JUDGMENT OF THE COURT OF FIRST INSTANCE (Third Chamber)
11 September 2002 *

In Case T-13/99,

Pfizer Animal Health SA, established in Louvain-la-Neuve (Belgium), represented by I.S. Forrester QC, M. Powell, Solicitor, E. Wright, Barrister, and W. van Lembergen, lawyer, instructed by S.J. Gale-Batten, Solicitor, with an address for service in Luxembourg,

applicant,

supported by

Asociación nacional de productores de ganado porcino (Anprogapor), having its registered office in Madrid (Spain),

and

Asociación española de criadores de vacuno de carne (Asovac), having its registered office in Barcelona (Spain),

* Language of the case: English.

represented by J. Folguera Crespo, A. Gutiérrez Hernández, J. Massaguer Fuentes and E. Navarro Varona, lawyers, with an address for service in Luxembourg,

and by

Fédération européenne de la santé animale (Fedesa), having its registered office in Brussels (Belgium),

and

Fédération européenne des fabricants d'adjuvants pour la nutrition animale (Fefana), having its registered office in Brussels (Belgium),

represented by D. Waelbroeck and D. Brinckman, lawyers, with an address for service in Luxembourg,

interveners,

v

Council of the European Union, represented by J. Carbery, M. Sims and F.P. Ruggeri Laderchi, acting as Agents,

defendant,

supported by

Commission of the European Communities, represented by P. Oliver, T. Christoforou and K. Fitch, acting as Agents, with an address for service in Luxembourg,

by

Kingdom of Denmark, represented by J. Molde, acting as Agent, N. Holst-Christensen and S. Ryom, with an address for service in Luxembourg,

by

Kingdom of Sweden, represented by A. Kruse and L. Nordling, acting as Agents, with an address for service in Luxembourg,

by

Republic of Finland, represented by H. Rotkirch, T. Pynnä and E. Bygglin, acting as Agents, with an address for service in Luxembourg,

and by

United Kingdom of Great Britain and Northern Ireland, represented by R. Magrill, acting as Agent, with M. Hoskins, Barrister, with an address for service in Luxembourg,

interveners,

APPLICATION for annulment of Council Regulation (EC) No 2821/98 of 17 December 1998 amending, as regards withdrawal of the authorisation of certain antibiotics, Directive 70/524/EEC concerning additives in feedingstuffs (OJ 1998 L 351, p. 4),

THE COURT OF FIRST INSTANCE
OF THE EUROPEAN COMMUNITIES (Third Chamber),

composed of: J. Azizi, President, K. Lenaerts and M. Jaeger, Judges,
Registrar: F. Erlbacher, Legal Secretary,

having regard to the written procedure and further to the hearing on 2 July 2001,

gives the following

Judgment

Legal framework

I — *The Act of Accession*

1 Article 151(1) of 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, 'the Act of Accession') provides as follows:

'The acts listed in Annex XV to this Act shall apply in respect of the new Member States under the conditions laid down in that Annex.'

2 Under Annex XV, Title VII, point E1(4) of the Act of Accession, the Kingdom of Sweden may maintain in force until 31 December 1998 its pre-accession legislation with regard to the restriction on, or prohibition of, the use in feedingstuffs of additives belonging to the group of antibiotics. Before that date, 'a decision shall be taken in accordance with the procedure laid down in Article 7 of Directive 70/524/EEC on requests for adaptation presented by the Kingdom of Sweden; those requests shall be accompanied by a detailed scientific statement of reasons.'

II — *The Community rules on additives in feedingstuffs*

A — *General description*

3 On 23 November 1970 the Council adopted Directive 70/524/EEC concerning additives in feedingstuffs (OJ, English Special Edition 1970 (III), p. 840). This Directive laid down the Community rules applying to the authorisation, and withdrawal of authorisation, of additives for incorporation in feedingstuffs.

4 Directive 70/524 has been amended and supplemented on several occasions. In particular, it was heavily amended by Council Directive 84/587/EEC of 29 November 1984 (OJ 1984 L 319, p. 13) and by Council Directive 96/51/EC of 23 July 1996 (OJ 1996 L 235, p. 39). It was supplemented *inter alia* by the decisions cited at paragraphs 24 to 26 and 28 below.

5 Directive 96/51 introduced new rules for authorisation, and withdrawal of authorisation, of additives in feedingstuffs ('the new rules') in place of the rules which had applied until then ('the original rules').

6 To bring about the transition from the original rules to the new rules, which took effect on 1 October 1999, Directive 96/51 introduced a number of rules applicable from 1 April 1998 to certain additives authorised under the original rules, including antibiotics ('the transitional rules'). For this purpose, Article 2(1)(a) of Directive 96/51 provided that the Member States were to bring into force the laws, regulations and administrative provisions necessary to comply with certain provisions of the directive by 1 April 1998.

B — *Definition of additives in feedingstuffs*

7 Under the original rules additives were defined in Article 2 of Directive 70/524, as amended by Directive 84/587, as 'substances... which, when incorporated in feedingstuffs, are likely to affect their characteristics or livestock production'.

8 According to recital 3 of the preamble to Directive 96/51, it was considered necessary, under the new rules, to draw a distinction between 'additives which are widely used and present no particular dangers for the manufacture of feedingstuffs' and 'high technology additives with a very specific composition for which the person responsible for putting them into circulation must receive authorisation, in order to avoid copies which might not be in conformity and

might therefore be unsafe'. Effect is given to that distinction by Article 2 of Directive 70/524, as amended by Article 1(3)(i) of Directive 96/51. Article 2, as amended, contains the following definitions:

'(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.'

9 It is apparent from Annex C to Directive 70/524, as inserted by Article 1(20) of Directive 96/51, that all additives belonging to the group of antibiotics or the group of growth promoters fall within the class of additives covered by Article 2(aaa) and are therefore subject to authorisation linked to the person responsible for putting them into circulation.

C — *The rules on authorisation and withdrawal of authorisation of antibiotics used as additives in feedingstuffs*

1. The rules on authorisation of additives

10 Under the original rules, Article 3(1) of Directive 70/524, which was repealed by Directive 96/51, provided that 'Member States shall provide that, as regards feedingstuffs, only those additives listed in Annex I which comply with this Directive may be marketed and that they may be incorporated in feedingstuffs only subject to the requirements set out in that Annex...'. However, under Article 4(1)(a) of Directive 70/524, repealed by Directive 96/51, the Member States could, by way of derogation from Article 3(1) and subject to certain conditions set out in Directive 70/524, authorise the marketing and use, within their own territory, of additives listed in Annex II to that Directive.

11 Under the new rules (Article 3 of Directive 70/524 as amended by Directive 96/51), only additives which have a Community authorisation granted under a Commission regulation may be put into circulation. Under the new Article 3a of Directive 70/524, authorisation of an additive is given *inter alia* if:

'...

(e) for serious reasons concerning human or animal health its use must not be restricted to medical or veterinary purposes.'

12 Article 4 of Directive 70/524, as amended by Directive 96/51, lays down the procedure for obtaining Community authorisation of an additive under both the new rules and the transitional rules.

13 Article 9 of Directive 70/524, as amended by Directive 96/51, provides that '[a]dditives as referred to in Article 2(aaa) which meet the conditions laid down in Article 3a shall be authorised and included in Chapter I of the list referred to in Article 9t(b)'. Chapter I includes additives whose authorisation is linked to a person responsible for putting them into circulation and is granted for a period of 10 years. Under the new Article 9b, authorisation is to be renewable for 10-year periods.

14 Furthermore, Article 2(k) of Directive 70/524, as amended by Directive 96/51, defines 'putting into circulation' and 'circulation' as: 'the holding of products for the purposes of sale, including offering for sale, or any other form of transfer, whether free or not, to third parties, and the sale and other forms of transfer themselves'.

15 Article 2(1) of Directive 70/524, as amended by Directive 96/51, defines 'person responsible for putting into circulation' as: 'the natural or legal person who has responsibility for the conformity of the additive which has been granted Community authorisation and for putting it into circulation'.

16 Under the new Article 9c(1) of Directive 70/524, 'the scientific data and other information in the initial dossier submitted for the purpose of the first authorisation may not be used for the benefit of other applicants for a period of 10 years'. The reasons for that restriction are given as follows in recital 14 of the preamble to Directive 96/51:

'[w]hereas the search for new additives [referred to in Article 2(aaa)] requires costly investment; whereas protection for a period fixed at 10 years should therefore be afforded to scientific data or information included in the dossier on the basis of which the first authorisation is granted'.

2. The withdrawal of authorisation of an additive

17 The procedure for withdrawing the authorisation of an additive is the same under the new rules as under the old ones and is laid down in Article 23 of Directive 70/524. However, under Article 11 of Directive 70/524, Member States may take safeguard measures in respect of an additive. In that case, the procedure for withdrawing the authorisation of an additive affected by such a safeguard measure is laid down in Article 24 of Directive 70/524.

18 Article 11 of Directive 70/524, as amended by Article 1(1) of Directive 84/587 and Article 1(7) of Directive 96/51, provides that:

'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 animal or human health or the environment, it shall initiate the procedure laid down in Article 24 with a view to adopting these amendments; the Member State which has adopted safeguard measures may in that event retain them until the amendments enter into force.'

19 Article 24 of Directive 70/524, as inserted by Article 1(1) of Directive 84/587 and most recently amended by Annex I to the Act of Accession, provides as follows;.

'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 [(now Article 205(2) EC)] 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.'

3. The transitional rules

20 For additives such as antibiotics, which were authorised under the original rules and whose authorisation Directive 96/51 thereafter linked to the person

responsible for putting them into circulation, Articles 9g, 9h and 9i of Directive 70/524, introduced by Directive 96/51, provide for a transitional period during which those additives remain provisionally authorised but must be the subject of a new authorisation under the new rules.

21 Article 9g of Directive 70/524 provides that:

'1. Additives as referred to in Article 2(aaaa) 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 authorisation; 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.

3. In accordance with the procedure laid down in Article 23, provisional authorisation of the additives shall be withdrawn through the adoption of a Regulation and they shall be deleted from the list in Chapter I of Annex B before 1 October 1999:

(a) if the documents prescribed in paragraph 2 are not submitted within the time allowed

or

(b) if, after scrutiny of the documents, it is established that the monographs and identification notes are not in accordance with the data in the dossier on the basis of which the original authorisation was given.

4. Member States shall ensure that the person responsible for putting an additive as referred to in paragraph 1 into circulation submits, as provided for in Article 4 and not later than 30 September 2000, the dossier referred to in Article 4 with a view to re-evaluation. Where he fails to do so, the authorisation of the additive in question shall be withdrawn through the adoption of a regulation in accordance with the procedure laid down in Article 23 and it shall be deleted from the list in Chapter I of Annex B.

5. The Commission shall take all necessary measures to ensure that re-evaluation of the dossiers referred to in paragraph 4 is completed no later than three years after the dossier is submitted.

In accordance with the procedure laid down in Article 23, authorisations of the additives referred to in Article 1:

(a) shall be withdrawn and they shall be deleted from the list in Chapter I of Annex B through the adoption of a regulation,

or

(b) shall be replaced by authorisations linked to the person responsible for putting them into circulation for a period of 10 years through the adoption of a regulation taking effect no later than 1 October 2003 and included in Chapter I of the list referred to in Article 9t(b).

...'

22 Article 9h contains provisions similar to those of Article 9g for additives included in Annex I to Directive 70/524 after 31 December 1987. These products are to be transferred to Chapter II of Annex B to the Directive, as amended by Directive 96/51. However, unlike the additives transferred to Chapter I of Annex B pursuant to Article 9g, which are subject to re-evaluation and in respect of which authorisation linked to the person responsible for putting them into circulation may be granted no later than 1 October 2003, the additives included in Chapter II of Annex B to Directive 96/51 pursuant to Article 9h must be authorised — or, where appropriate, prohibited — no later than 1 October 1999, without prior re-evaluation. Where authorisation is given, those additives are included for a period of 10 years in Chapter I of the list referred to in Article 9t(b), which was mentioned above.

23 For additives included in Annex II to Directive 70/524 before 1 April 1998, Article 9i contains provisions similar to those of Article 9h. Those additives are to be transferred to Chapter III of Annex B to the Directive, as amended by Directive 96/51. The period of provisional authorisation of those additives may not, however, exceed five years, account being taken of the period of inclusion in Annex II.

D — *The 'Standing Committee', the Scientific Committee for Animal Nutrition and the Scientific Steering Committee*

24 The Standing Committee for Feedingstuffs ('the Standing Committee'), which is referred to in Article 24 of Directive 70/524 cited at paragraph 19 above, 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.

25 By Decision 76/791/EEC of 24 September 1976 establishing a Scientific Committee for Animal Nutrition (OJ 1976 L 279, p. 35), replaced 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), the Commission appointed a Scientific Committee for Animal Nutrition ('SCAN'). Article 2(1) and (3) of Decision 97/579 provides as follows:

'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....'

26 The Annex to Decision 97/579 defines the field of competence of SCAN as '[s]cientific 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'.

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

'The Scientific Committee for Animal Nutrition established by [Decision 76/791] 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.'

28 Finally, by Decision 97/404/EC of 10 June 1997 establishing a Scientific Steering Committee (OJ 1997 L 169, p. 85; 'the SSC'), the Commission appointed such a Committee.

Background to the proceedings

Scientific background to the case as at the time when the contested regulation, Regulation (EC) No 2821/98, was adopted

29 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). Antibiotics, which may be

grouped into several classes, are used both in humans and animals to treat various bacterial infections and to prevent such infections.

30 Certain antibiotics, including virginiamycin, are also used as additives in feedingstuffs as growth promoters for animals. They are added in very low concentrations to the feedingstuffs of growing poultry, pigs and calves. This results in improved growth and improved weight gain, so that an animal needs less time and less food to attain its required weight for slaughter. The practice is also said to have beneficial side effects, in particular the prevention of diseases in animals and reduced production of waste in livestock-farming.

31 Certain bacteria are naturally resistant to certain antibiotics. Nevertheless, in humans and in animals bacteria which are, as a general rule, sensitive to certain antibiotics may develop the capacity to resist those antibiotics. The development of resistance of that kind enables a bacterium to live in the presence of an antibiotic which would, in normal circumstances, kill it or prevent its reproduction. Where a bacterium has developed resistance to an antibiotic, treatment of the patient concerned with that antibiotic becomes totally or partly ineffective. In addition, a bacterium resistant to one member of a class of antibiotics may also become resistant to other antibiotics of the same class. This process is called 'cross-resistance'.

32 The phenomenon of resistance to antibiotics in humans was discovered shortly after the first antibiotics were developed. However, generally speaking, resistance to antibiotics in humans has increased in recent years. At the same time, although the pharmaceutical industry continues to research and develop new products,

there has been a relative decline in the development and marketing of effective new antimicrobial chemotherapeutic agents designed to combat certain pathogens.

33 The recommendations made in the report on a European-Union conference held in Copenhagen in September 1998 on the subject of the microbial threat ('the Copenhagen Recommendations') state that 'resistance to antimicrobial agents is a major public health problem in Europe'. Antibiotic resistance in humans can result in a substantial rise in the number of complications in the treatment of certain diseases and even an increased mortality risk arising from those diseases.

34 The reasons for the development of resistance to antibiotics in humans have not yet been entirely clarified. It appears from the documents before the Court that there is a broad consensus among experts that this phenomenon is primarily caused by the excessive and inappropriate use of antibiotics in human medicine.

35 Nevertheless, the existence of a link between the use of antibiotics as growth promoters in animals and the development of resistance to those products in humans is, to a large extent, recognised by the scientific community. It is presumed that the antibiotic resistance which has developed in animals can be transferred to humans.

36 The possibility and the probability of such transfer and the risk which it may entail for public health continue to give rise to argument in scientific circles (see the parties' submissions on this point, particularly in connection with the plea concerning breach of the precautionary principle). However, on the basis of the available results of research, numerous international, Community and national bodies adopted various recommendations on the subject over the years preceding

the adoption of Council Regulation (EC) No 2821/98 of 17 December 1998 amending, as regards withdrawal of the authorisation of certain antibiotics, Directive 70/524 (OJ 1998 L 351, p. 4; 'the contested regulation'). (See in that regard the report of a World Health Organisation Meeting ('WHO') in Berlin in October 1997, 'The Medical Impact of the Use of Antimicrobials in Food Animals', ('the WHO report'); the Resolution of the European Parliament of 15 May 1998 on the use of antibiotics in feedingstuffs (OJ 1998 C 167, p. 306); the Opinion of the Economic and Social Committee of 9 September 1998 on the subject: 'Resistance to antibiotics: a threat to public health' (OJ 1998 C 407, p. 7); the Copenhagen Recommendations; the House of Lords Science and Technology Committee (United Kingdom), Seventh Report, March 1998, 'the House of Lords report'; the document from the Centre for Science in the Public Interest (Washington D.C., United States of America) entitled 'Protecting the Crown Jewels of Medicine', May 1998; the document from the United Kingdom Ministry of Agriculture, Fisheries and Food, 'A Review of Antimicrobial Resistance on the Food Chain', July 1998, 'the United Kingdom report'; the document from the Health Council of the Netherlands, 'Antimicrobial Growth Promoters', August 1998, 'the Netherlands report'.)

37 In particular, the abovementioned bodies have almost unanimously recommended increasing research efforts in this field. For example, in 1997 the Commission, jointly with the Member States and the pharmaceutical industry, set up a research programme ('Surveillance Programme'), the first results of which were to be published in 2000. In addition, some of those bodies recommend the systematic replacement of all antibiotics used as growth promoters by safer alternatives. Furthermore, several bodies, including the WHO, have recommended the immediate or gradual discontinuance of the use of antibiotics as growth promoters in animals. Some of the abovementioned reports suggest prohibiting the practice, first, where the antibiotics concerned are used in human medicine or their use in humans is envisaged and, second, where they are known to 'select' cross-resistance to antibiotics used as medicinal products for humans.

38 Virginiamycin is an antibiotic belonging to the streptogramin class. It has been used exclusively as a growth promoter for animals for more than 30 years. A certain level of resistance to virginiamycin has been observed in animals which have been treated with that product.

39 Other antibiotics belonging to the same class are used in human medicine, namely pristinamycin, used for 30 years in certain Member States, particularly France, and Synercid, which is a mixture of the antibiotics dalfopristin and quinupristin and has recently been developed and authorised in the United States but which, at the date of adoption of the contested regulation, had not yet been authorised in the Community.

40 Although at present dalfropristin and quinupristin are relatively little used in human medicine, they could play an important part in the Community in the treatment of infections caused in patients by bacteria which have developed resistance to other antibiotics, namely the bacteria *Enterococcus faecium* ('*E. faecium*') and *Staphylococcus aureus*. These bacteria may cause dangerous infections, particularly in hospital patients who already have a deficient immune system. Hitherto patients infected by these bacteria have been treated with an antibiotic belonging to another class, vancomycin. However, it has been found that these bacteria are becoming increasingly resistant to vancomycin. Experts refer to 'vancomycin-resistant *E. faecium*' (VRE) and 'methicillin-resistant *Staphylococcus aureus*' (MRSA), which has also become resistant to vancomycin ('vancomycin-resistant MRSA'). In those circumstances, the administration of streptogramins, particularly Synercid, could be the treatment of last resort against infections caused by those bacteria, at least until other antibiotics capable of combating those infections have been developed and placed on the market. However, the effectiveness of such treatment could be reduced or even eliminated by any transfer of resistance to virginiamycin from animals to humans and by the development of cross-resistance in humans to the other members of the streptogramin class.

41 It is common ground between the parties and is apparent from the preamble to the contested regulation that, at the time when the measure was adopted, the transfer and development of such resistance had not yet been scientifically established in respect of streptogramins.

The procedure leading to the adoption of the contested regulation

42 When the contested regulation was adopted, Pfizer Animal Health SA ('Pfizer') was the only producer in the world of virginiamycin, which was made in its factory in Rixensart, Belgium. The product was marketed under the trade name 'Stafac'.

43 Virginiamycin was authorised as an additive in feedingstuffs for certain poultry and pigs when Directive 70/524 entered into force and was included in Annex I to that Directive. That authorisation was subsequently extended to other animals. In certain cases the authorisation was without limitation as to time, while in others it was for a specific period. After Directive 96/51 entered into force, and for the purpose of granting a further authorisation under the new rules, the various authorisations of virginiamycin were transferred to Chapter I, II or III of Annex B to Directive 70/524 in accordance with Articles 9g, 9h and 9i of that directive.

44 In reliance on the safeguard clause provided for in Article 11 of Directive 70/524, the Kingdom of Denmark, by letters of 13 January 1998, informed the Commission and the competent authorities of the Member States of the European Economic Area ('EEA') of its decision to ban the use in its territory

of virginiamycin in feedingstuffs with effect from 16 January 1998. In doing so, it relied on a report from the National Veterinary Laboratory dated 7 January 1998 ('the Status Report'), which contains the following conclusions:

'It is strongly indicated that the use of virginiamycin as a growth promoter for pigs and broilers selects for virginiamycin-resistant *E. faecium* (selection). Virginiamycin-resistant *E. faecium* are simultaneously resistant to other streptogramins, such as pristinamycin and Synercid, potentially useful for treatment of human enterococcal infections (cross-resistance). In some of the virginiamycin-resistant *E. faecium* from animals, the *sat A* gene which confers streptogramin resistance was detected. This gene has also been found to occur in streptogramin-resistant *E. faecium* causing infection in human hospital patients in France. It is very probable that virginiamycin-resistant *E. faecium* can be transmitted from animals to human beings, and furthermore, it cannot be excluded that the *sat A* gene may be transferred from *E. faecium* animals to *E. faecium* in humans.

At present streptogramins are not in use for treatment of human infections in Denmark. Therefore an acute threat to public health does not exist. However, it cannot be ruled out that streptogramins will be used for treating human infections in the future. If that happens, the use of virginiamycin as a growth promoter will increase that risk of adverse resistance development.'

45 On 22 January 1998 the Kingdom of Belgium, the Member State acting as rapporteur for the purposes of Article 4 of Directive 70/524 on the dossier concerning virginiamycin, forwarded the Status Report to Pfizer and requested it to submit its observations.

46 On 2 February 1998 the Kingdom of Sweden, with a view to a decision being taken by 31 December 1998 and in accordance with Annex XV to the Act of Accession (see paragraph 2 above), submitted a request for the adaptation of Directive 70/524, together with a detailed scientific statement of reasons, seeking withdrawal of the authorisation, *inter alia*, of antibiotics used as growth promoters, including virginiamycin ('the Swedish report').

47 On 25 February 1998 the Kingdom of Denmark wrote to the Commission and the other Member States to notify them that at a later date it would send them a supplementary scientific report setting out its reasons for applying the safeguard clause in relation to virginiamycin.

48 On 12 and 13 March 1998 the Danish authorities sent the Commission and the Member States of the EEA two new scientific publications concerning the transfer of antimicrobial resistance from animals to humans.

49 On 16 and 23 March 1998 discussions took place between Pfizer and Commission officers dealing with the matter.

50 On 31 March 1998 Pfizer submitted its observations on the Status Report, together with scientific reports and literature, to the Commission, the Member States and the members of SCAN. In its observations Pfizer submits that examination of the reports and scientific literature annexed to them shows that scientific knowledge relating to the possible transfer of resistance to virgin-

iamycin from animals to human beings is either totally absent or inadequate. It concludes:

'The issue of antibiotic resistance is without question an important public health issue. It is also clear that the current body of scientific data — including the Danish studies — do not provide the scientific evidence necessary to conduct a detailed evaluation of any potential risk associated with the use of virginiamycin as a feed additive antibiotic. Aside from the methodological weakness or preliminary nature of the studies cited in the Status Report, new and relevant streptogramin susceptibility surveillance data from human clinical isolates stand in direct contradistinction to the risks hypothesised.'

51 On 1 April 1998 the Kingdom of Denmark sent the Commission and SCAN the supplementary report of the National Veterinary Laboratory, as it had said it would in the letter of 25 February 1998 ('the supplementary report from the Danish Veterinary Laboratory'). The report sets out the results of scientific research by the National Veterinary Laboratory, which are based on 10 conclusions and led the Danish authorities to adopt the safeguard measure.

52 On 13 May 1998 Pfizer submitted its observations on the Supplementary Report from the Danish Veterinary Laboratory to the Commission, the EEA Member States and the members of SCAN.

53 On 10 July 1998 SCAN published, at the Commission's request, a scientific opinion on the immediate and longer-term risk to the value of streptogramins in human medicine posed by the use of virginiamycin as an animal growth promoter ('the SCAN opinion'). In that opinion, SCAN analysed the conclusions in the

Supplementary Report from the Danish Veterinary Laboratory and added a comment in respect of each of those conclusions. Lastly, SCAN drew the following general conclusions:

'I. Having considered the evidence provided by the Danish Government in support of their action taken under the safeguard clause against virginiamycin, the SCAN concludes that:

1. No new evidence has been provided to substantiate the transfer of a streptogramin or vancomycin resistance from organisms of animal origin to those resident in the human digestive tract and so compromise the future use of therapeutics in human medicine.

2. The development of vancomycin resistance amongst *E. faecium* and methicillin-resistant strains of *Staphylococcus aureus*, which the SCAN recognises are increasingly responsible for nosocomial infections worldwide, are evidently a cause for concern. However, the data provided in the supplementary report from the Danish Veterinary Laboratory do not justify the immediate action taken by Denmark to preserve streptogramins as therapeutic agents of last resort in humans.

3. As survey data provided under the aegis of DANMAP and included in the supplementary report from the Danish Veterinary Laboratory failed to detect a single case of VRE, as Denmark has amongst the lowest incidence of MRSA in Europe and North America, and as coagulase-negative staphylococci

remain sensitive to vancomycin, there are no clinical reasons to require the introduction of streptogramins as human therapeutics in Denmark now or in the immediate future. Furthermore, as the Commission has elected to take the precautionary action of removing avoparcin from the antibiotics permitted for use as growth promoters to help preserve the efficacy of vancomycin in human therapy, any future need for streptogramins might be delayed further in Denmark.

For these reasons the SCAN concludes that the use of virginiamycin as a growth promoter does not constitute an immediate risk to public health in Denmark.

II. The SCAN is sympathetic to the general concern highlighted by the Danish action about the hazard that a reservoir of resistance genes within the animal population poses for humans. However, it is of the opinion that a full risk assessment cannot be made until quantitative evidence of the extent of transfer of antimicrobial resistance from livestock sources is obtained and the significance of this within the overall use of antimicrobials for clinical and non-clinical purposes evaluated. The SCAN is also of the opinion that this is best approached by considering the totality of antimicrobial use within the countries of the European Union rather than on a case by case basis. The Scientific Steering Committee has established a multidisciplinary working group with this remit.

The SCAN also notes that in countries that permit the use of streptogramins in both animal production and human medicine, notably France and the USA, the use of pristinamycin has not been compromised by the use of virginiamycin as growth promoter.

The SCAN is therefore firmly of the opinion that any risk that might be posed in the future by the use of virginiamycin as a growth promoter will not materialise in the time required to make such an evaluation and most probably not for some years afterwards. In the meantime monitoring initiated by the Danish Government and the EU will be able to detect any significant increases in glycopeptide and streptogramin resistance in enterococci and staphylococci should that occur.'

54 At the Standing Committee meeting of 16 and 17 July 1998, the Danish member of the Committee informed the other members that a new scientific study of live laboratory rats, carried out in Denmark after the adoption of the safeguard measure (B. Jacobsen and others, 'In vivo Transfer of the *Sat A* gene between isogenic strains of *Enterococcus faecium* in the Mammalian Gastrointestinal Tract': 'the new study on live rats') provided new relevant evidence that resistance to streptogramins could be transferred from animals to humans under normal conditions. A copy of it was distributed informally to all members of the Standing Committee. At the request of the Commission, on 27 August 1998 Denmark sent the study to Pfizer, the Commission and the EEA Member States.

55 On 15 September 1998 Pfizer, pursuant to Articles 9g(2) and 9h(2) of Directive 70/524, lodged new applications for the authorisation of virginiamycin as an additive linked to a person responsible for putting it into circulation.

56 On 5 October 1998 the Kingdom of Denmark sent Pfizer, the Commission, the EEA Member States and the members of SCAN its observations on the SCAN Opinion. Denmark requested the Commission and SCAN to re-examine the question posed in the light of the new study on live rats.

57 At the plenary session of 5 November 1998, SCAN made the following statement concerning the new study on live rats, which appears in the minutes of the meeting as approved at the meeting of 25 January 1999:

'The Committee considered the document submitted by Denmark on virginiamycin and stated that it does not bring new information on the subject.'

58 On 10 November 1998 a meeting took place between Pfizer and members of the cabinet of Mr Fischler, the Member of the Commission responsible for agriculture.

The contested regulation

59 On 17 December 1998 the Council adopted the contested regulation, which was published in the *Official Journal of the European Communities* on 29 December 1998. 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.

...'.

Procedure

60 By application lodged at the Registry of the Court of First Instance on 18 January 1999, Pfizer brought the present action.

61 By separate document lodged at the Court Registry on 10 March 1999, the Council raised an objection of inadmissibility pursuant to Article 114(1) of the Rules of Procedure. By order of 7 March 2000, the Court (Third Chamber) reserved its decision on the objection of inadmissibility for the final judgment

pursuant to Article 114(4) of the Rules of Procedure. In addition, by way of measures of organisation of procedure, the Court, on 13 March 2000, sent a number of written questions to the parties, who replied within the period allowed.

62 By separate document lodged at the Court Registry 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 might require. By order of 30 June 1999 in Case T-13/99 R *Pfizer Animal Health* v *Council* [1999] ECR II-1961, the President of the Court of First Instance dismissed the application for interim relief. Pfizer appealed against that order and its appeal was dismissed by order of the President of the Court of Justice of 18 November 1999 (Case C-329/99 P(R) *Pfizer Animal Health* v *Council* [1999] ECR I-8343).

63 Upon application by them, the President of the Third Chamber, by order of 25 June 1999, granted the following parties leave to intervene in support of Pfizer: Asociación nacional de productores de ganado porcino ('Anprogapor'), Asociación española de criadores de vacuno de carne ('Asovac'), Fédération européenne de la santé animale ('Fedesa'), Fédération européenne des fabricants d'adjuvants pour la nutrition animale ('Fefana'), and Mr Kerckhove and Mr Lambert. By the same order, the President dismissed the applications to intervene submitted by the Asociación española de productores de huevos and The Pig Veterinary Society. As a result of the withdrawal of Mr Kerckhove and Mr Lambert as interveners, the President of the Third Chamber removed their names from the list of interveners by order of 26 September 2000.

64 The interveners supporting Pfizer lodged their written observations, initially limited to the admissibility of the action, on 6 September 1999 (Anprogapor and Asovac) and 7 September 1999 (Fedesa and Fefana), and subsequently on the

substance of the case, on 30 June 2000 (Anprogapor and Asovac) and 13 July 2000 (Fedesa and Fefana).

65 Also upon application by them, the President of the Third Chamber, by orders of 25 March, 19 May and 6 September 1999, granted the Commission, the Kingdom of Denmark, the Kingdom of Sweden, the Republic of Finland and the United Kingdom of Great Britain and Northern Ireland leave to intervene in support of the form of order sought by the Council. The interveners lodged their written observations, initially limited to the admissibility of the action, on 31 May 1999 (the Commission) and 11 August 1999 (the Kingdom of Denmark). By letter of 25 October 1999, the United Kingdom of Great Britain and Northern Ireland stated that it did not intend to lodge observations as to admissibility. The Republic of Finland and the Kingdom of Sweden did not lodge observations on admissibility. Subsequently, the interveners lodged written observations on the substance of the case, on 30 June 2000 (the Republic of Finland and the Kingdom of Sweden), 17 July 2000 (the United Kingdom of Great Britain and Northern Ireland) and 25 July 2000 (the Commission).

66 By separate document of 30 July 2000, Pfizer requested, first, that the case be given priority under Article 55(2) of the Rules of Procedure and, second, that a number of measures of organisation of procedure be adopted pursuant to Article 64 of the Rules of Procedure. The Council lodged written observations on these requests on 9 September 1999. The interveners lodged their observations on 6 September 1999 (Fedesa and Fefana), 7 September 1999 (the Commission), 9 September 1999 (the Republic and Finland and the Kingdom of Sweden) and 13 September 1999 (Anprogapor and Asovac).

67 The written procedure was closed by the lodging of the rejoinder on 12 October 2000. Upon hearing the report of the Judge Rapporteur, the Court (Third Chamber) decided to open the oral procedure. By way of measures of

organisation of procedure, on 18 December 2000 and 20 June 2001, the Court called on the parties to reply to certain questions and to produce certain documents. The parties complied with those requests. Furthermore, the Court had regard, as far as possible given the volume of the pleadings and of the documentation produced, to the request that the case be given priority.

68 The parties were heard in oral argument and answered questions put to them by the Court at the hearing on 2 July 2001. At the hearing the Court asked the Council and the Commission to produce documents. Once they had complied with that request, Pfizer was requested to submit its observations on those documents. On 3 September 2001, the President of the Third Chamber of the Court of First Instance closed the oral procedure.

Forms of order sought

69 Pfizer claims that the Court should:

— annul the contested regulation in its entirety or as regards virginiamycin;

— take such other measures as it deems appropriate;

— order the Council to pay the costs.

70 The Council contends that the Court should:

— dismiss the action as manifestly inadmissible;

— in the alternative, dismiss the action as unfounded;

— order Pfizer to pay the costs.

71 Anprogapor, Asovac, Fedesa and Fefana intervene in support of the form of order sought by Pfizer.

72 The Commission, the Kingdom of Denmark, the Kingdom of Sweden, the Republic of Finland and the United Kingdom of Great Britain and Northern Ireland intervene in support of the form of order sought by the Council.

Admissibility

Arguments of the parties

73 The Council begins by observing that Pfizer, which seeks annulment of the contested regulation in its entirety, has adduced no arguments whatsoever with regard to additives which are not produced and marketed by it. Its action is in any event manifestly exorbitant in that respect.

74 In addition, according to the Council, the contested regulation is an act of general application which applies to objectively determined situations and produces legal effects on categories of persons viewed abstractly and in their entirety.

75 In the alternative, the Council contends that the contested regulation is not of individual concern to Pfizer for the purposes of the fourth paragraph of Article 173 of the EC Treaty (now, after amendment, the fourth paragraph of Article 230 EC). With regard to virginiamycin in particular, there is nothing to distinguish Pfizer from all other producers or potential producers of that product in the Community or in other parts of the world, who are subject to the same restrictions and are hence affected by the contested regulation in the same way. Furthermore, the Council considers that the ban on the use of the additive in question also affects farmers, who will no longer enjoy the economic benefits deriving from its use, as well as producers and distributors of feedingstuffs.

76 Nor can the action be considered admissible on account of the contacts which Pfizer had with the Commission prior to the adoption of the contested regulation, since the provisions of Directive 70/524 governing the withdrawal of authorisation of additives do not confer any procedural guarantee on the traders concerned.

77 Pfizer's situation in this case also differs from that of the applicant in Case C-309/89 *Codorniu* v *Council* [1994] ECR I-1853. The contested regulation does not concern the use of intellectual property rights, as was the case in *Codorniu*. It merely bans a particular use of the substances in question, whether they are marketed by Pfizer or by anyone else under a different name. Therefore Pfizer is not in a situation comparable to that of an undertaking such as Codorniu, which exploited a trade mark for sparkling wines, but rather in a situation comparable to that of champagne producers.

78 The Commission adds that, as regards the nature of the contested regulation, it is purely by chance that there was only one producer of virginiamycin in the world. That fact was in no way relevant to the adoption of the regulation. The fact that Pfizer was the only manufacturer of virginiamycin in the world did not mean that it had a manufacturing monopoly and there was nothing to prevent another undertaking from manufacturing the substance concerned.

79 The Kingdom of Denmark observes in particular that a case such as this should be dealt with exclusively by the national courts, which may make a reference to the Court of Justice for a preliminary ruling. It adds that there was nothing to prevent Pfizer from bringing an action before a national court and that it had in fact done so. Furthermore, with regard to the requirement that the applicant be individually concerned by the contested regulation, the Kingdom of Denmark observes that neither the product name, 'Stafac', nor Pfizer's name appears in the contested regulation. The Kingdom of Denmark adds that, were virginiamycin to be authorised again in the Community, there would be no legal obstacle to prevent other producers from obtaining authorisation to market it, provided that they applied for such authorisation. Consequently Pfizer has never had, and could never obtain, the exclusive right to produce and market virginiamycin.

80 Pfizer and the interveners supporting it maintain that the contested regulation is in the nature of a decision addressed to Pfizer. In any event, Pfizer is directly and individually concerned by the measure.

Findings of the Court

81 The fourth paragraph of Article 173 of the Treaty gives individuals the right to challenge *inter alia* any decision which, albeit in the form of a regulation, is of direct and individual concern to them. The particular objective of that provision

is to prevent the Community institutions from being able, merely by choosing 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, *inter alia*, Joined Cases 789/79 and 790/79 *Calpak and Società Emiliana Lavorazione Frutta* v *Commission* [1980] ECR 1949, paragraph 7, and Case T-298/94 *Roquette Frères* v *Council* [1996] ECR II-1531, paragraph 35).

82 The criterion distinguishing a regulation from a decision must be sought in the general application, or otherwise, of the measure in question (see, in particular, the order in Case C-168/93 *Gibraltar and Gibraltar Development* v *Council* [1993] ECR I-4009, paragraph 11, and the order in Case T-107/94 *Kik* v *Council and Commission* [1995] ECR II-1717, paragraph 35). A measure is of general application if it applies to objectively determined situations and produces its legal effects with respect to categories of persons viewed generally and in the abstract (see, for example, Case 307/81 *Alusuisse* v *Council and Commission* [1982] ECR 3463, paragraph 9, and the order in *Kik* v *Council and Commission*, cited above, paragraph 35).

83 In this instance the contested regulation provides for withdrawal of the authorisation to market certain additives in feedingstuffs, including virginiamycin, in the Community. That measure applies not only to all the existing or potential manufacturers of that product but also to other traders, such as livestock farmers and producers and distributors of feedingstuffs. It thus applies to objectively determined situations and has legal effects with respect to categories of persons viewed generally and in the abstract. It is therefore general in nature.

84 However, the fact that the contested regulation is of general application does not preclude it from being of direct and individual concern to certain natural and legal persons (see, to that effect, *Codorniu* v *Council*, cited at paragraph 77

above, paragraph 19, and the order in Case T-11/99 *Van Parys and Others* v *Commission* [1999] ECR II-2653, paragraph 40). In those circumstances, a Community measure can be of a general nature and, at the same time, *vis-à-vis* some of the traders concerned, in the nature of a decision (Joined Cases T-481/93 and T-484/93 *Exporteurs in Levende Varkens and Others* v *Commission* [1995] ECR II-2941, paragraph 50, and the order in *Van Parys and Others* v *Commission*, paragraph 40).

85 In so far as the contested regulation concerns additives other than virginiamycin which are not manufactured by Pfizer, the Court finds that it does not have any effect on Pfizer's legal situation. Consequently, the application must be dismissed as inadmissible to the extent to which it seeks annulment of the contested regulation in so far as it concerns additives other than virginiamycin.

86 As regards the requirement that the contested regulation should be of direct concern in so far as it concerns virginiamycin, it is appropriate to observe that, in order to meet that requirement, the measure at issue must directly affect the legal situation of the individual and leave no discretion to the addressees of that measure who are entrusted with the task of implementing it, such implementation being purely automatic and resulting from Community rules without the application of other intermediate rules (see, in particular, Case C-354/87 *Weddel* v *Commission* [1990] ECR I-3847, paragraph 19; Case C-404/96 P *Glencore Grain* v *Commission* [1998] ECR I-2435, paragraph 41; and Case C-386/96 P *Dreyfus* v *Commission* [1998] ECR I-2309, paragraph 43).

87 As the Council recognises, Pfizer is directly concerned by the contested regulation in so far as it withdraws the authorisation of virginiamycin as an additive in feedingstuffs. The effect of the measure, which applies directly to all the traders concerned without any need for intermediate rules to be adopted, is to remove Pfizer's authorisation to market that substance.

88 As to whether Pfizer is individually concerned by the contested regulation in so far as it concerns virginiamycin, the Court observes that natural or legal persons may claim that a measure of general application is of individual concern to them only if they are affected by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons (Case 25/62 *Plaumann* v *Commission* [1963] ECR 95, at 107; *Codorniu* v *Council*, cited at paragraph 77 above, paragraph 20; and Case T-12/93 *CCE de Vittel and Others* v *Commission* [1995] ECR II-1247, paragraph 36).

89 Contrary to Pfizer's submission, the fact that at the time when the contested regulation was adopted Pfizer was the only manufacturer of virginiamycin in the world and the only undertaking to market that substance in the Community is not, in itself, such as to distinguish Pfizer from all the other traders concerned. It must be borne in mind that the fact that it is possible to determine the number or even the identity of the persons to whom a measure applies at a given moment with a greater or lesser degree of precision does not mean that those persons must be considered to be individually concerned by it, as long as it is established that the measure is applied by virtue of an objective legal or factual situation defined by it (Case C-213/91 *Abertal and Others* v *Council* [1993] ECR I-3177, paragraph 17; and the order of 30 September 1997 in Case T-122/96 *Federolio* v *Commission* [1997] ECR II-1559, paragraph 55).

90 However, it is appropriate to analyse the provisions under which the contested regulation was adopted in so far as the latter concerns virginiamycin in order to ascertain whether Pfizer was affected by the adoption of the measure by reason of certain attributes which are peculiar to it or by reason of circumstances in which it is differentiated from all other persons.

91 Although the withdrawal of the authorisation of virginiamycin was adopted under Articles 11 and 24 of Directive 70/524, it is nevertheless appropriate to take into account that the authorisation was withdrawn in the course of the

procedure for re-evaluating the authorisation of that substance prescribed by the transitional rules laid down by Articles 9g, 9h and 9i of Directive 70/524, which were inserted by Directive 96/51 (see paragraphs 20 to 23 above).

92 Virginiamycin was authorised as an additive in feedingstuffs under the relevant provisions of the original rules, namely under Directive 70/524 prior to the entry into force of Directive 96/51. Under the original rules authorisation to market those substances as additives was not linked to specific manufacturers. Article 13 of Directive 70/524, as amended by Directive 84/587, merely provided, as regards manufacturers, that antibiotics could be put on the market as additives in feedingstuffs only if they had been produced by manufacturers found by at least one Member State to have fulfilled certain minimum conditions and whose names had been published by the Member State concerned and forwarded to the other Member States and to the Commission. Consequently, although, as Pfizer has pointed out, competitors had material difficulties in producing and marketing virginiamycin, from a legal standpoint any natural or legal person who met the abovementioned criteria could market it.

93 One of the major changes that Directive 96/51 made to the original rules was to link the authorisation of additives such as antibiotics to the person or, where appropriate, the persons responsible for putting the product into circulation, who are the only persons authorised to put the additives in question into circulation. The 'person responsible for putting [an additive] into circulation' was defined in Article 2(1) of Directive 70/524, as amended by Directive 96/51, as the natural or legal person who has responsibility for the conformity of the additive which has been granted Community authorisation and for putting it into circulation. Under the new rules, authorisations to market antibiotics as additives in feedingstuffs are thus granted by way of a Commission or Council regulation, in accordance with the procedure referred to in Article 4 of Directive 70/524, as amended by Directive 96/51, to specific producers whose names are published each year in the Official Journal in accordance with Article 9t of the Directive.

94 As is apparent from recital 2 of the preamble to Directive 96/51, the link between the authorisation of an additive, such as an antibiotic, and a specific producer was introduced in order to prevent poor copies of additives from being put into circulation in the Community.

95 It is true that, as the Council and the interveners supporting it have pointed out, at the time when the contested regulation was adopted, Pfizer had not acquired the status of person responsible for putting virginiamycin into circulation. At that time, the re-evaluation procedure prescribed by the transitional rules had not yet been completed.

96 However, under Articles 9g, 9h and 9i of Directive 70/524, as amended by Directive 96/51, which lay down the procedures for re-evaluation and new authorisation of the additives concerned, only the person or persons responsible for the dossier on the basis of which the former authorisation was granted, or their successor or successors, were in a position to make a new application, before 1 October 1998, for authorisation of the additive concerned; similarly, following that application, only that person or those persons could, on the basis of those provisions and by means of a regulation to be adopted no later than 1 October 2003, obtain a new authorisation as the person responsible for first putting the product concerned into circulation, for a period of 10 years or 5 years as appropriate.

97 In the present case Pfizer, the only producer of virginiamycin in the world, made applications on 15 September 1998 under Articles 9g and 9h for re-evaluation of that substance as an additive in the feedingstuffs of certain animals. Consequently, under those provisions, Pfizer was the only person who, at the time when the contested regulation was adopted, was in a legal position which would have enabled it to obtain, under those particular procedural provisions and through a Commission or Council regulation, authorisation to market virginiamycin as the person first responsible for putting it into circulation and thereby to be entered on the list provided for in Article 9t of Directive 70/524. Furthermore, if, following re-examination of the withdrawal of the authorisation

of virginiamycin, as provided for in Article 2 of the contested regulation, that product had been authorised again, only Pfizer, following the re-opening of the re-evaluation procedure, would have been in a position to obtain a new authorisation of virginiamycin as an additive linked to a person responsible for putting it into circulation. Consequently, although, at the time when the contested regulation was adopted, it had not acquired the status of person first responsible for putting virginiamycin into circulation, since the re-evaluation procedure laid down by Directive 96/51 was still continuing, Pfizer was already able to rely on an inchoate right in that regard.

98 Although it is also true that the status of person first responsible for putting an additive into circulation for the purposes of Articles 9g, 9h and 9i does not confer on that person an exclusive right to market the additive, it is none the less the case that, by virtue of having made an application for a further authorisation, Pfizer had obtained a position in respect of which Directive 70/524 offered legal safeguards. In particular, under Article 9c(1) of Directive 70/524, 'the scientific data and other information in the initial dossier submitted for the purpose of the first authorisation may not be used for the benefit of other applicants for a period of 10 years' from the date of the first authorisation by means of regulation. The reason for that provision is stated in recital 14 of the preamble to Directive 96/51 to be the fact that 'the search for new additives belonging to the group of substances for which authorisation is linked to those persons responsible for putting them into circulation requires costly investment'. In the particular circumstances of the present case, certain elements of that provision closely resemble a specific right comparable to the right on which the applicant undertaking could rely in *Codorniu* v *Council* (cited at paragraph 77 above).

99 Therefore, under the broad scheme of Directive 70/524, as amended by Directive 96/51, manufacturers who, like Pfizer, submit a new application for authorisation under Articles 9g, 9h and 9i of the Directive enjoy a particular legal situation. In accordance with those provisions, manufacturers such as Pfizer have taken all the steps necessary to acquire the status of person first responsible for putting the additive concerned into circulation, to take responsibility in the future for ensuring that the product complies with its Community authorisation and to

gain protection for the scientific data and other information provided by them in the dossier submitted with a view to obtaining for their product the first authorisation as an additive linked to a person responsible for putting it into circulation.

100 Consequently, even before the end of the transitional period, Pfizer was affected by withdrawal of the authorisation of virginiamycin following on the adoption of the contested regulation by reason of certain attributes which were peculiar to it and which differentiated it from all other persons.

101 As to Pfizer's participation in the procedure culminating in the adoption of the contested regulation, the Court observes that the regulation was adopted under the procedure laid down in Article 24 of Directive 70/524 and that that provision does not entitle the traders concerned to take part in the procedure (see paragraph 19 above). In that context, the Council rightly points out that, in accordance with settled case-law, the fact that a person is involved in some way or other in the procedure leading to the adoption of a Community measure is capable of distinguishing that person individually in relation to the measure in question only if the applicable Community legislation grants him certain procedural guarantees (see, to that effect, paragraph 55 of the judgment in *Exporteurs in Levende Varkens and Others* v *Commission*, cited at paragraph 84 above; and the order in Case T-585/93 *Greenpeace and Others* v *Commission* [1995] ECR II-2205, paragraphs 56 and 63).

102 Account must nevertheless be taken of the fact that, by making new applications for authorisation of virginiamycin in accordance with paragraphs (2) and (4) of Article 9g of Directive 70/524, as amended by Directive 96/51, Pfizer was in a position to be able to submit, in accordance with the procedure laid down in Article 4 of that directive and no later than 30 September 2000, a scientific dossier with a view to re-evaluation of the additive concerned. However, the procedure laid down in Article 4 is not only instigated on the application of the

operator concerned but also confers on that person procedural guarantees. The operator concerned must be notified, throughout the various stages of that procedure, if the application does not comply with the relevant provisions, if it is rejected or even if processing of it is merely postponed.

103 Although it is true, as the Council has pointed out, that the procedure in Article 24 of Directive 70/524, as applied in this instance, is different from the procedure under Articles 9g and 4 thereof, it is nevertheless the case that adoption of the contested regulation terminated or, at the least, suspended the procedure under Articles 9g and 4, which had been instigated by Pfizer's application for a new authorisation.

That fact is borne out by a letter of 8 November 1999, in which the competent officials at the Commission indicated to Pfizer, following its specific question, that 'as a consequence of the [contested] regulation, virginiamycin is not subject any more to Articles 9g, 9h and 9i... Thus, although Pfizer has submitted before 1 October 1998 identification notes and monographs in accordance with Article 9g, 9h and 9i(2), the above articles do not apply any longer to virginiamycin. As long as virginiamycin is not covered by the said provisions, it is not possible to submit or evaluate a dossier under the procedure they provide for.'

104 In such a context, by terminating or, at the least, suspending the procedure which had been opened, at Pfizer's request, for the purposes of obtaining a new authorisation of virginiamycin as an additive in feedingstuffs, and in the course of which Pfizer had the benefit of procedural guarantees, the contested regulation affects Pfizer by reason of a legal and factual situation which differentiates it from all other persons. That fact is also such as to distinguish Pfizer for the purposes of the fourth paragraph of Article 173 of the Treaty.

105 It follows that, so far as Pfizer is concerned, a series of factors exists, constituting a particular situation which differentiates Pfizer, as regards the measure in question, from all other traders concerned by the regulation. Pfizer must therefore be regarded as individually concerned by the contested regulation in so far as it concerns withdrawal of the authorisation of virginiamycin.

106 Therefore the application is admissible to the extent to which it seeks annulment of the contested regulation in so far as the latter withdraws the authorisation of virginiamycin as an additive in feedingstuffs.

Substance

107 Pfizer puts forward eight pleas in law alleging infringement of Article 11 of Directive 70/524 (first plea), manifest errors of assessment (second plea), breach of the precautionary principle (third plea), breach of the principle of proportionality (fourth plea), breach of the principle of legitimate expectations (fifth plea), breach of the obligation to state reasons (sixth plea), infringement of the right to property (seventh plea) and misuse of powers (eighth plea).

108 In the context of the first four pleas and the seventh and eighth pleas, Pfizer submits, in essence, that the contested regulation should be annulled, since the Community institutions have made errors in their analysis, by which is meant the assessment and management, of any risks to human health associated with the use of virginiamycin as a growth promoter, as well as in their application of the precautionary principle. The Court deems it appropriate to examine those pleas together.

I — *The pleas alleging errors of risk assessment and management and misapplication of the precautionary principle*

109 The preamble to the contested regulation shows that the Council, in adopting the measure, took the view that the use of virginiamycin as an additive in feedingstuffs involved a risk to human health and that accordingly it was necessary to withdraw the authorisations relating to the use of the product.

110 Following some preliminary remarks (A), the Court will start by examining whether, as Pfizer submits, the Council was wrong, on conclusion of a risk assessment that was not properly conducted, to find that the use of virginiamycin as a growth promoter constituted a risk to human health (B). It will then assess whether the Council, in adopting the contested regulation, made errors in its management of the risk (C).

A — *Preliminary considerations*

111 By the contested regulation, which was adopted on a proposal from the Commission, the Council withdrew Community authorisation from four antibiotics, including virginiamycin, as additives in feedingstuffs. The regulation was adopted on the basis of Directive 70/524, which, in turn, is founded on Article 43 of the EC Treaty (now, after amendment, Article 37 EC). Thus it forms part of the framework of the common agricultural policy.

112 More specifically, as regards virginiamycin, the contested regulation was adopted on the basis of Article 11(3) of Directive 70/524, which *inter alia* permits the

Commission to initiate under Article 24 a procedure amending the lists of authorised antibiotics where it considers such amendments necessary in order to mitigate the difficulties mentioned by a Member State in connection with a safeguard measure and to ensure the protection of human or animal health or the environment. In addition, it is apparent from recital 5 to the contested regulation that the Council took as its basis Article 3a(e) of Directive 70/524, which provides that Community authorisation of an additive in feedingstuffs is to be given only if 'for serious reasons concerning human or animal health its use must not be restricted to medical or veterinary purposes'. Finally, as the preamble, in particular recital 21 thereof, to the contested regulation shows, the Council took the view that, so far as virginiamycin was concerned, there was a 'serious reason', for the purposes of the abovementioned provision, justifying withdrawal of the authorisation of virginiamycin as an additive in feedingstuffs, namely the risk that the effectiveness of certain human medicinal products might be reduced or even eliminated as a result of the use of virginiamycin.

113 It is common ground between the parties that, at the time when the contested regulation was adopted, neither the reality nor the seriousness of the risk had been scientifically proven. It was against that background, as is clear from recital 29 to the contested regulation, that the Council relied on the precautionary principle as justification for adopting the regulation.

114 In accordance with Article 130r(2) of the EC Treaty (now, after amendment, Article 174(2) EC), the precautionary principle is one of the principles on which Community policy on the environment is based. It is not disputed by the parties that the principle also applies where the Community institutions take, in the framework of the common agricultural policy, measures to protect human health (see, to that effect, Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265, paragraph 100, 'the *BSE* judgment'; and Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 64, 'the *NFU* judgment'). It is apparent from Article 130r(1) and (2) of the Treaty that Community policy on the environment is to pursue the objective *inter alia* of protecting human health, that the policy, which aims at a high level of protection, is based in particular on the precautionary principle and that the requirements of

the policy must be integrated into the definition and implementation of other Community policies. Furthermore, as the third subparagraph of Article 129(1) of the EC Treaty (now, after amendment, Article 152 EC) provides, and in accordance with settled case-law (see, to that effect, Case C-146/91 *KYDEP* v *Council and Commission* [1994] ECR I-4199, paragraph 61), health protection requirements form a constituent part of the Community's other policies and must therefore be taken into account when the common agricultural policy is implemented by the Community institutions.

115 Moreover, the existence of such a principle has in essence and at the very least implicitly been recognised by the Court of Justice (see, in particular, Case C-331/88 *Fedesa and Others* [1990] ECR I-4023; Case C-405/92 *Mondiet* [1993] ECR I-6133; Case C-435/92 *APAS* [1994] ECR I-67; Case C-179/95 *Spain* v *Council* [1999] ECR I-6475; and Case C-6/99 *Greenpeace France and Others* [2000] ECR I-1651), by the Court of First Instance (see, in particular, Case T-199/96 *Bergaderm and Goupil* v *Commission* [1998] ECR II-2805, upheld on appeal by the Court of Justice in Case C-352/98 P *Bergaderm and Goupil* v *Commission* [2000] ECR I-5291, the order of 30 June 1999 in *Pfizer Animal Health* v *Council*, cited at paragraph 62 above, upheld on appeal by the order of 18 November 1999 in *Pfizer Animal Health* v *Council*, cited at paragraph 62 above, and the order of the President of the Court of First Instance of 30 June 1999 in Case T-70/99 R *Alpharma* v *Council* [1999] ECR II-2027) and by the EFTA Court (Case E-3/00 *EFTA Surveillance Authority* v *Norway*, not yet published in the EFTA Court Reports).

116 Although it is common ground that the Community institutions may, in the context of Directive 70/524, adopt a measure based on the precautionary principle, the parties nevertheless fail to agree on either the interpretation of that principle or whether the Community institutions correctly applied it in the present case.

117 Neither the Treaty nor the secondary legislation applicable to the present case contains a definition of the precautionary principle.

118 In that regard, whilst maintaining that the Community institutions have infringed Directive 70/524, Pfizer and the parties intervening on its behalf also claim that there has been a failure to act in accordance with two Commission documents concerning the interpretation of that principle under Community law. Those documents are, (i) a paper dated 17 October 1998 entitled 'Guidelines on the Application of the Precautionary Principle' and (ii) the Communication from the Commission on the Precautionary Principle of 2 February 2000 (COM(2000)1, 'the Communication on the Precautionary Principle').

119 There is certainly settled case-law to the effect that the Community institutions may lay down for themselves guidelines for the exercise of their discretionary powers by way of measures not provided for in Article 189 of the EC Treaty (now Article 249 EC), in particular by communications, provided that they contain directions on the approach to be followed by the Community institutions and do not depart from the Treaty rules (see, to that effect, Case T-7/89 *Hercules Chemicals* v *Commission* [1991] ECR II-1711, paragraph 53; Case T-149/95 *Ducros* v *Commission* [1997] ECR II-2031, paragraph 61; and Case T-214/95 *Vlaams Gewest* v *Commission* [1998] ECR II-717, paragraphs 79 and 89). In such circumstances, the Community judicature ascertains, applying the principle of equal treatment, whether the disputed measure is consistent with the guidelines that the institutions have laid down for themselves by adopting and publishing such communications.

120 However, in the present case, Pfizer cannot reasonably argue that the contested regulation is unlawful because it is inconsistent with the documents referred to at paragraph 118 above.

121 The first document, entitled 'Guidelines on the Application of the Precautionary Principle', dated 17 October 1998, was neither adopted nor published by the Commission but is exclusively a working document, prepared by the Directorate-General 'Consumer Policy and Consumer Health Protection' with a view to a communication being adopted by the Commission itself. It was sent to various interested parties with the sole aim of consulting them on the position taken therein by the Directorate-General. This is clear from a letter of 20 November 1998 from the Director-General of that Directorate General to Fedesa, in which the document was expressly described as a 'discussion paper' which '[did] not reflect the position of the Commission' but merely sought to 'obtain the views of the various interested parties straight away'. It follows that Pfizer — which, moreover, was not even the addressee of the letter of 20 November 1998 — cannot validly contend that the Commission informed the interested parties that it undertook to be bound by that document in the future. Consequently, that document, despite its title, was no more than a draft and could not, in this instance, entail any self-imposed limitation on the Community institutions' discretion for the purposes of the case-law cited at paragraph 119 above. That document is hereinafter referred to as the 'Draft Guidelines'.

122 As regards the Communication on the Precautionary Principle, the Court must point out that it was not published until over a year after the contested regulation had been adopted and that therefore it, too, was incapable, as such, of operating in this instance as a self-imposed limitation on the discretion of the Community institutions.

123 However, it is clear from the communication that, in publishing it, the Commission was seeking to inform all interested parties not only of the manner in which it intended to apply the precautionary principle in future but also of the way in which it was applying it at that time ('[t]he aim of this Communication is to inform all interested parties... of the manner in which the Commission applies or intends to apply the precautionary principle...', paragraph 2 of the Communication on the Precautionary Principle). Furthermore, the Commission contended before the Court that the approach taken in adopting the contested regulation was broadly consistent with the principles set out in the communi-

cation. Consequently, as the Commission acknowledged at the hearing, certain aspects of the communication could reflect the law as it stood at the time when the contested regulation was adopted in relation to the interpretation of the precautionary principle, as enshrined in Article 130r(2) of the Treaty.

124 Furthermore, the Court observes that in two Communications adopted and published prior to adoption of the contested regulation, namely the Communication of 30 April 1997 on Consumer Health and Food Safety (COM(97)183 final, 'the Communication on Consumer Health and Food Safety') and the green paper of 30 April 1997 on the general principles of food law in the European Union (COM(97)176 final, 'the green paper'), the Commission had already made a number of statements, in particular concerning the manner in which it intended to carry out risk assessment.

125 In view of the foregoing, rather than considering whether the Community institutions failed to act in accordance with the documents referred to at paragraph 118 above, the Court must assess, when dealing with these pleas, whether the institutions correctly applied the relevant provisions of Directive 70/524, as they are to be interpreted in the light of the rules of the Treaty and, in particular, of the precautionary principle, as enshrined in Article 130r(2) of the Treaty.

B — *Errors in assessing the risks associated with the use of virginiamycin as a growth promoter*

126 Pfizer does not dispute that, in principle, the Community institutions may take preventive measures under Directive 70/524 if, following a risk assessment, it is found that the use of an antibiotic, such as virginiamycin, as a growth promoter in animals involves a risk of a transfer of antimicrobial resistance from animals to

humans and, consequently, of a reduction in the effectiveness of certain medicinal products used in human medicine for the treatment of dangerous infections.

127 However, in the present case, Pfizer maintains that the Community institutions did not correctly assess that risk and complains essentially that they adopted a decision for reasons of political expediency without a proper scientific basis.

128 The various claims raised in this regard by Pfizer will be examined as follows. First, the Court will analyse the arguments of the parties concerning, in general, the purpose of risk assessment when the precautionary principle is applied (1). Second, it will consider whether, as Pfizer maintains, the contested regulation is unlawful because of the inadequate nature of the scientific data provided by the Danish authorities (2). Third, it will examine the argument that, in essence, the relevant findings of fact made by the Community institutions in the present case were incorrect (3). Fourth, it will consider whether, on the basis of the findings of fact thus made, the Community institutions exceeded the bounds of their discretion when they held that the use of virginiamycin as a growth promoter constituted a risk to human health (4).

1. The purpose of risk assessment when the precautionary principle is applied

(a) Arguments of the parties

129 Pfizer and the interveners supporting it take the view that the Community institutions may not take preventive measures until they have carried out a

scientific assessment of the risks allegedly associated with the product or procedure concerned.

130 Supported more specifically by Fedesa and Fefana, Pfizer submits that in any such risk assessment, the Community institutions must show that the risk, although it has not actually become a reality, is nevertheless probable. The existence of a 'very remote risk' should be allowed given the concrete positive elements arising from the use of the product concerned. In any event, the Community institutions cannot legitimately apply a test which Pfizer describes as a 'zero risk test'. Such a test is inappropriate since it is impossible to satisfy. It amounts essentially to requiring *probatio diabolica* from the industry, something which is recognised as unlawful in all the legal systems of the Member States (Opinion of Advocate General Mischo in the *Greenpeace* case cited at paragraph 115 above, ECR I-1651, at I-1653, point 72). It is never possible to prove conclusively that a chemical or pharmaceutical compound or anything created by modern technology represents a zero risk to public health now or that it will do so in the future. To apply such a test would quickly lead to the paralysis of technological development and innovation.

131 Nor is such a test in keeping with the rules governing additives in feedingstuffs. Pfizer submits that under Directive 70/524 those additives, before being authorised for marketing, are subject to very detailed examination in relation to the potential risks that they could represent to public health. In addition, once those products are on the market, an important monitoring procedure, known as 'pharmacovigilance', is applied to ensure that all side-effects of using them are identified, studied and mitigated. Finally, procedures are laid down which can lead to suspension or withdrawal of a marketing authorisation.

132 Furthermore, Pfizer submits that, generally, the fact that a measure is taken under the precautionary principle does not reverse the burden of proof. The manufacturers of an additive which has been authorised for marketing in the common market and which is subject to a procedure for withdrawal from the market are

not required to prove that the product is not dangerous to human health. On the contrary, in Pfizer's submission, under Article 11 of Directive 70/524, during a procedure for withdrawal of the authorisation of an additive, it is for the public authorities to demonstrate that, as a result of new information or of a reassessment of existing information, the use of the additive in question is a hazard to human health and to show the level of risk associated with it.

133 According to the Council and the interveners supporting it, the contested regulation was adopted on the basis of an adequate assessment of all the scientific knowledge available at the time of its adoption.

134 They confirm that any such measure withdrawing authorisation cannot be based on a test described as 'zero risk'. However, the fact that the competent authorities have, at a given time, considered that a particular additive meets the conditions for authorisation and have therefore authorised it does not imply that the manufacturer is freed from the onus of proving that its product continues to meet such conditions. Scientific knowledge and the risks to human health associated with use of a particular product evolve. Consequently, when faced with new scientific evidence that the use of an additive poses a hazard to public health and that the hazard has reached alarming proportions since the additive was first authorised, the Community institutions are fully entitled to require the manufacturer in question to demonstrate that its product continues not to represent a risk to human health.

(b) Findings of the Court

135 In view of the parties' arguments, it is necessary, first, to define the 'risk' which must be assessed when the precautionary principle is applied. It is then

appropriate to identify the two components of the task which falls to the competent public authority when a risk assessment is performed. Finally, it is necessary to determine how the burden of proof should be apportioned in the matter and to recall the settled case-law concerning the scope of judicial review in a situation of this kind.

(i) The 'risk' assessed when the precautionary principle is applied

136 It is clear from Article 11(1) and (3) of Directive 70/524 that the Community institutions may withdraw authorisation of an additive in feedingstuffs where use of the additive constitutes 'a danger to... human health'.

137 First, as regards the interpretation of 'danger', the Court observes that in the preamble to the contested regulation a different term is used in that regard, namely that, in the institutions' view, the use of virginiamycin as a growth promoter constitutes a 'risk' to human health. The same term, 'risk', was also used by the parties in their arguments before the Court.

138 The 'risk' associated with the product, the reality and the seriousness of which are in dispute between the parties, is the possibility that the use of virginiamycin as an additive in feedingstuffs will give rise to adverse effects on human health, namely a transfer of antimicrobial resistance from animals to humans, and, consequently, a reduction in the effectiveness of certain medicinal products in human medicine. As is clear from recital 5 to the contested regulation, the Council's finding of that 'risk' was considered by it to be a 'serious reason', within the meaning of Article 3a(e) of Directive 70/524, for restricting virginiamycin to medical use.

139 It is appropriate to bear in mind that, as the Court of Justice and the Court of First Instance have held, where there is scientific uncertainty as to the existence or extent of risks to human health, the Community institutions may, by reason of the precautionary principle, take protective measures without having to wait until the reality and seriousness of those risks become fully apparent (the *BSE* judgment, cited at paragraph 114 above, paragraph 99, the *NFU* judgment, cited at paragraph 114 above, paragraph 63, and the judgment at first instance in *Bergaderm and Goupil* v *Commission*, cited at paragraph 115 above, paragraph 66).

140 It follows, first, that as a result of the precautionary principle, as enshrined in Article 130r(2) of the Treaty, the Community institutions were entitled to take a preventive measure regarding the use of virginiamycin as an additive in feedingstuffs, even though, owing to existing scientific uncertainty, the reality and the seriousness of the risks to human health associated with that use were not yet fully apparent.

141 *A fortiori*, the Community institutions were not required, for the purpose of taking preventive action, to wait for the adverse effects of the use of the product as a growth promoter to materialise (see, in relation to the interpretation of Council Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds (OJ 1979 L 103, p. 1), the judgment of the Court of Justice in Case C-355/90 *Commission* v *Spain* [1993] ECR I-4221, paragraph 15).

142 Thus, in a situation in which the precautionary principle is applied, which by definition coincides with a situation in which there is scientific uncertainty, a risk assessment cannot be required to provide the Community institutions with conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality (see, in that context, *Mondiet*, cited at paragraph 115 above, paragraphs 29 to 31; and *Spain* v *Council*, cited at paragraph 115 above, paragraph 31).

143 However, it is also clear from the case-law cited at paragraph 139 above that a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified (see also, to that effect, *EFTA Surveillance Authority* v *Norway*, cited at paragraph 115 above, in particular paragraphs 36 to 38).

144 Rather, it follows from the Community Courts' interpretation of the precautionary principle that a preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully' demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken.

145 As Pfizer has rightly pointed out, the taking of measures, even preventive ones, on the basis of a purely hypothetical risk is particularly inappropriate in a matter such as the one at issue here. The parties do not dispute that in such matters a 'zero risk' does not exist, since it is not possible to prove scientifically that there is no current or future risk associated with the addition of antibiotics to feedingstuffs. Moreover, as Pfizer has also rightly pointed out, that approach is even less appropriate in a situation of this kind, in which the legislation already makes provision, as one of the possible ways of giving effect to the precautionary principle, for a procedure for prior authorisation of the products concerned (see, as to the specific procedural obligations relating to such prior authorisation, *Greenpeace France and Others*, cited at paragraph 115 above, paragraph 44).

146 The precautionary principle can therefore apply only in situations in which there is a risk, notably to human health, which, although it is not founded on mere hypotheses that have not been scientifically confirmed, has not yet been fully demonstrated.

147 In such a situation, 'risk' thus constitutes a function of the probability that use of a product or a procedure will adversely affect the interests safeguarded by the legal order. 'Hazard' ('danger') is, in this context, commonly used in a broader sense and describes any product or procedure capable of having an adverse effect on human health (see in that regard, at an international level, the provisional communication from the Codex Alimentarius Commission of the Food and Agriculture Organisation of the United Nations and the World Health Organisation, CX 2/20, CL 1996/21-GEN, June 1996).

148 Consequently, in a case such as this, the purpose of a risk assessment is to assess the degree of probability of a certain product or procedure having adverse effects on human health and the seriousness of any such adverse effects.

(ii) The two complementary components of risk assessment: ascertaining what level of risk is deemed unacceptable and conducting a scientific assessment of the risks

149 As the Commission stated in its Communication on the Precautionary Principle, which may be taken as a codification of the law as it stood at the time when the contested regulation was adopted (see paragraph 123 above), risk assessment includes for the competent public authority, in this instance the Community institutions, a two-fold task, whose components are complementary and may overlap but, by reason of their different roles, must not be confused. Risk assessment involves, first, determining what level of risk is deemed unacceptable and, second, conducting a scientific assessment of the risks.

150 As regards the first component, it is appropriate to observe that it is for the Community institutions to define, observing the applicable rules of the international and Community legal orders, the political objectives which they intend

to pursue within the parameters of the powers conferred on them by the Treaty. Thus within the World Trade Organisation ('the WTO') and, more specifically, in the Agreement on the Application of Sanitary and Phytosanitary Measures, which is set out in Annex 1A to the Agreement establishing the WTO, as approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ 1994 L 336, p. 1), it is specifically provided that members of that organisation may determine the level of protection which they deem appropriate (see the sixth recital to, and Article 3(3) of, the abovementioned Agreement and the Report of the Appellate Body of the WTO of 16 January 1998 on Community measures concerning growth hormones, particularly paragraphs 124 and 176).

151 In that regard, it is for the Community institutions to determine the level of protection which they deem appropriate for society. It is by reference to that level of protection that they must then, while dealing with the first component of the risk assessment, determine the level of risk — i.e. the critical probability threshold for adverse effects on human health and for the seriousness of those possible effects — which in their judgment is no longer acceptable for society and above which it is necessary, in the interests of protecting human health, to take preventive measures in spite of any existing scientific uncertainty (see, to that effect, Case C-473/98 *Toolex* [2000] ECR I-5681, paragraph 45). Therefore, determining the level of risk deemed unacceptable involves the Community institutions in defining the political objectives to be pursued under the powers conferred on them by the Treaty.

152 Although they may not take a purely hypothetical approach to risk and may not base their decisions on a 'zero-risk' (see paragraph 145 above), the Community institutions must nevertheless take account of their obligation under the first subparagraph of Article 129(1) of the Treaty to ensure a high level of human health protection, which, to be compatible with that provision, does not necessarily have to be the highest that is technically possible (Case C-284/95 *Safety Hi-Tech* [1998] ECR I-4301, paragraph 49).

153 The level of risk deemed unacceptable will depend on the assessment made by the competent public authority of the particular circumstances of each individual case. In that regard, the authority may take account, *inter alia*, of the severity of the impact on human health were the risk to occur, including the extent of possible adverse effects, the persistency or reversibility of those effects and the possibility of delayed effects as well as of the more or less concrete perception of the risk based on available scientific knowledge.

154 As regards the second component of risk assessment, the Court of Justice has already had occasion to note that in matters relating to additives in feedingstuffs the Community institutions are responsible for carrying out complex technical and scientific assessments (see Case 14/78 *Denkavit* v *Commission* [1978] ECR 2497, paragraph 20). The Council itself has drawn attention in its arguments to the fact that the decision to withdraw the authorisation of virginiamycin was based on extremely complex scientific and technical assessments over which scientists have widely diverging views (see in particular (4) below).

155 In such circumstances a scientific risk assessment must be carried out before any preventive measures are taken.

156 A scientific risk assessment is commonly defined, at both international level (see the provisional communication from the Codex Alimentarius Commission, cited at paragraph 147 above) and Community level (see the Communication on the Precautionary Principle, the Communication on Consumer Health and Food Safety and the green paper, cited at paragraphs 118 and 124 above), as a scientific process consisting in the identification and characterisation of a hazard, the assessment of exposure to the hazard and the characterisation of the risk.

157 In that regard, it is appropriate to point out, first, that, when a scientific process is at issue, the competent public authority must, in compliance with the relevant

provisions, entrust a scientific risk assessment to experts who, once the scientific process is completed, will provide it with scientific advice.

158 As the Commission pointed out in its Communication on Consumer Health and Food Safety (see paragraph 124 above), scientific advice 'is of the utmost importance at all stages of the drawing up of new legislation and for the execution and management of existing legislation' (page 9 of the Communication). Furthermore, the Commission stated there that it 'will use this advice for the benefit of the consumer in order to ensure a high level of protection of health' (ibid). The duty imposed on the Community institutions by the first subparagraph of Article 129(1) of the Treaty to ensure a high level of human health protection means that they must ensure that their decisions are taken in the light of the best scientific information available and that they are based on the most recent results of international research, as the Commission has itself emphasised in the Communication on Consumer Health and Food Safety.

159 Thus, in order to fulfil its function, scientific advice on matters relating to consumer health must, in the interests of consumers and industry, be based on the principles of excellence, independence and transparency, as stated in both the preamble to Commission Decision 97/579 and the Commission's Communications on the Precautionary Principle and on Consumer Health and Food Safety.

160 Second, it is common ground between the parties that, when the precautionary principle is applied, it may prove impossible to carry out a full risk assessment, as defined at paragraph 156 above, because of the inadequate nature of the available scientific data. A full risk assessment may require long and detailed scientific research. The case-law cited at paragraph 139 above shows that unless the precautionary principle is to be rendered nugatory, the fact that it is impossible to

carry out a full scientific risk assessment does not prevent the competent public authority from taking preventive measures, at very short notice if necessary, when such measures appear essential given the level of risk to human health which the authority has deemed unacceptable for society.

161 In such a situation, the competent public authority must therefore weigh up its obligations and decide either to wait until the results of more detailed scientific research become available or to act on the basis of the scientific information available. Where measures for the protection of human health are concerned, the outcome of that balancing exercise will depend, account being taken of the particular circumstances of each individual case, on the level of risk which the authority deems unacceptable for society.

162 So, where experts carry out a scientific risk assessment, the competent public authority must be given sufficiently reliable and cogent information to allow it to understand the ramifications of the scientific question raised and decide upon a policy in full knowledge of the facts. Consequently, if it is not to adopt arbitrary measures, which cannot in any circumstances be rendered legitimate by the precautionary principle, the competent public authority must ensure that any measures that it takes, even preventive measures, are based on as thorough a scientific risk assessment as possible, account being taken of the particular circumstances of the case at issue. Notwithstanding the existing scientific uncertainty, the scientific risk assessment must enable the competent public authority to ascertain, on the basis of the best available scientific data and the most recent results of international research, whether matters have gone beyond the level of risk that it deems acceptable for society (see paragraphs 150 to 153 above). That is the basis on which the authority must decide whether preventive measures are called for.

163 Furthermore, a scientific risk assessment must also enable the competent authority to decide, in relation to risk management, which measures appear to it to be appropriate and necessary to prevent the risk from materialising.

(iii) Apportionment of the burden of proof and the scope of judicial review

164 As regards apportionment of the burden of proof, it is clear from the finding made at paragraph 140 above that Pfizer was wrong to criticise the Community institutions for failing, in the risk assessment carried out during the procedure culminating in adoption of the contested regulation, to produce proof of the reality or the seriousness of the risks to human health associated with the use of virginiamycin as a growth promoter.

165 Rather, the Community institutions must show, first, that the contested regulation was adopted following as thorough a scientific risk assessment as possible, which took account of the particular circumstances of the present case, and, second, that they had available, on the basis of that assessment, sufficient scientific indications to conclude, on an objective scientific basis, that the use of virginiamycin as a growth promoter constituted a risk to human health.

166 As to the scope of judicial review, it is settled case-law that in matters concerning the common agricultural policy the Community institutions enjoy a broad discretion regarding definition of the objectives to be pursued and choice of the appropriate means of action. In that regard, review by the Community judicature of the substance of the relevant act must be confined to examining whether the exercise of such discretion is vitiated by a manifest error or a misuse of powers or whether the Community institutions clearly exceeded the bounds of their discretion (Case 98/78 *Racke* [1979] ECR 69, paragraph 5; Case 265/87 *Schräder* [1989] ECR 2237, paragraph 22; Joined Cases C-267/88 to C-286/88 *Wuidart and Others* [1990] ECR I-435, paragraph 14; *Fedesa and Others*, cited at paragraph 115 above, paragraph 14; the *BSE* judgment, cited at paragraph 114 above, paragraph 60; and the *NFU* judgment, cited at paragraph 114 above, paragraph 39).

167 It follows that, in this instance, the Community institutions enjoyed a broad discretion, in particular when determining the level of risk deemed unacceptable for society.

168 Furthermore, it is settled case-law that where a Community authority is required to make complex assessments in the performance of its duties, its discretion also applies, to some extent, to the establishment of the factual basis of its action (see, to that effect, Case 138/79 *Roquette Frères* v *Council* [1980] ECR 3333, paragraph 25; Joined Cases 197/80 to 200/80, 243/80, 245/80 and 247/80 *Ludwigshafener Walzmühle* v *Council and Commission* [1981] ECR 3211, paragraph 37; Case C-27/95 *Bakers of Nailsea* [1997] ECR I-1847, paragraph 32; Case C-4/96 *Nifpo and Northern Ireland Fishermen's Federation* [1998] ECR I-681, paragraphs 41 and 42; Case C-120/97 *Upjohn* [1999] ECR I-223, paragraph 34; and *Spain* v *Council*, cited at paragraph 115 above, paragraph 29).

169 It follows that in this case, in which the Community institutions were required to undertake a scientific risk assessment and to evaluate highly complex scientific and technical facts, judicial review of the way in which they did so must be limited. The Community judicature is not entitled to substitute its assessment of the facts for that of the Community institutions, on which the Treaty confers sole responsibility for that duty. Instead, it must confine itself to ascertaining whether the exercise by the institutions of their discretion in that regard is vitiated by a manifest error or a misuse of powers or whether the institutions clearly exceeded the bounds of their discretion.

170 In particular, under the precautionary principle the Community institutions are entitled, in the interests of human health to adopt, on the basis of as yet incomplete scientific knowledge, protective measures which may seriously harm legally protected positions, and they enjoy a broad discretion in that regard.

171 However, according to the settled case-law of the Court of Justice and the Court of First Instance, in such circumstances, the guarantees conferred by the Community legal order in administrative proceedings are of even more fundamental importance. Those guarantees include, in particular, the duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case (Case C-269/90 *Technische Universität München* [1991] ECR I-5469, paragraph 14).

172 It follows that a scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures.

173 It is in the light of the foregoing that the Court must examine whether the risk assessment carried out by the Community institutions in the present case is vitiated by the errors alleged by Pfizer.

2. Whether the contested regulation is unlawful because of the inadequate nature of the scientific data provided by the Danish authorities

(a) Arguments of the parties

174 In Pfizer's submission, the Danish authorities' safeguard measure was taken in breach of Article 11 of Directive 70/524. The authorities did not rely, at least at the time when the measure, which entered into force on 16 January 1998, was adopted on 15 January 1998, on 'new information' or on 'a reassessment of

existing information' for the purposes of Article 11 of Directive 70/524. In addition, as regards the additional information sent by the Danish authorities on 12 and 13 March, 1 April and 5 October 1998, i.e. after the safeguard measure was taken, Pfizer claims that on any view the national authorities were not entitled to take a safeguard measure and then provide scientific reasons for their decision at a later date. Such an approach is not consistent with Article 11.

175 Pfizer maintains that the fact that the safeguard measure is unlawful means that the contested regulation is also unlawful, given that it was adopted on the basis of that measure. Only a safeguard measure complying with the requirements of Article 11 empowers the Community institutions to initiate the procedure laid down in Article 24 of Directive 70/524.

176 The Council contends that the Danish authorities' dossier contained adequate scientific information. In any event, the contested regulation was not, in its contention, adopted on the basis of the Danish authorities' decision to adopt a safeguard measure but on the basis of an independent analysis carried out by the Community institutions of the risk associated with the use of virginiamycin.

(b) Findings of the Court

177 Under Article 11(1) and (2) of Directive 70/524, as it must be construed in light of the findings made in paragraphs 137 and 138 above, 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 an additive authorised in the Community for feeding animals constitutes a risk to human health, that Member State may adopt a safeguard

measure in respect of the product concerned. It must immediately inform the other Member States and the Commission thereof, 'giving reasons for its decision'. The Commission must, as soon as possible, examine those grounds and, after consulting the Member States within the Standing Committee, deliver its opinion on the measure. Then, in accordance with Article 11(3) of Directive 70/524, the Commission is to initiate the procedure for amending Directive 70/524, laid down in Article 24, '[s]hould [it] consider that amendments to the Directive are necessary in order to mitigate the difficulties mentioned [by the Member State concerned] and to ensure the protection of human... health'.

178 Under Article 24 the representative of the Commission is to submit to the Standing Committee a draft of the measures to be adopted. The Committee is to deliver an opinion on the measures before they are adopted by the Commission or, as the case may be, the Council on a proposal from the Commission.

179 It follows that where a Member State informs the Commission of its decision to take a safeguard measure under Article 11 of Directive 70/524 in respect of a product, the Commission must, as soon as possible, examine whether the measure is well founded. In particular, the Commission must ascertain whether, when it found the product to constitute a risk to human health, the Member State relied on detailed grounds including new scientific data or a reassessment of existing scientific information made since the product was authorised under the directive.

180 If, following that examination and after consultation of the Member States within the Standing Committee, the Commission takes the view that the safeguard measure was not based on such grounds, it may take 'appropriate measures', including, where necessary, infringement proceedings as provided for in Article 169 of the EC Treaty (now Article 226 EC). Otherwise, it initiates the procedure for amending Directive 70/524, laid down in Article 24 of that directive, following which the institutions may either withdraw the Community

authorisation from the product concerned — as in the present case — or maintain the authorisation.

181 In the present case, the Court notes that the Danish authorities sent the Status Report referred to at paragraph 44 above to the Commission among others, three days before the safeguard measure concerning virginiamycin entered into force. In that report the Danish authorities set out the grounds on which, in their view, the measure could be justified. However, the minutes of the meetings of the Standing Committee of 16 and 17 February 1998 and 16 and 17 March 1998 show that the Danish authorities had not initially sent a full scientific dossier in support of their safeguard measure. The dossier was completed on 1 April 1998 when the supplementary report from the Danish Veterinary Laboratory was forwarded (see paragraph 51 above).

182 However, contrary to Pfizer's submission, that does not invalidate the contested regulation.

183 First, the Status Report already showed that the Danish authorities were relying on a 'reassessment of existing information' within the meaning of Article 11(1) of Directive 70/524. Therefore, the Commission cannot be criticised for initiating the procedure laid down in Article 24 of Directive 70/524 on the basis of the grounds cited in the Status Report.

184 Second, it is for the Commission, once it decides to initiate the procedure laid down in Article 24 of Directive 70/524, to carry out at Community level its own risk assessment in respect of the product concerned. The risk assessment carried out by the Commission at Community level is independent of that carried out by the national authorities. Only the lawfulness of the Community-level risk assessment is subject to judicial review by the Court in this case. It follows that, even if the safeguard measure taken by the Danish authorities were unlawful,

notably because the scientific evidence provided by the authorities was inadequate, that would still not prove that the contested regulation was unlawful.

185 It follows that Pfizer's plea must be rejected as unfounded.

3. Errors in the relevant findings of fact in this case

186 It is clear from the preamble to the contested regulation that, in concluding that the use of virginiamycin as an additive in feedingstuffs constituted a risk to human health, the Community institutions relied, first, on the SCAN opinion, despite the fact that in the opinion SCAN concluded that virginiamycin did not entail an immediate risk to human health in Denmark. Second, the Community institutions cited a scientific study produced by the Danish authorities after SCAN had delivered its opinion. Third, the institutions took account of the conclusions and recommendations in a number of reports produced by international, Community and national bodies, published in the years preceding adoption of the contested regulation. Therefore, it is appropriate to consider whether the Community institutions, in their analysis of the various items of scientific evidence, made the errors that Pfizer alleges.

(a) The SCAN opinion

187 Pfizer considers, first, that it was not open to the Community institutions to disregard SCAN's conclusions and, second, that they distorted the SCAN opinion.

(i) The Community institutions' obligation to accept the SCAN opinion

Arguments of the parties

188 Pfizer and the interveners supporting it observe that SCAN carried out a scientific risk assessment and concluded in its opinion that there was no immediate risk associated with virginiamycin. However, despite the clarity of that conclusion, the Community institutions reached a diametrically opposed conclusion.

189 Pfizer acknowledges that under the relevant legislation the Community institutions are not bound by SCAN's opinion. However, referring to the judgment of the Court of First Instance in Case T-120/96 *Lilly Industries* v *Commission* [1998] ECR II-2571, paragraph 83, Fedesa and Fefana assert that where a scientific committee established by a Community measure publishes an opinion the Community institutions are bound by that opinion.

190 At the very least, the Community institutions could not ignore that opinion and allow themselves to be influenced instead by concerns expressed in the media. Similarly, they could not solely take account of the fact that, under Article 151 of the Act of Accession, they were obliged to take measures by 31 December 1998. Fedesa and Fefana submit that action of that kind amounted to a misuse of powers. Anprogapor and Asovac add that the Community institutions could not disregard the SCAN opinion without having obtained an alternative risk assessment to the one prepared by SCAN.

191 The Council and the interveners supporting it contend that the institutions are not bound by the SCAN opinion.

192 Furthermore, at the hearing the Council confirmed that SCAN is exclusively a Commission advisory body. In the present case, the contested regulation was adopted by the Council. Therefore, the Council stated at the hearing that 'whatever the SCAN might say [in its opinion], it cannot have any influence on the Council position'.

Findings of the Court

193 It is apparent from recital 15 to the contested regulation that the Council recognises that SCAN had concluded in its opinion that 'the use of virginiamycin as a growth promoter did not constitute a real immediate risk to public health in Denmark since Denmark had provided no new evidence to substantiate the transfer of streptogramin resistance from organisms of animal origin to those resident in the human digestive tract, which would compromise the future use of human medicinal products'. However, as is clear from recitals 16 and 21 to the regulation, the Council took account of the fact that in the Commission's view there was sufficient scientific information to conclude that a risk to human health associated with the use of virginiamycin did exist. In that regard, the Council relied, in particular, on various aspects of the scientific analysis in the SCAN opinion, summarised at recitals 17 to 19 to the contested regulation.

194 It follows, first, that, far from having ignored the SCAN opinion, the Council relied primarily on certain matters analysed in the opinion, although it decided not to accept the conclusions expressed there by SCAN.

195 It also follows that the Council was wrong to maintain at the hearing that the assessment made in the SCAN opinion could not have any influence on its own position. It is certainly the case, as the Council points out, that SCAN is an advisory committee attached to the Commission and that it is at the request of the Commission, which assumes responsibility therefor, that SCAN carries out risk assessments and delivers its scientific opinions. However, it is apparent from the preamble to the contested regulation, which was adopted in accordance with the procedure laid down in Article 24 of Directive 70/524 by the Council on a proposal from the Commission, that the Council did not ask for an alternative risk assessment to that carried out by SCAN, but that it endorsed the position adopted by the Commission in its proposal and did so on the basis, *inter alia*, of the SCAN opinion. It follows that the risk assessment carried out in this case by the Commission on the basis, *inter alia*, of the SCAN opinion also binds the Council.

196 That being so, under the relevant legislation the Commission, when it requests an opinion from SCAN, is not, as Pfizer acknowledges, bound to accept the conclusions reached in the opinion. It is clear from both Article 8(1) of Directive 70/524, as amended by Directive 96/51, and Decision 97/579, that SCAN is an advisory body.

197 Against that kind of legislative background, the role played by a committee of experts, such as SCAN, in a procedure designed to culminate in a decision or a legislative measure, is restricted, as regards the answer to the questions which the competent institution has asked it, to providing a reasoned analysis of the relevant facts of the case in the light of current knowledge about the subject, in order to provide the institution with the factual knowledge which will enable it to take an informed decision.

198 However, the competent Community institution must, first, prepare for the committee of experts the factual questions which need to be answered before it can adopt a decision and, second, assess the probative value of the opinion

delivered by the committee. In that regard, the Community institution must ensure that the reasoning in the opinion is full, consistent and relevant.

199 To the extent to which the Community institution opts to disregard the opinion, it must provide specific reasons for its findings by comparison with those made in the opinion and its statement of reasons must explain why it is disregarding the latter. The statement of reasons must be of a scientific level at least commensurate with that of the opinion in question. In such a case, the institution may take as its basis either a supplementary opinion from the same committee of experts or other evidence, whose probative value is at least commensurate with that of the opinion concerned. In the event that the Community institution disregards only part of the opinion, it may also avail itself of those parts of the scientific reasoning which it does not dispute.

200 It follows that the Commission — and the Council where, as in the present case, the measure is adopted by the Council on a proposal from the Commission — may disregard the conclusions drawn in the SCAN opinion, even though, in some places, it relies on certain aspects of the scientific analysis in the opinion.

201 That finding can also be justified on grounds of principle relating to the political responsibilities and democratic legitimacy of the Commission. Whilst the Commission's exercise of public authority is rendered legitimate, pursuant to Article 155 of the EC Treaty (now Article 211 EC), by the European Parliament's political control, the members of SCAN, although they have scientific legitimacy, have neither democratic legitimacy nor political responsibilities. Scientific legitimacy is not a sufficient basis for the exercise of public authority.

202 As to the judgment in *Lilly Industries* v *Commission*, pleaded by Fedesa and Fefana (see paragraph 189 above), it is appropriate to point out that, under the

provisions which applied in that case, consultation with the competent scientific committee within a period prescribed by those provisions was a pre-requisite for adoption of a Commission proposal. For that reason alone, the legal context of this case differs from that in *Lilly Industries*, which can therefore provide no support for the arguments of the interveners.

203 However, in this instance, where what is at issue is a measure taken for the purpose of protecting human health, the findings made by the institutions, which differ from those set out in the SCAN opinion, must be founded on that purpose alone. That also means that, if they are to disregard the findings set out in the opinion of the competent scientific committee, the Community institutions must be able to rely on a proper examination, carefully and impartially carried out, of all the relevant aspects of the individual case, which include the reasoning on which the committee concerned based the findings in its opinion.

204 In that regard, the Court observes that, contrary to Pfizer's submission, the Council, when it ratified the Commission's proposal, did give reasons for its decision not to accept the SCAN opinion, inasmuch as it took the view, on the basis of the precautionary principle and notwithstanding the existing scientific uncertainty, to which attention was drawn in the SCAN opinion, that 'the risk of reducing the effectiveness of human medicinal products... as a result of cross-resistance caused by virginiamycin should be avoided' (recital 21). In particular, taking into account both the SCAN opinion and the reports of specialist international, Community and national bodies, some of which are mentioned in recital 23 to the contested regulation, the Council found that the authorisations of additives used in feedingstuffs should be withdrawn from antibiotics used in human medicine or which, like virginiamycin, are known to select cross-resistance to antibiotics used in human medicine (recital 26).

205 It follows that the Community institutions explained their decision to depart from the SCAN opinion on the ground that it was in the interests of human health protection.

206 Nor is it possible to accept Pfizer's argument that the Community institutions took a decision solely in the light of the fact that, under Article 151 of the Act of Accession, a decision had to be taken before 31 December 1998 on the Swedish authorities' request that the legislation should be amended. It is certainly clear from the case-file that the institutions took account of that date during the procedure which culminated in adoption of the contested regulation and that, in addition, that date is also mentioned in the first recital to the regulation. However, as the Court has found above, that deadline, even though it might have provided an additional incentive for adopting the contested regulation, was not the main reason for its adoption. Pfizer's assertion to the contrary is not borne out by any evidence in the documents before the Court and is belied by the wording of the abovementioned recitals to the contested regulation. Nor, therefore, is there any ground for Pfizer's contention that the Community institutions misused their powers in that regard.

207 For the same reasons, the Court cannot, in the absence of any evidence, accept Pfizer's assertion that the Community institutions allowed themselves to be influenced, as regards the risk assessment, by concerns expressed in the media.

208 As to the requirement that the divergent view taken by the institutions should have a scientific basis, the Court, while noting that it may prove helpful in such a case to commission an alternative opinion drawn up in accordance with the principles referred to at paragraph 159 above, must nevertheless find that no obligation to do so exists under the relevant provisions.

209 On the contrary, it is apparent from the preamble to the contested regulation that in reaching its conclusion the Council relied primarily on various aspects of SCAN's own analysis. The Court will consider below whether, as Pfizer maintains, the Council distorted those aspects of the analysis and whether the Community institutions had a proper scientific basis on which to conclude, despite the findings in the SCAN opinion, that there was a risk to human health

which justified preventive measures. However, the Court observes that the Community institutions cannot be criticised for having founded their decision not to accept the conclusions in the SCAN opinion on various aspects of the analysis in the opinion. There is no doubt that the SCAN opinion meets the criteria of excellence, independence and transparency required of scientific advice. Furthermore, as is stated in point 15 of SCAN's rules of procedure, a SCAN opinion must include not only an answer to the question submitted by the Commission but also 'a scientific explanation and any minority opinions'. That is the only way in which an opinion enables a public authority to perform the duty imposed on it, namely to decide whether it is necessary to take measures, and, if so, what sort of measures.

210 Consequently, the Community institutions did not make an error when they decided not to accept the conclusions of the SCAN opinion.

(ii) Distortion of the SCAN opinion

211 Pfizer claims, both in its plea alleging breach of the obligation to state reasons and in those alleging errors of assessment and misuse of powers, that the preamble to the contested regulation incorrectly summarised or even distorted the SCAN opinion. That is shown by a comparison between the findings in the SCAN opinion, on the one hand, and the preamble to the contested regulation on the other.

212 First, Pfizer, supported by Fedesa and Fefana, refers to the following extracts from recital 15 to the contested regulation:

'Whereas after examining the grounds put forward, [SCAN] concluded in its opinion of 10 July 1998 [the SCAN opinion] that the use of virginiamycin as a growth promoter did not constitute a real immediate risk to public health in Denmark since Denmark had provided no new evidence to substantiate the transfer of streptogramin resistance from organisms of animal origin to those resident in the human digestive tract, which would compromise the future use of human medicinal products;...'

213 Pfizer and the interveners submit that the SCAN opinion was more forceful on this issue. They point out that it reads as follows:

'*E. faecium* resistant to virginiamycin could be detected in Danish food samples, particularly those of poultry origin.

The limited information provided, indicates that there are genetic factors (*sat A*) for virginiamycin resistance existing within the human population in the Netherlands. However, in the absence of data on prevalence, this information is of limited value. No corresponding data for the Danish population are presented. Reference to Danish faecal samples in Conclusion 5 is made on the basis of a single unsubstantiated statement in the [supplementary report from the Danish Veterinary Laboratory] (p. 7) commenting on data from the DANMAP survey yet to be published and so not available for evaluation.

...

Streptogramins are neither essential nor used for the treatment of human infections in Denmark at present. Danish concerns derive from the experience in

the USA and other parts of Europe where nosocomial infections involving staphylococci and enterococci have increased significantly' (description of conclusions 5 and 8 of the supplementary report from the Danish Veterinary Laboratory).

214 In that regard, SCAN stated in the general conclusions to its opinion that, first, 'no new evidence has been provided to substantiate the transfer of a streptogramin or vancomycin resistance from organisms of animal origin to those resident in the human digestive tract and so compromise the future use of therapeutics in human medicine' (see, for the full text, paragraph 53 above). Second, having summarised the reasons why the use of streptogramins in human medicine was less significant in Denmark than in some other Member States, SCAN concluded that 'the use of virginiamycin as a growth promoter does not constitute an immediate risk to public health in Denmark'.

215 It follows that recital 15 to the contested regulation contains an accurate summary of those two central findings of the SCAN opinion. The passages from that opinion cited by Fedesa and Fefana in support of their arguments do not alter that conclusion. It is true that those passages contain more detailed information about the reasons why, on the basis of available scientific knowledge, the use of streptogramins in human medicine was less significant in Denmark than in some other Member States. However, there is nothing in the wording of recital 15 to the contested regulation from which it might be concluded that the Community institutions tried to play down the criticisms made by SCAN regarding the information submitted by the Danish authorities in support of the safeguard measure.

216 Consequently, there are no grounds for Pfizer's view that the contested regulation misrepresents or distorts the SCAN opinion on that point.

217 Second, Pfizer refers to recital 16 to the contested regulation, which is worded as follows:

> '(16) Whereas, none the less, SCAN acknowledges that a reservoir of resistant genes within the animal population poses a potential risk for humans; whereas, contrary to the Commission, it is of the opinion that a full risk assessment cannot be made until, in particular, quantitative evidence of the extent of transfer of antimicrobial resistance from livestock sources is obtained'.

218 Pfizer observes that that recital is at variance with SCAN's comments on the ninth conclusion of the supplementary report from the Danish Veterinary Laboratory, in which it stated that the validity of the conclusion (that minimising the occurrence of virginiamycin-resistant *E. faecium* and staphylococci in animals and food could be critical for preserving the effect of streptogramins in human therapy) depended on the establishment of a link between a pool of resistance factors held within the bacteria comprising the animal gut flora and their transfer to human gut flora. It is apparent from the SCAN opinion that the reports submitted by the Danish authorities did not contain any new evidence to indicate the frequency of such transfers or whether they occurred at all.

219 In that regard, the Court observes that in recital 16 to the contested regulation, the Community institutions summarised the first two sentences of Part II of the general conclusions in the SCAN opinion:

> 'SCAN is sympathetic to the general concern highlighted by the Danish action about the hazard that a reservoir of resistance genes within the animal population

poses for humans. However, it is of the opinion that a full risk assessment cannot be made until quantitative evidence of the extent of transfer of antimicrobial resistance from livestock sources is obtained and the significance of this within the overall use of antimicrobials for clinical and non-clinical purposes evaluated.'

220 It follows that essentially SCAN confirmed that the use of virginiamycin as a growth promoter was a 'hazard' to human health but that, because of the inadequacy of the available quantitative scientific data, it was not possible to carry out a full scientific assessment of the risks associated with the product. In essence, Pfizer complains that the Community institutions were wrong to suggest in the recitals that, according to SCAN, there was a proper scientific basis on which to conclude that there was a 'risk' associated with the use of virginiamycin as a growth promoter. Pfizer relies, in this respect, on those parts of the SCAN opinion in which SCAN, conversely, expressed strong reservations about the likelihood of a link existing between the use of virginiamycin as a growth promoter and the development of resistance to streptogramins in humans.

221 However, although the Community institutions used the term 'risk', which has a different meaning from 'hazard' for the purposes of risk assessment and risk management (see paragraph 147 above), they did make clear that, according to SCAN, use of virginiamycin as a growth promoter entailed a 'potential risk'. It is clear from the preamble to the contested regulation as a whole that, by referring to a potential risk, the Community institutions intended to convey that SCAN did not exclude such a risk. It is only in recitals 17 to 20 to the contested regulation that the Community institutions summarised the various matters which they regarded as sufficient indication of the probability that use of the product would have adverse effects, leading them to conclude that the product entailed a risk to human health (see the analysis under (c) below).

222 Similarly, other parts of the SCAN opinion are at variance with Pfizer's arguments.

223 It is appropriate to point out that, in relation to conclusion 3 of the supplementary report from the Danish Veterinary Laboratory, according to which the *sat A* gene (which 'encodes' information about resistance to streptogramins) has been detected not only in virginiamycin-resistant *E. faecium* bacteria found in animals but also in streptogramin-resistant *E. faecium* bacteria causing infections in humans, SCAN adds the following comment:

'SCAN notes, however, that the presence of *sat A* was found only in a minority of animal strains in both studies but was associated with a far greater proportion of streptogramin-resistant human isolates. This difference may be an artefact reflecting the relatively low number of isolates examined, isolations made from farms which did not use virginiamycin, the quality of the PCR primer used to detect sat A or the presence of other, yet unrecognised, resistance factors. Also possible is that the constant use of a low concentration of virginiamycin in farm animals primarily selects for intrinsic resistance of a type that is almost universal amongst the related *E. faecalis* strains and that this provides the greatest source of resistance to streptogramins. In contrast, in humans where there is no selection pressure for intrinsic resistance, resistance is of the acquired type. Intrinsic resistance is less readily transferred than acquired resistance.'

224 In other words, SCAN takes the view that the conclusion drawn by the Danish authorities can be more satisfactorily accounted for by explanations other than the transfer of resistance via a transfer of the *sat A* gene. However, a transfer of resistance is not ruled out.

225 Similarly, as regards the *in vitro* tests carried out by the Danish authorities (conclusion 4 of the supplementary report from the Danish Veterinary Laboratory) and referred to in recital 19 to the contested regulation, SCAN takes the view that

'the data presented on frequency [are] misleading and [are], at best, an indication of the maximum rate possible. The likelihood of a mating occurring is directly related to the similarity of the genetic background between donor and recipient strains. The use of a single strain acting both as donor and recipient, and one selected on the basis of its aptitude for conjugation, is artificial. Data on the frequency of matings between the initial isolates, assuming that these were of animal origin, and the recipient strain would have been of greater value.'

226 Here too, SCAN expresses a view on the likelihood that the transfer effected *in vitro* will also occur in normal conditions and in no way excludes the possibility that such a transfer may occur under normal conditions.

227 Next, SCAN takes the view that the scientific data on which conclusions 5 and 6 of the supplementary report from the Danish Veterinary Laboratory relating to the discovery of virginiamycin-resistant *E. faecium* bacteria in food and human faecal samples were based were too inadequate to allow any conclusions to be drawn.

228 The same may be said in respect of conclusion 7 of the supplementary report from the Danish Veterinary Laboratory, according to which the '*vat B*' gene was detected in virginiamycin-resistant staphylococci found in poultry and in staphylococci responsible for human infections.

229 Furthermore, as regards conclusion 8 of the supplementary report from the Danish Veterinary Laboratory, according to which streptogramins were expected to play a pivotal role in the treatment of certain human infections, SCAN states:

'Data provided in the DANMAP survey [show] that in 1995/6, the latest information presented, none of the enterococci or coagulese-negative staphylococci isolated from blood cultures in Denmark were resistant to vancomycin. Most were also susceptible to penicillin or its semi-synthetic derivatives. In fact Denmark appears to have one of the lowest recorded incidences of methicillin-resistance among *Staphylococcus aureus* strains at < 1%, compared to 3% in the Netherlands, 8% in the UK, 10% in the USA and 30% in France. Thus, at present, existing strategies for coping with hospital infections caused by enterococci or staphylococci remain successful in Denmark and the [supplementary report from the Danish Veterinary Laboratory] contains no evidence that existing therapies are likely to be compromised in the short term.'

230 Consequently, in those comments, SCAN points out that, in its view, the medicinal products currently used in Denmark are successful in treating infections. However, its comments in no way indicate that SCAN is ruling out the possibility that resistance may be transferred to humans.

231 Instead, it is apparent from recital 16 to the contested regulation that rather than having disregarded or even distorted the SCAN opinion, the Community institutions drew different conclusions from the available scientific data. Unlike SCAN, they concluded that, despite the existing scientific uncertainty, they had a proper scientific basis for taking action under the precautionary principle.

232 It follows that recital 16 does not distort the SCAN opinion as regards the degree of probability of the risk associated with virginiamycin.

233 Third, Pfizer refers to recital 17 to the contested regulation, which is worded as follows:

'Whereas SCAN is also concerned about the development of vancomycin resistance amongst enterococci and methicillin-resistant strains of *Staphylococcus aureus*, which are increasingly responsible for nosocomial infections, particularly in the United States and southern Europe; whereas that could make it necessary to use streptogramins as therapeutic agents of last resort to treat germs which have developed resistance to other antibiotics'.

234 In Pfizer's submission, while acknowledging the existence of methicillin-resistant strains of *Staphylococcus aureus*, the SCAN opinion also stated that Denmark appeared to have one of the lowest recorded incidences of methicillin-resistance among strains of *Staphylococcus aureus*, i.e. less than 1%. SCAN thus concluded that existing strategies for coping with hospital infections caused by enterococci or staphylococci continued to be effective in Denmark. SCAN also noted that the Status Report contained no evidence that existing therapies were likely to be compromised in the short term.

235 That argument cannot be accepted either. First, recital 15 to the contested regulation states that SCAN concluded that the use of virginiamycin as a growth promoter did not pose an immediate risk to public health in Denmark (see paragraph 212 above). Second, as the Court has held at paragraph 184 above,

where, after a Member State has taken a safeguard measure, the Commission initiates the procedure for amending Directive 70/524 laid down in Article 24, it must carry out its own risk assessment at Community level. Therefore, it was right that attention was drawn to the fact, in the preamble to the contested regulation, that, as SCAN indicated in paragraph 2 of its general conclusions I (cited at paragraph 53 above), the development of multiple resistant strains of enterococci and staphylococci represents a significant problem worldwide and, in particular, in certain Member States.

236 Therefore it has not been proved in relation to recital 17 to the contested regulation that the facts have been in any way distorted.

237 Fourth, Pfizer refers to recital 18 to the contested regulation, which is worded as follows:

'Whereas, furthermore, SCAN notes in its opinion that the virginiamycin-resistant enterococci and staphylococci isolated from poultry and pigs all had cross-resistance to pristinamycin used in human medicine or the combination dalfopristin/quinupristin, which is due to be authorised as a human medicinal product shortly'.

238 On that point, Pfizer argues that the SCAN opinion (more specifically SCAN's comments on conclusion 2 of the supplementary report from the Danish Veterinary Laboratory) had indicated that, while the data submitted in the reports from the Danish authorities supported the general conclusions concerning

cross-resistance between streptogramins, they did not support the more specific statement in the body of the Danish reports that the resistance determinants were the same and could be specified.

239 The Court observes in that regard that the SCAN opinion bears out the Danish authorities' conclusion relating to the existence of cross-resistance between streptogramins. Furthermore, the more specific assertion by the Danish authorities that the resistance determinants were the same and could be specified was criticised by SCAN and was not referred to in the preamble to the contested regulation.

240 Fedesa and Fefana consider, for their part, that the SCAN opinion arrived at an entirely different conclusion from that summarised in recital 18 to the contested regulation. They refer to the following passages from the SCAN opinion:

'Despite the potential for transfer of resistance factors, virginiamycin does not appear to have greatly compromised the value of pristinamycin in those countries which allow the use of streptogramins as both growth promoter and human therapeutics. After more than 20 years' use of both streptogramins in France, resistance to pristinamycin amongst staphylococci remains low at around 5% of isolates. More importantly, in a survey of nearly 1 000 MRSA collected from hospitals throughout France, 98.5% were found susceptible to both pristinamycin and Synercid (Gazagne et al., 1998). Unfortunately, corresponding data for *E. faecium* in France [are] not available. However, evidence from the USA, where a survey of 1 000 strains of *E. faecium* found 95-97% sensitive to Synercid, also suggests that use of virginiamycin has not, in practice, reduced the value of streptogramins as a human therapeutic agent' (extracts from comments on conclusion 9).

241 However, the evidence relied on by those interveners does not relate to the existence of cross-resistance among streptogramins as such but to the fact, at issue between the parties (see paragraph 325 et seq. below), that, despite that phenomenon, the use of virginiamycin as a growth promoter has not yet brought about a significant reduction in the effectiveness of pristinamycin and Synercid, even in countries where virginiamycin has been used as an additive in feedingstuffs.

242 Therefore, recital 18 to the contested regulation does not contain any errors of assessment of the SCAN opinion either.

243 Fifth, Fedesa and Fefana maintain that recital 19 to the contested regulation expresses the Commission's opinion that the case of a Dutch farmer — in whom strains of *E. faecium* bacteria resistant to virginiamycin and pristinamycin were found which had the same genetic fingerprint as those isolated from his poultry — provided an indication that resistance might be transferred from animals to humans, something which might be confirmed by other cases in the future. According to Fedesa and Fefana, so far as that particular observation was concerned, the Community institutions failed to add SCAN's view that 'this generalisation from the particular remains unsound and without foundation' (comment on conclusion 6 of the supplementary report from the Danish Veterinary Laboratory).

244 The Court observes that the Community institutions, after summarising that scientific observation, in recital 19 to the contested regulation, went on to say that 'even if general conclusions about the transfer of resistant enterococci from animals to humans should not be drawn from a single case, the Commission sees it as an indication that this might be confirmed by other cases in the future'.

245 In doing so, the Community institutions took sufficient account of the criticisms made by SCAN of the conclusions of the Danish authorities relating to the scientific value of that observation. Therefore, the Community institutions have not distorted the SCAN opinion in that regard.

(iii) Conclusion

246 It follows from the foregoing that the Community institutions did not make any errors in their assessment of the SCAN opinion. Similarly, the Court has not found a misuse of powers. Consideration will be given below (see paragraph 312 et seq.) to Pfizer's allegation that the Community institutions made manifest errors of assessment in forming the view, contrary to the claims in the SCAN opinion, that the use of virginiamycin constituted a risk to human health.

(b) The fact that the new study on live rats was taken into account without SCAN's opinion being sought

(i) Arguments of the parties

247 Pfizer submits that the contested regulation is unlawful since the Community institutions took account in their risk assessment of the new study on live rats, which had been provided by the Danish authorities after the SCAN opinion. Pfizer asks on what scientific basis the Council and Commission could, as they

did in recital 20 to the contested regulation, properly describe that study as 'major fresh evidence' without having sought SCAN's opinion.

248 Although Pfizer recognises that the relevant legislation does not lay down an obligation to ask in every case for SCAN's opinion before authorisation of an additive is withdrawn, it none the less submits that, because of the scientific complexity of the dossier, the Commission was bound to seek a second scientific opinion from SCAN concerning that new scientific study in order to be in a position to make a proper assessment of its scientific value. Once the Commission had decided to consult SCAN about the safeguard measure taken by the Danish authorities, it could not decide, on grounds of political expediency, not to continue the dialogue with the experts on that committee when new scientific data were brought to its notice.

249 Referring to Case C-212/91 *Angelopharm* [1994] ECR I-171, paragraphs 31 to 41, Fedesa and Fefana submit that, to the extent to which the Commission does not itself have adequate scientific and technical knowledge to assess the relevant evidence in this type of case, then, regardless of the wording of the relevant legislation, consultation of the competent scientific committee becomes mandatory in all cases in order to ensure that measures taken at Community level are necessary and appropriate to the objective of protecting human health. Furthermore, it is clear from the judgments of the Court of First Instance in Case T-105/96 *Pharos* v *Commission* [1998] ECR II-285, paragraphs 65 and 68, and in *Bergaderm and Goupil* v *Commission*, cited at paragraph 115 above, paragraph 55, that in cases concerning public health the Community institutions must have enough time to prepare their decisions and, in particular, to arrange, where necessary, for the scientific issues which will determine their decisions to be examined afresh.

250 Furthermore, in Pfizer's submission, it is standard practice for the Commission to request an opinion from the competent scientific committee before acting, even if the relevant legislation does not require it to do so. That is clear both from the stance taken by the Commission in other cases before the Community Courts

(*Denkavit* v *Commission*, cited at paragraph 154 above, and *Pharos* v *Commission*, cited at paragraph 249 above, paragraph 59) and from its Communication on Consumer Health and Food Safety, cited at paragraph 124 above.

251 The Council and the interveners supporting it observe, first, that the relevant legislation does not impose any obligation to consult SCAN a second time about the observations carried out by the Danish authorities. Likewise, they contend that it cannot be inferred from either the case-law cited by Pfizer or the practice of the institutions that any such obligation exists.

252 In any event, the Council and the Commission contend that the scientific evidence in their possession was sufficient to allow them to assess the implications of the new study on live rats and that they were not necessarily obliged to consult SCAN formally again. Referring to the minutes of the SCAN meeting of 5 November 1998, the Council and the Commission point out, however, that, contrary to Pfizer's contention, the Commission consulted SCAN a second time about the study but that SCAN refused to deliver a second opinion to the Commission, confining itself to stating that the study 'does not bring new information on the subject'. At the hearing, the Council and the Commission maintained that a statement to that effect was an important scientific finding.

253 Finally, also at the hearing, the Council contended that it may base itself on scientific data which have not been assessed by the Commission's advisory body, SCAN, but which have been discussed in the Standing Committee. Even if it is the case that the Standing Committee is composed of representatives of Member States and the Commission and that the members did not necessarily have sufficient scientific knowledge, each member of the Committee is nevertheless assisted on the relevant scientific and technical questions by experts appointed for that purpose by his or her Member State. In this instance the Standing Committee held very detailed discussions about the scientific questions raised.

(ii) Findings of the Court

Introduction

254 As noted at paragraphs 54 and 56 above, it was in the context of the Standing Committee meetings that the Danish authorities, in the wake of the SCAN opinion, forwarded the new study on live rats to the other members of that Committee.

255 It is apparent from recital 20 to the contested regulation that the Community institutions found in that regard that the study constituted 'major fresh evidence ... 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* [bacteria]'.

256 It is necessary to assess whether the Community institutions could properly take that new study into account and describe it as 'major fresh evidence' without having first obtained an opinion on it from SCAN.

As to whether consultation of SCAN about the new study on live rats was mandatory or optional

257 First of all, under Article 8(1) of Directive 70/524 SCAN is to be 'responsible for assisting the Commission, at the latter's request, on all scientific questions relating to the use of additives in animal nutrition'. In addition, Article 2(1) of

Decision 97/579 provides that SCAN is to be consulted 'in the cases laid down by Community legislation' and that '[t]he Commission may also decide to consult it on other questions of particular relevance to consumer health and food safety'. In such cases, Article 2(3) of Decision 97/579 provides that '[a]t the Commission's request' the Committee is to provide 'scientific advice'.

258 Neither Article 11 nor Article 24 of Directive 70/524 makes provision for SCAN to be consulted.

259 Therefore, the abovementioned provisions of Directive 70/524 and Decision 97/579 of themselves have the effect that the Commission has the power to consult SCAN before withdrawing authorisation from an additive but is not under a duty to do so.

260 *A fortiori*, in a situation such as this, where new scientific evidence emerges after SCAN, at the Commission's request, has delivered its opinion, those provisions of Directive 70/524 and Decision 95/579 do not of themselves require the Commission to consult SCAN a second time in relation to that new scientific evidence.

261 Contrary to Pfizer's submission, neither the case-law of the Court of Justice or the Court of First Instance nor the Commission's practice provides grounds for inferring that there is an obligation to consult SCAN before any withdrawal of authorisation of an additive under Directive 70/524 and, therefore, an obligation to consult SCAN a second time about new evidence which has emerged after it has delivered its opinion.

262 To begin with, the Court notes that the *Angelopharm* judgment, cited at paragraph 249 above, deals with the interpretation of a directive relating to cosmetic products and, in particular, with whether consultation of the competent scientific committee (the Scientific Committee on Cosmetology) was mandatory or optional. The Court of Justice found that the directive at issue admitted of both the abovementioned interpretations (see paragraph 26 of the judgment). It was only in those circumstances that the Court of Justice found, following a purposive interpretation of the relevant provisions of the directive, that '[s]ince the purpose of consulting the Scientific Committee is to ensure that the measures adopted at Community level are necessary and adapted to the objective, pursued by the Cosmetics Directive, of protecting human health, consultation of the Committee must be mandatory in all cases' (see paragraph 38 of the judgment). Given the unequivocal wording of the provisions applying in this case (see paragraphs 25 and 27 above), that precedent is not applicable to the present case.

263 Likewise, Pfizer is wrong to rely on *Pharos* v *Commission*, cited at paragraph 249 above, upheld by the Court of Justice in Case C-151/98 P *Pharos* v *Commission* [1999] ECR I-8157, and *Bergaderm and Goupil* v *Commission*, cited at paragraph 115 above, in support of its argument. Certainly, in those judgments the Court of First Instance held that the Commission could not be criticised, in cases concerning public health, for having taken the time necessary to address the relevant scientific issues and, in particular, for having referred them for a second examination by the competent scientific committee (*Bergaderm and Goupil* v *Commission*, paragraph 55, and *Pharos* v *Commission*, cited at paragraph 249 above, paragraphs 65 and 68). However, since the relevant legislation confers a discretion on the Commission in that regard, those judgments do not constitute authority for the opposite conclusion that, in a situation such as this, the Commission would be obliged to act in that way.

264 As regards what is alleged to be the Commission's standard practice, which, Pfizer submits, emerges from the Communication on Consumer Health and Food Safety, cited at paragraph 124 above, the Court finds that the Commission specifically stated in the communication that consultation of scientific committees was not compulsory in all cases (see paragraph 2.3 of the communi-

cation). Moreover, as regards the position allegedly adopted by the Community institutions in the cases already decided by the Court of Justice and the Court of First Instance and cited at paragraph 249 above, the Community institutions have at no time stated that they were obliged to consult those committees. Rather, those cases concern the question whether, in the particular circumstances of the individual cases, the Community institutions could be criticised for having waited until the committees had delivered their opinions before taking the decisions which they were obliged to take.

265 Therefore, the Court must conclude that the intention of the Community legislature was that under Directive 70/524 the Community institutions should be able to withdraw authorisation from an additive in feedingstuffs, such as virginiamycin, without first having obtained an opinion from the abovementioned scientific committees.

266 *A fortiori*, in a case such as this, the contested regulation cannot be found to be unlawful merely because a second scientific opinion was not obtained from SCAN concerning the new study on live rats.

267 That being so, it has already been held at paragraph 154 above that the decision to maintain or withdraw the authorisation of antibiotics, including virginiamycin, called for particularly complex technical and scientific assessments on the part of the Community institutions. That finding clearly applies in relation to the new study on live rats. It is clear both from the study, prepared by four scientists at the Danish Veterinary Laboratory, and from recital 20 to the contested regulation that its purpose was to analyse whether, under experimental conditions in the gastro-intestinal tract of rats, a transfer of the *sat A* gene conferring resistance to virginiamycin via a plasmid could take place between isogenic strains of *E. Faecium* bacteria. The aim of the study, which had to be assessed by the Community institutions as part of their risk assessment, was thus to ascertain whether a transfer of genes similar to those observed in *in vitro* experiments could take place *in vivo*, in the gastro-intestinal system of live rats.

268 As held at paragraphs 158 and 159 above, in a case like this, expert scientific advice meeting the requirements of excellence, independence and transparency is of the utmost importance in risk assessment to ensure that the regulatory measures adopted by the Community institutions have a proper scientific basis and to ensure that the institutions were in a position to examine carefully and impartially all relevant evidence in a particular case.

269 In that connection, account must be taken of the fact that the Commission set up SCAN specifically with the aim of ensuring that Community legislation is founded on objective and sound scientific findings. The first recital to Decision 97/579 states that 'sound scientific advice is an essential basis for Community rules on consumer health'. Similarly, in the preamble to the decision, the Commission stated that advice from scientific committees, such as SCAN, 'must, in the interests of consumers and industry, be based on the principles of excellence, independence and transparency'.

270 In the light of the foregoing, the Court finds that it is only in exceptional circumstances and where there are adequate guarantees of scientific objectivity that the Community institutions may, when — as here — they are required to assess particularly complex facts of a technical or scientific nature, adopt a preventive measure withdrawing authorisation from an additive without obtaining an opinion from the scientific committee set up for that purpose at Community level on the relevant scientific material, in this case the new study on laboratory rats.

271 In that connection, the Community institutions have essentially put forward three main arguments.

The second consultation of SCAN

272 First, the Council states that, contrary to Pfizer's submission, the Commission did consult SCAN and that consequently Pfizer's argument can on no account be accepted.

273 In that regard, it is clear from the documents before the Court that, at the meeting of the Standing Committee on 16 and 17 July 1998, the Danish authorities informally brought the new study on live rats to the attention of the other members of the Committee. The study was formally distributed to members of the Committee, at the Commission's request, only on 27 August 1998. Furthermore, it is apparent from an undated transmission report that the Commission sent the study to SCAN, indicating that it would be discussed at SCAN's next meeting, which was scheduled to take place on 29 and 30 September 1998. However, no mention is made of that study in the minutes of the SCAN meeting of 29 and 30 September 1998. By contrast, it is apparent from the minutes of the SCAN meeting of 5 November 1998 that on that occasion SCAN examined the new study and stated that it 'does not bring new information on the subject.'

274 In so far as the Council essentially maintained at the hearing that that statement amounted to a scientific opinion, the Court begins by observing that it was not adopted in accordance with the rules of procedure which SCAN adopted on 12 March 1998 under Article 8(1) of Decision 97/579. Those rules provide for a formal procedure for obtaining an opinion from SCAN, a procedure which was not followed in the present case. As the Council and the Commission confirmed in their answers to the Court's written questions, consultation of SCAN is initiated by a written request from Commission staff — a request which was not made in the present case. Furthermore, under paragraph 15 of the SCAN rules of procedure, SCAN's opinion 'comprises the response given to a question posed by the Commission, a scientific explanation and any minority opinions'. Under Article 10 of Decision 97/579 and paragraph 15 of the rules of procedure, opinions of the committee are published subject to commercial confidentiality.

Those principles, which, in a case such as this, amount to significant procedural guarantees (see paragraphs 170 to 172 above), were not respected in this instance, since SCAN confined itself to stating that the new study on live rats 'does not bring new information on the subject', without providing any scientific explanation.

275 Furthermore, since no reasons are given in support of the statement, it is not possible to ascertain to what extent the Commission itself can have been aware of the reasons on which SCAN based its conclusion. Nor is it possible to ascertain from the statement whether the Commission was able, on sound scientific grounds, to draw conclusions from it which appeared to it to be adequate and which in some circumstances might (as they were here) be contrary to those put forward in SCAN's statement. As the Court has stated in paragraph 162 above, it is essential to provide a statement of reasons in order to enable the Community institutions to determine their position *vis-à-vis* the problem which has arisen in full knowledge of the facts.

276 In so far as the Council is of the view that SCAN refused to deliver a second opinion despite being consulted by the Commission, the Court finds that in any event, under Article 2(5) of Decision 97/579, the Commission could have 'require[d] the adoption of an opinion within a specified period', making use if necessary of the accelerated procedure provided for in SCAN's rules of procedure for urgent cases. Furthermore, the Community institutions cannot properly rely on organisational difficulties within departments and committees set up by them to explain their failure to comply with a duty incumbent upon them, namely to carry out as thorough a scientific assessment of the risks as possible and, in that connection, to obtain if necessary an opinion from the relevant scientific committees before adopting preventive measures.

277 It follows that the statement made by SCAN at its meeting on 5 November 1998 about the new study on live rats does not amount to a scientific opinion for the purposes of the relevant provisions but is merely a view expressed by the members of SCAN pursuant to informal consultation by the Commission. The statement as such is therefore not capable of refuting Pfizer's argument.

The role of the Standing Committee

278 Second, the Council and the Commission maintain that the new study on live rats was analysed by the Standing Committee.

279 In that regard, it is appropriate to point out *in limine* that it is clear from Articles 11 and 24 of Directive 70/524 that that Committee must be consulted by the Commission both at the stage of risk assessment and at the stage of risk management. Further, it follows from Article 2 of Decision 70/372 setting up the Standing Committee that, as well as its advisory functions, the Committee may 'consider any other question arising under such instruments [Directive 70/524] and referred to it by the Chairman either on his own initiative or at the request of a Member State'.

280 However, attention should be drawn to the fact that the responsibilities conferred by Directive 70/524 on the Standing Committee must not be confused with those conferred on SCAN. The Standing Committee was set up with a fundamentally different aim from that of SCAN.

281 It is apparent from the preamble to Decision 70/372 that the Standing Committee was set up in order to ensure close cooperation between Member States and the Commission in the sphere of feedingstuffs.

282 The Committee, set up under Article 145 of the EC Treaty (now Article 202 EC) and made up of representatives of Member States and the Commission, is part of a mechanism for review by the representatives of the Member States of the Commission's exercise of the powers delegated to it by the Council (see, to that effect, the Opinion of Advocate General Jacobs in *Angelopharm*, cited at paragraph 249 above, ECR I-171, at I-173, point 38). It is clear from Article 24(3) of Directive 70/524 that the Commission itself can adopt measures entailing amendment of the annexes to the directive only if the measures are in accordance with the opinion of the Standing Committee. If they are not in accordance with that opinion or if, as in this case, the Standing Committee has not delivered an opinion, the Council, on a proposal from the Commission, is to adopt the measures within 15 days. Under Article 24(2) and (3) of Directive 70/524, and as is the case with Council decisions following a proposal from the Commission, opinions from the Standing Committee are delivered by the majority laid down in Article 148(2) of the EC Treaty (now Article 205(2) EC). Furthermore, the votes of the representatives of the Member States within the Standing Committee are also weighted as provided for in that article.

283 Consequently, whatever professional qualifications its members may have, the Standing Committee must be regarded as a political body representative of the Member States and not as an independent scientific body.

284 Moreover, against the background of cooperation between the Member States and the Commission, the Standing Committee also assists the Commission in the exercise of the powers conferred on it by the Council (see, to that effect, Case T-188/97 *Rothmans* v *Commission* [1999] ECR II-2463, paragraphs 57 to 60). It is in that context that, as is clear from the short reports of the meetings of the Standing Committee held prior to adoption of the contested regulation, the members of the Committee analysed the relevant scientific evidence, including the SCAN opinion and the new study on live rats.

285 However, contrary to the substance of what the Council, supported by the Commission, asserted at the hearing, the results of the analysis of the scientific

material by the members of the Standing Committee cannot be regarded as scientific advice based on the principles of excellence, transparency and independence, even though the members of the Committee are assisted by experts appointed by the Member States who are capable of understanding and explaining the full significance of that scientific evidence.

286 First, as the Court has just held and as the Council itself acknowledged at the hearing, the Standing Committee is not an independent scientific committee.

287 Second, it must be noted that, unlike SCAN opinions, the Standing Committee's analysis of scientific material is not published. Certainly, as the Council pointed out at the hearing, short reports of the meetings of the Committee are published on the Commission's web-site. However, the short reports of the meetings held prior to adoption of the contested regulation do not contain any trace of a structured scientific analysis essential to scientific advice. Even if it were the case, as the Council none the less maintained in substance at the hearing, that the work actually done within the Standing Committee was consistent with the principle of excellence of scientific advice, it would not, failing publication, meet the requirement that scientific advice should be transparent.

288 Analysis of scientific material by members of the Standing Committee, assisted where necessary by scientists appointed by the Member States, performs another function as important as the scientific risk assessment carried out at the Commission's request by independent experts from SCAN. As the Council rightly pointed out, there are bound to be limits to the role of scientific committees. They are purely advisory bodies. It is for the competent political authority to decide upon the measures to be taken, in general on the basis of scientific advice but without being bound, at least under the provisions applying in this instance, by any conclusions expressed therein (see paragraph 199 above). Defining the objectives to be pursued and risk management — duties which are, under the

relevant provisions, divided between the Council and the Commission — can be properly performed by a public authority only if it acquires from the various bodies and departments working on its behalf and preparing the way for it to take a decision, sufficient technical knowledge to grasp the full significance of the scientific analysis performed by the independent experts and to decide, in full knowledge of the facts, whether a preventive measure should be taken and, if so, which.

289 It follows that the Standing Committee's analysis of the new study on live rats, provided by the Danish authorities after delivery of the SCAN opinion, cannot be regarded in itself as a scientific opinion. The Standing Committee's work does not therefore discharge the Community institutions from their duty to carry out a scientific risk assessment and, when doing so, to draw, as a general rule, on a scientific opinion delivered by the competent scientific committee set up at Community level or, in exceptional circumstances, on other appropriate scientific material (see paragraph 270). However, it is necessary to take account of the work when considering the errors of assessment allegedly made by the Community institutions in determining the level of risk deemed unacceptable and in managing the risk.

290 Therefore, the second argument advanced by the Council and the Commission must also be rejected.

The exceptional circumstances allowing the Community institutions to take account of the new study on live rats without having obtained a further opinion from SCAN

291 Finally, the Court must assess whether, as the Community institutions maintain, the Commission, following consultation of the Standing Committee, was in a

position to grasp the full significance of the new study on live rats and to take the view that there was a proper scientific basis on which to conclude that it amounted to 'major fresh evidence', which had to be taken into account in the assessment of the risks associated with the use of virginiamycin as a growth promoter.

292 It is clear from the summary of the study, which was carried out by four scientists at the Danish Veterinary Laboratory, and from recital 20 to the contested regulation that its purpose was to analyse whether, under experimental conditions, a plasmid transfer of the *sat A* gene conferring resistance to virginiamycin could take place between isogenic strains of *E. faecium* bacteria in the gastro-intestinal tract of rats.

293 In that regard, it is appropriate to take account of the fact that in its opinion, and as mentioned at the beginning of recital 19 to the contested regulation, SCAN had already assessed the issue of the transfer of the *sat A* gene between isogenic strains of *E. faecium* bacteria and had analysed the observations of that *in vitro* transfer. The SCAN opinion confirmed that the exchange of genetic information between isogenic strains of enterococci was a recognised phenomenon ('[e]nterococci are known to be promiscuous and exchange of genetic information between similar strains is a common occurrence', comments on conclusion 4 of the supplementary report from the Danish Veterinary Laboratory). Similarly, it concluded that the observation carried out in that regard *in vitro* by researchers at the Danish Veterinary Laboratory confirmed that was possible ('[t]his experiment confirms that such conjunctions can involve plasmids carrying resistance genes including *sat A*', ibid).

294 However, the SCAN opinion disputed in substance that it was possible to conclude from that observation that the genetic transfer of resistance could

take place under normal conditions. As noted at paragraph 225 above, it stated:

'However, the data presented on frequency is misleading and is, at best, an indication of the maximum rate possible. The likelihood of a mating occurring is directly related to the similarity of the genetic background between donor and recipient strains. The use of a single strain acting both as donor and recipient, and one selected on the basis of its aptitude for conjugation, is artificial. Data on the frequency of matings between the initial isolates, assuming that these were of animal origin, and the recipient strain would have been of greater value.'

295 Next, the Court observes that the fact that no observations had been carried out under natural conditions had also been criticised by Pfizer itself in its observations on the supplementary report from the Danish Veterinary Laboratory.

'Again, if one were to ignore the omissions in the report and make the assumption that the results are valid, this study would merely show that transfer of resistance genes can occur *in vitro*. The incidence recorded appears remarkably high, but if this were to have occurred *in vivo* [it] would have resulted in an extremely high incidence of resistance among the human population. Such is clearly not the case, and suggests that the results would therefore add little to the elucidation of whether such phenomenon occurs *in vivo* where contact between donor and recipient is less intimate and frequent' (page 11).

296 Pfizer criticised the method employed and submits that the observations, even though they were performed on live rats, were actually carried out in artificial conditions. However, that fact was not disputed by the scientists who had carried

out the *in vivo* study. It is clear from the summary of the study that it was carried out 'under experimental conditions' and that it merely suggests — rather than proves — 'that a similar transfer may take place under natural conditions'.

297 The statement made by SCAN at its meeting on 5 November 1998 also seems to bear that out — lack of probative value, in SCAN's submission, but some evidential value according to the Community institutions. In stating that the study did not bring any new information on the subject, SCAN, in essence, repeated its abovementioned criticisms concerning methodology.

298 It follows that, on the basis of the SCAN opinion, scientific data submitted by the Danish authorities and comments made in that regard by Pfizer itself, the Community institutions were well aware of the methodological limitations of the new study on live rats and of the fact that it was purely indicative as regards any risk associated with the use of virginiamycin as an additive in feedingstuffs. Contrary to Pfizer's submission, they were sufficiently well informed to take the study into account in their risk assessment as evidence supplementary to the scientific data evaluated in the SCAN opinion and to conclude, without necessarily being obliged to request a formal opinion from SCAN, that the study amounted to major fresh evidence.

Conclusion

299 Consequently, the Community institutions did not err when they took account of the new study on live rats without having obtained a second opinion on it from SCAN.

(c) The fact that the conclusions and recommendations of international, Community and national bodies were taken into account

(i) Arguments of the parties

300 Pfizer complains that the Community institutions based their risk assessment on certain conclusions and recommendations found in reports produced by various international, Community and national bodies and published over the years preceding adoption of the contested regulation.

301 In Pfizer's submission, those reports do not contain enough specific evidence relating to the risk associated with the use of virginiamycin to enable the Community institutions to carry out their risk assessment but deal with the problem of resistance to antibiotics in general. Any action taken in respect of virginiamycin should be founded not on general concerns but on the specific situation of virginiamycin.

302 The Council contends that those reports specifically concern the problem of resistance to antibiotics and the link between that phenomenon and the use of antibiotics as additives in feedingstuffs. It points out that virginiamycin is specifically mentioned in some of the reports.

(ii) Findings of the Court

303 It is clear from the preamble to the contested regulation that, contrary to Pfizer's submission, the Community institutions relied principally for the purpose of their risk assessment of virginiamycin on certain aspects of the scientific analysis in the

SCAN opinion, summarised at recitals 15 to 19 to the contested regulation, and on the new study on live rats.

304 However, it is evident from recital 23 to the contested regulation that the Community institutions took the conclusions and recommendations in the various reports from international, Community and national bodies into account only as supplementary material and did so for the purposes of their analysis of all the products affected by the measure.

305 It follows, first, that, contrary to what Pfizer in essence submits, the Community institutions did not replace a scientific analysis of the risks associated with the use of virginiamycin by references to the conclusions and recommendations of the various reports. Nor did they base their decision to depart from the findings in the SCAN opinion on the conclusions in those reports: rather they based it principally on aspects of the SCAN opinion.

306 Second, the Court observes that even if those reports relate to the problem of resistance to antibiotics in general, they deal, in particular, with the possible implications of the use of antibiotics as additives in feedingstuffs. Furthermore, those reports specifically analyse the risks associated with the use of antibiotics, such as virginiamycin, which may entail cross-resistance to antibiotics used in human medicine. Last, in some of those reports, virginiamycin is specifically mentioned as one of the products whose use as a growth promoter might lead to a reduction in the effectiveness of certain antibiotics in human medicine.

307 Third, and more specifically, it is clear that the WHO report and the Copenhagen Recommendations, cited at recital 23 to the contested regulation, were adopted

following wide consultation of a large number of scientists. It is also apparent from the Copenhagen Recommendations that representatives of the pharmaceutical industry attended the conference following which that report was adopted. The Court therefore has no reason to doubt that those reports were drawn up on the basis of the best scientific data available at international level.

308 Fourth, the same findings may be made as regards the reports of certain national specialist bodies, such as the Swedish report, the Netherlands report, the House of Lords report and the United Kingdom report (cited at paragraphs 36 and 46 above). Although, with the exception of the Swedish report, those documents are not referred to in the preamble to the contested regulation, the Council and the interveners supporting it nevertheless stated at the hearing that the Commission took account of those reports, which were brought to its notice in the context of the close cooperation between the Member States and the Commission within the Standing Committee. Mention is specifically made of the United Kingdom and Netherlands reports in the short report of the meeting of the Standing Committee held on 17 and 18 September 1998.

309 Consequently, there was nothing to preclude the Community institutions from taking account of those various reports in their assessment of the risks associated with virginiamycin. On the contrary, such an approach made it possible to ensure that the action taken by the Community institutions took account of the most recent results of international research.

310 It follows that the Community institutions did not err in that regard either.

(d) Conclusion

311 In the light of the foregoing, it must be concluded that the Community institutions did not make the errors alleged by Pfizer when they made findings in respect of the relevant facts in this case. The Court must nevertheless consider whether the Community institutions made a manifest error of assessment when they concluded, on the basis of those facts, that the use of virginiamycin as a growth promoter constituted a risk to human health.

4. The errors which the Community institutions are alleged to have made in concluding that the use of virginiamycin as a growth promoter constituted a risk to human health

(a) Introduction

312 Pfizer, supported by the parties intervening on its behalf, argues that the Community institutions were wrong to disregard the conclusions in the SCAN opinion and take the view that the use of virginiamycin as a growth promoter constituted a risk to human health and that preventive protective measures should be taken. The arguments put forward may be reordered in two claims. First, Pfizer claims that human resistance to streptogramins does not have any adverse effects on human health (b). Second, it submits that the Community institutions were not entitled, on the basis of the available scientific data, to find a link between the use of virginiamycin as an additive in feedingstuffs and the development of streptogramin resistance in humans (c).

313 Before ascertaining whether these claims are well founded, the Court will first summarise the scientific background described in the documents before it and recall the purpose and scope of judicial review.

314 As regards the scientific background, the parties are in agreement that the use of virginiamycin as an additive in feedingstuffs constitutes a risk to human health only (i) if, owing to such use, resistance to that antibiotic develops in the animals concerned, (ii) if that resistance can be transferred from animals to humans and (iii) if, owing to the development of resistance in humans, the effectiveness of that antibiotic — or antibiotics of the same class — against certain dangerous infections in humans is eliminated or reduced.

315 It is apparent from the documents before the Court that Pfizer does not dispute that it is broadly accepted by scientists that a consequence of using antibiotics in general, and virginiamycin in particular, as growth promoters is to increase the pool of bacteria resistant to those products in animals. Even though Pfizer argues that there are other explanations for that phenomenon, it does not put forward any specific argument to challenge the conclusion drawn by the Community institutions in that regard in recital 18 to the contested regulation. Moreover, that conclusion was endorsed by SCAN in its opinion (comment on conclusion 1 of the supplementary report from the Danish Veterinary Laboratory).

316 Likewise, it is clear from the documents before the Court that Pfizer does not deny that there is a possibility of cross-resistance between virginiamycin, which is used solely as an additive in feedingstuffs, and other antibiotics of the same class, namely pristinamycin and Synercid.

317 However, Pfizer denies that the Community institutions had a proper scientific basis as regards the other aspects of the link which they found between the use of

virginiamycin as a growth promoter and the development of streptogramin resistance in humans. Those other aspects are, first, the physical movement of resistant bacteria from animals to humans and, second, either the colonisation of the human organism by those bacteria or the transfer of resistance via transmission of genetic information.

318 In that regard, it is clear from the documents before the Court that, for a transfer of antimicrobial resistance from animals to humans to take place, resistant bacteria must first move physically from animals to humans. It is thought that the transfer could take place either via direct human contact with animal excrement or with water contaminated with those bacteria or via the food chain, which could happen if meat is contaminated with resistant bacteria when an animal is slaughtered in unhygienic conditions and if those bacteria survive both rinsing in the slaughterhouse and the preparation and cooking of the meat and pass into the human digestive system.

319 Once resistant bacteria have physically moved from animals to humans, the scientific reports submitted to the Court mention two ways in which actual resistance can be transferred to humans. The first involves resistant bacteria of animal origin colonising the human digestive system, i.e. surviving there and, if they are capable of doing so, causing infections (zoonotic bacteria). The second involves resistant bacteria of animal origin which, whether they are capable of causing infections or whether they are, in principle, harmless to humans (commensal bacteria, such as enterococci), transmit the resistance information 'encoded' in certain of their genes to bacteria normally present in humans which are themselves capable of causing infections (pathogens such as staphylococci).

320 In that regard, moreover, the parties are agreed that, at the time when the contested regulation was adopted, it was not yet scientifically established that the use of virginiamycin as an additive in feedingstuffs had or could have adverse

effects on human health caused by a transfer of antimicrobial resistance from animals to humans. Pfizer nevertheless accepted that the possibility that use of that product would have such a consequence could not be definitively precluded either.

321 Referring to the terms employed at paragraph 147 above, Pfizer accepts that use of virginiamycin entails a 'hazard' to human health. However, it argues that the mere fact that a hazard, within the meaning of those terms, exists is not enough to justify withdrawing authorisation from a product on the basis of the precautionary principle. When questioned at the hearing, the Council stated that in the present case, the mere existence of a 'hazard' within the meaning of the abovementioned terms, associated with the use of virginiamycin as a growth promoter, would not have allowed it to adopt the contested regulation, since any modern pharmaceutical product has some hazards.

322 It is therefore necessary to examine whether, in the present case, the scientific evidence available to the Community institutions was sufficiently reliable and cogent for them to conclude that there was a risk, within the meaning of the term used in paragraph 147 above, associated with the use of virginiamycin as a growth promoter.

323 As regards the purpose and scope of judicial review, the Court observes, first, that in support of their respective arguments, the parties have, both during the written procedure and at the hearing, submitted for review by the Court a large number of arguments of a scientific and technical nature, based on a large number of studies and scientific opinions from eminent scientists. In that regard, it must be borne in mind that where, as in such a situation, the Community institutions are required to make complex assessments of a scientific and technical nature, judicial review is restricted and does not imply that the Community judicature can substitute its assessment for that of the Community institutions (see paragraphs 168 and 169 above).

324 Second, in so far as the parties have referred to information which was not available at the time when the contested regulation was adopted, it must be borne in mind that the assessment made by the Community institutions can be challenged only if it appears incorrect in the light of the elements of fact and law which were available to them at the time when the contested regulation was adopted (see, to that effect, *Wuidart and Others*, cited at paragraph 169 above, paragraph 14, and Joined Cases C-133/93, C-300/93, C-362/93 *Crispoltoni and Others* [1994] ECR I-4863, paragraph 43, and Case T-6/99 *ESF Elbe-Stahlwerke Feralpi* v *Commission* [2001] ECR II-1523, paragraph 93, and the case-law cited there). It follows that, subject to that condition, the information in question cannot be taken into account for the purposes of the review of the legality of the contested regulation.

(b) The adverse effects on human health should streptogramin resistance develop in humans

325 Pfizer maintains, in essence, that even if streptogramin resistance were to develop in humans because of a transfer of resistance, that would not have any adverse effects on human health. It puts forward three lines of argument.

326 First, Pfizer draws attention to the fact that the SCAN opinion concluded that in Denmark existing strategies for coping with infections caused by enterococci and staphylococci remained successful and that the use of streptogramins for the treatment of such infections was not essential. It is apparent from recitals 17 and 21 to the contested regulation that the Community institutions disregarded that aspect of the SCAN opinion and concluded that it was necessary to preserve the effectiveness of streptogramins in human medicine for use as a treatment of last resort.

327 The Court observes *in limine* that SCAN has confirmed, and Pfizer has not disputed, that the development of resistance to antibiotics in bacteria in general, and among enterococci and staphylococci in particular, has been observed worldwide and constitutes a serious threat to human health.

328 Further, as regards more specifically the question of the use of antibiotics belonging to the class of streptogramins to fight infections caused by enterococci and staphylococci, it is clear from the SCAN opinion that streptogramins were not used for the treatment of human infections in Denmark and that, in any event, those antibiotics were not essential for such treatment. Moreover, SCAN noted that in that country infections caused by staphylococci could be treated with the assistance of other antibiotics, notably methicillin. It went on to confirm that a significant increase in methicillin-resistant staphylococci (MRSA) had been observed in certain Member States. In that regard, Synercid, although not yet authorised in Europe at that time, could be used as a treatment of last resort. SCAN noted that that development was relatively unimportant in Denmark and that therefore 'at present, existing strategies for coping with hospital infections caused by enterococci or staphylococci remain successful in Denmark and the [supplementary report from the Danish Veterinary Laboratory] contains no evidence that existing therapies are likely to be compromised in the short term' (comment on conclusion 8 of the supplementary report from the Danish Veterinary Laboratory).

329 It follows, first, that the SCAN finding to which Pfizer draws attention relates solely to the situation in Denmark and is not based on an analysis of the problem at Community level. The Court held at paragraph 184 above that in the procedure laid down in Article 24 of Directive 70/524 it is the responsibility of the Community institutions to carry out a risk assessment at Community level.

330 Second, it is apparent from the SCAN opinion that the presence of staphylococci and enterococci resistant to the antibiotics used until now for the treatment of

infections caused by those bacteria, in particular vancomycin, was perceived as a major problem in human medicine, in particular in the United States but also, to a lesser extent, in certain Member States. Moreover, that finding is corroborated by various reports by international, Community and national bodies produced to the Court. Synercid was, in that regard, seen as a treatment of last resort and preservation of its effectiveness was perceived as imperative. By way of example, in the House of Lords report, the situation was described as follows:

'Enterococci have natural resistance to numerous antibiotics, and cause serious infections in hospitalised immune-impaired patients. Infection with enterococci resistant to the glycopeptide vancomycin (VRE) is almost untreatable... The [WHO] report expresses concern at the possibility of increased dissemination of glycopeptide resistance genes to Enterococci faecalis and their spread to other gram-positive organisms, particularly to MRSA for which vancomycin is the drug of last resort' (paragraph 3.20 of the report).

331 It follows that, analysed at Community level, the development of streptogramin-resistant enterococci and staphylococci in humans was considered a serious threat to public health.

332 Third, as Pfizer points out, it is clear from the SCAN opinion and the various reports produced to the Court that the use of streptogramins in human medicine was still relatively unimportant in Europe, particularly because the rate of increase of VRE and MRSA had been lower than in the United States.

333 However, as Pfizer has itself recognised, that phenomenon has increased in recent years.

334 Furthermore, in response to questions put by the Court, the experts stated at the hearing that anti-microbial resistance has significant long-term effects on public health in that it is a virtually irreversible phenomenon and, therefore, is eliminated, if ever, only long after the antibiotic has ceased to be added to feedingstuffs.

335 The Community institutions cannot be criticised for having taken account of those factors in their assessment at Community level of the risks associated with the use of virginiamycin as a growth promoter (see paragraph 153 above). From that perspective, contrary to the view held by SCAN, which had ruled out any 'immediate' risk, the Community institutions could properly adopt a cautious approach and pursue the objective of preserving the effectiveness of products used in human medicine even though, at the time when the contested regulation was adopted, they were little used in that sphere.

336 Pfizer's first line of argument must therefore be rejected.

337 Second, Pfizer submits that, since the adoption of the contested regulation, the pharmaceutical industry has made unceasing efforts to develop new antibiotics effective in the treatment of bacteria which have become resistant to antibiotics available on the market. In particular, in the United States a new antibiotic, linezolid, has already been authorised for the treatment of *E. faecium* bacteria resistant to other antibiotics. Consequently, even if streptogramin resistance were to be observed in some patients, they could be treated with the new product.

338 In that regard, the Court observes that, when the experts called to give evidence for the institutions were questioned at the hearing, they emphasised, without

being challenged on that point by Pfizer's experts, the great importance in human medicine of the possibility of using several antibiotics to treat the same infection. Therefore, the Court must conclude that, given the fact that the new antibiotics mentioned by Pfizer, in particular linezolid, were not authorised in the Community at the time when the contested regulation was adopted and also the ever-increasing difficulty of creating new antibiotics effective in human medicine, and in view of the increasingly limited number of such antibiotics, the Community institutions could properly take the view that it was necessary to preserve the greatest possible number of antibiotics capable of being used in human medicine, irrespective of the existence of other products.

339 Third, Pfizer observes that *E. faecium* bacteria are, as a general rule, harmless and cause infections only in patients who already have a defective immune system, such as patients suffering from the human immunodeficiency virus ('HIV') or being treated with immuno-suppressive drugs, for example transplant patients. Those patients could, in principle, be treated with other antibiotics and medical complications would arise only if the *E. faecium* bacteria had already developed resistance to every other antibiotic on the market.

340 The Court considers that that argument cannot undermine the validity of the objective pursued by the Community institutions of preserving the effectiveness of streptogramins for the treatment of those infections. The objective of ensuring that patients with a reduced immune system, in particular those suffering from the greatest health scourge of modern times, HIV, are effectively treated is consonant with the objective laid down in the Treaty, namely ensuring a high level of human health protection. Similarly, there are no reasonable grounds for denying that preservation of the effectiveness of medicinal products capable of being used for the treatment of patients needing a particularly high level of

protection, such as transplant patients, is a valid objective. The fact that an antibiotic can only be important in the treatment of a particular category of patients can on no account be a valid reason for not taking all the measures necessary to ensure that it continues to be effective.

341 For all those reasons, the Court must conclude that the Community institutions did not make a manifest error of assessment when they found that the development of streptogramin-resistant enterococci and staphylococci was a serious threat to human health and that it was necessary, in order to prevent that adverse effect for human health from materialising, to preserve the effectiveness of streptogramins so that they may be used now or in the future in human medicine. Consequently, Pfizer's argument that the increase of streptogramin resistance in humans does not entail any adverse effects for human health cannot be accepted.

(c) The link between the use of virginiamycin as an additive in feedingstuffs and the development of streptogramin resistance in humans

342 Recitals 19 and 20 to the contested regulation reveal that when they accepted that there was a link between the use of virginiamycin as a growth promoter and the development of streptogramin resistance in humans, the Community institutions relied, in the main, on the results of recent scientific research submitted by the Danish authorities in support of their safeguard measure. Pfizer submits, in essence, that that research could not constitute a proper scientific basis. Before the merits of Pfizer's arguments are examined, it is appropriate to give a brief summary of the various pieces of scientific research.

(i) Summary of the research referred to in recitals 19 and 20 to the contested regulation

343 With reference to the physical movement of resistant bacteria from animals to humans, the Community institutions referred to a scientific study described in the supplementary report from the Danish Veterinary Laboratory. In that study a significant number of virginiamycin-resistant *E. faecium* bacteria were detected in food originating from pigs (22%) and poultry (54%) in sales outlets in Denmark. The study had shown that there was a high level of human exposure to resistant bacteria through the food chain.

344 Furthermore, the Community institutions cited an observation carried out by scientists from the Danish Veterinary Laboratory, in particular A.E. van den Bogaard, at a farm in the Netherlands, involving the farmer and his poultry. In that case, two strains of *E. faecium* bacteria with the same genetic fingerprint and resistant to virginamycin and pristinamycin were detected, one in the farmer's cells and the other in the excrement of one of the turkeys on his farm ('the Dutch farm observation'). In recital 19 to the contested regulation, the Council noted in respect of that observation that 'even if general conclusions about the transfer of resistant enterococci from animals to humans should not be drawn from a single case, the Commission sees it as an indication that this might be confirmed by other cases in the future'. That observation also demonstrated that the human digestive system can be colonised by resistant bacteria originating in animals.

345 The Community institutions also relied on two scientific studies carried out in laboratory conditions during which the transfer of the *sat A* gene, which confers resistance to virginiamycin on the bacteria concerned, between isogenic strains of *E. faecium* was examined. In the first study the *sat A* gene was transferred *in vitro* from a resistant *E. faecium* bacterium originating in animals to a non-resistant isogenic bacterium, i.e. one with a similar genetic structure ('the *in vitro* study of

genetic transfer'). In the second study (the new study on live rats referred to at paragraph 54 above), which was submitted by the Danish authorities only after the SCAN opinion had been delivered, a transfer of that gene between isogenic strains of *E. faecium* bacteria was demonstrated in live rats, more specifically in the gastro-intestinal tract of rats under experimental conditions.

346 Finally, the Community institutions cited a number of observations described in the Status Report, which indicated that strains of enterococci with genetic factors conferring resistance to virginiamycin existed within the human population.

(ii) Arguments of the parties

347 Pfizer claims essentially that the various pieces of scientific research cited by the Community institutions in recitals 19 and 20 to the contested regulation were not apt to prove that a risk existed, within the meaning of the terms cited above.

348 As regards the Dutch farm observation, Pfizer reiterates the criticism made by SCAN on 10 July 1998 in its opinion, i.e. that it is not possible to conclude from this single and anecdotal incident that *E. faecium* bacteria detected in the farmer originated in one of his turkeys. They could just as easily have a different common source. Similarly, the bacteria could have been transferred from the farmer to his poultry and not the other way around.

349 For the same reason, in Pfizer's submission, the observations relating to the presence of resistant bacteria both in meat intended for consumption and in the human population do not prove conclusively that those bacteria were actually of animal origin.

350 As regards the *in vitro* study of genetic transfer and the new study on live rats, Pfizer relies on the SCAN opinion, in which SCAN pointed out major methodological weaknesses of the experiments and gaps in the scientific data. SCAN's comments on the *in vitro* study of genetic transfer show that the same strain of *E. faecium* bacteria was used as donor and recipient. Given that the probability of a gene transfer is directly related to the similarity of the genetic material of the donor and recipient strains, the use of identical strains significantly increases the probability that gene transfer will occur. Thus there is nothing surprising in the fact that two identical strains of bacteria should reciprocally transfer genetic material between them. The same objections could, in Pfizer's submission, be made in respect of the new study on live rats, in so far as it was conducted under artificial conditions, since the rats used did not have the intestinal flora of animals living in natural conditions. Pfizer therefore maintains that that study, although carried out with live rats, adds little to the first *in vitro* experiment.

351 Pfizer submits that those observations and experiments could in reality serve only as working hypotheses, incapable of demonstrating that a risk existed. Before taking a decision as to whether to withdraw or maintain the authorisation of virginiamycin as an additive in feedingstuffs, the Community institutions should have awaited completion of other scientific research in order to ascertain whether those hypotheses were correct.

352 Before they acted, the Community institutions should, like the competent authorities in the United States and Australia, have embarked on a research

programme designed to ascertain the level of exposure of meat to resistant bacteria in order to obtain reliable data enabling the level of exposure to be quantified and the effectiveness of hygiene measures to be assessed.

353 Likewise, it was also necessary to verify the results of the Dutch farm observation by conducting other observations and experiments in order to be in a position to endorse or rebut the results obtained, which Pfizer deems insufficiently conclusive (Professor I. Phillips stated at the hearing: 'It's an important observation that really needs experimental exploration'). Without such research, the movement of virginiamycin-resistant *E. faecium* bacteria cannot be scientifically proved or disproved, nor can the prevalence of the phenomenon be measured.

354 As regards the *in vitro* study of genetic transfer and the new study on live rats, Pfizer submits that observations and experiments should have been carried out in the real world rather than, as was the case with those two studies, in artificial laboratory conditions. Thus, responding to a written question from the Court, Pfizer maintained:

'The key question, however, is whether this transfer actually happens in the real world'.

355 In Pfizer's submission, the fact that streptogramin resistance has developed in humans can be more plausibly explained by factors other than those connected with the use of virginiamycin as an additive in feedingstuffs.

356 First, referring in particular to the SCAN opinion, Pfizer argues that research carried out in France and the United States has shown that, in spite of the use of virginiamycin as a growth promoter, streptogramins have remained very largely effective in human medicine in those countries. Similarly, Pfizer points out that although virginiamycin has been used for more than 30 years, there is no known case of a patient being infected by streptogramin-resistant *E. faecium* bacterium of animal origin.

357 It goes on to point out that it is well known that certain bacteria, in particular some enterococci, *E. faecalis*, are naturally resistant to streptogramins. Similarly, the development of resistance in humans is, to a large extent, due to the excessive and inappropriate use of antibiotics in human medicine.

358 The Council contends, however, that the various pieces of research referred to in recitals 19 and 20 to the contested regulation together amounted to a coherent body of evidence suggesting that there was a link between the use of virginiamycin as a growth promoter and the development of streptogramin resistance in humans. It denies that the arguments put forward by Pfizer are capable of showing that proposition to be unfounded.

(iii) Findings of the Court

359 In the light of the foregoing, it is appropriate to consider whether the Community institutions could properly disregard the SCAN opinion and conclude that, by virtue of the various scientific studies referred to in recitals 19 and 20 to the contested regulation, they had a proper scientific basis as regards the various stages of the transfer of streptogramin resistance from animals to humans.

360 The Court observes *in limine* that Pfizer (like SCAN in its opinion) does not exclude the possibility that the various stages of the transfer of resistance, as summarised at paragraph 313 et seq. above, may occur.

361 Supported by Professor I. Phillips, Pfizer stated at the hearing that there was no doubt that the physical movement of resistant bacteria from animals to humans might occur. Likewise, in response to a written question put by the Court, Pfizer confirmed that it was not denying that genetic material conferring resistance to virginiamycin could be transferred between isogenic strains of *E. faecium* bacteria under experimental conditions in a laboratory. Pfizer also acknowledges that the results obtained can be explained by the transfer of resistance from animals to humans, even though, in its opinion, other explanations are more plausible.

362 Similarly, the Court observes that Pfizer does not question the relevance of the various observations and experiments cited by the institutions but rather the methods applied and the conclusions drawn from them.

363 As regards the discovery of resistant bacteria on meat intended for consumption, Pfizer has even confirmed, in answer to the Court's written question, that the level of resistant organisms on meat intended for human consumption was a critical component in the assessment of risks to human health associated with that food. Similarly, when questioned at the hearing, Professor I. Phillips confirmed that the Dutch farm observation was, in itself, 'impeccable'. Finally, Pfizer does not question that the *in vitro* experiment on gene transfer and the new study on live rats show that *E. faecium* bacteria can exchange genetic material conferring resistance to virginiamycin amongst themselves, as indeed SCAN confirmed in its opinion (comment on conclusion 4 of the supplementary report from the Danish Veterinary Laboratory).

364 In addition, Pfizer affirms that, as is also clear from the SCAN opinion, other observations and experiments, similar to those referred to in recital 19 to the contested regulation, had already been carried out in respect of other antibiotics.

365 In particular, it is clear from the documents before the Court that observations had been conducted in 1997 on the resistance of *E. faecium* bacteria to another antibiotic, vancomycin (Study by A.E. van den Bogaard and others entitled 'Vancomycin-Resistant Enterococci in Turkeys and Farmers', *The New England Journal of Medicine*, 1997). That study, which was submitted to the Commission by Pfizer in its observations on the Status Report and evaluated in the reports submitted by the Danish authorities and which formed the subject-matter of a number of scientific reports drawn up before the adoption of the contested regulation and submitted to the Court, concludes:

'These findings confirm the high prevalence of vancomycin-resistant enterococci in healthy persons living in areas where avoparcin [the related antibiotic] is used as an antimicrobial growth promoter'.

366 When asked at the hearing whether those studies were relevant to the instant case, Professor I. Phillips, giving evidence for Pfizer, confirmed that that observation 'contributes to the general case'.

367 Similarly, as regards the possibility of a transfer of resistance by means of a temporary colonisation of the human digestive system by resistant bacteria, the Court observes that a study published in 1997 by M. Blom and others entitled 'Ingestion of Vancomycin-Resistant *Enterococcus faecium* Strains of Food [of] Animal Origin by Human Healthy Volunteers' reveals that '[i]ngestion of VRE

strains of food [of] animal origin by healthy volunteers may result in temporary intestinal growth and colonisation. Since vancomycin resistance determinants are transferable, there is a potential risk for transferring vancomycin resistance to the commensal and pathogenic flora during a temporary colonisation'. Although, as Pfizer submits, that study failed to prove that that method of resistance transfer actually occurs, it also failed to disprove the results of research carried out in respect of streptogramins, as Pfizer acknowledged at the hearing.

368 Likewise, a study carried out in 1997 by Woodford and others entitled 'Methicillin-resistant *Staphylococcus aureus* and Vancomycin-resistant enterococci' described observations relating to the resistance of vancomycin-resistant enterococci. The Swedish report referred to at paragraph 46 above summarised that study as follows:

'Woodford and co-workers (1997) reported streptogramin resistance in vancomycin-resistant enterococci (VRE) isolated from raw chicken (3 isolates) and from a hospital patient (1 isolate) in the UK. The resistance trait included cross-resistance to macrolides and lincosamides and was transferable to other enterococci. The authors commented on the fact that no streptogramin is yet licensed for use in human therapy in [the] UK, whereas virginiamycin is widely used for growth promotion in animals. A reservoir of streptogramin resistance may be present in animal bacteria. Since infection with VRE is one of the main indications for quinpristin-dalfopristin [synercid] therapy, acquisition of streptogramin resistance by those organisms is most alarming' (see page 308 of the Swedish report).

369 The Court concludes that the Community institutions had a scientific basis on which to reach a decision, since they could draw on some results of the most recent scientific research on the matter.

370 That being so, Pfizer disputes that that scientific basis was adequate or appropriate. It submits that those various pieces of scientific research did not amount to adequate scientific evidence of a risk associated with the use of virginiamycin as a growth promoter.

371 Pfizer argues essentially that the research in question consisted exclusively of observations and experiments which were not scientifically controlled and that no definitive conclusions can be drawn from the results obtained. Relying in particular on the SCAN opinion, Pfizer submits that that research does not provide a definitive answer to the question whether bacteria discovered on meat intended for consumption or in the digestive system of the Dutch farmer were actually of animal origin. Similarly, Pfizer maintains that it is not possible to determine conclusively from those studies whether the cases examined are isolated cases — as it believes is more plausible and as SCAN maintained ('anecdotal', 'unsound and without foundation') — or whether, on the contrary, the cases examined are evidence of a widespread phenomenon in natural conditions.

372 The Court observes that the weaknesses in the various observations and experiments are not disputed by the defendant, which does not even contend that they admit of scientific certainty or allow any definitive conclusions to be drawn. On the contrary, the parties even seem to be agreed on the reasons for those weaknesses.

373 At the hearing, Professor P. Courvalin, giving evidence for the Community institutions, explained that, inasmuch as *E. faecium* bacteria are found in huge numbers everywhere in the environment, it is physically impossible to retrace their origin with any certainty. Professor I. Phillips, for Pfizer, said more or less the same thing when he stated in essence that, for the same reason, ('It's all over the place. It's in vegetables, it's in fish, it's in all sorts of things that have not been explored') it was in practice extremely difficult, if not impossible, to prove the origin of an *E. faecium* bacterium in an individual case.

374 Likewise, it is apparent from the documents before the Court that the difficulty, even the impossibility, of retracing the origin of *E. faecium* bacteria detected on meat intended for consumption and in the human population had already been raised in the course of the procedure before the Commission culminating in adoption of the contested regulation. In particular, in its submission on the conclusions of the supplementary report from the Danish Veterinary Laboratory, Pfizer stated:

'A potential pathway exists from animal to food either as a result of contamination of the natural environment (e.g. salad) or faecal contamination of carcasses during slaughter and subsequent inadequate cooking before eating. It is much more difficult to show that this movement truly occurs. In reality... it is impossible to fully retrace the path of contamination to the animal. Contamination detected at any point could have come from an extraneous source..., a retrospective study cannot be initiated to categorically determine the original source' (page 18).

375 Similarly, as regards experiments relating to gene transfer, Professor P. Courvalin explained at the hearing, without being challenged by Pfizer's expert witnesses, that, given the large number of bacteria in both the human and animal digestive system, it was physically impossible to observe a gene transfer between two bacteria in natural conditions outside the laboratory ('You cannot pick up two bacteria *in flagrante delicto*').

376 In those circumstances, the Court must consider whether, as Pfizer maintains in reliance on the SCAN opinion, the Community institutions were required to wait until additional scientific research of the type indicated by Pfizer had been carried out or whether, despite the weaknesses of the available research and disregarding the conclusions of the SCAN opinion, they could conclude on the basis of that research that the use of virginiamycin as a growth promoter involved a risk to human health.

377 In that regard, it is appropriate to bear in mind, first, that, when SCAN concluded that the scientific research in question did not justify the safeguard measure taken by the Danish authorities, it, in essence, maintained that although broadly it shared the authorities' concerns, it nevertheless took the view that a full risk assessment should be carried out on the basis of quantitative evidence of the extent of transfer of antimicrobial resistance and the significance of that phenomenon within the overall use of antibiotics (see the SCAN conclusions cited at paragraph 53 above).

It added that 'any risk that might be posed in the future by the use of virginiamycin as a growth promoter will not materialise in the time required to make such an evaluation and most probably not for some years afterwards. In the meantime monitoring initiated by the Danish Government and the EU will be able to detect any significant increases in glycopeptide and streptogramin resistance in enterococci and staphylococci should that occur.'

378 Second, the consequence of Pfizer's argument is that the real purpose of the research which, it submits, should have been carried out before a measure was taken with regard to virginiamycin is to determine conclusively, from experiments conducted in natural conditions, the origin of streptogramin-resistant bacteria detected on meat intended for human consumption and in the human digestive system. A further consequence of that argument is that, in Pfizer's submission, the research should have established whether a transfer between bacteria present in humans of genes conferring streptogramin resistance was possible and the degree of propagation of such genes.

379 Questioned at the hearing about the proof which should, in its submission, have been adduced to justify withdrawing the authorisation of virginiamycin, Pfizer stated: 'It would be proven with the first infection, or with the first proof of colonisation, or the first proof of transfer in a human'. Professor M.A. Pfaller expressed a similar view when he wrote in the scientific opinion submitted by

Pfizer: 'Caution and common sense would dictate that whenever possible, utilisation of agents that represent a therapeutic class as growth promoter should be avoided. However, this is only true if those agents have been documented to create strains of potential human pathogens that are resistant to the therapeutic agent and have been shown to be transmitted (organism or resistance gene) from the animal or food source to humans'.

380 Similarly, at the hearing, Pfizer explained that if in November 1998 a patient had been infected with an *E. faecium* bacterium and if that bacterium had turned out to be resistant to streptogramins, virginiamycin would have had to be removed very rapidly from the market, since in that case adverse effects on health would have been established. However, since, in Pfizer's submission, neither transfer nor infection had ever been observed, the whole question is one of pure speculation.

381 The Court finds that both the view taken by SCAN in its opinion and the arguments put forward by Pfizer are based on an incorrect interpretation of the precautionary principle.

382 First, it must be borne in mind that, when the precautionary principle is applied, the fact that there is scientific uncertainty and that it is impossible to carry out a full risk assessment in the time available does not prevent the competent public authority from taking preventive protective measures if such measures appear essential, regard being had to the level of risk to human health which the public authority has decided is the critical threshold above which it is necessary to take preventive measures.

383 Therefore, Pfizer cannot reasonably criticise the Community institutions for basing themselves on scientific studies which did not admit of scientific certainty as to the link between the use of virginiamycin as an additive in feedingstuffs and

the development of resistance to that product in man. Likewise, contrary to the claim made by Pfizer in reliance on the SCAN opinion, since the scientific data available were inadequate, it was not necessary to carry out a full scientific risk assessment before taking preventive measures in respect of the product (see paragraph 160 above).

384 Second, the Court held at paragraph 141 above that the Community institutions were not required, for the purpose of taking preventive action, to wait for the risk to become a reality and for any adverse effects to materialise.

385 In contrast to the view expressed by SCAN in its opinion, the Community institutions were entitled to take action on the basis of the precautionary principle before quantitative evidence of the extent of the problem posed by the use of virginiamycin as an additive in feedingstuffs was available. Research aimed at obtaining that evidence has as its purpose to observe and analyse the transfer of antimicrobial resistance from animals to humans and, above all, the extent of such transfer and, thus, the reality and the seriousness of any adverse effects of using virginiamycin, which the precautionary principle is specifically intended to prevent.

386 If the Community institutions were unable to take any preventive protective measures until such research was completed, the precautionary principle, the aim of which it to prevent the occurrence of any such adverse effects, would be rendered devoid of purpose.

387 The precautionary principle allows the competent public authority to take, on a provisional basis, preventive protective measures on what is as yet an incomplete scientific basis, pending the availability of additional scientific evidence. As the

Court held at paragraph 161 above, the competent public authority must weigh up its obligations and decide either to wait until the results of more detailed scientific research become available or to act on the basis of the scientific information available. Having taken account, first, of the seriousness of the repercussions should the risk of streptogramin resistance being transferred from animals to humans become a reality and, second, of the results of the scientific research examined above, the Court concludes that the Community institutions did not make a manifest error of assessment when they came to weigh up their obligations.

388 Contrary to what Pfizer submitted at the hearing, the Community institutions were entitled to take preventive protective measures before proof was provided of the first colonisation of the human intestinal system by streptogramin-resistant bacteria of animal origin or of the first case of a transfer of streptogramin resistance from animals to humans. Still less were the Community institutions obliged to await the first case of human infection by a streptogramin-resistant bacterium of animal origin, let alone the first human death to occur when such an infection proved untreatable owing to the development of resistance.

389 In the light of the foregoing, the Court finds that the Community institutions did not exceed the bounds of the discretion conferred on them by the Treaty when they took the view that the various experiments and observations referred to in recitals 19 and 20 to the contested regulation were not mere conjecture but amounted to sufficiently reliable and cogent scientific evidence for them to conclude that there was a proper scientific basis for a possible link between the use of virginiamycin as an additive in feedingstuffs and the development of streptogramin resistance in humans.

390 In those circumstances, Pfizer's arguments that the development of streptogramin resistance in humans can be more plausibly explained by other factors cannot be accepted.

391 Relying on the SCAN opinion and the advice of Professor Casewell and Professor Pugh, Pfizer has, admittedly, put forward a number of factors which could be advanced to counter the argument that there is a link between the use of virginiamycin as an additive in feedingstuffs and the development of streptogramin resistance in humans. In particular, Pfizer has drawn attention to research in France and in the United States which shows that in those countries streptogramins continued to be very effective although virginiamycin had been used there as an additive in feedingstuffs for many years. Similarly, Pfizer maintained that some bacteria had a certain level of natural resistance, which was one plausible explanation for the level of streptogramin resistance observed.

392 However, Pfizer does not claim that those arguments prove conclusively that there is no link between the use of virginiamycin as an additive in feedingstuffs and the development of streptogramin resistance in humans. They merely demonstrate that the existence of such a link is 'very unlikely' and that other 'plausible explanations' existed. Furthermore, the Council and the interveners challenged the merits of Pfizer's arguments relying, in their turn, on experts.

393 It is not for the Court to assess the merits of either of the scientific points of view argued before it and to substitute its assessment for that of the Community institutions, on which the Treaty confers sole responsibility in that regard. In the light of the foregoing, the Court nevertheless finds that the parties' arguments, supported in each case by the opinions of eminent scientists, show that there was great uncertainty, at the time of adoption of the contested regulation, about the link between the use of virginiamycin as an additive in feedingstuffs and the development of streptogramin resistance in humans. Since the Community institutions could reasonably take the view that they had a proper scientific basis for a possible link, the mere fact that there were scientific indications to the contrary does not establish that they exceeded the bounds of their discretion in finding that there was a risk to human health.

394 Finally, it is apparent from the documents before the Court that, at the time when the contested regulation was adopted, other scientists and specialist bodies had taken a different view from that of SCAN and the experts called by Pfizer.

395 The WHO report, referred to at paragraph 37 above, which was adopted in October 1997 following a working meeting attended by 522 specialists from 42 different countries, states that despite the uncertainty 'there is enough evidence to cause concern'. In particular, the report 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.'

396 Similarly, the Copenhagen recommendations include the following passage:

'For many years antibiotics have been used in animal husbandry as growth promoters. The potential for resistance development is our particular concern where similar or closely related antibiotics are or will be developed for use both as growth promoters and for the treatment of human infectious disease. The workshop recognised that this was a controversial subject. The large majority of the workshop considered the use of antibiotics for growth promotion was not justified and agreed with the opinion of the WHO expert meeting that "increased concerns regarding risks to human health resulting from the use of antimicrobial growth promoters indicate that it is essential to have a systematic approach

towards replacing growth promoting antimicrobials with safer non-antimicrobial alternatives"; and recommendations from the Economic and Social Committee of the EU (ESC), that "the emphasis should be first and foremost on limiting the use of antibiotics that can provoke cross resistance to drugs that are or will become relevant to human health care". Several members felt that before an antibiotic is permitted as a growth promoter, its lack of any risk for human health should be demonstrated. The workshop was, however, unanimous that the use of an antibiotic as a growth promoter should be stopped whenever there was clear evidence of a significant risk to human health from such usage.' (Page 35 of the recommendations).

397 Following a thorough analysis of the available scientific data, the authors of the Swedish report came to the following conclusion regarding virginiamycin:

'Increased resistance to... virginiamycin would hamper the therapeutic use of substances from these classes in both animals and humans. Exposure of bacteria to... virginiamycin... selects for resistant strains, usually carrying one or several transmissible resistance determinants. In order not to further diminish their therapeutic value, [virginiamycin] should be restricted to therapeutic use...'

398 Following a thorough analysis of the available scientific data based on an 11-page list of the literature used, the 13 scientists on the Netherlands Health Council stated:

'The Committee concludes that bacterial resistance development in humans is a health risk that cannot be neglected. In spite of the lack of knowledge concerning

the extent to which the use of growth promoters in livestock farming has contributed towards this development, measures to reduce and finally stop the use of antibiotics as growth promoters are justified and necessary' (see page 19 of the Netherlands report).

399 According to that body, there are particularly strong grounds for taking measures as regards products such as virginiamycin, for which the phenomenon of cross-resistance has been established.

400 Similar conclusions are drawn in the House of Lords report. It is apparent from that report that the House of Lords Select Committee on Science and Technology heard a large number of experts, some of whom represented the industry concerned (one of them was in fact employed by Pfizer). In that report the Committee drew, *inter alia*, the following conclusions:

'The new antibiotic Synercid is the PHLS's [Public Health Laboratory Service] best hope as a treatment for multi-resistant enterococci; but resistance to Synercid may have been induced already by use of the related growth promoter virginiamycin, used in pigs, poultry and cattle [paragraph 3.22 of the report]... On the evidence before us... we recommend that antibiotic growth promoters such as virginiamycin, which belong to classes of antimicrobial agent used (or proposed to be used) in man and are therefore most likely to contribute to resistance in human medicine, should be phased out, preferably by voluntary agreement between the professions and industries concerned, but by legislation if necessary...' (paragraph 11.20 of the report).

(d) Conclusion

401 In the light of the foregoing, the Court concludes that Pfizer has not established that the Community institutions erred when they disregarded the SCAN opinion and concluded, on the basis of the scientific knowledge available at the time of adoption of the contested regulation, that the use of virginiamycin as an additive in feedingstuffs entailed a risk to human health.

402 It is clear, on the contrary, that the Community institutions could properly find that there were serious reasons, within the meaning of Article 3a(e) of Directive 70/524, concerning human health for restricting streptogramins to medical use.

403 For the same reasons, Pfizer's argument that the Community institutions applied the so-called 'zero risk' test in this case is also unfounded.

5. Conclusion

404 In view of all of the foregoing, the Court concludes that Pfizer has not succeeded in proving that the Community institutions made errors in their risk assessment.

C — *Errors in managing the risks associated with the use of virginiamycin as a growth promoter*

405 As the Commission has indicated in its Communication on Consumer Health and Food Safety, the Community institutions must, when managing risks, determine the nature and scope of the measures to be taken in the light of the risk assessment.

406 On that point, it is appropriate to bear in mind that the Community institutions enjoy a broad discretion in that respect and that review by the Community judicature must be restricted to examining whether the exercise of such discretion is vitiated by a manifest error or a misuse of powers or whether the Community institutions clearly exceeded the bounds of their discretion (see paragraph 166 above).

1. Breach of the principle of proportionality and of the right to property, errors in the 'cost/benefit' analysis and misuse of powers

(a) Introduction

407 Pfizer argues that the contested regulation was adopted in breach of the principle of proportionality inasmuch as it is a manifestly inappropriate means of achieving the objective pursued and the institutions, which had a choice between a number of measures, failed to choose the least onerous one. Putting forward essentially

the same arguments, Pfizer also maintains that the contested regulation constituted a breach of the right to property and a misuse of powers.

408 Furthermore, in Pfizer's submission, the Community institutions made errors in the 'cost/benefit analysis', in which the costs and benefits to society expected from the action envisaged are compared with the costs and benefits which would apply if no action were taken.

409 Although the Council does not dispute that in a situation such as this the Community institutions were obliged to carry out such an analysis, it contends that no errors were made in that regard.

410 The Court considers that a cost/benefit analysis is a particular expression of the principle of proportionality in cases involving risk management. It therefore considers it appropriate to examine the merits of the arguments relating to that analysis together with those concerning breach of the principle of proportionality.

411 The Court observes *in limine* that the principle of proportionality, which is one of the general principles of Community law, requires that measures adopted by Community institutions should not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question, and where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (*Fedesa and Others*, cited at paragraph 115 above, paragraph 13).

412 Likewise, in matters concerning the common agricultural policy the Community legislature has a discretionary power which corresponds to the political responsibilities given to it by Article 40 of the EC Treaty (now, after amendment, Article 34 EC) and Article 43 of the Treaty. Consequently, the legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate regard being had to the objective which the competent institution is seeking to pursue (*Fedesa and Others*, cited at paragraph 115 above, paragraph 14).

413 In the light of the foregoing, the Court will examine the merits of the parties' arguments regarding the question, first, whether the contested regulation constitutes a manifestly inappropriate means of achieving the objective pursued (b), second, whether other less onerous measures could have been taken (c), third, whether the disadvantages caused by the contested regulation are disproportionate to the objective pursued (d), and, fourth, whether, in the framework of a cost/benefit analysis, those disadvantages are disproportionate by comparison with the advantages which would ensue if no action were taken (e).

(b) Whether the withdrawal of the authorisation of virginiamycin as an additive in feedingstuffs was manifestly inappropriate to the objective pursued

(i) The excessive and inappropriate use of antibiotics in human medicine

414 Pfizer reiterates that in its view the use of virginiamycin as a growth promoter does not constitute a risk to human health. At the very least, the possible or actual transfer of streptogramin resistance from animals to humans is still insufficiently documented. However, Pfizer maintains that there is a broad consensus among experts that the development of antibiotic resistance in humans is primarily due

to the excessive and inappropriate use of antibiotics in human medicine (see paragraph 34 above). The contested regulation was not apt to remedy the situation and was therefore a manifestly inappropriate means of achieving the objective which it pursued, i.e. preservation of the effectiveness of streptogramins in human medicine.

415 The Council does not dispute that the ban on the use of antibiotics as additives in feedingstuffs is only one of the measures for attaining the aim pursued. However, first, the measures envisaged by Pfizer to a large extent fall outside the powers of the Community institutions. Second, the fact that it may be necessary to adopt other measures does not support the conclusion that withdrawal of the authorisation of virginiamycin is inappropriate.

416 The Court observes that it has already held that the Community institutions did not make an error of assessment when they found that, despite existing uncertainty, they had a proper scientific basis on which to conclude that the use of virginiamycin as a growth promoter constituted a risk to human health.

417 It follows, first, that in such circumstances the Community institutions cannot be criticised for having taken protective measures without waiting for that scientific uncertainty to be dispelled.

418 Second, even on the assumption that the Community institutions had the power and the duty to adopt certain other measures to prevent an excessive and inappropriate use of antibiotics in human medicine, that could not affect the validity of the ban on virginiamycin as an additive in feedingstuffs.

419 Furthermore, inasmuch as the Community institutions were entitled to conclude that there was a link between the use of virginiamycin as an additive in feedingstuffs and the development of resistance in humans, the ban on that use constitutes an appropriate, albeit not the only, means of preventing the effectiveness of streptogramins in human medicine from being reduced or even eliminated. In such circumstances, contrary to Pfizer's submission, the Community institutions could reasonably conclude that the adoption of measures intended to reduce or improve the use of antibiotics in human medicine was not an alternative to withdrawing the authorisation of virginiamycin but came under the head of possible further action. The fact that it might be necessary to adopt such further measures does not establish that the contested regulation was inappropriate.

(ii) The negative effects of banning virginiamycin

420 In support of Pfizer, Fedesa and Fefana argue that a side-effect of using virginiamycin in feedingstuffs is improved animal welfare and that its use allows certain diseases to be prevented and the mortality rate in animals to be reduced. Consequently, drawing on reports published following the banning of antibiotics in Sweden and Finland, the interveners submit that the ban on virginiamycin as an additive in feedingstuffs will result in more antibiotics being used for therapeutic purposes in animals. Contrary to what emerges from the reports, use of antibiotics cannot simply be replaced by an improvement in husbandry and hygiene. In a world in which intensive farming plays even more than before a major part in producing more meat at lower cost, that is simply unrealistic ('wishful thinking'), at least in the majority of Member States. Furthermore, the ban on antibiotics which had been authorised as additives in feedingstuffs will result in alternative, unauthorised products being used by farmers, with considerable risk to consumers. In such circumstances, Fedesa and Fefana submit

that the risk of the development of resistance in animals and, consequently, in humans, is greater than if antibiotics continued to be used as growth promoters. Therefore, the adoption of the contested regulation will actually result in an increased — instead of a reduced — risk of resistance developing in humans.

421 The Council, supported in particular by the Kingdom of Denmark, the Republic of Finland and the Kingdom of Sweden, rejects that argument. Those parties contend that experiments carried out in those countries following the ban on the use of antibiotics as growth promoters do not substantiate the arguments put forward by Fedesa and Fefana. On the contrary, better animal husbandry and more hygienic farm conditions, in particular, have made it possible to reduce the use of antibiotics for therapeutic purposes without affecting the competitiveness of farmers in those countries.

422 The Court notes in that regard that, particularly since Sweden banned the use of antibiotics as additives in 1986, several studies have been undertaken with a view to ascertaining the implications of the ban for animal health and for the productivity of farms. The results of those studies have been summarised in some of the reports of national bodies mentioned at paragraphs 36 and 46 above (the Swedish report, the Netherlands report and the House of Lords report (paragraphs 3.27 to 3.29)). They concur, to a large extent, with the results of a study carried out by G. Bories and P. Louisot, dated February 1998, and submitted by Fedesa and Fefana in support of their arguments. In their submission, that study was brought to the attention of the institutions during the procedure culminating in the adoption of the contested regulation.

423 It is clear from the various reports that, although significant difficulties with animal health arose in the first three years following Sweden's ban on the use of antibiotics as growth promoters, considerable progress has been made in terms of hygiene, so that those difficulties have been overcome in recent years. Furthermore, those reports reveal that the total consumption of antibiotics in farming has been reduced since the ban was introduced. Finally, those reports

reveal that, after a phase when productivity declined sharply, Swedish farms have, with the exception of pig farms (- 2%), returned to pre-ban production levels. In total, the ban represented a loss of profit of SEK 74 million for pig farmers and SEK 12 million for poultry farmers.

424 However, as Fedesa and Fefana have pointed out, it is clear from those reports that the relatively positive results observed in Sweden can, in part, be explained by the low density of animals in that country (whose share of Community production does not exceed 1.5%), as compared with other Member States, such as Denmark, the Netherlands or France, which are large Community meat producers and which have more intensive farming methods. It is reckoned that the consequences of any ban in those countries on antibiotics as additives in feedingstuffs will be more negative than those observed in Sweden, both in terms of animal health (and thus in terms of antibiotic use for therapeutic or preventive purposes) and in economic terms (greater loss of profits).

425 However, those reports also reveal that alternative products exist, even though they are regarded by some experts as being less effective, and it is suggested in the reports that changes in farming methods should to some extent allow initial difficulties to be overcome. There are nevertheless differing points of view as regards the extent of those difficulties and the cost to society of such changes in farming methods. The report submitted by Fedesa and Fefana concludes that, although it is perfectly possible to rear animals without using antibiotics as growth promoters, doing so involves an increase both in the cost of meat production and in the quantities of antibiotics administered for therapeutic or preventive purposes. However, in its analysis of the possible consequences of a ban on antibiotics as growth promoters in the Netherlands, the Health Council of the Netherlands concluded that 'events in Sweden since 1986 suggest... that, although problems might initially occur, there is no reason why the therapeutic

veterinary use of antibiotics should increase following the complete withdrawal of [antimicrobial growth promoters]... [I]f appropriate countermeasures were taken, the effect on animal health and welfare would be small' (paragraph 5.3.2 of the Netherlands report).

426 Second, as regards the argument that the ban on virginiamycin as a growth promoter would result in an increase in the use of certain antibiotics for therapeutic purposes in animals, it is reasonable to accept, as the Kingdoms of Denmark and Sweden and the Republic of Finland have submitted, that, even on the assumption that such a correlation were established, the potential effects of an increase in the use of antibiotics for therapeutic purposes would, to some extent, be offset by the fact that antibiotics were no longer being used as growth promoters. As the Council and the interveners have argued, the WHO report reveals that long-term use of a small quantity of antibiotics as growth promoters is alleged to be more dangerous, as regards the development of resistance, than using large doses administered over a shorter period ('[l]ow-level, long-term exposure to antimicrobials may have a greater selective potential than short-term, full-dose therapeutic use').

427 Furthermore, Pfizer has not substantiated its argument that the ban on virginiamycin will result in the unlawful use of unauthorised additives. That argument, supposing it to have some basis, does not call in question the lawfulness of the contested regulation but at the most brings to the attention of the competent authorities the fact that it may be necessary to take appropriate measures to guard against any such unlawful use.

428 Those facts do not establish that the ban on virginiamycin as a growth promoter is a manifestly inappropriate measure. Although in Pfizer's opinion, which is not however shared by all the experts, the ban makes it necessary to change farming methods to avoid too great a use of antibiotics and entails increased production costs for farmers, it is nevertheless the case that the taking of such a measure is a matter for the Community legislature, on which the Treaty confers responsibility

for defining the policy which appears to it to be the most appropriate and power to put into effect, should it deem it necessary, a readjustment of the common agricultural policy.

429 It follows that the Court cannot accept Pfizer's argument that the contested regulation is manifestly inappropriate owing to the negative effects of withdrawing the authorisation of virginiamycin on animal health and, ultimately, human health.

(iii) No action against imports from non-member countries

430 Pfizer and the interveners supporting it point out that the ban on the use of virginiamycin by Community farmers was not accompanied by a ban on imports of meat produced in non-member countries in which its use as a growth promoter is authorised. On the contrary, it is apparent from recent statistics that, since the adoption of the contested regulation, there has been a significant increase in imports from non-member countries of meat from animals raised on feed containing the substances banned by the contested regulation.

431 Pfizer also observes that, following adoption of the contested regulation, the Commission was asked by the Council to present a report before 30 June 1999 on the economic, legal and public health implications of the case at the international level. Pfizer submits that such a report has never been presented by the Commission, which suggests that the contested regulation is a manifestly inappropriate means of attaining the aim pursued.

432 The Council contends that the legality of a measure must be assessed in the light of the legal and factual situation existing at the date of its adoption. At that time, the Council had already asked the Commission to present a report on the measures to be taken at an international level. The fact that the Commission has not yet done so cannot affect the legality of the contested regulation. Furthermore, use of antibiotics as additives by European farmers is in itself more dangerous, since it is thought that the transfer of resistance can take place not only via the food chain but also in other ways. Finally, relatively little meat is imported from non-member countries and the problem caused by those imports is thus negligible.

433 The Court observes, first, that the fact that the Community institutions have not adopted measures at international level against imports of meat produced using virginiamycin as a growth promoter cannot of itself affect the validity of the ban on the use of virginiamycin within the Community. It would rather have to be established that in the absence of any such action the contested regulation was in itself a manifestly inappropriate means of achieving the objective pursued.

434 Pfizer has not adduced any proof that that is so. On the contrary, by way of guidance, the Council, in its defence, submitted to the Court statistics for 1999, whose accuracy and value as a record of imports made before the contested regulation was adopted have not been disputed by Pfizer. It is clear from those statistics that imports of meat from all types of animals amounted to only 2.3% of Community production (3.3% for bovine meat, 0.3% for pig meat, 2.5% for poultry). Furthermore, those statistics show that 82% of beef imports and 82% of pork imports came from countries where antibiotics were not authorised as growth promoters in feedingstuffs at that time. As regards poultry imports, the parties present conflicting data: according to the Council, only 28% of imports came from countries where virginiamycin was still authorised as a growth promoter for chickens; according to Pfizer, that figure was as high as 53%.

435 Replying to the institutions, Pfizer rightly states that, although it is acknowledged that the transfer of streptogramin resistance can take place via the food chain (see paragraph 318 above), those statistics do not indicate that the risk caused by those meat imports is 'negligible'.

436 First of all, however, the Council's assertion that the risk is negligible is not consistent with what it did following adoption of the contested regulation, since it asked the Commission to consider the effect of those imports and to present a report in that regard. The fact that the Commission has not yet followed up that request cannot of itself call in question the lawfulness of the contested regulation.

437 Second, it is evident from those statistics that the institutions did not make a manifest error of assessment when they found that the risk to human health resulting from the import of meat produced using antibiotics as growth promoters was statistically much lower than the risk posed by meat produced with such additives in the Community. Furthermore, it is appropriate to bear in mind (see paragraph 318 above) that the transfer of resistance is thought to take place not only via the food chain but also by humans having direct contact with animal excrement or contaminated water, which does not apply in the case of imported meat.

438 Therefore, the risk to human health from imports of meat produced using antibiotics as additives must be regarded as distinct from the risk where antibiotics are used for the same purposes in the production of meat in the Community and as adding a risk to the latter risk. Consequently, the Community institutions cannot be criticised for having sought initially to eliminate the risk of a transfer of streptogramin resistance associated with the consumption of meat produced in the Community and having then gone on to assess the need for action at an international level.

439 Consequently, Pfizer has not succeeded in proving that, because no action was taken against imports of meat in whose production antibiotics were used as additives in feedingstuffs, the withdrawal of the authorisation of virginiamycin as an additive in feedingstuffs in meat production in the Community was a manifestly inappropriate means of preventing the effectiveness of streptogramins in human medicine from being reduced or even eliminated.

(iv) Conclusion

440 On the basis of the foregoing, the Court concludes that adoption of the contested regulation was not a manifestly inappropriate means of achieving the objective pursued.

(c) The duty to take other, less onerous, measures

441 First, Pfizer submits that the institutions should have awaited the results of the various ongoing studies. Those detailed and expensive studies, some of which were conducted by the industry concerned in cooperation with the Commission, were aimed at finding out whether there was a link between the use of antibiotics, particularly virginiamycin, and the development of resistance to antibiotics in humans. In particular, virginiamycin was undergoing re-evaluation pursuant to Directive 96/51, which provided a suitable framework for examining the issue in detail. The successful conclusion of the studies was jeopardised by withdrawal of the authorisation of virginiamycin. By depriving scientists of the chance to collect data at source, the effect of the measure was to cut off the supply of data to be checked. Pfizer also observes, that, faced with the same problem, the competent

authorities in the United States and Australia did not ban the use of virginiamycin as a growth promoter but decided, in 1999 and 2000 respectively, to embark on detailed studies in order to gather all the relevant evidence, on the basis of which a decision could subsequently be taken.

442 In that regard, the Court observes *in limine* that in the course of the risk assessment the institutions found that there had been a considerable increase in the rate of development of antibiotic resistance during the years preceding adoption of the contested regulation and that, at the same time, the rate at which new antibiotics were put on the market had slowed down. In addition, it has been found that antimicrobial resistance is a virtually irreversible phenomenon (see paragraph 334 above).

443 In such circumstances, and given that the existence of a link between the use of antibiotics as growth promoters and the development of resistance in humans had not yet been scientifically proved but was nevertheless corroborated by a certain amount of reliable scientific data, it was for the Council, on a proposal from the Commission, to exercise its discretion and assume its political responsibilities in the face of a particularly complex and delicate situation.

444 The institutions cannot be criticised for having chosen to withdraw provisionally the authorisation of virginiamycin as an additive in feedingstuffs, in order to prevent the risk from becoming a reality, and, at the same time, to continue with the research that was already under way. Such an approach, moreover, was consonant with the precautionary principle, by reason of which a public authority can be required to act even before any adverse effects have become apparent.

445 Contrary to Pfizer's submission, that finding is not undermined by the fact, even on the assumption that it is correct, that withdrawing the authorisation of

virginiamycin had an adverse impact on the relevance and effectiveness of the studies in progress. When faced with such a choice, the institutions were entitled to give priority to human health protection over the successful conclusion of research in progress and to do so even if the research had, in part, been initiated by the institutions themselves and gave rise to considerable expense for the industry concerned.

446 Furthermore, the documents before the Court show that some of the studies in progress were completed despite adoption of the contested regulation. As regards more specifically the procedure for the re-evaluation of antibiotics during the transitional period, as provided for in Directive 96/51, it should be observed, first, that no provision of that directive prohibits the institutions from initiating the procedure for withdrawal of the authorisation of additives during the transitional period. Second, under Article 2 of the contested regulation, the Commission was obliged to re-examine the withdrawal before 31 December 2000 on the basis of the results of the different investigations concerning the induction of resistances connected with the use of the antibiotics concerned.

447 Likewise, the fact that the competent authorities in the United States and Australia decided to undertake fuller research before taking action does not in itself call in question the lawfulness of the contested regulation. First, the fact that certain authorities adopted a different approach from that taken by the Community institutions does not establish that the institutions' action is disproportionate. Second, as the Council correctly pointed out, risk management necessarily entails political choices which can vary from one society to another according to the threshold of risk deemed acceptable.

448 Consequently, the first argument cannot be upheld.

449 Second, Pfizer goes on to maintain that it would have been possible to provide for veterinary scrutiny of the amount of virginiamycin consumed by different animals or to lower the maximum age limits up to which virginiamycin could be used. At the very least, the institutions ought to have provided for the gradual phasing out of the use of virginiamycin.

450 In that connection, Pfizer has not established whether or how such measures would have allowed the objective pursued by the contested regulation, namely to protect human health, to be achieved. Pfizer and the parties which have intervened in support of it have not succeeded in rebutting the argument of the defendant and the interveners supporting it that such measures are ineffective since antimicrobial resistance is, in the view of the experts, a virtually irreversible phenomenon (see paragraph 334 above) and, therefore, is eliminated, if ever, only long after the antibiotic has ceased to be added to feedingstuffs.

451 Consequently, Pfizer has not shown that other, less onerous, measures existed and would have allowed the objective pursued by the contested regulation to be achieved.

(d) The disproportionate nature of the disadvantages caused by comparison with the objective pursued, and breach of the right to property

452 Referring to the *BSE* judgment, cited at paragraph 114 above, Pfizer argues that withdrawing the authorisation of a product can be regarded as proportionate only if, as in the *BSE* case, there is a serious and identifiable risk causing great uncertainty and if there is evidence that the source against which action is to be taken is the most likely explanation of the risk faced.

453 Referring to the arguments submitted in connection with errors made in the risk assessment, Pfizer submits that, so far as virginiamycin is concerned, those conditions were not met at the time when the contested regulation was adopted. It further points out that it was the only producer of virginiamycin in the world, that the income from that product and substantial investment have been lost because of adoption of the contested regulation and that the regulation gives rise to significant job losses. Likewise, it points out that virginiamycin had been authorised for 30 years as a growth promoter and that the safety and efficacy of the product had been repeatedly checked. Consequently, in its submission, the immediate banning of the product as a growth promoter is a manifestly disproportionate measure.

454 For the same reasons the contested regulation also constitutes an interference with the right to property as recognised in Article 1 of the First Protocol to the European Convention on Human Rights and Fundamental Freedoms. Pfizer accepts that the objective of preserving human health is a legitimate reason for restricting that right. However, in this case, the restriction of its right to property, brought about by the contested regulation, is, in the light of the aim pursued, a disproportionate and intolerable interference with the rights of the owner, impinging upon the very substance of the right to property.

455 Finally, Pfizer submits that the institutions adopted the contested regulation with the sole aim of creating a favourable political impression in the eyes of the press and public opinion, which is tantamount to a misuse of powers.

456 The Court observes that the importance of the objective pursued by the contested regulation, i.e. the protection of human health, may justify adverse consequences, and even substantial adverse consequences, for certain traders (Case C-183/95 *Affish* [1997] ECR I-4315, paragraph 42, and *Fedesa and Others*, cited at paragraph 115 above, paragraph 17). The protection of public health, which the

contested regulation is intended to guarantee, must take precedence over economic considerations (see *Affish*, cited above, paragraph 43).

457 Furthermore, it is settled case-law that although the freedom to pursue a trade or business forms part of the general principles of Community law, that principle does not amount to an unfettered prerogative but must be viewed in the light of its social function. Consequently, it may be restricted, provided that the restrictions imposed in fact correspond to objectives of general interest pursued by the Community and do not, in relation to the aim pursued, constitute a disproportionate and intolerable interference which would affect the very substance of the right so guaranteed (Case 44/79 *Hauer* [1979] ECR 3727, paragraph 23, and Case T-113/96 *Dubois* v *Council and Commission* [1998] ECR II-125, paragraphs 74 and 75).

458 In that regard, it is necessary to start by referring to the conclusions which the Court has drawn from its assessment of the errors which the institutions were alleged to have made in their risk assessment.

459 Then, account must be taken of the fact that the use of antibiotics is not strictly necessary in animal husbandry and that there are alternative methods of husbandry even if they can lead to higher costs for farmers and, ultimately, consumers.

460 In addition, withdrawal of the authorisation of virginiamycin as a growth promoter is a provisional measure which is subject to the Community institutions' duty of re-examination, as is clear from Article 2 of the contested regulation. Finally, it is apparent from Article 3 of the contested regulation that the ban on the use of virginiamycin was subject to a transitional period of six

months, during which the product could continue to be marketed and used in those States which had not banned the product before entry into force of the measure, i.e. all the Member States apart from Sweden and Denmark.

461 From that perspective, the fact that the measure taken in the contested regulation entails serious economic consequences for Pfizer does not mean that it can be described as disproportionate for the purpose of challenging its lawfulness.

462 Pfizer's claim that the contested regulation was adopted with the sole aim of creating a favourable political impression in the press and with public opinion is not borne out by the evidence in the documents before the Court. Rather, those documents show that the contested regulation pursues, above all else, public health objectives. In any event, the restoration of consumer confidence can in such circumstances also be an important objective which may justify even substantial economic consequences for certain traders.

463 In those circumstances, the withdrawal by the contested regulation of the authorisation of virginiamycin as an additive in feedingstuffs is not disproportionate, nor does it amount to an unwarranted restriction of the right freely to pursue a trade or profession or of the right to property, regard being had to the public interest objectives pursued by the Community legislature.

(e) Errors in the cost/benefit analysis

464 According to Pfizer, if the elimination of an identified risk is very costly to society, not only in socio-economic terms but also in terms of well-being and

ethics, or if it leads to situations entailing a higher risk or shifting the risk to another population group, less drastic measures, or even no measures at all, should be considered.

465 In that regard, Pfizer claims that the ban on virginiamycin has a negative impact not only on it but also on farmers and feedingstuff dealers.

466 Virginiamycin has been used for 30 years and, with some variation depending on species, by around 50% of farmers in the European Union; it enables production costs to be kept down. For certain species of animal virginiamycin is the only authorised product on the market. Banning the product will therefore cause farmers and feedingstuff dealers to lose revenue: those facts should have been taken into account in any decision as to what action was appropriate. Anprogapor and Asovac estimate that losses for pork and beef producers in Spain alone will amount to approximately EUR 30 million. They submit that if the Community institutions had carried out a cost/benefit analysis, they would have come down in favour of an alternative, less onerous, solution which would also have achieved the objective pursued.

467 Lastly, Pfizer, together with Fedesa and Fefana, emphasise the fact that the ban on the use of antibiotics as growth promoters has significant adverse effects on the environment, which ought also to have been taken into account by the Community institutions. In their view, use of those products as additives allows waste from farming, such as nitrogen and phosphates, to be reduced and makes it unnecessary to use other additives based on zinc oxide, a heavy metal causing extensive pollution.

468 The Court notes *in limine* that the contested regulation is founded on a political choice, in respect of which the Community institutions were required to weigh

up, on the one hand, maintaining, while awaiting further scientific studies, the authorisation of a product which primarily enables the agricultural sector to be more profitable and, on the other, banning the product for public health reasons.

469 As regards Pfizer's complaint that the institutions, when making their policy choice, did not carry out a cost/benefit analysis, it is apparent from the documents before the Court that an assessment of that kind was made in several of the reports by international bodies which had been submitted to the institutions during the procedure culminating in adoption of the contested regulation and which were examined by the Standing Committee. In particular, the Netherlands report includes an assessment of the possible implications of banning antibiotics as growth promoters. Furthermore, a detailed analysis of Sweden's experience of the economic effects of ceasing to use antibiotics as growth factors can be found in the Swedish report. Similarly, it is clear from the conclusions in the Copenhagen Recommendations that the implications were extensively discussed by specialists from all the Member States, the Commission and the industry (pp. 8 and 9).

470 However, as regards Pfizer's claim that the institutions made errors when weighing up the various options, the Court observes that the legality of the contested regulation could be called in question only if the institutions had made a manifest error of assessment in deciding upon their policy.

471 In that regard, it is appropriate to begin by observing that public health, which the contested regulation is intended to protect, must take precedence over economic considerations (see paragraph 456 above).

472 Next, it is not disputed that use of antibiotics as growth promoters is not essential to meat production. Nor is it disputed that there were alternatives to that practice, even though, as Pfizer maintains, those alternatives make it essential to

alter farming methods and may entail higher production costs and higher meat prices. However, there is nothing to suggest that the policy choice made by the institutions was unreasonable in that regard.

473 Furthermore, following the ban on virginiamycin, farmers could continue to use the four other antibiotics which the Council did not ban under the contested regulation. In that regard it is clear from the lists of antibiotics authorised as growth promoters in the Community that, for almost all the animals for which virginiamycin was authorised before adoption of the contested regulation, an alternative product continued to be authorised.

474 Finally, as regards the arguments concerning increased environmental pollution, it is appropriate to point out, as the Republic of Finland submitted in its statement in intervention, that it is not the ban on the use of virginiamycin as a growth promoter, but a particular agricultural practice, that results in soil pollution and that other measures should be taken to resolve that problem on a broader scale.

475 It follows that the argument that errors were made in the cost/benefit analysis must also be rejected.

(f) Conclusion

476 It follows from all the foregoing considerations that the contested regulation is not vitiated by the breaches and errors pleaded by Pfizer.

2. Breach of the principle of non-discrimination

477 Pfizer also submits that the contested regulation is vitiated by breach of the principle of non-discrimination since other antibiotics, some of which may be used in veterinary or perhaps even human medicine, were not banned. Also discriminatory is the fact that the institutions' approach was highly protective of health by comparison with the risk posed by the use of antibiotics as growth promoters, whilst other hazards to human health, such as that posed by tobacco, are not treated in the same way.

478 The Court observes that the principle of non-discrimination, which constitutes a fundamental principle of law, prohibits comparable situations from being treated differently or different situations from being treated in the same way, unless such difference in treatment is objectively justified (see, for instance, Case C-174/89 *Hoche* [1990] ECR I-2681, paragraph 25; Case C-354/95 *National Farmers' Union and Others* [1997] ECR I-4559, paragraph 61; the *BSE* judgment, cited at paragraph 114 above, paragraph 114; and Case 203/86 *Spain* v *Council* [1988] ECR 4563, paragraph 25).

479 In that regard, it is appropriate to point out that the lack of any action against the use of other substances, even if assumed to be unlawful, could not in itself affect the lawfulness of the ban on virginiamycin (see, to that effect, *Safety Hi-Tech*, cited at paragraph 152 above, paragraph 41). It has been held above that the institutions were entitled to withdraw the authorisation of virginiamycin as an additive in feedingstuffs in the overriding interest of public health protection. Consequently, even if Pfizer had established that the authorisations of other products should also be withdrawn for reasons corresponding to the one which has prevailed in this case, it would not have proved that the contested regulation was unlawful for breach of the principle of non-discrimination, in so far as there is no equality in illegality, since the principle of non-discrimination does not

found an entitlement to the non-discriminatory application of unlawful treatment.

480 It is therefore solely in the interest of completeness that the Court will consider whether the contested regulation treats comparable situations differently and, if so, whether the difference in treatment is objectively justified, regard being had, in that respect, to the Council's broad discretion as regards the objective justification of any different treatment (see Case T-267/94 *Oleifici Italiani* v *Commission* [1997] ECR II-1239, paragraph 47).

481 First, Anprogapor and Asovac have not established in what way the risk posed to human health by certain other products, such as tobacco, and the protective measures that might be taken in that respect are comparable to the risk posed by the use of antibiotics such as virginiamycin as growth promoters.

482 Second, as regards the other antibiotics whose authorisation was not withdrawn by the contested regulation, the Court observes that the aim of the regulation was to withdraw from the market antibiotics which are used not only as growth promoters but also in human medicine or which are known to select cross-resistance with antibiotics used in human medicine. As is apparent from recitals 28, 30 and 31 to the contested regulation, unlike virginiamycin, the antibiotics still available on the market do not belong to either of those categories.

483 Therefore Pfizer has not established that the position of virginiamycin is comparable to that of other antibiotics.

484 Consequently, the contested regulation did not breach the principle of non-discrimination.

3. No transparency in the legislative process

485 Pfizer argues that, contrary to the statement in the Draft Guidelines (paragraph 3.2) mentioned at paragraph 121 above, the Community institutions did not involve all the parties concerned, with maximum transparency, in consideration of the various possible management options once the results of the risk assessment were known. In particular, Anprogapor and Asovac complain that the institutions failed to consult farmers at all before adopting the contested regulation, although farmers were directly affected by the ban.

486 In that regard, it must be borne in mind that the contested regulation was adopted under the procedure laid down in Article 24 of Directive 70/524 and that the provision does not confer on the traders concerned a right to take part in the procedure (see paragraph 121 above). Moreover, the Court held at paragraph 121 above that Pfizer cannot rely on the Draft Guidelines to found such a right.

487 The right to be heard in an administrative procedure taken against a specific person, which must be observed, even in the absence of any rules governing the procedure in question (Case C-32/95 P *Commission* v *Lisrestal and Others* [1996] ECR I-5373, paragraph 21; and Case T-50/96 *Primex Produkte Import-Export and Others* v *Commission* [1998] ECR II-3773, paragraph 59), cannot be transposed to a legislative procedure leading, as in the present case, to the adoption of a measure of general application (Case C-104/97 P *Atlanta* v *European Community* [1999] ECR I-6983, paragraphs 34 and 37; and Case T-521/93 *Atlanta and Others* v *European Community* [1996] ECR II-1707, paragraphs 70 to 74). The fact that Pfizer — unlike the farmers in particular —

is directly and individually concerned by the contested regulation does not alter that finding (*Atlanta* v *European Community*, cited above, paragraph 35; see also the Opinion of Advocate General Mischo in that case, ECR I-6983 at I-6987, points 57 to 70).

488 Furthermore, as Pfizer has itself accepted, the facts show that Pfizer, to a large extent, was able to make its views on the evidence used by the Commission known during the procedure culminating in adoption of the contested regulation.

489 Consequently, the argument Pfizer puts forward here must also be rejected.

4. Conclusion

490 It follows that Pfizer has not proved, either, that the institutions erred in managing the risk associated with the use of virginiamycin as a growth promoter.

D — *Conclusion*

491 Given all of the foregoing, the pleas alleging errors in the risk assessment and risk management and breach of the precautionary principle must be rejected.

II — *The plea alleging breach of the principle of protection of legitimate expectations*

492 Any trader with regard to whom an institution has given rise to justified hopes may rely on the principle of the protection of legitimate expectations (Case 78/77 *Lührs* [1978] ECR 169, paragraph 6; and Case T-489/93 *Unifruit Hellas* v *Commission* [1994] ECR II-1201, paragraph 51). However, a person may not plead a breach of that principle unless he has been given precise assurances (Case T-290/97 *Mehibas Dordtselaan* v *Commission* [2000] ECR II-15, paragraph 59). Likewise, where a prudent and discriminating trader could have foreseen the adoption of a Community measure likely to affect his interests, he cannot plead that principle if the measure is adopted (*Lührs*, cited above, paragraph 6; and *Exporteurs in Levende Varkens and Others*, cited at paragraph 83 above, paragraph 148).

493 Pfizer submits, in the first place, that under Article 11 of Directive 70/524 it could legitimately expect that the Commission would consult SCAN a second time on the new scientific evidence provided by the Danish authorities in August 1998 and referred to at paragraph 54 above.

494 The Court observes in that connection that, in the present case, the Commission was under no obligation to consult SCAN a second time about the new evidence before adopting a decision on the maintenance or withdrawal of the authorisation of virginiamycin as an additive in feedingstuffs (see paragraph 298 above). Pfizer was therefore not entitled to take that provision as a basis for a legitimate expectation.

495 In the second place, Pfizer relies on a statement made by the Member of the Commission responsible for agriculture, Mr Fischler, to the European Parliament on 15 May 1998, in which he emphasised that the withdrawal of antibiotics as growth promoters could be implemented only on the basis of appropriate and detailed scientific arguments. Similarly, Pfizer submits that at a meeting on 23 March 1998 the Commission officials dealing with the case indicated that there might be doubts as to whether the dossier provided by the Danish authorities in support of their safeguard measure included a proper scientific basis on which the authorisation of virginiamycin could be withdrawn. On the basis of those factors, Pfizer submits that it had justified hopes, which were breached by the contested regulation, which, in its submission, was adopted without a proper scientific basis.

496 The Court has also held that the institutions did not err when they took the view, in adopting the contested regulation, that they had a proper scientific basis for taking a preventive protective measure in respect of virginiamycin. Likewise, the Court has also held that, as regards the procedure laid down in Article 24 of Directive 70/524, the Community institutions are under a duty to carry out their own risk assessment and that that assessment is, in that regard, independent of the assessment carried out by the Member State which adopted a safeguard measure. Therefore Pfizer's argument cannot be accepted.

497 In the third place, Pfizer claims that it had a legitimate expectation that no decision would be taken concerning virginiamycin before the results of the various ongoing scientific studies were published, i.e., first, the conclusions of the Surveillance Programme set up in 1998 following the adoption of Directive 97/6 (see paragraph 37 above) and, second, the SSC report (see paragraph 28 above), publication of which was expected to be in May 1999.

498 Pfizer also produces an extract from Mr Fischler's answer to a written question from a Member of the European Parliament given during the session of 20 November 1998. On that occasion, Mr Fischler stated:

'The Commission is aware of the fact that resistance to antimicrobials is a major public health concern.... The Commission has asked the [SSC] to examine this question and its relationship with the use of antimicrobials in human and veterinary medicine, animal husbandry and plant protection. If necessary, the Commission shall propose measures in the light of this scientific opinion, which should be available around April next year...'.

499 According to Pfizer, in making that statement, Mr Fischler gave a specific assurance on behalf of the Commission that no action would be taken before 1999, and that any action would in any event be taken only on the basis of the SSC report, whereas in fact the institutions acted in December 1998 and were thus unable to base themselves on that report.

500 The Court observes, first, that neither the wording of the provisions referred to by Pfizer nor the Surveillance Programme set up by the Commission gives any indication that a decision on withdrawal or maintenance of the authorisation of antibiotics, including virginiamycin, as growth promoters would be conditional upon completion of the relevant research. In particular, Directive 96/51, which provides for the re-evaluation of antibiotics, including virginiamycin, does not preclude the possibility that certain products might be withdrawn even before conclusion of the re-evaluation, on the basis, in particular, of a safeguard measure taken by a Member State.

501 Next, the Court notes, first of all, that Mr Fischler's statement is taken from an answer to a parliamentary question concerning the Commission's policy on the

increase of antibiotic resistance as such. His answer is cast in general terms and cannot therefore give the precise assurance which Pfizer invokes. Furthermore, even though Mr Fischler indicated that the Commission intended to await publication of the SSC report before proposing any measures to be taken, the Council cannot be criticised for having decided, on a proposal from the Commission, for overriding reasons of public health protection and with a proper scientific basis for believing a risk of that kind to exist, to take preventive protective measures and to depart from the broad policy initially adopted.

502 That conclusion is all the more compelling in that, as the Council has rightly pointed out, Pfizer, as a prudent and discriminating operator in the pharmaceutical sector, knew or should have known, since the adoption of Directive 70/524, that where authorisation is granted under that directive it may be withdrawn by means of a safeguard clause. In addition, at least since the Act of Accession was signed by the Kingdom of Sweden, Pfizer, the only producer of virginiamycin, should have known that the Community institutions would take certain measures in respect of that product before the end of 1998. Likewise, the reports from international, Community and national bodies, recent scientific publications, the adoption of Directive 97/6 on avoparcin, the requests for amendment of Directive 70/524 made by the Kingdom of Sweden and the activation of the safeguard clause by the Danish authorities should all have put Pfizer on notice that it was not impossible that the Community institutions would act as they eventually did when they adopted the contested regulation.

503 Consequently, the documents in the case-file to which Pfizer refers do not lead to the conclusion that the institutions gave Pfizer precise assurances capable of giving rise to a legitimate expectation that no decision concerning virginiamycin would be taken before the results of the scientific studies were available and the re-evaluation procedure concluded.

504 Having regard to all of the foregoing, the Court concludes that the contested regulation is not vitiated by a breach of the principle of protection of legitimate expectations. The present plea must therefore be rejected as unfounded.

III — *The plea alleging breach of the obligation to state reasons*

505 In the first part of this plea, Pfizer claims that the preamble to the contested regulation contains a misleading description of the SCAN opinion and, in the second part, it claims that the preamble does not adequately explain the reasons which led to adoption of the regulation.

506 Regarding the first part of the plea, the Court held at paragraph 246 above that the institutions did not distort the SCAN opinion. Therefore, this part of the plea must be rejected as unfounded.

507 As regards the second part of the plea, Pfizer submits that the preamble to the contested regulation does not adequately explain why, despite the SCAN opinion, the Community institutions performed a *volte-face* after receiving the Danish authorities' observations on the SCAN opinion. If the Commission decides to act in spite of the lack of scientific data, or in spite of what is revealed by such data, it must, in Pfizer's submission, provide specific details which will allow the parties concerned and the Court to understand the reasons for its action.

508 Anprogapor and Asovac add that recital 26 to the contested regulation acknowledges that the ban on additives is only one of the possible means of achieving the objective of the regulation but that those alternative means are not specified.

509 The Council contends that the preamble to the contested regulation sets out concisely and comprehensively the objective of the regulation and the background against which it was adopted.

510 The Court observes that the statement of reasons required by Article 190 of the EC Treaty (now Article 253 EC) must be appropriate to the act at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in question in such a way as to enable the persons concerned to ascertain the reasons for the measure, in order to defend their rights, and to enable the Community Courts to exercise their power of review. It is not necessary for the reasoning to go into all the relevant facts and points of law, since the question whether the statement of reasons meets the requirements of Article 190 of the Treaty must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter in question (Case C-265/97 P *VBA* v *Florimex and Others* [2000] ECR I-2061, paragraph 93). In particular, in the case, as here, of measures of general application, it has consistently been held that the statement of reasons may be confined to indicating the general situation which led to its adoption, on the one hand, and the general objectives which it is intended to achieve, on the other (Case C-150/94 *United Kingdom* v *Council* [1998] ECR I-7235, paragraph 25 and the case-law cited there).

511 The Court finds that the first argument is founded on an incorrect assumption. The preamble to the contested regulation unequivocally shows that the institutions took the view that, on the basis of the SCAN opinion (recitals 15 to 19) and the scientific reports referred to in recital 23, they had sufficient information to take a preventive measure. Contrary to Pfizer's assertion, nothing suggests that, following the submission of new evidence by the Danish authorities in August 1998, the institutions suddenly performed a *volte face* in relation to the

risk posed by the use of virginiamycin as a growth promoter. On the contrary, it is clear from recital 20 to the contested regulation that the new study on live rats mentioned at paragraph 54 above is just one of the items which the institutions took as their basis.

512 Furthermore, the preamble to the contested regulation (in particular recital 16) clearly and unequivocally shows that the institutions did not accept the conclusions in the SCAN opinion, in particular SCAN's view that it was not possible to carry out an adequate scientific assessment on the basis of the scientific data available.

513 As to the second argument, the background to the contested regulation clearly shows that the measure which it implements forms part of a series of measures taken by the institutions in order to preserve the effectiveness of antibiotics used in human medicine. Those measures include the establishment of a surveillance programme, the systematic taking into account of ongoing research and of the SSC report at the time of the re-examination of the ban on virginiamycin, and the re-evaluation of authorised additives provided for in Directive 96/51. Moreover, recitals 28 and 30 to 32 to the contested regulation show that, as regards certain other antibiotics which were not used in human medicine, the institutions took a different approach, namely to await the results of ongoing research before deciding whether to maintain or withdraw the authorisations.

514 In the light of the foregoing, the plea alleging breach of the obligation to state reasons must also be rejected as unfounded.

515 Since none of the pleas put forward to challenge the contested regulation has been upheld, the application must be dismissed as unfounded.

Costs

516 Under Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since Pfizer has been unsuccessful, it must be ordered to pay the costs of these proceedings, including those relating to the proceedings for interim relief, in accordance with the form of order sought by the Council.

517 Under Article 87(4) of the Rules of Procedure, the Court may order an intervener to bear its own costs. Anprogapor, Asovac, Fedesa and Fefana, which have intervened in these proceedings on behalf of the unsuccessful party, are to bear their own costs and to pay those incurred by the Council in respect of their intervention in the main proceedings and the proceedings for interim relief.

518 The Asociación española de productores de huevos and the Pig Veterinary Society are to bear their own costs and to pay those incurred by the Council in respect of their applications for leave to intervene, those costs having been reserved in the order of 25 June 1999 by which their applications for leave to intervene were dismissed (see paragraph 63 above).

519 Under Article 87(4) of the Rules of Procedure, the Member States and institutions which intervened in the procedure are to bear their own costs. Consequently, the Commission, the Kingdom of Denmark, the Kingdom of Sweden, the Republic of Finland and the United Kingdom of Great Britain and Northern Ireland are to bear their own costs both in the main proceedings and in the proceedings for interim relief.

On those grounds,

THE COURT OF FIRST INSTANCE (Third Chamber),

hereby:

1. Dismisses the application;

2. Orders Pfizer to bear its own costs and to pay those incurred by the Council, including those relating to the proceedings for interim relief;

3. Orders the Asociación nacional de productores de ganado porcino, the Asociación española de criadores de vacuno de carne, the Fédération européenne de la santé animale and the Fédération européenne des fabricants d'adjuvants pour la nutrition animale to bear their own costs and to pay those incurred by the Council in respect of their intervention in the main proceedings and the proceedings for interim relief;

4. **Orders the Asociación española de productores de huevos and the Pig Veterinary Society to bear their own costs and to pay those incurred by the Council in respect of their applications for leave to intervene;**

5. **Orders the Commission, the Kingdom of Denmark, the Kingdom of Sweden, the Republic of Finland and the United Kingdom of Great Britain and Northern Ireland to bear their own costs, both in the main proceedings and in the proceedings for interim relief.**

Azizi Lenaerts Jaeger

Delivered in open court in Luxembourg on 11 September 2002.

H. Jung M. Jaeger

Registrar President

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