COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 14.04.2003
COM(2003) 180 final

2003/0071 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying down requirements for feed hygiene

(presented by the Commission)

EXPLANATORY MEMORANDUM

I. Current situation

The main purpose of the current 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 (as last amended by Council Directive 1999/29/EC of 22 April 1999) is to ensure that certain establishments and intermediaries that manufacture, produce or put into circulation certain additives, premixtures, compound feedingstuffs and products covered by Directive 82/471/EEC are approved or registered by competent authorities verifying compliance with the technical specifications detailed in the annexes.

Commission Directive 98/51/EC of 9 July 1998 lays down certain measures for implementing Council Directive 95/69/EC.

The production or use of some of the products requires only registration, based on an undertaking by the establishment to comply with a number of conditions.

The production or use of some other products requires approval of the plant on the basis of very strict conditions designed to safeguard animals, humans and the environment. Such approval is subject to a mandatory on-the-spot verification by the competent authority that the conditions laid down in the Directive have been complied with.

According to the current legislation, the different level of risk to human health, animal health and the environment justifies this dual regime for the production and use of the different substances. Approval applies to establishments which intend to manufacture or use products deemed sensitive, whilst mere registration applies to establishments using less sensitive products.

Upon completion of the procedure, applicants are issued with an approval number or a registration number, as the case may be, and the firms concerned are entered in lists drawn up by the competent authority.

Feed businesses operating in the feed chain and carrying out activities other than those described in Directive 95/69/EC are exempt from the registration or approval requirement.

The Directive has been in force since 8 February 1996, and Member States should have adopted, not later than 1 April 1998 the laws, regulations and administrative provisions necessary to comply with it.

II. The need for changes

Following the BSE crisis, the two occurrences of serious dioxin contamination and other concerns such as the contamination of feed materials and feedingstuffs with nitrofen or hormones, a need has been identified for an appropriate legal instrument to:

– ensure safety of all kinds of feed;

– ensure that all feed businesses operate in accordance with harmonised hygiene requirements; and

– improve traceability

III. Feed Hygiene

The implementation of Directive 95/69/EC has shown that some of the conditions remain valid and that their application could be extended to the production of all kinds of feed.

It therefore makes sense at the present time to lay down requirements for feed businesses which at present fall outside of the scope of Directive 95/69/EC and, at the same time, to revise the minimum conditions in order to make general and clearer rules applicable to all feed businesses, provide greater transparency and take into account recent developments in feed hygiene:

a) The HACCP system

In order to bring animal nutrition legislation into line with the principles of food hygiene laid down by the Codex Alimentarius, it is proposed that the Hazard Analysis and Critical Control Points (HACCP) principles prescribed by that organization be introduced. The implementation of these principles will be mandatory for all feed business operators other than at the level of primary production. It prescribes a number of steps to be followed by operators throughout the production cycle in order to facilitate - through hazard analysis - the identification of points where control is critical with regard to feed safety.

In implementing HACCP, operators will have to live up to their responsibilities. They will need to design a specific monitoring programme. All potential hazards must be identified and proper control procedures for each feed business individually established. Corrective action must be taken when controls show that problems may occur. Regular updates of the system must be made.

The principles contain the obligation to keep documents and records of whatever checks are carried out. This allows for more efficient and effective control by the competent authorities.

b) Traceability

Traceability is already a general requirement 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.

Experience has clearly shown animal feed to be the cause of some incidents that could pose a risk to human and animal health.

Successive feed crises have demonstrated that identifying the origin of feed is of prime importance in terms of health protection. In particular, traceability facilitates the withdrawal of feed and food and enables the competent authorities to be provided with targeted and accurate information on whatever products are involved.

The new proposal introduces the compulsory registration of all feed businesses by the competent authority. In certain cases, where it is necessary to have certainty about whether feed businesses are complying with the hygiene rules, approval will be required. In such cases the competent authority will give official approval following an on-the-spot visit to check on compliance.

c) Responsibilities and hygiene

Under European food law, and more especially in hygiene legislation, the primary responsibility for ensuring compliance with food law, and in particular the safety of food, rests with food businesses. This proposal will extend the principle to the entire feed chain.

This proposal seeks to ensure that feed safety is considered at all stages that may have an impact on feed and food safety. A feed business must therefore ensure that feed for which it is responsible does not have the potential to cause a feed or food safety problem, and should ensure that working practices are such that feed and food safety is not compromised. The proposal establishes a requirement that only safe feed be placed on the market and establishes a link with the need to ensure that food from animals fed on such feed is safe.

Conditions for feed business operators may differ according to whether they are or are not operating at the level of primary production.

For instance, the duration of the production cycle at primary level can predispose to unavoidable events that may occur, such as weather-related or environmental factors. It is difficult then to develop the awareness needed to identify all possible risks and to establish an appropriate control programme to deal with them.

Then again, unacceptable risks may occur on manufacturing premises, for example, as a result of wrong practices at any stage of the preparation, processing, manufacturing, packaging, storing, transportation, distribution and handling of feed. The idea is to improve preventive measures by establishing appropriate control systems, with the various processing stages being analysed to establish the relevant risk. The feed chain is very complex, and the multi-ingredient composition of feed is often also complicated, so failures at any stage in the chain

can have huge consequences. Feed business operators must ensure then, by providing a financial guarantee, that they are covered for risks related to their business, more especially, costs arising from the withdrawal from the market, treatment and/or destruction of feed, and food produced therefrom, that can present a serious risk to human or animal health and/or the environment.

d) Imports of feed from non-member countries

Provisions are made for feed imported into the Community to comply with the Community hygiene standards or with equivalent standards in Commission's proposal for a Regulation (EC) …/… on official feed and food controls.

More particularly:

- the third country of dispatch must appear on a list of third countries from which imports of feed are permitted;

- the establishment of dispatch must appear on a list of establishments from which imports of feed are permitted;

e) The farm to table approach and primary production

It is essential to be consistent with the cornerstone of the food and feed safety policy, i.e. the "farm to table" approach, and to include the primary production stage under conditions of registration and feed hygiene. Hazards in feed may originate at the farm, which is why it is proposed that the hygiene rules be extended to cover hygiene at farm level. This will provide Community legislation with an instrument that covers the entire feed chain and the food chain, from farm to table. To achieve the required level of hygiene at farm level, it is suggested that possible hazards occurring in primary production and methods to control such hazards be addressed in guides to good practice.

To exempt farms producing feed, and to exclude animal feeding, would give rise to a divergence in the approach to food legislation, a degree of inconsistency and some lacunae, which would be difficult to justify.

f) Flexibility

Experience in the Community has shown that a certain flexibility is needed, in particular for small businesses, especially those situated in regions suffering from special geographical constraints.

The proposal aims to provide for such flexibility by requiring Member States, as a matter of subsidiarity, to ensure the appropriate level of hygiene in these businesses, without compromising the objectives of feed safety. The competent authorities in the Member States are the most appropriate bodies to judge about the needs at that level, and they must take their responsibility in this issue.

The own-checking system has to be made sufficiently flexible to take account of the different circumstances which may be present in practice, in particular with regard to small businesses. For that purpose, guides of practices can be developed to help implement the HACCP system.

IV. Feed hygiene and the Commission's White Paper on food safety

The proposal takes into account the principles of food safety that are spelt out in the Commission's White Paper on food safety[1], in particular that:

- The farm to table policy, covering all sectors of the feed chain (including primary production, animal feeding and feed production), needs to be systematically implemented.
- Feed safety policy must be based on a comprehensive and integrated approach.
- Feed businesses, manufacturers and farmers have the primary responsibility for feed and food safety, with the competent authorities taking on a monitoring and enforcement role.
- A successful food policy depends on the traceability of feed and food and their ingredients.
- Feed safety policy must be risk-based.

This proposal also takes into account some of the provisions laid down in Regulation (EC) No 178/2002, such as:

- To provide a high level of animal and human health and also for the environment;
- To ensure effective functioning of the internal market in safe feed;
- To ensure feed traceability;
- To make feed business operators primarily responsible for safe feed;
- To make Member States responsible for the enforcement of food law;
- To ensure that only safe feed is placed on the market;
- To make feed business operators responsible where their products or activities may have an adverse impact on feed safety.

In conclusion, it is proposed in this Regulation that some general feed safety conditions be extended so as to cover hygiene at all levels in the feed chain.

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[1] COM (1999) 719 final, 12 January 2000

V. Summary

This proposal for a European Regulation responds to all these commitments by laying down requirements for a comprehensive system of registration of all feed business operators and requirements for feed production.

This Regulation will also lay down responsibilities and obligations for feed businesses which will address the causes of feed safety problems in a broad manner and will include requirements for feed businesses at the level of primary production.

General principles and definitions relating to feed production, including the responsibilities of feed business operators on the one hand and of the Member States' authorities on the other hand, are already laid down in Regulation (EC) 178/2002 and in the Commission's proposal for a Regulation (EC) …/…on feed and food controls.

VI. The Form of the Acts

As explained in the Commission's Green Paper on the general principles of food law in the European Union, the Commission believes that enacting Community law in the form of regulations presents a number of advantages, such as guaranteeing uniform application throughout the single market, making Community law more transparent and enabling it to be updated quickly to take account of technical and scientific developments. It is for these reasons that the present proposal is submitted in the form of a Regulation.

2003/0071 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying down requirements for feed hygiene

(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 Article 37(2) and Article 152 (4)(b) thereof,

Having regard to the proposal from the Commission[2],

Having regard to the opinion of the European Economic and Social Committee[3],

Having regard to the opinion of the Committee of the Regions[4],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[5],

Whereas:

(1) Livestock production plays a very important part in the agricultural sector of the Community. Satisfactory results depend to a large extent on the use of safe and good quality feed.

(2) The pursuit of a high level of protection of human health and animal health is one of the fundamental objectives of food law, as laid down in Regulation (EC) No 178/2002 of the European Parliament and the Council of 28 January 2002 laying down the general principals and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[6]. That Regulation also lays down other common principles and definitions for national and Community food law, including the aim of achieving free movement of feed within the Community.

(3) 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 70/542/EEC, 74/63/EEC, 79/373/EEC and 82/471/EEC[7] established the conditions and arrangements applicable

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2 OJ C , , p. .
3 OJ C , , p. .
4 OJ C , , p. .
5 OJ C , , p. .
6 OJ L 31, 1.2.2002, p. 1.
7 OJ L 332, 30.12.1995, p. 15. Directive as last amended by Directive 1999/29/EC (OJ L 115, 4.5.1999, p. 32).

to certain categories of establishments and intermediaries in the animal feed sector to enable them to exercise their activities. Experience has shown that these conditions and arrangements constitute a sound basis for ensuring feed safety

(4) Commission Directive 98/51/EC of 9 July 1998 laying down certain measures for implementing Council Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector[8] established certain measures for implementing Council Directive 95/69/EC, including arrangements for imports from non-member countries.

(5) Council Directive 95/69/EC established conditions for the approval of establishments producing certain substances listed in Council Directive 82/471/EEC[9] of 30 June 1982 concerning certain products used in animal nutrition.

(6) Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations[10] established the rules by which Member States can approve technical specifications.

(7) Experience has also shown that it is necessary to ensure that all feed businesses operate in conformity with harmonised safety requirements and that it is necessary to conduct a general review to take into account the need to ensure a higher level of protection of animal and human health, and of the environment.

(8) The principal objective of the new hygiene rules set out in this Regulation is to ensure a high level of consumer protection with regard to feed and food safety, taking particular account of the following principles:

(a) that primary responsibility for feed safety rests with the feed business operator;

(b) the need to ensure feed safety throughout the food chain, starting with primary production of feed up to and including the feeding of food producing animals;

(c) the general implementation of procedures based on the principles of hazard analysis and critical control points (HACCP) which, together with the application of good hygiene practice, should reinforce feed business operators' responsibility;

(d) that guides to good practice are a valuable instrument to help feed business operators at all levels of the feed chain comply with feed hygiene rules and with the application of HACCP principles;

(e) the establishment of microbiological criteria based on scientific risk criteria;

(f) the need to ensure that imported feed attains at least an equivalent standard as feed produced in the Community.

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8 OJ L 208, 24.7.1998, p. 43.

9 OJ L 213, 21.7.1982, p. 8. Directive as last amended by Council Directive 1999/20/EC (OJ L 80, 25.3.1999, p. 20)

10 OJ L 204, 21.7.1998, p. 37. Directive as last amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18)

(9) An integrated approach is necessary to ensure feed safety from and including primary production up to and including the placing on the market or export of feed.

(10) In accordance with the principles of proportionality and subsidiarity, it is appropriate that Community rules do not apply to certain cases of private domestic production of feed and feeding of certain animals nor to the direct supply of small quantities of primary products at local level and the retailing of pet food.

(11) It is necessary that feed hazards present at the level of primary production be identified and adequately controlled to ensure that the objectives of this Regulation are met. The fundamental principles of the rules in this Regulation should therefore apply to farms which manufacture feed solely for the requirements of their own production, as well as to farms which place feed on the market. But in the case of the direct supply of small quantities of primary products at local level by the producer to local farms, it is appropriate to ensure feed safety through rules and guidance.

(12) The application of HACCP principles to primary production of feed is not yet generally feasible. But guides to good practice should encourage the use of appropriate hygiene requirements.

(13) Feed safety depends on a number of factors. Legislation should lay down minimum hygiene requirements. Official controls should be in place to check feed business operators' compliance. In addition, feed business operators should take measures or adopt procedures to achieve a high level of feed safety.

(14) HACCP can help feed business operators attain a higher standard of feed safety. HACCP should not be regarded as a method of self-regulation and does not replace official controls.

(15) The implementation of the HACCP principles requires the full co-operation and commitment of feed businesses' employees.

(16) HACCP in feed production should take into account the principles contained in the Codex Alimentarius, but should allow sufficient flexibility in all situations. In certain feed business, it is not possible to identify critical control points and, in some cases, good practices can replace the monitoring of critical control points. Similarly, the requirement to establish "critical limits" does not require a numerical limit to be fixed in every case. The requirement to retain documents needs to be flexible to avoid undue burdens for very small businesses.

(17) Flexibility is also necessary to accommodate the needs of feed businesses situated in regions suffering from special geographical constraints or in respect of structural requirements. But such flexibility should not compromise feed hygiene objectives. In addition, since all feed produced in accordance with the hygiene rules is to be in free circulation throughout the Community, the procedure allowing Member States to exercise flexibility should be fully transparent. Provision should be made for discussion within the Standing Committee on the Food Chain and Animal Health where necessary to resolve disagreements.

(18) The registration of establishments and the co-operation of feed business operators are necessary if the competent authorities are to carry out official controls efficiently.

(19) It is appropriate that an approval system for feed businesses be maintained for activities which can present a higher risk in the manufacture of feed. Provision should be made for procedures to extend the current scope of the approval system as presently provided for in Directive 95/69/EC

(20) In order to be approved, feed businesses should meet several conditions concerning the facilities, equipment, personnel, production, quality control, storage, and documentation to ensure both feed safety and product traceability.

(21) Provision should be made for temporarily suspending, amending, withdrawing or renewing approval where establishments change or cease their activities or no longer fulfil the conditions applicable to their activity;

(22) A system of registration and approval by the competent authority of the Member State of all feed businesses is appropriate to ensure traceability from manufacturer to final user.

(23) The traceability of feed and feed ingredients throughout the feed chain is an essential element in ensuring feed safety. Regulation (EC) No 178/2002 contains rules to ensure the traceability of feed and feed ingredients and provides a procedure for the adoption of implementing rules applicable to specific sectors.

(24) Successive feed crises have shown that failures at any stage in the feed chain can have important economic consequences. Feed production and its complex distribution chain does not make it the withdrawal of feed from the market an easy task. The costs of rectifying the economic damages along the feed and food chain is often borne by public funds. The remedying of this economic consequence at a low cost to society could be improved if the operator, whose activity causes economic damage in the feed sector, is held financially responsible. This gives operators an incentive to meet high standards, which might not be met without such a system of financial liability. Operators should provide an appropriate financial guarantee, such as an insurance, in order to cover costs of the withdrawal of products from the market, treatment and/or destruction of feed and food produced therefrom. This can induce operators to adopt measures and develop practices to minimise the risks related to their activities.

(25) Feed imported into the Community must satisfy the general requirements laid down in Regulation (EC) No 178/2002 and the import conditions laid down in Regulation (EC) …/… on official feed and food controls[11].

(26) Community products exported to third countries must satisfy the general requirements laid down in Regulation (EC) No 178/2002.

(27) Scientific advice must underpin Community legislation on feed hygiene. To this end, the European Food Safety Authority should be consulted whenever necessary.

(28) To take account of technical and scientific progress, there should be close and effective co-operation between the Commission and the Member States within the Standing Committee on the Food Chain and Animal Health.

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[11] OJ L

(29) This Regulation takes account of international obligations laid down in the WTO Sanitary and Phytosanitary Agreement and the international food safety standards contained in the Codex Alimentarius.

(30) Directives 95/69/EC and 98/51/EC should be repealed;

(31) In accordance with Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[12], feed business operators may not mix for dilution purposes feed containing levels of an undesirable substance that exceed the maximum level.

(32) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.

(33) The requirements of this Regulation should apply one year after its entry into force, to allow the feed businesses affected by it time to adapt.

(34) 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[13],

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1
Subject matter

This Regulation lays down:

(a) general rules on feed hygiene;

(b) conditions and arrangements ensuring full traceability of feed.

Article 2
Scope

1. This Regulation shall apply to:

(a) the activities of feed business operators at all stages, from and including primary production up to and including the placing on the market of feed.

(b) the feeding of food producing animals;

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[12] OJ L 140, 30.5.2002, p. 10
[13] OJ L 184, 17.7.1999, p. 23

(c) imports from third countries.

2. This Regulation shall not apply to:

(a) the private domestic production of feed for food-producing animals for private domestic consumption and for animals not kept for food production;

(b) the feeding of food-producing animals for private domestic consumption and of animals not kept for food production;

(c) the direct supply of small quantities of primary products at local level by the producer to local farms;

(d) the retailing of petfood.

3. Member States shall establish rules and guidance governing the activities referred to in paragraph 2. Such national rules and guidance shall ensure the achievement of the objectives of this Regulation.

Article 3
Definitions

For the purposes of this Regulation, the definitions in Regulation (EC) No 178/2002 shall apply subject to these specific definitions:

(a) "feed hygiene": means the measures and conditions necessary to control hazards and to ensure fitness for animal consumption of a feed, taking into account its intended use;

(b) "feed business operator": means the natural or legal person responsible for ensuring that the requirements of the present Regulation are met within the feed business under their control;

(c) "feed additives": means substances or micro-organisms authorised under Regulation (…) on additives for use in animal nutrition;

(d) "establishment": means any unit of a feed business.

(e) "competent authority": means the authority of a Member State or a third country designated to carry out official controls

CHAPTER II

OBLIGATIONS

Article 4

General obligations

1. Feed business operators shall ensure that all stages of production, processing and distribution under their control are carried out according to good practice as referred to in

Chapter III of this Regulation and satisfy the relevant hygiene requirements laid down in this Regulation.

2. When feeding food-producing animals, livestock farmers shall:

(a) take measures and adopt procedures to minimise the risk of biological, chemical and physical contamination of feed, animals and animal products;

(b) apply good animal feeding practice as referred to in Annex III.

Article 5

Specific obligations

1. Feed business operators at the level of primary production of feed shall comply with the provisions in Annex I, including the following associated operations:

(a) the transport, storage and handling of primary products at the place of production, provided that this does not substantially alter their nature;

(b) transport operations to deliver primary products, the nature of which has not been substantially altered, from the place of production to an establishment.

2. Feed business operators other than at the level of primary production of feed as referred to in paragraph 1 shall comply with the provisions in Annex II.

3. Feed business operators shall:

(a) comply with specific microbiological criteria;

(b) take measures or adopt procedures necessary to meet specific targets.

The criteria and targets referred to in points (a) and (b) shall be adopted in accordance with the procedure referred to in Article 31 (2).

4. Feed business operators may use the guides provided for in Articles 21 to 23 to help them comply with their obligations under this Regulation.

5. Livestock farmers shall comply with the provisions set out in Annex III when feeding food producing animals

Article 6

Hazard analysis and critical control points (HACCP) system

1. Feed business operators other than at the level of primary production of feed shall put in place, implement and maintain a permanent procedure or procedures based on the principles of hazard analysis and critical control points (HACCP).

2. The HACCP principles referred to in paragraph 1 are:

(a) to identify any hazards that must be prevented, eliminated or reduced to acceptable levels,

(b) to identify the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels,

(c) to establish critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards,

(d) to establish and implement effective monitoring procedures at critical control points,

(e) to establish corrective action when monitoring indicates that a critical control point is not under control,

(f) to establish procedures to verify that the measures outlined in subparagraphs (a) to (e) are working effectively. Verification procedures shall be carried out regularly;

(g) to establish documents and records commensurate with the nature and size of the feed businesses to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

3. When any modification is made to a product, process, or any stage of production, processing, store and distribution, feed business operators shall review their procedure and make the necessary changes.

4. As part of the system of procedures referred to in paragraph 1, feed business operators may use guides to good practice in conjunction with guides on the application of HACCP, as developed in accordance with Article 21.

5. Measures to facilitate the implementation of this Article, including small businesses, may be adopted in accordance with the procedure referred to in Article 31 (2).

Article 7
Documents concerning the HACCP system

1. Feed business operators shall:

(a) provide the competent authority with evidence of their compliance with Article 6 in the form requested by the competent authority;

(b) ensure that any documents describing the procedures developed in accordance with Article 6 are up-to-date at all times;

2. The competent authority shall take into account the nature and size of the feed business where fixing requirements as to the form referred to in paragraph 1(a).

3. Detailed arrangements for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 26. Such arrangements may facilitate certain feed business operators' implementation of HACCP principles developed in accordance with Articles 21 to 23 with a view to complying with the requirements of Article 6 (1).

Article 8

Financial guarantees

Feed business operators shall ensure that a financial guarantee, such as insurance, is available to cover the cost of risks related to their businesses. This guarantee shall provide cover for the total costs of the withdrawal from the market, treatment and/or destruction of any feed and food produced therefrom.

Article 9
Official controls, notification and registration

1. Feed business operators shall co-operate with the competent authorities in accordance with other applicable Community legislation or, where there is none, national law.

2. The competent authority shall maintain a register of establishments

Feed business operators shall:

(a) notify the appropriate competent authority of any establishments under their control active in any of the stages of production, processing, store or distribution of feed in the form required by the competent authority with a view to registration.

(b) provide the competent authority with up-to-date information on any establishments under their control as referred in point (a) including notifying the competent authority of any significant change in activities and any closure of an existing establishment.

Article 10
Approval of feed business establishments

Feed business operators shall ensure that establishments under their control and covered by this Regulation are approved by the competent authority, where:

(1) such establishments carry out one of the following activities:

(a) manufacturing and/or placing on the market of feed additives or products covered by Directive 82/471/EEC and referred to in Chapter 1 of Annex IV to this Regulation;

(b) manufacturing and/or placing on the market of premixtures prepared from feed additives referred to in Chapter 2 of Annex IV to this Regulation;

(c) manufacturing (and/or placing on the market) or producing for the exclusive requirements of its holding, compound feedingstuffs containing premixtures prepared from feed additives referred to in Chapter 3 of Annex IV to this Regulation;

(2) approval is required under the national law of the Member State where the establishment is located;

(3) approval is required by a decision adopted in accordance with the procedure referred to in Article 31 (2).

Article 11

Feed business operators shall not operate without:

(a) registration as provided for in Article 9; or

(b) approval, when required in accordance with Article 13.

Article 12
Member States to provide information on national rules on approval

Any Member State requiring the approval under national law of certain establishments located on its territory shall inform the Commission and the other Member States of the relevant national rules.

Article 13
Approval of establishments by the competent authority

The competent authority shall approve establishments only where an on-site visit prior to start-up of any activity has demonstrated that they meet the relevant requirements of this Regulation.

Article 14
Suspension of registration or approval by the competent authority

The competent authority shall temporarily suspend the registration or approval of an establishment for one, more or all of the activities where it is shown that the establishment no longer fulfils the conditions applicable to those activities.

Such suspension shall last until the establishment again meets those conditions. Where such conditions are not met within one year, Article 15 shall apply.

Article 15
Revocation of registration or approval by the competent authority

The competent authority shall revoke the registration or approval of an establishment for one or more of its activities where:

(a) the establishment ceases one or more of its activities;

(b) it is shown that the establishment has not fulfilled the conditions applicable to its activities for a period of one year.

Article 16
Amendments to registration or approval of an establishment

The competent authority shall amend the registration or approval of an establishment where the establishment has demonstrated its ability to engage in activities which are additional to those for which it was first approved or which replace them.

Article 17
Renewal of approvals

The approval of establishments shall be renewable every five years.

The competent authority shall renew the approval of establishments only where an on-site visit has demonstrated that they meet the relevant requirements of this Regulation.

Article 18
Exemption from on-the-site visits

Member States are exempted from the obligation to carry out on-the-site visits as provided for in Articles 13 and 17 in feed businesses which act solely as traders without holding the products on their premises.

Such feed business shall submit to the competent authority a declaration to the effect that the feed placed on the market complies with the conditions of this Regulation.

Article 19
Transitional measures

1. Establishments and intermediaries approved and/or registered in accordance with Directive 95/69/EC may continue their activities until one year from the day of application of this Regulation, on condition that they submit, to the relevant competent authority in whose area their facilities are located, an application for approval before the day of application of this Regulation.

   In their application they must declare that the conditions laid down in this Regulation have been met.

   The competent authorities may request the applicant to provide only such additional information which guarantees compliance with the conditions of this Regulation.

2. Establishments and intermediaries requiring neither approval nor registration in accordance with Directive 95/69/EC but requiring registration in accordance with this Regulation may continue their activities until one year from the day of application of this Regulation, on condition that they submit, to the relevant competent authority in whose area their facilities are located, an application for registration before the day of application of this Regulation.

   In their application they must declare that the conditions laid down in this Regulation have been met.

Article 20

List of approved establishments

1. For each activity, the competent authority shall enter the establishments it has approved in accordance with Article 13 in a national list under an individual identifying number.

2. Member States shall update the entries of establishments in the list referred in paragraph 1 in accordance with the decisions referred to in Articles 14, 15 and 16 to suspend, withdraw or amend approval.

3. The list referred to in paragraph 1 must be drawn up in accordance with the model set out in Annex V, Chapter I.

4. The approval number referred to in paragraph 1 shall be in the form set out in Annex V, Chapter II.

5. Each Member State shall publish the list of the establishments approved in accordance with Article 13 for the first time in [November …], and thereafter each year, by 30 November at the latest, the consolidated list of amendments made during the year.

CHAPTER III

GUIDES TO GOOD PRACTICE

Article 21
Development, dissemination and use of guides

1. Member States shall encourage the development of national guides to good practice in the feed sector and for the application of HACCP principles in accordance with Article 22.

Community guides shall be developed in accordance with Article 23.

2. The dissemination and use of both national and Community guides shall be encouraged by the competent authorities.

3. Nevertheless, feed business operators may use these guides voluntarily.

Article22
National guides

1. National guides to good practice shall be developed and disseminated by feed business sectors, in consultation with representatives of parties whose interests may be substantially affected, including competent authorities, taking into account;

(a) relevant codes of practice of the Codex Alimentarius; and

(b) when they concern primary production, the requirements set out in Annex I.

2. National guides may be developed under the aegis of a national standards institute referred to in Annex II to Directive 98/34/EC.

3. Member States shall assess national guides to ensure that:

(a) they have been developed in accordance with paragraph 1;

(b) the contents of such guides are practicable for the sectors to which they refer;

(c) they are suitable as guides to compliance with the provisions of Articles 4, 5 and 6, in the sectors and/or for the feeds concerned.

4. Member States shall forward national guides complying with the requirements of paragraph 2 to the Commission.

The Commission shall set up and run a registration system for such guides and make this system available to the Member States.

Article 23
Community guides

1. Before Community guides to good practice for hygiene or for the application of HACCP principles are developed, the Commission shall consult the Committee referred to in Article 31 (1). The objective of that consultation shall be to consider the case for such guides, their scope and subject matter.

2. Where Community guides are prepared, the Commission shall ensure that they are developed and disseminated:

(a) by or in consultation with appropriate representatives of European feed business sectors and other interested parties, such as consumer groups;

(b) in collaboration with parties whose interests may be substantially affected, including competent authorities.

3. Community guides shall be developed and disseminated taking into account:

(a) relevant codes of practice of the Codex Alimentarius, and

(b) when they concern primary production, having regard to the requirements set out in Annex I.

4. The Committee referred to in Article 31(1) shall assess draft Community guides to ensure that:

(a) they have been developed in accordance with paragraphs 2 and 3;

(b) the contents of such guides are practicable throughout the Community for the sectors to which they refer, and

(c) they are suitable as guides to compliance with the provisions of Articles 4, 5 and 6, in the sectors and/or for the feeds concerned.

5. The Commission shall invite the Committee referred to in Article 31(1) periodically to review any Community guides prepared in accordance with this Article, in co-operation with the bodies mentioned in paragraph 2. The aim of this review shall be to ensure that the guides remain practicable and to take account of technological and scientific developments.

6. The titles and references of Community guides prepared in accordance with this Article shall be published in the C series of the Official Journal of the European Union.

CHAPTER IV

IMPORTS

Article 24
Imports

1. Feed business operators importing feed from third countries shall ensure that importation takes place only in accordance with the following conditions:

(a) the third country of dispatch appears on a list, drawn up in accordance with Article 48 of Regulation (EC) …/… on official feed and food controls, of third countries from which imports of feed are permitted;

(b) the establishment of dispatch appears on a list, drawn up and kept up-to-date by the third country in accordance with Article 48 of Regulation (EC) on official feed and food controls of establishments from which imports of feed are permitted;

(c) the feed was sent from the establishment of dispatch which may also use feed from another establishment appearing on the list referred to in point (b), or from the Community;

(d) the feed satisfies:

(i) the requirements laid down under this Regulation, and any other Community legislation laying down specific hygiene rules for feed; or

(ii) those conditions recognised by the Community to be at least equivalent thereto; or

(iii) where a specific agreement exists between the Community and the exporting country, with requirements contained therein.

2. A model import certificate may be adopted in accordance with the procedure referred to in Article 31 (2).

Article 25
Interim measures

Pending the compilation of the lists provided for in Article 24 (1) (a) and (b), any reference to such lists shall be interpreted as reference to the lists established on the basis of the Directive 98/51/EC[14]

CHAPTER V

FINAL PROVISIONS

Article26
Implementing measures

Implementing measures may be laid down in accordance with the procedure referred to in Article 31 (2).

Article 27
Amendments to Annexes I, II, and III

Annexes I, II and III may be amended or repealed in accordance with the procedure referred to in Article 31 (2), to take account of:

(a) the development of codes of good practice;

(b) the experience gained from the implementation of HACCP-based systems pursuant to Article 6;

(c) technological developments;

(d) scientific advice, particularly new risk assessments; and

(e) the setting of feed safety targets.

Article 28
Derogations from provisions of Annexes I, II and III

Derogations from the provisions of the Annexes I, II and III may be granted in accordance with the procedure referred to in Article 31 (2), provided that such derogations do not affect the achievement of the objectives of this Regulation.

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[14] Commission Directive 98/51/EC of 9 July 1998 laying down certain measures for implementing Council Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector (OJ L 208, 24.07.98, p. 43)

Article 29
National measures adapting the requirements of Annex II

1. Member States may, without compromising feed hygiene objectives, adopt national measures adapting the requirements laid down in Annex II in accordance with paragraphs 2 to 5 of this Article.

2. The national measures adapting the requirements laid down in Annex II shall:

(a) have the aim of accommodating the needs of feed businesses situated in regions suffering from special geographical constraints; or

(b) concern the construction, layout and equipment of establishments.

3. Any Member State wishing to adopt national measures adapting the requirements laid down in Annex II shall notify the Commission and other Member States. The notification shall:

(a) provide a detailed description of the requirements the Member State considers need to be adapted and the nature of the adaptation sought;

(b) describe the feed and establishment concerned;

(c) explain the reasons for the adaptation (including, where relevant, a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise hygiene objectives); and

(d) give any other relevant information.

4. Other Member States shall have three months from the receipt of a notification referred to in paragraph 3 to send written comments to the Commission.

In the case of adaptations referred to in paragraph 2 (a) of this Article, this period shall, at the request of any Member State, be extended to four months.

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 31 (1). The Commission may decide, in accordance with the procedure referred to in Article 31 (2), whether the measures envisaged may be implemented subject, where necessary, to appropriate amendments. Where appropriate, the Commission may propose measures of general application in accordance with Articles 27 or 28.

5. A Member State may adopt national measures adapting the requirements of Annex II only:

(a) in compliance with a decision adopted in accordance with paragraph 4; or

(b) where, one month after the expiry of the period referred to in paragraph 4, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision referred to in point (a)

Article 30
Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take the 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 to the Commission by 1 year after the date of publication of this Regulation at the latest and shall notify it without delay of any subsequent amendment affecting them.

Article 31
Standing Committee Procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up by Regulation (EC) No 178/2002 (hereinafter referred to as "the Committee").

2. 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 set at three months.

3. The Committee shall adopt its rules of procedure.

Article 32
Consultation of the European Food Safety Authority

The Commission shall consult the European Food Authority on any matter within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing criteria or targets in accordance with Article 5 (3).

Article 33
Repeal

The following Directives are repealed, without prejudice to the obligations of the Member States concerning the deadlines for transposition, with the effect from the date of application of this Regulation:

(a) 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;

(b) Commission Directive 98/51/EC of 9 July 1998 laying down certain measures for implementing Council Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector.

Article 34
Entry into force

This Regulation shall enter into force on the date of its publication in the *Official Journal of the European Union.*

It shall apply one year after the entry into force of this Regulation

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

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX I

Requirements for feed businesses at the level of primary production referred to in Article 5(1)

1. Feed business operators responsible for primary production shall ensure that operations are managed and carried out in such a way as to prevent, eliminate or minimise hazards with the potential to compromise feed safety, wherever possible taking account, where appropriate, of subsequent processing.

2. Feed business operators shall ensure, as far as possible, that primary products produced, prepared, cleaned, packed, stored and transported under their responsibility are protected against contamination and spoilage.

3. Feed business operators shall meet the obligations in paragraphs 1 and 2 by complying with appropriate Community and national legislative provisions relating to the control of hazards in primary production, including:

(i) measures to control contamination arising from the air, soil, water, fertilisers, plant protection products, biocides, veterinary medicinal products and handling and disposal of waste, and

(ii) measures relating to plant health, animal health and the environment that have implications for feed safety including programmes for the monitoring and control of zoonoses and zoonotic agents.

4. Feed business operators shall take adequate measures, as appropriate:

(a) to keep clean and, where necessary after cleaning, to disinfect in an appropriate manner facilities, equipment, containers, crates and vehicles used for producing, preparing, grading, packing, storing and transporting feed;

(b) to ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of, feed;

(c) to use clean water whenever necessary to prevent contamination;

(d) to prevent, as far as possible, animals and pests from causing contamination;

(e) to store and handle wastes and hazardous substances, separately and securely, so as to prevent contamination;

(f) to ensure that packaging materials are not a source of contamination of feed;

(g) to take account of the results of any relevant analyses carried out on samples taken from primary products or other samples relevant to feed safety.

RECORD-KEEPING

1. Feed business operators shall complete and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period,

commensurate with the nature and size of the feed business. Feed business operators must make relevant information contained in these records available to the competent authority.

2. Feed business operators must, in particular, keep records on:

(a) any use of plant protection products and biocides ;

(b) use of genetically modified seeds;

(c) any occurrence of pests or diseases that may affect the safety of primary products;

(d) the results of any analyses carried out on samples taken from primary products or other samples taken for diagnostic purposes that have importance for feed safety;

3. Other persons, such as veterinarians, agronomists and farm technicians, may assist the feed business operators with the keeping of records relevant to the activities they carried out in the farm.

GUIDES TO GOOD PRACTICE

1. National and Community guides referred to in Articles21 to 23 of this Regulation shall contain guidance on good practices for the control of hazards in primary production.

2. Guides to good practices shall include appropriate information on hazards arising in primary production and actions to control hazards, including relevant measures set out in Community and national legislation or national and Community programmes, such as:

(a) the control of contamination such as mycotoxins, heavy metals, radioactive material.;

(b) the use of water, organic waste and fertilisers;

(c) the correct and appropriate use of plant protection products and biocides and their traceability;

(d) the correct and appropriate use of veterinary medicinal products and feed additives and their traceability;

(e) the (preparation, storage and) traceability of feed materials;

(f) the proper disposal of dead animals, waste and litter;

(g) protective measures to prevent the introduction of contagious diseases transmissible to animals through feed and any obligation to notify the competent authority;

(h) procedures, practices and methods to ensure that feed is produced, prepared, packed, stored and transported under appropriate hygienic conditions, including effective cleaning and pest-control;

(i) measures relating to record-keeping.

ANNEX II

Requirements for feed businesses other than at the level of primary production referred to in Article 5 (2)

FACILITIES AND EQUIPMENT

1. Feed processing and storage facilities, equipment, containers, crates, vehicles and their immediate surroundings shall be kept clean, and effective pest control programmes shall be implemented.

2. The lay-out, design, construction and size of the facilities and equipment shall:

(a) permit adequate cleaning and/or disinfection

(b) be such as to minimise the risk of error and with a view to avoiding contamination, cross-contamination and any adverse effects generally on the safety and quality of the products. Machinery coming into contact with feed shall be dried following any wet cleaning process.

3. Facilities and equipment to be used for mixing and/or manufacturing operations shall undergo appropriate and regular checks, in accordance with written procedures pre-established by the manufacturer for the products.

(a) All scales and metering devices used in the manufacture of feeds shall be appropriate for the range of weights or volumes to be measured and tested for accuracy regularly.

(b) All mixers used in the manufacture of feeds shall be appropriate for the range of weights or volumes being mixed, and shall be capable of manufacturing suitable homogeneous mixtures and homogeneous dilutions.

4. Facilities must have adequate natural and/or artificial lighting.

5. Drainage facilities must be adequate for the purpose intended; they must be designed and constructed to avoid the risk of contamination of feedingstuffs.

6. Water used in feed manufacture shall be of potable quality for animals; the conduits for water shall be of an inert nature.

7. Sewage, waste and rain water shall be disposed of in a manner which ensures that equipment and the safety and quality of feed is not affected. Spoilage and dust shall be controlled to prevent pest invasion.

8. Windows and other openings must, where necessary, be fitted with pest-proof netted screens. Doors must be close-fitting and pest-proof when closed.

9. Where necessary, ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable moulds and the shedding of particles that can affect the safety and quality of feed.

PERSONNEL

Feed businesses must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the products concerned. An organization chart setting out the qualifications (e.g. diplomas, professional experience) and responsibilities of the supervisory staff must be drawn up and made available to the competent authorities responsible for inspection. All the staff must be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, in such a way as to obtain the desired product quality.

PRODUCTION

1. A qualified person responsible for production must be designated.

2. Feed business operators must ensure that the different stages of production are carried out according to pre-established written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process.

3. Technical or organisational measures must be taken to avoid or minimise, as necessary, any cross-contamination and errors. There must be sufficient and appropriate means of carrying out checks in the course of manufacture.

4. The presence of prohibited feed materials, undesirable substances and prohibited substances and pathogens in relation to human health or animal health shall be monitored, and appropriate control strategies to minimise the risk shall be in place.

5. Waste and unsaleable materials should be isolated and identified. Any such materials containing hazardous levels of veterinary drugs, contaminants or other hazards shall be disposed of in an appropriate way and not used as a feed.

QUALITY CONTROL

1. A qualified person responsible for quality control must be designated.

2. Feed businesses must, as part of a quality assurance scheme, have access to a laboratory with adequate staff and equipment to guarantee and check, before the release of the products with a view to putting them into circulation, that they comply with the specifications defined by the manufacturer.

3. A quality control plan must be drawn up in writing and implemented, to include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications - and the destination in the event of non-compliance - from processed materials to final products.

4. Samples of ingredients and of each batch of products placed on the market or of each specific portion of production (in the case of continuous production) must be taken in sufficient quantity using a procedure pre-established by the manufacturer and be retained in order to ensure traceability (on a regular basis in the case of manufacture solely for the manufacturer's own needs). The samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in

the composition of the sample or any adulteration. They must be kept at the disposal of the competent authorities for a period appropriate for the use to which the feed are placed in the market.

STORAGE AND TRANSPORT

1. Processed feeds shall be separated from unprocessed feed materials and additives in order to avoid any cross-contamination of the processed feed, and proper packaging materials shall be used.

2. Feeds shall be stored and transported in suitable containers. They shall be stored in places designed, adapted and maintained in order to ensure good storage conditions, to which only persons authorised by the feed business operators have access.

3. Feeds shall be stored and transported in such a way as to be easily identifiable, to avoid any confusion or cross-contamination and to prevent deterioration.

4. Containers and equipment used for transport, storage, conveying, handling and weighing shall be kept clean. Cleaning programmes shall be introduced, and traces of detergents and disinfectants shall be minimised.

5. Any spoilage shall be minimised and kept under control to reduce pest invasion.

6. Temperatures shall be kept as low as possible to avoid condensation and spoilage.

DOCUMENTATION

1. All feed businesses operators, including those who act solely as traders without ever holding the product in their facilities, shall keep in a register records with relevant data comprising purchase, production and sales for effective tracing from delivery or export to the final destination.

2. Feed business operators, except those who act solely as dealers without ever holding the product in their facilities, shall keep in a register the following documentation:

(a) Documentation relating to the manufacturing process and controls.

Feed businesses must have a system of documentation designed to define and ensure mastery of the critical points in the manufacturing process and to establish and implement a quality control plan. They must keep the results of the relevant controls. This set of documents must be kept so that it is possible to trace the manufacturing history of each batch of products put into circulation and to establish responsibility if complaints arise.

(b) Documentation relating to traceability

(i) Additives:

- the nature and quantity of the additives produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture;

- the nature and quantity of the additives delivered and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture;

(ii) Products covered by Directive 82/471/EEC:

- the nature of the products and the quantity produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture;

- the name and address of the establishments or users (establishments or stock-breeders) to whom these products have been delivered, together with details of the nature and quantity of the products delivered and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture.

(iii) Premixtures:

- the name and address of the manufacturers or suppliers of additives, the nature and quantity of the additives used and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture;

- the date of manufacture of the premixture and the batch number where appropriate;

- the name and address of the establishment to which the premixture is delivered, the delivery date, the nature and quantity of the premixture delivered, and the batch number where appropriate.

(iv) Compound feedingstuffs/feed materials:

- the name and address of premixture manufacturers or suppliers, the nature and quantity of the premixture used, with the batch number where appropriate;

- the name and address of the suppliers of the feed materials and the delivery date;

- the nature and quantity of feed materials or compound feedingstuffs manufactured, together with the date of manufacture, and the name and address of the buyer (e.g. stock-breeder, other feed businesses).

COMPLAINTS AND PRODUCT RECALL

1. Feed business operators shall implement a system for registering and processing complaints.

2. They shall be in a position to introduce, where this proves necessary, a system for the prompt recall of products in the distribution network. They shall define by means of written procedures the destination of any recalled products, and before such products are put back into circulation they must undergo a quality-control reassessment.

ANNEX III

Good Animal Feeding Practice

PASTURE GRAZING

The grazing of pastures and croplands should be managed in a way that minimises the contamination of foods of animal origin by biological and chemical hazards.

Where appropriate, an adequate rest period should be observed before allowing livestock to graze on pasture, crops and crop residues and between grazing rotations to minimise biological cross-contamination from manure, where such a potential problem exists, and to ensure that the withholding periods for agricultural chemical applications are observed.

STABLE FEEDING AND BATCH/INTENSIVE UNIT FEEDING

The animal production unit should be designed so that it can be easily cleaned. The animal production unit and feeding equipment should be cleaned thoroughly and regularly to prevent any build-up of biological hazards. Chemicals used for cleaning and sanitising should be used according to instructions and stored away from feed and feeding areas.

A pest control system should be put in place to control the access of pests to the animal production unit with a view to minimising the possibility of biological contamination of feed and bedding materials or animal units.

Buildings and feeding equipment should be kept clean. Systems should be put in place to regularly remove manure, waste material and other possible sources of biological contamination of feed.

Feed and bedding material used in the animal production unit should be frequently changed and not allowed to become mouldy.

FEEDING

1. Storage

Feed should be stored separately from chemicals. Storage areas and containers should be kept clean and dry and free from pests that may introduce biological contaminants. Storage areas and containers should be cleaned regularly to avoid unnecessary cross-contamination.

Seed should be stored properly and in such a way that is not accessible to animals.

Medicated feed, non-medicated feed and compound feedingstuffs intended for different categories or species of animals should be stored such as to reduce the risk of cross-feeding.

2. Distribution

The on-farm feed distribution system should ensure that the right feed is sent to the right destination. During distribution and feeding, feed should be handled in such a way as to ensure that biological contamination does not occur from contaminated storage areas and

equipment. Non-medicated feeds should be handled separately from medicated feeds to prevent contamination.

Feed transport vehicles and feeding equipment used to deliver and distribute medicated feed should be cleaned periodically.

FEED AND WATER

Farmers should evaluate and minimise the risks of biological or chemical contamination of animals through drinking water, or thorough direct contact with aquatic animals.

Feeding and watering equipment must be designed, constructed and placed such that contamination of feed and water is minimised. Watering systems should be cleaned and maintained regularly, where possible.

PERSONNEL

Animals should be fed by staff possessing the requisite ability, knowledge and professional competence.

ANNEX IV

CHAPTER 1

Additives

- Antibiotics: all additives in the group
- Coccidiostats and other medicinal substances: all additives in the group
- Growth promoters: all additives in the group
- Vitamins, provitamins and chemically well-defined substances having a similar effect : all additives in the group
- Trace elements: all additives in the group
- Enzymes: all additives in the group
- Micro-organisms: all additives in the group
- Carotenoids and xanthophylls: all additives in the group
- Substances with antioxidant effects: only those with a fixed maximum content

Products covered by Directive 82/471/EEC

- Proteins obtained from micro-organisms belonging to the group of bacteria, yeasts, algae, lower fungi: all products in the group (except for subgroup 1.2.1)
- Co-products of the manufacture of amino acids by fermentation: all products in the group
- Amino acids and their salts: all products in the group
- Hydroxy analogues of amino acids: all products in the group

CHAPTER 2

Additives

- Antibiotics: all additives in the group
- Coccidiostats and other medicinal substances: all additives in the group
- Growth promoters: all additives in the group
- Vitamins, provitamins and chemically well defined substances having a similar effect: A and D
- Trace elements: Cu and Se

CHAPTER 3

Additives

- Antibiotics: all additives in the group
- Coccidiostats and other medicinal substances: all additives in the group
- Growth promoters: all additives in the group

ANNEX V

CHAPTER I

I. 1. LIST OF REGISTERED FEED BUSINESSES

1	2	3	4	5
Registration number	Activity	Name or business name[15]	Address[16]	Remarks

I. 2. LIST OF APPROVED FEED BUSINESSES

1	2	3	4	5
Approval number	Activity	Name or business name[17]	Address[18]	Remarks

CHAPTER II

The approval number must have the following structure:

1. The character "α" if the feed business is approved;

2. The ISO code of the Member State or of the third country where the feed business is located;

3. The national reference number, to a maximum of eight alphanumerical characters.

15 Name or business name of the feed businesses.
16 Address of the feed businesses.
17 Name or business name of the feed businesses.
18 Address of the feed businesses.

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: REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN REQUIREMENTS FOR FEED HYGIENE

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

A 701: Mission expenses, travel expenses and incidental expenditure.

A 703: Expenditure on formal and other meetings

A704: Miscellaneous expenditure on the organisation of and participation in conferences, congresses and other meetings.

A-705: Studies and consultations

A-707- Development of management and information systems

2. OVERALL FIGURES

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

2.2. Period of application:

The activity will start in January 2005

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							
Payments							

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

Commitments							
Payments							

Subtotal a+b							
Commitments							
Payments							

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

Commitments/ payments	0,399	0,399	0,399	0,399	0,399	0,399	

TOTAL a+b+c							
Commitments	0,399	0,399	0,399	0,399	0,399	0,399	
Payments	0,399	0,399	0,399	0,399	0,399	0,399	

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:

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

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.)

(€ million to one decimal place)

		Prior to action	Situation following action					
Budget line	Revenue	[Year n-1]	[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

Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
Comp/	Diff/	YES/	NO	NO	Part A

4. LEGAL BASIS

Articles 37 and 152(4)

5. DESCRIPTION AND GROUNDS

5.1. Need for Community intervention

5.1.1. Objectives pursued

This proposal corresponds to action 25 of the White Paper on Food Safety.

The main objective is to ensure a high level of protection of human life as well as the protection of animal health and the environment.

Furthermore, this proposal:

– establishes feed hygiene requirements at all stages in the use, production, processing and distribution of feed;

– extends the registration obligation to all feed business operators (including primary producers) wishing to place feed on the market;

– requires approval in certain cases where feed business operators are dealing with more sensitive substances — in such cases, the competent authority will give official approval following an on-the-spot visit to check compliance;

– imposes the obligation to follow HACCP (Hazard Analysis and Critical Control Point) principles on all feed operators other than those operating at the level of primary production;

– encourages the development of national guides to Good Practices and guides to the application of HACCP and the creation of a register of such guides at Community level;

– establishes the possibility of harmonising guides to Good Practices and guides to the application of HACCP at Community level

– maintains certain requirements for imports from third countries, under which they have to comply with at least equivalent requirements to those laid down in the Regulation, and provides for the development of detailed implementation measures by comitology procedure in accordance the Regulation of the European Parliament and of the Council on official feed and food controls;

– ensures that feed business operators provide a financial guarantee in order to cover the risks related to their business;

– creates conditions for equal and fair competition.

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 wide-ranging evaluation of Community food safety policy. The objective of the European Commission is the achievement of the highest possible level of health protection for consumers across the EU. The White Paper sets out a plan for a radical reform of food law based on a comprehensive, integrated approach ("farm to fork" approach) as well as the establishment of a European Food Safety Authority.

The White Paper stresses, in particular, the need for comprehensive legislation in order to complete the current provisions laying down conditions for feed establishments.

5.1.3. Measures taken following ex post *evaluation*

Not applicable

5.2. Action envisaged and budget intervention arrangements

General objectives: links with the overall aim.

Target population: consumers are the ultimate beneficiaries; the target population comprises feed producers, feed manufacturers and feed users.

The specific objectives and actions set for this regulation are:

- to ensure that feed hygiene requirements are met at all stages in the production, use, processing and distribution of feed; this objective should be achieved by the operators and controlled by the competent authorities following the rules laid down in other Community legislation;

- to extend the registration obligation to all feed business operators (including primary producers) wishing to place feed on the market.

- to maintain the current system of approval for feed business operators wishing to place on the market certain sensitive substances or feedingstuffs containing these substances and to provide for the possible extension of this requirement to other kind of products by comitology procedure; this is the responsibility of the Member States;

- to impose the obligation to follow the principles of HACCP (Hazard Analysis and Critical Control Point) on all feed operators other than those operating at the level of primary production; this objective should be achieved by the operators and controlled by the competent authorities following the rules laid down in Community legislation;

- to encourage the development of national guides to Good Practices and guides to the application of HACCP and to create a register at Community level of such guides; the Member States shall assess those guides while the Commission should

create and maintain the Community register; this action will not require additional human resources but will require some budget allocations for the development of management and information systems;

- to establish the possibility of harmonising guides to Good Practices and guides to the application of HACCP at Community level; this action requires consultation of the Standing Committee on the Food Chain and Animal Health, experts, interested parties and Member States; the expenditure entailed by this action will require allocations for missions, meetings of the Standing Committee and working groups, conferences, studies or consultations;

- to maintain certain requirements for imports from third countries, under which they have to comply with at least equivalent requirements to those laid down in the Regulation and to provide for the development of detailed implementation measures by comitology procedure in accordance with the Regulation on official feed and food controls; the expenditure entailed by this action will require allocations for missions, meetings of the Standing Committee and working groups, conferences, studies or consultations in order to develop detailed implementation measures through a Commission Regulation;

- the Food and Veterinary Office (FVO), as concerns feed, will be responsible for making inspections to verify the effective implementation by the Member States of their obligations under this Regulation; the inspections may also be extended to third countries; it is difficult to assess to what extent this proposal will increase the current tasks of the FVO, in particular because the requirements for third countries will be developed later by a Commission Regulation; where the Commission Regulation calls for additional tasks, a specific financial statement will be produced.

Impact indicators: number of operators registered, number of national guides to Good Practices and guides to the application of HACCP included in the Community Register, number of Community Guides published in the Official Journal, number of decisions including implementation measures for imports from third countries, number of missions by the FVO to inspect Member States and third countries.

Assessment of the results obtained: the authorisation procedure provided for by the Regulation guarantees a high level of protection for human health.

5.3. Methods of implementation

Direct management by the Commission staff and, in some actions, in consultation with external experts in the field of animal nutrition.

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
Action 1							
Action 2							
etc.							
TOTAL							

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

	[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							
b) Other technical and administrative assistance: - *intra muros*: - *extra muros*: *of which for construction and maintenance of computerised management systems*							
Subtotal 1							
2) Support expenditure							
a) Studies							
b) Meetings of experts							
c) Information and publications							
Subtotal 2							
TOTAL							

6.2. Calculation of costs by measure envisaged in Part B (over the entire programming period)

(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)
Action 1				
- *Measure 1*				
- *Measure 2*				
Action 2				
- *Measure 1*				
- *Measure 2*				
- *Measure 3*				
etc.				
TOTAL COST				

If necessary explain the method of calculation

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 using existing ~~and/or additional~~ resources*		Total	Description of tasks deriving from the action
		Number of permanent posts	Number of temporary posts		
Officials or temporary staff	A	2		2	*1 A official will manage the Commission tasks except those related to inspections.*
	B	0.5		0.5	
	C	0.5		0.5	*1 A official in the FVO will deal with inspections.*
Other human resources					
Total		3		3	

7.2. Overall financial impact of human resources

Type of human resources	Amount (€)	Method of calculation *
Officials Temporary staff	€324.000	3x €108.000
Other human resources (specify budget line)		
Total	€324.000	

The amounts are total expenditure for twelve months.

7.3. Other administrative expenditure deriving from the action

Budget line (number and heading)	Amount (€)	Method of calculation
Overall allocation (Title A7) A0701 – Missions A07030 – Meetings A07031 – Standing Committee on the Food Chain and Animal Health A07032 – Non-compulsory committees [1] A07040 – Conferences A0705 – Studies and consultations Other expenditure (specify)	12.000 7.800 31.200 2.000 20.000	2 missions within EU for two people: €1000/person/mission. 2mission outside EU for two people: €2000/person/mission. 2met./year; €650x 6experts=€3900 €3900x2=7800. 3meet/year; €10400/ meeting. 3x10.400=31.200
Information systems A707	2.000	
Other expenditure - Part A (specify)		
Total	75.000	

The amounts are total expenditure for twelve months.

[1] Specify the type of committee and the group to which it belongs.

I.	Annual total (7.2 + 7.3)	€399.000
II.	Duration of action	indefinite
III.	Total cost of action (I x II)	€

8. FOLLOW-UP AND EVALUATION

8.1. Follow-up arrangements

The Commission will follow up the implementation of this Regulation:

- Member States shall inform the Commission of the list of approved establishments before 1 December of each year. Upon request, the Commission shall receive an updated version *of such lists.*

- Member States shall forward to the Commission and Member States the national guides to Good Practices and guides to the application of HACCP that they consider comply with the requirements of the Regulation.

- As regards third countries, appropriate implementation measures will be developed by comitology procedure, possibly with provision for the Commission to follow up these measures.

- The FVO will have an important role in ensuring that Member States comply with this regulation, and this may also be extended to third countries.

8.2. Arrangements and schedule for the planned evaluation

The Commission has to consider yearly the effectiveness of the system on the basis of the information submitted by the Member states and inspections by the FVO.

9. ANTI-FRAUD MEASURES

Not applicable for the financial risks encountered.

IMPACT ASSESSMENT FORM

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

TITLE OF PROPOSAL

Proposal for a Regulation of the European Parliament and of the Council laying down requirements for feed hygiene.

DOCUMENT REFERENCE NUMBER

THE PROPOSAL

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

This proposal corresponds to action 25 of the White Paper on Food Safety.

The main objective is to ensure a high level of protection of human life as well as the protection of animal health and the environment.

Other objectives of this proposal are:

(a) in accordance, among other things, with the commitments in the White Paper on Food Safety, to lay down general hygiene requirements applicable to all feed business operators, including the use of feed by farmers, based on:

- good agricultural and manufacturing practices;
- good feeding practices.

(b) to extend the current system of registration to all feed businesses (from primary production to the marketing of feed); this objective is contained in the action programme in the Annex to the Commission's White Paper on Food Safety;

(c) to maintain the current system of approval for feed business operators wising to place on the market certain sensitive substances or feed containing these substances ;

(d) to impose the obligation to follow HACCP principles (Hazard Analysis and Critical Control Point) on all feed operators other than those operating at the level of primary production;

(e) to encourage the development of national guides to Good Practices and guides to the application of HACCP (Hazard Analysis and Critical Control Point) and to create a register at Community level of such guides;

(f) to establish the possibility of harmonising guides for the application of HACCP principles at Community level;

(g) to maintain certain requirements for imports from third countries under which they have to comply with at least equivalent requirements to those laid down in this Regulation and to provide for the development of detailed implementation measures by comitology procedure in accordance with the Regulation on official feed and food controls;

(h) to ensure that feed business operators provide a financial guarantee in order to cover the risks related to their business

(i) to create conditions for equal and fair competition.

This proposal will replace 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[19] and Commission Directive 98/51/EC of 9 July 1998 laying down certain measures for implementing Council Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector[20].

[19] OJ L 332, 30.12.1995; p. 15
[20] OJ L 208, 27.7.1998; p. 43

The main differences between this proposal and Directive 95/69/EC are summarised in the following table:

DIRECTIVE 95/69/EC	PROPOSAL FOR A REGULATION LAYING DOWN FEED HYGIENE REQUIREMENTS
Scope Establishments and intermediaries producing or using certain additives and feed materials for the preparation of feed	**Scope** Feed business operators at all stages, from and including primary production up to and including the placing on the market of feed. It shall not apply to: – the private domestic production of feed for food-producing animals for private domestic consumption and for animals not kept for food production; – the feeding of food-producing animals for private domestic consumption and of animals not kept for food production; – the direct supply of small quantities of primary products at local level by the producer to local farms; – the retailing of petfood
Requirements for certain establishments and intermediaries. Requirements to ensure the quality of production for certain establishments.	**Requirements for all feed business operators (including intermediaries) and users.** Hygiene requirements are established for all feed business operators and users.
National registration of establishments and intermediaries: the operator must submit a declaration of its activity to the competent authority of the Member state. Registration is mandatory for: - establishments producing certain additives and premixtures - establishments using certain additives in the production of feed; - intermediaries of certain additives and premixtures.	**National registration of feed business operators: the operator must submit a declaration of its activity to the competent authority of the Member state.** All feed business operators and intermediaries wishing to place feed on the market shall be registered

DIRECTIVE 95/69/EC	PROPOSAL FOR A REGULATION LAYING DOWN FEED HYGIENE REQUIREMENTS
National approval of establishments: operators must submit an application to the competent authority of the Member State. Authorisation is granted within 6 months after on-the-spot verification. Mandatory approval for the following establishments and intermediaries by the competent authorities of the Member States: - establishments producing certain additives, premixtures and feed materials (bioproteins); - establishments using certain additives for the production of feed; - intermediaries of certain additives, premixtures and feed materials.	**National approval of feed business operators:** operators must submit an application to the competent authority of the Member state. Approval will be required where feed business operators are dealing and placing on the market more sensitive substances, or feedingstuffs containing these substances, and provision is made for this requirement to be extended to other kind of products by comitology procedure
Specific hygiene requirements No specific hygiene requirements	**Specific hygiene requirements** Good Practices applicable to all feed business operators and when feeding food producing animals. Procedures following HACCP (Hazard Analysis and Critical Control Point) principles are mandatory for all feed business operators other than those operating at the level of primary production.
National guides No provisions on this matter.	**National guides** Encourages the development of national guides to Good Practices and guides to the application of HACCP and the creation of a register at Community level.

DIRECTIVE 95/69/EC	PROPOSAL FOR A REGULATION LAYING DOWN FEED HYGIENE REQUIREMENTS
Community Guides No provisions on this matter	**Community Guides** Establishes the possibility of harmonising guides to Good Practices and guides to the application of HACCP at Community level
Imports from third countries Provisions for imports from third counties based on the principle of equivalence: – list of third countries. – list of establishments in those third countries. – possibility of carrying out on-the-spot checks. Detailed arrangements on those provisions established by comitology procedure.	**Imports from third countries** Maintains the principle of equivalence and provides for the development of detailed implementation measures by comitology procedure in accordance the Regulation on official feed and food controls
Financial guarantees No provisions on this matter.	**Financial guarantees** Operators shall provide financial guarantees to cover the risks related to their business.

The main purpose of the current Directive 1995/69/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 (as last amended by Council Directive 1999/29/EC of 22 April 1999) is to ensure that certain establishments and intermediaries that manufacture, produce or put into circulation (including importation) certain additives, premixtures, compound feedingstuffs and products covered by Directive 82/471/EEC are approved or registered by competent authorities that verify compliance with the technical specifications detailed in the annexes.

The putting into circulation of some of the products requires only registration, based on an undertaking by the establishment to comply with a number of conditions.

The putting into circulation of some other products requires approval of the plant on the basis of very strict conditions designed to safeguard animals, humans and the environment. Such approval is subject to mandatory on-the-spot verification by the competent authority that the conditions laid down in the Directive have been complied with.

THE IMPACT ON BUSINESS

2. Who will be affected by the proposal?

– which sectors of business: *all feed businesses*

– which sizes of business (what is the concentration of small and medium-sized firms): *all sizes, at all stages from primary production up to and including the placing on the market of feed for the final user.*

– are there particular geographical areas of the Community where these businesses are found: *The proposal has a similar impact over the entire Community. It is not aimed at any particular region. Feed businesses are situated all over the territory of the Community, including regions suffering from special geographical constraints.*

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

They must ensure conformity with general hygiene requirements (facilities and equipment, record-keeping, etc.), apply codes of good practice, apply the Hazard Analysis Critical Control Point (HACCP) system (other than at the level of primary production), and provide financial guarantees in order to operate in the feed sector.

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

– on employment: *neutral*

– on investment and the creation of new businesses: *New obligations may however call for additional organisational efforts, in particular the obligation for certain feed businesses to obtain approval from the competent authority and the obligation to implement a full HACCP system. An approval and registration system already applies at present. It is not expected that the proposed rules will require additional investment to bring businesses up to the required standard, apart from the provisions to provide a financial guarantee to operate in the feed sector.*

– on the competitiveness of businesses: *the proposal aims to improve feed safety. When correctly implemented and if feed businesses assume their responsibilities, consumer confidence should increase, which could benefit businesses.*

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

Measures to facilitate the implementation of the Hazard Analysis and Critical Control Point (HACCP) system in small businesses are planned. Account is taken of the specificity of different ways of feed production and manufacturing. Furthermore, Member States may, without compromising feed hygiene objectives, adopt national measures adapting the requirements laid down in the Regulation. Such measures may be aimed at accommodating the needs of feed businesses situated in regions suffering from special geographical constraints or concern the construction, layout and equipment of establishments.

CONSULTATION

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

COPA-COGECA, FEDESA (European Federation of Animal Health), FEDIAF (Federation Europeenne de l'Industrie des aliments pour Animaux Familiers), FEFAC (European Feed Manufacturers Federation), FEFANA (European Federation of the Animal Feed Additive Manufacturers), COCERAL (Comité du Commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures), BEUC (The European Consumers' Organisation)

These organisations welcomed the proposal in particular with regard to the obligation of registration of the entire universe of feed businesses and to the obligation of implementing HACCP by all feed businesses operators other than those operating at the level of primary production (farms).