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COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the placing on the market and use of feed

{SEC(2008) 275}
{SEC(2008) 276}

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

General context

Animal production contributes almost half to the output of the agricultural output in the EU. Feed is the major cost factor for the 5 million livestock farmers in the Community. The marketing conditions for feed have a crucial impact on the competitiveness of the livestock sector. The other important feed area is pet food, which is bought regularly by more than 60 million households in the EU keeping pet animals. The EU compound feed industry including pet food has an annual turn over of almost 50 billion €, not accounting the feed material business.

The label serves on the one hand for enforcement, traceability and control purposes and on the other hand to pass information to the user. Being the crucial mean of communication between vender and purchaser labelling should be as simple and clear as possible. The mandatory requirements should be checked against what is necessary to enable the average user to an informed choice. Labelling of feed should be seen in the wider context of user information. The purchase of feed for farm animals is nowadays a business to business activity.

Objectives of the proposal

The project is included in the Commission's rolling programme of simplification. Thus, with the prerequisite of assuring the high level of feed and food safety achieved in the Community the general objectives are to consolidate, revise and modernise the Directives on the circulation and labelling of feed materials and compound feed. The simplification of the existing rules shall not jeopardise the high level of the protection of animal health. The proposal shall achieve legal clarity, a harmonised implementation and facilitate the smooth functioning of the internal market. To increase the competitiveness of the EU feed and farming sector, technical requirements shall be simplified and unnecessary administrative burden removed. Further, users of feed shall be empowered to make an informed choice without being misled.

In concrete, the operational objective on the issue of feed material listing is the smooth functioning of the internal market by clear designations and proper information of the customer. Concerning authorisation procedures it is aimed to ensure that requirements of pre-market authorisations are proportionate to risk and to assure that emerging feed materials are adequately specified for a proper use. For compound feed increased innovation and competitiveness shall be achieved by reducing unnecessary labelling requirements. Concerning pet food the operational objective is to improve the appropriateness of the pet food labels to enable the purchaser of the pet food to prevent misleading labelling.

Existing provisions in the area of the proposal

Council Directive 79/373/EEC lays down the rules for the circulation of compound feedingstuffs. As a special kind of compound feed, Council Directive 93/74/EEC lays down the principles for feedingstuffs intended for particular nutritional purposes ("dietetic feeds"). Council Directive 96/25/EC contains the general rules for the circulation and use of feed materials. Council Directive 82/471/EEC lays down the marketing conditions for the so called "bio-proteins" (certain products used in animal nutrition) belonging to the category feed materials. Further, Council Directive 93/113/EC provides for rules on the use and marketing of enzymes, micro-organisms and their preparations in animal nutrition and the still valid Article 16 of the besides repealed Council Directive 70/524/EEC lays down the provisions for the labelling of feed additives incorporated in compound feed.

These legal provisions are implemented by Commission Directive 80/511/EEC authorising, in certain cases, the marketing of compound feedingstuffs in unsealed packages or containers, Commission Directive 82/475/EEC laying down the categories of ingredients which may be used for the purposes of labelling compound feedingstuffs for pet animals, Commission Directive 94/39/EC, establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes and Commission Decision 2004/217/EC adopting a list of materials whose circulation or use for animal nutrition purposes is prohibited ("negative list").

The proposal streamlines, simplifies, updates and modernises the above mentioned provisions

Consistency with the other policies and objectives of the Union

The proposal is in line with the Commission's Better Regulation Policy and the Lisbon Strategy. The emphasis is on simplifying the regulatory process, thus reducing the administrative burden and improving the competitiveness of the European food industry, while ensuring the safety of food, maintaining high level of public health protection and taking global aspects into consideration.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

Consultation of interested parties

The opinion of Member States, Third Country representatives and stakeholders has been sought through consultations, meetings or during bilateral contacts since 2002 with increasing intensity.

In 2003 the Commission assigned an external contractor to carry out a study on a revision of certain parts of the feed legislation. The final report entitled "Assessment of the possible adoption of a new proposal recasting legislation on feed labelling and amending the authorisation/withdrawal procedure for some categories of feed materials" was presented in June 2004.

In November 2005, the Commission launched with the general public an Interactive Policy Making consultation in order to collect information on the possible impacts of the main issues under consideration for the revision of the current legislation.

In January and February 2007, panel discussions were held with the Member States in the margins of the Standing Committee on the Food Chain and Animal Health, with the European Food Safety Authority and with stakeholders represented in the Advisory Group on the Food Chain and Animal and Plant Health. On elements of the draft legislative proposal, the Member States have been consulted in two full day working group meetings in June and July 2007.

Impact assessment

For each of the important policy actions proposed in the draft Regulation, as appropriate, several options ranging from repealing requirements (de-regulation), maintaining the status quo, adding new mandatory measures to delegating responsibility to stakeholders (co-regulation) have been examined with regard to their economic, social and environmental impact on the various stakeholders and authorities.

The Commission carried out an Impact Assessment the report of which is presented in parallel to this proposal as a Commission Staff Working Paper. It is also available at http://ec.europa.eu/food/food/animalnutrition/labelling/index_en.htm

3. LEGAL ELEMENTS OF THE PROPOSAL

Summary of the proposed action

Adoption of a Regulation of the European Parliament and of the Council on the placing on the market and use of feed. Replacing the existing legislation in the field of marketing and use of certain feed, it simplifies and modernises the provisions to assure adequate information of users and consumers whilst ensuring the effective functioning of the internal market, based on the protection of public health.

Legal basis

Articles 37 and 152(4) of the EC Treaty.

Subsidiarity principle

The subsidiarity principle applies insofar as the proposal does not fall under the exclusive competence of the Community.

The objectives of the proposal cannot be sufficiently achieved by the Member States for the following reasons:

The core of the community action is setting the conditions for the circulation and use of feed within the EU which can not be appropriately addressed by MS alone if the common internal market shall function smoothly; experience shows that differences in the transposition of the Directives by Member States hinder a harmonised common market i.e. the free movement of feed. Further, the Union has the right to act in order to improve productivity and income of the European agriculture through uniform production conditions.

Individual action by Member States could lead to differing levels of feed/food safety and confuse consumers. E.g. a fully harmonised legislation on the circulation of feed will ease the feed recalls after detection of a risk.

EU action is justified to pursue the effective functioning of the internal market in relation to circulation and use of feed with respect to the competitiveness of the European feed business and livestock farming. Additionally, harmonised rules are in the interest of the European feed users to be appropriately informed.

The proposal therefore complies with the subsidiarity principle.

Proportionality principle

The proposal complies with the proportionality principle for the following reasons.

The proposal harmonises the regulatory framework for the marketing and use of certain feed and thus contributes to the functioning of feeding sector in the EU. Under the prerequisite of ensuring feed/food safety, the proposed legislative measures had been scrutinised in comparing the expected benefits with the drawbacks. Moreover in each field it has been thoroughly evaluated that the concrete measures do not impose an excessive or unjustified burden.

The absence of harmonisation would retain individual national marketing and production conditions. Administrative burden is reduced.

Choice of instruments

Proposed instrument: One Regulation

Considering that the simplification is a crucial element of the proposal, the use of regulations is deemed generally supportive to simplify because it guarantees that all actors have to follow at the same time the same rules (Commission simplification communication COM (2005)535).

Other means would not be adequate for the following reasons.

The Community has developed extensive requirements relating to the circulation and use of feed. These are still laid down in several Directives with many cross references and overlaps within each other. However, the requirements were either adopted as a scattered response to the needs of the Internal Market or the Communities objective to increase feed and food safety. This has resulted in a series of different regimes, which can only be justified for historical reasons.

Further, the national implementation of the Directives lead to disharmonised marketing conditions resulting in barriers in internal EU-trade as proved by several ECJ-cases. The issue of different qualifications of certain feed is chronically preoccupying businesses, national and EU-authorities including the Courts. A uniform classification is hindered as long as the Community rules are laid down in Directives.

Finally, the various amendments made to the Directives concerned were actually drafted in such a way that no real "marge de manoeuvre" was left to the MS for the transposition, thus being more "Regulation-like" than in the spirit of Directives. The aim was precisely to avoid divergences in the application by MS. For several years, Community legislation in the field of animal nutrition is drafted in this way, responding to the need of legal certainty wanted by the operators and also often by Member States.

To resume, a new comprehensive Regulation would introduce consistency and clarity throughout the EU feed sector.

4. BUDGETARY IMPLICATION

The proposal has no implication for the Community budget.

5. ADDITIONAL INFORMATION

Simplification

The proposal provides for simplification of legislation, administrative procedures for public authorities (EU or national) and administrative procedures for private parties.

Repealing unnecessary possibilities for the Member States to derogate nationally from the general provisions and upgrading useful derogations onto the mandatory European level streamlines the legislation and increases transparency for the concerned parties. The wording will be updated and clarified.

The proposal is included in the Commission's simplification rolling programme and its Work and Legislative Programme 2007 under the reference 2007/SANCO/004.

European Economic Area

The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

Detailed explanation of the proposal

Chapter 1 – Introductory provisions

The provisions for circulation and use of feed materials and compound feed shall assure the level of feed/food safety whilst providing for a modern market environment for stakeholders. In doing so, the existing horizontal and special legislation in related areas has to be respected. Clear definitions of the different kinds of feed and expressions are crucial to achieve the objectives.

Chapter 2 – General requirements

General safety and marketing requirements shall be established for all feed. Special obligations for manufactures and other operators are laid down to allow proper control actions and feed safety measures.

The Commission shall be empowered to maintain and update a list of materials whose placing on the market is prohibited.

Chapter 3 – Placing on the market of specific types of feed

Impurity criteria for feed materials shall be laid down and in order to differentiate feed materials from other types of feed the Commission shall be entitled to issue guidelines.

A clarification for complementary feed is particularly important concerning the maximum content of feed additives.

The provisions for feed intended for particular nutritional purposes (dietetic feed) shall be maintained with the possibility to update the list of authorisations in Comitology after consultation of the European Food Safety Authority, if necessary.

Chapter 4 – Labelling, presentation and packaging

The general labelling provisions for all feed materials and compound feed shall assure accuracy and appropriateness. The responsibility for the correctness of the labelling along the food chain has to be clarified. Claims have to be scientifically substantiated on request of the control authorities.

The general mandatory labelling requirements shall be equal for feed materials and compound feed. The indication of feed additives shall be based on safety classification. For pet food flexibility shall avoid that the customer is confused by the additive labelling.

Appropriate specific mandatory labelling requirements shall be laid down for feed materials, compound feed and dietetic feed.

The feed user shall have the right to get on his initiative information supplementary to the mandatory labelling particulars.

For contaminated feed special labelling requirements shall be established.

Derogations from the basic and special labelling requirements shall be foreseen based on positive experiences in the past.

The framework for voluntary labelling of compound feed for food producing animals and for pet food shall be laid down.

Concerning the packaging of feed, the requirement to be placed on the market only in sealed containers shall be possibly derogated under certain conditions.

The principles for the labelling shall apply as well to the presentation and advertising of feed.

Chapter 5 – Community Catalogue for feed materials and Codes of good labelling practice

A more complete list of feed materials with proper product identification would be favourable in terms of market transparency. Considering that a list with specifications of feed materials has no influence on feed safety and that the stakeholders are best aware which priorities in terms of which products to address at first and level of detail listings, it is proportionate to delegate this task to the stakeholders.

Based on the positive experience with the elaboration of industry guides to good feed hygiene practice and the justified interest of stakeholders to get engaged in the field, stakeholders shall be encouraged to elaborate Community Codes to good labelling practice within the framework of the voluntary labelling.

The Commission shall be involved in the elaboration of the voluntary Community Catalogue and the Codes in an advisory and finally approving way. It shall be assured that all relevant stakeholders are involved in the elaboration of these instruments.

Chapter 6 – General and final provisions

Implementation of the measures proposed in the Regulation will be adopted by the Commission in accordance with the regulatory procedure laid down in Council Decision 1999/468/EC.

The labelling of premixtures as laid down in Article 16 of Regulation 1831/2003 shall be amended in order to remedy some inconsistencies.

Annexes: Technical provisions for the labelling of feed shall be laid down to provide necessary specifications. This includes concrete mandatory and voluntary labelling details for feed materials and compound feed. Further the tolerances for the control of the labelled particulars have to be laid down.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the placing on the market and use of feed

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission¹,

Having regard to the opinion of the European Economic and Social Committee²,

Having regard to the opinion of the Committee of the Regions³,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁴,

Whereas:

- (1) The pursuit of a high level of protection of human 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 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 safety⁵. That Regulation also established the farm-to-fork approach designating feed as a sensitive stage at the beginning of the food chain.
- (2) Feed can be categorised in feed materials, compound feed, feed additives and medicated feed. The rules for the marketing of feed additives are set out in Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition⁶ and for medicated feedingstuffs in Council Directive 90/167/EEC of 26 March 1990 laying down the conditions

¹ OJ C [...], [...], p. [...].

² OJ C [...], [...], p. [...].

³ OJ C [...], [...], p. [...].

⁴ OJ C [...], [...], p. [...].

⁵ OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).

⁶ OJ L 268, 18.10.2003, p. 29. Regulation amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

governing the preparation, placing on the market and use of medicated feedingstuffs in the Community⁷.

- (3) The existing legislation on the circulation and use of feed materials and compound feed which includes pet food, namely Council Directive 79/373/EEC of 2 April 1979 on the circulation of compound feedingstuffs⁸, Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes⁹ ("dietetic feed"), Council Directive 96/25/EC of 29 April 1996 on the circulation and use of feed materials¹⁰ and Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition¹¹ ("bio-proteins"), needs to be updated. The replacement of those Directives makes it necessary to replace Commission Directive 80/511/EEC of 2 May 1980 authorising, in certain cases, the marketing of compound feedingstuffs in unsealed packages or containers¹².
- (4) As a consequence of the replacement of Directive 79/373/EEC, Council Directive 93/113/EC of 14 December 1993 concerning the use and marketing of enzymes, micro-organisms and their preparations in animal nutrition¹³ should also be replaced. Furthermore, the repeal of Directive 79/373/EEC implies that Article 16 of Council Directive 70/524/EEC, which remained in force after the repeal of Directive 70/524/EEC by Regulation (EC) No 1831/2003, needs to be replaced by provisions for the labelling of feed additives incorporated in compound feed.
- (5) As water is not covered by the definition of feed, as provided for in Community food and feed law and is not marketed for animal nutrition purposes, this Regulation should not include conditions for water used in animal nutrition. Instead, the use of water by feed businesses is covered by Regulation (EC) No 1831/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene¹⁴.
- (6) In addition to the requirements for feed as laid down in Articles 15 and 16 of Regulation (EC) No 178/2002 and Article 4 of Regulation 183/2005 it is appropriate to lay down special safety and marketing provisions which should apply as well to feed for non-food producing animals.
- (7) The responsibilities of the feed business operators are laid down in Articles 17, 18 and 20 of Regulation (EC) No 178/2002. Those Articles do not cover feed for non food producing animals. Recent experiences have shown that these feeds can undermine feed and food safety. Therefore, provision has to be made to extend those Articles to feed for non-food producing animals.

⁷ OJ L 92, 7.4.1990, p. 42.

⁸ OJ L 86, 6.4.1979, p. 30. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

⁹ OJ L 237, 22.9.1993, p. 23. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

¹⁰ OJ L 125, 23.5.1996, p. 35. Directive as last amended by Regulation (EC) No 806/2003.

¹¹ OJ L 213, 21.7.1982, p. 8. Directive as last amended by Commission Directive 2004/116/EC (OJ L 379, 24.12.2004, p. 81).

¹² OJ L 126, 21.5.1980, p. 14. Directive as amended by Directive 98/67/EC (OJ L 261, 24.9.1998, p. 10).

¹³ OJ L 334, 31.12.1993, p. 17. Directive as amended by Directive 97/40/EC (OJ L 180, 9.7.1997, p. 21).

¹⁴ OJ L 35, 8.2.2005, p. 1.

- (8) In order to enforce compliance with this Regulation, Member States are to carry out official controls in accordance with Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules¹⁵. Those controls should cover not only the mandatory but also the voluntary labelling particulars. In order to allow controls of the compositional data, acceptable tolerances for the labelled values should be determined.
- (9) To manage feed safety risks, the list of products whose placing on the market for animal nutrition purposes is prohibited, as provided for in Commission Decision 2004/217/EC¹⁶, should be maintained. The existence of such a list should not mean that all products not listed can be considered to be safe.
- (10) The distinction between feed materials, feed additives and veterinary drugs has implications on the conditions for placing on the market. Feed materials are in the first place used to meet animals' needs, for example for energy, nutrients, minerals or dietary fibres. They are usually not chemically well defined except for basic nutritional constituents. Effects justifiable by scientific assessment and reserved to feed additives or veterinary drugs should be excluded from the objective uses of feed materials. It is appropriate to elaborate guidelines for the distinction between the kinds of products.
- (11) The definition of complementary feedingstuffs in Directive 79/373/EEC gave rise to application problems in various Member States. In order to allow a uniform application of the legislation, complementary feed should not contain additives above a certain level.
- (12) Directive 82/471/EEC aimed to improve the supply with protein-rich feed in the Community. That Directive requires a pre-market authorisation procedure for all possible bio-proteins. Only very few new authorisations have been granted in the past and the shortage in protein-rich feed is still evident. Thus, the general pre-market authorisation requirement proved to be prohibitive and safety risks could be tackled instead by means of prohibiting risky products based on market surveillance. In case the outcome of the risk assessment of a bio-protein was or is negative, its circulation or use should be prohibited. Hence, the special requirement of a general pre-market authorisation procedure for bio-proteins should be abolished with the consequence that the safety system for these products is the same as for all the other feed materials.
- (13) The provisions of Directive 93/74/EEC implemented by Directive 94/39/EC establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes¹⁷ proved to be working well and should be maintained in an updated form. The European Food Safety Authority (hereinafter referred to as "the Authority") should be consulted on the efficacy and the safety of such feed when on the basis of available scientific and technical information, there are reasons to believe that the use of the specific feed may not meet the particular intended nutritional purpose or may have adverse effects on animal health, human health, the environment and animal welfare.

¹⁵ OJ L 165, 30.4.2004, p. 1. Regulation as amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

¹⁶ OJ L 67, 5.3.2004, p. 31.

¹⁷ OJ L 207, 10.8.1994, p. 20.

- (14) Labelling serves enforcement, traceability and control purposes. In addition, labelling should provide the necessary information to the customers to enable them to make the optimal choice for their needs and should be consistent, coherent, transparent and understandable. As the customers in particular the livestock farmers are making their choice not only at the point of sale where they can peer the package of the feed the requirements concerning the labelling information must not only be valid for the labels on the product but as well for other kind of communication between vendor and customer. Furthermore, those principles should apply also to presentation and advertising of the feed.
- (15) Labelling provides mandatory, voluntary and additional information. The mandatory information should combine basic labelling requirements and specific ones for feed materials or compound feed respectively and additional ones in case of dietetic feed.
- (16) The existing principle that only certain feed additives have to be labelled once they are used in feed materials and compound feed proved to work well. Both the categorisation resulting from Regulation (EC) No 1831/2003 and the fact that particularly pet owners might be confused by some additive labelling requires an updating and modernisation.
- (17) As a consequence of the BSE- and dioxin crisis, the obligation to indicate the weight percentage of all feed materials incorporated in compound feed had been introduced in 2002. In parallel, the level of food and feed safety has been meanwhile significantly improved due to Regulations (EC) No 178/2002 and No 183/2005 and their implementing measures, explicitly the focus on the responsibility of the feed and food business operators, the improved traceability system, the introduction of the HACCP principle in feed businesses and the guides to good hygiene practice in feed businesses. These positive achievements, mirrored in the notifications to the Rapid Alert System for Food and Feed, justify that the obligation to indicate the weight percentage of all feed materials incorporated in compound feed should be abandoned. The exact percentages could be provided for on a voluntary basis.
- (18) To ensure proper information of the customer and to avoid misleading him, the exact weight percentage should be required in case the respective feed material is emphasised on the labelling of a compound feed.
- (19) In certain areas where the producer is not obliged to label particulars, the customer should have the possibility to request additional information. Nonetheless, the indication of the feed materials incorporated in compound feed in descending order of weight, already provides important information on compositional data. Taking into account the recent developments in Community legislation which give higher guarantees as regards in particular HACCP, traceability, strict hygiene rules and the development of Community guides to good practice for hygiene, the manufacturer should be allowed to reject the request if he considers the requested disclosure to infringe his intellectual property rights. This would not affect the food and feed safety, since the competent authorities always have the right to get the exact percentages of all feed materials.

- (20) Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed¹⁸ does not rule the labelling of feed with excessive levels of undesirable substances. Therefore, adequate provisions should be laid down.
- (21) Derogations from the general labelling requirements should be provided for as far as the application of those requirements is not necessary to protect human or animal health or consumer interests and would unduly burden the manufacturer or feed business operators responsible for the labelling particulars. Based on experience such derogations should be provided for with respect to feed delivered by one farmer to another farmer for use on his farm, for small quantities, for compound feed not constituted of more than three feed materials and for mixes of whole plant grains.
- (22) As a general rule, compound feed should be marketed in sealed containers, but appropriate derogations should be provided for.
- (23) Part B of the Annex to Directive 96/25/EC and the Annex to Directive 82/471/EEC contain lists with designations, descriptions and labelling provisions for certain feed materials. Those lists facilitate the exchange of information on the product properties between the manufacturer and the purchaser. Nevertheless, those lists are not exhaustive. This implies that non-listed feed materials can be marketed as well. Furthermore, emerging feed materials have not been listed since years with the effect that the feed materials on the market covered by the lists decreased. In particular as regards emerging feed materials, those lists should be extended in the interest of the stakeholders who are the beneficiaries of proper product descriptions.
- (24) The experience with engaging stakeholders to set standards by means of Community guidelines in the field of feed hygiene have been throughout positive. The accomplishment of a more extended listing by the stakeholders could be more flexible and better adapted to the information needs of the user than if undertaken by the legislator. The stakeholders can decide on the efforts they dedicate depending on the value of a feed material list. The current lists of feed materials in Directives 96/25/EC and 82/471/EEC should become the initial version of the Community Catalogue of feed materials to be completed by the stakeholders according to their interests. The use of the Catalogue should be voluntary but in order to avoid that the purchaser is misled as to the real identity of the product, the manufacturer should indicate if he uses designations listed in the Catalogue while not applying it.
- (25) Modern labelling facilitates a competitive market environment in which dynamic, efficient, innovative operators can make full use of labelling to sell their products. Having regard to both the business to business relation in the marketing of livestock feed and the relationship between the manufacturer and purchaser of pet food, Codes of good labelling for these two areas could be useful means of achieving the objectives of modern labelling. These Codes may interpret the framework given for voluntary labelling.

¹⁸ OJ L 140, 30.5.2002, p. 10. Directive as last amended by Commission Directive 2006/77/EC (OJ L 271, 30.9.2006, p. 53).

- (26) Involvement of all parties concerned is the crucial element for the quality and appropriateness of the Catalogue and the Codes for good labelling. In order to improve the users' right to proper information, their interest must be considered particularly. This can be ensured by the Commission by approving the Catalogue and the Codes.
- (27) Since the objectives of feed and food safety and a smooth functioning of the internal market for feed cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (28) 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 Commission¹⁹.
- (29) Power should be conferred on the Commission in particular to decide on products prohibited for use as feed, to authorise feed intended for particular nutritional purposes, to establish a list of labelling categories of feed materials for non-food producing animals, to amend the list of voluntary labelling particulars and to adapt the Annexes in the light of scientific and technical development. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, inter alia, by supplementing it, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (30) Article 16 of Regulation (EC) No 1831/2003 lays down the provisions for labelling and packaging of feed additives and premixtures. Particularly the rules concerning premixtures have proved to cause practical problems in the implementation for the industry and the competent authorities. In order to allow a more consistent labelling of premixtures, that Article should be amended.
- (31) Directives 79/373/EEC, 80/511/EEC, 82/471/EEC, 93/74/EEC, 93/113/EC and 96/25/EC should therefore be repealed.
- (32) The Member States should lay down rules on penalties applicable to infringements of the provision of this Regulation and should take all measures necessary to ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive,

¹⁹ OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

HAVE ADOPTED THIS REGULATION:

Chapter 1

Introductory provisions

Article 1 *Subject matter*

The objective of this Regulation in accordance with the general principles laid down in Regulation (EC) No 178/2002 is to harmonise the conditions for the placing on the market and use of feed, in order to ensure adequate information of users and consumers and the effective functioning of the internal market.

Article 2 *Scope*

1. This Regulation lays down rules on the placing on the market and use of feed within the Community including requirements for labelling, packaging and presentation.
2. The provisions of this Regulation shall apply without prejudice to other Community provisions applicable in the field of animal nutrition, namely:
 - (a) Directive 90/167/EEC;
 - (b) Directive 2002/32/EC;
 - (c) Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies²⁰;

²⁰ OJ L 147, 31.5.2001, p. 1

- (d) Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption²¹;
 - (e) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed²²; and
 - (f) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC²³.
3. This Regulation shall not apply to water, either taken in directly by the animals or intentionally incorporated into feed.

Article 3 *Definitions*

1. For the purposes of this Regulation, the definitions of ‘feed’, ‘feed business’, ‘feed business operator’, ‘placing on the market’ and ‘traceability’ as laid down in Regulation (EC) No 178/2002 and the definitions of “feed additive”, “premixture”, “processing aids” and “daily ration” as laid down in Regulation (EC) No 1831/2003 shall apply.
2. The following definitions shall also apply.
- (a) ‘Food producing animal’: any animal that is kept for the production of food for human consumption including animals that are not consumed but that belong to species that can be normally consumed in the Community;
 - (b) ‘Non-food producing animals’: animals kept or bred but not used for human consumption such as fur animals, pets and animals kept in laboratories, zoos or circus;
 - (c) ‘Fur animals’: animals kept or reared for the production of fur and not used for human consumption;
 - (d) ‘Pet’ or ‘pet animal’: animal belonging to species nourished, bred or kept, but normally not consumed by humans in the Community;

²¹ OJ L 273, 10.10.2002, p. 1.

²² OJ L 268, 18.10.2003, p. 1.

²³ OJ L 268, 18.10.2003, p. 24.

- (e) 'Feed materials': products of vegetable or animal origin, whose principal objective is to meet animals nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal feeding either directly as such, or after processing, in the preparation of compound feed or as carrier of premixtures;
- (f) 'Compound feed': mixture of feed materials, whether or not containing feed additives, for oral animal feeding in the form of complete or complementary feed;
- (g) 'Complete feed': compound feed which, by reason of its composition, is sufficient for a daily ration;
- (h) 'Complementary feed': compound feed with at least one feed material which has a high content of certain substances but which, by reason of its composition, is sufficient for a daily ration only if used in combination with other feed;
- (i) 'Mineral feed': complementary feed containing at least 40% crude ash;
- (j) 'Milk replacer': compound feed administered in dry form or after dilution in a given quantity of liquid for feeding young animals as a complement to, or substitute for, post-colostral milk or for feeding calves, lambs or kids intended for slaughter;
- (k) 'Carrier': substance used to dissolve, dilute, disperse or otherwise physically modify a feed additive in order to facilitate its handling, application or use without altering its technological function and without exerting any technological effect themselves;
- (l) 'Particular nutritional purpose': the purpose of satisfying the specific nutritional needs of animals whose process of assimilation, absorption or metabolism is or could be temporarily or irreversibly impaired and can therefore benefit from the ingestion of feed appropriate to their condition;
- (m) 'Feed intended for particular nutritional purposes': feed which can satisfy a particular nutritional purpose by virtue of its particular composition or method of manufacture, which clearly distinguish it from ordinary feed. Feed intended for particular nutritional purposes does not include medicated feedingstuffs in the meaning of Directive 90/167/EEC;
- (n) 'Minimum storage life': date until which, under proper storage conditions, the producer guarantees that the feed retains at least its specific properties;
- (o) 'Batch' or 'lot': unit of production from a single plant using uniform production parameters or a number of such units, when produced in continuous order and stored together. It consists of an identifiable quantity of feed and is determined to have common characteristics, such as origin, variety, type of packing, packer, consignor or labelling;

- (p) 'Labelling': attribution of any words, particulars, trade marks, brand name, pictorial matter or symbol to a feed by placing this information on any medium like packaging, container, notice, label, document, ring, collar or the internet referring to or accompanying such feed;
- (q) 'Label': any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, impressed on, or attached to a container of feed;
- (r) 'Presentation': the shape, appearance or packaging and the packaging materials used for the feed, further to the way in which it is arranged and the setting in which it is displayed.

Chapter 2

General requirements

Article 4

Safety and marketing requirements

1. For the purposes of this Regulation, Articles 15 and 16 of Regulation 178/2002 and Article 4 of Regulation (EC) No 183/2005 shall apply, mutatis mutandis, to feed for non-food producing animals.
2. Feed may only be placed on the market and used if:
 - (a) it is sound, genuine, fit for purpose and of merchantable quality;
 - (b) it does not have a direct adverse effect on the environment or animal welfare;
 - (c) it is labelled, packaged and presented in accordance with the provisions laid down in this Regulation, in Directive 90/167/EEC and in Regulation (EC) No 1831/2003, as applicable.
3. Feed shall comply with the technical provisions on impurities and other chemical determinants set out in Annex I.

Article 5

Responsibilities and obligations of the feed businesses

1. For the purposes of this Regulation, Articles 17, 18 and 20 of Regulation (EC) No 178/2002 shall apply, mutatis mutandis, to feed for non-food producing animals.
2. Manufacturers of feed shall make available to the authorities responsible for carrying out official controls any information concerning the composition or claimed properties of the feed they place on the market which enables the accuracy of the information given by the labelling to be verified.

Article 6
Prohibition

1. Feed shall not contain or consist of materials whose placing on the market or use for animal nutritional purposes is prohibited.
2. Taking into account in particular scientific evidence, technological progress, notifications under the Rapid Alert System for Food and Feed or results from official controls according to Regulation (EC) No 882/2004, the Commission shall adopt a list of materials whose placing on the market or use for animal nutritional purposes is prohibited.

Those measures which are designed to amend non-essential elements of this Regulation by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(4).

Chapter 3

Placing on the market of specific types of feed

Article 7
Characteristics of types of feed

In accordance with the procedure referred to in Article 29(2), the Commission may adopt guidelines clarifying the distinction between feed materials, feed additives and veterinary drugs.

Article 8
Content of feed additives in complementary feed

Without prejudice to the conditions of use provided for in the Regulation authorising the respective feed additive, complementary feed shall not contain feed additives incorporated at levels more than 100 times the relevant fixed maximum content in complete feed or five times in case of coccidiostats and histomonostats.

Article 9
Marketing of feed intended for particular nutritional purposes

Feed intended for particular nutritional purposes may only be marketed as such if it meets the essential nutritional characteristics for the respective particular nutritional purpose, representing the intended use, as authorised and included in the list established in accordance with Article 10.

Article 10
Authorisation of intended uses

1. Authorisations for intended uses may be granted on application from a person established in the Community or on request from a Member State. Such an application or request shall be submitted to the Commission.
2. The applicant shall compile a dossier demonstrating that the specific feed meets the particular intended nutritional purpose and that it has no adverse effects on animal health, human health, the environment and animal welfare.
3. The Commission shall forward the application dossier to the Member States.
4. If, on the basis of available scientific and technical information, the Commission, has reasons to believe that the use of the specific feed may not meet the particular intended nutritional purpose or may have adverse effects on animal health, human health, the environment and animal welfare, the Commission shall forward a request for a assessment together with the dossier to the European Food Safety Authority ('the Authority') within three months. The Authority shall give an opinion within six months of receipt of the request. This time limit shall be extended whenever the Authority seeks supplementary information from the applicant.
5. Within six months after forwarding the dossier to the Member States or, if appropriate, receiving the opinion of the Authority, the Commission shall adopt a Regulation to grant or deny the respective authorisation and establish a list, as referred to in Article 9, accordingly.

Those measures which are designed to amend non-essential elements of this Regulation by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(4).
6. The withdrawal of a listed intended use may be requested by the initial applicant or a Member State. The request shall be accompanied by a dossier justifying the withdrawal. The Commission may also initiate the withdrawal procedure in cases it disposes of substantial information to compile a respective dossier.
7. The Commission shall forward the dossier to the Member States and to the initial applicant for comments. The procedure as laid down in paragraphs 4 and 5 shall apply mutatis mutandis.

Chapter 4

Labelling, presentation and packaging

Article 11

General principles

1. The labelling and the presentation of feed shall not mislead the user
 - (a) as to the intended use or characteristics of the feed, in particular, the nature, method of manufacture or production, identity, properties, composition, quantity, durability, species or categories of animals for which it is intended;
 - (b) by attributing to the feed effects or characteristics that it does not possess or by suggesting that it possesses special characteristics when in fact all similar feeds possess such characteristics.
 - (c) as to the compliance of the labelling to the Community Catalogue and the Community Codes referred to in Articles 25 and 26.
2. Feed materials or compound feed marketed in bulk or in unsealed packages or containers in accordance with Article 23(2) shall be accompanied by a document containing all mandatory labelling particulars in accordance with this Regulation
3. Where feed is offered for sale by means of distance communication as defined in Article 2 of Directive 97/7/CE of the European Parliament and of the Council²⁴ the mandatory labelling particulars required by this Regulation shall appear on the material supporting the distance selling.
4. Additional general labelling provisions are laid down in Annex II.
5. Tolerances for discrepancies between the labelled compositional values of a feed material or compound feed and the values analysed in official controls in compliance with Regulation (EC) No 882/2004 are listed in Annex III to this Regulation.

Article 12

Responsibility

1. The manufacturer of the feed shall be responsible for the labelling particulars and ensure their presence and substantive accuracy.
2. If the feed is marketed with the name or business name of a feed business operator other than the manufacturer that feed business operator shall be responsible for the labelling particulars.

²⁴ OJ L 144, 4.6.1997, p. 19.

3. To the extent their activities affect labelling within the business under their control, feed business operators shall ensure that the information provided through whatever medium satisfies the requirements of this Regulation.
4. Feed business operators responsible for retail or distribution activities which do not affect labelling shall act with due care to help to ensure compliance with the labelling requirements, in particular by not supplying feed which they know or should have presumed, on the basis of the information in their possession and as professionals, do not comply with those requirements.
5. Within the business under their control feed business operators shall ensure that mandatory labelling particulars can be transmitted throughout the food chain in order to enable the provision of the information to the final user in accordance with this Regulation.

Article 13 *Claims*

1. The labelling and the presentation of feed may draw particular attention to the presence or the absence of a substance in the feed, to a specific nutritional characteristic or process or to a specific function related to any of these, provided that the following conditions are met:
 - (a) the claim is objective, verifiable by the competent authorities and understandable by the user of the feed, and
 - (b) the person responsible for the labelling provides on request of the competent authority a scientific substantiation of the truthfulness of the claim, either via publicly available scientific evidence or through documented company research. The scientific substantiation shall be available at the time the feed is placed on the market.
2. Without prejudice to paragraph 1, claims concerning optimisation of the nutrition and support or protection of the physiological conditions are permitted if they are not based on a pharmacological or immunological action.
3. The labelling or the presentation of feed shall not claim that it
 - (a) will prevent, treat or cure a disease, or
 - (b) has particular nutritional purposes and characteristics other than those provided for in the list as referred to in Article 9.

Article 14 *Presentation of mandatory labelling particulars*

1. The mandatory labelling particulars shall be given in their entirety in a prominent place on the packaging, the container or on a label attached thereto, in a conspicuous, clearly legible and indelible manner, in at least the language or one of the official languages of the Member State in which it is placed on the market.

2. The mandatory labelling particulars shall be easily identifiable and not be obscured by any other information. They shall be displayed in a colour, font and size that does not obscure or emphasize any part of the information, unless such variation is to draw attention to precautionary statements.
3. Specifications to the requirements laid down in paragraphs 1 and 2 may be included in the Community Codes referred to in Article 26.

Article 15 *General mandatory labelling requirements*

A feed material or compound feed shall not be placed on the market unless the following particulars are indicated by labelling:

- (a) the type of feed: feed material', 'complete feed' or 'complementary feed', as appropriate;

for 'complementary feed' the following designations may be used if appropriate: 'mineral feed', 'complete milk replacer feed' or 'complementary milk replacer feed';

for pets other than cats and dogs 'complete feed' or 'complementary feed' may be replaced by 'compound feed';
- (b) the name or business name and address of the feed business operator responsible for the labelling particulars;
- (c) if available, the establishment approval number granted in accordance with Article 17 of Regulation (EC) No 1774/2002 or with Article 10 of Regulation (EC) No 183/2005. If a manufacturer has several numbers he shall use the one obtained under Regulation 183/2005;
- (d) the batch or lot reference number;
- (e) the net quantity expressed in units of mass in the case of solid products, and in units of mass or volume in the case of liquid products;
- (f) the list of feed additives preceded by the name and the content in accordance with Chapter I of Annex V or VI, as applicable, and without prejudice to labelling provisions laid down in the Regulation authorising the respective feed additive.
- (g) the moisture content in accordance with point 6 of Annex I.

Article 16 *Specific mandatory labelling requirements for feed materials*

1. In addition to the requirements provided for in Article 15, the labelling of feed materials shall also include the name of the feed material accompanied by the compulsory declaration corresponding to the respective category as set out in the list in Annex IV.

2. The particulars referred to in paragraph 1 may be replaced by the particulars laid down in the Community Catalogue referred to in Article 25.
3. If the used name of the feed material corresponds to one of the names included in the Community Catalogue referred to in Article 25, but the person responsible for the labelling is not applying the provisions thereof, this shall be clearly indicated on the label.

Article 17

Specific mandatory labelling requirements for compound feed

1. In addition to the requirements provided for in Article 15, the labelling of compound feed shall also include the following:
 - (a) the species or category of animals for which the compound feed is intended;
 - (b) the instructions for proper use indicating the purpose for which the feed is intended;
 - (c) in case the manufacturer is not the person responsible for labelling particulars, the following shall be provided:
 - the name or business name and address of the manufacturer, or
 - the identifying number as granted according to Article 19 of Regulation (EC) No 183/2005; if such identifying number is not available, a registration number attributed on the manufacturers request in accordance with the format laid down in Chapter II of Annex V to Regulation (EC) No 183/2005;
 - (d) the indication of the minimum storage life in accordance with the following requirements:
 - ‘use before...’ followed by the date indicating a certain day in the case of feed highly perishable due to degradation processes;
 - ‘best before...’ followed by the date indicating a certain month in the case of other feed.

If the date of manufacture is labelled, the date may be indicated as well as ‘... (time period in days or months) after the date of manufacture’;
 - (e) the list of the feed materials of which the feed is composed, bearing the heading “composition” and indicating the name of each feed material and listing those feed materials in descending order by weight; that list may include the percentage of weight.
 - (f) the compulsory declarations provided for in Chapter II of Annex V or VI, as applicable.

2. As regards the list provided for in paragraph 1(e), the following requirements shall apply:
- (a) the name and percentage of weight of a feed material shall be indicated if its presence is named or emphasised on the labelling in words, pictures or graphics;
 - (b) if the percentages of weight for the feed materials incorporated in compound feed for food producing animals are not indicated on the label, the manufacturer shall make available on request information on the quantitative composition data in a range of +/- 15% of the value according to the feed formulation, unless he considers this information to be commercially sensitive and that the disclosure could infringe his intellectual property rights;
 - (c) in the case of compound feed intended for non-food producing animals, the indication of the specific name of the feed material may be replaced by the name of the category to which the feed material belongs to.
3. For the purposes of paragraph 2(c), the Commission shall establish a list of categories of feed materials which may be indicated instead of individual feed materials in the labelling of feed for non-food producing animals.

Those measures which are designed to amend non-essential elements of this Regulation by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(4).

Article 18

Additional labelling requirements for feed intended for particular nutritional purposes

In addition to the general mandatory requirements laid down in Articles 15 and 16 or in Article 17, as applicable, labelling of feed intended for particular nutritional purposes shall also include:

- (a) the qualifying expression 'dietetic', reserved solely for feed intended for particular nutritional purposes, next to the designation of the feed as laid down in Article 15(a);
- (b) the particulars prescribed for the respective intended use in columns 1, 2, 3, 4, 5 and 6 of the list as referred to in Article 9;
- (c) the indication that the opinion of a nutrition expert should be sought before using the feed or before extending the period of use.

Article 19

Additional labelling requirements for pet food

On the label of pet food a free telephone number shall be indicated in order to allow the customer to obtain information in addition to the mandatory particulars on:

- (a) the feed additives incorporated into the pet food, and

- (b) the feed materials incorporated that are designated by category as referred to in Article 17(2)(c).

Article 20

Additional labelling requirements for contaminated feed

1. In addition to the requirements laid down in Articles 15, 16, 17 and 18, feed containing a level of undesirable substances in excess of that permitted under Directive 2002/32/EC shall be labelled 'feed with excessive level(s) of ... (designation of the undesirable substance(s) in accordance with Annex I to Directive 2002/32/EC), only intended for authorised detoxification establishments'. The authorisation of those establishments shall be based on Article 10(2) or (3) of Regulation (EC) No 183/2005.
2. In case the contamination is intended to be reduced or eliminated by cleaning, the additional labelling of contaminated feed shall be 'feed with excessive level(s) of ... (designation of the undesirable substance(s) in accordance with Annex I to Directive 2002/32/EC), only to be used as feed after adequate cleaning'.

Article 21

Derogations

1. The particulars referred to in Article 15(c), (d) and (e) and Article 16(2) shall not be required where before each transaction the purchaser has stated in writing that he does not require this information. A transaction may consist of several consignments.
2. On packaged feed the particulars referred to in Article 15(c), (d) and (e) and Article 17(1)(c), (d) and (e) may be given on the package outside the place of the label as referred to in Article 14(1). In such cases it shall be pointed out where these particulars appear.
3. Without prejudice to Annex I to Regulation (EC) No 183/2005, the particulars referred to in Article 15(c), (d) and (e) and Article 16(2) of this Regulation shall not be mandatory for feed materials that do not contain feed additives, with the exception of preservatives or silage additives, and which are produced and delivered by a feed business operator according to Article 5(1) of Regulation (EC) No 183/2005 to a feed user in primary production for use within its own holding.
4. The compulsory declarations referred to in Article 17(1)(f) shall not be required for mixes of whole plant grains.
5. In the case of compound feed constituted from no more than three feed materials the particulars referred to in Article 17(1)(a) and (b) shall not be required where the feed materials used appear clearly in the description.

6. For quantities not exceeding 20 kg of feed materials or compound feed intended for the final user and sold in bulk, the particulars referred to in Articles 15, 16 and 17 may be brought to the purchaser's attention by means of an appropriate notice at the point of sale. In this case, the particulars referred to in Article 15(a) and Article 16(1) or Article 17(1)(a) and (b), as appropriate, shall be printed out for the customer at the latest on the invoice.
7. For quantities of pet food not exceeding the daily ration of the respective animal species sold in packages with several containers, the particulars referred to in Article 15(b), (c) and (f) and Article 17(1)(c), (e) and (f) may be given only on the package instead of each container.
8. By way of derogation from the provisions of this Regulation, Member States may apply national provisions for feed intended for animals kept for scientific or experimental purposes on condition that its label clearly indicates such purpose. The Member States shall notify those provisions to the Commission without delay.

Article 22

Voluntary labelling

1. In addition to the mandatory labelling requirements, the labelling of compound feed may also include voluntary labelling particulars, provided that the general principles laid down in Article 11 are respected.
2. The additional voluntary labelling may only include the following particulars:
 - (a) optional declarations as laid down in Annexes V and VI;
 - (b) the country of production or manufacture;
 - (c) the description or trade name of the product;
 - (d) an indication of the physical condition of the feed or the specific processing it has undergone;
 - (e) the moisture content;
 - (f) the date of manufacture;
 - (g) special storage conditions;
 - (h) the price of the product.
3. The Commission may amend the list of particulars laid down in paragraph 2.

Those measures designed to amend non-essential elements of this Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(4).

Article 23
Packaging

1. Feed may be placed on the market only in sealed packages or containers. Packages or containers shall be sealed in such a way that, when the package or container is opened, the seal is damaged and cannot be reused.
2. By way of derogation from paragraph 1, the following feed may be placed on the market in bulk or in unsealed packages or containers:
 - (a) feed materials;
 - (b) compound feed exclusively obtained by mixing grain or whole fruit;
 - (c) deliveries between producers of compound feed;
 - (d) deliveries of compound feed directly to the feed user;
 - (e) deliveries from producers of compound feed to packaging firms;
 - (f) quantities of compound feed not exceeding 50 kilograms in weight which are intended for the final user and are taken directly from a sealed package or container;
 - (g) blocks or licks.

Article 24
Change of package

1. If a batch of feed is divided, the mandatory labelling particulars provided for in this Regulation, together with a reference to the initial batch, shall be repeated on the packaging, container or accompanying document of each division of the batch.
2. Where the composition of a feed is modified after it has been placed on the market the mandatory labelling particulars shall be adapted accordingly under the responsibility of the feed business operator responsible for the modification of the feed.

Chapter 5

Community catalogue on feed materials and Community Codes of good labelling practice

Article 25

Community Catalogue of feed materials

1. The Community Catalogue of feed materials (hereinafter ‘the Catalogue’) shall be created as a tool to improve the labelling of feed materials. It shall include for each feed material listed:
 - (a) the name;
 - (b) the identification number;
 - (c) a description of the feed material including information on the manufacturing process, if appropriate;
 - (d) specific particulars concerning the nutritional composition that shall be included in the labelling as referred to in Article 16(2);
 - (e) a glossary with the definition of the different processes and technical expressions mentioned.
2. The first entries in the Catalogue shall be those listed in Part B of the Annex to Directive 96/25/EC and the Annex to Directive 82/471/EEC following the procedure laid down in Article 29(2).
3. The procedure laid down in Article 27 shall apply to amendments to the Catalogue.
4. The provisions of this Article apply without prejudice to the safety requirements as laid down in Article 4 of this Regulation.

Article 26

Community Codes of good labelling practice

1. The Commission shall encourage the development of two Community Codes of good labelling practice (hereinafter ‘Codes’), one for pet food and one for feed for food producing animals. They shall refer to the scope for voluntary labelling provided for in Article 22 and support to improve the appropriateness of the labelling.
2. The procedure laid down in Article 27 shall apply for the establishment and for any amendment to be made to the Codes.

Article 27
Establishment of the Catalogue and Codes

1. Where the Catalogue and Codes are created, they shall be, as appropriate, developed and amended by all appropriate representatives of European feed business sectors:
 - (a) in consultation with other concerned parties, such as feed users;
 - (b) in collaboration with the competent authorities of the Member States and, where appropriate, the Authority;
 - (c) taking into account relevant experiences from opinions issued by the Authority and developments in scientific or technical knowledge.
2. The Commission shall approve the Catalogue, draft Codes and draft amendments thereto in accordance with the procedure referred to in Article 29(2) provided that the following conditions are met:
 - (a) they have been developed in accordance with paragraph 1;
 - (b) their contents are practicable throughout the Community for the sectors to which they refer; and
 - (c) are suitable to meet the respective objectives.
3. The Commission shall publish the titles and references of the Catalogue and Codes in the C Series of the Official Journal of the European Union.

Chapter 6
General and final provisions

Article 28
Amendments to Annexes and implementing measures

1. The Commission may amend Annexes I to VI in order to adapt them in the light of scientific and technical development.

Those measures designed to amend non-essential elements of this Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(4).
2. Implementing measures necessary for the application of this Regulation may be adopted in accordance with the procedure referred to in Article 29(3).

Article 29
Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002, hereinafter referred to as the ‘Committee’.
2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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

4. Where reference is made to this paragraph, Article 5a (1) to (4), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 30
Amendment to Regulation (EC) No 1831/2003

Article 16 of Regulation (EC) No 1831/2003 is amended as follows:

- (1) Paragraph 1 is amended as follows:

- (a) Point (d) is replaced by the following:

‘(d) where appropriate, the approval number of the establishment manufacturing or placing on the market the feed additive or the premixture pursuant to Article 10 of Regulation (EC) No 1831/2003 of the European Parliament and of the Council*;

* OJ L 35, 8.2.2005, p. 1.’;

- (b) The following subparagraph is added:

‘In the case of premixtures, points (b), (d), (e) and (g) shall not apply to the incorporated feed additives.’

- (2) Paragraph 3 is replaced by the following:

- ‘3. In addition to the information specified in paragraph 1, the packaging or container of a feed additive belonging to a functional group specified in Annex III or of a premixture containing an additive belonging to a functional group specified in Annex III must bear the information, presented in a conspicuous, clearly legible and indelible manner, indicated in that Annex.’

(3) Paragraph 4 is replaced by the following:

- ‘4. In the case of premixtures, the word ‘Premixture’ shall appear in capital letters on the label and carriers shall be declared, in the case of feed materials, in compliance with Article 17(1)(e) of Regulation (EC) No .../... of the European Parliament and of the Council [on the placing on the market and use of feed]*.

* OJ L ... ’.

Article 31

Repeal

Directives 79/373/EEC, 80/511/EEC, 82/471/EEC, 93/74/EEC, 93/113/EC and 96/25/EC are repealed.

References to the repealed Directives shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex VII.

Article 32

Penalties

Member States shall lay down the rules on financial penalties applicable to infringements of the provision of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.

The Member States shall notify those provisions to the Commission by [date of application] at the latest and shall notify it without delay of any subsequent amendment affecting them.

Article 33

Transitional measures

Transitional measures shall be adopted in accordance with the procedure referred to in Article 29(3).

Article 34

Entry into force

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

It shall apply from twelve months after the date of its publication.

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

TECHNICAL PROVISIONS ON IMPURITIES, MILK REPLACER, FEED MATERIALS FOR BINDING OR DENATURISING, THE ASH LEVEL AND MOISTURE CONTENT REFERRED TO IN ARTICLES 4

1. Feed materials must, as according to the good manufacturing practices as laid down in Regulation (EC) No 1831/2003 be free from chemical impurities resulting from their manufacturing process and from processing aids, unless a specific maximum content is fixed in the Catalogue referred to in Article 25.
2. The botanical purity of feed materials shall not be less than 95 %, unless a different level has been laid down in the Catalogue as referred to in Article 25. Botanical impurities comprise impurities of plant materials without adverse effects on the animals e.g. straw and seeds of other cultivated species or weeds. Botanical impurities such as residues of other oil seeds or oil fruits derived from a previous manufacturing process, shall not exceed 0,5 % for each type of oil seed or fruit.
3. The iron level in milk replacer feed for calves of a live weight less than or equal to 70 kilograms must be at least 30 milligrams per kilogram of the complete feed at a moisture content of 12 %.
4. Where feed materials are used to denature or bind other feed materials, the product may still be considered to be a feed material. Name, nature and quantity of the feed material used to bind or denature must be labelled. If a feed material is bound by another feed material the percentage of the latter shall not exceed 3 % of the total weight.
5. The level of ash insoluble in hydrochloric acid shall not exceed 2,2 % of the dry matter. However, the 2,2 % level may be exceeded, in the case of
 - feed materials;
 - compound feed containing authorized mineral binding agents;
 - mineral compound feed;
 - compound feed containing more than 50 % of rice or sugar beet by-products;
 - compound feed intended for farmed fish with a fish meal content of over 15 %, provided that the level is declared on the label.

6. Provided that no other level is laid in the Annex III or the Catalogue referred in Article 25 the moisture content of the feed must be stated if it exceeds:
- 5 % in the case of mineral feed containing no organic substances;
 - 7 % in the case of milk replacer feeds and other compound feed with a milk-product content exceeding 40 %;
 - 10 % in the case of mineral feed containing organic substances;
 - 14 % in the case of other feed.

ANNEX II

GENERAL PROVISIONS ON LABELLING REFERRED TO IN ARTICLE 11(4)

1. Contents or levels indicated or to be declared relate to the weight of the feed, unless otherwise stated.
2. The list of additives shall be preceded by the heading ‘additives per kg’
3. The numeric indication of dates follows the order of day, month and year, unless otherwise stated on the labelling.
4. Synonymic expressions in certain languages;
 - (a) In German the designation “Futtermittel-Ausgangserzeugnis” may be replaced by “Einzelfuttermittel”, in Greek “πρώτη ύλη ζωοτροφών” may be replaced by “απλή ζωοτροφή” and in Italian “materie prime per alimenti degli animali” may be replaced by “mangime semplice”;
 - (b) In the designation of feed for pets the following expressions shall be allowed: in Dutch “samengesteld voeder”; in English ‘pet food’; in Hungarian “állateledel”; in Italian “alimento”; in Polish "karma"; in Slovenian " hrane za hišne živali; in Spanish “alimento”.
5. The instructions for proper use of complementary feed containing additives in excess of the maximum levels fixed for complete feed shall state the maximum quantity in grams or kilograms of complementary feed per animal per day.
6. Without affecting the analytical methods, the expression "crude protein" may be replaced by "protein", "crude oils and fats" may be replaced by “fat content” and "crude ash" may be replaced by “incinerated residue” or “inorganic matter”.

ANNEX III

TOLERANCES FOR THE COMPOSITIONAL LABELLING OF FEED MATERIALS AND COMPOUND FEED AS PROVIDED FOR IN ART 11(5)

1. The tolerances laid down in this Annex include technical and analytical deviations. Once analytical tolerances covering measurement uncertainties and procedural variations are fixed at Community level, the values set in paragraph 2 should be adapted accordingly in order to cover only the technical tolerances.
2. Where the composition of a feed material or compound feed is found to depart from the labelled composition in a manner such as to reduce its value, the following tolerances are permitted:
 - (a) for crude protein, sugars, starch and inulin;
 - 3 units for declared contents of 30 % or more,
 - 10 % of the declared content for declared contents of less than 30 % but not less than 10 %,
 - 1 unit for declared contents of less than 10 %;
 - (b) for crude fibre, crude oil and fats;
 - 2,2 units for declared contents of 15 % or more,
 - 15 % of the declared content for declared contents of less than 15 % but not less than 5 %,
 - 0,8 units for declared contents of less than 5 %;
 - (c) for moisture, crude ash, ash insoluble in hydrochloric acid and chlorides expressed as NaCl, total phosphorus, sodium, calcium carbonate, calcium, magnesium, acid index and matter insoluble in light petroleum:
 - 1,5 units for declared contents (values) of 15 % (15) or more, as appropriate,
 - 10 % of the declared content (value) for declared contents (values) of less than 15 % (15), but not less than 2 % (2), as appropriate,
 - 0,2 units for declared contents (values) of less than 2 % (2), as appropriate.
 - (d) For the energy value 5% and for the protein value 10 %;

(e) for feed additives²⁵;

- 10 % if the declared content is 1000 units and more;
- 100 units for declared contents of less than 1000 units but not less than 500 units;
- 20 % of the declared content of less than 500 units but not less than 1 unit;
- 0,2 units for declared contents of less than 1 unit but not less than 0,5 units;
- 40 % of the declared content of less than 0,5 units.

These tolerances shall apply also to the maximum levels of feed additives in compound feed.

3. As long as fixed maximum levels for feed additives are not exceeded, the depart from the declared content may go till three times the tolerance as laid down in paragraph 2.
4. For feed additives belonging to the group of micro-organisms the acceptable upper limit shall correspond to the fixed maximum level.

²⁵ 1 unit in this paragraph means 1 mg, 1.000 IU, 1×10^9 CFU or 100 enzyme activity units of the respective feed additive.

ANNEX IV

MANDATORY LABELLING PARTICULARS FOR FEED MATERIALS ACCORDING TO ARTICLE 16(1)

	Feed material consisting of	Compulsory declaration of
1.	Forages and roughage	<i>Crude protein, if > 10 %</i> <i>Crude fibre</i>
2.	Cereal grains	
3.	Products and by-products of cereal grains	Starch, if > 20 % Crude protein, if > 10 % Crude oils and fats, if > 5 % Crude fibre
4.	Oil seeds, oil fruits	
5.	Products and by-products of oil seeds, oil fruits	Crude protein, if > 10 % Crude oils and fats, if > 5 % Crude fibre
6.	Legume seeds	
7.	Products and by-products of legume seeds	Crude protein, if > 10 % Crude fibre
8.	Tubers, roots	
9.	Products and by-products of tubers and roots	Starch Crude fibre Ash insoluble in HCl, if > 3,5 %
10.	Products and by-products of the sugar beet processing industry	Crude fibre, if > 15 % Total sugar, calculated as sucrose Ash insoluble in HCl, if > 3,5 %
11.	Products and by-products of the sugar cane processing industry	Crude fibre, if > 15 % Total sugar calculated as sucrose
12.	Other seeds and fruits, their products and by-products	Crude protein Crude fibre Crude oils and fats, if > 10 %
13.	Other plants, their products and by-products	Crude protein, if > 10 % Crude fibre
14.	Milk products and by-products	Crude protein Moisture, if > 5 % Lactose, if > 10 %
15.	Land animal products and by-products	Crude protein, if > 10 % Crude oils and fats, if > 5 % Moisture, if > 8 %
16.	Fish, other marine animals, their products and by-products	Crude protein, if > 10 % Crude fat, if > 5 % Moisture, if > 8 %
17.	Minerals	<i>Calcium</i> <i>Sodium</i> <i>Phosphorus</i> <i>Other relevant minerals</i>
18.	Miscellaneous	Crude protein, if > 10 % Crude fibre Crude oils and fats, if > 10 % Starch, if > 30 % Total sugar, as sucrose, if > 10 % Ash insoluble in HCl, if > 3,5 %

ANNEX V

LABELLING PARTICULARS FOR FOOD PRODUCING ANIMALS

Chapter I: Feed additives as referred to in Articles 15(f) and 22(2)

1. The following additives shall be listed with their name, added amount, identification number and respective name of the functional group such as laid down in Annex I of Regulation (EC) No 1831/2003 or the category in case of ‘coccidiostats and histomonostats’:
 - (a) additives where a maximum content is set,
 - (b) additives belonging to the categories ‘zootechnical additives’ and ‘coccidiostats and histomonostats’,
 - (c) additives belonging to the functional group of ‘urea and its derivatives’ of the category ‘nutritional additives’ as laid down in Annex I of Regulation (EC) No 1831/2003.
2. Feed additives not mentioned in paragraph 1 may be voluntarily indicated in the same full form or partially.
3. The feed business operator placing the feed on the market shall disclose the names of the feed additives not mentioned in paragraph 1 to the customer on his request.
4. If a nutritional feed additive as referred to in Annex I of Regulation (EC) No 1831/2003 is labelled voluntarily its level of incorporation shall be indicated.
5. If an additive belongs to more than one of the functional groups, the group appropriate to its principal function in the case of the feed in question shall be indicated.

Chapter II: Analytical constituents as referred to in Articles 17(1)(f) and 22(2)

Feed	Analytical constituents and levels	Species or category of food producing animals	
		Compulsory declarations	Optional declarations
Complete feed	- Crude protein - Crude fibre - Crude oils and fats - Crude ash - Starch - Total sugar (as sucrose) - Total sugar with starch - Energy value* - Protein value* - Fibre fractions - Lysine - Methionine - Other amino acids - Vitamins - Trace elements - Calcium - Sodium - Phosphorus - Potassium - Magnesium	- All species - All species - All species - All species - Pigs and poultry - Pigs and poultry	- All species - All species - All species - All species - All species - Ruminants - Species other than pigs and poultry - Species other than pigs and poultry - All species - All species - All species - All species - All species - All species - All species - All species
Complementary feed – Mineral	- Crude protein - Crude fibre - Crude oils and fats - Crude ash - Starch - Total sugar (as sucrose) - Total sugar with starch - Energy value* - Protein value* - Fibre fractions - Lysine - Methionine - Other amino acids - Vitamins - Trace elements - Calcium - Sodium - Phosphorus - Potassium - Magnesium	- Pigs and poultry - Pigs and poultry - All species - All species - All species - All species - All species - All species - All species - All species - All species - Ruminants - Species other than pigs and poultry - Species other than pigs and poultry - All species - All species - All species - All species - All species - All species - Ruminants	- All species - All species - All species - All species - All species - All species - All species - All species - All species - Ruminants - Species other than pigs and poultry - Species other than pigs and poultry - All species - All species - All species - All species - Species other than ruminants

Complementary feed – Other	- Crude protein	All species	
	- Crude fibre	All species	
	- Crude oils and fats	All species	
	- Crude ash	All species	
	- Starch		All species
	- Total sugar (as sucrose)		All species
	- Total sugar with starch		All species
	- Energy value*		All species
	- Protein value*		All species
	- Fibre fractions		Ruminants
	- Lysine	Pigs and poultry	Species other than pigs and poultry
	- Methionine	Pigs and poultry	Species other than pigs and poultry
	- Other amino acids		All species
	- Vitamins		All species
	- Trace elements		All species
	- Calcium $\geq 5\%$	All species	
	- Sodium		All species
	- Phosphorus $\geq 2\%$	All species	
	- Potassium		All species
	- Magnesium	Ruminants	All species other than ruminants

* The value has to be declared according to the EC-method if available or to the respective official national method in the Member State where the feed is placed on the market if available.

ANNEX VI

LABELLING PARTICULARS FOR NON FOOD PRODUCING ANIMALS

Chapter I: Feed additives as referred to in Article 15(f) and 22(2)

1. The following additives shall be listed with their name and/or identification number, added amount and the respective name of the functional group such as laid down in Annex I of Regulation (EC) No 1831/2003 or the category in case of ‘coccidiostats and histomonostats’:
 - (a) additives where a maximum content is set,
 - (b) additives belonging to the categories ‘zootechnical additives’ and ‘coccidiostats and histomonostats’,
 - (c) additives belonging to the functional group of ‘urea and its derivatives’ of the category ‘nutritional additives’ as laid down in Annex I of Regulation (EC) No 1831/2003.
2. Feed additives not mentioned in paragraph 1 may be voluntarily indicated in the same full form or partially.
3. If a nutritional feed additive as referred to in Annex I of Regulation (EC) No 1831/2003 is labelled voluntarily its level of incorporation shall be indicated.
4. If an additive belongs to more than one of the functional groups, the group appropriate to its principal function in the case of the feed in question shall be indicated.

Chapter II: Analytical constituents as referred to in Articles 17(1)(f) and 22(2)

[illegible]

ANNEX VII

CORRELATION TABLE

Directive 79/373/EEC	Directive 96/25/EC	Other acts: Directives 80/511/EEC (1), 82/471/EEC (2), 93/74/EEC (3) or 93/113 EC (4)	This Regulation
-	-	-	Article 1
Article 1	Article 1	(2), (4): Article 1 (3): Article 4	Article 2
Article 2	Article 2	(2), (3): Article 2	Article 3
-	-	-	Article 4(1)
Article 3	Article 3	(3): Article 1(2)	Article 4(2)
	Article 4		Article 4(3)
-	-	-	Article 5(1)
Article 12		(3): Article 10(2)	Article 5(2)
Article 10a(3)	Article 11(b)	(2): Article 8	Article 6
-	-	-	Article 7
-	-	-	Article 8
		(3): Article 3	Article 9
		(3): Article 6	Article 10
Article 5e			Article 11(1)
Article 5(2)	Article 5(1)	(2): Article 5(2)	Article 11(2)
-	-	-	Article 11(3)
Article 5(6)	Articles 4 and 6(4)		Article 11(4)
Article 6	Article 4		Article 11(5)
Article 5(1)	Article 5(1)		Article 12
Article 5e	Article 5(2)	(3): Article 5(6)	Article 13
Article 5(1), Article 11	Article 5(1), Article 9		Article 14
Articles 5(1) and 5(5)(c)	Article 5(1)	(4): Article 7(1)E and Directive 70/524/EEC: Article 16	Article 15

	Article 5(1)(c), (d) and 7		Article 16
Articles 5(1), 5c and 5d			Article 17(1)
-	-	-	Article 17(2)
Article 5c(3)			Article 17(3)
		(3): Articles 5(1), (4), (7) and 6(a)	Article 18
-	-	-	Article 19
	Article 8		Article 20
	Article 6(1)(a)		Article 21(1)
Article 5(5)(d)			Article 21(2)
	Article 6(3)(a)		Article 21(3)
Article 5(5)(b)			Article 21(4)
Article 5(5)(a)			Article 21(5)
Article 5(2)	Article 5(3), 6(1)(b)		Article 21(6)
-	-	-	Article 21(7)
Article 14(c)			Article 21(8)
Article 5(3), 5c(4) and 5e	Article 5(2)		Article 22
Article 4(1)		(1): Article 1	Article 23
	Article 5(4)		Article 24
-	-	-	Article 25
-	-	-	Article 26
-	-	-	Article 27
Article 10	Article 11		Article 28
Article 13	Article 13	(2): Article 13 and 14 (3): Article 9	Article 29
-	-	-	Article 30
-	-	-	Article 31
-	-	-	Article 32
-	-	-	Article 33
-	-	-	Article 34

Annex Part A(2), (3), (4)	Annex Part A(II), (VI),		Annex I
Annex Part A(1) and Article 5(6),	Article 6(4)		Annex II
Annex Part A(5), (6)	Annex Part A(VII)		Annex III
	Annex Part C		Annex IV
Annex Part B			Annex V
Annex Part B			Annex VI