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

Annex B
Testing requirements
as regards whole blood and plasma donations

	Subject	Original text	Proposed modification	Justification for modification
France (Afssaps)	**General comment**		Il est proposé de demander à la Commission de ne pas réviser l'annexe IV de la directive 2002/98/CE.	Cette annexe avait été élaborée, il y a peu de temps, en procédure de codécision et ne nécessite pas aujourd'hui une révision.
Portugal	**General**		We prefer the annexes linked to Directive as annexes III and IV	
Sweden	**General**		***Replace*** Annex B with PART IV of the Council of Europe proposal of March 11	Directive article 29 d) justifies an extension of the Directive Annex IV. The PART IV of the Council of Europe proposal is preferred..
EMEA	**General**			Note: Labelling and testing requirements that may replace the existing annexes III and IV of Directive 2002/98/EC
EMEA	**Format (General)**			Under "testing requirements" each of the sub-columns should be titled.
Denmark	**Title**	Testing requirements as regards whole blood and plasma donations	*Replace the title* with "Testing required for whole blood and apheresis donations, including autologous predeposit donations"	***Rationale:*** It is necessary to include cellular apheresis and autologous donations in the scope of the Annex.
Finland	**Title**	Testing requirements As regards whole blood and plasma donations	Testing required for whole blood and apheresis donations, including autologous predeposit donations	It is necessary to include cellular apheresis and autologous donations in the scope of the Annex.
France	**Title**	Testing requirements as regards whole blood and plasma donations	Change to Testing required for whole blood and apheresis donations, including autologous predeposit donations	It is necessary to include cellular apheresis and autologous donations in the scope of this Annex.
United Kingdom UK Joint Professional Advisory Committee	**Title**		*Replace the title* with "Testing required for whole blood and apheresis donations, including autologous predeposit donations"	***Rationale:*** It is necessary to include cellular apheresis and autologous donations in the scope of the Annex.

EBA	**Title**	Testing requirements as regards whole blood and plasma donations	Change to: Testing required for whole blood and apheresis donations, including autologous predeposit donations	It is necessary to include cellular apheresis and autologous donations in the scope of this Annex.
Denmark **Ireland,** **Luxembourg,** **Netherlands** **France** **Finland** **United Kingdom** *UK Joint Professional Advisory Committee* **EBA**	**(General)**	Table	Replace the table with the below text ABO Group (excluding plasma for fractionation). Rh D typing (excluding plasma for fractionation). Testing for following infections in donors: Hepatitis B Hepatitis C HIV 1/2 Using reagents approved for the purpose under Directive 98/79/EC Additional tests may be required for specific components or donors, e.g. anti-red cell antibodies, CMV testing.	The format in the original text deals with several difficulties • There is no definition in the Directive of an "approved" test; • There is no general basis for a requirement for Rh C+E typing and this is not considered necessary by several national authorities; • There is no generally validated or approved test for malaria • There is a need to envisage the eventual requirement for genomic testing
EPFA	**Various**	(when required)	List only required tests and add footnote that additional tests may be required for specific components Note: Several tests, such as HTLV testing, are not required for plasma for fractionation	"when required" is imprecise
EMEA	**Test kits**		State-of-the-art, validated and approved tests should be used.	When testing is done in the EU the tests should be CE marked (still finishing transition[a]) but for testing in the US, the tests are licensed by the FDA. Therefore, a general wording is proposed to avoid creating difficulties with plasma collected outside the EU for use in the manufacture of plasma-derived medicinal products.

[a] At present national approvals and CE certifications are allowed in the EU. The 2nd transition phase starts 7 December 2003 when nationally approved test kits can still be on the EU market. All IVDs on the market will have to be CE marked by 7 December 2005.

EMEA	**List of tests**		*Not required for apheresis plasma intended only for fractionation: should be against all tests except anti-HIV-1/HIV-2, anti-HCV, HBsAg	These are the only tests required for plasma for fractionation.
EMEA	**Additional tests**		Additional tests may be required for specific components or donors or epidemiological situations.	This is part of the current text of Annex IV of the Blood Directive and should be retained. It will cover the situation of West Nile Virus, where US and Canada are expected to introduce testing this year. It may also be needed to cover screening for substance abuse (recent article by Peters *et al* in Vox Sang., 2003, **84**)
Italy	**Testing requirements**	Malaria for travellers to endemic areas	Malaria for immigrants or visitors of endemic areas	Self evident
PPTA	**Testing requirements**	Malaria for travellers to endemic areas	Malaria * Or if traveller has any signs of malaria like fever	Not necessary for Plasma for Fractionation (pff)
BAXTER	**Testing requirements**	Antibodies to red-cell antigens	Antibodies to red-cell antigens *	not necessary for pff (see European Pharmacopoeia) * not required for apheresis plasma, intended only for fractionation
IG PLASMA	**Testing requirements**	Antibodies to red-cell antigens	Antibodies to red-cell antigens*	Not necessary for Plasma for Fractionation
PPTA	**Testing requirements**	Antibodies to red-cell antigens	antibodies to red-cell antigens *	Not necessary for Plasma for Fractionation (pff) (according to European Pharmacopoeia).
PPTA	**Testing requirements**	HBc-Antibodies	HBc-Antibodies *	Not necessary for Plasma for Fractionation (pff)
BAXTER	**Testing requirements**	Syphilis (when required)	Syphilis (when required) *	not necessary for pff (see European Pharmacopoeia) * not required for apheresis plasma, intended only for fractionation
Spain	**Testing requirements**	Syphilis (when required)	Syphilis (when it is carried out)	Specification for Translation
PPTA	**Testing requirements**	Syphilis	Syphilis (when required) *	Not necessary for Plasma for Fractionation as the organism causing syphilis (treponema pallidum) is destroyed by freezing.
EPFA	**Testing requirements**	HCV	Add for plasma for fractionation: NAT testing for HCV	

Poland	**Testing requirements**	RhD typing	* - * cancel: intended only for fractionation Cancel: Testing for RhC and RhE	
Italy	**Testing requirements**	Rh C and E typing	*Cancelled*	Rh C and E typing is not needed for all red cell units.
Spain	**Testing requirements**	Rh C and E typing *	Delete	Excessive, they are less inmunogenic than other antigens (Kell…)
Czech Republic	**Testing requirements**	Rh C and E typing	Rh C and E typing: should be replaced with ***"Rh C, c, E, e typing"*** Tests mentioned as ***"when needed" and "when required"*** (HLA typing, HBc-Ab, Syphilis, CMV-Ab, HTLV-Abs) should be omitted as far as they are not intended to be obligatory, eg. there is no reason for listing these tests in legally binding document.	
PPTA	**Testing requirements**	HTLV	HTLV *	Not necessary for Plasma for Fractionation (pff)
PPTA	**Testing requirements**	CMV	CMV *	Not necessary for Plasma for Fractionation (pff)
PPTA	**Testing requirements**	HBc-Ab (when required), Syphilis (when required), CMV-Ab (when required), HTLV-Abs (when required), Malaria (when specified)		The general formulation used in Annex IV of the Directive 2002/98/EC is preferred: "*Additional tests may be required for specific components or donors or epidemiological situations*"
France Afssaps	**General comment**		Il est proposé de demander à la Commission de ne pas réviser l'annexe IV de la directive 2002/98/CE.	Cette annexe avait été élaborée, il y a peu de temps, en procédure de codécision et ne nécessite pas aujourd'hui une révision.

* Not required for apheresis plasma intended only for fractionation