COUNCIL

COUNCIL DIRECTIVE

of 16 July 1985

supplementing Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action

(85/358/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 43 and 100 thereof,

Having regard to Council Directive 81/602/EEC of 31 July 1981 concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action (1), and in particular Article 7 thereof,

Having regard to the proposal from the Commission (2),

Having regard to the opinion of the European Parliament (3),

Having regard to the opinion of the Economic and Social Committee (4),

Whereas Community control measures should be introduced to guarantee the uniform application, in all Member States, of the standards fixed in Directive 81/602/EEC ;

Whereas such control measures must cover the various phases running from manufacturing to the sale of the substances and the veterinary pharmaceutical preparations referred to in Directive 81/602/EEC ;

Whereas under Article 7 of Directive 81/602/EEC it is incumbent upon the Council to adopt in particular the detailed rules for carrying out controls covering farm animals in their farms of origin and at the slaughterhouse, and the meat of such animals and the meat products obtained therefrom ;

Whereas provisions should be made for the official taking of samples at the slaughterhouse ; whereas, furthermore, where there is a justified suspicion of infringement, provision should be made for the possibility taking such samples at the farm of origin ;

Whereas the analysis of samples must be carried out in an officially approved laboratory ;

Whereas, pending the adoption of a uniform Community method of analysis and reference methods, a common methodology should be adopted to be used in the event of dispute ;

Whereas, where the presence of prohibited substances or of the residues of such substances is confirmed, an investigation should be made at the farm of origin in order to exclude the meat in question from human and animal consumption and to place the prohibited substances under official control ;

Whereas in order to facilitate the implementation of the envisaged provisions, provision should be made for a procedure establishing close cooperation between the Member States and the Commission within the Standing Veterinary Committee set up by the Council Decision of 15 October 1968,

HAS ADOPTED THIS DIRECTIVE :

Article 1

The Member States shall ensure that official on-the-spot random controls are made on the substances referred to in Directive 81/602/EEC at the manufacturing, handling, storage, transport, distribution and sales stages for the presence of prohibited substances and veterinary pharmaceutical preparations containing prohibited substances which may be intended to be administered to animals for fattening purposes.

(1) OJ No L 222, 7. 8. 1981, p. 32.
(2) OJ No C 305, 22. 11. 1980, p. 2.
(3) OJ No C 50, 9. 3. 1981, p. 87.
(4) OJ No C 138, 9. 6. 1981, p. 29.

Article 2

Without prejudice to the controls provided for in Directives 64/433/EEC (1) and 72/462/EEC (2), Member States shall ensure that controls on farm animals, the meat of such animals and the meat products obtained therefrom are carried out within their territories, in accordance with the following Articles, in order to secure compliance in particular with the provisions of Directive 81/602/EEC.

Article 3

Member States shall ensure that :

1. where there is justified suspicion of an infringement, the competent departments make or arrange to have made :

   — random controls on animals on their farms of origin, particularly in order to detect traces of implants,

   — an official control for the presence of the substances the use of which is prohibited on farms where animals are reared, kept or fattened ;

   such controls may include the official taking of samples ;

2. random samples are taken from animals from fattening farms.

Article 4

Member States shall ensure that, at the slaughterhouse, before slaughter the animals are examined and that samples are taken officially to reveal the illegal use of the substances referred to in Directive 81/602/EEC or the presence of residues of such substances. Depending on the nature of the substances sought, these samples are to be taken from :

— live animals, including specimens of urine or controls of any remains of solid implants, or

— carcases after slaughter including a histopathological examination, or

— animals and meat.

Article 5

1. The samples referred to in Articles 3 and 4 shall be analysed in a laboratory approved by the competent authorities for the analysis of hormone residues.

2. Analysis of the samples provided for in paragraph 1 shall be carried out in accordance with methods to be determined in accordance with the procedure laid down in Article 11, within eighteen months of notification of this Directive.

Pending decisions to this effect, the Member States shall, in the event of dispute, recognize the findings obtained by radio-immunoassay (RIA) and by thin layer chromatography or by gas chromatography.

3. All positive findings must, if contested, be confirmed by an official laboratory duly approved for the purpose by the competent authorities, using the reference methods established by virtue of Article 4 (1) (b) of Directive 64/433/EEC.

Article 6

1. Where the analysis referred to in Article 5 confirms the presence of prohibited substances or of residues either exceeding the maximum natural physiological levels for the authorized substances or proving that authorized substances have been used abusively, the competent authorities shall be informed immediately of :

(a) all the particulars needed to identify the animal and its farm of origin. These particulars shall be determined in accordance with the procedure laid down in Article 10 ;

(b) the result of the analysis.

2. The competent authorities shall then ensure that :

(a) an investigation is made at the farm of origin to determine the reason for the presence of hormone residues ;

(b) an investigation of the source or sources of the substance concerned is made, as necessary, at the manufacturing, handling, storage, transport, distribution or sales stage.

3. The competent authorities shall also ensure that :

(a) the herd or animals at the farm of origin and the herds which, as a result of the investigations referred to in paragraph 2 may be considered to contain the residue in question, are officially marked and subjected to appropriate analysis ;

(b) if these analyses reveal the presence of prohibited substances, the animals may not be placed on the market for human or animal consumption ;

(c) if the analyses reveal the presence of residues of authorized hormone substances exceeding the limits mentioned in paragraph 1, the slaughter of the animals intended for human consumption shall be prohibited until it is possible to be sure that the residue level does not exceed the permitted limits. That period may in no case be shorter than the waiting period laid down for the

(1) OJ No L 121, 29. 7. 1964, p. 2012/64.
(2) OJ No L 302, 31. 12. 1972, p. 28.