applicable.

*Article 55*  
*Penalties*

1. Member States shall lay down the rules on penalties applicable to infringements of feed and food law and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions and any subsequent amendment to the Commission without delay.
2. For the purpose of paragraph 1, the activities referred to in Annex VI shall be criminal offences when committed intentionally or through serious negligence, insofar as they breach rules of Community feed and food law or rules adopted by the Member States in order to comply with such Community law.
3. The offences referred to in paragraph 2 and the instigation to or participation in such offences shall, as for natural persons, be punishable by sanctions of criminal nature, including as appropriate deprivation of liberty, and, as for legal persons, by penalties which shall include criminal or non-criminal fines and may include other penalties such as exclusion from entitlement to public benefits or aid, temporary or permanent disqualification from engaging in business activities, placing under judicial supervision or a judicial winding-up order.

## **Chapter II: Community enforcement measures**

### *Article 56* *Safeguard measures*

Where the Commission has evidence that there is a serious failure in the control systems of a Member State and where such failures may constitute a possible and widespread risk for human health, animal health or the welfare of the animals, either directly or through the environment, the emergency measures referred to in Article 53 of Regulation (EC) No 178/2002 may be applied.

These measures shall only be adopted after:

- (a) Community controls have shown and reported non-compliance with Community legislation; and
- (b) the Member State concerned has failed to correct the situation upon request and within the time limit set by the Commission.

## **TITLE VIII** **ADAPTATION OF COMMUNITY LEGISLATION**

### *Article 57* *Amendment of Directive 89/662/EEC*

In Annex A of Council Directive 89/662/EEC, Chapter I is replaced by the following:

"ANNEX A

CHAPTER I

Council Regulation (EC) No .../... laying down the animal health rules governing the production, placing on the market and importation of products of animal origin intended for human consumption.

### *Article 58* *Amendment of Directive 96/23/EC*

In Article 30 of Directive 96/23/EC, the part of paragraph 1 beginning "Where such additional checks demonstrate..." and ending "...or to use it for other purposes authorised by Community legislation, without indemnity or compensation", is replaced by the following text:

"Where checks demonstrate the presence of unauthorised substances or products or when maximum limits have been exceeded, the provisions of Articles 18 to 22 of Regulation (EC) No .../... (on official feed and food controls) shall apply. "

*Article 59*  
*Amendment of Directive 97/78/EC*

1. Article 1 of Directive 97/78/EC is replaced by the following text:

"Veterinary checks on products from third countries introduced into one of the territories listed in Annex I shall be carried out by Member States in accordance with this Directive and with Regulation (EC) No .../.... on official feed and food controls".
2. Article 2, paragraph 2(a) is replaced by the following text:

"(a) "products" means the products of animal origin referred to in Directives 89/662/EEC and 90/425/EEC, and in Regulation (EC) No 1774/2002 laying down health rules concerning animal by-products not intended for human consumption<sup>37</sup>; it also includes the plant products referred to in Article 19;"
3. In Article 7, the words "inspection fees referred to in Council Directive 85/73/EEC of 29 January 1985 on the financing of veterinary inspections and controls covered by Directives 89/662/EEC, 90/425/EEC, 90/675/EEC and 91/496/EEC (amended and consolidated)" are replaced by: "inspection fees referred to in Regulation (EC) No .../... on official feed and food controls".
4. In Article 10, paragraph 1 point (b), the following words are deleted : "or, in the case of establishments approved in accordance with Council Decision 95/408/EC of 22 June 1995 on the conditions for drawing up, for an interim period, provisional lists of third country establishments from which Member States are authorised to import certain products of animal origin, fishery products or live bivalve molluscs, from an establishment which has undergone either a Community or a national inspection".
5. In Article 12, paragraph 9 is deleted.
6. In Article 15, paragraph 5 is deleted.
7. Article 16 is replaced by the following text:

"Detailed rules for the introduction of products of animal origin sent by post or carried by passengers and crew of international means of transport shall be laid down in accordance with Article 25 of Regulation (EC) No .../... on official feed and food controls".
8. Article 17 is replaced by the following text:

"Consignments which have been introduced into one of the territories of the Community without being presented for veterinary checks in accordance with the requirements of Articles 3 and 4 shall be seized or confiscated, and handled in accordance with Articles 18 to 22 of Regulation (EC) No .../... on official feed and food controls".

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<sup>37</sup> OJ L 273, 10.10.2002, p. 1.

9. Article 21 is deleted.
10. Article 23 is deleted.
11. In Article 24, paragraph 1, second indent, the words "in accordance with Article 17(2) (a) and (b)" are replaced by the words "in accordance with Article 17".

*Article 60*  
*Amendment of Directive 2000/29/EC*

In Directive 2000/29/EC, the following Article 27(a) is added:

"Article 27(a)

For the purpose of this Directive, Articles 42 to 46 of Regulation (EC) No .../... (on official feed and food controls) shall apply"

*Article 61*  
*Repeal of Community acts*

Directives 70/373/EEC, 85/591/EEC, 89/397/EEC, 93/99/EEC, 95/53/EC and 96/43/EC and Decision 98/728/EC are repealed with effect from 1 January 2005.

However, the implementing rules adopted on the basis of these acts as listed in Annex VII shall remain in force insofar as they are not in contradiction with this Regulation, until they are repealed or where necessary replaced by rules having the same effect adopted on the basis of this Regulation.

Reference to the repealed acts shall be construed as references to this Regulation.

## **TITLE IX**

### **GENERAL PROVISIONS**

*Article 62*  
*Standing Committee procedure*

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 of Regulation (EC) No 178/2002, or where necessary for the purpose of this Regulation, by the Standing Committee on plant health set up by Council Decision 76/894/EEC<sup>38</sup>.
2. Where reference is made to this paragraph Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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<sup>38</sup> OJ L 340, 9.12.1976, p. 25.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be three months.

4. The Committee shall adopt its rules of procedure.

#### *Article 63*

##### *Implementing and transitional measures*

1. Implementing and transitional measures necessary to ensure a uniform application of this Regulation may be laid down in accordance with the procedure referred to in Article 62(3).
2. In order to take account of the specificity of Regulations (EEC) No 2092/91, (EEC) No 2081/92 and (EEC) No 2082/92, the rules laid down in this Regulation may be adapted in accordance with the procedure referred to in Article 62(3).

#### *Article 64*

##### *Amendment of Annexes and references to European standards*

In accordance with the procedure referred to in Article 62(3), amendments may be made to:

- (a) the Annexes to this Regulation, except for Annex VI, in order to take account of scientific and technological progress;
- (b) the references to the European Standards referred to in this Regulation in the event that these references are amended by CEN.

#### *Article 65*

##### *Community financial support*

1. The appropriations required for:
  - (a) the travel and subsistence expenses incurred by the Member State experts appointed by the Commission as referred to in Articles 45(1) and 46(1);
  - (b) the training of control staff referred in Article 51;
  - (c) the financing of other measures necessary to ensure the application of this Regulation,

shall be decided each year as a part of the budgetary procedure.

2. The measures referred to in paragraph 1(c) shall include in particular the organisation of conferences, the establishment of databases, the publication of information, the organisation of studies, the organisation of meetings in order to prepare the sessions of the Standing Committee on the Food Chain and Animal Health.

3. A Community technical support and financial contribution for the organisation of the activities referred to in Article 50 may be granted within the limits of the human and financial resources available to the Commission.

## **TITLE X**

### **FINAL PROVISION**

#### *Article 66* *Entry into force*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

It shall apply from 1 January 2005.

However, Article 55 paragraphs 2 and 3 shall apply from 1 July 2006.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*



## ANNEX I

### TERRITORIES REFERRED TO IN ARTICLE 2(9)

1. The territory of the Kingdom of Belgium.
2. The territory of the Kingdom of Denmark with the exception of the Faroe Islands and Greenland.
3. The territory of the Federal Republic of Germany.
4. The territory of the Kingdom of Spain with the exception of Ceuta and Melilla.
5. The territory of the Hellenic Republic.
6. The territory of the French Republic.
7. The territory of Ireland.
8. The territory of the Italian Republic.
9. The territory of the Grand Duchy of Luxembourg.
10. The territory of the Kingdom of the Netherlands in Europe.
11. The territory of the Portuguese Republic.
12. The territory of the United Kingdom of Great Britain and Northern Ireland.
13. The territory of the Republic of Austria.
14. The territory of the Republic of Finland.
15. The territory of the Kingdom of Sweden.

## **ANNEX II**

### **THE COMPETENT AUTHORITIES**

#### **Chapter I: subject matters for the training of staff performing official controls**

1. The different control techniques such as auditing, sampling and inspection.
2. The control procedures.
3. Feed law and food law.
4. The different stages of production, processing and distribution, and the possible risks for human health, and where appropriate for the health of the animals and plants and for the environment.
5. Assessment of non-compliance with feed law and food law.
6. Hazards in animal, feed and food production.
7. The Hazard Analysis and Critical Control Point (HACCP) procedures and the techniques for the assessment of the HACCP procedures.
8. Management systems such as quality assurance programmes operated by the feed and food businesses and the assessment thereof in so far as these are relevant for feed law and food law requirements.
9. Official certification systems.
10. Contingency arrangements in case of emergencies.
11. Legal proceedings and implications of official controls.
12. Examination of written, documentary material and other records, including those related to proficiency testing, accreditation and risk assessment, which may be relevant to the assessment of compliance with feed law or food law; this may include financial and commercial aspects.
13. Any other area, including animal health and animal welfare, that is deemed necessary to ensure that official controls are carried out in accordance with this Regulation.

#### **Chapter II: subject matters for control procedures and guidelines**

1. The organisation of the competent authority and the relationship between the central competent authorities and the authorities to which the competence for performing official controls has been conferred to.
2. The relationship between the competent authorities and the non-governmental bodies to which the competence for performing official controls has been delegated.

3. A statement on the objectives to be achieved.
4. The tasks, responsibilities and duties of staff.
5. The control methods and techniques.
6. Monitoring and surveillance programmes.
7. Mutual assistance in case the controls require action by more than one Member State.
8. Action to be taken following official controls.
9. The co-operation with other services or departments that may have responsibilities in the matter.
10. Verification of appropriateness of methods of analysis and detection tests.
11. Any other activity or information required for the proper functioning of the official controls.

### ANNEX III

#### CRITERIA FOR METHODS OF ANALYSIS

1. Methods of analysis should take into account the following criteria:
  - (a) accuracy;
  - (b) applicability (matrix and concentration range);
  - (c) limit of detection;
  - (d) limit of determination;
  - (e) precision; repeatability intra-laboratory (within laboratory), reproducibility inter-laboratory (within and between laboratories) generated from collaborative trial data and where performance criteria for analytical methods have been established, criteria compliance tests, rather than measurement uncertainty considerations;
  - (f) recovery;
  - (g) selectivity;
  - (h) sensitivity;
  - (i) linearity;
  - (j) other criteria that may be selected as required.
2. The precision values referred to in 1(e) shall either be obtained from a collaborative trial which has been conducted in accordance with an internationally recognised protocol on collaborative trials (e.g. ISO 5725:1994 or the IUPAC International Harmonised Protocol) or, where performance criteria for analytical methods have been established, be based on criteria compliance tests. The repeatability and reproducibility values shall be expressed in an internationally recognised form (e.g. the 95% confidence intervals as defined by ISO 5725:1994 or IUPAC). The results from the collaborative trial shall be published or freely available.
3. Methods of analysis which are applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities.
4. In situations where methods of analysis can only be validated within a single laboratory then they should be validated in accordance with IUPAC Harmonised Guidelines, or where performance criteria for analytical methods have been established, be based on criteria compliance tests.
5. Methods of analysis adopted under this Regulation should be edited in the standard layout for methods of analysis recommended by the International Organisation for Standardisation.

## ANNEX IV

### FEES RELATED TO THE CONTROL OF GOODS IMPORTED INTO THE COMMUNITY

#### **Chapter I Fees applicable to imported meat**

The fee for the official control of imported meat is fixed at a level of € 5 per tonne, with a minimum amount of € 30 per consignment.

#### **Chapter II Fees applicable to imported fishery products**

The fee for the official control of imported fishery products is fixed at a level of €5 per tonne, with a minimum amount of € 30 per consignment. Above 100 tonnes, the minimum standard amount of € 5 shall be reduced to:

- € 1,5 per additional tonne for fishery products which have undergone no preparation other than gutting;
- € 2,5 per additional tonne of other fishery products.

#### **Chapter III Fees applicable to imported live animals covered by Directive 91/496/EEC**

With regard to animals covered by Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC<sup>1</sup>, the following applies:

1. The fee for the control of the following species shall be at the standard rate of € 5 per tonne live weight with a minimum amount of € 30 per consignment: bovine, porcine and ovine animals, solipeds, poultry, rabbits. These include domestic and wild species.

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<sup>1</sup> OJ L 268, 24.9.1991, p. 56.

2. The fee for the control of other species is fixed at the actual cost of inspection expressed per animal or per tonne imported, with a minimum of € 30 per consignment, it being understood that this minimum does not apply to imports of species covered by Commission Decision 97/794/EC of 12 November 1997 laying down certain detailed rules for the application of Council Directive 91/496/EEC as regards veterinary checks on live animals to be imported from third countries<sup>2</sup>.

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<sup>2</sup> OJ L 323, 26.11.1997, p. 31.

## ANNEX V

### COMMUNITY REFERENCE LABORATORIES

1. Community reference laboratory for milk and milk products

AFSSA-LERHQA  
41, rue du 11 Novembre 1918  
94700 Maison Alfort  
France

2. Community reference laboratories for the analysis and testing of zoonoses

The laboratories designated in accordance with

- Directive .../... on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC<sup>1</sup>, and
- Regulation .../... on the control of salmonella and other food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC<sup>2</sup>.

3. Community reference laboratory for the monitoring of marine biotoxins

The laboratory referred to in Council Decision 93/383/EEC of 14 June 1993 on reference laboratories for the monitoring of marine biotoxins<sup>3</sup>, as amended by Decision 1999/312/EC<sup>4</sup>.

4. Community reference laboratory for viruses in molluscs

The laboratory referred to in Council Decision 1999/313/EC of 29 April 1999 on reference laboratories for monitoring bacteriological and viral contamination of bivalve molluscs<sup>5</sup>.

5. Community reference laboratories for residues

The laboratories referred to in Annex V, Chapter 1 of Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC<sup>6</sup>.

6. Community reference laboratory for transmissible spongiform encephalopathies (TSEs)

The laboratory referred to in Annex X, Chapter B of Regulation (EC) No 999/2001.

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<sup>1</sup> COM (2001) 452, document 2001/0176 (COD).

<sup>2</sup> COM (2001) 452, document 2001/0177 (COD).

<sup>3</sup> OJ L 166, 8.7.1993, p. 31.

<sup>4</sup> OJ L 120, 8.5.1999, p. 37.

<sup>5</sup> OJ L 120, 8.5.1999, p. 40.

<sup>6</sup> OJ L 125, 23.5.1996, p. 10.

## ANNEX VI

### CRIMINAL OFFENCES

#### **1. Feedingstuffs**

- (a) The use of materials whose circulation or use for animal nutrition purposes is restricted or prohibited, in breach of Article 1 of Commission Decision 91/516/EEC of 9 September 1991 establishing a list of ingredients whose use is prohibited in compound feedingstuffs<sup>1</sup> and Articles 3 and 11(b) of Council Directive 96/25/EC of 29 April 1996 on the circulation of feed materials,<sup>2</sup> or the use of which as feed materials for the preparation of compound feedingstuffs is prohibited in breach of Articles 3 and 10a(3) of Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs<sup>3</sup>.
- (b) The contamination of feedingstuffs with undesirable substances and products in breach of Articles 3 and 4 of Council Directive 1999/29/EC of 22 April 1999 on the undesirable substances and products in animal nutrition<sup>4</sup> and/or of the rules adopted by the Member States in order to comply with it.
- (c) The use of unauthorised or prohibited additives in feedingstuffs in breach of Article 3 of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs<sup>5</sup> and/or of the rules adopted by the Member States in order to comply with it.

#### **2. BSE/TSE**

- (a) The illegal handling and the placing on the market of specified risk materials in breach of Article 8 of Regulation (EC) No 999/2001.
- (b) The feeding to animals of prohibited products, in breach of the prohibition referred to in Article 7 of Regulation (EC) No 999/2001.
- (c) The use of ruminant material for the production of certain products of animal origin, in breach of Article 9(1) and (2) of Regulation (EC) No 999/2001.
- (d) The placing on the market of an animal suspect of being infected with TSE or any product thereof in breach of Article 12 of Regulation (EC) No 999/2001.
- (e) The placing on the market of any product of an animal confirmed to be infected with TSE in breach of Article 13 of Regulation (EC) No 999/2001.

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<sup>1</sup> OJ L 281, 9.10.1991, p. 23.

<sup>2</sup> OJ L 125, 23.5.1996, p. 35.

<sup>3</sup> OJ L 86, 6.4.1979, p. 30.

<sup>4</sup> OJ L 4.5.1999, p. 32.

<sup>5</sup> OJ L 14.12.1970, p. 1.



### 3. Food

- (a) The contamination and placing on the market of food with substances that may seriously affect human health, in breach of the provisions of Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food<sup>6</sup>.
- (b) The illegal handling, illegal placing on the market and illegal use in animals of prohibited substances in breach of the provisions of Directive 96/22/EC and/or of the rules adopted by the Member States in order to comply with it.
- (c) The use of unauthorised or prohibited additives in food in breach of Article 2 of European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners<sup>7</sup> and/or of the rules adopted by the Member States in order to comply with it.
- (d) The placing on the market of meat that has not been submitted to the official controls, in breach of Regulation (EC) No .../... (laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption).
- (e) The placing on the market of meat that has been declared unfit for human consumption at post-mortem inspection, in breach of Regulation (EC) No .../... (laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption).
- (f) The slaughter for human consumption of animals that have been found unfit for human consumption at ante mortem inspection, in breach of Regulation (EC) No .../... (laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption).

### 4. Pesticides

- (a) The use of prohibited pesticides in breach of Article 3 of Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances<sup>8</sup>.
- (b) The use of unauthorised pesticides in breach of Articles 3 and 4 of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market<sup>9</sup>.
- (c) The improper use of authorised pesticides in breach of Articles 3, 4 and 9 of Directive 91/414/EEC.

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<sup>6</sup> OJ L 37, 13.2.1993, p. 1.

<sup>7</sup> OJ L 91, 18.3.1995, p. 1.

<sup>8</sup> OJ L 33, 8.2.1979, p. 36.

<sup>9</sup> OJ L 230, 19.8.1991, p. 1.

- (d) The improper use of materials containing pesticides in feed and food, in breach of Articles 3, 4, 3, and 3 of Council Directives 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables<sup>10</sup>, 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals<sup>11</sup>, 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin<sup>12</sup> and 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables<sup>13</sup> respectively.

## 5. Safeguard restrictions

- Violation of a prohibition to import, export, place on the market, use or move animals, feed or foodstuff adopted according to the provisions laid down in Article 53 of Regulation (EC) n° 178/2002.
- Violation of a prohibition to import, export, place on the market, use or move animals, feed or foodstuff adopted according to the provisions of the relevant community feed and food legislation.

## 6. Animal by-products

The illegal placing on the market, the export or the use as feed material of processed animal protein and other processed products, in breach of the provisions laid down in Article 19 of Regulation (EC) N° 1774/2002 of the European Parliament and of the Council laying down health rules concerning animal by-products not intended for human consumption.

## 7. Animal health

- (a) The failure to notify the suspected presence of epizootic diseases in breach of:
- (i) Article 3 of Council Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease<sup>14</sup> and/or of the rules adopted by the Member States in order to comply with it;
  - (ii) Article 3(1) of Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever<sup>15</sup> and/or of the rules adopted by the Member States in order to comply with it;
  - (iii) Article 3 of Council Directive 92/40/EEC of 19 May 1992 introducing Community measures for the control of avian influenza<sup>16</sup> and/or of the rules adopted by the Member States in order to comply with it;

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<sup>10</sup> OJ L 340, 9.12.1976, p. 26.

<sup>11</sup> OJ L 221, 7.8.1986, p. 37.

<sup>12</sup> OJ L 221, 7.8.1986, p. 43.

<sup>13</sup> OJ L 350, 14.12.1990, p. 71.

<sup>14</sup> OJ L 315, 26.11.1985, p. 11.

<sup>15</sup> OJ L 316, 1.12.2001, p. 5.

<sup>16</sup> OJ L 167, 22.6.1992, p. 1.

- (iv) Article 3 of Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease<sup>17</sup>, and/or of the rules adopted by the Member States in order to comply with it;
  - (v) Article 3 of Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease<sup>18</sup>, and/or of the rules adopted by the Member States in order to comply with it;
  - (vi) Article 4 of Council Directive 93/53/EEC of 24 June 1993 introducing minimum Community measures for the control of fish diseases<sup>19</sup>, and/or of the rules adopted by the Member States in order to comply with it;
  - (vii) Article 5(1) of Council Directive 95/70/EC of 22 December 1995 introducing minimum Community measures for the control of certain diseases affecting bivalve molluscs<sup>20</sup>, and/or of the rules adopted by the Member States in order to comply with it;
  - (viii) Article 3 of Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue<sup>21</sup> and/or of the rules adopted by the Member States in order to comply with it;
  - (ix) Article 3(1) of Council Directive 2002/60 on African swine fever<sup>22</sup>, and/or the rules adopted by the Member States in order to comply with it;
  - (x) Article 3 of Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness<sup>23</sup>, and/or the rules adopted by the Member States in order to comply with it.
- (b) The non respect of the instructions given by the competent authority in case of a suspected or confirmed outbreak of one of the diseases referred to in Council Directive 82/894/EEC on the notification of animal diseases within the Community<sup>24</sup> and/or of the rules adopted by the Member States in order to comply with it.

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<sup>17</sup> OJ L 260, 5.9.1992, p. 1.

<sup>18</sup> OJ L 62, 15.3.1969, p. 69.

<sup>19</sup> OJ L 175, 19.7.1993, p. 23.

<sup>20</sup> OJ L 332, 30.12.1995, p. 33.

<sup>21</sup> OJ L 327, 22.12.2000, p. 74.

<sup>22</sup> OJ L 192, 20.7.2002, p. 27.

<sup>23</sup> OJ L 157, 10.6.1992, p. 19.

<sup>24</sup> OJ L 378, 31.12.1982, p. 58.

## 8. Animal welfare

The causing of unnecessary and severe pain, suffering or injury to animals in breach of

- (a) Article 3 or 4 of Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes<sup>25</sup>;
- (b) Article 3 or 4 of Council Directive 91/629/EEC of 19 November 1991 laying down minimum standards for the protection of calves<sup>26</sup>, as last amended by Commission Decision 97/182/EC<sup>27</sup>;
- (c) Article 3 or 4 (1) of Council Directive 91/630/EEC of 19 November 1991 laying down minimum standards for the protection of pigs<sup>28</sup>, as last amended by Commission Directive 2001/93/EC<sup>29</sup>;
- (d) Article 3 of Council Directive 1999/74/EC of 19 July 1999 laying down minimum standards for the protection of laying hens<sup>30</sup>;
- (e) Article 3 (1) of Council Directive 91/628/EEC of 19 November 1991 on the protection of animals during transport and amending Directives 90/425/EEC and 91/496/EEC<sup>31</sup>, last amended by Council Directive 95/29/EC<sup>32</sup>;
- (f) Article 3 or 5 (1) of Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing<sup>33</sup>.

## 9. Feed and food from third countries

The illegal introduction into the territory of the Community of feed and food in breach of Articles 14, 15 and 16 of this Regulation.

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<sup>25</sup> OJ L 221, 8.8.1998, p. 23.

<sup>26</sup> OJ L 340, 11.12.1991, p. 28.

<sup>27</sup> OJ L 76, 24.02.1997, p. 30.

<sup>28</sup> OJ L 340, 11.12.1991, p. 33.

<sup>29</sup> OJ L 316, 1.12.2001, p. 36.

<sup>30</sup> OJ L 203, 3.8.1999, p. 53.

<sup>31</sup> OJ L 340, 11.12.1991, p. 17.

<sup>32</sup> OJ L 148, 30.6.1995, p. 52.

<sup>33</sup> OJ L 340, 31.12.1993, p. 21.

## ANNEX VII

### INVENTORY OF THE IMPLEMENTING RULES THAT HAVE BEEN TAKEN ON THE BASIS OF THE DIRECTIVES REPEALED

1. **Implementing rules based on Directive 70/373/EEC on the introduction of Community methods of sampling and analysis for the official control of feedingstuffs.**
  - (a) First Commission Directive 71/250/EEC of 15 June 1971 establishing Community methods of analysis for the official control of feedingstuffs<sup>1</sup>.
  - (b) Second Commission Directive 71/393/EEC of 18 November 1971 establishing Community methods of analysis for the official control of feedingstuffs<sup>2</sup>.
  - (c) Third Commission Directive 72/199/EEC of 27 April 1972 establishing Community methods of analysis for the official control of feedingstuffs<sup>3</sup>.
  - (d) Fourth Commission Directive 73/46/EEC of 5 December 1972 establishing Community methods of analysis for the official control of feedingstuffs<sup>4</sup>.
  - (e) First Commission Directive 76/371/EEC of 1 March 1976 establishing Community methods of sampling for the official control of feedingstuffs<sup>5</sup>.
  - (f) Seventh Commission Directive 76/372/EEC of 1 March 1976 establishing Community methods of analysis for the official control of feedingstuffs<sup>6</sup>.
  - (g) Eight Commission Directive 78/633/EEC of 15 June 1978 establishing Community methods of analysis for the official control of feedingstuffs<sup>7</sup>.
  - (h) Ninth Commission Directive 81/715/EEC of 31 July 1981 establishing Community methods of analysis for the official control of feedingstuffs<sup>8</sup>.
  - (i) Tenth Commission Directive 84/425/EEC of 25 July 1984 establishing Community methods of analysis for the official control of feedingstuffs<sup>9</sup>.
  - (j) Eleventh Commission Directive 93/70/EEC of 28 July 1993 establishing Community methods of analysis for the official control of feedingstuffs<sup>10</sup>.

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<sup>1</sup> OJ L 155, 12.7.1971, p. 13; Directive as last amended by Directive 1999/27/EC (OJ L 118, 6.5.1999, p. 36).

<sup>2</sup> OJ L 279, 20.12.1971, p. 7. Directive as last amended by Directive 98/64/EC (OJ L 257, 19.9.1998, p. 14).

<sup>3</sup> OJ L 123, 29.05.1972, p. 6. Directive as last amended by Directive 1999/79/EC (OJ L 209, 7.8.1999, p. 23).

<sup>4</sup> OJ L 83, 30.3.1973, p. 21. Directive as last amended by Directive 1999/27/EC (OJ L 118, 6.5.1999, p. 36).

<sup>5</sup> OJ L 102, 15.4.1976, p. 1. Directive as amended by the Agreement on the European Economic Area (OJ L 1, 3.1.1994, p. 220).

<sup>6</sup> OJ L 102, 15.4.1976. Directive as last amended by Directive 94/14/EC (OJ L 94, 13.4.1994, p. 30).

<sup>7</sup> OJ L 206, 29.7.1978. Directive as last amended by Directive 84/4/EEC (OJ L 15, 18.1.1984, p. 28).

<sup>8</sup> OJ L 257, 10.9.1981, p. 38. Directive as amended by the Agreement on the European Economic Area.

<sup>9</sup> OJ L 238, 6.9.1984, p. 34.

<sup>10</sup> OJ L 234, 17.9.1993, p. 17.

- (k) Twelfth Commission Directive 93/117/EC of 17 December 1993 establishing Community methods of analysis for the official control of feedingstuffs<sup>11</sup>.
- (l) Commission Directive 98/64/EC of 3 September 1998 establishing Community methods of analysis for the determination of amino-acids, crude oils and fats, and olaquinox in feedingstuffs and amending Directive 71/393<sup>12</sup>.
- (m) Commission Directive 98/88/EC of 13 November 1998 establishing guidelines for the microscopic identification and estimation of constituents of animal origin for the official control of feedingstuffs<sup>13</sup>.
- (n) Commission Directive 1999/27/EC of 20 April 1999 establishing Community methods of analysis for the determination of amprolium, diclazuril and carbadox in feedingstuffs and amending Directives 71/250/EEC, 73/46/EEC and repealing Directive 74/203/EEC<sup>14</sup>.
- (o) Commission Directive 1999/76/EC of 23 July 1999 establishing a Community method of analysis for the determination of lasalocid sodium in feedingstuffs<sup>15</sup>.
- (p) Commission Directive 2000/45/EC of 6 July 2000 establishing Community methods of analysis for the determination of vitamin A, vitamin E and tryptophan in feedingstuffs<sup>16</sup>.
- (q) Directive 2002/70/EC of 26 July 2002 establishing requirements for the determination of levels of dioxins and dioxine-like PCBs in feedingstuffs<sup>17</sup>.

**2. Implementing rules based on Directive 95/53/EC of 25 October 1995 fixing the principles governing the organisation of official inspections in the field of animal nutrition**

- (a) Commission Directive 98/68/EC of 10 September 1998 laying down the standard document referred to in Article 9(1) of Council Directive 95/53/EC and certain rules for checks at the introduction into the Community of feedingstuffs from third countries<sup>18</sup>.
- (b) Commission Recommendation 2002/214/EC of 12 March 2002 on the coordinated inspection programmes in the field of animal nutrition for the year 2002 in accordance with Council Directive 95/53/EC<sup>19</sup>.

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<sup>11</sup> OJ L 329, 30.12.1993, p. 54.

<sup>12</sup> OJ L 257, 19.9.1998, p. 14.

<sup>13</sup> OJ L 318, 27.11.1998, p. 45.

<sup>14</sup> OJ L 118, 6.5.1999, p. 36.

<sup>15</sup> OJ L 207, 6.8.1999, p. 13.

<sup>16</sup> OJ L 174, 13.7.2000, p. 32.

<sup>17</sup> OJ L 209, 6.8.2002, p. 15.

<sup>18</sup> OJ L 261, 24.9.1998, p. 32.

<sup>19</sup> OJ L 70, 13.3.2002, p. 20.

## LEGISLATIVE FINANCIAL STATEMENT

**Policy area(s): Health and Consumer Protection**

**Activit(y/ies): Food safety, animal health, animal welfare and plant health**

**TITLE OF ACTION: PROPOSAL FOR REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON OFFICIAL FEED AND FOOD CONTROLS**

### 1. BUDGET LINE(S) + HEADING(S)

- B1-331: Other measures in the veterinary, animal welfare and public health field (ABB code: 170402)
- B1-334 (new): Feed and food safety and related activities (new ABB code: 170407)
- B1-334A (new): Feed and food safety and related activities – administrative expenditures (ABB code: 17010404)
- B5-3130B: Standardisation and approximation of legislation(ENTR) (ABB code: 020403)
- Support for developing countries in the framework of existing geographical programmes (DEV/AIDCO)

### 2. OVERALL FIGURES

**2.1. Total allocation for action (Part B): € 94.736 million for commitment**

**2.2. Period of application:** the duration of the action is unlimited

**2.3. Overall multiannual estimate of expenditure:**

(a) Schedule of commitment appropriations/payment appropriations (financial intervention) *(see point 6.1.1)*

€ million *(to three decimal places)*

	Year [n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. Years]	Total
Commitments	7.236	7.736	8.061	8.061	8.061	8.061	47.216
Payments	7.236	7.786	8.061	8.061	8.061	8.061	47.216

(b) Technical and administrative assistance and support expenditure (see point 6.1.2)

Commitments	7.920	7.920	7.920	7.920	7.920	7.920	47.520
Payments	7.920	7.920	7.920	7.920	7.920	7.20	47.520
Subtotal a+b							
Commitments	15.156	15.156	15.981	15.981	15.981	15.981	94.736
Payments	15.156	15.156	15.981	15.981	15.981	15.981	94.736

(c) Overall financial impact of human resources and other administrative expenditure (see points 7.2 and 7.3)

Commitments/ payments	18.844	18.844	18.844	18.844	18.844	18.844	113.064
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TOTAL a+b+c							
Commitments	34.000	34.000	34.825	34.825	34.825	34.825	207.800 *
Payments	34.000	34.000	34.825	34.825	34.825	34.825	207.800 *

\* out of which an indicative amount of € 16.2 Mio is linked to external aid programmes

#### 2.4. Compatibility with financial programming and financial perspective

[X] Proposal is compatible with existing financial programming.

[...] Proposal will entail reprogramming of the relevant heading in the financial perspective.

[...] Proposal may require application of the provisions of the Interinstitutional Agreement.

#### 2.5. Financial impact on revenue:<sup>1</sup>

[X] Proposal has no financial implications (involves technical aspects regarding implementation of a measure)\*\*

\*\* where appropriate, the financial impact on revenue could be subject to a further analysis, in particular as far as the training centre is concerned.

OR

[...] Proposal has financial impact – the effect on revenue is as follows:

***(NB All details and observations relating to the method of calculating the effect on revenue should be shown in a separate annex.)***

<sup>1</sup> For further information, see separate explanatory note.



(€ million to one decimal place)

Budget line	Revenue	Prior to action [Year n-1]	Situation following action					
			[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5]
	(a) Revenue in absolute terms							
	(b) Change in revenue	Δ						

*(Please specify each budget line involved, adding the appropriate number of rows to the table if there is an effect on more than one budget line.)*

### 3. BUDGET CHARACTERISTICS

**Budget line : B1-331 (ABB 170402)**

Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
Comp	Non-diff	NO	NO	NO	No [1A]

**Budget line : B1-334 (ABB 170407)**

Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
Comp	Non-diff	YES	NO	NO	No [1A]

**Budget line : B1-334A (ABB 17010404)**

Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
Comp	Non-diff	YES	NO	NO	No [1A]

**Budget line : B5-313 (ABB 020403)**

Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
Non-comp	Diff	NO	NO	NO	No [3]

**4. LEGAL BASIS**

Articles 37, 95 and 152, par. 4 of the Treaty

**5. DESCRIPTION AND GROUNDS****5.1. Need for Community intervention<sup>2</sup>***5.1.1. Objectives pursued*

Recent feed and food emergencies have highlighted deficiencies in national control systems. At the heart of the problem is the lack of a harmonised Community approach to the design and developments of national control systems. The White Paper on Food Safety places particular emphasis on this problem and clearly indicates this proposal to address the issues as one of the most important actions to achieve a high standard of consumer protection across the EU.

The present proposal is the result of a review of the existing Community rules on the subject, which were adopted separately for the animal feed sector, the food sector and the veterinary sector. It lays down uniform procedures to be respected by the competent authorities responsible for carrying out official controls as well as the tasks of the Commission with regards to the monitoring of these control activities. In accordance with the holistic approach, the proposal applies to the entire range of activities covered by feed and food law, which includes feed and food safety and other aspects that relate in general to consumer protection. Uniform and, in certain areas, strengthened procedures are also proposed for the control of feed and food imports from third countries.

In order to achieve the best results from this action, the proposal also contains enforcement measures, which include the imposition of sanctions at national and Community level in accordance with national and Community law respectively.

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<sup>2</sup> For further information, see separate explanatory note.

### *5.1.2. Measures taken in connection with ex ante evaluation*

On 12 January 2000, the Commission adopted the White Paper on Food Safety (COM (1999) 719 final). This paper constitutes a 360° degrees perspective evaluation of the Community Food Safety Policy.

The White Paper stresses, in particular, the need for a comprehensive piece of legislation in order to replace the different control requirements, taking into account the general principle that all parts of the feed and food production chain must be subject to official controls. It also indicates a clear need for a Community framework of national control systems, aimed at improving the quality of feed and food controls in the European Union. In response to these issues the White Paper sets out a plan for a radical reform of the food law based on a comprehensive, integrated approach ("farm to fork" approach) as well as the establishment of a European Food Authority.

### *5.1.3. Measures taken following ex post evaluation*

Not applicable, because it is a new action.

## **5.2. Action envisaged and budget intervention arrangements**

Implementation of the Feed and Food Control regulation will involve seven (7) principal actions, as detailed below. These concern, in particular, a new approach by the Commission to monitoring the implementation of relevant Community legislation, and actions to support this new approach. There is a clear need for these actions, which will improve the quality of controls at Community level and, consequently, raise food safety standards and provide a high level of consumer protection across the European Union. In addition, the implementation of these actions will enable food safety to be organised in a more co-ordinated and integrated manner with a view to a better functioning of the internal market.

1. At present, Community controls in Member States and in third countries are organised largely on a sectoral basis and are related to the mandates the Commission has in different sectoral or thematic legislation. The draft Regulation proposes a new approach to the way in which the Commission, and in particular the Food and Veterinary Office (FVO), monitors the implementation of feed and food law, including animal health and plant health, by Member States, and by third countries exporting feed, food, plants or animals to the EU.

Central to this new approach will be the requirement that all Member States and third countries (for the products they export to the EU) present to the Commission a general multi-annual control plan that describes how the national authorities ensure that the requirements of Community legislation on feed and food safety from "farm to fork" are met. In the case of third countries the general control plan shall form the basis of the guarantees that produce exported to the Community meets the prescribed requirements. Some of these third country plans will be quite modest since the range of products they export to the EU is limited. On the basis of these general multi-annual control plans the Commission will conduct, on a regular basis, general audits of the control activities of Member States and third countries. These general audits of overall control systems supplemented by inspections of specific sectors or particular control points as considered appropriate will largely replace the existing sectoral/thematic approach in both Member States and third countries.

At present, because of resource constraints, many of the control obligations placed on the Commission in the existing legislation cannot be completely met following the current sectoral/thematic control practices. However, the new approach does not request any additional staff because it is intended to enable the Commission to deploy its existing resources more efficiently and effectively by combining its various control activities into one overall integrated process. It also aims at ensuring that compliance by national authorities with all the main requirements of Community legislation is regularly checked and that no important gaps are left in the control process.

The existing practice of using national experts to supplement Commission expertise will be continued under the new approach. As the scope of general audits will be more far ranging and will involve a review of a wider range of Community legislation it is likely that there will be an increase in the number of national experts involved on an annual basis.

2. In order to achieve the objective pursued by this proposal, it will be also necessary to extend the existing network of Community Reference Laboratories (CRLs) operating with the Community financial support (see the list in Annex V of the proposal). The experience clearly shows that these laboratories have an important role in ensuring scientific and technical support in the area of food safety and in ensuring a high level of consumer protection. They must provide the national reference laboratories, for example, with details of analytical methods, organise comparative testing, co-ordinate research into new analytical methods, conduct specialised training and provide technical assistance to the Commission.

The designation of a number (6) of new CRLs is particularly needed in the sectors of microbiological risks (in relation to some emergent problems with pathogenic agents such as *Listeria*, *E. coli* and *Campylobacter*), feed, food contaminants, materials and articles intended to come into contact with foodstuffs, food additives.

Listeria, E. coli (verotoxigenic) and Campylobacter are responsible of important food-borne diseases with a relatively high mortality in humans and should be considered as a priority for new CRLs. The analytical methods are quite difficult and ring tests would be necessary, especially when there are problems in the intracommunity trade. It should be also considered that these zoonotic agents have been included in the list of pathogens and diseases to be monitored according to the new proposal for a Directive on the monitoring of zoonoses and zoonotic agents (COM (2001) 452 final). For food contaminants, food additives and material/articles intended to come into contact with foodstuffs, it is also considered important to establish CRLs. In these sectors, which are very complex, there is still a lack of methods to analyse all the substances for which regulations exist. The CRL will be requested, in particular, to provide national laboratories with the up-to-date information on analytical methods, to assist in the validation of analytical methods, to train the staff of the national laboratories in new methodologies, to ensure a harmonised application of methods of analysis, to provide reference materials and co-ordinate new research in the field.

As concerns the feed sector, and in particular in the field of feed additives and feed contaminants, there is also a need for a specialised expertise at Community level and the establishment of a CRL is considered necessary as for the other sectors above indicated.

3. Harmonisation of feed and food controls lead to an increased need for standardization activities, in particular as concerns the development of: common validated analytical methods in order to ensure necessary comparison of best results; sampling methods; methods for confirmation of test results and guidance documents based on new feed and food safety rules, in particular the HACCP (Hazard Analysis and Critical Control Points).

The involvement of standardization bodies such as CEN should therefore be considered as another important point in the framework of this draft proposal. European standards already today contribute to the quality and the safety of food by reinforcing European food policy and legislation (e.g. irradiated food materials, article in contact with food, aflatoxins, genetically modified organisms, Listeria monocytogenes, etc.). More than 100 European standards have already been produced by CEN in the food sector with the financial contribution of the Community. For this work, CEN has established several technical committees which have an active liaison with European trade federations and professional institutions.

4. A Country Profile database, in which all Community control activities, including control plans, reports on implementation, outcome of general audits, other inspections and follow up procedures, should be recorded, is needed. This would facilitate the integration of Community control activities and enable a comprehensive overview of the state of implementation of EU legislation. The development of this instrument will also enable the Commission to monitor the performance of control actions as well as setting prioritisation of activities.
5. Training is a strategic issue in the context of this proposal. The establishment of a Community training centre and the organisation of training programmes for officials from Member States are particularly needed with a view to ensuring that controls are carried out in a uniform way and to promoting a harmonised approach to feed and food safety across the EU. Community training programmes will also make an important contribution to improve uniform judgements in case of infringements. The new Commission facilities in Grange/Ireland, which is equipped for this purpose, as well as other facilities available in Brussels are suitable venues for the co-ordination and delivery of the training programmes.

However, the development and management of the training programme would be a separate and distinct task and not an integral part of Commission activities. It is envisaged that the provision and management of the overall training activity will be contracted from the private sector.

The costing of this training centre is provisionally based on a total number of 300 participants annually from Member States and from third countries (in particular developing countries). For the purpose of this estimate, around 15 courses of 2 weeks duration each should be provided annually.

Moreover, as the programme develops, it should be possible to provide additional training days or some lecture format courses with larger classes keeping within budget or at relatively little additional costs.

It is proposed that the contracted training provider develops the programme, in accordance with Commission directions. In this respect, the type of training foreseen, which is of high-specialised nature, will be directed at the operation of official controls in the context of implementation of EU legislation. In the case of developing third countries, specific training formats will be developed to meet specific training requirements.

Depending on the range of training, it is foreseen that this would be developed by a core group of 6 to 8 full-time staff who would also act as trainers, supplemented by expert input from specialists in all fields. The training contractors should provide the support services for language services, administration and management of the programme.

The global estimated expenditures for participation, training courses and training materials, language services (including interpretation and translation services) as well as administration and management of the programme would amount to around € 7.5 Mio each year. It is foreseen that the programme will be developed in incremental steps over a six year-period on the supposition that training will cover the full scope of the feed and food, animal health and animal welfare and plant-health legislation.

As programmes will also require updating and adjustment following evaluation, development is foreseen as a continuous process.

6. The draft Regulation also foresees the possibility to deliver assistance to developing countries through, in particular, technical assistance in the countries themselves, the promotion of twinning projects and the provision of training courses in the EU for officials from third countries (this training could be combined in part with that for officials from Member States).

Moreover the draft Regulation is in line with the objectives indicated in the Communication from the Commission to the Council and the European Parliament on Trade and Development, Assisting developing countries benefit from trade (COM (2002) 513 final) which put emphasis on the international dimension of Feed and Food Safety Standards. This Communication, as it is clearly stated on page 25, reveals the need “to reinforce current efforts to improve developing countries’ capacity in sanitary and phytosanitary field, as compliance with sanitary and phytosanitary standards has emerged as one of the major constraints on the increase of exports by developing countries to industrialised markets. In particular, pursue the development of a programme of action in the sanitary and phytosanitary field, including a standard approach to country assessment, a menu of possible technical assistance measures for common problems, including relevant training programmes, and the identification of sources of additional funding and relevant expertise”.

These activities will therefore be decided in the framework of external aid programmes and will focus on the countries listed by the Development Aid Committee of OECD.

The amounts indicated hereafter are only indicative as they refer to external aid appropriations.

7. The technical and legislative process (in particular because of the large number of implementation measures to be prepared and adopted following the adoption of the proposal) will be largely based upon the existing staff.

However, the cost of meetings with relevant experts of Member States and, where necessary, of external expertise should be taken into account. Travelling costs for such meetings are reimbursed for one expert per Member State.

A total of five meetings per year of the Standing Committee for Food Chain and Animal Health (already financed under Part A of the budget) is planned.

Twenty meetings of expert working groups per year (sectors: feed control, food control, co-ordinated control programmes, control of residues and contaminants, control on imports and list of third countries) are planned. These meetings are already financed under part A and should be, after the entry into force of this draft Regulation, financed under the Part B of the budget (B1-334A line, administrative expenditures).

The global number of estimated meetings for this activity should, however, not increase significantly in relation to the current situation.

A number of meetings will be required to review the outcome of general audits, the guidelines for the general control plans and the annual report on the outcome of controls. It is also intended to have more active dialogue between the Commission and Member States and third countries on the results of control activities generally. It is estimated that additional six meetings per year will be necessary for this purpose (to be financed under the administrative expenditure under the B1-334A line ).

Some additional expenditure will be also required for certain accompanying measures which include, in particular, the organisation of conferences, the establishment of the necessary databases and the publication of information relating to feed and food, animal health, animal welfare and plant health.

### **5.3. Methods of implementation**

Direct management i.e. technical and financial approval of the action by Commission staff.



## 6. FINANCIAL IMPACT

### 6.1. Total financial impact on Part B - (over the entire programming period)

*(The method of calculating the total amounts set out in the table below must be explained by the breakdown in Table 6.2.)*

#### 6.1.1. Financial intervention

Commitments (in € million to three decimal places)

Breakdown	[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. Years]	Total
Existing Community Ref. Lab. (currently financed under B1-331, to be financed under B1-334, 170407) (Art. 34)	2.661	2.661	2.661	2.661	2.661	2.661	15.966
New Community Ref. Laboratories ( <b>new to be financed under B1-334, 170407</b> ) (Art. 34)	0.500	1.000	1.500	1.500	1.500	1.500	7.500
Country profile database to current FVO database (MIS 24 – system) (part of the costs are currently financed under B5-100, to be financed under budget line B1-334, 170407)	0.375	0.375	0.200	0.200	0.200	0.200	1.550
Expenses for national experts participating in FVO missions (currently financed under B5-100, to be financed under budget line B1-334, 170407) (Art. 48, 49 and 69)	0.500	0.500	0.500	0.500	0.500	0.500	3.000
Standardisation of methods of analysis (currently financed by ENTR under budget line B5-3130B, 020403)	0.500	0.500	0.500	0.500	0.500	0.500	3.000
Support for developing countries – twin projects* (Art. 54)	2.500	2.500	2.500	2.500	2.500	2.500	15.000
Support for developing countries – technical assistance on-the-spot* Art. 54	0.200	0.200	0.200	0.200	0.200	0.200	1.200
<b>TOTAL</b>	<b>7.236</b>	<b>7.736</b>	<b>8.061</b>	<b>8.061</b>	<b>8.061</b>	<b>8.061</b>	<b>47.216</b>
* these amounts are only indicative as they refer to external aid actions within the geographical programmes							

6.1.2. *Technical and administrative assistance, support expenditure and IT expenditure (commitment appropriations)*

<b>New – to be financed under B1-334A</b>	[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. Years]	Total
1) Technical and administrative assistance							
a) Technical assistance offices – Training Centre (Art. 53 et 54) budget line B1-334A, 17010404)	7.500	7.500	7.500	7.500	7.500	7.500	45.000
b) Other technical and administrative assistance: - intra muros: - extra muros <i>of which for construction and maintenance of computerised management systems</i>							
Subtotal 1							
2) Support expenditure							
a) Studies/Conferences	0.100	0.100	0.100	0.100	0.100	0.100	0.600
b) Meetings of experts	0.270	0.270	0.270	0.270	0.270	0.270	1.620
c) Information and publications	0.050	0.050	0.050	0.050	0.050	0.050	0.300
Subtotal 2	0.420	0.420	0.420	0.420	0.420	0.420	2.520
<b>TOTAL</b>	7.920	7.920	7.920	7.920	7.920	7.920	47.520

## 6.2. Calculation of costs by measure envisaged in Part B (over the entire programming period)<sup>1</sup>

(Where there is more than one action give sufficient detail of the specific measures to be taken for each one to allow the volume and costs of the outputs to be estimated.)

Commitments (in € million to three decimal places)

Breakdown	Type of outputs (projects, files)	Number of outputs (total for years 1... n)	Average unit cost	Total cost (total for years 1...n)
	1	2	3	4=(2X3)
Existing Community Reference Laboratories (currently financed under B1-331, to be financed under B1-334, 170407) <i>(See annex V of Feed and Food Regulation : CRL milk, zoonoses, salmonella, marine biotoxins, bivalve molluscs, TSE, 4 CRL on residues)</i>	Laboratories	60	0.266	15.966
Community Reference Laboratories (new to be financed under B1-334, 170407) <i>(micro-biological risks such Listeria and E.Coli , food contaminants, food additives, feed, contact material, ...)</i>	Laboratories	30	0.250	7.500
Training programmes (budget line : B1-334A, 17010404)	Participants	1800	0.025	7.500
Country Profile database (B1-334, 170407)	Country	UE +200 third countries		1.550
Standardisation of methods of analysis (B5-3130B, 020403)	Analysis			3.000
Expenses for national experts participating in FVO missions (budget line B1-334, 170407) (Art. 48, 49 and 69)	Experts			3.000
Support for developing countries – twin projects	Projects	30	0.500	15.000
Support for developing countries – technical assistance on-the-spot	Missions	30	0.040	1.200

<sup>1</sup> For further information, see separate explanatory note.

## 7. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

### 7.1. Impact on human resources

Types of post		Staff to be assigned to management of the action <b>using existing additional resources</b>		Total	Description of tasks deriving from the action
		Number of permanent posts	Number of temporary posts		
Officials or temporary staff	A	107	11	118*	<i>If necessary, a fuller description of the tasks may be annexed.</i>
	B	6		6*	
	C	36		36*	
Other human resources				0	
Total		149	11	160*	

\* out of which staff for FVO : 107A , 6B, 36C (in total 149)

### 7.2. Overall financial impact of human resources

Type of human resources	Amount (€)	Method of calculation *
Officials	16.092.000	149 x 108.000
Temporary staff	1.188.000	11 x 108.000
Other human resources (specify budget line)		
Total	17.280.000	

The amounts are total expenditure for twelve months.

The needs for human and administrative resources shall be covered within the allocation granted to the managing DG in the framework of the annual allocation procedure.

### 7.3. Other administrative expenditure deriving from the action

Budget line (number and heading)	Amount €	Method of calculation
<b>Overall allocation (Title A7)</b>		
A0701 – Missions	1.512.000	Equivalent of 225 missions per year (new approach may involve some consolidation of missions using more inspectors per mission)
A07030 – Meetings		
A07031 – Compulsory committees <sup>1</sup>	52.000	
A07032 – Non-compulsory committees <sup>1</sup>		
A07040 – Conferences		
A0705 – Studies and consultations		5 meetings/year x 10.400€ = 52.000
Other expenditure (specify)		
<b>Information systems (A-5001/A-4300)</b>		
<b>Other expenditure - Part A (specify)</b>		
Total	1.564.000	

The amounts are total expenditure for twelve months.

1 Regulatory Committee (Standing Committee Food Chain and Animal Health)

I. Annual total (7.2 + 7.3)	18.844.000 €
II. Duration of action	illimited
III. Total cost of action (I x II)	€

## 8. FOLLOW-UP AND EVALUATION

### 8.1. Follow-up arrangements

The Commission will constantly monitor the implementation of this action. According to Article 46 of the proposal, Member States are requested to submit every year a report with the main information on the implementation of national control plans. The Commission shall assess the information provided by member States as well as the outcome of Commission controls in the Member States and establish a report on the overall operation of official control systems in the Member States. This report will be submitted to the European Parliament and the Council.

The Commission will also evaluate the outcome of Community controls in third countries and report on the results thereof (Article 49).

Appropriate procedures are already in place for evaluating the yearly technical work-programmes of the existing Community Reference Laboratories. Estimated costs are normally evaluated between the Commission services and the relevant CRL; they are revised if necessary, before a Commission decision is adopted each year. The same procedures will be followed for new designed CRLs.

Appropriate procedures will be also established for evaluating Community programmes concerning training and assistance for developing countries. The FVO will have an important role in ensuring the organisation, the management and adequate follow-up information on the inputs, outputs and results of these programmes.

## **8.2. Arrangements and schedule for the planned evaluation**

The Commission has to consider yearly the effectiveness of the feed and food control system through wide sources of information, in particular from reports and documentary evaluations indicated above in point 8.1.

## **9. ANTI-FRAUD MEASURES**

DG SANCO currently enforces appropriate measures, including controls and inspection, in order to prevent risk of fraud or irregularities concerning Community expenditures.

In this context, also OLAF may intervene on its own initiative or following information from different sources.

## **IMPACT ASSESSMENT FORM**

### **THE IMPACT OF THE PROPOSAL ON BUSINESS WITH SPECIAL REFERENCE TO SMALL AND MEDIUM-SIZED ENTERPRISES( SMEs)**

#### **TITLE OF PROPOSAL**

Regulation of the European Parliament and of the Council on official feed and food controls

#### **DOCUMENT REFERENCE NUMBER**

SANCO/ 1420/2002 REV 1 - COM (2003) 52 Final

#### **THE PROPOSAL**

1. Taking account of the principle of subsidiarity, why is Community legislation necessary in this area and what are its main aims?

The proposal is contained in the action programme in the Annex to the Commission's White Paper on Food Safety. The proposal aims to establish a Community framework of national and Community control systems by merging and completing the existing Community rules for national controls and Community controls within the European Union, at the borders and in third countries.

This proposal lays down at Community level the general principles to be respected by the competent authorities in the Member States for the performance of official feed and food controls and their follow up as well as the tasks of the Commission. The new system of official control, according to the stable to table approach, will cover all sectors of the food chain, including feed production and animal feeding, primary production, food processing, storage and distribution. Feed and food from a third country to be introduced in the territory of the European Union shall be submitted to official control prior to the release of feed and food for free circulation.

The harmonisation of control systems at Community level will guarantee a better and equal protection of consumers all around Europe and, besides, a smooth functioning of the internal market. All the interested parties agree that this harmonisation is needed.

#### **THE IMPACT ON BUSINESS**

2. Who will be affected by the proposal?

– which sectors of business

All feed and food businesses along the entire food chain - including businesses involved in feed production and animal feeding, primary production, food processing, storage, transport, distribution, retail level, importers and exporters - will be affected by this proposal due to the fact that they are the targets of official controls.

- which sizes of business (what is the concentration of small and medium-sized firms)

All sizes of businesses are affected, including a large proportion of small and medium-sized firms.

- are there particular geographical areas of the Community where these businesses are found

Businesses in the feed and food sectors are broadly distributed in all Member States, therefore the proposal has a similar impact over the entire Community and it is not aimed at any particular geographical area.

### 3. What will business have to do to comply with the proposal?

The proposal is mainly addressed to competent authorities in the Member States. It is their task to organise official controls in order to verify whether feed and food businesses uphold their responsibilities and to monitor the correct application of feed and food legislation by these businesses at all stages of the feed and food chain.

As a consequence of this, feed and food businesses will be subject to regular controls by the competent authorities in the Member States. This creates a situation where feed and food business operators have to assume their responsibility in the implementation and enforcement of the requirements of food law and have to ensure the safety and wholesomeness of products for which they are responsible.

Where non-compliance, including frauds, infringements, irregularities or any other failure, is identified and depending on the nature thereof, food business operators shall be requested by the competent authorities in the Member States to remedy the situation. Depending on the results of control activities, where necessary, food businesses shall be subjected to appropriate measures and sanctions.

The competent authorities in the Member States may subject feed and food businesses to the levying of fees for costs incurring for certain control activities. This is to ensure that adequate financial resources are made available for organising national official feed and food controls. As a matter of subsidiarity, it is left to the Member States to define what activities are subject to fees.

### 4. What economic effects is the proposal likely to have?

- on employment

The effect of the proposal on employment is expected to be more or less neutral.



- on investment and the creation of new businesses

Rules for the organisation of official feed and food controls already apply at present. This proposal aims to a better harmonisation and to establish an effective and consistent Community framework of national official control systems for ensuring protection of consumer health and safety and equal requirements of feed and food businesses. It is not expected that the proposed rules will create extra investments or the creation of new businesses.

- on the competitiveness of businesses

Beside a higher level of consumer protection, quality official control systems will make an effective contribution to the functioning of the internal market and to the improvement of business competitiveness. At present, businesses that do not respect the same standards for the protection of consumer health and safety might have an unfair advantage over those that do.

An effective implementation of official control systems at national and Community level will reduce such unfair competition between businesses both within the internal market and in the context of international trade. The whole business sector could also gain a marketing advantage in terms of the increased confidence by consumers as a result of the improvement in official control activities.

5. Does the proposal contain measures to take account of the specific situation of small and medium-sized firms (reduced or different requirements etc)?

This proposal follows a horizontal approach and its provisions are of general application. Therefore, it does not contain measures specifically aimed at or adapted for small and medium-sized firms.

It is mainly addressed to the Member States which have the task of organising official controls in order to verify and monitor the correct application of feed and food legislation by businesses at all stages of the feed and food chain.

## **CONSULTATION**

6. List the organisations which have been consulted about the proposal and outline their main views.

A broad consultation with Member States and the relevant organisations representative of social and economic parties has been carried out. Most of the comments received as a result of this consultation have been taken into consideration in the framework of this proposal.

An ad-hoc meeting of the Advisory Committee has been held to discuss the mayor issues in relation with the new official feed and food control system. Many of the organisations consulted within the Advisory Committee have confirmed their position on written.

List of organisation that participated at the meeting:

- Bureau Européen des Unions des Consommateurs (BEUC)
- European Community of Consumer Co-operatives (EUROCOOP);
- Federation of Veterinarians in Europe (FVE)
- Committee of Agricultural Co-operation in the European Union (COPE/COGECA)
- EUROCOMMERCE
- European Livestock and Meat Trading Union (UECBV)
- Association of Poultry Processors and Poultry Import and Export Trade in the European Union (AVEC)
- Confédération Internationale de la Boucherie et de la Charcuterie (CIBS)
- European Association of Craft, Small and Medium Sized Enterprises (EUAPME)
- European Dairy Association (EDA)
- Confédération des Industries Agroalimentaires de la CEE (CIAA)
- Fédération Européenne des Fabricants d'Aliments Composés (FEFAC)
- Union Européenne du Commerce de Gros des Produits Laitiers et Dérivés (EUCOLAIT)
- Fédération Européenne de l'Industrie des Aliments pour Animaux Familiers (FEDIAF)
- Fédération Européenne de l'Industrie de la Santé Animale (FEDESA)
- Fédération Européenne des Fabricants d'Adjuvants pour la Nutrition Animale (FEFANA)
- Liaison Centre for the Meat Processing Industry in the EU (CLITRAVI)
- Comité du Commerce des Céréales et des Aliments du Bétail auprès de la CEE (COCERAL)
- Eurogroup for animal welfare.

The main conclusions of this consultation are as follow:

- General endorsement of all organisation for the proposal and for most of the principles underlying it. The new concept of national control plans was particularly welcomed.

- Representatives of the feed and food production, processing and distribution sectors stressed that in carrying out official controls, account should be taken of the results of the own checks already carried out by the feed and food businesses.
- Concerning imports, representatives of the feed and food production, processing and distribution sectors expressed concern about the cost implications for the destruction, re-dispatch or storage of consignments when non-compliance is found at import.
- Concerning the laboratory tests, certain organisations requested to have access to the same laboratory, testing methods and reference materials as the competent authorities. They also request that a counter sample should be made available to them in order to safeguard their interests.
- Concerning inspection fees, certain groups stressed that official controls should be financed from national budget and not from fees imposed on feed and food businesses. Other groups insisted that the fees imposed to them should be balanced so as not to create excessive burdens on small businesses. One consumer organisation cautions against consumers ending up paying higher food prices when a system of fees is imposed.
- Some organisation expressed concern about possible consequences for third countries, in particular on the need to present control plan. From their part, consumers welcomed the proposal on the issue of assistance for developing countries.
- Certain organisations stressed the need to create a transparent situation with regard to standards to be respected by third countries when exporting feed and food to the Community.
- Representatives of the feed and food production, processing and distribution sectors stressed the need to be kept informed about the results of national and Community controls.