RESPONSES TO OPEN CONSULTATION
on Draft Technical Requirements for blood and blood components

Annex II
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. (p.4)

	Subject	Original text	Proposed modification	Justification for modification
EPFA	**General comments**	Requirements concerning the suitability of blood & plasma donors		Various requirements under sections 1 & 2 are solely for the protection of the donor, but will not affect the quality &/or safety of the products. Such requirements may not fall under the scope of the Directive 2002/98/EC, which aims to set standards for quality & safety.
Greece	**General comments**		Comment: this item presupposes full harmonisation of transfusion practices & acceptance of free circulation of blood & blood products intended for transfusion or use of blood products.	
Sweden	**General comments**		***Delete*** 1. Requirements for the protection of blood & plasma donors. ***Replace*** 2. Permanent Deferral Criteria & 3. Temporary deferral Criteria with the corresponding parts of PART II of the Council of Europe proposal of March 11. Temporary deferral periods should be reviewed taking into account the window period when testing for HIV, HBV & HCV, as being discussed by BWP of EMEA.	Article 152.5 does not justify EC legislation on donor health. Should remain a recommendation. This subject matter is obviously of great importance, but due to wide variations in organisational matters detailed regulation must be on a national level, which is foreseen in article 152.5 Deferral periods must be evidence based & evaluated regularly to achieve confidence from the patients, the donors & the professions.
Czech Republic	**General comments**	Requirements for the protection of blood & plasma donors	No comments / questions	

	Subject	Original text	Proposed modification	Justification for modification
EMEA	**General comments**			It is confusing to present this information as if it is a Table. The format of Council Recommendation 98/463/EC is preferable. It is not clear why changes have been made from the Council Recommendation. Is the protection of donors within the scope of the Blood Directive or does Article 152.5 of the EU Treaty mean that this is the responsibility of the Member States? Care should be taken that measures to protect EU donors do not exclude donations collected outside of the EU, particularly the USA, where other donor protection measures may be applied. This would have an adverse effect on supply of plasma-derived medicinal products.
SFVTT **(Société Française de vigilance et de thérapeutique transfusionnelle)**	**General comments**			Que faut-il comprendre sous 'dons entiers'?; Qu'entend-t-on par 'nombre de produits rejetés'? (s'agit-il du nombre de dons rejetés pour anomalie biologique ou poids ou volume insuffisant ... ou s'agit-il du nombre de **produits** à proprement parler, c'est à dire par exemple 3 - un CGR+un CPS+un plasma - pour un don de sang total?) A la fin du paragraphe concernant l'activité de prélèvement (donneurs, nombre de dons), on s'enquiert du nombre d'incidents et de réactions indésirables graves: s'agit -il des incidents transfusionnels chez les receveurs ou des incidents chez les donneurs? Un glossaire serait utile.
Baxter	**General comments**		In the requirements for the protection of blood & plasma donors, no distinction is made between manual & apheresis donation, & no mentioning of double red cell apheresis. Also, no recommendations in terms of maximal extra-corporeal volume	

	Subject	Original text	Proposed modification	Justification for modification
Denmark	**Title**	Requirements concerning the suitability of blood & plasma donors & the screening of donated blood	Change title to " … *Suitability of whole blood & apheresis donors* … "	Rationale: ***more accurate***
France *Afssaps*	**Title**	Requirements …	Requirements concerning the suitability of *blood & blood component***s** donors	More accurate
Portugal	**Title**	Requirements concerning the suitability... 1 . requirements....	Requirements ... suitability of *whole blood & apheresis donor* *(in title & n.1)*	This requirements should be applied to all donors
Finland	**Title**	Requirements …	Requirements concerning the suitability of whole blood & apheresis donors & the screening of donated blood	More accurate
United Kingdom *UK Joint Professional Advisory Committee*	**Title**	"	***Change** title to '* ***… Suitability of whole blood & apheresis donors …'***	Rationale: ***more accurate***
EBA	**Title**	"	**Change** to Requirements Concerning The Suitability Of **Whole Blood & Apheresis Donors**	More accurate
Denmark	**Sub title**	Requirements for the protection of blood & plasma donors	***Change** title to* ***'Requirements for the protection of whole blood & apheresis donors'***	***Rationale:*** as above
France *Afssaps*	**Sub title**	"	Requirements for the protection of blood & *blood components* donors	More accurate
United Kingdom *UK Joint Professional Advisory Committee*	**Sub title**	"	**Change** title to ***"Requirements for the protection of whole blood & apheresis donors"***	***Rationale:*** as above
EBA	**Sub title**	"	**Change** to Requirements for the **protection of whole blood & apheresis donors**	More accurate

	Subject	Original text	Proposed modification	Justification for modification
France *Afssaps*	a**) Physical criteria**		Ajouter une phrase générale : « l'examen pré-don, effectué par un professionnel de santé qualifié, permet d'apprécier l'aptitude au don des donneurs présentant les critères de référence d'admissibilité physique et biologique ci-dessous. En dehors de ces valeurs de référence, l'admissibilité des donneurs est laissée à la discrétion du médecin responsable. ».	
Greece	a**) Physical criteria**		Individual donations may be accepted outside these limits after consultation with the responsible physicians or as established by a national control authority based on norms for their specific populations	
France *Afssaps*	a**) Physical criteria**	**Physical** acceptance criteria	Physical & **<u>biological</u>** acceptance criteria	
United Kingdom *UK Forum*	**a) Physical criteria**		Add … 'individual donations may be accepted outside these limits after consultation with the responsible physician or as established by a national control authority based on normal for their specific populations'.	
United Kingdom *UK Forum*	**a) Physical acceptance criteria**		Consider only: age, body weight, Haemoglobin or Haematocrit, protein values for plasmapheresis donors only	
ARGE	**a) Physical acceptance criteria**	body weight, blood pressure pulse Hb, Ht protein only for the category 18 – 65 years	for all 4 types of donors	logical

	Subject	Original text	Proposed modification	Justification for modification
France *Afssaps*	**a) Physical acceptance criteria**	**Age** - 18-65 years - 60-65 years (first-time donor) at discretion of responsible physician - 17 years & not legally classified as a minor; otherwise written consent according to low - + 65 years, with permission of responsible physician given annually	18-65 ans pour sang total et plasma. A définir pour les autres composants sanguins. Dérogation : Cf phrase générale	
Italy	**a) Physical acceptance criteria**	**Age** + 65 years	Between 65 & 70 years	An upper limit is needed for the protection of the donor & 70 years covers all European guidelines or regulations
Finland	**a) Physical acceptance criteria**	**Age** 18-65 years, 60-65 years (first-time donors) at discretion of responsible physician, 17 years & not legally classified as a minor; otherwise written consent according to law, +65 years, with permission of responsible physician given annually	delete	Does not affect the quality of the product & thus the competence of determining this does not belong to the EU but to the Member States. Re: Paragraph 5 of Article 152 of the Treaty Establishing the European Community.
United Kingdom *UK Forum*	**a) Physical acceptance criteria:**	**Age**	18-65 (17 if legal in country; over 65 after consultation with responsible physician)	
France *Afssaps*	**a) Physical acceptance criteria:**	**Body weight** ≥ 50 kg for either whole blood or plasma	≥ 50 kg or at the discretion of responsible physician	In the case of an urgent HLA matched donation, for example a physician may accept a fit & otherwise well donor who is marginally below 50 kg in weight. Body weight may normally fluctuate by 1 kg or more from day to day.

	Subject	Original text	Proposed modification	Justification for modification
Finland	**a)Physical acceptance criteria**	**Body weight** >50 kg for either whole blood or plasma	Delete, Or write as: >50 kg or at the discretion of the responsible physician	Should be deleted, because this does not affect blood products & is out of scope of Directive. In the case of an urgent HLA matched donation, for example, a physician may accept a fit & otherwise well donor who is marginally below 50kg in weight. Body weight may normally fluctuate by 1 kg or more from day to day.
Denmark	**a)Physical acceptance criteria**	**Body weight** ≥ 50kg for either whole blood or plasma	***delete:*** "either whole blood or plasma**"**	*unnecessary, inaccurate* ***Include: "or at the discretion of the responsible physician"*** ***Rationale:*** in the case of an urgent HLA matched donation, for example, a physician may accept a fit & otherwise well donor who is marginally below 50kg in weight. Body weight may normally fluctuate by 1 kg or more from day to day.
Spain	**a)Physical acceptance criteria**	**Body weight** ≥ 50 Kg	The volume of extracted blood should not exceed the 13% of the theoretical total volume of blood (volemia) of the donor.	Increase donation
United Kingdom *UK Joint Professional Advisory Committee*	**a)Physical acceptance criteria**	**Body weight**	***Delete: '*** either whole blood or plasma' ***Include: "or at the discretion of the responsible physician"***	***Rationale:*** *unnecessary, inaccurate* ***Rationale:*** in the case of an urgent HLA matched donation, for example, a physician may accept a fit & otherwise well donor who is marginally below 50kg in weight. Body weight may normally fluctuate by 1 kg or more from day to day.
United Kingdom *UK Forum*	**a)Physical acceptance criteria**	**Body weight**	More than 50 Kg	
EBA	**a)Physical acceptance criteria**	**Body weight** ≥ 50 kg for either whole blood or plasma	Replace with <u>≥ 50 kg or at the discretion of the responsible physician</u>	In the case of an urgent HLA matched donation, for example a physician may accept a fit & otherwise well donor who is marginally below 50 kg in weight. Body weight may normally fluctuate by 1 kg or more from day to day.

	Subject	Original text	Proposed modification	Justification for modification
Denmark	**a)Physical acceptance criteria**	**Blood pressure**	Delete	***Rationale:*** Measuring blood pressure at a donation clinic is considered by some expert opinion to be at best useless & at worst potentially detrimental, both to the donor & to the safety of the blood supply. There is no published evidence of benefit from this practice, & to require it in the Directive is scientifically & medically unjustified on present evidence.
France *Afssaps*	**a)Physical acceptance criteria**	**Blood pressure** - Systolic ≤ 180 mm of mercury - Diastolic ≤ 100 mm of mercury	Delete	Measuring blood pressure at a donation site is considered by some expert opinion to be at best useless & at worst potentially detrimental, both to the donor & to the safety of the blood supply. There is no published evidence of benefit from this practice, & to require it in the Directive is scientifically & medically unjustified on present evidence.
Italy	**a)Physical acceptance criteria**	**Blood pressure** Systolic ≤ 180 mm of mercury Diastolic < 100 mm of mercury	Systolic ranging from 110 to 180 mm of mercury Diastolic ranging from 70 to 100 mm of mercury	Lower limits of blood pressure are needed for the protection of the donor; blood pressure of 100/60 is common in donors with vaso-vagal reactions
Finland	**a)Physical acceptance criteria**	**Blood pressure** Systolic ≦180 mm of mercury Diastolic ≦100 mm of mercury	delete	Measuring blood pressure at a donation clinic is considered by some expert opinion to be at best useless & at worst potentially detrimental, both to the donor & to the safety of the blood supply. There is no published evidence of benefit from this practice, & to require it in the Directive is scientifically & medically unjustified on present evidence. Does not affect the quality of the product & is out of the scope of the Directive.

	Subject	Original text	Proposed modification	Justification for modification
United Kingdom *UK Joint Professional Advisory Committee*	**a)Physical acceptance criteria**	**Blood pressure**	Delete	***Rationale:*** Measuring blood pressure at a donation clinic is considered by some expert opinion to be at best useless & at worst potentially detrimental, both to the donor & to the safety of the blood supply. There is no published evidence of benefit from this practice, & to require it in the Directive is scientifically & medically unjustified on present evidence.
EBA	**a)Physical acceptance criteria**	**Blood pressure**	Delete	Measuring blood pressure at a donation site is considered by some expert opinion to be at best useless & at worst potentially detrimental, both to the donor & to the safety of the blood supply. There is no published evidence of benefit from this practice, & to require it in the Directive is scientifically & medically unjustified on present evidence.
Denmark	**a)Physical acceptance criteria**	**Pulse**	Delete	*Rationale:* Measuring the pulse of a donor by donor clinic staff has no known benefit either to the donor or the donation. Venesection of 500 mls from a clinically well individual with no history of cardiovascular disease with a disorder clinically detectable by an abnormality in the radial pulse alone is of no known consequence to the individual.
France *Afssaps*	**Pulse**	- 50-100 beats per minute & regular - < 50 beats per minute accepted if undergoes intensive sport training	50-100 beats per minute & regular Dérogation : Cf phrase générale	

	Subject	Original text	Proposed modification	Justification for modification
Finland	**a)Physical acceptance criteria**	**Pulse** 50 –100 beats per minute & regular . 50 beats per minute. Accepted if undergoes intensive sport training	Delete	Measuring the pulse of a donor by donor clinic staff has no known benefit either to the donor or the donation. Venesection of 500 mls from a clinically well individual with no history of cardiovascular disease with a disorder clinically detectable by an abnormality in the radial pulse alone is of no known consequence to the individual. Does not affect the quality of the product & is out of scope of the Directive.
United Kingdom *UK Joint Professional Advisory Committee*	**a)Physical acceptance criteria**	**Pulse**	Delete	***Rationale:*** Measuring the pulse of a donor by donor clinic staff has no known benefit either to the donor or the donation. Venesection of 500 mls from a clinically well individual with no history of cardiovascular disease with a disorder clinically detectable by an abnormality in the radial pulse alone is of no known consequence to the individual.
EBA	**a)Physical acceptance criteria**	**Pulse**	Delete	Measuring the pulse of a donor by donor centre staff has no known benefit either to the donor or to the donation. Venesection of 500 ml from a clinically well individual with no history of cardiovascular disease with a disorder clinically detectable by an abnormality in the radial pulse alone is of no known consequence to the individual
EMEA	**a)Physical acceptance criteria**	**Haemoglobin or haematocrit** **Haemoglobin** For apheresis plasma: males & females ≥12.5 g/100 ml **Haematocrit** For apheresis plasma ≥38%	**Haemoglobin** For apheresis plasma: ~~males & females ≥12.5 g/100 ml~~ for females ≥12.5 g/100 ml, for males ≥13.5 g/100 ml **Haematocrit** For apheresis plasma ≥38%	Why has a change been made from Council Recommendation 98/463/EC?

	Subject	Original text	Proposed modification	Justification for modification
Denmark	**a)Physical acceptance criteria**	**Haemoglobin or haematocrit**	***Haemoglobin: Comment:*** units given should be either as g/litre or in S.I. units.	***Rationale:*** Units given are obsolete in Europe
France *Afssaps*	**a)Physical acceptance criteria**	**Haemoglobin :** for females ≥12.5 g/100 ml; for males ≥13.5 g/100 ml; for apheresis plasma: males & females ≥12.5 g/100 ml **Haematocrit**: for females ≥38%; for males ≥ 40%; for apheresis plasma ≥38%	- 12,5 g/100 ml<Hb<16,5 g/100 ml chez la femme et 13,5 g/100 ml<Hb<18,0 g/100 ml chez l'homme Dérogation : Cf phrase générale **- Interrogation : pouvez-vous indiquer l'origine de ces valeurs d'Ht > 38% chez les femmes et > 40% chez les hommes ?** Dérogation : Cf phrase générale	It is necessary to specify the interval of Haemoglobin or Haematocrit
Portugal	**a)Physical acceptance criteria**	**Haemoglobin** (or haematocrit**)** g/ml *(in haemoglobin*)	*g/dl or g/l*	Universal units
Finland	**a)Physical acceptance criteria**	**Haemoglobin** (or haematocrit**)** for females ≥ 12.5 g/100 ml for males ≥ 13.5 g/100 ml For apheresis plasma: males & females ≥ 12.5 g/100 ml	for females ≥ 125 g/l for males ≥ 135 g/l For apheresis plasma: males & females ≥ 125 g/l	Units given should be either as g/litre or in S.I. units, grams/100 ml are obsolete in Europe**.**
United Kingdom *UK Joint Professional Advisory Committee*	**a)Physical acceptance criteria**	**Haemoglobin**	***: Comment:*** units given should be either as g/litre or in S.I. units.	***Rationale:*** Units given are obsolete in Europe**.**

	Subject	Original text	Proposed modification	Justification for modification
United Kingdom *UK Forum*	**a)Physical acceptance criteria**	**Haemoglobin** (haematocrit)	females > 12.5g/dL (>38%) Males > 13.5 g/dL (> 40 %) Apheresis plasma >12.5 g/dL (> 38%)	
EBA	**a)Physical acceptance criteria**	**Haemoglobin** (or haematocrit)	**Comment:** Units in the original text should be either as g/litre or in S.I. units	Units in the original text are obsolete in Europe.
SFVTT (Société Française de vigilance et de thérapeutique transfusionnelle)	**a)Physical acceptance criteria**	**Haemoglobin**		Le taux d'hémoglobine d'exclusion est beaucoup trop haut, il faudrait un gramme plus bas pour les hommes et les femmes. Les médecins de collecte sont capables de jongler entre le poids des donneurs et les différents types de dons.
IG Plasma	**a)Physical acceptance criteria**	**Haemoglobin** For apheresis plasma: males & females ≥ 12.5 g/100 ml	For apheresis plasma: males & females > 12 g/100 ml	In whole blood donation the haemoglobin falls to 11.5 g/100 ml, whereas in plasma donation there is only an insignificant drop in the Hb value. This limit of > 12g/100 ml is already in practice in Austria for almost 30 years with sufficient experience.
PPTA	**a)Physical acceptance criteria**	**Haematocrit**	Haematocrit (or Haemoglobin)	Per analogy to previous haemoglobin determination where haematocrit is permitted as an alternative.
PPTA	**a)Physical acceptance criteria**	**Haemoglobin** 50-100 beats per minute & regular	50-**110** beats per minute & regular	Discordance with 98/463/EC, Annex II which defines 50-110 beats per minute as acceptable
PPTA	**a)Physical acceptance criteria**	**Haemoglobin** For apheresis plasma: males & females >12.5 g/100ml	For apheresis plasma: males & females >12 g/100ml	In whole blood donation the haemoglobin falls to 11.5 g/100ml, whereas in plasma donation the Hb value does not change drastically. This limit of >12 g/100ml is already in practice in different countries.
Denmark	**a)Physical acceptance criteria**	**Protein**	Include: "This analysis should be performed at least annually."	***Rationale:*** it is necessary to specify minimum frequency for protein analysis.
France *Afssaps*	**a)Physical acceptance criteria**	**Protein** For plasmapheresis 60 g/litre	For plasmapheresis **a minimum of** 60 g/litre. **This analysis should be performed at least annually**	It is necessary to specify minimum frequency for protein analysis

	Subject	Original text	Proposed modification	Justification for modification
Greece	**a)Physical acceptance criteria**	**Protein**	This analysis should be carried out at sustainable intervals but at least annually	
Italy	**a)Physical acceptance criteria**	**Protein** For plasmapheresis 60 g/litre	For regular plasmapheresis donors > or = 60 g/litre	Protein determination is not a mandatory test in all countries. Regular plasmapheresis donors are more at risk for protein depletion
United Kingdom *UK Joint Professional Advisory Committee*	**a)Physical acceptance criteria**	**Protein**	***Include: "This analysis should be performed at least annually."***	***Rationale:*** it is necessary to specify minimum frequency for protein analysis.
United Kingdom *UK Forum*	**a)Physical acceptance criteria**	**Protein**	plasmapheresis only > 60g/L	
Poland	**a)Physical acceptance criteria**	**Protein**	– add: At least annually	
EMEA	**a)Physical acceptance criteria**	**Protein** For plasmapheresis 60 g/litre	For plasmapheresis a minimum of 60 g/litre	Changes as in Council Recommendation 98/463/EC
EBA	**a)Physical acceptance criteria**	**Protein**	Add: This analysis should be performed at least annually	It is necessary to specify minimum frequency for protein analysis
EPFA	**a)Physical acceptance criteria**	**Protein** For plasmapheresis 60 g/litre	50 g/litre	EP Monograph for Human Plasma for Fractionation

	Subject	Original text	Proposed modification	Justification for modification
EMEA	**b) Donation criteria**	**Time interval:** For apheresis plasma Normally >2 weeks **Volume:**	**Time interval:** ~~For apheresis plasma Normally > 2 weeks~~ At least two days should elapse between donations. No more than two donations should be permitted within a seven-day period. **Volume:** Maximum volume per donation (excluding anticoagulant) 650ml	Text amended in line with Council Recommendation 98/463/EC. This is the current practice in many plasmapheresis centres. The practice in the USA of having a sliding scale where the maximum volume per donation depends on the size of the donor could also be considered. No maximum annual volume of plasma to be collected is specified. Member States currently apply different limits. There is no maximum limit in USA. If a maximum annual volume is specified to protect donor, there would need to be an exemption for collection outside EU, where other ways of ensuring donor protection are applied.
France **Afssaps**	**b) Donation criteria**	**Time interval:** for whole blood > 8 weeks; maximum 6 donations per year for males, 4 for females - for apheresis plasma Normally >2 weeks	**Time interval:** - for apheresis plasma Normally >2 weeks Prévoir des intervalles pour les dons d'autres composants sanguins	
Italy	**b) Donation criteria**	**Time interval** For apheresis plasma: Normally > 2 weeks	For apheresis plasma > 2 weeks	"Normally" is not needed in a Directive
Portugal	**b) Donation criteria**	**Time interval** For apheresis plasma...	For apheresis **donation** Normally>2 weeks & **no more than 20 times/year** ***(except red cells apheresis)***	It should included All apheresis donations
Poland	**b) Donation criteria**	**Time interval** For apheresis plasma	Add: Not more than 15 litres per year Not more than 1 litre per week	
ARGE	**b) Donation criteria**	**Time interval** For apheresis plasma normally > 2 weeks	1. as specified by national authorities 2. or twice a week, time interval minimum 48 hrs	long-term experience in Austria & Germany, preliminary results of SIPLA

	Subject	Original text	Proposed modification	Justification for modification
Denmark	**b) Donation criteria**	**Time interval**	***Include normally > 2 weeks for apheresis donations***	
Spain	**b) Donation criteria**	**Time interval** For whole blood > 8 weeks ; with a maximum of 6 donations per year for men & 4 for women	… with a maximum of 4 donations per year for men & 3 for women	Avoid low levels of Iron in blood.
Finland	**b) Donation criteria**	**Time interval** For whole blood ≥ 8 weeks Maximum 6 donations per year for males, 4 for females For apheresis plasma Normally > 2 weeks	delete delete	These criteria are made for the protection of the donor & do not affect the quality of the product, thus they are out of the scope of the Directive.
United Kingdom *UK Joint Professional Advisory Committee*	**b) Donation criteria**	**Time interval**	***Include*** in the table ***Time interval: normally > 2 weeks for apheresis donations***	
United Kingdom *UK Forum*	**b) Donation criteria**	**Time interval**	whole blood > 8 weeks	
EBA	**b) Donation criteria**	**Time interval** For apheresis plasma Normally > 2 weeks	Replace with <u>Normally > 2 weeks for apheresis donations</u>	
IG Plasma	**b) Donation criteria**	**Time interval** For apheresis plasma Normally > 2 weeks	As this matter regards donor safety & not the quality & safety of blood products this subject should not be regulated on a European level but rather on a national one.	Long-term experience in Austria with a minimum time interval of 72 hours.

	Subject	Original text	Proposed modification	Justification for modification
PPTA	**b) Donation criteria**	**Time interval** For apheresis plasma Normally > 2 weeks	Twice a week, time interval minimum 48 hrs	Long-term experience in Austria & Germany, preliminary results of SIPLA, experience USA. Discordance with 98/463/EC.
Denmark	**b) Donation criteria**	**Volume**	***≤ 600 mls (total volume of plasma & cells) for apheresis donations***	
France Afssaps	**b) Donation criteria**	**Volume:** **- per whole blood donation ≤ 500ml**	**Volume :** - per apheresis donations (total volume of plasma & cells) ≤ 600 ml (excluding anticoagulant) or ≤ 650 ml (including anticoagulant)	
Spain	**b) Donation criteria**	**Volume** ≤ 500 ml	Reconsider for persons of 50-55 Kg.	Excessive amount
Italy	**b) Donation criteria**	**Volume** Per whole blood donation < or = 500 ml	Per whole blood donation 450 ml + or - 50 ml	A lower limit is needed to standardise units
Portugal	**b) Donation criteria**	**Volume**	Add: <600 ml for apheresis donation	It is important to limit the volume of apheresis
Finland	**b) Donation criteria**	**Volume** Per whole blood donation ≤500 ml	delete	These criteria are made for protection of the donor & do not affect the quality of the product, thus they are out of scope of Directive.
United Kingdom *UK Joint Professional Advisory Committee*	**b) Donation criteria**	**Volume**	***≤ 600 mls (total volume of plasma & cells) for apheresis donations***	
United Kingdom *UK Forum*	**b) Donation criteria**	**Volume**	< 500mL	

	Subject	Original text	Proposed modification	Justification for modification
EBA	**b) Donation criteria**	**Volume** Per whole blood donation ≤ 500 ml	Replace with ≤ 600 ml (total volume of plasma & cells) for apheresis donations	
EPFA	**b) Donation criteria**	**Volume** Per whole blood donation ≤ 500 ml		Does this volume include samples taken for blood testing?
EUCOMED	**b) Donation criteria**	**Volume** Per whole blood donation ≤ 500ml	13% of donor's estimated blood volume	In-line with Council of Europe recommendations. Potentially safer & more practical for the donor
PPTA	**b) Donation criteria**	**Volume**	Up to 850 ml (incl. anticoagulant) per donation depending on body weight.	Volume per donation according to outcome of the SIPLA study & experience in US.

2. DEFERRAL CRITERIA FOR BLOOD AND PLASMA DONORS (p.5-7)

	Subject	Original text	Proposed modification	Justification for modification
France **Afssaps**	**General comments**		Il est nécessaire de classer les contre-indications en séparant les candidats au don se trouvant dans une situation particulière de ceux qui présentent des antécédents à cet égard (ex personne atteinte de CJD ou de diabète et personne ayant des antécédent familiaux de CJD ou de diabète) ; de séparer les personnes souffrant d'une maladie infectieuse de ceux ayant souffert de ces maladies (ex syphilis en cours ou syphilis ancienne traitée et guérie) ; quel risque est visé par telle ou telle mesure d'exclusion (ex tatouage piercing, si le risque visé est l'hépatite C, une exclusion temporaire de 4 mois serait suffisante par rapport à la fenêtre sérologique de 70 jours) ; de se limiter aux maladies et ne pas lister les symptômes (ex maladie neurologique et syncopes à répétition et convulsions)	
United Kingdom *UK Forum*	**General comments**		Add: "When assessing the suitability of the donor account should be taken of conditions which may lead to adverse events during or following the donation; such conditions should be formulated by national authorities & regularly reviewed.	All donor selection criteria must be subject to regular (at least annual) review & based on national & demographic criteria. When peer reviewed studies indicate that particular selection criteria should be modified national authorities should institute & document changes."
EMEA	**General comments**			Why have changes been made to the deferral list in the Council Recommendation 98/463/EC? The timeframes for deferral should be reviewed taking into account the window period of individual donation testing for HIV, HBV & HCV. Comparison is needed with deferral limits applied in the USA to avoid excluding donations collected in the US due to the use of historic deferral times that could now be reviewed.

Portugal	**2. Deferral criteria for blood and plasma donors**	all		We need to write this in a more comprehensive way
EBA	**2. Deferral criteria for blood and plasma donors**		Change to Deferral criteria for whole blood & apheresis donors	
EPFA	**2. Deferral criteria for blood and plasma donors**	Deferral Criteria for Blood & Plasma donors	Mark deferral criteria not applicable to plasma donors (such as HTLV I/II)	Deferral criteria for plasma for fractionation to be defined
Finland	**2.1 Permanent Deferral Criteria**	Prospective donors who have, or have a history of, any of the following:	Prospective donors who have, or have a history of, any of the following *require an evaluation of a professional staff member or by a physician:*	General remark: The Deferral criteria should not contain any such criteria for donor safety which do not affect the blood product, as the Directive itself is for the quality & safety of blood & blood components. Thus these are out of the scope of the Directive. *Re: sub-sub-paragraph (a) of the first sub-paragraph of paragraph 4; & paragraph 5 of Article 152 of the Treaty Establishing the European Community.*
United Kingdom *UK Forum*	**2.1 Permanent Deferral Criteria**		Remove 7 first conditions (autoimmune disease – severe & chronic gastrointestinal disease … inclusive) Infectious Diseases: persons suffering or having suffered from	

Czech Republic	**2.1 Permanent Deferral Criteria**		List of permanent deferral criteria should include only items important from the point of view of safety of the product, e.g. situations when a donor could harm a recipient. Disorders in which blood donation could harm the donor itself should be omitted (they are not covered by Article 152). Moreover formulation used etc) are too broad & vague. For example: are the hypertension stage I (cardiovascular disease), idiopathic autoimmune trombocytopenia in childhood (abnormal bleeding tendency), cured gastric ulcer (gastrointestinal disease) qualified reasons for permanent exclusion? - definitely not.	
IG Plasma	**2.1 Permanent Deferral Criteria**	**Infectious diseases** – Babesiosis – Leishmaniasis (Kala Azar) – Q fever – Chagas disease – Trypanosoma cruzi – Malaria	– Babesiosis* – Leishmaniasis (Kala Azar)* – Q fever* – Chagas disease* – Trypanosoma cruzi* – Malaria * * = not required for apheresis plasma intended only for fractionation	History of bacterial or parasitic diseases is not important for plasma for fractionation due to sterilisation in the fractionation procedure.
PPTA	**2.1 Permanent Deferral Criteria**	**Infectious diseases** – Babesiosis – Leishmaniasis – Q fever – Chagas disease – T. cruzi – Malaria	Babesiosis * leishmaniasis * Q Fever * trypanosomasiasis * malaria * T.cruzi * * = not required for apheresis plasma intended only for fractionation	If donor had a history of bacterial or parasitic diseases but is now healthy, there is no reason to defer him.
Italy	**2.1 Permanent Deferral Criteria**	**Auto-immune diseases** if more than one organ is affected	Auto-immune diseases	Auto-antibodies are a marker of aberrant lymphocyte clones

Finland	**2.1 Permanent Deferral Criteria**	**Auto-immune diseases** if more than one organ is affected	Auto-immune diseases if more than one organ is affected, as judged by a professional staff member or physician	Original expression is not sufficiently exact for a legally binding text. Eventual deleterious effect of the autoimmune disease to the product must be locally defined & judged by a physician.
EPFA	**2.1 Permanent Deferral Criteria**	**Auto-immune diseases** if more than one organ is affected	Idem + or donor with auto-immune disease with only one organ	More precise description of deferral criteria
Denmark	**2.1 Permanent Deferral Criteria**	**Cardiovascular diseases**	***Change** text to**:** "**Almost all prospective donors with a history of past or active cardiovascular disease. "***	***Rationale:*** Exceptions arise. For example a person with mild hypertension & a diastolic pressure maintained below 100 mmHg would not necessarily mandate permanent deferral.
France *Afssaps*	**2.1 Permanent Deferral Criteria**	**Cardiovascular diseases**	Almost all prospective donors with a history of past or active cardiovascular disease	Exceptions arise. For example a person with mild hypertension & a diastolic pressure maintained below 100 mmHg would not necessarily mandate permanent deferral.
Spain	**2.1 Permanent Deferral Criteria**	**Cardiovascular diseases**	It requires more detailed explanation	Donor retention
Finland	**2.1 Permanent Deferral Criteria**	**Cardiovascular diseases**	Delete	Ambiguous statement for legal text. Exceptions arise. For example a person with mild hypertension & a diastolic pressure maintained below 100 mmHg would not necessarily mandate permanent deferral. Ambiguous statement for legal text. Exceptions arise. [Does not] affect the quality of the blood product, thus out of the scope of the Directive.
United Kingdom *UK Joint Professional Advisory Committee*	**2.1 Permanent Deferral Criteria**	**Cardiovascular diseases**	***Change** text to**:** "**Almost all prospective donors with a history of past or active cardiovascular disease. "***	***Rationale:*** Exceptions arise. For example a person with mild hypertension & a diastolic pressure maintained below 100 mmHg would not necessarily mandate permanent deferral.

EBA	**2.1 Permanent Deferral Criteria**	**Cardiovascular diseases**	Replace with Almost all prospective donors with a history of past or active cardiovascular disease	Exceptions arise. For example a person with mild hypertension & a diastolic pressure maintained below 100 mmHg would not necessarily mandate permanent deferral.
Denmark	**2.1 Permanent Deferral Criteria**	**Central nervous system disease**	Change text to: "A history of serious CNS disease will usually result in permanent deferral."	***Rationale:*** Occasional exceptions may arise, such as a history of meningitis or encephalitis in the past.
France **Afssaps**	**2.1 Permanent Deferral Criteria**	**Central nervous system disease**	A history of serious CNS disease will usually result in permanent deferral	Occasional exceptions may arise, such as history of meningitis or encephalitis in the past.
Finland	**2.1 Permanent Deferral Criteria**	**Central nervous system diseases**	Delete	Ambiguous statement for legal text. Exceptions arise. For example a person with mild hypertension & a diastolic pressure maintained below 100 mmHg would not necessarily mandate permanent deferral. Ambiguous statement for legal text. Exceptions arise. [Does not] affect the quality of the blood product, thus out of the scope of the Directive.
United Kingdom *UK Joint Professional Advisory Committee*	**2.1 Permanent Deferral Criteria**	**Central nervous system diseases**	***Change*** text to: ***"A history of serious CNS disease will usually result in permanent deferral."***	***Rationale:*** Occasional exceptions may arise, such as a history of meningitis or encephalitis in the past.
EBA	**2.1 Permanent Deferral Criteria**	**Central nervous system diseases**	**Replace** with A history of serious CNS disease will usually result in permanent deferral	Occasional exceptions may arise, such as history of meningitis or encephalitis in the past.
Italy	**2.1 Permanent Deferral Criteria**	**Malignant diseases** except after successful treatment for non-invasive cervical cancer & rodent ulcer	Malignant diseases except for in-situ cancers after successful treatment [at least two years follow-up]	Most in-situ cancers have a tendency to recur

Finland	**2.1 Permanent Deferral Criteria**	**Malignant diseases** except after successful treatment for non-invasive cervical cancer & rodent ulcer	Malignant diseases except after successful treatment.	There are other malignant diseases than non-invasive cervical cancer & rodent ulcer, which can be permanently cured.
EMEA	**2.1 Permanent Deferral Criteria**	**Malignant diseases** except after successful treatment for non-invasive cervical cancer & rodent ulcer	Malignant diseases except after successful treatment for non-invasive cervical cancer & ~~rodent ulcer~~ ~~r~~	Rodent ulcer is an obsolete term (for a slowly enlarging ulcerated basal cell carcinoma, usually on the face).
PPTA	**2.1 Permanent Deferral Criteria**	**Malignant diseases** except after successful treatment for non-invasive cervical cancer & rodent ulcer	Malignant diseases except after successful treatment for non-invasive cervical cancer, rodent ulcer & minor skin cancer	From a medical point of view, donors with a history of minor skin cancer (e.g. basal cell or squamous cell carcinoma) may also be acceptable to donate after healing is complete.
Denmark	**2.1 Permanent Deferral Criteria**	**Abnormal bleeding tendency**	***Change*** text to***: "Prospective donors who give a history of abnormal haemorrhagic diathesis."***	***Rationale:*** Greater clarity. Easy bruising would not disqualify, for example
France **Afssaps**	**2.1 Permanent Deferral Criteria**	**Abnormal bleeding tendency**	Prospective donors who give a history of abnormal haemorrhagic diathesis	Greater clarity. Easy bruising would not disqualify, for example
Italy	**2.1 Permanent Deferral Criteria**	**Abnormal bleeding tendency**	Documented coagulopathy	Documentation allows to exclude from deferral donors with bleeding episodes related to local conditions [e.g. epistaxis]
Finland	**2.1 Permanent Deferral Criteria**	**Abnormal bleeding tendency**	Prospective donors who give a history of abnormal haemorrhagic diathesis	Greater clarity. Easy bruising would not disqualify, for example
United Kingdom *UK Joint Professional Advisory Committee*	**2.1 Permanent Deferral Criteria**	**Abnormal bleeding tendency**	***Change*** text to***: "Prospective donors who give a history of abnormal haemorrhagic diathesis."***	***Rationale:*** Greater clarity. Easy bruising would not disqualify, for example

EBA	**2.1 Permanent Deferral Criteria**	**Abnormal bleeding tendency**	**Replace** with **Prospective donors who give a history of abnormal haemorrhagic diathesis**	Greater clarity. Easy bruising would not disqualify, for example
Denmark	**2.1 Permanent Deferral Criteria**	**Fainting spells (syncope) or convulsions**	***Replace with:*** Repeated ***episodes of syncope, or a history of convulsions***. ***Insert*** text***: "other than childhood convulsions or where at least three years have elapsed off all anticonvulsant medication without recurrence."***	***Rationale:*** More specific; no need to define syncope for readers of this text. ***Rationale:*** Standard practice. No evidence to suggest that this is inappropriate.
France **Afssaps**	**2.1 Permanent Deferral Criteria**	**Fainting spells (syncope) or convulsions**	**Replace** with *Repeated episodes of syncope, or a history of convulsions other than childhood convulsions or where at least three years have elapsed off all anticonvulsant medication without recurrence*	More specific; no need to define syncope for readers of this text. Standard practice. No evidence to suggest that this is inappropriate.
Spain	**2.1 Permanent Deferral Criteria**	**Fainting spells (syncope) or convulsions**	It requires more detailed explanation	Donor retention
Italy	**2.1 Permanent Deferral Criteria**	**Fainting spells (syncope) or convulsions**	Fainting spells (syncope) excluding episodes occurring during childhood & adolescence	Syncope occurring in early age is not a marker of tendency to faint in adult age. Convulsions are a major symptom of epilepsy, which is considered a cause of temporal deferral, if successfully treated
Finland	**2.1 Permanent Deferral Criteria**	**Fainting spells (syncope) or convulsions**	Delete	Has nothing to do with the quality of blood or blood components & is thus out of the scope of the Directive.
United Kingdom *UK Joint Professional Advisory Committee*	**2.1 Permanent Deferral Criteria**	**Fainting spells (syncope) or convulsions**	***Replace with:*** Repeated ***episodes of syncope, or a history of convulsions***. ***Insert*** text***: "other than childhood convulsions or where at least three years have elapsed off all anticonvulsant medication without recurrence."***	***Rationale:*** More specific; no need to define syncope for readers of this text. *Rationale:* Standard practice. No evidence to suggest that this is inappropriate**.**

EBA	**2.1 Permanent Deferral Criteria**	**Fainting spells (syncope) or convulsions**	**Replace** with Repeated episodes of syncope, or a history of convulsions other than childhood convulsions or where at least three years have elapsed off all anticonvulsant medication without recurrence	More specific; no need to define syncope for readers of this text. Standard practice. No evidence to suggest that this is inappropriate.
Denmark	**2.1 Permanent Deferral Criteria**	**Severe or chronic gastrointestinal, haematological, metabolic, respiratory, or renal disease not included in preceding categories**	***Replace with: "Active severe disease, chronic disease, or relapsing disease in the gastrointestinal, genitourinary, haematological, immunological, metabolic, renal, or respiratory systems will usually require permanent exclusion of prospective donors."***	***Rationale:*** Clearer text.
France **Afssaps**	**2.1 Permanent Deferral Criteria**	**Severe or chronic gastrointestinal, haematological, metabolic, respiratory, or renal disease not included in preceding categories**	**Active** severe disease, chronic disease, **or relapsing disease in the** gastrointestinal, **genitourinary,** haematological, **immunological,** metabolic, renal, or respiratory **systems will usually require permanent exclusion of prospective donors**	Clearer text
Spain	**2.1 Permanent Deferral Criteria**	**Haematological disease**	It requires more detailed explanation: Accept thalassemia minor (if normal Hb), & some alterations of the coagulation	Donor retention
Spain	**2.1 Permanent Deferral Criteria**	**Renal disease**	It requires more detailed explanation: Pielitis, Acute Nephritis, renal malformation without clinical manifestation	Donor retention

Finland	**2.1 Permanent Deferral Criteria**	**Severe or chronic gastrointestinal, haematological, metabolic, respiratory, or renal disease not included in preceding categories**	Active severe disease, chronic disease, or relapsing disease in the gastrointestinal, genitourinary, haematological, immunological, metabolic, renal, or respiratory systems will usually require an evaluation by a physician & may lead to exclusion of prospective donors.	Clearer text
United Kingdom *UK Joint Professional Advisory Committee*	**2.1 Permanent Deferral Criteria**	**"**	*Replace with:* "Active severe disease, chronic disease, or relapsing disease in the gastrointestinal, genitourinary, haematological, immunological, metabolic, renal, or respiratory systems will usually require permanent exclusion of prospective donors."	***Rationale:*** Clearer text.
EBA	**2.1 Permanent Deferral Criteria**	**"**	Replace with Active severe disease, chronic disease, or relapsing disease in the gastrointestinal, genitourinary, haematological, immunological, metabolic, renal, or respiratory systems will usually require permanent exclusion of prospective donors.	Clearer text
France **Afssaps**	**2.1 Permanent Deferral Criteria**	– **Infectious diseases-persons suffering or having suffered from :** Babesiosis – Hepatitis B (HBsAg confirmed positive)	**Replace** with Hepatitis B (**except HbsAg negative persons who are demonstrated to be immune using a validated method.)**	More precise & accurate wording.

EMEA	**2.1 Permanent Deferral Criteria**	**Infectious diseases Hepatitis B** Permanent deferral: persons suffering or having suffered from - Hepatitis B (HBsAg confirmed positive)	*Discussion on harmonised criteria is needed.*	There is currently a lack of harmonisation amongst Member States on the re-entry of donors that have recovered from a hepatitis B infection. This can create difficulties during the evaluation of plasma-derived medicinal products. The proposed text makes hepatitis B infection a permanent deferral. Plasma from patients who have recovered from hepatitis B infection is used in the manufacture of hepatitis B immunoglobulin. Discussion is needed to agree harmonised criteria for acceptance of donors (See Appendix 1 of this document for further details.)
Denmark	**2.1 Permanent Deferral Criteria**	**Infectious diseases Hepatitis B**	***Replace*** "(HbsAg confirmed positive)**"** with ***"(except HbsAg negative persons who are demonstrated to be immune using a validated method.)"***	***Rationale:*** More precise & accurate wording
Finland	**2.1 Permanent Deferral Criteria**	**Infectious diseases Hepatitis B** (HBsAg confirmed positive)	Hepatitis B (except HBsAg negative persons who are demonstrated to be immune using a validated method)	More precise & accurate wording
United Kingdom *UK Joint Professional Advisory Committee*	**2.1 Permanent Deferral Criteria**	**Infectious diseases Hepatitis B**	***Replace*** "(HbsAg confirmed positive)**"** with ***"(except HbsAg negative persons who are demonstrated to be immune using a validated method.)"***	***Rationale:*** More precise & accurate wording
PPTA	**2.1 Permanent Deferral Criteria**	**Infectious diseases Hepatitis B**	To be deleted & to be placed under temporary deferrals	Hepatitis B does not belong to chronic persistent infections. In case of disease, infection is determined by the performed tests.
Italy	**2.1 Permanent Deferral Criteria**	**Infectious diseases Syphilis**	Cancel [shift to Temporary Deferral Criteria - Ineligible for two years after complete recovery*]*	Syphilis can be successfully cured & recovery can be documented monitoring serologic tests
Finland	**2.1 Permanent Deferral Criteria**	**Infectious diseases Syphilis**	Delete	History of syphilis should not lead to permanent deferral, because it can be cured.

United Kingdom *UK Forum*	**2.1 Permanent Deferral Criteria**	**Infectious diseases Syphilis**	Remove: syphilis	
EMEA	**2.1 Permanent Deferral Criteria**	**Infectious diseases** - Trypanosoma cruzi (Chagas' disease) – the blood of residents in an endemic area associated with poor living conditions may be used only for plasma fractionated products	- Trypanosoma cruzi (Chagas' disease) – ~~the blood of residents in an endemic area associated with poor living conditions may be used only for plasma fractionated products~~	The deleted text is not needed & would not be acceptable as part of legislative requirements; it would imply that a low quality of plasma is acceptable for plasma for fractionation.
Denmark	**2.1 Permanent Deferral Criteria**	**Infectious diseases** Trypanosomiasis cruzi …	Delete "the blood of residents**…"**	***Rationale:*** a history of Chagas' disease excludes permanently; prior residence in or travel to endemic areas & sleeping in poor quality accommodation in those areas excludes temporarily.
France **Afssaps**	**2.1 Permanent Deferral Criteria**	**Infectious diseases** Trypanosomiasis cruzi	Delete : – the blood of residents in an endemic area associated with poor living conditions may be used only for plasma fractionated products	A history of Chagas' disease excludes permanently; prior residence in or travel to endemic areas & sleeping in poor quality accommodation in those areas excludes temporarily.
Greece	**2.1 Permanent Deferral Criteria**	**Infectious diseases** Trypanosomiasis cruzi	**Delete:**(the blood of residents in an endemic area associated with poor living conditions may be used only for plasma fractionated products)	*Comment: In our* opinion, *acceptance of plasma* intended for fractionated production might be dangerous because in the same endemic areas for Cruzi other infectious factors are also endemic.

Italy	**2.1 Permanent Deferral Criteria**	Trypanosoma cruzi (Chagas' disease) - the blood of residents in an endemic area associated with poor living conditions may be used only for plasma fractionated products	Trypanosoma cruzi (Chagas' disease) - immigrants from endemic areas can be accepted as donors only if serologic assays for T. Cruzi infection are negative	Sensitive & specific serologic tests are available.
Finland	**2.1 Permanent Deferral Criteria**	**Infectious diseases** Trypanosoma cruzi (Chagas' disease) – the blood of residents in an endemic area associated with poor living conditions may be used only for plasma fractionated products	Trypanosoma cruzi (Chagas' disease)	A history of Chagas' disease excludes permanently; prior residence in or travel to endemic areas & sleeping in poor quality accommodation in those areas excludes temporarily.
United Kingdom *UK Joint Professional Advisory Committee*	**2.1 Permanent Deferral Criteria**	**Infectious diseases** Trypanosomiasis cruzi	Delete "the blood of residents…"	***Rationale:*** a history of Chagas' disease excludes permanently; prior residence in or travel to endemic areas & sleeping in poor quality accommodation in those areas excludes temporarily.
United Kingdom *UK Forum*	**2.1 Permanent Deferral Criteria**	**Infectious diseases** Trypanosomiasis cruzi	Add: Trypanosoma cruzi: unless a validated test is negative	

EBA	**2.1 Permanent Deferral Criteria**	**- Trypanosoma cruzi (Chagas'** disease) – the blood of residents in an endemic area associated with poor living conditions may be used only for plasma fractionated products		A history of Chagas' disease excludes permanently; prior residence in or travel to endemic areas & sleeping in poor quality accommodation in those areas excludes temporarily.
EBA	**2.1 Permanent Deferral Criteria**	**Infectious disease** – 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	Replace with *Hepatitis B (except HbsAg negative persons who are demonstrated to be immune using a validated method.)* Delete the blood of residents in an endemic area associated with poor living conditions may be used only for plasma fractionated products	More precise & accurate wording.
PPTA	**2.1 Permanent Deferral Criteria**	**Infectious disease** Hepatitis C, Hepatitis	Hepatitis C *, Hepatitis *	Discordance with R(95)15, 1.A6 page 38: individuals with a history of jaundice or hepatitis may be accepted after recovery, & provided they are found negative with an approved test.

Denmark	**2.1 Permanent Deferral Criteria**	**TSEs (or history thereof in genetic family)**	***Replace*** with ***"Transmissible Spongiform Encephalopathies*** (TSEs, Creutzfeldt-Jakob Disease). Persons who have a history of TSE in their genetic family, or who have received either a corneal or dura mater graft, or who have been treated in the past with medicines made from human pituitary glands.	***Rationale:*** more precise & accurate wording
Greece	**2.1 Permanent Deferral Criteria**	**TSEs (or history thereof in genetic family**	(A family history of TSE carries a presumption of family risk unless it is determined that: (a) the affected family member had TSE, or (b) the affected family member did not have a genetic relationship to the donor or (c) the cause of TSE in the affected family member was iatrogenic or (d) the donor was tested & is known to have a normal genetic polymorphism for $PrP^{c)}$.	
France **Afssaps**	**2.1 Permanent Deferral Criteria**	**TSEs (or history thereof in genetic family)**	**Replace** with Transmissible Spongiform Encephalopathies (TSEs, Creutzfeldt-Jacob Disease). Person who have a history of TSE in their genetic family, or who have received either a corneal or dura mater graft, or who have been treated in the past with medicines made from human pituitary glands.	More precise & accurate wording.
Finland5	**2.1 Permanent Deferral Criteria**	**TSEs (or history thereof in genetic family)**	Transmissible Spongiform Encephalopathies (TSEs, Creutzfeldt-Jakob Disease). Persons who have a history of TSE in their genetic family, or who have received either a corneal or dura mater graft, or who have been treated in the past with medicines made from human pituitary glands.	More precise & accurate wording
United Kingdom *UK Joint Professional Advisory Committee*	**2.1 Permanent Deferral Criteria**	**TSEs (or history thereof in genetic family)**	***Replace*** with ***"Transmissible Spongiform Encephalopathies*** (TSEs, Creutzfeldt-Jakob Disease). Persons who have a history of TSE in their genetic family, or who have received either a corneal or dura mater graft, or who have been treated in the past with medicines made from human pituitary glands.	***Rationale:*** more precise & accurate wording

EBA	**2.1 Permanent Deferral Criteria**	**TSEs (or history thereof in genetic family)**	Replace with *Transmissible Spongiform Encephalopathies (TSEs, Creutzfeldt-Jacob Disease). Person who have a history of TSE in their genetic family, or who have received either a corneal or dura mater graft, or who have been treated in the past with medicines made from human pituitary glands.*	More precise & accurate wording.
Finland	**2.1 Permanent Deferral Criteria**	**Alcoholism, chronic**	***Delete***	Alcoholism is always chronic, but one may be cured of it & then should be allowed to donate. Besides diagnosis of alcoholism is impossible to do at a donations session if the donor happens to be sober at the moment. Deferral is done solely for the protection of the donor & does not affect the quality of the product, & is thus out of the scope of this directive
United Kingdom *UK Forum*	**2.1 Permanent Deferral Criteria**	**Alcoholism, chronic**	Remove: Alcoholism	
PPTA	**2.1 Permanent Deferral Criteria**	**Alcoholism, chronic**	Alcohol abuse: 12 months deferral after successful rehabilitation	This is to avoid discrimination of rehabilitated individuals. The quality & safety of the product is not affected.
Denmark	**2.1 Permanent Deferral Criteria**	**Diabetes, if treated with insulin**	Replace ***with***: Diabetes, if <u>being</u> treated with insulin**.**	Rationale: ***a previous episode of glucose intolerance during pregnancy or while being treated with steroids for an acute illness, for example, would not disqualify.***
France **Afssaps**	**2.1 Permanent Deferral Criteria**	**Diabetes, if treated with insulin**	Replace with Diabetes, if <u>being</u> treated with insulin	A previous episode of glucose intolerance during pregnancy or while being treated with steroids for an acute illness, for example, would not defer permanently.
Finland	**2.1 Permanent Deferral Criteria**	**Diabetes, if treated with insulin**	Delete	Exclusion criteria solely for protection of the donor & does not affect the quality of the product being thus out of the scope of this Directive.

United Kingdom *UK Joint Professional Advisory Committee*	**2.1 Permanent Deferral Criteria**	**Diabetes, if treated with insulin**	***Replace*** with***:*** ***Diabetes, if <u>being</u> treated with insulin*** . .	Rationale: ***a previous episode of glucose intolerance during pregnancy or while being treated with steroids for an acute illness, for example, would not disqualify***
United Kingdom *UK Forum*	**2.1 Permanent Deferral Criteria**	**“**	***Remove: Diabetes***	
EBA	**2.1 Permanent Deferral Criteria**	**“**	**Replace** with Diabetes, if *being treated* with insulin	A previous episode of glucose intolerance during pregnancy or while being treated with steroids for an acute illness, for example, would not defer permanently.
Denmark	**2.1 Permanent Deferral Criteria**	**Intravenous (IV) drug use**	***Replace*** with: ***Any history of non-prescribed IV drug use, including any history of use of bodybuilding steroids.***	***Rationale:*** More precise, accurate, & comprehensive.
France **Afssaps**	**2.1 Permanent Deferral Criteria**	**Intravenous (IV) drug use**	Replace with Any history of non-prescribed IV drug use, including any history of use of body-building steroids	More precise, accurate, & comprehensive
Finland	**2.1 Permanent Deferral Criteria**	**Intravenous (IV) drug use**	Any history of non-prescribed IV drug use, including any history of use of bodybuilding steroids.	More precise, accurate, & comprehensive
United Kingdom *UK Joint Professional Advisory Committee*	**2.1 Permanent Deferral Criteria**	**Intravenous (IV) drug use**	***Replace*** with: ***Any history of non-prescribed IV drug use, including any history of use of bodybuilding steroids.***	***Rationale:*** More precise, accurate, & comprehensive.
United Kingdom *UK Forum*	**2.1 Permanent Deferral Criteria**	**Intravenous (IV) drug use**	Change: I/V drug use to injecting drug abuse	

EBA	**2.1 Permanent Deferral Criteria**	**Intravenous (IV) drug use**	**Replace** with Any history of non-prescribed IV drug use, including any history of use of bodybuilding steroids.	More precise, accurate, & comprehensive
Italy	**2.1 Permanent Deferral Criteria**	**Pituitary hormone of human origin recipient**	Pituitary hormone of human *or animal* origin recipient	Slow viruses & prions do not affect only humans but also animal species
EMEA	**2.1 Permanent Deferral Criteria**	**Sexual behaviour** that places them at high risk of transmitting infectious diseases, including (a) persons who have had sex in return for money or drugs (b) current sexual partners of people with HIV (c) current sexual partners of people with HBV unless demonstrated to be immune	Sexual behaviour that places them at high risk of transmitting infectious diseases, including ~~(a)~~ persons who have had sex in return for money or drugs ~~(b) current sexual partners of people with HIV~~ ~~(c) current sexual partners of people with HBV unless demonstrated to be immune~~	b) & c) are not permanent deferral criteria. Close contact with a case of hepatitis B or C appears under 2.2.4 *Ineligible for one year*. Sexual partner of people with HIV needs to be added under 2.2.4.

France **Afssaps**	**2.1 Permanent Deferral Criteria**	**Sexual behaviour** that places them at high risk of transmitting infectious diseases, including (a) persons who have had sex in return for money or drugs (b) current sexual partners of people with HIV (c) current sexual partners of people with HBV unless demonstrated to be immune	Difficile de trouver une logique entre cette exclusion permanente et celle d'exclusion temporaire d'1 an pour contact intime avec une personne présentant une hépatite B ou C (point 2.2.4) Exclusion permanente pour multipartenariat sexuel	

Italy	**2.1 Permanent Deferral Criteria**	**Sexual behaviour** that places them at high risk of transmitting infectious diseases, including (a) persons who have had sex in return for money or drugs (b) current sexual partners of people with HIV (c) current sexual partners of people with HBV unless demonstrated to be immune	(a) persons who have had sex in return for money or drugs, & *their partners* (b) sexual partners of people with HIV *(c) cancelled*	Both the person who gives money & drugs & the one who receives them are at high risk. "current" is not compatible with a permanent deferral applying to prospective donors "who have or have a history of…". This applies also to c) but in this case an active vaccination is possible; it would be more appropriate to include c) in a temporary deferral list
Finland	**2.1 Permanent Deferral Criteria**	**Sexual behaviour….**	Transferred to the section of Temporary deferral. This should be written as: – Sexual behaviour that places prospective donors at a risk of transmitting infectious diseases Delete from permanent deferral	Should be included under Temporary deferral, & there should be indicated that it may lead also to permanent deferral, but needs individual assessment case by case. .
Poland	**2.1 Permanent Deferral Criteria**	**Current sexual partners of people with HIV**	Add: Previous sexual partners of people with HIV are acceptable after one year after the last sexual contact	
Poland	**2.1 Permanent Deferral Criteria**	**Current sexual partners of people with HBV**	Add: Current sexual partners of people with HCV	
IG Plasma	**2.1 Permanent Deferral Criteria**	**Current sexual partners of people with HBV**	To be deleted	Is in contradiction with 2.2.4 (page 6).

PPTA	**2.1 Permanent Deferral Criteria**	**Current sexual partners of people with HBV**	To be deleted	Is in contradiction with 2.2.4 (page 6).
Italy	**2.1 Permanent Deferral Criteria**		Organ allo-transplant recipients	Self evident
Denmark	**2.1 Permanent Deferral Criteria**	**Allergy** – individuals with a documented history of anaphylaxis	Delete	***Rationale:*** anaphylaxis is not a specific clinical term, & may include any allergic reaction. The requirement to exclude donors with a history of sever immunological reactions or disorders is addressed by inclusion of the immunological system in the severe disease categories above.
France Afssaps	**2.1 Permanent Deferral Criteria**	**Allergy** – individuals with a documented history of anaphylaxis	Delete	Anaphylaxis is not a specific clinical term, & may include any allergic reaction. The requirements to exclude donors with a history of severe immunological reactions or disorders are addressed by inclusion of the immunological system in the severe disease categories above.
Italy	**2.1 Permanent Deferral Criteria**	**Allergy** - individuals with a documented history of anaphylaxis	Documented history of anaphylaxis	The mention of allergy, which was intended as a subtitle, may lead to exclude prospective donors with minor allergies.
Finland	**2.1 Permanent Deferral Criteria**	**Allergy** – individuals with a documented history of anaphylaxis	Delete	Anaphylaxis is not a specific clinical term, & may include any allergic reaction. The requirement to exclude donors with a history of severe immunological reactions or disorders is addressed by inclusion of the immunological system in the severe disease categories above.
United Kingdom *UK Joint Professional Advisory Committee*	**2.1 Permanent Deferral Criteria**	**Allergy** – individuals with a documented history of anaphylaxis	Delete	***Rationale:*** anaphylaxis is not a specific clinical term, & may include any allergic reaction. The requirement to exclude donors with a history of sever immunological reactions or disorders is addressed by inclusion of the immunological system in the severe disease categories above.

United Kingdom *UK Forum*	**2.1 Permanent Deferral Criteria**	**Allergy**	Remove: Allergy	
EBA	**2.1 Permanent Deferral Criteria**	**Allergy** - individuals with a documented history of anaphylaxis	Delete	Anaphylaxis is not a specific clinical term, & may include any allergic reaction. The requirements to exclude donors with a history of severe immunological reactions or disorders are addressed by inclusion of the immunological system in the severe disease categories above.
ARGE	**2.1 Permanent Deferral Criteria**	**Allergy**-individuals with a documented history of anaphylaxis	individuals with a documented history of anaphylaxis	anaphylaxis & not allergy is the criteria independent if allergic, pseudo-allergic or other reasons are the cause
IG Plasma	**2.1 Permanent Deferral Criteria**	**Allergy**-individuals with a documented history of anaphylaxis	Individuals with a documented history of anaphylaxis	Anaphylaxis & not allergy is the criteria independent if allergic, pseudo-allergic or other reasons are the cause.
PPTA	**2.1 Permanent Deferral Criteria**	**Allergy**-individuals with a documented history of anaphylaxis	Individuals with a documented history of anaphylaxis * * = not required for apheresis plasma intended only for fractionation	Anaphylaxis & not allergy is the criteria independent if allergic, pseudo-allergic or other reasons are the cause. This diseases are very common & not important for plasma for fractionation
EMEA	**2.1 Permanent Deferral Criteria**	**Malaria** –if test results positive for individual who lived in endemic area for first five years of life, reject as a cellular donor.	Text is oversimplified. New text is needed.	See Council of Europe Recommendations & US recommendations.
Denmark	**2.1 Permanent Deferral Criteria**	**Malaria**	Replace *text with*: individuals who lived in a malarial area within the first five years of life may be accepted as blood donors only if the results of a validated immunologic or molecular genomic test for malaria are negative.	***Rationale:*** more precise & accurate wording.

France **Afssaps**	**2.1 Permanent Deferral Criteria**	**Malaria** - if test positive for individual who live in endemic area for first five years of life, reject as a cellular donor **Malaria** (after return from last visit to endemic area & symptom free) TP 6 months	Proposer les recommandations françaises pour le paludisme exclusion définitive si antécédent de crise palustre ; exclusion temporaire de 3 ans si antécédent de détection des anticorps anti-*Plasmodium* positif en l'absence d'antécédent de crise palustre; acceptation du don au-delà de 3 ans si la détection des anticorps anti-*Plasmodium* est devenue négative ; exclusion au cours des 4 mois suivant le retour d'une zone d'endémie définie par l'OMS, qu'une prophylaxie ait ou non été suivie ; acceptation du don entre 4 mois et 3 ans après le retour d'une zone d'endémie définie par l'OMS, si aucune manifestation clinique n'est intervenue entre-temps et si la détection des anticorps anti-*Plasmodium* est négative ; la détection des anticorps anti-*Plasmodium* est effectuée sur tous les dons prélevés durant cette période ; acceptation du don au-delà de 3 ans après le retour d'une zone d'endémie définie par l'OMS : pour les voyageurs, sans dépistage sérologique associé si aucune manifestation clinique n'est survenue entre-temps, pour les résidents, si aucune manifestation clinique n'est intervenue entre-temps et si la détection des anticorps anti-*Plasmodium* est négative sur le premier don prélevé durant cette période; un résident est une personne ayant vécu plus de 3 mois consécutifs en zone d'endémie telle que définie par l'OMS ; l'exposition à une contamination palustre ne contre-indique pas le prélèvement de plasma destiné au fractionnement industriel.	

Italy	**2.1 Permanent Deferral Criteria**	**Malaria** - if test results positive for individual who lived in endemic area for first five years of life, reject as a cellular donor	Individuals who lived in endemic area for malaria for first five years of life, are not suitable as cellular donors if the result of a validated immunologic or molecular genomic test for malaria is positive	The mention of "malaria" at onset could give the false idea that restriction applies only to individuals who have suffered malaria
Finland	**2.1 Permanent Deferral Criteria**	**Malaria**	Individuals who lived in a malarial area within the first five years of life may be accepted as blood donors only if the results of a validated immunologic or molecular genomic test for malaria are negative.	More precise & accurate wording
United Kingdom *UK Joint Professional Advisory Committee*	**2.1 Permanent Deferral Criteria**	**Malaria**	Replace *text with*: individuals who lived in a malarial area within the first five years of life may be accepted as blood donors only if the results of a validated immunologic or molecular genomic test for malaria are negative.	***Rationale:*** more precise & accurate wording
United Kingdom *UK Forum*	**2.1 Permanent Deferral Criteria**	**Malaria**	Remove: Malaria	
SFVTT (Société Française de vigilance et de thérapeutique transfusionnelle)	**2.1 Permanent Deferral Criteria**	**Malaria**		Pour le paludisme les techniques proposées ne sont pas validées en France et sont peu fiables. Seule la recherche par immunofluorescence est considérée comme sûre, évidement c'est un gros travail.
EBA	**2.1 Permanent Deferral Criteria**	**Malaria**	**Replace** with Malaria – <u>individuals who have lived in a malarial area within the first five years of life may be accepted as blood donors only if the results of a validated immunologic or molecular genomic test for malaria are negative.</u>	More precise & accurate wording

ARGE	**2.1 Permanent Deferral Criteria**	– Babesiosis – Leishmaniasis – Q Fever – Trypanomasiasis – Malaria	– Babesiosis * – Leishmaniasis * – Q Fever * – Trypanomasiasis * – Malaria	history of bacterial or parasitic diseases is not important for pff due to sterilisation in the fractionation procedure
United Kingdom *UK Joint Professional Advisory Committee*	**<u>Sub-title</u>**		change heading to Deferral Criteria for blood & apheresis donors	Rationale: ***as above***
United Kingdom *UK Forum*	**General**		Remove whole section. Add general sentence: "Temporary deferral criteria should be subject to evidence based review-taking account of prevailing conditions in the country concerned.	National authorities should have in place organisations which review & document these criteria at least annually."
Denmark	**2.2 Temporary Deferral Criteria**		**Replace** the entire text as presented below. (i.e. Appendix)	**Rationale:** layout follows a more logical sequence, & gives greater clarity. Malarial deferral criteria are updated to reflect the current state of the art. Risk of infection is updated to reflect the use of NAT testing & to define better the acupuncture issue. Vaccinations more consistently categorised.
EBA	**2.2 Temporary Deferral Criteria**		**Replace** the entire original text with the below text. (i.e. Appendix)	Layout follows a more logical sequence, & gives greater clarity. Malaria deferral criteria are updated to reflect the current state of the art. Risk of infection is updated to reflect the use of NAT testing & to define better the acupuncture issue. Vaccinations are more consistently categorised.
France **Afssaps**		**2.2.1 Ineligible for five years** Acute Glomerulonephritis (following complete recovery) TD 5 years	Exclusion temporaire (attendre normalisation et/ou diagnostic étiologique)	

Italy	**2.2 Temporary deferral criteria**	**2.2.1 Ineligible for five years** Acute glomerulonephritis	*Cancelled*	There is no justification to mention particularly acute glomerulonephritis, omitting several other severe diseases that can be successfully cured, such as pneumonia
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.2 Ineligible for five** Epilepsy (off-treatment & without an attack) TD 3 years	Epilepsy (off-treatment without **recurrence**) TD 3 years	
Portugal	**2.2 Temporary deferral criteria**	**2.2.2 Ineligible for five years** Epilepsy ...	Epilepsy **(three years off treatment without recurrence)**	It is correct wait 3 years without any convulsion or syncope before accept as donor
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.3 Ineligible for 2 years Tuberculosis** (after declared cured) TD 2 years	Tuberculosis (after **confirmed** cured) TD 5 years	
France Afssaps	**2.2 Temporary deferral criteria**	**Osteomyelitis** (after declared cured) TD 2 years	Osteomyelitis (after **confirmed** cured) TD 2 years	
Portugal	**2.2 Temporary deferral criteria**	**2.2.3 Ineligible for 2 years ... Toxoplasmosis** (...)	Toxoplasmosis **(accept six months after clinical recovery)**	It is the state of the art
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.3 Ineligible for 2 years** Toxoplasmosis (after recovery & absence of IgM antibodies) TD 2 years	Toxoplasmosis (**following clinical** recovery) TD **1 year**	

IG Plasma	**2.2 Temporary deferral criteria**	**2.2.3 Ineligible for 2 years** – Toxoplasmosis – Brucellosis	Toxoplasmosis* Brucellosis* * = not required for apheresis plasma intended only for fractionation	History of bacterial or parasitic diseases is not important for plasma for fractionation due to sterilisation in the fractionation procedure.
PPTA	**2.2 Temporary deferral criteria**	**2.2.3 Ineligible for 2 years** – Toxoplasmosis – Brucellosis	Toxoplasmosis * Brucellosis * * = not required for apheresis plasma intended only for fractionation	History of bacterial or parasitic diseases is not important for plasma for fractionation due to sterilisation in the fractionation procedure. For toxoplasmosis, refer to R(95)15, 1A6, page 40.
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.3 Ineligible for 2 years** Brucellosis (after full recovery) TD 2 years	Ok proposition Commission	
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.3 Ineligible for 2 years** Rheumatic fever (after an attack if no evidence of chronic heart disease) TD 2 years	Rheumatic fever (**unless** evidence of chronic heart disease) TD 2 years	
Italy	**2.2 Temporary deferral criteria**	**2.2.3 Ineligible for two years**	Syphilis, after documented recovery	Syphilis can be successfully cured & recovery can be documented monitoring serologic tests
Greece	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Accidental exposure to blood or blood contaminated instruments	Endoscopy with biopsy using flexible instruments, inoculation injury, body piercing (acupuncture & tattooing according to national risk assessment) – defer twelve months. A deferral period of six months or less may be adequate to address HIV, HCV & HBV when a validated HCV NAT test with a sensitivity of ≤ 5 000 geq/ml is in place in addition to serological testing	

France Afssaps	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Accident exposure to blood or blood contaminated instruments TD 1 year	**<u>Exclusion temporaire 4 mois serait suffisante</u>**	
Italy	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Accidental exposure to blood or blood contaminated instruments	*Add*: A deferral period of six months may be adequate if validated HCV NAT, HIV NAT &, in endemic areas, HBV NAT tests are used in addition to serological testing	Current NAT technology allows to reduce to six months or less, the maximum window period for the three major transfusion-transmittable viruses [HBV, HCV, HIV]
PPTA	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Accidental exposure to blood or blood contaminated instruments	- Donors with a blood contaminated inoculation, needle injury or mucous membrane exposure to blood	The proposed wording would include ones own blood. To avoid confusion, the text needs some explanation & the wording of R(95) is proposed.
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Endoscopic examination TD 1 year	**<u>Exclusion temporaire 4 mois serait suffisante</u>**	
Italy	**.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Endoscopic examination	*Add*: A deferral period of six months may be adequate if validated HCV NAT, HIV NAT &, in endemic areas, HBV NAT tests are used in addition to serological testing	Current NAT technology allows to reduce to six months or less, the maximum window period for the three major transfusion-transmittable viruses [HBV, HCV, HIV]

France Afssaps	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Treatment involving use of catheters TD 1 year		
Italy	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Treatment involving use of catheters	Treatment involving use of *non disposable* catheters	Self evident
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Transfusion with blood or blood components TD 1 year	blood transfusion, **permanent deferral**	
Italy	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Transfusion with blood or blood components	*Add*: A deferral period of six months may be adequate if validated HCV NAT, HIV NAT &, in endemic areas, HBV NAT tests are used in addition to serological testing	Current NAT technology allows to reduce to six months or less, the maximum window period for the three major transfusion-transmittable viruses [HBV, HCV, HIV]
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Tissue or cell transplant TD 1 year	tissue or cell transplant **permanent deferral**	
Italy	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Tissue or cell transplant	Allogeneic tissue or cell transplant, if tissue or cell donor has been adequately screened & tested	Autologous tissue or cell transplant is not, per se, a risk factor. Only some countries test & screen for risk factors donors of cells or tissues.
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Major surgery TD 1 year	**Exclusion temporaire 4 mois serait suffisante**	

Italy	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Major surgery	*Add*: A deferral period of six months may be adequate if validated HCV NAT, HIV NAT &, in endemic areas, HBV NAT tests are used in addition to serological testing	Current NAT technology allows to reduce to six months or less, the maximum window period for the three major transfusion-transmittable viruses [HBV, HCV, HIV]
France Afssaps	**2.2 Temporary deferral criteria**	**New point**	**Exclusion temporaire de 4 mois pour relation sexuelle non protégée**	
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Acupuncture (if not performed by a qualified practitioner) TD 1 year	**Exclusion temporaire 4 mois serait suffisante**	
Italy	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Acupuncture (if not performed by a qualified practitioner)	*Add*: A deferral period of six months may be adequate if validated HCV NAT, HIV NAT &, in endemic areas, HBV NAT tests are used in addition to serological testing	Current NAT technology allows to reduce to six months or less, the maximum window period for the three major transfusion-transmittable viruses [HBV, HCV, HIV]
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Tattoo TD 1 year	**Exclusion temporaire 4 mois serait suffisante**	
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Body piercing TD 1 year	**Exclusion temporaire 4 mois serait suffisante**	
Italy	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Tattoo, Body piercing	*Add*: A deferral period of six months may be adequate if validated HCV NAT, HIV NAT &, in endemic areas, HBV NAT tests are used in addition to serological testing	Current NAT technology allows to reduce to six months or less, the maximum window period for the three major transfusion-transmittable viruses [HBV, HCV, HIV]

France Afssaps	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Drug allergy, in particular allergy to penicillin (after last exposure) TD 1 year	Exclusion temporaire d'1 an, mais à discuter par rapport à l'exclusion permanente pour antécédents certifiés d'anaphylaxie (point 2.2.1)	
Italy	**2.2 Temporary deferral criteria**	Drug allergy, in particular allergy to penicillin (after last exposure)	Severe drug allergy (after last exposure)	Drug allergy may be also a mild disease
EMEA	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** - Close contact with a case of hepatitis B or C	*Ineligible for one year* - Close contact with a case of hepatitis B or C - Previous sexual partners of people with HIV	Previous sexual partners of people with HIV should be a temporary & not a permanent deferral criteria.
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Close contact with a case of hepatitis B or C TD 1 year	Difficile de trouver une logique entre cette exclusion temporaire d'1 an et l'exclusion permanente des partenaires sexuels atteintes du VIH ou du VHB (point 2.2.1)	
Italy	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Close contact with a case of hepatitis B or C	*Add*: A deferral period of six months may be adequate if validated HCV NAT or [depending on the type of hepatitis] HBV NAT tests are used in addition to serological testing	Current NAT technology allows to reduce to six months or less, the maximum window period for HCV & HBV
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Rabies vaccine (if post exposure) TD 1 year	accept if well & if no exposure; 1 year if post exposure	

France **Afssaps**	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Rabies vaccine (prophylactic administration) TD 48 hours	accept if well & if no exposure; 1 year if post exposure	pas
ARGE	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** – toxoplasmosis – Brucellosis	toxoplasmosis * Brucellosis *	see Annex II, page 5 for bacterial diseases
Spain	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Close contact with a case of hepatitis B or C	It requires more detailed explanation: (vaccination)	Donor retention
Portugal	**2.2 Temporary deferral criteria**	**“**	Delete from this item & add: twice the window period after the last contact	It is more rationale, once the tests have high sensibility & specificity
Spain	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Major surgery	It requires more detailed explanation: (depends if transfusion)	Donor retention
Poland	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Major surgery	– not one year, but 6 months (transfer into 2.2.6.	
SFVTT **(Société Française de vigilance et de thérapeutique transfusionnelle)**	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year**		L'extension de l'exclusion au don pour un an pour tous les examens invasifs du piercing d'oreille à l'endoscopie. Avant le DGV l'exclusion était de 6 mois depuis le DGV elle a été ramenée à 4 mois. Mettre une exclusion d'un an est donc un retour en arrière qui ne se justifie pas.

ARGE	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** – Accidental exposure to blood or blood contaminated instruments – endoscopic examination – treatment involving use of catheters – transfusion with blood & blood components – tissue or cell transplant – major surgery – acupuncture – tattoo, piercing	– accidental exposure to blood or blood contaminated instruments – endoscopic examination ** – treatment involving – use of catheters – transfusion with blood & blood components – tissue or cell transplant – major surgery – acupuncture – tattoo, piercing ineligible for 4 months, if HCV – NAT (sensitivity <5000 geq/ml) is performed & negative	See also recommendation No. R (95) 15 8th edition: 2001 version, Council of Europe

IG Plasma	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** - Accidental exposure to blood or blood contaminated instruments -Endoscopic examination -Treatment involving use of catheters - Transfusion with blood & blood components - Tissue or cell transplant - Major surgery - Acupuncture - Tattoo - Body piercing	- Accidental exposure to blood or blood contaminated instruments* -Endoscopic examination*▪ -Treatment involving use of catheters*▪ - Transfusion with blood & blood components* - Tissue or cell transplant* - Major surgery* - Acupuncture*▪▪ - Tattoo* - Body piercing* * ineligible for 4 months, if HCV – NAT (Sensitivity <5000 geq/ml) is performed & negative ▪ not required if the examination or treatment was performed with single-use instruments or instruments that can be fully sterilised ▪▪ not required if performed under documented sterile circumstances	Based on Recommendation No. R (95) 15 9th edition: 2003 version, Council of Europe Treatment involving catheters is common use in Medicine & is usually performed with sterile single use catheters. Endoscopic instruments that are fully sterilised are no source of infection & are used under sterile circumstances (e. g. laparoscopy, arthroscopy) Acupuncture & ear-lobe piercing is common practice, & is no source of infection if performed with single use or sterilised tools

PPTA	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** - accidental exposure to blood or blood contaminated instruments, -endoscopic examination, - treatment involving use of catheters - transfusion with blood & blood components - tissue or cell transplant - major surgery - acupuncture - tattoo - body piercing	- accidental exposure to blood or blood contaminated instruments, -endoscopic examination *, - treatment involving use of catheters * - transfusion with blood & blood components - tissue or cell transplant - major surgery - acupuncture ** - tattoo - body piercing ** ineligible **for 4 months**, if HCV – NAT (sensitivity <5000 geq/ml) is performed & negative * not required if the examination or treatment was performed with single-use instruments or instruments that can be fully sterilised ** not required if performed under documented sterile circumstances	Based on Recommendation No. R (95) 15 8th edition: 2001 version, Council of Europe, page 34, respectively decision of RKI, Germany 2002 Treatment involving catheters is common use in Medicine & is usually performed with sterile single use catheters. Endoscopic instruments that are fully sterilised are no source of infection & are used under sterile circumstances in operating theatres (Laparascopy, Arthroscopy) Acupuncture & ear-lobe piercing is common practice, & is no source of infection if performed with single use or sterilised tools
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Tick-borne encephalitis vaccine (if post exposure) TD 1 year	accept if well & if no exposure; 1 year if post exposure	
IG Plasma	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Tick-borne encephalitis vaccine (if post exposure)	To be deleted	Administration of vaccines is listed under 2.2.9 Administration of the immunoglobuline is listed under 2.2.4 (Transfusion with blood or blood components).

PPTA	**2.2 Temporary deferral criteria**	**2.2.4 Ineligible for one year** Tick-borne encephalitis vaccine (if post exposure)	Tick-borne encephalitis vaccine if applied together with immunoglobulin (passive immunisation)	Should be listed under 2.2.6 (6 months) because the criterion is application of an immunoglobuline of human origin.
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.5 Ineligible for nine months** Pregnancy (after delivery) TD 9 months	**6** months after delivery	
Italy	**2.2 Temporary deferral criteria**	**2.2.4 Pregnancy (after delivery)** Ineligible for nine months **- Abortion** Ineligible for nine months	Ineligible for one year Ineligible for six months	Abortion is not comparable to a successful pregnancy, both in terms of blood losses & of physical stress.
Spain	**2.2 Temporary deferral criteria**	**2.2.5 Ineligible for nine months** Abortion	It requires more detailed explanation	Donor retention
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.5 Ineligible for nine months** Abortion TD 9 months	**6** months	
Poland	**2.2 Temporary deferral criteria**	**2.2.5 Ineligible for nine months** Pregnancy Abortion	Change: Pregnancy –deferral for as many months as the duration of pregnancy. Cancel: Abortion	

PPTA	**2.2 Temporary deferral criteria**	**2.2.5 Ineligible for nine months** Pregnancy Abortion	Change deferral to **6 months**	The 6 months temporary deferral is already in application in several countries including Germany. It should also be recommended that in case of termination of pregnancy (≤16 weeks), the deferral should only be 6 weeks.
Portugal	**2.2 Temporary deferral criteria**	**2.2.6 Ineligible for 6 months** Malaria (...)	Put it, like Council of Europe Guide	It more accurate
Italy	**2.2 Temporary deferral criteria**	**Malaria** (after return from last visit to endemic area & symptom free)	Individuals returning from a visit to endemic malaria area, if symptom free	The mention of "malaria" at onset could give the false idea that restriction applies only to individuals who have suffered malaria
PPTA	**2.2 Temporary deferral criteria**	**2.2.6 Ineligible for 6 months** Malaria (...)	Malaria* * = not required for apheresis plasma intended only for fractionation	History of bacterial or parasitic diseases is not important for plasma for fractionation due to sterilisation in the fractionation procedure.
IG Plasma	**2.2 Temporary deferral criteria**	**2.2.6 Ineligible for 6 months** Malaria	Malaria* * = not required for apheresis plasma intended only for fractionation	History of bacterial or parasitic diseases is not important for plasma for fractionation due to sterilisation in the fractionation procedure.
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.7 Ineligible for at least two weeks** Prophylactic immunisations (following administration of vaccines with attenuated bacteria & viruses (four weeks) TD 2 weeks	**3** weeks	

Italy	**2.2 Temporary deferral criteria**	**2.2.7** Ineligible for *at least* two weeks	Ineligible for two weeks	*"At least"* applies to all temporary deferral periods; there is no reason to mention it explicitly only here
EMEA	**2.2 Temporary deferral criteria**	**2.2.7 Ineligible for at least two weeks** - Prophylactic immunisations (following administration of vaccines with attenuated bacteria & viruses (four weeks)	*2.2.7 Ineligible for ~~at least two weeks~~ four weeks* - Prophylactic immunisations (following administration of vaccines with attenuated bacteria & viruses ~~four weeks~~	Text confusing.
EMEA	**2.2 Temporary deferral criteria**	**2.2.7 Ineligible for at least two weeks** - Prophylactic immunisations (following administration of vaccines with attenuated bacteria & viruses (four weeks) - Minor infectious diseases (two weeks) - Fever above 38º C, flu-like illness (following cessation of symptoms)	*2.2.~~7~~ 8 Ineligible for ~~at least~~ two weeks* ~~Prophylactic immunisations (following administration of vaccines with attenuated bacteria & viruses (four weeks)~~ - Minor infectious diseases (two weeks after recovery) - Fever above 38º C, flu-like illness (following cessation of symptoms)	Separate two week & four week periods to make the text clearer.

France Afssaps	**2.2 Temporary deferral criteria**	**2.2.7 Ineligible for at least two weeks** Minor infectious diseases TD 2 weeks	In general, after an infectious illness, prospective donors should be deferred for at least two weeks after full clinical recovery	
EMEA	**2.2 Temporary deferral criteria**	**Smallpox vaccination**		Recommendation is needed for deferral after smallpox vaccination e.g. 3 weeks after if the scab has fallen off, if not extended period.
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.8 Ineligible for at least one week** Minor surgery (without complications) TD 1 week	**72 hours**	
Italy	**2.2 Temporary deferral criteria**	**2.2.8** Ineligible for *at least* one week	Ineligible for one week	*"At least"* applies to all temporary deferral periods; there is no reason to mention it explicitly only here
EMEA	**2.2 Temporary deferral criteria**	**2.2.8 Ineligible for at least one week** - Minor surgery (without complications)	*2.2.~~8~~9 Ineligible for ~~at least~~ one week* - Minor surgery (without complications)	Clearer statement.
France Afssaps	**2.2 Temporary deferral criteria**	**2.2.9 Ineligible for 72 hours** Following administration of vaccines (desensitising) TD 72 hours	No deferral	

France **Afssaps**	**2.2 Temporary deferral criteria**	**2.2.10 Ineligible for 48 hours** Following administration of killed/inactivated viral/bacterial & rickettsial vaccines TD 48 hours	Following administration of killed/inactivated viral/bacterial & rickettsial vaccines **accept if well**	
Italy	**2.2 Temporary deferral criteria**	**2.2.10 Ineligible for 48 hours** Treatment by dentist or dental hygienist	Minor treatment by dentist or dental hygienist	Major treatments are comparable to major surgery in terms of infectious risks
EMEA		**CJD**		How to deal with the CPMP recommendation to exclude donors who have spent a cumulative period of 1 year in the UK for plasma for fractionation? The points raised in 9.2.1 b) of the CPMP Position Statement need discussion (see Appendix 2 of this document).
Poland	**2.2 Temporary Deferral Criteria**	Medication	Add: Medication – deferral according to underlying disease may be indicated. Deferral period for prescribed medication should be consistent with the pharmacokinetic properties of the drug concerned	

Finland	**2.2 Temporary Deferral Criteria**	**2.2.1 Ineligible for five years** – Acute glomerulonephritis (following complete recovery) **2.2.2 Ineligible for three years** – Epilepsy (off-treatment & without an attack) **2.2.3 Ineligible for two years** – Tuberculosis (after declared cured) – Osteomyelitis (after declared cured) – Toxoplasmosis (after recovery & absence of IgM antibodies) – Brucellosis (after full recovery) – Rheumatic fever (after an attack if no evidence of chronic heart disease) **2.2.4 Ineligible for one year** – Accidental exposure to blood or blood contaminated instruments – Endoscopic examination – Treatment involving use of catheters – Transfusion with blood or blood components – Tissue or cell	**2.2.1 INFECTIONS** Duration of deferral**.** In general, after an infectious illness, prospective donors should be deferred for at least two weeks after full clinical recovery. – Brucellosis, 2 years after full recovery – Infectious mononucleosis, six months after recovery – Osteomyelitis, 2 years after confirmed cured – Toxoplasmosis, 6 months following clinical recovery – Tuberculosis, 2 years after confirmed cured – Rheumatic fever, 2 years, unless – Evidence of chronic heart disease – Fever >38 degrees C, 2 weeks after – Cessation of symptoms.	The entire text is replaced by the proposed one. Justification: Layout follows a more logical sequence, & gives greater clarity. Malarial deferral criteria are updated to reflect the current state of the art. Risk of infection is updated to reflect the use of NAT testing & to define better the acupuncture issue. Vaccinations more consistently categorised.

Finland	**2.2 Temporary Deferral Criteria**	– Acupuncture (if not performed by a qualified practitioner) – Tattoo – Body piercing – Drug allergy, in particular allergy to penicillin (after last exposure) – Close contact with a case of hepatitis B or C – Rabies vaccine (if post exposure) – Tick-borne encephalitis vaccine (if post exposure) *2.2.5 Ineligible for nine months* – Pregnancy (after delivery) – Abortion *2.2.6 Ineligible for six months* – Infectious mononucleosis (after recovery) – Malaria (after return from last visit to endemic area & symptom free) *2.2.7 Ineligible for at least two weeks* – Prophylactic immunisations (following administration of vaccines with attenuated bacteria & viruses (four weeks)	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: Defer for three years following return from last visit to endemic area, provided person remains symptom free; may be reduced to six month deferral period if validated & accredited immunologic or molecular genomic test is negative. Individuals with a history of malaria: Defer from blood donation for three years following cessation of treatment & absence of symptoms. Accept thereafter only if accredited & validated immunologic or molecular genomic test is negative. May be accepted for plasma for fractionation only, after the cessation of treatment & symptoms. Asymptomatic visitors to endemic areas: Defer for six months after leaving the endemic area.	Layout follows a more logical sequence, & gives greater clarity. Malarial deferral criteria are updated to reflect the current state of the art. Risk of infection is updated to reflect the use of NAT testing & to define better the acupuncture issue. Vaccinations more consistently categorised.

Finland	**2.2 Temporary Deferral Criteria**	– Minor infectious diseases (two weeks) – Fever above 38º C, flu-like illness (following cessation of symptoms) *2.2.9 Ineligible for 72 hours* – Following administration of vaccines (desensitising) *2.2.10 Ineligible for 48 hours* – Treatment by dentist or dental hygienist – Following administration of killed/inactivated viral/bacterial & rickettsial vaccines – Rabies vaccine (prophylactic administration)	Individuals who have had such febrile episodes can be accepted if the results of a validated & accredited immunologic or molecular genomic test negative six months after cessation of symptoms & therapy. If such a test is not available the individual may be accepted as a donor three years after cessation of symptoms. Where the donation is used exclusively for plasma for fractionation the tests & deferral periods above may be waived. Tropical disease, Defer visitors to the tropics for six months following return. Accept thereafter only if they have not suffered an unexplained fever or illness.	Layout follows a more logical sequence, & gives greater clarity. Malarial deferral criteria are updated to reflect the current state of the art. Risk of infection is updated to reflect the use of NAT testing & to define better the acupuncture issue. Vaccinations more consistently categorised.

Finland	**2.2 Temporary Deferral Criteria**	**Sexual behaviour.** **Endoscopic examinations, etc.**	**2.2.2. Exposure to risk of acquiring a transfusion-transmissible infection** • Sexual behaviour that places prospective donors at a risk of transmitting infectious diseases. Deferral period may be temporary or permanent depending on the type of behaviour & its continuation, & should be assessed individually by qualified staff. Endoscopic examination using flexible instruments, mucosal splash with blood or needlestick injury, blood transfusion, tissue or cell transplant, major surgery, tattoo or body piercing, acupuncture unless performed by a qualified practitioner & with single use needles, close household contact with persons with hepatitis B or C. Defer for 12 months, or for six months provided a validated NAT test for hepatitis C & HIV is used.	Sexual behaviour should be asked. A binding European legislation is needed on this. Exclusion criteria must be determined locally & the judgement depends on whether the risk behaviour continues or not & of what type it is.
Finland	**2.2 Temporary Deferral Criteria**		2.2.3. Vaccination. Attenuated viruses or bacteria, 4 weeks. Inactivated/killed viruses, bacteria or rickettsiae, accept if well Toxoids, accept if well Hepatitis A or Hepatitis B vaccines, accept if well & no exposure. Rabies & tick-borne encephalitis vaccines, accept if well & if no exposure; 1 year post exposure.	
Finland	**2.2 Temporary Deferral Criteria**		2.2.4. Other temporary deferrals, Dental treatment, 48 hours Medication, consistent with pharmacokinetics of the drug prescribed; underlying for the medication may defer.	

Finland	**2.2 Temporary Deferral Criteria**	**2.2.4 Ineligible for one year** – Major surgery **2.2.5 Ineligible for nine months** – Pregnancy (after delivery) – Abortion **2.2.8 Ineligible for at least one week** – Minor surgery (without complications)	Delete Delete Delete Delete	Attention should be paid to such temporary deferral criteria that are solely for the protection of the donor & have no relation to the quality of the blood or blood components. They are not within the scope of this Directive.
Spain	**2.2 Temporary Deferral Criteria**	**2.2.10 Ineligible for 48 hours** Treatment by dentist or dental hygienist	It requires more detailed explanation	Donor retention

APPENDIX TO ANNEX II

REVISED TEXT PROPOSED BY Denmark, France, Ireland, Luxembourg, Netherlands, United Kingdom, EBA

2.2 Temporary Deferral Criteria	
Replace the entire text as below.	**Rationale:** layout follows a more logical sequence, & gives greater clarity. Malarial deferral criteria are updated to reflect the current state of the art. Risk of infection is updated to reflect the use of NAT testing & to define better the acupuncture issue. Vaccinations more consistently categorised.

2.2.1 Infections	**Duration of deferral.** In general, after an infectious illness, prospective donors should be deferred for at least two weeks after full clinical recovery.
	Brucellosis 2 years after full recovery
	Infectious mononucleosis 6 months after recovery
	Osteomyelitis 2 years after confirmed cured
	Toxoplasmosis 6 months following clinical recovery
	Tuberculosis 2 years after confirmed cured
	Rheumatic fever 2 years, unless evidence of chronic heart disease
	Fever > 38°C 2 weeks after 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: Defer for three years following return from last visit to endemic area, provided person remains symptom free; may be reduced to six-month deferral period if validated & accredited immunologic or molecular genomic test is available. Individuals with a history of malaria: Defer from blood donation for three years following cessation of treatment & absence of symptoms. Accept thereafter only if accredited & validated immunologic or molecular genomic test is negative. May be accepted for plasma for fractionation only, after the cessation of treatment & symptoms Asymptomatic visitors to endemic areas: Defer for six months after leaving the endemic area. Individuals who have had such febrile episodes can be accepted if the results of a validated & accredited immunologic or molecular genomic test are negative six months after cessation of symptoms & therapy. If such a test is not available the individual may be accepted as a donor three years after cessation of symptoms. Where the donation is used exclusively for plasma for fractionation the tests & deferral periods above may be waived.
	Tropical disease Defer visitors to the tropics for six months following return. Accept thereafter only if they have not suffered an unexplained fever or illness
2.2.2. EXPOSURE TO RISK OF ACQUIRING A TRANSFUSION-TRANSMISSIBLE INFECTION	Endoscopic examination using flexible instruments, mucosal splash with blood or needlestick injury, blood transfusion, tissue or cell transplant, major surgery, tattoo or body piercing, acupuncture unless performed by a qualified practitioner & with single use needles, close household contact with persons with hepatitis B or C. Defer for 12 months, or for six months provided a validated NAT test for hepatitis C & HIV is used.

2.2 3Vaccination		
	Attenuated viruses or bacteria	4 weeks
	Inactivated/killed viruses, bacteria or rickettsiae	accept if well
	Toxoids	accept if well
	Hepatitis A or Hepatitis B vaccines	accept if well & if no exposure
	Rabies & tick-borne encephalitis vaccines	accept if well & if no exposure; 1 year if post exposure.
2.2.4 Other temporary deferrals	Pregnancy	nine months after delivery or termination, except in exceptional circumstances & at the discretion of a physician: for example where the mother is required to be the donor of compatible platelets for the neonate.
	Major surgery	6 months
	Minor surgery	1 week
	Dental treatment	48 hours
	Medication	consistent with pharmacokinetics of the drug prescribed; underlying reason for the medication may defer
	Epilepsy	three years off treatment without recurrence