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# COMMISSION OF THE EUROPEAN COMMUNITIES

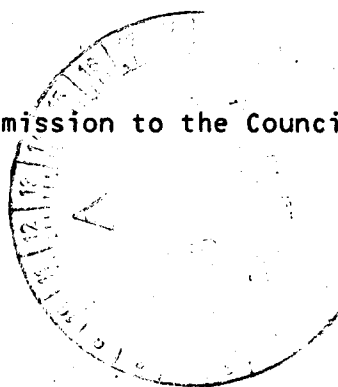
COM(80) 614 final

Brussels, 31st October 1980

PROPOSAL FOR A COUNCIL REGULATION (EEC)  
CONCERNING THE USE OF SUBSTANCES WITH A HORMONAL ACTION AND  
THOSE HAVING A THYROSTATIC ACTION IN DOMESTIC ANIMALS

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(presented by the Commission to the Council)



COM(80) 614 final

## EXPLANATORY NOTE

At its meeting of 30th September the Council invited the Commission to submit urgent proposals concerning substances with hormonal effect in animal production following its recent favourable orientation :

- envisaging the prohibition of the use of all hormonal substances for rearing animals and in consequence their presence in meat produced or imported into the Community,
- recognising the necessity to accelerate the work of harmonisation in this field, in order to provide uniform and reinforced controls not only at the level of the final product (by fixing levels for residues and methods of analysis) but also upstream at the level of production and distribution of hormones (rules concerning distribution of veterinary medicines) and at the place of livestock rearing and at the abattoirs.

The Commission has examined the subject of the use of hormones in animal production, the presence of these substances in meat and meat products, their possible effects on human health and the quality of the products. This examination has included both natural and artificial hormones.

The Commission considers that rapid action must be taken to prohibit the use of these substances for rearing animals. This is necessary in particular in respect of the artificial substances in view of the effects of these substances in relation to carcinogenicity, physiological effects and meat quality. The latter aspect is also important as regards use of natural substances since physiological effects may also occur when exposure to exceptional levels accidentally takes place. The need for control is obvious.

Although Member States already have national measures in force, it is clear that no control system will be fully effective unless it is developed and applied on a Community basis. These rules are needed so that trade of animals and fresh meat can flow unimpeded within the Community.

These controls need to be applied at the level of distribution of the products, at the level of the place of production in respect of livestock, and at the abattoirs producing fresh meat. As regards the production and distribution of hormones existing initiatives at Community level must be completed and where necessary extended. The Commission recalls that it made a proposal in respect of veterinary medicines in 1976. As a result of discussion of this proposal, the Commission considers that it should also include a provision that hormonal substances which can be used in the preparation of veterinary medicines should be supplied only to authorised persons. The Commission urges the Council to resolve this question and take an early decision.

A related initiative which the Commission is urgently considering concerns a draft proposal on medicated feedingstuffs. It is already necessary, however, to provide for controls on the distribution and use of hormones for veterinary therapeutic purposes.

To support this primary control, measures must be adopted to monitor live animals on the farm for illicit use of these substances. This action will need appropriate sampling procedures adopted to the different animal categories, and suitable sanctions in case of infringements.

A further strategic point where control must be considered is at the slaughterhouse, in the form of screening fresh meat for residues as part of the post-mortem examination. The extension of this examination to ante-mortem inspection of the live animal either at the slaughterhouse or farm of origin will probably provide a more effective control. In all cases it is essential to provide a common regulation for laboratory methods which must be used for these examinations. In addition, to enable tracing of the origin of animals when positive results are found, the establishment of a system to permit the identification of animals in the Community is important.

The work already done by the Commission in respect of the problems of control has concentrated particularly on methods of analysis. Good methods which are suitable both qualitatively and quantitatively are not easily developed but recent progress should enable the Commission to take appropriate action shortly in this respect particularly as regards artificial substances which are of special concern. This question is more difficult in respect of natural hormones as there is always a certain level of these hormones naturally present in meat animals. In consequence the development of checks on the use of these substances is more difficult.

In order to avoid distortion of competition it is necessary to provide for the harmonisation of the means of financing these controls. To this effect provision is included so that these costs must be borne by the product itself.

The proposal of the Commission lays down the basis for these controls.

The introduction of a ban at the Community level, and of the necessary control measures, will involve additional costs of production which may eventually be reflected in the long term on the price of meat. But at the same time consumers will be assured of better protection and a better quality product.

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PROPOSAL  
for a  
COUNCIL REGULATION  
concerning the use of substances with a hormonal  
action and those having a thyrostatic action in  
domestic animals

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;

Having regard to the Opinion of the Economic and Social Committee;

Whereas due to the residues that they leave in meat, substances with a hormonal action or thyrostatic action may be dangerous to human health; whereas these substances may also affect the quality of the meat;

Whereas for these reasons, their use for fattening purposes must be banned, in the interest of the consumer;

Whereas, moreover, if the use of natural substances may be authorised for therapeutic purposes, this must be at the same time strictly controlled, both by the establishment of a list of authorised products and by the establishment of the conditions under which they may be used; whereas the particular danger of artificial substances does not permit their inclusion under this autorisation;

Whereas the present Regulation calls for means of application in particular concerning the fixing of tolerances, frequency of sampling and methods used to detect the presence of residues;

Whereas means permitting the assurance of an effective control of Community provisions and of the application of the necessary sanctions must be established;

Whereas it is suitable, in order to avoid distortion of competition, to provide that the costs resulting from this control must be borne by the product itself in conformity with the current practice generally followed in the Community,

HAS ADOPTED THIS REGULATION :

#### Article 1

This Regulation shall apply to the use of substances with a hormonal action and those having a thyrostatic action in domestic animals and to the presence of residues of these substances in domestic animals, fresh meat and fresh poultry meat.

#### Article 2

For the purposes of this Regulation the following definitions shall apply :

- (a) Domestic animals : animals of the following species : bovine, swine, sheep, goats, domestic solipeds and poultry.
- (b) Fresh meat : fresh meat as defined in Article 1 of Directive 64/433/EEC and in Article 2 of Directive 72/462/EEC,
- (c) Fresh poultrymeat : fresh poultrymeat as defined in Article 1 of Directive 71/118/EEC.
- (d) Residue : detectable quantities of a substance with a hormonal or thyrostatic action and their metabolites.
- (e) Examination for residues : the examination for detection of residues.
- (f) Tolerance : the maximum permitted quantity of residue in domestic animals or in fresh meat.
- (g) Holding : an officially supervised agricultural, industrial or commercial undertaking in which domestic animals are regularly kept.



Article 3

Notwithstanding Article 4,

- (a) The use on domestic animals of substances with oestrogenic, androgenic and gestagenic effect and of substances having a thyrostatic effect is prohibited.
- (b) The putting into trade in the territory of the Community of domestic animals and of fresh meat containing residues in excess of the tolerance is prohibited.

Article 4

1. The use of natural hormonal substances with actions or effects referred to in Article 3(a) is authorised to treat domestic animals therapeutically including synchronisation of oestrus provided that :
  - the competent authority has approved the product for therapeutic use and its conditions of manufacture in accordance with Council Directive on the approximation of the laws of Member States on medicinal veterinary products, and has specified the conditions of use including a withdrawal period during which the domestic animal cannot be delivered for slaughter,
  - the product is administered by a veterinarian, who shall keep a record of the use of the product, including quantity date and identification of the treated domestic animal,
  - manufacturers and all handlers of these substances shall keep a record of production and sales.
2. Additional provisions concerning the application of paragraph 1, in particular the establishment of a Community List of natural hormonal substances, shall be adopted by the Council acting by a qualified majority on a Proposal from the Commission. This List may be amended in accordance with the procedure of Article 9.

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Article 5

1. Fresh meat put into trade in the Community must be subject to examination for residues of the substances referred to in Article 3.
2. However, the examination of the fresh meat may be replaced or supplemented by an examination of the domestic animal either at the place of slaughter or at the holding of origin or transit.
3. The Council, acting by a qualified majority on Proposal from the Commission, shall decide the general rules for the application of paragraphs 1 and 2 in particular :
  - the frequency of sampling,
  - the tolerances for residues.
4. The methods and procedures required for detecting the presence of residues of the substances shall be decided in accordance with the procedure laid down in Article 9.

Article 6

Domestic animals covered by this Regulation must be registered or identified to permit investigation where necessary at the holding of origin or transit.

Article 7

All costs for the controls and examinations provided for in Article 5 shall be borne by a tax on the product at the slaughterhouse without reimbursement from public funds.

Article 8

Member States shall ensure that, in case of contravention of the present Regulation:

- domestic animals and fresh meat concerned are confiscated and destroyed,
- sanctions are applied to all persons contravening the present Regulation.

Article 9

This Regulation shall not apply to the use of substances for the purposes of Research.

Article 10

1. Where the procedure laid down in this Article is to be used, the matter shall be referred without delay to the Standing Veterinary Committee (hereinafter referred to as 'the Committee'), set up by the Council Decision of 15 October 1968, by the chairman, either on his own initiative or at the request of a Member State.
2. Within the Committee, the votes of the Member States shall be weighted as provided in Article 148(2) of the Treaty. The chairman shall not vote.
3. The Commission representative shall submit a draft of the measures to be adopted. The Committee shall deliver its opinion on the measures within a period to be determined by the chairman in keeping with the urgency of the question submitted for examination. Opinions shall be delivered by a majority of 41 votes.
4. The Commission shall adopt the measures and shall 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 without delay submit to the Council a proposal on the measures to be adopted. The Council shall adopt the measures by a qualified majority.

If the Council has not adopted any measures within three months from the date on which the proposal was submitted to it, the Commission shall adopt the proposed measures and apply them immediately.

Article 11

This Regulation shall enter into force on 1 January 1981.

This Regulation shall be binding in its entirety and directly applicable in all Member States.