JUDGMENT OF THE COURT OF FIRST INSTANCE (Second Chamber)
7 March 2002 *

In Case T-212/99,

Intervet International BV, formerly Hoechst Roussel Vet GmbH, established in Boxmeer (Netherlands), represented by D. Waelbroek and D. Brinckman, lawyers, with an address for service in Luxembourg,

applicant,

v

Commission of the European Communities, represented by T. Christoforou, H. Stovlbaek and F. Ruggeri-Laderchi, acting as Agents, with an address for service in Luxembourg,

defendant,

APPLICATION for the annulment of an alleged Commission decision rejecting an application by the applicant for the insertion of the substance 'altrenogest' in Annex III to Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ 1990 L 224,

* Language of the case: English.

p. 1) and, in the alternative, for a declaration that the Commission unlawfully failed to prepare a draft of measures to be taken with a view to such insertion and to initiate the procedure laid down in Article 8 of that regulation.

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

composed of: R.M. Moura Ramos, President, J. Pirrung and A.W.H. Meij, Judges,

Registrar: H. Jung,

having regard to the written procedure and further to the hearing on 6 November 2001,

gives the following

Judgment

1 Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of

veterinary medicinal products in foodstuffs of animal origin (OJ 1990 L 224, p. 1; 'the 1990 Regulation') includes the following recitals in its preamble:

'[1] Whereas the use of veterinary medicinal products in food-producing animals may result in the presence of residues of foodstuffs obtained from treated animals;

...

[3] Whereas in order to protect public health, maximum residue limits must be established in accordance with generally recognised principles of safety assessment, taking into account any other scientific assessment of the safety of the substances concerned which may have been undertaken by international organisations, in particular the Codex Alimentarius or, where such substances are used for other purposes, by other scientific committees established within the Community;

...

[5] Whereas the establishment of different maximum residue levels by Member States may hinder the free movement of foodstuffs and of veterinary medicinal products themselves;

[6] Whereas it is therefore necessary to lay down a procedure for the establishment of maximum residue levels of veterinary medicinal products by the Community, following a single scientific assessment of the highest possible quality;

...

[10] Whereas, after scientific assessment by the Committee for Veterinary Medicinal Products, maximum residue levels must be adopted by a rapid procedure which ensures close cooperation between the Commission and the Member States

...'

2 Under the 1990 Regulation the Commission is to establish the maximum residue limit (hereinafter 'MRL'). Article 1(1)(b) of the Regulation defines that MRL as the maximum concentration of residue resulting from the use of a veterinary medicinal product which may be accepted by the Community to be legally permitted or recognised as acceptable 'in or on a food'.

3 The 1990 Regulation makes provision for four annexes to be established in which a pharmacologically active substance, intended for use in veterinary medicines to be administered to 'food-producing animals', may be included:

— Annex I, which is reserved for substances for which an MRL may be established following an assessment of the risks which such substance constitutes for human health;

— Annex II, which is reserved for substances which are not subject to an MRL;

— Annex III, which is reserved for substances for which it is not possible to establish an MRL definitively but for which, without compromising human health, a provisional MRL may be established for a fixed period which is dictated by the time needed to carry out appropriate scientific studies and which can only be extended once;

— Annex IV, which is reserved for substances for which no MRL can be established because such substances constitute a threat to consumer health in any amount.

4 Article 7 of the 1990 Regulation lays down the procedure which is to apply in respect of pharmacologically active substances authorised for use in veterinary medicinal products on the date of entry into force of the Regulation.

5 According to the first subparagraph of Article 7(2) of that regulation, after consulting the Committee on Veterinary Medicinal Products ('the CVMP'), the Commission is to publish a timetable for the consideration of those substances, including time-limits for submission of the information required for the purposes of establishing an MRL. In accordance with the second subparagraph, the persons responsible for marketing the veterinary medicinal products concerned are to ensure that all relevant information is submitted to the Commission.

6 Under Article 7(3) of that regulation, after verifying within 30 days that the information is submitted in correct form, the Commission must forthwith submit the information for examination to the CVMP, which is to deliver its opinion within a renewable period of 120 days.

7 Pursuant to Article 7(4) of that regulation, having regard to the observations formulated by the members of the CVMP, the Commission is to prepare, within a maximum period of 30 days, a draft of the measures to be taken.

8 According to Article 7(5) of that regulation, that draft is to be communicated forthwith by the Commission to the Member States and those persons responsible for marketing who have submitted information to the Commission. Those persons may, at their request, provide oral or written explanations to the CVMP.

9 Under Article 7(6) of that regulation, the Commission is forthwith to submit the draft measures to the Committee for Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products ('the Adaptation Committee') for the application of the procedure laid down in Article 8.

10 Under Article 8(2) of that regulation, the Adaptation Committee is to deliver its opinion on the draft measures to be taken within a time-limit set by its chairman, having regard to the urgency of the matter.

11 Article 8(3) of that regulation lays down the procedure under which the Commission or the Council, as appropriate, is to adopt the measures envisaged taking account of the opinion of the Adaptation Committee.

12 Article 14 of the 1990 Regulation provides:

'[W]ith effect from 1 January 1997, the administration to food-producing animals of veterinary medicinal products containing pharmacologically active substances which are not mentioned in Annexes I, II or III shall be prohibited within the Community...'

13 The first paragraph of Article 15 of the 1990 Regulation provides that the Regulation is in no way to prejudice the application of Community legislation prohibiting the use in livestock farming of certain substances having a hormonal action.

14 Council Regulation (EC) No 434/97 of 3 March 1997, amending the 1990 Regulation (OJ 1997 L 67, p. 1), deferred the time-limit set in Article 14 of the Regulation in cases such as the present case until 1 January 2000.

15 Council Regulation (EC) No 1308/99 of 15 June 1999 amending the 1990 Regulation with effect from 26 June 1999 (OJ 1999 L 156, p. 1) replaced Articles 6 and 7 of the 1990 Regulation by the following:

'Article 6

1. In order to obtain the inclusion in Annexes I, II or III of a pharmacologically active substance which is intended for use in veterinary medicinal products for administration to food-producing animals, an application to establish a maxi-

mum residue limit shall be submitted to the European Agency for the Evaluation of Medicinal Products set up by [Council] Regulation (EEC) No 2309/93 [of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1)], (hereinafter "the EMEA").

...

Article 7

1. The [CVMP] referred to in Article 27 of Regulation (EC) No 2309/93... shall be responsible for formulating the [EMEA's] opinion on the classification of substances referred to in Annexes I, II, III or IV to this regulation.

...

3. The [EMEA] shall ensure that the [CVMP's] opinion is delivered within a period of 120 days following the reception of a valid application.

If the information submitted by the applicant is not sufficient to enable such an opinion to be prepared, the CVMP may ask the applicant to supply additional information within a specific time-limit. The deadline for the opinion shall then be deferred until the additional information has been received.

4. The [EMEA] shall forward the opinion to the applicant. Within 15 days of receipt of the opinion, the applicant may provide written notice to the [EMEA] that he wishes to appeal. In that case he shall forward the detailed grounds for his appeal to the [EMEA] within 60 days of receipt of the opinion. Within 60 days of the receipt of the grounds for appeal, the [CVMP] shall consider whether its opinion should be revised and the reasons for the conclusion reached on the appeal shall be annexed to the report referred to in paragraph 5.

5. The [EMEA] shall forward the definitive opinion of the [CVMP] within 30 days of its adoption both to the Commission and to the applicant. The opinion shall be accompanied by a report describing the safety evaluation of the substance by the Committee, which shall give the grounds for its conclusions.

6. The Commission shall prepare draft measures taking account of Community legislation and shall start the procedure provided for in Article 8. The [CVMP] referred to in Article 8 shall adapt its rules of procedure in order to take account of the tasks conferred on it by this Regulation.'

Background to the dispute

16 Roussel Uclaf SA, whose rights were taken over by the initial applicant, Hoechst Roussel Vet GmbH, developed a pharmaceutical compound known as 'Altrenogest'. By letter of 19 April 2001, counsel for the initial applicant informed the Registry of the Court of First Instance that the entire business of Hoechst Roussel Vet GmbH had been transferred to Intervet International BV, which should therefore be regarded as the new applicant in this case (those three companies

being hereinafter referred to as 'the applicant'). Altrenogest is a derivative (chemically related substance) of progesterone and belongs to the group of sex hormones called gestagenes. It is used for zootechnical purposes to synchronise oestrus in mammals, mainly in pig breeding, in order to ensure that all the sows ovulate at the same time, enabling the piglets to be born, mature and leave the sties at the same time.

17 The applicant manufactures a medicinal product called 'Regumate porcine', containing Altrenogest. The product was first licensed in France (in 1984), then in Germany, the Netherlands, Belgium and the United Kingdom, and more recently in Spain (in 1993).

18 By letters dated 10 February 1993, the applicant conveyed to the Commission and the national members of the CVMP the information required in order to establish an MRL for Altrenogest.

19 By letter of 2 March 1993, the Commission informed the applicant that its application had been validated and that the period of 120 days allocated for the evaluation of Altrenogest by the CVMP had begun on 23 February 1993.

20 By faxes of 30 August 1993 and 7 September 1993, the applicant sought information from the Commission on the state of progress of the evaluation of Altrenogest.

21 By letter of 9 September 1993, the Commission informed the applicant that the CVMP had completed its initial evaluation of Altrenogest. It also sent the applicant some more questions to which the CVMP was seeking answers and stated that the time-limits were suspended until the applicant had provided those answers.

22 The applicant sent the CVMP the answers to the questions concerning pigs on 26 August 1994 and to those concerning horses on 27 March 1995.

23 By letter of 28 January 1997, the EMEA informed the applicant that the CVMP had delivered its opinion on Altrenogest. In that opinion the CVMP recommended the adoption of a provisional MRL for Altrenogest, that it to say, the inclusion of Altrenogest in Annex III to the 1990 Regulation, setting an MRL of 3 µ/kg, with an expiry date of 1 January 1999. The CVMP's opinion also contained a number of questions, and the applicant was asked to supply certain missing information and figures by 1 April 1998.

24 By letter of 22 April 1997, the Commission informed the EMEA that it had received various reports on beta-oestradiol and its toxicity to humans. According to the Commission, it appeared that some of the results of those reports could also apply to progesterone. In the light of those new scientific data the Commission asked the EMEA to re-evaluate both substances. As regards progesterone in particular, which had not so far been classified in any of the annexes to the 1990 Regulation but for which an evaluation report existed, the Commission indicated that it would like the evaluation report and its conclusions to be reviewed and if necessary amended.

25 By letter of 19 February 1998, the EMEA informed the applicant that the re-evaluation of Altrenogest in the light of the new scientific data had progressed well and the conclusions were expected within three months of the date of the letter. It also said that the deadline of 1 April 1998 previously set for answering the list of questions was suspended.

26 By letter of 15 April 1998, the Commission informed the EMEA of some recent scientific and other developments. It mentioned the existence of a report prepared by the WTO in the 'hormones case'. From the scientific point of view it noted, first, that the United States Government had embarked on a study of oestrogen-induced cancer, secondly, that the national cancer research agency based in Lyon (France) had begun a review of some of its monographs on hormones, thirdly, that the Commission had decided to fund studies by independent scientists of the use of hormones, including beta-oestradiol and progesterone, as growth promoters, and, fourthly, that the United States National Institute of Health had organised a symposium on the carcinogenic effects of oestrogens. In those circumstances, the Commission considered it would be appropriate for the CVMP to suspend the re-evaluation of progesterone beta-oestradiol which it had begun following its letter of 22 April 1997, so that all the new scientific evidence would be available and the CVMP could take it into consideration.

27 By letter of 12 August 1998, the applicant enquired of the EMEA about progress in the establishment of a provisional MRL for Altrenogest. It mentioned that it was still in a state of uncertainty and asked the EMEA to clarify the position.

28 By letter of 3 February 1999, the applicant drew the Commission's attention to the fact that on 28 January 1997 the CVMP had recommended that Altrenogest should be included in Annex III to the 1990 Regulation. It observed that since

that date it had been waiting for the approval of the MRL and the relevant publication in the *Official Journal of the European Communities*. It stated that should that situation be prolonged it would not be able to market its products containing Altrenogest after 1 January 2000, in view of Article 14 of the 1990 Regulation, as amended. Finally, it pointed out that its turnover of Altrenogest was about EUR 7 million and any further delay in establishing an MRL for Altrenogest could threaten its business.

29 On 23 April 1999 the Commission asked the EMEA to initiate the update of the evaluation of beta-oestradiol, progesterone and Altrenogest as soon as possible in order to allow the adoption and publication of the results of the evaluation to take place before 1 January 2000.

30 By letter of 25 May 1999, the Commission sent the EMEA the opinion of the Scientific Committee on Veterinary Measures relating to Public Health ('SCVPH'; a Commission internal committee) dated 30 April 1999 on the potential risks to human health from hormone residues in bovine meat and meat products. The opinion of the SCVPH contains an analysis of the risks from six hormones, including progesterone, where they are administered to animals as growth promoters. According to the opinion, it is possible that the six hormones have endocrine, genetic, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects. In the letter the Commission stresses that the CVMP should take into consideration the results of that opinion in the evaluation of all sex hormones currently being conducted under the 1990 Regulation.

31 On 26 May 1999, the applicant sent, through its lawyer, a registered letter to the Commission giving the Commission formal notice that it should adopt the necessary measures to ensure that Altrenogest be included at the earliest possible date in Annex III to the 1990 Regulation, and to take all necessary steps to that

effect. The applicant made known in that letter its intention to bring an action for failure to act under Article 232 EC if the measures sought were not adopted.

32 By letter of 16 July 1999, the Commission replied to the applicant as follows:

'[A]s you may be aware, the submission of a draft decision concerning the inclusion of the hormone Altrenogest into the Annexes of Council Regulation (EEC) No 2377/90 has been postponed due to concerns within the Commission regarding the effects of this substance on public health. These concerns were linked to new scientific findings which surfaced during the work of the Scientific Committee on Veterinary Measures relating to Public Health in their opinion on "the assessment of potential risks to human health from hormone residues in bovine meat and meat products". After careful consideration of the new information available the Commission felt obliged to ask the CVMP on 23 April 1999 to re-evaluate Altrenogest, taking into account the existence of new scientific evidence.

Even though such re-referral to the CVMP is not explicitly [provided for] by Regulation (EEC) No 2377/90, the Court of First Instance has recently confirmed in Cases T-105/96 (*Pharos* v *Commission*) and T-120/96 (*Lilly* v *Commission*) that the Commission must — in certain specific circumstances — be accorded the right to seek an additional opinion from the CVMP "where it is confronted with a matter which is highly complex and sensitive both scientifically and politically". In the case in question, the existence of new scientific findings concerning potential risks to human health from hormone residues in bovine meat and meat products which were not available when the CVMP first evaluated Altrenogest (1993-97) obliged the Commission to resubmit the dossier to the CVMP in order to assure the primary purpose of Regulation (EEC) No 2377/90, namely the protection of public health.

As soon as the new opinion of the CVMP on Altrenogest is available, the Commission will, without delay, take the necessary procedural steps foreseen by Articles 6 and 8 of the Regulation.

For the above reasons, I cannot share your view that the Commission has failed to act and I ask you to treat this letter as a definition of the Commission's position in the sense of Article 232 of the Treaty establishing the European Economic Community.'

Procedure

33 In those circumstances, by application lodged at the Registry of the Court of First Instance on 22 September 1999, the applicant brought the present action.

34 The applicant waived its right to lodge a reply.

35 The Court of First Instance prescribed measures of organisation of procedure, asking the parties to reply to written questions. The parties complied with those requests.

36 Upon hearing the report of the Judge-Rapporteur, the Court of First Instance (Second Chamber) decided to open the oral procedure.

37 In a document of 17 October 2001, addressed to the Court of First Instance (and communicated by the Registrar to the applicant), the Commission informed the Court of First Instance of a number of recent developments concerning the fixing of an MRL for Altrenogest.

38 The parties presented oral argument and replied to the Court's questions at the hearing on 6 November 2001.

Forms of order sought

39 The applicant claims that the Court of First Instance should:

— annul the Commission decision contained in its letter of 16 July 1999 by which the Commission informed the applicant of its refusal to take the necessary measures to include Altrenogest, the active substance produced by the applicant, in Annex III to the 1990 Regulation;

— in the alternative: declare pursuant to Article 232 EC that the Commission has failed to fulfil its obligations under Community law and, more particularly, failed, following receipt of the definitive opinion of the CVMP,

to prepare draft measures including Altrenogest in Annex III to the 1990 Regulation and failed to initiate the procedure under Article 8 thereof;

— order the Commission to pay the costs of the proceedings.

40 The Commission contends that the Court of First Instance should:

— dismiss the application;

— order the applicant to pay the costs.

The claim for annulment

Arguments of the parties

41 The Commission challenges the admissibility of the claim for annulment. In its submission, the letter of 16 July 1999 does not constitute a decision that can be the subject of an action for annulment under Article 230 EC. Referring in this connection to the judgment of the Court of First Instance in Case T-154/94 *CSF and CSME* v *Commission* [1996] ECR II-1377, paragraph 37, the Commission argues that the letter of 16 July 1999 merely explained the reasons for the delays in including Altrenogest in one of the annexes to the 1990 Regulation and stated that the Commission would take the necessary procedural steps laid down by the 1990 Regulation as soon as the new opinion of the CVMP was available. Consequently, the legal position of the applicant was not altered by that letter, which did no more than give the applicant information about the state of the procedure. In particular, the letter does not constitute a decision of any kind as to the inclusion of Altrenogest in any of the annexes to the 1990 Regulation but merely a definition of the Commission's position, within the meaning of Article 232 EC.

42 The applicant contends its action is admissible. It points out that, under Article 230 EC, legal persons may bring actions for annulment against Commission decisions addressed to them. Since the letter of 16 July 1999 was addressed to counsel for the applicant, it follows that the applicant has standing to challenge it before the Court of First Instance.

Findings of the Court of First Instance

43 It is settled case-law that any measure which produces binding legal effects such as to affect the interests of an applicant by bringing about a distinct change in his legal position constitutes an act or decision which may be the subject of an action for annulment (Case 60/81 *IBM* v *Commission* [1981] ECR 2639, paragraph 9; *CSF and CSME*, cited above, paragraph 37; Joined Cases T-125/97 and T-127/97 *Coca-Cola* v *Commission* [2000] ECR II-1733, paragraph 77).

44 As the Commission has rightly observed, the letter of 16 July 1999 is confined to explaining the reasons for the delays in including Altrenogest in one of the annexes to the 1990 Regulation and states that the Commission will take the procedural steps laid down by that regulation once the new opinion of the CVMP is available. The letter of 16 July 1999 does not contain any decision as to the inclusion of Altrenogest in one of the annexes to that regulation. On the contrary, that letter clearly shows that the Commission is waiting for the second opinion of the CVMP before taking such a decision. Consequently, the applicant's position is not changed by that letter, which merely informs it of the state of the procedure.

45 In those circumstances, the letter of 16 July 1999 does not constitute a decision which may be the subject of an action for annulment under Article 230 EC.

46 It follows that the claim for annulment must be dismissed as inadmissible.

The claim for a declaration that the Commission failed to act

Arguments of the parties

47 The applicant states that the Commission, after receiving the definitive opinion of the CVMP of 28 January 1997, did not prepare any draft measures and did not initiate the procedure under Article 8 of the 1990 Regulation for the adoption of measures. Even after it had been formally requested to act, the Commission did not take the appropriate steps to rectify that unlawful situation. The applicant contends that, after receiving a favourable opinion from the CVMP, the Commission was required to act without delay. At all events, it was under a duty to ensure that a decision to include the substance concerned in Annex III was taken by 1 January 2000, since otherwise the applicant's product would be excluded from the market.

48 In its replies to the written questions put to it by the Court of First Instance, the applicant stated that, particularly by virtue of Articles 7 and 8 of the 1990 Regulation, the Commission was under an obligation, after receiving the positive CVMP opinion of 28 January 1997, to draft a regulation including Altrenogest in Annex III to that regulation and to submit it to the Adaptation Committee for adoption. By failing to draft such a regulation expeditiously, the Commission was in breach of the obligations incumbent on it by virtue of those provisions of the 1990 Regulation and the principle of sound administration.

49 As for its interest in bringing an action, the applicant maintains in its replies to the written questions put to it by the Court of First Instance that the Commission was in any event required, as the deadline of 1 January 2000 approached, to take timely action to preserve the applicant's rights, and that nothing prevented the Commission from fixing the expiry of the MRL at a date later than 1 January 1999.

50 The Commission argues that, under Article 232 EC, an action for a declaration that a Community institution has failed to act may be brought only if, at the expiry of a period of two months from the request that action be taken, the institution has not defined its position. In this case, it is obvious that the disputed letter constitutes a 'definition of position' within the meaning of that article, since the Commission clearly set out in that letter the measures which it had taken in relation to the establishment of an MRL for Altrenogest and the formalities which it was still going to carry out in that respect.

51 Moreover, at the time when the applicant formally requested the Commission to act, namely 26 May 1999, it would have been 'absurd' to accede to its request on the basis of the CVMP opinion of 1997, since all that could have resulted would have been the establishment of a provisional MRL with only a 'validity' limited to 1 January 1999. Consequently, the applicant has no real interest in bringing an action for failure to act. The Commission would even go so far as to say that it would, rather, be in the interests of the applicant for the CVMP opinion of 1997 to be amended so as potentially to extend the recommendation to include Altrenogest in Annex III to the 1990 Regulation.

52 Moreover, the Commission contends essentially, that its sole concern in the procedure for establishing an MRL for Altrenogest was the protection of public health, that scientific uncertainties as to existence of risks for public health justified it delaying its decision until it was fully informed, and that it is not required to follow the CVMP opinion in all circumstances, that opinion being only advisory in character.

Findings of the Court of First Instance

53 It is appropriate to consider, first, the question whether the applicant has an interest in bringing an action, in the light of the fact that the CVMP opinion of 28 January 1997 envisaged the inclusion of Altrenogest in Annex III to the 1990 Regulation only until 1 January 1999.

54 In that respect, it should be noted, first of all, that in its letter of formal notice of 26 May 1999, the applicant reminded the Commission that, under Article 14 of the 1990 Regulation (as amended by Regulation No 434/97), the administering to food-producing animals of veterinary medicinal products containing pharmacologically active substances not appearing in Annexes I, II or III is prohibited in the Community as from 1 January 2000. Given that deadline, the Commission was put on formal notice to take the necessary measures for including Altrenogest in Annex III to the Regulation. The letter of formal notice thus clearly sought to have Altrenogest included in Annex III for the period after 1 January 2000.

55 Next, it should be noted that the provisional period of inclusion, initially proposed by the CVMP in its opinion of 28 January 1997, had already expired in 1999, in consequence of the Commission's inaction.

56 Finally, it should be observed that the provisions of the 1990 Regulation do not preclude the Commission, if necessary after consulting the CVMP on the subject, from preparing draft measures concerning the inclusion of an active substance in one of the annexes to that regulation for a period extending beyond that proposed by the CVMP.

57 In those circumstances, the Commission's argument that the applicant does not have an interest in bringing an action, since its request could not have led to the establishment of an MRL for a period extending beyond that proposed by the CVMP, cannot be accepted.

58 Second, it is necessary to consider whether the Commission's letter of 16 July 1999 constitutes a 'definition of position' within the meaning of Article 232 EC.

59 It is clear from the second paragraph of Article 232 EC that an action for failure to act is not admissible if, after being requested to act, the institution concerned adopted a position on that request.

60 The letter of 16 July 1999 merely sets out the reasons for the delays in including Altrenogest in one of the annexes to the 1990 Regulation, and states that the Commission will carry out the formalities required by that regulation once the new opinion of the CVMP is available.

61 A letter emanating from an institution, stating that examination of the questions raised is in progress, does not constitute a definition of position which brings to an end a failure to act (Joined Cases 42/59 and 49/59 *SNUPAT* v *High Authority* [1961] ECR 53, at p. 74; Case 13/83 *Parliament* v *Council* [1985] ECR 1513, paragraph 25; Case T-95/96 *Gestevision Telecinco* v *Commission* [1998] ECR II-3407, paragraph 88).

62 The Commission's letter of 16 July 1999 cannot therefore be characterised as a 'definition of position' for the purposes of the second paragraph of Article 232 EC.

63 It follows from the foregoing considerations that the claim for a declaration of failure to act is admissible.

64 However, in reply to the written questions put to them by the Court of First Instance, the parties informed it that the CVMP gave its second opinion on 8 December 1999, and that, in that opinion, the CVMP proposed the inclusion of Altrenogest in Annex III to the 1990 Regulation until 1 January 2002.

65 In its document of 17 October 2001, the Commission indicated that on 25 July 2001 it had adopted a draft regulation for including Altrenogest in Annex III to the 1990 Regulation until 1 January 2003, that it had submitted that draft to the Adaptation Committee on 1 August 2001, that that committee had given an unfavourable opinion at its meeting on 12 September 2001, and that the Commission would shortly submit its proposal to the Council in accordance with the procedure laid down by Article 8 of the 1990 Regulation. At the hearing, the Commission stated that it had indeed submitted its proposal to the Council on 26 October 2001. The applicant has not challenged the accuracy of that information.

66 It follows from those facts, occurring after the action for failure to act was brought, that, by adopting a draft regulation and submitting it first to the Adaptation Committee and then to the Council, the Commission defined its position in relation to the request for it to act.

67 It is settled case-law that, where such a definition of position occurs after an action for failure to act is brought, it terminates the Commission's failure to act and deprives that action of its subject-matter (see, to that effect, Case C-282/95 P *Guérin automobiles* v *Commission* [1997] ECR I-1503, paragraph 31; Case T-28/90 *Asia Motor France and Others* v *Commission* [1992] ECR II-2285, paragraphs 34, 35 and 36).

68 It follows that there is no longer any need to adjudicate on the claim for a declaration of failure to act.

Costs

69 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. Under Article 87(6), where a case does not proceed to judgment, the costs are to be in the discretion of the Court of First Instance.

70 Since, on the one hand, the applicant's claim for annulment has failed, and, on the other, the Commission did not define its position until 1 August 2001, the Court of First Instance considers that the circumstances of the case will be fairly reflected by ordering the Commission to bear its own costs and pay one half of the applicant's costs.

On those grounds,

THE COURT OF FIRST INSTANCE (Second Chamber),

hereby:

1. **Dismisses the claim for annulment as inadmissible;**

2. **Declares that there is no longer need to adjudicate on the claim for a declaration that the Commission failed to act;**

3. **Orders the Commission to bear its own costs and to pay one half of the applicant's costs.**

Moura Ramos Pirrung Meij

Delivered in open court in Luxembourg on 7 March 2002.

H. Jung R. M. Moura Ramos

Registrar President