Reports of Cases

OPINION OF ADVOCATE GENERAL
MENGOZZI
delivered on 17 July 2014[1]

Case C-528/13

Geoffrey Léger
v
Ministre des affaires sociales, de la Santé et des Droits des femmes
and
Établissement français du sang
(Request for a preliminary ruling

from the Tribunal administratif de Strasbourg (France))

(Public health — Blood donation — Eligibility criteria for donors — Criteria for permanent or temporary deferral — Permanent deferral of men who have had sexual relations with another man — Principle of non-discrimination on grounds of sexual orientation — Proportionality)

Table of contents

I – Legal framework . . . 2
A – EU law . . . 2
B – French law . . . 3
II – The main proceedings and the question referred . . . 4
III – The procedure before the Court . . . 5
IV – Legal analysis . . . 5
A – Summary of the position of the French Government . . . 5
B – Assessment . . . 7
1. The interpretation of Point 2.1 of Annex III to Directive 2004/33 . . . 7

1 — Original language: French.

a) Point 2.1 of Annex III to Directive 2004/33 can be implemented only where there is a high risk of acquiring severe infectious diseases which can be transmitted by blood 7

b) Does the fact that a man has had or has sexual relations with another man constitute 'sexual behaviour' within the meaning of Point 2.1 of Annex III to Directive 2004/33? 8

2. The discretion left to the Member States by Directive 2004/33 and the possibility granted to them to maintain or introduce more stringent protective measures 10

a) Compliance with the provisions of the Treaty as a limit on the exercise of national powers 10

b) The ministerial decree constitutes indirect discrimination on the combined basis of sex and sexual orientation 11

c) Is the difference in treatment justified and proportionate? 12

V – Conclusion 15

1. The present request for a preliminary ruling raises a delicate question: that of the compatibility with EU law of a national measure which, on a permanent basis, prevents men who have had, or have, sexual relations with other men from donating blood.

I – Legal framework

A – *EU law*

2. The legal framework under EU law can be summarised as follows.

3. Adopted on the basis of Article 152(4)(a) EC [now Article 168(4)(a) TFEU], 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[2] was born of the finding by the legislature of the Union that there existed a situation in which the 'quality and safety [of whole blood, plasma and blood cells of human origin], in so far as they are intended for transfusion and not processed as such, are not subject to any binding Community legislation'.[3] The legislature therefore expressed its intention to adopt provisions ensuring that 'whatever the intended purpose, … blood and its components are of comparable quality and safety throughout the blood transfusion chain in all Member States', since the establishment of high standards of quality and safety should help to reassure the public.[4] Directive 2002/98 therefore pursues the objective of laying down standards of quality and safety of human blood and of blood components, in order to ensure a high level of human health protection.[5] In particular, it required the Member States to ensure that only duly designated and accredited establishments could carry out the

2 — OJ 2003 L 33, p. 30.
3 — Recital 3 to Directive 2002/98.
4 — Recital 3 to Directive 2002/98.
5 — Article 1 of Directive 2002/98.

activities of collection, checking, preparation, storage and distribution of blood and blood components and that they are subject to various inspections and control measures.[6] It also established the principles of the traceability of blood, of unpaid and voluntary donation and of mandatory testing of each donation.[7]

4. However, the requirements for the eligibility of blood and plasma donors, that is to say, inter alia, permanent deferral criteria and temporary deferral criteria, were not adopted by Directive 2002/98 but, instead, were adopted by Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98 as regards certain technical requirements for blood and blood components,[8] under the committee procedure referred to in Article 28 of Directive 2002/98.[9]

5. Accordingly, it was Directive 2004/33 which laid down those requirements. Annex III thereto determines the eligibility criteria for donors of whole blood and blood components. Point 2 of Annex III establishes the deferral criteria for such donors.

6. Point 2.1 of Annex III lists, in a table, the permanent deferral criteria for donors of allogeneic donations.[10] The description of sexual behaviour, as covered by the table, is worded as follows: 'Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood.'

7. Point 2.2 of Annex III lists the temporary deferral criteria for donors of allogeneic donations and Point 2.2.2 of that annex refers, in particular, to the deferral criteria linked with exposure to risk of acquiring a transfusion-transmissible infection. The table entry relating to '[p]ersons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood' lays down the following deferral: 'Defer after cessation of risk behaviour for a period determined by the disease in question, and by the availability of appropriate tests.'

B – *French law*

8. On 12 January 2009, the Minister of Health and Sports adopted a decree setting criteria for the selection of blood donors[11] ('the ministerial decree').

9. Article 1 of the ministerial decree lays down the conditions under which a blood donation can be made. Under Article 1, Title V, point 1, which relates to the clinical characteristics of the donor, it is for the person authorised to select donors to assess the possibility of a donation in the light of the contraindications and their duration, their priority and their evolution through questions supplementary to the questionnaire prior to donation.[12] Those questions are asked, where appropriate, during the interview prior to the donation, which, for its part, is systematic. Also according to that provision, the donor is excluded from making a donation if he presents a contraindication referred to in one of the tables in Appendix II to the ministerial decree. Provision is made for the health authorities to modify, add or delete contraindications to the donation of blood, depending on particular epidemiological situations or haemovigilance data.

6 — Articles 5 and 8 of Directive 2002/98.

7 — Respectively, Articles 14, 20 and 21 of Directive 2002/98 and Annex IV thereto.

8 — OJ 2004 L 91, p. 25.

9 — See Article 29 of Directive 2002/98.

10 — That is to say donations intended for another individual and not oneself, the only situation which is of interest in the present case (see Point 2 of Annex I to Directive 2004/33).

11 — Journal Officiel de la République Française of 18 January 2009, p. 1067.

12 — The questionnaire can be consulted at the following Internet address: http://www.dondusang.net/content/medias/media1832_giCQxWpZDhBErjG.pdf?finalFileName=Questionnaire_pr %E9-don_pour_la_m %E9tropole.pdf.

10. Annex II to the ministerial decree contains the tables concerning contraindications. Specifically, Table B lists the contraindications in case of a risk to the recipient. The part of Table B which covers the risk of transmission of a viral infection is as follows:

Transmission of a viral infection	Risk of exposure of the prospective donor to a sexually transmissible infectious agent	Unprotected sexual relation(s) with a casual partner	CI [13] of four months after the last unprotected sexual relation
		Multiple sexual partners: more than one partner in the last four months	CI of four months after the end of the multiple partner situation
		A man who has had sexual relations with another man	Permanent CI
		Unprotected sexual relations with a new partner for less than two months	CI of four months after the last unprotected intercourse sexual relationship
	Risk of exposure of the sexual partner of the prospective donor to a sexually transmissible infectious agent	Partner who has himself had more than one partner in the last four months	CI of four months
		Partner who has injected drugs or doping substances having an unknown HIV [14] and HBV status	CI of four months after the last sexual relations
		Partner with positive tests for: HIV, HTLV, HCV, HBV (HBsAg+)	CI of four months after the last sexual relations …
		Partner having had a recent STI or in treatment	CI of four months after recovery of partner

II – The main proceedings and the question referred

11. On 29 April 2009, the doctor of the Établissement français du sang (EFS) refused the blood donation that Geoffrey Léger wished to make, on the ground that he stated that he was homosexual.

12. By his refusal, the EFS doctor applied the ministerial decree, which regards the fact that a prospective donor has had sexual relations with another man as a permanent contraindication to giving blood.

13. Mr Léger brought before the referring court an action for annulment of that decision. He argues in particular that the ministerial decree, in that it lays down the permanent contraindication referred to above, infringes Directive 2004/33, in particular Point B of Annex II thereto [15] and Point 2.1 of Annex III thereto. Moreover, he claims the ministerial decree also infringes Articles 3, 8 and 14 of the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 ('the ECHR') and the principle of equality.

13 — CI: contra-indications.

14 — HIV: human immunodeficiency virus.

15 — Part B of Annex II to Directive 2004/33 covers the information to be obtained from donors by blood establishments at the time of every donation.

14. Thus faced with a difficulty relating to the interpretation of EU law, the Tribunal administratif of Strasbourg decided to stay the proceedings and, by order received at the Court Registry on 8 October 2013, to refer the following question to the Court for a preliminary ruling on the basis of Article 267 TFEU:

'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 behaviour placing him at 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 can be transmitted by blood and justifying a temporary deferral from blood donation for a period determined after the cessation of the risk behaviour?'

III – The procedure before the Court

15. Only the French Government and the European Commission submitted written observations to the Court.

IV – Legal analysis

A – *Summary of the position of the French Government*

16. The French Government considers that Directive 2004/33 does not preclude a Member State from considering that the fact that a man has sexual relations with another man (MSM) [16] constitutes a sexual behaviour placing him at a high risk of acquiring severe infectious diseases transmissible by blood which justifies a permanent deferral of donation.

17. First, the sexual behaviour consisting in a man's having sexual relations with another man constitutes, in itself, a sexual behaviour capable of justifying permanent deferral of donation. Directive 2002/98 fits into the broader context of the establishment of a common public health policy and seeks to set high standards of quality and safety — objectives which are omnipresent in the directive — through a coordinated approach to the safety of blood in response to various cases of infections through transfusion. Directive 2002/98 was therefore adopted on the basis of Article 152(4)(a) EC. The overarching objective is, moreover, that of protecting the recipient of the donation and, in that regard, the directive stresses that donations must 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. [17] Specifically, the selection of donors is one of three methods of reducing that risk. [18]

18. Although Directive 2004/33 provides that there should be permanent deferral of donation by individuals whose sexual behaviour puts them at risk of acquiring severe infectious diseases which can be transmitted by blood, it does not define the concept. Moreover, it is that very exposure to risk which is referred to in Point 2.2.2 of Annex III to that directive, covering temporary deferral criteria. Moreover, there are differences in the other language versions. In such a case, the settled case-law of the Court requires reference to the overall scheme and purpose of the directive, which is, according to the French Government, the maximum limitation of the risk and the establishment of high safety and

16 — The acronym HSH is the French equivalent of the English expression 'men who have sex with men' (MSM) developed in the 1990s by epidemiologists to describe men who have sex with other men, regardless of their possible sexual relations with women or their identity as bisexual or gay at a personal or social level (Source: '*UNAIDS Terminology Guidelines*', revised version, October 2011, p. 19).

17 — Recital 24 to Directive 2002/98.

18 — Together with each donation being subject to testing and to virus-attenuation treatment.

quality standards. In that context, a transitional risk justifies temporary deferral, whereas a higher risk capable of justifying a more stringent measure should give grounds for permanent deferral. Since EU action in this field is a supplement to action by the Member States and respects the responsibilities of the latter,[19] it is for the Member States to assess the risk according to their own specific epidemiological situations.

19. In that respect, the French Government refers to statistical evidence showing that the proportion of people living with HIV[20] in the MSM population is 65 times higher than in the rest of the population. As regards the incidence of HIV infection,[21] in 2008 of 6 940 new infections identified, 3 320 persons belonged to the MSM population. However, given the 'window period' during which the HIV 1 and HIV 2 viruses cannot be detected during screening tests — respectively 12 and 22 days — such a situation is particularly problematic for blood donations. The Council of Europe, in its resolution of 27 March 2013,[22] has also confirmed that the MSM population is at high risk of acquiring, and therefore transmitting, severe infectious diseases that can be transmitted by blood.

20. Secondly, the French Government argues that, in light of those factors, applying only a temporary deferral is not possible. Thus, the Council of Europe recommends applying a temporary contraindication only after establishing that the behaviour in question does not expose an individual to a high risk. However, the Council of Europe concluded, when assessing the impact on the safety of transfusions using donations from the MSM population, that there was an increased risk of HIV transmission.[23] The French Government considers that MSM 'behaviour' exposes a person to a non-temporary, high-risk, as evidenced by the data referred to above. It adds that the residual risk of HIV infection — that is to say the ratio of infected donations in relation to the total number of donations — is one potentially contaminating donation out of 2 900 000 and that half of HIV-infected donations come from the MSM population, which is increasing likely to give blood, despite the permanent contraindication. The French Government considers that the change from permanent deferral to temporary deferral would be a false signal to the MSM population, which has, nevertheless, a tendency, currently, to exclude itself from the transfusion chain and might both turn donations into an additional means of HIV screening and minimise the effects of general discussions on HIV prevention.

21. The French Government also argues that holding that the permanent deferral of men who have sex with men is contrary to Directive 2004/33 would deprive Point 2.1 of Annex III to that directive of any practical effect. Although there are other sexual behaviours which put an individual at risk of contamination,[24] all put him at a lower risk than the MSM population of acquiring severe infectious diseases which can be transmitted by blood, as evidenced by the statistical data outlined above. If such a risk is not a situation covered by Point 2.1 of Annex III, the French Government questions what might be covered. It concludes that the MSM population may be subject only to permanent deferral.

22. Thirdly, even if Point 2.1 of Annex III to Directive 2004/33 was to be interpreted as meaning that the MSM population could only be covered by a temporary deferral, a Member State could always apply more protective measures and consider that such a level of risk of contamination warranted permanent deferral. The French Government mentions Articles 6(a) TFEU and 168(4)(a) TFEU. The

19 — The French Government refers here to Article168(7) TFEU.

20 — That is to say, the prevalence traditionally defined as the proportion of individuals in a population who are living with HIV at a speci?c point in time (Source: '*UNAIDS Terminology Guidelines*', cited above, p. 23).

21 — That is to say the number of new cases arising in a given period in a speci?ed population (Source: '*UNAIDS Terminology Guidelines*', cited above, p. 16).

22 — Resolution CM/Res(2013)3 adopted by the Committee of Ministers of the Council of Europe on 27 March 2013 on sexual behaviours of blood donors that have an impact on transfusion safety.

23 — The French Government relies on that point on Resolution CM/Res(2013)3, cited above.

24 — Such as having unprotected sexual relations with a casual partner or a new partner for less than two months, having sexual relations with more than one partner in the last four months or having sexual relations with a partner who, himself, has had more than one partner in the last four months.

latter provides that Member States may maintain or introduce such measures, which is set out not only in Recital 22 in the preamble to Directive 2002/98 but also by Article 4(2) thereof, which states that the directive does not prevent Member States from maintaining or introducing more stringent protective measure which comply with the provisions of the Treaty. Since the health and human life, according to the settled case-law, rank foremost among the assets and interests protected by the Union, and the Member States are free to decide the level of protection and how to achieve it, there is nothing to prevent a Member State from taking the view that the MSM population must be subject to permanent deferral from donation on account of the high risk to which that population would expose donors, a risk which is confirmed by the epidemiological data provided by the French Government. Accordingly, such permanent deferral would constitute a more stringent protection measure which would be proportionate to the legitimate objective pursued.

B – *Assessment*

23. First of all, it is necessary to determine whether the fact that a man has sexual relations with another man constitutes a 'sexual behaviour' placing him at a high risk of acquiring severe infectious diseases, within the meaning of Point 2.1 of Annex III to Directive 2004/33.

24. Should that not be the case, it will then be necessary to examine, subsequently, whether a Member State may, in the exercise of the discretion which is traditionally conferred on it in matters of public health, adopt a measure which is more protective than that directive, such as that consisting in the permanent exclusion of the MSM population from giving blood.

1. The interpretation of Point 2.1 of Annex III to Directive 2004/33

a) Point 2.1 of Annex III to Directive 2004/33 can be implemented only where there is a high risk of acquiring severe infectious diseases which can be transmitted by blood

25. The interpretation of the ground for deferral referred to in Point 2.1 of Annex III to Directive 2004/33 is a particular subject of debate, since, as the French Government has pointed out, one of the grounds for temporary deferral listed in Point 2.2.2 of that annex is worded in the same terms, since it refers to '[p]ersons whose behaviour or activity *places them at risk* of acquiring infectious diseases that may be transmitted by blood'.[25] Clearly, the legislature's intention cannot have been that of providing that behaviour defined in the same terms is to be subject to both permanent and temporary deferral. The French Government and the Commission have pointed out, in that respect, the existence of differences in the available language versions of Annex III to Directive 2004/33.

26. Indeed, according to the proposed language versions, either temporary deferral covers only the existence of a risk, compared with a high risk covered by permanent deferral;[26] or Annex III refers, in both cases, to a high risk;[27] or, as is the case with the French version, the annex refers, in both cases, to the single concept of 'risk', without further details.[28] However, the need for a uniform interpretation of EU law prevents, in the case of doubt, the text of a provision from being considered in isolation but requires, on the contrary, that it also be interpreted in the light of the versions in the other official languages — a comparison which, we have seen, is no more illuminating — and according to the

25 — Emphasis added.

26 — See, for example, the versions in Italian, Greek, English and Portuguese.

27 — See, for example, versions in Spanish and German.

28 — The same lack of precision exists in relation to the wording of Point 2.2.2 of Annex III to Directive 2004/33. Although the French version refers to sexual behaviour or professional activity, the Spanish and Italian versions merely refer to sexual behaviour or activity, while the Portuguese version mentions only behaviour or activity, without specifying their nature, to mention only these language versions of Directive 2004/33.

general scheme and purpose of the rules of which that provision forms part.[29] In other words, the mere fact that Point 2.1 of Annex III to Directive 2004/33, in the French language version, applies only to individuals whose sexual behaviour puts them at a 'simple' risk of acquiring severe infectious diseases is not in itself a sufficient basis for concluding that permanent deferral at national level is compatible with the directive.

27. Since Directive 2004/33 specifies the technical requirements of Directive 2002/98, it pursues the same purpose as the latter. As the French Government pointed out, the legislature has made improvement of the quality and safety of the transfusion chain a priority for Directive 2002/98.

28. Its adoption is part of a context in which the Member States had previously experienced failings in their systems for monitoring and securing the transfusion chain. Consequently, the supranational authorities took up the matter, at the level of both the Council of Europe[30] and the Union. However, it was not until Directive 2002/98, whose legal basis is Article 152(4)(a) EC — which provided for the adoption of 'measures setting high standards of quality and safety of … blood' — that the Union adopted its first binding legislation in this matter.[31] The objective of quality and safety is omnipresent in it.[32] The objective is to prevent the transmission of diseases[33] while ensuring that donations are 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 is minimised,[34] in order to reinforce individuals' confidence.[35] Those same concerns are apparent from a reading of Directive 2004/33,[36] the stated objective of which is to ensure a high level of human health protection.[37]

29. It is therefore clear that the annexes to Directive 2004/33 must be interpreted in light of that objective. I am also of the opinion that Point 2.1 of Annex III to Directive 2004/33 must be interpreted, as also recognised by the French Government in its pleadings, as meaning that individuals whose sexual behaviour puts them at a *high* risk of acquiring severe infectious diseases which can be transmitted by blood are to be definitively excluded from giving blood. Such an interpretation seems not only appropriate, in order that the distinction drawn by the EU legislature between, on the one hand, the grounds of temporary deferral and, on the other hand, the grounds of permanent deferral retains all its relevance, but also consistent with the idea, which is also present in the directive, of minimising the risk of transmission. Thus, a high risk leads to permanent deferral, while a lower, more limited risk results in only temporary deferral.

b) Does the fact that a man has had[38] or has sexual relations with another man constitute 'sexual behaviour' within the meaning of Point 2.1 of Annex III to Directive 2004/33?

30. If, having regard to the above, the boundary between temporary and permanent deferral seems to be clearer, it remains necessary to define what may constitute 'sexual behaviour' which places a person at a high risk of contamination.

29 — See, among numerous cases, *Haasová* (C-22/12, EU:C:2013:692, paragraph 48 and the case-law cited) and *Drozdovs* (C-277/12, EU:C:2013:685, paragraph 39 and the case-law cited).

30 — For example, Recommendation No R(95)14 of the Committee of Ministers of the Council of Europe of 12 October 1995 on the protection of the health of donors and recipients in the area of blood transfusion.

31 — See recital 3 to Directive 2002/98. For non-binding actions undertaken by the institutions, see recitals 6 to 9 to that directive.

32 — See recitals 1, 3 and 5 to Directive 2002/98 and Article 1 thereof.

33 — Recitals 1 and 2 to Directive 2002/98.

34 — Recital 24 to Directive 2002/98.

35 — Recitals 3 and 6 to Directive 2002/98.

36 — See, in particular, recitals 2 and 4 to Directive 2004/33 and Articles 4 and 6 thereto.

37 — Recital 1 to Directive 2004/33.

38 — According to the wording of the questionnaire.

31. In that respect, the documents before the Court contain no evidence relating to the *travaux préparatoires* for Directive 2004/33 which is capable of indicating what the legislature intended 'sexual behaviour' to mean and the directive contains no relevant definition. A review of the documents from the Council of Europe is no more illuminating, since the Committee of Ministers merely defined risky sexual behaviour as 'a sexual behaviour which puts persons at risk or at high risk of acquiring severe infectious diseases that can be transmitted by blood'. [39] Reference must therefore be made to the common meaning.

32. From a strictly literal point of view, behaviour defines how an individual behaves, the manner in which he conducts himself; it covers all his reactions, that is to say his conduct. [40] The concept of behaviour results, a priori, in a subjective assessment and sexual behaviour may therefore be defined by the sexual practices and habits of the individual concerned, in other words by the specific circumstances in which the relevant sexual relations take place.

33. Accordingly, a question arises: does the permanent deferral of men who have sex with men seek to affect a particular sexual orientation or rather a true behaviour strictly speaking?

34. Indeed, the criterion for deferral used by the ministerial decree is the fact that a man has had or has sexual activity comprising sexual relations with another man and the conditions of those relations, their frequency and the practices involved are of little importance. Of course, the criterion is not explicitly and directly expressed on the basis of sexual orientation, since the MSM category is not officially defined according to sexual orientation. [41] It nevertheless raises a kind of irrebuttable presumption that an MSM relationship necessarily and systematically puts a person at high risk of contamination. Moreover, in practice, it is essentially, if not exclusively, [42] the entire male homosexual and bisexual population which is, in fact, forever excluded from donation for the sole reason that those men have had, or currently have, sexual relations with another man.

35. In my view, the national criterion adopted is formulated in a way which is both too broad and too general, while the concept of 'sexual behaviour' used by the EU legislature requires a specific behaviour or attitude which places the prospective donor at a high risk of contamination to be identified. Moreover, the Commission has already highlighted the fact that the 'sexual behaviour' referred to in Directive 2004/33 should not be understood as synonymous with 'sexual orientation'. [43]

36. To hold that Point 2.1 of Annex III to Directive 2004/33 requires that persons concerning whom there has been identified a specific, detailed behaviour which has placed or places them at a high risk must be forever excluded from donating blood and that it is not amenable to a form of exclusion which is as general as that provided for by the ministerial decree does not amount, contrary to what was argued by the French Government, to depriving Point 2.1 of Annex III to Directive 2004/33 of effectiveness. Nevertheless, it is true that this does require a refinement of the criteria for permanent deferral. However, one may readily think of sex workers, [44] who, in my opinion, would fulfil the requirements for permanent deferral under Point 2.1 of that Annex.

39 — See Annex 1 to Resolution CM/Res(2013) 3, cited above.

40 — According to the definition given by *Le petit Larousse illustré*, 2011 Edition, Larousse, Paris.

41 — See the definition of HSH in footnote 16 of this Opinion and the third recital to Resolution CM/Res(2013)3, cited above.

42 — The case, put forward by the Commission in its written observations, of part of the male homosexual or bisexual population which is totally abstinent, and therefore eligible to donate, seems to me sufficiently marginal overall not to taken into account in the present arguments.

43 — See the Commission's answer of 17 August 2011 to the parliamentary question for written answer dated 1 July 2011 (E-006484/2011).

44 — Moreover, that case was envisaged by the Council in its Recommendation of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community (OJ 1998 L 203, p. 14: see, in particular, Point C(1) of Annex II to that recommendation) and by the Committee of Ministers of the Council of Europe, in particular in the third recital to its Resolution CM/Res(2013)3, cited above.

37. It follows from the foregoing that Point 2.1 of Annex III to Directive 2004/33 must be interpreted as meaning that the mere fact that a man has had or has sexual relations with another man does not, in and of itself, constitute a sexual behaviour placing him at a high risk of acquiring severe infectious diseases which can be transmitted by blood.

2. The discretion left to the Member States by Directive 2004/33 and the possibility granted to them to maintain or introduce more stringent protective measures

a) Compliance with the provisions of the Treaty as a limit on the exercise of national powers

38. As I have already noted, Directive 2002/98, for which Directive 2004/33 laid down the technical requirements, was adopted on the legal basis of Article 152(4)(a) EC, which set out the conditions under which the Council could contribute to the attainment of certain objectives and in particular that of adopting 'measures setting high standards of quality and safety of … blood and blood derivatives'. Article 152(4)(a) EC further stated that 'these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures'.[45] Article 152(5) EC provided that Community action in the field of public health must fully respect the responsibilities of the Member States and, in particular, that the 'measures referred to in paragraph 4(a) shall not affect national provisions on the donation … of … blood'.[46]

39. Though it must be concluded from the foregoing that Community action in the past, and that of the Union today, can take the form only of accompanying, incentive or coordination measures, but certainly not of harmonisation measures, the Court never interpreted those provisions as meaning that the national measures are not subject to a review of their compatibility with EU law.

40. Thus, in the field of social security, the Court held that, '[w]hilst it is established that EU law does not detract from the power of the Member States to organise their social security systems and that, in the absence of harmonisation at EU level, it is for the legislation of each Member State to determine the conditions for the grant of social security benefits … It should also be noted that, under Article 152(5) EC, action by the European Union in the field of public health must fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. The fact nevertheless remains that, when exercising that power, Member States must comply with EU law and, in particular, with the provisions on the freedom to provide services … Accordingly, the Court has held that Article 152(5) EC does not exclude the possibility that the Member States may be required under other Treaty provisions … to make adjustments to their national systems of social security, *but that it does not follow that this undermines their sovereign powers in the field*'.[47]

41. *Mutatis mutandis*, the Court should also consider that making the exercise of the other national powers referred to in Article 152(5) EC compliant with the provisions of the Treaty does not detract from their sovereign powers in that area. The final detail contained in that article, which specifically refers to blood donation, does not appear necessarily to preclude this.

45 — Now Article 168(4)(a) TFEU.

46 — In the same spirit, see the current Article 168(7) TFEU.

47 — *Commission* v *Portugal* (C-255/09, EU:C:2011:695, paragraphs 47 to 49 and the case-law cited), emphasis added. The Court therefore adopted the Opinion of the Advocate General in that case, who, in that respect, concluded that 'the Portuguese Republic … [could not] successfully rely on its inherent responsibility for the organisation and delivery of health services and medical care within its national territory in order to escape from the obligations imposed on it by other primary EU law' [see point 64 of the Opinion of Advocate General Trstenjak (EU:C:2011:246)].

42. Thus, faced with national legislation seeking to ensure that donations are voluntary and unpaid, and seeming to be more protective in relation to the requirements of Directive 2002/98,[48] the Court has not curbed its control on the ground that the national legislation fell within the scope of Article 152(5) EC. On the contrary, it reviewed that legislation for compatibility with other provisions of the Treaty, in that case those concerning the free movement of goods. Moreover, it concluded that Article 28 EC, read in conjunction with Article 30 EC, precluded national legislation according to which the importation of blood or blood components from another Member State was permitted only on the condition, which was also applicable to national products, that the donations of blood on which those products were based were made without any payment being made to the donors and also without any reimbursement of the costs incurred by them in connection with those donations[49].

43. I note, finally, that the fact that compliance with the provisions of the Treaty constitutes the natural limit to the exercise of national powers is confirmed by the first subparagraph of Article 4(2) of Directive 2002/98, which provides that '[t]his Directive shall not prevent a Member State from maintaining or introducing in its territory more stringent protective measures *which comply with the provisions of the Treaty*',[50] and is disputed neither by the French Government[51] nor by the Commission.[52]

b) The ministerial decree constitutes indirect discrimination on the combined basis of sex and sexual orientation

44. Since the Member States' freedom ends when compliance with the primary law of the Union is threatened, I will merely observe, in that regard, that the ministerial decree, by imposing a permanent deferral on any man who has had or has sexual relations with another man, introduces into the system of donor selection clear indirect discrimination[53] consisting of a combination of different treatment on grounds of sex — since the criterion in question relates only to men — and sexual orientation — since the criterion in question relates almost exclusively to homosexual and bisexual men.

45. Although Recommendation R(95)14 pointed out the importance of establishing appropriate donor selection avoiding any possibility of discrimination, Resolution CM/Res(2013)3, cited above, acknowledged that the MSM population, that is to say a whole category of the population, was excluded, because it had not been possible to narrow down the available statistical data based on individual risk taking. The statistics specifically and regularly contrast the MSM population with the heterosexual population: in fact, the expression MSM has, in the minds of ordinary as well as scientific

48 — This more protective measure being authorised by the second indent of Article 4(2) of Directive 2002/98.

49 — *Humanplasma* (C-421/09, EU:C:2010:760, paragraph 46).

50 — Emphasis added.

51 — See paragraph 90 of its written observations.

52 — See answers from the Commission of 1 April 2009 to Parliamentary Question No E-0910/2009 (which refers to compliance with the principle of proportionality) and of 17 August 2011 to Parliamentary Question No E-006484/2011 [which refers in particular to Article 21 of the Charter of Fundamental Rights of the European Union ('the Charter') (OJ 2007 C 303, p. 1)].

53 — In my view, there may be doubts as to that classification. The Court has, at least twice, concluded that there has been direct discrimination based on sexual orientation in *Maruko* (C-267/06, EU:C:2008:179) and *Hay* (C-267/12, EU:C:2013:823). The first case was concerned, in essence, with national legislation which reserved the payment of a survivor's pension to widows and widowers, it being understood that only a married person can rely on that capacity and where marriage was not itself open to persons of the same sex. In the second case, there was a collective agreement providing for the acquisition of a right to leave and to the payment of a bonus on marriage, without provision for corresponding rights in the event that the persons concerned had entered into a civil partnership, the only form of partnership open to people of the same sex. However, in both cases, and contrary to the exclusion at issue in the main proceedings, the less favourable treatment affected the entire homosexual community, both male and female.

people, become synonymous with 'homosexual' or 'bisexual'.[54] The male homosexual and bisexual community is excluded from giving blood and definitively so: it is therefore subject to discrimination. However, the EU seeks to combat discrimination based on sex and sexual orientation, as evidenced by both the former Article 13 EC and the current Article 19 TFEU and Article 21 of the Charter.[55]

46. It might certainly be objected that any mechanism of selection is inherently discriminatory. Nevertheless, it is important to ensure that such differences in treatment are properly justified and proportionate.

c) Is the difference in treatment justified and proportionate?

47. The Court has repeatedly held that 'the health and life of humans rank foremost among the assets and interests protected by the EC Treaty'.[56] Since the ministerial decree resulting in the total and permanent exclusion of the MSM population from giving blood is a more stringent protection measure within the meaning of Article 4(2) of Directive 2002/98, it is indisputable that it pursues a legitimate objective, that of minimising the risks of contamination for recipients and thus of contributing to the overall objective of ensuring a high level of protection of public health, now recalled in both Article 168(1) TFEU and Article 35 of the Charter.

48. Although the legislation at issue in the main proceedings does pursue a legitimate objective, it remains to be ascertained whether it also observes the principle of proportionality, that is to say whether it is appropriate and necessary in order to attain the objective pursued, which means that 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.[57]

49. First, the permanent deferral of the MSM population is indeed intended to attain the legitimate objective pursued.

50. Secondly, with regard to the disadvantages caused, in view of what is at stake, they should be regarded as relatively tolerable, since the feeling of exclusion for reasons relating to the individual's private life must be weighed against the best interests of the protection the health of recipients. Moreover, I can imagine that the rejection of a gesture of selfless generosity and solidarity, such as the donation of blood, may cause a reaction of misunderstanding on the part of the person whose

54 — In addition to the data provided by the French Government, see also 'VIH/sida en France: données de surveillance et études', Bulletin épidémiologique hebdomadaire of 1 December 2012, No 46-47, p. 523 (downloadable from www.invs.sante.fr) or the graph of the Institut français de veille sanitaire (French Institute for Public Health Surveillance) concerning the number of new diagnoses of HIV by mode of transmission and country of birth for the years 2003 to 2011 (available at http://www.invs.sante.fr/Dossiers-thematiques/Maladies-infectieuses/VIH-sida-IST/Infection-a-VIH-et-sida/Donnees/Donnees-epidemiologiques-sur-l-infection-a-VIH-et-les-IST).

55 — I also note that. in his Opinion in *Römer* (Case C-147/08, EU:C:2010:425) and after an analysis with which I fully concur, Advocate General Jääskinen invited the Court to enshrine the prohibition of discrimination on grounds of sexual orientation as a general principle of law (see paragraph 122 et seq.). In its judgment (C-147/08, EU:C:2011:286), the Court, however, was able to answer the questions referred to it without having to take a view on that issue. Perhaps the time to take such a view has come, since the decree at issue in the main proceedings was adopted in January 2009, that is before the entry into force of the Lisbon Treaty and therefore before the Charter acquired binding force.

56 — *Müller Fleisch* (C-562/08, EU:C:2010:93, paragraph 32 and the case-law cited). See also *Humanplasma* (EU:C:2010:760, paragraph 32).

57 — See *Müller Fleisch* (EU:C:2010:93, paragraph 43).

donation is refused, but it must be recognised that giving blood is not, in itself, a right, that its universality has never been recognised, since donors are subject to selection and must, in that regard, satisfy a certain number of conditions, and that, in any event, it is the medical authorities, which alone shoulder full immediate responsibility for their decisions, which must have the last word. [58]

51. Thirdly, in the field of human health, assessing whether the principle of proportionality has been observed requires that 'account … be taken of the fact that a Member State has the power to determine the degree of protection which it wishes to afford to human health and the way in which that degree of protection is to be achieved. Since that degree of protection may vary from one Member State to another, Member States must be allowed discretion'. [59] Accordingly, the fact that a Member State imposes rules which are less strict than those applicable in another Member State does not mean that the latter are disproportionate. [60]

52. In practice, that means that the fact that Spain, Italy, Slovakia, Finland and the United Kingdom neither systematically nor definitely exclude the MSM population from giving blood [61] must not be taken into account when deciding whether a measure less detrimental to the principle of equal treatment, but capable of achieving the same result, could be adopted by the French Government. That is particularly true since the level of risk is not uniform between the Member States, because their epidemiological situation, in particular with regard to HIV infection, is very diverse and it is undisputed that France has a particularly high HIV prevalence rate in the MSM population. [62]

53. However, in determining whether or not the permanent deferral contained in the ministerial decree goes beyond what is necessary, the referring court must carry out a number of checks, which the documents before the Court, as they stand, do not allow the Court to do.

54. Thus, it is necessary, first, to consider the specific epidemiological situation in France, ensuring that the statistical data provided are recent, [63] representative and reliable.

55. Secondly, a number of factors relating to the health technology should be verified.

56. The argument of the French Government was almost exclusively focused on the risk of contracting HIV facing the MSM population. If permanent deferral is essentially justified by the risk faced by the recipient because of the 'window period', I would note that the French Government has stated that the longest period — that concerning HIV 2 virus — is estimated to be 22 days. Now, unless I am mistaken, the maximum period of storage of blood is approximately 45 days. The systematic quarantining of donations from the MSM population during such a period before they are tested could objectively be a solution that best allows the objective pursued to be attained.

58 — See Point 4.1 of Resolution CM/Res(2008)5 of the Committee of Ministers of the Council of Europe on donor responsibility and on limitation to donation of blood and blood components, which recommends ensuring that blood establishments are ultimately responsible for the quality of the blood and that they should 'be responsible for the final acceptance or deferral of donors on the grounds of a risk assessment based on regularly updated epidemiological data, and bearing in mind the right of blood recipients to the protection of their health, and the resulting obligation to minimise the risk of transmission of infectious diseases. These rights and obligations override any other considerations, *including individuals' willingness to donate blood*' (emphasis added).

59 — *Humanplasma* (EU:C:2010:760, paragraph 39) and *Venturini and Others* (C-159/12 to C-161/12, EU:C:2013:791, paragraph 59 and the case-law cited).

60 — *Müller Fleisch* (EU:C:2010:93, paragraph 45 and the case-law cited) and *Humanplasma* (EU:C:2010:760, paragraph 40).

61 — Spain and Italy provide only for temporary deferral in the case of multiple partners or a change of partner, regardless of the nature of the relationship in question (the change in legislation which occurred in the course of proceedings before the European Court of Human Rights also allowed the latter to avoid carrying out a review as to whether excluding homosexuals from giving blood is compatible with the ECHR: see Eur. Court H.R., *Tosto* v *Italy* of 15 October 2002, Application No 49821/99); Slovakia (as is clear from the wording of Parliamentary Question No E-0910/09 of 17 February 2009) and, most recently, Finland and the United Kingdom have adopted a 12-month abstinence requirement for men who declare that they have had sexual relations with another man.

62 — If we accept the data provided by the French Government, which seem to be confirmed by the special report 'Thematic report: 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' (see in particular pp. 4 and 5 and Annex 2) of the European centre for disease prevention and control 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).

63 — *France* v *Commission* (C-601/11 P, EU:C:2013:465, paragraph 136).

57. The referring court should therefore question whether such a quarantine would be economically bearable and scientifically feasible for all or part of blood components. In particular, it should ensure that this would not undermine the proper functioning of the transfusion chain. To do so, it could, for example, rely on the conclusions of the report on the blood sector presented in 2013 to the Minister of Social Affairs and Health by the French MP Olivier Véran ('the Veran Report'), which states that 'experts agree that the systematic quarantining of plasma, associated with virological screening, would make it possible to neutralise any risk of viral transmission'.[64] In terms of protecting the health of recipients, such a solution seems to be optimal: first, it overcomes the problems associated with the feeling of discrimination which might be experienced by members of the MSM population — a feeling which could incite them not to respond truthfully to the questionnaire — and, secondly, it makes all donations subject to the same treatment, by letting the period during which the virus is not detectable elapse before testing them, thereby coming considerably closer to zero risk. I note that the observations of the French Government, although subsequent to the presentation of that report, make no mention of it.

58. Further, there is some doubt as to whether permanent deferral is consistent. In accordance with the permanent contraindication laid down by the ministerial decree and a reading of the latter in conjunction with the questionnaire referred to above,[65] the fact that a man has had, at least once in his life — albeit 10 years ago –, sexual relations with another man leads to his permanent deferral from giving blood. It must be inferred from this that the ongoing nature of the risk behaviour is irrelevant, whereas, since all blood donations are tested for HIV, it is, in fact, the window period which is the most critical period and which places recipients at the highest risk.[66] However, once again, if the primary motivation is that of the window period, it may be considered that a temporary deferral, determined according to the date of the last sexual relations, is more appropriate.

59. Similarly, one might question why there is no specific contraindication for a woman whose partner belongs to the MSM population. Moreover, a person whose partner is HIV-positive is subject to a temporary contraindication of four months. On the one hand, it is conceivable that increased vigilance is exercised by such a couple but, on the other hand, it might also be considered that, in such a case, the risk exposure is real, whereas for the MSM population it seems less certain, without an individual examination of the practices followed. It is also necessary to consider the case of a man who has had, once in his life or occasionally, protected homosexual relations (who is permanently excluded) in the light of that of a heterosexual person who regularly has unprotected sexual relations, but who will nevertheless be subject only to a temporary contraindication. Is the mere fact of that an individual belongs to the MSM population capable of justifying, in such a case, a permanent deferral?

60. Returning to the statistics, I note that 2 400 people in the MSM population discovered that they were HIV positive in 2011. In the same year, 3 500 people were infected through heterosexual sexual relations, including 2 400 heterosexuals born abroad.[67] The referring court should seek to clarify why that category of donors is not the subject of any contraindication under the ministerial decree at issue in the main proceedings.[68]

64 — See page 35 of that report.

65 — See point 9 of this Opinion.

66 — Article 20 of Recommendation No R(95)14 of the Committee of Ministers of the Council of Europe states that '[t]he following should be excluded (temporarily or permanently as the case may be): persons belonging to categories who by virtue of their medical history or *current* activities or behaviour present a high risk of transmission of infectious diseases' (emphasis added).

67 — Source: graph of the Institut français de veille sanitaire concerning the number of new diagnoses of HIV by mode of transmission and country of birth for the years 2003 to 2011, cited above. They are essentially people born in sub-Saharan Africa (77%) and women (58%).

68 — It is clear that, since the MSM population is numerically much smaller than the heterosexual population, the infection rate is proportionately higher among this population; this is not what I wish to discuss here. However, it is also undeniable that heterosexual persons born abroad constitute, proportionately, a category particularly at risk of contracting HIV, though, from my reading of the ministerial decree, they are not subject to any specific precautionary measure.

61. Finally, and perhaps above all, the questionnaire could be revised so that it can be used to identify risk behaviours in the MSM population, as it does, in a seemingly satisfactorily manner, for the rest of the donor population. More targeted questions — concerning the period since the last sexual relations, the number of partners, the nature of the sexual relations, whether the sexual relations were protected, attendance at certain nightspots — would make it possible not to identify sexual orientation, but instead to assess the level of risk that each donor individually presents on account of his own sexual behaviour. [69]

62. It follows from the foregoing that it is for the referring court to ensure that, in permanently excluding men who have had, or have, sexual relations with another man from giving blood, the French Government has exercised the discretion which is traditionally afforded to Member States in the area of protecting public health in a manner which is consistent with the requirements of the principle of non-discrimination on grounds of sexual orientation and in particular of the principle of proportionality. By ensuring that the permanent exclusion measure does not go beyond what is necessary to attain the legitimate objective of protecting the health of recipients, the referring court must, in particular, ensure, first, that the specific epidemiological situation in France, as presented to the Court, is based on reliable, representative and recent statistics and, secondly, that as scientific knowledge now stands, it is not possible, without subjecting the transfusion chain to excessive constraints, to provide quarantine measures for donations pending expiry of the window period. Finally, it is also for the referring court to examine possible reasons why an assessment of individual risk-taking, by means of a possibly revised questionnaire and an individual interview conducted by medical staff to identify whether the prospective donor's sexual behaviour is what is known as 'risk behaviour', though it is possible for the rest of the population, would be unsuitable for adequately ensuring the protection of recipients in connection with donations from men who have had, or have, sexual relations with another man.

V – Conclusion

63. In light of all the foregoing considerations, I propose that the Court give the following answer to the question referred by the Tribunal administratif de Strasbourg: 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 mere fact that a man has had or currently has sexual relations with another man does not, in and of itself, constitute a sexual behaviour placing him at a high risk of acquiring severe infectious diseases which can be transmitted by blood It is for the referring court to ensure that, in permanently excluding men who have had, or have, sexual relations with another man from giving blood, the French Government has exercised the discretion which is traditionally afforded to Member States in the area of protecting public health in a manner which is consistent with the requirements of the principle of non-discrimination on grounds of sexual orientation and in particular of the principle of proportionality. By ensuring that the permanent exclusion measure does not go beyond what is necessary to attain the legitimate objective of protecting the health of recipients, the referring court must, in particular, ensure, first, that the specific epidemiological situation in France, as presented to the Court, is based on reliable, representative and recent statistics and, secondly, that as scientific knowledge now stands, it is not possible, without subjecting the transfusion chain to excessive constraints, to provide quarantine measures for donations pending expiry of the window period. Finally, it is also for the referring court to examine possible reasons why an assessment of individual risk-taking, by means of a possibly

69 — I note, in that regard, that this is also a recommendation contained in the Véran Report, cited above: see p. 36 of that report.

revised questionnaire and an individual interview conducted by medical staff to identify whether the prospective donor's sexual behaviour is what is known as 'risk behaviour', though it is possible for the rest of the population, would be unsuitable for adequately ensuring the protection of recipients in connection with donations from men who have had, or have, sexual relations with another man.