OMMISSION OF THE EUROPEAN COMMUNITIES

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Communication from the Commission to the Council

and to the European Parliament on control of residues in meat.

Hormones - Beta-Agonists - Other Substances

PRELIMINARY REMARK

1. This communication relates to control of residues, especially of hormones and beta-agonists, in fresh meat. Against the background of an exhaustive enquiry into the situation in the Member States, the communication proposes a series of measures, including new legislation, in order to better combat the illegal use of anabolic* substances (hormones and beta-agonists**), as well as the improper use of authorised veterinary medicinal products.

EXISTING COMMUNITY LEGISLATION***

HORMONES

2. The initial Council Directives (81/602/EEC and 85/358/EEC) prohibited the use of certain hormones (stilbenes and thyreostatics) for fattening purposes, but left open the option for Member States to authorise the use of other hormones. This situation continued until 1 January 1988 when a total prohibition (Directive 88/146/EEC) was introduced on the use of any hormone for fattening purposes. Naturally occurring hormones could continue to be authorised for therapeutic or zootechnical purposes.

   These requirements have applied also to third countries which export live animals and meat to the Community. The rules came into effect from 1 January 1989 in the case of six suppliers which authorise the use of hormones (South Africa, Argentina, Australia, Canada, New Zealand, and the United States). Third countries are obliged to put in place systems which guarantee that meat sent to the European Community originates in animals never treated with hormones.

   It should be noted that beta-agonists (clenbuterol and its derivatives), while chemically speaking are not hormones, also exercise an anabolic function; beta-agonists are not however covered by Community legislation on hormones.

CONTROL OF RESIDUES

3. Council Directive 86/469/EEC harmonises controls on residues in live animals and fresh meat, both within the Community and in third countries which export to the Community.

   In 1987 all Member States presented to the Commission for the first time a plan to identify illegal use of hormones; in 1988 they presented a plan for the identification of other substances (antibiotics, sulphonamides, pesticides, heavy metals). Third

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* designed to increase feed conversion efficiency, yield or lean content, and growth rate.

** referred to also as repartitioning agents; effect on carcase is to increase protein (muscle) while reducing fat.

*** see Annex 1 for details of the relevant Council and Commission texts.

countries are required to present comparable plans. These plans are updated each year in the light of experience - positive results in previous year, search for new substances, improvements in laboratory techniques, etc.

Community residue controls apply to slaughter animals only (bovines, pigs, sheep, goats and horses). Poultry and other products (fish, milk products, eggs, honey) are governed by national requirements, since the rules are not harmonised. The proposed new legislation would cover these products.

ENQUIRY IN THE MEMBER STATES

4. Following the request of the Parliament, the Commission decided in 1990 to initiate a comprehensive enquiry in the Member States on the difficulties of applying Community legislation on residues in fresh meat. This decision was motivated by several factors:-

   - the obligation on the Commission to check the transposition and application of the Directives
   - the Pimenta Report to the European Parliament (March 1989)
   - public allegations about illegal use of hormones.

   The scope of the enquiry, which lasted from May 1990 to January 1992,covered slaughter animals only. The enquiry was comprehensive - an average of 4 weeks was spent investigating the situation in each Member State.

   The Commission officials received full cooperation in their contacts with the branches of the national administrations concerned (Agriculture, Public Health, Customs, Justice). There was a general welcome for the enquiry.

   In each Member State also, the enquiry teams took the opportunity of hearing the views of the various interest groups involved (farmers, butchers, veterinarians, pharmacists, the pharmaceutical industry, importers of chemicals and medicines) as well as of consumer associations.

5. The results of the enquiry showed that

   - anabolic substances (hormones and beta-agonists) were generally available, leading to illegal use.

   - antibiotic and sulphonamide residues were frequently found in meat, especially in the case of intensive livestock rearing systems (veal calves, young fattening bovines, and fattening pigs);

   - other residues were detected occasionally (heavy metals including cadmium, pesticides, antiparisitic substances).

   At Member State level, serious weaknesses were identified in several key areas, for example, in the transposition of directives, in detecting frauds, in the equipment and performance of laboratories, in controls on raw chemical substances. It was evident also that coordination between the various national services concerned was unsatisfactory. The absence of effective

dissuasive measures, the slowness of the judicial system, and in some cases a lack of clarity about the willingness at the highest levels to provide the necessary resources, were added difficulties.

6. The lack of effective organisational arrangements and doubts about the real commitment to tackle the problems, were seen as important demotivating factors for the controllers on the ground, who found themselves faced with a difficult and at times dangerous task in their pursuit of irregularities.

7. It has to be acknowledged also that the Community texts were not altogether conducive to an efficient control system. Different interpretations were possible on some important aspects, with the result that plans which concentrated on getting through a certain volume of testing rather than focussing on risk areas, could be justified without difficulty having regard to the texts of the Directives. It was considered also that the carcase classification scheme, an integral part of the Community's beef regime, was a factor influencing farmers to use illegal substances with a view to achieving better gradings and thereby greater returns. The slowness in bringing into operation the Community reference laboratories was an important factor also in delaying a more effective control programme in the Member States.

FOLLOW UP TO ENQUIRY

8. Following the enquiry in each Member State, the Commission sent a detailed communication to the competent authorities setting out the deficiencies that had come to light, and requesting that the necessary measures be taken to remedy the situation. All Member States have now replied setting out the progress made and measures in hand. The Commission has also been in continual contact with Member States in order to follow closely the measures taken.

   The latest (March 1993) indications suggest a general improvement in the situation, especially as regards the transposing of directives, the execution of control plans and sampling arrangements, the contribution of laboratories due largely to the purchase of high performance testing material, coordination of the internal services, identification of farms of origin, increase in judicial sanctions, and in some instances use of administrative penalties. Other important changes in procedures and in legislation are being prepared in the Member States.

9. There has been useful progress also at the Community level. Initial financing problems of the four Community reference laboratories should be resolved shortly. This will allow them to fulfil their role of coordinating and improving the performance of national laboratories. Directive 92/102/EEC on the identification and recording of animals, which came into operation from 1 April 1993 in the case of bovine animals, will be an important help also in tracing positive carcases to the farm of origin. As regards administrative sanctions, Council Regulation (EEC) No 2066/92 of 30 June 1992 provides that where the rules on illegal use of hormones are infringed the animal concerned is not eligible for beef premiums.

PRESENT SITUATION

10. The Commission's overall assessment of the situation is that there is now a greater awareness among Member States about the need to take effective measures to combat the use of illegal substances, to commit additional resources to the campaign, and to introduce more effective dissuasive measures. There is support also for changes in Community legislation that will facilitate the task.

11. The extent to which awareness has been translated into fully effective measures to control the situation is more difficult to say. Whatever improvements are made in legislation and in procedures, the campaign against use of unauthorised substances will have to be unrelenting. More sophisticated illegal products are under continual development, there is now widespread availability and misuse of beta-agonists, the network for the distribution of illegal substances is well developed, and securing convictions through the Courts is time-consuming and problematic. The profit motive will continue to provide a powerful incentive to continued use of these substances. It is estimated, for example, that a beef producer could stand to gain between 100 ECU and 200 ECU per animal from their use. Substantial profits are available also to distributers, to unscrupulous feed manufacturers, and to agents who supply animals for slaughter. An effective campaign against prohibited substances will reduce substantially the income now available to these interests. They can be expected to use all possible means to preserve their illicit trade.

12. It is clear that the public health risks involved require further action by the Community and by the Member States. But before going on to outline a framework that might be the basis for improving the situation, it is necessary to indicate the limits of the possibilities available to the Commission.

    The Commission will continue to be active in monitoring the situation in the Member States, in carrying out special investigations where necessary, and in taking proceedings where Community legislation is not being implemented correctly.

    But the Commission cannot assume the responsibilities of the Member States or other competent authorities, in the control of illegal substances. It is for the competent authority in each Member State to take effective measures to ensure that conditions are such that the objectives of the Directives can be attained. In particular they must ensure that legal procedures are in place to facilitate prompt convictions and that the penalties are dissuasive, that the necessary resources in manpower and materials are available, that there is full coordination between the national services involved, and that those charged with what is a disagreeable and at times dangerous task, ie the controllers on the ground, are adequately remunerated and protected. It is for the Member State also to influence public opinion to take a greater interest in this issue and to encourage wholesale and retail outlets to insist that supplying abattoirs provide effective guarantees on the safety of meat. They can exercise an important role also in controlling the network of distribution of pharmaceutical products and raw materials. Use of unsafe products

could be discouraged also by competitive prices for authorised veterinary medicinal products. This could be brought about as a result of wholesalers and retailers applying more reasonable margins on sale.

13. Neither can the Commission exercise the role of the international policeman in the campaign against the distribution of these substances, which often takes on a transnational dimension. This is an aspect that falls within the scope of other international arrangements. But the Commission is well placed to bring together representatives of the Member States on a regular basis, in order to exchange information on their experiences, on points of difficulty with the rules, on the emergence of new illegal practices and strategies by manufacturers and distributers, and on the measures that should be taken at Community level to deal with the situation. The Commission is prepared to provide for a more flexible approach on this front, for example through workshops, seminars and by bringing together representatives of Member States in less formal settings. The Commission attaches special importance to flexibility and rapidity of reaction. The proposed new legislation should be framed in a way that will allow for rapid adaptation of the control arrangements to deal with problems emerging in the light of experience, and to forestall other dangerous developments.

PRODUCER RESPONSIBILITY

14. In considering how the control arrangements might be improved, the Commission's objective has been to identify measures that will be of practical benefit to those immediately charged with the task of combatting the use of prohibited substances. These measures should also allow the Member states to use existing resources more effectively. The measures focus on the principal parties concerned, above all on the producer and the meat supplier, who share a singular responsibility to produce a safe, healthy, product for human consumption.

15. In a normal situation it might be expected that all producers would recognise their overwhelming interest to supply a guaranteed product, not least since most meats are in surplus and the consumer is becoming more and more demanding as regards guarantees of safety and quality. If it were only a question of the market, there would be argument for leaving it to the producer to satisfy the consumer without any intervention by a regulatory authority. But the serious public health dimension of the current situation requires active involvement by the responsible authorities, including the Commission. There is also the competition aspect which requires that the great majority of producers who observe the rules be guaranteed that their competitive position is not eroded by others who profit from illegal substances.

16. The Commission believes that the primary focus of attention must be the producer. It is he or she who must accept primary responsibility for the safety of his or her product. That responsibility could in future be reflected in a formal written guarantee on the non-use of anabolic substances and an assurance that the withdrawal period in the case of authorised veterinary medicinal products, will be observed. This undertaking could be

part of the producer's application for all Community-financed (wholly or partially) aids under the Common Agricultural Policy. It would involve a corresponding acceptance that, in the event of the producer declaration not being respected, ie as a result of the discovery of prohibited substances, the producer's entitlement to aid in the product sector concerned would be automatically forfeit. Forfeiture of aids in whole or in part for a single year might be envisaged for an initial infringement, and debarment from Community aids for a period to be defined, in the case of a subsequent infringement. The present rules which provide for loss of beef premium on a single animal found to have been treated with illegal substances are an insufficient deterrent.

Failure to cooperate with the investigating authorities, for example, by refusing to give information or to provide facilities on the farm, by obstruction, etc, would be a valid reason for disallowing aids.

In the case of animals delivered for slaughter, it could be a requirement also that they be accompanied by a similar written guarantee. This would heighten the sense of responsibility of the supplier and would provide a basis also for effective sanctions where the undertaking proved to be false. The sanction in the case of the non-producer supplier could be, for example, to place any further supplies from him in a "suspect" category, thereby requiring systematic checking at his own expense. The sanction for a producer supplier could be forfeiture of aids as already indicated. This would be in addition to the judicial penalties decided by the Member State.

In the same vein the intention would be that the producer should bear the cost of follow-up analyses on suspect animals at the farm of origin, where samples taken at the slaughterhouse prove positive.

The destruction of animals, in a rendering plant, would be an automatic consequence of discovery of illegal substances on the farm or at slaughter, or of failure to observe the necessary withdrawal period in the case of an authorised medicine. The only exception to this would be duly notified urgent slaughterings where destruction of the carcase would apply only where residues were still present following analysis.

17. The need to increase awareness of these problems raises the question of the value of publishing in local newspapers, agricultural journals, as well as displaying prominently in public offices, the names and addresses of those convicted of offences. A coordinated publicity campaign at Community level with the emphasis on the producer's role would be essential also. The Commission would support this campaign.

18. This series of measures is designed to bring home to producers the seriousness of the use of prohibited substances and the misuse of other products. The measures would make an important contribution to control of the problem at the operational level.

The measures indicated would give rise to no difficulty for the vast majority of law abiding farmers. Indeed responsible producers

would benefit as the threat to their livelihoods from the unscrupulous minority which insist on using prohibited products would be diminished.

19. On a more positive note, the Commission wishes to encourage the emergence of producer groups which would develop auto-control systems to guarantee hormone-free beef. This will be an important element in the financing, by the promotion fund (10 MECU in 1993), of measures to increase beef consumption as agreed as part of the reform of the Common Agricultural Policy last year. The Commission remains committed to supporting this programme on a multiannual basis.

THE ROLE OF THE ABATTOIR

20. Apart from the producer, the most valuable source of information and dissuasion also when it comes to use of illegal substances is the owner and management of the abattoir. The abattoir is the point at which the animals can be most easily inspected, both in live and in carcase form, and where full information is available about their origin. Experience to date suggests that the level of cooperation from some abattoirs, and their willingness to discourage use of prohibited substances, is unsatisfactory. This may be due to a perception that an abattoir which discourages illegal substances will put itself at a commercial disadvantage due to the deflection of supplies to more "accommodating" premises. This is a perverse situation in that the abattoir should have an overwhelming commercial interest to supply a safe, quality, product for consumption.

21. Against this background measures are necessary to improve cooperation by abattoirs. It could be a condition of continued authorisation of a slaughtering premises that its owners and employees cooperate fully in the identification and tracing of illegal substances. Where this is not the case Member States should be in a position to suspend authorisation. Furthermore where there is evidence of non-cooperation, entitlement to Community or national aids could be withdrawn. This would be apart from the judicial penalties decided by the Member state.

22. The Commission believes also that there should be an opportunity for slaughtering establishments which are prepared to introduce autocontrol systems to be granted special recognition. Wholesale and retail outlets should be encouraged to give priority to supplies from such establishments and Member States could introduce approved systems based on strict specifications.

    Publicity should be given also to establishments operating approved autocontrol systems.

23. The influence of the abattoir is often a factor in the temptation for producers to use hormones and beta-agonists to obtain the highest grading level on the beef carcase classification grid. The grid is part of the beef market organisation for price reporting purposes and for determining buying in prices of cattle accepted into intervention.

    The Commission considers that a recasting of the present grid, with the object of removing the incentive to artifically well formed

carcases could have an important impact in discouraging the use of prohibited substances, especially of beta-agonists (authorised at present for therapeutic purposes only). This would not prevent purchasers and sellers of beef from putting in place a grading system on a voluntary basis. From the financial viewpoint alone it could be argued that the present high level of intervention stocks (over 1 million tonnes) and the substantial loss on sale of product sold from intervention requires a review of the present grading system in any event.

The limit on carcase weights for beef accepted into intervention will have an important beneficial impact also in discouraging the use of prohibited substances in parts of the Community.

OTHER INTERESTS

24. In identifying the producer and the abattoir as key influences in discouraging use of illegal substances the Commission is not implying that other parties for example pharmacists, veterinary practitioners, manufacturers and importers of veterinary medicines, etc do not have an important role. The Commission would stress in particular the responsibility of manufacturers of feedingstuffs which are well placed to prevent misuse of feed products. At the level of the Member State it will be necessary to provide for effective sanctions where irregularities are committed. The Commission would review also the conditions for approval of manufacturers of feedingstuffs and would make proposals to the Council on this aspect.

CONTROL MEASURES

25. In its review of existing control measures the Commission has come to two main conclusions:-

(i) it is no longer appropriate to apply a control system for the detection of prohibited substances based on random sampling; future arrangements have to be focussed on risk situations, for example in terms of type of farming eg fattening units or previous histories of fraud.

(ii) the focus of targetted investigations must be at the level of the farm rather than that of the abattoir. This is because of the growing development of sophisticated substances and the careful timing of administration to animals so that they cannot be easily detected on laboratory analysis when sampled at the slaughterhouse.

26. These basic conclusions could be reflected in proposals for legislative changes along the following lines

- a common requirement for targetted investigations for prohibited substances covering a minimum of 0.1% of all fattening animals (bovines) on farms and 0.05% of such animals at the abattoir. [The present arrangements provide for the reverse proportion, that is 0.1% in slaughterhouses and 0.05% on farms.]

- the rules to be followed in case of on farm investigations following a positive sample at the slaughterhouse, will be clarified; an analysis of feedingstuffs and drinking water - a source especially of beta-agonists - as well as of animals will be required; a minimum percentage of animals (say 30%) would have to be tested in the case of suspect farms.

The farm/abattoir proportion could be reviewed in the event of the emergence of proven and practical methods for more effective identification of positive samples.

27. In the case of authorised substances (largely antibiotics) used incorrectly, the approach would be based on a minimum number of samples at the abattoir for all such substances, with greater flexibility for Member States to deal with individual problematic substances at national level. In these cases also, the focus would be on a biased sampling approach, except in the case of environmental contamination where problems are likely to be more random.

RESEARCH

28. The Commission attaches special importance to the Community and national reference laboratories exercising fully the role for which they are intended. These laboratories play a key role in developing effective testing methods in diffusing information to other laboratories, and in ensuring a uniformly high level of testing throughout the Community. This key role has been built up and strengthened via several Community research projects. These projects are providing the necessary tools such as certified reference materials, reference compounds and a reference manual to develop, improve and validate current and new methodologies. In addition a special project is in train to help identify beta-agonists in animal feed. The laboratories have not been able to exercise their coordination role because of problems with Community financing. These problems are expected to be resolved shortly and the Commission will keep under constant review their functioning and performance. Likewise, the Commission will pay special attention to the search for new and more effective methods for the precise identification of prohibited substances. It would be especially important in this context to develop methods that would allow for easier detection both in the case of samples at the farm and at the abattoir. The Commission envisages the financing of a pilot project that may yield significant results in this sector.

FINANCIAL ASPECT

29. The arrangements for charging the minimum fee for the examination of residues at the abattoir ie 1.35 ECU per tonne need to be reviewed especially since the focus of enquiry in the case of prohibited substances will be at farm level. Apart from the actual rate of fee, the more important aspect relates to the use of the income deriving from the fees charged, and its specific attribution to the costs of national anti-hormone campaigns. Apart from the competition aspect, the revenue from fees provides an important opportunity for Member States to finance their campaigns adequately. It is essential also that the rules on fees be implemented fully and in a transparent way.

BETA-AGONISTS

30. Apart from the question of illegal hormones, there is a growing concern about the use of beta-agonists, sometimes in conjunction with hormones, for the improvement of carcase conformation. As already shown in the Community misuse of beta-agonists can be a serious risk to health. This is a question on which the views of the competent scientific bodies can be sought.

    Beta-agonists are currently authorised for therapeutic reasons in most Member States (except DK and Greece) and by several third countries also, but authorisation is not allowed as a feed additive.

    The question arises as to whether control of the misuse of beta-agonists would be substantially improved by their total prohibition, including for therapeutic uses. The broad consensus among those charged with control in the Member States is that the misuse of beta-agonists has become a serious problem and that a prohibition would greatly ease the difficulty of proving illegal intent. While normally reluctant to propose removal from the market of a product with therapeutic uses, the Commission considers that a total ban on beta-agonists, except for the therapeutic treatment of horses and pet animals, would be a significant help to control. In taking this view the Commission is influenced also by indications that replacement products are generally available for therapeutic purposes.

31. The question arises whether the Community can require that third countries apply a similar prohibition as a pre-condition for exporting live animals and meat to the Community. This is a difficult issue that must be influenced on the one hand by the competition aspect and the need to protect the Community against a similar trend towards mis-use of beta-agonists which may well develop in third countries also. On the other hand, it may be difficult for the Community to insist on a corresponding prohibition where there is no evidence at present of significant misuse of beta-agonists in third countries. Any measure affecting the position of third countries would require consultations with our trading partners and that account be taken also of the principle of non-discrimination.

CONCLUSIONS

32. Despite recent improvements in awareness and actions of the Member States in controlling the use of prohibited substances, the Community is faced with a determined, flexible, and organised network which is likely to continue to make these substances available at considerable profit to users and distributors. This is a situation which poses a serious risk to public health. The inability of national legal systems to apply effective and rapid sanctions in cases of infringements and the lack of resources currently available in the Member States are likely to be ongoing difficulties in dealing with the problem.

33. The Commission is prepared to bring forward several proposals to remedy the principal defects in the control arrangements and to

make producers and suppliers of cattle realise the consequences of failure to observe the regulations.

But for this initiative to succeed, there will have to be a more determined effort by the competent authorities in the Member States to increase and to coordinate resources, and to develop more effective legal sanctions. It will require also active support and cooperation on the part of owners and managers of slaughterhouses, of manufacturers of feedingstuffs, and above all of producers themselves. Apart from their primary responsibility to make available a product which is safe, producers and sellers of meat have an over-riding interest in maintaining the confidence of the consumer. While important improvements can be made in the control arrangements, in the last analysis the whole-hearted commitment of producers is essential to success. So too is the political will to make the campaign against prohibited substances a national priority, with a clear willingness in all Member States to take difficult measures to redress the situation .

ANNEX

EXISTING COMMUNITY LEGISLATION

I. HORMONES

- 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.

- Council Directive 85/358/EEC of 16 July 1985 supplementing Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action.

- Council Directive 88/146/EEC of 7 March 1988 prohibiting the use in livestock farming of certain substances having a hormonal action.

- Council Directive 88/299/EEC 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.

- Commission Decision 87/410/EEC of 14 July 1987 laying down the methods to be used for detecting residues of substances having a hormonal action and of substances having a thyrostatic action (this Decision will shortly be amended).

- Council Decision 87/561/EEC of 18 November 1987 on transitional measures concerning the prohibition on administration to farm animals of certain substances having hormonal action.

- Commission Decision 89/358/EEC of 23 May 1989 laying down measures for the application of Article 8 of Council Directive 85/358/EEC.

II. RESIDUE MONITORING

- Council Directive 86/469/EEC of 16 September 1986 concerning the examination of animals and fresh meat for the presence of residues.

- Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin.

- Commission Decision 89/153/EEC of 13 February 1989 concerning the correlation of samples taken for residue examination with animals and their farms of origin.

- Council Decision 89/187/EEC of 6 March 1989 determining the powers and conditions of operation of the Community reference laboratories provided by for Directive 86/469/EEC concerning the examination of animals and fresh meat for the presence of residues.

- Commission Decision 89/610/EEC of 14 November 1989 laying down the reference methods and the list of national reference laboratories for detecting residues (this Decision will shortly be amended).

- Commission Decision 90/515/EEC of 26 September 1990 laying down the reference methods of detecting residues of heavy metals and arsenic.

- Council Decision 91/664/EEC of 11 December 1991 designating the Community reference laboratories for testing certain substances for residues.

- Commission Regulation (EEC) 675/92 of 18 March 1992 amending Annexes I and III of Council Regulation (EEC) No 2377/90 laying down the Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

- Commission Regulation (EEC) No 3093/92 of 27 October 1992 amending Annex III of Council Regulation (EEC) No 2377/90 laying down the Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

- Council Decision 79/542/EEC of 21 December 1979 drawing up a list of third countries from which the Members States authorize imports of bovine animals, swine, and equidae, fresh meat and meat products (as last amended by Commission Decision No 3/100/EEC of 19 January 1993).

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