COUNCIL DIRECTIVE

of 31 December 1985

prohibiting the use in livestock farming of certain substances having a hormonal action

(85/649/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas the administration to farm animals of certain substances having a hormonal action is at present regulated in different ways in the Member States; whereas while their immediate effect on animals from the farmer's point of view is clear, assessments of their effect on human health vary and this is reflected in the regulations governing their use; whereas this divergence distorts the conditions of competition in products that are the subject of common market organizations and is a serious barrier to intra-Community trade;

Whereas these distortions of competition and barriers to trade must therefore be removed by ensuring that all consumers are able to buy the products in question under largely identical conditions of supply and that these products correspond to their anxieties and expectations in the best possible manner; whereas such a course of action is bound to bring about an increase in consumption of the product in question;

Whereas the use of hormonal substances for fattening purposes should therefore be prohibited; whereas the use of certain substances for therapeutic purposes may be authorized but must be strictly controlled in order to prevent any misuse of them;

Whereas, furthermore, since it would be difficult to be certain of correct operation of the scheme as a whole if animals so treated and the meat from such animals were to be traded, this should as a general rule be prohibited; whereas, however, derogations from this rule may be allowed where satisfactory guarantees can be provided;

Whereas as part of the adoption of harmonized rules in the Community arrangements for importation from third countries that offer equivalent guarantees should be introduced; whereas these guarantees can be required under Directives 72/462/EEC (3) and 85/358/EEC (4);

Whereas in order to ensure that the provisions of this Directive can be implemented effectively the latest date for introduction of the provisions of Directive 85/358/EEC should be made to fall before that for introduction of the provisions of this Directive; whereas Community control measures should ensure uniform application in all Member States of the rules applicable on administration of substances having a hormonal or thyrostatic action,

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(1) OJ No C 288, 11. 11. 1985, p. 158.

(2) OJ No C 44, 15. 2. 1985, p. 14.

(3) OJ No L 302, 31. 12. 1972, p. 28.

(4) OJ No L 191, 23. 7. 1985, p. 46.

HAS ADOPTED THIS DIRECTIVE:

Article 1

For the purposes of implementation of this Directive the definitions ot meats and of farm animals given in Article 1 of Directive 81/602/EEC (1) shall apply.

For the purposes of implementation of this Directive and of Directive 81/602/EEC 'therapeutic treatment' shall mean the administering to an individual farm animal of any of the substances authorized in Article 3 of this Directive to treat a fertility problem diagnosed, on examination, by a veterinarian. Such therapeutic treatment shall be prohibited for animals intended for fattening.

Article 2

Without prejudice to Article 4 of Directive 81/602/EEC, Member States may not authorize any derogation from Article 2 of the said Directive. However, the administering to farm animals for therapeutic purposes of oestradiol -17-β, testosterone and progesterone and those derivatives which readily yield the parent compound on hydrolysis after absorption at the site of application may be authorized.

Article 3

For the purposes of implementation of this Directive:

(a) there shall be established, after the Committee for Veterinary Medicinal Products has given its opinion on the measures provided for in the first two indents, and in accordance with the procedure laid down in Article 8 :

— a list of the products containing as active substances the substances referred to in Article 2 and satisfying the relevant principles and criteria of Directive 81/851/EEC (2) and 81/852/EEC (3) that may be authorized by the Member States,

— the conditions of use of these products, in particular the waiting period necessary and detailed provisions concerning the control of these conditions of use,

— the means of identification of animals.

Pending the decisions referred to in the first subparagraph, products which have already received authorization to be placed on the market shall continue to be authorized.

Products authorized pursuant to the above provisions shall be subject to the rules of Articles 24 to 50 of Directive 81/851/EEC, with the exception of those which relate to national marketing authorizations;

(b) products used for therapeutic treatment may be administered only by a veterinarian, in the form of an injection — to the exclusion of implantation — to farm animals which have been clearly identified.

Treatment of identified animals must be registered by the veterinarian. An animal which has been treated may not be slaughtered before expiry of the period fixed pursuant to the provisions set out in (a);

(c) any decision on the possible inclusion in the group of substances referred to in Article 2 of any new substance having a direct or indirect oestrogenic, androgenic or gestagenic action shall be taken by the Council acting on a proposal from the Commission in accordance with the voting procedure laid down in Article 43(2) of the Treaty. Any new substance must, in order to be able to be subject to such a decision, satisfy the relevant principles and criteria of Directives 81/851/EEC and 81/852/EEC.

Article 4

The Member States shall prescribe that undertakings producing substances having a thyrostatic, oestrogenic, androgenic or gestagenic action and those authorized for whatever purpose to market those substances, and undertakings producing pharmaceutical and veterinary products based on those substances, must keep a register detailing, in chronological order, quantities produced or acquired and those sold or used for the production of pharmaceutical and veterinary products.

Article 5

Member States must ensure, that no animals are dispatched from their territory to that of another Member State which have had administered to them in any way whatsoever substances with a thyro-

(1) OJ No L 222, 7. 8. 1981, p. 32.
(2) OJ No L 317, 6. 11. 1981, p. 1.
(3) OJ No L 317, 6. 11. 1981, p. 16.