ORDER OF THE PRESIDENT OF THE COURT
18 November 1999 *

In Case C-329/99 P(R),

Pfizer Animal Health SA, established at Louvain-la-Neuve, Belgium, represented by I.S. Forrester QC and E. Wright, Barrister, instructed by S.J. Gale-Batten, Solicitor, with an address for service in Luxembourg at the Chambers of A. May, 31 Grand-Rue,

appellant,

APPEAL against the order of the President of the Court of First Instance of the European Communities of 30 June 1999 in Case T-13/99 R *Pfizer Animal Health* v *Council* [1999] ECR II-1961, seeking annulment of that order and referral of the case back to the President of the Court of First Instance for further consideration or grant of the application at first instance and an order that the Council pay the costs,

the other parties to the proceedings being:

Council of the European Union, represented by J. Carbery and M. Sims, Legal Advisers, acting as Agents, with an address for service in Luxembourg at the

* Language of the case: English.

office of A. Morbilli, Manager of the Legal Affairs Directorate of the European Investment Bank, 100 Boulevard Konrad Adenauer,

defendant at first instance,

Commission of the European Communities, represented by P. Oliver and T. Christoforou, Legal Advisers, and F. Ruggeri Laderchi, of its Legal Service, acting as Agents, with an address for service in Luxembourg at the office of C. Gómez de la Cruz, also of its Legal Service, Wagner Centre, Kirchberg,

Kingdom of Denmark, represented by J. Molde, Head of Division, Ministry of Foreign Affairs, acting as Agent, with an address for service in Luxembourg at the Danish Embassy, 4 Boulevard Royal,

Republic of Finland, represented by H. Rotkirch, Ambassador, Director of the Legal Service, Ministry of Foreign Affairs, and T. Pynnä, Legal Adviser in the same Ministry, acting as Agents, with an address for service in Luxembourg at the Finnish Embassy, 2 Rue Heinrich Heine,

Kingdom of Sweden, represented by A. Kruse, Departementsråd in the Ministry of Foreign Affairs, acting as Agent, with an address for service in Luxembourg at the Swedish Embassy, 2 Rue Heinrich Heine,

Fédération Européenne de la Santé Animale (Fedesa) and **Fédération Européenne des Fabricants d'Adjuvants pour la Nutrition Animale (Fefana)**, established in

Brussels, represented by D. Waelbroeck and D. Brinckman, of the Brussels Bar, with an address for service in Luxembourg at the Chambers of E. Arendt, 8-10 Rue Mathias Hardt,

Hedwig Kerckhove and **Paul Lambert**, resident in Wingene, Belgium, represented by J. Bourgeois, of the Brussels Bar, and N. Köhncke, Rechtsanwältin, Düsseldorf, with an address for service in Luxembourg at the Chambers of A. May, 31 Grand-Rue,

and

Asociación Nacional de Productores de Ganado Porcino and **Asociación Española de Criadores de Vacuno de Carne**, established respectively in Madrid and Barcelona, Spain,

interveners at first instance,

THE PRESIDENT OF THE COURT

after hearing Advocate General Jacobs,

makes the following

Order

1 By application lodged at the Registry of the Court of Justice on 1 September 1999, Pfizer Animal Health SA appealed, pursuant to the second paragraph of Article 50 of the EC Statute of the Court of Justice, against the order of the President of the Court of First Instance of 30 June 1999 in Case T-13/99 R *Pfizer Animal Health* v *Council* [1999] ECR II-1961, 'the contested order'); in that order the President of the Court of First Instance dismissed Pfizer's application for suspension of the operation of Council Regulation (EC) No 2821/98 of 17 December 1998 amending, as regards withdrawal of the authorisation of certain antibiotics, Directive 70/524/EEC concerning additives in feedingstuffs (OJ 1998 L 351, p. 4, 'the contested regulation') or for the adoption of such other measures as justice might require.

2 The appellant asks that the contested order be set aside, in whole or in part, that the case be referred back to the President of the Court of First Instance for further consideration or that the President of the Court of Justice order suspension of the operation of the contested regulation or any other interim measure considered necessary, and that the Council be ordered to pay the costs.

3 The written observations of the other parties were lodged at the Registry of the Court of Justice on 23 September 1999 by the Kingdom of Sweden, on

27 September 1999 by the Commission, Fédération Européenne de la Santé Animale ('Fedesa') and Fédération Européenne des Fabricants d'Adjuvants pour la Nutrition Animale ('Fefana'), on 28 September 1999 by H. Kerckhove and P. Lambert, on 5 October 1999 by the Council and the Republic of Finland, and on 7 October 1999 by the Kingdom of Denmark.

Legal background

4 It is clear from paragraphs 1 to 11 of the contested order that the case arises in the context of Council Directive 70/524/EEC concerning additives in feeding-stuffs (OJ, English Special Edition 1970 (III), p. 840), as amended by Council Directive 96/51/EC of 23 July 1996 (OJ 1996 L 235 p. 39).

5 The purpose of Directive 70/524 is to lay down a list of additives the incorporation of which in feedingstuffs is authorised at Community level for an indeterminate period, together with the conditions attaching to their incorporation. It also sets out the circumstances in which and the procedure by which, for their part, Member States are entitled to adopt safeguard measures temporarily to suspend or restrict the use of an authorised additive on their territory and, for its part, the Commission may have amendments to the Directive adopted in order to ensure the protection of human or animal health or the environment.

Facts

6 The present state of knowledge of antibiotics and of the resistance which bacteria can develop from the use of antibiotics designed to combat them ('antibiotic

resistance'), as assessed by the President of the Court of First Instance, is set out in paragraphs 12 to 16 of the contested order.

7 In particular, according to paragraph 15 thereof, '[s]cientists are agreed that there exists a real danger that antibiotics may become ineffective both in the short term and in the long term, that fewer new remedies are being developed and that permanent resistance to various remedies is becoming entrenched'.

8 It is also clear from paragraph 17 et seq. of the contested order that the appellant is the sole manufacturer of an antibiotic called 'virginiamycin', produced exclusively in its factory at Rixensart (Belgium), which was approved under the authorisation procedure initially provided for by Directive 70/524.

9 In 1998, first the Kingdom of Denmark, invoking the safeguard clause in Article 11 of Directive 70/524, prohibited the use of virginiamycin in animal feed on its territory and then the Kingdom of Sweden, pursuant to the Act concerning the conditions of accession of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded (OJ 1994 C 241, p. 21, and OJ 1995 L 1, p. 1), submitted to the Commission requests for adaptation of Directive 70/524 with regard to eight antibiotic substances, including virginiamycin.

10 By the contested regulation, the Council, citing the precautionary principle, removed virginiamycin from the list of additives the incorporation of which in

animal feeding-stuffs is authorised at Community level, but required the Commission to re-examine the decision before 31 December 2000.

11 As a transitional measure, it was laid down that in Member States where an antibiotic referred to by the contested regulation had not been banned on the date on which the latter entered into force, it was to remain authorised until 30 June 1999.

12 The Council's reasons for adopting the contested regulation, as they appear in its preamble, are set out in paragraphs 24 to 30 of the contested order. Essentially they express concern with regard to the emergence of antibiotic resistance referred to in paragraphs 6 and 7 of this order.

Procedure

13 By application lodged at the Registry of the Court of First Instance on 18 January 1999, Pfizer sought the annulment, in whole or in part, of the contested regulation.

14 By separate document lodged at the Registry of the Court of First Instance on 15 February 1999, Pfizer also applied, pursuant to Articles 185 and 186 of the EC Treaty (now Articles 242 EC and 243 EC), first, for suspension, either in whole or in part, of operation of the contested regulation pending judgment in the

main action or until a date to be fixed, and, second, for the adoption of such other measures as justice might require.

The contested order

15 By the contested order, the President of the Court of First Instance dismissed the application for interim measures after dealing in turn with the issues of admissibility, the existence of a *prima facie* case, urgency and the balancing of the interests at stake.

16 Paragraphs 120 to 127 of the contested order indicate that the President of the Court of First Instance found that there were certain factors enabling him to conclude that the main application was *prima facie* admissible with the result that the application for interim measures had to be declared admissible. Although the contested regulation took the form of a measure having general application within the meaning of Article 189 of the EC Treaty (now Article 249 EC), it might be of direct and individual concern to Pfizer, since it was the sole manufacturer of virginiamycin in the world and was, in that capacity, scientifically and financially involved in the surveillance programme concerning microbial resistance in animals which have received antibiotics, the reliability of which in terms of its results might be affected by the contested regulation.

17 On the question of a *prima facie* case, the President of the Court of First Instance considered, in paragraphs 131 to 133 of the contested order, that Pfizer's plea alleging, in essence, that the precautionary principle had been contravened could

not, *prima facie*, be regarded as wholly unfounded, but required very thorough examination which could not be undertaken in the context of proceedings for interim relief.

18 The President of the Court of First Instance went on to consider, at paragraphs 134 to 181 of the contested order, whether the application had the degree of urgency required before the measure requested could be ordered and whether the balancing of the interests at stake operated in the applicant's favour.

19 In that connection the President of the Court of First Instance held, at paragraph 136 of the contested order, that the only damage that could be taken into account in his examination of the criterion of urgency was that which might be caused to the interests of the party seeking the interim relief.

20 With regard to damage of a purely pecuniary nature, the President of the Court of First Instance examined, first, whether Pfizer's very existence was likely to be endangered, concentrating on the effects of application of the contested regulation on the Rixensart factory and on Pfizer's financial viability and, second, whether its market share was likely to be irremediably affected.

21 As far as the Rixensart factory was concerned, the President of the Court of First Instance found that it could not be concluded, on the evidence before him, that the entry into force of the contested regulation would inevitably result in the rapid closure of the plant in view of the high volume and value of sales of virginiamycin on markets other than the West European market.

22 In his view, it had not been shown that the reduction in employment envisaged by Pfizer, concerning 18% of the Rixensart staff, was likely to lead to the closure of

the factory, that the sales teams could not be switched to other activities, or that the profitability as a whole of the investments made or envisaged in the Rixensart factory was affected.

23 The President of the Court of First Instance also declined to take into account the situation of subcontractors whose precise relationship to the Rixensart factory had not, moreover, been established.

24 As to Pfizer's financial viability, the President of the Court of First Instance noted that forecasts indicated an appreciable fall in sales of virginiamycin following the ban on marketing in the European Community. However, in view of the proportion of the Pfizer group's total business represented by that activity, as far as it could be assessed, he did not consider that the financial harm that Pfizer would suffer would prevent it from continuing to pursue its activities pending judgment in the main action.

25 The President of the Court of First Instance also examined the effects that the ban would have on Pfizer's market share. In his view, the decrease in sales in countries which are not Member States of the Union could not be taken into account, since it was not the direct consequence of the contested regulation. As far as market share in the European Community was concerned, there was nothing in the documents before the Court to show that it would be irremediably compromised.

26 Having concluded, in paragraph 165 of the contested order, that the applicant had not succeeded in showing that it would suffer serious and irreparable damage if operation of the contested regulation were not suspended, the President of the Court of First Instance considered that, in any event, the balancing of the interests at stake favoured the maintenance of the contested regulation, since damage to the commercial and social interests of the kind which the applicant and the parties supporting it would sustain could not outweigh the damage to public

health which would be liable to be caused by suspension of the contested regulation.

27 The President of the Court of First Instance found that the documents before him confirmed that bacteria resistant to virginiamycin in animals were transmissible to humans. It followed, in his view, that the risk of increased antimicrobial resistance in human medicine on account of the use of virginiamycin in animal feed could not be ruled out, and the potential consequences for public health would be very serious. In the circumstances, the President considered that, without prejudging the examination by the Court of First Instance of the assessment of the extent of the risk which must be established by the institutions concerned when adopting a precautionary measure, the mere existence of the risk so identified was enough in itself to justify taking into account, in the balancing of interests, the protection of human health.

Arguments of the parties

28 Three of the grounds of appeal, together with the additional plea put forward by H. Kerckhove and P. Lambert, concern the assessment by the President of the Court of First Instance of the urgency of the matter. The last ground of appeal concerns the balancing of interests undertaken in the contested order.

Wrongful determination of harm because the situation of Pfizer's parent company was taken into account

29 The appellant alleges, first, that the determination as to whether it would suffer serious and irreparable harm, as set out in the contested order, is

wrongful, in that account was taken not only of its situation, but also of that of its parent company.

30 According to the appellant, the case-law cited in paragraph 155 of the contested order is irrelevant to this case. The financial resources of the Pfizer group cannot remedy the consequences of the contested regulation for its own business, which are that its employees will leave and its factory will close. Even if the continued existence of the Pfizer group will not be threatened, that does not mean that there will be no serious and irreparable harm to the appellant. It considers that a small company in a large group should be eligible for the benefit of interim measures if faced with serious and irreparable harm, notably job losses. Moreover, employees should not be deprived of their legitimate interest in their jobs simply because they work for a company belonging to a large group. The test applied by the President of the Court of First Instance amounts to denying effective judicial protection to companies which are part of a substantial corporate group.

31 For their part, the Commission and the Danish Government state that the financial situation of the group to which the appellant belongs was only one factor of many taken into account by the President of the Court of First Instance.

32 The Council, the Commission and the Finnish Government also contend that the case-law cited in paragraph 155 of the contested order is entirely relevant and confirm that it was wholly justifiable to take into account the situation of the appellant's parent company. The Commission considers the complaint that that criterion would lead to discrimination against large groups to be wholly misconceived. In its view, when it comes to deciding whether a measure will have serious and irreparable financial consequences for an applicant, it is obviously necessary to have regard to the latter's financial situation, which clearly cannot be assessed without taking account of the financial situation of the group to which it belongs. For its part the Council, emphasising the appellant's links with its parent

company, states that it has at its disposal the vast resources of a multinational company to assist it in coping with the withdrawal of a single product.

Wrongful determination of damage with regard to the case-law of the Court of Justice on irretrievable loss of market share

33 The second ground of appeal alleges an infringement of Community law by reason of the fact that the President of the Court of First Instance wrongly concluded that there would be no irretrievable loss of market share. Such loss was not acknowledged in this case, in which the product concerned is wholly banned in the 15 Member States, whereas a much lower level of loss in a few Member States has previously been regarded as irreparable damage.

34 The appellant refers in this connection to the order of the President of the Court of First Instance in Case T-41/96 R *Bayer* v *Commission* [1996] ECR II-381, in which it was concluded that the risk that a Bayer subsidiary in a different country might lose market share, resulting in the possible dismissal of employees there, was a relevant factor in proceedings for interim relief.

35 The appellant also refers to the order of 8 April 1987 in Case 65/87 R *Pfizer International* v *Commission* [1987] ECR 1691, in which it was acknowledged that a sharp decrease in sales, particularly in three Member States, had caused serious financial loss and that this damage was irreparable since the market shares lost to competitors during 11 months' absence from the market could not be subsequently regained in practice. According to the appellant, its own situation in this case is even worse in terms of length of exclusion from and geographic extent of the markets concerned and should have led to the same case-law being applied or at least an adequate statement of reasons for the case-law not being followed. The different factual circumstances in the two cases was a

factor that should not have been taken into consideration until the balancing of interests stage, rather than when the criterion of urgency was being examined.

36 Moreover, pointing out that 31 employees will have to be dismissed if the contested regulation is not suspended, the appellant claims that its supposed financial capacity to keep on staff who have no work to do does not alter the fact that the regulation has caused it serious and irreparable harm.

37 According to the Council, the Commission and the Danish Government, the findings of the President of the Court of First Instance that the market share concerned could be recovered and that the appellant was financially able to bear the cost of keeping on those 31 employees of the Rixensart factory are findings of fact, so that the second ground of appeal is inadmissible.

38 Furthermore, the Council, the Commission and the Danish and Finnish Governments consider that the appellant's situation in this case is, in point of fact, quite distinct from that of the undertakings involved both in *Bayer* v *Commission*, cited above, in which it was held that there was a real risk that the business of a subsidiary could be irreversibly harmed in so far as 56% of the subsidiary's turnover was affected, and in *Pfizer International* v *Commission*, cited above, in which loss of market share was held to be irretrievable in view of the characteristics of the product concerned.

Wrongful determination of damage because the situation in third countries was not taken into account

39 In the third ground of appeal, the appellant challenges the refusal by the President of the Court of First Instance to take into consideration, when determining

damage, the effects of the ban on virginiamycin in the European Community on its sales in third countries which, *de jure* or *de facto,* apply Community legislation, on the ground that such damage is not a direct consequence of the contested regulation.

40 The appellant states that the 13 countries that are seeking accession to the European Union and the eight countries making up the Commonwealth of Independent States ('CIS') with which the European Community has concluded Partnership and Cooperation Agreements are under a legal obligation to bring their national legislation into line with the *acquis communautaire.*

41 The contested order is therefore vitiated by an error of law on this point with regard to the countries that are candidates for accession and the CIS countries.

42 More generally, the President of the Court of First Instance should have taken into account the fact that the adoption by third countries of measures analogous to those contained in the contested regulation was a foreseeable consequence of the adoption of that regulation.

43 The Council, the Commission and the Danish Government consider that that ground of appeal is inadmissible because it was not pleaded in full at first instance.

44 In addition, according to the Commission and the Danish Government, this plea is wrong in law, since the obligations of the 21 third countries to which the appellant refers amount merely to an undertaking that they will use their best endeavours to ensure that their legislation will be made compatible with Community law, rather than to an obligation to achieve that result. For its part, the Council does not dispute the fact that there might be such an obligation on the five countries which have begun pre-accession negotiations. That is not, however,

the case as regards the 16 other countries cited. In any event, the Council, together with the Danish Government, points out that the appellant has failed to indicate the actual loss of market share which it would sustain in those 21 countries, in terms of volume or percentages of sales, following the ban on sale in the European Community. As far as the other third countries are concerned, the Council endorses the assessments set out in paragraph 160 of the contested order.

Failure to take into account the damage sustained by the interveners

45 H. Kerckhove and P. Lambert further maintain that the President of the Court of First Instance was wrong in refusing to take into account, in his assessment of urgency, the damage caused to the interveners and in postponing consideration of that damage until the stage of balancing the interests at stake. Third parties who do not themselves have an admissible case but who are given leave to intervene in proceedings for interim relief on the ground that their interests could be affected by the result of the case ought to have their interests protected, which is impossible if the damage they allege may be ignored when the urgency of the application is assessed. In the absence of such protection, those third parties might be prompted to turn to a national court in order to obtain interim protection of their interests, which would undermine the uniform application of Community law.

Over-restrictive application of the criteria for granting an interim measure, leading to a failure to weigh up the interests at stake

46 In its last ground of appeal, the appellant complains that the President of the Court of First Instance applied over-restrictive criteria for granting interim measures in a case that concerned the precautionary principle. More specifically,

the possibility of future harm to public health was transformed into an assumption that such harm would flow from the suspension of operation requested, which led the President to decline to weigh up the consequences of granting suspension against the consequences of not granting it.

47 The appellant points out, first, that precautionary bans should be imposed only where there is plainly convincing specific evidence that the product actually or probably presents a danger. In its view, that is patently not the case here. The Council was therefore wrong in contending that virginiamycin should continue to be banned until conclusively proven to pose no present or future risk to human health.

48 The President of the Court of First Instance had, in paragraph 173 of the contested order, wrongly proceeded on the assumption that bacteria resistant to virginiamycin in animals are transmissible to humans, although that is merely a hypothesis still to be tested by the scientific studies that are being carried out.

49 According to the appellant, just as the Council should have weighed up the purely theoretical risk that virginiamycin might one day cause damage in terms of public health against the harm that a ban would cause, the President of the Court of First Instance should have undertaken a genuine balancing of the interests at stake.

50 The appellant adds that in this case the situation, in terms of public health, is substantially less serious than that which prevailed at the time of the embargo on British beef, so that the principles applied then in Cases C-157/96 *National*

Farmers' Union and Others [1998] ECR I-2211 and C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265 could not simply be transposed here.

51 The appellant claims that the Community institutions' assertion that a risk may exist is necessary, but not sufficient, to justify a ban. Similarly, when examining an application for interim measures, the Court should not just consider the allegation of a risk but must examine its gravity and the proximity of possible harm. According to the appellant, in refusing to balance the interests at stake the President of the Court of First Instance thus committed an error of law.

52 Fedesa and Fefana support those assertions and lay emphasis, first, on the importance of applying the precautionary principle correctly. They challenge the statement in paragraph 181 of the contested order that the fact that the fatal nature of bovine spongiform encephalopathy was taken into account in the order in Case C-180/96 R *United Kingdom* v *Commission* [1996] ECR I-3903 'does not mean that measures cannot be adopted by the Community institutions in the absence of any serious factor of that kind'. They consider that the Council must show the gravity of the hazard before withdrawing a product from the market, in view of the length of the prior product approval process and the financial costs involved. In this case no proper assessment of the evidence available concerning the alleged risk was made before the adoption of the contested regulation. Instead of simply accepting the allegations of the Council, the President of the Court of First Instance should therefore have examined whether *prima facie* the alleged risk was reasonably well established.

53 Fedesa and Fefana contend, secondly, that the President of the Court of First Instance wrongly failed to take account of the arguments which they had put

forward to the effect that the ban would lead to the emergence of other risks, relating in particular to animal welfare and the environment.

54 H. Kerckhove and P. Lambert also maintain that a sales ban motivated by the protection of health and consumer safety is justified only if the existence of a risk has been established. It is clear from paragraphs 180 and 181 of the contested order that the President of the Court of First Instance identified only a potential risk that might one day develop into an actual risk. In their view, as long as a potential risk has not developed into an actual risk, precautionary measures are generally premature unless a thorough balancing of interests clearly favours the adoption of such measures. Where Community measures are taken otherwise than in order to protect against an immediate danger to public health, it cannot, contrary to what is stated in paragraphs 170 and 171 of the contested order, be presumed that public health must take precedence without a detailed weighing up of all the interests involved, including those of the interveners.

55 The Council and the Finnish Government consider that the appellant is not entitled to challenge the findings of fact made by the President of the Court of First Instance. Those findings are based on a World Health Organisation Report and evidence put forward by Pfizer itself, as is clear from paragraphs 179 and 180 of the contested order, and the President concluded that the existence of a risk to human health could not be ruled out. The Council also considers that there is no legal obligation to examine the gravity of such a risk once the existence of a risk has been established.

56 For its part, the Commission claims that the whole of the appellant's plea relating to the balancing of interests is based on the flawed premiss that the risk posed by virginiamycin was merely theoretical. The Commission cites the studies carried

out on the subject, while pointing out that the question is one of fact and as such cannot be raised in this appeal.

57 According to the Danish Government, in balancing the interests at stake the President of the Court of First Instance took account of all the factors available and his specific weighing up of those factors may not be reviewed on appeal, since that would amount to a fresh assessment of the facts.

58 Moreover, according to the Danish and Finnish Governments, the existence of a risk to human health could legitimately be taken into consideration without its being necessary to wait for actual damage to materialise.

59 Since the parties' written observations contain all the information necessary to enable the Court of Justice to decide the appeal, there is no need to hear oral argument.

Assessment

60 First of all, under Article 225 EC and Article 51 of the EC Statute of the Court of Justice, an appeal is to be limited to points of law and must lie on the grounds of lack of competence of the Court of First Instance, a breach of procedure before it which adversely affects the interests of the appellant or the infringement of Community law by the Court of First Instance.

61 The Court of First Instance has exclusive jurisdiction to establish the facts, save where a substantive inaccuracy in its findings is apparent from the documents submitted to it, and to appraise those facts.

62 Furthermore, the Court of Justice does not in principle have jurisdiction to examine evidence which the Court of First Instance has accepted in support of its findings of fact or assessment of the facts. Where the general principles of law and rules of procedure governing the burden of proof and the taking of evidence have been observed, it is for the Court of First Instance alone to assess the weight to be attributed to the evidence produced (Case C-159/98 P(R) *Netherlands Antilles* v *Council* [1998] ECR I-4147, paragraph 68).

63 It is in the light of those factors that the grounds of appeal must be examined.

First ground

64 According to the first ground of appeal, the contested order is vitiated by an error of law because the assessment as to whether Pfizer would suffer serious and irreparable harm took into account the fact that it is part of a corporate group.

65 The first point to note is that, as is made clear in paragraph 137 of the contested order, the serious and irreparable damage allegedly caused to the appellant amounts in substance to damage of a pecuniary nature.

66 It follows from paragraph 139 of the contested order that, in order to determine whether that damage is irreparable, the President of the Court of First Instance drew a distinction between the effects which the contested regulation might have, first, on the Rixensart factory, and second, on the appellant's financial viability.

67 Only in his examination of Pfizer's financial viability, in paragraphs 153 to 158 of the contested order, did the President of the Court of First Instance take into consideration the financial characteristics of the Pfizer Group.

68 However, in order to determine the effects which the contested regulation might have on the Rixensart factory, the President of the Court of First Instance took into account, as is shown in paragraphs 140 to 152 of the contested order, only the volume of sales of virginiamycin within and outside the European Union, the relative number of job losses forecast by Pfizer, the possibility of switching sales teams from virginiamycin and the profitability of the investments made or envisaged in the Rixensart factory.

69 The appellant is therefore mistaken in its claim that the President of the Court of First Instance took into account the characteristics of the group to which it belongs when assessing the effects which the contested regulation might have on the Rixensart factory.

70 As for the interests of the Rixensart factory employees, the President of the Court of First Instance pointed out, in paragraph 149 of the contested order, that it hardly seemed likely that the appellant would be unable to bear the financial burden which would be involved in keeping 31 persons in employment pending judgment in the main action.

71 That assessment by the President of the Court of First Instance, which implies that an adverse effect on the interests of employees is not an inevitable consequence of the operation of the contested regulation, is not open to challenge in an appeal.

72 The first ground of appeal must therefore be dismissed.

Second ground

73 In its second ground of appeal, the appellant maintains, essentially, that the President of the Court of First Instance was wrong in the determination he made as to whether the loss of market share that the appellant would sustain could be recovered.

74 For the reasons referred to in paragraph 61 of this order, the findings of the President of the Court of First Instance as to the existence and characteristics of the loss of market share claimed by Pfizer cannot, however, be called into question in this appeal.

75 It follows from settled case-law that it is for the party claiming such damage to establish the irreparable nature of the loss of market share that will supposedly be sustained (see, to that effect, the order in Case 119/86 R *Spain* v *Council and Commission* [1986] ECR 2241, paragraph 30), so that mere reference to previous cases in which the Court hearing the application reached different conclusions is not a cogent criticism of the contested order.

76 In any event, it is clear from paragraphs 161 to 164 of the contested order that the President of the Court of First Instance examined very thoroughly the nature of the loss of market share claimed by Pfizer before concluding that the market share it had held until then did not appear irretrievably compromised. The line of reasoning followed is enough to show that the factual situation in this case is notably different from that in the two cases to which the appellant refers.

77 With regard to the argument that 31 employees will have to be dismissed as a result of the entry into force of the contested regulation, this overlaps with the arguments in the first ground of appeal and must be rejected for the reasons set out in paragraphs 64 to 71 of this order.

78 The second ground of appeal must therefore be dismissed.

Third ground

79 In its third ground of appeal, the appellant complains that the President of the Court of First Instance did not take into consideration, in determining damage, the impact of the contested regulation on sales of virginiamycin in third countries.

80 That plea is based, first of all, on the content of the agreements linking the European Community with third country applicants for accession, on the one hand, and with the CIS countries on the other, which are said to impose a legal obligation on those two categories of country to adopt a ban analogous to that provided for in the contested regulation.

81 It must be remembered that, under Article 113(2) of the Rules of Procedure of the Court of Justice, the subject-matter of the proceedings before the Court of First Instance may not be changed in the appeal.

82 The appellant cannot therefore allege, at the appeal stage, that there is a legal obligation for certain third countries to adopt measures analogous to those adopted by the Council if it did not do so at first instance. It had confined itself to stating that, as part of their adoption of the *acquis communautaire*, the countries applying for accession were likely to follow the example set by the European Union. It did not, moreover, specifically mention the CIS countries.

83 For the rest, the appellant essentially confines itself to repeating the arguments which it put forward at first instance, according to which one of the foreseeable consequences of the Community ban would be that other countries would automatically impose a similar ban.

84 On the grounds referred to in paragraph 61 of this order, the findings of the President of the Court of First Instance at paragraph 160 of the contested order, according to which, first, it had not been established that suspension of operation of the contested regulation would prevent third countries from banning the marketing of virginiamycin on their territory and, second, reduced sales in third countries were not a direct consequence of the contested regulation, cannot be reviewed in this appeal.

85 The third ground of appeal must therefore be dismissed.

Fourth ground

86 In a supplementary plea, H. Kerckhove and P. Lambert maintain that the damage sustained by them should have been taken into consideration by the President of the Court of First Instance when he assessed the question of urgency.

87 In support of this plea, those interveners contend that since they have been recognised as having a sufficient interest to intervene, that interest can only be protected if, for the purpose of assessing the question of urgency, the damage they claim they will sustain is taken into consideration. Furthermore, the contrary practice followed by the President of the Court of First Instance is likely to jeopardise the uniform interpretation of Community law, by encouraging interested third parties to turn to their national courts in order to obtain interim protection of their interests.

88 The first point to note is that it follows from the first subparagraph of Article 83(1) of the Rules of Procedure of the Court of Justice that only the person who has challenged a measure of an institution in proceedings before the Court has standing to apply for suspension of operation of that measure.

89 Furthermore, in order for that application for suspension of operation to be held admissible, the applicant must establish that there are grounds for concluding *prima facie* that the main application to which the application for interim measures relates is admissible, in order to prevent a situation where that person is able, by means of an application for interim measures, to obtain suspension of the operation of a measure which the Court subsequently refuses to declare void because, on examination of the substance of the case, the application is declared inadmissible (see Case 376/87 R *Distrivet* v *Council* [1988] ECR 209, paragraphs 21 and 22).

90 Those requirements follow from the fact that the purpose of proceedings for interim relief is solely to ensure that interim protection is available to individuals, if it is necessary in order for the definitive future decision to be fully effective, in order to ensure that there is no lacuna in the legal protection provided by the Court of Justice (see, to that effect, Case C-399/95 R *Germany* v *Commission* [1996] ECR I-2441, paragraph 46).

91 However, the conditions which a person must satisfy in order to obtain leave to intervene in a case are less stringent, since Article 37 of the EC Statute of the Court of Justice requires only that he establish an interest in the result of the case.

92 An intervention in proceedings before the Community judicature is of an ancillary nature in relation to the subject-matter of the case.

93 It follows that, in the context of an application for suspension of operation of a measure, although an intervener may assert his interests, he cannot widen the

subject-matter of the dispute by laying claim to a personal right to interim legal protection.

94 The urgency of an application for the adoption of interim measures must therefore be assessed in the light of the extent to which an interlocutory order is necessary in order to avoid serious and irreparable damage to the party seeking the adoption of the interim measure, as has moreover repeatedly been confirmed by the Court (see, in particular, Case 310/85 R *Deufil* v *Commission* [1986] ECR 537, paragraph 15).

95 That conclusion cannot be undermined by the considerations of expediency formulated by H. Kerckhove and P. Lambert on the basis of the objective of the uniform interpretation of Community law.

96 It is, moreover, quite clear that the President of the Court of First Instance took into consideration the interest of the interveners when balancing the interests at stake, so that their intervention was not rendered futile.

97 It follows from the foregoing that the plea raised by H. Kerckhove and P. Lambert must be dismissed.

Fifth ground of appeal

98 In its final ground of appeal, the appellant complains that the President of the Court of First Instance applied over-restrictive criteria for the grant of an interim

measure in a case such as this, which led him wrongly to decline to weigh up the interests at stake.

99 The first point to be noted is, as the Danish Government has rightly observed, that the manner in which the court hearing an application for interim measures established and assessed the facts and accepted certain evidence submitted to it, in order to balance the interests at stake, cannot in principle be challenged in an appeal.

100 Furthermore, contrary to the appellant's contention, it is not apparent from the contested order that the President of the Court of First Instance declined to balance the interests at stake on the sole ground that considerations of public health were involved.

101 It follows from paragraphs 174 to 179 of the contested order that the President of the Court of First Instance sought to determine the extent of the risk of transmissibility from animals to humans of bacteria resistant to antibiotics, which formed the basis of the contested regulation, by examining the documents produced by the parties. As he indicates at paragraph 180 of the contested order, the President also examined the seriousness of the risk and concluded that the consequences of increased antimicrobial resistance in human medicine, if they materialised, were potentially very serious for public health.

102 Having thus assessed the extent and the seriousness of the risk linked to use of virginiamycin in animal feed, the President of the Court of First Instance was fully entitled to compare those factors with the damage claimed by Pfizer and the parties supporting it, in terms of commercial and social interests, and to reach the conclusion that such damage 'cannot outweigh the damage to public health

which would be liable to be caused by suspension of the contested regulation, and which could not be remedied if the main action were subsequently dismissed'.

103 The ground of appeal concerning the balancing of interests must therefore be rejected as well.

104 In the light of all the above considerations, the appeal must be dismissed.

Costs

105 According to Article 69(2) of the Rules of Procedure, applicable to the appeal procedure by virtue of Article 118 thereof, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Article 69(4) provides that the Member States and institutions which intervene in proceedings are to bear their own costs and that the Court may order other interveners to do the same. Since the appellant's pleas have been unsuccessful, and the Council has applied for costs, the appellant must be ordered to pay the costs of this appeal. The Commission, the Kingdom of Denmark, the Republic of Finland, the Kingdom of Sweden, Fedesa and Fefana and H. Kerckhove and P. Lambert must bear their own costs.

On those grounds,

THE PRESIDENT OF THE COURT

hereby orders:

1. **The appeal is dismissed.**

2. **Pfizer Animal Health SA is ordered to pay the costs.**

3. **The Commission of the European Communities, the Kingdom of Denmark, the Republic of Finland, the Kingdom of Sweden, Fédération Européenne de la Santé Animale and Fédération Européenne des Fabricants d'Adjuvants pour la Nutrition Animale, Hedwig Kerckhove and Paul Lambert are ordered to bear their own costs.**

Luxembourg, 18 November 1999.

R. Grass — Registrar

G.C. Rodríguez Iglesias — President