Proposal for a Directive of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components and amending Council Directive 89/381/EEC

(2001/C 154 E/14)

(Text with EEA relevance)

COM(2000) 816 final — 2000/0323(COD)

(Submitted by the Commission on 26 January 2001)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(a) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

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

(2) The availability of blood and blood components used for therapeutic purposes is dependent on Community citizens who are prepared to donate; in order to safeguard public health and to prevent the transmission of infectious diseases by blood derivatives, all precautionary measures during their collection, processing, distribution and use need to be taken.

(3) The quality, safety, and efficacy requirements of proprietary industrially-prepared medicinal products derived from human blood or human plasma were ensured through Council Directive 89/381/EEC of 14 June 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma [1]; the specific exclusion of whole blood, plasma, and blood cells of human origin from that Directive, however, has led to a situation whereby their quality and safety, in so far as they are intended for transfusion and not processed as such, are not subject to any binding Community legislation. It is essential, therefore, that whatever the intended purpose, Community provisions should ensure that blood and its components are of comparable quality and safety throughout the blood transfusion chain in all Member States, bearing in mind the freedom of movement of citizens within Community territory. The establishment of high standards of quality and safety, therefore, will help to reassure the public that human blood and blood components that are derived from donations in another Member State nonetheless carry the same guarantees as those in their own country.

(4) In respect of blood or plasma as a starting material for the manufacture of proprietary medicinal products, Article 3 of Directive 89/381/EEC refers to measures to be taken by Member States to prevent the transmission of infectious diseases, comprising the application of the monographs of the European Pharmacopoeia and the recommendations of the Council of Europe and the World Health Organisation as regards in particular the selection and testing of blood and plasma donors. Furthermore, Member States should take measures to promote Community self-sufficiency in human blood or human plasma; and to encourage voluntary unpaid donations of blood and plasma. Consequently, these provisions cover blood and blood components collected and tested for the sole purpose of being used as starting material for medicinal products.

(5) In order to ensure that there is an equivalent level of safety and quality of blood components, whatever their intended purpose, technical adaptation of both Directive 89/381/EC and this Directive should be undertaken in accordance with the committee procedure provided for in this Directive. Directive 89/381/EEC should be amended accordingly.

(6) The Commission's Communication of 21 December 1994 on Blood Safety and Self-sufficiency in the European Community [2] identified the need for a blood strategy in order to reinforce confidence in the safety of the blood transfusion chain and promote Community self-sufficiency.

[1] OJ L 181, 28.6.1989, p. 44.

[2] COM(94) 652 final.

(7) The Council in its Resolution of 2 June 1995, on blood safety and self sufficiency in the Community [1], invited the Commission to submit appropriate proposals in the framework of the development of a blood strategy.

(8) The Council in its Resolution of 12 November 1996 on a strategy towards blood safety and self-sufficiency in the European Community [2] invited the Commission to submit proposals as a matter of urgency with a view to encouraging the development of a coordinated approach to the safety of blood and blood products.

(9) The European Parliament in its resolutions of 14 September 1993 [3], 18 September 1993 [4], 14 July 1995 [5], and 17 April 1996 [6] on blood safety and self-sufficiency through voluntary unpaid donations in the European Community has stressed the importance of ensuring the highest level of blood safety and has reiterated its continued support for the objective of Community self-sufficiency.

(10) In accordance with the principles of subsidiarity and proportionality set out in Article 5 of the Treaty, the objectives of the proposed action, namely to contribute to general confidence both in the quality of donated blood and plasma and in the health protection of donors, to attain self-sufficiency at a Community level and to enhance confidence in the safety of the transfusion chain among the Member States, cannot be sufficiently achieved by the Member States and can therefore by reason of its scale and effects be better achieved by the Community. This Directive confines itself to the minimum required in order to achieve those objectives and does not go beyond what is necessary for that purpose.

(11) In elaborating the provisions of this Directive account has been taken of the opinion of the Scientific Committee for Medicinal Products and Medical Devices as well as international experience in this field.

(12) Blood and plasma used for therapeutic purposes or for use in medical devices should be obtained from individuals whose health status is such that no detrimental effects to their state of health 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 Community citizens who are the recipients of blood and blood components.

(13) Modern blood-transfusion practice has been founded on the principles of voluntary donor services, anonymity of both donor and recipient, benevolence of the donor, and absence of profit on the part of the establishments involved in blood transfusion services.

(14) All necessary measures need to be taken in order to provide prospective donors of blood or plasma with assurances regarding the confidentiality of any health-related information provided to the authorised personnel, the results of the tests on their donations as well as any future traceability of their donation.

(15) Directive 95/46/EC of the European Parliament and the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and the free movement of such data [7] requires that data related to the health of an individual be subject to reinforced protection. However, it covers only personal data and not that rendered anonymous so that the person is no longer identifiable. This Directive should therefore introduce additional safeguards to prevent any unauthorised changes to donation registries, or processing records, or the unauthorised disclosure of information.

(16) A common system of accreditation for blood establishments and notification of adverse events and reactions linked to the collection, processing, testing, storage, and distribution of blood and blood components should be established in Member States. Accreditation should be provided for a period not exceeding three years and be renewable only following a satisfactory inspection by the responsible authorities.

(17) Member States should organise inspection and control measures, to be carried out by officials representing the competent authority, to ensure the compliance of the blood establishment with the provisions of this Directive.

(18) Personnel directly involved in the collection, testing, processing, storage and distribution of blood and blood components need to be appropriately qualified and provided with timely and relevant training. The provisions laid down in this Directive as regards training should be applicable without prejudice to existing Community legislation on the recognition of professional qualifications and on the protection of workers.

(19) An adequate system to ensure traceability of whole blood and blood components should be established; traceability should be enforced through accurate donor, patient, and laboratory identification procedures, through record maintenance, and through an appropriate labelling system.

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[1] OJ C 164, 30.6.1995, p. 1.

[2] OJ C 374, 11.12.1996, p. 1.

[3] OJ C 268, 4.10.1993, p. 29.

[4] OJ C 329, 6.12.1993, p. 268.

[5] OJ C 249, 25.9.1995, p. 231.

[6] OJ C 141, 13.5.1996, p. 131.

[7] OJ L 281, 23.11.1995, p. 31.

(20) The Commission should be empowered to adopt any necessary changes to the Annexes in order to take into account scientific and technical progress.

(21) It is necessary that the best possible scientific advice is available to the Community in relation to the safety of blood and blood components, in particular as regards adapting the provisions of this Directive to scientific and technical progress.

(22) Since the measures necessary for the implementation of this Directive are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1], they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision.

(23) In order to increase the effective implementation of the provisions adopted under this Directive it is appropriate to provide for penalities to be applied by Member States.

(24) Responsibility for the organisation of health services and the provision of medical care should remain the responsibility of each Member State,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

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.

However, when human blood and blood components are collected and tested for the sole purpose and exclusive use as starting materials for the manufacture of medicinal products as defined by Directive 89/381/EEC, the provisions of that Directive shall apply.

Article 2

Objectives

1. This Directive lays down standards of quality and safety of human blood and of blood components which are neither medicinal products within the meaning of Council Directive 65/65/EEC [2] nor reagents within the meaning of Directive 98/79/EC of the European Parliament and of the Council [3], in order to ensure a high level of human health protection.

2. This Directive applies without prejudice to Directive 98/79/EC or to Directive 95/46/EC.

Article 3

Definitions

1. For the purposes of this Directive:

(a) 'Blood' shall mean whole blood collected from a donor and processed either for transfusion or for further manufacturing.

(b) 'Blood component' shall mean a therapeutic constituent of blood (red cells, white cells, platelets, plasma) that can be prepared by centrifugation, filtration, and freezing using conventional blood bank methodology.

(c) 'Blood product' shall mean any therapeutic product derived from human blood or plasma, and shall include both labile blood components and stable plasma derivatives.

(d) 'Blood establishment' shall mean any enterprise or body that is involved in any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion.

(e) 'Responsible person' shall mean an individual with relevant qualifications and experience for the scope of activities carried out in a blood establishment.

(f) 'Accreditation' shall mean formal acknowledgement of compliance with accepted standards for procedures, activities, or services following an inspection by an authorised institute or organisation.

(g) 'Inspection' shall mean formal and objective control according to adopted standards to identify problems and approaches to their resolution.

(h) 'Adverse event' shall mean any untoward occurrence associated with the collection, testing, processing, storage, distribution, and transfusion of blood and blood components.

(i) 'Adverse reaction' shall mean a harmful and unintended response in donor or in patient associated with the collection or transfusion of blood or blood components.

(j) 'Serious adverse event' shall mean an adverse event that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in or prolongs hospitalisation

(k) 'Serious adverse reaction' an adverse reaction that is fatal, life-threatening, disabling, incapacitating, or which results in or prolongs hospitalisation.

[1] OJ L 184, 17.7.1999, p. 23.

[2] OJ 22, 9.2.1965, p. 369/65.

[3] OJ L 331, 7.12.1998, p. 1.

(l) 'Deferral' shall mean suspension of the eligibility of an individual to donate blood or blood components such suspension being either of lifetime duration (permanent deferral) or for a fixed period (temporary deferral).

2. The terminology used in Annexes II to IX shall be as set out in Annex I.

Article 4

Implementation

1. Member States shall establish, or designate, the competent authority responsible for implementing the requirements of this Directive.

2. Member States shall ensure that the competent authority implements accreditation requirements and organises inspections and other control measures intended to guarantee quality and safety of human blood and blood components, in accordance with the provisions of this Directive.

3. This Directive shall not prevent a Member State from maintaining or implementing on its territory more stringent protective measures which comply with the provisions of the Treaty. Those more stringent measures shall be safety measures based on current scientific knowledge and shall not present an obstacle to the implementation of this Directive, in particular as regards the free circulation of labile blood products.

4. In carrying out the activities covered by this Directive the Commission may have recourse to technical and/or administrative assistance to the mutual benefit of the Commission and of the beneficiaries, relating to identification, preparation, management, monitoring, audit and control, as well as to support expenditure

CHAPTER II

OBLIGATIONS ON MEMBER STATES' AUTHORITIES

Article 5

Accreditation of blood establishments

1. Prior to undertaking activities relating to the collection and testing of human blood and blood components, whatever their intended purpose, and to their preparation, storage, and distribution when intended for transfusion, the blood establishment shall apply for accreditation from the competent authority.

To this end, it shall deliver a notification to the competent authority, providing its name, address, telephone and fax numbers, as well as the name of the responsible person and the information listed in Annex II, Part A.

2. Where the responsible person is replaced, the blood establishment shall provide immediately to the competent authority the name of the new responsible person and his/her date of commencement.

3. The competent authority shall inform the blood establishment that it may only commence the activities for which it sought accreditation upon receipt, by the responsible person, of the competent authority's written approval and compliance with any conditions referred to therein.

4. The competent authority empowered to grant the accreditation shall verify that the particulars submitted in the application comply with the requirements set out in this Directive.

5. The competent authority shall acknowledge the date of receipt of the information provided in paragraph 1, and within 90 days shall respond in writing to the responsible person, indicating either:

(a) that the information provided complies with this Directive and that the activities for which the blood establishment sought accreditation may proceed, or

(b) that the activities for which the blood establishment sought accreditation do not fulfil the conditions of this Directive and that the accreditation is therefore rejected.

6. For the purpose of calculating the period referred to in paragraph 5, no account shall be taken of any period of time during which the competent authority is:

(a) awaiting additional information which it may have requested from the responsible person, or

(b) carrying out any inspection or control measure in accordance with Article 4(2).

7. The accreditation shall be given for a maximum period of three years. The accreditation shall be renewable, in accordance with the provisions of Article 7.

Article 6

Provisions for existing establishments

Member States may decide to maintain national provisions for nine months after the date laid down in Article 30 so as to enable blood establishments operating under their legislation to comply with its requirements.

Article 7

Renewal of accreditation

1. For the purposes of the renewal of accreditation, the responsible person shall submit to the competent authority to which the original application was transmitted, not less than nine months before the expiry of the accreditation, a notification that contains in particular the information listed in Annex II, Part B and any relevant information listed in Annex II, Part A if modified since the first notification.

The blood establishment may only proceed with the activities for which it is accredited upon receipt of the written accreditation, and compliance by the responsible person with any conditions referred to therein, from the competent authority.

2. The competent authority shall respond in writing to the responsible person, within 60 days following receipt of the notification in accordance with the first subparagraph of paragraph 1, indicating either:

(a) that the information is in compliance with this Directive and that the activities for which it was granted an authorisation may continue; or

(b) that its activities for which it was granted accreditation do not fulfil the conditions of this Directive and that the accreditation is therefore suspended.

3. For the purpose of calculating the period referred to in paragraph 2, no account shall be taken of any periods of time during which the competent authority is:

(a) awaiting further information which it may have requested from the responsible person, or

(b) carrying out any inspection or control measure in accordance with Article 4(2).

4. The accreditation shall be renewed for a maximum period of three years.

Article 8

Inspection and control measures

1. The competent authority shall organise inspections and other appropriate control measures in blood establishments to ensure that the requirements of this Directive are complied with.

2. Inspection and control measures shall be organised by the competent authority on a regular basis. The interval between two inspections and control measures shall not exceed one year.

3. Such inspection and control measures shall be carried out by officials representing the competent authority who must be empowered to:

(a) inspect blood establishments as well as facilities of any third parties entrusted by the holder of the accreditation referred to in Article 5 with the task of carrying out evaluation and testing procedures pursuant to Article 18;

(b) take samples;

(c) examine any documents relating to the object of the inspection, subject to the provisions in force in the Member States at the time of notification of this Directive and which place restrictions on these powers with regard to the descriptions of the method of preparation.

(4) The competent authority shall organise inspection and other control measures as appropriate in the event of any serious adverse reaction or event notified in accordance with Article 14.

CHAPTER III

PROVISIONS FOR BLOOD ESTABLISHMENTS

Article 9

Responsible person

1. The responsible person shall fulfil the following minimum conditions of qualification:

(a) he/she shall possess a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognised as equivalent by the Member State concerned, extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines: pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology;

(b) he/she shall have practical experience for at least two years, in one or more establishments which are authorised to undertake activities related to collection and testing of human blood and blood components, or to their preparation, storage, and distribution.

2. The responsible person shall be responsible for ensuring that each batch of blood or blood components has been collected and tested, whatever its intended purpose, and processed, stored, and distributed, when intended for transfusion, in compliance with the laws in force in the Member State.

Article 10

Personnel

1. Personnel directly involved in collection, testing, processing, storage, and distribution of human blood and blood components shall be provided with timely and relevant training.

2. The training of the personnel shall be provided on recruitment, and then at regular intervals of at least once every year. It shall be repeated in the event of a transfer or a change of job, as well as following the introduction of any new technology.

It shall be assessed periodically and at least every two years (proficiency testing).

3. Training guidelines addressing the issues listed in Annex III shall be provided for personnel.

CHAPTER IV

QUALITY MANAGEMENT

Article 11

Quality system for blood establishments

1. The competent authority shall take all necessary measures to ensure that each blood establishment establishes and maintains a quality system for blood establishments ('QSBE').

2. The QSBE shall involve all activities of blood establishments that determine the quality policy, objectives, and responsibilities and implement them by such means as quality planning, quality control, quality assurance, and quality improvement within the quality system.

3. The Commission shall establish in accordance with the procedure referred to in Article 26(2) detailed Community standards and specifications relating to the activities set out in paragraph 2 of this Article, to be carried out by a blood establishment.

Article 12

Documentation

1. Member States shall take all necessary measures in order to ensure that blood establishments maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms.

2. Member States shall take all necessary measures in order to ensure that access is provided to these documents for officials entrusted with inspection and control measures referred to in Article 8.

Article 13

Traceability

1. Member States shall take all necessary measures in order to ensure that blood and blood components collected, tested, processed, stored or distributed on their territory can be traced from donor to patient and vice versa.

To this end, Member States shall ensure that blood establishments under the responsibility of the responsible person implement a donor identification system and assign a number to each donation and its products.

2. Member States shall take all necessary measures in order to ensure that blood and blood components collected, tested, processed, stored and distributed on their territory comply with the labelling requirements listed in Annex IV.

Article 14

Notification of adverse reactions and events

1. Member States shall ensure that there is a system in place to collect, collate, and transmit information about adverse reactions and events related to the collection, testing, processing, storage and distribution of blood and blood components to the competent authority.

2. The responsible person shall notify the competent authority of any serious adverse reaction or event linked to the collection of blood and blood components.

3. The Community procedure for notifying these adverse reactions and events, referred to in paragraphs 1 and 2 of this Article, and the notification format shall be established by the Commission in accordance with the procedure referred to in Article 26(2).

Article 15

Record keeping

1. Member States shall take all necessary measures to ensure that blood establishments maintain records of the information required in Annexes V, VI, and VII, as well as the prevalence of viral markers in blood and plasma donors, and confirmed positive seroconversions.

2. The competent authority shall keep records of the data received from the blood establishments according to the provisions of Articles 5, 6, 7, and 14.

3. The records shall be kept for a minimum of 30 years.

CHAPTER V

PROVISIONS FOR THE QUALITY AND SAFETY OF BLOOD AND BLOOD COMPONENTS

Article 16

Provision of information to donors

Member States shall ensure that all donors of blood or plasma are provided with information as outlined in Annex V, Part A.

Article 17

Information required from donors

Member States shall take all necessary measures to ensure that, upon agreement of a willingness to commence the donation of blood or blood components, all donors provide the information listed in Annex V, Part B to the blood establishment.

Article 18

Eligibility of donors

1. Blood establishments shall ensure that in order to protect the health of both the donor and the recipient, there are evaluation procedures in place for all donors of blood and blood components and that the criteria for donation set out in Annex VI are met.

2. Blood and blood components shall be collected from donors who meet the criteria for donation set out in Annex VI.

3. Any deviation in the age of donors, blood pressure, pulse, haemoglobin or haematocrit shall not go beyond the requirements listed in Annex VI.

4. The time interval between two donations for whole blood or for apheresis plasma and the volume given during each donation by the donors shall comply with the requirements of Annex VI.

5. If any of the diseases or symptoms listed in Annex VI are identified during the donation process, donors shall be deferred permanently.

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

Article 19

Testing of donations

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

Article 20

Storage and freezing conditions

1. Blood establishments shall ensure that the storage conditions of blood and blood components comply with the provisions listed in Annex VIII, Part A.

2. Blood establishments shall ensure that requirements as regards time of freezing of blood and blood components after collection are clearly identified according to Annex VIII, Part B.

Article 21

Quality requirements for blood components

Blood establishments shall ensure that quality requirements for blood components meet high standards in compliance with the provisions listed in Annex IX.

CHAPTER VI

DATA PROTECTION

Article 22

Data protection

1. Member States shall, in accordance with Directive 95/46/EC, ensure the confidentiality of sensitive medical information about donors, including information obtained according to Article 17.

2. Member States shall ensure that donors are informed about the protection of their personal data, including the guarantee of no unauthorised disclosure of the name of the donor, of information concerning his health, or of the results of the tests performed.

3. Member States shall take all necessary measures to ensure that all data collated within the scope of this Directive have been rendered anonymous so that the donor is no longer identifiable.

For that purpose, they shall ensure:

(a) that data security measures are in place as well as safeguards against unauthorised data additions, deletions or modifications to donor files or deferral registers, and transfer of information;

(b) that procedures are in place to resolve data discrepancies;

(c) that no unauthorised disclosure of such information occurs, whilst guaranteeing the traceability of donations.

CHAPTER VII

EXCHANGE OF INFORMATION, REPORTS AND PENALTIES

Article 23

Information exchange

In order to facilitate the exchange of information associated with the collection, testing, processing, storage and distribution of blood and blood components, including information on adverse events or reactions, the Commission shall meet regularly with the competent authorities designated by the Member States to exchange information on the experience acquired with regard to the implementation of measures for the protection of human health.

Article 24

Reports

1. Member States shall send to the Commission, commencing on 31 December 2003 and thereafter annually, a report on the activities undertaken in relation to the provisions of this Directive, including an account of the national measures taken in relation to inspection and control.

2. The Commission shall transmit to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, the reports submitted by the Member States on the experience gained in implementing this Directive.

3. The Commission shall transmit to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, every three years, a report on the functioning of requirements in the Directive, and in particular those relating to inspection and control.

Article 25

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive. Member States shall notify those provisions to the Commission by the date specified in Article 30 at the latest and shall notify it without delay of any subsequent amendments affecting them.

CHAPTER VIII

COMMITTEES

Article 26

Committee procedure

1. The Commission shall be assisted by a committee composed of representatives of the Member States and chaired by the representative of the Commission.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 27

Adaptation to technical progress

Annexes I to IX shall be adapted to scientific and technical progress in accordance with the procedure referred to in Article 26(2).

Article 28

Consultation of scientific committee(s)

The Commission may consult the relevant scientific committee(s) when adapting the Annexes of this Directive to scientific and technical progress, in particular with a view to ensuring a comparable level of quality and safety of blood and plasma used for transfusion and blood and plasma used as a starting material for the manufacture of medicinal products.

CHAPTER IX

FINAL PROVISIONS

Article 29

Amendment of Directive 89/381/EEC

The following Article is inserted into Directive 89/381/EEC:

'*Article 6a*

In respect of the use of human blood or human plasma as a starting material for the manufacture of medicinal products as referred to in Article 3, the amendments to the Annex to Directive 75/318/EEC as provided for in Article 6 shall be adapted to technical progress in accordance with the procedure referred to in Articles 26 and 28 of Directive . . . /. . . /EC of the European Parliament and of the Council [1] (setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components and amending Council Directive 89/381/EEC).

[1] OJ L . . .'

Article 30

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 2002. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the texts of the provisions of national law that they have already adopted or which they adopt in the field governed by this Directive.

Article 31

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

Article 32

Addressees

This Directive is addressed to the Member States.

ANNEX I

TERMINOLOGY USED IN ANNEXES

1. Apheresis: process by which one or more blood components is selectively obtained from a donor by withdrawing whole blood, separating it by centrifugation or filtration into its components, and returning those not required to the donor;

2. Buffy coat: a blood component prepared by centrifugation of a unit of whole blood that contains most of its leukocytes and, depending on the centrifugation, its platelets;

3. Cell-derivative: a therapeutic product derived from a blood component (as derived from leukocytes — interferon, cytokines — or from outdated erythrocytes — haemoglobin solution);

4. Cryoprecipitate: a blood component obtained from a unit of fresh frozen plasma and containing the major portion of factor VIII, von Willebrand factor, fibrinogen, factor XIII and fibronectin;

5. Cytapheresis: an apheresis procedure intended for the collection of a cellular component of blood, such as red cells, leukocytes or platelets;

6. Donor: a person in normal health with a good medical history who voluntarily gives blood or plasma for therapeutic use;

7. Expiry date: the last day on which the blood or blood component is safe to use for transfusion;

8. Granulocytes: a kind of leukocyte; also used as name for a blood component, obtained either by the separation of whole blood or by apheresis, and in which granulocytes are represented several times more than in whole blood;

9. Granulocytes, apheresis: a granulocyte concentrate prepared by cytapheresis;

10. Leukocytes: white blood cells also used as a name for a blood component obtained either by the separation of whole blood or by apheresis and in which leukocytes are represented several times more than in whole blood;

11. Plasma derivative: highly purified human plasma protein prepared from pooled plasma under licensed pharmaceutical manufacturing conditions;

12. Plasma: the liquid portion of anticoagulated blood remaining after separation from the cellular components;

13. Plasma, cryoprecipitate depleted: the supernatant plasma removed during the preparation of cryoprecipitate. The content of albumin and immunoglobulins is comparable with fresh frozen plasma, factor VIII, von Willebrand factor, fibrinogen, factor XIII and fibronectin are reduced;

14. Plasma, fresh frozen: plasma that has been separated from a unit of whole blood within a few hours of donation or selectively collected by an apheresis procedure, has been rapidly frozen, and stored at a temperature below – 20 °C (and preferably below – 30 °C);

15. Plasma, recovered: plasma prepared from individual donations of whole blood;

16. Plasma, thawed: plasma that has been thawed for clinical use after having been fresh frozen;

17. Platelets (single unit): a platelet concentrate prepared by processing a unit of whole blood;

18. Platelets pool (buffy coat): a platelet concentrate prepared by processing a pool of buffy coats obtained from different units of whole blood;

19. Platelets, apheresis: a platelet concentrate prepared by apheresis;

20. Platelets, cryopreserved: apheresis: a blood component prepared by the freezing of platelets within 24 hours of collection by apheresis, using a cryoprotectant and storing them at – 80 °C or below;

21. Platelets: a blood component obtained either by separation of whole blood or by apheresis and suspended in a small volume of plasma from the same donation;

22. Red cells in additive solution, buffy coat removed: a blood component prepared by centrifugation of whole blood, removal of the buffy coat and most of the plasma, with subsequent addition to the red cells of an appropriate nutrient solution;

23. Red cells in additive solution: a blood component obtained by centrifugation of whole blood and removal of most of the plasma, with subsequent addition to the red cells of an appropriate nutrient solution;

24. Red cells, buffy coat removed: a blood component prepared by centrifugation of whole blood and removal of the buffy coat and most of the plasma;

25. Red cells, cryopreserved: a blood component derived from whole blood in which red cells are frozen, preferably within 7 days of collection, using a cryoprotectant, and stored at – 80 °C or below;

26. Red cells, deglycerolized: red cells that have been thawed and from which glycerol has been removed by washing;

27. Red cells, frozen in 20 % glycerol: red cells that have been stored continuously at – 65 °C or below, and to which 20 % glycerol has been added before freezing;

28. Red cells, frozen in 40 % glycerol: red cells that have been stored continuously at – 65 °C or below, and to which 40 % glycerol has been added before freezing;

29. Red cells, frozen in glycerol: red cells that have been stored continuously at – 65 °C or below, and to which glycerol has been added before freezing;

30. Red cells, frozen: red cells that have been stored continuously at – 65 ° or below, and to which a cryoprotectant agent such as glycerol has been added before freezing;

31. Red cells, leukocyte-reduced: a blood component prepared by centrifugation of whole blood, removal of most of the plasma and reduction of leukocytes through filtration;

32. Red cells, washed: a blood component prepared by washing centrifuged red cells with a volume of compatible solution in order to remove leukocytes, platelets and almost all of the plasma;

33. Red cells: a blood component prepared by centrifugation of whole blood and removal of most of the plasma.

ANNEX II

INFORMATION TO BE PROVIDED BY BLOOD ESTABLISHMENT TO THE COMPETENT AUTHORITY

PART A

— Identification of blood collection establishment (address, telephone & fax numbers, emergency numbers)

— Identification of responsible person, qualified personnel

— Number and qualifications of personnel; their responsibilities; written job descriptions

— Hygiene requirements (e.g. protective garments, hygiene in work area)

— Identification of products prepared

— Compliance of premises and equipment with regulatory requirements

— Disposal of infectious waste

— Standard Operating Procedures (SOPs) for donor suitability, testing, preparation, processing, distribution

— Storage requirements (time, temperature)

— Labelling provisions to be applied

PART B

— Total number of donors per year

— Total number of donations per year

— Number of donors/donations rejected

— Incidence of diseases in the donations

— Donor identification numbers

— Donation identification numbers

— Number of donations separated into components.

ANNEX III

GUIDELINES FOR TRAINING

To Be Provided For Personnel Directly Involved in the Collection, Testing, Processing, Storage and Distribution of Whole Blood and blood components

Training guidelines for all personnel	Supplementary training guidelines for technicians	Supplementary training guidelines for nurses	Supplementary training guidelines for scientists (biology, chemistry)	Suppl. training guidelines for physicians	Suppl. training guidelines for physicians managers
General overview about blood and blood transfusion; Basic steps in the blood collection and transfusion process; Importance of adhering to procedures whose scope is to ensure both quality and safety of final product; Importance of respecting and complying with confidentiality regulations; Elements of quality management.	Technical training in preparation of blood components; Training in testing of blood donations and pre-transfusion testing.	Technical training in blood collection and processing — theory related to collection procedures; — practice in whole blood collection and apheresis procedures; Training in interviewing/assessing potential donors; Training in storage, quality control requirements for blood and blood components; Training in identifying contra-indications to donation/ collection; Training in completing and maintaining manual/ computerised records (donor, donation, patients)	Training in transfusion medicine	Training in epidemiology /haemo-vigilance procedures; Emergency procedures	Management training

ANNEX IV

LABELLING REQUIREMENTS

Component	The label on specimen receptacles and containers should contain at least the following information
GENERAL LABELLING REQUIREMENTS	
	Specify — Nature of whole blood or component (or intended component) — Volume of component — Unique numeric or alphanumeric donation identification — Producer's name and address (clear text or code) — ABO group — Rh (D) group, specifying 'Rh (D)-positive' if D positive or 'Rh (D) negative' if D negative — Date of collection and expiry date — Temperature of storage — Name of anticoagulant (not required for frozen, deglycerolized, rejuvenated, or washed red blood cells) — Approximate volume of blood collected from the donor — That the blood or component must not be used for transfusion if abnormal haemolysis or other deterioration is evident — That blood or component must be administered through a 170-200 μm filter
SUPPLEMENTARY SPECIFIC LABELLING REQUIREMENTS	
Plasma, fresh frozen	Specify — Whether component is from whole blood or apheresis donation; — Volume and composition of anticoagulant used; — Whether quarantined or virus inactivated
Platelets: apheresis	— Volume of content and average number of platelets; if unit does not meet recommended standard, actual number of platelets to be specified; — Whether leukocyte depletion has been carried out
Platelets, recovered	— Donation number (if platelets are pooled, labelling system must allow identification of original donations); — Whether or not leukocyte depleted; — Composition of anticoagulant solution
Red cells	— Name and volume of component; — Composition of anticoagulant or additive solution
Red cells, cryopreserved	— Date and time of preparation and expiry; — Composition and volume of suspending solution; — Extra caution should be applied in identification of frozen bag units
Red cells, buffy coat removed	— Composition of anticoagulant solution
Red cells, in additive solution	— Composition and volume of additive solution
Red cells in additive solution, buffy coat removed	— Composition and volume of additive solution
Red cells, leucocyte-depleted	— Composition of anticoagulant solution
Red cells, washed	— Time of preparation and expiry; — Composition and volume of the suspending solution
Whole blood	— Volume of preparation; — Composition and volume of anticoagulant solution

ANNEX V

INFORMATION REQUIREMENTS

A. INFORMATION TO BE PROVIDED TO DONORS ACCORDING TO ARTICLE 16

1. Accurate but generally understandable educational materials about the essential nature of blood, the products derived from it, and the important benefits to patients of blood and plasma donations;

2. The reasons for requiring a medical history, physical examination, and the testing of donations; information on the risk of infectious diseases that may be transmitted by blood and blood products; the signs and symptoms of AIDS, and the significance of 'informed consent', self-deferral, and temporary and permanent deferral;

3. Information about protection of personal data: No unauthorised disclosure of the name of the donor, of information concerning his health, and of the results of the tests performed;

4. The reasons why they should not donate which may be detrimental to their own health;

5. The reasons why they should not donate which put recipients at risk, such as unsafe sexual behaviour, HIV/AIDS, hepatitis, drug addiction and the use and abuse of drugs;

6. The option of changing their mind about donating prior to proceeding further without any undue embarrassment or discomfort;

7. Information on the possibility of withdrawing or self-deferring at any time during the donation process;

8. The opportunity to ask questions at any time;

9. The undertaking that if test results shows evidence of any pathology, they will be contacted by the blood collection centre;

10. Specific information on the nature of the procedures involved in the donation process and associated risks for those willing to participate in apheresis programmes, whether for plasma or cellular components.

B. INFORMATION TO BE OBTAINED FROM DONORS ACCORDING TO ARTICLE 17

1. **Identification**

Appropriate means of identification, providing

— name (first and surname),

— address,

— date of birth,

or alternative means allowing the donor to be uniquely identified.

2. **Health history**

Health and medical history

— any relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to themselves or a risk of transmitting diseases to others, by way of a written questionnaire addressing the criteria listed in Annex VI and a personal interview with a trained health care staff member;

3. **Signature**

— Signature, on the donor questionnaire, countersigned by the health care staff member conducting the interview under the responsibility of the responsible person, or subject to the approval of this responsible person

— Signature on a separate attestation,

— to acknowledge

— that educational materials provided have been read and understood,

— that opportunity to ask questions has been presented, and

— that satisfactory responses have been received.

— to agree that his/her blood or plasma donation could be used for patients needing transfusion or blood products in the country where the donation is made or in another country, to which it would be transferred in accordance with the provisions of the legislation of the country where the donation is made, particularly with regard to the destination of the donation; and

— to indicate his/her informed consent of the wish to proceed with the donation process.

ANNEX VI

REQUIREMENTS CONCERNING THE SUITABILITY OF BLOOD AND PLASMA DONORS AND THE SCREENING OF DONATED BLOOD

1. **Requirements for the protection of blood and plasma donors**

(a) *Physical acceptance criteria*

Age	18-65 years	60-65 years (first-time donor) at discretion of responsible physician	17 years and not legally classified as a minor; otherwise written consent according to law	+ 65 years with permission of responsible physician given annually
Body weight	≥ 50 kg for either whole blood or plasma			
Blood pressure	Systolic ≤ 180 mm of mercury	Diastolic ≤ 100 mm of mercury		
Pulse	50-110 beats per minute and regular	< 50 beats per minute Accepted if undergoes intensive sport training		
Haemoglobin (or haematocrit)	for females ≥ 12.5 g/100 ml	for males ≥ 13.5 g/100 ml	For apheresis plasma: males and females ≥ 12.5 g/100 ml	
Haematocrit	for females ≥ 38 %	for males ≥ 40 %	For apheresis plasma ≥ 38 %	
Protein	For plasmapheresis 60 g/litre			

(b) *Donation criteria*

Time interval	For whole blood > 8 weeks	For apheresis plasma > 72 hours
Volume	Per whole blood donation ≤ 500 ml	

2. **Permanent Deferral Criteria**

(a) *For protection of donor*

— Auto-immune diseases

— Cardiovascular diseases

— Central nervous system diseases

— Malignant diseases

— Abnormal bleeding tendency

— Fainting spells (syncope) or convulsions

— Severe or chronic gastrointestinal, haematological, metabolic, respiratory, or renal disease not included in preceding categories

b) *For protection of recipient*

Prospective donors who have, or have a history of, any of the following:

— Auto-immune diseases

— Infectious diseases — persons suffering or having suffered from

  — Babesiosis

  — Hepatitis B (HBsAg confirmed positive)

  — Hepatitis C,

  — Hepatitis, infectious (of unexplained aetiology)

  — HIV/AIDS

  — HTLV I/II

  — Leprosy

  — Kala Azar (leishmaniasis)

  — Q fever

  — Syphilis

  — Trypanosoma cruzi (Chagas' disease)

— Malignant diseases

— TSEs (or history thereof in genetic family)

— Alcoholism, chronic

— Cornea/dura mater transplantation recipient

— Diabetes, if treated with insulin

— Intravenous (IV) drug use

— Pituitary hormone of human origin (e.g. growth hormone) recipient

— Sexual behaviour that places them at high risk of transmitting infectious diseases, including persons who have had sex in return for money or drugs

3. **Temporary Deferral Criteria**

Whether for protection of the donor or recipient: should take fully into account Recommendation 98/463/EC.

ANNEX VII

TESTING REQUIREMENTS AS REGARDS WHOLE BLOOD AND PLASMA DONATIONS

Components	Testing requirements		Required outcome
Whole blood/Plasma	Serological tests	ABO typing (*)	Determined using approved blood grouping reagents
		Rh D typing (*)	Determined using approved anti-D blood grouping reagents
		Rh C and E typing	Determined using approved blood grouping reagents
		HLA typing	
		Antibodies to red cell antigens	
	Surface antigen of Hepatitis B	HbsAg	Negative using an approved ELISA or RIA test
	Antibodies to the human immunodeficiency virus 1	Anti-HIV 1	Non-reactive for antibodies to HIV-1 using approved screening tests
	Antibodies to the human immunodeficiency virus 2	Anti-HIV 2	Non-reactive for antibodies to HIV-2 using approved screening tests
	Antibodies to the Hepatitis C virus	Anti-HCV	Non-reactive for antibodies to HCV using approved screening tests
		ALT (when required)	not elevated (as specified by national authorities)
		HBc-Ab (when required)	Negative by approved screening test
	Treponema pallidum (syphilis)	Syphilis (when required)	Negative by screening test
		CMV-Ab (when required)	Negative by screening test
		HTLV-Abs (when required)	Negative by screening test
	Malaria for travellers to endemic areas		

(*) Not required for apheresis plasma intended only for fractionation.

ANNEX VIII

STORAGE AND FREEZING

A. STORAGE

Blood product	Storage temperature	Length of storage	Transportation temperature	Transportation time
Cryoprecipitate	– 18 °C — – 25 °C – 25 °C — – 30 °C ≤ 30 °C	3 months 6 months 12 months	Similar to storage temperature	
Granulocytes	+ 20 °C — + 24 °C	Administered ASAP and within 12 hours of collection.		
Plasma, cryoprecipitate-depleted	– 18 °C — – 25 °C – 25 °C — – 30 °C ≤ 30 °C	3 months 6 months ≤ 12 months	Similar to storage temperature	
Plasma, fresh frozen	18 °C — – 25 °C – 25 °C — – 30 °C ≤ 30 °C	3 months 6 months ≤ 12 months	Similar to storage temperature	
Plasma, thawed	Thawed between + 30 °C — + 37 °C	Transfused as soon as possible		
Platelets	+ 20 °C — + 24 °C	24 hours — 5 days (with continuous gentle agitation) < 6 hours (after open system manipulation)	Similar to storage temperature (with continuous gentle agitation)	
Platelets (single unit)	+ 20 °C — + 24 °C	According to container bag	Similar to storage temperature	
Platelets, apheresis	+ 20 °C — + 24 °C	According to container bag	Similar to storage temperature	
Platelet concentrate, recovered	+ 20 °C — + 24 °C	24 hours — 5 days (with continuous gentle agitation)		
Platelets, cryopreserved: apheresis	Frozen platelets: maintained at: – 80 °C (in electrical freezer) – 150 °C (in vapour phase liquid nitrogen). Thawed platelets To be stored at + 20 °C to + 24 °C with adequate agitation, if short term storage required	+ 12 months To be used immediately after thawing	Similar to storage temperature	
Platelets pool (buffy coat)	+ 20 °C — + 24 °C	According to container bag	Similar to storage temperature	
Red cells	+ 2 °C — + 6 °C	≤ 35 days (in adenine supplemented anti-coagulant)	+ 1 °C — + 10 °C	≤ 12 hours
Red cells in additive solution	+ 2 °C — + 6 °C	≤ 35 days according to anticoagulant and additive solution	+ 1 °C — + 10 °C	≤ 12 hours

Blood product	Storage temperature	Length of storage	Transportation temperature	Transportation time
Red cells in additive solution, buffy coat removed	+ 2 °C — + 6 °C	≤ 35 days according to anticoagulant and additive solution	+ 1 °C — + 10 °C	≤ 12 hours
Red cells, leukocyte-reduced	+ 2 °C — + 6 °C	≤ 35 days with adenine supplemented anti-coagulant. < 12 hours if prepared in open system	+ 1 °C — + 10 °C	≤ 12 hours
Red cells, frozen in glycerol	– 80 °C	10 years from phlebotomy		
Red cells, frozen in 20 % glycerol	< – 120 °C	10 years from phlebotomy		
Red cells, frozen in 40 % glycerol	< – 65 °C	10 years from phlebotomy		
Red cells, washed	+ 2 °C — + 6 °C	< 12 hours	+ 2 °C — + 10 °C	≤ 12 hours
Whole blood (for transfusion as whole blood)	+ 2 °C — + 6 °C	< 35 days with adenine supplemented anti-coagulant	+ 1 °C — + 10 °C	≤ 12 hours
Whole blood (for component preparation)	+ 1 °C — + 6 °C (within 8 hours of collection)			

B. FREEZING

Blood product	Time of freezing
Plasma A	Frozen within 6 hours of phlebotomy
Plasma B	Frozen within 24 hours of phlebotomy
Plasma C	Frozen after 24 hours of phlebotomy
Platelets	Frozen within 24 hours
Red cells	Frozen within 7 days

ANNEX IX

QUALITY REQUIREMENTS FOR BLOOD COMPONENTS

Component	Properties	Parameter to be checked on all units (unless otherwise indicated)	Quality requirements
Cryoprecipitate	Contains a major portion of Factor VIII, von Willebrand factor, fibrinogen, Factor XIII and fibronectin present in freshly drawn and separated plasma	Blood donation testing requirements listed in Annex VII plus	
		Volume	10-25 ml
		Factor VIIIc Sampling — 1 % of all units Every two months: (a) pool of 6 units of mixed blood groups during first month of storage; (b) pool of 6 units of mixed blood groups during last month of storage	> 70 I.U./unit
		Fibrinogen Sampling — 1 % of all units;	> 140 mg/unit
Granulocytes, apheresis	Principal function is phagocytosis of bacteria	Blood donation testing requirements listed in Annex VII plus	
		Volume	< 500 ml
		Granulocytes	> 10×10^9/unit ≥ 10^{10} in 75 % of all units
Plasma, cryoprecipitate-depleted	Content of albumin, immuno-globulins and coagulation factors comparable to fresh frozen plasma. Reduced levels of Factors V, VIII, XIII, von Willebrand factor, fibrinogen, & fibronectin	Blood donation testing requirements listed in Annex VII plus (unless plasma itself is the source)	
		Volume Sampling — all units	Stated volume ± 10 %
Plasma, fresh frozen	Contains normal plasma levels of stable coagulation factors, albumin & immunoglobulins; at least 70 % of original Factor VIIIc, other labile coagulation factors, & naturally occurring inhibitors European Community legislation applies if source material for fractionated products	Blood donation testing requirements listed in Annex VII plus (unless plasma itself is the source)	
		Volume Sampling: 3 units/day	(recovered) 150-300 ml with anti-coagulant solution (apheresis) 500-600 ml with anti-coagulant solution
		Appearance Sampling: all units	Clear
		Red Cells Sampling: all units	< 6×10^9

Component	Properties	Parameter to be checked on all units (unless otherwise indicated)	Quality requirements
		HBc-Abs (*) (when required)	Negative by approved screening test
Platelets, apheresis	Platelet content per procedure variable depending on method of preparation and machine used. Same applies to leukocyte and red cell contamination of product. Standard unit = 5-6 single units by PRP	Blood donation testing requirements listed in Annex VII plus	
		Volume	> 40 ml/60 × 10^9 platelets
		Platelet content Sampling — all units. (75 % of units sampled should fall within specified values)	> 240 × 10^9 platelets/donation
		Residual leukocytes — before leukocyte depletion — after leukocyte depletion Sampling — all units. (90 % of units sampled should fall within specified values.)	< 1.0 × 10^9/standard unit < 1.0 × 10^6/standard unit
		Swirling Sampling — all units	+ 1 (score)
		HLA or HPA (when & as required)	Typing
		ph measured Sampling — all swirling negative units	6.5-7.4
Platelets, cryopreserved: apheresis	Reconstituted unit of cryopreserved platelets is practically free of red cells and granulocytes	Blood donation testing requirements listed in Annex VII plus	
		Volume	50-200 ml
		Platelet content	> 40 % of original pre-frozen platelet content
		Residual leukocytes	< 0.2 × 10^6 × 10^{11} platelets
Platelets, recovered from single unit by PRP	Amount of platelets in adult 'standard dose' equivalent to that obtained from 4-6 units of whole blood	Blood donation testing requirements listed in Annex VII plus	
		HLA or HPA (when & as required)	Typing

Component	Properties	Parameter to be checked on all units (unless otherwise indicated)	Quality requirements
		Volume Sampling — all units	40-60 ml of plasma/donation
		Platelet content Sampling — 1 % of all units: ≥ 10 units/month (75 % of units sampled should fall within values specified).	≥ 55×10^9 platelets/single unit equivalent
		Residual leukocyte content — before leukocyte depletion — after leukocyte depletion Sampling — 1 % of all units; ≥ 10 units/month (75 % of units sampled should fall within values specified)	< 0.2×10^9/single unit equivalent < 0.2×10^6/single unit equivalent
		pH (at end of recommended shelf life) Sampling — 1 % of all units	6.4-7.4
Platelet pool from buffy coat		Blood donation testing requirements listed in Annex VII plus	
		HLA or HPA (when & as required)	
		Volume	n. s.
		Platelet content Sampling	2.5×10^{11}
		Residual leukocyte content — before leukocyte depletion — after leukocyte depletion Sampling — 1 % of all units; ≥ 10 units/month (75 % of units sampled should fall within values specified)	< 0.05×10^9/single unit equivalent < 0.2×10^6/single unit equivalent
		pH	6.5—7.4
Red cells	Contains all red cells from donated unit after centrifugation. No procedures taken to remove leukocytes or platelets	Blood donation testing requirements listed in Annex VII plus	
		Volume Sampling — 3 units/day	280 ± 50 ml
		Haematocrit (Hct) Sampling — 3 units/day	55-75 %
		Haemoglobin Sampling — 3 units/day	≥ 45 g
Red cells, buffy coat removed	All red cells from donated unit, except 10-30 ml, remain after centrifugation	Blood donation testing requirements listed in Annex VII plus	

Component	Properties	Parameter to be checked on all units (unless otherwise indicated)	Quality requirements
		Volume Sampling — 3 units/day	280 ± 60 ml
		Haematocrit (Hct) Sampling — 3 units/day	50-75 %
		Haemoglobin Sampling — 3 units/day	> 43 g/unit
		Leukocyte content Sampling — 3 units/day (75 % of units sampled should fall within specified values)	$< 1.2 \times 10^9$ cells/unit
		Platelet content Sampling	$< 10 \times 10^9$ cells/unit
Red cells in additive solution	All red cells from donated unit remain after centrifugation. No procedures taken to remove leukocytes or platelets	Blood donation testing requirements listed in Annex VII plus	
		Volume Sampling — 1 % of all units (75 % of units sampled should fall within specified values)	280-420 ml
		Haematocrit (Hct) Sampling — 75 % of units sampled should fall within specified values	50-70 % (depending on additive solution, method of centrifugation, & quantity of remaining plasma)
		Haemoglobin. Sampling	≥ 45 g/unit
Red cells in additive solution, buffy coat removed	All red cells from donated unit, except 10-30 ml, remain after centrifugation.	Blood donation testing requirements listed in Annex VII plus	
		Volume Sampling — 3 units/day	280 ± 60 ml
		Haematocrit (Hct) Sampling — 3 units/day	50-70 % (depending on nature of additive solution, method of centrifugation, & amount of remaining plasma)
		Haemoglobin. Sampling — 3 units/day	43 g/unit
		Leukocyte content Platelet content Sampling — 3 units/day	$< 1.2 \times 10^9$ cells/unit (in 75 % of units sampled) $< 20 \times 10^9$ cells/unit
Red cells, cryopreserved		Blood donation testing requirements listed in Annex VII plus	

Component	Properties	Parameter to be checked on all units (unless otherwise indicated)	Quality requirements
		Volume	> 185 ml
		Hb (supernatant) (Final suspending solution)	< 0.2 g/unit
		Haematocrit (Hct)	0-0.75
		Hämoglobin	≥ 36 g/unit
		Osmolarity. Sampling — 1 % of all units:	< 340 mOsm/L
		Leucocytes Sampling — 1 % of all units: (75 % of units sampled fall within values specified)	< 0.1×10^9
		Sterility. Sampling — 1 % of all units:	Sterile
Red cells, leukocyte-reduced		Blood donation testing requirements listed in Annex VII plus	
		Volume	280 ± 60 ml
		Residual leukocyte content Sampling: validation with 100 filtrations for each kind of filter	< 5×10^6 cells/unit
		Haematocrit (Hct)	50—75 %
		Haemoglobin. Sampling — validation with 100 filtrations for each kind of filter	≥ 40 g/unit
Red cells, washed	Amount of residual plasma depends upon washing protocol	Blood donation testing requirements listed in Annex VII plus	
		Volume	280 ± 60 ml
		Haematocrit (Hct)	65—75 %
		Haemoglobin Sampling — 3 units/day	≥ 40 g/unit
		Residual protein of final supernatant	< 0.5 g/unit (To ensure IgA content < 0.2 mg/unit)
Whole blood		Blood donation testing requirements listed in Annex VII plus	
		Volume Sampling — all units:	400—500 ml excluding anticoagulant
		Haematocrit (Hct)	35-45 %
		Hämoglobin Sampling	≥ 45 g/unit
		Haemolysis at end of storage Sampling	< 0.8 % of red cell mass

(*) Not required for apheresis plasma intended only for fractionation.