ANNEX III

ELIGIBILITY CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS
(as referred to in Article 4)

1. ACCEPTANCE CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

Under exceptional circumstances, individual donations from donors who do not comply with the following criteria may be authorised by a qualified healthcare professional in the blood establishment. All such cases must be clearly documented and subject to the quality management provisions in Articles 11, 12, and 13 of Directive 2002/98/EC.

The following criteria do not apply to autologous donations.

1.1. Age and body weight of donors

Age	18 to 65 years	
	17 to 18 years	— unless classified as a minor by law, or with written consent of parent or legal guardian in accordance with law
	First time donors over 60 years	— at the discretion of the physician in the blood establishment
	Over 65 years	— with permission of the physician in the blood establishment, given annually
Body weight	≥ 50 kg for donors either of whole blood or apheresis blood components	

1.2. Haemoglobin levels in donor's blood

Haemoglobin	for females ≥ 125 g/l	for males ≥ 135 g/l	*Applicable to allogeneic donors of whole blood and cellular components*

1.3. Protein levels in donor's blood

Protein	≥ 60 g/l	*The protein analysis for apheresis plasma donations must be performed at least annually*

1.4. Platelet levels in donor's blood

Platelets	Platelet number greater than or equal to 150×10^9/l	*Level required for apheresis platelet donors*

2. DEFERRAL CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

The tests and deferral periods indicated by an asterisk (*) are not required when the donation is used exclusively for plasma for fractionation.

2.1. Permanent deferral criteria for donors of allogeneic donations

Cardiovascular disease	Prospective donors with active or past serious cardiovascular disease, except congenital abnormalities with complete cure
Central nervous system disease	A history of serious CNS disease
Abnormal bleeding tendency	Prospective donors who give a history of a coagulopathy
Repeated episodes of syncope, or a history of convulsions	Other than childhood convulsions or where at least three years have elapsed since the date the donor last took anticonvulsant medication without any recurrence of convulsions
Gastrointestinal, genitourinary, haematological, immunological, metabolic, renal, or respiratory system diseases	Prospective donors with serious active, chronic, or relapsing disease
Diabetes	If being treated with insulin
Infectious diseases	Hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune
	Hepatitis C
	HIV-1/2
	HTLV I/II
	Babesiosis (*)
	Kala Azar (visceral leishmaniasis) (*)
	Trypanosomiasis cruzi (Chagas' disease) (*)
Malignant diseases	Except *in situ* cancer with complete recovery

Transmissible spongiform encephalopathies (TSEs), (e.g. Creutzfeldt Jakob Disease, variant Creutzfeldt Jakob Disease)	Persons who have a family history which places them at risk of developing a TSE, or persons who have received a corneal or dura mater graft, or who have been treated in the past with medicines made from human pituitary glands. For variant Creutzfeldt Jacob disease, further precautionary measures may be recommended.
Intravenous (IV) or intramuscular (IM) drug use	Any history of non-prescribed IV or IM drug use, including body-building steroids or hormones
Xenotransplant recipients	
Sexual behaviour	Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood

2.2. Temporary deferral criteria for donors of allogeneic donations

2.2.1. Infections
Duration of deferral period

After an infectious illness, prospective donors shall be deferred for at least two weeks following the date of full clinical recovery.

However, the following deferral periods shall apply for the infections listed in the table:

Brucellosis (*)	*2* years following the date of full recovery
Osteomyelitis	*2* years after confirmed cured
Q fever (*)	*2* years following the date of confirmed cured
Syphilis (*)	*1* year following the date of confirmed cured
Toxoplasmosis (*)	*6* months following the date of clinical recovery
Tuberculosis	*2* years following the date of confirmed cured
Rheumatic fever	*2* years following the date of cessation of symptoms, unless evidence of chronic heart disease
Fever > °C	*2* weeks following the date of cessation of symptoms
Flu-like illness	*2* weeks after cessation of symptoms
Malaria (*)	
— individuals who have lived in a malarial area within the first five years of life	*3* years following return from last visit to any endemic area, provided person remains symptom free;

	may be reduced to 4 months if an immunologic or molecular genomic test is negative at each donation
— individuals with a history of malaria	*3* years following cessation of treatment *and* absence of symptoms. Accept thereafter only if an immunologic or molecular genomic test is negative
— asymptomatic visitors to endemic areas	*6* months after leaving the endemic area unless an immunologic or molecular genomic test is negative
— individuals with a history of undiagnosed febrile illness during or within six months of a visit to an endemic area	*3* years following resolution of symptoms; may be reduced to 4 months if an immunologic or molecular test is negative
West Nile Virus (WNV) (*)	**[***F1 28* days after leaving a risk area of locally acquired West Nile Virus unless an individual Nucleic Acid Test (NAT) is negative**]**

Textual Amendments

F1 Substituted by Commission Directive 2014/110/EU of 17 December 2014 amending Directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donations (Text with EEA relevance).

2.2.2. Exposure to risk of acquiring a transfusion-transmissible infection

— Endoscopic examination using flexible instruments, — mucosal splash with blood or needlestick injury, — transfusion of blood components, — tissue or cell transplant of human origin, — major surgery, — tattoo or body piercing, — acupuncture unless performed by a qualified practitioner and with sterile single-use needles, — persons at risk due to close household contact with persons with hepatitis B.	Defer for *6* months, or for *4* months provided a NAT test for hepatitis C is negative
Persons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood.	Defer after cessation of risk behaviour for a period determined by the disease in question, and by the availability of appropriate tests

2.2.3. Vaccination

Attenuated viruses or bacteria	*4* weeks
Inactivated/killed viruses, bacteria or rickettsiae	No deferral if well
Toxoids	No deferral if well
Hepatitis A or hepatitis B vaccines	No deferral if well and if no exposure
Rabies	No deferral if well and if no exposure If vaccination is given following exposure defer for one year
Tick-borne encephalitis vaccines	No deferral if well and if no exposure

2.2.4. Other temporary deferrals

Pregnancy	*6* months after delivery or termination, except in exceptional circumstances and at the discretion of a physician
Minor surgery	*1* week
Dental treatment	Minor treatment by dentist or dental hygienist — defer until next day (NB: Tooth extraction, root-filling and similar treatment is considered as minor surgery)
Medication	Based on the nature of the prescribed medicine, its mode of action and the disease being treated

2.3. Deferral for particular epidemiological situations

Particular epidemiological situations (e.g. disease outbreaks)	Deferral consistent with the epidemiological situation (These deferrals should be notified by the competent authority to the European Commission with a view to Community action)

2.4. Deferral criteria for donors of autologous donations

Serious cardiac disease	Depending on the clinical setting of the blood collection
Persons with or with a history of — hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune — hepatitis C — HIV-1/2 — HTLV I/II	Member States may, however, establish specific provisions for autologous donations by such persons

Active bacterial infection	