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REPORT

drawn up on behalf of the Committee on the Environment, Public Health and Consumer Protection

on the proposal from the Commission of the European Communities to the Council (Doc. 1-359/84 - COM (84) 295 final) for a Directive amending Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action

Rapporteur: Mr R. COLLINS

PE 95.615/fin.
Or. En.

By letter of 11 July 1984, the President of the Council of the European Communities requested the European Parliament to deliver an opinion pursuant to Article 43 of the EEC Treaty, on the proposal from the Commission of the European Communities to the Council for a Directive amending Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action.

On 24 July 1984, the President of the European Parliament referred this proposal to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Committee on Agriculture, Fisheries and Food for an opinion.

At its meeting on 20 September 1984, the Committee on the Environment, Public Health and Consumer Protection appointed Mr COLLINS rapporteur.

The committee considered the Commission's proposal and the draft report at its meetings of 21 November 1984, 19 December 1984, 28 February 1985 and 26 June 1985. At the last meeting, the rapporteur withdrew the draft report and agreed to submit a revised text by the end of July.

At its meeting of 19 September 1985, the committee considered the revised draft report and decided unanimously to recommend to Parliament that it approve the Commission's proposal with the following amendments.

The committee decided to reserve the right to propose to Parliament the application of Rule 35(3), after having heard the opinion of the Commission.

The committee then unanimously adopted the motion for a resolution as a whole.

The following took part in the vote: Mrs Weber, chairman; Mr Collins, vice-chairman and rapporteur; Mr Avgerinos (deputising for Mr Bombard), Mrs Banotti, Mr Cottrell, Mr Dalsass (deputising for Mr Alber), Mr Elliott (deputising for Mr Schmid), Mr Falconer (deputising for Mr Tognoli), Mrs van Hemeldonck (deputising for Miss Tongue), Mr Hughes, Mrs Jackson, Mr van der Lek, Mrs Lentz-Cornette, Mr Mertens, Mr Muntingh, Mr Nordmann, Mr Parodi, Mr Pearce, Mr Roelants du Vivier, Mr Schwalba-Hoth (deputising for Mrs Bloch von Blottnitz), Mr Sherlock, Mrs Squarcialupi, Mr Stevenson (deputising for Mr Vittinghoff) and Mrs Veil.

The opinion of the Committee on Agriculture, Fisheries and Food is attached.

The report was tabled on 26 September 1985.

The deadline for tabling amendments to this report will be indicated in the draft agenda for the part-session at which it will be debated.

C O N T E N T S

The Committee on the Environment, Public Health and Consumer Protection hereby submits to the European Parliament the following amendments to the Commission's proposal and motion for a resolution together with explanatory statement:

Proposal for a Council Directive amending Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action.

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
	Amendment No.1
Title	Title
Proposal for a Council Directive amending Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action	Proposal for a Council Regulation amending Directive 81/602/EEC concerning the prohibition .....
Recitals 1 to 6 unchanged	
	Amendment No.2
Recital 7	Recital 7
Whereas, on scientific grounds, it appears that the use of Oestradiol 17B, Testosterone and those derivatives which readily yield the parent compound on hydrolysis after absorption from the site of application would not present any harmful effects to the health of the consumer nor harm the consumer by altering the characteristics of meat when used under the appropriate conditions as growth promoters in farm animals; whereas, in consequence, Member States may authorise their use for fattening purposes;	Delete and replace with: 7 (a) Whereas since 1981 differences have existed in national regulations concerning Oestradiol 17B, Progesterone, Testosterone, Zeranol and Trenbolone; considering that scientific information about these substances is far from complete and that considerable doubt therefore exists about the desirability of their use and of their effect on human health; 7 (b) Whereas, in particular, there seems to be doubt as to the effects on the immunity against various diseases of animals treated with hormone cocktails and that this in turn may lead to an increased use of antibiotics;

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
	7 (c) Whereas, however, it will be very difficult, if not impossible, to carry out conclusive checks on the use of non-authorised hormones so as to protect the safety of consumers,
	7 (d) Whereas there is overproduction of meat and meat products in the European Community which adds considerably to the cost of the CAP:
	7 (e) Whereas the authorisation of the hormones Oestradiol 17B, Testosterone and Progesterone, like Trenbolone and Zeranol, is neither necessary or desirable, except for therapeutic purposes[1];
	Amendment No.3
Recital 8	Recital 8
Whereas approval of products containing authorised substances must comply with the relevant principles and criteria set out in Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products[6], and Council Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products[7];	Delete
	Amendment No.4
Recital 9	Recital 9
Whereas additional requirements as regards carrier substances, conditions of use and withdrawal periods must also be complied with; whereas a Community procedure within the Standing Veterinary Committee, set up by Council Decision of 15 October 1968[8], should be used to establish a list of products which may be approved and the conditions of their use, as well as to modify the list of authorised substances in the light of progress in scientific and technical knowledge;	Delete

[1] The terms "therapeutic purposes" as used throughout the text of this report should be understood to mean "action of remedial agents in disease"

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
	Amendment No.5
Recital 10	Recital 10
Whereas Member States may choose not to allow in their territory the marketing and administration to farm animals, for fattening purposes, of substances and products which may be authorised under the present Community rules, but must not raise any obstacle for human health reasons to the importation of animals, meat and meat products from other Member States where such substances and products have been authorised in accordance with Community rules;	Delete
Recital 11 unchanged	
	Amendment No.6
Article 1(1)	Article 1(1)
Article 5 is replaced by the following:	New Article 5(1) to read:
"Article 5	
1. By way of derogation from Article 2, Member States may authorise the administering to farm animals, for fattening purposes, of Oestradiol 17B, Testosterone and Progesterone and those derivatives which readily yield the parent compound on hydrolysis after absorption form the site of application."	1. Without prejudice to Article 4(1) no derogation may be made from Article 2 except insofar as Member States may authorise the administering to farm animals for therapeutic purposes of Oestradiol 17B, Testosterone and Progesterone and those derivatives which readily yield the parent compound on hydrolysis after absorption from the site of application.
	Amendment No.7
Article 1(1)	Article 1(1)
Article 5(2)	Article 5(2) to read:
2. Member States shall ensure that the aforementioned substances are: - only administered to farm animals by implantation which is located in a part of the animal which must be discarded at slaughter, - only administered to animals which are identified at the time of implantation and that these animals	2. Member States shall ensure that the aforementioned substances are only administered to farm animals that have been clearly identified, that the dosage is recorded and that the animal is not slaughtered before the expiry of the delay period laid down in application of subparagraph 3a. The substances must be administered only by a veterinary surgeon or by a person acting under his direction.

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
are not slaughtered before the expiry of the delay period laid down in application of subparagraph 3a)	
- administered by a veterinarian.	
	Amendment No.8
Article 1(1)	Article 1(1)
Article 5	Article 5
3 a) Before 1 April 1986 in accordance with the procedure laid down in Article 16 and following the relevant principles and criteria of Directives 81/851/EEC and 81/852/EEC there shall be established:	3 a) Before 1 April 1986 in accordance with the procedure laid down in Article 16 and following the relevant principles and criteria of Directives 81/851/EEC and 81/852/EEC there shall be established:
- a list of products containing as active substances the substances referred to in paragraph 1 which may be approved for marketing and use in the Community,	- a list of products containing as active substances the substances referred to in paragraph 1 which may be approved for marketing and use for therapeutic purposes in the Community,
- the conditions of use of products contained in the abovementioned list of paragraph 2, in particular the delay period necessary and detailed provisions concerning the control of these conditions of use,	rest unchanged
- the means of identification of animals.	
Article 5. 3(b) unchanged	
	Amendment No.9
Article 1(1)	Article 1(1)
Article 5	Article 5
4. In order to take account of scientific and technical progress, the list of substances referred to in paragraph 1 which may be administered to animals for fattening purposes, may be completed or amended in accordance with the procedure laid down in Article 16.	4. In order to take account of scientific and technical progress, the list of substances referred to in paragraph 1 which may be administered to animals for therapeutic purposes, may be completed or amended .....
Any substance which may be authorised:	rest unchanged
- must have a favourable effect on farm animal production,	

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
Article 5(4) continuation	
- must not endanger human or animal health nor harm the consumer by altering the characteristics of farm animal products,	
- must comply with the relevant principles and criteria of Directives 81/851/EEC and 85/852/EEC.	
	Amendment No.10
Article 1(1)	Article 1(1)
Article 5	Article 5
5. However, any decision concerning the possible inclusion of Trenbolone or Zeranol on the list shall be made by the Council, acting by a qualified majority on a proposal from the Commission, and in conformity with the other conditions laid down in paragraph 4.	5. However, any decision concerning the possible inclusion of Trenbolone or Zeranol on the list shall be made by the Council, acting by a qualified majority on a proposal from the Commission, after consultation with the European Parliament, and in conformity with the other conditions laid down in paragraph 4.
Article 1(2) Articles 7 to 11 unchanged	
	Amendment No.11
Article 1(2)	Article 1(2)
Article 12	Article 12
1. Where examination as referred to in Article 11(3) has confirmed the presence of prohibited substances or of residues exceeding the maximum natural physiological levels of authorised substances, the competent authorities shall be informed without delay of:	1. Where examination as referred to in Article 11(3) has confirmed the presence of prohibited substances or of residues exceeding the maximum natural physiological levels of authorised substances (these levels to be published by the Commission), the competent authorities shall be informed without delay of:
a) all information needed to identify the origin of the animals,	rest unchanged
b) the result of the examination.	
Article 12(2) unchanged	
Article 12(3) (a) and (b) unchanged	

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
	Amendment No.12
Article 12	Article 12
3 (c) if the examination reveals the presence of residues of authorised substances above the limits mentioned in paragraph 1, the slaughter of the animals concerned for human consumption shall be prohibited until it can be ensured that the amount of residue no longer exceeds the permitted levels. This period may in no case be shorter than the delay period fixed for the substance in application of Article 5(3) (a). However, where it is ascertained that the conditions of use laid down have not been complied with, the animals concerned shall be confiscated or destroyed.	3 (c) if the examination reveals the presence of residues of substances which have been authorised for use for therapeutic purposes above the limits mentioned in paragraph 1, the slaughter of the animals concerned for human consumption shall be ....

Articles 12(3) (d) and 12(4) unchanged

Articles 13 to 15 unchanged

	Amendment No.13
Article 16	Article 16
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 initiative or at the request of a Member State, to the committee.	1. Where the procedure laid down in this Article is to be used, the Commission shall transmit any proposed amendments to the European Parliament at least three months or two part-sessions, whichever is the greater period, before the adoption of such amendments is required.
2. Within the committee, the votes of Member States shall be weighted as provided in Article 148 of the Treaty. The chairman shall not vote.	2. Where the European Parliament informs the Commission that it wishes to give an opinion on such proposed amendments, their adoption shall be postponed for an additional three months or two part-sessions, whichever is the greater period.

Text proposed by the Commission of the European Communities	Amendments tabled by the Committee on the Environment, Public Health and Consumer Protection
	Article 16 (cont'd...)
3. The representative of the Commission shall submit a draft of the measures to be adopted. The committee shall deliver its opinion on such 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 45 votes.	3. The Commission shall adopt the measures envisaged where they are in accordance with the opinion of the European Parliament or if no such opinion is adopted.
4. 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, without delay, propose to the Council the measures to be adopted. The Council shall adopt the measures by a qualified majority. If, within three months from 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 these measures by a simple majority.	4. Where the measures envisaged are not in accordance with the opinion of the European Parliament, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by a qualified majority. 5. If, within three months of the proposals being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.
	Amendment No.14
Article 2	Article 2
Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive - not later than 1 July 1985 as regards the prohibition of the administration of Trenbolone and Zeranol to farm animals for fattening purposes, in application of Articles 2 and 5 of Directive 81/602/EEC, as amended by Article 1(1) of this Directive, - not later than 1 July 1986 for the remaining provisions. They shall forthwith inform the Commission thereof.	Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Regulation - not later than 1 January 1986 They shall forthwith inform the Commission thereof.

closing the procedure for consultation of the European Parliament on the proposal from the Commission of the European Communities to the Council for a directive amending Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action

The European Parliament,

- having regard to the proposal from the Commission to the Council (COM(84) 295 fin.)[1],
- having been consulted by the Council pursuant to Article 43 of the EEC Treaty (Doc.1-359/84),
- having regard to its previous resolution concerning the use of anabolic agents of 13 February 1981[2],
- having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the opinion of the Committee on Agriculture, Fisheries and Food (Doc. A 2-100/85),
- having regard to the result of the vote on the Commission's proposal,

A. whereas protection of public health and the interests of the consumer are major concerns of the Community;

B. whereas it is essential therefore for the Community to produce food of the highest quality which will have no harmful effects on human health;

C. whereas it is also essential for these standards to apply to food which is imported for consumption in the Community;

D. considering that anabolics have been widely used in many countries for some 30 years as therapeutic substances as well as growth promoters;

E. considering that scientific information about these substances is far from complete and that considerable doubt therefore exists about the desirability of their use and of their effect on human health;

F. whereas, in particular, there seems to be doubt as to the effects on the immunity against various diseases of animals treated with hormone cocktails and that this in turn may lead to an increased use of antibiotics;

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[1] OJ No.C170 29.6.1984, p.4 and OJ No.C106, 27.4.1985, p.7
[2] OJ No.C 50 9.3.1981, p.87

G. whereas since 1981 differences have existed in national regulations concerning Oestradiol 17 B, Progesterone, Testosterone, Zeranol and Trenbolone;

H. whereas in certain countries of the Community it has recently been shown that existing regulations on the use of hormones have been flouted;

I. whereas there is overproduction of meat and meat products in the European Community which adds considerably to the cost of the CAP;

J. whereas the resultant uncertainty over the safety of these substances has had an adverse effect on consumer confidence;

K. whereas the reactions of consumer organisations in the Member States have shown that those organisations reject the authorisation of hormones in meat production;

L. whereas, however, it will be very difficult, if not impossible, to carry out conclusive checks on the use of non-authorised hormones so as to protect the safety of consumers;

1. regrets that the Commission has taken so much time to draw up its present proposal and that the Scientific Committee has not yet produced its final report on zeranol and trenbolone;

2. considers that in order to protect the consumer, uniform standards should be laid down in all the Member States and that this should be done by means of a Regulation;

3. regrets, however, that evidence seems to suggest that the use of stilbenes which were banned in 1981 is still widespread in certain Member States;

4. considers therefore that any ban or restriction on the use of anabolics cannot be effective without a system of controls which is capable of enforcement;

5. condemns the fact that without any consultation of the European Parliament, Council has recently adopted a Directive relating to the controls already referred to;

6. welcomes the proposed ban on zeranol and trenbolone in view of the fact that their safety has not been conclusively proven;

7. does not approve the proposed authorisation of the three natural hormones except for therapeutic purposes;

8. recognises that there is considerable difficulty involved in checking whether such substances have been used because, where they have been properly administered, the measurable residue concentrations are well within normal physiological limits relatively soon after application;

9. believes, therefore, that the permitted use of hormones for therapeutic purposes must be strictly controlled and documented by means of the following:

   a) full records to be kept for every animal treated, these records to include the time and specification of the dose administered, the time of slaughter and the site of application or place of injection;

   b) the permitted substances to be made available only on the prescription of a veterinary surgeon;

   c) the use of the permitted substances to be allowed only by a veterinary surgeon or a person acting under his direction;

10. approves the principle of random inspections at all levels of production for the purpose of detecting the illicit use of banned substances;

11. believes, however, that there is a need for the Commission to produce more specific proposals concerning the inspection procedure in order to ensure that the alleged misuse and abuse of anabolic agents in certain Member States does not continue; calls on the Commission to draw up such proposals immediately;

12. calls on the Commission to publish details of the maximum natural physiological levels for the hormones authorised for therapeutic purposes;

13. notes that the ban on artificial and natural hormones for fattening purposes will inevitably affect trade with third country suppliers of meat products; calls for immediate discussions to be held with the trading partners concerned with a view to securing a total ban on imports of meat which have been treated with these substances;

14. rejects the authorisation of artificial and natural hormones as growth promoters and notes that any further decision on Zeranol and Trenbolone will be subject to a Council decision; calls on the Council and Commission to consult Parliament if any further amendment is proposed as a result of the Scientific Committee's forthcoming report;

15. requests the Commission to adopt, on the basis of Article 149, second paragraph of the EEC Treaty, the amendments which it has tabled to the Commission's proposal;

16. instructs its President to forward to Council and Commission as Parliament's opinion, the Commission's proposal as voted by the Parliament and the corresponding resolution.

EXPLANATORY STATEMENT

Background

1. In recent years there has been considerable consumer concern over the use of hormones in livestock production. Questions have been raised as to whether the hormones used as anabolic agents have any harmful side-effects on the health of the consumer. Discussion of their safety came to a head in 1980 following the discovery in Italy of undissolved residue of Diethylstilboestrol (DES - an artificial hormone) in tinned baby food. The European Community's response to the public outcry which followed was to adopt a Directive[1] in July 1981 banning the use of all substances having a thyrostatic action (including DES) and restricting most other hormones to therapeutic uses. However, existing national regulations were allowed to remain in force for five specific hormones: oestradiol 17 B, progesterone, testosterone, trenbolone and zeranol. The Commission agreed to consult its scientific committees and report back to the Council as soon as possible on the conclusions reached concerning these five hormones.

2. A scientific working group on Anabolic Agents in Animal Production was set up under the chairmanship of Professor Lamming of the University of Nottingham. This group, along with the scientific committees, submitted its report in September 1982. There was general agreement that "when used under the appropriate conditions as growth promoters in farm animals", the three natural hormones, oestradiol 17 B, progesterone and testosterone, would not present any harmful effects to the health of the consumer. Indeed, the natural hormones used as anabolic agents are indistinguishable from the hormones already existing in the animals. As such, their presence at specific levels is extremely difficult to detect.

3. Before a final conclusion could be given on the two artificial hormones, zeranol and trenbolone, however, it was felt that additional information was necessary concerning the toxicology of these substances. Further scientific data was received by the Lamming working group in January 1984. It is regrettable that the working group has still not produced any conclusions even though it has been in possession of this scientific data for over twelve months now.

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[1] OJ No. C 50, 9.3.1981, p.87

3. (Cont'd)

This delay is all the more regrettable for the fact that discussion of the problem of hormone use in meat production has been dragging on for more than 3 years. This can do nothing to improve consumers' confidence in the products they are buying, nor can it improve retailers' confidence in the products they are selling.

The Commission Proposal

4. As a result of the findings of the scientific committees, the Commission proposes to authorize the use of oestradiol 17 B, testosterone and progesterone. With regard to zeranol and trenbolone, however, the Commission proposes to prohibit their use from 1 July 1985, until such time as their safety can be definitely established.

5. It is the responsibility of the Standing Veterinary Committee to establish a list of products containing the three authorised substances and their conditions of use. New substances may be added to the list in the light of progress in scientific and technical knowledge. As for zeranol and trenbolone, though, they may only be added to the list of permitted substances with the approval of Council based on a qualified majority.

6. The Commission proposal also stipulates requirements for the administration of the authorised substances and lays down the control procedure which Member States would have to implement to ensure that the provisions of the Directive are being complied with.

The Health and Safety Aspects

7. Whereas the metabolism of natural hormones has been thoroughly investigated and the residues in farm animals have been identified, not all the metabolites of the artificial hormones have yet been identified. There is not yet sufficient proof therefore to confirm that zeranol and trenbolone are not carcinogenic. The committee therefore approves of the Commission proposal to ban the use of these two hormones.

8. It must be noted, however, that there is no definite evidence condemning zeranol and trenbolone. Indeed, the pharmaceutical industry would argue that both products have been approved by (among other organisations) the FDA in the USA and the DHSS in the UK and are used in over 50 countries. As a result of worldwide use, there has been no reason to suspect safety problems and there are regular reviews of their safety, taking account of the most recent scientific data. Finally, it has been argued that the two artificial hormones present less of a danger through misuse and abuse than the natural hormones. There is no injectable form (recognised as being more dangerous than implants) and there is no economic advantage in using larger than recommended quantities.

9. The consumers' organisations, on the other hand, believe that use of all hormones, both artificial and natural, should be banned. Their principal concern is that the system of controls is ineffective and open to abuse. Evidence we have received would suggest that the use of dangerous illegal substances such as DES and other stilbenes (banned in 1981) remains widespread in certain Member States. It has also been alleged that injectable forms of permitted anabolics have been extensively used. This is obviously deplorable and poses a potential threat to human health.

10. The problem of controls cannot be separated from any ban or restrictions on the use of hormones. To date, it is the ineffectiveness of enforcement procedures in certain Member States, rather than any lack of legislation which has allowed the practices mentioned above. This committee stresses therefore that it is essential that any system of controls be enforceable. It is unfortunate, in the committee's view, that Council should have recently adopted a directive on a control system, without consulting the European Parliament.

11. As far as natural hormones are concerned, there is a definite problem here. Humans are exposed to variable levels of natural hormones in food from untreated animals. In fact, it has been shown that oestrogen levels in steers with implanted hormones are lower than those occurring normally in untreated cycling and pregnant cattle. Since it is impossible to distinguish between natural hormones used as growth promoters and the same hormones existing already in the animals, it is questionable whether it would be feasible to carry out effective controls. The committee nonetheless feels

that in view of widespread disquiet among the public and in view of the fact that there is no demand on the part of consumers for the authorisation of hormones in meat production, these substances should not be authorised, except for therapeutic purposes.

12. At very high dose levels, the hormones oestradiol 17 B, progesterone and testosterone have been found to be carcinogenic. The question is whether the residues in animal products are at concentrations which would be carcinogenic to the consumer. Humans would need to consume enormous quantities of meat (estimates suggest levels far in excess of human body weight every day) for any danger to result from the residues of hormones. According to the scientific committees' reports, there is no danger of harmful side-effects when natural hormones are used under appropriate conditions. However, given that a doubt exists, and in view of the arguments outlined above, the committee stresses that these substances should be banned, at least until such time as it can be clearly shown that they are not only harmless but that their use produces desirable effects.

13. We wish to stress, also, that their use for therapeutic purposes must be strictly controlled and documented. To this end, we would recommend that full records be kept for every animal treated. These records should include: specification of the dose administered; the place of implant; and the time of slaughter, and treated animals should be clearly identified. It is also essential that every implant is made in a part of the body that will be discarded after slaughter.

Furthermore, the Commission proposals should specifically prohibit all injectable forms of anabolics for fattening purposes. We cannot emphasise enough the importance of these records, in particular in relation to the need to ensure that animals are not slaughtered before the delay period has expired (a practice which, though not widespread, it has been suggested may still be used).

14. Clearly, these controls would be more watertight if, as the Commission proposed, all treatment was carried out under the supervision of a veterinary surgeon. While agreeing that the substances should be made available only through proper veterinary surgeons, we feel it is not realistic to demand that only veterinarians should administer the substances. We have to recognise the unequal distribution of veterinary surgeons across the Community

with the result that some areas simply do not have enough veterinary surgeons to make the Commission proposal practicable. It should be sufficient, therefore, for administration to be carried out by a veterinary surgeon or by a person acting under his direction.

15. The system of checks, as proposed by the Commisison in Articles 7 - 11, has been criticised from all sides. From the pharmaceutical industry's and the veterinary associations' points of view, the proposals are "excessive", require disproportionately large resources and will not be enforceable. From the consumers' side comes the criticism that they are too general (for example, Article 8: "The Member States shall ensure that on-the-spot random checks ...") and do not make any precise statement about how to put them into practice. By leaving the precise definition and functioning of control programmes to Member States, it is argued, the Commission is opening the door to national disparities, and consequently, potential fraud. We would recommend therefore that the Commission draw up more specific proposals concerning the inspection procedure in order to ensure that the alleged misuse and abuse of anabolic agents in certain Member States does not continue.

16. Article 12 of the Commission's proposal talks of "maximum natural physiological levels of authorised substances". In view of the difficulty in distinguishing natural anabolic agents from existing hormones in the animal's body, we believe the Commission should publish more details of what these levels are. The vagueness of the current wording again leaves the door open to abuse.

Economic Aspects

17. It has been argued by industry that the use of hormones as growth promoters has the following economic advantages:

- increased yield through increased growth rate;
- improved conversion rate of feed into meat;
- an estimated 10% reduction in the necessary consumption of cereal-based feeds;
- a subsequent saving on land used for cereal crops. (On this latter point, it is important for us to note the beneficial impact this could have on the environment).

It is further argued that use of anabolics improves the ratio of lean meat to fat, so invoking the quality argument. Apart from the advantages to the EEC, it is claimed that use of anabolics would also benefit the farmers, through reduced production costs, and eventually the consumers, through cut prices.

18. Consumer groups completely refute the arguments concerning economic benefits, except insofar as use of hormones will benefit manufacturers. Firstly, because of the complications of the CAP pricing system, it is not necessarily true that consumers themselves will pay less for the meat they buy. More fundamentally, however, the question arises as to the usefulness of producing an estimated 450,000 extra tonnes of meat when Community stores of meat are at present in excess of 400,000 tonnes. (We would like to note, however, that this represents only a few days' consumption of meat in the Community). Indeed, national experts on the "beef meat" committee estimate that 50% of present stores are a direct result of the use of hormones in production.

19. The committee acknowledges that use of hormones will increase the total amount of beef available and so increase the costs of the CAP through intervention and storage. It also recognises, however, that the full effect of the milk quotas has not yet been realised and that these are likely to have a marked effect on Community meat production.

20. It cannot be denied that the proposed ban on zeranol and trenbolone is likely to cause some difficulties with regard to trade with third countries. Most of the major countries supplying the Community use substances that would be prohibited under the new Directive. It is essential, therefore, that the Community should enter immediately into negotiations with affected trading partners with a view to securing a total ban on imports of meat which have been treated with these substances.

21. As regards intra-Community trade, it is clear that the amendment to the Directive is necessary. Under the original Directive, Member States were permitted to retain their national regulations concerning the five hormones in question here. Different attitudes to the substances existed across the EEC. As well as preventing free intra-Community trade, the different standards encouraged illegal use of substances where standards were perhaps more stringent than elsewhere. It is only by introducing uniform Community standards and controls that free trade can be guaranteed.

Future decisions concerning zeranol and trenbolone

22. There is considerable disagreement over the procedure laid down in the Commission's proposal for the possible inclusion in the future of trenbolone and zeranol on the list of authorised substances used for fattening purposes. Industry argues that it is improper to judge such substances on anything other than scientific evidence. That this should be a decision of Council (Article 1.5) amounts to a political decision. For consumer groups on the other hand, the inclusion of any substance on the list should be subject to a unanimous Council decision, following consultations with both consumer organisations and the European Parliament. We would support the consumers' view insofar as we believe that consumers and the European Parliament should be consulted if any further amendment is proposed to the restrictions on the use of anabolic agents.

ANNEX

The following groups and organisations have been consulted by the rapporteur during the drafting of the report:

Bureau Européen des Unions de Consommateurs (BEUC)
British Veterinary Association
Crown Chemicals Company Limited
European Federation of Pharmaceutical Industries' Associations (EFPIA)
European Feed Manufacturers Federation (FEFAC)
Euroscot Meat (Exports) Ltd.
Hoechst UK Ltd.
Lilly/Elanco Products Company
National Farmers Union (UK and Scotland)
National Federation of Meat Traders
The Retail Consortium (UK)
Roussel UCLAF
The Royal Environmental Health Institute of Scotland
University of Glasgow Veterinary School
PFMA - Pet Food Manufacturers' Association
Cooperative Society
Ministry for Agriculture, Ireland
CECG - Consumers in the European Community Group
Institution of Environmental Health Officers
Hill & Knowlton International
The Institute of Trading Standards Administration

OPINION

(Rule 101 of the Rules of Procedure)

of the Committee on Agriculture, Fisheries and Food

Draftsman: Mr. T.J. MAHER

At its meeting on 30 October 1985, the Committee on Agriculture, Fisheries and Food appointed Mr T.J. Maher draftsman of the opinion.

At its meeting of 28/29 March 1985, the committee decided to include in its opinion the motion for a resolution tabled by Mr Graefe zu Baringdorf pursuant to Rule 47 of the Rules of Procedure on the implementation by the Commission of the European Communities of a ban on the use of fattening agents - such as natural and artificial hormones, antibiotics and penicillin - to protect consumers and promote systems of animal husbandry appropriate to the particular species in an environmentally acceptable and non-industrial system of agriculture, and the recognition that such a measure is compatible with the EEC Treaty (Doc. 1761/84).

The committee considered the draft opinion at its meetings of 26/27 February, 19/20 March and 28/29 March 1985. At the meeting of 15/16 May 1985 it adopted the conclusions by 28 votes to 9 with 3 abstentions.

The following took part in the vote: Mr Tolman, chairman; Mr Eyraud, Mr Graefe zu Baringdorf and Mr Mouchel, vice-chairmen; Mr Maher, draftsman; Mr Bocklet, Mrs Castle, Mr Christensen, Mr Clinton, Mr Collins (deputizing for Mr Sutra), Mr Dalsass, Mr Elles (deputizing for Mr Battersby), Mrs Ewing (deputizing for Mr Musso), Mr Früh, Mr Gatti, Mr Guarraci, Mr Happart, Mr Klinkenborg (deputizing for Mr Wettig), Mr Ligios (deputizing for Mr N. Pisoni), Mr MacSharry, Mr Maffre-Baugé, Mr Marck, Mr Mertens, Mr Morris, Mr Mühlen (deputizing for Mr Debatisse), Mr Newens (deputizing for Mr Crawley), Mr B. Nielsen, Mr Pasty (deputizing for Mr Fanton), Mr F. Pisoni, Mr Pranchère, Mr Provan, Mr Romeos, Mr Rossi, Mrs Rothe, Mr Simmonds, Mr Späth (deputizing for Mr Borgo), Mr Stavrou, Mr Thareau, Mr Vernimmen and Mr Woltjer.

1. Under Council Directive 81/602/EEC of 31 July 1981[1], the Member States were required to prohibit the administering of substances having a thyrostatic action or substances having an oestrogenic, androgenic or gestagenic action to farm animals. The directive also banned the slaughtering or marketing of farm animals to which these substances had been administered and the marketing and processing of their meat. The Member States were further required to prohibit the marketing of stilbenes (synthetic compounds having an oestrogenic action), stilbene derivatives, their salts and esters and thyrostatic substances for administering to animals of all species.

   By way of a derogation from the general ban on the administering of the abovementioned substances, the directive authorizes the use of substances with an oestrogenic, androgenic or gestagenic action - excluding stilbenes and thyrostatic substances - for veterinary purposes, provided that the substance is administered by a veterinarian or a person under his direct responsibility.

   Since scientific investigations have not yet been completed, the directive excludes the natural hormones (sex hormones) Oestradiol, Progesterone, Testosterone and the synthetic compounds Trenbolone and Zeranol, which have a similar action, from the ban, which means that these substances may still be administered to farm animals for fattening purposes in the Member States concerned. The use of some of these substances is currently authorized for fattening purposes in Ireland, the United Kingdom and France. The maintenance of the ban in countries where their use is prohibited is not guaranteed.

2. The Commission asked the Scientific Veterinary Committee, the Scientific Committee for Animal Nutrition and the Scientific Committee for Food to carry out the requisite tests to provide scientific information on the action of anabolic substances used to stimulate growth and on possible threats to public health. The three committees joined to form a Working Group on Anabolic Agents in Animal Production to coordinate their research. The results of its inquiries can be summarized as follows:

   2.1 The sex hormones Oestradiol, Testosterone, Progesterone, Trenbolone and Zeranol are anabolic agents which can lead to increased feed conversion and hence protein deposition in the muscle fibres of farm animals although insufficient research has been done into the processes occurring inside and between molecules. Some Member States authorize the use of these substances for fattening purposes, provided that certain conditions are fulfilled (implantation of the hormones into a specific part of the animal, e.g. ear or base of the ear, and discarding of that part on slaughtering, observance of a delay period between implantation and slaughtering).

[1] OJ No. L 222, 7.8.1981, p. 32

2.2 The natural sex hormones Oestradiol, Testosterone and Progesterone regulate the anabolism, i.e. all the processes involving the exchange of substances and energy, in humans and animals. The hormones are rapidly broken down (mainly in the liver) with little or no biological effect. Since all animals produce these hormones naturally, they must be regarded as an unavoidable part of any foodstuff of animal origin. There is no qualitative means of determining whether hormonal residues of Oestradiol, Progesterone and Testosterone in farm animals are derived from hormones produced by the animal itself or were artificially administered. Similarly, there is no quantitative difference in residual hormone levels between animals which have received additional doses of hormones and those which have not, provided that the recommendations for administering these substances are followed.

The level of toxicity of hormone residues absorbed by humans as a result of the consumption of foodstuffs of animal origin is negligible since it is not possible for an effective concentration to reach the major hormone receptors in the human body, unlike the sex hormones actually produced within the body.

The Working Group therefore concluded that administering the natural hormones Oestradiol, Progesterone and Testosterone presents no danger for human health, provided they are used correctly and in the appropriate form.

2.3 The situation concerning the synthetic hormones Trenbolone and Zeranol, however, is somewhat different. These two substances are powerful growth stimulants in some ways similar to natural hormones but it has proved impossible to establish an exact 'no-hormone effect' dose and hence determine the level of toxicity as the animals used in the experiments reacted to minute doses and it was not possible to determine how far the changes were due to the administering of the two hormones. The Working Group therefore reached no final conclusions on the use of Trenbolone and Zeranol and expressed the view that further research is necessary.

3. This proposal for a directive[1] aims to amend the existing Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action, taking into account the latest information on the effect of the hormones Oestradiol, Testosterone, Progesterone, Trenbolone and Zeranol. The purpose behind the adoption of Community provisions governing the use of hormonal substances in animal husbandry is to serve the interests of the producer and the consumer by protecting public health and by removing obstacles to trade in animals and meat which arise as a result of differences in the relevant legislation in the Member States. The major changes contained in the proposal are as follows:

[1] OJ No. C 170, 29.6.1984, p. 4

3.1 Notwithstanding the general ban on administering hormones to farm animals for fattening purposes, the Member States may authorize the administering of the three natural hormones Oestradiol, Testosterone and Progesterone provided that the substance is administered through a part of the body which must be discarded when the animal is slaughtered, that the animals concerned are clearly marked, that they are not slaughtered until the delay period to be established by the Standing Veterinary Committee has expired and that the substance is administered by a veterinarian (new Article 5(2)).

3.2 Until 1 April 1986, the list of admissible products containing the three hormones, their marketing and use in individual cases and the means of identification of animals so treated will be laid down in accordance with the procedures of the Standing Veterinary Committee (new Article 5(3)(a)).

3.3 New and as yet unapproved hormones for fattening purposes may only be approved provided that they have a favourable effect on all aspects of farm animal production, do not endanger human or animal health nor harm the consumer by altering the characteristics of animal products and comply with existing directives on veterinary medicines (new Article 5(4), second subparagraph).

Any decision on the approval of the synthetic hormones Trenbolone and Zeranol will be taken by the Council acting by a qualified majority (new Article 5(5)). Until that time both substances are banned.

3.4 Pursuant to the second paragraph of Article 149 of the EEC Treaty, the Commission has submitted an amendment[1] to the present proposal for a directive to ensure that meat derived from animals treated with hormones bears an indication to that effect. The indication is to be reprodued clearly at all stages of preparation of meat until sale to the final consumer.
(new Article 5a)

3.5 The Member States must ensure that the basic ban on the administering of hormones and the conditions governing the use of the three natural hormones exempted from this ban are observed. To this end, they must carry out official spot checks on manufacturing, handling, storage, transport, distribution and sale of the banned substances and other spot checks on agricultural holdings and in slaughterhouses. The samples from these spot checks are to be investigated by authorized laboratories (new Articles 7, 8, 9, 10 and 11).

3.6 Where these controls confirm the presence of hormonal residues of banned substances, the competent authorities must organize an investigation in the farm of origin to determine the reason for the presence of these residues. Any animals whose bodies are found to contain banned substances must be confiscated or destroyed and all stocks of banned hormones will be confiscated until such time as the appropriate sanctions have been decided (new Articles 12 and 13).

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[1] OJ No. C 106, 27.4.1985, p. 7

3.7 Article 2 of the present proposal stipulates that the Member States must take the appropriate steps to ensure that the ban on the administering of Trenbolone and Zeranol to farm animals for fattening purposes can come into force on 1 July 1985. The Member States must comply with all other provisions contained in this proposal for a directive no later than 1 July 1986.

4. The Committee on Agriculture, Fisheries and Food has been keeping a sceptical eye on developments in the field of additives used for fattening farm animals for some considerable time. Scientists have published the results of a vast amount of research proving that these additives lead to a considerable improvement in the growth of farm animals and in the quality of meat, which is in the consumer's favour. However, the committee also shares the concern expressed by the general public and by many consumer associations that abuse of these additives could conceivably pose a threat to human health.

Of all the additives used for fattening farm animals, special importance is attached to hormones. These are substances which occur naturally in the bodies of humans and animals, although their concentration may differ. Administering hormones for therapeutic purposes raises no problems whatsoever, provided that these substances comply with existing directives on veterinary medicines and that the relevant safety provisions designed to protect the consumer (e.g. delay period prior to slaughter) are applied. However, the administering of regular doses to farm animals for fattening purposes and without medical grounds should only be authorized if there is proof that the hormone in question has no harmful effects on human health, if abuse can be prevented and if there is a general economic advantage to be obtained by additional doses of hormones. In the committee's view, the three natural hormones Oestradiol, Progesterone and Testosterone, which the Commission proposes to approve, do not satisfy these conditions:

4.1 The working group set up by the Commission to carry out research into the effect of these hormones concluded that these three hormones have no harmful effects on the health of consumers if administered as a growth stimulant to farm animals under appropriate conditions. More specifically, it expressed no reservations in connection with toxicity as the concentration of any hormone residues contained in the meat of farm animals would not be sufficient to provoke a reaction in the hormone receptors of the human body. As regards the absorption of hormone residues as a result of the consumption of meat, there is no appreciable difference between the meat of treated and untreated farm animals. The working group considers that the three natural hormones are harmless provided that they are used 'correctly'. Their incorrect use - e.g. overdoses or an inadequate delay period prior to slaughter - creates certain risks for human beings as the level of hormone residue in the meat may be too high.

4.2 The Commission feels that the use of the three natural hormones can also be justified in economic terms. The administering of hormones leads to a significant increase in the daily growth rate and consequently in the carcass weight. Their main effect, however, is to bring about a significant improvement in the conversion of feed into meat. This aspect becomes all the more important when the availability of imported feed is restricted to promote the use of domestic feed (corn). This has a definite effect on the cost factor of meat

production as the Commission estimates show that using the same amount of feed, an agricultural holding can increase its production levels by about 10%. It was also established that administering hormones can improve the composition of the carcass as regards the proportions of meat, fat and bones, thereby providing the consumer with a higher quality product.

4.3 However, the committee takes the view that the report by the Scientific Group on Anabolic Agents in Animal Production cannot be considered exhaustive as regards the effects on human health and that further information therefore needs to be obtained before the substances concerned are permitted for fattening purposes.

5. In the case of the synthetic hormones Trenbolon and Zeranol, the Scientific Working Party stated that since some data on the 'no-hormone effect' dose and toxicity were still missing, it could not give a final conclusion.

The committee therefore takes the view that the administering of Trenbolone and Zeranol must be prohibited until a scientific evaluation of the missing data is available[1].

6. In the light of the deliberations set out above, the Committee on Agriculture, Fisheries and Food calls on the Committee on the Environment, Public Health and Consumer Protection to take account of the following points in its motion for a resolution:

CONCLUSIONS

The Committee on Agriculture, Fisheries and Food,

6.1 Takes the view that the report by the Scientific Group on Anabolic Agents in Animal Production cannot be considered exhaustive as regards the effects on human health and that further information therefore needs to be obtained;

6.2 Rejects the Commission's proposal approving the use of three natural hormones : Oestradiol, Testosterone and Progesterone;

6.3 Considers that a ban on the two synthetic hormones Trenbolone and Zeranol can be justified until the scientific evaluation of their 'no-hormone-effect' dose and toxicity has been completed.

6.4 Does not endorse the proposal for a Council directive amending Directive 81/602/EEC concerning the prohibition of certain substances having a hormonl action and of any substances having a thyrostatic action, and calls on the Commission to submit a proposal amending this directive with a view to the general prohibition in all the Member States of the Community having a hormonal or thyrostatic action.

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[1]The committee therefore endorsed the motion for a resolution tabled by Mr Graefe zu Baringdorf pursuant to Rule 47 of the Rules of Procedure (Doc. 2-1761/85) and calling for a ban on all such substances.