OPINION OF ADVOCATE GENERAL SAGGIO

delivered on 27 January 2000 *

1. By order of 17 July 1998, the College van Beroep voor het Bedrijfsleven of the Netherlands referred to the Court for a preliminary ruling four questions relating to Council Directive 88/407/EEC of 14 June 1988 'laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species' [1] and Directive 93/60/EEC of 30 June 1993 'amending Directive 88/407/EEC'. [2] Those questions were submitted by the Netherlands court in the context of appeal proceedings brought by K.V.S. International BV (hereinafter 'KVS') against the refusal by the Minister van Landbouw, Natuurbeheer en Visserij (hereinafter the 'Netherlands Ministry of Agriculture') to issue a certificate for the export to other Member States of deep-frozen semen from the bull If de Focant.

Relevant Community provisions

2. Directive 88/407 of 14 June 1988 lays down animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species

3. The fourth recital in its preamble reads '(...) in the context of intra-Community trade in semen, the Member State where the semen is collected should be under an obligation to ensure that such semen has been collected and processed at approved and supervised semen collection centres, has been obtained from animals whose health status is such as to ensure that the risk of spread of animal disease is eliminated, has been collected, processed, stored and transported in accordance with rules which preserve its health status and is accompanied during transport to the country of destination by an animal health certificate in order to ensure that this obligation has been fulfilled'.

4. Article 3 provides that 'Each Member State shall ensure that only semen meeting the following general conditions is sent from its territory to the territory of another Member State:

(...)

(b) it must have been collected from domestic animals of the bovine species whose health status complies with Annex B

(...)'.

* Original language: English.

1 — OJ 1988 L 194, p. 10.

2 — OJ 1993 L 186, p. 28.

5. Annex B to the directive in question lays down the conditions which bovine animals must meet in order to be admitted to approved semen collection centres and also the routine tests and treatment to be applied to the animals during their stay at those centres. According to paragraph 1(b) of Chapter I of Annex B, 'All bovine animals admitted to a semen collection centre must:

(...)

(b) prior to their stay in the isolation accommodation described in (a) have belonged to herds:

(i) which are officially tuberculosis free;

(ii) which are officially brucellosis free or brucellosis free. The animals may not previously have been kept in other herds of a lower status'.

6. Finally, Article 6.1 provides that 'Member States shall make the admission of semen conditional upon submission of an animal health certificate drawn up by an official veterinarian of the Member State of collection in accordance with Annex D'.

7. A transitional period is allowed for the implementation of the above provisions. According to the 13th recital in the preamble '(...) this Directive does not affect trade in semen produced before the date on which the Member States must comply with it.' In this connection, Article 20 provides that '[T]his Directive shall not be applicable to semen collected and processed in a Member State before 1 January 1990'.

8. In 1993, Directive 88/407 was amended by Directive 93/60/EEC. [3] In the fourth recital in its preamble it is stated that '(...) it is opportune to make further amendments to the (...) Directive [88/407/EEC] to clarify certain issues and to take account of technical progress, particularly in respect of treatment of bulls against leptospirosis, and to align the rules with respect to brucellosis, tuberculosis and leucosis on those laid down in Directive 64/432/EEC'. [4]

3 — Cited above.

4 — Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ, English Special Edition 1963–1964, p. 164), last amended by Directive 92/102/EEC (OJ 1992 L 355, p. 32).

9. The changes which Directive 93/60 made to the provisions relating to the conditions for the admission of the animals to approved semen collection centres are contained in Article 1(8), according to which: 'In Annex B, Chapter I, paragraph 1(b) shall be replaced by the following: (b) prior to their stay in the isolation accommodation described in (a), have belonged to a herd which is officially tuberculosis free and officially brucellosis free in accordance with Directive 64/432/EEC'. [5]

The change made to the last sentence of (b) which, in the new text, reads: '[T]he animals may not previously have been kept in one or more herds of a lower status' is especially relevant as far as the case being discussed today is concerned.

10. Directive 93/60 does not set any transitional period, simply providing, in Article 3, that Member States are to bring into force the provisions necessary to comply with the Directive by 1 July 1994.

Relevant national provisions

11. The national legislation which is relevant as far as the case under discussion today is concerned is essentially to be found in three sources: the Netherlands Law on the Health and Welfare of Animals (Gezondheids- en welzijnswet voor dieren); the Decree on the Export of Animals and Products of Animal Origin (Besluit uitvoer dieren en producten van dierlijke oorsprong) and the Regulation on Trade in Live Animals and Live Products (Regeling handel levende dieren en levende producten). From that legislation it may be seen that bovine semen can be exported to another Member State of the Community only if it is accompanied by a certificate issued following an examination carried out on the initiative of the national authority, from which it is clear that the conditions laid down by Article 3(b) and (c) of Directive 88/407 have been met.

5 — I feel it should be stated that Annex A to Directive 64/432/EEC cited above defines, among other things, what is meant by a bovine holding 'officially free from brucellosis' and 'free from brucellosis'. According to paragraph 2 of that Annex, a bovine holding is to be regarded as 'officially free from brucellosis' if: '(a) it contains no bovine animals which have been vaccinated against brucellosis by use of a live vaccine; (b) all the bovine animals have been free from clinical signs of brucellosis for at least six months; (c) all the bovine animals over twelve months old: (aa) have shown a brucella count lower than 30 international units of agglutination per millilitre when given at six-monthly intervals two official sero-agglutination tests complying with Annex C; the first sero-agglutination test may be replaced by three ring-tests carried out at three-monthly intervals provided, however, that the second sero-agglutination test is carried out at least six weeks after the third ring-test; (bb) are checked annually, to establish that brucellosis is not present by means of three ring-tests carried out at intervals of at least three months or two ring-tests and one sero-agglutination test carried out at intervals of at least three months; when the ring-test cannot be made, two sero-agglutination tests shall be carried out each year, at six-monthly intervals; in Member States whose entire bovine herd is under official veterinary supervision and has a rate of brucellic infection lower than 1%, only two ring-tests need be carried out each year or, if this cannot be done, one sero-agglutination test; (d) no bovine animal has been introduced without a certificate from an official veterinarian showing that its brucella count was lower than 30 international units of agglutination per millilitre when given a sero-agglutination test not more than thirty days before it was taken into the herd and, in addition, that it is from an officially brucellosis-free bovine herd.' In accordance with paragraph 3 of that Annex, a bovine holding is, on the other hand, to be regarded as 'free from brucellosis' in the following cases: 'A bovine herd is considered to be brucellosis-free if: (a) by way of derogation from paragraph 2 (a), it contains bovine animals between five and eight months old which have been vaccinated only with live vaccine Buck 19; (b) all the bovine animals fulfil the conditions laid down in paragraph 2 (b), (c) and (d); bovine animals less than thirty months old may, however, show a brucella count equal to or higher than 30 international units of agglutination per millilitre but lower than 80 international units of agglutination per millilitre, the complement fixation reaction being negative'.

Facts and questions referred for a preliminary ruling

12. KVS, which is the plaintiff in the main proceedings, manages an AI centre in the Netherlands which was officially approved by the European Union as a semen collection centre from 16 May 1992. Previously, it had only had national approval.

13. In 1991, KVS imported the breeding bull If de Focant from Belgium to bring it into its centre. This bull came from the herd belonging to Mr Eugène Detal, in which it had been born in 1988 and had remained continuously until it was transferred to the collection centre.

On the birth of If de Focant, Mr Detal's herd was regarded by the Belgian authorities as a 'centre of brucellosis', since it was located in an area in which bovine brucellosis was rife. On 1 January 1990, however, it was assigned the health status 'officially free from brucellosis' and this was its status when If de Focant was imported into the Netherlands.

14. The admission of the Belgian bull to the Netherlands collection centre was the subject of a dispute between the competent authorities of the two countries. On 16 December 1991 the Belgian Veterinary Inspectorate sent a letter to the Netherlands Meat and Livestock Inspectorate (RVV — Rijksdienst voor de Keuring van Vee en Vlees) in which it challenged that admission, maintaining that the herd in which the bull in question was born and had remained had been a centre of brucellosis for a time. According to the Belgian Inspectorate, If de Focant did not accordingly meet the conditions in Directive 88/407 for admission to a semen collection centre officially approved by the European Union; this was because, in the Inspectorate's view, paragraph 1(b) of Chapter I of Annex B to that Directive was construed as ruling out any health risk, particularly the potential risk posed by a breeding bull which, for part of its life, had belonged to 'a non-qualified herd', in other words failing to meet the requirements of Community provisions.

15. This interpretation was not shared by the Netherlands Ministry of Agriculture's Legal and Commercial Affairs Directorate, which in March 1992 recognised the legality of the admission of If de Focant to the collection centre on the grounds that it deemed the conditions laid down by Community law — particularly Annex B to Directive 88/407 — to have been fully satisfied. According to the Directorate, it sufficed that the bull came from a herd whose status of 'officially free from brucellosis' had been recognised at the time it had entered the collection centre. Any other status which that herd might have had in the past was of no relevance whatever.

16. The Belgian veterinary authorities' response to this was to turn to the European Commission. In a letter dated 23 November 1992, however, the Commission in fact espoused the interpretation of Community law proposed by the Netherlands Government, maintaining that, in its view also, the conditions of Annex B to Directive 88/407 had been met. The Commission added that, in 1992, during the proceedings for the official approval of the collection centre, If de Focant had been subjected to various checks for brucellosis, all of which proved negative. Accordingly, the conclusion had to be that the bull in question posed no risk of transmitting this disease and that its admission to the centre was, accordingly, entirely lawful.

On 28 June 1993, two days before the adoption of Directive 93/60, the European Commission changed its mind. In a letter to the Belgian Permanent Representation in Brussels, it stated that the semen of a bull born in a centre of brucellosis could not be the subject of intra-Community trade.

17. On the basis of that letter, the Belgian Ministry of Agriculture's Veterinary Inspectorate again approached its Netherlands counterpart on 2 August 1993 requesting that the bull in question should leave the collection centre and that requisite arrangements should be made for its semen not to be traded any longer within the Community.

18. If de Focant was slaughtered in November 1993 following a hip displacement. On 7 June 1996, KVS asked the Netherlands [Meat and] Livestock Inspectorate for a certificate to export to Belgium and France deep-frozen semen from that bull which had been collected before 1 July 1994, the date of implementation of Directive 93/60.

19. By decision of 10 June 1996, the abovementioned Inspectorate refused KVS the requested certificate. According to the grounds for this decision, If de Focant did not meet the conditions imposed by the version of Annex B to Directive 88/407, then in force, inasmuch as it had been born in, and been part of, a herd of a status lower than that of 'officially free from brucellosis'.

20. KVS appealed against that decision to the Netherlands Ministry of Agriculture but the appeal was dismissed. KVS contested the measure dismissing the appeal before the College van Beroep voor het Bedrijfsleven.

During the proceedings, it maintained that, among other things, the Netherlands Ministry of Agriculture's refusal to certify the semen for export was based entirely on the fact that that Ministry was — erroneously — applying the legislation in force at that time, specifically paragraph 1(b) of Chapter I of Annex B to Directive 88/407, as amended by Directive 93/60. According

to the appellant in the main proceedings, however, the semen of If de Focant had to be subjected exclusively to the legislation in force at the time of production and therefore to the conditions of the above-cited provision of Directive 88/407 in its original version; this was because the amendments made in 1993, which introduced more restrictive conditions for the admission of bulls to collection centres, could not be applied to semen collected before they entered into force.

21. Taking the view that the settlement of the dispute depended on the interpretation and validity of the directives which have been cited a number of times, the College van Beroep voor het Bedrijfsleven stayed proceedings in order to refer the following questions to the Court:

'(1) Must Article 3(b) of Directive 88/407/EEC be construed as meaning that semen from a bull which was admitted to an approved semen collection centre before the adoption of amending Directive 93/60/EEC on the ground that it satisfied the admission requirements in force at that time does not (any longer) satisfy the condition set out in Article 3(b) of the directive if the animal in question fails, at the time when certification of the semen is applied for, to satisfy the amended requirement governing admission to a semen collection centre as laid down in paragraph 1(b) of Chapter I of Annex B to Directive 88/407/EEC?

If the answer to Question (1) is affirmative:

(2) Should the transitional rule set out in Article 20 of Directive 88/407/EEC be construed as meaning that it is applicable by analogy to semen which was collected and processed prior to 1 July 1994?

If the answer to Question (1) is affirmative and the answer to Question (2) negative:

(3) Is Directive 93/60/EEC invalid as being contrary to general principles of law, in particular the principle of the protection of legitimate expectations and the principle of proportionality, in so far as that directive does not provide for transitional measures to counter obstacles to intra-Community trade in the semen of bulls which had already, in accordance with the provisions then in force, been admitted to an approved semen collection centre before Directive 93/60 was adopted?

If the answer to Question (1) is negative:

(4) The provision in Article 1(8) of Directive 93/60/EEC amended the second subparagraph of paragraph 1(b) of Chapter 1 of Annex B to Directive 88/407/EEC ("The animals may not previously have been kept in other herds of a lower status") to read "The animals may not previously have been kept in one or more herds of a lower status". Must this amendment be construed as being exclusively a clarification or as a substantive amendment to the requirements applying in regard to the admission of bovine animals to an approved semen collection centre?'

The fourth question

22. Let me say at once that, in replying to the questions from the national court, I will be following an order which is partially different from that proposed in the order for reference

23. By means of the first question, the national court is asking the Court of Justice whether the provisions which have to be applied in order to establish whether the semen of If de Focant can be the subject of intra-Community trade are those in force at the time of the collection of the semen itself (at that time paragraph 1(b) of Chapter I of Annex B to Directive 88/407 in its original version) or those in force on the date of the marketing of the abovementioned product, or alternatively the same provision but in the text amended by Directive 93/60. From the way the question is framed, however, it may easily be seen that it is based on the premiss that the directive just referred to substantially amended the previous legislation.

However, the substantive or formal nature of such amendment is specifically the subject of the fourth question put by the national court. I consider, therefore, that this question must be answered first of all. I would further like to add that the reply to this question might also prove to be decisive in the case now before us. Should the conclusion have to be reached that the 1993 directive did not substantively change the text previously in force but simply clarified its meaning, the other questions would no longer be relevant. For all of these reasons, therefore, I will deal with the fourth question first.

24. By means of that question, the national court is asking this Court whether Directive 93/60 has, by replacing the sentence '[T]he animals may not previously have been kept in other herds of a lower status' by another, namely '[T]he animals may not previously have been kept in one or more herds of a lower status', made a substantive amendment to the criteria laid down for the

admission of a bull to a semen collection centre or simply clarified and set out in more detail the content of the provision already in force.

25. I should like to begin by stating that the fact that Directive 93/60, where it refers to 'one or more herds', has to be construed as meaning that a bull must never have stayed in any herd having a health status lower than that of 'officially brucellosis-free' in order to be allowed into a semen collection centre, is not disputed. This prohibition therefore refers either to the herd which the bull comes from at the time of admission to the collection centre or to any other herds of which it has formed part. As regards the former hypothesis, the prohibition means not only that that herd must possess the health status of 'officially brucellosis-free' at the time the bull is transferred to the collection centre but also that it has not previously had any lower status. This applies in respect of the entire period in which the bull remained with it.

26. That point having been considered, the reply to the question from the national court depends on the interpretation of the sentence in the original version of Annex B to Directive 88/407. It needs to be established in particular what is to be understood by the expression 'other herds' and whether this expression has the same significance as that of 'one or more herds' in the amended version.

27. KVS and the Netherlands Government maintains that this equivalence does not exist. More precisely, according to the Netherlands Government, the expression 'other herds' ought to be read as meaning that it makes a distinction between the herd the bull comes from before its admission to the collection centre and any other herds to which the animal has previously belonged. According to that government, this would entail the prohibition against allowing into collection centres those bulls which have formed part of herds of a lower status referring only to the second and not to the first. The last herd the bull belonged to must accordingly meet solely the requirements of paragraph 1(b)(i) and (ii) of Chapter I of Annex B. In other words, it is subject to the sole condition of having the status of 'officially free from brucellosis' at the time when the bull is admitted to the collection centre, while any other health status it may have had in the past would not be relevant.

28. The Commission, the Council and the French Government contend, to the contrary, that a wider meaning should be assigned to the expression 'other herds', coinciding with that of the expression 'one or more herds'. Their submission is that in order to be able to attain the objective of protection of human health, the prohibition in the last sentence of the provision in point extends without distinction to all herds to which the bull has belonged.

29. I consider that this point of view is the one to be supported. It is well known that when the literal wording of a provision

lends itself to various interpretations, the choice between them should be made taking account of the context of that provision and 'the objects of the rules of which it is part'. [6] The case-law is in fact orientated towards favouring the interpretation most consistent with the aims pursued by the provision in question. [7]

30. These are the criteria to be followed in this case in order to interpret the provision in paragraph 1(b) of Chapter I of Annex B to Directive 88/407. The interpretation which, taking those criteria into account, must be accepted is the broader one suggested by the Commission and the French Government.

31. As may be seen from the fourth recital in its preamble, Directive 88/407 should be considered in this connection to have among its aims that of preventing the collection, treatment and intra-Community trade in bovine semen possibly posing a danger as regards the spread of livestock diseases. [8]

32. With regard to brucellosis in particular, that objective assumes especial importance. As the Commission and the Council point out in their observations, this disease is particularly serious and contagious and it can entail grave risks to human health inasmuch as it is transmissible to man, either by direct contact or via the consumption of milk or products derived from milk.

33. To this it must be added that, in this area, the protection of human health is particularly complicated. The testimony of a medical expert on the subject which was reported in the order for reference reveals that there are no certain methods of definitively eliminating brucellosis infection in a herd. There have been cases in Germany where, notwithstanding the fact that all possible steps have been taken (such as the evacuation of housing, disinfestation and restocking with healthy animals), the disease has resurfaced after 16 months. Moreover, as the Council points out in its observations, the presence of brucellosis bacteria in bull semen cannot be ruled out on the basis of any bacteriological examination.

34. Having regard to the objectives which the directive pursues, the interpretation of the expression 'other herds' cannot manifestly be related only to herds other than the one to which the animal in question belongs, bearing in mind that the risk of spreading the disease which is taken into account by the directive stems from the fact

6 — Case 292/82 *Merck* [1983] ECR 3781, paragraph 12. See also Case 187/87 *Saarland and Others* [1988] ECR 5013, paragraph 19 and Case C-355/95 P *TWD* v *Commission* [1997] ECR I-2549, paragraph 21.

7 — In particular, see again the *Merck* case cited, paragraph 12. See also Case 9/70 *Grad* [1970] ECR 825, paragraphs 12 and 13; Case 23/70 *Haselhorst* [1970] ECR 881, paragraphs 13 and 14, Case 20/70 *Transports Lesage* [1970] ECR 861, paragraphs 13 and 14 and Case 67/79 *Fellinger* [1980] ECR 535, paragraphs 6 and 7.

8 — See, on this point, point 4 of this Opinion.

that a bull has been part of a herd at a given time with a health status which is lower than that of 'officially free from brucellosis' and that such risk is equally great when it is related to the presence of the bull in a herd other than that to which it belongs or when it is related to the presence of that bull in the same herd but at an earlier time. To a very substantial extent, therefore, an interpretation which takes account of the former kind of danger of infection and not also of the latter would limit the actual effects of the directive by impeding the attainment of its purpose, or at least making it more difficult.

35. I therefore consider that the expression 'other herds' contained in paragraph 1(b) of Chapter I of Annex B to Directive 88/407 must be interpreted as meaning that it refers to any herds to which the bull belonged prior to its admission to the semen collection centre. Accordingly, Article 1(8) of Directive 93/60, by affirming a concept which is already to be found in preceding legislation, has not in reality entailed any substantive change in the rules governing the criteria for the admission of bovine animals to semen collection centres.

36. It is worth adding that further confirmation of the conclusions I have just reached is afforded by the fourth recital in the preamble to Directive 93/60. In that recital it is stated that the reasons which made it necessary to amend the original text of the Directive include that of providing clarifications regarding certain aspects of the rules. The fact that these clarifications relate in particular to the provisions governing brucellosis is evident in the preparatory work on the Directive showing that one of the main reasons for which the Commission deemed it appropriate that Directive 88/407 be amended was precisely that of setting out in specific terms the situation as far as the status of the bull was concerned on its entry to a collection centre in relation to brucellosis. [9]

37. In the result, therefore, I consider that the answer to the national court's fourth question must be that the amendment made in 1993 to the text of paragraph 1(b) of Chapter I of Annex B to Directive 88/704 constitutes merely a statement in more precise terms of the original text of the Directive.

38. Should the Court agree with my proposed reply, it would be unnecessary for it to rule on the other questions formulated by the national court. If the original version of Directive 88/407 is held to have provided that a bovine animal should not have ever remained in any herd having a health status lower than that of 'officially free from brucellosis' to be admitted to a semen collection centre then it must be concluded that If de Focant was not lawfully admitted to the Netherlands collection centre and

9 — See Commission document COM(92) 462 final of 12 November 1992.

that, accordingly, its semen cannot be the subject of trade within the Community.

The first question

39. If, on the other hand, the Court were to reach the conclusion that Directive 93/60 changed the rules previously in force by introducing more restrictive conditions for admission, the other questions for a preliminary ruling would become relevant to the settlement of the dispute in the main proceedings. I accordingly consider it appropriate to answer also the other three questions put by the national court.

40. The first of these, as I have already had occasion to anticipate, [10] asks whether semen belonging to a bull lawfully admitted to a collection centre (inasmuch as it satisfies the conditions of Community law in force at the time of admission) can be regarded as non-marketable in a Community context on account of the fact that it no longer satisfies the abovementioned conditions at the time of the application for an export certificate since those conditions have changed in the meantime. In other words, the Court is asked whether, where there has been a substantive amendment of the rules relating to the admission of bulls to collection centres in the period between the semen production stage and the marketing stage, the issue of export certification has to be regarded as being subject to the conditions of the legislation in force at the time of admission or those applying at the time the certificate is applied for.

41. According to the Council and the Commission, this question should be answered in the light of the principle of the non-retroactive nature of Community acts. In this connection, both institutions refer to the *Salumi* judgement, [11] according to which 'although procedural rules (...) apply to all proceedings pending at the time when they enter into force, this is not the case with substantive rules'. This is because '(...) the latter are usually interpreted as applying to situations existing before their entry into force only in so far as it clearly follows from their terms, objectives or general scheme that such an effect must be given to them' and because '(...) the principle of legal certainty precludes a Community measure from taking effect from a point in time before its publication.' According to the Court of Justice 'it may be otherwise only exceptionally, where the purpose to be achieved so demands and where the legitimate expectations of those concerned are duly respected.' [12] Referring to this case-law, both institutions submit that neither the text nor the objectives of Directive 93/60 reveal an intention on the part of the legislature to attribute retrospective effect to the amendments made to the provisions relating to the conditions governing the admission of bulls to semen collection centres. Accordingly, the Directive is not applicable to semen collected

10 — In point 22 of this Opinion.

11 — Joined Cases 212/80 to 217/80 *Salumi* [1981] ECR 2735.

12 — *Salumi*, cited above, paragraphs 9 and 10.

prior to its implementation. They therefore conclude that the legislation to which reference should be made in the present case for the purpose of issuing the export certificate is that in force at the time If de Focant entered the semen collection centre, namely Directive 88/407 in its original version.

42. That view cannot be upheld. Although still concerning the problem of determining the scope of the provisions in question, the question raised by the national court should not be answered on the basis of the possibility or otherwise of according retroactive effect to the new provisions, even though they are in accordance with the principle laid down by the Court, according to which 'amending legislation applies, except where otherwise provided, to the effects in the future of situations which have arisen under the law as it stood before amendment'. [13]

43. This principle should be read with reference to the specific nature of the case now before us, in which the application of a rule to a developing situation comes into consideration. [14] In cases of this type, it is a question of ascertaining whether, and within what limits, the rule which has supervened is to apply. According to the case-law of this Court which has been cited, such a situation has to be distinguished from true and proper retroactivity. Whereas that retroactivity means that provision may have an impact on situations which have already arisen before it first came into existence, the application of a provision to developing situations relates to a different hypothesis — one in which a situation, albeit already developing when the new provision comes into force, has not yet produced the effects which the provision seeks to regulate and which render its application necessary and useful.

44. The Court reached these conclusions in the *Butterfly Music* judgment. [15] In that case, the subject of the dispute was the interpretation of Council Directive 93/98/EEC harmonising the term of protection of copyright and certain related rights. [16] In Italy, the transposition into national law of that directive had resulted in the period of protection of the rights of artists and actors/actresses being extended from 30 to 50 years, creating situations in some cases in which recordings which had fallen into the public domain under preceding legislation had become newly protected as a result of the entry into force of the new legislation. In interpreting the above directive, the Court stated that '(...) since the revival of copyright and related rights has no effect on acts of exploitation definitively performed by a third party before the date on which revival occurred, it cannot be con-

13 — Case 68/69 *Brock* [1970] ECR 171, paragraph 7. See also Case 143/73 *Sopad* [1973] ECR 1433, paragraph 8, Case 96/77 *Bauche* [1978] ECR 383, paragraph 48, Case 125/77 *Koninklijke* [1978] ECR 1991, paragraph 37, Case 40/79 *Sig.ra P.* [1981] ECR 361, paragraph 12, and Case 203/86 *Spain* v *Council* [1988] ECR 4563, paragraph 19.

14 — See in this connection the Opinion of Advocate General Cosmas delivered on 19 January 1999 in Case C-321/97 *Andersson* [1999] ECR I-3551 and the Opinion of Advocate General Roemer in Case 1/73 *Westzucker* [1973] ECR 733.

15 — Case C-60/98 *Butterfly Music* [1999] ECR I-3939.

16 — OJ 1998 L 290, p. 9.

sidered to have retroactive effect. Its application to the future consequences of situations which are not definitively settled means, on the other hand, that it has an effect on a third party's rights to continue the exploitation of a sound recording where the copies already manufactured have not yet been marketed and sold on that date.' [17]

45. From all the foregoing considerations it follows that when there is a separation in the time between the coming into existence of a legally relevant situation and the point at which its consequences are taken into account, the amendments to the rules made after the situation in question arose but before it produced its effects must be immediately applied.

46. The case now before us can be brought within that hypothesis. It must be remembered that Directive 88/407 is specifically aimed at regulating intra-Community trade in deep-frozen bovine semen and seeks to prevent such trade from endangering human health by encouraging the spread of livestock diseases. [18] To this end, Article 3 provides that semen may only be consigned from one Member State of the Community to another if the donor bovine animals have a health status which complies with Annex B.

17 — *Butterfly Music*, cited above, paragraph 24.

18 — See the fourth recital in the preamble.

47. In such circumstances, I do not think there can be any doubting the fact that the admission of animals to collection centres and the marketing of semen represent two moments in one and the same situation, separated by a period of time corresponding to that during which the semen produced remains stored at the centre. Of these two moments, the former represents exclusively a condition for the application of the latter, which gives rise to the facts to which the Directive applies.

48. I therefore consider that, on the basis of the considerations set out above, the answer to the first question for a preliminary ruling must be that the relevant provisions for establishing whether the certification needed for the admission to intra-Community trade of the semen of If de Focant can be issued are those of Directive 88/407, in the version amended by Directive 93/60.

The second question

49. By its second question, the national court asks the Court of Justice whether the transitional rules set out in Directive 88/407, which excludes from its scope semen produced prior to 1 January 1990, can be extended by analogy to Directive 93/60, excluding semen collected prior to 1 July 1994 from the application of the amendments introduced by it. This, I recall, is the date by which the States had to comply with the abovementioned directive.

50. The answer to this question should be in the negative. The preconditions for an analogous application such as that envisaged by the national court are entirely lacking. It must be considered that recourse to application by analogy presupposes some lacuna in the legislative provision and is aimed at remedying this by applying provisions relating to similar cases. The requirement for recourse to application by analogy is therefore a lacuna in the system.

In the present case, however, there was no lacuna. The absence of any transitional provisions in Directive 93/60 corresponding to those contained in Directive 88/407 constitutes a choice on the part of the legislature aimed at enabling the more recent legislation to produce its effects immediately and thus to ensure a more effective protection of human health.

The third question

51. Finally, by means of the third question, the national court essentially asks whether the absence of transitional provisions renders Directive 93/60 invalid on account of infringement of the principle of protection of legitimate expectations and of the principle of proportionality.

52. As regards the alleged infringement of the principle of protection of legitimate expectations, it need merely be observed, bearing in mind the observations made earlier concerning the first question, that the Court has on several occasions affirmed that '(...) while the principle of the protection of legitimate expectations is one of the fundamental principles of the Community, it is settled case-law that this principle cannot be extended to the point of generally preventing new rules from applying to the future consequences of situations which arose under the earlier rules'. [19]

53. This should be understood as meaning that there is no legitimate expectation to safeguard in such circumstances because the situation regulated is still developing and thus has not yet given rise to subjective situations deserving of protection. [20]

54. I should also like to add that the existence of legitimate expectations on the part of KVS as regards the marketing of the semen of If de Focant cannot in any case be validly invoked. As stated earlier, [21] the question had already been raised at the time when the bull was admitted to the collection centre whether it did or did not meet all the requirements under the legislation in force. In importing the bull, therefore, KVS would have had to have been at least aware of the fact that the animal had

19 — *Butterfly Music* cited above, paragraph 25. See also Case 278/84 *Germany* v *Commission* [1987] ECR 1, paragraph 36, Case 203/86 *Spain* v *Council* [1988] ECR 4563, paragraph 19, and Case C-221/88 *Busseni* [1990] ECR I-495, paragraph 35.

20 — See in this context the Opinion of Advocate General Capotorti delivered on 24 January 1978 in Case 96/77 *Bauche* [1978] ECR 402, point 8.

21 — See points 14 to 17 of this Opinion.

been born in a herd which, from the health-status point of view, was at the limit of legality and that, accordingly, even a minimal restrictive amendment to the provisions would certainly have made its semen no longer marketable.

55. As regards, moreover, the alleged infringement of the principle of proportionality, it seems to me that, in the case before us, the judgment in *United Kingdom* v *Commission*, delivered in 1998, assumes a particular importance.[22] In that case the United Kingdom had asked the Court of Justice to annul the decision by which the Commission transitionally prohibited exports of bovine meat and derived products from the territory of the United Kingdom. The intention was to deal with the epidemic of bovine spongiform encephalopathy ('mad cow' disease) which had broken out in the United Kingdom in 1996. In that judgment, the Court affirmed that '(...) the principle of proportionality, which is one of the general principles of Community law, requires that measures adopted by Community institutions do not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by the legislation in question; when there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (...).' It further affirmed that 'with regard to judicial review of compliance with the abovementioned conditions, in matters concerning the common agricultural policy the Community legislature has a discretionary power which corresponds to the political responsibilities given to it by Articles 39 and 40 of the Treaty [which respectively became Article 33 EC and, after amendment, Article 34 EC]' and that 'consequently, the legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate having regard to the objective which the competent institution is seeking to pursue (...)'. It also added that "at the time when the contested decision was adopted, there was great uncertainty as to the risks posed by live animals, bovine meat and derived products" and that 'where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent'.[23]

56. In my opinion, the judgment just cited provides an unambiguous reply to the question we are dealing with. The most interesting point to emerge from that judgment is the fact that scientific uncertainty, combined with the existence of a serious risk to human health, is acknowledged to be of decisive importance as a justification for particularly drastic legislative intervention.[24]

57. Such a justification may also be put forward in the case before us today. It has already been pointed out[25] that great

22 — Judgment of 5 May 1998 in Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265. See also the judgment delivered on the same date in Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211.

23 — *United Kingdom* v *Commission*, cited, paragraphs 96 to 99.

24 — See, also to this affect, the order in Case T-76/96 R *National Farmer's Union* [1996] ECR II-815, paragraph 88, and Case T-199/96 *Bergaderm* [1998] ECR II-2805, paragraphs 64 to 67.

25 — See point 33 of this Opinion.

uncertainty surrounds the campaign against brucellosis, particularly as regards the means whereby infected animals are to be identified. Bearing in mind, then, the risks associated with the possible transmission of the disease to man, the legislature's choice not to provide for a transitional regime in Directive 93/60 — thereby making the new and more restrictive conditions governing the admission of bulls into semen collection centres immediately and generally operative — cannot be regarded as disproportionate in relation to the objective of those amendments, which is to protect human health.

58. As regards the third question, I therefore consider that the absence of transitional measures in Directive 93/60/EEC does not render that directive invalid for infringement of the principle of the protection of legitimate expectations or the principle of proportionality.

Conclusion

59. In light of the foregoing considerations, I suggest that the Court answer the fourth question from the College van Beroep voor het Bedrijfsleven as follows:

(1) Article 1(8) of Directive 93/60/EEC which amended the second sentence of paragraph 1(b) of Chapter I of Annex B to Directive 88/407/EEC ('The animals may not previously have been kept in other herds of a lower status') to read 'The animals may not previously have been kept in one or more herds

of a lower status' must be construed as relating to prior keeping in any herd, including the last herd they belonged to.

Should the Court decide on an answer contrary to that suggested, I propose that the replies to the first, second and third questions respectively should be as follows:

(2) Article 3(b) of Directive 88/407/EEC must be construed as meaning that semen from a bull which had been admitted to an approved semen collection centre before the adoption of amending Directive 93/60/EEC on the ground that it satisfied the admission requirements in force at that time no longer satisfies the condition set out in Article 3(b) of the directive where the animal in question fails, at the time when certification of the semen is applied for, to satisfy the amended requirement governing admission to a semen collection centre as laid down in paragraph 1(b) of Chapter I of Annex B to Directive 88/407/EEC.

(3) The transitional rules set out in Article 20 of Directive 88/407/EEC cannot be construed as meaning that they are applicable by analogy to semen which was collected and processed prior to 1 July 1994.

(4) Directive 93/60/EEC is valid inasmuch as it is not incompatible with the general principles of law, in particular the principle of the protection of legitimate expectations and the principle of proportionality.