II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 7 March 1988

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

(88/146/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 provisons 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,

HAS ADOPTED THIS DIRECTIVE:

Article 1

For the purposes of implementation of this Directive the definitions of meats and of farm animals given in Article 1 of Directive 81/602/EEC (5) shall apply.

(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.
(5) OJ No L 222, 7. 8. 1981, p. 32.

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-ß, 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 [1] and 81/852/EEC [2] 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 provisons 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 purposes 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 thyrostatic, oestrogenic, androgenic or gestagenic action, and that no meat from such animals is dispatched. They shall reserve the Community stamp for meat from untreated animals.

With effect from the date of notification of this Directive and until the measures adoped pursuant to Article 2 and 6 are applicable:

— national provisions governing produce intended for Member States' domestic markets shall not be affected,

— Member States which prohibit the use of the substances referred to in Article 5 of Directive 81/602/EEC of fattening may restrict entry into their territory to untreated fattening animals and meat from untreated fattening animals.

Article 6

1. Member States shall prohibit importation from third countries of animals and of meat from animals to which have been administered in any way whatsoever substances with a thyrostatic, oestrogenic, androgenic or gestagenic action.

[1] OJ No L 317, 6. 11. 1981, p. 1.
[2] OJ No L 317, 6. 11. 1981, p. 16.

2. To this end the decisions to be taken for implementation of Directive 72/462/EEC, taking account of Article 13 of Directive 85/358/EEC in the case of meat and of the equivalent guarantee in the case of live animals, must be adopted before 1 January 1988.

3. Member States shall ensure that imported fresh meat coming from approved slaughterhouses in third countries in respect of which a decision within the meaning of paragraph 2 has been taken is, without prejudice to animal health measures, circulated in the Community in accordance with Article 25 of Directive 72/462/EEC.

4. National rules on substances with a hormonal action dealing with imports from third countries shall remain applicable, with due regard for the general provisions of the Treaty, until each of the decisions referred to in paragraph 2 comes into force.

5. As from 1 January 1988, Member States shall suspended imports coming from third countries in respect of which no decision within the meaning of paragraph 2 has been taken.

6. For the purposes of application of paragraphs 1 to 5, the Commission shall draw up a list of the products authorized by third countries for the therapeutic treatments referred to in Article 4 of Directive 81/602/EEC.

7. In accordance with the producedure laid down in Article 8, a control programme shall be drawn up regarding imports from third countries, to ensure that imports do not receive more favourable treatment than Community products.

With regard to routine inspections, this programme:

— will establish the frequency of controls on imports from each third country,

— will take account of the guarantees offered by the inspection regulation of third countries.

In the event of positive results, imports from third countries will be subject to systematic inspections until the situation is re-established.

Article 7

The Council, acting by a qualified majority on a proposal from the Commission, may adopt derogations from Articles 5 and 6 in respect of trade in animals intended for reproduction and reproductive animals at the end of their career which, in the course of their existence, have been treated unter the provisions of Article 4 of Directive 81/602/EEC and in respect of meat from these various animals, taking into account the guarantees given.

Article 8

1. Where the procedure laid down in this Article is to be used, matters shall without delay be referred by the Chairman, either on his own initiative or at the request of a Member State, to the Standing Veterinary Committee (hereinafter called 'the Committee') set up by the Council Decision of 15 October 1968.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by a majority of 54 votes, the votes of the Member States being weighted as provided for in Article 148 (2) of the Treaty. The Chairman shall not vote.

3. The Commission shall adopt the measures and implement them immediately where they are in accordance with the opinion of the Committee. Where they are not in accordance with the opinion of the Committee or if no opinion is delivered, the Commission shall immediately submit to the Council a proposal on the measures to be taken. The Council shall act by a qualified majority.

If within three months of the date on which a matter was referred to it the Council has not adopted any measures, the Commission shall adopt the proposed measures and implement them immediately, save where the Council has decided against the measures by a simple majority.

Article 9

The measures necessary to ensure the transition to the final arrangements extending the ban laid down in Article 2 to domestic production may be adopted in accordance with the procedure laid down in Article 8 during a maximum period of one year.

Article 10

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply:

— with Directive 85/358/EEC, by 1 January 1987 at the latest;

— with this Directive, by 1 January 1988 at the latest.

They shall immediately inform the Commission thereof.

Article 11

This Directive is addressed to the Member States.

Done at Brussels, 7 March 1988.

For the Council

The President

I. KIECHLE