ORDER OF THE PRESIDENT OF THE COURT OF FIRST INSTANCE
5 July 2001 *

In Case T-55/01 R,

Asahi Vet, SA, established in Barcelona (Spain), represented by C. Bittner, lawyer,

applicant,

supported by

Kingdom of Spain, represented by M. López-Monís Gallego, lawyer, with an address for service in Luxembourg,

interveners,

* Language of the case: German.

Commission of the European Communities, represented by G. Braun and K. Fitch, acting as Agents, with an address for service in Luxembourg,

defendant,

APPLICATION for the grant of provisional authorisation of Toyocerin as an additive in the feedingstuff of certain animals in the territory of the European Union, except Sweden,

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

makes the following

Order

Legal context

1 On 23 November 1970 the Council adopted Directive 70/524/EEC concerning additives in feedingstuffs (OJ, English Special Edition 1970 (II), p. 840). Annex I

to the directive lists the additives which, in principle, are the only ones the marketing and use of which in feedingstuffs are authorised by the Member States, subject only to compliance with the conditions for their use laid down by the directive. Annex II to the directive lists the additives which may, by derogation from Annex I, exceptionally be authorised on a provisional basis by the Member States until it is decided, by tests, that they may be finally authorised, that is to say, included in Annex I, or not, which means that, in the latter situation, they are removed from Annex II.

2 Directive 70/524 has been amended on several occasions, in particular by Council Directive 96/51/EC of 23 July 1996 (OJ 1996 L 235, p. 39). Article 3a of Directive 70/524, as inserted by Article 1(4) of Directive 96/51, lays down the conditions for the grant of Community authorisation of an additive used in feedingstuffs.

3 Article 9e of Directive 70/524, as inserted by Article 1(4) of Directive 96/51, is entitled 'Provisional authorisation for a maximum of four or five years' and provides as follows:

'1. In the case of the additives referred to in Article 2(aaaa), provisional authorisation may be given at Community level for the use of a new additive or a new use of an additive already authorised, provided that the conditions laid down in Article 3a(b), (c) (d) and (e) are met and it is reasonable to assume that the condition laid down in Article 3a(a) is also met. These additives shall be included in Chapter IV of the list referred to in Article 9t(b).

2. Provisional authorisation as referred to in paragraph 1 may not exceed four years from the date on which it takes effect.

3. Additives as referred to in Article 2(aaaa), included in Annex II before 1 April 1998, may continue to be the subject of national provisional authorisations; they shall be included in Chapter IV of the list referred to in Article 9t(b). The period of provisional authorisation of these additives may not exceed five years taking account of the period of inclusion in Annex II referred to above.'

4 By Decision 76/791/EEC of 24 September 1976 establishing a Scientific Committee for Animal Nutrition (OJ 1976 L 279, p. 35), the Commission appointed a scientific committee for animal nutrition. This decision was 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). Article 12 of that decision provides as follows:

'1. The scientific committees established by this decision replace the present scientific committees as follows:

...

(b) the Scientific Committee for Animal Nutrition replaces the Scientific Committee for Animal Nutrition established by Decision 76/791.'

5 The Annex to Decision 97/579 shows that the sphere of competence of the Scientific Committee for Animal Nutrition ('SCAN') covers 'scientific and technical questions concerning animal nutrition, its effect on animal health, on

the quality and health of products of animal origin, and concerning the technologies applied to animal nutrition'.

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

'The [SCAN] 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.'

7 The Standing Committee for Feedingstuffs ('the Standing Committee') referred to in Article 23 of Directive 70/524 was established by Council Decision 70/372/EEC of 20 July 1970 setting up a Standing Committee for Feedingstuffs (OJ 1970 L 170, p. 1). It consists of representatives of the Member States with a representative of the Commission as chairman. The object of the Standing Committee is to provide a procedure for close cooperation between the Member States and the Commission in the area of feedingstuffs. The Standing Committee must be consulted before any feedingstuff is authorised to be put into circulation.

8 Article 23 of Directive 70/524, as inserted by Article 1(1) of Council Directive 84/587/EEC of 29 November 1984 amending Directive 70/524 (OJ 1984 L 319, p. 13) and last amended by Annex I to the Act concerning the conditions of accession of the Kingdom of Norway, 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. 155) provides as follows:

'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... .

2. The representative of the Commission shall submit to the [Standing] Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time-limit to be fixed, 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 Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the [Standing] 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 [Standing] 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.'

9 More specifically, the procedure referred to in Article 4 of Directive 70/524, as inserted by Article 1(4) of Directive 96/51, for obtaining Community authorisation of an additive used in feedingstuffs is described as follows:

'1. In order to obtain the Community authorisation for a substance or a preparation as an additive or for a new use in the case of an already authorised additive, the applicant for authorisation shall select a Member State to act as rapporteur during the scrutiny procedure on the dossier he has compiled in accordance with the provisions of Directive 87/153 of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition. Where the applicant is established in a third country, he must have a representative in the Community.

...

4. Member States shall have a period of 60 days from the date on which the dossier was dispatched to them in which to check whether the dossier has been compiled in accordance with Directive 87/153/EEC and, where appropriate, to submit their comments in writing to the Commission and the other Member States. If, on expiry of the period referred to in the first paragraph, no objection has been made, the representative of the Commission shall have a period of 30 days in which to include the authorisation application on the agenda for the Standing Committee for Feedingstuffs....

5. If, after consultation of the [Standing Committee], it is deemed that the rules on presentation of dossiers have not been complied with, a representative of the Commission shall so notify the applicant for authorisation to put into circulation and the Member State acting as rapporteur; where necessary, a new application must be submitted in accordance with paragraphs 1, 2 and 3.

6. The Commission shall ensure that a decision is taken, in accordance with the procedure laid down in Article 23, on the application for Community authorisation within 320 days following its inclusion on the agenda for the Standing Committee... in accordance with the second subparagraph of paragraph 4, However, this time-limit shall be interrupted where a request for additional information is made by a Member State in the Standing Committee... or at the request of the [SCAN]. Where an application for Community authorisation to put an additive into circulation is rejected or the decision on it is postponed, a representative of the Commission shall inform the applicant for authorisation and the Member State acting as rapporteur of the reasons for the rejection or postponement of the decision.'

Facts and procedure

10 The applicant is a subsidiary of the Japanese company Asahi Vet Japan Co. Ltd. which developed Toyocerin, an additive used in feedingstuffs, and is the only producer of it in the world. The applicant prepares only this additive at its Spanish centre for the European market and distributes it in Europe. In that capacity the applicant is at the same time the applicant in the procedure for obtaining Community authorisation for Toyocerin, as provided for by Directive 70/524.

11 Toyocerin is a preparation of micro-organisms of the strain *Bacillus cereus var. toyoi* containing at least $1 \times 10^{[10]}$ UFC (units forming colonies) per gramme of additive. The additive has been used in Europe since the mid-1980s.

12 On 26 April 1991 the applicant applied for Community authorisation for Toyocerin for the first time. For this purpose it sent an application accompanied by a dossier to the Commission, the Member States and the SCAN, through the Kingdom of Spain as intermediary, the Member State acting as rapporteur. A

provisional authorisation for Toyocerin was then granted for rearing pigs, piglets and sows by Commission Directive 94/17/EC of 22 April 1994 amending Directive 70/524 (OJ 1994 L 105, p. 19), and Toyocerin was included in Annex II to the latter directive. That authorisation, which was for a limited period, was regularly extended until 21 April 1999, that is to say, five years after the original authorisation. There was no further extension under Article 9e(3) of Directive 70/524, which limited provisional authorisations to five years.

13 On 16 October 1995 the applicant applied for authorisation for Toyocerin as an additive in the feedingstuffs of fattening chickens, laying hens, calves, fattening cattle, fattening rabbits and breeding rabbits. Toyocerin was provisionally authorised for those categories of animals by Commission Regulation (EC) No 1411/1999 of 29 June 1999 concerning the authorisation of new additives and new additive uses in feedingstuffs (OJ 1999 L 164, p. 56). That provisional authorisation was extended until 20 February 2001 by Commission Regulation (EC) No 2697/2000 of 27 November 2000 concerning the provisional authorisation of additives in feedingstuffs (OJ 2000 L 319, p. 1).

14 After 21 April 1999, the expiry date of the provisional authorisation for Toyocerin for rearing pigs, piglets and sows, that additive was examined by the SCAN and the Standing Committee on several occasions.

15 On 2 June 1999 an *ad hoc* working party, set up by the SCAN, examined the data concerning Toyocerin and delivered a favourable opinion on the effectiveness of the product for piglets less than two months old and for sows. A summary of that examination was made and presented to the plenary session of the SCAN on 10 June 1999, which accepted the working party's findings.

16 On 18 June 1999 the Commission therefore drew up a draft regulation providing for the authorisation of Toyocerin for an unlimited period for piglets of not more than two months and for sows, with retroactive effect from 21 April 1999, the expiry date of the provisional authorisation.

17 On 22 June 1999 Spain, as the Member State acting as rapporteur, received a letter from the Commission asking for additional information on the effectiveness of Toyocerin in pigs two to four months old.

18 The meeting of the Standing Committee took place on 28 and 29 June 1999. At the meeting the Committee adjourned adoption of the decision concerning the authorisation of Toyocerin for an unlimited period, in accordance with the draft regulation, because at the meeting the Danish delegation raised a new question concerning the harmlessness of Toyocerin. The Danish delegation asked whether the strains of *Bacillus cereus*, to which the micro-organisms used in the production of Toyocerin belong, were likely to produce toxins.

19 On 20 July 1999, in reply to the Commission's letter of 22 June 1999, Spain, as the Member State acting as rapporteur, sent the additional information on the effectiveness of Toyocerin in pigs two to four months old.

20 After asking the applicant to send strains of the bacteria it used to Norway for examination, the Danish delegation stated, by letter of 8 October 1999 to the Member State acting as rapporteur, that it had received an exhaustive reply to its question on the harmlessness of Toyocerin.

21 By letter of 18 November 1999 to the Commission, the Member State acting as rapporteur requested that the application for the authorisation of Toyocerin for rearing pigs of four months, piglets of not more than two months and, possibly, those aged two to four months, and for sows, be included on the agenda of the next meeting of the Standing Committee.

22 By letter of 16 February 2000 to the Member State acting as rapporteur, the Commission stated that it had asked the SCAN to re-examine the safety of all 'bacillus products' and to determine the data which would have to be provided to characterise strains which might be dangerous. The Commission added that, pending the SCAN's opinion as to the safety of Toyocerin, the Commission could not propose to the Standing Committee the adoption of a decision concerning the application for authorisation of Toyocerin for an unlimited period as an additive in the feedingstuffs of rearing pigs, piglets and sows.

23 On 17 February 2000 the SCAN announced its decision on the question of the safety of strains of the bacillus with regard to the possible formation of toxins. It recommended a test procedure to verify the possible formation of toxins connected with strains of the bacillus.

24 By letter of 13 September 2000 from the Member State acting as rapporteur, a supplementary dossier on this question, in conformity with the SCAN's opinion of 17 February 2000, was sent to the Commission, the members of the SCAN, the secretariat of the latter and the Member States.

25 In October 2000 the SCAN working party for the safety of micro-organisms met and examined, in particular, the question of the safety of Toyocerin in relation to

the production of toxins. On completion of the examination, the working party reached no negative conclusions on this particular aspect of the safety of the additive in question.

26 At the plenary sessions of the SCAN in October and December 2000, the SCAN did not comment on the harmlessness of Toyocerin. The application for the authorisation of this additive was not placed on the agenda of this last plenary session.

27 On 23 January 2001 the working party discussed the draft report prepared by several of its members and asked for a supplementary analysis regarding the question of the genetic localisation of the resistance to tetracyclin of Toyocerin on a mobile or fixed gene. The applicant was therefore asked, by letter of 29 January 2001 to the Member State acting as rapporteur, to furnish information on this question.

28 On 24 and 25 January 2001 a further plenary session of the SCAN was held. The discussion of the results of the working party which considered the question of the production of toxins from the micro-organisms used in the additives and the conclusions of the discussion were summarised in the minutes which were adopted by the plenary session of the SCAN at the following meeting on 21 and 22 March 2001. It appears from the minutes that the strains of the bacillus used in the production of Toyocerin do not present any problems connected with the production of toxins.

29 On 29 and 30 January 2001 the first meeting of the year took place of the Standing Committee. The question of the authorisation of Toyocerin was not on the agenda.

30 In a letter of 14 February 2001 to the Directorate-General for Health and Consumer Protection of the Commission, the Member State acting as rapporteur stated that the applicant had produced within the specified periods all the information which it had been asked for before the Standing Committee meeting of 29 and 30 January 2001. It added that at present it was impossible for the applicant to reply to the question in the letter of 29 January 2001 before 21 February 2001, the expiry date of the provisional authorisation of Toyocerin for fattening chickens, laying hens, calves, fattening cattle, fattening rabbits and breeding rabbits.

31 On 19 February 2001 a meeting took place between the Commission, the Member State acting as rapporteur and representatives of the applicant.

32 Following that meeting, the provisional authorisation of Toyocerin for fattening chickens, laying hens, calves, fattening cattle, fattening rabbits and breeding rabbits was not extended. With regard to rearing pigs, piglets and sows, no decision was given on the applicant's application for the authorisation of Toyocerin for an unlimited period.

33 By separate document lodged at the Court Registry on 9 March 2001, the applicant brought an action under the fourth paragraph of Article 230 EC for the annulment of the Commission's decision of 29 January 2001, for deferment of a decision on the application for the authorisation of Toyocerin for an unlimited period as an additive in certain feedingstuffs, and for a direction to the Commission to propose to the Standing Committee, under Article 23(2) of Directive 70/524, draft measures providing for the authorisation of Toyocerin for an unlimited period for rearing pigs, piglets and sows, and for extension of the provisional authorisation of Toyocerin as an additive in feedingstuffs for

fattening chickens, laying hens, calves, fattening cattle, fattening rabbits and breeding rabbits.

34 By separate document lodged at the Court Registry on the same day, the applicant initiated the present proceedings for the grant of provisional authorisation of Toyocerin as an additive in the feedingstuffs of certain animals. The applicant also sought the application in the present case of Article 105(2) of the Rules of Procedure.

35 The applicant and the Commission presented oral argument at the hearing on 14 March 2001, in the course of which the Commission was asked to give the SCAN's reply to the question whether the strains of the bacillus used in the manufacture of Toyocerin were likely to produce toxins, as that reply was to be announced by the SCAN at its meeting on 21 and 22 March 2001. The judge hearing the application for interim relief also informed the applicant and the Commission that he proposed to await the SCAN's findings before giving a decision on the request for the application of Article 105(2) of the Rules of Procedure.

36 By letter of 16 March 2001, the Kingdom of Spain applied for leave to intervene, pursuant to Article 37 of the Protocol of the EC Statute of the Court of Justice and in accordance with Article 115 of the Rules of Procedure, in support of the form of order sought by the applicant in the present proceedings for interim relief.

37 On 23 March 2001 the Commission lodged the minutes of the plenary session of the SCAN on 24 and 25 January 2001, approved at the plenary session of 21 March 2001. It appears from the minutes that the SCAN found that the strains contained in Toyocerin do not produce toxins.

38 On 26 and 27 March 2001, at the Standing Committee meeting, the SCAN report and findings concerning the harmlessness of Toyocerin in relation to the production of toxins, and a draft regulation providing for the provisional authorisation of Toyocerin for fattening chickens, laying hens, calves, fattening cattle, fattening rabbits and breeding rabbits, based on the SCAN report, were considered. Following the meeting, the judge hearing the application for interim relief decided that there were no grounds for applying Article 105(2) of the Rules of Procedure.

39 By order of 27 March 2001, the President of the Court of First Instance granted the Kingdom of Spain leave to intervene and requested it to present oral argument at a further hearing which was fixed for 2 April 2001.

40 On 29 March 2001 the Commission lodged its observations on the present application for interim relief.

41 The applicant and the Commission presented oral argument at the hearing on 2 April 2001. As the Kingdom of Spain was unable to attend that hearing, it was given a time-limit for lodging its statement in intervention. At the hearing the Commission confirmed that, at the next meeting of the Standing Committee on 27 April 2001, a decision would be taken on the application for the provisional authorisation of Toyocerin for fattening chickens, laying hens, calves, fattening cattle, fattening rabbits and breeding rabbits. Consequently the judge hearing the application for interim relief informed the applicant and the Commission that he proposed to await the meeting before ruling on the present application.

42 On 10 April 2001 the Kingdom of Spain lodged its statement in intervention.

43 By letter of 27 April 2001, the Commission informed the judge hearing the application for interim relief of the Standing Committee's decision adopted at the meeting of the same day. It appears from that letter that the Committee was in favour of Toyocerin being once again provisionally authorised as an additive in the feedingstuffs of fattening chickens, laying hens, calves, fattening cattle, fattening rabbits and breeding rabbits. Further to that opinion, the Committee submitted a draft regulation to the Commission with the object of authorising Toyocerin for those categories of animals from 1 June 2001 to 1 March 2002. The judge hearing the application for interim relief requested the applicant to submit its observations on the Standing Committee's decision.

44 On 30 April 2001 the Commission presented its observations on the statement in intervention.

45 On 7 May 2001 the applicant presented its observations on the statement in intervention and on the Standing Committee's decision of 27 April 2001. In its observations, it stated that it would maintain its application for interim relief in its entirety in so far as it referred to rearing pigs, piglets and sows at the same time as fattening chickens, laying hens, calves, fattening cattle, fattening rabbits and breeding rabbits. With regard to species of animals other than pigs, the applicant claimed that the Commission's draft regulation was not sufficient to satisfy its 'interest in judicial protection' because of the time-limits laid down for the provisional authorisation and the discrimination against Toyocerin in that document.

46 By letter of 21 May 2001, the Commission informed the judge hearing the application for interim relief of the adoption on 11 May 2001 of Regulation No 937/2001 concerning the authorisation of new additives, new additive uses, new additive preparations, the prolongation of provisional authorisations and the 10-year authorisation of an additive in feedingstuffs (OJ 2001 L 130, p. 25), which authorises Toyocerin as an additive in the feedingstuffs of fattening

chickens, laying hens, calves, fattening cattle, fattening rabbits and breeding rabbits until 1 March 2002.

The subject of the application

47 In its application for interim relief, the applicant seeks the grant of provisional authorisation of Toyocerin as an additive in the feedingstuffs of certain animals.

48 At the hearing it made it clear that such authorisation is sought for the territory of the European Union, except Sweden.

Law

49 Under the combined provisions of Articles 242 and 243 EC and Article 4 of Council Decision 88/591/ECSC, EEC, Euratom of 24 October 1988 establishing a Court of First Instance of the European Communities (OJ 1988 L 319, p. 1), as amended by Council Decision 93/350/Euratom, ECSC, EEC of 8 June 1993 (OJ 1993 L 144, p. 21), the Court of First Instance may, if it considers that circumstances so require, order that application of the contested act be suspended or prescribe any other necessary interim relief.

50 Under the second subparagraph of Article 104(1) of the Rules of Procedure, an application for an interim relief is admissible only if it is made by a party to a case before the Court of First Instance. This rule is not a mere formality, but means that the action on the substance of the case to which the application for interim relief relates can actually be examined by the Court.

51 It has consistently been held that in principle the issue of the admissibility of the main application should not be examined in proceedings relating to an application for interim relief, so as not to prejudge the substance of the case. It may nevertheless be found necessary, when, as in this case, it is contended that the main application to which the application for interim relief relates is manifestly inadmissible, to establish whether there are any grounds for concluding *prima facie* that the main application is admissible (see the orders of the President of the Court of Justice in Case 376/87 R *Distrivet* v *Council* [1988] ECR 209, paragraph 21, and in Case C-300/00 P(R) *Federación de Cofradías de Pescadores de Guipúzcoa and Others* v *Council* [2000] ECR I-8797, paragraph 34, and of the President of the Court of First Instance in Case T-222/99 R *Martinez and De Gaulle* v *Parliament* [1999] ECR II-3397, paragraph 60).

52 In the present case, the President of the Court considers that it is necessary to establish whether there are grounds for concluding *prima facie* that the main application is admissible.

The parties' arguments

53 The applicant observes that the main application seeks to obtain the annulment of the Commission's decision of 29 January 2001 deferring a decision on the application for the authorisation of Toyocerin and seeks a direction to the Commission to propose to the Standing Committee, under Article 23(2) of

Directive 70/524, draft measures providing for an authorisation of Toyocerin for an unlimited period for rearing pigs, piglets and sows and an extension of the provisional authorisation of Toyocerin as an additive in feedingstuffs for fattening chickens, laying hens, calves, fattening cattle, fattening rabbits and breeding rabbits. It adds that if its application for interim relief were granted, it could not result in measures prejudging the main application. On that point, the applicant refers to the order of the President of the Court of Justice in Case 65/87 R *Pfizer* v *Commission* [1987] ECR 1691, in which the Commission was ordered to propose to the Standing Committee the authorisation of an additive in order to restore the *status quo*.

54 The applicant contends that the fact that the Standing Committee did not comment on the application for the authorisation of Toyocerin on 29 January 2001 and that it postponed the adoption of such authorisation constitutes a decision within the meaning of the Treaty, against which it is possible to bring an action for annulment. The applicant puts forward three arguments in support.

55 Firstly, it refers to settled case-law, in particular the order of the President of the Court of First Instance in Case T-219/95 R *Danielsson and Others* v *Commission* [1995] ECR II-3051, according to which an act may be challenged by means of an action for annulment because it is of the nature of a decision, regardless of its formal aspects.

56 In the present case the Commission's omission with regard to Toyocerin, the application for the authorisation of which was not placed on the agenda of the Standing Committee meeting, created a situation likely to affect the applicant's economic interests as it was unable to continue production of that additive.

57 Second, the applicant questions the distinction between an ordinary omission and an act arguing that, in accordance with general principles of law, an omission is to

be regarded as equivalent to an act in the sense that it concerns an act which ought to have been done and was not. Applying that argument to its case, the applicant pleads the fact that it was always assured by the Commission that the authorisation for Toyocerin would be extended in February 2001, and therefore the necessity to take a decision at that time, in conjunction with Article 4(4) of Directive 70/524, which provides that 'the Commission shall have a period of 30 days in which to include the authorisation application on the agenda for the Standing Committee'. The applicant contends that the words 'shall have' must be construed as meaning that the Commission has an obligation to place the application for authorisation of the product in question on the agenda of the Standing Committee. If no action were taken, this would be a failure to act on the part of the Commission, which would correspond in fact to a positive act, a decision not to act.

58 Third, the applicant argues that, when main applications have been dismissed as inadmissible, the Court of First Instance has always begun by considering whether there were other judicial remedies. In the present case the applicant claims that it had no alternative but to bring an action for annulment. If it had chosen to bring an action for failure to act, it would have had to await the expiry of the two-month period and the damage would have been caused during that period.

59 The Kingdom of Spain confines itself to referring to the order in *Pfizer* v *Commission*, cited above, the similarity of which to the present case is, it submits, obvious, and to settled case-law according to which 'an action for annulment must be available in the case of all measures adopted by the institutions, whatever their nature or form, which are intended to have legal effects' (see the judgment in Case 22/70 *Commission* v *Council* [1971] ECR 263).

60 The Commission submits that the applicant's application for annulment is manifestly inadmissible. The act which the applicant seeks to have annulled does not exist because no decision was taken on the application for the authorisation of Toyocerin.

Findings of the Court

61 As a preliminary point, it should be observed that it has been consistently held that only measures producing binding legal effects of a nature such as to affect the interests of the applicant by bringing about a distinct change in his legal position constitute acts or decisions, which may be the subject of an application for annulment under Article 230 EC (see judgments in Case 60/81 *IBM* v *Commission* [1981] ECR 2639, paragraph 9, and Case T-541/93 *Connaughton and Others* v *Council* [1997] ECR II-549, paragraph 30, and order in Case T-22/98 *Scottish Soft Fruit Growers* v *Commission* [1998] ECR II-4219, paragraph 34).

62 It should be added that, in the case of acts or decisions adopted by a procedure involving several stages, in particular where they are the culmination of an internal procedure, only measures definitively establishing the position of the institution on the conclusion of that procedure, and not provisional measures intended to pave the way for the final decision, may be the subject of an action for annulment (see Case T-37/92 *BEUC and NCC* v *Commission* [1994] ECR II-285, paragraph 27, and Case T-277/94 *AITEC* v *Commission* [1996] ECR II-351, paragraph 51).

63 In so far as the applicant and the Kingdom of Spain rely on the order in *Pfizer* v *Commission*, cited above, claiming that the circumstances which gave rise to that order are similar to those in the present case, it should be noted that Toyocerin was not on the agenda of the Standing Committee meeting of 29 and 30 January 2001 because the SCAN had not yet formally expressed an opinion on the safety of Toyocerin with regard to the production of toxins. It follows that the facts of the case in the present application for interim relief *prima facie* differ significantly from those which gave rise to the order in *Pfizer* v *Commission*. In that case the Commission had taken the view, in the light of two favourable reports by the SCAN, that the tests had demonstrated sufficiently that the substance in question was harmless, and therefore the Commission submitted to the Standing

Committee a draft measure for including that substance in Annex I to Directive 70/524. Similarly, it may be seen from the order in *Pfizer* v *Commission* that the Committee had examined the Commission's draft but had not been able to deliver an opinion in default of the necessary majority of votes, given the negative vote of certain Member States. Finally, it should be noted that the problem of the admissibility of the main application was not considered in the abovementioned order. It follows that that order is not relevant to the assessment of the present application for interim relief.

64 As for the question whether there is a challengeable act in the present case, it should be noted that the Standing Committee could not have adopted a decision extending the provisional authorisation of Toyocerin at the meeting of 29 and 30 January 2001 because there was no proposal to that effect on the agenda. That is partly explained by the fact that, so far as rearing pigs, piglets and sows are concerned, the duration of a provisional authorisation cannot exceed five years by virtue of Article 9e(3) of Directive 70/524. On 29 January 2001 Toyocerin had already received provisional authorisation for those animals for five years. So far as authorisation for an unlimited period is concerned, the conditions laid down in Article 3a of the above directive must be fulfilled. On this point, the applicant confirmed at the hearing on 14 March 2001 that the information which it had been asked to provide by the SCAN and by letter of 29 January 2001, namely the genetic localisation of the resistance to tetracyclin of Toyocerin on a mobile or fixed gene, necessitated a series of tests which would take a further three or four months. With regard to fattening chickens, laying hens, calves, fattening cattle, fattening rabbits and breeding rabbits, the fact that a proposal for the adoption of a decision extending the provisional authorisation of Toyocerin was not on the agenda of the SCAN meeting of 29 and 30 January 2001 is explained by the fact that the SCAN had not formally expressed an opinion on the safety of Toyocerin with regard to the production of toxins. It should be pointed out that, in any case, at the abovementioned meeting the SCAN did not have all the information it needed for assessing the application for the authorisation of Toyocerin as an additive in the feedingstuffs of rearing pigs, piglets and sows and also of fattening chickens, laying hens, calves, fattening cattle, fattening rabbits and breeding rabbits.

65 It must therefore be found that there is no formal decision of 29 January 2001 which could constitute a decision capable of being the subject of an application for annulment. The only document dated 29 January 2001, namely the Commission's letter to the Member State acting as rapporteur, asking for additional information on the safety of Toyocerin, is not such as to affect the applicant's interests by bringing about a significant change in its legal position.

66 The next question is whether the fact that the Standing Committee did not express an opinion on 29 January 2001 concerning the application for the authorisation of Toyocerin may be regarded *prima facie* as an implied decision against which an action for annulment can be brought, as the applicant claims. On that point, it contends that the Commission's inaction constitutes a failure to act on its part corresponding to a decision not to act.

67 It is common ground that the procedure for obtaining Community authorisation for an additive comprises several stages and that, in the present case, the procedure had not been completed by 29 January 2001 because the SCAN had not formally expressed an opinion on the safety of Toyocerin with regard to the production of toxins. Therefore it must be found that the fact that the application for the authorisation of Toyocerin was not on the agenda of the Standing Committee meeting of 29 and 30 January 2001 and that consideration of the matter was postponed to the next meeting on 26 and 27 March 2001 does not constitute a measure definitively establishing the Commission's position on the conclusion of the abovementioned procedure, in the sense contemplated in the case-law cited in paragraph 62 above.

68 It follows that, as regards the application for the authorisation of Toyocerin as an additive in the feedingstuffs of rearing pigs, piglets and sows and also of fattening

chickens, laying hens, calves, fattening cattle, fattening rabbits and breeding rabbits, *prima facie* no challengeable act exists.

69 It should be added that, contrary to the applicant's contentions, judicial remedies other than the present action for annulment were available. In that regard, so far as rearing pigs, piglets and sows are concerned, it should be noted that, in reply to a question from the President of the Court at the hearing on 14 March 2001, the applicant admitted that it had made a mistake in that it had not sought to obtain a declaration that the Commission's inaction was unlawful by means of an action for failure to act brought after 21 April 1999, but had waited until the national authorisations expired before bringing an action for annulment before the Court of First Instance. As regards the other categories of animals, in so far as the applicant's economic situation is affected by the fact that it had no authorisation for the sale of Toyocerin as an additive in the feedingstuff for those animals from 21 February 2001, that is *prima facie* the result of the limitation of the extension of the provisional authorisation in respect of those animals in Regulation No 2697/2000. As the Commission has pointed out, that regulation has not been challenged by the applicant.

70 With regard to the claim for directions to be issued to the Commission, the President of the Court observes that they are *prima facie* inadmissible because the power to annul measures conferred upon the Court by Article 230 EC does not authorise it to issue directions to the Community institutions (see, for example, Case 15/85 *Consorzio Cooperative d'Abruzzo* v *Commission* [1987] ECR 1005, paragraph 18, and Case T-124/96 *Interporc* v *Commission* [1998] ECR II-231, paragraph 61).

71 Consequently, in the absence of reasonable grounds for concluding that the main application may be admissible, the present application for interim relief must be held to be inadmissible.

On those grounds,

THE PRESIDENT OF THE COURT OF FIRST INSTANCE

hereby orders:

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

2. **The costs are reserved.**

Luxembourg, 5 July 2001.

H. Jung

Registrar

B. Vesterdorf

President