ANNEX I

PRIMARY PRODUCTION

PART A

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

I. Hygiene provisions

- 1. Feed business operators responsible for primary production of feed shall ensure that operations are managed and carried out in such a way as to prevent, eliminate or minimise hazards with the potential to compromise feed safety.
- 2. Feed business operators shall ensure, as far as possible, that primary products produced, prepared, cleaned, packed, stored and transported under their responsibility are protected against contamination and spoilage.
- 3. Feed business operators shall meet the obligations set out in points 1 and 2 by complying with appropriate Community and national legislative provisions relating to the control of hazards, including:
 - (i) measures to control hazardous contamination such as that arising from the air, soil, water, fertilisers, plant protection products, biocides, veterinary medicinal products and handling and disposal of waste, and (ii) measures relating to plant health, animal health and the environment that have implications for feed safety, including programmes for the monitoring and control of zoonoses and zoonotic agents.
- 4. Where appropriate, feed business operators shall take adequate measures, in particular:
 - (a) to keep clean and, where necessary after cleaning, to disinfect in an appropriate manner, facilities, equipment, containers, crates and vehicles used for producing, preparing, grading, packing, storing and transporting feed;
 - (b) to ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of, feed;
 - (c) to use clean water whenever necessary to prevent hazardous contamination;
 - (d) to prevent, as far as possible, animals and pests from causing hazardous contamination;
 - (e) to store and handle wastes and hazardous substances, separately and securely, so as to prevent hazardous contamination;
 - (f) to ensure that packaging materials are not a source of hazardous contamination of feed;
 - (g) to take account of the results of any relevant analyses carried out on samples taken from primary products or other samples relevant to feed safety.

II. Record-keeping

- 1. Feed business operators shall keep records relating to measures put in place to control hazards, in an appropriate manner and for an appropriate period, commensurate with the nature and size of the feed business. Feed business operators must make relevant information contained in these records available to the competent authority.
- 2. Feed business operators must, in particular, keep records on:
 - (a) any use of plant protection products and biocides;
 - (b) use of genetically modified seeds;
 - (c) any occurrence of pests or diseases that may affect the safety of primary products;
 - (d) the results of any analyses carried out on samples taken from primary products or other samples taken
 - for diagnostic purposes that have importance for feed safety;
 - (e) the source and quantity of each input of feed and the destination and quantity for each output of feed.
- 3. Other persons, such as veterinarians, agronomists and farm technicians, may assist the feed business operators with the keeping
- of records relevant to the activities they carry out on the farm.

- the control of contamination such as mycotoxins, heavy metals, radioactive material;
- the use of water, organic waste and fertilisers;
- the correct and appropriate use of plant protection products and biocides and their traceability;
- the correct and appropriate use of veterinary medicinal products and feed additives and their traceability;
- the preparation, storage and traceability of feed materials;
- the proper disposal of dead animals, waste and litter;
- protective measures to prevent the introduction of contagious diseases transmissible to animals through feed and
 any obligation to notify the competent authority thereof;
- procedures, practices and methods to ensure that feed is produced, prepared, packed, stored and transported under appropriate hygienic conditions, including effective cleaning and pest-control;

ANNEX II

REQUIREMENTS FOR FEED BUSINESSES OTHER THAN AT THE LEVEL OF PRIMARY PRODUCTION OF FEED REFERRED TO IN ARTICLE 5(1)

FACILITIES AND EQUIPMENT

- 1. Feed processing and storage facilities, equipment, containers, crates, vehicles and their immediate surroundings shall be kept clean, and effective pest control programmes shall be implemented.
- 3. The lay-out, design, construction and size of the facilities and equipment shall:
 - (a) permit adequate cleaning and/or disinfection;
 - (b) be such as to minimise the risk of error and to avoid contamination, cross-contamination and any adverse effects generally on the safety and quality of the products. Machinery coming into contact with feed shall be dried following any wet cleaning process.
- 4. Facilities and equipment to be used for mixing and/or manufacturing operations shall undergo appropriate and regular checks, in accordance with written procedures pre-established by the manufacturer for the products.
 - (a) All scales and metering devices used in the manufacture of feeds shall be appropriate for the range of weights or volumes to be measured and shall be tested for accuracy regularly.
 - (b) All mixers used in the manufacture of feeds shall be appropriate for the range of weights or volumes being mixed, and shall be capable of manufacturing suitable homogeneous mixtures and homogeneous dilutions. Operators shall demonstrate the effectiveness of mixers with regard to homogeneity.
- 4. Facilities must have adequate natural and/or artificial lighting.
- 5. Drainage facilities must be adequate for the purpose intended; they must be designed and constructed to avoid the risk of contamination of feedingstuffs.
- 6. Water used in feed manufacture shall be of suitable quality for animals; the conduits for water shall be of an inert nature.
- 7. Sewage, waste and rainwater shall be disposed of in a manner which ensures that equipment and the safety and quality of feed is not affected. Spoilage and dust shall be controlled to prevent pest invasion.
- 8. Windows and other openings must, where necessary, be proofed against pests. Doors must be close-fitting and proofed against pests when closed.
- 9. Where necessary, ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable moulds and the shedding of particles that can affect the safety and quality of feed.

PERSONNEL

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

PRODUCTION

- 1. A qualified person responsible for production must be designated.
- 2. Feed business operators must ensure that the different stages of production are carried out according to preestablished written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process.
- 3. Technical or organisational measures must be taken to avoid or minimise, as necessary, any cross-contamination and errors. There must be sufficient and appropriate means of carrying out checks in the course of manufacture.
- 4. The presence of prohibited feed undesirable substances and other contaminants in relation to human or animal health shall be monitored, and appropriate control strategies to minimise the risk shall be put in place.
- 5. Waste and materials not suitable as feed should be isolated and identified. Any such materials containing hazardous levels of veterinary drugs, contaminants or other hazards shall be disposed of in an appropriate way and not used as feed.
- 6. Feed business operators shall take adequate measures to ensure effective tracing of the products.

QUALITY CONTROL

- 1. Where appropriate, a qualified person responsible for quality control must be designated.
- 2. Feed businesses must, as part of a quality control system, have access to a laboratory with adequate staff and equipment.
- 3. A quality control plan must be drawn up in writing and implemented, to include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications and the destination in the event of non-compliance from processed materials to final products.
- 4. Documentation relating to the raw materials used in final products must be kept by the manufacturer in order to ensure traceability. Such documentation must be available to the competent authorities for a period appropriate for the use to which the products are placed on the market. In addition, samples of ingredients and of each batch of products manufactured and placed on the market or of each specific portion of production (in the case of continuous production) must be taken in sufficient quantity using a procedure pre-established by the manufacturer and be retained, in order to ensure traceability (on a regular basis in the case of manufacture solely for the manufacturer's own needs). The samples must be sealed and labelled for easy identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any adulteration. They must be kept at the disposal of the competent authorities for a period appropriate to the use for which the feed is placed on the market. In the case of feedingstuffs for animals not kept for food production, the manufacturer of the feedingstuff must only keep samples of the finished product.

STORAGE AND TRANSPORT

- 1. Processed feeds shall be separated from unprocessed feed materials and additives, in order to avoid any crosscontamination of the processed feed; proper packaging materials shall be used.
- 2. Feeds shall be stored and transported in suitable containers. They shall be stored in places designed, adapted and maintained in order to ensure good storage conditions, to which only persons authorised by the feed business operators have access.
- 3. Feeds shall be stored and transported in such a way as to be easily identifiable, in order to avoid any confusion or crosscontamination and to prevent deterioration.

- 3. Containers and equipment used for the transport, storage, conveying, handling and weighing of feed shall be kept clean. Cleaning programmes shall be introduced, and traces of detergents and disinfectants shall be minimised.
- 4. Any spoilage shall be minimised and kept under control to reduce pest invasion.
- 5. Where appropriate, temperatures shall be kept as low as possible to avoid condensation and spoilage.

RECORD-KEEPING

- 1. All feed business operators, including those who act solely as traders without ever holding the product in their facilities, shall keep in a register relevant data, comprising details of purchase, production and sales for effective tracing from receipt to delivery, including export to the final destination.
- 2. Feed business operators, except those who act solely as dealers without ever holding the product in their facilities, shall keep in a register:
 - (a) Documentation relating to the manufacturing process and controls. Feed businesses must have a system of documentation designed to define and ensure mastery of the critical points in the manufacturing process and to establish and implement a quality control plan. They must keep the results of the relevant controls. This set of documents must be kept so that it is possible to trace the manufacturing history of each batch of products put into circulation and to establish responsibility, if complaints arise.
 - (b) Documentation relating to traceability, in particular:
 - (i) for feed additives:
 - the nature and quantity of the additives produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture,
 - the name and address of the establishment to which the additives were delivered, the nature and quantity of the additives delivered and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture;
 - (ii) for products covered by Directive 82/471/EEC:
 - the nature of the products and the quantity produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture,
 - the name and address of the establishments or users (establishments or farmers) to whom these products have been delivered, together with details of the nature and quantity of the products delivered and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture;
 - (iii) for premixtures:
 - the name and address of the manufacturers or suppliers of additives, the nature and quantity of the additives used and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture,
 - the date of manufacture of the premixture and the batch number where appropriate,
 - the name and address of the establishment to which the premixture is delivered, the delivery date, the

nature and quantity of the premixture delivered, and the batch number where appropriate.

- (iv) for compound feedingstuffs/feed materials:
- the name and address of additive/premixture manufacturers or suppliers, the nature and quantity of the premixture used, with the batch number where appropriate,
- the name and address of the suppliers of the feed materials and complementary feeds and the delivery date,
- the type, quantity and formulation of the compound feed,
- the nature and quantity of feed materials or compound feedingstuffs manufactured, together with the date of manufacture, and the name and address of the buyer (e.g. farmer, other feed business operators).

COMPLAINTS AND PRODUCT RECALL

- 1. Feed business operators shall implement a system for registering and processing complaints.
- 2. They shall put in place, where this proves necessary, a system for the prompt recall of products in the distribution network. They shall define by means of written procedures the destination of any recalled products, and before such products are put back into circulation they must undergo a quality-control reassessment.

GOOD ANIMAL FEEDING PRACTICE

PASTURE GRAZING

The grazing of pastures and croplands shall be managed in a way that minimises the contamination of foods of animal origin by physical, biological or chemical hazards. Where appropriate, an adequate rest period shall be observed before allowing livestock to graze on pasture, crops and crop residues and between grazing rotations to minimise biological cross-contamination from manure, where such a potential problem exists, and to ensure that the withholding periods for agricultural chemical applications are observed.

REQUIREMENTS FOR STABLE AND FEEDING EQUIPMENT

The animal production unit shall be designed so that it can be adequately cleaned. The animal production unit and feeding equipment shall be cleaned thoroughly and regularly to prevent any build-up of hazards. Chemicals used for cleaning and sanitising shall be used according to instructions and stored away from feed and feeding areas. A pest control system shall be put in place to control the access of pests to the animal production unit with a view to minimising the possibility of contamination of feed and bedding materials or animal units. Buildings and feeding equipment shall be kept clean. Systems shall be put in place to regularly remove manure, waste material and other possible sources of contamination of feed. Feed and bedding material used in the animal production unit shall be frequently changed and not allowed to become mouldy.

FEEDING

1. Storage

Feed shall be stored separately from chemicals and other products prohibited for animal feed. Storage areas and containers shall be kept clean and dry and appropriate pest-control measures implemented where necessary. Storage areas and containers shall be cleaned regularly to avoid unnecessary cross-contamination. Seed shall be stored properly and in such a way that it is not accessible to animals.

Medicated feed and non-medicated feed intended for different categories or species of animals shall be stored such as to reduce the risk of feeding to non-target animals.

2. Distribution

The on-farm feed distribution system shall ensure that the right feed is sent to the right destination. During distribution and feeding, feed shall be handled in such a way as to ensure that contamination does not occur from contaminated storage areas and equipment. Non-medicated feeds shall be handled separately from medicated feeds to prevent contamination.

On-farm feed transport vehicles and feeding equipment shall be cleaned periodically, in particular when used to deliver and distribute medicated feed.

FEED AND WATER

Water for drinking or for acquaculture shall be of appropriate quality for the animals being produced. Where there is cause for concern about contamination of animals or animal products from the water, measures shall be taken to evaluate and minimise the hazards.

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

PERSONNEL

The person responsible for the feeding and handling of animals shall possess the requisite ability, knowledge and competence.