JUDGMENT OF THE COURT (Third Chamber)

15 June 2006 *

In Case C-28/05,

REFERENCE for a preliminary ruling under Article 234 EC from the College van Beroep voor het bedrijfsleven (Netherlands), made by decision of 18 January 2005, received at the Court on 28 January 2005, in the proceedings

G.J. Dokter,

Maatschap Van den Top,

W. Boekhout

v

Minister van Landbouw, Natuur en Voedselkwaliteit,

THE COURT (Third Chamber),

composed of A. Rosas, President of the Chamber, J. Malenovský (Rapporteur), A. Borg Barthet, U. Lõhmus and A. Ó Caoimh, Judges,

* Language of the case: Dutch.

Advocate General: M. Poiares Maduro,
Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 8 December 2005,

after considering the observations submitted on behalf of:

— G.J. Dokter, by N.W.A. Tollenaar, advocaat,

— the Netherlands Government, by H. Sevenster and C. ten Dam, acting as Agents,

— the Commission of the European Communities, by T. van Rijn, F. Erlbacher and M. van Heezik, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 19 January 2006,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Council Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease (OJ 1985 L 315, p. 11), as amended by Council Directive 90/423/EEC of 26 June 1990 (OJ 1990 L 224, p. 13) ('Directive 85/511').

2 The reference was made in the context of proceedings between G.J. Dokter, Maatschap Van den Top and W. Boekhout ('the claimants in the main proceedings') and the Minister van Landbouw, Natuur en Voedselkwaliteit (Minister for Agriculture, Nature and Food Quality) concerning the slaughter of animals belonging to the claimants in the main proceedings.

Legal framework

3 Points (c) to (e) of the second paragraph of Article 2 of Directive 85/511 contain the following definitions:

'(c) "infected animal" means any animal of a susceptible species:

— in which clinical symptoms or post-mortem lesions which may arise from foot-and-mouth disease have been ascertained,

or

in which the presence of foot-and-mouth disease has been officially ascertained following a laboratory examination;

(d) "animal suspected of being infected" means any animal of a susceptible species showing clinical symptoms or post-mortem lesions which are such that the presence of foot-and-mouth disease may reasonably be suspected;

(e) "animal suspected of being contaminated" means any animal of a [susceptible] species which may — according to the epizootiological information collected — have been directly or indirectly exposed to the foot-and-mouth virus.'

4 According to Article 4(1) of that directive:

'Member States shall ensure that, where a holding contains one or more animals suspected of being infected or of being contaminated with foot-and-mouth disease, official means of investigation to confirm or rule out the presence of the disease are set in motion immediately and, in particular, that the official veterinarian takes the necessary samples, or has them taken, for laboratory examination.

...'

5 According to Article 5 of the directive, 'As soon as it has been confirmed that one or more of the animals defined in Article 2(c) are on a holding', the competent authority is to introduce the measures provided for in Article 5, including that all animals of susceptible species on the holding are to be slaughtered on the spot under official supervision in such a way as to avoid all risk of spreading the foot-and-mouth virus.

6 Article 11(1) of the directive provides:

'Member States shall ensure that:

— laboratory testing to detect the presence of foot-and-mouth disease is carried out by a national laboratory indicated in Annex B, which may be amended or

supplemented in accordance with the procedure laid down in Article 17. This laboratory testing should, if necessary and especially on the first appearance of the disease, show the type, subtype or, where appropriate, the variant of the relevant virus which may be confirmed, if necessary, by a reference laboratory designated by the Community;

...'

7 According to Article 13(1) and (2) of the directive:

'1. Member States shall ensure that:

— ...

— the manipulation of foot-and-mouth virus for research, diagnosis and/or manufacture of vaccines shall be carried out only in approved establishments and laboratories listed in Annexes A and B;

— ...

— the establishments and laboratories referred to in the second indent shall be approved only if they fulfil the minimum standards recommended by the [Food and Agriculture Organisation] FAO for laboratories working on foot-and-mouth viruses *in vitro* and *in vivo*.

2. Veterinary experts from the Commission, in collaboration with the competent authorities of the Member States, shall carry out spot-checks to ascertain whether the security systems applied in the establishments and laboratories referred to in Annexes A and B comply with the FAO's minimum standards.

The Commission shall carry out these checks at least once a year ...

...'

8 Annex B to Directive 85/511, entitled 'National laboratories dealing with foot-and-mouth disease', under the heading 'Netherlands', refers to the 'Centraal Diergeneeskundig Instituut, Lelystad'.

9 The list of laboratories in that annex is regularly updated, pursuant to the second subparagraph of Article 13(2) of Directive 85/511, according to a comitology procedure provided for in Article 17 of that directive. In that procedure, the Commission submits a draft of the measures to be adopted to the Standing Veterinary Committee composed of representatives of the Member States and, where necessary, to the Council of the European Union.

10 According to the third recital in the preamble to Directive 90/423:

'... [in] a Commission study ... it has been concluded that a risk exists in the manipulation of virus in laboratories due to the possibility of escape to local

susceptible animals and in the use of vaccine if inactivation procedures do not ensure its safety[.]'

11 Article 10(1) of Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (OJ 1990 L 224, p. 29) states:

'Each Member State shall immediately notify the other Member States and the Commission of any outbreak in its territory, in addition to an outbreak of diseases referred to in [Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community (OJ 1982 L 378, p. 58)] of any zoonoses, diseases or other cause likely to constitute a serious hazard to animals or to human health.

The Member State of dispatch shall immediately implement the control or precautionary measures provided for in Community rules, in particular the determination of the buffer zones provided for in those rules, or adopt any other measure which it deems appropriate.

...'

12 According to the fourth recital in the preamble to Commission Decision 2001/246/EC of 27 March 2001 laying down the conditions for the control and eradication of foot-

and-mouth disease in the Netherlands in application of Article 13 of Directive 85/511/EEC (OJ 2001 L 88, p. 21):

'In addition to the measures within the framework of Directive 85/511/EEC, the Netherlands apply as a precautionary measure the pre-emptive killing of susceptible animals in holdings situated in close proximity to infected or suspect holdings, taking into account the epidemiological situation and the high density of susceptible animals in certain parts of the territory.'

13 According to Article 1 of that decision:

'For the purpose of this Decision the following definitions shall apply:

1. "Pre-emptive killing" shall mean the killing of susceptible animals on holdings within a certain radius around holdings placed under the restrictions laid down in Article 4 or 5 of Directive 85/511/EEC.

...

2. "Suppressive vaccination" shall mean emergency vaccination of animals of susceptible species in identified holdings situated in a defined area, the vaccination zone, which is carried out exclusively in conjunction with pre-emptive killing as defined in paragraph 1.

...'

14 According to Article 2(1) of that decision:

'Without prejudice to Directive 85/511/EEC, and in particular Articles 4, 5 and 9 thereof, the Netherlands may decide on resorting to suppressive vaccination under the conditions set out in the Annex.'

15 That annex states inter alia that the 'extent of the geographical area in which suppressive vaccination is to be carried out' corresponds to an area of up to two kilometres' radius around a holding placed under the restrictions laid down in Article 4 or 5 of Directive 85/511. Moreover, the vaccination zone must be situated in the parts of the territory of the Netherlands included in Annex I to Commission Decision 2001/223/EC of 21 March 2001 concerning certain protection measures with regard to foot-and-mouth disease in the Netherlands (OJ 2001 L 82, p. 29), that is, the provinces of Gelderland, Overijssel, Flevoland and Noord-Brabant.

The main proceedings and the questions referred for a preliminary ruling

16 The Netherlands authorities were informed of a suspicion of foot-and-mouth disease in the Teunissen holding, which is situated less than two kilometres from the holdings of the claimants in the main proceedings, and on 20 and 22 March 2001 a team of specialists from the Rijksdienst voor de keuring van Vee en Vlees (national cattle and meat inspection service) ('the RVV') carried out an inspection of that holding, during which several samples were collected and sent for analysis to the laboratory ID-Lelystad BV ('ID-Lelystad'). That team also carried out clinical examinations, slaughtered 14 animals and, on 27 March 2001, evacuated the holding.

17 On 28 March 2001, ID-Lelystad sent the RVV a fax in which it stated that the samples from the Teunissen holding were positive.

18 Consequently, the Director of the RVV declared the Teunissen holding to be contaminated and, by decisions of 29 March 2001, informed the claimants in the main proceedings that all biungulate animals on their holdings had to be considered as suspected of being contaminated on the ground that a case of foot-and-mouth disease had been found nearby. Following those decisions, and following an unsuccessful application for interim measures brought by those claimants, measures to control the virus on their holdings were implemented, namely, first, the vaccination of the animals and, second, the slaughter of those animals.

19 The claimants in the main proceedings lodged complaints against those decisions with the Director of the RVV, who rejected them. They then brought an action against those rejection decisions before the national court.

20 They claimed, first, that the Director of the RVV could not base the decisions of 29 March 2001 solely on the content of the fax sent by ID-Lelystad which stated the results of the laboratory tests. He should have requested the file from the laboratory, studied it and checked whether that laboratory had carried out the tests correctly. Next, in basing the decisions of 29 March 2001 on the analysis done by ID-Lelystad, the Director infringed Directive 85/511, because ID-Lelystad is not included in Annex B to that directive and is therefore not a laboratory for the purposes of the first indent of Article 11(1) and the second indent of Article 13(1) of that directive. That annex refers to the Centraal Diergeneeskundig Instituut, Lelystad ('CDI'), which is separate from ID-Lelystad, whose name and legal status are different.

21 The Director of the RVV, for his part, maintained that he was bound by the laboratory results and that he could not check their accuracy. He therefore had no discretion regarding the finding of the foot-and-mouth disease at the holding in question. Consequently, he was required to take the measures to control the disease as soon as the presence of the virus had been confirmed by the laboratory. He then found it appropriate to interpret Annex B to Directive 85/511 as meaning that it also included ID-Lelystad. The transformation from CDI to ID-Lelystad was due to a mere change in legal status. It had been the same laboratory as of 1995, established at the same address, with the same equipment and carrying out the same tasks.

22 In those circumstances, the College van Beroep voor het bedrijfsleven (Administrative Court for Trade and Industry) decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Does the obligation on Member States under the first indent of Article 11(1) read in conjunction with the second indent of Article 13(1) of Directive 85/511 to ensure that laboratory testing to detect the presence of [foot-and-mouth disease] is carried out by a laboratory listed in Annex B to Directive 85/511 have direct effect?

(2) (a) Must Article 11(1) of Directive 85/511 be interpreted as meaning that legal consequences must be attached to the fact that the presence of foot-and-mouth disease is found by a laboratory which is not listed in Annex B to Directive 85/511?

(b) If the answer to Question 2(a) is in the affirmative:

Is the purpose of Article 11(1) of Directive 85/511 to protect the interests of individuals, such as [the claimants] in the main proceedings? If not, can

individuals, such as [the claimants] in the main proceedings, plead possible failure to fulfil the obligations which this provision places on the authorities of the Member States?

(c) If the answer to Question 2(b) means that individuals can rely on Article 11(1) of Directive 85/511:

What legal consequences must be attached to a finding of the presence of [foot-and-mouth disease] by a laboratory which is not listed in Annex B to Directive 85/511?

(3) Must Annex B to Directive 85/511 be interpreted, having regard to Articles 11 and 13 thereof, as meaning that the mention in Annex B to Directive 85/511 of "Centraal Diergeneeskundig Instituut, Lelystad" can or must refer also to ID-Lelystad BV?

(4) If it follows from the answers to the above questions that the presence of [foot-and-mouth disease] can be found by a laboratory which is not listed in Annex B to Directive 85/511 or that Annex B to Directive 85/511 must be interpreted as meaning that the mention of the "Centraal Diergeneeskundig Instituut, Lelystad" can or must refer also to ID-Lelystad BV:

Must Directive 85/511 be interpreted as providing that the national administrative authority authorised to adopt decisions is bound by the outcome of an examination by a laboratory which is listed in Annex B to Directive 85/511 or — if the answer to Question 2(a) means that the administrative authority may base its foot-and-mouth disease control measures also on results obtained by a laboratory which is not listed in Annex B to Directive 85/511 — by the results of

the latter laboratory, or does the determination of final authority in that regard fall within the procedural autonomy of the Member State and must the court before which the main proceedings are pending examine whether the rules in that respect apply irrespective of whether the laboratory examination is carried out by virtue of a Community or national legal obligation and of whether or not the application of the provisions of national procedural law renders the implementation of the Community rules extremely difficult or practically impossible?

(5) If the answer to Question 4 means that the issue of whether national authorities are bound by the laboratory result is governed by Directive 85/511:

Are the national authorities bound unconditionally by the result of a foot-and-mouth disease examination carried out by a laboratory? If not, what margin of discretion does Directive 85/511 leave these national authorities?'

The questions

The first, second and third questions

23 By those questions, which should be considered together, the national court asks essentially, first, what changes to the particulars of a laboratory included in Annex B to Directive 85/511, not made in accordance with the procedure provided for in Article 17 of that directive, lead to that laboratory's losing its status as a laboratory included in that annex and, second, whether the competent national authority may base measures to control foot-and-mouth disease on the results of tests carried out

by a laboratory which does not have that status. Next, the national court asks whether that directive precludes a Member State from taking, in circumstances such as those at issue in the main proceedings, measures to control foot-and-mouth disease on the basis of results from a laboratory which is not included in that annex, whether individuals could then rely on infringement of the rules in Directive 85/511 before the national court, and whether that infringement would have legal consequences.

24 The Court notes, as a preliminary point, that on 27 March 2001, that is, two days before the contested national decisions, the Commission adopted Decision 2001/246, based on Article 10 of Directive 90/425 and Article 13(3) of Directive 85/511. By that decision the Commission authorised the suppressive vaccination and pre-emptive killing of animals, the latter measure designating, according to Article 1 of that decision, the killing of susceptible animals on holdings within a certain radius around holdings placed under the restrictions laid down in Article 4 or Article 5 of Directive 85/511. According to the fourth recital in the preamble to that decision, the Kingdom of the Netherlands had, in addition to the measures within the framework of Directive 85/511, begun, as a precautionary measure, the pre-emptive killing of susceptible animals on holdings situated in close proximity to 'infected or suspect' holdings (see Joined Cases C-96/03 and C-97/03 *Tempelman and van Schaijk* [2005] ECR I-1895, paragraphs 37 and 38).

25 Under Decision 2001/246, read together with Article 10 of Directive 90/425 and Articles 4 and 2(d) and (e) of Directive 85/511, the competent Netherlands authorities were empowered to proceed, once a suppressive vaccination had been carried out, to the killing of susceptible animals on holdings situated within a radius of two kilometres around a holding where there was either an animal suspected of being infected, that is, an animal showing clinical symptoms or post-mortem lesions which were such that the presence of foot-and-mouth disease could reasonably be suspected, or an animal suspected of being contaminated, that is, an animal which might, according to the epizootiological information collected, have been directly or indirectly exposed to the foot-and-mouth virus.

26 Decision 2001/246 does not require such information concerning the holding where there is an animal suspected of being infected or contaminated to be based solely on the results from the laboratories included in Annex B to Directive 85/511. Thus, the fact that that information has been provided by a laboratory which does not have that status does not affect the compatibility of those measures with Community law.

27 Moreover, in paragraph 40 of the judgment in *Tempelman and van Schaijk*, the Court found that Directive 85/511 cannot be interpreted as meaning that the measures which it lays down could not be supplemented by Community or national measures adopted on the basis of Directive 90/425. Decision 2001/246 constitutes a Community measure based, inter alia, on Article 10 of Directive 90/425.

28 It is for the national court to assess, in the light of the facts described in paragraph 16 of this judgment, whether the national authorities took the measures at issue in the main proceedings in accordance with the conditions laid down in Decision 2001/246. If so, it follows from the foregoing that the claimants in the main proceedings may not rely on infringement of Articles 11(1) and 13(1) of Directive 85/511, and that Community law does not preclude those measures.

29 It is still necessary to determine whether those claimants could rely on those provisions in the event that the decision by the Netherlands authorities to declare the biungulate animals on their holdings as being suspected of being contaminated on the ground that a case of foot-and-mouth disease had been found on the Teunissen holding and to order the slaughter of all those animals could not be based on Decision 2001/246.

30 According to the first indent of Article 11(1) and the second indent of Article 13(1) of Directive 85/511, Member States are required to ensure that the manipulation of foot-and-mouth virus for diagnosis is carried out only in approved laboratories listed in Annex B to that directive.

31 The only information listed in that annex for the purpose of identifying those laboratories is, in principle, their name and location, in the case of the Netherlands, 'Centraal Diergeneeskundig Instituut' and 'Lelystad'. That directive, moreover, provides in Article 17 for a single procedure for all changes to that information.

32 That procedure, and the abovementioned Articles 11 and 13, exists because, as also stated in the third recital in the preamble to Directive 90/423, there is an inherent risk in the manipulation of the foot-and-mouth virus in laboratories, given the possibility of contaminating local susceptible animals. This finding is, moreover, supported by the first recital in the preamble to Commission Decision 2003/11/EC of 10 January 2003 amending Council Directive 85/511/EEC as regards the lists of laboratories authorised to handle live foot-and-mouth disease virus (OJ 2003 L 7, p. 82), according to which '[t]he cessation of routine vaccination against foot-and-mouth disease virus in the Community in 1991 has increased the susceptibility of Community herds to this disease. It is therefore essential to ensure that laboratories which handle the virus do so under secure conditions, to avoid the dissemination of the virus which might endanger the Community herds'.

33 Thus, the diagnosis of the disease must be done by responsible laboratories, it being understood that their reliability is to be assessed before their inclusion in that annex and, where necessary, when changes concerning them are entered.

34 This requirement of registration for laboratories must nevertheless be considered in the light of the core objective of Directive 85/511, which is the effective control of foot-and-mouth disease (see *Tempelman and van Schaijk*, paragraph 35), which implies, in particular, that measures must be taken upon the first sign of the disease. The Court notes in this regard that the effectiveness of such control requires that the public authorities are able to have a diagnosis established to detect the disease in a timely manner.

35 If a failure to include in Annex B to Directive 85/511 changes concerning a laboratory listed in that annex meant every time that that laboratory would lose its status as a listed laboratory, the national authorities would be required, under the aforementioned Articles 11 and 13, not to have any more examinations carried out by that laboratory until the change in question had been entered in the list. A requirement such as that would lead to an emphasis on formalities which would be likely to prevent those authorities from having a laboratory nearby with which to detect the virus in a timely manner, which would run counter to the objective of effective control of foot-and-mouth disease.

36 Accordingly, the requirement that those changes be entered must not go beyond what is necessary to safeguard the interests it seeks to guarantee, namely the prevention of the risk of dissemination of the virus during laboratory examinations.

37 It should therefore be assessed, in each individual case, whether the changes made are likely to have repercussions on the safety of the laboratory in question such that they increase the risk of contamination of susceptible local animals. If not, there is no reason for the laboratory concerned to lose its status as a laboratory listed in Annex B to Directive 85/511, even though its particulars have been changed.

38 Such is the case, inter alia, when changes to that laboratory's name or legal status are of a purely formal nature and have no effect on its safety or reliability, particularly when its staff, premises and equipment remain essentially unchanged.

39 Contrary to what the claimants in the main proceedings have maintained, it is of no importance that, under the national rules, the laboratory is an entity legally distinct from the one included in the list in Annex B, in the light of the changes made to it.

40 In the present case, it is common ground that ID-Lelystad was created from CDI following a series of mergers and successions. The claimants in the main proceedings have claimed that ID-Lelystad cannot be equated with CDI for the purposes of application of Directive 85/511, inter alia on the grounds that they are two distinct legal entities which do not share the same legal status, that CDI, unlike ID-Lelystad, was required to divulge publicly internal documents relating to the cases dealt with and that, unlike ID-Lelystad, CDI was under the responsibility of the competent minister.

41 Although in preliminary ruling proceedings it is for the national court to establish, in the light of the considerations referred to in paragraphs 30 to 39 of this judgment, whether, despite such changes, ID-Lelystad must be regarded as being a laboratory referred to in Article 11(1) and Article 13(1) of Directive 85/511, the Court of Justice, which is called on to provide answers of use to the national court, may provide guidance based on the documents in the file and on the written and oral observations which have been submitted to it, in order to enable the national court to give judgment (see, to that effect, Case C-278/93 *Freers and Speckmann* [1996] ECR I-1165, paragraph 24, and Case C-77/02 *Steinicke* [2003] ECR I-9027, paragraph 59).

42 In that connection, it will be for the national court to take account also of the Commission's viewpoint, since the Commission is empowered, under Article 13(2) of Directive 85/511, to carry out checks from time to time on the security systems applied in the laboratories referred to in Annex B, and it likewise has a particular responsibility in the procedure provided for in Article 17 of that directive, which is in place precisely for the assessment of the reliability of a laboratory for the purposes of application of that directive.

43 Moreover, the Commission stated, both in its written observations and at the hearing, that it has never had any doubts as to the identity of the ID-Lelystad laboratory and that it has always considered the changes between CDI and ID-Lelystad to be merely formal.

44 It is, moreover, clear that, in the circumstances at issue in the main proceedings, the mere fact that the original entity became a legally distinct entity following mergers or successions does not mean that the laboratory's level of safety is now lower as regards the risk of dissemination of the virus.

45 Likewise, the Court notes that there is no link between the risk of dissemination of the virus and the obligation of a laboratory to divulge publicly the internal documents relating to cases dealt with.

46 However, as regards the fact that the laboratory is no longer under the authority of the public authorities, is no longer required to follow their instructions and thus cannot effectively be required to comply with the obligations under Directive 85/511, the Court cannot prima facie exclude the possibility of such a change having repercussions on safety as regards the risk of dissemination of the virus and, consequently, the possibility that a laboratory might lose its status as a laboratory listed in Annex B to that directive. It will be for the national court to assess, in the light of the facts of the case, whether or not such a change has had an impact on safety at the laboratory at issue in the main proceedings.

47 Should the Court find, in the light of the aforementioned considerations, that ID-Lelystad lost its status as a laboratory listed in Annex B to Directive 85/511, the national court also asks whether that directive precludes a Member State from taking, in circumstances such as those at issue in the main proceedings, measures to control foot-and-mouth disease on the basis of results of a laboratory which is not included in that annex, whether individuals could then rely on infringement of the rules in Directive 85/511 before the national court, and whether that infringement would have legal consequences.

48 In the context of the main proceedings, it should be borne in mind that Article 10(1) of Directive 90/425 confers on Member States the power to adopt measures to control foot-and-mouth disease in addition to those provided for in Directive 85/511, in particular, as in the present case, the power to order the slaughter of animals belonging to a holding adjacent to or within a specific radius of a holding containing infected animals (*Tempelman and van Schaijk*, paragraph 52).

49 However, those States may adopt those measures only in compliance with Community law, and they are thus required to respect the objectives pursued by the Community legislation in force, in particular such as those referred to in Directive 85/511 (see, to that effect, *Tempelman and van Schaijk*, paragraph 31).

50 Regarding that directive, the Court notes, first, that, according to Article 5, read together with point (c) of the second paragraph of Article 2, it is for the competent authorities to take the measures provided for in Article 5 — including the slaughter of all animals of susceptible species — on any holding where it has been confirmed that there are one or more animals of susceptible species:

— in which clinical symptoms or post-mortem lesions which may arise from foot-and-mouth disease have been ascertained; or

— in which the presence of foot-and-mouth disease has been officially ascertained following a laboratory examination.

51 Given the objective of effective control of foot-and-mouth disease, those means of diagnosis must be interpreted broadly.

52 Point (c) of the second paragraph of Article 2 uses the term 'laboratory' without providing further specification and its wording therefore does not indicate that measures may be taken only on the basis of results from a laboratory included in the list in Annex B to Directive 85/511.

53 Furthermore, the same provision requires that measures to control the disease should also be taken as soon as clinical symptoms or post-mortem lesions which 'may' arise from foot-and-mouth disease have been found in an animal. However, a finding that the virus is present based on such a method would appear, by definition, to have less evidential value than an examination done by a laboratory, even if that laboratory is not recognised by the Commission, under the procedure under Article 17 of Directive 85/511, as a laboratory authorised to manipulate the virus.

54 Next, although the competent authorities have power, under Article 10(1) of Directive 90/425, to adopt measures to control foot-and-mouth disease in addition to those provided for in Directive 85/511, their additional nature implies that those authorities may take measures analogous to those provided for in Article 5 of Directive 85/511 on the basis of the same laboratory results as those on the basis of which the latter measures were taken and, therefore, also on the basis of results from a laboratory which is not included in Annex B to Directive 85/511.

55 Lastly, the Court notes that, contrary to what the claimants in the main proceedings allege, the provisions of the first indent of Article 11(1) and the second indent of Article 13(1) of Directive 85/511 do not affect this finding.

56 It should be borne in mind that those provisions impose on the Member States the obligation to use the laboratories listed in Annex B for diagnosis, on the ground that the manipulation of the virus in other laboratories carries a risk of disseminating the virus.

57 The obligation not to use, for the purpose of taking measures to control foot-and-mouth disease, a laboratory result which was furnished previously in violation of the above obligation, and therefore at the risk of spreading the virus by the laboratory not listed in that annex, is an obligation independent of the first obligation. Although the competent authorities may infringe Directive 85/511 by not complying with that first obligation, that infringement does not affect the considerations discussed in paragraphs 50 to 54 of this judgment, in the light of which the Member States may use results from a laboratory not listed in that annex in order to take those measures.

58 In those circumstances, it is not necessary to consider whether individuals may rely before the national court, in circumstances such as those at issue in the main proceedings, on an infringement of Directive 85/511 arising from the use by the public authorities of results from a laboratory not included in that annex, and whether such an infringement has legal consequences.

59 In the light of the foregoing, the answer to the first, second and third questions must be that Directive 85/511 must be interpreted as meaning that changes to the particulars of a laboratory included in Annex B to that directive, which were not entered in accordance with the procedure provided for in Article 17 of the directive, lead to that laboratory's losing its status as a laboratory included in that annex only if those changes are likely to have repercussions on the safety of the laboratory as regards the risk of dissemination of the foot-and-mouth virus during the examinations performed by the laboratory and thus increase the risk of contamination of susceptible local animals. Moreover, Directive 85/511 does not preclude a Member State from taking the measures to control foot-and-mouth

disease provided for in Article 10(1) of Directive 90/425 on the basis of results of an examination carried out by a laboratory which is not included in Annex B to Directive 85/511.

The fourth and fifth questions

60 By those questions, which should be considered together, the national court seeks to know how far the national authority with competence to take measures to control foot-and-mouth disease is bound by the results of tests carried out by a laboratory which has the status of a laboratory listed in Annex B to Directive 85/511, and to what extent it is bound by the results provided by a laboratory which does not have that status, in particular a laboratory which has lost that status, where applicable, for the reasons given in paragraph 46 above.

61 First, it is appropriate to consider the case where the results have been provided by a laboratory which has that status.

62 Article 5 of Directive 85/511 states that the competent national authorities are required to take immediately the measures provided for in that provision as soon as it has been confirmed that there are on a holding one or more animals in which the presence of foot-and-mouth disease has been officially ascertained following a laboratory examination.

63 Furthermore, other provisions, such as Article 2 of Decision 2001/246 and Article 10(1) of Directive 90/425, empower those authorities to take additional measures.

64 Next, it must be borne in mind that the control of foot-and-mouth disease requires that appropriate measures be taken promptly and effectively.

65 To that end, Article 13 in particular of Directive 85/511 subjects the laboratories listed in Annex B to strict requirements concerning their security systems and checks from time to time by veterinary experts from the Commission and by the competent authorities of the Member States. It follows that the organisation of the examinations carried out by those laboratories is likely to offer guarantees such that the authority responsible for the control of foot-and-mouth disease can, in principle, rely on their results.

66 In the light of the foregoing, it must be concluded that the competent authority is required to follow up those results and to adopt, in principle, the measures provided for in Directive 85/511 or any other appropriate measure, given the necessity to control foot-and-mouth disease promptly and effectively.

67 It is only if the competent authority has evidence casting serious doubt on the reliability of the results from those laboratories that it may refrain from taking those measures immediately. In such a case, it may inter alia obtain another diagnosis to confirm or contradict those results.

68 Second, the case where the results have been provided by a laboratory which does not have the status of a laboratory listed in Annex B to Directive 85/511 should be considered.

69 It follows from paragraph 54 above that the competent authority may not refrain from taking appropriate measures solely on the ground that the presence of foot-and-mouth disease on a holding has been ascertained by a laboratory which does not have the status of a laboratory listed in Annex B to Directive 85/511.

70 Given the highly contagious nature of foot-and-mouth disease and the need to control it promptly and effectively, the competent authority is required to take account of the results provided by such a laboratory in order to adopt, where necessary, the appropriate measures provided for by Community legislation. However, as that laboratory no longer necessarily offers the same guarantees of reliability as a laboratory having the status of a laboratory listed in Annex B to Directive 85/511, the competent authority must, before taking appropriate measures, make sure that the results are reliable.

71 Next, it is clear in this context that, in any event, irrespective of whether the results of the examinations have been provided by a laboratory which has the status of a laboratory listed in Annex B to Directive 85/511, the competent authority may adopt those measures only in compliance with the general principles of Community law, including in particular the principle of proportionality and fundamental rights (see, to that effect, *Tempelman and van Schaijk*, paragraph 31).

72 In that connection, it should be borne in mind that, according to settled case-law, the principle of proportionality requires that measures implemented through Community provisions should be appropriate for attaining the objective pursued and must not go beyond what is necessary to achieve it (Case C-434/02 *Arnold André* [2004] ECR I-11825, paragraph 45; Case C-210/03 *Swedish Match* [2004] ECR I-11893, paragraph 47; and Joined Cases C-453/03, C-11/04, C-12/04 and C-194/04 *ABNA and Others* [2005] ECR I-10423, paragraph 68).

73 Regarding the safeguarding of fundamental rights, the claimants in the main proceedings submit in particular that the national authorities took the measures at issue in the main proceedings in violation of the principle of respect for the rights of the defence.

74 It is equally settled case-law that respect for the rights of the defence is, in all proceedings initiated against a person which are liable to culminate in a measure adversely affecting that person, a fundamental principle of Community law which must be guaranteed even in the absence of any rules governing the proceedings in question. That principle requires that the addressees of decisions which significantly affect their interests should be placed in a position in which they may effectively make known their views on the evidence on which the contested decision is based (see, inter alia, Case C-32/95 P *Commission* v *Lisrestal and Others* [1996] ECR I-5373, paragraph 21; Case C-462/98 P *Mediocurso* v *Commission* [2000] ECR I-7183, paragraph 36; and Case C-287/02 *Spain* v *Commission* [2005] ECR I-5093, paragraph 37). Given the important consequences for breeders flowing from decisions taken on the basis of Article 5 of Directive 85/511, Article 2 of Decision 2001/246 and Article 10(1) of Directive 90/425, that principle requires, in connection with the control of foot-and-mouth disease, that the addressees of such decisions be, in principle, placed in a position in which they may effectively make known their views on the evidence on which the contested measure is based.

75 It should, however, be borne in mind that fundamental rights, such as respect for the rights of the defence, do not constitute unfettered prerogatives and may be restricted, provided that the restrictions in fact correspond to objectives of general interest pursued by the measure in question and that they do not constitute, with regard to the objectives pursued, a disproportionate and intolerable interference which infringes upon the very substance of the rights guaranteed. Objectives which may justify such restrictions include the protection of public health (see, to that effect, Case C-62/90 *Commission* v *Germany* [1992] ECR I-2575, paragraph 23, and Case C-44/94 *Fishermen's Organisations and Others* [1995] ECR I-3115, paragraph 55).

76 In that context, it must be concluded that, if the competent authority were not able to take measures against foot-and-mouth disease unless all potentially concerned parties had previously been given the opportunity to familiarise themselves with the facts and documents on which those measures are based and had expressed a view on those facts and documents, that authority could be prevented from acting promptly and effectively. Accordingly, the protection of public health justifies, in

principle, that that authority adopts those measures, even without first obtaining the views of interested parties on the elements on which the measures are based. Such a restriction would, moreover, be a disproportionate and intolerable intervention infringing upon the very substance of the rights of the defence only if the interested parties were given no opportunity to contest those measures in subsequent proceedings and to make their views known effectively at that stage.

77 Moreover, given the imperative need to act promptly against foot-and-mouth disease, the principle of respect for the rights of the defence does not necessarily require that the implementation of those measures be postponed until those proceedings have come to an end.

78 Lastly, if it should emerge in such proceedings that the authority responsible for control of foot-and-mouth disease could take the measures provided for in Directives 85/511 and 90/425 or Decision 2001/246 solely on the basis of the results from the laboratory as communicated to it by fax, the principle of respect for the rights of the defence does not preclude the court ruling in those proceedings from basing its decision on that document alone, provided that the parties have been given a proper opportunity to put forth their views.

79 In the light of the foregoing, the answer to the fourth and fifth questions must be that the competent authority is required to follow up the results of examinations provided by a laboratory which has the status of a laboratory listed in Annex B to Directive 85/511 and to adopt, in principle, the measures provided for in that directive or any other measure required, given the need to control foot-and-mouth disease promptly and effectively. The competent authority is required to take into consideration even results provided by a laboratory which does not have that status in order to adopt, where necessary, the appropriate measures provided for by Community legislation. However, as that laboratory no longer necessarily offers the same guarantees of reliability as a laboratory having the status of a laboratory listed

in Annex B, the competent authority must make sure, before taking the appropriate measures, that those results are reliable. In any event, the authority may adopt measures to control foot-and-mouth disease only in compliance with the general principles of Community law, including in particular the principle of proportionality and fundamental rights.

Costs

80 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Third Chamber) hereby rules:

1. **Council Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease, as amended by Council Directive 90/423/EEC of 26 June 1990, must be interpreted as meaning that changes to the particulars of a laboratory included in Annex B to that directive, which were not entered in accordance with the procedure provided for in Article 17 of the directive, lead to that laboratory's losing its status as a laboratory included in that annex only if those changes are likely to have repercussions on the safety of the laboratory as regards the risk of dissemination of the foot-and-mouth virus during the examinations performed by the laboratory and thus increase the risk of contamination of susceptible local animals. Moreover, Directive 85/511 does not preclude a Member State from taking the measures to control foot-and-mouth disease provided for in Article 10(1) of Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and**

zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market on the basis of results of an examination carried out by a laboratory which is not included in Annex B to Directive 85/511.

2. The competent authority is required to follow up the results of examinations provided by a laboratory which has the status of a laboratory listed in Annex B to Directive 85/511 and to adopt, in principle, the measures provided for in that directive or any other measure required, given the need to control foot-and-mouth disease promptly and effectively. The competent authority is required to take into consideration even results provided by a laboratory which does not have that status in order to adopt, where necessary, the appropriate measures provided for by Community legislation. However, as that laboratory no longer necessarily offers the same guarantees of reliability as a laboratory having the status of a laboratory listed in Annex B, the competent authority must make sure, before taking the appropriate measures, that those results are reliable. In any event, the authority may adopt measures to control foot-and-mouth disease only in compliance with the general principles of Community law, including in particular the principle of proportionality and fundamental rights.

[Signatures]