JUDGMENT OF THE COURT

26 February 2002 *

In Case C-23/00 P,

Council of the European Union, represented by M. Sims-Robertson and I. Díez Parra, acting as Agents, with an address for service in Luxembourg,

appellant,

APPEAL against the judgment of the Court of First Instance of the European Communities (Second Chamber) of 1 December 1999 in Joined Cases T-125/96 and T-152/96 *Boehringer* v *Council and Commission* [1999] ECR II-3427, seeking to have that judgment set aside in part,

the other parties to the proceedings being:

Boehringer Ingelheim Vetmedica GmbH

C. H. Boehringer Sohn,

* Language of the case: English.

established in Ingelheim am Rhein (Germany), represented by D. Waelbroeck and D. Fosselard, avocats, with an address for service in Luxembourg,

applicants at first instance,

Commission of the European Communities, represented by X. Lewis, acting as Agent, with an address for service in Luxembourg,

intervener at first instance in Case T-125/96
and defendant at first instance in Case T-152/96,

Fédération Européenne de la Santé Animale (Fedesa), established in Brussels (Belgium), represented by A. Vandencasteele, avocat, with an address for service in Luxembourg,

Stichting Kwaliteitsgarantie Vleeskalverensector (SKV), established in The Hague (Netherlands), represented by G. van der Wal, advocaat, and L. Parret, avocat, with an address for service in Luxembourg,

interveners at first instance,

and

United Kingdom of Great Britain and Northern Ireland, represented by G. Amodeo, acting as Agent, assisted by D. Lloyd Jones QC, with an address for service in Luxembourg,

intervener at first instance in Case T-125/96,

THE COURT,

composed of: G.C. Rodríguez Iglesias, President, P. Jann, F. Macken and N. Colneric (Presidents of Chambers), A. La Pergola (Rapporteur), J.-P. Puissochet, M. Wathelet, R. Schintgen and V. Skouris, Judges,

Advocate General: D. Ruiz-Jarabo Colomer,
Registrar: R. Grass,

having regard to the report of the Judge-Rapporteur,

after hearing the Opinion of the Advocate General at the sitting on 4 October 2001,

gives the following

Judgment

1 By application lodged at the Registry of the Court of Justice on 27 January 2000, the Council of the European Union brought an appeal pursuant to Article 49 of the EC Statute of the Court of Justice against the judgment of the Court of First Instance of 1 December 1999 in Joined Cases T-125/96 and T-152/96 *Boehringer* v *Council and Commission* [1999] ECR II-3427 ('the contested judgment'), seeking to have that judgment set aside in part.

Legal background

2 On 26 June 1990, the Council adopted 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 1990 L 224, p. 1).

3 Under Regulation No 2377/90, the Commission is to establish a maximum residue limit (hereinafter 'MRL'), defined in Article 1(1)(b) of that regulation as the maximum concentration of residue resulting from the use of a veterinary medicinal product 'which may be accepted by the Community to be legally permitted or recognised as acceptable in or on a food'.

4 Regulation No 2377/90 provides that, after assessment of the risks which they represent for public health, pharmacologically active substances used in veterinary medicinal products are to be included in one of the four lists set out in Annexes I to IV. Annex I concerns substances in respect of which an MRL may be established, and Annex II those in respect of which it does not appear to be necessary to establish an MRL. Annex III concerns substances which may, under certain conditions, be given a provisional MRL, and Annex IV concerns

substances in respect of which no MRL can be established, by reason of their hazardous nature.

5 Article 6(1) of Regulation No 2377/90 provides:

'In order to obtain the inclusion in Annex I, II, or III of a new pharmacologically active substance which is:

— intended for use in veterinary medicinal products for administration to food-producing animals,

and

— intended to be placed on the market of one or more Member States which have not previously authorised the use of the substance concerned in food-producing animals,

the person responsible for marketing shall submit an application to the Commission. ...'

6 On 29 April 1996, the Council adopted Directive 96/22/EC concerning the prohibition on the use in stockfarming 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).

7 According to the sixth recital in the preamble to Directive 96/22, the improper use of beta-agonists can be a serious risk to human health, so that, in the interests of the consumer, the holding, administering to animals of any species and the placing on the market for that purpose of beta-agonists should be prohibited.

8 To that end, Article 2(b) of Directive 96/22 provides that Member States are to prohibit 'the placing on the market of beta-agonists for administering to animals the flesh and products of which are intended for human consumption for purposes other than those provided for in point 2 of Article 4.'

9 Article 3 of Directive 96/22/EC provides:

'Member States shall prohibit:

(a) the administering to a farm ... animal ... of beta-agonists;

(b) the holding, except under official control, of animals referred to in (a), on a farm, the placing on the market or slaughter for human consumption of farm animals ... which contain the substances referred to in (a) or in which the presence of such substances has been established, unless proof can be given that the animals in question have been treated in accordance with Articles 4 or 5;

...

(d) the placing on the market of meat of the animals referred to in (b);

(e) the processing of the meat referred to in (d).'

10 In accordance with point 2 of the first paragraph of Article 4 of Directive 96/22, the Member States may, by way of derogation from Articles 2 and 3, authorise the administering for therapeutic purposes of authorised veterinary medicinal products containing (*inter alia*) beta-agonists for certain categories of bovines, equidae and pets.

11 Article 1(2)(b) of Directive 96/22 defines 'therapeutic treatment' as 'the administering — under Article 4 of this directive — to an individual farm animal of an authorised substance to treat, after examination by a veterinarian, a fertility problem ... and, in the case of beta-agonists, to induce tocolysis in cows when calving and to treat respiratory problems and to induce tocolysis in equidae raised for purposes other than meat production'.

12 On 8 July 1996, the Commission adopted Regulation (EC) No 1312/96 amending Annex III to Regulation No 2377/90 (OJ 1996 L 170, p. 8).

13 Following the amendment made by Regulation No 1312/96, Annex III to Regulation No 2377/90 fixes provisional MRLs for a particular beta-agonist substance, clenbuterol chlorhydrate ('clenbuterol'), specifying, under its heading 'Other provisions', first, the expiry date of those MRLs, namely 1 July 2000, and, second, the therapeutic indications authorised for that substance, 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.

14 In that respect, Regulation No 1312/96 states, in the seventh recital in its preamble, that 'Directive [96/22] prohibits the use of clenbuterol in all farm animals with the exception of some specific therapeutic purposes in equines and in cows'.

Facts and procedure before the Court of First Instance

15 The facts underlying the dispute, as described in paragraphs 3, 4, 36 and 37 of the contested judgment, are the following.

16 Boehringer Ingelheim Vetmedica GmbH (hereinafter 'BI Vetmedica'), develops and markets veterinary medicinal products. It is a wholly owned subsidiary of C.H. Boehringer Sohn (hereinafter 'Boehringer'), which is one of the leading 20 pharmaceutical companies in the world.

17 According to its own statements before the Court of First Instance, BI Vetmedica accounts for about 97% of the sales in the European Union of the veterinary medicinal products affected by the prohibition of beta-agonists laid down by Directive 96/22.

18 On 20 July 1994, on the basis of Regulation No 2377/90, BI Vetmedica applied to the Commission for the establishment of MRLs for clenbuterol as regards bovines and equidae. In an opinion dated 3 January 1996, the Committee for

Veterinary Medicinal Products recommended, for reasons of scientific methodology, the adoption of provisional MRLs, expiring on 1 July 2000. It was following that request that the Commission adopted Regulation No 1312/96.

19 In those circumstances, on 9 August 1996, BI Vetmedica and Boehringer brought an action before the Court of First Instance, registered as Case T-125/96, claiming *inter alia* that the Court should:

— annul Articles 1, 2, 3 and 4 of Directive 96/22/EC in so far as they prohibited the placing on the market of veterinary medicinal products containing beta-agonists intended to be administered for therapeutic purposes to animals the flesh and products of which were intended for human consumption;

— order the Community to make good the damage suffered by them as a result of the adoption of the contested measure.

20 On 27 September 1996, BI Vetmedica and Boehringer brought a second action before the Court of First Instance, registered as Case T-152/96, claiming *inter alia* that the Court should:

— declare, in accordance with Article 184 of the EC Treaty (now Article 241 EC), that Directive 96/22/EC, in so far as it prohibited the placing on the market of veterinary medicinal products containing beta-agonists for administration for therapeutic purposes to farm animals, was illegal and therefore could not serve to justify the restrictions contained in Regulation No 1312/96;

— annul Regulation No 1312/96 in so far as it restricted the validity of the MRLs established for clenbuterol to certain specific therapeutic purposes.

21 By a separate application lodged at the Registry of the Court of First Instance on 31 October 1996, the Council raised a plea of inadmissibility in Case T-125/96, pursuant to Article 114 of the Rules of Procedure of the Court of First Instance.

22 By order of 13 June 1997 in Case T-125/96, the Court of First Instance granted leave to intervene, on the one hand, to the Fédération Européenne de la Santé Animale ('Fedesa') and the United Kingdom of Great Britain and Northern Ireland, in support of the forms of order sought by BI Vetmedica and Boehringer and, on the other, to Stichting Kwaliteitsgarantie Vleeskalverensector ('SKV') and the Commission, in support of the form of order sought by the Council. By an order of the same date in Case T-152/96, the Court granted Fedesa leave to intervene in support of BI Vetmedica and Boehringer, and SKV and the Council leave to intervene in support of the Commission.

The contested judgment

23 The Court of First Instance began by observing, in paragraph 57 of the contested judgment, that:

'The application for the partial annulment of Regulation No 1312/96 in Case T-152/96 is essentially based on the plea of illegality raised against Directive 96/22, the partial annulment of which forms part of the subject-matter of the action in Case T-125/96. Moreover, the arguments used by the applicants to challenge the legality of that directive are substantially the same in both cases.'

24 In those circumstances, the Court of First Instance considered it appropriate, in paragraph 58 of the contested judgment, to rule first on the question of the legality of Directive 96/22, which was common to both cases, before examining the other issues of admissibility and substance raised by each of them.

25 Having examined the question of the legality of Directive 96/22 in paragraphs 59 to 141 of the contested judgment, the Court of First Instance concluded, in paragraph 142, that the four pleas in law relied upon by BI Vetmedica and Boehringer for the purposes of establishing the illegality of Directive 96/22 had to be rejected as unfounded.

26 Consequently, the Court of First Instance concluded, in paragraph 143 of the contested judgment, that the claim by BI Vetmedica and Boehringer in Case T-125/96 for the partial annulment of Directive 96/22 had to be declared unfounded in any event, without there being any need to rule on the objection of inadmissibility raised by the Council.

27 Similarly, in paragraph 146 of the contested judgment, noting that it had already held that Directive 96/22 did not infringe any of the rules of law relied upon by BI Vetmedica and Boehringer, the Court of First Instance held that the claim for compensation brought by them in Case T-125/96, being based on the alleged infringement of those rules, must be dismissed as unfounded in any event, without there being any need to rule on the objection of inadmissibility raised by the Council.

28 As regards the action, in Case T-152/96, brought by BI Vetmedica and Boehringer for the annulment of Regulation No 1312/96, the Court of First Instance first concluded, in paragraphs 173 and 175 of the contested judgment, that it was admissible.

29 On the substance, the Court of First Instance then held, in paragraph 176 of the contested judgment, that the two pleas in law relied upon BI Vetmedica and Boehringer in support of that action were underpinned by a single objection, to the effect that Directive 96/22 was unlawful.

30 The Court of First Instance went on to hold, in paragraph 180 of the contested judgment, that since the various pleas in law raised by BI Vetmedica and Boehringer for the purpose of establishing the illegality of Directive 96/22 had been dismissed, their objection of illegality had to be dismissed as unfounded in any event, without there being any need to rule on the submission by the Commission and the Council that the objection was inadmissible.

31 In those circumstances, the Court held, in paragraph 181 of the contested judgment, that the two pleas on which BI Vetmedica and Boehringer based their action for the annulment of Regulation No 1312/96 therefore also had be dismissed as unfounded, in so far as they were based on the alleged illegality of Directive 96/22.

32 Finally, in paragraphs 182 to 197 of the contested judgment, the Court of First Instance examined a third plea in law, raised by Fedesa in its statement in intervention and by BI Vetmedica and Boehringer in their replies to the written questions of the Court, to the effect that the Commission exceeded the power conferred upon it by Regulation No 2377/90 by limiting the validity of the MRLs for a veterinary medicinal product to certain specified therapeutic indications.

33 At the conclusion of that examination, the Court of First Instance held, at paragraph 198 of the contested judgment, that, by limiting the validity of the MRLs established for clenbuterol to certain specified therapeutic indications for bovines and equidae, in Regulation No 1312/96, the Commission exceeded the powers exercised by it under Regulation No 2377/90.

34 Consequently, in paragraph 199 of the contested judgment, the Court of First Instance held that Regulation No 1312/96 had to be annulled in so far as it restricted the validity of the MRLs which it established for clenbuterol to certain specified therapeutic indications for bovines and equidae.

35 In those circumstances, the Court of First Instance gave judgment as follows:

'1. Cases T-125/96 and T-152/96 are joined for the purposes of this judgment.

2. ... Regulation ... No 1312/96 ... is annulled, in so far as it restricts the validity of the MRLs which it establishes for clenbuterol to certain specified therapeutic indications for bovines and equines.

3. For the rest, the applications are dismissed.

4. In Case T-125/96, the applicants and Fédération Européenne de la Santé Animale (Fedesa), as regards its intervention, are ordered to bear their own costs and those of the Council. The United Kingdom, the Commission and Stichting Kwaliteitsgarantie Vleeskalverensector (SKV) are ordered to bear their own costs.

5. In Case T-152/96, the Commission is ordered to bear its own costs and to pay one-half of the costs of the applicants and Fedesa, the other half to be borne by them. The Council and SKV are ordered to bear their own costs.'

The appeal

36 The Council claims that the Court of Justice should:

— rule on the objection of inadmissibility which it raised at first instance in Case T-125/96;

— set aside the part of the contested judgment in which the Court of First Instance dispenses with the need to rule on that objection of inadmissibility.

37 In support of its appeal, the Council raises a single plea, alleging that the Court of First Instance erred in law by failing to examine, as it should have done, the objection of inadmissibility which the Council had raised before it. The Council contends that, by not ruling on the right of a natural or legal person to bring an action for annulment of a directive before any examination of the substance of the case, the Court of First Instance failed to comply with either the letter or the spirit of Article 173 of the EC Treaty (now, after amendment, Article 230 EC) and, moreover, took a decision contrary to its own case-law.

38 The Commission claims that the Court of Justice should:

— set aside that part of the contested judgment in which the Court of First Instance declares that there is no need to rule on the objection of inadmissibility raised by the Council;

— declare the action for annulment in Case T-125/96 to be inadmissible.

39 SKV claims that the Court of Justice should:

— rule on the objection of inadmissibility raised by the Council in Case T-125/96;

— set aside that part of the contested judgment in which the Court of First Instance declares that there is no need to rule on the objection of inadmissibility raised by the Council.

40 BI Vetmedica and Boehringer contend that the Court of Justice should:

— dismiss the appeal as inadmissible, or, in the alternative, as unfounded;

— order the Council to pay the costs.

41 In support of their contention that the appeal should be dismissed as inadmissible, BI Vetmedica and Boehringer argue, first, that, since the Council was entirely successful in its defence in Case T-125/96, it cannot, by virtue of the second paragraph of Article 49 of the EC Statute of the Court of Justice, lodge an appeal against the judgment of the Court of First Instance. Secondly, BI Vetmedica and Boehringer argue that the appeal does not fulfil the requirements of Article 225 EC, Article 51 of the EC Statute of the Court of Justice and Article 112(1)(c) of the Rules of Procedure because it fails to indicate precisely the contested elements of the judgment which the appeal seeks to have set aside and also the legal arguments which specifically support that request.

42 Fedesa contends that the Court of Justice should:

— dismiss the appeal as manifestly inadmissible and in any event unfounded;

— order the Council to pay the costs.

43 The United Kingdom contends that the Court of Justice should:

— dismiss the appeal.

The admissibility of the appeal

44 According to the first paragraph of Article 49 of the EC Statute of the Court of Justice:

'An appeal may be brought before the Court of Justice, within two months of the notification of the decision appealed against, against final decisions of the Court of First Instance and decisions of that Court disposing of the substantive issues in part only or disposing of a procedural issue concerning a plea of lack of competence or inadmissibility.'

45 The Council's appeal seeks to have set aside by the Court of Justice the part of the contested judgment in which the Court of First Instance dispensed with the need to rule on the objection of inadmissibility which the Council had raised in Case T-125/96. In that regard, the Council refers in its appeal to paragraphs 143 and 146 of the contested judgment.

46 The Court must examine of its own motion whether the claim thus formulated by the Council is directed against a decision of the Court of First Instance that is open to appeal under the first paragraph of Article 49 of the EC Statute of the Court of Justice.

47 In that respect, it should be noted at the outset that the decision of the Court of First Instance which disposed of the proceedings in Case T-125/96 for the purposes of that provision is that whereby the Court of First Instance, in paragraph 3 of the operative part of the contested judgment, disposed of the substantive issues in their entirety by dismissing the claims submitted by BI Vetmedica and Boehringer in that case.

48 The decision of the Court of First Instance thus disposing of the proceedings in Case T-125/96 is not disputed by the Council, to which it gave satisfaction.

49 It must therefore be considered that, in its appeal, the Council's intention is to claim that, in addition to the abovementioned decision which disposed of the proceedings, the contested judgment contained, in the light of paragraphs 143 and 146 thereof, a second decision open to appeal in relation to Case T-125/96, namely that whereby the Court of First Instance disposed of the procedural issue concerning the objection of inadmissibility, within the meaning of the first paragraph of Article 49 of the EC Statute of the Court of Justice.

50 However, decisions which dispose of a procedural issue concerning a plea of inadmissibility, within the meaning of that provision, are decisions which

adversely affect one of the parties by upholding or rejecting that objection of inadmissibility. Thus, for example, the Court of Justice allowed an appeal against a judgment of the Court of First Instance in so far as the latter had dismissed an objection of inadmissibility raised by one party against an action, whereas the Court of First Instance had, in the remainder of the same judgment, dismissed that action as unfounded (Case C-73/97 P *France* v *Comafrica and Others* [1999] ECR I-185).

51 However, it does not appear from the contested judgment that the Court of First Instance intended to rule by way of decision on the admissibility of the action brought by BI Vetmedica and Boehringer in Case T-125/96 before dismissing it on the merits. Paragraphs 143 and 146 of the contested judgment show, on the contrary, that the Court of First Instance considered that it was not necessary to rule on the objection of inadmissibility raised by the Council since the claims by BI Vetmedica and Boehringer in Case T-125/96 had in any event to be dismissed on the merits.

52 It was for the Court of First Instance to assess, as it did, whether in the circumstances of the case the proper administration of justice justified the dismissal of the action on the merits in this case without ruling on the objection of inadmissibility raised by the Council, a course of action which cannot be regarded as adversely affecting that institution.

53 It follows that the appeal by the Council is not directed against any decision of the Court of First Instance which is open to appeal by virtue of the provisions of the first paragraph of Article 49 of the EC Statute of the Court of Justice.

54 It follows that, without there being any need to examine the pleas in law raised by BI Vetmedica and Boehringer, the appeal must be dismissed as inadmissible.

Costs

55 Under Article 69(2) of the Rules of Procedure, applicable to the procedure on appeal by virtue of Article 118, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since BI Vetmedica and Boehringer have asked for the Council to be ordered to pay the costs, and the latter has been unsuccessful, it must be ordered to pay the costs.

56 Article 69(4) of the Rules of Procedure, which also applies to the procedure on appeal by virtue of Article 118, provides in its first subparagraph that Member States and institutions which intervene in the proceedings are to bear their own costs. In accordance with that provision, the United Kingdom and the Commission must be ordered to bear their own costs. Under the third subparagraph of Article 69(4), the Court may order interveners other than Member States or institutions to bear their own costs. Accordingly, Fedesa and SKV will be ordered to bear their own costs.

On those grounds,

THE COURT

hereby:

1. **Dismisses the appeal;**

2. Orders the Council of the European Union to pay the costs incurred by Boehringer Ingelheim Vetmedica GmbH and C.H. Boehringer Sohn;

3. Orders the United Kingdom of Great Britain and Northern Ireland, the Commission of the European Communities, the Fédération Européenne de la Santé Animale (Fedesa) and the Stichting Kwaliteitsgarantie Vleeskalverensector (SKV) to bear their own costs.

Rodríguez Iglesias	Jann	Macken
Colneric	La Pergola	Puissochet
Wathelet	Schintgen	Skouris

Delivered in open court in Luxembourg on 26 February 2002.

R. Grass
Registrar

G.C. Rodríguez Iglesias
President