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

In Case T-70/99,

Alpharma Inc., established in Fort Lee, New Jersey (United States of America), represented by G. Robert, Solicitor, and B. Van de Walle de Ghelcke, lawyer, with an address for service in Luxembourg,

applicant,

v

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

defendant,

* Language of the case: English.

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

Republic of Finland, represented by H. Rotkirch, T. Pynnä and E. Bygglin, acting as Agents, 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,

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 3 July 2001,

gives the following

Judgment

Legislative 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 the first subparagraph of point E1(4) of Title VII of Annex XV to 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. According to the second subparagraph of that provision, 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 25 to 27 and 29 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 Under the original rules, Article 7(1) of Directive 70/524, which was repealed by Directive 96/51, provided that '[a]mendments to be made to Annexes on account of the growth of scientific and technical knowledge shall be adopted in accordance with the procedure laid down in Article 23'. Furthermore, Article 7(2)(A) of that directive set out the conditions on which additives could be included in Annex I thereto. Article 7(2)(B) stated that '[a]n additive shall be deleted from Annex I if any of the conditions listed under A is no longer satisfied'.

18 Under the new rules, Article 9m of Directive 70/524, as amended by Directive 96/51, provides that the authorisation of an additive is to be withdrawn by means of a regulation, *inter alia*, 'if any of the conditions for the authorisation of the additive referred to in Article 3a are no longer met' (second indent). Under the new Article 9r, '[a]mendments to be made to the Annexes shall be adopted in accordance with the procedure laid down in Article 23'.

19 Article 23 of Directive 70/524, as amended by Directive 84/587 and most recently by Annex I to the Act of Accession, provides:

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

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 on the draft within a time-limit which the chairman may lay down according to the urgency of the matter. 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 three months 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.'

20 Furthermore, under Article 11 of Directive 70/524, as amended by Directive 84/587, 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.

3. The transitional rules

21 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.

22 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).

...'

23 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.

24 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', 'SCAN' and the Scientific Steering Committee*

25 The Standing Committee for Feedingstuffs ('the Standing Committee'), which is referred to in Article 23 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.

26 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....'

27 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.'

28 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.'

29 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

30 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.

31 Certain antibiotics, including bacitracin zinc, 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.

32 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

by 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'.

33 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.

34 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.

35 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.

36 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.

37 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/EEC concerning additives in feedingstuffs (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 ESC Opinion'); 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'.)

38 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 where, first, 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.

39 Bacitracin zinc is an antibiotic used as a growth promoter for livestock and also in the treatment of certain infections in human medicine.

40 The parties disagree as to whether and to what extent bacitracin zinc does or might play a role in human medicine, in particular for 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'). However, the potential effectiveness of treatment of those infections with bacitracin zinc could be reduced or even eliminated by any transfer from animals to humans of resistance to that product.

41 It is common ground between the parties, and is apparent from the recitals 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 bacitracin zinc.

The procedure leading to the adoption of the contested regulation

42 At the time when the contested regulation was adopted, Alpharma Inc. ('Alpharma') was the only manufacturer and the largest supplier of bacitracin zinc in the European Economic Area. It marketed that product, which was manufactured in Norway, under the name 'Albac'.

43 Bacitracin zinc was authorised as an additive in feedingstuffs for certain poultry, calves, lambs and kids, pigs and animals bred for fur when Directive 70/524 entered into force and was included in Annex I to that Directive. That authorisation was subsequently extended to other animals. Bacitracin zinc was also included, as an additive in the feedingstuffs of certain animals, in Annex II to that directive. In particular, a new use for bacitracin zinc for chickens for fattening and pigs was authorised and included in Annex II by Commission Directive 94/41/EC of 18 July 1994 amending Council Directive 70/524 (OJ 1994 L 209, p. 18). By Commission Regulation (EC) No 2786/98 of 22 December 1998 concerning the modification of the period of authorisations of additives referred to in Article 9i(1) of Directive 70/524 (OJ 1998 L 347, p. 25), the period of those authorisations was extended until 17 July 1999. In certain cases the authorisation of bacitracin zinc was granted 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 bacitracin zinc 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 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 bacitracin zinc ('the Swedish report'). At point B.10 (p. 244) of that report, the following conclusions were drawn as regards bacitracin zinc:

'Bacitracin has a bactericidal effect mainly on gram-positive bacteria, by inhibiting the formation of bacterial cell wall peptidoglycan. It is used, albeit not to any large extent, in both human and animal therapy. Lately it has been increasingly used for the treatment of vancomycin-resistant enterococci in humans.

In-feed bacitracin affects the antimicrobial resistance of the intestinal microflora, mainly in *E. faecium* but possibly also in other species.

Data available on colonisation by enteric pathogens in animals fed bacitracin [are] too inconsistent and too scarce to form the basis of any firm conclusions about the effects of bacitracin.

Bacitracin administered at growth promoting concentrations has prophylactic and therapeutic effects on necrotic enteritis in poultry.

Allergic reactions to bacitracin are documented in humans undergoing bacitracin treatment. People who are exposed to the substance on a daily basis may be at risk of being sensitised.

Bacitracin is degraded in soil. The environmental degradation appears to be inversely related to soil temperature.

In conclusion, available information is too scarce for an assessment of the possible risks of bacitracin usage to human and animal health. Bacitracin usage does not appear to represent any substantial danger to the environment.'

45 Following those requests for adaptation, the Standing Committee discussed the Swedish report on a number of occasions. Similarly, that report was included on the agenda of a number of SCAN meetings. At the meeting held on 16 and 17 April 1998, the SSC decided to set up a multidisciplinary working group to examine the problem of antibiotic resistance and to present a report on the subject towards the middle of 1999.

46 On 6 June 1998, Alpharma, pursuant to Articles 9g(2) and 9h(2) of Directive 70/524, lodged new applications for the authorisation of bacitracin zinc as an additive the authorisation of which is linked to a person responsible for putting it into circulation.

47 Following the request for adaptation of Directive 70/524 presented by the Swedish authorities and the setting-up of the Surveillance Programme (see paragraph 38 above), on 21 August 1998 Alpharma sent the United Kingdom of Great Britain and Northern Ireland, the Member State acting as rapporteur for the purposes of the application for authorisation of bacitracin zinc, information concerning the resistance to that product. At Alpharma's request, the United Kingdom forwarded that information to the Commission, the member States of the European Economic Area, the members of SCAN and the members of the Standing Committee.

48 On 5 November 1998, Alpharma was informed by the Fédération européenne des fabricants d'adjuvants pour la nutrition animale ('Fefana') that the Commission had drawn up a draft proposal for a regulation including bacitracin zinc on the list of antibiotics banned as additives in feedingstuffs. That was confirmed to Alpharma on 6 November 1998 by the Belgian member of the Standing Committee. On 9 November 1998, Alpharma received a copy of the Commission's draft proposal from the same member of the Standing Committee.

49 Between 10 November and 13 December 1998, Alpharma sent a large number of letters, together with scientific opinions, to Mr Fischler, the Member of the Commission responsible for agriculture, to the authorities of the United Kingdom (the Member State acting as rapporteur), to the United Kingdom member of the Standing Committee, to certain other authorities of the Member States and to the Commission, expressing its concern about the proposal to ban bacitracin zinc and requesting a hearing by the Commission on the subject.

50 On 12 November 1998, a meeting was held between, in particular, Alpharma, the Commission services dealing with the matter and members of Mr Fischler's cabinet.

51 On 30 November 1998, the Commission services informed Alpharma that its observations would be taken into account when the draft regulation was being examined.

52 On 11 December 1998, a second meeting took place between Alpharma and the responsible services of the Commission.

The contested regulation

53 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:

— bacitracin zinc,

...

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.

...'.

54 Recital 22 to the contested regulation is worded as follows:

'Whereas bacitracin zinc, a cyclic polypeptide, is also used in human medicine mainly for topical treatment of infections of the skin and mucosal surfaces; whereas publications show that it could possibly be used for the treatment of

vancomycin resistant enterococci, which represent a clinical problem in human medicine; whereas selected resistances from the use of bacitracin zinc as a feed additive inevitably increase the reservoir of resistances to bacitracin zinc; whereas the percentage of [*E. faecium*] resistant to bacitracin zinc is higher in chickens which have received bacitracin zinc than in chickens which have not received it; whereas these resistances could be transferred from animals to humans and reduce the effectiveness of bacitracin zinc used as a human medicinal product; whereas the effectiveness of bacitracin zinc in human medicine should therefore be preserved.'

Procedure

55 By application lodged at the Registry of the Court of First Instance on 11 March 1999, Alpharma brought the present action.

56 By separate document lodged at the Court Registry on 14 April 1999, the Council raised an objection of inadmissibility pursuant to Article 114(1) of the Rules of Procedure of the Court of First Instance. 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 Council, which the Council answered within the period allowed.

57 By separate document lodged at the Court Registry on 11 March 1999, Alpharma also applied, pursuant to Articles 185 and 186 of the EC Treaty (now Articles 242 EC and 243 EC), first, for suspension of operation of the contested regulation pending judgment in the main action and, second, for the adoption of

any other measures deemed appropriate. By order of 30 June 1999 in Case T-70/99 R *Alpharma* v *Council* [1999] ECR II-2027, the President of the Court of First Instance dismissed the application for interim relief.

58 Upon application by them, the President of the Third Chamber of the Court of First Instance, by orders of 19 May and 11 October 1999, granted the Commission, the Republic of Finland, the Kingdom of Sweden and the United Kingdom 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 10 August 1999 (the Commission) and 30 November 1999 (the United Kingdom). By letter of 16 August 1999, the Republic of Finland stated that it did not intend to lodge observations as to admissibility. The Kingdom of Sweden did not lodge observations on admissibility within the period allowed. 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) and 25 July 2000 (the Commission).

59 The written procedure was closed by the lodging of the rejoinder on 10 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 January and on 20 and 27 June 2001, the Court called on the parties to reply to certain questions and to produce certain documents. The parties complied with those requests.

60 The parties were heard in oral argument and answered questions put to them by the Court at the hearing on 3 July 2001. At the hearing the Court asked the Council and the Commission to produce documents. Once they had complied with that request, Alpharma was requested to submit its observations on those documents. On 4 September 2001, the President of the Third Chamber of the Court of First Instance closed the oral procedure.

Forms of order sought

61 Alpharma claims that the Court should:

— annul Regulation No 2821/98 in its entirety or in so far as it concerns bacitracin zinc;

— order the Council to pay the costs.

62 The Council contends that the Court should:

— dismiss the action as manifestly inadmissible;

— in the alternative, dismiss the action as unfounded;

— order Alpharma to pay the costs.

63 The Commission, the Kingdom of Sweden, the Republic of Finland and the United Kingdom of Great Britain and Northern Ireland, interveners, support the form of order sought by the Council.

Admissibility

Arguments of the parties

64 The Council begins by observing that Alpharma, 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.

65 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.

66 In the alternative, the Council contends that the contested regulation is not of individual concern to Alpharma 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 bacitracin zinc, in particular, there is nothing to distinguish Alpharma 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.

67 Nor can the action be considered admissible on account of the contacts which Alpharma 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.

68 In particular, according to the Council, the fact that Alpharma participated in the procedure laid down by Articles 9g and 9h of Directive 70/524, as inserted by Directive 96/51, does not mean that Alpharma is individually concerned by the contested regulation. The re-evaluation procedure is undertaken between the Member State acting as rapporteur and the Commission. Referring to Case 38/64 *Getreide-Import* v *Commission* [1965] ECR 203, the Council adds that the fact that Alpharma was the only undertaking to apply for authorisation of bacitracin zinc with a view to its re-evaluation pursuant to Articles 9g and 9h does not alter that conclusion. There is a fundamental difference between the re-evaluation procedure and the procedure which led to the adoption of the contested regulation. Whereas the re-evaluation procedure would have led to the adoption of an act marking the conclusion of an individual procedure following the application for authorisation submitted by Alpharma itself, the contested regulation has a different legal basis and an entirely different objective. Furthermore, unlike the situation in Case T-120/96 *Lilly Industries* v *Commission* [1998] ECR II-2571, Alpharma played no part in the procedure.

69 Alpharma'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 Alpharma or by anyone else under a different name. Therefore Alpharma 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.

70 The Commission adds that, as regards the nature of the contested regulation, it is purely by chance that there was only one producer of bacitracin zinc in the European Economic Area. The fact that Alpharma was the only manufacturer of bacitracin zinc there did not mean that it had a manufacturing monopoly and there was nothing to prevent another undertaking from manufacturing the substance concerned.

71 The United Kingdom contends in particular that Alpharma is not differentiated from all other persons by reason of being the only one to have submitted an application for re-evaluation under Article 9g. Following the adoption of the contested regulation, neither Alpharma nor any other trader could submit an application for authorisation, whether it was based on Article 9g, in Alpharma's case, or on Article 4, in the case of any other trader. Nor is Alpharma individually concerned because it participated in the administrative procedure. In the present case, the applicable legislation contains no specific provision requiring the Community institutions to take Alpharma's specific situation into account.

72 Alpharma maintains that the contested regulation is in the nature of a decision addressed to it. In any event, Alpharma is directly and individually concerned by the measure.

Findings of the Court

73 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).

74 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).

75 In this instance the contested regulation provides for withdrawal of the authorisation to market certain additives in feedingstuffs, including bacitracin zinc, 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.

76 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*, cited at paragraph 69 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).

77 In so far as the contested regulation concerns additives other than bacitracin zinc which are not manufactured by Alpharma, the Court finds that it does not have any effect on Alpharma'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 bacitracin zinc.

78 As regards the requirement that the contested regulation should be of direct concern in so far as it concerns bacitracin zinc, 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).

79 As the Council recognises, Alpharma is directly concerned by the contested regulation in so far as it withdraws the authorisation of bacitracin zinc 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 Alpharma's authorisation to market that substance.

80 As to whether Alpharma is individually concerned by the contested regulation in so far as it concerns bacitracin zinc, 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 69 above, paragraph 20; and Case T-12/93 *CCE de Vittel and Others* v *Commission* [1995] ECR II-1247, paragraph 36).

81 Contrary to Alpharma's submission, the fact that at the time when the contested regulation was adopted Alpharma was the only manufacturer and by far the largest supplier of bacitracin zinc in the European Economic Area is not, in itself, such as to distinguish Alpharma 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 (judgment in Case C-213/91 *Albertal 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).

82 However, it is appropriate to analyse the provisions under which the contested regulation was adopted in so far as the latter concerns bacitracin zinc in order to ascertain whether Alpharma 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.

83 Although the withdrawal of the authorisation of bacitracin zinc was adopted on the basis of the procedure laid down in Article 23 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 22 to 24 above).

84 Bacitracin zinc 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 Alpharma has pointed out, competitors had material difficulties in producing and marketing bacitracin zinc, from a legal standpoint any natural or legal person who met the abovementioned criteria could market it.

85 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.

86 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.

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

88 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.

89 In the present case Alpharma, the only producer and largest supplier of bacitracin zinc in the European Economic Area, made applications on 6 June 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, Alpharma 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 bacitracin zinc 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 bacitracin zinc, as provided for in Article 2 of the contested regulation, that product had been authorised again, only Alpharma, following the re-opening of the re-evaluation procedure, would have been in a position to obtain a new authorisation of bacitracin zinc 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 bacitracin zinc into circulation, since the re-evaluation procedure laid down by Directive 96/51 was still continuing, Alpharma was already able to rely on an inchoate right in that regard.

90 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, Alpharma 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 69 above).

91 Therefore, under the broad scheme of Directive 70/524, as amended by Directive 96/51, manufacturers who, like Alpharma, 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, those manufacturers 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.

92 Consequently, even before the end of the transitional period, Alpharma was affected by withdrawal of the authorisation of bacitracin zinc 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.

93 As to Alpharma'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 23 of Directive 70/524 and that that provision does not entitle the traders concerned to take part in the procedure (see paragraph 17 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 76 above; and the order in Case T-585/93 *Greenpeace and Others* v *Commission* [1995] ECR II-2205, paragraphs 56 and 63).

94 Account must nevertheless be taken of the fact that, by making new applications for authorisation of bacitracin zinc in accordance with paragraphs (2) and (4) of Article 9g of Directive 70/524, as amended by Directive 96/51, Alpharma 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.

95 Although it is true, as the Council has pointed out, that the procedure in Article 23 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 Alpharma's application for a new authorisation.

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

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

98 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 bacitracin zinc as an additive in feedingstuffs.

Substance

99 Alpharma puts forward four pleas in law alleging, respectively, breach of essential procedural requirements (first plea), manifest errors of assessment (second plea), infringement of fundamental principles of Community law (third plea) and breach of the obligation to state reasons (fourth plea).

100 In the context of the plea alleging manifest errors of assessment, Alpharma relies essentially on errors, first, in the risk assessment and, second, in the application of the precautionary principle. By the plea alleging infringement of essential principles of Community law, it claims that the contested regulation breaches the principles of proportionality and protection of legitimate expectations and that it breaches the rights of the defence. A number of the arguments raised in relation to those pleas overlap.

101 The Court considers it appropriate to deal with those pleas in a different order and will begin by examining the plea alleging breach of essential procedural requirements (I). It will then analyse the plea alleging manifest errors of assessment in so far as it concerns the claim that the Community institutions did not properly assess the risks associated with the use of bacitracin zinc as an additive in feedingstuffs. In doing so, the Court will take account of a number of the arguments put forward in the second part of that plea (II). Then, taking into account the remaining arguments put forward in the context of the second part of the second plea, relating to errors in the application of the precautionary principle, the Court will consider whether the contested regulation is vitiated by a breach of the principle of proportionality (III) and the principle of protection of legitimate expectations (IV) and whether it was adopted in breach of Alpharma's rights of defence (V). Last, it will consider whether the contested regulation breaches the obligation to state reasons (VI).

I — *Breach of essential procedural requirements*

102 This plea consists of two parts. First, Alpharma alleges that the contested regulation has no clear legal basis. Second, it maintains that the contested regulation has an illegal combination of legal bases.

A — *The absence of a clear legal basis*

103 First, Alpharma maintains that in the present case Article 151 of the Act of Accession cannot as such constitute the appropriate legal basis of the contested regulation. It submits that that provision merely authorises the Kingdom of Sweden to maintain in force for a transitional period its national legislation banning the use of antibiotics as growth promoters and does not confer power on the Council to impose such a ban at Community level.

104 The Court finds that it follows from the preamble thereto that the contested regulation was adopted on the basis of Article 151 of the Act of Accession in conjunction with point E1(4) of Title VII of Annex XV to the Act of Accession, and of Article 11(3) of Directive 70/524. As regards bacitracin zinc, it is common ground between the parties that, since no safeguard measures had been taken in respect of that product, the contested regulation cannot have been adopted on the basis of Article 11(3) of Directive 70/524.

105 It is necessary to consider, therefore, whether Article 151 of the Act of Accession, in conjunction with point E1(4) of Title VII of Annex XV thereto, could constitute an appropriate legal basis for the adoption of the contested regulation in so far as it relates to bacitracin zinc.

106 In the context of the organisation of the powers of the Community the choice of a legal basis for a measure must rest on objective factors which are amenable to judicial review. Those factors include in particular the aim and the content of the measure (Case C-36/98 *Spain* v *Council* [2001] ECR I-779, paragraph 58; Case C-269/97 *Commission* v *Council* [2000] ECR I-2257, paragraph 43; Case C-300/89 *Commission* v *Council* [1991] ECR I-2867, paragraph 10; and Case T-106/96 *Wirtschaftsvereinigung Stahl* v *Commission* [1999] ECR II-2155, paragraph 109).

107 A provision of an Act of Accession may serve as the legal basis on which to adopt legislative measures (see, to that effect, Case C-259/95 *Parliament* v *Council* [1997] ECR I-5303, concerning the legality of a Council Decision adopted on the basis of an Act of Accession).

108 It follows from the first subparagraph of point E1(4) of Title VII of Annex XV to the Act of Accession (see paragraph 2 above) that the first subparagraph, together with Article 151 of that Act (see paragraph 1 above), constitutes the legal basis on which the Kingdom of Sweden may, during a transitional period, derogate from the provisions of Directive 70/524. On the other hand, the second subparagraph of point E1(4) of Title VII of Annex XV to the Act of Accession, in conjunction with Article 151 of the Act of Accession, constitutes a specific legal basis on which the Community institutions may adopt appropriate measures for the purpose of ensuring the uniform application of Directive 70/524 in all Member States at the end of the transitional period, i.e. after 31 December 1998. It is not disputed that in the present case both the aim and the terms of the contested regulation were consistent with that purpose.

109 It follows that Article 151 of the Act of Accession, in conjunction with point E1(4) of Title VII of Annex XV thereto, could serve as the legal basis for the adoption of the contested regulation.

110 Second, Alpharma submits that, even if Article 151 of the Act of Accession, in conjunction with point E1(4) of Title VII of Annex XV thereto, could serve as the legal basis for the contested regulation, that legal basis was not sufficiently precise as regards the procedure to be followed in adopting that regulation. It states that the second subparagraph of point E1(4) of Title VII of Annex XV to the Act of Accession refers to 'Article 7 of Directive 70/524/EEC', which at the time when the contested regulation was adopted had already been repealed by Directive 96/51 and replaced by other provisions, notably Article 9m. In referring to Article 2 of Directive 96/51 (see paragraph 6 above), Alpharma observes that when the contested regulation was adopted Article 9m was not yet in force. It further states that that provision is not referred to in the contested regulation.

111 In those circumstances, according to Alpharma, the contested regulation must be annulled in so far as the Council failed to meet its obligation to state clearly the legal basis of the contested regulation (Case C-325/91 *France* v *Commission* [1993] ECR I-3283, paragraph 26). In the absence of such a clear indication of the legal basis for withdrawing the authorisation of bacitracin zinc, Alpharma maintains that it is left uncertain as to the legal basis of the regulation (Case 45/86 *Commission* v *Council* [1987] ECR 1493, paragraph 9). In particular, it submits, with reference to Case C-143/93 *Van Es Douane Agenten* [1996] ECR I-431, paragraphs 27 to 32, that, in essence, in a situation such as this, where certain provisions of a measure to which reference is made in other measures are amended, the Community institutions are required at the same time to make all the necessary consequential amendments to those other measures, in order to ensure a sufficient degree of legal certainty as to the applicable conditions for the parties concerned.

112 The Court recalls, first of all, that the principle of legal certainty, which is a general principle of Community law, requires Community legislation to be clear and its application foreseeable for all interested parties. As a result of that requirement, the binding nature of any act intended to have legal effects must be derived from a provision of Community law which prescribes the legal form to be taken by that act and which must be expressly indicated therein as its legal basis

(*France* v *Commission*, cited above, paragraph 26). However, the Court of Justice has also held that failure to refer to a precise provision of the Treaty need not necessarily constitute an infringement of essential procedural requirements when the legal basis for the measure may be determined from other parts of the measure. However, explicit reference is indispensable where, in its absence, the parties concerned and the Court are left uncertain as to the precise legal basis (*Commission* v *Council*, cited in the preceding paragraph, paragraph 9).

113 In the present case, the second subparagraph of point E1(4) of Title VII of Annex XV to the Act of Accession provides that a decision on a request for adaptation of the Community legislation presented by the Swedish authorities is to be taken 'in accordance with the procedure laid down in Article 7 of Directive 70/524/EEC'. Article 7 of that directive, which was repealed by Article 1(4) of Directive 96/51, provided in paragraph 1 that '[a]mendments to be made to Annexes... shall be adopted in accordance with the procedure laid down in Article 23'. Article 7(2) of Directive 70/524 set out the conditions on which the annexes to that directive could be amended (see paragraphs 17 and 18 above).

114 It is quite clear from the second subparagraph of point E1(4) of Title VII of Annex XV to the Act of Accession that the reference to the former Article 7 of Directive 70/524 concerned only the procedure to be followed when requests for adaptation of the Community legislation were presented by the Swedish authorities. In that regard, the reference to the former Article 7(1) of Directive 70/524 in reality constituted only an indirect reference to Article 23 of that directive, cited at paragraph 17 above, which lays down the procedure to be followed when one of the annexes to that directive is to be amended and which was not amended by Directive 96/51.

115 It follows from recital 35 to the contested regulation, when read in context, that when withdrawing the authorisation of bacitracin zinc the Community authorities applied the procedure laid down in Article 23 of Directive 70/524.

116 Furthermore, contrary to what Alpharma appears to be arguing, Article 9m of Directive 70/524, as inserted by Directive 96/51, defines the circumstances in which authorisation of an additive is to be withdrawn under the new rules. It is not concerned with the procedure to be followed when authorisation is withdrawn. That procedural aspect is governed by the new Article 9r of Directive 70/524, which in that regard is identical to the former Article 7(1) of that directive, in so far as it states that '[a]mendments to be made to the Annexes shall be adopted in accordance with the procedure laid down in Article 23'.

117 It follows that neither Alpharma nor the Court is left uncertain as to the procedure to be followed in order to withdraw the authorisation of bacitracin zinc. That conclusion is also confirmed by Alpharma's own arguments, in particular those relating to the allegedly illegal combination of legal bases in so far as, in that context, Alpharma seeks to establish that the Community institutions did not properly follow the procedure laid down in Article 23 of Directive 70/524 (see paragraphs 123 to 130 below).

118 Alpharma further submits that Article 9m of Directive 70/524, as amended by Directive 96/51, is not mentioned in the preamble to the contested regulation.

119 In that regard, the Court observes, first of all, that Article 9m of Directive 70/524, cited by Alpharma, and also Article 9r of that directive constitute legal bases for the adoption of the contested regulation (see the case-law cited at paragraph 111 above). Next, contrary to Alpharma's argument that the new Article 9m of Directive 70/524, as regards the decision adopted by the Community institutions, became fully effective only from 1 April 1998, Articles 9m and 9r of that directive entered into force on 7 October 1996, in

accordance with Article 191(2) of the EC Treaty (now Article 254(2) EC), i.e. well before the contested regulation was adopted (see paragraph 5 above). Article 2(1)(a) of Directive 96/51, cited by Alpharma in support of that argument, concerns not the entry into force of that directive but the date on which, in derogation from Article 2(1)(b) thereof, Member States were required to comply with certain provisions of the directive (see paragraph 6 above).

120 None the less, it is apparent that the absence of any express reference to those two provisions in the preamble to the contested regulation as the legal bases for its adoption cannot constitute a substantive defect. As regards Article 9m of Directive 70/524, as amended by Directive 96/51, it follows from recital 5 to the contested regulation that the Community institutions took the view that one of the conditions laid down in Article 3a of that directive for the authorisation of the antibiotics concerned, including bacitracin zinc, was no longer met. It follows, by implication but necessarily, that the Community institutions relied on the second indent of the first subparagraph of Article 9m of Directive 70/524, which provides that a regulation is to be adopted to withdraw the authorisation of an additive 'if any of the conditions for the authorisation of the additive referred to in Article 3a are no longer met'.

121 So far as Article 9r of Directive 70/524, as amended by Directive 96/51, is concerned, the Court has already held at paragraph 117 above that the fact that that provision forms the legal basis of the contested regulation as regards the procedure to be followed is borne out by other aspects of the regulation, namely the express reference to Article 23 of Directive 70/524 in recital 35 to the contested regulation.

122 The first part of this plea in law is therefore unfounded.

B — *The combination of legal bases*

123 In the alternative, Alpharma submits that, in order to adopt the contested regulation, the Community institutions had to apply two different procedures. First, it was necessary, in the case of additives other than bacitracin zinc, to follow the procedure laid down in Article 24 of Directive 70/524 in order to withdraw an additive in respect of which a safeguard measure had been taken by a Member State. Second, in the case of bacitracin zinc, the Community institutions had to apply the procedure laid down in Article 23 of that directive, since no safeguard measure had been taken in respect of that product. Alpharma submits that the essential difference between those two procedures is that under the procedure laid down in Article 24 of Directive 70/524 the periods within which the merits of the measure taken by the Member State are to be examined are much shorter than those prescribed by Article 23 of that directive.

124 Alpharma maintains that in the present case the Community institutions in reality followed the procedure laid down in Article 24 of Directive 70/524 in respect of all the products concerned by the contested regulation, including bacitracin zinc, and thus deprived Alpharma of the advantages of the procedure laid down in Article 23 of that directive. If the Community institutions had not accelerated the procedure in order to comply with time-limits laid down in Article 24 of Directive 70/524, when they were required to apply Article 23 of that directive in respect of bacitracin zinc, the authorisation of bacitracin zinc would probably not have been withdrawn. Alpharma maintains, first, that if the period of three months, as prescribed in Article 23(3) of Directive 70/524, within which the Council must adopt the measure proposed by the Commission, had been applied rather than the period of 15 days prescribed in Article 24(3) of that directive, the Council and the Standing Committee would have been able to examine the Commission's proposal thoroughly and to take account of scientific data that were better supported. Second, if the longer period had been observed, the Community institutions would have been able to rely on important scientific reports published at the end of 1998 and the beginning of 1999. Third, owing to the application of such a short period, it was impossible to consult SCAN. For the

same reason, it was also impossible for the Standing Committee to give an opinion on the Commission's proposal. Fourth, a further consequence of the lack of time was that the contested regulation was given only the barest statement of reasons in respect of bacitracin zinc by comparison with the other products concerned.

125 The Court observes that Article 23(2) of Directive 70/524 provides that '[t]he representative of the Commission shall submit a draft of the measures to be adopted' and that '[t]he [Standing] Committee shall deliver its opinion on such measures within a time-limit set by the chairman according to the urgency of the matters'. Article 23(4) of Directive 70/524 provides that '[t]he Commission shall adopt the measures and implement them forthwith where they are in accordance with the opinion of the [Standing] Committee. Where they are not in accordance with the opinion of the [Standing] Committee, or if no opinion is delivered, the Commission shall without delay propose to the Council the measures to be adopted.... If the Council has not adopted any measures within three months of the proposal being submitted to it, the Commission shall adopt the proposed measures...'.

126 As Alpharma rightly states, Article 24 of the directive lays down time-limits which are stricter in two respects than those laid down in Article 23 of Directive 70/524. Article 24(2) of that directive provides that, after the representative of the Commission has submitted to the Standing Committee a draft of the measures to be adopted, the '[Standing] Committee shall deliver its opinion on such measures within two days'; and under Article 24(3) of Directive 70/524 the Council has only '15 days' from the date on which the Commission submits its proposal to adopt those measures, failing which the Commission is to adopt the proposed measures.

127 As regards the procedure followed in the present case, it follows from the short reports of the meetings of the Standing Committee, submitted to the Court at its request, that the representatives of the Commission submitted their draft proposal for a regulation on the withdrawal of antibiotics, including bacitracin

zinc, to the Standing Committee, first informally at the meeting of 12 and 13 November 1998 and then formally at the meeting of 1 and 2 December 1998. It was at the latter meeting that a vote was taken on the draft proposal, although no time-limit had been set in that regard by the Chairman of that Committee. As the majority required by Article 23(2) of Directive 70/524 was not achieved, the Standing Committee did not adopt an opinion: see also recital 35 to the contested regulation. Next, on 11 December 1998, the Commission submitted its proposal for a regulation to the Council, which adopted the contested regulation on 17 December 1998, i.e. within the three-month period prescribed in Article 23(3) of Directive 70/524.

128 It follows that the procedure laid down in Article 23 of Directive 70/524 was followed in this case.

129 As regards Alpharma's argument that, owing to the rapidity of the procedure followed, the Community institutions were not in a position properly to consult the committees attached to them or to adopt a decision on whether to maintain or withdraw the authorisation of bacitracin zinc as an additive in feedingstuffs with knowledge of the relevant evidence, the Court notes, first of all, that Alpharma does not dispute that the Council is not obliged to await the expiry of the three-month period prescribed in Article 23(3) of Directive 70/524 before adopting the measure withdrawing the authorisation of bacitracin zinc on the basis of the Commission's proposal. Furthermore, since that argument is not readily distinguishable from the argument put forward in the context of the pleas alleging manifest error of assessment and breach of the obligation to state reasons, it must be examined in that context.

130 It follows that the second part of the first plea in law is also unfounded. The first plea in law, alleging infringement of essential procedural requirements, must therefore be rejected in its entirety.

II — *Manifest errors of assessment in the risk assessment*

131 Alpharma submits that the Community institutions did not correctly assess the risks associated with the use of bacitracin zinc as an additive in feedingstuffs before adopting the contested regulation in reliance on the precautionary principle. Essentially, Alpharma criticises the Community institutions for not having consulted the competent scientific committee, SCAN, before withdrawing authorisation of that product and claims that that assessment should not have been made other than on the basis of a scientific opinion from SCAN (B). Second, Alpharma seeks to show that the Community institutions were wrong to conclude, on the basis of the scientific information available at the time of adoption of the contested regulation, that such use of bacitracin zinc constituted a risk for human health (C). Before examining those arguments in two parts, the Court will set out its preliminary considerations (A).

A — *Preliminary considerations*

1. The sources of the interpretation of the precautionary principle

132 By the contested regulation, which was adopted on a proposal from the Commission, the Council withdrew Community authorisation from four antibiotics, including bacitracin zinc, 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.

133 It follows from the preamble to the contested regulation, and in particular from recital 22 thereto, that the Community institutions considered that that use of bacitracin zinc constituted a risk for human health and that 'the effectiveness of bacitracin zinc in human medicine should... be preserved'. It follows from recital 5 to the contested regulation, moreover, that the Council relied on Article 3a(e) of Directive 70/524, which provides that Community authorisation of an additive 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'.

134 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.

135 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. Alpharma does not dispute 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.

136 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 the President of the Court of First Instance in Case T-13/99 R *Pfizer Animal Health* v *Council* [1999] ECR II-1961, upheld on appeal by the order of the President of the Court of Justice in Case C-329/99 P(R) *Pfizer Animal Health* v *Council* [1999] ECR I-8343, and the order in *Alpharma* v *Council*, cited at paragraph 57 above, and by the EFTA Court (Case E-3/00 *EFTA Surveillance Authority* v *Norway*, not yet published in the EFTA Court Reports).

137 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.

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

139 In that regard, whilst maintaining that the Community institutions have infringed Directive 70/524, Alpharma also claims 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').

140 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 those measures 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.

141 However, in the present case, Alpharma cannot reasonably argue that the contested regulation is unlawful because it is inconsistent with the documents referred to at paragraph 139 above.

142 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 the Fédération européenne de la santé animale (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 Alpharma — 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 140 above. That document is hereinafter referred to as the 'Draft Guidelines'.

143 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.

144 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 communication. 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.

145 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.

146 In view of the foregoing, rather than considering whether the Community institutions failed to act in accordance with the documents referred to at paragraph 139 above, the Court must assess, when dealing with this plea, whether the Community 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.

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

(a) Arguments of the parties

147 Alpharma takes 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.

148 Alpharma maintains that in the present case, instead of carrying out a proper scientific assessment of the risks, the Community institutions applied the 'zero risk' approach. They withdrew the authorisation of bacitracin zinc without having a scientific opinion and without relying on scientific proof relating to the specific risks posed by that product. It is illegal to withdraw an authorised product on the basis of a 'zero risk' approach. The Community institutions cannot properly ban a product solely on the basis of rumours and without taking the scientific data relating to that product into account. Alpharma acknowledges that the precautionary principle allows the Community institutions to act rapidly and to take preventive protective measures where, because new scientific data indicate that a decision needs to be taken as a matter of urgency, they cannot wait until more precise data on the risk represented by the product concerned are available. However, the precautionary principle cannot provide an excuse for not carrying out a thorough assessment of all the scientific evidence available.

149 The Council and the interveners observe at the outset that it has consistently been held that, in determining their policy in matters of agriculture, the Community institutions enjoy a wide measure of discretion regarding definition of the objectives to be pursued and choice of the appropriate means of action.

150 The Council and the Commission contend that Alpharma itself acknowledges that there is a risk that resistance to bacitracin zinc will be transmitted from animals to humans. Alpharma merely considers that it is a theoretical rather than a quantified risk. The Council and the Commission contend that there is no need to carry out a quantitative risk assessment when applying the precautionary principle. It is sufficient that the risk exists, that serious concerns have been expressed in scientific literature and in the reports of various conferences and bodies and that, if such transmission actually occurred, it could have serious consequences for human health. It does not matter that the extent of the risk has not yet been clearly established and that there are differences of opinion between

scientists. It would be absurd and contrary to the Community institutions' obligation, which the applicant acknowledges, to ensure a high level of public health protection if no action could be undertaken until the risks had become reality.

(b) Findings of the Court

151 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 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

152 It is appropriate to bear in mind first of all 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 135 above, paragraph 99, the *NFU* judgment, cited at paragraph 135 above, paragraph 63, and the judgment at first instance in *Bergaderm and Goupil* v *Commission*, cited at paragraph 136 above, paragraph 66).

153 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 bacitracin zinc 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.

154 *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, the judgment of the Court of Justice in Case C-355/90 *Commission* v *Spain* [1993] ECR I-4221, paragraph 15).

155 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 136 above, paragraphs 29 to 31; and *Spain* v *Council*, cited at paragraph 136 above, paragraph 31).

156 However, it is also clear from the case-law cited at paragraph 152 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 136 above, in particular paragraphs 36 to 38).

157 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.

158 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, 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 136 above, paragraph 44).

159 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.

160 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).

161 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 for 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

162 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 144 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.

163 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).

164 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.

165 Although they may not take a purely hypothetical approach to risk and may not base their decisions on a 'zero-risk' (see paragraph 157 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).

166 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.

167 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 bacitracin zinc was based on extremely complex scientific and technical assessments over which scientists have widely diverging views (see in particular (C) below).

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

169 A scientific risk assessment is commonly defined, at both international level (see the provisional communication from the Codex Alimentarius Commission, cited at paragraph 160 above) and at Community level (see the Communication on the Precautionary Principle, the Communication on Consumer Health and Food Safety and the green paper, cited at paragraphs 142 and 145 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.

170 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.

171 As the Commission pointed out in its Communication on Consumer Health and Food Safety (see paragraph 145 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.

172 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.

173 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 169 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 152 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.

174 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.

175 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 163 to 166 above). That is the basis on which the authority must decide whether preventive measures are called for.

176 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) The scope of judicial review

177 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 136 above, paragraph 14; the *BSE* judgment, cited at paragraph 135 above, paragraph 60; and the *NFU* judgment, cited at paragraph 135 above, paragraph 39).

178 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.

179 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 136 above, paragraph 29).

180 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 Community institutions of their discretion in that regard is vitiated by a manifest error or a misuse of powers or whether the Community institutions clearly exceeded the bounds of their discretion.

181 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.

182 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).

183 It follows, as Alpharma has rightly submitted, 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.

184 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 Alpharma.

B — *The absence of a scientific opinion*

1. Arguments of the parties

185 Alpharma acknowledges that under the applicable legislation there is no obligation to request in every case a scientific opinion from SCAN before a decision is taken to withdraw authorisation of an additive. However, it maintains that in the present case the Commission was required to request SCAN's opinion before submitting its proposal for a regulation to the Council.

186 Alpharma submits that the present case is comparable in every respect with Case C-212/91 *Angelopharm* [1994] ECR I-171, paragraphs 31 to 41. In that case, the Court of Justice found that, where authorisation of a product was to be withdrawn on health and safety grounds, consultation of the competent Scientific Committee was mandatory even though not expressly required by the relevant legislation. The Court of Justice took into account that consultation of the Scientific Committee was necessary in order to provide a proper scientific context for consideration of the scientific basis for the proposed measures while ensuring that account was taken of the most recent scientific and technical research and that only prohibitions necessary on grounds of public health were imposed. Furthermore, in that case, the Court of Justice held that neither the Commission nor the Standing Committee was in a position to carry out a risk assessment of that kind itself.

187 Therefore, according to Alpharma, a SCAN report must be requested whenever a product is withdrawn on grounds of human health and safety, except in cases of genuine and demonstrable urgency or emergency. That is particularly so when the precautionary principle is applied (when, by definition, the scientific data are incomplete and require particularly careful assessment) in a non-urgent situation.

188 Alpharma further observes that in April 1998 the Commission itself instructed the SSC to produce a multidisciplinary scientific report on the risks associated with the use of additives in feedingstuffs, to include an analysis of all antibiotics used as additives in feedingstuffs, including bacitracin zinc. Alpharma maintains that, in order to allow a correct assessment of the risks to be commenced, the Commission should have awaited the SSC's conclusions, which were expected in mid-1999, before submitting its proposals for bacitracin zinc to the Council.

189 The Council, supported by the interveners, contends, first of all, that even though the relevant provisions allowed it to act without having a scientific opinion from SCAN or from another scientific committee, the Commission consulted SCAN about the request for adaptation of Directive 70/524 submitted by the Swedish authorities, but SCAN refused to deliver an opinion on that subject. The Commission could not force SCAN to deliver an opinion within the period laid down in Article 151 of the Act of Accession, i.e. by 31 December 1998. It was likewise impossible to obtain a scientific report from the SSC within that period.

190 In essence, the Council stated at the hearing that in any event, even if the Commission had erred in not having a SCAN opinion or a scientific report from the SSC, such an error could not be imputed to the Council. In this instance the contested regulation was adopted by the Council and the Council was therefore

responsible for assessing and managing the risks associated with the use of antibiotics as growth promoters. Both SCAN and the SSC were set up by the Commission, without any particular legal basis. When the Commission decides that it has no need of a scientific opinion from those committees before submitting a proposal for a regulation to the Council, that is a 'purely internal organisational arrangement by the Commission'.

191 Furthermore, according to the Council and the interveners, the Community institutions were entitled to conclude that there was a risk associated with bacitracin zinc without having a scientific opinion from SCAN relating specifically to that product.

192 First, the Council states that in the WHO report (point III, cited at paragraph 37 above), the WHO, confirming the conclusions of the Swann report of 1969, recommended ending the use of any antibiotic as a growth promoter if it was or might be used in human medicine. The Council also states that, since the publication of the WHO report, many international, Community and national bodies have adopted essentially the same recommendation as that of the WHO (the Copenhagen recommendations, p. 35; the ESC Opinion, paragraph 4.2; the House of Lords report, point 12.6; the Netherlands report, pp. 17-20, all cited at paragraph 37 above). The Council also refers to the Swedish report, cited at paragraph 44 above.

193 The Commission states that the Community institutions may lawfully adopt a provisional preventive measure on the basis of the results of scientific research carried out by national scientific bodies and submitted by a Member State before carrying out a scientific risk assessment at Community level. The legality of that approach was confirmed by the Court of Justice in the *BSE* judgment, cited at paragraph 135 above. The Commission states that in *BSE* the Community

institutions initially acted solely on the basis of the opinion of the competent national scientific committee and did not carry out a full risk assessment on the basis of the opinions of the Community scientific committees until later.

194 Last, at the hearing the Council, supported by the interveners, claimed that examination of all the technical and scientific factual evidence relating specifically to bacitracin zinc was carried out within the framework of the Standing Committee. While the Council acknowledges that the Standing Committee is not an independent scientific body but a committee composed of representatives of the Member States and of the Commission, the fact remains, according to the Council, that the members of that Committee are assisted by scientific experts appointed by their Member States whose task it is to advise them on all relevant scientific and technical questions. In the present case, all those matters were examined within the framework of that Committee.

2. Findings of the Court

(a) Introduction

195 In essence, Alpharma is criticising the Community institutions for not having based their scientific assessment of the risks specifically associated with bacitracin zinc on appropriate scientific material.

196 In that regard, the Court observes, first of all, that it follows from the preamble to the contested regulation that, in accordance with the procedure laid down in Article 23 of Directive 70/524, the Council adopted the contested regulation following a scientific risk assessment for which the Commission assumed

responsibility. The Council did not itself carry out such an assessment but merely endorsed the position adopted by the Commission in its proposal for a regulation. In those circumstances, contrary to what the Council essentially maintained at the hearing, any errors committed by the Commission within the context of the scientific risk assessment are imputable to the Council. That conclusion is not invalidated by the fact that, as the Council emphasises, both SCAN and the SSC are advisory committees attached to the Commission and that it is at the request of the Commission, which assumes responsibility therefor, that they carry out scientific risk assessments and deliver their scientific opinions and reports.

197 Next, it follows from recital 1 to the contested regulation that, in the context of its application for adaptation of Directive 70/524, submitted pursuant to Article 151 of the Act of Accession, the Kingdom of Sweden on 2 February 1998 requested withdrawal of authorisation, at Community level, of all antibiotics then authorised under Directive 70/524 as additives in feedingstuffs. That request covered eight antibiotics, including bacitracin zinc, and the Kingdom of Sweden submitted detailed grounds for its application (the Swedish report, see paragraph 44 above).

198 Similarly, as stated at recital 3 to the contested regulation, on 12 March 1997 the Republic of Finland submitted a request for adaptation of Directive 70/524 in respect of two of those eight antibiotics, tylosin phosphate and spiramycin. Furthermore, recital 4 to the contested regulation states that on 15 January 1998 the Kingdom of Denmark made use of the safeguard clause provided for in Article 11 of Directive 70/524 and prohibited the use on its territory of another of those eight antibiotics, virginiamycin, as an additive in feedingstuffs. It is clear from recitals 8 and 14 to the contested regulation that before that regulation was adopted the Commission consulted SCAN on the risks specifically associated with the use of the three antibiotics concerned by the request submitted by the Republic of Finland and by the safeguard measure taken by the Kingdom of Denmark. SCAN delivered scientific opinions in respect of those products on 5 February and 10 July 1998 and Alpharma submitted copies of those opinions to the Court in the present case.

199 On the other hand, it may be inferred from recital 22 to the contested regulation that the Commission did not obtain a scientific opinion from SCAN relating specifically to bacitracin zinc.

200 Furthermore, the Commission stated before the Court that in April 1998 it instructed the SSC to provide a multidisciplinary scientific report on the risks associated with the use of the additives in feedingstuffs and that the report, the initial conclusions of which were requested for May 1999, related, *inter alia*, to the risks associated with the use of the antibiotics as additives in feedingstuffs, including bacitracin zinc. As grounds for withdrawing the authorisation of that product, the Commission could not therefore rely on that scientific report, which postdated the contested regulation.

201 In the absence of a scientific opinion from SCAN or a scientific report from the SSC relating specifically to bacitracin zinc, the Community institutions relied in particular on the Swedish report. Furthermore, as stated in recital 23 to the contested regulation, they took account of the conclusions and recommendations of the various international and Community bodies referred to at paragraph 37 above.

202 Last, as is apparent from recital 35 to the contested regulation, the Commission consulted the Standing Committee about the withdrawal of authorisation of the four antibiotics, including bacitracin zinc, named in Article 1 of that regulation, but the Standing Committee did not deliver an opinion on the subject.

203 It is against that background that the Court must, first, consider whether, as Alpharma maintains, the Community institutions erred in withdrawing the authorisation of bacitracin zinc as an additive in feedingstuffs without obtaining a scientific opinion from SCAN relating specifically to the risks associated with

that product and without waiting until the SSC had delivered its scientific report and, second, examine whether and to what extent, in the absence of those two scientific documents, the Community institutions were entitled to base their scientific assessment of the risks associated with that product on the other sources of information referred to at paragraphs 37 and 44 above.

(b) As to whether consultation of the scientific committees is mandatory or optional

204 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' SCAN is to provide 'scientific advice'.

205 Article 23 of Directive 70/524 makes no provision for SCAN to be consulted.

206 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 of an additive but is not under a duty to do so.

207 Contrary to Alpharma's contention, that conclusion is not invalidated by the judgment of the Court of Justice in *Angelopharm*, cited at paragraph 186 above.

That judgment 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 in that case admitted of both 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 that 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 26 and 28 above), that precedent is not applicable to the present case.

208 Under the provisions applicable to the present case there is likewise no requirement to consult the SSC. Directive 70/524 makes no provision for the involvement of that scientific committee, which was set up by Decision 97/404; and it follows from Article 2(3) of Decision 97/404 that, like SCAN, the SSC is to prepare scientific advice only following a request from the Commission.

209 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 of an additive in feedingstuffs, such as bacitracin zinc, without first having obtained an opinion from the abovementioned scientific committees.

210 That being so, it has already been held at paragraph 167 above that the decision to maintain or withdraw the authorisation of antibiotics, including bacitracin zinc, called for particularly complex technical and scientific assessments on the part of the Community institutions.

211 Furthermore, in such circumstances a scientific risk assessment is a prerequisite of the adoption of any preventive measure (see paragraph 168 above). It was likewise held at paragraphs 172 and 173 above that 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.

212 In that connection, account must be taken of the fact that the Commission set up SCAN and the SSC 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, it is apparent from the preamble to Decision 97/404 that the SSC is called upon to provide the Commission with 'sound scientific advice' where the Commission is required to deal with issues of a multidisciplinary nature relating to consumer health. In the preamble to each of those decisions, the Commission stated that advice from those committees 'must, in the interests of consumers and industry, be based on the principles of excellence, independence and transparency'.

213 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 complex facts of a technical or scientific nature, adopt a preventive measure withdrawing authorisation from an additive without obtaining an opinion from those scientific committees.

214 The Court will examine below whether the Community institutions were entitled to conclude that that was so in the present case.

215 Be that as it may, the Commission's argument that it consulted SCAN but that SCAN refused to deliver an opinion cannot be accepted.

216 Admittedly, the records of the SCAN meetings show that the Commission consulted SCAN about the requests for adaptation submitted by the Swedish authorities on 2 February 1998, that those requests were placed on SCAN's agenda on 5 February 1998 but that SCAN did not consider them because it took the view that they were a matter for the SSC. However, even though there was nothing to prevent the Commission from referring the matter to the SSC as well, it is by no means clear that SCAN was, as it claims, not competent to deal with it. Furthermore, even supposing that in any event SCAN was not competent to give its opinion in the present case, 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. In that regard, 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.

(c) The adequacy of the other material relied on by the Community institutions

217 The Court must consider whether and to what extent, in the absence of a scientific opinion from SCAN and a scientific report from the SSC, the other matters relied on by the Community institutions, such as those referred to at paragraph 192 above, could validly serve as the basis on which to carry out a

scientific assessment of the risks associated with the use of bacitracin zinc as an additive in feedingstuffs.

(i) The scientific opinions delivered by SCAN on the other antibiotics concerned by the contested regulation

218 It is clear from recitals 8 and 15 to the contested regulation that in its scientific opinions of 5 February and 10 July 1998 concerning tylosin phosphate, spiramycin and virginiamycin, SCAN concluded essentially that the available scientific data relating to those antibiotics did not provide sufficient evidence that there was any risk associated with those products. Consequently, according to SCAN, there was no reason as matters stood to conclude that the authorisation of those products as additives in feedingstuffs should be withdrawn. However, it is clear from recitals 8 to 23 to the contested regulation that the Commission took the view, in spite of the position thus taken by SCAN, that, on the basis of the factual evidence submitted to it and examined by SCAN in its scientific opinions, it had sufficient scientific information to conclude that the use of those antibiotics as additives in feedingstuffs presented a risk for human health and that it was therefore necessary to adopt a preventive measure in respect of them.

219 The Court will consider below whether in the particular circumstances of the present case the Community institutions were entitled to rely on certain parts of those scientific opinions to conclude that there was a risk associated with bacitracin zinc. None the less, since under the provisions applicable to the present case the Community institutions were under no obligation to consult SCAN in every case before withdrawing authorisation of an additive, they cannot be criticised as such for having relied, when assessing the risks associated with bacitracin zinc, on some aspects of the analysis in the scientific opinions relating to the other antibiotics concerned.

(ii) The reports of the various international, Community and national bodies.

220 First of all, it is not the contention of the Council and the interveners that the various reports of international, Community and national bodies referred to at paragraphs 37 and 44 above are scientific opinions relating to the risks specifically associated with the use of bacitracin zinc as an additive in feedingstuffs.

221 None the less, the Council and the interveners rightly claim that, even if those reports relate to the problems of resistance to antibiotics in general, they deal in particular with the possible implications of their use as additives in feedingstuffs. Furthermore, those reports specifically analyse the risks associated with the use of antibiotics, such as bacitracin zinc, which are used in human medicine and at the same time as additives in feedingstuffs. Last, in some of the reports bacitracin zinc is specifically mentioned as one of the products whose use as a growth promoter might lead to its reduced effectiveness in human medicine.

222 Furthermore, with more particular regard to the WHO report and the Copenhagen recommendations, referred to at recital 23 to the contested regulation, those documents show that they were adopted after wide consultation of a large number of scientific experts. It follows from the Copenhagen recommendations, moreover, that representatives of the pharmaceutical industry participated in 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.

223 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 37 and 44 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 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.

224 Alpharma, admittedly, rightly submitted at the hearing that, under Directive 70/524, it is the Community institutions that have the political power and responsibility to decide, in the common interest, whether to maintain or withdraw the authorisation of additives in feedingstuffs at Community level. Consequently, the fact that the bodies referred to in the previous paragraph carried out a risk assessment on the basis of their respective terms of reference cannot release the Community institutions from their obligation to carry out, in the exercise of the powers conferred on them by the Treaty, an assessment of the risks at Community level, if necessary consulting the competent scientific committee set up at Community level, before deciding to withdraw Community authorisation of an additive.

225 Contrary to the Commission's argument at the hearing (see paragraph 193 above), that was also the approach taken by the Community institutions in *BSE*, cited at paragraph 135 above. It follows from the grounds of that judgment that the impugned Commission decision, adopted on 27 May 1996 as an emergency measure, to prohibit exports from the United Kingdom to other Member States of bovine animals, bovine meat and certain products obtained therefrom, was based on a statement issued on 20 March 1996 by the scientific committee responsible for advising the United Kingdom Government on the likelihood of a link between bovine spongiform encephalopathy and cases of Creutzfeldt-Jakob disease in

humans. In those circumstances, the Commission, notwithstanding that such consultation was optional, consulted the competent scientific committee at Community level, which, in spite of the urgency, made recommendations on 22 and 24 March 1996 on the measures to be taken at Community level on the basis of an analysis of the available scientific data.

226 That being so, in the present case, as Alpharma acknowledged at the hearing, there was nothing to prevent the Community institutions from taking account of the various reports referred to at paragraphs 37 and 44 above when carrying out their risk assessment. On the contrary, such an approach made it possible to ensure that the action taken by the Community institutions would take account of the most recent results of international research.

(iii) The role of the Standing Committee

227 At the hearing, the Council and the Commission claimed, in essence, that the scientific and technical evidence relevant to the present case was assessed by the Standing Committee. In that regard, the Court observes, first of all, that it follows from Article 23(2) of Directive 70/524 that the Commission must consult the Standing Committee before adopting measures or submitting proposals to the Council.

228 Next, it follows from Article 2 of Decision 70/372 that, as well as having an advisory role, the Standing 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'.

229 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.

230 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.

231 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 186 above, ECR I-171, at I-173, point 38). It is clear from Article 23(3) of Directive 70/524 that the Commission itself can adopt measures entailing an amendment of the annexes to that 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 in question within three months. Under Article 23(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.

232 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.

233 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 the adoption of the contested regulation, the members of the Committee analysed the relevant scientific material, including the scientific opinions of the SCAN relating to the other antibiotics whose authorisation was withdrawn by the contested regulation and the reports on antimicrobial resistance drawn up by the various international, Community and national bodies (see paragraphs 37 and 44 above).

234 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 material.

235 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.

236 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 website. 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.

237 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 applicable in this instance, by any conclusions expressed therein. 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 knowledge of the facts, whether a preventive measure should be taken and, if so, which.

238 It follows that the Standing Committee's analysis of the scientific data on the risk associated with the use of bacitracin zinc as an additive in feedingstuffs that were available when the contested regulation was adopted 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 para-

graph 213 above). 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.

239 Accordingly, that argument put forward by the Council and the Commission must also be rejected.

(iv) Conclusion

240 Under the provisions applicable to the present case, there is nothing to preclude the Community institutions, in the absence of a SCAN opinion or of a scientific report from the SSC, from assessing the risks specifically associated with bacitracin zinc on the basis of information contained in the SCAN opinions relating to the other antibiotics whose authorisation was withdrawn by the contested regulation and in the reports of the various international, Community and national bodies. However, they cannot rely in this context on the work carried out within the Standing Committee.

(d) Conclusion

241 In the light of the foregoing, it must be concluded that, contrary to Alpharma's contention, the fact that the Council, acting on a proposal from the Commission, withdrew the authorisation of bacitracin zinc as an additive in feedingstuffs without having a SCAN opinion and without waiting until the SSC had delivered its scientific report does not of itself mean that the contested regulation is illegal

as concerns bacitracin zinc. However, it remains to examine whether the Community institutions made a manifest error of assessment in concluding, on the basis of the other factual evidence, that the use of bacitracin zinc as a growth promoter constituted a risk to human health.

C — *The errors which the Community institutions are alleged to have made in concluding that the use of bacitracin zinc as a growth promoter constituted a risk to human health*

1. Introduction

242 Alpharma claims that the Community institutions were wrong to conclude that the use of bacitracin zinc as a growth promoter constituted a risk to human health and that preventive protective measures should be taken. The arguments put forward may be re-ordered in two claims. First, Alpharma claims that human resistance to bacitracin zinc does not have any adverse effects on human health (2). 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 bacitracin zinc as an additive in feedingstuffs and the development of antimicrobial resistance in humans (3).

243 First, before ascertaining whether these claims are well founded, the Court will summarise the scientific background described in the documents before it.

244 The parties are in agreement that the use of bacitracin zinc 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 against certain dangerous infections in humans is eliminated or reduced.

245 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.

246 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).

247 Second, 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 179 and 180 above).

248 Third, 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 or should have been available to them at the time when the contested regulation was adopted (see, to that effect, *Wuidart and Others*, cited at paragraph 177 above, paragraph 14, and Joined Cases C-133/93, C-300/93 and 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.

2. The adverse effects on human health should resistance to bacitracin zinc develop in humans

(a) Arguments of the parties

249 Alpharma maintains that, even on the assumption that resistance to bacitracin zinc were to develop in humans owing to the use of that product as an additive in feedingstuffs, that could not have serious consequences for human health.

Consequently, there cannot have been any serious reasons, within the meaning of Article 3a(e) of Directive 70/524, allowing the Community institutions to restrict bacitracin zinc to human use.

250 First, Alpharma does not dispute that, as stated in recital 22 to the contested regulation, in addition to being used as an additive in feedingstuffs, 'bacitracin zinc... is also used in human medicine mainly for topical treatment of infections of the skin and mucosal surfaces'. However, relying more particularly on the report by Professor M.W. Casewell, Alpharma claims that the use of bacitracin zinc in human medicine is negligible.

251 It alleges that medicinal products containing bacitracin zinc are not used or are virtually unused in human medicine. Alpharma states that those medicinal products are of dubious effectiveness for the treatment of the infections for which they had been authorised. It is for that reason that bacitracin zinc is not mentioned in modern medical formularies and that in many countries certain medicinal products containing the product are available without prescription, which shows its relative unimportance for human medicine.

252 Furthermore, according to Alpharma, there is not and cannot be in the future significant use of bacitracin zinc in human medicine because when it enters the human bloodstream, whether by injection or by other means, it is highly nephrotoxic, i.e. it has a poisonous effect on the kidneys. Owing to its nephrotoxicity, bacitracin zinc is known to have caused death in patients. In any event, Alpharma observes that for each of the topical treatments for which bacitracin zinc is authorised in human medicine there is a range of alternative products which are satisfactory or even more effective than bacitracin zinc.

253 Second, Alpharma disputes the merits of the assertion in recital 22 to the contested regulation that 'publications show that [bacitracin zinc] could possibly be used for the treatment of vancomyn resistant enterococci [VRE], which represent a clinical problem in human medicine'.

254 Alpharma accepts that VRE presents a significant clinical problem in human medicine. Relying on Professor M.W. Casewell's report, it none the less states that, owing to its nephrotoxic effect and regard being had to the phenomenon of the natural resistance of enterococci to bacitracin zinc (see paragraphs 277 and 296 to 302 below), bacitracin zinc is ineffective in the treatment of infections caused by VRE. Consequently, even though it could in theory have some effect against VRE, which has never been established, it could never be used in a way which was of significance in terms of human medicine.

255 Alpharma also accepts that, according to the publication referred to in recital 22 to the contested regulation, namely the study by J.K. Chia and others 'Use of bacitracin therapy for infection due to Vancomycin-resistant Enterococcus faecium' (Clin. Inf. Dis. 1995, 21:1520 ('the Chia study')), bacitracin zinc could be used against VRE. Alpharma criticises the fact that the Chia study was based on scientific experiments of limited scope and duration and that the results of the experiments had not been subject to scientific supervision such as to preclude any distortion of the results by external factors. The other, more recent, scientific studies which Alpharma submitted to the Court with its reply concluded that bacitracin zinc should be regarded as a 'product without a future' for the treatment of infections caused by VRE. However, the Community institutions simply chose to ignore those sources.

256 The Council and the interveners reject that argument. Referring essentially to the various reports on antimicrobial resistance by international, Community and

national bodies, referred to at paragraphs 37 and 44 above, they maintain in substance that the development of resistance to bacitracin zinc in humans had adverse effects on human health and therefore constituted a serious reason for the purposes of Article 3a(e) of Directive 70/524.

(b) Findings of the Court

257 First, the parties are in agreement that bacitracin zinc is used in human medicine for the topical treatment of certain infections. By way of illustration, Alpharma has itself submitted to the Court, in an annex to its application, a document showing that approximately 100 medicinal products containing bacitracin zinc had been authorised in the Community as human medicinal products for various topical treatments, in particular infections of the eyes, nasal tracts, mouth, ears, throat, skin, stomach and intestines, caused by various organisms including, in particular, staphylococci. It is also apparent from the reports submitted to the Court, such as the Swedish report ('[Bacitracin] is used, albeit not to any large extent, in both human and animal therapy', p. 244) or the United Kingdom report ('Bacitracin is used topically in man for the treatment of wound infections... and is effective', p. 89), that bacitracin zinc has only relatively limited use in human medicine but that it is successfully used to treat certain infections.

258 Nor do the Council and the interveners dispute that the possibilities for using bacitracin zinc in human medicine are reduced owing to its nephrotoxic effect. However, Alpharma does not establish, or even seek to establish, that its nephrotoxicity compromises every use of the product in human medicine. Apart from the topical external uses of bacitracin zinc, Alpharma does not argue that it cannot be administered orally, except in cases in which it might enter the bloodstream owing to pre-existing damage to the intestinal tissue. Furthermore,

the documents in the case-file do not confirm Alpharma's argument that bacitracin zinc can never be administered by injection. Following an assertion by the Council in its defence, Alpharma submitted to the Court a package leaflet from a medicinal product called 'Baciim' which shows that that medicinal product, containing bacitracin zinc, had been authorised in the United States in 1997 for administration by injection in paediatric medicine to treat certain cases of pneumonia caused by staphylococci. Although it is true that in that leaflet the user's attention is particularly drawn to the nephrotoxic side-effects of Baciim and to the special precautions to be taken when administering it, the fact remains that an application of bacitracin zinc by injection in some patients and in particular conditions does not seem to have been ruled out at that stage of medical research.

259 In those circumstances, it is clear that the Community institutions were entitled to find, on the basis of material available to them when the contested regulation was adopted and, in particular, without having a SCAN opinion and without awaiting the scientific report of the SSC, that bacitracin zinc was used in human medicine for the topical treatment of certain infections.

260 Second, as Alpharma rightly states, it is clear from certain scientific studies completed and published before the contested regulation was adopted that, without excluding any oral application of bacitracin zinc to treat VRE, its effectiveness against VRE was regarded as minimal or insignificant ('The use of oral bacitracin is minimally effective in reducing VRE stool colonisation', M.A. Montecalvo and others, 'Effect of Oral Bacitracin (B) on the Number of Vancomycin Resistant enterococci (VRE) in Stool', Proceedings of the 37th ICAAC Meeting, Toronto 1997, p. 303; 'In conclusion, the use of oral bacitracin... was not well tolerated and had little effect in reducing VRE colonisation. Therefore, the use of a better combination or alternative effective

drug for eradication of VRE colonisation remains to be determined', Hachem, R. and others, 'Are Bacitracin and Gentamicin Useful in Combination for the Eradication of Vancomycin-Resistant Enterococcus (VRE) Fecal Carriage?', Abstracts from the 38th Annual ICAAC Session, 1998, p. 186).

261 However, other scientists have drawn different conclusions on that point. Relying, in particular, on the Chia study, referred to in recital 22 to the contested regulation (see paragraph 255 above), the scientists who drew up the Swedish report concluded that '[bacitracin zinc's] effectiveness against [VRE] has led to an increase in its use for oral treatment' (p. 233 of the Swedish report). Likewise, also relying on the Chia study, the scientists who drew up the Netherlands report, cited at paragraph 37 above, which was published in September 1998, drew the following conclusion:

'Bacitracin and everninomycin are two "new" antibiotics under development for the treatment of patients with VRE infections which are currently generating a great deal of interest. In the past, the use of bacitracin in humans has been confined to topical use in the treatment of patients with infections of the skin or the mucous membrane. Recently, though, it has entered experimental use for the treatment of patients infected by VRE' (pp. 42, 62 and 65 of the report).

262 As regards Alpharma's criticisms of the method used by the scientists who carried out the Chia study, the Court notes, first, that the Community institutions do not claim to have been in possession of conclusive scientific results showing that it was in fact possible to use bacitracin zinc to treat VRE but merely stated, at recital 22 to the contested regulation, that bacitracin zinc 'could possibly be used for [VRE]'. Second, there is no indication in the reports mentioned in the preceding paragraph that the scientists who drafted them considered that those experiments were unsatisfactory from a methodological aspect and that certain provisional conclusions could not therefore be drawn from them.

263 Last, in the observations on the Swedish report which it submitted to the Commission in August 1998, Alpharma stated: 'According to these experimental data there may be an indication that bacitracin could play a role in VRE eradication. These findings are experimental findings only and not a generally accepted standard practice'. It follows that before the contested regulation was adopted Alpharma itself took a less rigid approach to the subject before the Commission, which itself never claimed that the use of bacitracin zinc for the treatment of VRE was a 'generally accepted standard practice'.

264 Consequently, without having a SCAN opinion on the subject and without awaiting the scientific report of the SSC, the Community institutions could properly find that, at the time when the contested regulation was adopted, there were significant differences of opinion between scientists as to whether bacitracin zinc could be used then or in the future to treat VRE. Alpharma has therefore failed to show that the Community institutions erred in concluding, on the basis of the material available at the time of adoption of the contested regulation, that bacitracin zinc might possibly be used to treat VRE.

265 Third, in so far as Alpharma maintains that in any event there would be no serious consequences for human health should there be a reduction in the effectiveness of the various actual and potential uses of bacitracin zinc which have just been analysed, the Court observes, first of all, that it is for the competent public authority to determine the level of risk which it deems appropriate for society and that, in the performance of that duty, the Community institutions have a broad discretion (see paragraph 178 above).

266 In that regard, Alpharma confirmed in its application that, generally, the development of antimicrobial resistance in humans, which renders antibiotic medicinal products less effective, was regarded as a serious threat to human health. As Alpharma emphasised, that development is of greatest concern in

respect of infections contracted in hospitals, where bacteria, in particular enterococci and staphylococci, may have already developed resistance to the most commonly-used antibiotics and where new antibiotics must therefore be discovered in order to treat infections caused by those bacteria.

267 In such a situation, it cannot be validly contended that the Community institutions made a manifest error of assessment in concluding that the possibility of a reduction in the effectiveness of certain human medicinal products, such as those containing bacitracin zinc, constituted a serious reason within the meaning of Article 3a(e) of Directive 70/524 for confining the use of bacitracin zinc to human medicine. That finding cannot be invalidated by the fact, put forward by Alpharma, that at the time of adoption of the contested regulation bacitracin zinc was used only to a relatively limited extent in human medicine, since the effectiveness of its use in human medicine could be reduced owing to its use as an additive in feedingstuffs.

268 Nor can the fact mentioned by Alpharma that satisfactory or even more effective alternatives to bacitracin zinc were available on the market and could replace bacitracin zinc should certain patients develop resistance to that product establish that there has been a manifest error of assessment. In that regard, it was reasonable for the Community institutions to pursue the objective of having a number of antibiotics available in human medicine to treat the same infection and the merits of that objective have not as such been called in question by Alpharma.

269 Last, nor did the Community institutions make a manifest error of assessment by taking account of the fact that in future bacitracin zinc might be used in certain special circumstances to treat VRE and that that potential use might be compromised if bacitracin zinc continued to be authorised as an additive in

feedingstuffs, notwithstanding that at the time of adoption of the contested regulation that potential use was the subject of significant scientific uncertainty. In that regard, the Community institutions were entitled to take into account the fact that it is increasingly difficult to create new antibiotics that are effective in human medicine. It was likewise reasonable for them to take into account the fact that antimicrobial resistance is a virtually irreversible phenomenon and, accordingly, is eradicated, if ever, only long after the antibiotic ceases to be added to the feedingstuff. Finally, it was also reasonable for them to take into account the fact that the number of antibiotics available was increasingly limited. In the light of the foregoing, since the rapid development of VRE was regarded as a particularly important problem in human medicine, the Community institutions are not to be criticised for having taken a cautious approach and for having pursued the objective of preserving the effectiveness of bacitracin zinc as well for that potentially important use in human medicine, namely the treatment of VRE.

270 It follows that the Community institutions did not err in concluding that the possibility that the effectiveness of bacitracin zinc in human medicine might be reduced for both present and potential use constituted a serious reason within the meaning of Article 3a(e) of Directive 70/524 and that that possibility entailed an adverse effect for human health which could justify the adoption of preventive measures.

3. The link between the use of bacitracin zinc as an additive in feedingstuffs and the development of resistance to that product in humans

271 Recital 22 to the contested regulation reveals that, when they concluded that there was a link between the use of bacitracin zinc as an additive in feedingstuffs and the development of resistance to that product in humans, the Community

institutions considered that 'selected resistances from the use of bacitracin zinc as a feed additive inevitably increase the reservoir of resistance to bacitracin zinc;... the percentage of [*E. faecium*] resistant to bacitracin zinc is higher in chickens which have received bacitracin zinc than in chickens which have not received it'. The Community institutions further noted that 'these resistances could be transferred from animals to humans and reduce the effectiveness of bacitracin zinc used as a human medicinal product'.

(a) Arguments of the parties

272 Alpharma maintains that the Community institutions were wrong to conclude that there was such a link in the case of bacitracin zinc, although it accepts that the possibility of such a link cannot be ruled out.

273 First, relying more particularly on the scientific report of Professor M.W. Casewell, Alpharma submits that there is no proof that the use of bacitracin zinc as an additive in feedingstuffs contributes to the development of antimicrobial resistance in humans. Even though bacitracin zinc has been used as a growth promoter for more than 40 years, no increase in resistance to it has been observed. According to Professor Casewell's scientific report, an infection caused by bacitracin zinc-resistant bacteria shown to be of animal origin has never been demonstrated in human medicine.

274 Nor, quite apart from the absence of any evidence, was there any proper scientific basis relating specifically to bacitracin zinc on which the Community institutions could carry out a scientific assessment of the risks associated with that product. Alpharma observes, in particular, that even in the Swedish report it was

concluded that 'available information [concerning bacitracin zinc] is [too] scarce for an assessment of the possible risks of bacitracin usage to human and animal health' (p. 244). Alpharma likewise observes that in its second opinion on antimicrobial resistance, adopted on 10 and 11 May 2001, the SSC noted that a 'thorough scientific evaluation' of the risks specifically linked to bacitracin zinc had not been carried out before it was withdrawn from the market. In any event, unlike, in particular, the situation in *BSE* and *NFU*, cited at paragraph 135 above, when the contested regulation was adopted there were no new scientific data relating to bacitracin zinc.

275 Alpharma acknowledges that the scientists who wrote the Netherlands report, cited at paragraph 37 above, concluded that such a link existed in the case of bacitracin zinc. However, it criticises the fact that the report refers to just one publication on the use of bacitracin zinc and that its conclusions are too general. It also observes, in that context, that the United Kingdom report, cited at paragraph 37 above, which was published in July 1998, concluded:

'No link between the animal use of bacitracin and resistance in the human use is reported or was found in the references selected' (p. 89).

276 Last, Alpharma maintains that there are sound specific reasons why such a link in the case of bacitracin zinc was extremely improbable, to say the least.

277 First, there is a high level of intrinsic natural resistance to bacitracin zinc in certain bacteria, notably in enterococci. Consequently, contrary to the assertion

of the Community institutions at recital 22 to the contested regulation, the use of bacitracin zinc as a growth promoter cannot increase the phenomenon of resistance. Alpharma submits that the study published in 1985 by A.H. Linton and others, entitled 'Monitoring for antibiotic resistance in enterococci consequent upon feeding growth promoters active against Gram-positive bacteria' (J. vet Pharmacol. Therap. 8, 62-70, 1985 ('the Linton study')), which is referred to by implication in recital 22 to the contested regulation, does not support the Community institutions' argument. Contrary to their contention, that study showed the existence of a high level of natural resistance to bacitracin zinc.

278 Second, resistance to bacitracin zinc cannot be transferred from animals to humans, since, as opposed to the case of other antibiotics, information about resistance to that product has never been found on a genetically mobile part of the bacteria, such as plasmids, for example. All available evidence suggests that resistance to bacitracin zinc is found only on chromosomes, which are not genetically mobile.

279 The Council and the Commission do not dispute that at the time when the contested regulation was adopted there were very few scientific data available relating specifically to bacitracin zinc, especially by comparison with the three other antibiotics whose authorisations were withdrawn by the contested regulation. They explain that circumstance by the fact that up to then scientific research had essentially concentrated on the transfer of antimicrobial resistance in regard to other antibiotics. Neither do they dispute that the SSC had concluded in its second report, published in 2001, that a detailed scientific assessment had not been carried out in respect of bacitracin zinc before it was withdrawn from the market.

280 However, referring to the SCAN opinions relating to the other antibiotics whose authorisations were withdrawn by the contested regulation and to the scientific

reports adopted at international, Community and national level referred to at paragraphs 37 and 44 above, the Council and the Commission contend that they were in possession of sufficient scientific evidence on which to conclude that the use of bacitracin zinc not only in human medicine but also as a growth promoter constituted a risk to human health.

(b) Findings of the Court

(i) The absence of evidence and the fact that it was impossible to carry out a full risk assessment

281 First of all, the fact that at the time when the contested regulation was adopted a link between the use of bacitracin zinc as an additive in feedingstuffs and the development of resistance to bacitracin zinc in humans had not been fully demonstrated could not prevent the Community institutions from adopting a preventive measure in respect of that product (see paragraph 153 et seq. above).

282 *A fortiori*, contrary to what Alpharma would have the Court believe, the Community institutions were entitled, under the precautionary principle, to take action before the existence and the extent of the phenomenon of the transfer of antimicrobial resistance from animals to humans, and, therefore, the reality and the seriousness of the adverse effects associated with the use of that product as an additive in feedingstuffs, were actually observed. If the Community institutions were required to await completion of such research before being entitled to take protective measures, the precautionary principle, whose purpose is to prevent such adverse effects from arising, would be rendered nugatory.

283 Similarly, it was held at paragraph 173 above that a preventive measure may be adopted despite scientific uncertainty and in spite of the fact that it is impossible to carry out a full scientific risk assessment if such a measure appears essential having regard to the risk to human health as identified by the competent public authority.

284 Consequently, the conclusions of the Swedish report and the second SSC report on antimicrobial resistance adopted on 10 and 11 May 2001, in which the SSC stated, essentially, that in the absence of scientific data a full scientific risk assessment had not been carried out before authorisation of bacitracin zinc as an additive in feedingstuffs was withdrawn, cannot demonstrate that the contested regulation is illegal.

285 The Court must examine, on the other hand, whether, in spite of the incomplete state of scientific knowledge relating specifically to bacitracin zinc, the Community institutions were entitled to conclude, on the basis of as thorough a risk assessment as possible and taking account of the best scientific data available at the time when the contested regulation was adopted, that there could be a link between the use of bacitracin zinc as an additive in feedingstuffs and the development of resistance to that product in humans.

(ii) The general decision to exclude any 'dual use of antibiotics'

286 In that regard, it is apparent from the documents before the Court, and in particular from a minute which Alpharma drew up of a meeting held with the responsible Commission officials on 11 December 1998 that the Commission services took the view that, in principle, the authorisations of all antibiotics which, in addition to being used as additives in feedingstuffs, were also used as human medicinal products or which were known to select for cross-resistance to

antibiotics used in human medicine should be withdrawn. As may be seen from recital 26 to the contested regulation, that general position was also adopted by the Council.

287 It is also apparent from the documents before the Court that in spite of the considerable scientific uncertainty as to such a link, there was at the time of adoption of the contested regulation a very broad consensus among scientists that the likelihood of antimicrobial resistance developing in humans owing to the use of antibiotics as additives in feedingstuffs was greatest in the case of antibiotics which, in addition to being used as additives in feedingstuffs, were also used in human medicine or were known to select for cross-resistance to antibiotics used in human medicine (hereinafter 'dual use of antibiotics').

288 Scientists at both international and Community level recommended that all dual use of antibiotics be halted. That was, in particular, the main conclusion reached in the WHO report adopted in October 1997 following a working meeting attended by 522 scientists from 42 different countries (p. 8).

289 Similarly, the Copenhagen recommendations include, *inter alia*, 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' (p. 35 of the recommendations).

290 Similarly, the 13 scientists who drafted the Netherlands report concluded, after a detailed analysis of the available scientific data:

'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 p. 19 of the Netherlands report).

291 In that regard, they made the following recommendation:

'As soon as possible termination of the use of substances which confer resistance to (related) antibiotics currently used to treat patients from bacterial infections.... This recommendation also applies to antimicrobial growth promoters for which

related compounds will be available for human therapy in the long term, and cross-resistance has been established (virginiamycin, avilamycin and bacitracin)' (pp. 19 and 20 of the Netherlands report).

292 Similar conclusions were drawn in the House of Lords report. It follows from that report that the House of Lords Select Committee on Science and Technology heard evidence from a large number of scientists, some of whom represented the industry concerned. In the report, the committee drew, *inter alia*, the following conclusions: '... on the evidence before us..., we recommend that antibiotic growth promoters... 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' (point 11.20 of the report).

293 Last, Professor Ø. Olsvik, giving evidence for Alpharma at the hearing, confirmed that, as regards the dual use of antibiotics, most scientists agreed with the WHO recommendations.

294 Regard being had to the foregoing, Alpharma cannot validly criticise the Community institutions for having made a manifest error of assessment in forming the view that, in principle, any dual use of an antibiotic as a growth promoter and as a human medicinal product entailed a risk for human health.

295 The Court must therefore examine whether the Community institutions were entitled to conclude on the basis of the factual evidence available at the time when the contested regulation was adopted that that general position was not invalidated in the specific case of bacitracin zinc. In that regard, the Court must analyse, first, Alpharma's argument that bacteria are naturally resistant to bacitracin zinc and, second, its argument that antimicrobial resistance to bacitracin zinc cannot be genetically transferred.

(iii) Bacteria are naturally resistant to bacitracin zinc

296 First, it is apparent from the documents before the Court that at the time when the contested regulation was adopted there was broad consensus among scientists that, generally, a degree of use of antibiotics had the consequence of increasing the reservoir of antibiotic-resistant bacteria in animals. By way of example, the WHO report concludes that 'Antimicrobial use leads to the selection of resistant forms of bacteria in the ecosystem of use. This will occur with all uses including... growth promotion. Low-level, long-term exposure to antimicrobials may have a greater selective potential than short-term, full-dose therapeutic use' (p. 34 of the WHO report).

297 That link between the use of antibiotics as growth promoters and the increase in the reservoir of resistance to those products or related products was also analysed by SCAN in its scientific opinions on the other antibiotics banned by the contested regulation. In its opinion on tylosin phosphate and spiramycin, SCAN concluded that 'it is generally accepted that there is a correlation... between

development of resistance and the amount of particular antibiotic used over time' (point 1.2 of the opinion). In its scientific opinion on virginiamycin, SCAN stated that it 'accepts the commonly held view that the pressure created by constant exposure to an antibiotic, will select initially in favour of those organisms demonstrating intrinsic resistance and latterly for acquired resistance to that antibiotic provided that the appropriate resistance genes are present in the population'.

298 Then, as regards the particular circumstances which in Alpharma's submission confirm that there was no such correlation in the case of bacitracin zinc owing to the natural resistance of certain bacteria to that product, it is clear from Alpharma's arguments themselves that a significant degree of natural resistance was observed only in respect of certain bacteria capable of causing human infections for which bacitracin zinc could be applied. Even in those bacteria, moreover, natural resistance does not appear to be universal. In his report, Professor M.W. Casewell merely stated that enterococci are 'often' naturally resistant to bacitracin zinc. It follows that, even in the case of those bacteria, it seems possible that certain strains which are sensitive to bacitracin zinc could become more resistant to it because it is used as an additive in feedingstuffs.

299 In any event, it is clear from the documents before the Court that, at the time when the contested regulation was adopted, scientific opinion was sharply divided on the question of natural resistance in the particular case of bacitracin. First, according to a scientific report drawn up by Professor Ø. Olsvik on 12 November 1998, which Alpharma submitted to the competent authorities of the United Kingdom, the Member State acting as rapporteur for bacitracin zinc, the only possible type of resistance to bacitracin zinc was natural resistance. The scientists responsible for the Swedish report were of the view that no clear conclusion could be drawn in that regard. They considered, in particular, that the results of the Linton study would be 'hard to evaluate' (point 3.2.1 of the Swedish report). Last, according to the scientists who drafted the Netherlands report,

there was a clear correlation between the use of bacitracin zinc as an additive in feedingstuffs and the development of resistance to it: 'There is sufficient evidence to conclude that the use of... bacitracin.. leads to the development of bacterial resistance to the agents in question in livestock'. That report also states that, according to those scientists, 'it has been proven beyond doubt that the use of various antibiotics, such as... bacitracin... as antimicrobial growth promoter can produce resistance to these substances within livestock' (pp. 18 and 50 of the Netherlands report). In particular, they considered that 'Linton found a statistically significant increase in bacterial resistance to these antibiotics in herds of piglets and flocks of poultry to which they were given' (p. 50 of the report).

300 In such circumstances, it must be concluded that the Community institutions were entitled to take the view that, generally, the existence of a link between the use of antibiotics as additives in feedingstuffs and the development of resistance to those products or to related products is broadly accepted among scientists. In that regard, they could properly rely, *inter alia*, on the analysis made by SCAN in its opinions on the other antibiotics whose authorisations were withdrawn by the contested regulation.

301 As regards that link, in the case of bacitracin zinc in particular, between use as an additive in feedingstuffs and the development of resistance, it is, admittedly, evident that the very positive nature of the conclusion made in that regard in recital 22 to the contested regulation is not entirely borne out by the evidence before the Court. In the light of the foregoing, however, the Court finds that the Community institutions were entitled to conclude on the basis of the factual evidence available to them at the time of adoption of the contested regulation that scientific opinion was divided.

302 Thus, even without a SCAN opinion and without awaiting the scientific report from the SSC, it was reasonable for the Community institutions to conclude that the existence of some degree of natural resistance to bacitracin zinc in certain bacteria was not capable of casting doubt on the correctness of the position adopted in relation to the risks associated with the dual use of antibiotics in general.

(iv) Antimicrobial resistance to bacitracin zinc cannot be genetically transferred

303 First, it is common ground between the parties that at the time when the contested regulation was adopted very few results of research into the specific question of the transfer of resistance to bacitracin zinc were available.

304 However, it is clear from the various scientific reports submitted to the Court that at the material time a large number of results of research into the mechanisms of the transfer of resistance in general were available. Although there was no scientific certainty in that regard, it is nevertheless apparent from those documents that most scientists believed that much was known about the mechanisms of transfer of antimicrobial resistance for certain bacteria.

305 The WHO report states that '[b]acteria and genes, including resistant genes, can pass between human, animal and other ecosystems' (p. 4). Similarly, the Copenhagen conclusions state that 'transmission of resistant bacteria and resistance genes from animal to man especially via the food chain takes place, and is well documented for some bacteria' (p. 20). The Netherlands report states

that '[r]esistant bacteria from the intestinal flora can infect humans, either directly or indirectly, via foodstuffs of animal origin. There is convincing evidence that both pathogenic bacteria... and indicator bacteria from the normal intestinal flora, such as *E. coli* and enterococci, can be transferred in this way' (p. 55).

That report likewise concludes that '[l]aboratory research and field studies have provided convincing evidence that resistance genes can be transferred from bacteria found in farm animals to micro-organisms which are pathogenic for humans. However, the extent to which the prevalence of resistant pathogenic micro-organisms in humans is attributable to the transfer of resistance genes from animals is not clear' (p. 57).

306 Furthermore, it follows in particular from recitals 8 to 11 and 16 to 20 to the contested regulation that a number of experiments and observations were carried out during the years preceding adoption of that regulation on the transfer of antimicrobial resistance as regards, in particular, the other three antibiotics (spiramycin, tylosin phosphate and virginiamycin) whose authorisations were withdrawn by the regulation. Those experiments and observations were largely analysed by SCAN in its scientific opinions of 5 February and 10 July 1998 (see paragraph 198 above) and were relied on by the Community institutions in support of their conclusion that there was a risk associated with those products. Similarly, it follows from recital 6 to the contested regulation that when Directive 97/6/EC of 30 January 1997 amending Council Directive 70/524/EEC concerning additives in feedingstuffs (OJ 1997 L 35, p. 11) was adopted, SCAN delivered a scientific opinion on the subject.

307 At the hearing, the Court asked the various expert witnesses called by Alpharma and by the Community institutions and the Member States whether and to what extent the Community institutions could reasonably conclude, on the basis of the

scientific information available at the time of adoption of the contested regulation, that those observations and experiments, although relating specifically to the other antibiotics, were also material to the issue of the transfer of antimicrobial resistance to bacitracin zinc. The expert witnesses called by the Council and the interveners stated that, since experiments relating specifically to bacitracin zinc had not yet been completed when the contested regulation was adopted, it was possible, on the basis of available scientific knowledge relating to those other antibiotics, to accept that the transfer mechanisms were similar for all antibiotics and that the transfer of resistance to bacitracin zinc was therefore highly probable. The expert witnesses called by Alpharma, on the other hand, stated that each antibiotic had different characteristics and that, from a strictly scientific viewpoint, reliable conclusions regarding the transfer of resistance to bacitracin zinc could only be drawn from the results of experiments relating to that specific product. However, following oral questions put by the Court, Professor Ø. Olsvik, for Alpharma, stated that, from the point of view of the public authority responsible for carrying out a risk assessment, even in the absence of specific data relating to bacitracin zinc, it was acceptable to rely on the experiments in respect of the other antibiotics and to draw similar conclusions for bacitracin zinc.

308 Furthermore, as regards Alpharma's arguments relating specifically to the transfer of resistance to bacitracin zinc, the documents before the Court do not wholly support Alpharma's contention that the genetic transfer of resistance to bacitracin zinc was excluded.

309 First, Alpharma stated in reply to written questions put by the Court that chromosomes were also to a certain extent genetically mobile and that consequently the fact that information on resistance to bacitracin zinc is located on chromosomes does not make it possible to exclude a genetic transfer between different bacteria of resistance to bacitracin zinc. That transfer is only 'less likely'.

It is also apparent from the SCAN opinion on tylosin phosphate and spiramycin that, in SCAN's view, the fact that resistance to a given product is located on a plasmid or a chromosome can only be regarded as a factor determining the probability of the transfer (point 1.4 of the SCAN opinion).

310 Second, it is apparent from the documents before the Court that, as scientific knowledge stood at the time of adoption of the contested regulation, the possibility that bacitracin zinc could be located on a plasmid could not be excluded. As Alpharma confirmed in response to written questions put by the Court, it follows from the Swedish report (p. 238) that experiments had been carried out on that subject even though, as Alpharma emphasised in its observations on that report, those experiments had been carried out *in vitro* and not under natural conditions.

311 Last, Alpharma does not dispute that the fact that resistance to bacitracin zinc is located on a chromosome does not mean that the transfer of that resistance cannot take the form of a colonisation of the human digestive system by resistant bacteria of animal origin. Alpharma maintains, in that regard, that the Community institutions did not have a proper scientific basis on which to conclude that that mechanism for the transfer of resistance existed. However, it is clear from the recitals to the contested regulation concerning the other antibiotics withdrawn by that regulation that the Community institutions had relied on a number of recent experiments which showed that such a mode of transfer could take place. Further confirmation may be seen in the United Kingdom report submitted to the Court by Alpharma. Although it states that no link between the use of bacitracin zinc as an additive in feedingstuffs and the development of resistance to that product in humans had been identified in the literature (p. 89), the report concludes that, like the other antibiotics whose authorisations were withdrawn by the contested regulation, bacitracin zinc 'may... select antibiotic resistant organisms, which could subsequently colonise man or cause disease' (p. 95).

312 Consequently, Alpharma has not succeeded in demonstrating that the Community institutions made a manifest error of assessment in forming the view that they had sufficient cogent and reliable scientific indications on which to conclude that resistance to bacitracin zinc could be transferred from animals to humans.

4. Conclusion

313 In the light of the foregoing, the Court finds that Alpharma has not demonstrated that the Community institutions erred in concluding, on the basis of the factual evidence available at the time of adoption of the contested regulation, that the use of bacitracin zinc as a growth promoter constituted a risk for human health. It is clear, on the contrary, that they could reasonably take the view that there were serious reasons concerning human health, within the meaning of Article 3a(e) of Directive 70/524, why bacitracin zinc, as an antibiotic with a dual use as an additive in feedingstuffs and at the same time as a medicinal product for human use, should be confined to medical use.

314 As to whether the Community institutions were entitled to carry out a scientific assessment of the risks associated with the use of bacitracin zinc as an additive in feedingstuffs without having a SCAN opinion relating to that use of the product and without awaiting the scientific report of the SSC, the Court makes the following findings. It follows from the foregoing analysis that, on the basis, first, of the SCAN opinions concerning the other antibiotics whose authorisations were withdrawn by the contested regulation and, second, of the reports on antimicrobial resistance of the various international, Community and national bodies referred to at paragraphs 37 and 44 above, the Community institutions were entitled to decide upon a coherent general public health policy on the use of

antibiotics as additives in feedingstuffs and, in so doing, to adopt provisional preventive measures in respect of those antibiotics which were also authorised for use in human medicine. Despite the as yet incomplete state of scientific knowledge in that area, that general policy was decided upon on the basis of the best scientific data available at the time of adoption of the contested regulation and corresponds to the opinions on the subject expressed by the great majority of scientists.

315 Rather than adopting a 'zero risk' approach, as Alpharma maintains, the Community institutions chose to take preventive measures with regard to a category of antibiotics in respect of which, according to an opinion widely shared by scientists, including those who gave evidence before the Court on behalf of Alpharma, the likelihood of a transfer of resistance, and therefore of the emergence of adverse effects for human health, was greatest. That conclusion is also borne out by the fact that, in acting consistently with their general policy on the use of antibiotics as additives in feedingstuffs, the Community institutions decided not to withdraw the authorisations of antibiotics which, at the time of adoption of the contested regulation, were not used in human medicine and were not known to select for cross-resistance to antibiotics used in human medicine.

316 In the particular case of bacitracin zinc, even without a scientific report relating specifically to that product, the Community institutions were entitled to note that at the time of adoption of the contested regulation, very little scientific research had been carried out in respect of that product. However, on the basis of the SCAN opinions on the other antibiotics and the reports on antimicrobial resistance drawn up by the various international, Community and national bodies cited at paragraphs 37 and 44 above, they had sufficient scientific material for the purpose of assessing the functioning of the mechanism of the transfer of antimicrobial resistance in general, to find that bacitracin zinc came within the category of antibiotics having a dual use as an additive in feedingstuffs and as a medicinal product which was currently employed, and might in the future be employed, in human medicine and to conclude, in full knowledge of the facts, that the arguments put forward by Alpharma did not allow them to depart, in the

case of bacitracin zinc, from the general policy of imposing a temporary ban on any dual use of antibiotics.

317 It follows that the Community institutions did not exceed the bounds of the discretion conferred on them by the Treaty when they concluded that, notwithstanding the highly complex and technical nature of the questions with which they were required to deal in this instance, they could, in the special and exceptional circumstances of the present case, carry out as thorough as possible a scientific assessment of the risks associated with the use of bacitracin zinc as an additive in feedingstuffs even though they did not have a SCAN opinion relating to that particular product and had not awaited the scientific report of the SSC.

318 In those circumstances, it was also in keeping with the precautionary principle that the Community institutions decided, in the context of their broad discretion and their responsibility for defining the public health policy which they deem most appropriate, not to await completion of more thorough research into the transfer of resistance to bacitracin zinc but to adopt, on a provisional basis and in reliance on available scientific knowledge, preventive measures in respect of that product.

D — *Conclusion*

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

III — *Breach of the principle of proportionality*

1. *Introduction*

320 Alpharma 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 Community institutions, which had a choice between a number of measures, failed to choose the least onerous one.

321 Furthermore, in Alpharma'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.

322 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.

323 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.

324 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 136 above, paragraph 13).

325 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 136 above, paragraph 14).

326 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 (2), second, whether other, less onerous, measures could have been taken (3), third, whether the disadvantages caused by the contested regulation are disproportionate to the objective pursued (4), 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 (5).

2. *Whether the withdrawal of the authorisation of bacitracin zinc as an additive in feedingstuffs was manifestly inappropriate to the objective pursued*

327 Relying more particularly on the evidence of Professor M.W. Casewell and Professor H. Hellig, Alpharma submits that the ban on bacitracin zinc will probably have significant negative effects on human and animal health.

328 In effect, according to Alpharma, the ban on the use of bacitracin zinc entails an increased veterinary use of alternative antibiotics also used for humans. Bacitracin zinc has a prophylactic effect against necrotic enteritis, which, if bacitracin zinc is not used, requires treatment with more powerful new-generation antibiotics, such as amoxycillin and ampicillin. Research completed since the contested regulation was adopted confirms that use of those products has increased. Current and potential human use of those antibiotics is much greater than that of bacitracin zinc, so that the increased use of those other antibiotics for therapeutic purposes involves a higher risk for human health than the use of bacitracin zinc as an additive in feedingstuffs. Alpharma also states that the ban on bacitracin zinc will increase the risk of meat being contaminated by faecal bacteria owing to rupture of the intestinal wall in poultry during processing, since it is established that treatment of chickens with bacitracin zinc strengthens their intestines.

329 In reality, therefore, according to Alpharma, the contested regulation entails the risk to human health which it seeks to reduce and constitutes a manifestly inappropriate means of achieving the objective pursued.

330 That conclusion is not invalidated by experiments carried out in Sweden and Finland since the use of antibiotics as additives in feedingstuffs was wholly or partially abolished in those countries. Alpharma states that the agricultural sector in those countries is not comparable with the agricultural sector in other Member States, where farming is much more intensive. Alpharma also criticises, essentially, the research methods employed in Finland. It therefore submits that it could not properly be inferred that the ban on bacitracin zinc could be regarded as an appropriate means of generally reducing the risk of transmission of resistance.

331 The Council, supported more particularly by 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 Alpharma's arguments. 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.

332 The Court notes that it is apparent from the documents before it 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 37 and 44 above (the Swedish report, the Netherlands report and the House of Lords report (paragraphs 3.27 to 3.29)).

333 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.

334 However, as Alpharma has 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 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).

335 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. In particular, 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).

336 Second, as regards the argument that the ban on bacitracin zinc as an additive in feedingstuffs would result in an increase in the use of certain antibiotics for therapeutic purposes, it is reasonable to accept 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').

337 As regards, moreover, the arguments relating to the prophylactic effects of the use of bacitracin zinc against necrotic enteritis and the increase in meat contamination by faecal bacteria, such as salmonella, owing to the ban on bacitracin zinc as an additive in feedingstuffs, the Court observes that, as the Council, supported by the Commission, the Kingdom of Sweden and the United Kingdom, rightly submitted, under Article 3a(d) of Directive 70/524, as amended by Directive 96/51, authorisation of an additive is to be given only if, at the level permitted, treatment or prevention of animal disease is excluded. Alpharma cannot therefore validly rely on the prophylactic effect of the use of bacitracin zinc as an additive in feedingstuffs to demonstrate that the contested regulation is inappropriate.

338 In any event, the fact, confirmed by certain documents before the Court, such as the report by Professor H. Hellig and the report of the TNO Nutrition and Food Research Institute ('A risk assessment of the use of bacitracin as growth promoting substance for animals'), dated 8 December 1998, which the applicant submitted to the Court only in summary form, that the use of bacitracin zinc as

an additive in feedingstuffs has certain positive effects on human health owing to the more limited use of antibiotics for therapeutic purposes in animals, does not assist Alpharma. Such positive effects cannot in themselves demonstrate that the ban on bacitracin zinc as a growth promoter is manifestly inappropriate given that the ban allows resistance in animals and the risk of transfer to humans to be reduced. Although in Alpharma's opinion, which is not shared by all scientists, withdrawal of the use of antibiotics such as bacitracin zinc makes it necessary to change farming methods in order to achieve the objective of reducing resistance in animals and the risk that it will be transferred to humans, and of avoiding too great a use for therapeutic purposes of other antibiotics in animals, the fact remains that such a measure is the prerogative of the Community legislature, on which the Treaty has conferred 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.

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

3. *The obligation to take other, less onerous, measures*

340 First, Alpharma observes that it is widely accepted among scientists that the development of antibiotic resistance in humans is primarily due to the excessive and inappropriate use of antibiotics in general in human medicine (see paragraph 35 above). However, the contested regulation was not apt to remedy that situation. Rather, the Community institutions should, according to Alpharma, first have taken measures to limit the uncontrolled sale of antibiotics, including bacitracin zinc, without a prescription. Since bacitracin zinc is used only to a negligible extent in human medicine, especially by comparison with its significant

use in animals, those measures would not only have been less onerous, they would also have been more effective. That conclusion is borne out by the ESC opinion (point 4.2 of the opinion) cited at paragraph 37 above, where the committee noted that '[t]he rational use of antibiotics will best be ensured if over-the-counter sales of antibiotics [are] avoided'.

341 The Court considers that, 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, which the Council disputes, that could not affect the validity of the ban on bacitracin zinc as an additive in feedingstuffs.

342 The risk to human health arising from the excessive and inappropriate use of antibiotics in human medicine is independent of the risk arising from the use of antibiotics as additives in feedingstuffs and adds a risk to the latter risk. Since the Community institutions were entitled to conclude that the use of bacitracin zinc in feedingstuffs carries a risk that resistance to that product will develop in humans, the ban on that use constitutes an appropriate, albeit not the only, means of ensuring that the effectiveness of the present or potential use of that product in human medicine is not reduced, or indeed eliminated. In such circumstances, contrary to Alpharma's submission, the Community institutions could reasonably conclude that the adoption of measures intended to reduce the use of antibiotics in human medicine was not an alternative to withdrawing the authorisation of bacitracin zinc 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.

343 Second, Alpharma submits that the Community institutions could and should have gradually replaced bacitracin zinc as an additive in feedingstuffs rather than ban it immediately.

344 The Court observes that Alpharma has not established whether or how such measures would have allowed the objective pursued by the contested regulation to be achieved. In particular, Alpharma has not succeeded in rebutting the argument of the defendant and the interveners that such measures are ineffective since antimicrobial resistance is, in the view of the experts, a virtually irreversible phenomenon (see paragraph 269 above) and, therefore, is eliminated, if ever, only long after the antibiotic has ceased to be added to feedingstuffs.

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

4. *The disproportionate nature of the disadvantages by comparison with the objective pursued*

346 Referring to the *BSE* case, cited at paragraph 135 above, Alpharma seeks essentially to demonstrate that the withdrawal of the authorisation of bacitracin zinc as an additive in feedingstuffs was disproportionate to the objective pursued.

347 Putting forward the arguments already submitted in the first part of the second plea Alpharma reiterates that the use of bacitracin zinc as a growth promoter presents no risks to human health. There is, it submits, a significant difference in the potential degree of risk to human health between the *BSE* case and the present case. In *BSE*, the risk was that a fatal and incurable disease would be transmitted, whereas in the present case the risk is, allegedly, that resistance to a medicinal product which is not, and will not be, widely used in human medicine will be increased. There was also, it maintains, a significant difference in the urgency of the measures to be taken. In *BSE* new scientific data had established the existence of a risk of such a kind that the Commission was required to take prompt action. That contrasts with the present case, where no fresh evidence establishing the existence of a serious risk to human health associated with bacitracin zinc was obtained. The fact that the contested regulation provides for a transitional period of six months to enable traders to use up their stocks of bacitracin zinc shows the relative lack of urgency. At the very least, therefore, the Community institutions could and should have awaited the results of the various pieces of scientific research being conducted. A further authorisation for that purpose of between 6 and 12 months for bacitracin zinc, which had been present on the market for 40 years as a growth promoter and for 50 years as a human medicinal product, would probably not, in Alpharma's submission, have been of decisive significance for human health.

348 Alpharma maintains that the illegality of the measure adopted by the Community institutions is confirmed by a report published in London in 1999 by the 'UK Advisory Committee on the Microbiological Safety of Food', entitled 'Report on Microbial Antibiotic Resistance in relation to Food Safety'. That report recommended an immediate ban on growth promoters 'where there was a medical equivalent antibiotic in current or planned use' (paragraph 10.25). On the other hand, '[f]or those antibiotics where there was currently no medical equivalent, or where their medical use was rare — ... bacitracin zinc... — the

Working Group did not feel that there was currently sufficient information to justify calling for an immediate ban. However, they recommended that the use of these substances should be kept under close review, and if any evidence became available of medical equivalents being developed for clinical use, then their use as growth promoters should be phased out' (paragraph 10.26).

349 The Court observes, first of all, that in a situation such as the present one, it was for the Community institutions to exercise their discretion and to assume their political responsibility in the face of a particularly complex and delicate situation.

350 It must be borne in mind that at the time when the contested regulation was adopted there was great uncertainty about the risks to human health associated with the general use of antibiotics as growth promoters in animals.

351 In spite of that scientific uncertainty, however, it is common ground (see paragraphs 33 and 34 above) that the development of antimicrobial resistance and the possible implications of the use of antibiotics as additives in feedingstuffs were regarded by a large number of scientists as a serious threat to human health. In addition, the rate of increase in the development of resistance to antibiotics had significantly increased during the years preceding adoption of the contested regulation. At the same time, fewer new antibiotics were placed on the market, whereas antimicrobial resistance is a virtually irreversible phenomenon.

352 Admittedly, it was stated at paragraph 257 above that bacitracin zinc has only a relatively limited use in human medicine and that, by comparison with the other antibiotics whose authorisations were withdrawn by the contested regulation, very few scientific data relating to bacitracin zinc were available when that measure was adopted.

353 None the less, it should be borne in mind that during the years preceding adoption of the contested regulation scientists increasingly took the view that any dual use of antibiotics as additives in feedingstuffs and as human medicinal products entailed a risk to human health. Similarly, it was stated at paragraph 306 above that new scientific experiments and observations concerning the transfer of antimicrobial resistance had been carried out during that period. Although those experiments and observations did not specifically concern bacitracin zinc and did not conclusively show that there was a link between the use of additives in animals and antimicrobial resistance in humans, they none the less led to a better understanding of the mechanism of the transfer of resistance as such and could reasonably be taken as scientific indications of the existence of such a link in the case of bacitracin zinc. Last, it should be borne in mind that at that time scientists were contemplating the possibility that bacitracin zinc would be used to treat VRE, a particularly significant clinical problem in human medicine (see paragraphs 260 to 264 above).

354 Furthermore, the Community institutions could in that context reasonably take account 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.

355 In such a situation, the Community institutions are not to be criticised for having opted for a coherent general public health policy (see paragraph 314 above) consisting in promoting the provisional withdrawal of the authorisations of all antibiotics which, like bacitracin zinc, were used both in human medicine and as additives in feedingstuffs and, at the same time, in proceeding with current scientific research into, in particular, resistance to that product. Such an approach, which sought to ensure that the risk of a transfer of resistance would not become a reality, was consistent with the precautionary principle, under which a public authority may be required to take action even before adverse effects have become apparent.

356 That conclusion is not called in question by the fact that Alpharma made significant investments to place bacitracin zinc on the market and that bacitracin zinc had been used for a very long period. It must be borne in mind 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 136 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).

357 In addition, withdrawal of the authorisation of bacitracin zinc 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 bacitracin zinc as an additive in feedingstuffs 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.

358 In the light of the foregoing, the withdrawal of the authorisation of bacitracin zinc does not appear to be manifestly disproportionate to the objective pursued.

5. The cost/benefit analysis

359 Referring to the fourth principle of the Draft Guidelines and to point 6.3.4. of the Communication on the Precautionary Principle, Alpharma claims that as far as it

is aware no cost/benefit analysis of the ban on bacitracin zinc was ever carried out. It submits that, according to those documents, such an analysis is to include a comparison between the most likely positive and negative consequences of the proposed action and those which would follow if no action were taken, in terms of the overall short-term and long-term cost for the Community, and that the analysis must also include non-economic considerations.

360 Relying, in particular, on a scientific study published in 1996 (W. Verbeke and J. Viaene, 'Environmental Impact of Using Feed Additives', University of Gent), Alpharma submits that the ban on bacitracin zinc will entail significantly higher farming costs owing to the larger volumes of feed required and to greater environmental constraints because more manure is produced.

361 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.

362 As regards Alpharma'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).

363 However, as regards Alpharma's claim that the Community 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.

364 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 356 above).

365 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 Alpharma 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 Community institutions was unreasonable in that regard.

366 Furthermore, following the ban on bacitracin zinc, farmers could continue to use the four other antibiotics which the Council did not ban under the contested regulation.

367 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 bacitracin zinc 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.

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

6. *Conclusion*

369 It follows from all the foregoing considerations that the contested regulation is not vitiated by a breach of the principle of proportionality.

IV — *Breach of the principle of protection of legitimate expectations*

370 Alpharma acknowledges that, in accordance with settled case-law (Case C-350/88 *Delacre and Others* v *Commission* [1990] ECR I-395, paragraph 33), it cannot have a legitimate expectation that an existing situation which is capable of being altered by the Community institutions in the exercise of their discretionary power will be maintained. It therefore accepts that it could not have a legitimate expectation that the Community institutions would never exercise their discretionary power to withdraw the authorisation of bacitracin zinc as an additive in feedingstuffs if it were in the interests of public health to do so.

371 None the less, Alpharma states that when it adopted directive 97/6 (see paragraph 306 above) the Commission decided to establish a programme for the surveillance of microbial resistance 'to pinpoint the problem of possible resistance to antibiotics induced by the use of additives in animal feed and transferred to man' (sixth recital of the preamble to Directive 97/6). Alpharma observes that bacitracin zinc was included in that programme, which was sponsored and partly financed by a number of producers of additives, including itself. In its submission, the ban on antibiotics such as bacitracin zinc significantly reduces the validity of that programme. In setting up the Surveillance Programme, the Commission created a situation which led Alpharma to harbour reasonable expectations that no decision banning bacitracin zinc would be taken before the results of the programme were known. Those expectations were encouraged by a letter from the Commission to the Chairman of Fefana, dated 31 March 1998, and by statements made by Mr Fischler, the Member of the Commission responsible for agriculture, on 15 May 1998 during the plenary sitting of the European Parliament.

372 Alpharma denies that it could and should have foreseen, even before November 1998, that the Community institutions might ban bacitracin zinc. First, it states that the request for amendment of the Community legislation submitted by the Swedish authorities related to eight antibiotics, only four of which were eventually banned. In addition, it observes that, as regards bacitracin zinc, the Swedish report states: 'In conclusion, available information is too scarce for an assessment of the possible risks of bacitracin usage to human and animal health' (paragraph B.10 of the report). That conclusion is comparable to the one which the same report draws in respect of other antibiotics which were not subsequently banned by the contested regulation. On the other hand, it contrasts with the statements in that report relating to the three other antibiotics banned by the contested regulation. Alpharma further states that it disputed the results of the Swedish report by lodging, on 21 August 1998, its own scientific study of bacitracin zinc. It never received either a request for further information or any other reaction after lodging that study and therefore felt certain that bacitracin zinc was not seen as controversial.

373 In that context, Alpharma states that press releases were issued following the meeting of the Council of Ministers for Agriculture on 19 and 20 October 1998 and that, according to those documents, four antibiotics, not including bacitracin zinc, were to be banned. Similarly, in a letter of 8 July 1998 to the United Kingdom Minister for Agriculture, the Chairman of the 'UK Advisory Committee on the Microbiological Safety of Food' stated that the use of three antibiotics, not including bacitracin zinc, were the subject of a procedure before the Community institutions.

374 The Court observes that 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 76 above, paragraph 148).

375 Next, neither Directive 97/6 nor the Surveillance Programme set up by the Commission gives any indication that a decision to withdraw or to maintain the authorisation of antibiotics, including bacitracin zinc, as growth promoters would be conditional upon completion of the relevant research.

376 Furthermore, the Court has already held that the Community institutions did not err when they took the view, in adopting the contested regulation, that they had a proper scientific basis for concluding that the use of bacitracin zinc as an additive

in feedingstuffs constituted a risk to human health and for taking a preventive protective measure.

377 In such a situation, the Community institutions were entitled to give priority to human health protection over the successful conclusion of research in progress, even though that research had, in part, been initiated by the Community institutions themselves and given rise to considerable expense for the industry concerned. Nor, for the same reason, and contrary to Alpharma's contention, is that conclusion called in question by the fact, even on the assumption that it were well founded, that the withdrawal of the authorisation of bacitracin zinc has the consequence of distorting the results of ongoing studies.

378 Moreover, contrary to Alpharma's contention, no assurance was given in the letter of 31 March 1998 to the Chairman of Fefana that certain antibiotics would continue to be authorised until the Surveillance Programme had ended. In that letter, which, moreover, was not addressed to Alpharma, the Director-General of the Directorate-General for Agriculture (DG VI) merely expressed the Commission's satisfaction that the industry was participating in the programme. He also stated, in essence, that he hoped that the programme would be carried out as envisaged, but added that safeguard measures in respect of an additive might be adopted by the Member States when they had sufficient grounds to conclude that there was a risk, in particular to human health.

379 Similarly, in his statements to the Parliament, Mr Fischler did not give any specific assurance to Alpharma, but presented, in general terms, the broad lines of the Commission's policy on the development of resistance to antibiotics. In any event, while it is true that in those statements Mr Fischler emphasised the

importance of the current research programmes, he also stated that a decision was to be taken by 31 December 1998 on the request for amendment of Directive 70/524 submitted by the Swedish authorities and that, on an earlier occasion, the Commission had already withdrawn the authorisation of an additive, under the precautionary principle, where there was a risk to human health.

380 Alpharma is also wrong to maintain that it could not reasonably foresee that, on the basis of the factual evidence available to them, the Community institutions might withdraw the authorisation of bacitracin zinc as an additive in feedingstuffs. As the Council has rightly pointed out, Alpharma, 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 where there is a risk to human health. In addition, at least since the Act of Accession was signed by the Kingdom of Sweden, Alpharma, the largest producer of bacitracin zinc in the European Economic Area, 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 and the requests for amendment of Directive 70/524 made by the Swedish authorities should all have put Alpharma on notice that it was not impossible that the Community institutions would act as they eventually did by means of the contested regulation.

381 Consequently, the documents in the case-file to which Alpharma refers do not lead to the conclusion that the Community institutions gave it precise assurances capable of giving rise to a legitimate expectation that no decision concerning bacitracin zinc would be taken before the conclusion of the Surveillance Programme.

382 Last, contrary to Alpharma's contention, the press release issued following the meeting of the Council on 19 and 20 October 1998 does not contain a list of the products the withdrawal of whose authorisation was envisaged. The Court finds

that the letter of 8 July 1998 from the Chairman of the UK Advisory Committee on the Microbiological Safety of Food to the United Kingdom Minister for Agriculture in no way reflects any position adopted by a Community institution and cannot therefore be claimed to found a legitimate expectation on Alpharma's part.

383 Having regard to all of the foregoing, the Court concludes that the adoption of the contested regulation does not constitute a breach of the principle of protection of legitimate expectations. The present plea must therefore be rejected as unfounded.

V — *Breach of the rights of defence*

384 Referring to the case-law of the Court of Justice (Case C-32/95 P *Commission* v *Lisrestal and Others* [1996] ECR I-5373, paragraph 21) and the Court of First Instance (Case T-50/96 *Primex Produkte Import-Export and Others* v *Commission* [1998] ECR II-3773, paragraph 59), Alpharma argues that the Council adopted the contested regulation in breach of its rights of defence. The fact that the present case differs from those cases in that it concerns a measure of general application does not in its view alter that conclusion, since the contested measure adversely affects Alpharma by reason of specific characteristics which distinguish it individually.

385 Alpharma further claims that, contrary to the statement in the Draft Guidelines (paragraph 3.2), 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. It was never given a proper opportunity at any stage of the legislative procedure to put forward its views, adduce evidence in its possession or participate in genuine consultation with the Community institutions. It submitted its observations on the Swedish authorities' report on 21 August 1998, together with a substantial

scientific file. However, the Community institutions never consulted it on the subject and never informed it during the legislative procedure of the reasons why that evidence was inconclusive or unsatisfactory. It argues that the meeting with the Commission officials on 11 December 1998 could not be regarded as a proper consultation, since that meeting took place on the last working day before the Council was to vote and, accordingly, after the Commission had submitted its proposal for a regulation.

386 Alpharma maintains that in the present case the Community institutions were required to put in place a mechanism which made it possible to gather and examine carefully and impartially all the relevant evidence before taking a preventive measure and were therefore required to involve the parties concerned ('stakeholders'), including itself, in the legislative process. In that regard, it submits that it is the principal stakeholder affected by the contested regulation, since it is the leading world producer of bacitracin zinc and the only one in the world to produce bacitracin zinc for human use. Furthermore, in the absence of a SCAN opinion dealing specifically with the risk associated with bacitracin zinc, it was not only the obvious source of all the most recent scientific data on that product but it should also have been able to put forward its own arguments concerning the evidence and the documents on which the Community institutions based their decision.

387 The Court observes, first of all, that the contested regulation was adopted under the procedure laid down in Article 23 of Directive 70/524 and that that provision does not confer on the traders concerned a right to take part in the procedure. Moreover, the Court held at paragraph 142 above that Alpharma cannot rely on the Draft Guidelines to found such a right.

388 Contrary to Alpharma's argument, 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 (*Commission* v *Lisrestal and Others*, cited above, paragraph 21, and *Primex Produkte Import-Export and Others* v *Commission*, cited above, 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 Alpharma — unlike the farmers in particular — is directly and individually concerned by the contested regulation does not alter that finding (C-104/97 P *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).

389 Furthermore, it is apparent from the documents before the Court that Alpharma was able to submit its observations on the Swedish report through the United Kingdom, the Member State acting as rapporteur for bacitracin zinc, and was received by Commission officers before the contested regulation was adopted. To a certain extent, therefore, Alpharma was able to make known its views during the procedure which led to the adoption of the contested regulation.

390 Consequently, this plea in law must also be rejected.

VI — *Breach of the obligation to state reasons*

391 According to Alpharma, the contested regulation is not based on a proper statement of reasons. First, it reiterates the arguments already put forward in connection with the plea alleging a manifest error of assessment to support its

contention that the use of bacitracin zinc as a growth promoter did not constitute a risk to human health and that the Community institutions did not properly apply the precautionary principle.

392 In that regard, the Court finds that in reality Alpharma is criticising the Community institutions for having made a manifest error of assessment, which is a different plea from that alleging breach of the obligation to state reasons (Case C-265/97 P *VBA* v *Florimex and Others* [2000] ECR I-2061, paragraphs 114 and 115) and which has already been examined above. This complaint must therefore be rejected.

393 Second, Alpharma submits that the inadequacy of the statement of reasons on which the contested regulation is based is evident from a comparison of the reasons provided in respect of bacitracin zinc, which amount to only 18 lines, with those provided in respect of the other antibiotics affected by the contested regulation, namely spiramycin and tylosin phosphate (83 lines in all) and virginiamycin (71 lines).

394 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 (*VBA* v *Florimex and Others*, cited at paragraph 392 above, 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).

395 In the present case, the contested regulation sets out, at recital 22, reasons which, admittedly, are very concise in the specific case of bacitracin zinc. None the less, when read in context, the regulation states clearly and sufficiently that, according to the Community institutions, the use of bacitracin zinc as a growth promoter entailed a risk to human health, in particular owing to its dual use as an additive in feedingstuffs and as a human medicinal product. It follows that, according to the Community institutions, in spite of the existing scientific uncertainty, there were sufficient scientific indications for them to conclude, under the precautionary principle, that the use of bacitracin zinc as an additive in feedingstuffs led to a resistance to that product in animals and that that resistance might be transferred from animals to humans with the effect of reducing the effectiveness of bacitracin zinc as a human medicinal product.

396 The reasons given by the Community institutions in the contested regulation as regards bacitracin zinc therefore appear to be clear and unequivocal.

397 Third, Alpharma submits that the reasons stated in the preamble to the contested regulation contradict those given in Regulation No 2786/98 (see paragraph 43 above). It states that, by Regulation No 2786/98, which was adopted only five days after the contested regulation, the Commission extended the period of provisional authorisation of bacitracin zinc for chickens and pigs until 17 July 1999 and that it follows from the second recital to that regulation that the Commission considered that the use of bacitracin zinc as a growth promoter '[did] not adversely affect human... health'. Alpharma further observes that Regulation No 2786/98 states, in the fourth and fifth recitals thereto, that the Commission consulted SCAN concerning that extension of authorisation and that SCAN gave a favourable opinion.

398 The Court finds that by Regulation No 2786/98 the Commission decided, on the basis of Article 9i of Directive 70/524, as amended by Directive 96/51, that bacitracin zinc could be the subject of national provisional authorisations for certain animals, namely chickens for fattening and pigs. That regulation was adopted on 22 December 1998, it was published on 23 December 1998 and it was to apply with retroactive effect from 1 December 1998.

399 By the contested regulation, on the other hand, the Council provisionally deleted the entry for bacitracin zinc from Annex B to Directive 70/524, i.e. from the annex containing the list of antibiotics authorised during the re-evaluation period, and did so in respect of all animals. That regulation was published on 29 December 1998 and, pursuant to Article 3 thereof, was to apply from 1 January 1999 in the Kingdom of Sweden only and only from 1 July 1999 in the other Member States.

400 From those dates, the contested regulation thus derogated from Regulation No 2786/98, whereby the authorisation of certain uses of bacitracin zinc as an additive in feedingstuffs had been provisionally granted until such time as the contested regulation became applicable.

401 In such a context, differences in the statements of reasons on which those regulations were based cannot amount to a breach of the obligation to state the reasons on which the contested regulation was based.

402 Consequently, the plea alleging breach of the obligation to state reasons is also unfounded.

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

Costs

404 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 Alpharma 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.

405 Under Article 87(4) of the Rules of Procedure, the Member States and Community institutions which intervened in the procedure are to bear their own costs. Consequently, the Commission, the Kingdom of Sweden, the Republic of Finland and the United Kingdom of Great Britain and Northern Ireland must be ordered 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 Alpharma 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 Commission, 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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