JUDGMENT OF THE COURT OF FIRST INSTANCE
(Third Chamber)
25 June 1998 *

In Case T-120/96,

Lilly Industries Ltd, a company incorporated under English law, having its registered office in Basingstoke (United Kingdom), represented by Denis Waelbroeck, of the Brussels Bar, with an address for service in Luxembourg at the Chambers of Ernest Arendt, 8-10 Rue Mathias Hardt,

applicant,

supported by

Fédération Européenne de la Santé Animale (Fedesa), 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,

intervener,

v

Commission of the European Communities, represented initially by Richard Wainwright, Principal Legal Adviser, and Fernando Castillo de la Torre, of its Legal Service, acting as Agents, and subsequently by Richard Wainwright alone, with an address for service in Luxembourg at the office of Carlos Gómez de la Cruz, of the Commission's Legal Service, Wagner Centre, Kirchberg,

defendant,

* Language of the case: English.

APPLICATION for the annulment of the Commission decision of 22 May 1996 rejecting the applicant's request for the inclusion of somidobove, a recombinant bovine somatotrophin (BST), in Annex II to Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ 1990 L 224, p. 1),

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

composed of: V. Tiili, President, C. P. Briët and A. Potocki, Judges,

Registrar: A. Mair, Administrator,

having regard to the written procedure and further to the hearing on 5 March 1998,

gives the following

Judgment

Legislative background

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).

2 Under that regulation, the Commission is to establish the maximum residue limit (hereinafter 'MRL'). Article 1(1)(b) of the regulation defines that MRL as the maximum concentration of residue resulting from the use of a veterinary medicinal product which may be accepted by the Community to be legally permitted or recognised as acceptable 'in or on a food'.

3 Regulation No 2377/90 makes provision for four annexes to be established in which a pharmacologically active substance, intended for use in veterinary medicines to be administered to 'food-producing animals', may be included:

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

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

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

— Annex IV, which is reserved for substances for which no MRL can be established because such substances constitute a threat to consumer health in any amount.

4 Article 6(1) of Regulation No 2377/90 provides:

'In order to obtain the inclusion in Annex I, II, or III of a new pharmacologically active substance which is:

— intended for use in veterinary medicinal products for administration to food-producing animals, and

— intended to be placed on the market of one or more Member States which have not previously authorised the use of the substance concerned in food-producing animals,

the person responsible for marketing shall submit an application to the Commission ...'

5 Under Article 6(2), after verifying within a period of 30 days that the application has been submitted in correct form, the Commission is to submit it 'forthwith' for examination by the Committee for Veterinary Medicinal Products (hereinafter 'the 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 its members, the Commission is to 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 CVMP with additional information.

7 Under Article 6(4), within 90 days of receipt of that information, the Commission is to prepare a draft of the measures to be taken, which is to be communicated forthwith to the Member States and the person responsible for marketing. Within a further 60 days, the person responsible for marketing may, at his request, provide oral or written explanations for consideration by the CVMP.

8 Article 6(5) provides that, 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 the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector (hereinafter 'the Adaptation Committee').

9 Under Article 8(2), the Adaptation Committee is to deliver its opinion on the draft measures to be taken within a time-limit set by its chairman, having regard to the urgency of the matter.

10 Under Article 8(3), the Commission is to adopt the measures envisaged where they are in accordance with the opinion of the Adaptation Committee. Where they are not in accordance with its opinion, or if no opinion is adopted, the Commission is to propose to the Council without delay the measures to be adopted. The Council is to act by a qualified majority. If, after a period of three months of the proposal being referred to it, the Council has not acted, the proposed measures are to be adopted by the Commission, unless the Council has voted against them by a simple majority.

11 Article 14 provides:

'With effect from 1 January 1997, the administration to food-producing animals of veterinary medicinal products containing pharmacologically active substances which are not mentioned in Annexes I, II or III shall be prohibited within the Community, except in the case of clinical trials ...'

12 Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1) lays down a procedure for the issue of Community authorisation for the marketing of veterinary medicines.

13 Under Article 31(3)(b) of that regulation, in the case of a veterinary medicinal product intended for administration to food-producing animals, a classification of the pharmacologically active substance in one of the annexes to Regulation No 2377/90 is a precondition for the issue of Community authorisation to market the product.

14 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) lays down, *inter alia*, rules for the issue of national authorisation for the marketing of veterinary medicines.

15 Article 4(1) of that directive, in the version resulting from Council Directive 93/40/EEC of 14 June 1993 amending Directive 81/851/EEC (OJ 1993 L 214, p. 31), provides that no veterinary medicinal product may be placed on the market

of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with Directive 81/851 or a marketing authorisation has been granted in accordance with Regulation No 2309/93.

16 Under Article 4(2) of Directive 81/851, as amended, from 1 January 1997 the Member States are not to permit foodstuffs for human consumption to be taken from test animals unless MRLs have been established by the Community in accordance with the provisions of Regulation No 2377/90.

17 Article 2(1) of Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology (OJ 1987 L 15, p. 38) provides that, as soon as the competent authorities of the Member States receive an application for marketing authorisation relating to a high-technology medicinal product, they are, at the request of the person responsible for placing the product on the market, to bring the matter before either the Committee for Proprietary Medicinal Products or the CVMP, in accordance with their competence, for an opinion.

18 Council Decision 90/218/EEC of 25 April 1990 concerning the administration of bovine somatotrophin (BST) (OJ 1990 L 116, p. 27), as most recently amended by Council Decision 94/936/EC of 20 December 1994 (OJ 1990 L 366, p. 19), imposed a moratorium on the marketing of recombinant bovine somatotrophin, a growth hormone (hereinafter 'BST').

19 Under the first paragraph of Article 1 of Decision 90/218, as amended by Decision 94/936, Member States are to ensure that, until 31 December 1999, the placing on the market of bovine somatotrophin for the purposes of its marketing and the administration thereof on their territory to dairy cows by any means whatsoever will not be authorised. The second paragraph of that article states that this decision

is not to affect the production of bovine somatotrophin for the purposes of its export to third countries.

20 Under the first subparagraph of Article 2(1) of Decision 90/218, as amended, Member States may, by way of derogation from Article 1, carry out limited practical tests on the use of BST in order to obtain any other scientific data that might be taken into account by the Council when it takes a final decision.

Background to the dispute

21 The applicant has developed a medicinal product called Optiflex 640 (hereinafter 'Optiflex'), in which the pharmacologically active substance is somidobove. It is a BST intended for administration to dairy cows in order to boost milk production.

22 On 28 September 1987, at the request of the applicant and in accordance with Article 2(1) of Directive 87/22, the competent authorities of the United Kingdom referred the application for marketing authorisation in respect of Optiflex to the CVMP for an opinion. From 1987 to 1991 the applicant replied to various requests for information from the CVMP.

23 By letter of 26 September 1991, the Commission informed the applicant that, following the entry into force of Regulation No 2377/90, it would not need to submit a further application for the inclusion of somidobove in Annex II to Regulation No 2377/90 (hereinafter 'Annex II') since an application had already been referred to the CVMP in accordance with Directive 87/22.

24 On 27 January 1993 the CVMP issued its opinion.

25 That opinion reads *inter alia* as follows:

'The use of Optiflex 640 in dairy cattle does not present any risk to the health of consumers of meat or milk obtained from treated animals resulting from residues of somidobove or the possible presence of insulin-like growth factors in meat or milk. The product may be safely accepted for use without any withdrawal period for meat or milk ...

The Committee considers that it is not necessary for the protection of public health to establish maximum residue limits for somidobove, the active ingredient in the product, and it therefore recommends that somidobove should be included in the list of substances not subject to maximum residue limits in Annex II ...'

26 By letter of 11 May 1995 the Commission, referring to the opinion of the CVMP, informed the applicant that it had prepared a draft regulation including somidobove in Annex II and that it intended to refer the matter to the Adaptation Committee in accordance with Article 8 of Regulation No 2377/90.

27 However, a year after the appearance of the CVMP's report, somidobove had still not been included in Annex II. Accordingly, the applicant formally requested the Commission, pursuant to Article 175 of the EC Treaty, 'to take the necessary measures to ensure that somidobove ... be included at the earliest possible date in the list of substances not subject to maximum residue limits of Annex II'.

28 On 22 May 1996 the Commission adopted Decision C(96) 1374 final (hereinafter 'the contested decision').

29 The latter part of the decision provides as follows:

'...

Whereas, under Article 6 of Council Regulation (EEC) No 2377/90, in order to obtain the inclusion of a new pharmacologically active substance in these lists, the substance must be intended for use in veterinary medicinal products and must be intended to be placed on the market of one or more Member States;

Whereas, on 20 December 1994, the Council adopted Decision 94/936/EEC, amending Decision 90/218/EEC concerning the placing on the market and administration of bovine somatotrophin (BST);

Whereas, this decision provides in Article 1: "Member States shall ensure that, until 31 December 1999, the placing on the market of bovine somatotrophin for the purposes of its marketing and the administration thereof on their territory to dairy cows by any means whatsoever will not be authorised", and therefore its effect is that bovine somatotrophin cannot be marketed nor administered in the Community, since it is only administered to dairy cows;

Whereas, since one of the conditions for applying for the inclusion into the annexes of Council Regulation (EEC) No 2377/90 is not complied with, the Commission considers that it should not proceed with that request,

has adopted this decision:

Article 1

The request for the inclusion of somidobove (bovine somatotrophin) in Annex II of Council Regulation (EEC) No 2377/90 is rejected.

Article 2

This decision is addressed to Elanco Animal Health Product Registration, Lilly Industries Limited, Kingsclere Road, Basingstoke, GB ...'

Procedure and forms of order sought

30 By application lodged at the Registry of the Court of First Instance on 31 August 1996, the applicant brought this action.

31 By application lodged at the Registry of the Court of First Instance on 24 January 1997, the European Federation of Animal Health (hereinafter 'Fedesa') sought leave to intervene in support of the form of order sought by the applicant, which was granted by order of the President of the Third Chamber of the Court of First Instance on 28 May 1997.

32 Upon hearing the Report of the Judge-Rapporteur, the Court (Third Chamber) decided to open the oral procedure without any preparatory inquiry. However, it decided to put two questions to the Commission in writing, to which the latter replied within the prescribed period.

33 The applicant claims that the Court should:

— annul the contested decision;

— order the Commission to pay the costs.

34 Fedesa, the intervener, has intervened in support of the form of order sought by the applicant. It also claims that the Commission should be ordered to pay the costs of its intervention.

35 The Commission contends that the Court should:

— declare the application inadmissible;

— in the alternative, dismiss the application as unfounded;

— order the applicant to pay the costs.

Admissibility

Arguments of the parties

36 The Commission takes the view that the application is inadmissible.

37 It considers, in the first place, that the contested decision is not a reviewable act.

38 It argues that the decision does not have definitive legal effects. It merely 'froze' or 'blocked' the request for the inclusion of somidobove in Annex II. It was never the intention of the Commission to rule out the inclusion of somidobove in Annex II in the future. Thus, if the moratorium on BST were to be lifted, the applicant would not have to reapply for the inclusion of somidobove in that list. Accordingly, the rights and obligations of the applicant remained unchanged and its legal position was unaffected by the decision (Case T-16/91 *Rendo and Others* v *Commission* [1992] ECR II-2417, paragraph 45 et seq.).

39 Second, in the Commission's view, the applicant was not individually concerned by the contested decision as required by the principle established in Case 25/62 *Plaumann* v *Commission* [1963] ECR 95, at p. 107. It was affected in the same way as any other actual or potential producer of somidobove, a substance which was not patented.

40 The Commission points out that if an individual requests it to adopt a regulation and it refuses to do so, the adverse decision containing the refusal must be regarded for purposes of annulment as a legislative measure of general application,

even though the refusal is addressed solely to the person concerned (Case 42/71 *Nordgetreide* v *Commission* [1972] ECR 105; Case C-87/89 *Sonito and Others* v *Commission* [1991] ECR I-1981; and Joined Cases C-15/91 and C-108/91 *Buckl and Others* v *Commission* [1992] ECR I-6061).

41 Third, in the Commission's view, an adverse decision can be reviewed only if the act which the Community institution has refused to adopt is itself open to review.

42 The act adoption of which was refused, it is argued, was a *draft* regulation designed to amend Annex II, which the Commission was to submit to the Adaptation Committee pursuant to Article 8(2) of Regulation No 2377/90. As it was a preparatory measure, such a draft was not a reviewable act (Case 60/81 *IBM* v *Commission* [1981] ECR 2639, paragraphs 9 to 12).

43 Moreover, the inclusion of somidobove in Annex II had of necessity to be achieved by means of a Commission or Council regulation (see Article 8(3) of Regulation No 2377/90), that is to say by a measure of general application. The applicant cannot bring an action against such an act unless it is directly and individually concerned by it.

44 Fourthly and finally, the Commission maintains that the applicant has no interest in bringing an action.

45 The Commission argues, in particular, that the fact that somidobove has not been included in Annex II in no way prevents the applicant from undertaking clinical trials. It argues further that it is not bound to submit a draft regulation to the

Adaptation Committee merely in order to allow the marketing of foodstuffs from animals subjected to such trials.

46 Moreover, no interest in bringing an action can be derived from the applicant's wish to have somidobove included on the list in Annex II so as to qualify for authorisation to market Optiflex as soon as possible once the moratorium on BST has been lifted. Indeed, it would be preferable, from the point of view of public health, for the decision on an MRL to be taken at about the same time as the decision to grant authorisation to market the product.

47 The applicant, supported by the intervener, takes issue with the objection of inadmissibility raised by the Commission.

Findings of the Court

48 In order to assess whether the application is admissible, it must first be ascertained whether the contested decision constitutes a reviewable act under Article 173 of the Treaty and, if so, whether the applicant has standing to bring an action under that article and an interest in doing so.

Whether the contested decision is a reviewable act under Article 173 of the Treaty

49 According to settled case-law, any measure which produces binding legal effects and is such as to affect the interests of an applicant by bringing about a distinct

change in his legal position is an act or decision which may be the subject of an action under Article 173 for a declaration that it is void (see, by way of example, Case T-154/94 *CSF and CSME* v *Commission* [1996] ECR II-1377, paragraph 37).

50 In this case, the applicant has submitted a request under Article 6 of Regulation No 2377/90 for the inclusion of somidobove in Annex II.

51 The Commission adopted the contested decision after the applicant had called upon it to act pursuant to Article 175 of the Treaty.

52 Article 1 of that decision rejects the request for the inclusion of somidobove (bovine somatotrophin) in Annex II.

53 The contested decision, inasmuch as it rejects the applicant's request, thus constitutes the final stage in the procedure initiated by the applicant on the basis of Regulation No 2377/90.

54 Whilst it is true that, if the moratorium on BST were to be lifted, the Commission might decide to reconsider its decision, the fact remains that, until then, the decision establishes the Commission's position definitively.

55 Accordingly, the contested decision produces binding legal effects such as to affect the interests of the applicant and brings about a distinct change in its legal position.

56 Consequently, it constitutes an act which may be the subject of an action for annulment.

Whether the applicant has standing to bring proceedings

57 Under the fourth paragraph of Article 173 of the Treaty, any natural or legal person may institute proceedings against a decision addressed to that person or against a decision which, although in the form of a regulation or a decision addressed to another person, is of direct and individual concern to the former.

58 The contested decision is addressed to the applicant and marks the culmination of a procedure initiated pursuant to Regulation No 2377/90 by the applicant itself.

59 Moreover, this case differs from those in which the judgments cited by the defendant were given (see paragraph 40 above). In this case, the Commission has no discretion to decide whether there is any need to rule on the request made by the applicant under Article 6(1) of Regulation No 2377/90. Rather, as it has exclusive authority to deal with requests made under that article, it was under an obligation to rule on the applicant's request.

60 In the circumstances, the applicant has standing to bring proceedings for annulment.

61 That conclusion is not undermined by the Commission's argument that the application is inadmissible because the applicant would have no standing to bring an

action under Article 173 of the Treaty for annulment of the substantive measure which could have been adopted in place of the contested decision, that is to say a draft regulation to be drawn up by the Commission under Article 8(2) of Regulation No 2377/90 or a definitive regulation to be adopted by the Commission or the Council under Article 8(3) of that regulation (see paragraphs 41 to 43 above).

62 In that connection, the Commission refers to case-law to the effect that, when a decision of the Commission amounts to a rejection, it must be appraised in the light of the nature of the request to which it constitutes a reply. In particular, a refusal constitutes an act in respect of which an action for annulment may be brought under Article 173 of the Treaty, provided that the act which the Community institution refuses to adopt could itself have been contested under that provision (Case T-330/94 *Salt Union* v *Commission* [1996] ECR II-1475, paragraph 32, and the case-law cited).

63 That case-law is not applicable where, as in this case, the Commission's decision is taken in a procedure which is clearly defined by a Community regulation, under which the Commission is required to rule on a request made by an individual under that regulation.

64 That argument of the Commission must therefore be rejected.

Whether the applicant has an interest in bringing proceedings

65 As the applicant has rightly observed, whilst under Article 2(1) of Decision 90/218 clinical trials on the use of BST are in theory authorised, the fact remains that, under Article 4(2) of Directive 81/851, as of 1 January 1997 the Member States no longer allow foodstuffs for human consumption to be taken from test animals

unless MRLs have been established by the Community in accordance with Regulation No 2377/90.

66 Consequently, in the absence of an MRL for somidobove, foodstuffs (milk, meat) from animals to which the applicant's product has been administered in the course of clinical trials cannot be used for human consumption, which is likely to have an adverse effect on the interests of the applicant.

67 The applicant, moreover, has an interest in obtaining the inclusion of somidobove in Annex II in order to be able to secure marketing authorisation for its product as soon as possible once the moratorium on BST has been lifted.

68 Consequently, it has an interest in bringing an action for annulment.

69 It follows from the foregoing that the application is admissible.

Substance

70 The applicant relies on six pleas in support of its application. The first alleges infringement of Regulation No 2377/90, the second alleges breach of the principles of legal certainty and protection of legitimate expectations, the third alleges breach of the principle of proportionality, the fourth alleges misuse of powers, the fifth alleges infringement of Article 2(1) of Decision 90/218 and the sixth alleges breach

of the Final Act embodying the results of the Uruguay Round of multilateral trade negotiations.

The first plea alleging infringement of Regulation No 2377/90

Arguments of the parties

71 The applicant argues that, where the Commission has all the necessary information at its disposal and the CVMP has given a favourable opinion on the inclusion of the substance in Annex II, the Commission is obliged, under Articles 6(5) and 8(2) of Regulation No 2377/90, to submit the draft measures to be taken to the Adaptation Committee. In this case, the Commission did not submit such a draft to the Adaptation Committee, and accordingly acted in breach of Regulation No 2377/90.

72 The applicant points out that, in the contested decision, the Commission rejected its request on the ground that Article 6 of Regulation No 2377/90 only permitted the inclusion in the annexes thereto of substances which 'may' be marketed and administered in the Community. However, that article merely requires the person responsible for marketing who wishes to obtain the inclusion in Annex I, II or III of substances which are 'intended' for use in certain veterinary medicinal products and to be placed on the market to submit an application to the Commission containing the information referred to in the regulation itself. Somidobove was always 'intended' to be used and placed on the market, within the meaning of Article 6, even though for the time being this was not possible because of a temporary moratorium.

73 In the applicant's view, the Commission's interpretation of Article 6 of the regulation is not borne out by the objective of the regulation which is to 'protect

public health' (see third recital in the preamble). The Commission cannot refuse to grant MRLs for reasons other than public health. The contested decision was not justified on grounds of public health, but simply by the existence of the moratorium on BST, which was imposed for reasons other than the protection of public health.

74 The contested decision, it claims, was the result of confusion between the concepts of MRL and marketing authorisation and of a mistaken interpretation of the moratorium on BST. The fact that the moratorium temporarily prohibits the marketing of the product in question should not be taken into account in connection with consideration of a request for the inclusion of that product in an annex to Regulation No 2377/90. That regulation did not make the establishment of an MRL subject to the condition that it should be possible for the substance concerned to be marketed in the Community at once.

75 The intervener submits that, while it is true that the moratorium on BST must be considered to be a *lex specialis,* it concerns only the marketing of BST. In particular, the moratorium does not derogate from the general procedure for the establishment of an MRL under Regulation No 2377/90 and no such derogation is necessary in order to safeguard the objective pursued by the moratorium.

76 The Commission denies having confused the concepts of MRL and marketing authorisation. It has never required that a product for which the establishment of an MRL is sought should be capable of being marketed at once. It accepts that the criteria for obtaining an MRL and marketing authorisation are not the same. However, the existence of a link between the two concepts in undeniable. The applicant

sought the inclusion of somidobove in Annex II in connection with its request for marketing authorisation in respect of Optiflex, in which somidobove is the pharmacologically active substance.

77 In this case, it submits, the decision to refuse marketing authorisation preceded, by way of exception, the decision on the establishment of an MRL, which is a preliminary step in the procedure for the issue of Community marketing authorisation.

78 In the Commission's view, BST constitutes an exceptional case in the Community. It is subject to a ban on marketing and administration. Consequently, its immediate use by any means whatsoever is prohibited. Whereas, normally, the grant of marketing authorisation is uncertain, but always possible, in this case, both the marketing and administration of the substance are prohibited by Community legislation.

79 Hence the conditions laid down by Article 6(1) of Regulation No 2377/90, according to which the substance concerned must be both intended for use in veterinary medicinal products for administration to food-producing animals and intended to be placed on the market, have not been met.

80 The Commission considers that if the applicant's interpretation of Article 6 were followed, the second indent of Article 6(1) would make no sense.

81 Finally, the Commission notes that the inclusion of somidobove in Annex II might be interpreted as authorising the use of the substance in the Community. Even if an expert would not take that view, the situation this has created is ambiguous nevertheless. In view of the — in all likelihood — negative reaction of the consumer to the approval of BST (see also Case C-331/88 *Fedesa and Others* [1990] ECR I-4023, paragraph 9) and in the absence of any interest on the part of the applicant, the establishment of an MRL for somidobove would needlessly give rise to uncertainty in this sector.

Findings of the Court

82 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.

83 In particular, 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, submitted under Article 6(1) of Regulation No 2377/90, 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 pursuant to Article 6(4) and (5).

84 In this case, instead of drawing up a draft regulation including somidobove in Annex II and submitting it to the Adaptation Committee, the Commission rejected the applicant's request on the ground that the marketing of somidobove

was banned because of the moratorium on BST, with the result that the conditions in Article 6(1) of Regulation No 2377/90 were not met.

85 In that connection, it should be noted that a request made on the basis of that article must be for the inclusion of a new pharmacologically active substance which is both intended for use in veterinary medicinal products for administration to food-producing animals (Article 6(1), first indent), and intended to be placed on the market of one or more Member States which have not previously authorised the use of the substance concerned in food-producing animals (Article 6(1), second indent).

86 However, as the applicant has rightly pointed out, Article 6(1) of Regulation No 2377/90 does not make the inclusion of a substance in an annex to the regulation subject to the condition that a product containing the substance should be capable of being used and marketed at once.

87 In particular, in a case such as this, where the marketing of a product is banned under a moratorium, which is by definition temporary, a request by a trader for the inclusion of a pharmacologically active substance in one of the annexes to Regulation No 2377/90 satisfies the condition laid down by the second indent of Article 6(1) of the regulation if it is clear, as it is here, that the trader concerned intends to market the product in question once the moratorium has been lifted.

88 Moreover, as regards more specifically the reference in the contested decision to the marketing ban imposed by the moratorium on BST, it should be noted, as the Commission itself concedes, 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 Directive 81/851 and Regulation No 2309/93.

89 Those two measures, which govern respectively the issue of national and Community authorisations for the marketing of veterinary medicines, expressly provide that marketing authorisation for a product will be refused where its use is prohibited under other provisions of Community law (see point 3 of the first paragraph of Article 11 of Directive 81/851 and point 3 of the first paragraph of Article 33 of Regulation No 2309/93). They thus allow marketing authorisation to be refused where, as in this case, a moratorium has been established.

90 However, Regulation No 2377/90 which governs the establishment of MRLs for veterinary medicinal products in foodstuffs of animal origin contains no provision authorising the Commission to take account of a marketing ban in refusing to establish an MRL.

91 In that connection, the objective of Regulation No 2377/90 is to protect public health (see third recital in the preamble), whereas it is clear from the case-file that the moratorium on BST was introduced for socio-economic reasons.

92 Consequently, in this case, the Commission was not legally entitled to base the contested decision on the existence of the moratorium on BST.

93 As regards the Commission's fear that the inclusion of somidobove in Annex II would give rise to confusion on the part of consumers, suffice it to note that the institution could easily inform the public by any appropriate means that, notwithstanding the inclusion of that substance, the marketing of a product such as Optiflex would continue to be prohibited as long as the moratorium on BST was in force.

94 It follows from the foregoing that the contested decision must be annulled, without there being any need to consider the other pleas raised by the applicant.

Costs

95 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.

96 Since the Commission has been unsuccessful, it must be ordered to pay the costs, including those of the intervener, in accordance with the forms of order sought by the applicant and the intervener.

On those grounds,

THE COURT OF FIRST INSTANCE (Third Chamber)

hereby:

1. **Annuls the Commission decision of 22 May 1996 rejecting the request for the inclusion of somidobove, a recombinant bovine somatotrophin (BST), 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. **Orders the Commission to pay the costs, including those of the intervener.**

Tiili Briët Potocki

Delivered in open court in Luxembourg on 25 June 1998.

H. Jung V. Tiili

Registrar President