# OPINION OF ADVOCATE GENERAL RUIZ-JARABO COLOMER
delivered on 4 October 2001 [1]

1. The Council of the European Union is seeking to have a judgment of the Court of First Instance partially set aside, on the ground that it failed to examine the objection of inadmissibility raised by the Council in a case in which two undertakings were seeking annulment of a directive and compensation for the damage resulting therefrom. [2]

The directive was not annulled since the application was dismissed as unfounded. However, the Council is appealing, since it considers that the Court of First Instance committed a fundamental error of law and an infringement of the fourth paragraph of Article 230 EC and departed from its own case-law by not ruling on the preliminary issue as to whether the applicants had *locus standi* to apply for annulment of a directive.

The appellant requests the Court of Justice to set aside paragraphs 143 and 146 of the judgment of the Court of First Instance [3] and to rule on the objection of inadmissibility raised by it in Case T-125/96. It is not, however, seeking an order for costs against the defendants.

## I. The judgment delivered by the Court of First Instance

2. On 29 April 1996 the Council adopted Directive 96/22/EC, [4] Article 2(b) of which provides that Member States are to ensure that the placing on the market of beta-agonists for administering to animals intended for human consumption is prohibited. Under Article 4(2) Member States may authorise the oral administering for therapeutic purposes of veterinary medicinal products containing allyl trenbolone or beta-agonists to *equidae* and pets, provided they are used in accordance with the manufacturer's instructions, and beta-agonists, in the form of an injection to induce tocolysis in cows when calving.

1 — Original language: Spanish.

2 — Case T-125/96.

3 — Joined Cases T-125/96 and T-152/96 *Boehringer and Others* v *Council and Commission* [1999] ECR II-3427.

4 — Directive concerning the prohibition on the use in stock-farming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ 1996 L 125, p. 3).

3. Boehringer Ingelheim Vetmedica GmbH ('BI Vetmedica') is practically the only pharmaceutical company within the European Union to produce and market veterinary medicinal products containing a beta-agonist, namely clenbuterol, for the treatment of respiratory disorders in animals intended for human consumption. It accounts for about 97% of sales of the veterinary medicinal products affected by the prohibition on the marketing and administering of beta-agonists laid down in Directive 96/22.

The adoption of that directive meant that, with effect from 1 July 1997 (the date on which Member States were to have adapted their domestic laws), BI Medica was unable to market in those States its veterinary medicines containing clenbuterol for animals intended for human consumption, except for the therapeutic purposes listed in Article 4(2).

4. BI Vetmedica and C.H. Boehringer Sohn ('Boehringer'), which is the sole owner of the former and one of the leading 20 pharmaceutical companies in the world, brought an application on 9 August 1996 seeking the partial annulment of Directive 96/22 and compensation for damage.

5. By a separate document lodged at the Registry on 31 October 1996, the Council raised an objection of inadmissibility pursuant to Article 114 of the Rules of Procedure. Two years later, by an order of 19 November 1998, the Court of First Instance decided to join the objection of inadmissibility to an examination of the merits of the case.

6. On 8 July 1996 the Commission adopted Regulation (EC) No 1312/96, [5] in which it established provisional maximum residue limits for clenbuterol in foodstuffs of animal origin, but exclusively for the therapeutic purposes authorised under Directive 96/22/EC, namely, in the case of bovines, solely for inducing tocolysis in cows when calving and, in the case of equines, for inducing tocolysis and treating respiratory ailments.

7. On 27 September 1996, BI Vetmedica and Boehringer brought an action [6] raising a plea of illegality with regard to Directive 96/22 and seeking the partial annulment of Regulation No 1312/96.

8. The parties stated that they had no objection to the cases being joined for the purposes of the judgment.

5 — Regulation amending Annex III of Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ 1996 L 170, p. 8).

6 — Case T-152/96.

Realising that the application for the partial annulment of Regulation No 1312/96 in Case T-152/96 was essentially based on the plea of illegality raised against Directive 96/22, the partial annulment of which formed part of the subject-matter of the action in Case T-125/96, and that the arguments used by the applicants to challenge the legality of that directive were substantially the same in both cases, the Court of First Instance deemed it appropriate to rule on the issue, common to both cases, of the legality of Directive 96/22, before examining the outstanding questions of admissibility and substance raised by each of them.

9. For the purpose of establishing the illegality of Directive 96/22, the applicants raised four pleas in law: breach of the principle of proportionality; breach of the principles of legal certainty and protection of legitimate expectations; breach of the principle of sound administration; and infringement of Article 43 of the EC Treaty on the ground of failure to comply with the requirement to consult the European Parliament further when the text finally adopted, taken as a whole, differed materially from the text on which it had already been consulted.

Paragraphs 49 to 142 of the judgment under appeal are given over to an examination of those four pleas in law, which are dismissed in turn. For that reason, in paragraph 143, the Court of First Instance declared the claim for annulment of Directive 96/22 unfounded and considered that there was no need to rule on the objection of inadmissibility raised by the Council.

The claim for compensation was based on an alleged breach of the rules of law relied on by the applicants. Since the Court of First Instance had already held that Directive 96/22 did not infringe any of those rules, it dismissed the claim as unfounded, adding that there was no need to rule on the objection of inadmissibility raised by the Council.

10. In its operative part, the judgment annulled Commission Regulation (EC) No 1312/96 in so far as it restricted the validity of the maximum residue limits established for clenbuterol to certain specified therapeutic indications for bovines and equines, and for the rest dismissed the applications.

## II. The Appeal

11. The Council acknowledges that the judgment under appeal is favourable to it since the Court of First Instance accepted the arguments which it raised against the claim for partial annulment of Directive 96/22 and the claim for compensation for

damage in Case T-125/96 and against the plea of illegality raised in the context of the application for partial annulment of Regulation No 1312/96 in Case T-152/96. However, it is lodging an appeal since it considers that the Court of First Instance erred in law by failing to examine the objection of inadmissibility raised on the ground of the applicants' lack of *locus standi*.

In their response, BI Vetmedica, Boehringer and the Fédération de la santé animale (Fedesa), which in the proceedings before the Court of First Instance was granted leave to intervene in support of the forms of order sought by those undertakings, maintained that the Council's appeal was manifestly inadmissible, in particular since it did not comply with the conditions laid down in the second paragraph of Article 49 of the EC Statute of the Court of Justice, given that the Council had been successful.

12. The President of the Court of Justice authorised the Council to prepare a succinct reply dealing only with that issue.

BI Vetmedica, Boehringer and Fedesa lodged rejoinders. The Government of the United Kingdom, which intervened in the proceedings at first instance with the aim of challenging the Council's contention that the claim for compensation should be dismissed as inadmissible, focuses on the same point in its response and has not submitted a rejoinder.

The Stichting Kwaliteitsgarantie Vleeskalverensector (SKV) and the Commission, which intervened before the Court of First Instance in support of the forms of order sought by the Council, lodged a response but not a rejoinder.

13. Since none of the parties submitted an application setting out its reasons for wishing to be heard, the Court of Justice decided, in accordance with the provisions of Article 120 of the Rules of Procedure, to dispense with the hearing.

14. For the purposes of an analysis of the legal questions to which this case gives rise, I shall deal with the admissibility of the appeal as a preliminary issue. I shall then look at the merits of the case in the following order: I shall examine the objection of inadmissibility raised before the Court of First Instance in the action for annulment of Directive 96/22 and then the objection of inadmissibility raised in the action for compensation for damage; and, lastly, I shall express my view on the admissibility of the application for annulment.

A. *The admissibility of the appeal*

15. BI Vetmedica and Boehringer contend that the appeal brought by the Council (the defendant before the Court of First Instance) is inadmissible for two reasons,

the first being that the fact that it has been successful prevents it from appealing, in accordance with Article 49 of the Statute of the Court of Justice. Since the application was held to be unfounded, as the Council contended it should be, the Council cannot maintain, for the purpose of seeking to have the judgment set aside, that it was unsuccessful in its submissions.

The second reason is that the application does not satisfy the requirements of Article 225 EC, Article 51 of the Statute and Article 112(1)(c) of the Rules of Procedure of the Court of Justice, since the appellant confines itself to reproducing the arguments that it put forward before the Court of First Instance. It does not identify the error of law in the judgment. Nor does it cite the provision that has been infringed.

16. Fedesa endorses the first ground put forward by the respondent undertakings and proposes that the consistent line of decisions in which it has been held that any measure which produces binding legal effects such as to affect the interests of an applicant by bringing about a distinct change in his legal position may be the subject-matter of an action for a declaration that it is void should also be applied to acts which are amenable to appeal. [7]

7 — It relies on Case 60/81 *IBM* v *Commission* [1981] ECR 2639, paragraph 9, and on Joined Cases C-68/94 and C-30/95 *France and Others* v *Commission* [1998] ECR I-1375, paragraph 62.

17. The Council contends that its appeal is admissible and claims that the form of order sought in the document in which it claimed that the action for annulment was inadmissible, and which it submitted in accordance with Article 114(1) of the Rules of Procedure of the Court of First Instance, was not granted. It submits that, according to the fourth paragraph of Article 230 EC, a private individual does not have *locus standi* to institute proceedings for annulment of a directive, so that, if the Court of First Instance is satisfied that the contested act is in the nature of a directive, there is no need to proceed with its examination of the act since the action is inadmissible in any event. The Council states, last, that it does not claim to restrict the discretion of the Court of First Instance to organise its procedure, but that it seeks a determination of the question of the applicants' *locus standi* and a decision as to the stage at which such a matter should be considered.

18. It must be acknowledged that the present appeal is already distinguished by a certain novelty as regards its admissibility, which is revealed by the following details: the appeal has been lodged by the defendant at first instance, which recognises that its claims as to the substance were upheld in the judgment, since the contested directive was not declared void; the appellant is seeking not to have the judgment at first instance set aside but a decision on the objection that the action was inadmissible on the ground that the applicants lacked *locus standi*, which was

not expressly resolved; should the Court of Justice allow the appeal, its decision would have no effect on the operative part of the contested judgment; and, last, the grounds on which the judgment is challenged are that the Court of First Instance failed to consider whether there existed any absolute bar to proceeding with the action when it should have done so.

However, those characteristics, which distinguish the present appeal from the vast majority of appeals to the Court of Justice, do not mean that the Council's appeal should be declared manifestly inadmissible, as BI Vetmedica, Boehringer and Fedesa propose.

19. In my view, the Council is entitled to appeal against the judgment, for a number of reasons.

20. First, because, pursuant to Article 114(1) and (4) of the Rules of Procedure of the Court of First Instance, an application for a decision by that Court on admissibility which does not go to the substance of the case is to be made by a separate document. The Court then decides on the application or reserves its decision for the final judgment.

The Council complied with the requirements of that provision by submitting, on 31 October 1996, the document in which it requested the Court to declare the application of BI Vetmedica and Boehringer inadmissible. Instead of resolving that issue directly, the Court of First Instance reserved its decision for the final judgment. When it delivered its judgment, however, it decided to resolve the substance of the case first and then, since it did not annul the contested measure, it held that there was no need to rule on the objection of inadmissibility.

21. Second, because, under the first paragraph of Article 49 of the Statute, an appeal may be brought, *inter alia*, against a decision of the Court of First Instance disposing of a procedural issue concerning a plea of inadmissibility.

Had the Court of First Instance resolved the issue by means of a decision declaring the application admissible and thus recognising that the applicants had *locus standi*, the Council would have been able to appeal. Had the Court of First Instance decided to reserve its decision on the objection for the final judgment and then decided not to annul the directive, the admissibility of an appeal by the Council would not have given rise to major problems. The difficulty in the present case seems to lie in the fact that the Court of First Instance did not expressly rule on the objection.

22. I believe that once the Court of First Instance dealt with the substance of the

case without first considering whether the applicant had *locus standi*, in spite of having been requested to do so in writing and in spite of the views expressed by the Council throughout the informal meeting held in Luxembourg in November 1998 between the Judge Rapporteur and the representatives of the parties to the case, it must be taken to have accepted implicitly that the parties had *locus standi* to bring the action.

23. On that point, there is only one precedent which seems to me to be relevant to this case. France was the first Member State to make use of the third paragraph of Article 49 of the Statute of the Court of Justice. It did so because it disagreed with the Court of First Instance, which, after reserving its decision for the final judgment, dismissed the Commission's objection that the action was inadmissible on the ground that the applicants lacked *locus standi*. In that case, the Court of First Instance had expressly declared the action admissible and, after considering the substance of the matter, dismissed it as unfounded. [8]

Advocate General Mischo emphasised the novelty of the appeal in points 5 to 16 of his Opinion [9] and pointed out that it did not appear to seek to set aside, in whole or in part, the decision of the Court of First Instance within the meaning of Article 113(1) of the Rules of Procedure of the Court of Justice.

8 — Case C-73/97 P *France* v *Comafrica and Others* [1999] ECR I-185.

9 — Opinion in Case C-73/97 P *France* v *Comafrica and Others*, cited in footnote 7 above.

24. In point 13 of his Opinion, Advocate General Mischo states *a propos* the admissibility of the appeal: 'The fact that the Court of First Instance then logically moved on to examine the substance of the case and that there is no separate judgment concerning the plea of inadmissibility alone (as would have been the case if the plea had been upheld) should not hide the fact that, in reality, the Court took two successive decisions. An appeal must be possible against each of them.'

In the judgment, the Court of Justice allowed the appeal, annulled the judgment of the Court of First Instance and, giving final judgment in the matter, dismissed the application for annulment lodged by Comafrica Spa and Dole Fresh Fruit Europe Ltd & Co. as inadmissible.

25. Third, there is a further argument for declaring the Council's appeal admissible. Under the third paragraph of Article 49 of the Statute of the Court of Justice, with the exception of cases relating to disputes between the Community and its servants, an appeal may be brought not only by Member States which did not intervene in the proceedings at first instance but also by the Community institutions, which are in the same position as Member States or institutions which intervened at first instance. Since the Council would have been able to lodge the present appeal without having been a party at first instance, there are even more compelling reasons why it should be able to do so

when, as in the present case, it was a party and its claim that the action for annulment was inadmissible was wholly unsuccessful, as required by the second paragraph of Article 49 of the Statute.

I must therefore maintain that the Council has *locus standi* to lodge this appeal.

26. Nor do I agree with the further grounds on which the respondents allege that the appeal is inadmissible, for the following reasons.

First, the Council does not merely reproduce the arguments put forward at first instance, since it does not claim in the appeal that the objection was well founded: the ground on which it relies is the Court of First Instance's failure to rule on the objection; and, for obvious reasons, that omission could not be addressed by the parties prior to pronouncement of the judgment under appeal.

Second, the Council has identified the error of law as the Court of First Instance's omission to resolve the objection of inadmissibility before dealing with the substance of the case.

And, third, the Council identifies the provision infringed by the judgment as Article 230 EC.

27. I therefore consider that the admissibility of the present appeal does not give rise to any doubt.

B. *The substance of the appeal*

(a) The objection of inadmissibility in the annulment proceedings

28. Although the Court of First Instance upheld its claims and did not annul Directive 96/22, the Council considers that that outcome was only apparently successful and has appealed against the judgment, seeking a declaration that the Court of First Instance committed a fundamental error of law by not dealing with the objection of inadmissibility based on the applicants' lack of *locus standi* when it should have done so. The Council maintains that by not ruling on the right of a natural or legal person to seek the annulment of a directive before proceeding to examine the substance of the case, the Court of First Instance did not act in accordance with either the letter or the spirit of the fourth paragraph of Article 230 EC and that the decision is inconsistent with its own case-law. Whether or not the applicant has *locus standi* is a preliminary issue which must be evaluated before the substance of a case is

examined; and the admissibility of an action assumes such importance for the proceedings that its analysis cannot be omitted without a substantial reason, even though the Court of First Instance dismissed the action as unfounded. In the interests of the sound administration of the judicial system and in order to avoid unnecessary actions, the parties must be told as soon as possible whether or not they have capacity to take part in the proceedings. In an application for annulment of what is in fact a directive, there is no need to proceed with the remainder of the case, since it would be superfluous to establish whether, in spite of satisfying the requirements of every directive, the contested act may be of direct and individual concern to the applicant.

SKV further states that, although the Court of First Instance, for reasons of procedural efficiency, proceeded to deal with the legality of Directive 96/22 before turning to issues of admissibility and substance, it was not entitled to ignore the objection of inadmissibility raised by the Council, taking into account the questions of principle raised in this case.

The Commission, which agrees with the Council, further maintains that if the lack of jurisdiction of the Court of First Instance to take cognisance of an action determines that the application is devoid of purpose and that it must be dismissed, the inadmissibility of the application is a ground for finding that the Court has no jurisdiction to hear the case. The admissibility of an application is not at the discretion of the parties, since a bar to proceeding with the case is mandatory and the Court is under an obligation to rule on an objection of that nature raised by one of the parties. Furthermore, in this case, other avenues were open to the Court of First Instance: for example, it could have ruled on the objection raised by the Council and given judgment on the substance, or annulled Regulation No 1312/96 on the same ground as that on which the judgment under appeal is based, without there being any need to examine the other grounds put forward, and declared that the application for annulment of Directive 96/22 was inadmissible. Had it done so, the applicants would have been in the same position as they are now. The Court of First Instance could also have severed the action for annulment from the action for compensation for damage and declared the latter action admissible and the former inadmissible.

29. BI Vetmedica and Boehringer contend that, under the general principle of procedural law whereby the Court is master of both procedure and evidence, [10] the Court of First Instance has a wide discretion to organise the procedure in accordance with the characteristics of each case and of the connexity of the issues raised. This discretion includes the power to proceed to the substance of a case before investigating the admissibility of the application, provided that this course of action seems preferable for reasons of procedural economy or for any other reason. In this specific case, they consider that it was necessary, in the interest of the sound administration of justice and in order to facilitate the proper conduct of the proceedings, to rule on the legality of Directive 96/22 before examining the admissibility of the application,

10 — They cite the Opinion of Advocate General Cosmas in Case C-199/92 P *Hüls* v *Commission* [1999] ECR I-4287, point 48.

since the former was the central issue in Cases T-125/96 and T-152/96. To seek to limit the discretion of the Court of First Instance, as the Council does in its appeal, is equivalent to attacking the principle of separation of powers between institutions laid down in the EC Treaty. Fedesa fully supports the respondents' arguments.

30. As the respondents and Fedesa claim, the Court of First Instance does indeed have a wide discretion to organise the procedure. Thus, to take some examples, Article 64 of its Rules of Procedure regulates the measures of organisation of procedure which, pursuant to Article 49, may be prescribed at any stage of the proceedings; Article 51 establishes the grounds on which cases may be referred to the various differently-constituted benches; and Article 50 confers on the President the power to order that two or more cases be joined on account of the connection between them.

However, I do not believe that those discretionary powers are sufficiently wide to extend to the preliminary issues regulated exhaustively in Articles 111 to 114 of the Rules of Procedure, or that they include the power to refrain from expressly resolving an objection of inadmissibility raised by one of the parties.

31. That view is based on a number of reasons. First, the *locus standi* of the applicant to bring an action is a requirement which must be satisfied if the case is to proceed: where it is not, the Court has no jurisdiction to deal with the substance of the proceedings. Proof of that assertion lies in the fact that the persons with a right of access to the Community Courts are defined in the Treaty (Articles 226 EC to 228 EC for actions for failure to fulfil obligations under the Treaty; Article 230 EC for actions for annulment; Article 232 EC for actions for failure to act; or Article 236 EC for actions by officials) and in the Statute (Article 37 for intervention; and Articles 49 and 50 for appeals), not in the Rules of Procedure. Second, lack of *locus standi* is one of the absolute bars to proceeding with an action which the Court of First Instance may at any time consider of its own motion.

It is true that under Article 114(4) of its Rules of Procedure the Court of First Instance may decide on such an application or reserve its decision for the final judgment. In that regard, the Court of Justice has held that it is for the Court of First Instance to decide whether or not the proper administration of justice justifies immediate adjudication upon an objection of inadmissibility or postponement of such adjudication until final judgment. [11]

However, to my mind that does not mean that the Court of First Instance can address the substance of the case before resolving the issue of the alleged lack of *locus standi*. To take the opposite approach, which is precisely what it did in the judgment which the Court of Justice is asked to set aside, seems to me to prejudge the *locus standi*

11 — Case C-126/90 P *Bocos Viciano* v *Commission* [1991] ECR I-781, paragraph 6.

issue, since it would be illogical to declare an application inadmissible after adjudicating on the substance of the case. If the judgment at first instance fails to resolve the issue, a further problem arises: the Court of First Instance has treated the action as admissible without providing its reasons for doing so and the parties are therefore unable to determine whether their rights have been harmed and the Court of Justice is unable to exercise its power of review.

32. With a view to determining whether the judgment under appeal should be set aside, I have reviewed the cases of the Court of Justice and those of the Court of First Instance in which an objection of inadmissibility had been reserved for final judgment, in order to ascertain how each Court has acted in that regard. I shall examine the two groups of cases separately.

33. In the 30 cases to have come before the Court of First Instance which I have examined, I have found that, as a general rule, the Court refers to the objection of inadmissibility before dealing with the substance of the case, whether it is alleged that the applicant lacks of *locus standi*, [12] that the action is out of time, [13] that the contested measure is not open to challenge, [14] that the applicant has no interest in bringing the action, [15] that the contested measure does not harm the applicant, [16] that the action should not have been brought against the defendant, [17] or that the document containing the application does not satisfy the requirements of Article 44(1)(c) of the Rules of Procedure. [18] In one case, moreover, of the four grounds on which the defendant claimed that the action was inadmissible, the Court of first Instance considered three as preliminary issues and stated that the other, that the action was devoid of purpose, was a question of substance. [19]

Among this group I encountered one case which departed from the general rule. The Commission raised a plea of inadmissibility by means of a separate document and the Court made an order joining the plea to the main proceedings [20] without stating what the plea was or making any further reference to it.

In any event, in accordance with the case-law of the Court of First Instance, among the absolute bars to proceeding with an action, the existence of which it may consider at any time, even of its own

12 — Joined Cases T-528/93, T-542/93, T-543/93 and T-546/93 *Métropole Télévision and Others* v *Commission* [1996] ECR II-649.

13 — Joined Cases T-374/94, T-375/94, T-384/94 and T-388/94 *European Night Services and Others* v *Commission* [1998] ECR II-3141; and Case T-37/97 *Forges de Clabecq* v *Commission* [1999] ECR II-859.

14 — Case T-3/93 *Air France* v *Commission* [1994] ECR II-121.

15 — Joined Cases T-369/94 and T-85/95 *DIR International Film and Others* v *Commission* [1998] ECR II-357.

16 — Case T-167/97 *Skrikas* v *Parliament* [1998] ECR-SC I-A-287, II-857.

17 — Case T-112/95 *Dethlefs and Others* v *Council and Commission* [1998] ECR II-3819.

18 — Case T-72/99 *Meyer* v *Commission* [2000] ECR II-2521.

19 — Case T-37/92 *BEUC and NCC* v *Commission* [1994] ECR II-285.

20 — Order in Case T-136/95 *Industria del Frío Auxiliar Conservera* v *Commission* [1998] ECR II-3301, paragraph 22.

motion, are those relating to the requirements of admissibility of actions laid down in the fourth paragraph of Article 230 EC. [21]

34. Of the 40 cases to have come before the Court of Justice which I have examined, in practically all, including actions for failure to fulfil obligations, [22] the objection of inadmissibility is resolved before the substance of the case is examined, regardless of the bar to proceeding with the case alleged to exist: that the action is out of time, [23] that the applicant lacks *locus standi*, [24] that the action has been brought against a measure which is not among the acts amenable to challenge set out in the first paragraph of Article 230 EC, [25] that the applicant has no interest in bringing the action, [26] that the Court of Justice has no jurisdiction to hear the case, [27] that no prior complaint was lodged (in staff cases), [28] that there is no harmful act, [29] or that the action cannot be directed against the defendant. [30] On one occasion, moreover, despite analysing the plea of inadmissibility, the Court of Justice decided that the question whether the objection of inadmissibility was well founded must be determined together with the substantive issues raised by the dispute. [31]

In this group of decisions, too, I encountered a number which depart from the rule. In *Van Reenen* v *Commission* [32] the Commission claimed that the application was out of time and the Second

21 — Case T-239/94 *EISA* v *Commission* [1997] ECR II-1839, paragraph 26; Case T-100/94 *Michailidis and Others* v *Commission* [1998] ECR II-3115, paragraph 49; Case T-114/96 *Biscuiterie-confiserie LOR and Cofiserie du Tech* v *Commission* [1999] ECR II-913, paragraph 24; Case T-194/95 *Area Cova and Others* v *Council* [1999] ECR II-2271, paragraph 22; and Case T-12/96 *Area Cova* v *Council* [1999] ECR II-2301, paragraph 21.

22 — Case C-279/94 *Commission* v *Italy* [1997] ECR I-4743; and Case C-35/96 *Commission* v *Italy* [1998] ECR I-3851.

23 — Case 15/59 *Société métallurgique de Knutange* v *High Authority* [1960] ECR 1; Joined Cases 25/65 and 26/65 *Simet and Others* v *High Authority* [1967] ECR 113; Case 79/71 *Heinemann* v *Commission* [1972] ECR 579; Case 11/72 *Giordano* v *Commission* [1973] ECR 417; and Case 159/86 *Canters* v *Commission* [1988] ECR 4859.

24 — Case 106/63 *Toepfer* v *Commission* [1965] ECR 405; Joined Cases 41/70 to 44/70 *International Fruit Company and Others* v *Commission* [1971] ECR 411; Case 113/77 *NTN Toyo Bearing* v *Council* [1979] ECR 1185; Case 118/77 *ISO* v *Council* [1979] ECR 1277; Case 119/77 *Nippon Seiko* v *Council* [1979] ECR 1303; Case 120/77 *Koyo Seiko* v *Council and Commission* [1979] ECR 1377; Case 264/82 *Timex* v *Council and Commission* [1985] ECR 849; Joined Cases 87/77, 130/77, 22/83, 9/84 and 10/84 *Salerno and Others* v *Commission and Council* [1985] ECR 2523; Joined Cases C-305/86 and C-160/87 *Neotype Techmashexport* v *Commission and Council* [1990] ECR I-2945; Joined Cases C-320/86 and C-188/87 *Stanko France* v *Commission and Council* [1990] ECR I-3013; Case C-309/89 *Codorniu* v *Council* [1994] ECR I-1853; Case C-157/90 *Infortec* v *Commission* [1992] ECR I-3525; and Case C-65/90 *Parliament* v *Council* [1992] ECR I-4593.

25 — Case 22/70 *Commission* v *Council* [1971] ECR 263; Case C-213/88 *Luxembourg* v *Parliament* [1991] ECR I-5643; Case C-316/91 *Parliament* v *Council* [1994] ECR I-625; Case C-135/93 *Spain* v *Commission* [1995] ECR I-1651; and Case C-25/94 *Commission* v *Council* [1996] ECR I-1469.

26 — Joined Cases 177/73 and 5/74 *Reinarz* v *Commission* [1974] ECR 819; Case 4/74 *Scuppa* v *Commission* [1975] ECR 919; and Case 167/86 *Rousseau* v *Court of Auditors* [1988] ECR 2705.

27 — Case 126/76 *Dietz* v *Commission* [1977] ECR 2431; and Joined Cases 271/83, 15/84, 36/84, 113/84, 158/84, 203/84 and 13/85 *Ainsworth* v *Commission and Council* [1987] ECR 167.

28 — Case 6/79 *Grassi* v *Council* [1980] ECR 2141; Case 23/87 *Aldinger and Others* v *Parliament* [1988] ECR 4395; and Case 126/87 *Del Plato* v *Commission* [1989] ECR 643.

29 — Case 806/79 *Gerin* v *Commission* [1980] ECR 3515.

30 — Case 267/82 *Développement SA and Clemessy* v *Commission* [1986] ECR 1907.

31 — Case C-57/95 *France* v *Commission* [1997] ECR I-1627, paragraphs 9 and 10. This was proposed to the Full Court by Advocate General Tesauro in his Opinion.

32 — Case 189/73 [1975] ECR 445.

Chamber of the Court of Justice held that, since the action clearly lacked any foundation, there was no need to give a ruling on the objection of inadmissibility. [33] In *Giry* v *Commission* [34] the Commission put forward, as reasons why the action should not be admitted, the failure to lodge a prior administrative complaint and the absence of interest in bringing the action. The same Chamber considered that, in view of the close connection between those objections and the submissions on the substance, it would first examine the substance of the case. As it dismissed the application, there was no need to consider the grounds of inadmissibility raised. [35] In Joined Cases 193/82 to 198/82 *Rosani and Others* v *Council* [1983] ECR 2841 the Council put forward as grounds of inadmissibility the fact that no prior administrative complaint was lodged and that no negative decision had been taken, either expressly or by implication. On this occasion the Third Chamber considered, without stating its reasons, that it was appropriate to determine the substance of the case and to determine subsequently whether it was still necessary to rule on the objections of inadmissibility. [36] In *Tradax* v *Commission* (Case 64/82 [1984] ECR 1359) the Commission claimed that the action was inadmissible because, *inter alia*, it was directed against a measure which was not susceptible of review within the meaning of Article 230 EC. The First Chamber held in paragraph 12 of the judgment that, in view of the close relationship between the question of admissibility and the substance of the action, it was appropriate to proceed directly to consideration of the substance of the case. [37] Last, in *Bocos Viciano* v *Commission* [38] the Commission claimed that the appeal was inadmissible owing to a procedural irregularity in the way in which the application had been submitted and mentioned up to five omissions. In the Order, the President of the Court of Justice dismissed the appeal as clearly unfounded, in accordance with Article 119 of the Rules of Procedure, and stated that it was not necessary to rule on the objections of inadmissibility.

35. None of the above decisions, taken in isolation or in combination, provides grounds for interpreting Article 92(2) of the Rules of Procedure of the Court of Justice and Article 113 of the Rules of Procedure of the Court of First Instance as meaning that the possibility of considering at any time, of its own motion, whether there exists any absolute bar to proceeding with an action may be understood as an option of the Court. On the contrary, in my view, the emphasis should be placed on the fact that this examination may be carried out by the Court of its own motion and at any time, which does not mean that it can dispense with doing it. The examples in which the Court of Justice has failed to deal first with an objection of inadmissibility in a dispute are rare, as seen above, and, furthermore, four were resolved by Chambers of three judges, while the fifth is an Order of the President applying Article 119 of the Rules of Procedure.

33 — It was Advocate General Mayras who suggested that, in spite of the fact that, regardless of how the time-limits were calculated, the action was out of time, the interests of the equitable administration of justice demanded (since in his view the application was unfounded) that the Court should not confine itself to the consideration of the objection of inadmissibility but should give a definitive ruling on the case.

34 — Joined Cases 126/75, 34/76 and 92/76 [1977] ECR 1937.

35 — Advocate General Capotorti, on the other hand, undertook a detailed examination of the objections to admissibility in his Opinion and proposed that they be rejected.

36 — Advocate General Verloren Van Themaat examined both objections and concluded that they should be rejected.

37 — In his Opinion, Advocate General Sir Gordon Slynn did examine the grounds of inadmissibility put forward by the Commission.

38 — Cited in footnote 11 above.

In any event, moreover, in the cases which I have examined the objection of inadmissibility did not consist in the lack of *locus standi* of the applicant, which was the position in Case T-125/96, where the Council maintained that the applicant undertakings' application for annulment of a directive was inadmissible.

36. For the reasons stated, I consider that the Court of First Instance erred in law by not examining the Council's objection that the application in Case T-125/96 was inadmissible on the ground that the applicants lacked *locus standi* before dealing with the substance of that case. The appeal is therefore well founded and the judgment of the Court of First Instance must be set aside in so far as the latter failed to examine that objection and in fact admitted the application for annulment.

(b) The objection of inadmissibility of the action for compensation raised before the Court of First Instance and the failure to determine that objection which gave rise to the appeal

37. In paragraph 6 of its application, under the heading 'Background', the Council quotes paragraph 146 of the judgment under appeal, where the Court of First Instance held that there was no need to rule on the objection of inadmissibility because Directive 96/22 would not be annulled. The Council merely observes that this is the only point in the entire judgment at which the Court of First Instance refers to the objection. However, it does not expand on that alleged ground for setting aside the judgment, either in the application or in the reply. Nor is it addressed by either the respondent undertakings or the interveners, with the exception of the United Kingdom, which devotes its entire response to it.

38. In the proceedings at first instance, the Council argued that the action for compensation for damage was inadmissible owing to the nature of the contested act and to the fact that the damage had not been identified.

39. In the present proceedings, the United Kingdom claims that the Council's appeal should be dismissed in so far as it relates to paragraph 146 of the judgment. It contends that the special nature of the directive does not mean that it cannot give rise to the non-contractual liability of the Community. Although it is the national authorities that incorporate the rule into their domestic law, and although that legislation is the immediate source of the damage to individuals, it cannot be precluded at the outset that the origin of the liability may lie in the Community act. For this reason it disagrees with the Council's argument that individuals lack *locus standi* if the act which can allegedly give rise to non-contractual lia-

bility is a directive; and it maintains that it is necessary to ascertain in each case whether the origin of the damage lies in the conduct of the Member State or the conduct of the Community institutions, in order to know against whom the action for compensation must be brought.

40. On the assumption that the Council has also challenged the judgment of the Court of First Instance as regards the failure to examine the objection of inadmissibility of the action for non-contractual liability, which to my mind is not clear in view of the technique employed, which I have described in point 36, my position would be different from the one I expressed in relation to the failure to rule on the objection of inadmissibility on the ground that individuals lack *locus standi* to bring an action for annulment.

41. There are a number of reasons. First, it is settled case-law that the action for compensation provided for by Articles 235 EC and 288 EC was introduced as an autonomous form of action with a particular purpose to fulfil within the system of actions and subject to conditions on its use dictated by its specific nature, so that the fact that the action for annulment is declared inadmissible does not automatically mean that the action for compensation is inadmissible. [39] The conditions of admissibility of both actions are therefore not the same.

The second reason is that, unlike the position regarding the appeal, *locus standi* to bring an action for damages is not expressly regulated. It may be concluded from Articles 235 EC and 288 EC that what is required is damage caused by the institutions of the Community or by their servants in the exercise of their duties. As the Court of Justice has put it, non-contractual liability on the part of the Community under the second paragraph of Article 288 EC is subject to a number of conditions relating to the illegality of the conduct alleged against the Community institutions, actual damage and the existence of a causal link between the conduct of the institution and the damage complained of. If any one of those conditions is not satisfied, the entire action must be dismissed and it is unnecessary to consider the other conditions for non-contractual liability on the part of the Community. [40]

However, the Court has consistently held that the Community's non-contractual liability cannot be incurred through the adoption of a legislative measure involving a choice of economic policy unless a sufficiently flagrant violation of a superior rule of law for the protection of the individual has occurred. Thus in a legislative context characterised by a wide margin of discretion, which is essential for

39 — Case C-87/89 *Sonito and Others* v *Commission* [1990] ECR I-1981, paragraph 14; and order in Case C-257/93 *Van Parijs and Others* v *Council and Commission* [1993] ECR I-3335, paragraph 14.

40 — Case C-146/91 *KYDEP* v *Council and Commission* [1994] ECR I-4199, paragraph 19, and Case C-104/97 P *Atlanta* v *European Community* [1999] ECR I-6983, paragraph 65.

the implementation of the common agricultural policy, such liability can therefore be incurred only if the institution concerned has manifestly and gravely disregarded the limits on the exercise of its powers. [41]

42. In the light of that case-law, whether or not an action for compensation is admissible can to my mind depend only on whether the document containing the application satisfies the formal requirements laid down in the procedural rules.

Furthermore, the jurisdiction of the Court of Justice to entertain the case according to whether the damage sustained has its origin in an act of the Community institutions or in an act of the national authorities, the existence of damage, the unlawfulness of the conduct of the authority in question or of its servants in the exercise of their duties, the causal link and, where appropriate, a manifest and grave breach of the limits on the exercise of their powers are questions which fall to be examined when the Court is dealing with the substance of a case.

It is quite clear, moreover, that Article 235 EC and Article 288 EC do not limit the acts which, if the remaining conditions are satisfied, may give rise to a declaration that the Community has incurred non-contractual liability.

43. I consider, therefore, that the Court of First Instance did not err in law in paragraph 146 of the judgment under appeal when it failed to resolve the objection of inadmissibility raised by the Council, claiming that Directive 96/22 did not infringe any of the rules of law relied on in the procedure; and that, since the claim for compensation was based on an alleged breach of such rules, it should be dismissed as unfounded.

(c) The admissibility of the action for annulment

44. Pursuant to the second sentence of the first paragraph of Article 54 of the Statute, if the Court of Justice sets aside the decision under appeal, it may itself give final judgment in the matter, where the state of the proceedings so permits. In my view that provision should be applied, and the Court should proceed to examine the admissibility of the action for annulment submitted by BI Vetmedica and Boehringer against Directive 96/22, which formed the subject-matter of Case T-125/96.

41 — Joined Cases 83/76, 94/76, 4/77, 15/77 and 40/77 *HNL* v *Council and Commission* [1978] ECR 1209, paragraph 6, and Case 20/88 *Roquette frères* v *Commission* [1989] ECR 1553, paragraph 23.

45. In support of its claim that the action is inadmissible, the Council submits that under the fourth paragraph of Article 230 EC a natural or legal person may only institute proceedings for annulment of a decision addressed to that person or one which, although in the form of a regulation or a decision addressed to another person, is of direct and individual concern to the person in question. Those measures which are open to challenge are distinguished by the fact that they are not of general application or normative in nature, since, even where an action against a regulation is admitted, the measure in question is in reality a disguised decision. A further requirement is that the persons to whom the measure is addressed or those to whom it is of direct and individual concern be affected in legal terms owing to a factual situation which applies to them and distinguishes them from other persons.

On the other hand, directives, like regulations, are normative measures of general application, which apply in the abstract to situations determined objectively. However, directives differ from regulations in that, in order to produce legal effects, their provisions must be incorporated into the domestic law of the Member States, as provided for in Article 249 EC, since it is the national rules that confer rights and impose obligations on individuals. The essential difference between regulations and directives is that the former produce direct effects whereas the latter normally do not, since it is necessary to await the expiry of the period within which the Member States are to implement a directive; and when the application for annulment of Directive 96/22 was lodged at first instance that period had not yet expired.

SKV claims that if an individual were allowed to seek annulment of a directive, the interpretation of Article 230 EC would be stretched to the point of exceeding the permitted limits of the system of judicial protection laid down in the Treaty. Furthermore, the characteristics of directives are such that judicial protection for individuals is always possible in each State once they have been incorporated into domestic law.

46. BI Vetmedica and Boehringer contend that their action is admissible. They claim that the purpose of the fourth paragraph of Article 230 EC is to ensure the legal protection of individuals in all circumstances in which they, although they are not addressed by a decision, are directly and individually concerned by a Community measure, whatever its appearance. Furthermore, the fact that a measure enjoys normative character does not in itself prevent individuals from being able to challenge it, provided that the condition that they are affected by it is satisfied. Therefore, when the Court of Justice decides whether their application in Case T-125/96 was admissible, it will have to consider whether, in spite of the legislative nature of Directive 96/22, it was of direct and individual concern to the applicants.

Fedesa takes the same view and requests that if the Court of Justice should set aside the judgment it should refer the case back to the Court of First Instance, since the decision as to whether BI Vetmedica and Boehringer were directly and individually concerned raises complex questions of fact.

47. There is no doubt that, as already seen, the fourth paragraph of Article 230 EC restricts the *locus standi* of natural and legal persons to seek annulment of a Community measure. As the Court of First Instance has recently held, that paragraph makes no provision, for the benefit of individuals, for a direct action before the Community judicature challenging a directive. [42]

I would point out, however, that when an individual seeks annulment of a directive, the application is not declared inadmissible at the outset: the Court of First Instance considers whether the impugned measure is a legislative provision of general application and whether it is of direct and individual concern to the applicants. [43] The Court of Justice does likewise. [44]

48. The applicants at first instance sought the partial annulment, specifically of Articles 1 to 4, of Directive 96/22, the provisions of which should have been incorporated into the domestic law of the Member States by 1 July 1997, but the annulment of those articles was sought solely in so far as they prohibit the placing on the market of beta-agonists for administering to animals intended for human consumption.

However, none of those articles contains specific provisions having the nature of a disguised individual decision for the applicants at first instance. They form part of a legislative measure of general application aimed universally and in the abstract at a wide range of economic operators involved in activities associated with the raising of livestock for human consumption, who, once the national legal systems have been adapted, will not be allowed to carry out the following activities: placing on the market, marketing, administering to animals and possessing specific substances referred to, and placing on the market for human consumption animals to which those substances have been administered. In spite of that prohibition, Article 4 provides that Member States may authorise the administering for therapeutic purposes of

42 — Joined Cases T-172/98 and T-175/98 to T-177/98 *Salamander and Others* v *Parliament and Council* [2000] ECR II-2487, paragraph 27.

43 — See, by way of example, orders in Case T-463/93 *Guna* v *Council* [1993] ECR II-1205 and in Case T-99/94 *Asocarne* v *Council* [1994] ECR II-871 and judgments in Case T-135/96 *UEAPME* v *Council* [1998] ECR II-2335 and in *Salamander and Others* v *Parliament and Council*, cited in footnote 42 above.

44 — See orders in Case 138/88 *Flourez* v *Council* [1988] ECR 6393, Case 160/88 *Fédération européenne de la santé animale and Others* v *Council* [1988] ECR 6399 and Case C-10/95 P *Asocarne* v *Council* [1995] ECR I-4149 and judgment in Case C-298/89 *Gibraltar* v *Council* [1993] ECR I-3605.

certain substances listed exhaustively; and in order for those provisions to be applicable in the Member States, they must be incorporated into the internal legal order by means of national implementing measures.

49. It is settled case-law that the general application, and thus the legislative nature, of a measure is not called in question by the fact that it is possible to determine more or less precisely the number or even the identity of the persons to whom it applies at any given time, as long as it is established that such application takes effect by virtue of an objective legal or factual situation defined by the measure in question in relation to its purpose. [45]

50. In addition to classifying a directive as a measure of general application, [46] the Court of Justice has also held that although in principle it is binding only on the parties to whom it is addressed, namely the Member States, a directive constitutes a form of indirect regulatory or legislative measure. [47]

51. BI Vetmedica and Boehringer claim that they are individually concerned by those provisions, which, they allege, are aimed at a closed category of undertakings made up of those holding the necessary authorisations, including themselves, and that there is a specific link between that closed category of undertakings and the content of the decision. Furthermore, Directive 96/22 affected the specific rights of BI Vetmedica and Boehringer, recognised by the authorisations, to manufacture and market veterinary medicinal products containing clenbuterol. The effect which the measure has on those undertakings is such that it distinguishes them from all other producers, because, in addition, they are practically the sole manufacturers of the prohibited medicines.

52. Since the judgment in *Plaumann* v *Commission*, [48] the Court of Justice has held that a decision addressed to a Member State is of direct and individual concern to natural or legal persons only if that decision affects them by reason of certain attributes which are peculiar to them, or by reason of circumstances in which they are differentiated from all other persons, and by virtue of these factors distinguishes them individually just as in the case of the person addressed. [49]

As I have already stated when examining the nature of Directive 96/22, it is a

45 — Case 6/68 *Zuckerfabrik Watenstedt* v *Council* [1968] ECR 409; Case 64/69 *Compagnie française commerciale et financière* v *Commission* [1970] ECR 221, paragraph 11; Case 242/81 *Roquette Frères* v *Council* [1982] ECR 3213, paragraph 7; Joined Cases 97/86, 193/86, 99/86 and 215/86 *Asteris and Others* v *Commission* [1988] ECR 2181, paragraph 13; order in Case 160/88 R *Fédération européenne de la santé animale* v *Council* [1988] ECR 2181, paragraph 29; and judgment in Joined Cases C-15/91 and C-108/91 *Buckl* [1992] ECR I-6061, paragraph 25.

46 — Case 70/83 *Kloppenburg* [1984] ECR 1075, paragraph 11; and order in *Fédération européenne de la santé animale* v *Council*, cited in footnote 45 above, paragraph 28.

47 — *Gibraltar* v *Council*, cited in footnote 44 above, paragraph 16.

48 — Case 25/62 [1963] ECR 95.

49 — Case 97/85 *Deutsche Lebensmittelwerke* v *Commission* [1987] ECR 2265.

legislative measure of general application, aimed in a universal and abstract manner at a wide range of economic operators involved in activities connected with the raising of livestock for human consumption, varying from undertakings which market substances with hormonal and tireostatic effects and beta-agonists to those with livestock farms, including those which market meat products and also veterinary surgeons. The directive cannot therefore be regarded as having concerned a specific number of persons at the time when it was adopted.

Even if that were the position, however, and the directive had to be regarded as being aimed at a closed category of identifiable undertakings at the time when it was adopted, the fact that the Member States were given more than one year to implement it meant that there was no reason why some undertakings should not have ceased to carry on those activities and others begun to do so before the period in question had expired.

Consequently, Directive 96/22 could concern the applicant undertakings only by virtue of their position on the market and not individually.

53. BI Vetmedica and Boehringer further maintain that the impugned provisions of Directive 96/22 directly affect their legal situation, since no discretion is left to the Member States, which were required simply to prohibit any use whatsoever of the products in question, with the exception of their application for the therapeutic purposes restrictively defined in Article 4(2).

The Court's case-law shows that, for a person to be directly concerned by a Community measure, the latter must directly affect the legal situation of the individual and leave no discretion to the addressees of that measure who are entrusted with the task of implementing it, such implementation being purely automatic and resulting from Community rules without the application of other intermediate rules.[50] It must be borne in mind, moreover, that a directive may not of itself

50 — See *International Fruit Company and Others* v *Commission*, cited in footnote 24 above, paragraphs 23 to 29; Case 92/78 *Simmenthal* v *Commission* [1979] ECR 777, paragraphs 25 and 26; *NTN Toyo Bearing* v *Council*, cited in footnote 24 above, paragraphs 11 and 12; *ISO* v *Council*, cited in footnote 24 above, paragraph 26; *Nippon Seiko* v *Council*, cited in footnote 24 above, paragraph 14; *Koyo Seiko* v *Council and Commission*, cited in footnote 24 above, paragraph 25; Case 121/77 *Nachi Fujikoshi and Others* v *Council* [1979] ECR 1363, paragraph 11; *Salerno and Others* v *Commission and Council*, cited in footnote 24 above, paragraph 31; Case 333/85 *Mannesmann-Röhrenwerke and Benteler* v *Council* [1987] ECR 1381, paragraph 14; Case 55/86 *Arposol* v *Council* [1988] ECR 13, paragraphs 11 to 13; Case 207/86 *Apesco* v *Commission* [1988] ECR 2151, paragraph 12; Case C-152/88 *Sofrimport* v *Commission* [1990] ECR I-2477, paragraph 9; and Case C-404/96 *Glencore Grain* v *Commission* [1998] ECR I-2435, paragraph 41.

impose obligations on an individual and may therefore not be relied on as such against such a person. [51]

Therefore, a directive such as the contested directive, which requires the Member States to prohibit the marketing of certain substances for administering to animals for human consumption, for other than therapeutic purposes, cannot of itself, before the national implementing measures have been adopted, directly affect the legal position of the appellant undertakings within the meaning of the fourth paragraph of Article 230 EC. Directive 96/22 leaves the Member States a certain discretion when implementing it, since they may authorise the prohibited substances to be administered for therapeutic purposes to certain animals and in certain circumstances. If the use of such substances is allowed in those terms, the conditions set out in Article 6, which refers in turn to two other directives, will have to be satisfied. Where those uses are authorised a register must be set up, in which the responsible veterinarians must record the treatment carried out. Last, the Council reserves the possibility to adopt transitional measures necessary for the introduction of the arrangements provided for in the contested directive.

Directive 96/22 is therefore not capable of affecting the legal situaton of the applicant undertakings.

54. For the reasons stated, I consider that the application for annulment submitted by BI Vetmedica and Boehringer is inadmissible.

## III. Costs

55. Under Article 122 of the Rules of Procedure, the Court of Justice is to make a decision as to costs where the appeal is well founded and the Court itself gives final judgment in the case.

Since the Council has not applied for costs, each of the parties must be ordered to bear its own costs.

51 — See Case 152/84 *Marshall* [1986] ECR 723, paragraph 48; Case 80/86 *Kolpinghuis Nijmegen* [1987] ECR 3969, paragraph 9; Case C-91/92 *Faccini Dori* [1994] ECR I-3325, paragraph 25; and Case C-192/94 *El Corte Inglés* [1996] ECR I-1281, paragraph 15.

## IV. Conclusion

56. In the light of the foregoing considerations, I propose that the Court of Justice should:

(1) set aside the judgment of the Court of First Instance of 1 December 1999 in so far as it fails to resolve the objection of inadmissibility raised by the Council in the action for annulment;

(2) declare inadmissible the action for annulment brought by Boehringer Ingelheim Vetmidica GmbH and C.H. Boehringer Sohn Ltd Partnership;

(3) dismiss the remainder of the appeal;

(4) order the parties to bear their own costs.