COMMISSION OF THE EUROPEAN COMMUNITIES



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# **REPORT FROM THE COMMISSION**

# ON THE FEASIBILITY OF A POSITIVE LIST OF FEED MATERIALS

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#### **REPORT FROM THE COMMISSION**

#### ON THE FEASIBILITY OF A POSITIVE LIST OF FEED MATERIALS

### **EXECUTIVE SUMMARY**

During the conciliation procedure concerning the adoption of Directive 2002/2/EC which changed the rules on the labelling of compound feedingstuffs, the Council and the Parliament agreed on a recital stating the following:

"On the basis of a feasibility study, the Commission will submit a report to the European Parliament and the Council by 31 December 2002, accompanied by an appropriate proposal for the establishment of a positive list, taking into account the conclusions of the report".

The Commission reacted to such a statement considering that it affects its right of initiative making a statement for the record of the conciliation committee. In the same statement the Commission also drew attention to the complexity of the establishment of such positive list.

The present report clarifies the concept of a positive list of feed materials: it is an exclusive list of materials that upon assessment are considered safe for human and animal health and can therefore be used in animal feed. This means that only feed materials included on the list can be used by business operators.

It also analyses the implications of the adoption of such a list by the European Union, in relation to trade, labelling, national and regional diversity, and innovation on the feed sector and environment, in particular highlighting its implications for feed and food safety.

The report examines different ways to guarantee feed safety as, for example, lists of feed materials, legislation regarding manufacturing processes and codes of practice to be used by feed business operators.

Finally the report concludes that the establishment of a positive list is not decisive in ensuring feed safety. However the Commission recognises the interest of a list of feed materials for the purposes of trade, labelling, traceability and fraud prevention.

Therefore the conclusion of the report is that the establishment of a positive list does not contribute to feed safety and, in consequence, the Commission will not present a proposal in order to make such a list.

It considers that the improvement of the safety of feed requires measures:

- to lay down provisions for feed hygiene;
- to improve existing provisions for feed controls;
- to enlarge the scope of the legislation concerning the list of ingredients whose use is prohibited in feed;
- to extend the existing non-exclusive list of feed materials for labelling and traceability purposes; and

- to recast feed labelling provisions.

The Commission already presented a proposal on food and feed controls, a proposal on feed hygiene and will shortly present initiatives on the other issues.

# I. BACKGROUND

## Current and future legislative situation in respect of feed

- 1. Feed safety is guaranteed by a corpus of legislation that together forms a coherent set of rules. Detailed description of feed legislation is given in Annex I.
- 2. Regulation of the European Parliament and of the Council EC/178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>1</sup>, the "general food law", deals with general feed safety requirements, responsibilities of feed businesses operators, implementation of the rapid alert system for feed, traceability, reaction to crises and the role of science when ensuring food and feed safety.
- 3. Existing legislation on feedingstuffs provides for a comprehensive set of rules on different areas:
  - (a) <u>Circulation and use of feed materials</u> and compound feedingstuffs: feed materials and compound feedingstuffs may be put into circulation only if they are sound, genuine and of merchantable quality. They may not represent any danger to animal health, human health or to the environment and may not mislead the purchaser about the real identity of the feed. Some specific feed materials that need specific risk assessment requires approval before placing on the market e.g. protein form bacteria fermentation
  - (b) <u>Non-exhaustive list of feed materials</u>: there is a non-exhaustive list of the main feed materials used in the European Union. Each feed material is described and accompanied by a name and the level of certain constituents. Although the list contains the most common feed materials used, about 166, it is necessary to complete the list in order to improve traceability and to ensure informative labelling. Currently, Member States allow the circulation of other feed materials not listed provided that they are safe and do not mislead the user. This may cause discrepancies with the names and characteristics of some feed materials.
  - (c) <u>Negative list of feed materials</u>: Since 1991 there is a list of feed materials that cannot be used in compound feedingstuffs. Nevertheless, that prohibition was not applicable when those feed materials were used directly. The legal basis has been changed to extend the prohibition or restriction to the use of those feed materials directly and incorporated into compound feedingstuffs.
  - (d) <u>Positive list of additives</u>: rules for authorisation, use and marketing of feed additives are laid down in the legislation.

OJ L 31, 1.2.02. p. 1

- (e) Labelling and traceability: there are provisions for labelling feed materials and compound feed as well as additives. The rules have been changed recently to include on the label of a compound feedingstuff the list of feed materials with an indication of the percentages by weight with a tolerance of +/-15%. Traceability requirements are not developed for all types of feeds, only for certain categories the traceability of the manufacturing process was required before the adoption of the "general food law".
- (f) <u>Undesirable substances:</u> since 1974 there is legislation laying down maximum limits of undesirable substances in feeds. The incoming legislation will improve the current system: prohibits dilution of contaminated feed, establishes limits of undesirable substances in additives (before was only in feed materials and compound feedingstuffs) and introduces thresholds on the presence of undesirable substance that must trigger intervention by the competent authorities.
- (g) Controls: the principles governing the organisation of official inspections are established. The legislation was amended in 2001, notably to introduce legal basis for safeguard measures with respect to third countries and for on-the spot inspections by the Food and Veterinary Office inside and outside the Community.
- (h) Conditions for feed establishments and intermediaries: the production and use of some feeds requires registration by the competent authorities of the Member States and to comply with certain conditions. For other feeds deemed sensitive, the establishments require approval by the competent authorities subject to a mandatory on-the-spot verification and compliance with very strict conditions on facilities and equipment, personnel, quality control, storage, documentation, complaints and product recall. Nevertheless, no hygienic requirements are laid down.
- (i) <u>Safety of feed from animal origin</u>: a new Regulation has strengthened the safety requirements for animal by-products by defining the source material for animal by-products that can be used for feed, and then, only on condition that they meet safety requirements and are produced by establishments complying with specific conditions.
- 4. There have been substantial developments in the past decades in the production, marketing and control of feeds. Nevertheless, the Commission has identified some areas that are necessary to improve food safety, in particular, the following areas of existing legislation have to be brought up to date:
  - (a) *Feed hygiene*: A proposal for a Regulation laying down requirements for feed hygiene is a milestone to ensure food safety. This proposal will extend the registration by the competent authorities to all feed business operators and will establish the obligation for feed business operators, other than those operating at primary production, to comply with the Hazard Analysis and Critical Control Point (HACCP). The proposal encourages the development of national guides to good agricultural practices and for the application of a HACCP system and provides for the establishment of Community guides.

- (b) *Negative list of feed materials*: the negative list of feed materials needs to be completed by a comitology procedure in accordance with the new legal basis. This will allow banning or restricting the use of feed materials that may compromise food safety in an efficient way. The comitology procedure provides for flexibility and efficiency to be incorporated in the list feed materials that should not be authorised.
- (c) Labelling, *traceability and authorisation of feed materials*: recast legislation on feed materials and compound feedingstuffs with the objective to adapt approval procedures for certain categories of feed materials according to the new responsibilities of the European Food Safety Authority (EFSA) (e.g. bioproteins), to harmonise labelling requirements, to delete certain derogations to the labelling provisions, to introduce provisions for nutritional claims. Also foreseen is to extend the current non-exhaustive list of feed materials by comitology. These provisions will enable the users to have more accurate information on the label and will facilitate the traceability requirements laid down in the "general food law" and withdrawal of products that may have adverse effects on human health, animal health and the environment.
- (d) Controls: The Commission has adopted on February 2003 a proposal for a Regulation of the EP and of the Council on official feed and food controls that shall replace Directive 95/53/EC, fixing the principles governing the organisation of official inspections in the field of animal nutrition. This proposal is a comprehensive piece of legislation that recasts different control requirements, introduces a harmonised Community-wide approach to the design and development of national control systems and improves the efficiency of the control services of the Commission and of the Member States.

### The reason for this report

- 5. Directive 2002/2/EC changed the rules concerning the labelling of feed materials on compound feedingstuffs. In general terms, the listing of feed materials is now required with an indication, in descending order, of the percentages by weight. As regards these percentages, a tolerance of around 15% of the declared value is permitted.
- 6. During the conciliation procedure concerning the adoption of this Directive the Council and the Parliament agreed on a recital stating the following: "On the basis of a feasibility study, the Commission will submit a report to the European Parliament and the Council by 31 December 2002, accompanied by an appropriate proposal for the establishment of a positive list, taking into account the conclusions of the report".
- 7. In this context the Commission made the following statement for the record of the conciliation committee:

"The Commission declares that it cannot guarantee that it will be possible to respond to the request laid down in recital 10(a), which affects its right of initiative.

The Commission emphasises that establishing a positive list is a complex issue in which Member States and stakeholders are involved. For this reason, the Commission launched a feasibility study on the establishment of a positive list of feed materials. The Commission will send a report on the outcome of this study to the Council and the European Parliament before 31 December 2002. Taking the

outcome of this report into account, the Commission intends to make the appropriate proposals in due course"<sup>2</sup>.

## The concept of a positive list of feed materials

- 8. A positive list of feed materials is an exclusive list of materials that upon assessment are considered safe for human and animal health and can therefore be used in animal feed. This means that only feed materials included on the list can be used by feed business operators.
- 9. Prior to the European feed legislation, some Member States such as Germany, Denmark and Sweden had positive lists. Directive 96/25/EC prohibits more restrictive national measures. Recently, Germany has developed a list pursuing the objective that feed materials used in animal feed should be duly authorised. Nevertheless, the German list is applicable by operators only on a voluntary basis, since Community legislation does not allow for the implementation of real positive lists in Member States.
- 10. Lists of feed materials are also used in non-EC countries such as Switzerland, the United States (the AAFCO list <sup>3</sup>) and Canada. However, the only one that is positive (meaning exclusive and legally binding) is Switzerland's.
- 11. In the 1970s, the purpose of EC feed legislation within the framework of the Common Agricultural Policy was to guarantee transparency throughout the feed chain, while improving the quality of agricultural production, in particular livestock production. Council Directive 77/101/EEC of 23 November 1976, subsequently replaced by Directive 96/25/EC, recognised that Member States still had different traditions as regards regulating the marketing of raw materials and allowed them to provide for derogations in certain cases.
- 12. Directive 96/25/EC provided for a harmonised definition of feed materials: "various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic and inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding either directly as such, or after processing, in the preparation of compound feedingstuffs or as carriers of premixtures". The same Directive also clarified (recital 8) that the term "feedingstuffs" could be used in EC legislation as a general concept that includes raw materials and compound feedingstuffs.
- 13. In this report the term "feed material", as defined by Directive 96/25/EC, will be used. Additives used in feed fall therefore outside this definition and are not included in the discussions concerning the list of feed materials.

<sup>&</sup>lt;sup>2</sup> OJ C 27, 31.1.02, p. 2

The Association of American Feed Control Officials (AAFCO) list is incorporated into feed law in all States in the USA with the exception of Alaska. Although Canada, Puerto Rico and Costa Rica are members of AAFCO, their legal systems are different from those of the USA and they therefore may have their own official list.

### The feasibility study

14. On 7 June 2001, the Commission launched a general invitation to tender No 2001/S 107-072830 relating to an evaluation of the feasibility of a positive list of authorised feed materials at Community level. The intention was to evaluate that feasibility by describing different options to create and manage (including amend) the list, as well as the resources required for appropriate implementation. The advantages and disadvantages of the different options should also be included. The following information was requested:

Background: information on other positive lists of feed materials already in place, describing the responsible entities for those lists, principles, objectives, establishment and management procedures, etc.

Different options for preparing and establishing the list: principles, objectives, status, criteria, to amend the list, criteria for describing products on the list, level of detail, etc.

Management of the list (different options): maintenance, accessibility, mechanisms to amend the list, electronic support, etc.

Resources (different options): precise data on human, economic, and technical resources to maintain the list.

15. This feasibility study can be consulted on the web site of the Health and Consumer Protection Directorate General.

### The purpose of the present report

16. The present report fulfils the obligation of the Commission towards the Parliament and the Council referred to in Directive 2002/2/EC. Taking into account the feasibility study just mentioned, it expresses the Commission's views concerning the scope of an eventual positive list of feed materials, the implications of such a list for feed safety policy and for trade.

### II. REQUIREMENTS FOR A POSITIVE LIST

#### Preamble

17. This chapter aims at examining the requirements that a positive list might fulfil in order to become operational. Different parameters are under consideration: exclusivity, categories of feed materials, criteria for authorisation, labelling, nutritional characteristics, definition of the feeds, method of production and use of the list for non-food producing animals.

#### Exclusive list

18. An exclusive list must make reference to all products that are used within the Community as a feed material for animals, regardless of their scale of production or marketability. The positive list, if adopted, should apply in all Member States.

19. The scope and the level of detail of the positive list will depend on the objectives. If feed safety is the only objective, certain aspects need not be taken into account such as the need to apply the list to non-food-producing animals or the level of differentiation between different feed materials. If the purpose is also to facilitate trade, labelling will have to be taken into account. The implementation of Directive 2002/2/EC imposes the obligation to list all feed materials present in a compound feedingstuff by their specific names. The obligation to list feed materials on the label will also facilitate the implementation of the traceability requirements laid down in the General Food Law but, at the same time, will require a detailed harmonised list of feed materials.

### Categories of feed materials

- 20. In principle, the choice of categories has no safety implications: the basis for the choice of categories is to make the list as easy as possible to manage while minimising confusion to users, bearing in mind that the legal obligation to list feed materials on the labelling would require a high level of detail.
- 21. Directive 96/25/EC establishes 12 categories. Current lists of feed materials in Germany and Switzerland are based on the same basic structure as that of Directive 96/25/EC; both lists have 18 categories. The AAFCO (Association of American Feed Control Officials) list has 35 categories, but these include substances or microorganisms which in the EU are regarded as additives.
- 22. In establishing a framework for the list, it is essential that the general approach be practical and pragmatic rather than theoretical. The German and North American lists provide examples of a practical approach, offering room for flexibility in difficult areas of naming. The German list has what could be called "general purpose" categories, i.e. where feeds can be listed when they have a potentially similar safety status but would be unnecessarily complicated to describe. This approach is used for forages and also for feed materials originating from the manufacture of human food. In the German list, these are assumed to be safe unless other regulations apply.
- 23. Forages would increase the complexity of the list, although for feed safety purposes they may only need to be listed in broad categories. In most cases, these feeds in themselves present little or no risk to feed and food safety although inappropriate handling, storage or preservation can compromise their safety. The list would therefore need to reflect this. The presence of noxious weeds in forages and undesirable substances resulting from processing would be regulated by legislation on undesirable substances. It is noticeable that the Canadian list does not include fresh or ensiled forages, although it details a number of dry forage and roughage feeds. This reflects the importance of the list for traded products.
- 24. With a few exceptions, the current list established by Directive 96/25/EC does not include moist and liquid feed materials. Those products are normally by-products (or co-products) of food and drink processing industries, which are used as animal feed and have a long history of safe use.
- 25. Feedingstuffs of animal origin are regulated by two sets of specific legislation: general legislation on feedingstuffs on the one hand, and veterinary legislation on the other. To prevent divergences between feedingstuffs legislation and veterinary

legislation it is necessary to establish a specific category for these products with a flexible mechanism to update the list in accordance with the relevant provisions in veterinary legislation.

### Criteria for authorisation.

- 26. In order to comply with EC legislation, a feed which is to be included on the list should meet the following criteria:
  - it does not have adverse effects on human health, animal health and the environment.
  - it does not mislead the user;
  - it does not harm the consumer by impairing the distinctive features of the animal products;
  - its normal consumption would not be nutritionally disadvantageous for animals.
- 27. In addition to these basic requirements, the nature of the feed material should be known with sufficient precision to ensure that it can be properly identified and that its nature will be consistent over time.
- 28. In approving feed materials for inclusion on the list, primary consideration should be given to the feed's safety rather than to its nutritional value, since this may not be the rationale for giving certain feeds to animals. For example, products may have beneficial properties, such as to provide bulk, which are not strictly nutritional. However, that scientific risk assessment alone may not be the only or the most appropriate basis on which to approve feed materials in all cases. Other factors such as societal, economic and animal welfare concerns may legitimately be taken into consideration on a case-by-case basis.

### Labelling

- 29. Directive 2002/2/EC amending Council Directive 79/373/EEC on the circulation of compound feedingstuffs establishes that, as from 6 November 2003, all feed materials used in a compound feedingstuff for food-producing animals should be listed by their specific name and in descending order of the percentages by weight present in the compound feedingstuff. As regards the percentages, a tolerance of +/-15% of the declared value is permitted. For non-food-producing animals it is possible to replace the specific name of the feed material by the name of the category to which the feed material belongs.
- 30. The labelling of the feed requires certain standardisation of the feed names in order not to give misleading information to the user. The feed name should be the common name to be used on labels, accompanying documents and other documentation.
- 31. It is argued that if feed safety were the only objective, there would be no need to differentiate between many different feed materials. For example, whole potatoes, liquid potato products, mixtures of mashed potato and peelings, potato pieces and potato peelings could all be given a generic name (e.g. 'potatoes and potato by-products'). This is not completely true in all cases: animals consume plants and plant parts where the concentration of toxins and undesirable substances may be different

and differentiation is therefore necessary in those products. The feed safety approach would not reflect the innovation and developments in processing in many of these industries and would not be suitable for trade and labelling purposes. Nor would it allow potential purchasers to differentiate between feed materials derived from the same manufacturing process but having different composition and nutritional value. For example, it is important to differentiate between grape pulp and grape pips, maize gluten feed and maize gluten meal, potato peelings and peeled potatoes. In practice, it is useful for labelling purposes that the main feed materials be specified individually, although there is likely to be a need for a 'miscellaneous' or 'other products' category to accommodate a few minor feeds. This would permit flexibility where new or different by-products became available. They may not remain in the 'other' category for long, but this could be the 'entry level' prior to separate listing.

32. A number of similar or identical feed materials are labelled and traded under different names within the Community, while in some instances the same name may be used for different feed materials. Failure to recognise this would lead to discrimination against certain feed materials that may have a long history of safe use, and result in distortion of trade. Local names should also be considered where these differ from the generally accepted names, provided that in all other respects the feed materials are similar. This will be a major challenge and the problems of achieving this should not be underestimated.

#### Nutritional characteristics

33. Current feed lists include references to certain nutritional characteristics, e.g. in Directive 96/25/EC there is the following specification for soya(bean) dehulled, extracted and toasted: "maximum crude fibre 8%". The AAFCO and the Swiss lists are much more detailed than Directive 96/25/EC and contain nutritional specifications which are necessary for trade and labelling purposes and to protect against fraud, but not for safety purposes. These are primarily intended to differentiate one feed from another, both as an aid to purchasers and to prevent fraud. Lists of feed materials which include considerably more detail on nutritional characteristics have been developed and are in use in a number of Member States. These, however, are primarily used for feed formulation purposes. There is no justification to include references to specific nutritional characteristics unless it is clearly necessary to differentiate one feed material from another or is justified for safety purposes.

#### Definition of the feed and method of production

- 34. The feed definition must describe unambiguously the biological nature (species or chemical formula, plant or animal part used) and the process to which the feed material has been subjected. In order not to prejudice free movement and use of feed materials the definition must reflect the wide variety of processes and terminology employed throughout the EU.
- 35. In order to achieve a comprehensive list of definitions, it is necessary to examine both the range of feed materials available and the processes to which they are exposed. The AAFCO list contains over 250 different terms and associate definitions relating to feed materials (e.g. grain, bran, etc.), and processes (e.g. extruded, dry-milled, etc.). In contrast, Directive 96/25/EC lists only 17 definitions.

36. The safety of a feed material may be influenced as much by the processing to which it is exposed as the nature and quality of the original material. The entry of a feed onto a positive list should therefore be accompanied by a description of the process applied. At first sight some of these processes appear to be relatively standard, e.g. "dried", but even this is not a standard process and changes in the amount and duration of heat applied can significantly affect the quality and safety of a feed. This is clearly a complex issue where a safety-oriented classification is required. The effect of processing on the safety of a particular feed should be an underlying principle in determining the degree of detail required. Nevertheless, it should be noted that in general feed scares are linked to manufacturing practices that have been incorrectly implemented. These problems may be overcome by the strict enforcement of HACCP (Hazard Analysis and Critical Control Point) principles and Good Manufacturing Practices.

### Non-food-producing animals

- 37. Currently, Directive 96/25/EC and other Community legislation in the field of animal nutrition do not make a distinction between feed intended for non-food-producing animals and feed intended for food-producing animals. Nevertheless, there are some specific rules for feeds intended for non-food-producing animals, such as specific provisions for labelling and presentation or authorisation of feeds intended to satisfy certain particular nutritional purposes for pets. It should be noted that veterinary legislation allows the use of certain feed materials of animal origin, which are forbidden for food-producing animals, to feed non-food-producing animals.
- 38. In addition to this, manufacturers of petfoods use a number of feed materials that are not used by other feed manufacturers or by livestock farmers. These include slaughterhouse by-products and a wide range of speciality feed materials, including nuts, insects, crustacean shells, plankton (fresh or dried) etc. Many of these have a long history of use.
- 39. Pet food manufacturers have pointed out that since pet foods do not form part of the human food chain, they pose no risk to the safety of food for human consumption. It was therefore questionable whether they should be part of a positive list established for food safety purposes. This approach appears to have been adopted in the development of the German and Swiss lists; in contrast, the AAFCO list does contain descriptions of feeds approved in some cases exclusively so for the manufacture of pet foods.

# III. ESTABLISHMENT AND MAINTENANCE OF A POSITIVE LIST

### Establishment of an initial list

- 40. The establishement of the initial positive list would imply the following steps:
  - The process of compiling a list is highly technical and would best be achieved by experts in different areas of animal nutrition and from different countries.
  - It would require safety assessment by a competent body (EFSA).

- It would require a decision legally binding on all feed-business operators. The decision on the positive list should take into consideration not only risk assessment but also other legitimate factors.
- 41. The current Community legislation on feed materials does not allow for the establishment of a positive list. The adoption of a legal basis for positive list would therefore require a Regulation/Directive of the European Parliament and of the Council to be adopted by co-decision procedure.

# Maintenance of the positive list

- 42. It is clear that a list of feed materials cannot be a static document. A flexible mechanism should be established for approving and withdrawing feed materials from the list.
- 43. In Switzerland, there are about 20 applications per year to have new feeds approved and included on the official list, which already contains more than 300 feeds. About half the requests are rejected, usually on the basis of lack of information or the general unsuitability of the proposed feed material. While it is difficult to extrapolate these figures to the whole of the EU, it may be reasonable to assume that at EU level there would be significantly more applications each year. Countries such as France, Spain, Italy, the Netherlands, Germany and the UK have highly innovative feed industries, on a much larger scale than Switzerland.
- 44. A long lead-time to include a feed material in the list would be a disincentive to use many feed materials and would have consequent adverse effects on livestock production, trade and the environment. In the USA, it takes a minimum of about 12 months for a feed to be classified as GRAS<sup>4</sup>, although it can be longer in some instances.
- 45. The information submitted by the applicant for approval needs to be proportionate to the risk. A degree of flexibility may be appropriate for the majority of feed materials, while others may require more detailed information. Directive 82/471/EEC<sup>5</sup> provides for a special system of authorisation for certain sources of proteins that are produced using certain technologies.
- 46. Existing systems such as those in Switzerland and USA implement a tentative provisional list. For feed materials with a low risk and where there is a high probability of them being approved and accepted provisionally, this facility allows them to be used and marketed before full approval is granted. The decision on whether or not an application follows this 'fast-track' approach is based on an initial assessment of the risk that the new feed material is likely to pose to animals or consumers of animal products. Taking into account the experience with Directive 70/524/EEC, the provisional authorisation of feed materials may be problematic in the long term if the final assessment results in withdrawal from the list.
- 47. Reference has been made to the use of feed materials within the EU that are frequently only available in small quantities, on an irregular basis, and which are only used locally. Seeking approval for these feed materials may be disproportionate

<sup>&</sup>lt;sup>4</sup> Generally Recognised As Safe

<sup>&</sup>lt;sup>5</sup> OJ L 213, 21.7.1982, p 15.

to their use, with potentially adverse effects on livestock systems and the environment. One approach would be to adopt the principle of subsidiarity with respect to feed materials that are available and used only within a region or an individual Member State. Any local approval procedure would need to adopt the same principles relating to safety, labelling etc. as would apply at EU level. If the particular feed material were to be traded or used outside the local region or Member State for which approval had been granted, then full EU approval would be required, as described above. This approach has been adopted in the USA, where the AAFCO list is used for regulatory purposes and trade across all States, but where individual States may approve additional feeds that are produced and used exclusively within that State.

#### IV. IMPLICATIONS OF A POSITIVE LIST

#### Status of the existing lists

- 48. Prior to the European feed legislation some Member States developed positive lists. Nevertheless, those lists cannot satisfy the current necessities of the feed sector, taking into account that innovation in the feed industry has incorporated a lot of new feeds to improve feed efficiency and to reduce cost. Those lists were applicable in one Member State with limited production systems and weather conditions that cannot represent the wide variety of production in the European Union.
- 49. The lists used in other non-EU countries such as the USA are not really legally binding lists. The same applies for the current German list. For this reason, it is difficult to extrapolate the consequences for the implementation of a positive list at EU level. An example of a real positive list is Switzerland.
- 50. The Swiss list contains more than 300 feed materials while, for example, an expert group, created to prepare Directive 96/25/EC, identified at that moment 620 feed materials. The production in this country is mainly orientated to dairy products, beef and pork meat. For other productions such as poultry meat and eggs the production is very low and they need to import from other countries. Those examples show that the implementation of a positive list in the EU is on a different scale of magnitude and complexity.
- 51. The Swiss positive list did not prevent a big incidence of BSE in that country. It is impossible to include in a positive list thousands of different products that are produced in different sites with different technologies and that may have different safety status and nutritional and technical characteristics. For these reasons, the positive list is simplified and products are grouped in accordance with a potential similar safety status. This simplification cannot ensure food safety in all the cases. Similarly, the question is that for a product listed it should be produced in accordance with adequate hygienic conditions. The implementation of the rapid alarm system and the recent feed scandals have showed that the origin of the problem in the majority of the cases was not the feed material *per se* but the contamination during the production, storage and transport with substances that are not allowed in animal nutrition. For example, the contamination of glucose syrup with hormones (medroxy progesterone acetate) is a problem of residues of prohibited substances in a feed material. Glucose syrup is per se a safe feed material that was contaminated by a substance which is not authorised in feed.

### Traceabilty and labelling.

- 52. According to the principles of the General Food Law laid down in Regulation EC/178/2002, traceability of feed must be established at all stages of production, processing and distribution. Feed business operators must be able to identify any person from whom they have been supplied with a feed and the businesses to which their products have been supplied. The General Food Law also recognises the link between labelling and traceability by saying that feed must be adequately identified or labelled to facilitate its traceability. These provisions will become applicable in January 2005.
- 53. Within the current legislative framework, Directive 95/69/EC includes requirements relating to traceability of the manufacturing process for certain establishments using or producing certain feed materials and additives. Directive 2002/2/EC, amending Council Directive 79/373/EEC on the circulation of compound feedingstuffs has introduced the obligation to include the batch number on the label, the packaging, the container or in an accompanying document (in bulk products) of compound feedingstuffs. Directive 96/25/EC does not provide for similar provision for feed materials; the batch number is required only for certain categories of feed materials. In addition to this some operators are exempted from certain labelling provisions.
- 54. Therefore, traceability systems need to be able to link a unique batch of feed with information about when and where it was produced, and the source of feed materials used, throughout the food chain. Clearly, traceability systems have the potential to be very effective in enhancing feed and food safety. An effective and comprehensive list of feed materials (not specifically a positive list in the meaning of this report) may facilitate this process, since it would allow precise feed names and descriptions to be used throughout the chain and would apply to a much larger number of feeds than those in the current list. Even those opposed to the establishment of a positive list indicated that they would welcome the development of a comprehensive list for labelling purposes.

# *Implications for trade – overview of the feed sector*

- 55. The value of livestock production (amounting to 108 369 million €) accounts for 41% of the overall EU-15 agricultural output, which amounted to 267 019 million € in 1999<sup>6</sup>
- 56. EU feed consumption in 2001 was approximately 394 million t. Half was forage and roughage produced on-farm, 10% were grains produced on-farm that may be potentially traded, 10% purchased feed materials and 30% industrial compound feed. See figure 1 of the Annex.
- 57. The level of commercially traded feed (Figure 2 of the Annex) remained stable in recent years at around 200 million t (this quantity includes all feed except forage on-farm).
- 58. Industrial compound feed production by species of animal shows that the majority of production is intended for pigs, followed by poultry. From 1996 the BSE crisis resulted in a reduction in cattle feed that has been offset by a parallel increase in feed

<sup>&</sup>lt;sup>6</sup> Source Eurostat

for pork and poultry meat production as a result of the increase of consumer demand for that type of meat.

- 59. Feed materials and compound feed are the main input into livestock production. In 1999 there were 3 794 enterprises manufacturing feedingstuffs, with a production value of 30 248 million €. These figures exclude the production value at farm level or the production of other feed ingredients such as additives. See Table 1 of the Annex.
- 60. The EU is the biggest world importer of feed. The most representative products imported during the period 1990-2000 are soybean meal, oilseed, corn gluten feed (CGF), manioc, molasses, cereals and citrus pulp. See table 2 of the Annex.
- 61. The 1990s introduced important changes in the EU agricultural policy that has affected world trade. Lower cereal support prices and the increasing value of the dollar have closed the gap between EU and world prices. Prices on the EU market of certain products such as CGF and manioc have followed cereal prices and the use of these products as substitutes for grains fell. EU cattle production (except dairy cows, which also consume significant quantities of concentrate) is based largely on pastures. During recent years the trend in European agriculture has led to a shift in production from animals consuming grass to animals consuming concentrate (pigs and poultry). In the 1990s there was an increase in soybean meals and a shift away from CGF and manioc in the feed rations. The increased use of feeds during the 1990s was not accompanied by a rise in EU imports: in 1998-2000 they were only 2% greater than in the EU-12 in 1990-1992.
- 62. The increase in feed use required significantly greater imports of protein feeds (soya meal). Soybean imports rose from 39% of total imports to 50%. The increase in protein feeds was offset by a significant reduction in imports of CGF and manioc.
- 63. The disruptions caused by epidemic diseases and other feed scandals make all forecasts difficult. Nevertheless, it is reasonable to expect that lower grain prices and lower poultry and pork meat prices would lead to a period of growth in consumption of such meat. With the accession of eastern countries, grains, sunflower seed and rapeseed may become available at relatively cheap prices.
- 64. The forecasts for beef consumption are slightly below to those of 1995 but this does not seem to affect pork and poultry meat consumption. Although forecasts are difficult, the trend for the next decade indicates an increase in imports of soybean meal, while CGF and manioc may decline.
- 65. The adoption of an exclusive list would, by definition, prevent the importation or use of any feed materials into the EU until such time as their safety had been determined and they had been entered in the positive list. As seen in the previous paragraphs, this is not going to pose major problems as the majority of imports are materials traditionally used in the EU. However, certain feed materials are imported which, although they represent a relatively small proportion of the total feeds used in the EU, are very important both for niche markets in the Community and for manufacturers in third countries.
- 66. The importation from third countries of compound feeds and feed mixtures containing feed materials that are not on an EU positive list would be prohibited. In

particular, this would apply to a number of pet foods that are manufactured in third countries from feed materials that are not available in the EU.

- 67. The recent BSE scare in the beef sector resulted in a shift in demand towards other kinds of meats. Poultry production increased by around 3.7% in 2001 and was accompanied by an increase in poultry imports (407 000 t between 1999 and 2001 from Brazil and Thailand). It is assumed that poultry imports will continue to increase and the EU may become a net importer of poultry meat. The medium and long-term outlook for pork meat consumption is in general positive. Imports of pork meat are expected to increase over the medium term.
- 68. In conclusion, over the coming years the expected increase in pork and poultry production will depend on an increase in the use of feed materials produced in Europe (cereals), and an increase in soybean imports, but not on an increase in imports of manioc and corn gluten feed. In order to be competitive with the production of animal products on the world market, the European feed industry will continue to search for and use new sources of feed materials.

# Regional and national implications

- 69. Exclusive positive lists have been produced at national level (Swiss list and lists of some Member States applied prior to the implementation of EU legislation), frequently involving one or few languages. The number of feed materials involved, and the processes to which they have been exposed, has been relatively small. The AAFCO list of the USA (which is not an exclusive list) is more complex, and includes a very extensive list of feed materials<sup>7</sup>. These lists are generally effective and well received by the feed and farming industry. However, they are mainly based on a single language and require human resources to manage them.
- 70. A positive list at Community level would need to accommodate all regional and local feed manufacturing practices.
- 71. Standardisation of the feed names would be essential. However a number of similar or identical feed materials are traded under different names, while in some cases the same name may be used for different feed materials. Local names may differ from the generally accepted name.
- 72. There are also feed materials within the EU that are frequently only available in small quantities, on an irregular basis, and which are only used locally. Different approaches to address this issue should be also taken into consideration.

# Implications for a feed safety policy

- 73. Table 3 of the Annex lists the notifications which have been issued since the implementation of the Rapid Alert System for Food and Feed in February 2002:
- 74. From the analysis of recent alerts in the feed sector, it can be concluded that the majority concern the use of forbidden substances such as chloramphenicol or undesirable substances whose use is restricted in accordance to Directive 1999/29/EC. There have been a large number of notifications relating to the presence

7

The annual publication runs to some 450 pages

of chloramphenicol in skimmed milk powder. Skimmed milk powder is an authorised feed material that is included on the non-exclusive list of the main feed materials (Council Directive 96/25/EC). Chloramphenicol is included in Annex IV to Council Regulation (EC) 2377/90<sup>8</sup>, so the administration of this substance to food-producing animals is prohibited throughout the Community. A recent case in Germany of contamination of bakery products (those products were included in the current list agreed by the German operators) with dioxins is another example that the adoption of a list of feed materials is not the solution for all the incidents.

- 75. As to the BSE crisis, the positive list established in Switzerland since 1975 has not prevented a significant incidence of BSE in that country. In 2001, the Court of Auditors in its Special report No. 14/2001<sup>9</sup> has included certain recommendations to prevent the incidence of BSE. Those recommendations do not contemplate the need to develop a positive list of feed materials. It should be noted that the report concludes that the second BSE crisis has to be seen in the context of Member States' poor implementation of existing EU legislation, poor surveillance (control) and poor implementation of the mammalian meat and bone meal (MBM) feed ban. The report indicates that the institutional legislative process has also caused long delays in the implementation of BSE measures.
- 76. There has been a comprehensive body of legislation in the feed sector to avoid feed crises. In many cases, if rigorously implemented, it is sufficient to protect against the risks associated with feed. Nevertheless, the Commission has recognised the need to improve existing feed legislation and has developed many initiatives (see paragraph 13) to that end.
- 77. In conclusion, recent crises were caused by the presence of contaminants, illegal use of drugs or additives or fraudelent use of forbidden feed materials. Consequently, the existence of a positive list would not have prevented the incidents referred to in table 3.

# Implications for innovation

- 78. Each authorisation for inclusion on the positive list should be preceded by an assessment based on a dossier. This leads to the conclusion that the positive list might well hamper innovation in the use of new substances or products in the feed sector.
- 79. In the USA, it takes a minimum of about 12 months for a feed to be classified as "GRAS". This is likely to be the minimum amount of time for any approval process linked to the EC regulatory mechanism.
- 80. A degree of flexibility may be appropriate, with individual feeds dealt on a case-bycase basis. In the case of feed materials, a certain amount of basic information would be required for the authorisation. Additional information would be necessary depending on the potential risk associated to the use of the feed.

<sup>&</sup>lt;sup>8</sup> OJ L 224, 18.8.1990, p. 1.

<sup>&</sup>lt;sup>9</sup> OJ C 324, 20.11.2001, p.1

81. The financial margins on many feeds, in particular livestock feeds, are minimal and may not support the cost of gaining approval. Many feed materials are generic by nature so that companies would be reluctant to pay the cost of the approval.

### Implications for the environment

82. The exclusion of a feed material from the positive list will increase the pressure for the disposal of those materials.

# V. ALTERNATIVE OPTIONS TO GUARANTEE FEED SAFETY

# Lists of feed materials

83. The purpose of the legislative measures to be taken is to guarantee feed safety. The Commission considers that the introduction of a positive list of feed materials would not in itself achieve that aim. Reference has been made to a number of recent feed safety incidents that have occurred since the entry into force of RASFF that would not have been prevented by the existence of a positive list. The Commission considers that the proposal to establish a positive list as an answer to feed safety is a political answer rather than a technical one. Therefore, with regard to the substances that may and may not be used in animal nutrition, the management of the existing lists of prohibited substances can achieve the objective of ensuring feed safety.

# Actions dealing with manufacturing processes

- 84. The field of animal feeding is already subject to a large and complex corpus of EU and national regulations. However it must be borne in mind that there are no rules applicable to feed hygiene, apart from the general rules of Regulation EC/178/2002 (Food Law) and specific rules applicable to operators dealing with particular categories of additives or feed materials (Directive 95/69/EC).
- 85. The Commission considers that the top priority is to fill this gap, in order to guarantee the safety of manufacturing processes and hence the safety of the feed.

# The Codex Alimentarius approach

- 86. The Codex Alimentarius is a joint FAO/WHO Food Standards programme whose main purpose is to protect the health of consumers and ensure fair practices in the food trade. In 2000, the Codex Alimentarius Commission established a Task Force on Animal Feeding to complete the work (begun in March 1999 by an FAO consultation) on drafting the Code of Practice on Good Animal Feeding. The Task Force was given four years to complete this work.
- 87. The draft proposals contain recommendations on feed materials, labelling, traceability, inspection and procedures (including sampling and analytical procedures), industrial production of animal feeds and on-farm production of feed materials. One component of the control procedure is HACCP analysis as described by FAO/WHO<sup>10</sup>. HACCP is a production control system that identifies where

<sup>&</sup>lt;sup>10</sup> FAO/WHO. 1997. Report of the 30th session of the Codex Committee on Food Hygiene, Appendix IV. ALINORM 99/13. Rome.

hazards might occur in a food production process and identifies actions that prevent the hazards from occurring. By strictly monitoring and controlling each step of the process, there is less chance for hazards to occur. It therefore has considerable potential to contribute to the safe manufacture of feed materials. The Commission considers it necessary to follow such an approach in EU feed legislation.

88. During the second session of the *ad hoc* Intergovernmental Codex Task Force on Animal Feeding (March 2001) an open-ended meeting was organised to discuss, amongst other things, the positive/negative lists. The meeting recognised the arguments in favour and against each of the two approaches. The meeting acknowledged that there were time constraints on compiling any such listing which would need to be dynamically maintained within the discussion on the draft code given the four year duration, therefore, the group did not recommend the establishment of a positive list.

#### Codes of practice

- 89. A number of Member States already have, or are in the process of developing, farm assurance schemes and codes of practice for the handling and manufacture of feed materials and compound feeds and for the storage and transport of feeds. Many of these codes are based on risk assessment and HACCP analysis and are increasingly being demanded by retailers and consumers of milk, meat and eggs and derived products.
- 90. The Commission considers that the adoption of codes of practice and quality assurance schemes would be more effective than the introduction of a positive list in ensuring safe feed. These codes and assurance schemes are defined and maintained by the operators in response to market demands. They are effective because they apply to the whole production process and provide a means of traceability in the event of any breakdown in feed safety.
- 91. However, before these codes can be fully effective within the EU, national schemes need to have a legal existence, be rationalised at EU level, and be adopted by all producers and manufacturers of raw materials. Future EU legislation must provide the legal base for this purpose. The concept of codes of good manufacturing practices is already included in the proposals on food and feed hygiene.
- 92. The EU framework for these codes must take into account that farmers or small producers should not have to bear substantial costs if they are compelled to adopt the codes. However, where a risk exists there should be effective regulation, and the HACCP approach provides a means of addressing this. Rather, the extent to which the HACCP approach is applied should be commensurate with the degree of risk associated with the production process. Undoubtedly, codes of practice and farm assurance schemes are making a major contribution towards ensuring feed safety. They provide a framework for minimising the risk of unsafe feed reaching the consumer and raise awareness throughout the feed production chain of the major issues that can affect feed quality. Where effective, they can provide consumers with assurance of the quality of livestock foods and of their methods of production.

The Commission considers that taking into account the need for such codes in future legislative proposals will address the possibility that the absence of EU-wide

schemes is creating 'uneven playing fields' with respect to products produced in other Member States.

# VI. POLICY ORIENTATION

### Rationale

- 93. Current legislation already ensures a high level of safety throughout the feed chain. The Commission nevertheless considers that recent feed safety incidents have shown the need to improve the legislation, with the overall objective of improving food safety.
- 94. Recent food and feed safety crises have highlighted deficiencies in national systems of control and poor implementation of Community legislation by Member States. The Commission will adopt a proposal to harmonise and improve national controls and consequently raise safety standards in the European Union.
- 95. Other horizontal measures already included in the General Food Law will certainly contribute to detecting and managing emergencies and crises, defining responsibilities for feed business operators and ensuring proper information to the user and competent authorities through the feed chain.
- 96. The Commission considers that provisions concerning hygiene conditions for the manufacture, transport systems and use of feed are the priority. They must include a legal framework in order that Codes of Good Practice have a legal existence and operate without harming the working of the internal market.
- 97. The Commission considers that the establishment of a positive and exclusive list (permitting the use of only feed materials on the list, and therefore previously assessed and authorised) is not decisive in ensuring feed safety and it will not prevent the occurrence of contaminations, fraud and misuse of chemical and other pharmaceuticals..
- 98. The Commission recognises the interest of a list of feed materials for the purposes of trade, labelling and traceability and fraud prevention. However a non-exclusive list of feed materials already exists (Directive 96/25/EC) but it is limited in both the number and type of feed ingredients included.
- 99. The fact that current legislation only prohibits the use of certain ingredients in compound feedingstuffs and does not prevent their circulation as feed materials is a major shortcoming. The Commission considers it necessary to address this issue in future proposals.

### Measures to take

100. The Commission considers that the extension of the current non-exclusive list, completion of a list of prohibited feed materials and development of the HACCP approach and EU wide Codes of Practice is the appropriate line to take in order to ensure feed safety together with the relevant proposal to improve food and feed controls. The Commission therefore intends:

- a) to present as soon as possible to the European Parliament and to the Council a proposal for a Regulation laying down provisions for feed hygiene.
- b) to adopt by comitology procedure a Decision concerning the list of prohibited feed ingredients. The purpose is to extend the list and to prohibit the use of ingredients either as single feed material or included in compound feedingstuffs. The scope of current legislation (Decision 91/516/EEC), which deals only with the use of those substances in compound feedingstuffs, will thus be substantially enlarged.
- c) to amend by comitology procedure the non-exclusive list of feed materials laid down in the Annex to Directive 96/25/EC. The purpose is to extend the list of feed materials to take into account the constant development of food technology and the use of new raw materials by the feed industry. This will make it possible to give to the buyers or users of feed materials accurate and valid information providing a clear distinction between the different feed materials. The indication on the label of recognised specific names of feed materials will therefore be possible. As in the case of current legislation feed materials listed may only circulate under the names specified in the legislation and only on condition that they correspond to the descriptions in the legislation.
- d) to recast existing legislation on feed materials and compound feedingstuffs in order to harmonise labelling and delete certain derogations to the labelling provisions, to adapt approval procedures for certain categories of feed materials in accordance with the new responsibilities of the EFSA and to introduce provisions for nutritional claims.

### ANNEX I

#### Current legislative situation in respect of feed

- 101. Until the entry into force of Commission Decision 91/516/EEC, Member States were able to require that compound feedingstuffs marketed in their own territories were free of certain ingredients that pose a danger to human or animal health. The need to remove barriers to intra-Community trade resulting from such restrictions was the reason for adopting, at Community level, a list of prohibited ingredients. That list of ingredients prohibited in compound feedingstuffs has been amended several times. However, these ingredients were excluded from use only in compound feedingstuffs and not from direct use as feed materials since until 2000 there was no legal basis to ban them. The new legal basis was created by Directive 2000/16/EC<sup>11</sup> of the European Parliament and the Council amending both Council Directive 79/373/EEC on the circulation of compound feedingstuffs<sup>12</sup> and Council Directive 96/25/EC on the circulation and use of feed materials<sup>13</sup>. This new legal basis allows the Commission to draw up a list of materials whose use, directly or incorporated into compound feedingstuffs, is prohibited or restricted. Accordingly, Decision 91/516/EEC should be replaced by a new list drafted in accordance with the new legal base. When operational, this list will be a true negative list, which will be adopted via the comitology procedure.
- 102. The circulation and use of feed materials is regulated by Council Directive 96/25/EC on the circulation and use of feed materials, which has been implemented into national law in each of the Member States. Feed materials may be put into circulation only if they are sound, genuine and of merchantable quality. They may represent no danger to animal or human health or to the environment and may not be put into circulation in a manner liable to mislead the purchaser as to the real identity of the product offered to him. This Directive includes a non-exclusive list of the main materials used as animal feed within the European Union. Each name is accompanied by a description of the feed, and the levels of certain constituents (oil, protein etc.) which need to be declared when the product is traded and fed to animals. They may be put into circulation only under the names specified and on condition that they correspond to the descriptions given therein. However, in order not to restrict the freedom of choice of manufacturers and farmers, other feed materials not on the list may be put into circulation, provided that the names or descriptions used differ from those on the list so that the purchaser is not misled. Thus, any feed may be used freely in the European Union as a feed material without any previous assessment or authorisation, provided that the general rules of Directive 96/25/EC are met and that the provisions of other feed legislation, if relevant, are also met.
- 103. In conclusion, this list has the only objective of facilitating trade as it lays down labelling conditions for the main feed materials. Therefore it is not a list of the feed materials that may or may not be used.
- 104. Feed safety is guaranteed by a corpus of legislation that together forms a coherent set of rules. Regulation of the European Parliament and of the Council EC/178/2002

<sup>&</sup>lt;sup>11</sup> OJ L 105, 3.5.2000, p. 36

<sup>&</sup>lt;sup>12</sup> OJ L 86, 6.4.1979, p. 30

<sup>&</sup>lt;sup>13</sup> OJ L 125, 23.5.96, p. 35

laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>14</sup>, the "general food law", deals with general feed safety requirements, responsibilities of feed businesses operators, implementation of the rapid alert system for feed, traceability, reaction to crises and the role of science when ensuring food and feed safety.

- 105. Directive 96/25/EC deals with specific requirements for the labelling, circulation and use of feed materials. Directive 79/373/EEC on the circulation of compound feedingstuffs lays down provisions for the marketing of compound feedingstuffs, namely labelling. Directive 2002/2/EC of the European Parliament and of the Council amending Council Directive 79/373/EC<sup>15</sup> changed the rules concerning the labelling of feed materials in compound feedingstuffs. In general terms, the listing of feed materials is now required with an indication, in descending order, of the percentages by weight. As regards these percentages, a tolerance of around 15% of the declared value is permitted. Special rules have also been set for feed materials which may act as direct or indirect protein sources such as "bioproteins". Bioproteins are for example by-products from fermentation processes. Council Directive 82/471/EEC concerning certain substances used in animal nutrition<sup>16</sup> gives rules for the authorisation of the use in feed of those feed materials. Council Directive 93/74/EEC on feedingstuffs intended for particular nutritional purposes<sup>17</sup> sets the rules for the marketing and labelling of feedingstuffs intended for particular nutritional purposes, known as "dietetic feedingstuffs", - as opposed to ordinary or medicated feedingstuffs. This is, for example, special feed for cats and dogs with diabetes.
- 106. Council Directive 95/69/EC lays down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector<sup>18</sup>. This Directive is not applicable to all feed establishments, only those that deal with certain feed materials and additives, in order to forestall any potentially adverse effects on animal health, human health and the environment, given the risks inherent in using them. In function of the risk involved in the production and use of the substances they handle, some operators require only registration, while others require approval following a mandatory on-the-spot check by the competent national authority to verify that the establishment complies with the conditions of the Directive. These conditions concern facilities and equipment, qualifications of personnel, production processes and quality control, storage, and documentation concerning materials used, controls, complaints and product recall.
- 107. Council Directive 95/53/EC fixing the principles governing the organisation of official inspections in the field of animal nutrition<sup>19</sup>, requires that the competent national authorities regularly inspect feedingstuffs, whether imported from Third Countries or produced within the EU and provides harmonised rules for carrying out such inspections. Controls at the place of origin of feed materials and feedingstuffs are the basis for the mutual recognition of controls amongst Member States as

<sup>17</sup> OJ L 237, 22.9.93, p. 23

<sup>&</sup>lt;sup>14</sup> OJ L 31, 1.2.02. p. 1

<sup>&</sup>lt;sup>15</sup> OJ L 63, 6.3.02, p 23

<sup>&</sup>lt;sup>16</sup> OJ L 213, 21.7.1982, p. 8

<sup>&</sup>lt;sup>18</sup> OJ L 332, 30.12.1995, p.15

<sup>&</sup>lt;sup>19</sup> OJ L 265, 8.11.1995, p. 17

common in internal market legislation. For reasons of efficiency, controls are mostly carried out at the place of origin rather than destination. This is to avoid that a batch of feed is already distributed to outlets in different countries before it is checked for compliance with legislative rules. This Directive was amended by Directive 2001/46/EC of the European Parliament and of the Council amending Council Directive 95/53/EC fixing the principles governing the organisation of official inspections in the field of animal nutrition<sup>20</sup>, notably to introduce a legal basis for safeguard measures with respect to Third Countries and for on-the-spot inspections by the Commission's Food and Veterinary Office inside and outside the Community.

- 108. Basic rules for authorisation, use and marketing of feed additives are set out by Council Directive 70/524/EEC concerning additives in feedingstuffs<sup>21</sup>.
- 109. Undesirable substances are dealt by Council Directive 1999/29/EC on undesirable substances and products in animal nutrition<sup>22</sup>, which will be replaced as from 1 August 2003 by Directive 2002/32/EC of the European Parliament and of the Council on undesirable substances in animal feed<sup>23</sup>. This Directive includes maximum limits for heavy metals such as arsenic, lead, mercury and cadmium, as well as for dioxin, aflatoxin, certain pesticides and botanical impurities in certain feedingstuffs. The new Directive has introduced important changes in order to improve feed safety. It sets out provisions to prohibit dilution of contaminated feed materials with other feed materials, to add rules for setting maximum limits of undesirable substances in feed additives, to remove any possibility of derogation to the provisions of the Directive and to introduce thresholds on the presence of undesirable substances that must trigger intervention by competent authorities if they are exceeded.
- 110. The Commission made a proposal for a Regulation of the European Parliament and of the Council on Official Feed and Food Safety Control. This proposal will recast existing Community rules on the food, feed and veterinary sectors and will provide for a Community harmonised approach to the design and development of national control systems and define the role of the Commission so as to ensure the most efficient use of resources.
- 111. Regulation (EC) N° 1774/2002<sup>24</sup> of the European Parliament and of the Council laying down health rules concerning animal by-products not intended for human consumption replaces Council Directive 90/667/EEC laying down the veterinary rules for the disposal and processing of animal waste, for its placing on the market and for the prevention of pathogens in feedingstuffs of animal or fish origin<sup>25</sup>. This Regulation will strengthen the safety requirements for animal by-products used in feed. by defining the source material for animal by-products that can be used for feed. In particular, it should be noted that only by-products from animals fit for human consumption can be used as feed, and then only on condition that they meet certain safety requirements and are produced by establishments complying with the specific conditions laid down in the Regulation. Regulation of the European

<sup>&</sup>lt;sup>20</sup> OJ L 234, 1.9.2001, p. 55

<sup>&</sup>lt;sup>21</sup> OJ L 270, 14.12.1970, p. 1

<sup>&</sup>lt;sup>22</sup> OJ L 115, 4.5.1999, p. 32

<sup>&</sup>lt;sup>23</sup> OJ L 140, 30.5.2002, p. 10

<sup>&</sup>lt;sup>24</sup> OJ L 273, 10.10.2002, p.1

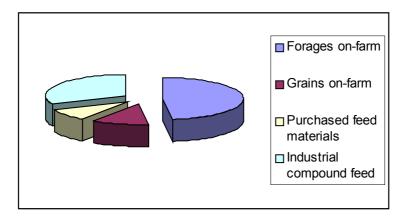
<sup>&</sup>lt;sup>25</sup> OJ L363, 27.12.1990, p. 51

Parliament and of the Council 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)<sup>26</sup> is also relevant as it provides list of substances that are not allowed in animal feeding.

<sup>&</sup>lt;sup>26</sup> OJ L 147, 31.5.2001, p. 1

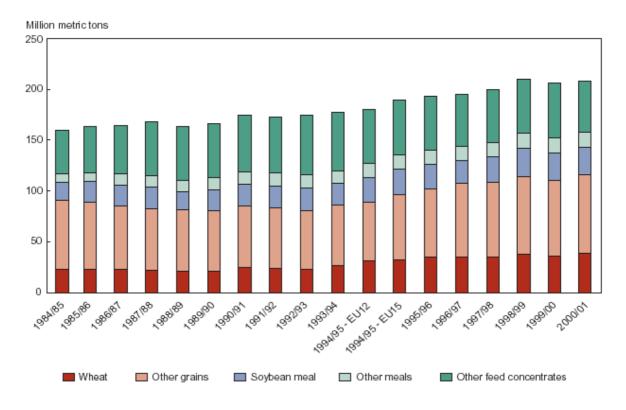
# ANNEX II

**FIGURE 1** EU feed sourcing in the EU



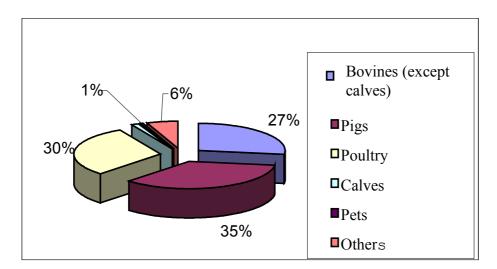
Source : FEFAC

FIGURE 2 Commercially traded feed



Source: European Commission.

**FIGURE 3** Industrial compound feed by species in 2000



Source: FEFAC

	TABLE 1	
Production value and number of enter	prises manufacturing comp	oound feedingstuffs in 1999.

COUNTRY	<b>PRODUCTION VALUE</b> (€ million)	NUMBER OF ENTERPRISES	
BELGIUM	1982.1	208	
DENMARK	582.8	63	
GERMANY	4584.7	325	
GREECE	No information	No information	
SPAIN	4526.2	704	
FRANCE	6967.6	617	
IRELAND	597.1	62	
ITALY	4348.3	670	
LUXEMBOURG	No information	No information	
NETHERLANDS	3879.6	230 (in 1998)	
AUSTRIA	274.3	46	
PORTUGAL	926	112	
FINLAND	415	74	
SWEDEN	300	85	
UNITED KINGDOM	5081	598 (in 1997)	
TOTAL	34464.7	3794	

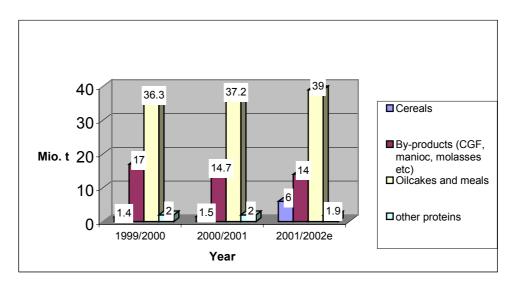
Source: EUROSTAT (data for the number of enterprises in the NL relates to 1998 and for the UK to 1997). For the production value Greece is excluded from the calculation.

Type of feed	% of total imports of feed	
Soybean meal and meal equivalent	44	
Oil seed meals and meal equivalent	14	
Corn gluten feed (CGF)	10	
Manioc	8	
Molasses	6	
Cereals	4	
Citrus Pulp	3	
Other	11	

 TABLE 2

 Imports 1990-2000

**FIGURE 4** Imports of feed in EU-15



# TABLE 3

	Cases of incidents in	the feed sector	notified in the	Rapid Alert System
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	Product		Substance	No Notifications
Cereal grains, products and by-products Cereals		Plant protection products (Nitrofen	) 4	
		Wheat starch water	Hormones (MPA)	1
	Oil seeds, oil fruits, products and by-products			
	Legume seeds, products and by-products			
	Tuber, roots, products and by-products			
	Other seeds and fruits, products and by-products			
	Lucerne meal		Dioxin	1
	Forages and roughage	Grass (alfalfa) meal	Dioxin	1
Feed Materials		Forage pellets	Dioxin	1
Feed Materials			Dioxin and Fluorine	2
	Other plants, products and by-products			
	Milk products	Skimmed milk powder	Chloramphenicol	17
	Land animal products			
		Fish meal	Dioxin	2
	Fish, other marine animals, products and by-products	Fish oil	PCB's	1
		Condensed dried fish solu	ibles PCB's	
	Dried shrimp shells		Dioxin	2
		Zincsulphate monohydrat	cadmium	1
Mineral	Minerals	Copper salts	Dioxin	1
		Premixtures of minerals	Lead	4
	Others	Glucose syrup Hormones (MPA)		1
	TOTAL			39
Additives and/or		Copper di-oxide	Dioxin	1
premixtures		Diatomaceous earth	Dioxin	1
	TOTAL	·		2
Compound			Aflatoxins	1
feedingstuffs	Complementary feed		PCB's	1
Complete feed			Meat and bone meal	1
	Complete feed		Meat and bone meal	7
			Antibiotics and coccidiostatics	12
			Sulphamides	2
			Cyanide	1
			Dioxin	3
	TOTAL			28
TOTAL	1			69
				09