JUDGMENT OF THE COURT OF FIRST INSTANCE (Second Chamber)
26 February 2003 *

In Joined Cases T-344/00 and T-345/00,

CEVA Santé animale SA, established in Libourne (France), represented by D. Waelbroeck and D. Brinckman, lawyers, with an address for service in Luxembourg,

applicant in Case T-344/00,

Pharmacia Entreprises SA, formerly Pharmacia & Upjohn SA, established in Luxembourg, represented by D. Waelbroeck and D. Brinckman, lawyers, with an address for service in Luxembourg,

applicant in Case T-345/00,

* Language of the case: English.

supported by

Fédération européenne de la santé animale (Fedesa), established in Brussels, represented by A. Vandencasteele, lawyer, with an address for service in Luxembourg,

intervener in Case T-345/00,

v

Commission of the European Communities, represented by T. Christoforou and M. Shotter, acting as Agents, with an address for service in Luxembourg,

defendant,

APPLICATION for (1) a declaration under Article 232 EC that, by failing to take the necessary measures for the inclusion of progesterone in Annex II 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, p. 1), the Commission has failed to comply with its obligations under Community law and (2) damages under Article 235 EC and the second paragraph of Article 288 EC,

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: J. Plingers, Administrator,

having regard to the written procedure and further to the hearing on 25 September 2002,

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, hereinafter '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 [in] 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') in accordance with the procedure laid down in the regulation. Article 1(1)(b) of the regulation defines 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 drawn up in which pharmacologically active substances, 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 the substance presents to human health;

— Annex II, which is reserved for substances in respect of which it does not appear necessary, for the protection of public health, to fix 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 that applies 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 the regulation, after consulting the Committee on Veterinary Medicinal Products ('the CVMP'), the Commission is to publish a timetable for the consideration of these 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 the 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 must deliver its opinion within a renewable period of 120 days.

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

8 According to Article 7(5), the draft is to be communicated forthwith by the Commission to the Member States and to the persons responsible for marketing who have submitted information to the Commission. The latter may, if they so request, provide oral or written explanations to the CVMP.

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

10 Under Article 8(2) of the 1990 Regulation, the Standing Committee must deliver its opinion on the draft within a time-limit set by its chairman, having regard to the urgency of the matter.

11 Article 8(3) of the regulation lays down the procedure under which the Commission or the Council, as appropriate, may adopt the measures envisaged. Account is taken of the opinion of the Standing Committee.

12 Article 14 of the 1990 Regulation provides:

'With 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 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 fixed in Article 14 of the 1990 Regulation for substances such as that in issue in the present case to 1 January 2000.

15 Council Regulation (EC) No 1308/1999 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 with 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 [an MRL] 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 referred to as "the [EMEA]".

...

Article 7

1. The [CVMP] referred to in Article 27 of Regulation... 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 [CVMP], 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 Committee 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 The applicant in Case T-344/00, hereinafter referred to as 'CEVA' (formerly called SANOFI Santé Nutrition Animale SA), is a pharmaceutical company which markets a veterinary medicinal product under the brand name 'PRID'. The active ingredient in PRID is progesterone, which belongs to the group of progestogen hormones.

17 The product marketed by CEVA is intended to be used, mainly in cattle rearing, for zootechnical purposes, namely for synchronisation of the oestrus cycle and for the therapeutic treatment of fertility problems.

18 The applicant in Case T-345/00, hereinafter referred to as 'Pharmacia', also a pharmaceutical company, markets a veterinary medicinal product under the brand name 'CIDR'. It too contains the active ingredient progesterone.

19 The product marketed by Pharmacia is intended to be used to control oestrus and ovulation in cows, cow-buffaloes, ewes and goats. It may also be used for the therapeutic treatment of fertility problems in those animals.

20 On 14 September 1993, pursuant to Article 7 of the 1990 Regulation, CEVA submitted an application to the Commission for the establishment of an MRL for progesterone in cattle and horses.

21 By letter of 18 November 1996, the EMEA informed CEVA that, at its meeting on 22 and 23 October 1996, the CVMP had recommended the inclusion of progesterone in Annex II to the 1990 Regulation and that the opinion of the CVMP would be forwarded to the Commission for adoption by the Standing Committee.

22 On 22 April 1997 the Commission sent new scientific information to the EMEA and asked the CVMP to re-assess the risks relating to the hormones oestradiol-17ß and progesterone.

23 On 24 October 1997 the EMEA wrote to CEVA saying 'the Commission has decided to stop the adoption procedure for progesterone as new scientific data have recently become apparent concerning oestradiol, which are considered

relevant also for progesterone. The CVMP has therefore been requested to undertake a reconsideration of the assessment in light of these additional data. You will be kept informed on further developments concerning the establishment of MRLs for progesterone.'

24 On 15 April 1998 the Commission again asked the CVMP to review its previous opinion, taking account of the latest scientific information available from a number of sources, such as the International Agency for Research on Cancer ('IARC'), an advisory body to the World Health Organisation, and the United States National Institute of Health, and the results of a number of specific studies commissioned by the European Commission.

25 In May 1998 the Commission learned that JECFA, the scientific committee which advises the Codex Alimentarius Commission on food additives and contaminants, was also planning to re-evaluate the three natural hormones, including progesterone, in February 1999.

26 By letter of 19 November 1998, the CEVA inquired of the Commission as to the progress of the procedure for the adoption of an MRL for progesterone.

27 By letter of 11 January 1999, the Director-General of the Directorate-General for Industry (DG III) replied:

'my services are well aware that a veterinary medicinal product containing substances listed in the Communication of the EMEA on the evaluation of medicines according to Article 1 of Council Regulation No 434/97 of 3 March

1997 (so-called [prohibited] substances) have to be included in Annex I, II, III of Council Regulation (EEC) No 2377/90 and published in the Official Journal before 1 January 2000 in order to remain on the market. Progesterone therefore will be presented for adoption to the Standing Committee for veterinary medicinal products in 1999.'

28 On 26 February 1999 the Commission published in the Official Journal a 'call for scientific documentation required for risk assessment of oestradiol-17ß, progesterone, testosterone, zeranol, trenbelone acetate and melengesterol acetate used for animal growth promotion purposes'.

29 In April 1999 or thereabouts JECFA published its re-evaluation.

30 On 23 April 1999 the Commission asked the EMEA to send it 'the update of the evaluation', which it had requested in 1997, of the hormones oestradiol-17ß and progesterone 'at your earliest convenience, in order to allow the adoption and publication of the results of this evaluation before 1 January 2000'.

31 That letter was followed on 25 May 1999 by another letter from the Commission, which forwarded to the EMEA the opinion of the Scientific Committee on Veterinary Measures Relating to Public Health ('the SCVPH') dated 30 April 1999.

32 By letter of 20 December 1999, the EMEA informed CEVA that, at its meeting of 7 to 9 December 1999, the CVMP had confirmed its earlier opinion on the inclusion of progesterone in Annex II to the 1990 Regulation. The opinion of the CVMP and its summary report were appended to that letter.

33 The CVMP stated in its report:

'The Committee, having evaluated the applications, recommended in October 1996 to include progesterone in Annex II of Council Regulation (EEC) No 2377/90. That opinion was, however, not adopted by the Commission.

In 1997 and 1999 the European Commission brought new data on steroidal sex hormones to the attention of the Committee and requested a re-evaluation of the substance in the light of new data.

The Committee, having considered the applications and the new data as stated in the appended summary report, confirmed the previous opinion and recommended that the above-mentioned substance shall be inserted in Annex II of Council Regulation (EEC) No 2377/90...'

34 The summary report states:

'Between 1997 and 1999, new data became available on the genotoxicity and carcinogenicity of steroid hormones, although not including progesterone (apart from some carcinogenicity data). Those data were also reviewed and discussed by the Joint FAO/WHO Experts Committee on Food Additives (JECFA) in 1999, by the Scientific Committee on Veterinary Measures Relating to Public Health (SCVPH) of the European Commission in 1999 and by the International Agency for Research on Cancer (IARC) in 1999. Upon evaluation of these data, mainly concerning oestradiol-17ß, the CVMP concluded that steroid hormones are

devoid of genotoxic activity *in vivo* and that these compounds exert their carcinogenic action only after prolonged exposure and at levels considerably higher than those required for a physiological (hormonal) response. Hence, the previous conclusions with respect to genotoxicity and carcinogenicity could be endorsed.

...

Having considered the criteria laid down by the Committee for the inclusion of substances into Annex II of Council Regulation (EEC) No 2377/90, and in particular that:

— Progesterone is of endogenous origin, and is a natural constituent of food of animal origin,

— The oral bioavailibility of progesterone is less than 10%,

— The animals are unlikely to be sent for slaughter during or immediately after treatment,

— Milk, tissue and plasma levels after treatment with progesterone have shown to be at or within physiological limits,

the Committee considers that there is no need to establish an MRL for progesterone and recommends its inclusion into Annex II of Council Regulation (EEC) No 2377/90.'

35 On 3 May 2000 the CVMP adopted a re-evaluation of its opinion of 30 April 1999.

36 On 12 July 2000, through the intermediary of their lawyers, the applicants sent registered letters to the Commission putting it on formal notice to take the necessary measures for including progesterone in Annex II to the 1990 Regulation as soon as possible, and to carry out all necessary steps for that purpose. The applicants also gave notice of their intention to bring an action for failure to act under Article 232 EC if the measures requested were not adopted within two months, and to bring an action for compensation.

37 On 7 August 2000, the Commission replied to those letters in the following terms:

'Mr Romano Prodi, President of the Commission, has asked me to reply to your letter of 12 July which you sent on behalf of the company [CEVA/Pharmacia]. In this letter, you invite the Commission to take the necessary measures to include, as soon as possible, the substance progesterone in Annex II of Regulation (EEC) No 2377/90.

We understand the concerns of [CEVA/Pharmacia] about any delay in including progesterone in the annexes of Regulation (EEC) No 2377/90 and about the economic consequences which could result. However, it must be emphasised that

the application to include progesterone in particular, and hormones more generally, in the annexes of Regulation (EEC) No 2377/00 raises complex issues of a scientific nature related to public health and consumer protection.

The above-mentioned dossier is still under consideration within the Commission services. Whilst we will do all we can to ensure that this consideration is conducted as speedily as possible, at this stage, it is unfortunately not possible for us to give you a timetable for the publication of the Regulation including progesterone in the Official Journal.'

38 On 25 July 2001, after the present actions had been brought, the Commission adopted a draft regulation proposing to classify progesterone in Annex I to the 1990 Regulation. On 1 August 2001 that draft was sent to the Standing Committee in accordance with the procedure laid down by Article 8 of the 1990 Regulation. The Standing Committee did not give a favourable report and, on 26 October 2001, the Commission submitted the draft to the Council. It was, however, rejected at the Council of Ministers for Agriculture of 21 and 22 January 2002.

Procedure

39 By applications lodged at the Registry of the Court of First Instance on 13 November 2000, the applicants brought the present actions.

40 By order of 23 July 2001, la Fédération européenne de la santé animale (the European Federation of Animal Health (FEDESA)) was given leave to intervene in support of the form of order sought by Pharmacia in its action for failure to act.

41 FEDESA lodged its statement in intervention on 3 September 2001.

42 The Commission submitted its observations on FEDESA's statement in intervention on 24 October 2001.

43 On 13 November 2001, after lodging its rejoinders, the Commission lodged, in both cases, documents entitled 'measures of organisation of procedure'.

44 The applicants and FEDESA submitted their observations on the Commission's documents on 17 December 2001.

45 The Court adopted measures of organisation of procedure, calling on the parties to answer a number of written questions. The parties complied with those requests.

46 On hearing the report of the Judge-Rapporteur, the Court (Second Chamber) decided to commence the oral procedure.

47 At the hearing on 25 September 2002, the parties presented oral argument and replied to the questions put to them by the Court; they also made submissions concerning the joinder of Cases T-344/00 and T-345/00 for the purposes of the judgment.

48 The cases were joined for the purposes of the judgment in accordance with Article 50 of the Court's Rules of Procedure.

Forms of order sought by the parties

49 The applicants claim that the Court should:

— declare pursuant to Article 232 EC that the Commission has failed to comply with its obligations under Community law by failing to take the necessary measures for the inclusion of progesterone in Annex II to Regulation No 2377/90 following the issuing of the positive opinion of the CVMP and in particular to draw up a draft regulation including progesterone in Annex II and submitting it to the Standing Committee for approval;

— order the Community, as represented here by the Commission, to repair the damage suffered by the applicants as a result of its unlawful failure to act and to set the amount of compensation at EUR 258 453 in Case T-344/00, and at EUR 271 170 in Case T-345/00, or at any other amount reflecting the damage suffered by the applicants as further established by them in the course of these proceedings, and especially taking due account of future damage;

— in the alternative, order the parties to produce to the Court within a reasonable period from the date of the judgment figures as to the amount of the compensation agreed between the parties or, failing agreement, order the parties to produce to the Court within the same period their submissions with detailed figures in support;

— order that interest at the annual rate of 8%, or any other appropriate rate to be determined by the Court, be paid on the amount payable as from the date of the Court's judgment until actual payment;

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

50 FEDESA supports the first head of claim of Pharmacia.

51 The Commission contends that the Court should:

— dismiss the applications as inadmissible and/or unfounded;

— order the applicants to pay the costs.

The actions for failure to act

52 In view, in particular, of the fact that the parties' arguments in support of their actions for failure to act are equally relevant to their actions in damages, the Court considers it appropriate to begin by setting out all their arguments concerning both admissibility and the merits before ruling on the actions for failure to act.

Arguments of the parties

Admissibility

53 The Commission begins by challenging the admissibility of the actions for failure to act. It argues that, according to Article 232 EC, an action for a declaration that a Community institution has failed to act may be brought only if 'within two months of being [called upon to act], the institution concerned has not defined its position'. In this case, the letter of 7 August 2000 is clearly a 'definition of position' within the meaning of that article, as the Commission stated therein why the file was still under consideration by its staff, and also stated the further procedural steps which it was about to take in response to CEVA's request.

54 According to the applicants, the letter of 7 August 2000 merely stated that the file was still under examination and does not constitute a definition of position by the Commission relieving it of liability for its failure to act. They refer, in this connection, to the judgment in Joined Cases 42/59 and 49/59 *SNUPAT* v *High Authority* [1961] ECR 53 and the order of the Court of First Instance in Case T-274/97 *Ca' Pasta* v *Commission* [1998] ECR II-2925, paragraphs 26 to 28.

55 In its rejoinders the Commission adduces additional arguments in support of its contention that the actions for failure to act are inadmissible. It maintains that, whilst CEVA's application for the establishment of an MRL for progesterone might confer upon it special procedural rights during the examination by the CVMP, it does not do so in the subsequent stages of the procedure laid down by the 1990 Regulation. Any measure concerning MRLs for progesterone would be

a legislative measure of general application concerning an open, objectively defined category of persons and, with regard to such a measure, the applicants' position is no different from that of any other person falling within the open category. Thus, the applicants are not individually concerned by the Commission's refusal to adopt such a measure.

56 In Case T-345/00, the Commission also adds that Pharmacia has at no point made an application under the 1990 Regulation for the establishment of an MRL for progesterone. Nor has it shown that the Commission was under any obligation to address to it a measure concerning it directly and individually.

57 FEDESA supports, in substance, the arguments of Pharmacia.

The merits

58 The applicants raise four pleas in law in support of their actions for failure to act. The first alleges infringement of the obligations imposed on the Commission by the 1990 Regulation, the second, infringement of the general principles of the protection of legitimate expectations and sound administration, the third, incompatibility of the Commission's inaction with the authorisation to use progesterone for therapeutic and zootechnical purposes and misuse of power, and the fourth, infringement of the applicants' fundamental right to carry on their business and of the principle of proportionality.

59 FEDESA supports, in substance, the pleas and arguments put forward by Pharmacia.

— The first plea: the Commission's failure to fulfil its obligations under the 1990 Regulation

60 According to the applicants, the CVMP is, under the legal framework laid down by the 1990 Regulation, the only Community committee competent to give a scientific opinion on all matters relating to veterinary medicinal products and, more particularly, on the scientific evaluation of files for establishing MRLs. The regulation specifically designates the CVMP as the sole competent body for formulating scientific opinions on the safety of a product.

61 Moreover, once the CVMP has given its scientific opinion on the classification of a substance in one of the annexes to the 1990 Regulation, the Community administration is, the applicants say, under an obligation to adopt the MRLs under a rapid procedure. In their submission, that obligation flows from Article 7(5) and (6) of the regulation and is confirmed by the judgments in Case T-120/96 *Lilly Industries* v *Commission* [1998] ECR II-2571, paragraph 83, and Case T-112/97 *Monsanto* v *Commission* [1999] ECR II-1277, and by the Opinion of Advocate General Mischo in Case C-151/98 P *Pharos* v *Commission* [1999] ECR I-8157, at I-8159.

62 In this case, according to the applicants, notwithstanding the obligations arising under the 1990 Regulation and the interpretation thereof given by the Court of First Instance, the Commission has failed to take the necessary measures, despite the fact that the CVMP gave a positive opinion in 1996 and again in December 1999, confirming the safety of progesterone in the light of all the available scientific data. Consequently, the Commission has manifestly failed to act.

63 The Commission begins by challenging the applicants' argument that, within the applicable legal framework, the CVMP is the sole committee in the Community competent to give any scientific opinion on all matters relating to veterinary medical products. The Commission does not dispute the advisory role of the CVMP, but argues that, in an area of Community law designed to protect human health, it would be illogical to suggest that the Commission, in assessing the risk management measure to be adopted, is obliged to follow only the opinion of the CVMP and to disregard scientific information coming from any other reliable source. The old version of Article 6(3) and (5) and Article 7(4) and (6) and the current version of Article 7(6) of the 1990 Regulation exclude such a restrictive interpretation.

64 Secondly, the Commission considers that the principal flaw in the applicants' reasoning lies in the fact that they regard the opinion of the CVMP as leaving the Commission no margin of discretion whatsoever as regards the choice of appropriate regulatory measures and as imposing on it an obligation to propose without delay a draft regulation to include, if appropriate, the substance in question in Annex II to the 1990 Regulation and submit it to the Standing Committee. In the Commission's view, the regulation leaves it a margin of discretion, as part of the risk management authority which it bears in the Community, to depart under certain circumstances from the opinion of the CVMP.

65 Thirdly, the Commission refers to the judgments in *Lilly Industries* v *Commission* and *Pharos* v *Commission*, cited above, arguing that its discretionary power must be assessed on a case-by-case basis, with account being taken of the complexity and sensitivity of the matter in question. That conclusion is further supported by a systematic interpretation of the relevant provisions of the 1990 Regulation and other regulations and acts in this area of Community law, which demonstrate that the opinion of the CVMP is purely advisory for the Commission.

66 Fourthly, the Commission argues that a high level of human health protection may be achieved only if assessments made by committees such as the CVMP are balanced by the competent institutions against all the scientific information available, taking into account scientific uncertainty, consumers' concerns, ethical or moral considerations or other legitimate factors and the precautionary principle. The Court of Justice and the Court of First Instance have explicitly upheld this right to balance different factors in a number of cases, notably those giving rise to the order in Case C-180/96 R *United Kingdom* v *Commission* [1996] ECR I-3903, the judgment in that case (Case C-180/96 [1998] ECR I-2265) and the judgment in Case T-199/96 *Bergaderm and Goupil* v *Commission* [1998] ECR II-2805).

67 The Commission concludes that the applicants have failed to establish that the Commission's action in this case is manifestly inappropriate having regard to the overriding objective that it is pursuing, namely the protection of public health.

— The second plea: breach of the general principles of the protection of legitimate expectations and sound administration

68 The applicants argue that, in this case, the Commission was well aware that an MRL had to be adopted and published in the Official Journal prior to 1 January 2000, given that Article 14 of the 1990 Regulation, as amended by Regulation No 434/97, explicitly provides that, with effect from 1 January 2000, the administration to food-producing animals of veterinary medicinal products containing pharmacologically active substances which are not mentioned in Annexes I, II or III is prohibited within the Community, except in the case of clinical trials. CEVA points out that, in his letter of 11 January 1999, the Director-General of DG III wrote that '[his] services [were] well aware that a veterinary medicinal product containing substances listed in the Communication

of the EMEA on the evaluation of medicines according to Article 1 of Council Regulation No 434/97 of 3 March 1997 (so-called [prohibited] substances) have to be included in Annex I, II or III to Council Regulation (EEC) No 2377/90 and published in the Official Journal before 1 January 2000 in order to remain on the market. Progesterone therefore [would] be presented for adoption to the Standing Committee for veterinary medicinal products in 1999'. The applicants therefore maintain that they had a legitimate expectation that measures to be taken before 1 January 2000 would include progesterone in Annex II to the 1990 Regulation, and that the Commission's failure to act is a breach not only of its obligations under the 1990 Regulation and the case-law of the Court but also of the general principles of the protection of legitimate expectations and sound administration.

69 The Commission argues that it could not be legitimately expected that a substance would be included in one of the annexes to the 1990 Regulation before 1 January 2000 if there were valid and objective reasons for the Commission to continue its examination of the substance in question. The exceptional technical and scientific complexities which progesterone, like the other natural hormones, presents justify the Commission's prudent approach in this case.

— The third plea: incompatibility of the Commission's inaction with the authorisation to use progesterone for therapeutic and zootechnical purposes and misuse of power

70 The applicants point out that the use of hormones for therapeutical and zootechnical purposes is specifically excluded from the prohibition laid down by Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ 1996 L 125, p. 3), and that, in its proposal for a Directive of the European Parliament and of the Council amending Directive 96/22/EC, adopted on 24 May 2000 (COM (2000) 320 final) (OJ 2000 C 337 E, p. 163), the Commission explicitly stated that, after review of the scientific findings, the use

of testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate 'may continue to be authorised for therapeutical purposes and zootechnical treatment under the conditions of Council Directive 96/22/EC'. There is therefore a clear and incomprehensible contradiction between Council Directive 96/22/EC expressly authorising the use of progesterone for zootechnical and therapeutic purposes — as confirmed by the Commission's proposal of 24 May 2000 — and the Commission's failure to include progesterone in Annex II to the 1990 Regulation. Indeed, the inclusion of an active substance in Annex I, II or III to the 1990 Regulation is necessary in order to obtain or retain market authorisation of medicinal products containing that active substance.

71 The applicants submit that the lack of transparency and coherence in the Commission's approach in this case demonstrates that, by failing to act, the Commission is in reality misusing its powers. Despite the fact that the CVMP issued a positive opinion in 1996, which was subsequently confirmed on the basis of all the scientific evidence in December 1999, the Commission failed to adopt the necessary measures for introducing progesterone into Annex II to the 1990 Regulation and has in fact been blocking the adoption of an MRL for progesterone for whatever reason it sees fit. In so doing, the Commission is manifestly using its powers for purposes other than the protection of public health. To the extent to which the Commission is pursuing goals which clearly have nothing to do with the protection of public health, its failure to act not only conflicts with the authorisation in the Community to use progesterone for therapeutical and zootechnical uses and with the recent initiatives of the Commission itself confirming that the use of hormonal substances for those purposes should continue, but also constitutes a genuine misuse of powers.

72 The Commission argues that there is no contradiction between its proposal for a directive of 24 May 2000, which provides that progesterone may continue to be authorised for therapeutic or zootechnical treatment under the strict conditions laid down by Council Directive 96/22, and its approach to establishing an MRL for progesterone. It points out that the level of endogenous production of

progesterone varies from animal to animal according to a number of factors and that, consequently, it is extremely difficult to establish an MRL. This technical difficulty appears also to have motivated the opinions of the CVMP of November 1996 and December 1999, which proposed the inclusion of progesterone in Annex II to the 1990 Regulation. Where a substance is proposed for inclusion in Annex II, this is done on the basis that residues from the substance in edible animal tissue are not considered to be dangerous to human health. Where no MRL is fixed, as the CVMP proposes in this case, no residue control would be carried out. This has the potential to undermine the Commission's and the Community's efforts to protect human health and is, in particular, the aspect on which the Commission services are concentrating their efforts especially after adoption on 24 May 2000 of the proposal to amend Council Directive 96/22/EC.

73 The Commission states that it explained in its letters to the applicants that its services had been and were still working on progesterone, and all the other pending hormonal substances for which an application had been made under the 1990 Regulation, in order to clarify the scientifically and technically complex issues involved. There is no basis, therefore, for the claim that the Commission is pursuing goals which have nothing to do with the protection of public health.

— The fourth plea: infringement of the applicants' fundamental right to carry on their business and of the principle of proportionality

74 The applicants claim that the Commission's failure to take the necessary measures to include progesterone in Annex II to the 1990 Regulation deprives them of the marketing authorisations which they enjoy under national law and thereby interferes with the very substance of their property right and their fundamental right to pursue economic activities.

75 The Commission, they argue, gave no justification for this interference. Moreover, and in any event, the Commission cannot rely on reasons relating to public health, now that the CVMP has, at the Commission's request, reviewed its assessment in the light of all the available scientific data and confirmed that the use of progesterone in veterinary medicinal products is safe, as the residues present no risk or danger to human health. The Commission's inaction was thus clearly unnecessary for the protection of public health and constitutes a disproportionate measure.

76 The Commission argues that, whilst it recognises the applicants' legitimate right to pursue their business, it is not guilty of any abuse or disproportionate act in violation of that right. The Court of Justice has held in several cases that, when examining the rights in issue, the Commission should take into account the principle that the requirements linked to the protection of public health should be given greater weight than economic considerations. Moreover, according to settled case-law, the fundamental right relied on by the applicants is not an absolute prerogative. Restrictions may be imposed on its exercise, particularly in the context of a common organisation of the market, provided that the restrictions correspond in fact to objectives of general interest pursued by the Community and do not, with regard to the objective pursued, constitute a disproportionate and intolerable interference which infringes upon the very substance of the rights thereby guaranteed.

— The relevance to the actions for failure to act of the facts communicated by the Commission in its documents headed 'measures of organisation of procedure'

77 The applicants argue that the Commission's adoption of a draft regulation for including progesterone in Annex I to the 1990 Regulation does not bring its failure to act to an end. They argue that, in that draft, the Commission did not follow the opinion of the CVMP, which recommended inclusion in Annex II to the 1990 Regulation, reserved for substances not subject to an MRL. Instead it

proposed inclusion in Annex I and indicative MRLs so that possible illegal use of progesterone might be checked. The applicants argue that the Commission's attempt to establish additional control measures by means of the procedure for fixing MRLs is contrary to the 1990 Regulation. In this connection, they cite the judgments in *Lilly Industries* v *Commission* and Joined Cases T-125/96 and T-152/96 *Boehringer* v *Council and Commission* [1999] ECR II-3427.

Findings of the Court of First Instance

78 It is appropriate, first of all, for the Court to consider whether the Commission's letter of 7 August 2000 amounts to the definition of a position, within the meaning of Article 232 EC, capable of putting an end to its failure to act.

79 It is quite evident that the letter does no more than state that the application for inclusion of progesterone in particular, and hormones more generally, in the annexes to the 1990 Regulation raises complex scientific issues of public health and consumer protection and that the dossier is still under examination within the Commission's services.

80 A letter emanating from an institution, stating that examination of the questions raised is in progress, does not, however, constitute the definition of a position which brings to an end a failure to act (*SNUPAT* v *High Authority*, cited above, at p. 74, Case 13/83 *Parliament* v *Council* [1985] ECR 1513, paragraph 25, Case T-95/96 *Gestevisión Telecinco* v *Commission* [1998] ECR II-3407, paragraph 88, and Case T-212/99 *Intervet* v *Commission* [2002] ECR II-1445, paragraph 61).

81 The Commission's letter of 7 August 2000 cannot therefore be regarded as defining its position, within the meaning of the second paragraph of Article 232 EC.

82 Secondly, it is appropriate to consider whether the draft regulation which the Commission adopted on 25 July 2001 and submitted to the Standing Committee on 1 August 2001 amounts to the definition of a position, within the meaning of Article 232 EC, putting an end to the Commission's failure to act.

83 It should be noted in this connection that the draft regulation deviates from CEVA's application and the two opinions given by CVMP in that it proposes that progesterone be included in Annex I to the 1990 Regulation, rather than Annex II, and proposes 'indicative' MRLs. According to settled case-law, Article 232 EC addresses failure to act in the sense of failure to take a decision or to define a position, not the adoption of a measure different from that desired or considered necessary by the persons concerned, and the fact that the position adopted by the Commission has not satisfied the applicants is of no relevance in this respect (Case 8/71 *Deutscher Komponistenverband* v *Commission* [1971] ECR 705, paragraph 2, Joined Cases C-15/91 and C-108/91 *Buckl and Others* v *Commission* [1992] ECR I-6061, paragraphs 16 and 17, Case C-44/00 P *Sodima* v *Commission* [2000] ECR I-11231, paragraph 83, and Case T-38/96 *Guérin automobiles* v *Commission* [1997] ECR II-1223, paragraph 24).

84 In the present case, the draft regulation did address the subject-matter of the applications. By adopting that draft regulation on 25 July 2001 and submitting it first to the Standing Committee then to the Council, the Commission has defined its position on the matter with regard to which the applicants called upon it to act.

85 According to settled case-law, if, after an action for failure to act has been commenced against it, the Commission defines its position, that terminates the

failure to act and renders the action devoid of purpose (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, and *Intervet* v *Commission*, cited above, paragraph 67).

86 It follows that there is no longer any need to rule on the actions for failure to act.

The actions in damages

Arguments of the parties

87 The applicants, relying also on the arguments which they put forward in support of their actions for failure to act, argue that the Commission's failure to act constitutes an illegality which gives rise to liability on the part of the Community. The measures which the Commission is under an obligation to take so as to allow the inclusion of progesterone in Annex II to the 1990 Regulation pertain clearly to pure administrative action. Even if the regime pertaining to illegal legislative action were applicable in this case, it is clear that the Commission's failure to act is explicit, manifest and serious and infringes higher-ranking rules of law for the protection of individuals.

88 The applicants maintain that, as a result of the Commission's failure to adopt the necessary measures to include progesterone in Annex II to the 1990 Regulation, they have sustained and continue to sustain specific and quantifiable damage. As from 1 January 2000 they have been unable to market their products for

administration to food-producing animals and several competent national authorities, the Austrian authorities in particular, have withdrawn marketing authorisations for their products or not extended such authorisation. CEVA calculates its damage up to the time of lodging its application at EUR 258 453 and Pharmacia at EUR 271 170. Their loss was caused directly and exclusively by the Commission's failure to act. The fact that the Commission adopted a draft regulation for the inclusion of progesterone in Annex I to the 1990 Regulation has not made good the damage they have sustained.

89 The three conditions for establishing non-contractual liability on the part of the Community (unlawful conduct, actual damage and a causal link between the unlawful conduct and the damage) are therefore, in their view, satisfied in this case.

90 The Commission submits that the present case concerns an area of Community law in which it enjoys a certain margin of discretion as regards the draft measures it is required to propose under Article 7(6) of the 1990 Regulation. It is not an area of purely administrative action, as the applicants claim.

91 The Commission maintains that its actions in this case have been motivated solely by its duty to ensure a high level of public health protection and that none of the arguments advanced by the applicants has demonstrated a manifest and serious breach of a higher-ranking rule of law.

92 Nor, moreover, have the applicants demonstrated any real damage, let alone damage that is actual and certain, given that, apart from a reference to Austria, they have not explained where and why sales of their products have fallen. The Commission also disputes the calculations submitted by the applicants.

93 Lastly, the Commission argues that the applicants have also failed to establish with sufficient precision the existence of a direct causal link between the alleged damage and its alleged failure to fulfil its obligations under Community law inasmuch as they fail to take sufficient account of the fact that, for the withdrawal of an existing marketing authorisation of their products, separate decisions by the competent national authorities of the Member States are required.

Findings of the Court

Preliminary remarks

94 The second paragraph of Article 288 EC provides that, in the case of non-contractual liability, the Community must, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its institutions or by its servants in the performance of their duties.

95 According to well-established case-law, the Community's non-contractual liability is dependent on the coincidence of a series of conditions as regards the unlawfulness of the acts alleged against the Community institution, the fact of damage and the existence of a causal link between the wrongful act and the damage complained of (see, *inter alia*, Joined Cases 197/80 to 200/80, 243/80, 245/80 and 247/80 *Ludwigshafener Walzmühle and Others* v *Council and Commission* [1981] ECR 3211, paragraph 18, and Joined Cases T-481/93 and T-484/93 *Exporteurs in Levende Varkens and Others* v *Commission* [1995] ECR II-2941, paragraph 80).

96 As regards the first of those conditions, the unlawfulness of the act, case-law has made it plain that the Community can incur liability for a legislative measure only if there has been a breach of a higher-ranking rule of law for the protection of individuals. Moreover, if the institution has adopted the measure in the exercise of a broad discretion, the Community cannot be liable unless the breach is clear, that is to say, if it is of a manifest and serious nature (Case 5/71 *Aktien-Zuckerfabrik Schöppenstedt* v *Council* [1971] ECR 975, paragraph 11, Joined Cases 83/76, 94/76, 4/77, 15/77 and 40/77 *Bayerische HNL and Others* v *Council and Commission* [1978] ECR 1209, paragraph 6, and Case 20/88 *Roquette Frères* v *Commission* [1989] ECR 1553, paragraph 23).

97 Any refusal on the part of the Community institutions to adopt a legislative measure must be assessed by reference to the same criteria (Case 50/86 *Grands Moulins de Paris* v *Council and Commission* [1987] ECR 4833, paragraph 9).

98 In the present case, the Court is called upon to consider the Commission's inaction between 1 January 2000 and 25 July 2001. Indeed, the applicants do not claim to have suffered any damage as a result of the Commission's inaction before the time-limit fixed in Article 14 of the 1990 Regulation and, as the Court found on considering the actions for failure to act, the Commission's inaction came to an end on 25 July 2001.

— Unlawful conduct

99 First of all, it should be observed that, in view of the sixth and tenth recitals in its preamble and Articles 7 and 8, the 1990 Regulation, before as well as after amendment by Regulation No 1308/1999, lays down a reasonably speedy procedure for establishing MRLs in which the opinion of the CVMP occupies a central place. In *Pharos* v *Commission*, cited above, at paragraph 26, the Court

nevertheless acknowledged, in the particular circumstances of that case, that, where it is confronted with a matter which is scientifically and politically complex and sensitive, the Commission is entitled to seek a further opinion from the CVMP, even though the 1990 Regulation is silent on the point.

100 Secondly, it must be acknowledged that, quite clearly, the progesterone file is a scientifically and politically complex file. Amongst other things, progesterone is an endogenous substance and there are at present no reliable analytical methods by which to check abuse of the substance. The complexity of the file is further confirmed by what happened to the draft regulation which the Commission adopted and then submitted to the Standing Committee and the Council.

101 However, that complexity does not excuse the Commission's inaction after 1 January 2000. Given that the CVMP entirely confirmed its first opinion, even after taking into consideration the new scientific data presented to it by the Commission, and the fact that the Commission itself has always maintained the view that progesterone should continue to be authorised for therapeutic and zootechnical treatment, the Commission disregarded the legitimate interests of the applicants, of which it was perfectly well aware, in a clear and serious way by failing to adopt the measures needed for its continued use, for therapeutic and zootechnical purposes, after 1 January 2000, the date from which, under Article 14 of the 1990 Regulation, the administration to food-producing animals of veterinary medicinal products containing pharmacologically active substances which are not mentioned in Annexes I, II or III to the 1990 Regulation was prohibited within the Community. It is important to note in this context that the application for an MRL to be established for progesterone was made as early as September 1993.

102 Even if the scientific and political complexities of the file were such as to prevent the Commission from adopting, shortly after the CVMP issued its second opinion, a draft regulation conforming to that opinion, the Commission ought to

have concerned itself with the interests of the applicants, for example by adopting draft measures establishing a provisional MRL on the basis of Article 4 of the 1990 Regulation or by arranging for a (second) deferral of the time-limit laid down in Article 14 thereof.

103 That being so, the inaction of the Commission between 1 January 2000 and 25 July 2001 constitutes a clear and serious breach of the principle of sound administration giving rise, in principle, to liability on the Community's part. There is therefore no need in the present case to establish whether the Commission's inaction was administrative or legislative in nature, or to determine the exact scope of its discretion in setting MRLs.

— The damage sustained and the causal link between the unlawful conduct and the damage

104 The applicants claim that, since 1 January 2000, with no MRL defined for progesterone, they have been unable to market their products in the Member States of the Community. They estimate the damage which they sustained up to the time of bringing their actions at EUR 258 453 in the case of CEVA and EUR 271 170 in the case of Pharmacia.

105 According to the written reply which CEVA gave to a question raised by the Court, it appears that the regulatory situation governing its product throughout the Community has not been affected by the Commission's inaction, except for the suspension of the Austrian marketing authorisation from 26 July 2000 to 31 May 2001. Whilst the harm actually suffered might therefore be different from what is stated in the application, it has been sufficiently well established that CEVA could have sustained a loss.

106 According to the written reply which Pharmacia gave to a question raised by the Court, it appears that the regulatory situation governing its product CIDR in France, Finland, Ireland and the United Kingdom has not been affected by the Commission's inaction, although its marketing authorisation was suspended, in Austria, from 26 July 2000 to 18 July 2001. In addition, Pharmacia points out that the procedure for obtaining marketing authorisation for CIDR in Belgium, Germany, Italy and the Netherlands is at a standstill because no MRL has been fixed for progesterone. The same is true of its product 'CIDR 1900 Plus' in France. Whilst the amount of damages has not yet been determined, the Court treats it as sufficiently well established that Pharmacia could have sustained a loss.

107 The Commission's argument that there is no causal link between its inaction and the damage sustained, on the ground that it is for the competent national authorities to adopt marketing authorisation decisions, cannot be accepted. Indeed, if national authorities have withdrawn or suspended marketing authorisations or suspended procedures for issuing such authorisations because no MRL has been fixed for progesterone, they did so simply in order to comply with the prohibition under Article 14 of the 1990 Regulation and Article 4(2) of Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (OJ 1981 L 317, p. 1) (now Article 6 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1). That being so, the damage is attributable to the Commission's inaction. The Austrian authorities' decisions to suspend marketing authorisations were clearly taken in view of the lack of any MRL for progesterone.

108 In view of the fact that it is not yet possible to fix the amount of damages, it is appropriate, for reasons of economy of procedure, to give an initial interlocutory ruling on the liability of the Community and defer to a subsequent stage of the proceedings the question of assessing the damage attributable to the Commis-

sion's inaction between 1 January 2000 and 25 July 2001 (see, to that effect, Joined Cases C-104/89 and C-37/90 *Mulder and Others* v *Council and Commission* [1992] ECR I-3061, paragraph 37, and Case T-76/94 *Jansma* v *Council and Commission* [2001] ECR II-243, paragraph 102).

109 It follows that the pleas which the applicants put forward in the alternative may be upheld.

Costs

110 Costs are reserved.

On those grounds,

THE COURT OF FIRST INSTANCE (Second Chamber)

hereby rules by way of interlocutory judgment:

1. **There is no longer any need to give judgment on the actions for failure to act.**

2. The Commission's inaction between 1 January 2000 and 25 July 2001 is such as to render the Community liable.

3. Within six months of the date of delivery of the present judgment the parties shall inform the Court of the amount of damages which they claim, as agreed with the Commission.

4. In the event of failure to agree the amount, the parties shall submit to the Court, within the same period, their calculations of the amount of damages attributable to the Commission's inaction between 1 January 2000 and 25 July 2001.

5. The costs are reserved.

Moura Ramos Pirrung Meij

Delivered in open court in Luxembourg on 26 February 2003.

H. Jung

Registrar

R.M. Moura Ramos

President