

## 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.
2. The lay-out, design, construction and size of the facilities and equipment shall:
  - (a) permit adequate cleaning and/or disinfection;
  - (b) be such as to minimise the risk of error and 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.
3. Facilities and equipment to be used for mixing and/or manufacturing operations shall undergo appropriate and regular checks, in accordance with written procedures pre-established by the manufacturer for the products.
  - (a) All scales and metering devices used in the manufacture of feeds shall be appropriate for the range of weights or volumes to be measured and 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 pre-established written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process.
3. Technical or organisational measures must be taken to avoid or minimise, as necessary, any cross-contamination and errors. There must be sufficient and appropriate means of carrying out checks in the course of manufacture.
4. The presence of prohibited feed 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 cross-contamination 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 cross-contamination and to prevent deterioration.
4. 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.
5. Any spoilage shall be minimised and kept under control to reduce pest invasion.
6. 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.