ORDER OF THE PRESIDENT OF THE COURT OF FIRST INSTANCE
30 June 1999 *

In Case T-13/99 R,

Pfizer Animal Health SA/NV, a company incorporated under Belgian law, established at Louvain-la-Neuve, Belgium, represented by Ian S. Forrester QC, Elisabethann Wright, Barrister, and Mark Powell, Solicitor, with an address for service in Luxembourg at the Chambers of Aloyse May, 31 Grand-Rue,

applicant,

supported by

Asociación Nacional de Productores de Ganado Porcino and **Asociación Española de Criadores de Vacuno de Carne**, associations governed by Spanish law, established in Madrid and Barcelona, represented by Jaime Folguera Crespo and Alfonso Gutiérrez Hernández, of the Madrid Bar, and José Massaguer Fuentes and Edurne Navarro Varona, of the Barcelona Bar, with an address for service in Luxembourg at the Chambers of Messrs Bonn and Schmitt, 7 Val Sainte-Croix,

Fédération Européenne de la Santé Animale (Fedesa) and **Fédération Européenne des Fabricants d'Adjuvants pour la Nutrition Animale (Fefana)**, established in Brussels, represented by Denis Waelbroeck and Dirk Brinckman, of the Brussels Bar, with an address for service in Luxembourg at the Chambers of Ernest Arendt, 8-10 Rue Mathias Hardt,

* Language of the case: English.

and

Hedwig Kerckhove and **Paul Lambert**, established at Wingene, Belgium, represented by Jacques Bourgeois, of the Brussels Bar, and Nina Köhncke, Rechtsanwältin, Düsseldorf, with an address for service in Luxembourg at the Chambers of Aloyse May, 31 Grand-Rue,

interveners,

v

Council of the European Union, represented by John Carbery and Moyra Sims, Legal Advisers, acting as Agents, with an address for service in Luxembourg at the office of Alessandro Morbilli, Manager of the Legal Affairs Directorate of the European Investment Bank, 100 Boulevard Konrad Adenauer,

defendant,

supported by

Commission of the European Communities, represented by Peter Oliver and Theofanis Christoforou, Legal Advisers, and Francesco Ruggeri Laderchi, of its Legal Service, acting as Agents, with an address for service in Luxembourg at the office of Carlos Gómez de la Cruz, of its Legal Service, Wagner Centre, Kirchberg,

Kingdom of Denmark, represented by Jørgen 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,

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

and

Republic of Finland, represented by Holger Rotkirch, Director of the Legal Service in the Ministry of Foreign Affairs, and Tuula 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,

interveners,

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) or for other interim measures,

THE PRESIDENT OF THE COURT OF FIRST INSTANCE
OF THE EUROPEAN COMMUNITIES

makes the following

Order

Legislative framework

1 On 23 November 1970 the Council adopted Directive 70/524/EEC concerning additives in feedingstuffs (OJ, English Special Edition 1970 (III), p. 840, hereinafter 'Directive 70/524'). That directive, which has been amended several times, lays down, in Annex I thereto, 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.

2 Article 2 of the initial version of Directive 70/524 defined additives as 'substances which, when incorporated in feedingstuffs, are likely to affect their characteristics or livestock production'.

3 The regime established by Directive 70/524 was substantially modified by Council Directive 96/51/EC of 23 July 1996 amending Directive 70/524 (OJ 1996 L 235, p. 39, hereinafter 'Directive 96/51'). Article 2 of Directive 96/51 provides that the Member States are to bring into force the laws, regulations and administrative provisions necessary to comply with Article 1(4) thereof, in so far as it enacts new Articles 6(1), 9d(2), 9e(3), 9f, 9g, 9h, 9i, 9j, 9n

and 9o of Directive 70/524, and Article 1(10), (12), (19) and (20) thereof on 1 April 1998 and with its other provisions on 1 October 1999.

4 In particular, Article 1(3)(i) of Directive 96/51 provides for the replacement of Article 2(a) of Directive 70/524 by the following wording:

'(a) additives: substances or preparations used in animal nutrition in order to:

— affect favourably the characteristics of feed materials or of compound feedingstuffs or of animal products; or

— satisfy the nutritional needs of animals or improve animal production, in particular by affecting the gastro-intestinal flora or the digestibility of feedingstuffs; or

— introduce into nutrition elements conducive to attaining particular nutritional objectives or to meeting the specific nutritional needs of animals at a particular time; or

— prevent or reduce the harmful effects caused by animal excretions or improve the animal environment;

(aa) "micro-organisms": micro-organisms forming colonies;

(aaa) additives subject to authorisation linked to the person responsible for putting them into circulation: the additives listed in Part I of Annex C;

(aaaa) other additives: additives not subject to authorisation linked to the person responsible for putting them into circulation and referred to in Part II of Annex C'.

5 Article 9g of Directive 70/524, as inserted by Article 1(4) of Directive 96/51, provides:

'1. Additives as referred to in Article 2(aaa) [additives subject to authorisation linked to the person responsible for putting them into circulation: the additives listed in Part I of Annex C] included in Annex I before 1 January 1988 shall be provisionally authorised as from 1 April 1998 and transferred to Chapter I of Annex B with a view to their re-evaluation as additives linked to a person responsible for putting them into circulation.

2. With a view to their re-evaluation, the additives as referred to in paragraph 1 must, before 1 October 1998, be the subject of new applications for authorisa-

tion; such applications, accompanied by the monographs and the identification notes provided for in Articles 9n and 9o respectively, shall be addressed by the person responsible for the dossier on the basis of which the former authorisation was granted or by his successor or successors, via the Member State acting as rapporteur, to the Commission, sending copies to the other Member States, which shall acknowledge receipt thereof.'

6 Article 11 of Directive 70/524, in the version thereof resulting from the replacement of its original wording by that contained in Article 1(1) of Council Directive 84/587/EEC of 29 November 1984 amending Directive 70/524 (OJ 1984 L 319, p. 13, hereinafter 'Directive 84/587'), as amended by Article 1(7) of Directive 96/51, provides:

'1. Where a Member State, as a result of new information or of a reassessment of existing information made since the provisions in question were adopted, has detailed grounds for establishing that the use of one of the additives authorised or its use in conditions which may be specified constitutes a danger to animal or human health or the environment although it complies with the provisions of this directive, that Member State may temporarily suspend or restrict application of the provisions in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving reasons for its decision.

2. The Commission shall, as soon as possible, examine the grounds cited by the Member State concerned and consult the Member States within the Standing Committee for Feedingstuffs; it shall then deliver its opinion without delay and take the appropriate measures.

3. Should the Commission consider that amendments to the directive are necessary in order to mitigate the difficulties mentioned in paragraph 1 and to ensure the protection of human or animal health or the environment, it shall initiate the procedure laid down in Article 24 with a view to adopting those amendments; the Member State which has adopted safeguard measures may in that event retain them until the amendments enter into force.'

7 Article 24 of Directive 70/524, as inserted by Article 1(1) of Directive 84/587 and last amended by Annex I 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, hereinafter 'the Act of Accession'), provides:

'1. Where the procedure laid down in this article is to be followed, matters shall be referred to the [Standing] Committee [for Feedingstuffs] without delay by the chairman, either on his own initiative or at the request of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion within two days. The opinion shall be delivered by the majority laid down in Article 148(2) of the EC Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that article. The chairman shall not vote.

3. The Commission shall adopt the measures and implement them forthwith where they are in accordance with the opinion of the Committee. Where they are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall adopt the measures by a qualified majority.

If the Council has not adopted any measures within 15 days of the proposal being submitted to it, the Commission shall adopt the proposed measures and

implement them forthwith, except where the Council has voted by a simple majority against such measures.'

8 The Standing Committee for Feedingstuffs referred to in Article 24 of Directive 70/524 was established by Council Decision 70/372/EEC of 20 July 1970 setting up a Standing Committee for Feedingstuffs (OJ, English Special Edition 1970 (II), p. 534). It consists of representatives of the Member States with a representative of the Commission as chairman.

9 Decision 76/791/EEC of 24 September 1976 establishing a Scientific Committee for Animal Nutrition (OJ 1976 L 279, p. 35) set up under the auspices of the Commission a Scientific Committee for Animal Nutrition (hereinafter 'the SCAN'). That decision was repealed by Commission Decision 97/579/EC of 23 July 1997 setting up scientific committees in the field of consumer health and food safety (OJ 1997 L 237, p. 18), which provides, in Article 2(1) and (3):

'1. The scientific committees shall be consulted in the cases laid down by Community legislation. The Commission may also decide to consult them

on other questions of particular relevance to consumer health and food safety.

...

3. At the Commission's request, the scientific committees shall provide scientific advice on matters relating to consumer health and food safety...'

10 The Annex to Decision 97/579 defines the competence of the SCAN as covering 'scientific and technical questions concerning animal nutrition, its effect on animal health, on the quality and health of products of animal origin, and concerning the technologies applied to animal nutrition'.

11 In addition, Article 8(1) of Directive 70/524, as amended by Directive 96/51, provides:

'The Scientific Committee for Animal Nutrition established by Commission Decision 76/791/EEC [of 24 September 1976] shall be responsible for assisting

the Commission, at the latter's request, on all scientific questions relating to the use of additives in animal nutrition.'

Facts

12 Defined in general terms, an antibiotic is a substance of biological or synthetic origin, specifically acting at an essential stage of the metabolism of bacteria (antibacterial agents) or fungi (antifungal agents).

13 Antibiotics are used, both in humans and in animals, to treat various bacterial diseases. In animals, antibiotics may be used for therapeutic or prophylactic purposes or as growth promoters.

14 It is common knowledge, moreover, that bacteria exposed to antibiotics may develop resistance to those antibiotics. The term 'antibiotic resistance' refers, therefore, to the ability of a bacterium to live in the presence of an antibiotic which should, in normal circumstances, prevent its replication or kill it. Once a bacterium has developed resistance to an antibiotic, treatment with that antibiotic will be ineffective. In addition, if a bacterium becomes resistant to one member of an antibiotic class, it may also be resistant to other antibiotics from the same class; this phenomenon is called 'cross-resistance'.

15 Recent years have seen a relative decline in the development of effective new antimicrobial chemotherapeutic agents designed to combat certain pathogens. In that regard, bacteria of the *Enterococcus faecium (E. faecium)* species have

developed a resistance to all authorised antibiotics, including vancomycin. Scientists 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.

16 The Copenhagen recommendations on antimicrobial resistance, a report of a conference on the microbial threat held in Copenhagen in September 1998 at the instigation of the European Union Directors-General/Chief Medical Officers, states (on p. 7): 'Resistance to antimicrobial agents is a major public health problem in Europe.'

17 Virginiamycin is an antibiotic belonging to the streptogramin family of antibiotics, other members of which are pristinamycin and Synercid, which are human therapeutic antibiotics. Virginiamycin is manufactured only by the applicant; it is produced in its factory at Rixensart, Belgium ('the Rixensart factory') and marketed under the trade name 'Stafac'.

18 When administered on a regular basis to livestock, especially pigs and poultry, virginiamycin promotes growth, in particular by enhancing the functioning of the animal's intestinal flora and reducing the incidence of digestive problems.

19 Virginiamycin has been approved under the authorisation procedure initially provided for by Directive 70/524. Since 1 April 1998 it has been subject to a re-evaluation procedure pursuant to Directive 96/51.

20 On 15 January 1998 the Kingdom of Denmark, invoking the safeguard provision contained in Article 11 of Directive 70/524, prohibited the use of virginiamycin

in animal feed on its territory, after submitting to the Commission and to the other Member States a report on the situation dated 7 January 1998 which had been drawn up by the national veterinary laboratory. In addition, on 13 March and 1 April 1998, it communicated to the other Member States and to the Commission the detailed grounds justifying its decision.

21 Since 1986 the Kingdom of Sweden has prohibited the use of all antibiotics as animal growth promoters. Article 151(1) of the Act of Accession, read in conjunction with Title VII, E(4), of Annex XV thereto, provided that the Kingdom of Sweden was to be authorised to maintain in force until 31 December 1998 its pre-accession legislation with regard to the restriction or prohibition of the use in feedingstuffs of additives classed as antibiotics. The Kingdom of Sweden was also afforded the option of submitting, before 31 December 1998, requests for adaptation of Directive 70/524, which were to be accompanied by a detailed scientific statement of reasons. In accordance with those provisions, the Kingdom of Sweden submitted to the Commission on 2 February 1998 requests for adaptation of Directive 70/524 accompanied by detailed scientific statements of reasons with regard to eight antibiotic substances, including virginiamycin.

22 On 17 December 1998 the Council adopted Regulation (EC) No 2821/98 amending, as regards withdrawal of the authorisation of certain antibiotics, Directive 70/524 (OJ 1998 L 351, p. 4, hereinafter 'the contested regulation'), which removed virginiamycin from the list in Annex B to Directive 70/524.

23 The operative part of the contested regulation reads as follows:

'*Article 1*

The entries in Annex B to Directive 70/524/EEC for the following antibiotics shall be deleted:

...

— virginiamycin,

...

Article 2

The Commission shall re-examine the provisions of this regulation before 31 December 2000 on the basis of the results given by

— the different investigations concerning the induction of resistances by the use of the antibiotics concerned,

and

— the surveillance programme of microbial resistance in animals which have received antibiotics, to be carried out in particular by the persons responsible for putting the additives concerned into circulation.

Article 3

This regulation shall enter into force on the day of its publication in the *Official Journal of the European Communities.*

It shall apply from 1 January 1999.

However, where, on the date on which this regulation enters into force, a Member State has not banned, in accordance with Community law, one or more of the antibiotics referred to in Article 1 of this regulation, such antibiotic or antibiotics shall remain authorised in that Member State until 30 June 1999.'

24 In recitals 14 to 19 in the preamble to the contested regulation, the Council gives an account of the conclusions reached by the SCAN in its opinion of 10 July 1998 on the question whether or not streptogramin-resistant *E. faecium* and staphylococci selected by the use of virginiamycin as a growth promoter constituted a public health risk at that time or could constitute such a risk if streptogramins assumed a pivotal role in the treatment of serious human infections in the future.

25 Recitals 20 and 21 in the preamble to the contested regulation are worded as follows:

'(20) Whereas, after the SCAN opinion, Denmark produced major fresh evidence in August 1998 demonstrating a transfer *in vivo* under experimental conditions in the gastro-intestinal tract of rats of the *sat A* gene, via a plasmid, between isogenic strains of *E. faecium*;

(21) Whereas, in the light of the foregoing, the Commission, for its part, takes the view that the risk of reducing the effectiveness of human medicinal products such as pristinamycin and the new combination dalfopristin/quinupristin [Synercid],

which is due to be authorised shortly as a human medicinal product, as a result of cross-resistance caused by virginiamycin should be avoided'.

26 Recitals 23 to 27 in the preamble to the contested regulation state:

'(23) Whereas according to the conclusions of the World Health Organisation conference held in Berlin in October 1997, the Economic and Social Committee of the European Union, the International Office of Epizootics and the conference on antibiotic resistance held in Copenhagen in September 1998, antibiotic resistance must henceforth be regarded as a major, complex problem of international dimensions; whereas, in the sense of the recommendations arising from these conferences, it is desirable to set up a system of general surveillance of antimicrobial resistance resulting from the use of antibiotics; whereas, furthermore, the phenomena of resistance encountered not only in hospitals but also in the general population should be addressed;

(24) Whereas medicinal products belonging to new classes of antibiotics are not ready to be approved in the immediate future; whereas it is therefore imperative to preserve the effectiveness of those human medicinal products which are still effective;

(25) Whereas one of the ways of achieving that aim, along with others relating to use of human medicinal products, is not to increase the reservoir of resistances in animals, especially where such resistances could be transferred to humans, thereby reducing the effectiveness of human medicinal products; whereas numerous scientific data demonstrate such a transfer not only for the organisms responsible for zoonoses but also for commensals;

(26) Whereas one of the ways of preventing such a phenomenon, which originates in the use in livestock farming of antibiotics administered either as a

veterinary medicinal product or as a feed additive, is no longer to authorise the use of antibiotics authorised as human medicinal products or known to select cross-resistance to antibiotics used in human medicine as additives, restricting the use of such substances for fundamental reasons to human medicine;

(27) Whereas, for the sake of protecting human health, the authorisations for the antibiotics bacitracin zinc, spiramycin, virginiamycin and tylosin phosphate should be withdrawn'.

27 The programme of surveillance of microbial resistance in animals which have received antibiotics, referred to in Article 2 of the contested regulation and introduced following the adoption of Commission Directive 97/6/EC of 30 January 1997 amending Directive 70/524 (OJ 1997 L 35, p. 11), has been conducted under the auspices of the Commission since April 1998. That programme, involving the industry concerned, the Commission and six Member States, is being carried out by the persons responsible for putting the additives concerned into circulation. Its aim is to gauge, over a period of two years, the prevalence of resistance in animal enterococci, or the degree of sensitivity of those enterococci, to seven antibiotics used in locations with different practices as regards the use of feedingstuffs.

28 In addition, the Scientific Steering Committee within the Commission's Directorate-General for Consumer Policy and Consumer Health Protection (DG XXIV) established a Multidisciplinary Scientific Steering Committee on Antibiotic Resistance in March 1998. The remit of that steering committee is to conduct a broad review of the literature and output of other institutions relating to the use of antibiotics and the development of resistance in the areas of human pharmaceuticals, veterinary pharmaceuticals and feed additives.

29 Lastly, recital 23 in the preamble to the contested regulation refers to the World Health Organisation (WHO) conference held in Berlin in October 1997 on 'The

Medical Impact of the Use of Antimicrobials in Food Animals'. In the report of that conference (p. 6), the WHO stated as follows:

'Due to the limited number of agents available for the treatment of glycopeptide-resistant enterococci, antimicrobial agents not previously used in humans are being sought, including drugs from classes currently used as growth promoters in animals. Therefore the selection of further resistance in enterococci is undesirable, e.g. streptogramin resistance due to use of virginiamycin as a feed additive in animals.'

30 In the same report, the WHO recommended that the use of any antimicrobial agent for growth promotion in animals should be terminated if it is used in human therapeutics or known to select for cross-resistance to antimicrobials used in human medicine.

Procedure

31 By application lodged at the Registry of the Court of First Instance on 18 January 1999, Pfizer Animal Health SA/NV (hereinafter 'Pfizer' or 'the applicant') brought proceedings under the fourth paragraph of Article 173 of the EC Treaty (now, after amendment, the fourth paragraph of Article 230 EC) for the annulment, in whole or in part, of the contested regulation, by which the Council deleted the entry in Annex B to Directive 70/524 relating to the antibiotic virginiamycin.

32 On 10 March 1999 the Council raised, pursuant to Article 114 of the Rules of Procedure, an objection to the admissibility of the application for annulment.

33 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 wholly 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 may require.

34 By application lodged at the Registry of the Court of First Instance on 23 February 1999, the Asociación Nacional de Productores de Ganado Porcino ('Anprogapor'), the Asociación Española de Criadores de Vacuno de Carne ('Asovac') and the Asociación Española de Productores de Huevos ('Aseprhu'), associations governed by Spanish law, applied for leave to intervene in support of the form of order sought by the applicant in the proceedings for interim relief.

35 By application lodged at the Registry of the Court of First Instance on 24 February 1999, the Pig Veterinary Society, an association governed by English law, established in London, applied for leave to intervene in support of the form of order sought by the applicant in the proceedings for interim relief.

36 By application lodged at the Registry of the Court of First Instance on 25 February 1999, the Commission applied for leave to intervene in support of the form of order sought by the defendant in the proceedings for interim relief.

37 By application lodged at the Registry of the Court of First Instance on 1 March 1999, the Fédération Européenne de la Santé Animale (Fedesa) and the Fédération Européenne des Fabricants d'Adjuvants pour la Nutrition Animale (Fefana) applied for leave to intervene in support of the form of order sought by the applicant in the proceedings for interim relief.

38 By letter of 12 March 1999, the Kingdom of Denmark applied for leave to intervene in support of the form of order sought by the defendant in the proceedings for interim relief.

39 By application lodged at the Registry of the Court of First Instance on 17 March 1999, Mr Kerckhove and Mr Lambert applied for leave to intervene in support of the form of order sought by the applicant in the proceedings for interim relief.

40 By letters of 18 and 25 March 1999 respectively, the Kingdom of Sweden and the Republic of Finland applied for leave to intervene in support of the form of order sought by the defendant in the proceedings for interim relief.

41 Those applications for leave to intervene were served in accordance with Article 116(1) of the Rules of Procedure on the applicant and the defendant, which submitted their observations within the time-limits prescribed.

42 By order of 22 March 1999 the President of the Court of First Instance allowed the intervention of Anprogapor and Asovac, of Fedesa and Fefana, of the Commission and of the Kingdom of Denmark, and dismissed the applications for leave to intervene submitted by Aseprhu and the Pig Veterinary Society. He also granted, at that stage of the proceedings for interim relief, the applicant's request for confidential treatment *vis-à-vis* the parties granted leave to intervene.

43 By order of 8 April 1999 the President of the Court of First Instance allowed the intervention of the Kingdom of Sweden, the Republic of Finland and Mr Kerckhove and Mr Lambert, and granted, at that stage of the proceedings for interim relief, the applicant's request for confidential treatment *vis-à-vis* the parties granted leave to intervene.

44 Each of the parties granted leave to intervene lodged its observations within the period prescribed.

45 The parties presented oral argument at the hearing on 26 April 1999.

Law

46 Under the combined provisions of Articles 185 and 186 of the EC Treaty and Article 4 of Council Decision 88/591/ECSC, EEC, Euratom of 24 October 1988 establishing a Court of First Instance of the European Communities (OJ 1988 L 319, p. 1), as amended by Council Decision 93/350/Euratom, ECSC, EEC of 8 June 1993 (OJ 1993 L 144, p. 21), the Court may, if it considers that circumstances so require, order the operation of the contested act to be suspended or prescribe any necessary interim measures.

47 Article 104(2) of the Rules of Procedure provides that applications for interim measures must state the circumstances giving rise to urgency and the pleas of fact and law establishing a prima facie case for the measures applied for. Those requirements are cumulative, so that an application for suspension of operation must be dismissed if either of them is not met (order of the President of the Court of First Instance of 15 July 1998 in Case T-73/98 R *Prayon-Rupel* v *Commission* [1998] ECR II-2769, paragraph 25). In addition, the Court hearing an application for interim relief must balance the interests at stake (order of 12 July 1996 in Case C-180/96 R *United Kingdom* v *Commission* [1996] ECR I-3903, paragraph 44).

Arguments of the parties

Admissibility

48 Whilst the Council does not formally plead the inadmissibility of the application for interim measures, it nevertheless asserts that the claim in the main proceedings is inadmissible. It considers, in essence, that the contested regulation is not of individual concern to the applicant within the meaning of the fourth paragraph of Article 173 of the EC Treaty, a position it restated at the hearing.

The existence of *a prima facie case*

49 The applicant, supported in that regard by Anprogapor, Asovac, Fedesa, Fefana, Mr Kerckhove and Mr Lambert, considers, in essence, that the defects in the procedure leading to the adoption of the contested regulation are such as to vitiate the latter by manifest errors of assessment.

50 In the context of its first plea, alleging procedural errors, it maintains, first, that the Commission did not submit all the relevant scientific evidence held by it to the SCAN's expert advisers, in particular the Danish test concerning germ-free rats which was none the less regarded as 'major fresh evidence' (recital 20 in the preamble to the contested regulation). Once a dialogue with scientific advisers has been initiated, it should be pursued fairly and consistently.

51 Second, the contested regulation was adopted at a time when several scientific studies regarding resistance to antibiotics, conducted under the auspices of the Commission, were still pending, namely the surveillance programme concerning

microbial resistance in animals which have received antibiotics, the investigation by the Multidisciplinary Scientific Steering Committee on Antibiotic Resistance and the studies carried out under Directive 96/51 in relation to antibiotic additives. The applicant states, with regard to that directive, that it has completed the first step required for the re-evaluation of virginiamycin and has begun to prepare the dossiers to be submitted by 1 October 2000. Each dossier is to contain a section on safety, dealing, in particular, with investigation into cross-resistance to therapeutic antibiotics. By not waiting until it was in possession of relevant data, the Commission disregarded the principle of prudent administration, although it had confirmed during the plenary sessions of the European Parliament on 15 May and 17 November 1998 that any action taken by it would be based on the conclusions reached in those scientific studies.

52 Third, the applicant claims that the Kingdom of Denmark's decision prohibiting virginiamycin is illegal, and that the Commission was therefore wrong to use that national measure as the basis for imposing a generalised Community-wide ban. The adoption and implementation of the Danish measure infringed Article 11 of Directive 70/524, since the Kingdom of Denmark was not, in January 1998, in possession of scientific data justifying a ban. Furthermore, although the Commission allowed the Kingdom of Denmark to file additional data after January 1998, the SCAN, in its opinion of 10 July 1998, criticised the Danish conclusions, considering them to be 'unsound and without foundation' (comment, Conclusion 6 to the SCAN opinion). The SCAN also found that the use of virginiamycin as a growth promoter did not constitute an immediate risk to public health in Denmark. The applicant concludes from this, in essence, that experience in Denmark has not shown, any more than the other studies carried out, that any human being has been attacked or colonised by virginiamycin-resistant bacteria from animals. Consequently, the procedure leading to the adoption of the contested regulation was set in motion on the basis of unfounded allegations.

53 The applicant infers from those procedural defects that a manifest error of assessment has been committed in the present case. It argues in that regard, first, that, in a field where the scientific aspects are technical and difficult, the assistance of experts is essential (Case T-105/96 *Pharos* v *Commission* [1998]

ECR II-285). However, in the case of virginiamycin, the advice of the SCAN was not frankly described in the contested regulation and was not sought in relation to the 'major fresh evidence' (recital 20 in the preamble to the contested regulation). In an area which is 'both delicate and controversial' (Case T-199/96 *Bergaderm and Goupil* v *Commission* [1998] ECR II-2805, paragraph 55), the Commission should have arranged for a scientific examination of the 'major fresh evidence'.

54 Next, the applicant maintains that the opinion of the SCAN was misrepresented. Contrary to what is suggested in the preamble to the contested regulation, the SCAN opinion specifically opposed the Danish ban on virginiamycin. For example, contrary to the statements made in recital 16 in the preamble to the regulation, the SCAN did not acknowledge that a reservoir of resistant genes within the animal population posed a potential risk to humans; while it expressed sympathy for the Danish concern about such a hazard, the SCAN opinion (comment on Conclusion 9) stated that the validity of the Danish conclusions depended on the establishment of such a link, of which the Danish report provided no new evidence.

55 Moreover, the precautionary principle, as enunciated in the Guidelines adopted by the Commission in October 1998, was disregarded. That principle should be defined as an approach to risk management which is applied in circumstances of scientific uncertainty, reflecting the need to take action in the face of a potentially serious risk without awaiting the results of scientific research. An objective and complete assessment of the risk requires reliable scientific data and logical reasoning, leading to a conclusion which expresses the probability of occurrence (risk) and gravity of a threat for a given population (hazard). In the present case, the applicant doubts that the Commission clearly identified the 'risk' and the 'hazard'. According to Professor Casewell (whose statement is annexed to the application for interim measures): 'Not only is the hazard of virginiamycin theoretical but its occurrence has not been recorded and the risk is thus at present zero.'

56 In that context, the applicant considers that, whilst the use of antibiotics in animals can lead to the development of antibiotic resistance in some animal bacteria, there exists no evidence of any risk to human health with respect to virginiamycin; there is no reason to suppose that virginiamycin-resistant *E. faecium* of animal origin would survive in the human gut; there is no compelling evidence that resistant animal enterococci can colonise in the human gut, nor any evidence showing that relevant bacteria of animal origin can transfer genes to bacteria normally resident in the human gut; and there is not a single reported case of enterococci of animal origin causing disease in humans. The Danish authorities' claim that animals and humans can harbour identical strains of virginiamycin-resistant *E. faecium*, which could show that virginiamycin resistance can be transmitted from animals to humans, concerned the isolated case of a Dutch turkey farmer who could have swallowed bacteria living in or around his poultry by breathing air full of bacteria or by handling his birds and then touching food.

57 The applicant cites the statement by Professor Phillips, an expert on the prevalence and mechanisms of antibiotic resistance, that 'No case has ever been recognised of infection in man by a streptogramin-resistant *E. faecium* from an animal source' (annexed to the application for interim measures). It maintains, moreover, that although virginiamycin has been used during the past 30 years as an additive in feedingstuffs, and another streptogramin, pristinamycin, has been used over a comparable period in humans, there is not a single known case of streptogramin-resistant *E. faecium* bacteria of demonstrable animal origin causing disease in humans. There exists substantial recent evidence indicating only a very low level of streptogramin resistance in human clinical isolates in countries (such as France) where pristinamycin is used as a human therapeutic antibiotic and virginiamycin is used as a feed additive.

58 An article recently published in the United States of America (Jones et al., *Diagn. Microbiol. Inf. Dis* 1998, 30:437-451) reports on a study which concluded that the overwhelming majority of bacteria are not resistant to Synercid. Virginiamy-

cin has been on the market in the United States of America as an animal growth promoter for some 25 years. Thus, while some level of resistance to virginiamycin has developed in animals over the years, it has manifestly not posed a problem of risk of resistance to Synercid in humans.

59 Professor Casewell has stated, with regard to very extensive studies of human organisms from a broad sample of the populations in France, Canada and the United States, that they give no support to the hypothesis that virginiamycin use in animals is producing Synercid-resistant infections in humans. According to him, there is inadequate rigorous scientific, microbiological or epidemiological evidence to suggest that the use of the growth promoter virginiamycin in animals creates antibiotic-resistant bacterial strains which cause infection in humans (statement annexed to the application for interim measures).

60 The applicant further asserted at the hearing that the risk alleged by the Community is not as widespread as it claims, since imports of meat from countries in which virginiamycin is authorised have not been banned.

61 Fedesa and Fefana submit, for their part, that the Council's approach is inconsistent with the current regulatory framework. The procedure for registering feed additives or veterinary medicinal products is designed to ensure that only products which are safe, effective and of high quality may be placed on the market. Already at that stage, all necessary precautions are taken to ensure a proper assessment of the risks in accordance with scientific criteria. In such a situation, therefore, the degree of any risk which may exist is necessarily regarded as acceptable by the legislature. Moreover, even after a product has been placed on the market, a strict system of surveillance is applied (see, for example, Directive 84/587).

62 Once the product is on the market, as virginiamycin has been for almost 30 years, the role of the competent Community institutions is that of a risk manager. It is then up to the competent authority and the scientific community to establish the existence of an unacceptable risk before banning a product. A failure to adopt that approach would discourage investment by companies active in the European animal health and feed additives industry. Furthermore, the prohibition of the antibiotics in question will make it impossible to complete the requested surveillance study, since the circumstances in which it is to be carried out will be falsified (on account of the absence of four antibiotics), thus making reliable comparisons impossible.

63 Anprogapor and Asovac maintain that the Guidelines on the Application of the Precautionary Principle required not only an objective risk assessment but also consultation with interested parties, inasmuch as the banning of the four antibiotics was not fully justified from the scientific point of view.

64 The applicant further argues that, by imposing severe burdens on individuals, companies and farmers, and on animal welfare, without any benefit in respect of the legitimate legislative goal of protecting public health, the contested regulation disregards the principle of proportionality. The implementation of that regulation will disrupt livestock and poultry businesses in several Member States, destroy the applicant's virginiamycin business and result in its employees being laid off. Yet the public interest could also have been safeguarded by a measure far less drastic than a total ban, such as, Anprogapor and Asovac suggest, the adoption of rules imposing stricter veterinary control on the use of virginiamycin or a reduction in the amount of virginiamycin given to animals.

65 Mr Kerckhove and Mr Lambert observe that, according to recital 27 in the preamble to the contested regulation, it was necessary, 'for the sake of protecting human health', to withdraw the authorisations for four antibiotics. Yet the Community market is not protected against imports of meat from third countries which continue to allow the use of antibiotics such as virginiamycin. They

conclude from this that the contested regulation cannot achieve the aim of protecting the population of the Community from the risk of the development of cross-resistance in humans to certain antibiotics due to the use of virginiamycin.

66 In addition, the principle of the protection of legitimate expectations has been violated, inasmuch as the Commission disregarded current procedures, based on Community legislation, for the re-evaluation of authorisation of additives in feedingstuffs, focusing on microbiological safety despite having previously given explicit assurances that any action with respect to antibiotic additives in feedingstuffs would be based on scientific considerations. Furthermore, the Commission breached its own established practice by not respecting the procedure set out in Article 11 of Directive 70/524. The regulation thus frustrated the legitimate expectations of those engaged in the re-evaluation procedure and the various scientific studies.

67 The contested regulation is inadequately and defectively reasoned and is inconsistent with the first protocol to the European Convention for the Protection of Human Rights and Fundamental Freedoms and the basic right to property recognised by Community law.

68 Lastly, there has been a misuse of powers, since the only proper justification for the ban on virginiamycin, namely the protection of public health, is lacking. The public health risk is negligible or non-existent. The manipulation of the scientific evidence with a view to embarking on the process of imposing a ban suggests that the Commission was pursuing an objective other than health protection. Mr Kerckhove and Mr Lambert also maintain in that connection that the risk perceived by the institutions cannot be as grave or as imminent as they claim, since the ban does not apply to imports of meat. They infer from this that the regulation was not adopted purely for purposes of health protection.

69 The Council, supported by the Commission, the Kingdom of Denmark, the Kingdom of Sweden and the Republic of Finland, considers that the applicant has clearly not succeeded in showing that the institutions failed to follow the procedure provided for in Article 11 of Directive 70/524, or that they committed any manifest errors of assessment.

70 It argues, first, that the Commission enjoys a wide discretion, particularly as to the nature and scope of the measures which it adopts, and that the task of the Community judicature, in reviewing those measures, is to determine whether the exercise of such discretion is vitiated by a manifest error or misuse of powers or whether the Commission did not clearly exceed the bounds of its discretion.

71 In the present case, Article 11 of Directive 70/524 imposes no procedural, temporal or territorial restriction on the exercise of its discretion by the Commission. The applicable rules merely provide for the obligatory consultation of the Standing Committee for Feedingstuffs in the context of the implementation of the safeguard clause. By contrast, the applicable legislation imposes on the Commission no obligation to consult the SCAN in the course of the procedure leading to the adoption of a measure under Article 11(3) of Directive 70/524; that is a matter lying within the Commission's discretion. Nevertheless, in the present case, the Commission did request the SCAN, in response to the action taken by the Kingdom of Denmark, to give its opinion on the immediate and longer-term risk to the value of streptogramins in human medicine posed by the use of virginiamycin as a growth promoter. As is shown by the preamble to the contested regulation, the Commission and the Council had regard to the SCAN's opinion of 10 July 1998, passages from which are cited in nine recitals.

72 The Council therefore contends that the applicant's arguments should be rejected. It maintains, first, that the Community institutions, which were not bound by the SCAN's opinion, had the power to review and evaluate the possible risk of the adverse effect on human health identified by the SCAN and to take the measures necessary to eliminate or contain that risk. The decision in that connection lies with the risk manager, who is entitled to depart from the opinion of the scientific

committee when this is necessary to achieve the level of health protection which is required by the Community legislation and the Treaty. The Commission states in that regard that Pfizer's assertion that the contested measure is based on the Danish ban disregards, first, the fact that the legality of measures adopted by the Commission or the Council under Article 11(3) of Directive 70/524 is not in any way dependent on the validity of measures taken by Member States under Article 11(1) and, second, the fact that the contested regulation is also based on Title VII, E(4), of Annex XV to the Act of Accession. Consequently, even if that regulation were contrary to Article 11(3), *quod non*, its legality would be guaranteed by its other legal basis, in this case the Act of Accession.

73 The Council maintains, second, that the applicant ignores the fact that the SCAN opinion was concerned with the public health risk in Denmark and not the risk posed to the Community as a whole. However, the duty of the Community legislature under Article 11(3) of Directive 70/524 is to protect human health at Community level, and not only in a given Member State.

74 Third, the SCAN identified the hazard, namely the development of resistance to streptogramins used for human therapy. The Council further states that Community law does not require a quantitative assessment of the risk before protective action is allowed in order to achieve the desired level of health protection. The Court of Justice has in several instances explicitly upheld the validity of such action by the Community institutions, stating that where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent (Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265, paragraph 99; Case C-157/96 *R* v *MAFF and Another, ex parte National Farmers' Union and Others* [1998] ECR I-2211, paragraph 63; *Bergaderm and Goupil* v *Commission*, cited above, paragraph 66). The Council argues that, inasmuch as neither the SCAN nor the applicant contests the existence of a risk to human health, it is only the extent and seriousness of the risk identified that is disputed. The SCAN opinion, together with numerous scientific articles and the reports from the competent national and international organisations, provided the competent Community institutions with

a clear basis on which to decide that the risk in this case was probably too great to be assumed without compromising the level of health protection which they are obliged to ensure in all the Member States of the Community. Against that background, the Commission considers that, in stating that there was uncertainty regarding the existence of a risk to human health, Pfizer has not in any way proved that an error was committed.

75 Fourth, the Council contends that, contrary to what is stated by the applicant, the Commission did submit the new evidence to the SCAN, in September and November 1998, but that the latter did not consider it necessary to modify its opinion of 10 July 1998.

76 Lastly, the Council states that the role of the competent Community institutions is to evaluate the opinion of the SCAN in the light of all the scientific evidence available to the Commission from numerous other sources and to weigh up the different interests at stake on the basis of that scientific information. The Council maintains in that respect that it was entirely appropriate to adopt the contested measure in order to prevent all actual and foreseeable risks to public health arising from cross-resistance to antibiotics used in human medicine from antibiotics currently used as growth promoters. Thus, in making its choice in favour of protecting the overriding interest of public health, on the basis of the different scientific evidence before it and following an assessment of the possible risks to public health, the Community decided to withdraw the products until it can be conclusively demonstrated that they pose no present or future risk to human health. Consequently, the Community institutions acted in a precautionary manner.

77 The Council also denies any breach of the principle of proportionality, as set out in paragraph 96 of the judgment in *United Kingdom* v *Commission*, cited above. In matters concerning the common agricultural policy, the Community legislature has a discretionary power, so that the legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate to the objective pursued (Case C-331/88 *Fedesa and Others* [1990] ECR I-4023, paragraphs 13

and 14). On the basis of the scientific evidence available, the Community institutions did not act in a manifestly inappropriate manner. Moreover, the Kingdom of Sweden submits, in the light of experience in that country following the banning of antibiotic growth promoters in 1986, that it is possible to raise animals without growth-promoting antibiotics whilst retaining proper health conditions.

78 The Council maintains that there has been no breach of the principle of the protection of legitimate expectations either. Referring in that regard to the judgment in Joined Cases T-481/93 and T-484/93 *Exporteurs in Levende Varkens and Others* v *Commission* [1995] ECR II-2941, it denies having given the applicant any precise assurance giving rise to a justified expectation that the use of virginiamycin as a growth promoter would be authorised indefinitely in accordance with Directive 70/524. As a prudent and discriminating trader in the pharmaceuticals sector, the applicant had been aware since 1970, on the basis of the safeguard procedure, and since 1995, on the basis of the Act of Accession of Sweden, that there could be no legal guarantee that the Community would not act as it did, especially in the light of the growing scientific evidence.

79 As regards the plea of failure to comply with the obligation to state reasons, the Council merely observes that the preamble to the contested regulation contains 35 recitals and that the reasoning set out therein consequently goes beyond the test laid down by the Court of Justice.

80 In addition, the right to property and freedom to pursue a commercial activity, pleaded by the applicant, are not absolute rights but must be viewed in relation to their social function. They may therefore be restricted, provided that the restrictions imposed correspond to objectives of general interest pursued by the Community and do not, in relation to the aim pursued, constitute disproportionate and intolerable interference impairing the substance of the right guaranteed (Case C-280/93 *Germany* v *Council* [1994] ECR I-4973 and Case C-183/95 *Affish* v *Rijksdienst Keuring Vee en Vlees* [1997] ECR I-4315, paragraph 42). Moreover, it has been held that the importance of the objectives pursued is such as to justify even substantial negative financial consequences

(*Fedesa and Others*, cited above, paragraph 17). In the present case, the contested regulation falls within the category of measures which may be envisaged under normal commercial conditions.

81 There is, therefore, nothing in the contested regulation which could lead to the conclusion that it was adopted for a purpose other than that of ensuring the highest possible level of protection of public health.

82 More specifically, the Commission observes in its statement in intervention that the ban on the use of virginiamycin for sows does not arise from the contested regulation, since the provisional authorisation with respect to those animals expired in June 1998.

83 The Kingdom of Denmark, whilst fully endorsing all the arguments advanced by the Council, makes various additional observations with regard to the specific points concerning the Danish scientific documentation. It also states that the applicant's use of the notion of risk presupposes the existence of actual, recorded harm to human health. That requirement is not consistent with the prevailing principles of risk assessment, from which it is clear that harm does not need to have occurred before steps are taken to counter a possible risk. It is sufficient to show that there is potential for harm occurring. As it is, the risk that the use of virginiamycin for animals may result in resistant infections in humans has been documented as extensively as is ethically and scientifically possible.

Urgency

84 The applicant claims that, if operation of the contested regulation is not suspended, it will result in job losses, a negative impact on production at the

Rixensart factory and on its competitive position, a fall in its sales in other countries and the loss of its ability to manufacture the product, and other categories of damage.

85 First, in late January 1999, in consequence of the contested regulation, Pfizer announced a plan for the collective redundancy of 31 employees, 15 of them being white-collar staff and 16 blue-collar workers. The climate of uncertainty which the contested regulation has generated with respect to the professional future of the white-collar employees is prompting them to leave the plant in order to join competing undertakings. That exodus of qualified staff, and the loss of skill and experience resulting from it, will force the applicant to close the factory. A cut in production of over 50% will also harm the blue-collar workers, both from a financial standpoint and in terms of their morale, as well as the employees of Pfizer's local subcontractors, and will bring about the disbandment of the teams engaged in the sale and marketing of virginiamycin throughout Europe (Belgium, France, Spain, Italy, Germany, the United Kingdom, Ireland and the Netherlands).

86 Second, the applicant describes the impact of the contested regulation on its production capacity. It states that, due to the success of the product since the 1960s, the fermentation capacity of the Rixensart factory has been geared to the production of virginiamycin. Today, no other plant in the world has the same equipment, the same fermentation processes or the same production techniques. Even though virginiamycin is no longer covered by any patent, the last patent for virginiamycin having expired in 1991, the products manufactured by the Rixensart factory and the efficiency of its production methods have been such that no competitor has imitated it with any success. Since the acquisition of the Rixensart factory by Pfizer in 1995, its performance has constantly improved, reflecting substantial investment in the plant. However, the results of the efforts made to date are being jeopardised by the inability to market virginiamycin from 1 July 1999: it has already brought about the interruption of investment projects and will result in the loss of very substantial investment in the plant, together with the deferral of capital investment. Moreover, the plan to build a new granulation line has been abandoned.

87 In addition, the applicant states that the manufacturing process in use in the Rixensart factory is conceived only for the production of virginiamycin, and that it is not possible to convert the plant into a site for the production of an alternative product. Consequently, even if it were to decide to manufacture another product in that plant, such production could not commence until the virginiamycin production equipment had been dismantled, so that virginiamycin could no longer be produced.

88 Third, the applicant claims, with reference to the fact that 38% of current sales of virginiamycin take place in the 15 Member States of the European Union, that there will be an immediate production cut of at least 50% as soon as the ban comes into force. The production cost of the remaining volume will increase by 25%, because the fixed costs, including capital costs, will remain the same; this will mean either that prices will have to rise in the markets where the product can still be sold or that Pfizer will have to absorb the increase or simply cut its profits. At the hearing, the applicant produced graphs illustrating sales trends following the imposition of the ban on the marketing of virginiamycin in the Community, together with forecasts of the cost structure and financial results for the year 2000.

89 The applicant further maintains that the contested regulation will bring about a fall in sales of virginiamycin in other countries. Approximately 6.5% of sales are generated in central and eastern Europe (Poland, the Czech Republic, Hungary, Slovenia, Latvia, Lithuania, Estonia and Slovakia). Those countries are adopting the *acquis communautaire* as part of the current accession negotiations and are thus likely, as the Czech Republic and Hungary have already done, to announce a ban on virginiamycin. In addition, a fast food chain in the latter country has already stated that, as from 1 April 1999, it will refuse delivery of meat from animals whose feed contains virginiamycin. As a result of customs union or trade association agreements, Turkey, Cyprus and Malta will follow suit; sales in those countries represent approximately 1-2% of total sales. The financial losses will also extend to markets such as Japan and Australia, which are traditionally influenced, as the figures testify, by the European Union's policy in this area. The position is the same as regards China, Korea and Thailand.

90 The applicant also claimed at the hearing that the ban provided for by the contested regulation would have an effect in the United States, whose legislation prohibits the sale of products which may not be sold lawfully in the country where they are manufactured. Consequently, the sale of virginiamycin could be banned in the United States as a result of the contested regulation.

91 The applicant considers, in the light of that data, that the risk that part of its activities may have to cease and that it may be excluded from the market constitutes serious and irreparable harm (orders of the President of the Court of Justice of 8 July 1974 in Case 20/74 R II *Kalie Chemie* v *Commission* [1974] ECR 787, of 30 October 1978 in Joined Cases 209/78 R to 215/78 R and 217/78 R *Van Landewyck and Others* v *Commission* [1978] ECR 2111 and of 8 April 1987 in Case 65/87 R *Pfizer* v *Commission* [1987] ECR 1691). The losses which it is facing can only be due to the adoption of the contested regulation (see, with regard to a contrary finding, the order of the President of the Court of Justice of 19 August 1988 in Case 191/88 R *Co-Frutta* v *Commission* [1988] ECR 4551). It points out that the test for irreparable damage is that it is impossible to safeguard the applicant's position retroactively in the event of success in the main action (order of the President of the First Chamber of the Court of Justice of 28 November 1966 in Case 29/66 R *Gutmann* v *Commission* [1967] ECR 241), the object of interim relief being to prevent the final judgment from being rendered meaningless by the passage of time and to prevent the infliction of damage that is irreversible (order of 5 October 1969 in Case 50/69 R *Germany* v *Commission* [1969] ECR 449). In the present case, the applicant is in danger of losing touch with its customers as a result of the ban, and there is the risk that its competitors in regard to the supply of feedingstuff additives will have taken control of the market before judgment is given in the main action.

92 Moreover, the nature of the right infringed by a measure must be such that its infringement is capable of causing serious and irreparable damage to the holder of that right (order of the President of the Court of First Instance of 21 November 1994 in Case T-368/94 R *Blanchard* v *Commission* [1994] ECR II-1099). The right at issue in the present case is the right to manufacture and sell within the Community a product which has undergone, and continues to undergo, a stringent scientific regulatory review and approval process and has been used safely for almost 30 years.

93 Lastly, the applicant alleges a series of other instances of damage caused by the contested regulation. In that connection, it pleads, first, the adverse impact of the ban in social terms on the town and the region of Rixensart.

94 Next, it describes the adverse impact which the ban will have on livestock farmers who have been using virginiamycin for almost 30 years, and the absence of any other substance entirely capable of being used as a substitute for it.

95 In that connection, Anprogapor and Asovac claim that the ban on the use of four feed additives will result in an increase in production costs, caused in particular by a rise in the volumes of feed needed and higher veterinary costs, as well as a reduction in the productivity of farmers rearing pigs, sows and calves, whose financial losses are quantified. The withdrawal of the antibiotic in question from 1 July 1999 will mean, first, that animals will have to be fed more in order to obtain the desired weight of meat, and second, that its prophylactic benefits will be eliminated, thereby increasing the incidence of diseases in previously healthy animals and farmers' expenditure on veterinary care.

96 Mr Kerckhove and Mr Lambert, farmers engaged in the rearing of pigs to slaughter weight, maintain in their statement in intervention that the ban on the use of virginiamycin from 1 July 1999 will inevitably cause them financial damage. They state that the prohibition introduced by the contested regulation will lead to a fall in the fertility of sows, slower animal growth, increased production costs on account of the extra feed required and the treatment of additional slurry, and more frequent recourse to prophylactic treatment. In addition, they deny the Commission's allegation that virginiamycin has not been available for use in feed for sows since June 1998.

97 The applicant, supported in that respect by Fedesa and Fefana, also pleads the adverse impact which the ban will have on animal welfare. Virginiamycin boosts

animal welfare in a number of ways, by preserving the nutritional health of animals, protecting them against various digestive ailments and reducing stress. Those allegations are supported by the statistical findings arrived at in Sweden following the ban on feed additive antibiotics in 1986.

98 Lastly, the applicant pleads, like Fedesa and Fefana, the adverse impact which the ban will have on the environment. Virginiamycin enables animals to digest feed more efficiently, thereby shortening the period needed for them to reach the required size and weight for slaughter. By reducing the amount of feed needed by an animal throughout the growth process, it reduces the overall quantity of waste produced, which in turn reduces the amount of harmful substances, such as nitrogen and phosphates, released into the environment. The ban will also affect water and air quality.

99 The Council denies that the urgency criterion has been satisfied. It considers that the applicant has failed to show that the damage allegedly caused to the Rixensart factory by the entry into force of the contested regulation would be irreparable and endanger the very existence of the plant, or that that damage would cause irreparable harm to Pfizer Animal Health SA/NV and endanger its very existence.

100 It observes in that connection that any claim that irreparable damage is going to be suffered by entities other than the party applying for interim relief must be substantiated by evidence showing that it in turn causes irreparable damage to the applicant. The Republic of Finland considers that, for the purposes of assessing urgency, regard may not be had to possible damage caused to parties who are not parties to the present proceedings.

101 In the Council's view, the applicant's assertions do not show that a temporary fall in sales of virginiamycin, pending the outcome of the main proceedings, will inevitably lead to the immediate closure of the Rixensart factory.

102 First, the contested regulation does not bring about the disappearance of all markets for virginiamycin, since the product can still be sold in markets outside the Community. It points out in that regard that those markets account for 62% of the current sales volume and that the Rixensart factory is the only one in the world which manufactures the product. The loss of part of the sales will not therefore automatically give rise to any need for the cessation, either immediately or in a very short time, of all production of virginiamycin by the plant.

103 Second, the applicant has not shown that the Rixensart factory cannot be used for other purposes, in particular for the production of alternative products. The Council observes that none of the applicant's assertions is substantiated by any hard evidence (apart from a particular witness statement), whereas it is well known that the plant has produced products other than virginiamycin in the past. In particular, until the Community prohibition introduced by Commission Directive 97/72/EC of 15 December 1997 amending Directive 70/524 (OJ 1997 L 351, p. 55), that plant had produced ardacin, another additive also used in growth promotion.

104 Third, the applicant has not shown that the expected reduction in sales of the product will have direct and irreparable consequences for employment, either at the plant or in the area. In particular, Pfizer has not explained why it is absolutely necessary at this stage to dismiss employees or make them redundant. In the Council's view, this chain of events has in fact been triggered by an autonomous decision taken by Pfizer itself.

105 The Council likewise considers that the applicant has failed to show that the damage allegedly caused to the Rixensart factory is such as to jeopardise Pfizer's

very existence. It observes that the Rixensart factory is not the only plant which that company owns in Belgium, and that Pfizer's activities in that country are not limited to the production of virginiamycin. Furthermore, when assessing the risk of serious and irreparable harm to a party, the economic circumstances of the entire group are to be taken into account (orders of the President of the Court of First Instance of 10 December 1997 in Case T-260/97 R *Camar* v *Commission and Council* [1997] ECR II-2357, paragraph 36, and of the President of the Court of Justice of 15 April 1998 in Case C-43/98 P(R) *Camar* v *Commission and Council* [1998] ECR I-1815, paragraph 36).

106 The interveners endorse the arguments put forward by the Council in their entirety.

107 As regards the interests of the livestock farmers, however, the Commission observes that there are a number of other growth promoters which are perfectly good substitutes for all types of livestock and which continue to be authorised, since the Commission has not accepted the Kingdom of Sweden's request for a blanket ban on the use of all antibiotics as growth promoters. Moreover, the estimates of financial loss submitted by the farmers can be taken into consideration in the present case only in so far as they relate to the withdrawal of virginiamycin and exclude the rearing of sows. In any event, the existence of substitutes nullifies the alleged adverse impact on animal welfare and the environment.

108 The Kingdom of Denmark states that the applicant can continue to sell over 70% of the volume of virginiamycin hitherto sold. In that connection, it cites Pfizer's 1998 Annual Report, according to which 'Stafac is an antibiotic effective in increasing the amount of weight gain and improving feed efficiency in poultry, cattle and swine. Total 1998 sales were USD 82 million, of which western European sales represented USD 24 million.' As it is, the applicant has not shown that the Rixensart factory will be unable to survive on the basis of such a market, the annual value of which amounts to USD 58 million.

109 Moreover, the Kingdom of Denmark doubts that the applicant will be unable, should it succeed in the main proceedings, to win back the market share lost by it as a result of the temporary ban. The market share of virginiamycin in Denmark has been found to have fluctuated considerably from year to year between 1989 and 1997. Those fluctuations can be explained by the need to avoid a situation in which the prolonged use of a given antibiotic in livestock gives rise to the selection of bacteria which are resistant to the antibiotic in question. Since tylosin, spiramycin and bacitracin zinc were banned at the same time as virginiamycin, it is highly likely that virginiamycin will be able to win back its market share following a ban of three or four years' duration, if it can be shown in the interim that the product can be used without any adverse health consequences.

110 The Kingdom of Denmark considers, on the basis of the data contained in the applicant's 1998 Annual Report, that it is clear from the turnover of Pfizer's Animal Health Division and of the Pfizer Group as a whole, and from the profits made by the latter, that the applicant will not suffer serious and irreparable damage as a result of the ban on virginiamycin.

111 Lastly, it observes, with regard to the effects which the ban will have on farmers who use virginiamycin in their business, that, by using non-antibiotic growth promoters or by altering their production methods, farmers can obtain results which are just as good as when antibiotic growth promoters are used. It relies in that connection on studies carried out in Denmark.

The balancing of interests

112 The applicant submits, with reference to the order of the President of the Court of First Instance of 3 June 1996 in Case T-41/96 R *Bayer* v *Commission* [1996] ECR II-381, that the Court hearing the present application for interim measures is required to weigh the burdens imposed by the contested regulation on the applicant, on the parties intervening in its support and on any third parties having an interest in the grant of the order sought against the alleged advantages for

public health which that regulation is supposed to secure. Thus, the Court should balance the certainty of real harm — the destruction of Pfizer's virginiamycin business, the loss of jobs of those working in that business and the denial to farmers of a proven growth promoter which contributes to animal welfare — against a theoretical risk which has not been proven. When balancing those certainties against the speculative factors invoked by the contested regulation, account should be taken of the fact that virginiamycin has been used in animal feed for nearly 30 years without resulting in any instances of infection due to antibiotic resistance in either humans or animals, the fact that Synercid, a streptogramin antibiotic, is not currently on the market and the fact that it has not been established that virginiamycin affects human health. Lastly, for the purposes of assessing whether the interim measures sought would involve an unacceptable risk, account should be taken of the SCAN opinion of 10 July 1998 and of the views expressed by eminent experts. The public posture of the Commission supports the applicant's request, since that institution gave assurances, notably in November 1998, that no action would need to be taken until the scientists had completed the studies in progress.

113 The applicant also points out that the contested regulation reflects the view that the continued use of virginiamycin for an interim period will not present a risk to the public, since it authorises that use to continue, save in Denmark and Sweden, for the first six months of 1999. Consequently, the interim period of six months could be extended until the Court has given its decision in the main proceedings. Furthermore, the regulation does not find that virginiamycin presents an immediate risk to human health; the legislature left open the possibility that the product may be validated by scientific inquiry.

114 Lastly, the applicant draws attention to the differences between the present case and that of bovine spongiform encephalopathy, which gave rise to the order in *United Kingdom* v *Commission*, cited above (in particular, paragraphs 52, 59, 60 and 61). In that order, the Court of Justice balanced the harm which might be done to the interests of the United Kingdom with respect to beef export markets against the interests of the other parties concerned. The Court gave particular attention to verifying whether, as the Commission claimed, 'there was in fact a grave hazard to animal and human health' (paragraphs 52 and 59). It observed

that the transmissibility to humans of a fatal disease 'had ceased to be a theoretical hypothesis' (paragraph 60). An animal disease — bovine spongiform encephalopathy — was now 'the most likely explanation' of the new variant of Creutzfeldt Jakob disease in humans (ibid.). 'The information which the Commission took into consideration when adopting [the decision in issue] was thus particularly serious' (paragraph 61). Ultimately, the interim measures sought were refused, inasmuch as the existence of a grave public health hazard was established on the basis of a valid scientific conclusion.

115 In the case of the contested regulation, the circumstances are different. It is agreed that there is no grave hazard to animal and human health. Concern about antibiotic resistance due to the use of virginiamycin is indeed a theoretical hypothesis. The information at the Commission's disposal is not 'particularly serious' in the case of virginiamycin.

116 If its operation is not suspended, moreover, the contested regulation will have the effect of imposing a definitive ban on virginiamycin, since the factory will cease to exist, with the consequent loss of its employees, technicians, sales staff, customers and farming users. By contrast, suspension of operation of the contested regulation will be a provisional measure. If the risks are not confirmed, then the product will still exist, and its continued presence on the market can be confirmed. If, on the other hand, the risks perceived are confirmed by the scientists as being a matter of real concern, the product can be banned after an objective and transparent review of the evidence.

117 The applicant claims, after weighing up all the evidence referred to, that the balance of convenience favours the mature completion of the relevant studies and the attainment, in transparent circumstances, of a balanced conclusion on the desirability of continuing to use virginiamycin. In other words, it favours suspension of operation of the contested regulation pending final judgment in the main proceedings or, as the case may be, until such time as the three principal

scientific inquiries (namely, the surveillance programme, the report of the Multidisciplinary Scientific Steering Committee on Antibiotic Resistance and the studies carried out under Directive 96/51) are completed and their findings analysed by the institutions.

118 According to the Council, the balance of interests militates in favour of the maintenance of the contested regulation, inasmuch as that interest is not readily comparable to the applicant's interest in having the regulation suspended (order of 12 July 1996 in *United Kingdom* v *Commission*, cited above, paragraph 90; order of the President of the Court of Justice of 24 September 1996 in Joined Cases C-239/96 R and C-240/96 R *United Kingdom* v *Commission* [1996] ECR I-4475). Even if it were acknowledged that there may be some damage to the applicant's commercial interests, that damage cannot outweigh the serious harm to public health which is liable to be caused by suspension of the contested decision, and which could not be remedied if the main action were subsequently dismissed (order of 12 July 1996 in *United Kingdom* v *Commission*, cited above, paragraph 92). Any possible damage to Pfizer's commercial interests cannot outweigh the potentially serious harm to public health which could be caused by permitting the routine use of virginiamycin as a growth promoter to continue.

119 The parties intervening in support of the form of order sought by the Council endorse those arguments.

Findings of the Court

Admissibility

120 In accordance with the second paragraph of Article 104(1) of the Rules of Procedure, an application for the adoption of interim measures is admissible only

if it is made by a party to a case before the Court of First Instance. That rule is not a mere formality; it presupposes that the main action which is accompanied by the application for interim measures is capable of being properly considered by the Court.

121 It is settled case-law that, in principle, the issue of the admissibility of the main action should not be examined in proceedings for interim relief, so as not to prejudge the Court's decision on the substance of the case. It may nevertheless appear necessary, when, as in this case, it is contended that the main application to which the application for interim measures relates is manifestly inadmissible, to establish whether there are any grounds for concluding prima facie that the main application is admissible (see, in particular, the orders of the President of the Court of Justice of 27 January 1988 in Case 376/87 R *Distrivet* v *Council* [1988] ECR 209, paragraph 21, and of 13 July 1988 in Case 160/88 R *Fédération Européenne de la Santé Animale and Others* v *Council* [1988] ECR 4121, paragraph 22; orders of the President of the Court of First Instance of 15 March 1995 in Case T-6/95 R *Cantine dei Colli Berici* v *Commission* [1995] ECR II-647, paragraph 26, and of 22 December 1995 in Case T-219/95 R *Danielsson and Others* v *Commission* [1995] ECR II-3051, paragraph 58; order of the President of the Fifth Chamber of the Court of First Instance of 28 April 1999 in Case T-11/99 R *Van Parys and Others* v *Commission* [1999] ECR II-1355, paragraph 50).

122 The fourth paragraph of Article 173 of the EC Treaty gives individuals the right to challenge any decision which, although in the form of a regulation, is of direct and individual concern to them. The particular purpose of that provision is to prevent the Community institutions from being able, simply by choosing to use the form of a regulation, to preclude an individual from bringing an action against a decision which concerns him directly and individually and thus to make it clear that the nature of a measure cannot be changed by the form chosen (see, in particular, Case T-47/95 *Terres Rouges and Others* v *Commission* [1997] ECR II-481, paragraph 39).

123 In the present case, the contested regulation withdraws four specified antibiotics from the list in Annex B to Directive 70/524 and prohibits their sale in all the Member States of the Community with effect, pursuant to Article 3, from 1 January 1999 or 1 July 1999. As is apparent from recital 27 in the preamble to the contested regulation, the reason for the withdrawal of authorisation for the

four antibiotics is the protection of human health; it is therefore aimed not only at the manufacturers of the products concerned but also at those using them and, more generally, at the entire population of the European Union. That regulation is therefore in the form of a measure having general application within the meaning of Article 189 of the EC Treaty (now Article 249 EC).

124 However, the fact that a provision is, by its nature and scope, of a legislative nature does not prevent it from being of individual concern to natural or legal persons if it 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 those factors, distinguishes them individually just as in the case of the addressee of a decision (Case C-309/89 *Codorniu* v *Council* [1994] ECR I-1853, paragraph 19, and order of 26 March 1999 in Case T-114/96 *Biscuiterie-Confiserie LOR and Confiserie du Tech* v *Commission* [1999] ECR II-913, paragraph 30).

125 It suffices in that regard to note, in the context of the present proceedings, that the applicant is in a special situation, since it is the sole manufacturer of virginiamycin in the world and is, in that capacity, scientifically and financially involved in the surveillance programme concerning microbial resistance in animals which have received antibiotics, which has been conducted under the auspices of the Commission since April 1998 and the reliability of which in terms of its results may be affected by the contested regulation.

126 Moreover, it is common ground that the contested regulation is of direct concern to the applicant.

127 Consequently, there are important factors prompting the Court to conclude that the contested regulation may be of direct and individual concern to the applicant and that the applicant may thus be entitled to seek its annulment under the fourth paragraph of Article 173 of the EC Treaty. Consequently, the present application for interim measures must be declared admissible.

The existence of *a prima facie case*

128 The parties disagree fundamentally as to the circumstances in which the competent authorities may, as a precautionary step, adopt a measure withdrawing authorisation in respect of an antibiotic the effect of which is to prohibit the sale of that product in the Community.

129 The applicant considers that, in the event of scientific uncertainty, the precautionary principle may be applied without having to await the results of the scientific research embarked upon, if there is a need for prompt action to counter an unacceptable risk to human health. It claims, however, that that condition is not fulfilled in the present case, since the risk to human health resulting from the use of virginiamycin as an additive in animal feed has not been established.

130 The Council, by contrast, maintains that the principal objective of the contested regulation, in withdrawing authorisation for four antibiotics, was to ensure the protection of human health against the actual and potential risks of increased antimicrobial resistance in human medicine resulting from the regular use of antibiotics, including virginiamycin, in the raising of animals. That measure must, it contends, be seen as a precautionary safeguard which can be reviewed in the light of the investigations and the surveillance programme. The Council, supported by the Commission and the intervening Member States, considers, in essence, that, where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent. In the present case, although the experts are unable to quantify the health risk, reports such as those of the WHO, the House of Lords Select Committee and the Health Council of the Netherlands, together with the Copenhagen recommendations on antimicrobial resistance, show that there is a risk of cross-resistance and recommend the prohibition of the antibiotics concerned as growth promoters.

131 It must be observed in that regard that, if the Court were in fact to find that the Council was mistaken in its interpretation of the criteria for the application of the precautionary principle, such a finding would constitute, in the circumstances of this case, a crucial factor for the purposes of assessing the extent of the risk to human health which may justify the withdrawal of authorisation in respect of virginiamycin as an additive in animal feed.

132 The very detailed arguments, supported by numerous annexes, which the applicant has advanced regarding this issue accordingly require very thorough examination, which cannot be undertaken in the context of these proceedings for interim relief.

133 It follows that the applicant's plea alleging, in essence, that the precautionary principle has been contravened cannot, prima facie, be regarded as wholly unfounded and justifies consideration by the Court of the other conditions for the grant of interim relief.

Urgency and the balancing of interests

134 It is settled case-law that the urgency of an application for interim measures must be assessed in relation to the necessity for an interim order to prevent serious and irreparable damage to the party applying for those measures. It is for the party seeking suspension of operation of an act to prove that it cannot wait for the outcome of the main proceedings without suffering damage that would entail serious and irreparable consequences (order in *Prayon-Rupel* v *Commission*, cited above, paragraph 36).

135 The damage pleaded by the applicant in the present case is composed, in essence, of two elements. The operation of the contested regulation will cause it harm, but will also cause harm to third parties and to the environment.

136 First, the serious and irreparable damage alleged, which suspension of operation of a contested act is intended to avoid, can be taken into account by the Court hearing an application for interim measures, in its consideration of the criterion of urgency, only in so far as it may be caused to the interests of the party seeking the interim relief. It follows that the damage, if any, which the operation of the contested act may cause to a party other than the party seeking the interim relief can be taken into consideration by the Court hearing the application for interim measures only when balancing the interests at stake. Consequently, the possible damage to third parties or the environment pleaded by the applicant is to be taken into account only when that factor is considered for the purposes of suspension of operation.

137 Second, it is necessary to examine the effects which the operation of the contested regulation will have on the Rixensart factory and on the position of the applicant. According to well-established case-law, damage of a purely pecuniary nature cannot, save in exceptional circumstances, be regarded as irreparable or even as being reparable only with difficulty, if it can ultimately be the subject of financial compensation (order of the President of the Court of Justice of 18 October 1991 in Case C-213/91 R *Abertal and Others* v *Commission* [1991] ECR I-5109, paragraph 24, and order of the President of the Court of First Instance of 7 November 1995 in Case T-168/95 R *Eridania and Others* v *Council* [1995] ECR II-2817, paragraph 42).

138 Under those principles, the suspension sought could be justified, in the circumstances of the present case, only if it appeared that, in the absence of such relief, the applicant would be placed in a situation which could endanger its very existence or irremediably affect its market share.

139 In order to determine whether the operation of the contested regulation is likely to endanger the applicant's existence, it is necessary to ascertain the effects which it may have, first, on the Rixensart factory, and second, on the applicant's financial viability.

140 The applicant claims that the reduction in the production of virginiamycin which the operation of the contested regulation will bring about, and the consequent reduction in sales of that product, will inevitably mean that the factory will rapidly have to close. It states in that regard that it will be compelled to cut its production immediately by over 50% and, as a result, to lay off employees.

141 In the circumstances of the present case, the Court does not consider, for the purposes of this application for interim measures, that it can conclude on the evidence before it that the entry into force of the contested regulation will inevitably result in the rapid closure of the plant.

142 Even assuming that the Rixensart factory cannot be used for the production of substances other than virginiamycin, as the applicant claims, the contested regulation only prohibits the sale of virginiamycin in the Community. Consequently, that product can continue to be manufactured for sale in markets outside the Community.

143 In that regard, the documents before the Court show that the Rixensart factory is the only one in the world producing virginiamycin and that that antibiotic is sold, under the name Stafac, not only in western Europe but also in north America, Latin America, Asia, central and eastern Europe and Africa.

144 According to the 1998 Annual Report of the Pfizer group, total sales of Stafac amounted to USD 82 million, of which sales in western Europe accounted for USD 24 million. Consequently, sales of virginiamycin in markets other than western Europe amounted to USD 58 million in 1998.

145 The applicant has further stated that 38% of current sales of virginiamycin take place in the 15 Member States of the European Union.

146 Consequently, the Court is unable to accept that the reduction in sales on account of the operation of the contested regulation, whether assessed in terms of volume or of value, will inevitably result in the rapid cessation of all production of virginiamycin. Moreover, even if the production costs of the Rixensart factory rise as a result of the applicant's inability to sell virginiamycin in the Community and thus lead to a fall in the profits made by the applicant on sales of that product, or even to a financial loss, such an assertion is not sufficient to establish the existence of an imminent risk of closure of the Rixensart factory.

147 The applicant also claims that the dismissal of staff employed at the Rixensart plant will inevitably result from the operation of the contested regulation, arguing that this will have an impact, in terms of employment, on its subcontractors. It states, in particular, that it has drawn up a plan for the dismissal of 31 persons employed at the Rixensart plant, and that the current climate of uncertainty is prompting white-collar staff to leave the factory.

148 The documents before the Court show that the Rixensart factory itself employs 173 persons, so that the reduction in employment to be undertaken concerns 18% of the staff directly employed in the plant.

149 However, a measure of that kind cannot lead to the closure of the Rixensart factory. Quite apart from the fact that it hardly seems likely that the applicant will be unable to bear the financial burden which would be involved in keeping 31 persons in employment pending judgment in the main action, it must be stated that those dismissals, were they to take place, would not suffice to establish that the applicant will inevitably lose its know-how and thus be compelled to discontinue all of its activities. First, the plant will continue directly to employ

142 persons, not too few to operate the factory in such a way as to enable it to continue manufacturing virginiamycin for sale in markets outside the Community. Second, Annex 10 to the application for interim measures, consisting of a statement by the acting personnel manager at the Rixensart factory, states that the proposed dismissals concern employees qualifying under an early retirement scheme and staff recruited on a temporary or probationary basis. Lastly, it cannot be maintained that the voluntary departures of skilled staff from the Rixensart factory result solely from the effects of the contested regulation, since it is still open to the applicant, by means of its social policy, to retain a workforce which it claims, moreover, has strong links with that factory.

150 Nor, moreover, can the effects which, according to the applicant, the reduction of activity at the Rixensart factory will have on its subcontractors be taken into account by the Court in proceedings for interim measures. Not only is such damage caused to third parties and must therefore be assessed in the context of the balancing of interests, but it has also not been shown that those subcontractors carry on their economic activities solely for the benefit of the Rixensart factory or that, even if they do, they will be unable to sell their services to other undertakings.

151 Nor has it been shown that the virginiamycin sales teams operating in various Member States will be unable to switch their activities to promoting sales of other products manufactured by the applicant, or even products manufactured by other companies in the Pfizer group.

152 It should also be observed that the profitability of the investments made or envisaged in the Rixensart factory is only partially affected by the contested regulation, since it will still be possible to sell virginiamycin outside the Community.

153 Next, as regards the question whether its inability to sell virginiamycin in the Community will affect the applicant's financial viability, it should be noted that, inasmuch as the ban on that product is limited to the Community, the applicant will still be able to sell virginiamycin outside the Community after 1 July 1999. Having regard to the results achieved in 1998 (see paragraph 144, above), the possibility remains that, in terms of sales of that product, it will be able to achieve 70% of the turnover recorded in that year.

154 At the hearing, the applicant produced graphs illustrating sales trends following the introduction of the ban on the marketing of virginiamycin in the Community, together with forecasts of the cost structure and financial results for the year 2000. Those documents show an appreciable fall in the projected value of sales, and predict a financial loss (USD 0.7 million) in the year 2000 with respect to virginiamycin.

155 However, for the purposes of assessing the economic circumstances of an applicant, consideration may be given, in particular, to the characteristics of the group of which, by virtue of its shareholding structure, it forms part (orders of the President of the Court of Justice of 7 March 1995 in Case C-12/95 P *Transacciones Marítimas and Others* v *Commission* [1995] ECR I-467, paragraph 12, and of 15 April 1998 in *Camar* v *Commission and Council*, cited above, paragraph 36; orders of the President of the Court of First Instance of 4 June 1996 in Case T-18/96 R *SCK and FNK* v *Commission* [1996] ECR II-407, paragraph 35, and of 10 December 1997 in *Camar* v *Commission and Council*, cited above, paragraph 50).

156 The 1998 Annual Report states that the turnover ('revenues') of the Animal Health Division of the Pfizer group amounted to USD 1 314 million. It shows that the value of sales of virginiamycin accounted for 6% of total sales of products in that area of activity. Commenting on the ban imposed by the contested regulation on Stafac in the Community, the 1998 Annual Report states: 'We do not expect any ban on sales of virginiamycin to have a material effect on future results of our operations.'

157 The financial data provided by the 1998 Annual Report also reveal that the value of the applicant's sales of Stafac in western Europe in 1998, amounting to USD 24 million, represents 0.2% of the net sales of the Pfizer group in that year, the value of which was USD 12 677 million.

158 Consequently, even though the proportion of the Pfizer group's total business represented by the activities of the applicant is not apparent from the case-file, the Court does not consider, on the basis of the evidence and case-law referred to above, that the financial harm which the applicant will suffer will prevent it from continuing to pursue its activities pending judgment in the main action.

159 As to the effect which that prohibition will have on market share, a distinction must be drawn between markets outside the Community and the Community market.

160 The applicant claims that its sales in countries which are not Member States of the Union will decrease as a result of the Community legislation. The Court considers that such an argument can only be validly relied on to establish urgency in ordering suspension of the contested act in so far as an order for suspension would be liable to prevent the alleged damage from materialising. As it is, the applicant has not in any way shown that the interim relief, if granted, would prevent the countries concerned from banning the sale of virginiamycin in their territory. Furthermore, in so far as the banning of virginiamycin in the Community has actually led to a reduction, or even a prohibition, of sales of that product in other countries, such damage is not a direct consequence of the contested regulation, resulting instead from decisions taken by the competent national authorities with a view to ensuring, in their absolute discretion, the protection of human health. In those circumstances, it is for the applicant to bring proceedings before the national courts for a review of the legality of the decisions which are causing it to sustain the commercial damage alleged. Consequently, the specific argument advanced by the applicant at the hearing, to the effect that the ban imposed by the regulation will have an impact in the United States, whose legislation prohibits the sale on its territory of products which may not be sold lawfully in the country where they are manufactured, cannot be accepted.

161 The applicant further claims that it is in danger of losing the market shares acquired by its product in the Community. However, those market shares cannot be regarded as irremediably compromised. Even if the share of the Community market held by virginiamycin is lost to competing products from 1 July 1999, there is nothing in the documents before the Court to justify the conclusion that it would be impossible for the product in issue to regain its previous position.

162 It should be noted in that regard, first, that the ban is not definitive in nature, since, according to Article 2 of the contested regulation, its provisions are to be re-examined before 31 December 2000 on the basis of the results of the various investigations concerning the development of resistance following the use of the antibiotics concerned and the surveillance programme concerning microbial resistance in animals which have received antibiotics.

163 Furthermore, the parties intervening in support of the applicant, namely Asovac and Anprogapor, Fedesa and Fefana, and Mr Kerckhove and Mr Lambert, have asserted that the qualities of virginiamycin are highly valued by those using it and that there exists no equivalent substitute product. This has been reflected, in commercial terms, by a constant increase in sales of the product in the Community. In addition, on the assumption that the contested regulation had not been adopted, the forecasts regarding sales of the product throughout the world, and thus within the Community, as set out in the document provided by the applicant at the hearing, pointed to a very considerable increase in the coming years. The sales figure for 1997 amounted to USD 94.6 million, whereas that forecast for 2001 amounted to USD 160.7 million.

164 In reply to a question at the hearing as to whether it would be impossible to win back the market shares lost in the Community to competitors in the event of the contested regulation being annulled by the Court, the President of the Animal Health Division of the Pfizer group in Europe, giving evidence on behalf of the

applicant, stated that it would not be impossible to win back those market shares, but that to do so would impose a very substantial financial burden.

165 Having regard to all the foregoing, it must be concluded that the applicant has not succeeded in showing that it would suffer serious and irreparable damage if operation of the contested regulation were not suspended.

166 In any event, even if the applicant succeeded in establishing beyond any doubt the existence of serious and irreparable damage, the Court would still be required, in the context of the present application, to weigh the interest of the applicant and of the parties intervening in its support in obtaining suspension of the ban on the sale of virginiamycin in the Community against the interest of the other parties in securing its continuance in force. The applicant asserts that, apart from economic and social considerations, the operation of the contested regulation will jeopardise the investigations which are currently being conducted under the auspices of the Commission in the context of the surveillance programme and that, consequently, it will no longer be able, at a later date, to rely on the results of the investigations in question in order to show that the use of virginiamycin as an additive in animal feed is harmless. The parties intervening in support of the form of order sought by the applicant also have an interest in suspension of the operation of the contested regulation, inasmuch as they are undertakings engaged in the rearing of livestock, national associations representing the animal health industry in Europe and manufacturers of animal health products, and national associations representing the animal nutrition additives industry and manufacturers of animal nutrition additives, and, generally, inasmuch as they plead protection of the environment.

167 In the context of its examination of an application for interim measures, the Court is required to determine whether the possible annulment of the contested act by the Court hearing the main action would allow the situation brought about by its immediate implementation to be reversed and, conversely, whether suspension of the operation of that act would be such as to prevent its being fully effective in the event of the main application being dismissed (see, in particular, the order of the President of the Court of Justice of 11 May 1989 in Joined Cases 76/89 R, 77/89 R and 91/89 R *RTE and Others* v *Commission* [1989] ECR 1141, paragraph 15, the order of 12 July 1996 in *United Kingdom* v

Commission, cited above, paragraph 89, and the order of the President of the Court of First Instance of 21 March 1997 in Case T-41/97 R *Antillean Rice Mills* v *Council* [1997] ECR II-447, paragraph 42).

168 In that regard, it should be noted, first of all, that the conduct of the surveillance programme in which the applicant is participating, and the results of which will be taken into account by the Commission in its re-examination, before 31 December 2000, of the provisions of the contested regulation pursuant to Article 2 thereof, is not jeopardised by the operation of that regulation. According to the written and oral explanations provided by the parties, it was initially envisaged that, in the context of that programme, a second set of samples of faeces would be taken from poultry and pigs at the end of 1999, two years after the first set of samples had been taken, in an environment which had remained unchanged during the period elapsing between the two. As it is, the environment in which the second set of samples is to be taken has been altered by the contested regulation, since virginiamycin will no longer be sold in the Community with effect from 1 July 1999. However, although the objectives of the surveillance programme cannot be attained on the basis of the parameters initially envisaged, the fact remains that an expert from the Commission stated, in reply to a question from the Court, that, notwithstanding the change of environment brought about by the entry into force of the contested regulation, the second set of samples will enable adequate results to be obtained in order to assess — albeit with difficulty, as pointed out by an expert witness called by the applicant — the development of resistance characteristics over time.

169 In any event, such a balancing of interests favours the maintenance of the contested regulation, inasmuch as the interest in having the contested regulation maintained is not readily comparable to the interest of the applicant, and of the parties supporting it, in having that regulation suspended.

170 Damage to commercial and social interests of the kind which the applicant and the parties supporting it would sustain 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.

171 In the light of that consideration, there can be no question but that the requirements of the protection of public health must take precedence over economic considerations (order of 12 July 1996 in *United Kingdom* v *Commission*, cited above, paragraph 93; judgment in *Affish*, cited above, paragraph 43; and order of 15 September 1998 in Case T-136/95 *Industria del Frio Auxiliar Conservera* v *Commission* [1998] ECR II-3301, paragraph 58).

172 In addition, it has been held that, where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent (judgments in *National Farmers' Union and Others*, cited above, paragraph 63, and *United Kingdom* v *Commission*, cited above, paragraph 99; judgment in *Bergaderm and Goupil* v *Commission*, cited above, paragraph 66).

173 In the present case, without in any way prejudging the assessment to be made by the Court concerning the pleas raised by the applicant in the main action, it must be observed that the stated objective of the withdrawal of authorisation in respect of virginiamycin is to combat the risks of increased antimicrobial resistance in human medicine resulting from the regular use of that antibiotic in the raising of animals. Consequently, that risk of increased antimicrobial resistance in human medicine is based on the assumption that bacteria resistant to virginiamycin in animals are transmissible to humans.

174 The documents before the Court substantiate that assumption.

175 Thus, in the report of the conference held in Berlin in October 1997 on 'The Medical Impact of the Use of Antimicrobials in Food Animals', the WHO stated (p. 1):

'Certain antimicrobials used for treatment or growth promotion in agriculture are also used for disease control in humans. Others select for cross-resistance in bacteria to antimicrobials used in human medicine. Microbiological and clinical evidence is mounting that resistant bacteria or resistance determinants might be passed from animals to humans, resulting in infections that are more difficult to treat. With an increase in the prevalence and distribution of antimicrobial-resistant infections in hospitals and the community, the question has been raised as to how this escalation of resistance could have been influenced by the use of antimicrobials in livestock production.

The magnitude of the medical and public health impact of antimicrobial use in food animal production is not known. Despite the uncertainty, however, there is enough evidence to cause concern. It is unrefuted that the use of antimicrobials leads to the selection of resistant bacteria and that the scope of the emerging problem depends, among other things, on duration of exposure to and concentration of the antimicrobial.'

176 That report further states (p. 6):

'Due to the limited number of agents available for the treatment of glycopeptide-resistant enterococci, antimicrobial agents not previously used in humans are

being sought, including drugs from classes currently used as growth promoters in animals. Therefore the selection of further resistance in enterococci is undesirable, e.g. streptogramin resistance due to use of virginiamycin as a feed additive in animals.'

177 In the same report, the WHO recommended that the use of any antimicrobial agent for growth promotion in animals should be terminated if it is used in human therapeutics or known to select for cross-resistance to antimicrobials used in human medicine.

178 A study annexed to the application of Fedesa and Fefana for leave to intervene ('Report concerning the use of antibiotics as growth factors in animal feeds', by Georges Bories and Professor P. Louisot), which was circulated to all the parties at the hearing, states as follows (p. 16):

'There is no strict barrier between man and farm animals, firstly for those who work in contact with farm animals, in slaughterhouses and in the meat industry, and subsequently for consumers of animal products. Exchanges have been observed involving both bacteria and genes, especially resistance genes.

... However, recent studies demonstrating the simultaneous presence, in the same bacterial strain isolated in man, of genetic material (DNA fragments) from commensal bacteria characteristic of pigs and chickens, indicate that enterococci, including *Enterococcus faecium*, are ubiquitous.'

179 Finally, at the hearing, one of the expert witnesses called by the applicant stated that the possibility of bacteria which have become resistant to virginiamycin transmitting their resistance characteristics to humans could not be ruled out.

180 In those circumstances, since it is not impossible, according to the sources quoted, that bacteria which have become resistant due to the feeding to livestock of antibiotic additives such as virginiamycin may be transmissible from animals to humans, the risk of increased antimicrobial resistance in human medicine on account of the use of virginiamycin in animal feed cannot be ruled out. If increased antimicrobial resistance in human medicine were to occur, the potential consequences for public health would be very serious, since, if they developed resistance, certain bacteria could no longer be effectively combated by medicines used in the treatment of humans which are still effective at present, in particular the streptogramin family of antibiotics, which includes virginiamycin.

181 In those circumstances, without prejudging the examination by the Court 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 is enough in itself to justify taking into account, in the balancing of interests, the protection of human health. Consequently, the applicant cannot found an argument on the differences between the present case and that which gave rise to the order of 12 July 1996 in *United Kingdom* v *Commission*, since the fact that the fatal nature of the disease transmissible to humans and the grave hazard to human health were taken into account in that case does not mean that measures cannot be adopted by the Community institutions in the absence of any serious factor of that kind.

182 It follows, in the light of all the foregoing, that the conditions for ordering suspension of operation of the contested regulation are not satisfied in the present case. This application must therefore be dismissed.

On those grounds,

THE PRESIDENT OF THE COURT OF FIRST INSTANCE

hereby orders:

1. **The application for interim measures is dismissed.**

2. **The costs are reserved.**

Luxembourg, 30 June 1999.

H. Jung

Registrar

B. Vesterdorf

President