An evaluation of the feasibility of a positive list of authorised feed materials at Community level

A report prepared for

The Health & Consumer Protection Directorate-General of the European Commission

by

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ADAS

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1 EXECUTIVE SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

1.1 Summary

1. The need to assess the feasibility of establishing a positive list has arisen as a result of public concern over the feeding of food-producing animals and a number of feed-related incidents in recent years.

2. Following discussions in European Institutions on percentage declarations of feed materials[1], and following publication of the White Paper on Food Safety, the European Commission (EC) was requested to submit, to the Parliament and Council, proposals for the development and maintenance of a positive list of feed materials. This report has been prepared in response to that request.

3. Throughout this report, reference to a 'positive list' implies an exclusive positive list. Feed materials that do not appear on the positive list would therefore not be permitted to be used or marketed within Member States of the European Union.

4. The primary objective of establishing a positive list at Community level is to ensure feed safety and the safety of products (milk, meat and eggs) derived from food producing animals.

5. There is a large corpus of European legislation aimed specifically at maximising feed safety. It was suggested by a number of those who were consulted that many of the recent safety-related incidents resulted from a failure to enforce current legislation, and did not necessarily reflect the justification for additional legislation.

6. A consortium consisting of ADAS, an agricultural consultancy based in the UK, and AFZ, a non-profit association based in France, was commissioned to undertake the study. The study commenced in November 2001 and was completed in March 2002.

7. The work of the Consortium focused on three main areas of activity, namely

   - An evaluation of lists – positive or not - currently in use in countries outside of the European Union (EU) or lists of feed materials which were in use in Member States prior to their accession to the EU.
   - Consultation with stakeholders (trade and farming associations, industry and individual experts).

[1] OJ L 63, 3.3.2002 p23.

- Consultation with official experts representing Member States and consultation with the Standing Committee on the Food Chain and Animal Health (Animal Nutrition Section).

8. Lists of feed materials were incorporated into national law of a number of Member Sates prior to accession to the European Union. The study reviewed some of these, together with positive lists that have regulatory function and are currently operated in Switzerland, the USA and Canada. Recently, Germany produced a voluntary positive list[2] in response to a number of feed-related incidents and the need for clear definitions of feed materials for labelling purposes.

9. Consultation with Stakeholders revealed that the need for systems that maintain feed and food safety is universally accepted.

10. Resources required for the establishment and maintenance of a positive list are provided in the text and in Annex 1.

11. Codes of Practice and Quality Assurance Schemes relating to the manufacture, storage and handling of feed materials have been briefly considered as alternative or complementary approaches to improving feed and food safety. These may employ HACCP principles and as a result incorporate key safeguards. The rules and codes embody the key responsibility to check the provenance and safety of what is included in feed.

1.2 Conclusions

12. This report concludes that it would be difficult – though feasible - to establish a positive list of feed materials, and identified key components of it. We believe that a positive list should not be seen as an alternative to sound manufacturing practice, but complementary to it.

13. A number of feed safety incidences that have occurred in recent years (lead contamination of rice bran, dioxin contamination of citrus pulp) would not have been prevented by the presence of a positive list, as they concerned products generally recognised as safe.

14. We believe that greater efforts to standardise Codes of Practice and Quality Assurance schemes at Community level would significantly enhance feed and food safety.

15. There is experience in the development and management of lists of feed materials – positive or not - both within and outside of the Community.

[2] While this list is called a “positive list” by its promoters, it is not considered here as a positive list as it does not have official regulatory control.

16. A positive list would need to contain reference to every feed material used within the Community for animals. Many feeds are traded under different names within the Community, and the list would need to accommodate this.

17. The purpose of the positive list will determine its' nature and scope. If it is for safety purposes alone, the number of feeds and categories would be significantly fewer than if the list were used for labelling and trade purposes. If a positive list is established for labelling and trade purposes, the entry onto the list will need to be considerably more detailed and the positive list will be far larger.

18. The Regulation (EC) N° 178/2002 of the European Parliament and of the Council establishes that the European Food Safety Authority (EFSA) will be established to address a range of issues, including products or substances used in animal feed, animal health and welfare[3]. It is therefore clearly within the remit of the EFSA to provide opinions as to which feed materials should be included or excluded from the list. These opinions would be based on scientific risk assessment regarding the safety of the feeds concerned.

19. While there is widespread support for the need to ensure feed safety and the safety of products (milk, meat and eggs) derived from food producing animals, we believe that a positive list in itself will not do this. Rather it is the rules that apply to, and enforcement of such a list that will determine its effectiveness in meeting these objectives.

1.3 Recommendations

20. We recommend that before undertaking the task of establishing an EU-wide positive list, it is necessary to question whether this is the most effective means of minimising the risks associated with the use of unsafe feed.

21. In the event of a positive list being established for safety purposes, we propose that the European Food Safety Authority would have responsibility for providing opinions about the inclusion of feed materials in a positive list, and that the Commission would be responsible for authorisation of feed materials. Risk assessment should be a primary consideration in assessing the suitability of a feed for inclusion in a positive list. As discussed in the report, however, this may not be the sole criterion for deciding whether a feed should be included or excluded from the list, and other factors may legitimately be taken into account.

22. In the event of a positive list being established we recommended that a Working Group of specialists be established with responsibility for (a) compiling an initial list and (b) maintaining the list. The Group would be appointed by and

[3] OJ L 31, 1.2.2002, p1.

answerable to the Commission, and would be given organisational responsibility for compiling a list of feed materials currently in use within the EU, EFTA and future Member States. The list of feed materials, together with the appropriate details would be submitted to the European Food Safety Authority, who would be asked to provide an opinion on the feed materials on the list. Once an opinion has been issued, this would be notified to the Commission for authorisation. In the case of a negative opinion, the Working Group would advise the Commission of other factors (e.g. environmental factors or safe history of use) that may justify inclusion in the list.

23. We recommend that the Working Group would require a full-time co-ordinator with a sound background in feed science and feed industry. Other members of the working group would serve on a part-time basis, and would collectively provide the appropriate expertise to assess information provided by third parties and take decisions in the many fields of feed science and feed safety.

24. In developing a positive list, and to avoid confusion, we recommend that the current categories used in Directive 96/25/EC[4] should be used as the basis of a positive list.

25. To improve the safety of feed materials and food, we believe that greater efforts should be devoted, at Community level, to the development and adoption of codes of practice relating to the manufacture, handling, transport and storage of feed materials.

[4] OJ L 125, 23.5.1996, p 35.

2 BACKGROUND

There was general public concern when it became known that animal protein was used as a feed material for animals, particularly since this is believed to have contributed to the spread of bovine spongiform encephalopathy (BSE). This concern has been reinforced as a result of a number of recent animal feed safety 'incidents' which have occurred within the European Union (EU), and which have focused attention on potential risks to consumers of animal products. These incidents have highlighted the need for measures whose primary objective is to improve the safety of feed materials and food. In addition, such measures may also have the effect of restoring public confidence in the food chain, and in products of animal origin.

For many years there have been calls for greater openness in declaring what farm animals eat. There was particular concern during the 1980's that livestock farmers had no way of knowing whether animal material was in the feeds they purchased and fed. In 1990, via Council Directive 90/44/EEC which amended Directive 79/373/EEC on the circulation of compound feedingstuffs, ingredient listing became mandatory, using either broad category descriptions or by each ingredient in full. In each case this was to be in descending order by weight. In 2002, Directive 2002/2/EC, on the circulation of compound feedingstuffs, was adopted by the European Parliament and the Council[5] which repealed the option for labelling by category. Instead, ingredients have to be declared in full, in descending order by weight, indicating the percentage inclusion. There has thus been a major change in openness as regards feed materials, as reflected in procedures for the adoption of Directive 2002/2/EC[6].

During discussions in the European Parliament on percentage declarations of feed materials, it was claimed that "the BSE crisis and the recent dioxin crisis have shown once again that the safety of feedingstuffs can only be guaranteed by a binding definition of permissible feed materials"[7]. The European Commission (EC) was requested to submit, to the European Parliament and Council, proposals for a report on the feasibility of establishing a positive list of feed materials.

In response to this request, and in the context of considerations included in the White Paper on Food Safety[8], the European Commission published a declaration in which it announced its intention to commission a feasibility study on the establishment of a positive list of feed materials[9]. This document reports the

[5] OJ L 63, 6.3.2002, p. 23.
[6] OJ L 63, 6.3.2002, p. 23.
[7] Amendment of the European Parliament submitted during the co-decision procedure on Recital 10a of the proposal of the Commission having led to Directive 2002/2/EC.
[8] COM (1999) 719, adopted by the Commission in January 2000.
[9] OJ C 27/2, 31.1.2002

outcome of that study. In addition, it considers alternative or complementary approaches to enhancing feed and food safety.

The study has been undertaken by a Dr B R Cottrill (ADAS, UK) and Mr. G Tran (AFZ, France)[10] on behalf of the Commission.

3 RATIONALE FOR THE ESTABLISHMENT OF A POSITIVE LIST

In the light of the issues described above, the primary objective of establishing a positive list at Community level is to ensure feed safety and the safety of products (milk, meat and eggs) derived from food producing animals. For this reason, the main emphasis of this report is on the evaluation of a positive list for safety purposes. However, we recognise that there may be other benefits to be derived from adopting a positive list, and some of these are discussed in this report (8.3, 8.5, 8.6). In particular, the presence of a comprehensive list of feed materials will facilitate new labelling provisions requiring the percentage inclusion of ingredients in compound feeding stuffs to be declared. Although legislation concerning labelling is currently available[11], the list of feed materials is relatively small in comparison to the number and type of feed materials currently marketed and used within the EU.

4 CONSULTATION

In undertaking this evaluation, the Contractors have consulted widely with stakeholders. Names of individuals, companies and trade associations within the EU that have been consulted are given in Annex 3. On 5 February 2002 the Contractors met with experts from six Member States (at the invitation of the European Commission). In addition, all members of the Standing Committee on the Food Chain and Animal Health (Animal Nutrition Section) were invited to comment on a draft version of this report.

The evaluation also involved an examination of positive lists currently used outside of the EU, and accordingly the Contractors consulted with those involved in the development and management of positive lists of feed materials in Switzerland and the United States of America.

5 DEFINITIONS

[10] Hereafter referred to as the Contractors.

[11] OJ L 125, 23.5.1996, p.35; Directive 96/25/EC of the European Parliament and of the Council.

For the purpose of this report the following definitions apply:

- **Feed materials** mean products as defined in Article 2(a) of Council Directive 96/25/EC[12], i.e. various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or 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.

- **Additive** means a chemically defined substance or combination of substances or micro-organisms not normally used as feed materials which are intentionally added to feedingstuffs or drinking water[13].

- **Positive list** means an exclusive list of feed materials. Because it is an exclusive list, feed materials not on the list may not be used for feed purposes or put into circulation within the EU.

- **Undesirable substance** means any substance or product, with the exception of pathogenic agents, which is present in and/or on the product intended for animal feed and which presents a potential danger to animal or human health or to the environment or could adversely affect livestock production.

6 CURRENT COMMUNITY LEGISLATION IN THE FIELD OF ANIMAL NUTRITION

The circulation and use of feed materials within the EU is currently regulated by Directive 96/25/EC[14] (as subsequently amended), which is transposed into national law in each of the Member States. This includes a non-exclusive list of the main materials for use as animal feeds within the EU. The feed materials listed in the directive may only be circulated under the names specified therein and on condition that they correspond to the descriptions given therein. Each name is accompanied by a description of the feed, and the levels of certain chemical constituents (e.g. oil, protein) that need to be declared when the product is traded. Feed materials that are not on the list may still be traded and fed to animals provided that they are "of sound, genuine and merchantable quality" and "do not represent any danger to animal or human health or to the environment" [15]. In addition, they must not be put into circulation in a manner that is likely to

[12] OJ L 125, 13.5.1996, p.35; Directive96/25/EC, as subsequently amended by Directive 2001/46/EC of the European Parliament and of the Council (OJ L 234, 1.9.2001, p.55).
[13] COM (2002) 153, adopted by the Commission on 22.3.2002.
[14] OJ L 125, 23.5.1996, p.35.
[15] This provision, of course, also applies to feed materials on the list.

mislead the purchaser as to the real identity of the product offered to him[16]. Thus any feed may be used freely in the EU as a feed material, provided that these conditions apply and that it confirms with other specific measures (e.g. those concerning additives, undesirable substances or products of animal origin). Substances of an undetermined nature are therefore prevented from entering the food chain if they represent any danger to animal or human health or to the environment.

In addition to Directive 96/25/EC (as subsequently amended), there is a large and complex corpus of EU legislation relating to animal nutrition. Although not an exhaustive list of legislation, the main Directives, in the context of this report, are:

- Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs[17].
- Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs (and subsequently amended) which introduced the negative list of feed materials.
- Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition (and as subsequently amended).
- Council Directive 90/667/EEC of 27 November 1990 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 feedstuffs of animal or fish origin and amending Directive 90/425/EEC.
- Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes
- Commission Directive 94/39/EC of 25 July 1994 establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes.
- Council Directive 95/53/EC of 25 October 1995 fixing the principles governing the organization of official inspections in the field of animal nutrition.
- Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector and amending Directives 70/524/EEC, 74/63/EEC, 79/373/EEC and 82/471/EEC.
- Council Directive 1999/29/EC of 22 April 1999 on the undesirable substances and products in animal nutrition. This directive will be repealed on 1 August 2003.
- Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed - Council statement. This directive will be effective on 1 August 2003.

As a follow-up to the White Paper on Food Safety[18], the Commission presented to Council and the European Parliament a proposal for a Regulation laying down health rules concerning animal by-products not intended for human

[16] OJ L 125, 23.5.1996, p.35; Article 7.2.

[17] COM (2002) 153, adopted by the Commission on 22.3.2002 - Proposal presented by the Commission to the Council and the European Parliament for a Regulation on Additives for use in Animal Nutrition.

[18] COM (1999) 719.

consumption[19]. Although this has not yet been adopted, it aims to integrate the animal by-product sector in the 'farm to table' approach to food safety. One of the principles is that the only material allowed to be used in feed would be material derived from animals declared fit for human consumption.

In 2002, Regulation (EC) No 178/2002 of the European Parliament and of the Council was adopted which outlined the general principles and requirements of food law. It established the European Food Safety Authority (EFSA) and laid down procedures in matters of food safety[20], notably regarding the responsibilities of the EFSA.

Given this armoury of legislation, it is has been suggested that some, at least, of the recent cases of feed and food safety occurred as a result of a lack of enforcement of existing legislation, rather than the need for further legislation.

7 REVIEW OF CURRENT LISTS OF FEED MATERIALS

Before undertaking a feasibility study of the establishment of a positive list at Community level, a review of lists of feed materials that are currently in operation in non-EU countries has been undertaken. Details have been obtained of lists in Switzerland, North America (the AAFCO[21] list) and Canada. In addition, a list has recently been developed in Germany, and is anticipated that this will be used in both Germany and Austria on a voluntary basis. Details of these are given in Annex 2 of this report.

Are these lists positive as defined in this document? The answer is not always clear. The German list is defined as positive by its developers, but it currently has no regulatory status. The AAFCO list is not official *per se* but is translated in state laws, with local adaptations. Nor is it an exhaustive list, since it does not include certain common or usual feeds. The Canadian list is official but does not seem exhaustive. The only non-EU list that is "positive" within the definition adopted in this report appears to be the Swiss list.

Exclusive positive lists of feed materials are currently prohibited in EU Member States[22]. However, a number of Member States used positive lists prior to implementation of EC feed legislation. They include Germany, Denmark and Sweden. In Norway, two lists were operated, one for terrestrial animals and one for fish (established in 1983 and 1991, respectively). Both lists were incorporated into Norwegian legislation until the EEA agreement came into force in 1995, although we believe that relatively few changes were made to the lists prior to

[19] COM (2000) 574.
[20] OJ L 31, 1.2.2002, p. 1
[21] Association of American Feed Control Officials.
[22] Directive 96/25/EC harmonised this matter via the prohibition of more restricted national measures.

that date. A number of non-exclusive lists of feed materials have also been developed in other Member States.

While the objectives for producing each of these lists may have been different, in all cases they have been developed on a national basis[23]. As a result, compilers of the lists have had the advantage of dealing with relatively small numbers of feed materials. With the exception of the Switzerland, they have also had the advantage of working in a single language.

In the early 1990's, the Commission convened a mini-group of experts charged with drawing up a list of the main feed materials used in the manufacture of compound feeds within the European Union. The Group identified some 620 feed materials. This list subsequently formed the basis of the list of feed materials given in Directive 96/25/EC.

There is clearly considerable expertise in other countries, particularly North America, in establishing and maintaining lists of feed materials. In addition, recent history in a number of Member States suggests that some expertise exists within EU Member States. Despite the expertise that exists, however, we believe that the development of a positive list for use at Community level would be a major undertaking, and on a different scale of magnitude and complexity to that involved in developing and maintaining any of the national lists.

8 SCOPE OF A POSITIVE LIST OF FEED MATERIALS

8.1 The scope of a positive list

By definition, an exclusive list must make reference to every product that is used within the Community as a feed material for animals, regardless of their scale of production or marketability. The use of additives in feed materials is covered by other EC measures, and these therefore do not need to be included in a positive list. So-called "botanicals" or "herbal" products may be problematic, depending on the nature of the claim made for them and their proposed usage. It is noted that the AAFCO list of feed materials is quite pragmatic in this respect, since the presence of feeds on the list appears to be on the basis of their safety status rather than on their nature.

The list would also need to include forages, which would increase the complexity of the list, although for food 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 and the list would need to reflect this. The presence of noxious weeds in forages, and undesirable substances resulting

[23] The AAFCO list is incorporated into feed law in all States in the USA with the exception of Alaska. Although Canada, Puerto Rico and Costa Rico are members of AAFCO, their legal systems are different from those of the USA and therefore have their own official lists.

from processing, would be regulated by reference to a list of 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.

With a few exceptions, the current list[24] does not include moist and liquid feed materials, many of them by-products (or co-products) of the food and drink processing industries, which are used as animal feeds and have a long history of safe use. The adoption of a positive list would provide an opportunity for these to be appropriately recognised.

The positive list, if adopted, should apply in all Member States. It was suggested during our consultations that this could pose problems, since some feed materials may be acceptable in some countries but not in others as a result of local customs or traditions[25]. The introduction of derogations for individual feed materials would however be both impractical and contrary to the principle of free circulation of feeds within the EU. Market forces would determine what feed materials were used aided by full and comprehensive labelling, and therefore we believe that there is no need for a derogation.

In addition to the list of individual feeds, the German list includes a miscellaneous category that includes molassed sugar beet pulp. This is a mixture of feed materials (i.e. molasses and sugar beet pulp) and is therefore a compound feeding stuff. As such it would not require authorisation. The justification for including this in the German list is that it is widely traded as such, and failure to include it could lead to confusion and may have implications for trade. We believe, however, that this approach should not be appropriate for a positive list for the EU.

It is clear that the potential size of a Community list is therefore enormous. As a guide, the AAFCO list gives definitions of over 1,000 feed materials in 35 categories[26], although this also includes certain "additives"[27]. The current German and Swiss lists each contain more than 300 feed materials, which is about twice the number of feed materials currently named in Directive 96/25/EC (as subsequently amended)[28].

[24] OJ L 125, 23.5.1996, p35; Directive 96/25/EC (as subsequently amended)

[25] An example is the use of horsemeat in pet foods. While it is safe in itself, its use for this purpose may be considered unacceptable in certain Member Sates. It would, however, be inappropriate to exclude its use throughout the EU, since other Member States may have a different view.

[26] The AAFCO list does not include "common or usual" feed materials, such as corn, wheat, oats, salt, or feeds that are approved for use in individual States. The list also includes definitions for a number of substances that, under EU legislation, would be classified as additives.

[27] The AFFCO define an additive as "An ingredient or combination of ingredients added to the basic feed mix or parts thereof to fulfill a specific need.. Usually used in micro quantities and requires careful handling". The definition of food additives under federal law defines is more specific with regards the affect and safety of an additive.

[28] The associated glossary of terms was intended to allow for considerable extension to this list.

8.2 Criteria for approval of feed materials

The minimum criteria for inclusion of feed materials on a list would be:

- It is suitable for feed use, i.e. there are rational motives for using it as a feed for animals, such as the presence of nutriments or other beneficial properties. The target species should be mentioned if relevant. This provision is necessary to prevent attempts to include products that would not normally be considered to be feed materials;
- It does not represent a danger to humans, animals or the environment;
- 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. This particularly includes the description of the manufacturing process, if relevant.

In approving feed materials for inclusion on the list, primary consideration should be given to safety rather than nutritional value, since this may not be the rationale for giving certain feed materials to animals (e.g. products may have beneficial properties, such as bulk, which are not strictly nutritional). We believe, however, that scientific risk assessment alone may not be the only or most appropriate basis on which to approve feed materials in all cases. Other factors such as societal, economic, welfare or environmental concerns may legitimately be taken into consideration on a case-by-case basis. In each case, the balance between risk and these other factors would need to be considered.

8.3 Labelling

EC legislation requires manufacturers of compound feedingstuffs to list all feed materials. The current basis of these labelling requirements is the non-exclusive list of feed materials, which already exists. It would seem logical and appropriate that the names of feed materials on the positive list should also be those used for labelling purposes, i.e. the list would serve both safety and labelling/trade purposes. Pet foods now have ingredient listing by category since the amending directive for Directive 79/373/EEC has been adopted.

There may be situations where the name of a feed material on the list is too long or likely to confuse when used on a label. A number of Member States have produced abbreviated terms with a view to making feed material names more understandable to farmers and to provide clearer labels. We propose that abbreviations for certain feed materials should be sanctioned as part of the 'master' list, provided that the use of abbreviated names did not confuse or mislead.

8.4 Pet foods

Community legislation in the field of animal nutrition is directed towards protection of human health, animal health and of the environment. Accordingly, the Commission Services indicated that this study should also include pet foods. Their inclusion however raises a number of issues with respect to the scope of a positive list. These arise primarily from the fact that manufacturers of pet foods 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.

In discussions with pet food manufacturers it was 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[29]. 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. As indicated above, however, the adoption of a positive list of feed materials might be expected to have wider significance than only food safety

The second issue relates to labelling. As recommended above, the names included in a positive list of feed materials should be the same as that used for labelling purposes. However, our attention has been drawn to certain situations in the manufacture of pet foods where, for purposes of trade, it is necessary to describe feed materials in terms that would not be acceptable for labelling purposes. These situations may arise either because certain feed names could confuse or be unacceptable to purchasers of the product, or be too long to fit onto labels. Examples of this include certain animal products from abattoirs and meat processing plants. Currently, these are broadly described under categories in the Animal By-products Regulation[30] (e.g. “Land animal products”). Such a name may be suitable for labelling purposes, but not be specific enough for trade purposes.

One approach to resolving this problem would be to have a positive list with two entries for the same feed, i.e. one for labelling and one for trade purposes. For the majority of feed materials the ‘trade’ and ‘labelling’ names would be the same, but for certain categories of feed two separate names would be provided. This approach would clearly be unacceptable for a list of feed materials used for food-producing animals, and it would therefore necessitate a separate list for pet foods. However, since many of the feed materials used in the manufacture of pet foods do not enter the food chain, it may be more appropriate with regards to safety. Whether this would be acceptable to pet food purchasers within the EU is not clear. Failure to address this problem may result in rejection – by pet owners

[29] It is not beyond the bounds of possibility that humans could consume pet food, either by mistake or for economic reasons, but we do not believe that the scope of a positive list should be constrained by these eventualities.

[30] OJ L 363, 27.12.1990, p.31; Animal Waste Directive 90/667/EEC .

- of certain pet foods containing animal products. The potentially adverse environmental consequences of this should not be underestimated.

8.5 Nutrition

Current positive feed lists include reference to certain nutritional characteristics, e.g. less than 10 % oil, greater than 25% crude fibre, etc. These are primarily intended to differentiate one feed from another, both as an aid to purchasers and to prevent fraud. A number of 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. Since feed safety is the primary objective in developing an EU positive list, there is no justification in extending the detail required beyond that currently required in Directive 96/25/EC.

8.6 Customs

Customs nomenclatures, particularly those concerning feed materials, do not usually address the technical aspects of the described products, and products of different nature can be grouped together under the same customs code. If a positive list were created, it would be essential to ensure that definitions of feed materials in the list could readily be cross-referenced to those in the custom codes. Failure to do so would lead to confusion and potentially create barriers to trade.

8.7 Status of the list

The current EU non-exclusive list is an integral part of current feed legislation, and a positive list should be similarly integrated within Community legislation.

9 STRUCTURE OF THE LIST

9.1 Categories

Current lists of feed materials in use in Germany and Switzerland are based on the same basic structure as that of Directive 96/25/EC. In the AAFCO list, there are 35 categories, but these include enzymes, mineral products, vitamins and a general-purpose miscellaneous product category. Since the choice of categories has no safety implications, the basis for the choice of categories should be to maximise the ease of management of the list while minimising confusion to users of the list. To avoid confusion, we recommend that the current categories should be used as the basis of a positive list.

9.2 Feed name

The feed name should be the common name of the feed, to be used on labels, documentation etc. The present rules and provisions for naming, as adopted in Directive 95/25/EC (as subsequently amended), should apply. In addition, all

names by which a particular feed material is known must be included if disruption to trade is to be avoided.

Standardisation of the feed names is essential. However, a number of similar or identical feed materials are traded under different names within the Community, while in some instances the same name may be used for different feed materials.[31] 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. A positive list must include the facility for an entry of a local name where this differs from the generally accepted name, provided that in all other respects the feed materials are similar. We believe that this will be a major challenge in developing an EU-wide positive list, and the problems of achieving this should not be underestimated.

For a number of feed materials, the name of the feed – and thus the need to differentiate it from another feed by use of a different name - will be determined by the purpose of the list. If feed safety were the only objective, then 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 the generic name (e.g. 'potatoes and potato by-products'). Similar examples could be found in other industries, particularly those associated with human food production. This approach would not, however, reflect the innovation and developments in processing in many of these industries, and would not therefore 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. Thus, for example, it would be important to differentiate between grape pulp and grape pips, maize gluten feed and maize gluten meal, potato peels and peeled potatoes, and so on. In practice, it is likely that the main feed materials would be specified separately, with the remainder covered by a 'miscellaneous' or 'other products' category. 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.

In addition to a unique name, a feeding stuff on the list should be given a unique number.

9.3 Feed definition and description

The feed definition must describe unambiguously the biological nature (species or chemical formula, plant or animal part used), the process to which the feed material has been subjected and nutrient-based thresholds necessary to differentiate between closely related feed materials (e.g. "containing less that 4% fibre"). The definition must reflect the wide variety of processes and terminology

[31] In Portugal, carob meal comprises carob pods only, whereas the same name is used in Greece to refer to unseparated pods and beans.

employed throughout the EU in order not to prejudice free movement and use of feed materials throughout the EU.

To achieve this, a comprehensive list of definitions is necessary to reflect both the wide range of feed materials available, and the range of 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 (as subsequently amended) lists only 17 definitions. In this connection, AAFCO list could form the basis of an EC list.

All of the lists reviewed during the course of this study include reference to specific nutritional characteristics. For example, the AAFCO definition of wheat germ meal includes the statement that "it must not contain less than 25% crude protein and 7% crude fat." This is clearly necessary to differentiate it from other feed materials derived from wheat processing, and is appropriate for trade and labelling purposes and to protect against fraud. For safety purposes, however, there is no justification in this distinction. Wheat germ meal with a protein content of less than 25% may pose no greater risk to consumers of animal products than that which would come within the current AAFCO definition. This would apply provided that the lower protein content is not a side effect of a different process, with different safety issues. Again, the ultimate purpose of the list is critical in determining the degree of detail required.

In establishing a framework for the list, it is essential that the general approach be practical and pragmatic, rather than theoretical. Examples of this may be seen in the German and North American lists, which make use of systems that allow for flexibility in difficult areas of naming. The German list has what could be called "general purpose" categories, i.e. where feeds with potentially similar safety status but which would be unnecessarily complicated to describe can be put together. This approach is used for forages[32] 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[33].

The feed names in the US lists sometimes assume the form of templates, e.g. "Condensed _____ fermentation soluble". The feed description proposes a non-exhaustive list of terms to be used in the template (in this case, whey, grain or molasses). It is mandatory for the feed trader to create a complete feed name by replacing the blank with an appropriate term. By using templates, it is assumed that a number of feed materials are taken care of without the additional overhead of creating separate entries in the list.

[32] While forages may, generally, be considered to be intrinsically 'safe', poor handling and storage, application of manure to pasture, etc. can seriously compromise their safety.

[33] For example, human foods containing animal products when given to food producing animals, or human food containing additives that have not been approved for feeding to food producing animals.

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, and therefore the entry of a feed onto a positive list should be accompanied by a description of process applied. At first sight some of these processes appear to be relatively standard, e.g. "dried"[34], 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. In the German system, for instance, processes which change the chemical nature of the feed (e.g. hydrolysis) warrant separate entries, while those that change only the structure (e.g. grinding) are grouped together within the same entry. However, this type of rule can lead to endless - and pointless - debate. Nevertheless, the effect of processing on the safety of a particular feed should be an underlying principle in determining on the degree of detail required.

The extent to which changes in the manufacturing process necessitate a re-evaluation of a feed on the positive list would depend on a risk assessment of the effect of the change on feed safety. Some changes may, superficially, appear to have little or no effect on the resultant feed, but this may not always the case. The clearest example of this is the manufacture of meat and bone meal. The body responsible for recommending the inclusion of a feed on a positive list would have responsibility for deciding this, on a case-by-case basis. It would not be unreasonable to require re-approval for feed materials where significant changes in processing practice occur.

Undesirable substances in feed materials, which arise as a result of manufacture or storage, would be addressed by the Undesirable Substances legislation.

9.4 Other compulsory declarations

This section would include reference to limitations on use for certain products. Information would be provided on a case-by-case basis, and would include maximum dietary concentrations for specific classes of animal where appropriate.

10 ESTABLISHMENT AND MAINTENANCE OF A POSITIVE LIST

There would be two stages and a number of discrete functions involved in the establishment and management of a positive list of feed materials. The two stages would be:

1. Establishment of an initial list

[34] Materials from which water or other liquid has been removed (AAFCO definition).

2. Maintenance of the list once the list has been authorised and incorporated into Community law

Within each of these stages there are a number of specific functions:

i. Management and organisation
ii. Recommendations for feed materials to be included or excluded from the list
iii. Authorisation for feed materials to appear on, or be subsequently removed from, the list.

10.1 Establishing an initial positive list of feed materials

The initial list of feed materials should be as exhaustive as possible to ensure that feed trade and animal production chains do not suffer from bureaucratic impediments during the initial period following the implementation of the list. The initial development of a list would therefore involve extensive consultation with EU farmers, feed operators and traders, through their respective trade organisations, to obtain an exhaustive census of existing feed materials. This census would also provide the basis for the harmonisation of feed names.

Previous experiences suggest that the development of a positive list at Community level will involve considerable time and resources. During the preparation of Directive 96/25/EC, a Commission mini-group was established with the objective of developing a list of the main feed materials in compound feed materials, and a negative list of feed materials that should not be used in the manufacture of compound feed materials within the EU. The group met on many occasions over a period of a few years. As a result of their deliberations they identified 620 feed materials[35], although this list did not include the considerable number of moist and liquid feeds, or forages, that would also need to be considered.

Reference has been made to the considerable experience of developing and maintaining lists that exists in the EU and North America, and it would be logical for this wealth of experience to be used in developing an EU list. The development of the German list may be an appropriate starting point. Not only does it contain the previous EU lists (96/25/EC and 82/471/EC), but it is also the result of co-ordinated work between representatives of industry, farmers and administration. We have been advised that in its present form it is immediately operational. Although it does not contain all the feed materials used in EU Member States, the framework and processes used in Germany could form the basis of the development of a more comprehensive EU list.

[35] The list was subsequently reduced to the 166 feeds in the current Directive. This was achieved by introducing the glossary of terms (R Crawshaw, *personal communication*).

10.1.1 Responsibility for recommending inclusion of a feed material in a positive list

Regulation (EC) No 178/2002 states that the European Food Safety Authority (EFSA) will be set up to address a number of issues, including products or substances used in animal feed, animal health and welfare[36]. It is therefore clearly within the remit of the EFSA to express opinions, based on risk assessments as to which feed materials should be included or excluded from the list.

Decisions to exclude feed materials from the list would be taken on the basis of the degree of risk they posed to animal or human safety or the environment, and taking account of the undesirable substances and the limits on these laid down in the relevant Directive. As discussed above, additives would also not be included on the list, although it is acknowledged that the distinction between additives and feed materials may not always be clear.

10.1.2 Authorisation of feed materials.

As outlined above (10.1.1) EFSA is not a "risk manager" and therefore would be expected to provide opinions rather than specifically authorise the use of feed materials. Furthermore, as discussed above (8.2), scientific risk assessment may not be the only criteria for deciding whether feeds should be included or excluded from a positive list. Nutritional aspects and other factors, such as societal, economic, welfare or environmental concerns may legitimately be taken into account on a case-by-case basis. For these reasons, we believe that it is appropriate that authorisation of feed materials should be granted by the Commission.

10.1.3 Management and organisation of the list.

It is essential that a suitable management structure be established to compile the initial list. In the USA, management of the AAFCO list involves dozens of experts, each specialised in maintaining a particular category of feed materials. This confirms that dealing with a continent-wide list is a complex task, even when using a common language[37]. Details of the personnel and resources involved in establishing the current (non-regulatory) German list are given in Annex 2. In Switzerland, the 'list committee' is made up of industry and government

[36] OJ, L 31, 1.2.2002, p. 1.

[37] AAFCO's missions also include the drafting of state feed laws, the harmonization of feed analysis and feed trials. It acts as an unofficial feed authority, self-governed by State officials, and representatives of Food and Drugs Administration (FDA) and United States Department of Agriculture (USDA).

representatives, but an official scientific institution is responsible for accepting or rejecting feed materials.

All those consulted during the course of this study have stressed the need for a rapid process of evaluation and authorisation of feeds. While the roles of the EFSA and the Commission in evaluating and authorising feeds on the list were generally accepted by those consulted, there was a divergence of views as to how the overall process of establishing – and subsequently maintaining – the list should be managed. Three options were considered during our consultations:

1. Some of those consulted during the course of the study expressed the view that the Committee in EFSA responsible for providing opinions regarding the inclusion of feed materials in a positive list should also be charged with management of the list, i.e. gathering information, compiling the list and submitting it to the Commission for authorisation. As discussed above (10.1.2), this is outside the remit of EFSA and, therefore we do not consider that this is an appropriate approach.

2. A Committee within the Health & Consumer Protection Directorate-General of the European Commission could be given responsibility for compiling the list. The list would be submitted it to EFSA for their opinions as to which feed materials should or should not be included on the list, based on risk assessment. Many of those consulted during the course of this study expressed concerns that this approach would lead to unacceptable delays in the registration process. We believe that the process of compiling a list is highly technical and would best be achieved by experts working outside of, but answerable to, the Commission.

3. A Working Group should be established and given organisational responsibility for compiling a list of feed materials currently in use within the EU, EFTA and future Member States. The Group would be appointed by and report to the European Commission. The list of feed materials, together with the appropriate details would be submitted to the European Food Safety Authority, who would be asked to provide risk assessment opinions. These opinions would be notified to the Commission who would then take them into account in granting or refusing authorisation. The Working Group would also be in a position to advise the Commission of factors other than safety that may justify inclusion in the list. This approach mirrors that adopted in the USA, which has evolved over many years and appears to satisfactorily address feed and food safety concerns in that country.

   The Working Group would require a full-time co-ordinator with a solid background in feed science and the feed industry, and with good managerial and communication skills. Other members of the working group would serve the Group on a part-time basis. They would include experts in the manufacture and trade of feed materials, in livestock production and nutrition, and in risk assessment. The members of the working group should therefore

represent sufficient collective expertise to be able to assess information provided by third parties and take decisions in the many fields of feed science and feed safety. The group should ideally have native speakers of all community languages so that differences and similarities between feed names in different languages can be readily identified.

Using the development of the German list as a model, it is anticipated that a working group of a minimum of 12 individuals will be required to achieve these objectives and establish the positive list. A part-time secretariat would be needed to assist with the administration.

The working group would need to seek advice and information from other parties. To do so, it would be necessary to create a database of external experts and correspondents from all the relevant fields of practice and national backgrounds. European-level trade organisations could form the core of the network but the working group will have to seek advice from national organisations, companies and individual experts when necessary.

If it is decided that a positive list of feed materials be established at Community level, we consider that this approach would best meet the needs of all stakeholders, and that it would expedite the development of the list. We therefore recommend that this approach be adopted.

10.1.4 Time-scale

It is anticipated that completion of the initial list of feed materials by the Working group would require a minimum of two years following establishment of the Working Group. The list compiled by the Working Group would be sent to EFSA, who would be expected to give an opinion within six months. Their opinion would be forwarded to the Commission and the Member States. The opinion would be made public, and the public may make comments to the Commission. The Commission would prepare a draft Regulation within 3 months of receipt of the opinion of the EFSA. In the event of a Regulation granting authorisation of a feed ingredient, this will be entered in the positive list.

There would need to be an appeal procedure for those feeds which are not approved by the Commission. The appeal would be to the Commission, who would consider whether there were any other grounds for authorisation, or whether the application should be referred back to the EFSA. It would be the responsibility of the Working Group to advise the Commission and the EFSA of any additional information that may be available to assist in resolving the appeal.

Given this schedule, we estimate that the earliest that a positive list could be established and authorised would be three years from the establishment of the Working Group, i.e. two years for the creation of the list (Working Group) followed by one year for risk assessment (EFSA) and authorisation (Commission). There

would be some overlap of activities, such that opinions from EFSA may be sought on some feed materials before the full list was completed.

10.1.5 Physical and human resources required for the establishment of a positive list.

The estimated time schedule for establishing the initial list by the Working Group is 2 years. The first year will be dedicated to the merging of the existing lists into a common list, and to its translation in EU languages. The second year will be dedicated to the consultation rounds, and to the finalisation of the list. The working group should meet on a regular basis (every 2 months) and meetings would be arranged with trade organisations, although much of the work would be done by correspondence.

Achieving this schedule – which some believe is optimistic - will depend on the amount of time that the part-time members of the working group spend on the project. Ideally, the part-time members of the group should receive a mandate by their respective administration to work for the group and be discharged from other duties, so that this task becomes part of their work and not done on their remaining available time. To facilitate this, and in order to minimise any conflicts of interest, we believe that they should receive appropriate remuneration, possibly on a *per deum* basis, for their time.

The resources needed are summarised in Annex 1. These are based on the assumption that the working group would be located within, if not part of, a larger organisation such as EFSA or the Commission, and thus have access to this organisation's infrastructure (accommodation, communications etc.). They do not include accommodation or telecommunication costs. It should also be noted that this estimate of costs does not include time and other resources spent by Commission officials and by industry and officials in Member States on business associated with the establishment of a positive list.

The overall cost of the Working Group associate with establishing the list would be around 932,000 Euro over 2 years.

We do not provide estimates for the costs of risk assessment (EFSA) and authorisation (Commission), as these tasks would be part of the regular activities of these organisations.

10.2 Maintenance of a positive list

It is clear that a list of feed materials cannot be a static document, and all the accumulated experience confirms that. In Switzerland, there are about 20 petitions per year to get new feeds approved in the official list, which already contains more than 300 feeds. About half of the requests are rejected, usually on

the basis of missing information or 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 an EU-level there would be significantly more petitions 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 may be present in Switzerland.

Once the initial list is drawn up, any feed material overlooked in the establishment of the list and new feed material developed subsequently should be able to enter the list without delay. Many of those consulted indicated that the maximum acceptable time between submission of a petition and (tentative) approval would be about two to three months. It has been suggested to us that any period greater than this would be a disincentive to use many feed materials, and thus have adverse impacts on trade and the environment. In the USA, it takes a minimum of about 12 months for a feed to be classified as GRAS[38], although it can be longer in some instances. This is likely to be the minimum amount of time for any system linked to EC regulatory mechanism.

10.2.1 Requirements for entry to the list (proportionate requirements)

The large majority of feed materials pose no risk to animals or consumers of animal products. Where feed materials do pose a risk, the cause is frequently an external one (e.g. pesticide residues, mycotoxins) and these are dealt with by other regulations. In the presence of a truly exclusive positive list, there would be no need for a negative list of feed materials to control the use of feeds which pose a risk to humans, animals or the environment.

The evidence in support of entry of a particular feed onto a positive list should be proportionate to the risks involved in using it, and the history of use would be a factor in the determining this. For the large majority of feeds the GRAS approach based on use over long periods of time would be appropriate. This would certainly be the case for the 166 feed materials (182 when non-protein nitrogen (NPN) feed materials are included) on the present list, and is likely to apply to the larger number on the German list.

In 2002 the Commission presented a proposal to the Council and the European Parliament for a Regulation on Additives for use in Animal Nutrition[39]. Article 8 of the proposal describes the particulars and documents that are likely to be required for approval of additives. While this might form the basis of applications for inclusion in the positive list, we believe that the applicant should not need to provide details of studies that have been carried out to confirm safety and efficacy (Article 8(d)), that there should be no requirement to send samples to the Community Reference Laboratory (Article 8(f)), and there should be no obligation for post-market monitoring (Article 8(g)). However, it may be necessary to deal

[38] Generally Recognized As Safe

[39] COM (2002) 153, adopted by the Commission on 23.3.2002

with individual feeds on a case-by-case basis. This approach is contrary to that being proposed for additives, where a strict protocol for all additives is described. In the case of feed materials, there would clearly be a basic minimum amount of information that would be required of all applications for entry to the list, with additional information required depending on the potential risk associated with the use of the feed.

We recommend that the minimum information required for approval of a feed material would be:

1. the name and the address of the applicant;
2. the designation of the feed material, including a proposal for its classification by category and functional group;
3. a description of the method of production, manufacturing and intended uses of the feed material;
4. proposed conditions for placing the feed material on the market, including labelling requirements and, where appropriate, specific conditions for use and handling;
5. a summary of the dossier.

10.2.2 Tentative list

To minimise distortion to trade and ensure optimum utilisation of feed materials, it is essential that the approval process is as rapid as possible. For this reason, existing systems such as those in Switzerland and North America implement a tentative, provisional list. The decision on whether or not a petition follows this 'fast-track' approach would be based on an initial assessment of the risk that the new feed material is likely to pose to food producing animals or consumers of animal products. For feed materials with a low risk, there is a high probability of them being approved and accepted provisionally, allowing them to be used and marketed before full approval is granted.

We recommend therefore that a tentative list be established. Petitioners would indicate whether they wished their feed material to follow the fast-track procedure, and this would be relayed to EFSA who would be requested to give a view within one month. If they are unable to do this – because there is perceived, on initial examination of the data, to be a risk associated with the feed – the applicant would be notified and consideration of the application would follow the normal course. Inclusion on the provisional list would follow a positive opinion from the EFSA.

10.2.3 Costs of Petitions

Applications for feed materials to be included in a positive list may be made by individuals, companies or organisation willing to introduce a new feed in the market. For applicants residing outside of the EU, a resident of the EU or a company registered within the EU would need to be designated to co-sign applications.

There will be costs associated with the entry of a feed material to the positive list. In addition to costs incurred by the petitioner in preparing an application (dossier), it is likely that there will be fees payable by the petitioner[40] although it is not possible at present to estimate what these will be. In both Switzerland and the USA, the petitioner pays for any costs associated with ingredient approval or recognition. In Canada, costs of assessment range from $120 (Category 1 – Standard feed requiring no safety and efficacy assessment) to $450 (Category 3 – Novel feed requiring safety and efficacy assessment).

The cost of obtaining approval relative to the commercial advantages to be gained from being able to market a feed material will be a major factor influencing any decision to apply for approval. If the costs associated with gaining entry onto the list were high, companies would be dissuaded from commencing the approval process. The consequence of this could be two-fold: the livestock industry would be deprived of potentially useful feed materials, and pressures on the environment would increase because the material would need to be disposed of in other ways. In this respect, the costs of disposing of by-products in other ways should not be ignored.

During consultation it has been pointed out that the financial margins on many livestock feeds are minimal and may not support the costs of gaining approval. Unlike additives and drugs, which are often patented products designed by an individual company, many feed materials are generic by nature. This raises the question of who would be prepared to pay for the development of a petition, knowing that others (and probably competitors) would simply wait for approval to be granted without having to contribute to the costs of the approval process itself? There might be more incentive if approval were given, for a limited period at least, specifically to the petitioner, although there are those who suggest that this would be contrary to free trade.

10.2.4 Subsidiarity

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. During our discussions it was suggested that the resources required and time taken to gain approval of these feed materials may be a disproportionate to their use, with potentially adverse effects on livestock systems and the environment. One approach may be to adopt the principal 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, although it is possible that the process of approval may be faster if undertaken at a local level, by experts having knowledge of local conditions. 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

[40] Subject to the outcome of the report provided for in Article 45 of Regulation (EC) No 178/2002 establishing the European Food Safety Authority, it is likely that fees will be charged for the consideration of applications by EFSA.

described above. This approach has been adopted in the United States, 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.

Criteria for local approval should never be less than at an EU-level, and therefore the argument for lower costs associated with local approval processes is not sustainable. There is merit in the argument that under certain circumstances a fast-track procedure is required at local level. Consideration might be given to allow authorisation to be granted by a Member State for locally produced feed materials. This situation should, however, be the exception rather than the rule. Within a short period of time EFSA would need to provide an opinion on individual local approvals, and in the fullness of time they would, subject to a positive opinion of EFSA, be authorised at Community level and be included in the positive list.

10.2.5 Enforcement of a positive list

This issue goes beyond the scope of the current feasibility study, but it would nevertheless need to be addressed in due course, since no legislation is justified if enforcement cannot be carried out. In the United States, the definition of enforcement procedures and subsequent penalties occupy a large place in AAFCO's concerns and activities.

10.2.6 Physical and human resources required to maintain a positive list.

Basically, the working group that is set up to establish the list would be also be responsible for maintaining it. We believe that a full-time co-ordinator will still be needed. While there would be fewer feed materials to be examined[41], the co-ordinator would have to spend more time assessing the dossiers, discussing with the petitioners and seeking advice from the members of the working group and from other people. On the other hand, travel, translation and secretarial expenses would be reduced.

Based on these assumptions, and experience in maintaining the French feed database, we estimate that the annual cost of list maintenance would be around 110,000 Euro per year. Details of the estimates of the costs of the different activities are given in Annex 1. Again, accommodation and telecommunication costs are not included in this calculation.

[41] It is not possible to predict the number of petitions likely to be received each year, but on the basis of experience in Switzerland and the USA a maximum of 100 petitions has been assumed.

11 IMPLICATIONS FOR TRADE ON THE ADOPTION OF A POSITIVE LIST

The implementation of a positive list of feed materials at Community level will have implications for trade, both in respect of imports to and exports from the EU, as it has already been experienced through the implementation of positive lists of less common substances, as for example has been experienced with the implementation of the World Trade Organisation SPS Agreement[42].

There is a general agreement that a list of feed materials would be beneficial to trade. However, there are notable divergences of opinions regarding the implications for trade of such a list, and much would depend on how it was implemented in practice.

11.1 Labelling and traceability

The most basic level of agreement is the following: a list of feed materials, appropriately described, is clearly needed for the purposes of trade, labelling and traceability and in the prevention of fraud. Within the current legislative framework, Directive 95/69/EC include requirements relating to traceability. The recently agreed EU General Food Law Regulation[43] defines traceability as "the ability to trace and follow food, feed, and food producing animals or substance … through all stages of production, processing and distribution". 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 may facilitate this process since it would allow precise feed names and descriptions to be used throughout the chain, and this for a much larger number of feeds than those listed in Directive 96/25/EC[44]. Even those opposed to the establishment of an exclusive list indicated that they would welcome the development of a comprehensive list for labelling purposes.

11.2 A barrier to trade?

The adoption of an exclusive list would, by definition, prevent the importation for use of any feed materials into the EU until such time as their safety had been determined and they had been entered on the positive list. For many of the feed materials widely used in the EU as animal feeds, this is unlikely to pose

[42] Sanitary and Phytosanitary (SPS) Measures. The SPS agreement recognizes the right of individual countries to restrict to set standards for the importation of feed materials on the basis of health or safety concerns.

[43] OJ L 31, 1.2.2002, p. 1; Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

[44] OJ L 125, 23.5.1996, p. 35.

problems. However, certain feed materials are imported which, although they represent a relatively small proportion of the total feeds used, are very important both for niche markets in the EU and for manufacturers in third countries. Because these are often produced in small quantities, the cost of getting a feed listed on the positive list could be prohibitive, thus posing a restriction to both exports from third countries and production in the Community.

Similarly, the importation of a compound feeds and feed mixtures from third countries that contain 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. Again, the cost and logistics of obtaining approval for these feeds to be included in an EU list may be more than the market can sustain.

Although it is outside the scope of this report, consideration should also be given to the implications for imports of animal products where the animals have been fed on feed materials not included in the EU Positive list.

11.3 Regional and national issues

In most cases, exclusive positive lists have been produced at a national level, frequently involving only one language, while the number of feed materials involved, and the processes to which they have been exposed, has been relatively small. The North American list is more complex, and includes a very extensive list of feed materials. Reports are that it is generally effective and well received by the feed and farming industry. However, it has taken some 90 years or more to evolve, is again based on a single language and requires a small army of experts to manage it[45].

In contrast, an EU-wide exclusive list would need to accommodate all local feed manufacturing and farming processes, languages and customs of the Community, covering practices from Finland to Madeira, from Ireland to Bulgaria and Cyprus. The issue or national and regional conditions was cited as a major impediment in establishing positive and negative lists, as in the report of the Codex Alimentarius referred to in section12.2.

11.4 Using the additives framework

In theory it would be possible to develop a list of feed materials along the lines of that adopted for additives since 1970[46]. Since the Commission have proposed a new Regulation on additives[47], it is appropriate to consider whether a similar framework and approach might be appropriate for a positive list of feed materials.

[45] The annual publication runs to some 450 pages
[46] OJ L 270, 14.12.1970, p.1; Directive 70/524/EEC
[47] COM (2002) 153

Firstly, it is important to distinguish between roles of the positive list of additives and a potential positive list of feed materials. Feed 'products' are defined as additives where they are claimed to favourably affect the characteristic of the feed, the characteristics of animal products, the nutritional needs of animals or environmental consequences of animal production. Understandably, the approval process requires evidence in support of any claims. In contrast, feed materials do not make such claims, and therefore there is no requirement for such rigorous evaluation. Unlike additives, there are usually no particular claims of efficacy about feed materials, so there is no need to verify them.

Secondly, additives are generally 'new' substances, the products of well-defined manufacturing processes designed specifically for a particular purpose. This is not the case with feed materials, which are either natural products or by-products, with ample variation in nature and origin, which are frequently difficult to anticipate, and whose existence predates the purpose. In addition, they frequently have a long history of safe use; where this can be appropriately described (target animals, limits on intake etc.) the need for a thorough safety assessment, as envisaged in the proposed additives Regulation, would appear unnecessary.

Thirdly, current experience of approval of feed additives is that it is a very long and expensive process. An additive producer who has already invested large sums of money into product development, and expects a good return on investment, may be prepared to expose his product to the costly and lengthy approval process. This situation is extremely uncommon for regular feed materials, where margins are small. It is generally feared that an additive-like approval process would remove any incentive to introduce new feed materials for the livestock feed or pet food industries. There is genuine concern that producers would be more inclined to dispose of the product by simpler means, i.e. burning or burying, with potentially adverse environmental costs while at the same time depriving farmers of useful feed materials.

It would therefore seem unnecessarily ambitious and complicated to establish a positive list of feed materials using the framework proposed for additives or demanding the same degree of evaluation.

12 ALTERNATIVE APPROACHES TO FEED AND FOOD SAFETY

All those consulted during the course of this study accepted the importance of feed safety in the production of food from food producing animals. Nevertheless, there is a widely held view that the introduction of a positive list of feed materials would not, in itself, ensure feed and food safety. Reference has been made to a number of feed safety incidences that have occurred in recent years (lead contamination of rice bran, dioxin contamination of citrus pulp) which would not

have been prevented by the presence of a positive list, as they concerned products generally recognised as safe. It appears to many of those consulted that the proposal to establish a positive list as a solution to feed safety is a political answer rather than a technical one, and therefore the wrong solution to a very important problem. Furthermore, it appears both paradoxical and illogical to create a positive list for feed materials, when no such list exists for human foods. The reason why feed materials should be subject to stricter regulations than foods is unclear to many of the people consulted.

As a consequence, alternative approaches to feed and food safety have been considered during the course of this study.

12.1 Current legislation and food safety

As mentioned above (Section 6), the field of animal feeding is already subject to a large, complex corpus of EU and national regulations, and it is the view of many of those consulted that current and impending EU legislation will meet requirements for feed and food safety. For example, food hygiene legislation based on risk assessment and HACCP[48] analysis is due to be introduced in 2002, and will apply to the whole food chain. Directive 79/373/EEC provides a negative list of feed materials[49] while several toxic plants and weeds already appear on the list of undesirable substances or products. However, it is generally accepted that an exhaustive negative list could be as cumbersome to manage as a positive one, as it is impossible to take account, in advance, of every possible safety issue.

12.2 Codex Alimentarius

The Codex Alimentarius is a joint FAO/WHO Food Standards programme, the main purpose of which is to protect the health of consumers and ensure fair practices in the food trade. As such, it is a truly international organisation. 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 Good Animal Feeding. The Task Force was given a 4-year time span to complete this work.

The first session of the Codex Task force on Animal Feeding discussed briefly the matter of feed lists and concluded that “the establishment of positive and negative lists would be very difficult, as such lists would be determined by the

[48] Hazard Analysis and Critical Control Point
[49] Now incorporated in Directive 96/25/EC; OJ.L.125, 23.5.1996, p. 35.

nature of animal production in different countries and therefore subject to national and even local conditions"[50].

The second meeting of the Task Force discussed the prospects for developing a positive list of feed materials, but no conclusions have yet been reached. A further draft of the Code of Practice on Good Animal Feeding has been circulated to member Governments of Codex and other interested international organisations for comment prior to the third meeting of the Task Force in June 2002.

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[51]. HACCP is a production control system that identifies where hazards might occur in a food production process and installs 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 a considerable role in contributing to the safe manufacture of feed materials. And a number of countries have already adopted the HACCP approach as the basis of feed and food safety initiatives.

It should be noted that there is some opposition to the adoption of HACCP principles at primary production levels in the food supply chain. The HACCP approach was originally developed in the United States by NASA[52] to ensure food safety in space, and it is considered by some to be unnecessarily complex for everyday use in feed production, particularly at farm level.

12.3 Farm Assurance Schemes and Codes of Practice

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 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 products derived from them. For example, the Animal Feed Product Board in the Netherlands has established the GMP+ scheme that requires that only assured feed materials may be used. To achieve this, it operates a positive list of feed suppliers - which includes farmers - and only those on the list may market (or put into circulation) feed materials.

[50] Paragraph 47 of the Report of the 1st session of the joint *Ad hoc* Inter-Governmental Codex Task force on Animal Feeding, Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission (113-15 June, 2000, Copenhagen, Denmark)

[51] FAO/WHO. 1997. Report of the 30th session of the Codex Committee on Food Hygiene, Appendix IV. ALINORM 99/13. Rome.

[52] National Aeronautical and Space Administration

This approach has been extended to Belgium, and there is interest amongst a number of other Member States in adopting it.

In the UK, the UKASTA[53] Feed Assurance Scheme (UFAS) was introduced in 1999 and since then has been adopted by feed manufacturers producing more than 90%, by volume, of compound feed fed to UK livestock. The requirement that all feed materials should come from assured sources – as is the case in the Dutch scheme – will be introduced within the next two years. In the meantime, the UFAS-registered feed manufacturer requires, at least annually, written assurance on all feed materials used. A number of suppliers are also externally audited, including UK-cereal producers and some companies marketing processed feed materials. UFAS thus forms part of a more comprehensive array of Assurance Schemes and Codes of Practice currently in operation within the UK.

At a farm level, the National Dairy Farm Assurance Scheme (NDFAS) was introduced in the UK in 1997. Under this scheme, dairy farmers supplying milk to companies that have registered with the scheme are obliged to adhere to codes of practice relating to the safe storage and use of feed. The NDFAS has recently been extended and requires that all compound feeds be purchased from suppliers accredited with UFAS. There is, therefore, within the UK a "farm to table" approach to feed and food safety, which is reflected in other Member States.

At a European level, FEFAC, which represents European feed manufacturers, has produced a series of guidelines for the implementation of a Code of Practice for the manufacture of animal feedingstuffs. This Code incorporates the legal obligations relating to a number of EU Directives on animal feedingstuffs. A number of other pan-European Codes of practice have been produced or are in the process of development by other bodies. The Code of Good Trading Practices (relating to the transport, storage and handling of food and feed materials) was issued by COCERAL in October 2000. Other Codes relate to the production of by-products form the crushing industry, and the production of animal fats, animal meals, fish oils and meals, by-products of the sugar industry and of the flour milling industry for use as feed materials. For pet food manufacturers, FEDIAF is in the process of introducing a Code of Practice for the Manufacture of Safe Pet Foods.

It is widely believed the adoption of Codes of Practice and Quality Assurance Schemes would be more effective in ensuring safe feed and food than the introduction of a positive list. While some see the establishment of a positive list as an academic exercise, these Codes and Assurance schemes are defined and maintained by the operators in response to market demands and are independently audited. They are effective because they apply to the whole process of production and provide a means of traceability in the event of any breakdown in feed or food safety.

[53] United Kingdom Agricultural Supply Trade Association

However, the effectiveness of current Codes and Assurance schemes has been questioned. Before they can be fully effective within the EU, national schemes need to be rationalised at EU level, and be adopted by all producers and manufacturers of raw materials. Some of the present schemes in operation or under development are complex, and it has been suggested by some that their adoption may impose considerable costs on many farmers or small producers if they were forced to adopt them. However, this argument is not invalid; where a risk exists there should be effective regulation, and the HACCP approach provides a means of addressing this. Some of the assurance schemes and Codes of Practice have been introduced to meet specific market demands, and differences between the schemes have, in some instances, lead to confusion amongst consumers. Other schemes however have been developed specifically to address feed and food safety; the UFAS scheme, for example, was specifically introduced to enhance food safety – and in the process restore public confidence in feedingstuffs and livestock products – following the BSE crisis in 1996.

Finally, the fact that the Codes and Schemes are designed and maintained by the industries themselves has prompted some to question the confidence that the general public can have in them. In response to this criticism, most of the generic schemes require auditors to be certified by an independent third party. Certification bodies are usually required to be registered to the EN45011 Standard.

Undoubtedly, Codes of Practice and Farm Assurance schemes are making a major contribution towards ensuring feed and food safety. They provide a framework for minimising the risk of unsafe food reaching the consumer, and raise awareness throughout the food production chain of the major issues that can affect food quality. Where effective, they can provide consumer with assurance of the quality of livestock foods and of their methods of production. There is criticism that some schemes set standards that are uneconomic to achieve, and incur additional work with little or no immediate benefit to the producer. However, bitter experience in recent years has demonstrated that the confidence of consumers in food derived from farm animals can be lost far more quickly than it can be built.

There is some justification in the claim that the absence of EU-wide schemes is creating ‘uneven playing fields’ with respect to products produced in other Member States or third countries. It is clear, however, that if Codes of Practice and Assurance Schemes are to achieve their full potential with respect to feed and food safety, they must be harmonised at EU level, and not left to local and voluntary initiatives.

13 CONCLUSIONS

a) Current legislation already ensures a high level of feed and food safety, although inadequate application of the legislation may impede its effectiveness. Nevertheless, recent feed safety incidences have highlighted the potential risks to consumers of animal products, and the need for measures whose primary objective is to improve the safety of feed materials. We believe that a positive list of feed materials, authorised at Community level, would make a positive contribution to the overall objective of improving feed safety.

b) In addition, a list of feed materials, appropriately described, is needed for the purposes of trade, labelling and traceability and in the prevention of fraud. A list of feed materials currently exists[54], but it is limited in both the number and type of feeds given. For instance, it does not provide clear definitions for many moist and liquid by-products used as feed materials in the EU today.

c) A positive list should be exclusive, i.e. it should make reference to every product that is used within the EU as an animal feed, regardless of the scale of production and marketability. It should include forages and the many liquid and moist feeds that are used in the EU today. An EU-wide exclusive list would need to accommodate all local feed manufacturing and farming processes, languages and customs of the Community, covering practices from Finland to Portugal, from Ireland to Greece. We recognise that this would be a major challenge in establishing a positive list. Indeed, a recent report of the Codex Alimentarius cited the issue of national and regional conditions as a major impediment in establishing positive (and negative) lists.

d) Safety would be the primary consideration for assessing the suitability of a feed for inclusion in a positive list. However, other factors such as societal, economic, welfare or environmental concerns may legitimately be taken into account in approving a feed material, or excluding it from the positive list.

e) There is considerable expertise in other countries, notable the United States, Canada and Switzerland, in establishing and maintaining extensive lists – whether positive or not - of feed materials. The Unites States list is the most complex of all, but it appears to be effective and is well received by the feed and farming industry. However, it has taken some 90 years or more to evolve and requires a small army of experts to manage it. The establishment and management of the list are made easier by the fact that it is based on a single language, which would not be the case for a European list.

[54] OJ L 125, 13.5.1996, p.35; Directive96/25/EC, as subsequently amended by Directive 2001/46/EC of the European Parliament and of the Council (OJ L 234, 1.9.2001, p.55).

f) A number of Member States operated positive lists prior to accession to the EU. In addition, a non-regulatory positive list has recently been developed in Germany. We believe, therefore, that the necessary expertise exists within the EU to establish and manage a positive list at community level. It would, however, be a major undertaking, and on a different scale of magnitude and complexity to that involved in developing and maintaining any of the national lists. The complexity of the task and the resources required to complete it should not be underestimated.

g) Responsibility for establishing a list of all feed materials currently used in the EU should be given to a Working Group established by, and reporting to, the Commission. The Group would consist of experts in the manufacture and trade of feed materials, in livestock production and nutrition, and in risk assessment. We believe that the development of an initial list of all EU feed materials would take two years to complete.

h) In establishing a positive list for safety purposes alone, it may not always be necessary to differentiate between many different feed materials originating from a common source. However, such an approach would reduce the value of a positive list for labelling and traceability purposes.

i) Responsibility for providing opinions about the inclusion of feed materials in the list, or removal from it, should rest with the EFSA. Their opinions would be based on risk assessment.

j) Responsibility for authorising feed material in a positive list would rest with the Commission.

k) The whole process of establishing an initial list of feeds used in the EU, risk assessment by EFSA and authorisation by the Commission would be expected to take a minimum of three years.

l) In essence, the approach recommended mirrors that recently proposed for additives[55]. However, we believe that the requirements for the approval of feed materials do not need to be as stringent as those for additives. In particular, anybody wanting to have a feed included in the positive list should not, as a matter of course, be expected to undertake studies to demonstrate efficacy and safety, although this may be required by EFSA in the case of individual feeds where there may be legitimate concerns over safety.

m) We recognise that there will be costs associated with gaining entry for a feed material in a positive list. These will include costs associated with developing a dossier, and the risk assessment undertaken by EFSA. However, we believe that excessive costs associated with the approval process could stifle incentives to introduce some feed materials for livestock feed or pet foods. We are concerned that those wishing to market by-products, for which financial margins

[55] COM (2002) 153, adopted by the Commission on 23.3.2002

are relatively small, may be more inclined to dispose of the product by simpler means, e.g. burning or burying. This could have adverse environmental consequences while at the same time deprive the livestock industry of potentially useful feed materials.

n) Before undertaking the task of establishing an EU-wide positive list, we believe that it is necessary to question whether this is the most effective means of minimising the risk of unsafe food reaching the consumer. The view of many of those consulted during the course of this study, and with which we concur, is that it is not. While the list would help food and feed safety, it would not guarantee it. It has been noted that a number of the feed-related incidents in the past years occurred with common, traditional feed materials that would have been on a positive list had such a list existed, and which are present on the current non-exclusive list of feed materials[56]. While a positive list would describe details of a feed material, including its origin and processes used in its manufacture, it would not be possible to specify ways in which feeds are transported and stored.

   It has also been noted that there is no positive list for food products, and no plans for one as far as we know. It seems paradoxical to propose a positive list of feed materials as a solution for feed safety when this approach has not been adopted for food products, even though the stakes are much higher. In fact, as in the food industry, only a HACCP-type approach to feed production and handling can identify hazards and provide safety assurance on a particular feed supply. A number of Codes of Practice and Quality Assurance Schemes have been established within the EU which attempt to do this. However, if Codes of Practice and Assurance Schemes are to achieve their full potential with respect to feed and food safety, they need to be harmonized at EU level and not left to local or voluntary initiatives.

o) We conclude that there are a number of options available. These, together with their respective advantages and disadvantages, are summarized below:

[56] OJ L 125, 23.5.1996, p.35

Options	Advantages	Disadvantages
1. Retain current legislation (Directive 96/25/EC, as subsequently amended).	• No resource costs incurred over and above those associated with maintaining and developing current legislative framework.	• Would not improve on the way feed safety issues are currently addressed. • Would not address the need for a more comprehensive list of feed materials for labelling and traceability purposes. • The ability to use feed materials of unknown safety within the EU would remain.
2. Development of a non-exclusive positive list (i.e. extension of the current positive list)	• Would address the need for better definition of the main feed materials for labelling purposes. • Resource costs would be lower than for other options described below.	• Would not improve on the way in which feed safety issues are currently addressed. • Would still permit the use of feed materials of unknown safety.
3. Development of EU-wide HACCP-based Codes of Practice, but retaining the current list of feed materials.	• This would address feed and food safety issues across the whole production chain. • There would be no direct costs specifically associated with the development of a positive list.	• Current codes of practice focus on aspects of manufacturing, storage and transport of feed materials. The development of these Codes may not therefore result *specifically* in an extended list of feed materials (although the Codes require manufacturers to comply with all aspects of legislation).

4. Development of an exclusive positive list of feed materials.	• This option would address the need for the control of feed materials, and facilitate labelling and traceability requirements. • Provide clarity to users of feed materials and consumers as to the nature and origin of feeds.	• This option would incur significant resource costs to establish and maintain the list. • It would not address <u>all</u> issues relating to feed and food safety, and in particular the transport and storage of feeds after manufacture. • Possible problems with respect to imports of feed materials from countries outside of the EU. • Adoption of an exclusive positive list may affect the development and marketing of new feed materials • Possible adverse environmental effects from discarding potential feed materials.
5. Establishment of an exclusive positive list and development of EU-wide HACCP-based Codes of Practice.	• This option would address the need for the control of feed materials, including labelling and traceability issues, • It would also address safety issues relating to the manufacture, storage and handling of feeds.	• Significant resource costs to establish and maintain the list. • Possible problems with respect to imports of feed materials from countries outside of the EU. • Possible environmental side effects of discarding potential feed materials.

Annex 1: Costs of establishing and maintaining a positive list of feed materials.

a) Establishment

Full-time co-ordinator	2 years x 12 months x € 6000/month	€ 144,000
Part-time secretariat	0.5 x 2 years x 12 months x € 3000/month	€ 36,000
Per deum expenses of members of the Working Group	12 experts x 50 days/year x 2 years x €400/day	€ 480,000
Travel expenses	12 experts x 12 meetings x € 600 €	€ 86,400
Documentation, computers etc.	2 computers + databases + maintenance + documentation	€ 20,000
Translation of existing lists	5 lists x 300 items x 100 words x € 0.1	€ 15,000
Translation of the final list	10 languages x 600 items x 200 words x € 0.1	€ 120,000
Other (publication etc.)		€ 30,000
Total		**€ 931,400**

Note: The number of words by item in the final list takes into account the fact that additional safety-related information will be necessary.

b) **Maintaining a positive list.** The annual costs (Euro) of maintaining the list is estimated as follows:

Full-time co-ordinator	12 months x € 6000/month	€ 72,000
Part-time secretariat	0.25 x 12 months x € 3000/month	€ 9,000
Travel expenses	20 experts x 2 meetings x € 500	€ 20,000
Documentation, computers etc.	Maintenance + documentation	€ 3,000
Translation of the final list	10 languages x 20 items x 200 words x € 0.1 + other	€ 5,000
Other (publication etc.)		€ 2,000
Total		**€ 111,000**

Annex 2. A summary of positive feed lists in development or in use elsewhere.

1 CREATION, MANAGEMENT AND IMPLEMENTATION OF A POSITIVE LIST OF FEED MATERIALS IN GERMANY

Based on information provided by Dr Volker Potthast, Director of LUFA (Agricultural Laboratory for the Agricultural Chamber of Rheinland) and head of the Normenkommission für Einzelfuttermittel.

1.1 Background

West Germany had a positive list of feed materials until 1977, when the general frame of the European legislation was implemented in Germany, replacing previous regulations.
In response to a number of feed crisis that have occurred recently in Germany (and particularly the BSE scare), it was decided, at political level, to implement a positive list to make sure that the feed materials used in animal feeding were duly authorised. There was in fact a strong political will to reduce drastically the number of authorised feed materials, regardless of their nutritional interest.
Meanwhile, there was a growing demand for open feed formulas, where the ingredient inclusion would be declared in percentages. It was apparent that this was not feasible without a fixed list of feed materials. Both concerns led the different German states to start working on their own lists, until it was judged more beneficial to work on a unique list at federal level. The Central Committee for German Agriculture (Zentralausschuss der Deutschen Landwirtschaft) was appointed as the main organisation responsible for the project. This Committee represents 4 organisations: Deutscher Bauernverband (German Farmer's Union), Deutsche Landwirtschafts-Gesellschaft (German Agricultural Society), Deutscher Raiffeisen Verband (German List description).

As has been already noted in this report, the developers of the current German list refer to it as a "positive" list, even though the list is a voluntary, trade-maintained one. It is certainly positive as it does define a list of authorised feed materials but this authorisation is not an official one. A true positive list in the EU meaning would be in contradiction with EU legislation.

1.2 Origin of the information

The list was derived from the former German positive list. It used elements from Feed Manufacturers Union) and Verband der Landwirtschaftskammen (Union of the Chambers of Agriculture). Within the Committee, a specific commission (Normenkommission für Einzelfuttermittel) undertook the work of creating a list.

Members of this commission came from these four organisations, as well as other “guest” organisations (unions, administrations). The work started in May 2000 and was completed in December 2001.

1.3 List description

1.3.1 Origin of the information

The list was derived from the former German positive list. It used elements other sources, including the current EU list, and of course the expertise of the members of the Normenkommission. In particular, it was emphasized that the definitions and the quantification of differentiating features of feed materials (e.g. the different kinds of wheat milling by-products) was to be undertaken by the commercial sectors involved.

1.3.2 Feed classes

The feed materials are classified according to 18 categories, similar but not identical to the ones used in the 96/25/CEE directive. Classes 5 and 13 are specific to the German list, and there is no class for the non-dairy products from land animals.

1. Cereal grains, their products and by-products
2. Oil-bearing seeds and fruits, their products and by-products
3. Grain legumes, their products and by-products
4. Tubers and roots, their products and by-products
5. By-products of fermentation and distillation
6. Other seeds and fruits, their products and by-products
7. Coarse fodder and green forage products produced on the farm where they are used
8. Other plants, their products and by-products
9. Dairy products
10. Fish and other marine animals, their products and by-products
11. Minerals
12. Miscellaneous straight feedingstuffs
13. Foods suitable for human consumption, their products and by-products.

The list also includes permitted straight feedingstuffs requiring a license under EC law, broken down into the following groups:

14. Protein products derived from micro-organisms
15. Amino acids and their salts
16. Hydroxy analogues of methionine and their salts
17. Urea and its derivatives, and ammonium salts
18. Other NPN compounds

1.3.3 Structure of the list

The list has a dual purpose of food safety and labelling. It has also a more general purpose of providing an official framework for the description of feed materials, and therefore contains elements regarding the nutritional value of the feed materials. For instance, it may mention that a material can only be fed when processed. The list is organized as follows:

- **Number***:* This refers to the group classification, in alphabetical order of the pure products in each case. There may be some exceptions to alphabetical order. Under the pure products are grouped the relevant processed products, in order of the amounts in which they occur in processing. The feedingstuffs are given a numerical code in Column 1, the first figure designating the group, the second the type of feeding stuff and the last the product or by-product.

- **Name***:* In this column, the feeding stuff is given a unique name. Parts of words placed in brackets may be omitted, e.g., (bean) in Soya (bean) meal extracted.

- **Description***:* This column gives a description of the products, describing unambiguously the part of the product or co-product used (e.g., grains, seeds, tubers, flour, cake, etc.), the process to which the product or co-product has been subjected (e.g., drying, extraction, heating, etc.) and, where applicable, the degree of ripeness and/or the quality of the product/co-product (e.g., 'low glucosinolate', 'low sugar').

- **Differentiating features**: The differentiating features given serve to distinguish between similar products within the processing of a given product. Threshold values apply for typical contents (in relation to the dry matter).

- **Requirements**: Here are entered the typical requirements for the products (as a percentage of dry matter where not otherwise specified).

- **Labelling details**: In this column, the contents to be listed in the declaration are shown.

- **Additional information on the manufacturing process**: This column contains the following details:

  a) "Currently not required", i.e., on the basis of the current state of knowledge, further information on manufacture and marketing is not necessary;

  b) "Supplementary information required", i.e., adjuvants and supplements are used in the manufacturing process and/or the production process consists of a number of stages, or else fractions from processes running in parallel are added to the starting material. Here, supplementary information, such as manufacturing flow charts, standard analyses, etc, is to be provided by the manufacturer so that, if applicable, a list of critical points can be drawn up;

c) “Datasheet required”, i.e., for these products a datasheet is required, since an HACCP evaluation has indicated chemical, physical or biological risks, or the starting material is subject to considerable variability in its contents (nutrient contents, or even undesirable substances);

d) “Provided under the licensing procedure”, i.e., in the case of permitted straight feedingstuffs requiring a license, additional information has already been provided as part of the licensing procedure. Here it must be checked how accessible and/or relevant the details provided are in relation to the objectives in drawing up the Positive List.

- **Comments:** Comments are entered here further to Column 7 relating to supplementary information already provided and/or still to be formulated by the manufacturer, questions about certain products which have not yet been answered, and further notes, e.g., on the questionable feed value or critical contents of a feeding stuff.

  There is also a *glossary of terms* for the proper identification of processes.

1.4 Contents of the list

The list contains more than 330 feed materials, most of them concentrate, forages and minerals. Information on forages is less detailed than concentrate feed materials, as there is less need to regulate them. There are few forage categories (prairie grass, forage cereals, beet, alfalfa…) and each category can accept the fresh product, the dehydrated product and the ensiled product. There are general provisions for the type of preservation agent.

The list does not include additives, with the exception of amino acids (which caused some problems, as they are also regulated as additives). It does not include simple mixtures of feed materials, with the exception of molassed beet pulps. It does not include specific pet foods.

The list is not supposed to cover every aspect of the potential problems caused by feed materials, nor is it intended to replace the current law. In fact, it relies whenever possible on existing regulations, and, more generally, on common sense. Some examples of this rationale are given below:

- *GMO products* are not dealt with in the list as such, as there is a current legislation concerning them.
- *Products which, under the laws in force, are not permitted to be fed to farm animals* – e.g., products deriving from warm-blooded terrestrial animals and those forbidden for BSE-related issues – are assessed and evaluated, but are not included in the list. It is, however, possible at any time to include such products in the list – subject to the appropriate risk evaluation – if there should be a change in the legal situation.

- *Feedingstuffs having a very low feed value*, but which are specifically permitted under the laws in force, are not excluded from the list, but an appropriate note is entered in the 'Comments' column.
- *Human food products* are considered as safe for animals, unless a specific regulation states otherwise (regarding the use of animal products for ruminant feeding, for instance). In the case of these products, two general purpose "bins" have been created in the list: one for the food products themselves, and one for the food co-products. For the latter, it is only necessary that the co-product be a part of the original food (no foreign material), and that the product be properly identified and described by the producer (or trader or importer).
- *Corn gluten feed quality* is defined through other regulations (customs) and this item was judged too political to be dealt properly within the positive list. The product is therefore in the list, but in a somehow less detailed fashion than other similar feeds.

1.5 List maintenance

1.5.1 Staff and budget

There are no specific individuals or budget dedicated to the maintenance of the list. The members of the Normenkommission work on it within the context of their regular duties. Around 10,000 DM/year have been used to cover the expenses (travels etc.). Christine Chudaske, from the DLG, has acted as co-ordinator and general secretary.

1.5.2 List changes

The Normenkommission is in charge of the maintenance of the list. Petitions for the inclusion of new feed materials, or for changes in the list, will be submitted to the head of the commission (Dr Potthast) for discussion by the commission members, with external assistance if necessary.

Criteria for inclusion of a feeding stuff on the list must primarily be:

a) Discernible feed value (this need not relate solely to energy or nutrient content);
b) Safety in terms of human and animal health;
c) Discernible significance in the market;
d) Legally permissible use.

When an organisation asks for the addition of a new feed, the commission requires the following information (depending on the feed):

- Descriptive data, such as the name, the definition and if necessary the various processes involved in the production of the feed
- Analytical results (chemical composition, undesirable substances etc.), potential health risks
- Reports of *in vivo* trials.

This information may come from previous studies, provided that they are considered reliable. In the absence of such information, the organisation may be required to carry out (and pay for) the missing analysis or experiments.

1.6 List implementation

1.6.1 Schedule

While the list is currently complete, some work is still needed before it can be used. Particularly, full descriptions of processes are still missing. It is intended that the list will be operational in 2002 and is already available from the DLG. (http://www.dlg.org/de/landwirtschaft/futtermittelnet/positivliste/index.html).

1.6.2 Operation

The primary goal of the list is to ensure that any feed material given to an animal is appropriate, safe and authorised. At any moment of the feed chain, one should be able to clearly identify the material and to find it in accordance with the list requirements.
From a practical point of view, this means that an organisation that sells or produces a material for feed uses has to comply with the following:

- The feed must be in the list
- A data sheet must be provided to the buyer

The documentation can be more or less exhaustive, depending on the requirements of the list. Essentially, there are three basic scenarios:

- Feed materials generally considered as safe, such as forages or cereal grains. Documentation for these products is minimal.
- Feed materials obtained by a standard process, such as oilseed meals. The data sheet must be provided only once.
- Feed materials obtained by a complex process. In these cases, the producer is supposed to provide a data sheet for every batch. In some cases, a prior HACCP evaluation should have indicated chemical, physical or biological risks.

The producer, importer or trader is the one required to provide the documentation. Traders and importers are supposed to obtain the process description from the producers. In any case, the seller is deemed responsible for the safe use of the feed. However, the feed user (the compound feed manufacturer or the farmer) must be able to prove that all required documents have been obtained.

This does not prevent a feed material to be traded for other purposes, for instance for prior processing before use, but when the material is actually fed to animal, it must be documented.

1.6.3 Legal aspects

It is not intended that the German positive list will be translated into law immediately, nor will it be enforced as such by an official body. To do so would be incompatible with the current EU legislation. While this possibility is not ruled out, it seems that it will work much in the same lines as the AAFCO list (see below) does presently. It is proposed that there will be an extended period of time during which the list will be operational, but without official control. It is expected that the market, and the several trade organisations involved, will make sure that the list is enforced and properly used.

1.6.4 Other countries

Other countries have shown their interest in the German list. In particular, Austria is likely to adopt it. The Netherlands have shown interest, but they have their own project of a positive list, apparently much more comprehensive.

1.7 The current list and the European Union project of a positive list

Dr Potthast believes that the German list could very well exist within a more general European legal framework. Obviously, the present list only takes into account feed materials relevant to the German feed situation, but a global European list is welcomed.

2 CREATION, MANAGEMENT AND IMPLEMENTATION OF A POSITIVE LIST OF FEED MATERIALS IN SWITZERLAND

Based on an interview with Mr. Claude Chaubert, from the RAP Federal Research Station of Animal Production, Posieux, Switzerland.

2.1 The Swiss feed law

2.1.1 Background

Switzerland has used a positive list of feed materials for many years, at least since 1975. The main purpose of this list (Livre des Aliments des Animaux, « Book of Feeds ») was to protect the consumer from deceptive practices. Animal and human health was secondary objectives. In 1995, the list was revised, using the EU directives as a basis, and the order of priorities were shifted with food safety, animal health and environment on top. The new list was put into practice on March 1st, 1995 and then revised several times.

The Swiss list can be considered is a “true” positive list, since it is exhaustive and is incorporated into Swiss law.

2.1.2 Content

The current Swiss feed law (Ordinance 916.307 on the production and circulation of feeds, May 26th, 1999) uses a positive list, which is annexed to the law. The Ordinance contains several articles relevant to the use of the list of feed materials and to the procedure of approval. There are also two other lists: one for the GMO feeds or GMO-containing feeds and one for the additives and health feeds. The Ordinance is not concerned with feed materials produced on the farm and not circulated. It is not applicable to feed materials exported to countries with which there is no reciprocal agreement on feed standards.

The general principle of the law is as follows:

All feed materials in circulation must be approved. They must be sound and fair marketable quality, and be named according to the prescriptions. A feed can be circulated only if it is suitable for the proposed use, and does not represent a risk for people, animals and the environment when used as prescribed. Feed materials should maintain or improve the performances of farm animals, and should not have negative effects on the products derived from them, or be unhealthy for them, or be misleading.

The articles relevant to raw materials other than GMO feed materials, compound feeds, additives, and health feeds can be summarised as follows.

Raw materials and simple feed materials (raw materials used directly to feed animals) can be circulated only if they are registered on the official list of feed materials. The list defines the properties of each feed, particularly its name, its description and the various requirements that make it suitable for feed use.

The Department of Economy, through the Federal Office of Agriculture, maintains the list. The organisation in charge of maintaining the list is the Federal Research Station of Animal Production of Posieux (RAP). Requests for the approval of new feed materials are generally accepted. The Office of Agriculture can grant a temporary approval of 6 months for feed materials that comply with the general requirements (sound and fair marketable quality, etc.). The Office can also approve feed materials not registered on the list if only small quantities are in circulation, or if they are circulated in a limited perimeter. If it appears that a feed is harmful for people, animals or the environment after it has been approved, even when it is used as prescribed, the Office can temporarily add additional requirements, or cancel the approval.

Requests for approval of new feed materials must be made by individuals or companies domiciled in Switzerland. The request must be sent to the Federal Research Station of Posieux, and must consist in a comprehensive case file. GMO feeds or GMO-containing feeds must also comply with the other parts of the Swiss law concerning them. The application must contain the name and address of the requesting party, the place where the feed is produced, its proposed name, comprehensive information about its composition, properties and suitability for feed use, and proof of the harmless nature of the feed regarding persons, animals and environment, within the prescribed conditions of use. The application must refer to or contain all the necessary evidence, such as scientific publications, trial reports, expert reports and official communications. A period of time can be granted to the requesting party to complete the file if necessary, but the request is not examined if the required documents are not provided once this period is over.

The Station is usually mostly concerned with verifying the documents of the case file. It first takes into consideration the generally known facts about the feed. It may, if needed, carry out trials or have them carried out. Alternatively, it may base its approval decision only on the available documents if the requesting party refuses to co-operate, for instance by declining to provide for free the necessary amounts of feeds, or the equipment, staff of facilities for experiments that cannot be performed in the usual frame of work. This can also be the case if the requesting party declines to assume the responsibility for damages occurring during the experiments, when the Station or a third party did not cause the damages.

2.2 List description

2.2.1 Origin of the information

The list is derived from the European lists (currently 96/25/CEE). It uses the same 12 categories as 96/25/CEE for the main feed materials, and 5 categories for the nitrogen compounds (slightly different from the 96/25/CEE categories for these products). When the feed materials are the same, the names and definitions are based on the European ones but are usually not identical. The codes are different too.
The new feed materials and the modifications of the feed names and descriptions were introduced progressively through the various revisions.

2.2.2 Structure of the list

The list contains 8 fields.

a) *Code identifier*: xx.yy where xx is the code of the feed category (cereals grains, their products and by-products…) and *yy* the code of the feed within this category.
b) *Category:* category code for labelling (this is similar to the categories in Part C in the 96/25/EEC list)
c) *Feed name*: the common feed name
d) *Feed description*: short definition of the feed, including its biological nature, the process used etc.
e) *Mandatory declarations*: mandatory characteristics that must be indicated on feed label
f) *Optional declarations*: optional characteristics that can be indicated on feed label
g) Content requirements: minimum or maximum content required for a characteristic of the feed (e.g. maximum protein content)
h) *Remarks*: miscellaneous information.

The nitrogen compounds are identified through the same system (the fields are not the ones used in 96/25/CEE)

2.3 Contents of the list

The list contains 325 feed materials, most of them concentrate feeds, forages and minerals. It is much more comprehensive than the 96/25/EC list.

The table below presents the category and the number of feed materials in each one in the Swiss law and in the 96/25 UE directive.

Category	Switzerland	EU
Cereal grains, their products and by-products	69	43
Oil seeds and fruit, their products and by-products	53	32
Grain legumes, their products and by-products	13	13
Tubers and roots, their products and by-products	26	11
Other seeds and fruit, their products and by-products	18	6
Forages	11	7
Other plants, their products and by-products	6	5
Dairy products	13	7
Products from land animals	13	8
Products from fish and other marine animals, their products and by-products	7	4
Simple mineral feeds	48	13
Miscellaneous products	16	4
Protein products from microbial origin	5	4
Amino acids, their salts and similar products	14	14
Hydroxyled methionine analogues and their salts	2	2
Urea, its derivatives and ammonium salts	7	7
Other non-protein nitrogen compounds	4	2

2.4 List maintenance

2.4.1 Principle

The maintenance of the list is a two-step process. Requests for adding a new feed are sent to the RAP Station so that it can be approved temporarily. Every 3-4 years, a committee of representatives of the feed sector revises the list and

decides on registering or not the feed materials that have been granted temporary approval since the last revision.

2.4.2 Staff

Two persons at the RAP station are in charge of maintaining the list and are entitled to approve temporarily of new feed materials. As these two persons have other duties at the station, the total amount of work necessary to manage the requests is equivalent to a week of full-time work per month. The RAP station carries out experiments, so other staff and facilities are involved, but in a less permanent basis.
The committee in charge of revising the list is made up of 7-8 persons. These people include the RAP officials, representatives of the compound feed manufacturers (private and co-operative), representatives of the importers, and a legal consultant. This committee is not permanent and only meets when a revision is due.

2.4.3 List changes

Petitions are sent to the RAP, where Mr. Guidon and his assistant (Mr. Chaubert) mostly decide by themselves, after a thorough examination of the case, to approve or not to approve temporarily the new feed materials. Each year, 10 to 20 requests are received, and half of them are accepted. The approval process can take a variable time, from a few days to a few months, depending on the type of feed, on the willingness of the requesting company to provide additional information, and on the type of additional analysis or trial required. Additional trials or analysis are frequently necessary, and are paid for by the company. Other products are accepted simply after reviewing the material provided: this was the case for instance for products as unusual as “hazelnut peelings”, “fruit vinegar” and “Chinese reed by-product”.

2.5 Comments

Switzerland uses the positive list system in a rather tolerant way. It is explicitly mentioned that new feed materials are generally accepted (Chapter 2, Section 1, Article 5). Feed materials that are immediately considered as safe and are likely to be used in relatively insignificant amounts may receive immediate approval and never enter the list, although this does not happen very frequently
.
The actual procedure does not seem very complicated, and only two persons handle most of the groundwork (and temporary approval). In that respect, it appears less demanding than the German project, where every new feed must go through the approval committee. Also, in the Swiss system, there is less emphasis on having the feed processes completely described (HACCP is not mentioned).

It is apparent that the German and Swiss system share several important features, namely:

- The lists are based on the 96/25/CEE framework, share a similar structure and have about 320-350 feed materials (about twice the number of the current EC list);
- Companies requesting the addition of a feed must provide analysis and trial results, proving not only the safety of the feed, but also its suitability as a feed;
- The body controlling the list contains both representatives of the government and representatives from the feed industry.

3 EUROPEAN UNION

During the 1990's there was an initiative by the European Commission to develop a list of feed materials as part of a project to establish a European Network of Feed Information Centres (ENFIC). Two lists of notable importance are the one maintained by the Association Française de Zootechnie in France (French Feed Database) and the one maintained by the Central Veevoederbureau in the Netherlands. These lists contained several hundreds of feed materials (more than 2000 for the AFZ list). In the UK a list of feed materials is being compiled using the ENFIC model.

4 THE REGULATION OF FEED MATERIALS IN THE UNITED STATES OF AMERICA.

4.1 Introduction.

In the United States, the Food and Drug Administration (FDA) has primary responsibility in the federal government for food safety, and in particular the enforcement of the Federal Food, Drug, and Cosmetic Act (FFDCA) and food safety related aspects of the Public Health Service Act (PHSA). The FFDCA defines food as "articles used for food or drink *for man or other animals*." Therefore any product, regardless of source, that is intended to be used as a feed ingredient or to become part of an ingredient or feed is considered a "food" and is subject to regulation by the FDA.

In addition to federal regulations, individual States have their own laws relating to animal feeds, which may be more stringent than Federal regulations. In most States, regulatory programmes were in place before the FDA and its feed programmes were established, and as a result federal law has, to some extent,

evolved to complement State laws and regulations. Some States have very progressive programmes, while others do not. State Agencies do most of their work within Sate boundaries, while Federal law applies to interstate trade. On a practical level, a firm doing business in a number of states may need to comply with the most restrictive set of regulations found in any of those states, whether state or federal. Where interstate trade is involved, the federal regulations might be considered the minimum, with the firm complying with whatever state has the most restrictive regulation.

The USA operates with essentially two sets of feed lists.

1. The US Code of Federal Regulations (CFR) lists feed materials approved by the Federal Food and Drug Administration Food Additive Petition (FAP) process and those feeds that are Generally Recognised as Safe (GRAS), together with those feeds that are prohibited for use in animal feed.

2. The AAFCO[57] Official Definitions.

In addition, there is a list of common or usual products that have not been defined elsewhere. This list is intended to cover those feed materials that are common and need not be defined, i.e., corn, wheat, oats, salt etc. However, it is recognised that this provides a potential loophole for products that lack the research or use experience necessary for inclusion of the product in either of the other lists. Certain substances approved for use in human foods may also be used in animal feed, as long there is a similar approved food use. For example, if a flavouring is approved only for use in alcoholic beverages, there would be no corresponding use in animal feed and it would therefore not be permitted for use in animal feeds.

There are two ways in which a previously unapproved non-drug product can be accepted for use in animal feed, namely

- the Food Additive Petition (FAP) process, administered by the FDA, or
- the AAFCO definition process.

The decision as to which process is adopted, which is made by the FDA, is based largely on the degree of risk associated with the use of the material.

4.2 The Food Additive Petition (FAP) process and the GRAS list

New feed materials and additives entering the Additives list must undergo the Food Additive Petition (FAP) process. This involves a detailed review of the human safety, animal safety, utility, and manufacturing of the compound. The sponsor of the product must also address potential environmental impacts,

[57] Association of American Feed Control Officials.

although in most cases is not required to undertake a complete environmental assessment. If upon review the product is found to be safe, efficacious, capable of being manufactured consistently and does not adversely affect the environment, then approval is given and a regulation identifying the product and giving its conditions of use is published in the Federal Register.

Revoking the approval of a product is also a formal process, which generally requires substantially more data than would be required to remove regulatory discretion. Also, products that were not subject to the pre-approval process, generally products that are GRAS or were in use prior to 1958 can be removed from the market place if scientific data no longer supports the safe use of the product. FDA removes these products from the market by developing a regulation stating why FDA believes the product is no longer safe. The regulation can prohibit all uses or can limit the use. Currently, three products that were previously permitted in animal feed are now prohibited[58].

The GRAS list contains details of approximately 150 feed materials, and is essentially a static list. It consists predominantly of feeds that were in common use as feed materials before 1958, and general recognition of their safety is based on scientific procedures or experience based on experience of safety as a feed material. Although the list was established over 40 years ago, the FDA may reassess feeds on the GRAS list at any time. Reasons for removal from the list would include new studies, data, or other information that show that the substance is, or may be, no longer safe, or because there is no longer the basis for an expert consensus that it is safe.
The legal status of whether a product should be considered Generally Recognised As Safe (GRAS) or as an unapproved food additive is not always clear and may be often questioned and debated. The decision on whether to consider a product GRAS or an unapproved food additive is largely based on whether there are significant safety concerns related to the product or a similar product, whether there is currently an approved food additive use for the product, and its history of use in animal feed. The pivotal issue in the decision is whether there is sufficient safety data available in the open scientific literature, which would enable an unbiased panel of experts to judge the safety of the product. If such data exist, the ingredient is a good candidate for being considered GRAS and allowed to be used in animal feed via the AAFCO definition process. If the data are not available or the experts disagree on the interpretation, then the ingredient will very likely have to undergo the food additive process.

4.3 The AAFCO definition process and the AAFCO list

[58] Gentian violet, propylene glycol in or on cat food, and animal protein prohibited in animal feed (the BSE regulation).

The AAFCO definition process may be used for products for which there are few safety concerns but which have not meet all of the requirements to be considered GRAS. Both processes require data on the safety, utility, and manufacturing process, together with information on the proposed use, species for which the use is intended, the amount to be used, and a proposed label. The FDA decides whether a new feed is approved under the FAP or AAFCO processes.

The AAFCO list has been in operation for ~95 years, and is updated annually and published in a register each December. It contains details of over one thousand feed materials listed in 35 different categories. For each feed material the list provides a name, a reference number, a description and the date it was adopted onto the list. In some cases it provides labelling instructions and minimum/maximum concentrations of specific constituents.

As with feeds on the GRAS list, those on the AAFCO list can be reassessed by FDA, as new information becomes available. If this information shows that a feed is, or may be, no longer safe or that there is no longer the basis for an expert consensus that it is safe, then regulatory approval can be withdrawn at anytime.

It is recognised that the Register will cease to be functional without constant maintenance. Even currently defined feed materials change and therefore must be continuously reviewed. This is a major challenge for AAFCO. In theory, the time taken for getting a feed onto the AAFCO list is relatively short, particularly where there are no concerns over safety and the applicant has provided adequate documentation. Approval does not need to wait until the annual publication of the AAFCO list, but is assumed once letters of support have been issued by the FDA and ratified by the AAFCO membership.

4.4 Other functions of AAFCO

The Association of American Feed Control Officials (AAFCO) was formed in 1909 to establish a framework for uniform regulation of the feed industry. It is an advisory group consisting of state and federal government agencies, and volunteers from within those member agencies do its work. AAFCO has no regulatory authority, but seeks ways to improve the work done by its members, develops these “projects” or “products” co-operatively, and shares the results with its membership. AAFCO has no regulatory authority, but it is up to the individual members to adopt the recommendations, and ultimately to act on them as the regulatory agency.

AAFCO establishes standards or models for regulations aimed at ensuring that manufacturers provide clear, accurate, and consistent information about animal feed, including pet food. Reference has been made to the annual AAFCO *Official Publication* — also referred to as the AAFCO Manual. This manual, in addition to listing ingredient definitions and feed terms, addresses labelling issues such as label format, ingredient lists, nutrition claims, and guaranteed analysis.

The Association also writes "model" rules that many states then use for their own feed (including pet food) laws and regulations. Individual States may make changes to the model bill and regulations to meet the format of their individual State laws and/or to address local conditions not addressed by AAFCO.

There have been instances where the FDA has declined to approve a feeding stuff or give it GRAS status, but neither has it banned its use. An example of this is recycled animal waste. While the FDA acknowledged that such material might have some nutritional value, it argued that because it is generally used within the State where it is produced, and that the States have the capacity to effectively regulate its use, the practice of using this material was generally a local one. The FDA therefore effectively handed responsibility for authorisation to State officials.

5 REGULATION OF FEED MATERIALS IN CANADA

Although Canadian officials are members of the AAFCO, Canada has its own 'List of approved ingredients'[59]. It consists of >900 feed materials and additives listed in two Schedules and eight categories. It does not include pasture range plants and forages fed green, or silages, but it has numerous entries for dried forages, indicating the importance of the list for labelling purposes. For many of these – but not all – definitions and labelling requirements are similar as for the AAFCO list. In addition to this list, there is a list of approved additives. While the list is quite extensive and often extremely detailed, it does not appear exhaustive: for instance, lentils, chickpeas and lupin seeds are not listed though there is evidence that they are used as feed materials in Canada.

Unlike the US model, responsibility for approval of feeds onto the list and management of the list itself rests with the Animal Products Directorate of the Canadian Food Inspection Agency. Using the authority of the federal Feeds Act, the Canadian Food Inspection Agency administers a national livestock feed program to verify that livestock feeds manufactured and sold in Canada or imported into Canada are safe, effective and are labelled appropriately. Effective feeds contribute to the production and maintenance of healthy, efficient livestock. Applicants wishing to have feeds included in the list must submit an application, together with an appropriate fee, to the Directorate.

The principal thrust of the national feed program is safety. The program is delivered by means of pre-sale product evaluation and registration by staff of the Feed Section, and post-market inspection and monitoring by Agency field staff located in all provinces of Canada.

[59] Details at http://www.inspection.gc.ca

ANNEX 3: PERSONS, COMPANIES AND TRADE ASSOCIATIONS CONSULTED DURING THE PROJECT.

Company/organisation	Name	Sector	Area
	Professor P. C. Thomas	Private Consultant	Europe
	Dr J. Blake	Private Consultant	UK
	Mr. R. Crawshaw	Private Consultant	UK
AAFCO	Mr. S. Jordre, Dr S A Benz, Mr. R Hoestenbach	AAFCO official	USA
AFCA/CIAL	Mr. Guibert	Trade Association, premixes, liquid supplements	France
Ajinomoto Eurolysine	Mr. Guion	Company, amino acids	International
COCERAL	Mr. B Gruner,	Trade Association, feed material traders	Europe
	Mr. R. Warin,		
Durepaire et Cie	Mr. Ménard	Company, feed materials	France
EDE Ile-de-France	Mr. Dupré, Mr. Besancenot	Trade association, farmers	France
EMFEMA	Mr. Dubois	Trade Association, mineral products	EU
FACCO	Mr. Avit, Mr. Moreau	Trade Association, Pet food manufacturers	France
FEFAC	Mr. A Döring, Mr. A Bouxin	Trade Association, Feed manufacturers	Europe
FEFANA	Mr. Jans	Trade association, additives	EU
Ferme de Grignon	Mrs Saadé	Company, farmers	France
LUFA	Mr. Potthast	Laboratory of the Regional Chamber of	Germany

		Commerce	
ORFFA	Mr Paumelle	Company, additives and feed materials	France, International
Pet Food Manufacturers Association	Mr. G Grantham	Trade Association, Pet food manufacturers	UK
Prosper De Mulder Ltd	Mr. P Foxcroft	Renderer	UK, International
Provimi Research and Technology Centre	Dr J. Newbold, Mr. M. Montanaro, Ir P. Gerardy	Supplement manufacturers	International
RAP Posieux	Mr Chaubert	Federal Research Station	Switzerland
Ste Guyon	Mr. Cordier	Company, mineral products	France
SYNPA	Mme Ribault	Trade association, additives	France
United Kingdom Agricultural Supply Trade Association (UKASTA)	Dr H. Raine, Dr J. Allen, Miss J. Nelson	Trade Association	UK
USA Food and Drug Administration	Dr D McChesney	USA official	USA
The Malt Distillers Association of Scotland	Mr. N Ross	By-product supplier	UK
Brewing, Food and Beverage Industry Suppliers Association	Mr. M Raynor	By-product supplier	UK
National Farmers Union	Mr. J Pettit,	Farmers union	UK
European Cereal Starch Association (AAC)	Iliana Axiotiades	Trade association	EU
Palabora Europe Ltd	Mike Darling	Mineral manufacturers	EU

In addition to the above, the Contractors met with met with experts from six Member States (at the invitation of the European Commission). Also, all members of the Standing Committee on the Food Chain and Animal Health (Animal Nutrition section) were invited to comment on a draft version of this report. Copies of the draft were also sent to other individuals, trade and farmer organisations within the EU. Where no response was received from them their names have not been included in the list above.

ANNEX 4: LIST OF ABBREVIATIONS USED IN THIS REPORT

AAFCO	Association of American Feed Control Officials
BSE	Bovine spongiform encephalopathy
COCERAL	Comité du Commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures (European association representing trade in cereals, feedstuffs, oilseeds, olive oil and agrosupply in the European Union)
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organisation
FEDIAF	European Pet Food Industry Federation
FEFAC	Fédération Européenne des Fabricants d'Aliments Concentrés
GMO	Genetically modified organism(s)
GMP	Good Manufacturing Practices
GRAS	Generally recognised as safe
HACCP	Hazard Analysis and Critical Control Point
NDFAS	National Dairy Farm Assurance Scheme
NPN	Non-protein nitrogen
UFAS	UKASTA Feed Assurance Scheme
UKASTA	United Kingdom Agricultural Supply Trade Association
WHO	World Health Organisation