# JUDGMENT OF THE COURT (Fifth Chamber)
18 November 1999 *

In Case C-151/98 P,

**Pharos SA**, established in Seraing, Belgium, represented by A. Vandencasteele, of the Brussels Bar, with an address for service in Luxembourg at the Chambers of E. Arendt, 8-10 Rue Mathias Hardt,

appellant,

APPEAL against the judgment of the Court of First Instance of the European Communities (Third Chamber) of 17 February 1998 in Case T-105/96 *Pharos* v *Commission* [1998] ECR II-285, seeking to have that judgment set aside,

the other parties to the proceedings being:

**Commission of the European Communities**, represented by M. Nolin, of its Legal Service, acting as Agent, with an address for service in Luxembourg at the

* Language of the case: French.

Chambers of C. Gómez de la Cruz, also of its Legal Service, Wagner Centre, Kirchberg,

defendant at first instance,

**Fédération Européenne de la Santé Animale** (Fedesa), established in Brussels, Belgium, represented by D. Waelbroeck, of the Brussels Bar, with an address for service in Luxembourg at the Chambers of Arendt and Medernach, 8-10 Rue Mathias Hardt,

intervener in the appeal,

THE COURT (Fifth Chamber),

composed of: D.A.O. Edward, President of the Chamber, J.C. Moitinho de Almeida, L. Sevón (Rapporteur), C. Gulmann and J.-P. Puissochet, Judges,

Advocate General: J. Mischo,

Registrar: H.A. Rühl, Principal Administrator,

having regard to the Report for the Hearing,

after hearing oral argument from the parties at the hearing on 29 April 1999,

after hearing the Opinion of the Advocate General at the sitting on 20 May 1999,

gives the following

## Judgment

1 By application lodged at the Court Registry on 17 April 1998, Pharos SA brought an appeal under Article 49 of the EC Statute of the Court of Justice against the judgment of the Court of First Instance of the European Communities of 17 February 1998 in Case T-105/96 *Pharos* v *Commission* [1998] ECR II-285 (hereinafter 'the contested judgment'), in which the Court of First Instance declared that there was no need to adjudicate on the application for a declaration that the Commission unlawfully failed to pursue the procedure for including somatosalm produced by the appellant in the list of substances not subject to maximum residue levels (hereinafter 'MRL') 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), and dismissed as unfounded the application for an order that the Commission make good the damage which the applicant considered itself to have suffered through such inaction.

2 By application lodged at the Court Registry on 28 July 1998, the Fédération Européenne de la Santé Animale (European Federation of Animal Health

(Fedesa)) requested leave to intervene in support of the forms of order sought by the appellant. By order of 28 September 1998, the President of the Court of Justice granted leave to intervene.

## Legislative background

3 Article 1(1)(b) of Regulation No 2377/90 defines the 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'.

4 In paragraphs 3 to 9 of the contested judgment the Court of First Instance set out the relevant provisions of Regulation No 2377/90 as follows:

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

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

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

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

— Annex IV, reserved for substances for which an MRL cannot be established because such substances constitute a threat to consumer health in any amount.

4 Under Article 6(1) of the Regulation, in order to obtain the inclusion in Annex I, II, or III of a new pharmacologically active substance, the person responsible for marketing the product concerned is to submit an application to the Commission containing certain information and particulars.

5 According to Article 6(2), after verifying within a period of 30 days that the application is submitted in correct form, the Commission is forthwith to submit the application for examination by the Committee for Veterinary Medicinal Products (hereinafter "CVMP").

6 Article 6(3) provides that:

"[W]ithin 120 days of referral of the application to the [CVMP], and having regard to the observations formulated by the members of the Committee, the

Commission shall prepare a draft of the measures to be taken. If the information submitted by the person responsible for marketing is insufficient to enable such a draft to be prepared, that person will be requested to provide the Committee with additional information for examination. ..."

7 Under Article 6(5), within a further 60 days the Commission is to submit the draft measures to the Committee for the Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products (hereinafter "the Adaptation Committee").

8 Under Article 8(2) the Adaptation Committee is to deliver its opinion on the draft measures within a time-limit set by its chairman, having regard to the urgency of the matter. It is to act by a qualified majority, the votes of the Member States being weighted as provided for in Article 148(2) of the Treaty.

9 Article 8(3) provides as follows:

"(a) The Commission shall adopt the measures envisaged where they are in accordance with the opinion of the [Adaptation] Committee.

(b) Where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is adopted, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by a qualified majority.

(c) If, after a period of three months of the proposal being referred to it, the Council has not acted, the proposed measures shall be adopted by the

Commission, unless the Council has voted against them by a simple majority."'

**Facts and procedure before the Court of First Instance**

5 The facts as set out in the contested judgment are as follows:

'10 The applicant is a company specialising in biotechnology. It is active *inter alia* in the pharmaceuticals industry.

11 In 1994 its pharmaceutical research resulted in the development of a veterinary product called "Smoltine" designed to help salmon make the transition from fresh water to sea water. The pharmacologically active substance in Smoltine is somatosalm, a substance belonging to the somatotropin family.

12 On 17 October 1994 the applicant submitted an application for the inclusion of somatosalm in Annex II to Regulation No 2377/90 (hereinafter "Annex II").

13 Having verified that the application had been submitted in correct form, the Commission referred the application for examination to the CVMP, pursuant to Article 6(2) of Regulation No 2377/90.

14 By letter of 13 April 1995 it informed the applicant that the CVMP had recommended that somatosalm be included in Annex II. It added that the draft measures to be taken, drawn up on the basis of the CVMP's proposal, would be sent to the Adaptation Committee for adoption, in accordance with Article 8 of Regulation No 2377/90.

15 By letter of 31 August 1995 it informed the applicant that it had referred to the Adaptation Committee a draft regulation including somatosalm in Annex II, but that, at its meeting, the Committee deleted somatosalm from the draft.

16 On 16 October 1995 it referred to the Adaptation Committee a new draft regulation including somatosalm in Annex II. However, that draft did not receive the assent of a qualified majority of the Adaptation Committee to the measures proposed.

17 Four Member States opposed the measures, taking the view that the moratorium on Bovine Somatotropin (hereinafter "BST"), imposed by Council Decision 90/218/EEC of 25 April 1990 concerning the administration of Bovine Somatotropin (BST) (OJ 1990 L 116, p. 27), as last amended by Council Decision 94/936/EC of 20 December 1994 (OJ 1994 L 366, p. 19), would be undermined indirectly if somatosalm, which is also a somatotropin, were included in one of the annexes to Regulation No 2377/90. Moreover, six Member States abstained from the vote in question.

18 On 6 March 1996, the applicant sent a registered letter to the Commission, formally calling upon it to act by taking "the necessary steps, in accordance

with Article 175 of the Treaty, to ensure that the procedure for including somatosalm in ... Annex II ... is completed as soon as possible".

19 On 23 April 1996 the Commission sent a letter to the CVMP informing it of its decision to stay the procedure for including somatosalm in Annex II until further scientific information had been obtained. It explained that there had been a certain amount of opposition to somatosalm in the Adaptation Committee because the substance could be used to boost growth. It therefore asked the CVMP for a further opinion as to whether abuses of the product were possible.

20 By letter of 14 May 1996 the Commission informed the applicant that it had decided to ask the CVMP for that further opinion before continuing with the procedure for including somatosalm in one of the annexes to Regulation No 2377/90.

21 By letter of 27 June 1996 the CVMP stated in reply to the request for a further opinion that, following a specific study, it had concluded that the risk that somatosalm might be abused to boost growth could be considered to be non-existent.

22 On 25 September 1996, following that reply, the Commission sent the Council a new proposal for a regulation including somatosalm in Annex II.

23 The Council did not act on that proposal within the period of three months provided for by Article 8(3)(c) of the Regulation.'

6 It is against that background that the appellant, on 8 July 1996, brought an application before the Court of First Instance for a declaration that the Commission unlawfully failed to pursue the procedure for including somatosalm produced by the appellant in the list of substances not subject to an MRL in Annex II and for an order that the Commission make good the damage which it considered itself to have suffered through such inaction.

7 By the contested judgment the Court of First Instance declared that there was no need to adjudicate on the application for a declaration of failure to act, the subject-matter of the application for a declaration of failure to act having ceased to exist since, on 25 September 1996, the Commission submitted to the Council a proposal for a regulation including somatosalm in Annex II, and also dismissed the claim for damages as unfounded.

## The appeal

8 The appellant seeks the partial annulment of the contested judgment in so far as it dismissed its claim for damages and an order that the Commission bear the costs of both sets of proceedings or, in the alternative, that the case be referred back to the Court of First Instance for judgment.

9 In support of its appeal the appellant relies on two pleas alleging misinterpretation, first, of Article 8(3)(b) of Regulation No 2377/90, which provides that 'the Commission shall without delay propose to the Council the measures to be

adopted', and, second, of the Regulation itself, since it does not confer on the Commission the right to seek a further opinion from the CVMP.

10 Fedesa asks the Court to grant the forms of order sought by the appellant and to order the Commission to bear the costs of its intervention.

11 The Commission contends that the appeal should be dismissed and that the appellant should be ordered to pay the costs and Fedesa to pay its own costs.

*Arguments of the parties*

12 By its first plea the appellant criticises the finding of the Court of First Instance at paragraph 65 of the contested judgment that the expression 'without delay' in Article 8(3)(b) of Regulation No 2377/90, whilst requiring the Commission to act swiftly, allows it some latitude.

13 Its principal argument is that it is clear from the various language versions and from the general structure of Regulation No 2377/90 that the Commission is not allowed a time margin for submitting a proposal to the Council.

14 In the alternative, the appellant submits that, even if the interpretation given to Article 8(3)(b) by the Court of First Instance were to be upheld, a period of 11 months clearly does not correspond to the idea of 'without delay'. In holding that the Commission had met the requirement to act swiftly when it had remained

inactive for six months and not adopted the measure it was required to take until 11 months had elapsed, the contested judgment was not properly reasoned.

15 By its second plea the appellant submits that the Court of First Instance erred in stating in paragraph 69 of the contested judgment that, where it is confronted with a matter which is highly complex and sensitive both scientifically and politically, the Commission has the right to seek a further opinion from the CVMP even though Regulation No 2377/90 is silent on the point. On the contrary, the procedure laid down by Articles 6 and 8 of Regulation No 2377/90 is clear, precise and unconditional in that regard, makes exhaustive provision for all possible situations and does not allow the Commission to act otherwise.

16 The appellant submits that the fact that, as stated in paragraph 70 of the contested judgment, the Commission, as a result of the further opinion of the CVMP, 'greatly facilitated the work of the Council, which, having noted the further opinion of the CVMP, did not oppose the inclusion of somatosalm in Annex II', is of no relevance in this context. In any event, the interpretation of the facts by the Court of First Instance is clearly wrong. The further opinion had no influence on the position taken by the Member States.

17 Fedesa argues further that the judgment of the Court of First Instance in Case T-120/96 *Lilly Industries* v *Commission* [1998] ECR II-2571, paragraph 90, makes clear that the Commission was not legally entitled to base its decision rejecting the request for inclusion of the substance in Annex II on the existence of the moratorium on BST, particularly as that moratorium was not introduced to protect public health but for socio-economic reasons. According to paragraph 91

of the judgment in *Lilly Industries* v *Commission*, the Commission was not authorised to take account of such considerations.

*Findings of the Court*

18 It is appropriate to consider these two pleas together.

19 It should first be observed that, according to consistent case-law, in interpreting a provision of Community law it is necessary to consider its wording, its context and its aims (Case 337/82 *St. Nikolaus Brennerei* [1984] ECR 1051, paragraph 10, and Case C-84/95 *Bosphorus* [1996] ECR I-3953, paragraph 11).

20 Nothing in the wording of Article 8(3)(b) of Regulation No 2377/90 suggests any conclusion regarding the length of time indicated by the expression 'without delay', other than that, while a certain degree of rapidity is required, the Commission is not required to act within a precise period of time nor at once, contrary to the appellant's submission.

21 As regards context and aims, it should be observed that, by Article 8 of Regulation No 2377/90, the Council conferred implementing powers on the Commission, in accordance with Articles 1 and 2, procedure III, Variant (b), of Council Decision 87/373/EEC of 13 July 1987 laying down the procedures for

the exercise of implementing powers conferred on the Commission (OJ 1987 L 197, p. 33).

22 It is clear from Article 8(3) of Regulation No 2377/90 that, once the Commission has proposed to it the measures to be taken, the Council has its full legislative powers, including the right, provided for by Article 189a of the EC Treaty (now Article 250 EC), to amend the Commission's proposal by unanimous decision. However, under Article 8(3)(c) of Regulation No 2377/90, if, after a period of three months, the Council has not acted on the proposal, the Commission once again has the power to adopt the proposed measures, unless the Council has decided against them by a simple majority.

23 It follows that, where the measures proposed by the Commission are not in conformity with the opinion of the Adaptation Committee, or where no opinion is delivered, the Commission is not obliged to submit the same measures, without amendment, to the Council.

24 Accordingly, if the Commission has the right to amend the proposal relating to the measures to be taken which it submits to the Council, it must have sufficient time to consider the various courses of action open to it.

25 It follows that the Court of First Instance was right to hold, at paragraph 65 of the contested judgment, that Article 8(3)(b) of Regulation No 2377/90 does not specify exactly the period within which the Commission must propose to the Council the measures to be adopted and that in using the expression 'without

delay' the Community legislature, whilst requiring it to act swiftly, did allow the Commission a certain degree of latitude.

26 It also follows that the Court of First Instance was right to hold, at paragraph 69 of the contested judgment, that where it is confronted with a matter which is highly complex and sensitive the Commission must be accorded the right to seek a further opinion from the CVMP even though Regulation No 2377/90 is silent on the point.

27 In circumstances such as those in the present case, in which four Member States on the Adaptation Committee, fearing that somatosalm might be used to boost growth, opposed the draft measures and six Member States abstained from voting, the Commission cannot be criticised for having sought a scientific opinion in an effort to prevent its proposal from being rejected by the Council by simple majority.

28 As regards the appellant's claim that the Court of First Instance was wrong to take the view that the further opinion of the CVMP had an influence on the position taken by the Member States in the Council, it suffices to note that this claim calls into question the appraisal of the facts by the Court of First Instance, which the Court of Justice has no jurisdiction to review on appeal (see Case C-7/95 P *Deere* v *Commission* [1998] ECR I-3111, paragraph 21).

29 Fedesa's argument alleging that the Commission took account of the moratorium on BST is of no relevance in the present appeal. As Advocate General Mischo

observes at point 68 of his Opinion, the Court of First Instance did not authorise the Commission to refuse to include somatosalm in Annex II on the basis of that moratorium and, second, it was the representatives of the Member States on the Adaptation Committee who raised the matter of the moratorium and not the Commission, which requested a scientific opinion to allay the concerns thus raised.

30 As regards the appellant's alternative submission that no grounds or insufficient grounds were stated for the contested judgment in that the Court of First Instance found that the Commission respected the obligation to act swiftly, it should be observed that the amount of time the Commission has to consider the various courses of action open to it (see paragraph 24 above) must be appraised in the light of the complexity of the matter concerned.

31 In the present case, it is not disputed that the risk that somatosalm might be used to boost growth and that its inclusion in Annex II might indirectly undermine the moratorium on BST was raised for the first time in the Adaptation Committee, in which four delegations opposed the Commission's draft and six abstained from the vote.

32 In the circumstances, a period of 11 months, during which the Commission initially reconsidered the file for six months and then sought a second scientific opinion, cannot be considered to be an excessively long period.

33 Accordingly, in finding at paragraph 68 of the contested judgment that, since certain Member States had objected to the inclusion of somatosalm in Annex II because of the fears outlined above, the Commission could not be criticised for having reconsidered the matter for a certain time and then asking the CVMP for a further opinion, the Court of First Instance gave sufficient grounds for its appraisal of the question whether the Commission respected the obligation to act swiftly.

34 It follows from all the foregoing considerations that the pleas put forward by the applicant are unfounded and that the appeal must be dismissed.

## Costs

35 Under Article 69(2) of the Rules of Procedure, which applies to appeals by virtue of Article 118, the unsuccessful party is to be ordered to pay the costs, if they have been asked for in the successful party's pleadings. Since the Commission has asked for costs and the appellant has been unsuccessful, it must be ordered to pay the costs. As regards Fedesa, which intervened in support of the forms of order sought by the appellant, it must be ordered to bear its own costs and those of the Commission arising from its intervention, pursuant to Article 69(4) of the Rules of Procedure.

On those grounds,

THE COURT (Fifth Chamber)

hereby:

1. **Dismisses the appeal;**

2. **Orders Pharos SA to pay the costs;**

3. **Orders the Fédération Européenne de la Santé Animale (Fedesa) to pay its own costs and those of the Commission arising from its intervention.**

Edward Moitinho de Almeida Sevón

Gulmann Puissochet

Delivered in open court in Luxembourg on 18 November 1999.

R. Grass

Registrar

D.A.O. Edward

President of the Fifth Chamber