JUDGMENT OF THE COURT OF FIRST INSTANCE (Third Chamber)
17 February 1998 *

In Case T-105/96,

Pharos SA, a company incorporated under Belgian law, having its registered office in Seraing (Belgium), represented by Alexandre Vandencasteele, of the Brussels Bar, with an address for service in Luxembourg at the Chambers of Ernest Arendt, 8-10 Rue Mathias Hardt,

applicant,

v

Commission of the European Communities, represented by Fernando Castillo de la Torre and Michel Nolin, of its Legal Service, acting as Agents, with an address for service in Luxembourg at the office of Carlos Gómez de la Cruz, of its Legal Service, Wagner Centre, Kirchberg,

defendant,

APPLICATION, first, under Article 175 of the EC Treaty, for a declaration that the Commission unlawfully failed to pursue the procedure for including somatosalm produced by the applicant in the list of substances not subject to maximum

* Language of the case: French.

residue levels 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, second, under Articles 178 and 215 (second paragraph) of the Treaty for an order that the Commission make good the damage which the applicant considers itself to have suffered through such inaction,

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

composed of: B. Vesterdorf, President, C. P. Briët and A. Potocki, Judges,

Registrar: B. Pastor, Principal Administrator,

having regard to the written procedure and further to the hearing on 14 October 1997,

gives the following

Judgment

The regulation in question

1 On 26 June 1990 the Council 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, hereinafter 'the Regulation' or 'Regulation No 2377/90').

2 Under the Regulation the Commission is to establish a maximum residue limit (hereinafter 'MRL'). Article 1(1)(b) of the Regulation defines the limit 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 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 underlying the dispute

10 The applicant is a company specialising in bio-technology. 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.

Procedure and forms of order sought

24 By application lodged at the Registry of the Court of First Instance on 8 July 1996 the applicant brought this action.

25 On hearing the report of the Judge-Rapporteur, the Court of First Instance (Third Chamber) decided to open the oral procedure without any preparatory inquiry.

26 Oral argument was heard from the representatives of the parties at the hearing on 14 October 1997, when they replied to questions put by the Court.

27 The applicant claims that the Court should:

— declare that, in breach of its obligations, the Commission failed to pursue the procedure for the inclusion of somatosalm produced by the applicant in the list of substances not subject to an MRL in Annex II;

— order the Commission to pay the applicant damages provisionally estimated at BFR 512 million or, at least, and again provisionally, at BFR 353 million;

— order the defendant to pay the costs.

28 The Commission contends that the Court should:

— declare that there is no need to adjudicate on the application under Article 175 of the Treaty;

— order that evidence be heard from the shareholders who lent funds to the applicant company;

— dismiss the applicant's claim under Articles 175 and 215 (second paragraph) of the Treaty;

— order the applicant to pay the costs.

On the application for a declaration of failure to act

Pleas in law and arguments of the parties

29 The applicant states that, on 17 October 1994, it submitted an application to the Commission for the inclusion of somatosalm in Annex II. It also states that, when the Commission referred draft measures including somatosalm in Annex II on 16 October 1995 to the Adaptation Committee, that Committee did not give its assent to the planned measures.

30 The applicant refers to Article 8(3)(b) of Regulation No 2377/90, under which where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is adopted, the Commission is to propose *without delay* to the Council the measures to be adopted.

31 When the application was lodged, on 8 July 1996, the Commission had not yet made any such proposal to the Council. Accordingly, the Commission unlawfully failed to pursue the procedure for the inclusion of somatosalm in Annex II. Moreover, whilst it did, on 25 September 1996, finally submit a proposal for a regulation to the Council, it none the less failed to act for 11 months.

32 The applicant is not unaware that, on 23 April 1996, the Commission asked the CVMP for a further opinion on the possible use of somatosalm to boost growth. However, Article 8(3)(b) of Regulation No 2377/90 does not provide for the Commission's right to ask the CVMP for a further opinion under any circumstances.

33 In any event, the further action taken by the Commission was not pursued with diligence. The applicant points out that the fact that the Adaptation Committee had not delivered an opinion was noted on 16 October 1995, but the request for a further opinion was not submitted to the CVMP until 23 April 1996, that is to say after six months of inactivity. That period of inactivity was, on any view of the matter, not compatible with the obligation to act 'without delay', laid down in Article 8(3)(b) of Regulation No 2377/90.

34 Thus, in breach of its obligations, the Commission failed to pursue the procedure for the inclusion of somatosalm produced by the applicant in the list of substances not subject to an MRL in Annex II. Accordingly, the application for a declaration of failure to act is well founded.

35 The Commission's primary contention is that there is no longer any need to adjudicate on the application for a declaration of failure to act.

36 It points out that, on 25 September 1996, it submitted to the Council a proposal for a regulation including somatosalm in Annex II. In its submission, it thereby adopted, before delivery of judgment in this case, the measures sought by the applicant. Accordingly, the subject-matter of the application for a declaration of failure to act has ceased to exist, so that there is no longer any need to adjudicate on it (Case 377/87 *Parliament* v *Council* [1988] ECR 4017, paragraph 10).

37 The Commission contends, in the alternative, that the application for a declaration of failure to act is unfounded.

38 It acknowledges that Article 8(3)(b) of Regulation No 2377/90 requires it to act with some expedition. However, that obligation has to be reconciled with the other obligations laid down by the Regulation and, in particular, that laid down in Article 15, under which: 'This regulation shall in no way prejudice the application of Community legislation prohibiting the use in livestock farming of certain substances having a hormonal action.'

39 The Commission points out that somatosalm is a somatotropin from the same family as BST, which is subject to a moratorium on its marketing. It also points out that it was because of that moratorium and the fact that it would be implicitly undermined if another somatotropin were to appear on the Community market, that several Member States objected, in the Adaptation Committee, to the very principle of including somatosalm in one of the annexes to Regulation No 2377/90.

40 According to the Commission, it was in the light of that risk alluded to by the Member States and of the terms of Article 15 of Regulation No 2377/90 that it decided, notwithstanding the absence of any procedure expressly provided for by that regulation, to consult the CVMP again. As a result of the second opinion

issued by that committee, the Commission was in a position to dispel all doubts about the matter at issue and thus to facilitate greatly the work of the Council as regards the inclusion of somatosalm in Annex II.

Findings of the Court

41 It is settled case-law that the remedy provided for in Article 175 of the Treaty is founded on the premiss that unlawful inaction on the part of the European Parliament, the Council or the Commission enables the other institutions and the Member States and, in circumstances such as those in point in the present case, private persons, to bring the matter before the Court of Justice or the Court of First Instance in order to obtain a declaration that the failure to act is contrary to the Treaty, in so far as it has not been repaired by the institution concerned. The effect of that declaration, under Article 176 of the Treaty, is that the defendant institution is required to take the necessary measures to comply with the judgment of the Court of Justice or of the Court of First Instance holding that the institution has failed to act, without prejudice to any actions to establish non-contractual liability to which the aforesaid declaration may give rise (Joined Cases C-15/91 and C-108/91 *Buckl and Others* v *Commission* [1992] ECR I-6061, paragraph 14 and Case T-28/90 *Asia Motor France and Others* v *Commission* [1992] ECR II-2285, paragraph 36).

42 Where the act whose absence constitutes the subject-matter of the proceedings was adopted after expiry of the period of two months following the request to act, but before judgment, a declaration by the Court of Justice or by the Court of First Instance to the effect that the initial failure to act was unlawful can no longer bring about the consequences prescribed by Article 176 of the Treaty. It follows that in such a case, as in cases where the defendant institution has responded within a period of two months after being called upon to act, the subject-matter of the action has ceased to exist (on this point see the judgments cited above, at paragraphs 15 and 37 respectively).

43 Moreover, in certain circumstances, an act which is not challengeable by an action for annulment may constitute a definition of position terminating the failure to act if it is the prerequisite for the next step in a procedure which has, in principle, to culminate in a legal act which itself will be challengeable by an action for

annulment (Case 302/87 *Parliament* v *Council* [1988] ECR 5615, paragraph 16, and Case T-186/94 *Guérin Automobiles* v *Commission* [1995] ECR II-1753, paragraph 25).

44 In the present case, on 25 September 1996, the Commission referred to the Council a proposal for a regulation including somatosalm in Annex II. In so doing, the institution adopted a position, before delivery of judgment, on the applicant's call for it to act.

45 That being so, there is no need to adjudicate on the application for a declaration of failure to act.

The claim for damages

Preliminary observations

46 The second paragraph of Article 215 of the Treaty provides that in the case of non-contractual liability, the Community, in accordance with the general principles common to the laws of the Member States, is to make good any damage caused by its institutions in the performance of their duties.

47 According to well-established case-law, the Community's non-contractual liability is not incurred unless a set of conditions relating to the illegality of the Community institution's conduct which is the subject of complaint, the occurrence of actual damage and the existence of a causal link between the unlawful conduct and the harm alleged are all fulfilled (see, by way of example, Joined Cases C-258/90 and C-259/90 *Pesquerias de Bermeo and Naviera Laida* v *Commission* [1992]

ECR I-2901, paragraph 42 and Joined Cases T-481/93 and T-484/93 *Exporteurs in Levende Varkens and Others* v *Commission* [1995] ECR II-2941, paragraph 80).

48 In the present case it is appropriate first to consider the condition relating to the existence of unlawful conduct.

The existence of unlawful conduct on the part of the Commission

Arguments

— The rules governing liability

49 The Commission refers to Cases T-571/93 *Lefebvre and Others* v *Commission* [1995] ECR II-2379 and T-167/94 *Nölle* v *Council and Commission* [1995] ECR II-2589, paragraph 52, and argues that inasmuch as the alleged failure to act causing the damage concerns the submission of a draft regulation, the applicant must demonstrate that there has been a sufficiently serious breach of a superior rule of law for the protection of individuals.

50 The applicant does not deny that it must prove that there has been such a breach.

— The existence of a breach of a superior rule of law for the protection of individuals

51 The applicant submits that the Commission has breached two superior rules of law for the protection of individuals, namely, first, the principles of legal certainty and of protection of legitimate expectations, and, second, the principle of proper administration.

52 It argues that the principles of legal certainty and the protection of legitimate expectations require that the application of a legislative provision to a specific situation must be foreseeable (Case 13/61 *Kledingverkoopbedrijf de Geus en Uitdenbogerd* [1962] ECR 45 and Case 81/72 *Commission* v *Council* [1973] ECR 575). In this case it was entitled to expect the Commission to apply the procedure laid down by Regulation No 2377/90 correctly, by proposing to the Council the measures to be adopted 'without delay', since, on 16 October 1995, the Adaptation Committee had not given its assent to the measures proposed by the Commission.

53 As from 16 October 1995 the Commission did nothing to advance the procedure for six months, in the event until 23 April 1996, when it decided to ask the CVMP for further information. It thus violated the principles of legal certainty and the protection of legitimate expectations.

54 The principle of proper administration has also been violated, in that the Commission should have compiled all the information it considered necessary when the first draft measures were referred to the Adaptation Committee, as the moratorium on BST already existed at that point.

55 In remaining inactive for the six months between 16 October 1995 and 23 April 1996 for no reason, the Commission offended against that principle, which requires a Community institution to be diligent and efficient.

56 The Commission contends that it applied the procedure laid down in Regulation No 2377/90 correctly. Accordingly, it did not violate the principle of the protection of legitimate expectations. In its submission, if the applicant's arguments were to be accepted, any breach of a provision of Community law would be contrary to the principle of the protection of legitimate expectations, because an individual is always entitled to expect the Community institutions to comply with Community law.

57 The Commission points out that, according to the case-law, the right to rely on the principle of the protection of legitimate expectations extends to any individual who is in a situation in which it is apparent that the Community administration, by giving him precise assurances, has led him to entertain justified expectations (Case T-336/94 *Efisol* v *Commission* [1996] ECR II-1343, paragraph 31). The applicant has not explained what these 'precise assurances' were in the present case.

58 As regards the alleged breach of the principle of proper administration, the Commission points out that it requested a further opinion from the CVMP at the point when doubts arose as to whether the inclusion of somatosalm in Annex II might undermine the moratorium on BST. This second consultation of the CVMP was called for precisely for reasons of proper administration. If, during the course of the procedure laid down by Regulation No 2377/90, doubts arise as to the legality of the act in question, it is the Commission's duty to take them into account. Moreover, the duty of diligence, which is implied by the principle of proper administration, cannot be carried to the point where an institution incurs liability on the ground that it did not take account of all the aspects of a matter from the start of a procedure.

59 The Commission refers to the case which gave rise to the judgment of the Court of Justice in *Denkavit* v *Commission* (Case 14/78 [1978] ECR 2497), in which the applicant complained that the Commission had waited 21 months before taking measures, in circumstances comparable to those in this case. It points out that, in the judgment in that case (paragraph 20), the Court of Justice held that the Commission could not be blamed for having waited until it was fully informed before adopting a decision on a matter as complex as the presence in feeding-stuffs of substances which might prove to be undesirable from the point of view of human or animal health.

60 Finally, the Commission contends that the Court of First Instance must take an overall view of the advantages and disadvantages for traders of the acts or omissions of the Community institutions. In the present case, by consulting the CVMP a second time, the Commission considerably facilitated, in practice, the adoption of a regulation including somatosalm in Annex II.

61 The Commission accordingly contends that it violated neither the principles of legal certainty and the protection of legitimate expectations, nor the principle of proper administration.

Findings of the Court

62 As the parties acknowledge, the Community's liability can be incurred in this case only if it is proved that there has been a sufficiently clear breach, by the Commission, of a rule of law for the protection of individuals, since the alleged failure to act relates to a legislative act.

— The existence of a breach of the principles of legal certainty and the protection of legitimate expectations

63 The principle of legal certainty aims *inter alia* to ensure that situations and legal relationships governed by Community law remain foreseeable (Case C-63/93 *Duff and Others* [1996] ECR I-569, paragraph 20, and Case T-229/94 *Deutsche Bahn* v *Commission* [1997] ECR II-1689, paragraph 113).

64 The principle of the protection of legitimate expectations can be relied on by any individual whom a Community institution has caused to entertain justified expectations (Case T-489/93 *Unifruit Hellas* v *Commission* [1994] ECR II-1201, paragraph 51). In contrast, it is not open to anyone, in the absence of specific assurances given by the administration, to plead breach of the principle of protection of legitimate expectations (Case T-521/93 *Atlanta and Others* v *EEC* [1996] ECR II-1707, paragraph 57).

65 In the present case it should be observed 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. To the contrary, in using the expression 'without delay', the Community legislature allowed the Commission a certain margin for manoeuvre, whilst requiring it to act swiftly.

66 Accordingly, it cannot be inferred from the relevant rules that the period within which the Commission had to act was perfectly foreseeable and that *precise* assurances were given to the applicant with regard to that period.

67 Moreover, whilst it is true that it took the Commission 11 months to propose to the Council, on 25 September 1996, the measures to be adopted, it is also true that, on 23 April 1996, it asked the CVMP for a further opinion.

68 Since certain Member States had objected to the inclusion of somatosalm in Annex II because they feared that the substance could be used to boost growth, the Commission cannot be criticised for having reconsidered the matter for a certain time and then asked the CVMP for a further opinion.

69 Where it is confronted with a matter which is highly complex and sensitive both scientifically and politically, the Commission must be accorded the right to seek such an opinion even though Regulation No 2377/90 is silent on the point.

70 Moreover, as the Commission has rightly observed, it was as a result of the further opinion it obtained that it was able to dispel all doubt regarding the question whether somatosalm could be used to boost growth. In those circumstances, the Commission 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.

71 In the result, through asking for a further opinion on 23 April 1996, only six months elapsed after 16 October 1995, the date on which the Adaptation Committee failed to give its assent to the measures proposed by the Commission, without the Commission taking any decision.

72 Under those circumstances, the Commission was not in breach, and *a fortiori* did not commit a sufficiently clear breach, of either the principle of legal certainty or that of the protection of legitimate expectations.

— The existence of a breach of the principle of proper administration

73 The question arises whether the principle of proper administration has been violated in that the Commission did not ask the CVMP for further information at the stage when the first draft measures were referred to the Adaptation Committee. The question also arises whether, in requesting a further opinion six months after 16 October 1995, when the measures proposed failed to receive the assent of the Adaptation Committee, the Commission violated the principle of proper administration.

74 On that point, it is clear from the documents before the Court that the Commission did not initially ask the CVMP for further information because it did not foresee that the representatives of the Member States would object to the inclusion of somatosalm in Annex II because of the moratorium on BST.

75 It was entitled to take the view initially that the inclusion of somatosalm would not meet with any serious opposition, since the moratorium on BST related only to BST and not to other somatotrophins.

76 When, later in the procedure, it became apparent that the representatives of the Member States were establishing a link between the moratorium and somatosalm, it requested a further opinion from the CVMP following a reasonable period of reflection.

77 In those circumstances, the Commission's reasoning and the steps which it took in no way disclose any mismanagement of the matter on its part.

78 Accordingly the Commission did not commit a breach of the principle of proper administration such as to give rise to the liability of the Community.

Conclusion

79 It follows from the foregoing that the applicant has not demonstrated that the condition relating to illegal conduct on the part of the Commission is fulfilled.

80 Accordingly, the claim for damages must be dismissed as unfounded, without there being any need to consider whether the conditions relating to the occurrence of actual damage and the existence of a causal link are fulfilled.

81 Consequently, there is no need to grant the Commission's request for evidence to be heard from the shareholders who lent funds to the applicant company.

Costs

The claim for a declaration of failure to act

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

83 In the present case, the Commission cannot be criticised for the way in which it managed the matter. The applicant should therefore be ordered to pay the costs.

The claim for damages

84 Under Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission has applied for costs, and the applicant has been unsuccessful in its claim for damages, the applicant should be ordered to pay the costs.

On those grounds,

THE COURT OF FIRST INSTANCE (Third Chamber)

hereby:

1. Declares that there is no need to grant the Commission's request for evidence to be heard;

2. Declares that there is no need to adjudicate on the application for a declaration of failure to act;

3. Dismisses the claim for damages as unfounded;

4. Orders the applicant to pay the costs.

Vesterdorf Briët Potocki

Delivered in open court in Luxembourg on 17 February 1998.

H. Jung B. Vesterdorf

Registrar President