II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 17 May 1988

on trade in animals treated with certain substances having a hormonal action and their meat, as referred to in Article 7 of Directive 88/146/EEC

(88/299/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 88/146/EEC of 7 March 1988 prohibiting the use in livestock farming of certain substances having a hormonal action (1), and in particular Article 7 thereof,

Having regard to the proposal from the Commission,

Whereas Directive 88/146/EEC prohibited the use in livestock farming of certain substances having a hormonal action, while permitting those exceptions already laid down in Article 4 of 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 (2), as last amended by Directive 85/358/EEC (3);

Whereas, in order to ensure the correct operation of the scheme as a whole, trade in animals which have treated, and of their meat has, in general, been prohibited; whereas, however, pursuant to Article 7 of Directive 88/146/EEC, derogations may be allowed in respect of intra-Community trade and importation from third countries of animals intended for reproduction and reproductive animals at the end of their career, which, in the course of their existence, have been treated under Article 4 of Directive 81/602/EEC and in respect of meat from those various animals;

Whereas such derogations may be allowed where satisfactory guarantees can be provided such as would not cause distortions of trade; whereas these guarantees must be given as regards the products which may be used, the conditions of their use and the control of such conditions in particular, regarding compliance with the necessary waiting period; whereas these requirements should be established in accordance with a Community procedure;

Whereas equivalent guarantees must be accepted, in accordance with a Community procedure, in respect of importations from third countries, taking into account the guarantees given by the third country concerned,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive lays down the conditions for applying the derogations provided for in Article 7 of Directive 88/146/EEC from the prohibition on trade in certain categories of animals and their meat.

Article 2

Notwithstanding Article 5 of Directive 88/146/EEC, Member States shall authorize trade in animals intended for reproduction and reproductive animals at the end of their career which, during their reproductive career, have undergone one of the treatments referred to in Article 4 of Directive 81/602/EEC, or shall authorize the affixing of the Community stamp to meat from such animals, provided the following conditions are complied with:

(1) OJ No L 70, 16. 3. 1988, p. 16.
(2) OJ No L 222, 7. 8. 1981, p. 32.
(3) OJ No L 191, 23. 7. 1985, p. 46.

1. Only one of the following substances or products has been administered to the animals:

   (a) for therapeutic treatment, oestradiol 17 B, testosterone and progesterone and those derivatives which readily yield the parent compound on hydrolysis after absorption at the site of application and which, in accordance with Article 3 of Directive 88/146/EEC, appear on the list of products to be drawn up in compliance with the other conditions laid down in Article 3 (1) (a) and (b);

   (b) for synchronization of oestrus, termination of unwanted gestation, the improvement of fertility and the preparation of donors and recipients for the implantation of embryos, the substances mentioned in Article 4 (1) of Directive 81/602/EEC, provided that the products in which they are contained appear on a list drawn up in accordance with the procedure provided for in Article 8 of Directive 88/146/EEC after the Committee for Veterinary Medicinal Products has given its opinion, and in accordance with the conditions set out in point 2 below.

2. In the case referred to in point 1 (b):

   — the conditions of use, in particular the conditions under which these products are made available to breeders, the necessary waiting period and detailed provisions concerning the monitoring of those conditions of use, shall be laid down in accordance with the procedure referred to in point 1 (b),

   — the means of identification of animals shall be laid down in accordance with the procedure provided for in Article 8 of Directive 88/146/EEC.

   Pending the decisions referred to in point 1 (a) and (b), products which have already received authorization to be placed on the market shall continue to be so authorized.

3. The following criteria shall be considered at the time of adoption of the lists of products referred to in point 1 which may be administered to the animals defined in that point and intended for intra-Community trade:

   — possibility of monitoring that that product is used in conformity with the provisions of this Directive,

   — the need to exclude sustained-release products or salts or esters with long half-life, where the therapeutic objective could be achieved by using products with a shorter half-life which, by reason of their composition, do not act as a deposit, so as to preclude the use of hormones as growth factors and reduce the risk of residues,

   — the need to exclude products with a waiting period exceeding 15 days after the end of the treatment,

   — the availability of reagents and materials required for the methods of analysis for detecting the presence of residues exceeding the permitted limits.

   Products authorized pursuant to the above paragraph shall be subject to Articles 24 to 50 of Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products [1].

4. The veterinarian directly responsible must keep a register of at least the following particulars:

   — nature of the treatment,

   — nature of the products authorized,

   — date of the treatment,

   — identity of the animals treated.

   These particulars shall be made available to the competent authority at its request.

Article 3

1. Member States shall ensure that the animals mentioned in Article 2 are sent from their territory to the territory of another Member State only if:

(a) the general conditions laid down in this Directive and in particular the waiting period laid down pursuant to the second indent of Article 3 (a) of Directive 88/146/EEC and to Article 2 (2) of this Directive have been complied with;

(b) in the case of reproductive animals at the end of their career, they have not received any of the treatments referred to in Article 4 of Directive 81/602/EEC with any of the products authorized in accordance with Article 2 (1) (a) or (b) or Article 6 during the fattening period following the end of their breeding life.

2. However, trade in high-value horses, particularly racehorses, competition horses, circus horses or horses intended for stud purposes or for exhibitions, including horses in these categories to which oral preparations containing allyl Trenbolone have been administered for the purposes mentioned in Article 2 (1) (b), may take place before the end of the waiting period, provided that the other conditions of Article 2 are fulfilled and that the nature and date of the treatment are mentioned on the certificate accompanying the horses.

Article 4

Without prejudice to the application to the requirements of Directive 86/469/EEC of 16 September 1986 concerning the examination of animals and fresh meat for the presence of residues [2], and by way of derogation from the first paragraph of Article 5 of Directive 88/146/EEC, Member States shall authorize trade in meat of animals intended for reproduction and of reproductive animals at the end of their career which might have been the subject of intra-Community trade in accordance with Article 3 (1) of this Directive.

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[1] OJ No L 317, 6. 11. 1981, p. 1.
[2] OJ No L 275, 26. 9. 1986, p. 36.

The Community stamp may be affixed to the meat only if the waiting time has ended before the animals are slaughtered.

Article 5

By way of derogation from Article 6 (1) of Directive 88/146/EEC and for the purposes of applying Article 7 (2) of Directive 86/469/EEC, guarantees at least equivalent to those laid down by this Directive shall be established in accordance with the procedure provided for in Article 8 of Directive 88/146/EEC, which imports from third countries of animals intended for reproduction and reproductive animals at the end of their career or the meat of such animals must satisfy.

Article 6

Pending the decisions provided for in Article 2 (1) (a) and (b), the following transitional measures shall apply:

— Member States shall monitor compliance of the substances or products which have been the subject of a national authorization for placing on the market with the requirements of Article 2 (3). They shall notify the Commission and the other Member States of their findings, within the Standing Veterinary Commitee,

— on the basis of these findings, the Commission shall, under the procedure laid down in Article 11 of Directive 85/358/EEC draw up a provisional list of substances or products which may be used for the requirements of this Directive, and the conditions and means laid down in Article 2 (2).

Animals treated with these substances or products included in the provisional list or lists, and the meat of those animals, cannot be the subject of trade barriers.

The provisional lists shall cease to be valid after 31 December 1991.

Article 7

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 1988 at the latest. They shall forthwith inform the Commission thereof.

Article 2 (1) and Articles 3, 4 and 6 shall apply from the notification (1) of this Directive.

Article 8

This Directive is addressed to the Member States.

Done at Brussels, 17 May 1988.

For the Council

The President

I. KIECHLE

(1) This Directive was notified to the Member States on 20 May 1988.