OPINION OF MR ADVOCATE GENERAL MISCHO
8 March 1990 *

Mr President,
Members of the Court,

1. In connection with an application for judicial review of the regulations transposing into national law Council Directive 88/146/EEC of 7 March 1988 prohibiting the use in livestock farming of certain substances having a hormonal action, [1] the High Court of Justice has referred to the Court seven questions relating to the validity of that instrument.

2. Before examining these questions, which are fully reproduced in the Report for the Hearing, I should point out that Directive 88/146 is a successor to Directive 81/602/EEC of 31 July 1981. [2]

3. Whereas Article 2 of the latter directive in principle prohibited the administering to a farm animal, by any means whatsoever, of substances having a thyrostatic action or substances having an oestrogenic, androgenic or gestagenic action, Article 5 authorized, until a decision had been taken by the Council, the continuance in force of national regulations permitting the administering of oestradiol 17β, progesterone, testosterone, trenbolone and zeranol for fattening purposes.

4. Article 2 of Directive 88/146, on the other hand, provides that Member States may no longer authorize any derogation from Article 2 of Directive 81/602. However, the administration for therapeutic purposes of oestradiol 17β, testosterone and progesterone may be authorized. The use of the five hormones for fattening purposes is thus prohibited. Trenbolone and zeranol may no longer be administered even for therapeutic purposes.

5. The statement of the reasons on which Directive 88/146 is based is in the following terms. First of all, the Council made two findings, that:

(i) the administration to farm animals of certain substances having a hormonal action was regulated in different ways in the Member States because of differing assessments of their effect on human health vary;

(ii) this divergence distorted the conditions of competition in products that are the subject of common market organizations and was a serious barrier to intra-Community trade.

6. From these findings, the Council drew a first conclusion, namely that

* Original language: French.

1 — OJ 1988 L 70, p. 16.

2 — Council Directive concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action (OJ 1981 L 222, p. 32).

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

Finally, the Council concluded that

'the use of hormonal substances for fattening purposes should therefore be prohibited'.

7. I should also point out that the directive in issue is identical to Directive 85/649/EEC,[3] which the Court declared void in its judgment of 23 February 1988 because it had been adopted in breach of the Council's Rules of Procedure.[4] Certain of the questions raised by the national court relate to matters which were decided by the Court in that judgment. Others, however, relate to points which were not then decided by the Court. In the interest of clarity, I shall deal with the seven questions in sequence, even though the first five are interrelated and certain arguments which are substantially the same are adduced several times.

Infringement of the principle of legal certainty

8. Strictly speaking, the concept of 'legal certainty' conveys the notion that there must be no doubt as to the law applicable at a given time in a given area and, consequently, as to the lawful or unlawful nature of certain acts or conduct.

9. It is clear, however, in the light of the explanations given by the national court and the observations of the applicants in the main proceedings, that it is not in that sense that the words 'legal certainty' are being used in this question.

10. As the United Kingdom explained, the first question in fact seeks to ascertain whether a measure may be deemed to be valid if it is said to be based on the existence of varying assessments by the Member States and anxieties and expectations of consumers, but no scientific evidence has been adduced in support of those assessments and anxieties. In the opinion of both the plaintiffs in the main proceedings and the United Kingdom, the reply to this question must be in the negative. But in the United Kingdom's opinion, the unlawfulness of the measure stems from an infringement of the principle of protection of legitimate expectations rather than a breach of the principle of legal certainty. The manufacturers, distributors and users of the substances covered by the contested directive were, in the United Kingdom's view, entitled to expect that a prohibition on administering them for non-therapeutic purposes would not be introduced unless it was based on scientific evidence showing that they were insufficiently safe or of inadequate quality or efficacy (see points 9 to 11 of the United Kingdom's observations). What is one to make of this?

11. In my opinion, it is clear from both the context and the statement of the reasons on

3 — Council Directive of 31 December 1985 prohibiting the use in livestock farming of certain substances having a hormonal action (OJ 1985 L 382, p. 228).

4 — Judgment in Case 68/86 *United Kingdom* v *Council* [1988] ECR 855.

which the directive is based that, at the time it was adopted, the Council was confronted with one of those complex economic and political situations in which the Court traditionally allows it a wide area of discretion.

12. In the *Roquette* judgment[5] the Court held that:

'When the implementation by the Council of the agricultural policy of the Community involves the need to evaluate a complex economic situation, the discretion which it has does not apply exclusively to the nature and scope of the measures to be taken but also to some extent to the finding of the basic facts inasmuch as, in particular, it is open to the Council to rely if necessary on general findings. In reviewing the exercise of such a power the Court must confine itself to examining whether it contains a manifest error or constitutes a misuse of power or whether the authority in question did not clearly exceed the bounds of its discretion.'

13. In the *Stölting* judgment[6] the Court stated, in connection with a difference of opinion concerning in particular the 'expediency and effectiveness' of a measure adopted by the Council that:

'if a measure is patently unsuited to the objective which the competent institution seeks to pursue this may affect its legality, but on the other hand the Council must be recognized as having a discretionary power in this area which corresponds to the political responsibilities which Articles 40 and 43 impose upon it'.

In its judgment in *Schräder*, after referring also to the political responsibilities of the Community legislature, the Court stated even more categorically that

'Consequently, only the manifestly inappropriate nature of a measure in this domain in relation to the objective pursued by the competent institution may affect its legality' (judgment in Case 265/87 [1989] ECR 2237, paragraph 22).

14. In fact, the Council had to exercise its discretionary power and assume its political responsibilities in the following situation.

15. On the one hand, there were scientific opinions which prompted the Commission to state in the seventh recital of its initial proposal[7] that:

'on scientific grounds, it appears that the use of oestradiol 17β, testosterone and progesterone, 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'.

5 — Judgment in Case 138/79 *Roquette Frères* v *Council* [1980] ECR 3333, at p. 3358, paragraph 25.

6 — Judgment in Case 138/78 *Stölting* v *Hauptzollamt Hamburg Jonas* [1979] ECR 713, at p. 722, paragraph 7.

7 — OJ 1984 C 170, p. 4.

The authorization of these three substances at least was also supported by the negative reactions expressed by non-Member countries which are exporters of meat to the idea that the Community might close its borders to imports of meat from animals which had been treated with hormones.

16. On the other hand, a whole series of arguments was adduced in favour of the prohibition of these five substances.

(a) Most of the Member States, which had for a long time prohibited the use of all hormonal substances, were still not convinced that these substances were harmless. The Spanish and Italian Governments confirmed during the course of these proceedings that that was still their point of view. The Commission itself made its initial proposal to authorize the three substances (new Article 5) subject to very specific conditions, namely that the Member States were to ensure that the substances in question were:

(i) only administered to farm animals by implantation which was located in a part of the animal which must be discarded at slaughter;

(ii) only administered to animals which were identified at the time of implantation and that these animals were not slaughtered before the expiry of the delay period laid down in application of subparagraph 3(a);

(iii) administered by a veterinarian.

The Council, during the course of these proceedings, expressed the fear that were these rules not to be observed or were excessive quantities to be used the hormones could entail negative consequences for consumers. It also pointed out that any scientific opinion is subject to the reservation that it is given 'in the current state of knowledge'.

The applicants replied that the same consideration applies to any medicament. In my view, however, there is a very important difference between the use of a medicament for therapeutic purposes and its massive use in order to accelerate the growth of animals.

(b) Moreover, at the time of the adoption of the directive in issue in this case, the directive of 7 March 1988, the Council had in its possession the Court's judgment of 23 February 1988 in the hormones case, mentioned above. At paragraphs 34 and 35 of that judgment the Court made some remarks about the scope of the 'report on the experience acquired and scientific developments, accompanied, if necessary, by proposals which take these developments into account' which the Commission was required to submit to the Council under Article 8 of Directive 81/602. The Court held that:

'Article 8 of Directive 81/602 imposed an obligation on the Commission only, which was under a duty to have the report drawn up and, if appropriate, to take account of it in its proposals. Consequently, the Council was not under an obligation to refer to those antecedents'.

In other words, the Council was not obliged to authorize the use of the five hormonal substances for fattening purposes, even if

that scientific report concluded that they were safe.

In addition, the Commission amended its initial proposal to provide for the prohibition of all hormonal substances.

(c) The Council had before it the viewpoint of the European Parliament which took the opposite stance to the Commission's initial proposal. As will be seen further on, the Parliament's opinion, given on 11 November 1985, was to be regarded as still having validity in March 1988. The Parliament considered that:

'Scientific information about these substances is far from complete and ... considerable doubt therefore exists about the desirability of their use and of their effect on human health ... the resultant uncertainty over the safety of these substances has had an adverse effect on consumer confidence. ... the reactions of consumer organizations in the Member States have shown that those organizations reject the authorization of hormones in meat production'. [8]

The Economic and Social Committee confirmed this viewpoint, stating that:

'The representatives of consumers and workers have for a long time been unequivocally opposed to the use of anabolics in livestock fattening'. [9]

(d) The Council was thus referred to the opinion of consumer organizations. It is common ground that in many countries of the Community campaigns have been launched by those organizations, which have even called for boycotts on hormone-treated meat. The Commission, moreover, stated at the hearing that the consumption of meat had already gone down on two occasions as a result of such campaigns. In that situation the Council committed no manifest error when it found that meat produced without the use of hormones corresponded in the best possible manner to the anxieties and expectations of consumers, and that such a course of action was bound to bring about an increase in meat consumption.

To a large extent, these campaigns were not, moreover, solely based on fears as to the harmful nature of hormones, but were also the manifestation of a more general trend in public opinion, namely a growing aversion on the part of the public to the use of chemical products in agriculture. The Council could therefore expect with a high degree of probability that legalization of hormones would set in motion still greater protests and a yet more marked reduction in the consumption of meat, with all the negative consequences that that would have entailed for farmers.

The Commission pointed out that negative opinions on the use of hormonal substances had again been expressed recently by the European Bureau of Consumers' Unions, the Consumer Federation of America and by the Public Voice for Food and Health Policy.

8 — OJ 1985 C 288, p. 158.
9 — OJ 1985 C 44, p. 14.

(e) Finally, the assessment made by the Council also dealt with the question whether authorization of the three 'natural' substances would be likely to eliminate the clandestine use of substances whose harmfulness is acknowledged by everyone, and should therefore be allowed as the 'lesser evil', or whether only prohibition of all the substances could be effectively supervised. As I shall explain below, in connection with the alleged infringement of the principle of proportionality, I consider that the Council did not commit a manifest error in taking the view that, in regard also to the possibility of supervision, a general prohibition was the solution to be preferred.

17. My general view is that none of the arguments taken into consideration by the Council contained a manifest error and that it did not manifestly go beyond the limits of its discretionary power by drawing the conclusion, from the totality of the arguments before it, that it was appropriate and justifiable to prohibit the administration of the five substances for fattening purposes, even in the absence of scientific evidence showing that they were harmful. A total prohibition was the only solution which could bring to an end the distortions of competition and barriers to intra-Community trade in meat, eliminate all risks to public health, even if they were purely hypothetical ones, and avoid a further reduction in consumption.

18. For the sake of completeness, however, I should still like to express my viewpoint on some of the other arguments which have been adduced.

19. The applicants submitted that the barriers to intra-Community trade stemming from divergent legislation could have been eliminated by the application of Article 30 of the Treaty, which prohibits measures having equivalent effect to quantitative restrictions. However, this is not absolutely certain, since it is perfectly conceivable that the Court, in proceedings under Articles 169 or 177 of the EEC Treaty, might have decided that the conditions for the application of Article 36 were satisfied. In such a case the barriers and distortions would have continued to exist. Unlike the method chosen by the Council, therefore, that suggested by the applicants would not definitely have solved the problem.

20. The applicants in the main proceedings also believe that they are right to assert that consumers are reluctant to buy meat which has not been treated with hormones, on account of its less appetizing appearance and its greater fat content. However, it has in no way been established that consumers would prefer leaner meat if it were pointed out to them that such meat came from animals which had been treated with hormones. Consumers organizations have, on the contrary, shown they do not want meat of that kind.

21. Finally, the United Kingdom submits that since 1965 the practice followed by the Community has been to base legislation authorizing pharmaceutical products on a scientific assessment of the safety, quality and efficacy of the products concerned. Given that the Council stated, in connection with Directive 81/602 of 31 July 1981 that:

'the harmless or harmful effects of the use of oestradiol 17β, progesterone, testosterone, trenbolone and zeranol still have to be examined in detail' (fourth recital),

producers and users of these substances therefore had a 'legitimate expectation' that the use of these substances for fattening purposes would be permitted as soon as a scientific assessment had shown that they were harmless. The harmlessness of trenbolone and zeranol were demonstrated a short time after the three other substances had been shown to be safe.

22. These arguments call for three observations. First of all, it follows from Article 4 of Directive 81/602 taken in conjunction with Articles 2 and 3 of Directive 88/146 that a list of products containing oestradiol 17β, testosterone and progesterone, which may be authorized by Member States for the purposes of therapeutic treatment, is to be drawn up in compliance with the relevant principles and criteria of Directive 81/851/EEC [10] and Directive 81/852/EEC, [11] even if those substances themselves have not been the subject-matter of a scientific study in accordance with those directives. It has not been alleged that, on this ground, it should not be possible to use them for therapeutic purposes.

23. At all events, as I have already stated, there is a major difference between the use of a substance for therapeutic purposes and its use, on a much greater scale, for fattening purposes. The Council did not exceed its margin of appreciation in taking the view that authorizing the former did not oblige it at the same time to permit the latter.

24. Secondly, although it is true that Directive 81/602 may have aroused hope in the circles concerned that, following further studies, the use of the five substances for fattening purposes would be permitted, that is merely a hope and not a legitimate expectation.

25. That is to say, 'in examining the Court's case-law on this point it will be observed that the focus of the Court's attention is to discover, in each case, a "foundation for the expectation". If there is such a foundation, the applicant's situation deserves to be protected. If not, the general rule must be applied. In accordance with that case-law, considered as a whole, it seems that such a foundation will only subsist if a public authority has made an undertaking of some kind, that is to say in the context of a contractual or quasi-contractual relationship between the public authority and the person relying, as against it, on the protection of a legitimate expectation'. [12]

26. Finally, it should be pointed out that at paragraphs 34 and 35 of the 'hormones' judgment of 23 February 1988, cited above, the Court held that the Council was not bound by the conclusions of the scientific report provided for in Article 8 of Directive 81/602.

10 — Council Directive of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (OJ 1981 L 317, p. 1).

11 — Council Directive of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (OJ 1981 L 317, p. 16).

12 — P. Pescatore: 'Les principes généraux du droit en tant que source du droit communautaire' in: *Rapports du 12e congrès de la Fédération internationale pour le droit européen*, Paris, 1986, Vol. 1, p. 35.

27. For all these reasons, I propose that the Court should find that Directive 88/146 is not incompatible with the principles of legal certainty and the protection of legitimate expectations.

Infringement of the principle of proportionality

28. The applicants in the main proceedings, supported by the United Kingdom, set forth a whole series of arguments designed to establish that the total prohibition of the five substances under consideration is unlawful on the ground that it infringes the principle of proportionality.

29. First of all, they emphasize that this prohibition in no way assists in achieving its stated objectives, in particular because it is impossible to apply in practice. Moreover, since the danger to health is non-existent, less restrictive measures, such as information campaigns and labelling requirements, would have been sufficient to allay the anxieties of consumers.

30. Not only does the measure adopted have no positive effect but, on the contrary, it causes a number of disadvantages. It causes economic loss which is sustained first of all by the pharmaceutical companies which are no longer able to sell certain preparations, then by farmers who are denied the savings in costs and gains in productivity made possible by the use of these substances, and finally by veterinarians who are denied clinical freedom to administer the hormones and the income they would have earned from doing so.

31. The effect of the prohibition, they say, is that the beef produced is higher in fat content than that treated with hormones, with all the ill consequences which that entails for public health. It has also caused a considerable expansion of a black market in dangerous substitute substances, which previously existed only in Member States where the prohibition was already in force.

32. I suggest, however, that the Court should find the arguments to the contrary, submitted by the Council, the Commission, the Spanish Government and the Italian Government more convincing. I subscribe to these arguments, reproduced in some detail in the Report for the Hearing, to which reference may be made. The following points seem to me to be particularly worthy of consideration.

33. The measure adopted is certainly not manifestly unsuitable [13] for achieving the objective pursued. Only a total prohibition of all substances having a hormonal action, of whatever kind, was capable of truly allaying the anxieties, whether justified or not, of consumers. It is true that such a total prohibition does not preclude the formation of a black market and the clandestine administration of hormones. But, as the Commission emphasizes, the authorization of only so-called 'natural' hormones would not have prevented the creation of a black market for other substances which are undeniably dangerous but cheaper.

34. The applicants reply, however, that if it were permitted at least to administer

13 — See the aforementioned *Stölting* judgment and the judgment in Case 59/83 *Biovilac* [1984] ECR 4057, paragraph 17.

oestradiol, testosterone and progesterone, farmers would be less tempted to use stilbenes and thyrostatic substances (prohibited since 1981) or mixtures of various kinds. That is possible, but it was for the Council to exercise its discretionary power and to weigh the advantages and drawbacks of the two possibilities available to it: a total prohibition, with the risk of a black market, or the authorization of these three substances, with the certainty of arousing fresh calls for boycotts, without, however, eliminating the black market.

35. Furthermore, supervision of the rules is easier if all the substances are prohibited because then it is no longer necessary to check whether the substances used come within the category of prohibited products.

36. Even if the applicants are correct in maintaining that it is not possible to detect the use of the five hormonal substances in question by tests on the livestock or the meat, owing to the presence of natural hormones, other control measures are available to the competent authorities. It should not be forgotten that, under Article 1 of Council Directive 85/358/EEC of 16 July 1985 supplementing Directive 81/602/EEC: [14]

'The Member States shall ensure that official on-the-spot random controls are made on the substances referred to in Directive 81/602/EEC at the manufacturing, handling, storage, transport, distribution and sales stages.'

14 — OJ 1985 L 191, p. 46.

37. By comparing the quantities produced or sold with those which, on average, are needed for therapeutic treatments, it is possible to detect whether the prohibition has been infringed.

38. Moreover, Article 3 of Directive 85/358 provides for random controls on animals on their farms of origin, particularly in order to detect traces of implants, together with an official control for the presence of substances the use of which is prohibited on farms. Once all the substances are prohibited it is no longer necessary to analyse the precise nature of products, and in particular of mixtures.

39. As regards the possibility of achieving the objective pursued by means of a less restrictive measure, the applicants claim, first of all, that it would have been possible to allay the fears of consumers by disseminating information on the harmlessness of the five substances and the advantages of leaner meat. But this argument presupposes the solution of the precise problem on which opinions differ, namely whether the available scientific reports demonstrate in a definitive and irrefutable manner that the substances in question are totally innocuous.

40. Secondly, the applicants consider that it would have been sufficient to impose a labelling requirement for meat from treated animals.

41. In my opinion, the Council and the Commission have however convincingly demonstrated that labelling is not a real alternative. In fact, it would be necessary to

'follow' the meat of each animal from the slaughterhouse to the butcher or to the supermarket, and to label separately each of the numerous pieces of meat, as well as cold-meat preparations such as sausages. In most Member States such labelling would, moreover, be counter-productive, since meat labelled in that way would be refused.

42. As regards proportionality in the narrow sense, that is to say the weighing of damage caused to individual rights against the benefits accruing to the general interest, it should be stated that the maintenance of public health must take precedence over any other consideration. Once the Council had taken the view, in the context of its discretionary power, that it could not ignore the doubts felt by many Member States, and a large proportion of public opinion, as to the harmlessness of these substances, it was entitled to impose financial sacrifices on the persons concerned.

43. I therefore consider that the reply to the second question should be in the negative.

Infringement of the principle of equality

44. The applicants in the main proceedings maintain that the directive is discriminatory because its economic effect varies considerably as between the Member States. The administering of hormones is, in fact, practised much more widely in the United Kingdom, Spain, France and Ireland than in the other Member States, owing to different livestock-rearing traditions. The High Court has informed the Court that these facts are correct.

45. It is, however, interesting to note that amongst the countries mentioned only the United Kingdom seems to have voted against the directive. In the observations which it submitted, the Spanish Government expressly denies that the directive is discriminatory. It submits that 'that argument cannot be accepted inasmuch as the very rationale for the directive is the existence of disparate rules in the various Member States. If the situation were identical in all the Member States, no harmonizing legislation would be required . . . . Furthermore, no discrimination can arise when the Community provisions apply in the same manner in all the Member States. They contain no special derogation in respect of any one Member State which places it at an advantage over the others' (Section III, pp. 5 and 6 of the Spanish Government's observations). I subscribe to these arguments, and to those submitted to the same effect by Italy, the Council and the Commission. The judgments cited by the applicants in support of their argument relate to situations of such a different nature that they cannot serve as precedents in this case.

Misuse of powers

46. In its fourth question, the national court asks whether Directive 88/146 must be held to be invalid by reason of the Council's misuse of powers, on the ground that the directive is inconsistent with the objectives of the common agricultural policy contained in Article 39 of the EEC Treaty.

47. In this regard, the applicants in the main proceedings rely on arguments

adduced in connection with the preceding questions and deduce from those arguments that since the measure adopted affords no benefit, it cannot contribute to the achievement of the objectives of Article 39 of the Treaty and is, consequently, in fact intended to achieve a different objective, not admitted by the Council, namely a reduction in beef surpluses, to be made possible by the decrease in production due to the fall in productivity caused by the measure adopted.

48. The applicants have produced witness statements seeking to show that the Parliament was very exercised by the surpluses at the time when it held its debate on the Commission's proposal, and other statements which are said to show that this preoccupation was also shared by the Commission.

49. But in the Court's judgment in Case 63/83 *Lux* v *Court of Auditors* [1984] ECR 2447, at p. 2465, it is stated that:

'As the Court has repeatedly held . . . , a decision may amount to a misuse of powers only if it appears, on the basis of objective, relevant and consistent [facts], to have been taken for purposes other than those stated.'

50. Whilst it is possible that the institutions perceived that a reduction in meat production would be an additional positive benefit of the prohibition, the evidence adduced by the applicants does not reveal that this consideration was the real or decisive ground on which the Council's action was based, and that all the reasons set out in the recitals served only to conceal that ground.

51. I therefore propose that the Court's reply to the fourth question should be in the negative.

Inadequate statement of reasons

52. On this point the applicants in the main proceedings present argument which is closely linked to the preceding question. They maintain that since the directive was dictated not by the reasons appearing in its statement of reasons but by the desire to tackle meat surpluses, this consideration ought to have appeared in the statement of the reasons underlying the directive, which is therefore void for failure to state adequately the reasons on which it is based.

53. Having already established that the applicant's arguments as to the real reasons for the directive cannot be accepted, for want of adequate evidence, I am led to the conclusion that this argument must necessarily also be rejected. Moreover, I would recall that the Court has already held, at paragraph 28 of the aforementioned judgment in Case 68/86, that the preamble to the directive gives a sufficiently clear statement of the objectives pursued.

54. It follows that my proposed reply to the fifth question is also in the negative.

Infringement of essential procedural requirements

55. The applicants in the main proceedings plead three formal defects which, in their opinion, affect the validity of the directive.

56. They argue first of all that as a result of the annulment of Directive 85/649, all preparatory acts, including the Commission's proposal and the opinion of the European Parliament, which were

obtained prior to the 'adoption' of the directive, are of no effect.

57. Like the Commission and the Council, I consider, however, that the annulment of the earlier directive by the Court, on account of a purely procedural defect occurring at the last stage of adoption, could not have any effect on the validity of the procedure completed prior to the unlawful use by the Council of the written procedure. Consequently, both the Commission's proposal and the Parliament's opinion remained valid in spite of the annulment of Directive 85/649.

58. As regards the Commission's proposal, it should also be pointed out that the third paragraph of Article 149 of the EEC Treaty provides that 'as long as the Council has not acted, the Commission may alter its original proposal . . . '. It follows that a proposal 'stays on the table' until the Council has acted (unless, of course, it has been formally withdrawn). Now, as Directive 85/649 was declared void on account of a formal defect, the Council had not acted validly on the Commission's proposal and it remained capable of being taken up.

59. In the applicant's view, the Parliament's opinion and the Commission's proposal ought also to have been regarded as superseded because they have related to the situation prevailing in 1984 and 1985 and were based on the totality of scientific and other knowledge available at that time. The answer to that must be that if the Parliament in February and March 1988 had been of the opinion that the directive ought not to be adopted again in the version which was declared void by the Court, it would certainly have passed a resolution to that effect, and that the Commission, which is represented at Council meetings, would have been perfectly able to inform the Council of any change of view on its part.

60. The applicants in the main proceedings also place reliance on the fact that the composition of the Parliament and the Commission has changed since 1984/85 following the accession of Spain and Portugal. This consideration is of no relevance, as the Parliament and the Commission always act as institutions, whatever may be their composition.

61. Finally, the United Kingdom further maintains that even in 1985 the Parliament should in any event have been consulted again, since the proposal was considerably amended after it had given its opinion. However, it cannot be denied that that amendment followed the direction indicated by the Parliament in its opinion, which favoured the total prohibition of the five substances and was finally agreed to by the Council, whereas the proposal submitted to it provided only for the prohibition of zeranol and trenbolone. A fresh consultation of the Parliament was therefore not necessary.

62. It follows from all the foregoing that there has been no infringement of essential procedural requirements.

Infringement of the principle that legislation should not be retroactive in effect

63. The High Court of Justice in its last question asks the Court whether Directive 88/146 is void by reason of its inconsistency with the principle that legislation should not be retrospective in effect, particularly when it seeks to impose criminal penalties for acts committed before its publication. That is to say, Article 10 of the directive requires Member States to comply with it by 1 January 1988 at the latest, although it was adopted only on 7 March 1988.

64. In this connection, regard should be had first of all to the important difference which exists between a classic case of retroactivity, that is, a situation where new legislation suddenly becomes applicable to factual situations which have already occurred, and the present case, where:

(i) the persons concerned were given two years notice that with effect from 1 January 1988 certain practices would be forbidden (Directive 85/649 was in fact published in the Official Journal on 31 December 1985);

(ii) the practices in question were in fact prohibited in all the Member States with the exception of one from 1 January 1988 until the date of the Court's judgment, namely 23 February 1988.

65. Secondly, it should be observed, as the Italian Government and the Council have done, that it is in principle the national implementing measures which produce effects for individuals and not the directives themselves. The directive in question, moreover, contains no provision of a penal nature.

66. Thirdly, the annulment of a directive does not necessarily create a legal vacuum in all the Member States. That depends on the nature of the measures adopted at national level.

67. In the case before the Court, eight Member States had already prohibited the five hormonal substances, by way of independent decisions, well before the adoption of the directive in 1985. The national measures in question certainly did not become invalid after the annulment of the directive. Other Member States took such measures only in order to comply with the directive. In some of these countries the measures in question were probably adopted in pursuance of the usual legislative or regulatory competences, as if it were a question of a purely national decision. There again, the annulment of the directive would not have called in question provisions of internal law and no problem of retroactivity can therefore arise.

68. In the United Kingdom, on the other hand, Directive 85/649 seems to have constituted the one and only legal basis for the provisions adopted in national law, namely the Medicines (hormone growth promoters) (prohibition of use) Regulations 1986, SI 1986 No 1876, which entered into force on 1 December 1986. If these regulations in fact became invalid by reason of the annulment of Directive 85/649 there was, at that time, no provision of national law prohibiting the administering to animals of the five hormonal substances, and the administering thereof was therefore not a punishable offence.

69. As to Directive 88/146, it was implemented by national regulations having the same title (SI 1988 No 705), which entered into force only on 13 April 1988. The Council is therefore probably right to draw attention to the fact that the applicants in the main proceedings do not seem, at any time, to have been subject to a provision of domestic law having retroactive effect. The question whether the United Kingdom has failed to fulfil its obligations under the directive by not making the provisions of its national regulations retroactive need not be examined here.

70. These reflections do not however relieve me from examining whether Directive 88/146 must be deemed to be invalid on account of the retroactive effect which it provides for.

71. It is clear from the Court's case-law that 'the principle that penal provisions may not have retroactive effect is one which is common to all the legal orders of the Member States and is enshrined in Article 7 of the European Convention for the Protection of Human Rights and Fundamental Freedoms as a fundamental right; it takes its place among the general principles of law whose observance is ensured by the Court of Justice'. [15]

72. The Court has, however, held that apart from this aspect the principle that provisions may not have retroactive effect is not absolute, by stating that 'although in general the principle of legal certainty precludes a Community measure from taking effect from a point in time before its publication, it may exceptionally be otherwise where the purpose to be achieved so demands and where the legitimate expectations of those concerned are duly respected'. [16]

73. Are those conditions satisfied in this case? Did the objective to be achieved require the directive to have retroactive effect to 1 January 1988?

74. It may be observed firt of all that the Council was evidently of the opinion that since the directive had been annulled simply on account of a procedural defect, it was appropriate to adopt it afresh as rapidly as possible in unchanged form. That explains why one finds the formula, which in the meantime had become unrealistic, whereby the Member States must comply with the directive 'by 1 January 1988 at the latest'.

75. The Council thus took the view that it was necessary to prevent, during the few days between the annulment of the directive and its fresh adoption, a legal vacuum from arising in which the administering of hormonal substances might be resumed. It therefore wished to give a new legal basis in Community law to provisions which had already been adopted by the Member States in compliance with Directive 85/649, in so far as the continued validity of these provisions depended on the existence of a valid directive, even if it was doubtless aware that penalties could not be imposed in respect of acts committed during the period in question.

76. It was also necessary to give retroactive effect to the directive in order to bring into force certain of its provisions which impose major obligations in connection with the implementation of the directive, such as, for example, Article 4, which was cited by the United Kingdom and requires the keeping of a register detailing quantities of substances produced, acquired, sold or used from 1 January 1988 onwards.

77. I consider that retroactive effect was justified by these objectives and that it was not necessary to state grounds, which would have required an alteration of the preamble to the directive.

78. It also seems clear to me that between 23 February and 7 March 1988 the persons concerned, including the applicants in the main proceedings, could not 'have acquired a legitimate expectation that the substances in question would be made legal' (see the

15 — See the judgment of the Court in Case 63/83 *Regina* v *Kent Kirk* [1984] ECR 2689, and also the judgment of the Court in Case 80/86 *Kolpinghuis Nijmegen* [1987] ECR 3969, where the Court included the principle that provisions may not have retroactive effect amongst 'the general principles of law forming part of Community law'.

16 — See in particular the judgments in Case 99/78 *Decker* v *Hauptzollamt Landau* [1979] ECR 101 and, most recently, in Case C-337/88 *Società agricola fattoria alimentare SpA* [1990] ECR I-1

Council's viewpoint, as it is summarized in the Report for the Hearing). On the contrary, since the directive had been annulled only on the ground of a formal defect and there was reason to conclude that there had been a change of view in a majority of the Member States and in public opinion, it was to be expected in all probability that the directive would be adopted again, and this time validly.

79. That said, the principle that penal provisions may not have retroactive effect must not be whittled away. What is to happen, therefore, if in fact in one or other of the Member States the provisions adopted in order to implement Directive 85/649 have lapsed because in national law they were founded on a legal basis whereby acts of the European institutions may be implemented only in so far as they are valid, and if such a Member State, in order to comply with Directive 88/146, has adopted a new provision in national law having retroactive effect to 1 January 1988?

80. In such a case, the directive does not require national courts to impose penalties in respect of facts occurring before the date on which the national measure implementing the directive became applicable to individuals. Those courts are entitled to interpret Article 10 of the directive in the light of the principle that penal provisions may not have retroactive effect, and to take for granted that, in drawing up that article, the Council neither sought nor was able to derogate from that principle.

81. It follows from all the foregoing that Directive 88/146 may not be deemed to be void on the ground that it is incompatible with the principle that provisions may not have retroactive effect, since it is to be interpreted in the way in which I have indicated.

Conclusion

82. I propose that the Court should reply to the High Court as follows:

'Consideration of the questions raised has disclosed no factor of such a kind as to affect the validity of Directive 88/146/EEC of 7 March 1988 prohibiting the use in livestock farming of certain substances having a hormonal action, it being understood that Article 10 thereof must be interpreted as meaning that it does not require Member States to impose penalties on individuals in respect of facts which occurred prior to the date when the provision of domestic law implementing the directive became applicable to them.'