

JUDGMENT OF THE COURT (Fourth Chamber)

29 April 2015 (\*)

(Reference for a preliminary ruling — Public health — Directive 2004/33/EC — Technical requirements relating to blood and blood components — Blood donation — Eligibility criteria for blood donors — Criteria for permanent or temporary deferral — Persons whose sexual behaviour puts them at a high risk of acquiring severe infectious diseases that can be transmitted by blood — Man who has had sexual relations with another man — Charter of Fundamental Rights of the European Union — Articles 21(1) and 52(1) — Sexual orientation — Discrimination — Justification — Proportionality)

In Case C-528/13,

REQUEST for a preliminary ruling under Article 267 TFEU from the Tribunal administratif, Strasbourg (France), made by decision of 1 October 2013, received at the Court on 8 October 2013, in the proceedings

**Geoffrey Léger**

v

**Ministre des Affaires sociales, de la Santé et des Droits des femmes,**

**Établissement français du sang,**

THE COURT (Fourth Chamber),

composed of L. Bay Larsen, President of the Chamber, K. Jürimäe, J. Malenovský, M. Safjan (Rapporteur) and A. Prechal, Judges,

Advocate General: P. Mengozzi,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

- the French Government, by D. Colas and F. Gloaguen, acting as Agents,
- the European Commission, by C. Gheorghiu and M. Owsiany-Hornung, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 17 July 2014,

gives the following

**Judgment**

1 This request for a preliminary ruling concerns the interpretation of point 2.1 of Annex III to Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components (OJ 2004 L 91, p. 25).

2 The request has been made in proceedings between Mr Léger and the *Ministre des Affaires sociales, de la Santé et des Droits des femme* (Minister for Social Affairs, Health and Women's Rights) and the *Établissement français du sang* (French Blood Agency) concerning the refusal to accept Mr Léger's blood donation on the ground that he had had sexual relations with another man.

### **Legal context**

#### *EU law*

#### Directive 2002/98/EC

3 Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ 2003 L 33, p. 30), is based on Article 152(4)(a) EC.

4 Recitals 1, 2, 24 and 29 in the preamble to Directive 2002/98 state:

‘(1) The extent to which human blood is used therapeutically demands that the quality and safety of whole blood and blood components be ensured in order to prevent in particular the transmission of diseases.

(2) The availability of blood and blood components used for therapeutic purposes is dependent largely on Community citizens who are prepared to donate. In order to safeguard public health and to prevent the transmission of infectious diseases, all precautionary measures during their collection, processing, distribution and use need to be taken making appropriate use of scientific progress in the detection and inactivation and elimination of transfusion transmissible pathogenic agents.

...

(24) Blood and blood components used for therapeutic purposes or for use in medical devices should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation and that any risk of transmission of infectious diseases is minimised; each and every blood donation should be tested in accordance with rules which provide assurances that all necessary measures have been taken to safeguard the health of individuals who are the recipients of blood and blood components.

...

(29) Tests should be carried out in conformity with the latest scientific and technical procedures that reflect current best practice as defined by, and regularly

reviewed and updated through, an appropriate expert consultation process. This review process should also take due account of scientific advances in the detection, inactivation and elimination of pathogens which can be transmitted via transfusion.’

5 Article 1 of that directive provides:

‘This Directive lays down standards of quality and safety of human blood and of blood components, in order to ensure a high level of human health protection.’

6 According to Article 2(1) of that directive:

‘This Directive shall apply to the collection and testing of human blood and blood components, whatever their intended purpose, and to their processing, storage, and distribution when intended for transfusion.’

7 Article 18 of Directive 2002/98, entitled ‘Eligibility of donors’ provides:

‘1. Blood establishments shall ensure that there are evaluation procedures in place for all donors of blood and blood components and that the criteria for donation referred to in Article 29(d) are met.

2. The results of the donor evaluation and testing procedures shall be documented and any relevant abnormal findings shall be reported to the donor.’

8 Article 19 of that directive, entitled ‘Examination of donors’, states:

‘An examination of the donor, including an interview, shall be carried out before any donation of blood or blood components. A qualified health professional shall be responsible, in particular, for giving to and gathering from donors the information which is necessary to assess their eligibility to donate and shall, on the basis thereof, assess the eligibility of donors.’

9 Article 20(1) of that directive, entitled ‘Voluntary and unpaid blood donation’, provides:

‘Member States shall take the necessary measures to encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are in so far as possible provided from such donations.’

10 Article 21 of Directive 2002/98, headed ‘Testing of donations’, provides:

‘Blood establishments shall ensure that each donation of blood and blood components is tested in conformity with requirements listed in Annex IV.

Member States shall ensure that blood and blood components imported into the Community are tested in conformity with requirements listed in Annex IV.’

11 Article 29, second paragraph, (d) of that directive is worded as follows:

‘The following technical requirements and their adaptation to technical and scientific progress shall be decided in accordance with the procedure referred to in Article 28(2):

...

d) requirements concerning the suitability of blood and plasma donors and the screening of donated blood including:

- permanent deferral criteria and possible exemption thereto,
- temporary deferral criteria’.

12 Pursuant to Annex IV of that directive, headed ‘Basic testing requirements for whole blood and plasma donations’:

‘The following tests must be performed for whole blood and apheresis donations, including autologous predeposit donations:

...

- testing for the following infections in the donors:
- Hepatitis B (HBs-Ag),
- Hepatitis C (Anti-HCV),
- HIV 1/2 (Anti-HIV 1/2),

Additional tests may be required for specific components or donors or epidemiological situations.’

Directive 2004/33

13 Directive 3 of Directive 2004/33, entitled ‘Information required from donors’, states:

‘Member States shall ensure that upon agreement of willingness to commence the donation of blood or blood components, donors provide the information set out in Part B of Annex II to the blood establishment.’

14 Article 4 of Directive 2002/22, entitled ‘Review of obligations’, provides:

‘Blood establishments shall ensure that donors of whole blood and blood components comply with the eligibility criteria set out in Annex III.’

15 Points 2 and 4 of Annex 1 to that directive contain the following definitions:

‘2. “Allogeneic donation” means blood and blood components collected from an individual and intended for transfusion to another individual, for use in medical devices or as starting material/raw material for manufacturing into medicinal products.

...

4. “Whole blood” means a single blood donation.’

16 Under the heading: ‘Information to be obtained from donors by blood establishments at every donation’, Part B of Annex II to that directive, provides in point 2 that donors must provide the following information:

‘Health and medical history, provided on a questionnaire and through a personal interview performed by a qualified healthcare professional, that includes relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases, or health risks to themselves.’

17 Annex III to Directive 2004/33, entitled ‘Eligibility criteria for donors of whole blood and blood components’, sets out, in point 2, the criteria for excluding donors of whole blood and blood components.

18 Point 2.1 of that annex is entitled ‘Permanent deferral criteria for donors of allogeneic donations’. Those criteria concern essentially the following four categories of persons: persons who are carriers of certain diseases, including ‘HIV 1/2’ or who have certain malignant diseases; intravenous or intramuscular drug users; xenotransplant recipients; ‘persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood’.

19 Point 2.2 of that annex, headed ‘Temporary deferral criteria for donors of allogeneic donations’, contains point 2.2.2 concerning exposure to risk of acquiring a transfusion-transmissible infection.

20 In point 2.2.2, in the table entry concerning ‘[p]ersons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood’ is accompanied by the following comment: ‘[d]efer after cessation of risk behaviour for a period determined by the disease in question, and by the availability of appropriate tests’.

#### *French law*

21 On 12 January 2009, the *Ministre de la Santé et des Sports* (Minister for Health and Sport) adopted the Decree laying down the selection criteria for blood donors (JORF of 18 January 2009, p. 1067) (‘the Decree of 12 January 2009’), which mentions Directive 2004/33 in its preamble.

22 With regard to the clinical characteristics of a donor, Article 1(V)(1) of that decree provides:

‘At the interview prior to donation, it is for the person authorised to carry out the selection of donors to assess the possibility of donation in the light of any contraindications and their duration, precedence in time and development, using questions supplementary to the questionnaire prior to the donation.’

...

The prospective donor shall defer giving blood if he presents a counter indication mentioned in one of the tables set out in Annex II to the present decree...

...’

23 Annex II to that decree contains the tables relating to contraindications, including Table B concerning risks for the recipient. The section of that table on the risk relating to the transmission of a viral infection provides that, as far as concerns the risk of exposure of the prospective donor to a sexually transmissible infectious agent, there is a permanent contraindication to blood donations where a ‘man has had sexual relations with another man’.

### **The dispute in the main proceedings and the question referred for a preliminary ruling**

24 Mr Léger attended the collection centre of the *Établissement français du sang* (French Blood Agency) in Metz (France) in order to give blood.

25 By decision of 29 April 2009, the doctor responsible for donations refused the blood donation on the ground that Mr Léger had had sexual relations with another man.

26 The doctor based his decision on the Decree of 12 January 2009. Table B in Annex II thereto provides, as regards the risk of exposure of a prospective donor to a sexually transmissible infectious agent, for a permanent contraindication to blood donation for a man who has had sexual relations with another man.

27 Mr Léger brought an action against that decision before the *Tribunal administratif de Strasbourg* (Administrative Court, Strasbourg) arguing, *inter alia*, that Annex II to the Decree of 12 January 2009 was incompatible with the provisions of Directive 2004/33.

28 The referring court explains that the issue as to whether the existence of a permanent contraindication to blood donation for a man who has had sexual relations with another man is consistent with Annex III to that directive presents a serious difficulty and is decisive for the resolution of the dispute in the main proceedings.

29 In those circumstances, the *Tribunal administratif de Strasbourg* decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:

‘In the light of Annex III to Directive [2004/33], does the fact that a man has sexual relations with another man constitute in itself sexual conduct placing him at a risk of acquiring severe infectious diseases that can be transmitted by blood and justifying a permanent deferral from blood donation for persons having engaged in that sexual behaviour, or is it merely capable of constituting, in the light of the circumstances of the individual case, sexual behaviour placing him at a risk of acquiring infectious

diseases that may be transmitted by blood and justifying a temporary deferral from blood donation for a period determined after cessation of the risk behaviour?’

### **Consideration of the question referred for a preliminary ruling**

30 By its question, the referring court asks essentially whether point 2.1 of Annex III to Directive 2004/33 must be interpreted as meaning that the criterion for permanent deferral from blood donation referred to in that provision, relating to sexual behaviour which places a person at risk of acquiring severe infectious diseases that can be transmitted by blood, precludes a Member State from providing for a permanent contraindication to blood donation for men who have had sexual relations with other men.

31 As a preliminary point, it must be noted, as the French Government and the European Commission have argued, that there are differences between the language versions of points 2.1 and 2.2.2 of Annex III to that directive as regards the level of risk referred to by those provisions.

32 In the French version of those provisions, permanent deferral from blood donation provided for in point 2.1 and temporary deferral in point 2.2.2 both apply to persons whose sexual behaviour puts them at ‘risk’ of acquiring severe infectious diseases that can be transmitted by blood. In that language version, the level of risk justifying the permanent deferral from blood donation is therefore exactly the same as that applicable to temporary deferral.

33 However, in some language versions of point 2.1 of Annex III to Directive 2004/33, while temporary deferral requires the presence of a ‘risk’, permanent deferral requires a ‘high risk’. That is the case, in particular, in the Danish (‘stor risiko’), Estonian (kõrgendatud ohtu’), English (‘high risk’), Italian (‘alto rischio’), Dutch (‘groot risico’), Polish (‘wysokie ryzyko’) and Portuguese (‘grande risco’) versions of those provisions.

34 In yet other language versions, points 2.1 and 2.2.2 of that annex both refer to a ‘high risk’, as in the Spanish (‘alto riesgo’) and German (‘hohes Risiko’) versions.

35 According to the settled case-law of the Court, the wording used in one language version of a provision of EU law cannot serve as the sole basis for the interpretation of that provision, or be made to override the other language versions in that regard. Provisions of EU law must be interpreted and applied uniformly in the light of the versions existing in all EU languages. Where there is divergence between the various language versions of an EU legislative text, the provision in question must be interpreted by reference to the purpose and general scheme of the rules of which it forms part (judgments in *Cricket St Thomas*, C-372/88, EU:C:1990:140, paragraphs 18 and 19; *Kurcums Metal*, C-558/11, EU:C:2012:721, paragraph 48; and *Ivansson and Others*, C-307/13, EU:C:2014:2058, paragraph 40).

36 As regards the general scheme of points 2.1 and 2.2.2 of Annex III to Directive 2004/33, it must be observed that that annex distinguishes between permanent and temporary deferral from blood donation for which, logically, the applicable criteria

must differ. Therefore, permanent deferral, which is a stricter measure, requires the existence of a greater risk than that for temporary deferral.

37 Furthermore, as stated in recital 24 in the preamble to Directive 2002/98, blood and blood components used for therapeutic purposes or for use in medical devices should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation and that any risk of transmission of infectious diseases is minimised. It follows that, as regards the purpose of Directive 2004/33, permanent deferral must apply where the risk of such transmission is higher.

38 Accordingly, the general scheme and purpose of that directive mean that it is necessary to adopt the interpretation according to which the permanent deferral from blood donation provided for in point 2.1 of Annex III to that directive concerns persons whose sexual behaviour puts them at a 'high risk' of acquiring severe infectious diseases that can be transmitted by blood, while temporary deferral from blood donation concerns a lower risk

39 As regards permanent deferral, it must be observed that the expression 'persons whose sexual behaviour puts them at risk' of acquiring infectious diseases used in point 2.1 of Annex III to Directive 2004/33 does not precisely determine the persons or categories of persons concerned by that deferral, which leaves a margin a discretion to the Member States in the application of that provision.

40 Therefore, it is necessary to determine to what extent the permanent contraindication provided for by French law in the case of a 'man who has had sexual relations with another man' satisfies the requirement of a 'high risk' referred to in point 2.1 of Annex III to Directive 2004/33, while respecting the fundamental rights recognised by the EU legal order.

41 According to the settled case-law of the Court, the requirements flowing from the protection of those fundamental rights are binding on Member States when they implement EU rules, so that they are bound to apply the rules in accordance with those requirements (see, to that effect, judgment in *Parliament v Council*, C-540/03, EU:C:2006:429, paragraph 105 and the case-law cited). In that context, the Member States must make sure they do not rely on an interpretation of wording of secondary legislation which would be in conflict with those fundamental rights (see judgments in *Ordre des barreaux francophones et germanophone and Others*, C-305/05, EU:C:2007:383, paragraph 28, and *O and Others*, C-356/11 and C-357/11, EU:C:2012:776, paragraph 78).

42 In the first place, as regards the assessment of whether there is a high risk of acquiring severe infectious diseases that can be transmitted by blood, account must be taken of the epidemiological situation in France, which has a very specific character, according to the French Government and the Commission, under reference to data supplied by the Institut de veille sanitaire français (French Institute for Public Health Surveillance). It is clear from those data that almost all HIV infections for the period from 2003 to 2008 were due to sexual relations, and that men who have had sexual relations with other men represent the population most affected, corresponding to 48% of new infections. In the same period, while the overall incidence of HIV infection has gone down, in particular as regards heterosexual relations, it has not

diminished for men who have had sexual relations with other men. Furthermore, in the same period, they represented the population most affected by HIV infection, with an incidence rate of 1% per annum, which is 200 times greater than that for the heterosexual population in France.

43 The Commission also refers to a report by the European Centre for Disease Prevention and Control, which was established by Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 (OJ 2004 L 142, p. 1). According to that report, entitled ‘Men who have sex with men (MSM), Monitoring implementation of the Dublin Declaration on Partnership to Fight HIV/AIDS in Europe and Central Asia: 2012 progress’, published in October 2013, the prevalence of HIV in men who have had sexual relations with other men in France is the highest of all the States studied.

44 It is for the referring court to ascertain, in the light of current medical, scientific and epidemiological knowledge, whether the data in paragraph 42 of the present judgment is reliable and, if that is the case, whether it is still relevant.

45 In the second place, if the referring court concludes, in particular in the light of those data, that the national authorities could reasonably consider that, in the case of a man who has had sexual relations with another man, there is in France a high risk of acquiring severe infectious diseases that can be transmitted by blood, within the meaning of point 2.1 of Annex III to Directive 2004/33 it must be determined whether, and under what conditions, a permanent deferral from blood donation, such as that at issue in the main proceedings, may be compatible with the fundamental rights recognised by the EU legal order.

46 In that connection, it should be recalled that the scope of the Charter of Fundamental Rights of the European Union (‘the Charter’) with regard to the action of the Member States, is defined in Article 51(1) thereof, according to which the provisions of the Charter are addressed to Member States ‘only when they are implementing Union law.’

47 In the present case, the Decree of 12 January 2009, which expressly refers to Directive 2004/33 in its preamble, implements EU law.

48 Accordingly, among the provisions of the Charter, that decree must respect inter alia Article 21(1) thereof, according to which any discrimination based on sexual orientation must be prohibited. Article 21(1) is a particular expression of the principle of equal treatment, which is a general principle of EU law enshrined in Article 20 of the Charter (see, to that effect, judgments in *Römer*, C-147/08, EU:C:2011:286, paragraph 59, and *Glatzel*, C-356/12, EU:C:2014:350, paragraph 43).

49 In that connection, taking as a criterion for a permanent contraindication to blood donation the fact of being a ‘man who has had sexual relations with another man’, Table B of Annex II to the Decree of 12 January 2009 determines the deferral from blood donation on the basis to the homosexuality of the male donors who, on account of the fact that they have had homosexual sexual relations, are treated less favourably than male heterosexual persons.

50 In those circumstances, the Decree of 12 January 2009 may discriminate against homosexuals on grounds of sexual orientation within the meaning of Article 21(1) of the Charter.

51 Therefore, it must be determined whether the permanent contraindication to blood donation provided for in the Decree of 12 January 2009 for a man who has had sexual relations with another man nonetheless satisfies the conditions laid down by Article 52(1) of the Charter in order to be justified.

52 That provision states that any limitation on the exercise of the rights and freedoms recognised by it must be provided for by law and respect the essence of those rights and freedoms. In addition, that article provides that, subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the European Union or the need to protect the rights and freedoms of others.

53 In the present case, it is common ground that the permanent contraindication to blood donation for a man who has had sexual relations with another man, which constitutes a limitation on the exercise of the rights and freedoms recognised by the Charter, must be regarded as being provided for by law, within the meaning of Article 52(1), since it stems from the Decree of 12 January 2009.

54 Furthermore, that limitation respects the essential contents of the principle of non-discrimination. That limitation does not call into question the principle as such, as it concerns only the question, which is limited in scope, of deferrals from blood donation in order to protect the health of the recipients.

55 However, it must still be determined whether that limitation meets an objective of general interest, within the meaning of Article 52(1) of the Charter, and, whether, in the affirmative, it respects the principle of proportionality within the meaning of that provision.

56 In that connection, it must be recalled that Directive 2004/33 implements Directive 2002/98. The latter directive, in accordance with its legal basis, namely Article 152(4)(a) EC, is intended to protect public health.

57 In the present case, the permanent deferral from blood donation aims to minimise the risk of transmitting an infectious disease to recipients. That deferral thereby contributes to the general objective of ensuring a high level of human health protection, which is an objective recognised by the EU in Article 152 EC, and in particular in Article 152(4) and (5) EC, and Article 35, second sentence of the Charter, which requires a high level of human health protection to be ensured in the definition and implementation of all Union policies and activities.

58 As regards the principle of proportionality, it follows from the case-law of the Court that the measures laid down by national legislation must not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by that legislation; when there is a choice between several appropriate measures, recourse must be had to the least onerous among them, and the disadvantages caused must not be disproportionate to the aims pursued (see

judgments in *ERG and Others*, C-379/08 and C-380/08, EU:C:2010:127, paragraph 86; *Urbán*, C-210/10, EU:C:2012:64, paragraph 24; and *Texdata Software*, C-418/11, EU:C:2013:358, paragraph 52).

59 In a case such as that in the main proceedings, that principle is respected only where a high level of health protection for the recipients cannot be ensured by effective techniques for detecting HIV which are less onerous than the permanent deferral from blood donation for the entire group of men who have had sexual relations with other men.

60 On one hand, it is conceivable that, even where sexual behaviour which puts participants to a high risk of acquiring severe infectious diseases that can be transmitted by blood, within the meaning of point 2.1 of Annex III to Directive 2004/33, which concerns the risk of transmitting such diseases to partners as a result of sexual relations, there are effective techniques which ensure a high level of health protection for recipients.

61 In that connection, as is clear, inter alia, from Article 21 of Directive 2002/98, in order to ensure the quality and safety of blood and blood components, each donation of blood must be tested in conformity with the requirements listed in Annex IV to that directive, it being understood that those requirements will evolve in line with scientific and technical progress (judgment in *Humanplasma*, C-421/09, EU:C:2010:760, paragraph 42). Pursuant to Annex IV, donors must be tested, inter alia, for HIV I/II.

62 The French Government and the Commission observe none the less that, according to the present state of scientific knowledge there is a ‘window period’ which follows a viral infection, during which the biological markers used in testing donated blood remain negative despite the donor being infected. Therefore, it is recent infections which present a risk of non-detection during tests and, therefore, of transmission of HIV to the recipient.

63 It is for the referring court to ascertain whether, in such a situation and in compliance with the principle of proportionality, there are effective techniques for detecting HIV in order to avoid its transmission to recipients of such a virus, the tests requiring to be performed according to the most recent scientific and technical procedures, pursuant to recital 29 in the preamble to Directive 2002/98.

64 In particular, it is for the referring court to verify whether scientific or technical progress in the field of science or health, taking account in particular of the cost of systematic quarantining of blood donations from men who have had sexual relations with other men or the cost of the systematic screening for HIV for all blood donations, allows a high level of health protection for recipients to be ensured without the resulting burden being excessive as compared with the objectives of protecting health.

65 On the other hand, even if, with the current state of scientific knowledge there is no technique satisfying the conditions laid down in paragraphs 63 and 64 of the present judgment, a permanent deferral from blood donation for the whole group of men who have had sexual relations with other men is proportionate only if there are no less onerous methods of ensuring a high level of health protection for recipients.

66 In that connection, it is for the referring court to determine in particular whether the questionnaire and individual interview with a medical professional, provided for in Annex II B(2) to Directive 2004/33, are able to identify more precisely the type of behaviour presenting a risk for the health of recipients, in order to impose a less onerous contraindication than a permanent contraindication for the entire group of men who have had sexual relations with a man.

67 To that effect, as the Advocate General noted, in paragraph 61 of his Opinion, the referring court must verify in particular whether the specific questions concerning the period which has elapsed since the prospective donor's most recent sexual relations in relation to the length of the 'window period', the stability of the relationship of the person concerned, or whether sexual relations were protected, enable an evaluation of the level of risk presented by each individual donor on account of his own sexual behaviour.

68 In those circumstances, it must be concluded that if effective techniques for detecting severe diseases that can be transmitted by blood or, in the absence of such techniques, less onerous methods than the permanent deferral of blood donation for the entire group of men who have had sexual relations with other men ensure a high level of health protection to recipients, such a permanent contraindication would not respect the principle of proportionality, within the meaning of Article 52(1) of the Charter.

69 Having regard to the foregoing considerations, the answer to the question referred is that point 2.1 of Annex III to Directive 2004/33 must be interpreted as meaning that the criterion for permanent deferral from blood donation in that provision relating to sexual behaviour covers the situation in which a Member State, having regard to the prevailing situation there, provides for a permanent contraindication to blood donation for men who have had sexual relations with other men where it is established, on the basis of current medical, scientific and epidemiological knowledge and data, that such sexual behaviour puts those persons at a high risk of acquiring severe infectious diseases and that, with due regard to the principle of proportionality, there are no effective techniques for detecting those infectious diseases or, in the absence of such techniques, any less onerous methods that such a counter indication for ensuring a high level of health protection of the recipients. It is for the referring court to determine whether, in Member State concerned, those conditions are met.

### **Costs**

70 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 (Fourth Chamber) hereby rules:

- 1. Point 2.1 of Annex III to Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood**

**components must be interpreted as meaning that the criterion for permanent deferral from blood donation in that provision relating to sexual behaviour covers the situation in which a Member State, having regard to the prevailing situation there, provides for a permanent contraindication to blood donation for men who have had sexual relations with other men where it is established, on the basis of current medical, scientific and epidemiological knowledge and data, that such sexual behaviour puts those persons at a high risk of acquiring severe infectious diseases and that, with due regard to the principle of proportionality, there are no effective techniques for detecting those infectious diseases or, in the absence of such techniques, any less onerous methods than such a counter indication for ensuring a high level of health protection of the recipients. It is for the referring court to determine whether, in Member State concerned, those conditions are met.**

[Signatures]

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\* Language of the case: French.