Council Directive of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community (90/167/EEC)

Article 4

1 Member States shall take all necessary measures to ensure that medicated feedingstuffs are manufactured only under the conditions set out below:

a the manufacturer shall have premises which have been previously approved by the competent national authority, technical equipment and suitable and adequate storage and inspection facilities;

b the medicated feedingstuffs manufacturing plant shall be manned by staff whose knowledge of and qualifications in mixing technology are adequate;

c the producer shall be responsible for ensuring that:

— only feedingstuffs or combinations thereof which comply with Community provisions on feedingstuffs are used,

— the feedingstuff used produces a homogeneous and stable mix with the authorized medicated pre-mix,

— the authorized medicated pre-mix is used during the manufacturing process in accordance with the conditions laid down when authorization for placing on the market was given and, in particular, that:

(i) there is no possibility of any undesirable interaction between veterinary medicinal products, additives and feedingstuffs;

(ii) the medicated feedingstuff will keep for the stipulated period;

(iii) the feedingstuff to be used for producing the medicated feedingstuff does not contain the same antibiotic or the same coccidiostat as those used as an active substance in the medicated pre-mix;

— the daily dose of medicinal product is contained in a quantity of feedingstuff corresponding to at least half the daily feed ration of the animals treated or, in the case of ruminants, corresponding to at least half the daily requirement of nonmineral supplementary feedingstuffs;

d premises, staff and equipment used and participating in the entire manufacturing process must comply with the manufacturing hygiene rules and principles of the Member State in question; the manufacturing process must conform to the rules of good manufacturing practice;

e the medicated feedingstuffs manufactured shall undergo regular checks — including appropriate laboratory tests of homogeneity — by the manufacturing establishments, under the supervision and periodic control of the official department, to ensure that the medicated feedingstuff complies with the requirements of this Directive, especially in respect of its homogeneity, stability and storability;

f manufacturers shall be obliged to keep daily records of the types and quantities of the authorized medicated pre-mixes and feedingstuffs used and of the medicated feedingstuffs manufactured, held or dispatched, together with the names and addresses of the breeders or holders of the animals, and in the case provided for in Article 10 (2), the name and address of the authorized distributor and, where appropriate, the name and address of the prescribing veterinarian. The records, which must meet the requirements of Article 5 of Directive 81/851/EEC, must be kept for at least three years after the date

of the last entry and must be made available at any time to the competent authorities in case of checking;

g pre-mixes and medicated feedingstuffs shall be stored in suitable separate and secured rooms or hermetic containers which are specially designed for the storage of such products.

2 Member States may, by way of derogation from paragraph 1, subject to any additional guarantees appropriate, authorize the manufacture of medicated feedingstuffs on farms provided that the said paragraph is complied with.