JUDGMENT OF THE COURT (Grand Chamber)

12 July 2005 *

In Case C-198/03 P,

APPEAL under Article 56 of the Statute of the Court of Justice, brought on 12 May 2003,

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

appellant,

the other parties to the proceedings being:

CEVA Santé Animale SA, having its registered office in Libourne (France), represented by D. Waelbroeck, avocat, N. Rampal, abogada, and U. Zinsmeister, Rechtsanwältin,

applicant at first instance in Case T-344/00,

* Language of the case: English.

Pfizer Enterprises Sàrl, formerly Pharmacia Enterprises SA and, prior to that, Pharmacia & Upjohn SA, having its registered office in Luxembourg (Luxembourg), represented by D. Waelbroeck, N. Rampal and U. Zinsmeister,

applicant at first instance in Case T-345/00,

supported by

International Federation for Animal Health (IFAH), formerly Fédération européenne de la santé animale (Fedesa), established in Brussels (Belgium), represented by A. Vandencasteele, avocat,

intervener at first instance in Case T-345/00,

THE COURT (Grand Chamber),

composed of V. Skouris, President, P. Jann (Rapporteur), C.W.A. Timmermans and A. Borg Barthet, Presidents of Chambers, J.-P. Puissochet, R. Schintgen, N. Colneric, S. von Bahr, J.N. Cunha Rodrigues, M. Ilešič, J. Malenovský, U. Lõhmus and E. Levits, Judges,

Advocate General: F.G. Jacobs,
Registrar: L. Hewlett, Principal Administrator,

having regard to the written procedure and further to the hearing on 6 July 2004,

after hearing the Opinion of the Advocate General at the sitting on 23 September 2004,

gives the following

Judgment

1 By its appeal, the Commission of the European Communities is seeking partial annulment of the judgment delivered by the Court of First Instance of the European Communities on 26 February 2003 in Joined Cases T-344/00 and T-345/00 *CEVA* and *Pharmacia Enterprises* v *Commission* [2003] ECR II-229 (hereinafter 'the judgment under appeal') in so far as it held that the Commission's inaction between 1 January 2000 and 25 July 2001 was of such a kind as to give rise to liability on the part of the Community.

The legal framework

Regulation No 2377/90

2 On 26 June 1990 the Council of the European Communities adopted Regulation (EEC) No 2377/90 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).

3 The preamble to that regulation contains, among others, the first, third and sixth recitals, which are worded as follows:

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

...

... 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;

...

... 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;

...'

4 Under Regulation No 2377/90 the Commission is required to establish the maximum residue limit (hereinafter 'MRL'), defined in Article 1(1)(b) of the Regulation as being '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'.

5 Regulation No 2377/90 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 comprises the list of substances for which MRLs have been fixed, Annex II comprises the list of substances that are not subject to MRLs, Annex III comprises the list of substances for which provisional MRLs have been fixed, and Annex IV comprises the list of substances for which no MRL can be fixed.

6 Article 4 of Regulation No 2377/90 provides that a provisional MRL may be established only 'provided that there are no grounds for supposing that residues of the substance concerned at the level proposed present a hazard for the health of the consumer.'

7 In its original version, Article 14 of Regulation No 2377/90 provided as follows:

'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 ...'.

8 Council Regulation (EC) No 434/97 of 3 March 1997 amending Regulation No 2377/90 (OJ 1997 L 67, p. 1) deferred to 1 January 2000 the date initially fixed in Article 14 for most of the substances the use of which was authorised on the date of entry into force of Regulation No 2377/90 and in respect of which documented applications for the establishment of MRLs had been lodged before 1 January 1996. The substances in question included progesterone.

Directive 96/22

9 Article 3(a) of 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) requires Member States to prohibit the administration to farm animals of substances having a gestagenic action, of which progesterone is one.

10 Article 4 of that directive provides that Member States may, by way of derogation and subject to certain conditions, authorise the administration of progesterone to farm animals for therapeutic purposes.

The facts of the dispute and the proceedings before the Court of First Instance

11 CEVA Santé animale SA ('CEVA') and Pfizer Enterprises Sàrl, formerly Pharmacia Enterprises SA and, before that, Pharmacia & Upjohn SA ('Pfizer'), are pharmaceutical undertakings which have, from a date prior to the entry into force of Regulation No 2377/90, marketed a veterinary medicinal product containing the active ingredient progesterone.

12 CEVA submitted an application to the Commission in 1993 for the establishment of an MRL for progesterone in cattle and horses.

13 In November 1996 the European Agency for the Evaluation of Medicinal Products ('the EMEA') informed CEVA that, at its meeting in October 1996, the Committee on Veterinary Medicinal Products ('the CVMP') had recommended that progesterone be included in Annex II to Regulation No 2377/90 and that the opinion of the CVMP would be forwarded to the Commission for adoption by the Committee for Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products ('the Standing Committee').

14 In April 1997 the Commission sent new scientific information to the EMEA and requested a re-assessment of the risks relating to the hormones oestradiol-17ß and progesterone.

15 In October 1997 the EMEA informed CEVA that '... 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.'

16 In April 1998 the Commission wrote again to the EMEA requesting it to allow the CVMP to take account of scientific information which was to become available in the course of 1998 from a number of sources, such as the International Agency for Research on Cancer ('IARC'), an advisory body to the World Health Organisation, the United States National Institute of Health, and the results of a number of specific studies commissioned by the Commission.

17 The Commission was informed in May 1998 that the Joint FAO/WHO Expert Committee on Food Additives ('JECFA'), the scientific committee which advises the Codex Alimentarius Commission on food additives and contaminants, was also planning to re-evaluate three natural hormones, including progesterone, in February 1999.

18 In February 1999 the Commission published in the *Official Journal* a 'call for scientific documentation required for risk assessment of ... progesterone ... used for animal growth promotion purposes'.

19 The JECFA published the summary of its evaluation on the three natural hormones in or around April 1999. The JECFA concluded that, on the basis of the available data, it would not be necessary to establish numerical MRLs for the three hormones examined.

20 In 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'.

21 In May 1999 the Commission forwarded to the EMEA the opinion of the Scientific Committee on Veterinary Measures Relating to Public Health ('the SCVPH') of 30 April 1999. The summary of that report concluded as follows:

'Taking into account both the hormonal and non-hormonal toxicological effects ..., it has to be concluded that the issues of concern include neurobiological,

developmental, reproductive and immunological effects, as well as immunotoxiocity, genotoxicity and carcinogenicity. In consideration of the recent concerns relating to the lack of understanding of critical developmental periods in human life as well as the uncertainties in the estimates of endogenous [naturally occurring] hormone production rates and metabolic clearance capacity, particularly in prepubertal children, no threshold level and therefore no ADI [acceptable daily intake] can be established for any of the six hormones'.

22 By letter of 20 December 1999 the EMEA informed CEVA that, at its meeting in early December 1999, the CVMP had confirmed its earlier opinion recommending that progesterone be included in Annex II to Regulation No 2377/90.

23 The CVMP stated as follows in its opinion:

'The Committee, having evaluated the applications, recommended in October 1996 to include progesterone in Annex II [to] ... Regulation ... 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 [to] ... Regulation ... No 2377/90 ...'.

24 On 3 May 2000 the SCVPH adopted a re-evaluation of its opinion of April 1999. Asked to confirm that there was no recent scientific information that would lead it to revise its previous opinion or to revise the relevant parts thereof as necessary, it concluded that recent scientific information did not provide convincing data or arguments making a revision of its previous conclusions necessary. It stated that it had again discussed the obvious gaps in the present knowledge on the metabolism of animals treated with the hormones under consideration and on residue disposition of those hormones and that it expected that the ongoing European Union research programmes would provide additional data on those two matters.

25 On 24 May 2000 the Commission adopted a proposal for a directive of the European Parliament and the Council amending Directive 96/22 (COM (2000) 320 final) (OJ 2000 C 337 E, p. 163). The proposal required, inter alia, Member States provisionally to prohibit the administration of progesterone to farm animals while allowing them to maintain the derogation for therapeutic and zootechnical purposes.

26 In July 2000 CEVA and Pfizer put the Commission on formal notice to take the necessary measures for including progesterone in Annex II to Regulation No 2377/90 as soon as possible.

27 In November 2000 CEVA and Pfizer brought proceedings before the Court of First Instance seeking, principally, a declaration pursuant to Article 232 EC that, by failing to take the necessary measures for the inclusion of progesterone in Annex II to Regulation No 2377/90, the Commission had failed to comply with its obligations under Community law and, secondly, damages under Articles 235 EC and 288 EC. The International Federation for Animal Health, formerly Fédération européenne de la santé animale ('IFAH'), intervened in support of the form of order sought by Pfizer.

Legislative developments after the actions had been brought

28 On 25 July 2001 the Commission adopted a proposal for a Council regulation amending Annex I to Regulation (EEC) No 2377/90 (COM (2001) 627 final) classifying progesterone in Annex I to that regulation.

29 In accordance with Article 8 of Regulation No 2377/90, that proposal was referred to the Standing Committee. As the latter did not issue a favourable opinion, the proposal was rejected during the Council meeting of agriculture ministers held on 21 and 22 January 2002.

30 In December 2002 the Commission submitted to the Standing Committee a second proposal classifying progesterone in Annex III to Regulation No 2377/90. That proposal did not obtain the favourable opinion of the Standing Committee.

31 On 22 September 2003 the European Parliament and the Council adopted Directive 2003/74/EC amending Directive 96/22 (OJ 2003 L 262, p. 17). In its amended version, Article 3 of Directive 96/22 prohibits provisionally the administration of progesterone to farm animals. Article 5 of that directive, as amended, provides for a derogation from that prohibition in regard to the administration of progesterone for therapeutic or zootechnical purposes.

32 On 24 October 2003 the Commission adopted Regulation (EC) No 1873/2003 amending Annex II to Regulation No 2377/90 (OJ 2003 L 275, p. 9). That regulation includes progesterone in Annex II only for intravaginal therapeutic or zootechnical use on female bovine, ovine, caprine and equine animals.

The judgment under appeal

33 The Court of First Instance joined the actions in Cases T-344/00 and T-345/00 for purposes of the judgment. In the judgment under appeal, the Court of First Instance held that there was no longer any need to rule on the actions for failure to act inasmuch as the Commission had acted by submitting a proposal for a regulation on 25 July 2001.

34 With regard to the form of order seeking damages, the Court of First Instance began by pointing out, in paragraph 99 of the judgment under appeal, 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 and, in paragraph 100 thereof, that the progesterone file is indeed a scientifically and politically complex file. The Court of First Instance then went on to rule:

> '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 [respondents], 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 [respondents], 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.'

35 With regard to the existence of a causal link between the Commission's inaction and the harm suffered by the then applicants, the Court of First Instance held:

'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. ...'

36 The Court of First Instance allowed the parties a six-month period to reach an agreement on the amount of damages, failing which it would itself rule on the matter.

The forms of order sought by the parties

37 The Commission submits that the Court should set aside the judgment under appeal as regards the actions for damages, rule on the substance of the applications for damages by dismissing them as unfounded, and order CEVA and Pfizer to pay the costs.

38 CEVA and Pfizer, supported by IFAH, submit, primarily, that the appeal should be dismissed and the Commission ordered to pay the costs.

39 CEVA and Pfizer had brought a cross-appeal by which they sought to have the judgment under appeal set aside to the extent to which it dismissed the action concerning the failure to act. They withdrew that cross-appeal following the adoption of Regulation No 1873/2003.

The appeal

40 The Commission puts forward five grounds of appeal: error in the interpretation and application of Article 14 of Regulation No 2377/90; error in the interpretation and application of the principle of good administration; misconstruction of the evidence, or at least insufficient reasons in that regard; error in the interpretation and application of Article 288 EC; and failure to rule on the objection of inadmissibility which the Commission had raised against the action brought by Pfizer for failure to act.

The ground of appeal alleging an error in the interpretation and application of Article 14 of Regulation No 2377/90

Arguments of the parties

41 According to the Commission, the Court of First Instance, in paragraphs 101 and 102 of the judgment under appeal, interpreted Article 14 of Regulation No 2377/90 as imposing an obligation on the Commission to act before 1 January 2000. The Commission contends that it was under no absolute obligation to take a decision on the applications submitted before that date. That time-limit was nothing more than a default risk management rule in the sense that, if the risk assessment was not completed in time, only the administration of veterinary medicinal products containing the substances in question to food-producing animals would be prohibited for as long as those substances were not placed on one of the first three annexes to Regulation No 2377/90.

42 CEVA and Pfizer submit that the ground is new and, for that reason, inadmissible. In the alternative, they argue that the Commission itself acknowledged that it was under an obligation to act before 1 January 2000. The interpretation supported by the Commission would have the consequence that the substances which had not been examined prior to that date would become de facto prohibited, something which would have been contrary to the legislative intention of maintaining veterinary medicinal products on the market.

Findings of the Court

43 With regard to the admissibility of this ground, it is clear from the documents before the Court of First Instance that the issue of the binding nature of the date set out in Article 14 of Regulation No 2377/90 was raised by CEVA and Pfizer, inter alia in points 51 to 57 of the application in Case T-344/00 and in points 44 to 49 of the application in Case T-345/00, and that the Commission addressed that issue, inter alia in points 53 to 55 and in points 51 to 55 of its respective statements in defence in those two cases. The objection of inadmissibility raised by CEVA and Pfizer in which they contend that that ground is new must for that reason be rejected.

44 On the merits, it must be noted that the wording of Article 14 of Regulation No 2377/90 is limited to stating that, with effect from the date indicated, 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 to be prohibited within the Community. That wording does not allow the inference to be drawn, as CEVA and Pfizer contend, that that date constituted for the Commission a time-limit by which it was obligated to ensure that the substances in question would be included in the corresponding annexes to Regulation No 2377/90.

45 However, the indication of a date with effect from which the administration of veterinary medicinal products containing active substances is to be prohibited unless those substances are included on one of the lists provided for by Regulation No 2377/90 does mean that the absence of a decision on that point must be justified.

46 It does not follow from paragraphs 101 and 102 of the judgment under appeal that the Court of First Instance interpreted Article 14 of Regulation No 2377/90 any differently and derived from it, as the Commission contends, an obligation on that institution to have concluded the appraisal and classified the substances concerned before the date indicated. The Court of First Instance does not state that the Commission was under an obligation to take a formal decision before 1 January 2000 but confines itself to establishing that the absence of a decision after that date was not justified.

47 In those circumstances, the ground must be rejected.

The ground of appeal alleging misconstruction of the evidence or, in any event, insufficient reasons in that regard

Arguments of the parties

48 By this ground of appeal, the Commission argues that, in paragraph 101 of the judgment under appeal, the Court of First Instance misconstrued the evidence which the Commission had adduced in order to establish that there was scientific uncertainty in so far as it failed to take all of the factual information into account. The Court of First Instance overlooked entirely the relevance of scientific data other than the opinion of the CVMP, in particular the evaluation of progesterone-related risks conducted by the competent committee, namely the SCVPH. The extreme brevity of the reasoning of the Court of First Instance may also be regarded as constituting inadequate reasoning.

49 In response, CEVA and Pfizer state that, in addition to the fact that it is not its function to rule on scientific issues, the Court of First Instance took due account of the scientific difficulties presented by the progesterone file and the findings of the CVMP, to which the new data on the use of the hormone in question had been submitted.

Findings of the Court

50 While it is for the Court of First Instance alone to assess the value to be attached to the items of evidence adduced before it, and while it cannot be required to give express reasons for its assessment of the value of each piece of evidence presented to it, in particular where it considers that evidence to be unimportant or irrelevant to the outcome of the dispute (Case C-237/98 P *Dorsch Consult* v *Council and Commission* [2000] ECR I-4549, paragraphs 50 and 51), the Court of First Instance is none the less obligated to provide reasons which will allow the Court to exercise its judicial review. Those reasons must make it possible for the Court to review any distortion of the evidence submitted to the Court of First Instance.

51 In the present case, it is clear from the documents before the Court of First Instance that the Commission explained, in point 23 of its statement in defence in Cases T-344/00 and T-345/00, that 'when [it] received on 6 January 2000 the opinion of the CVMP on the hormones, including progesterone, it found itself faced with divergent and in some respects conflicting scientific information.' The Commission stressed in particular the differences between the opinions of the CVMP, the SCVPH, the JECFA and the IARC.

52 In paragraph 101 of the judgment under appeal, the Court of First Instance referred to the fact that 'the CVMP entirely confirmed its first opinion, even after taking into consideration the new scientific data presented to it by the Commission' and to the 'fact that the Commission itself [had] always maintained the view that progesterone should continue to be authorised for therapeutic and zootechnical treatment' for the purpose of concluding that the Commission had disregarded the legitimate interests

of the then applicants in a clear and serious way by failing to adopt the measures required for the continued use of progesterone, for therapeutic and zootechnical purposes, after 1 January 2000.

53 The Court of First Instance thus confined itself to referring to the second opinion of the CVMP without explaining why the Commission was obliged to follow that opinion, and disregarded the differing opinions from other sources, which, in accordance with the third recital in the preamble to Regulation No 2377/90, had to be regarded as being relevant, such as the SCVPH, the JECFA or the IARC. That sole reference, without any mention of the other opinions available, does not allow the Court to identify the link which the Court of First Instance established between the opinion of the CVMP and the consequences in law which it derived from that opinion. It follows that the Court of First Instance failed to provide adequate reasoning for its judgment on that point.

54 The reference to the fact that the Commission had always taken the view that the use of progesterone had to continue to be authorised for therapeutic or zootechnical purposes cannot remedy that shortcoming. That designation of the Commission's conduct, in addition to being itself bereft of any indication as to the findings on which it is based, provides no clearer details as to the scope which the Court of First Instance attributed to the second opinion of the CVMP.

55 It follows that the ground must be upheld.

The ground of appeal alleging a mistaken interpretation and application of Article 288 EC

Arguments of the parties

56 By this ground of appeal the Commission argues that, in holding that the conditions for establishing the Community's non-contractual liability had been satisfied, the Court of First Instance committed two errors of law.

57 First, it submits, the Court of First Instance erred in taking the view, in paragraph 103 of the judgment under appeal, after having found that the Commission's conduct constituted a clear and serious infringement of the principle of sound administration, that there was no need in the case to determine the exact scope of the Commission's discretion in setting MRLs. That reasoning, the Commission argues, is erroneous inasmuch as an analysis of the seriousness of the alleged infringement presupposes an analysis of the degree of discretion enjoyed by the institution concerned.

58 Second, in holding, in paragraph 107 of the judgment under appeal, that there was a causal link between the Commission's inaction and the damage sustained by CEVA and Pfizer, that is to say, the impossibility which they faced of selling their products in the Community as from 1 January 2000, the Court of First Instance, according to the Commission, misinterpreted the provisions of Regulation No 2377/90 and its relationship with other relevant provisions of Community law, in particular Directive 81/851.

59 CEVA and Pfizer take the view that the Commission was under an obligation to take the measures necessary to guarantee the continued marketing and administration to food-producing animals of veterinary medicinal products containing progesterone after 1 January 2000. The absence of any action by the Commission to guarantee their legitimate expectations and rights constitutes, in their opinion, a serious and manifest breach of that obligation, irrespective of its exact nature.

60 So far as concerns the existence of a causal link, CEVA and Pfizer argue that the failure of the Commission to establish an MRL had the result that the veterinary medicinal products containing progesterone could no longer be administered and that the national authorities withdrew or suspended marketing authorisations for those products.

Findings of the Court

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

62 The system of rules which the Court has worked out with regard to that provision takes into account, inter alia, the complexity of the situations to be regulated, difficulties in the application or interpretation of the texts and, more particularly, the margin of discretion available to the author of the act in question (Joined Cases C-46/93 and C-48/93 *Brasserie du Pêcheur and Factortame* [1996] ECR I-1029, paragraph 43; Case C-352/98 P *Bergaderm and Goupil* v *Commission* [2000] ECR I-5291, paragraph 40; Case C-312/00 P *Commission* v *Camar and Tico* [2002] ECR I-11355, paragraph 52; and Case C-472/00 P *Commission* v *Fresh Marine* [2003] ECR I-7541, paragraph 24).

63 The Court has ruled that Community law confers a right to reparation where three conditions are met: the rule of law infringed must be intended to confer rights on individuals; the breach must be sufficiently serious; and, finally, there must be a direct causal link between the breach of the obligation devolving on the institution and the damage sustained by the injured parties (*Brasserie du Pêcheur and Factortame*, paragraph 51; *Bergaderm and Goupil* v *Commission*, paragraphs 41 and 42; *Commission* v *Camar and Tico*, paragraph 53; and *Commission* v *Fresh Marine*, paragraph 25, all cited above).

64 With regard to the second condition, the Court has stated that the decisive test for determining whether a breach of Community law is sufficiently serious is whether the Community institution concerned manifestly and gravely disregarded the limits

on its discretion (*Brasserie du Pêcheur and Factortame*, paragraph 55; *Bergaderm and Goupil* v *Commission*, paragraph 43; *Commission* v *Camar and Tico*, paragraph 54; and *Commission* v *Fresh Marine*, paragraph 26).

65 Where that institution has only a considerably reduced, or even no, discretion, the mere infringement of Community law may be sufficient to establish the existence of a sufficiently serious breach (*Bergaderm and Goupil* v *Commission*, paragraph 44; *Commission* v *Camar and Tico*, paragraph 54; and *Commission* v *Fresh Marine*, paragraph 26).

66 The determining factor in deciding whether there has been such an infringement is therefore the discretion available to the institution concerned (*Bergaderm and Goupil* v *Commission*, paragraph 46; *Commission* v *Camar and Tico*, paragraph 55; and *Commission* v *Fresh Marine*, paragraph 27).

67 While the question as to the scope of the Commission's discretion in establishing MRLs had been the subject of discussion between the parties, with the applicants at the time arguing that the Commission did not have any discretion and the Commission, on the contrary, arguing that it had a broad discretion (see paragraphs 61, 64 and 65 of the judgment under appeal), the Court of First Instance did not at any point in the judgment under appeal explain in detail the discretion which the Commission enjoys in establishing MRLs.

68 Nor did the Court of First Instance set out adequately for legal purposes the reasons or circumstances which might exceptionally have explained why such an analysis would serve no purpose (for the inadequacy of the reasoning given in paragraph 101 of the judgment under appeal, see above paragraphs 52 to 54 of the present judgment).

69 It must for those reasons be concluded that the Court of First Instance erred in law in holding in paragraph 103 of the judgment under appeal, without having established the scope of the discretion enjoyed by the Commission, that the Commission's inaction between 1 January 2000 and 25 July 2001 constituted a clear and serious breach of Community law giving rise to liability on the part of the Community.

70 The ground of appeal must therefore be upheld.

71 In those circumstances, without it being necessary to rule on the other grounds adduced in support of the appeal, in particular that alleging misinterpretation and incorrect application of the principle of sound administration to the facts of the present case, the appeal must be upheld and the judgment under appeal set aside to the extent to which it found that there had been inaction on the part of the Commission between 1 January 2000 and 25 July 2001 of such kind as to give rise to liability on the part of the Community.

Substance

72 Under the first paragraph of Article 61 of the Statute of the Court of Justice, the latter may, where it sets aside a judgment of the Court of First Instance, itself give final judgment in the matter where the state of the proceedings so permits.

73 In this case, it is first necessary to determine whether the Commission's conduct between 1 January 2000 and 25 July 2001, the period in respect of which the Court of First Instance found that there had been inaction of such kind as to give rise to liability on the part of the Community, constitutes a clear and serious disregard of the limits imposed on the Commission's discretion.

74 It is thus necessary to determine the extent of that discretion.

75 It must be remembered in this regard that the Court, ruling in relation to a legal procedure similar to that provided for under Regulation No 2377/90, held that, in delicate and controversial cases, the Commission must have a sufficiently broad discretion and enough time to submit for re-examination the scientific questions which determine its decision (see *Bergaderm and Goupil* v *Commission*, paragraph 66).

76 That case-law is germane to the present case in the light of the recitals in the preamble to Regulation No 2377/90.

77 It follows from the third recital in the preamble to Regulation No 2377/90 that the establishment of MRLs for veterinary medicinal products administered to food-producing animals is intended to protect public health.

78 The third recital also states that MRLs are to 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.

79 The sixth recital in the preamble states that the procedure for the establishment of MRLs at Community level must involve a single scientific assessment of the highest possible quality.

80 It follows that the Commission must be given a discretion which is sufficient to allow it to determine, on a fully informed basis, the measures that are necessary and appropriate for the protection of public health.

81 As the Court of First Instance properly recognised in paragraph 100 of the judgment under appeal, the progesterone file is one that is particularly complex.

82 That complexity is attributable, inter alia, to the facts, as noted by the Court of First Instance in paragraph 100 of the judgment under appeal, that progesterone is an endogenous substance and that there are at present no reliable analytical methods by which to check abuse of that substance. It is apparent from the documents before the Court of First Instance that, although an application to have an MRL established for progesterone had been before it since 1993, the Commission found itself facing a situation of continuing scientific uncertainty characterised by divergences between the scientific opinions adopted between 1996 and 1999 by the CVMP, on the one hand, and, on the other, the SCVPH and other international scientific bodies, which the Commission, in accordance with the third recital in the preamble to Regulation No 2377/90, takes into account.

83 In those circumstances, the Commission was entitled to seek an additional opinion from the CVMP (Case C-151/98 P *Pharos* v *Commission* [1999] ECR I-8157, paragraph 26), as the Court of First Instance, moreover, recognised in paragraph 99 of the judgment under appeal.

84 In its second opinion of December 1999 the CVMP had maintained its recommendation in favour of including progesterone in Annex II to Regulation No 2377/90, which is reserved for substances in respect of which it does not appear necessary to establish an MRL. In its report of April 1999 the SCVPH had concluded

that greater exposure to hormones might be associated with an increased risk of cancer and negative effects on development and that continued exposure, even at small dosages, appeared likely to increase that risk further, even though no quantification was possible at that stage.

85 In those circumstances, it does not appear unreasonable for the Commission to have awaited the adoption by the SCVPH in May 2000 of a re-evaluation of its report of April 1999 prior to taking a decision on the authorisation in principle of the use of progesterone for therapeutic purposes.

86 The Commission adopted a position on that issue on 24 May 2000 when it adopted a draft directive amending Directive 96/22, which provided inter alia for Member States to prohibit on a temporary basis the administration of progesterone to food-producing animals, while maintaining the possibility of derogating in the case of administration for therapeutic or zootechnical purposes.

87 That position on the maintenance of the use of progesterone for therapeutic or zootechnical purposes constituted a stage which necessarily had to precede the taking of a position on the establishment of an MRL for that substance, since an MRL may be established for a pharmacologically active substance only if that substance is intended to be placed on the market (Case C-248/99 P *France* v *Monsanto and Commission* [2002] ECR I-1, paragraph 80).

88 In its opinion of December 1999 the CVMP had recommended that progesterone be included in Annex II to Regulation No 2377/90 and, as a consequence, that opinion did not contain any recommendation as to the establishment of an MRL. The Commission explained that, in view of the opinion of the SCVPH, it considered that

that direction did not amount to an acceptable risk management measure and that, as a result, it decided to propose that progesterone be included in Annex I to that regulation. That meant that an MRL would be established in the draft regulation to be submitted. According to the Commission, in the light of the continuing scientific uncertainties, that operation was complex in nature, a fact which explains why the Commission was not able to submit the draft regulation until 25 July 2001.

89 Regard being had to the extent of the discretion available to the Commission and to all of the factual circumstances, it does not appear that, in taking that decision on the basis of public-health considerations, the Commission disregarded in a clear and serious manner the limits on its discretion.

90 In paragraph 102 of the judgment under appeal, the Court of First Instance ruled that, even if the scientific and political complexities of the file were such as to prevent the Commission from adopting, shortly after the CVMP had issued its second opinion, a draft regulation conforming to that opinion, the Commission ought none the less to have adopted measures to safeguard the interests of CEVA and Pfizer.

91 With regard to the first measure referred to by the Court of First Instance, that is to say, the Commission's adoption of draft measures establishing a provisional MRL on the basis of Article 4 of Regulation No 2377/90, it must be borne in mind that that article applies only 'provided that there are no grounds for supposing that residues of the substance concerned at the level proposed present a hazard for the health of the consumer', a condition which precisely was not satisfied in a situation of scientific uncertainty and disquiet in regard to public health.

92 With regard to the second measure referred to by the Court of First Instance by way of alternative argument, that is to say, a new deferral by the Commission of the time-

limit laid down in Article 14 of Regulation No 2377/90, suffice it to point out that the deferral of that time-limit would also not have been an appropriate measure for safeguarding public health.

93 In the light of all those considerations, it therefore does not appear that, in not submitting a draft regulation prior to 25 July 2001, the Commission breached Community law in a sufficiently serious way as to give rise to liability on the part of the Community.

94 Accordingly, without it being necessary to examine the other conditions necessary for the establishment of non-contractual liability on the part of the Community, the actions must be dismissed.

Costs

95 Under the first paragraph of Article 122 of the Rules of Procedure, where the appeal is well founded and the Court itself gives final judgment in the case, the Court is required to make a decision as to costs. Under Article 69(2) of the Rules of Procedure, applicable to appeal proceedings by virtue of Article 118 thereof, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

96 CEVA and Pfizer have been unsuccessful in their defence and the Commission has asked for the costs to be awarded against them. CEVA and Pfizer must accordingly be ordered to pay the costs of both the proceedings before the Court of First Instance and the present proceedings.

97 In accordance with the third subparagraph of Article 69(4) of the Rules of Procedure, applicable to appeal proceedings by virtue of Article 118 thereof, IFAH shall bear its own costs in both the proceedings before the Court of First Instance and the present proceedings.

On those grounds, the Court (Grand Chamber) hereby:

1. **Sets aside the judgment of the Court of First Instance of the European Communities of 26 February 2003 in Joined Cases T-344/00 and T-345/00 *CEVA and Pharmacia Enterprises* v *Commission* in so far as it established that there had been inaction on the part of the Commission of the European Communities between 1 January 2000 and 25 July 2001 of such a kind as to give rise to liability on the part of the Community;**

2. **Dismisses the actions;**

3. **Orders CEVA Santé Animale SA and Pfizer Enterprises Sàrl to pay the costs of both the proceedings before the Court of First Instance of the European Communities and the present proceedings;**

4. **Orders the International Federation for Animal Health to bear its own costs in both the proceedings before the Court of First Instance and the present proceedings.**

[Signatures]