OPINION OF ADVOCATE GENERAL MISCHO

delivered on 20 May 1999 *

1. The appeal of which this Court has been seised by Pharos SA (hereinafter 'Pharos') seeks the annulment of the judgment of the Court of First Instance of 17 February 1998 [1] (hereinafter 'the contested judgment') in so far as it dismissed the claim for damages brought by Pharos against the Commission under Article 235 EC (formerly Article 178) and the second paragraph of Article 288 EC (formerly the second paragraph of Article 215). Pharos claims that the Commission, in breach of its obligations, failed to pursue the procedure for including somatosalm produced by the appellant in the list of substances not subject to maximum 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. [2]

Legislative background [3]

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. Regulation No 2377/90 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

* Original language: French.

1 — Case T-105/96 *Pharos* v *Commission* [1998] ECR II-285.

2 — OJ 1990 L 224, p. 1.

3 — As stated by the Court in the contested judgment.

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 Regulation No 2377/90, 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 the 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:

'Within 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 [4]

10. Pharos 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 Pharos submitted an application for the inclusion of somatosalm in Annex II to Regulation No 2377/90.

13. Having verified that the application had been submitted in the correct form, the Commission referred the application for

4 — As stated by the Court in the contested judgment.

examination to the CVMP, pursuant to Article 6(2) of Regulation No 2377/90.

14. By letter of 13 April 1995 it informed Pharos 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 appellant that it had referred a draft regulation including somatosalm in Annex II to the Adaptation Committee, but that, at its meeting, the Committee had deleted somatosalm from the draft.

16. On 16 October 1995 the Commission referred a new draft regulation including somatosalm in Annex II to the Adaptation Committee. 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),[5] as last amended by Council Decision 94/936/EC of 20 December 1994,[6] 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, Pharos 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

5 — OJ 1990 L 116, p. 27.
6 — OJ 1994 L 366, p. 19.

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 Pharos 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.

24. On 8 July 1996 Pharos lodged an application at the Registry of the Court of First Instance for a declaration, under Article 175 of the EC Treaty, 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 to Regulation No 2377/90 and for an order, under Article 178 and the second paragraph of Article 215 of the Treaty, that the Commission make good the damage which it considered itself to have suffered through such inaction.

The contested judgment

25. By the contested judgment the Court of First ruled 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 somatsalm in Annex II. The appeal does not relate to that part of the contested judgment.

26. With regard to the claim for damages, the Court ruled that the Commission was not in breach of either the principle of legal certainty or the principle of the protection of legitimate expectations. The following

are the relevant paragraphs of the contested judgment:

'63 The principle of legal certainty aims *inter alia* to ensure that situations and legal relationships governed by Community law remain foreseeable ...

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 ... 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 the protection of legitimate expectations ...

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 manœuvre, 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 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.'

27. With regard to the existence of a breach of the principle of proper administration, the Court held that the Commission's reasoning and the steps which it took in no way disclosed any mismanagement of the matter on its part.

The appeal

28. Pharos submits that the findings of the Court of First Instance in respect of the claim for damages contain errors of law and that the contested judgment should accordingly be annulled. In essence, it 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.

The alleged misinterpretation of Article 8(3)(b) of Regulation 2377/90

— Arguments of the parties

29. The appellant's principal argument is that the expression '*sans tarder*' means 'at

once'; and that this is borne out by other language versions of Regulation No 2377/90. Accordingly, the English version uses the phrase 'without delay', the Dutch version the expression '*onverwijld*' and the German version the term '*unverzüglich*'. The legislature did not, therefore, allow the Commission a time margin for submitting a proposal to the Council.

30. In its view, this interpretation is in any case confirmed by the general structure of Regulation No 2377/90 which is designed to lay down and ensure a rapid procedure for the establishment of MRLs of veterinary medicinal products in foodstuffs of animal origin. For new pharmacologically-active substances Article 6 provides a fixed time limit, of between 30 and 120 days, for each stage in the procedure for the establishment of MRLs.

31. The right of the inventor of a new substance to a decision within a short time is demonstrated *a contrario* by the greater flexibility provided in Article 7 with regard to the establishment of MRLs for substances already authorised for use on the date on which Regulation No 2377/90 entered into force. Article 7 provides that the Commission is to publish a timetable for the consideration of these substances and that the period allowed for examination by the CVMP is to be 120 days, this period being renewable.

32. Pharos considers that it was therefore entitled to expect the Commission, in accordance with the principle of legitimate expectations, to apply the prescribed procedure properly, by proposing to the Council 'without delay' the measures to be adopted. By holding that the expression 'without delay' allows the Commission to wait eleven months before submitting a proposal to the Council, the Court had erred in law.

33. In the alternative, the appellant submits that, even if it were necessary to accord the Commission 'a certain margin for manœuvre', it must, nevertheless, be declared that the expression 'without delay' indicates a short time, to say the least, and that a period of 11 months clearly does not correspond to that idea. 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.

34. La Fédération européenne de la santé animale (European Federation of Animal Health) (hereinafter 'Fedesa'), intervening in support of the forms of order sought by Pharos, argues that, although one of the two stages comprising the procedure for the establishment of MRLs, namely the scientific stage, may take quite a long time, it is a different matter for the stage at which the MRLs are adopted. This is apparent from the tenth recital in the preamble to Regulation No 2377/90 which states: 'after scientific assessment by the Committee for Veterinary Medicinal Products, maximum

residue levels must be adopted by a rapid procedure.'

35. The Commission submits that the Court was right in holding that the expression 'without delay' does not specify exactly the period within which the Commission is supposed to act, whilst requiring it to act within a reasonable time. It maintains that, if the legislature had not wished to allow the Commission any time margin for submitting the proposal to the Council, it would have used the expression 'immediately' as it has done for the administrative committees. [7]

36. With regard to the appellant's argument concerning Article 7 of Regulation No 2377/90, the Commission points out that the article is not designed to uphold the rights of traders or to introduce provisional authorisation rules. Article 7 establishes, for substances already on the market, a procedure similar to the one provided for new substances by Article 6. Having imposed the obligation to determine a Community MRL for every substance, the legislature could hardly apply this requirement to all the medicinal products already on the market without spreading out the work to be done and establishing a transitional period. [8] The timetable mentioned in Article 7(2) of Regulation No 2377/90 is therefore intended to spread over several years the consideration of the hundreds of substances already on the market on 1 January 1992.

37. Moreover, the period of six months which elapsed between the opinion of the Adaptation Committee and the request to the CVMP for a further opinion was not unreasonable in view of the fact that the Commission itself had to reconsider the matter.

— Assessment of the merits of the plea

38. I, for my part, think that, with regard to this plea, a ruling should be given only in respect of the six-month period during which the Commission claims that it reconsidered the matter, that is to say, the period between 16 October 1995, the date on which the Adaptation Committee failed to adopt the measures proposed, and 23 April 1996, the date on which the Commission decided to request the further opinion (hereinafter 'the six-month period'). The legality of the request is the subject of the second plea in the appeal and a ruling on the additional extension of the

7 — See 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).

8 — See Article 14 of Regulation No 2377/90.

procedure (hereinafter 'the five-month period') resulting from that request can therefore be given only in the light of the legality of the request for a further opinion.

39. With regard to whether the six-month period is compatible with Article 8(3)(b) of Regulation No 2377/90, in the first place it seems to me indisputable that, as the Court has quite rightly held, the use of the expression 'without delay' cannot be construed as specifying *exactly* [9] the period within which the Commission must propose to the Council the measures to be adopted. Nor is it possible to infer that the Community legislature intended that the Commission should send the Council a draft of the measures at once, that is to say, immediately after learning that the Adaptation Committee had not given its assent to the measures. If, as Pharos maintains, this had been the legislature's intention, I think it would have used the term 'forthwith' or, as the Commission suggests, 'immediately'. As this intention is not apparent, we must conclude that the use of the expression 'without delay' indicates that the legislature wished, as the Court rightly held, to allow the Commission a certain margin for manœuvre, whilst requiring it to act swiftly.

40. Moreover, even though it is not the decisive argument, the wording of the provision in question can be interpreted as meaning that the Commission may submit to the Council a proposal which is not necessarily the same as the one it submitted to the Adaptation Committee. Article 8(3)(b) actually reads: '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 [10] to the Council the measures to be adopted.' Admittedly, the Commission told the Court at the hearing that it feels obliged, in principle, to submit to the Council a proposal which is identical in content to the one submitted to the Adaptation Committee, and that certainly ought to be the rule.

41. However, if, in exceptional circumstances, the Commission concludes, in the light of the proceedings of the Adaptation Committee, that the Council would, in all probability, not give its assent to the inclusion of the product in the list of substances not subject to MRLs (Annex II) but might approve inclusion of the same product in the list of substances for which provisional MRLs have been fixed (Annex III), the wording does not preclude the Commission from submitting to the Council a proposal along those lines.

42. It must be borne in mind that the Adaptation Committee procedure amounts

9 — Emphasis added.

10 — In French: '... soumet ... *une* proposition ... ' (emphasis added).

to a delegation of powers from the Council to the Commission, and that the Council recovers its full legislative jurisdiction the moment a proposal is presented to it.

43. Consequently, the Council may even adopt different measures from those proposed by the Commission provided, of course, that it observes the rule of unanimity established in Article 250 EC (formerly Article 189 A). Indeed, Article 8(3)(c) of Regulation No 2377/90 provides:

'If, after a period of three months of the proposal being referred to it, the Council has not acted,[11] the proposed measures shall be adopted by the Commission, unless the Council has voted against them by a simple majority.'

44. The Commission must therefore be accorded the right to consider all these possibilities.

45. If the Commission, although under a duty to act swiftly, has a margin for manœuvre, the interim conclusion must be the same as that reached by the Court of First Instance,[12] namely that 'it cannot be inferred from the relevant rules that the period within which the Commission had to act was perfectly foreseeable and that *precise*[13] assurances were given to the applicant with regard to that period.'

46. Furthermore, the margin for manœuvre or period for reflection afforded to the Commission must also be evaluated in the light of the complexity of the matter in question and particularly, as in this case, in relation to the reasons which caused assent to be withheld.

47. The Court was therefore right to hold that the Commission cannot be criticised for having reconsidered the matter for a certain time, 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 and that its inclusion in Annex II might indirectly undermine the moratorium on BST.

48. It must be borne in mind that, when the Commission was accorded that period for reflection, the Court had not yet given its

11 — In French: '... arrêté *de* mesures ...' (emphasis added).

12 — Paragraph 66 of the contested judgment.

13 — Emphasis present in the contested judgment.

judgment in *Lilly Industries* v *Commission*[14] which makes it clear that the procedure for the establishment of an MRL under Regulation No 2377/90 is independent of and distinct from the procedures for the issue of marketing authorisations laid down in other provisions of Community law, and that the Regulation contains no provision authorising the Commission to take account of a marketing ban in refusing to establish an MRL.

49. Finally, Pharos has not presented us with any evidence to show that the six-month period of reconsideration was disproportionate to the complexity of the matter.

50. Under those circumstances the Court was right to rule, on this point, that 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. It is also clear from the above considerations[15] that the alternative submission that no grounds or insufficient grounds were stated for the contested judgment cannot be upheld.

51. The first plea should therefore be rejected as unfounded.

14 — Case T-120/96 *Lilly Industries* v *Commission* [1998] ECR II-2571.

15 — See paragraphs 46 and 47 above.

The alleged misinterpretation of the whole of the Regulation, inasmuch as it does not confer on the Commission the right to seek a further opinion from the CVMP.

— Arguments of the parties

52. The appellant refers to the procedure established in Articles 6 and 8 of Regulation No 2377/90, pointing out that, at the end of the procedure, if the Adaptation Committee gives an unfavourable opinion or no opinion at all, jurisdiction is transferred to the Council. Indeed, in such cases, the Commission has no alternative but to submit the draft to the Council. The Council then has a period of three months in which to adopt the proposed measures by a qualified majority. If it does not do so, jurisdiction to adopt the proposed measures will revert to the Commission, unless the Council has voted against them by a simple majority.

53. The procedure is clear, precise and unconditional; it examines all possible situations exhaustively and leaves the Commission no latitude to act otherwise than as laid down by Regulation No 2377/90.

54. According to the appellant, the fact that, as the Court pointed out, the further

opinion greatly facilitated the work of the Council [16] is irrelevant in this regard. In any event, the interpretation of the facts by the Court of First Instance is clearly wrong. The contested judgment acknowledges that the Council did not rule on the Commission's proposal. Its failure to reach a decision meant that there was no majority in the Council either for or against, a situation which exactly mirrored that of the national experts on the Adaptation Committee before the further opinion was requested from the CVMP and, *a fortiori*, before its contents were known. The further opinion therefore had no influence on the position taken by the Member States.

55. Fedesa points out that the Court relies on the moratorium on BST to justify the Commission's decision to seek a further opinion. However, the Court also acknowledges, in paragraph 83 of the judgment in *Lilly Industries* v *Commission*, that, where the CVMP, having all the necessary information at its disposal, has given a favourable opinion on a request for the inclusion of a substance in Annex II, the Commission is under an obligation to draw up a draft regulation including that substance in Annex II and to submit it to the Adaptation Committee for approval.

56. The sole objective of Regulation No 2377/90 is to protect public health, and this can be achieved only by carrying out a scientific assessment of the matter. Considerations of a political or socio-economic nature cannot be taken into account. [17] By giving the Commission the opportunity to rely on such considerations, the contested judgment allows it an almost unlimited margin for manœuvre, which undermines the stability necessary to the European animal health industry. If the Commission does not adhere strictly to the Regulation, undertakings will lose the legal certainty which the act is supposed to afford them.

57. The Commission maintains that it decided to consult the CVMP again in order to dispel all doubt regarding a possible breach of Article 15 of Regulation No 2377/90 with respect to the moratorium on BST and, consequently, to facilitate the work of the Council, very probably ensuring that the Council did not reject the draft regulation by a simple majority.

58. The Commission points out that four Member States on the Adaptation Committee objected to the inclusion of somatosalm in one of the Annexes to Regulation No 2377/90 on the basis of the moratorium on BST. Therefore the assent by a qualified majority was not received. Furthermore, six Member States abstained from voting without giving reasons other than, apparently, their wish to reserve their freedom of manœuvre for the discussions in the Council. The effect of the CVMP's further opinion was, therefore, to prevent those Member States which had abstained

16 — See paragraph 70 of the contested judgment.

17 — See paragraph 91 of the judgment in *Lilly* v *Commission*.

from voting in the Committee from opposing the Commission's draft regulation in the Council, and, consequently, impeding, by a simple majority, the adoption of the draft.

59. In that context, the Commission notes that the Court held in *Moskof*,[18] that the Commission had the power to delay the adoption of its draft regulation for six months even though it had received the assent of the relevant committee. Even though the committee in that case was a management committee, not an adaptation committee, the principles may none the less be transposed to the present case.

60. Finally, with regard to the arguments put forward by Fedesa, the Commission points out that it was certain Member States, not the Commission, which raised the issue of the risk that somatosalm could be used to boost growth. As this situation might have prevented the adoption of the draft concerned, it became necessary to ask the CVMP for a further opinion. In the circumstances, the *Moskof* judgment was relevant inasmuch as it authorised the Commission to find a solution which 'might better resolve the problems raised by certain delegations'.

61. As regards the judgment in *Lilly Industries* v *Commission*, on which Fedesa's argument is based, the Commission observes, first of all, that, in paragraph 82, the Court of First Instance itself draws a distinction between that judgment and its judgment in the case giving rise to the present appeal:

'The Commission has only limited discretion in examining requests for the establishment of an MRL submitted pursuant to Regulation No 2377/90. Except in certain specific circumstances (see Case T-105/96 *Pharos* v *Commission* [1998] ECR II-285, paragraphs 69 and 70), the institution must apply the procedure laid down by that regulation strictly.'

62. Indeed, there are fundamental differences between the situations leading to the two judgments. In the case of *Lilly Industries* v *Commission*, the Commission, after receiving the opinion of the CVMP, did not prepare a draft regulation including the relevant substance in one of the annexes to Regulation No 2377/90 with a view to submitting it to the Adaptation Committee but, instead, rejected the request for inclusion on the basis of the moratorium on BST. However, in the present case, the Commission certainly did not reject a request for inclusion but asked the CVMP

18 — Case C-244/95 [1997] ECR I-6441, paragraphs 38 to 40.

for a further opinion on the basis of scientific, not political or socio-economic, considerations in order, in particular, to facilitate the subsequent work of the Council. The Commission did not, therefore, cause 'the undertakings to lose the legal certainty which the Regulation (Regulation No 2377/90) is supposed to afford them'.

— Assessment of the merits of the plea

63. First of all, I should point out that, if the Commission had submitted to the Council the proposal which the Adaptation Committee had not approved by a qualified majority, there would have been a real risk that it would have been definitively rejected. If only four of the six Member States which abstained from voting at the committee meeting were to vote against the proposal in the Council, that would be enough to give a simple majority of eight votes against.

64. However, whether or not it was beneficial, the influence of the further opinion on the position taken by the Member States in the Council is in any case irrelevant for determining the legality of the request for that opinion. This is apparent from the wording of Article 8(3)(b) of Regulation No 2377/90.

65. Admittedly, the article does not expressly provide that the Commission has the right to ask the CVMP for a further opinion. However, as I have already said, [19] nor does it require the Commission to submit to the Council the same measures as it submitted to the Adaptation Committee.

66. On the contrary, the Commission must be able, when drawing up the proposal to submit to the Council, to take into account the opinions expressed in the Adaptation Committee. *A fortiori*, it must be able to seek arguments likely to convince the undecided Member States of the merit of the proposal submitted to and rejected by the Adaptation Committee. This was precisely the aim of the request to the CVMP for a further opinion: in view of the fact that four Member States voted against the proposal and six others abstained, the Commission sought a scientific opinion in order to dispel any uncertainty about a problem raised by the national experts on the Adaptation Committee.

67. The judgment in *Moskof*, which the Commission cites in this connection, fully confirms this interpretation and, contrary to Fedesa's contention, the request for a further opinion may quite properly be compared with the efforts made by the Commission in the *Moskof* case. Even though the relevant committee had already adopted the proposed text, the Court

19 — See point 42 of this Opinion.

nevertheless held that the Commission was entitled to delay the adoption of the act for six months in order to try to find a compromise acceptable to the two delegations which had refused to approve the initial version. The consequence of this was that the Regulation had retroactive effect. *A fortiori*, when only five delegations have voted in favour for the proposal, four have voted against it and six have abstained, preferring to reserve their freedom of manœuvre for the discussions in the Council, the Commission must be entitled to look for ways of achieving, in the Council, a qualified majority in favour of the proposal at issue. It sought the opinion of the experts on the CVMP in order to support its proposal with scientific, conclusive and indisputable arguments.

68. Finally, as regards the arguments put forward by Fedesa, suffice it to say that the Court did not authorise the Commission to refuse to establish an MRL on the basis of the moratorium on BST. The question was whether somatosalm could be included in Annex II to Regulation No 2377/90, which would have prevented the substance being subject to an MRL. Moreover, it was not the Commission which raised the issue of the moratorium in order to oppose its inclusion, but certain representatives of the Member States on the Adaptation Committee. The Commission simply looked for scientific arguments to allay the fears expressed by those delegations and to convince the delegations which had abstained from voting.

69. It is true that, as the Court held in *Lilly Industries* v *Commission*,[20] where the CVMP has given a favourable opinion on a request for the inclusion of a substance in Annex II, the Commission is under an obligation to draw up a draft regulation including that substance in Annex II and to submit it to the Adaptation Committee for approval. However, in this case we are at a later stage of the procedure laid down by Regulation No 2377/90, namely the point at which the Adaptation Committee has issued its opinion on the proposal to include the substance at issue in Annex II. At this stage, if the Adaptation Committee has not given a favourable opinion, the Commission has, as I have already said, a certain margin for manœuvre, at least with regard to the period within which a draft must be submitted to the Council and, I believe, also with regard to the content of the proposal itself.

70. Therefore, in dismissing the claim for damages on the grounds that the Commission, when it is confronted with a matter which is highly complex and sensitive both scientifically and politically, must be accorded the right to seek such an opinion even though Regulation No 2377/90 is silent on the point, the Court has not misinterpreted Article 8(3)(b) of Regulation No 2377/90.

71. Consequently, the second plea should also be rejected as unfounded.

20 — See paragraph 83.

Conclusion

72. Having considered this case, I propose that the Court should:

— dismiss the appeal;

— order Pharos SA to pay the costs.