EUROPEAN COMMISSION
HEALTH AND CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C6 - Health measures

Summary Table re risk of vCJD transmission by blood and donor deferrals[∇] (as of 6 September 2004)

(Updated comments since April given in italics)

Member State	Risk of transmission of vCJD	Impact of permanent deferral of recipients of blood transfusion from blood donation	Permanent deferral of blood donors who have received a blood transfusion in the UK since 1980	Is modification to statement made in Luxembourg on 20 January required?
BE	The risk of transmission of vCJD by blood looks very small. Issues to be discussed at a meeting of the Senior Health Council.	Impact of permanent deferral of recipients of blood transfusion not yet known.	This measure is in line with the deferral of donors who stayed in the UK for 6 months or more & could be taken *Re donors who have received a blood component: Out of 35,124 donors, 2,785 had been transfused in their lifetime. 8%.* *The survey was conducted in the 'Service du Sang' during June & July 2004..*	The statement made at the January 20 meeting does not need to be modified. *In Belgium nothing has changed. The table reflects the Belgian situation.*
CZ	There is no new 'official position statement' on vCJD risks. In general, the risk is considered to be very low & transmission of vCJD should be extremely rare. But 'British case' & EU	Up to now donors from 'at risk countries' excluded - cumulative stay for more then 6 months in period 1980-1996 in UK & France. Exclusion (obligatory) of donors	*Blood donors spending more then 6 months in UK or France during 1980-1996 are excluded (applied since 2001)*	Statement from January 20 does not have to be revised. (This question has not been subjected to any governmental body yet) *National Advisory Blood Transfusion*

[∇] Data provided to the Commission by national blood experts

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	recommendation from Jan 20 are under discussion *Risk of vCJD transmission via blood is an item of high interest & situation abroad is carefully followed. Due to very low incidence of BSE in the Czech Republic the risk of transfusion transmitted vCJD is considered to be extremely low.* *Possible exclusion of donors transfused abroad (excl. Slovakia) is in discussion.*	transfused abroad but this is not a current official practice (since 1998). Nevertheless donor with surgery abroad with possible transfusion exposure are usually excluded due to 'unknown/not-sure anamesis'. They were very few. No data on numbers of donors being transfused in the past relevant for Czechia. There are some doubts about reliability of this information obtained from patients (especially for transfusion far in the past & transfusion of plasma). Donors transfused in the last year excluded (due to the risk of hepatitis)		*Committee did not recommend any additional measure yet. An item is scheduled for discussion at meeting in September.*
DK	The risk for transmission of vCJD by blood is almost zero (for all practical purposes: non-existent)	Two surveys (500 & 1,500 donors respectively) have shown that 10% of donors will be lost due to a history of transfusion.	Donors who have been more than 6 months in the UK have been deferred for two years since 1 January 2004. This was implemented only because a change to a foreign fractionator resulted in a demand for this donor selection criterion. The blood banks did not like different criteria for blood components & blood derivatives, so it was enforced on all donations. A decision whether to make it a criterion for permanent deferral is pending in the Ministry of Interior and Health.	*DK does not intend to introduce new UK requirements. There is no change to information previously provided.*

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DE	The risk of transmission of vCJD by transfusion will depend on several factors determining exposure & susceptibility, & it is likely that several of these factors are not yet known. The risk will certainly depend on the number of infected persons who are within the incubation time, but not yet clinically ill, & who might become blood donors. The number of those persons is unknown, but it appears reasonable to assume that it is to some extent proportional to the number of already manifest cases of vCJD. This number is still fundamentally different between UK (> 145 cases) & Germany. *The second suspected case of transfusion-transmitted vCJD in the UK in a patient heterozygous at codon 129 of PRNP without signs of a neurological disorder might lead to the assumption that a larger number of people may be healthy vCJD carrier who either will not develop clinical signs of the disease or will have a lengthy incubation period. Those persons might still pose the risk of transmitting the disease.* *The epidemiological situation regarding vCJD is fundamentally different between the UK & Germany. The risk of vCJD transmission is therefore considered to be very low in Germany with no reported case of vCJD until now.*	A survey performed in Germany some years ago & more recent data from a large donation centre indicate that circa 3 to 4 % of donors report about previous blood transfusions (excluding receipt of plasma derivatives). The actual number of donors who would have to be excluded 'in reality' might be higher. *Even though the number of excluded donors could be higher than the estimated 4%, the exclusion of transfusion recipients is being considered*	The deferral from donating blood in Germany of persons who received a transfusion in the UK would have no significant impact on the blood supply in Germany *No new comments.*	The essential facts about the suspected case of vCJD transmission in UK were already known at meeting & carefully considered. The only new development is that a decision already seriously considered at the time has now actually been taken by the UK government. The detailed reasons behind this final decision were not yet communicated. At present, the need for modification of the Luxembourg statement not seen. It is still appropriate that every Member State performs its own risk assessment & acts accordingly. *Given this new aspect for the assessment of vCJD, the responsible authority in Germany is preparing a hearing which involves all blood establishments with the aim of obtaining more detailed information in preparation for a probable decision to exclude transfusion recipients from whole blood & apheresis donation.* *No new comments, as it has already been outlined that every Member State has to perform its own specific risk assessment & to act accordingly.*

Member State	Risk of transmission of vCJD	Impact of permanent deferral of recipients of blood transfusion from blood donation	Permanent deferral of blood donors who have received a blood transfusion in the UK since 1980	Is modification to statement made in Luxembourg on 20 January required?
EE	*There has never been documented case of vCJD in our country. So the risk of transmission vCJD via blood is not existing.*	*The impact has not yet been evaluated. According to our experts it probably will not dramatically impact the size of our donor population*	*The impact has also not been evaluated. In our donor questionnaire there are three questions linked to vCJD.* *1. donors residency in other countries outside of Europe during past year;* *2. donors residency during 1980-96 in Great Britain lasting six months or more;* *3. fixed diagnosis of vCJD amongst donors relatives.*	*The statement does not need any modifications.* *Currently we do not plan to make any new changes in our donor deferral criteria. If the situation changes, we must re-consider.*
EL	The National Committee for Blood transfusion has taken into account recent developments in the UK & has proposed to the Ministry of Health that no additional precautionary measures other than those implemented since 1st March 2001 should be taken at the moment.	The National Committee for Blood Transfusion has advised against this measure. In the opposite situation, the loss of blood donors is estimated 7%.	No accurate national data on this issue. However, following a national randomized study performed in the year 2001 on 1470 blood donors, representing 0.4% of annual supply, about 'Traveling habits & deferral of blood donors on the basis of time spent in the UK' the loss of such blood donors was estimated 2.3% of the total blood donor population.	*No additional measures have been taken since our previous report. The issue of permanent deferral of donors with history of blood transfusion & platelet apheresis in the UK since 1980 shall be discussed by the National Committee for Blood Transfusion.* *It is anticipated that the members of the Committee will support the introduction of the UK precautionary measures.*

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ES	First assessment of transmission carried out in 2000. This risk assessment should be updated. The comments & statement made at the 20 January meeting were transmitted to our Scientific Committee on Blood Transfusion Safety. The Committee discussed the inherent difficulties on such study, & took the decision to try the re-evaluation in the next few months. In my opinion, it is too soon to get ready new data.	The impact of permanent deferral of recipients of blood transfusion in Spain is being studied in several areas. First figures on impact show a low number of donors deferred, maybe less than 0.5 %. *New figures (still too preliminary & geographically limited): 1.5-2%.*	The permanent deferral in UK has been published by different media in Spain, but no negative consequences on blood donation have been detected. The Scientific Committee considered this measure as understandable but didn't consider its implementation in Spain to be convenient, for the moment. They're awaiting the results of the impact study. *The issue will be discussed again in September, but it could be implemented because it is in line with previous measures.*	The statement does not need to be modified. *The Spanish Scientific Committee will discuss these points in September.*
FR	Les risques existants mais mal connus en matière de transmission: C'est le cas de la maladie de Creutzfeld Jacob (MCJ) et de son variant (vMCJ) connu jusqu'à une date récente pour être transmissible par voie alimentaire. Il n'existe pas de test in vivo et la transmission inter humaine était inconnue. La prévention du risque de transmission relève donc du principe de précaution par, notamment, l'exclusion du don d'éléments du corps humain de toute personne ayant subi une intervention chirurgicale dans la sphère neurologique. Mais le cas anglais récent d'une probable transmission du vMCJ par voie transfusionnelle et les expérimentations animales ont conduit à réexaminer les mesures de prévention du risque. Le groupe d'experts constitué par l'Afssaps en 2000 sur le risque nMCJ avaient émis des recommandées en France en décembre 2000 ces mesures ont été réactualisées en 2003 et à nouveau réexaminées en février 2004 par le groupe d'expert et son rapport est imminent mais aucune mesure ne devraient finalement pas être modifiées. Elles sont les suivantes : **Pour les produits sanguins labiles (PSL):** • Exclusion des donneurs de sang ayant un risque au regard de la MCJ. • Exclusion des donneurs de sang ayant séjourné plus d'un an en Grande-Bretagne pendant la période 1980-1996. • Déleucocytation des produits transfusionnels dès 1998 pour les concentrés globulaires et les plaquettes. Il est à noter que cette mesure n'a pas été mise place pour le risque MCJ mais plus largement pour diminuer le risque de transmission d'agents infectieux intracellulaires portés par les leucocytes. • Déleucocytation des plasmas pour transfusion, mise en place spécifiquement pour réduire le risque MCJ en 2000 dans le cadre d'une phase expérimentale, puis officialisée en 2001. Comme pour la déleucocytation la mesure ne portait pas initialement sur le risque MCJ mais avait pour objet plus général de limiter le risque de "recirculation" d'agents pathogènes transmissibles par voie sanguine. Selon les virologues la "recirculation" potentialiserait la virulence des germes.			
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	Pour les médicaments dérivés du sang : • Mêmes mesures d'exclusion des donneurs pour les PSL ; • Analyse du risque et évaluation des capacités des procédés de fractionnement du plasma à éliminer les agents pathogènes et mise en place par le LFB d'étapes supplémentaires, comme la nanofiltration, sur les produits utilisés de façon chronique. Toutefois ces mesures ne concernaient initialement que le sang et ses composants. Le futur rapport devrait porter également sur la greffe d'organes, tissus et cellules souches. Exclusion définitive du don de sang des personnes transfusées dés septembre 1997. A noter que cette mesure a exclu environ 5 à 6 % de candidat au don correspondant à 6 à 7 % des dons la première année.			
	Mesures mises en place en France pour MCJD classique et le vMCJ ***1) Exclusion permanente du don de sang :*** • *des sujets à risque de développer une MCJ classique : antécédents familiaux, antécédents de neurochirurgie ;* • *de toute personne ayant reçu une greffe de tissus, cellules, organes ;* • *de toute personne ayant reçu un traitement par hormones extractives hypophysaires et de glucocérébrosidase placentaire (1994) ;* • *des donneurs de sang ayant des antécédents de transfusion (09/1997)* • *des donneurs ayant séjourné dans les îles Britanniques pendant une durée supérieure ou égale à un an (période cumulée) entre 1980 et 1996 (janvier 2001)* ***2) Mesures mises en place pour les produits sanguins*** • *Déleucocytation des concentrés de globules rouges et des concentrés de plaquettes mise en place en juillet 1998.* • *Déleucocytation du plasma (PFC sécurisé, PFC pour préparation de PCA) effective le 15 avril 2001.* • *Analyse du risque et évaluation des capacités des procédés de fractionnement, pour les médicament dérivés du sang, à éliminer les agents pathogènes et mise en place d'étapes supplémentaires.* • *Amélioration des procédés de préparation des médicaments dérivés du sang produits par le laboratoire français du fractionnement et des biotechnologies (LFB), mise en place d'un procédé de nanofiltration pour la Facteur IX (décembre2000), le Facteur VIII (janvier 2001), Immunoglobulines polyvalentes (février 2002) , Facteur Willebrand (janvier2004), association Facteur VIII- Facteur Willebrand (mars 2004).* *Révision des recommandations sur l'utilisation des produits sanguins labiles (PSL) en 1997 et en août 2002;*			

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IE	At present, this risk is not readily quantified. It has several components - the number of blood donors who may be incubating vCJD in Ireland, who in turn may have got the infection from one of three main sources - UK meat in the UK, UK meat in Ireland, Irish meat in Ireland; the eventual number of cases in the UK, also unknowable at present; the transmissibility of disease during the incubation period; the transmissibility from heterozygotes for methionine at codon 129. We are working on the assumption that there is definite chance that infectious donors exist in Ireland, but the number is likely to be very small, & may be zero.	From May 1st of this year, all donors who have received a blood transfusion ever will be deferred. The result from polling the population indicates this is 3 - 5% of donors. *Have now absorbed donor losses from deferring all transfusion recipients, & will shortly extend deferral on the basis of UK residency to 1 year cumulative from 1980 to 1996.*	Since 2001, people who ever received a transfusion outside Ireland have been deferred. *Apart from donor deferrals - UK residency, transfusion recipients - have also following measures in place: import of plasma for transfusion from the USA (Octaplas from a US source) since April 2002; import of all corneas from the USA since March 2004; an active programme of optimal blood use.*	*Position unchanged since April table; no update to our position in relation to that information required.*
IT	Currently unable to evaluate the risk of transmission of vCJD by blood in Italy.	Permanent deferral of recipients of blood transfusion from blood donation in Italy would impact negatively on our national self-sufficiency to an extent that could not be compensated by the expected virtual benefit of this policy	~~Permanent deferral of blood donors who have received an allogeneic blood transfusion in the UK since 1980 has been approved by the National Commission for Blood Transfusion Service & will be soon adopted~~ *'From May 2004 blood donors who have received an allogeneic blood transfusion in the UK since 1980 are permanently deferred.*	No need to change the 20 January statement. *Do not intend to introduce these new UK requirements in Italy*
CY	There are no cases of vCJD & as a result there is no risk of transmission of vCJD by blood	The policy is to defer recipients of blood transfusion from blood donation for two years. Permanent deferral would increase the blood shortages.	Blood donors who are residents of countries at high risk or have been transfused in the UK are permanently excluded from blood donations.	The new UK requirements about blood donors, who had a transfusion in the UK since 1980 will be required in Cyprus.

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LV	There has never been a documented case of v CJD in our country. Latvian State Health Ministry & blood service institutions informed re current situation about possible transmission of vCJD via blood. Information provided to blood service institutions to develop quality system & traceability to ensure that all donors are traceable to recipients & vice versa.	We reject all potential donors during 12 month after blood transfusion ,persons, who have in the past been treated with extracts derived from human pituitary glands, have been recipients of dura mater or corneal grafts, have undergone another neurosurgery or who have been told of a family risk of CJD. We are also recommending to avoid unnecessary exposure to allogeneic blood transfusion.	We have recommended to reject potential donors after spending cumulative period of 6 month in UK since 1996.	*We have reconsidered our deferral criteria & adopted as permanent deferral any potential apheresis or blood donors having received blood in UK since 1980.*
LT	Till now there is no fixed evidence of vCJD in our country.	No collected data about number of the donors who have received a blood transfusions in Lithuania, but we consider that permanent rejection such donors really would have negative impact on blood supply	According to a law of Ministry of Health, all donors having received a blood transfusion are temporary deferred for 12 months & all donors who had resided 6 months & more since 1980 in UK or France are permanently rejected.	
LU	No proper study has been undertaken to assess the risk of transmission of vCJD by blood transfusion.	The potential impact of permanent deferral of recipients of a blood transfusion can calculated based on data available in 2003 on index donations; we can calculate that the permanent exclusion from blood donation of recipients of a blood transfusion would lead to a loss of 6.16% of 2003-active donors.	Data on the possible impact of permanent deferral of recipients of a blood transfusion in the UK since 1980 are not available, but the rate is probably very low .	*No new comments*
HU	*The risk of transmission vCJD via blood transfusion looks extremely small, almost zero. There are no cases of vCJD or BSE in Hungary*	*We haven't a survey for the impact. The estimated loss ratio can be between 2 and 10%*	*There are no existing regulations for this special deferral.* *Any person, who received blood anywhere temporarily deferred for one year.*	*We do not propose any modifications*

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MT	No vCJD cases. The disease has not been identified in our cattle stock either.	All potential donors who have had a transfusion outside the Maltese islands are deferred. Effects on donor base are negligible.	All donors who have been to the UK for a cumulative period of more than 6 months between 1980-1996 deferred. This has reduced current donors by close to 10%. Though donors are being actively replaced.	Statement is valid as it is. *No changes in policy (donors transfused at any time outside Malta are permanently deferred*)
NL	This risk relates to the geographical BSE risk as assessed by the Scientific Steering Committee in Category III for The Netherlands. There have been no cases of vCJD in The Netherlands. The risk of vCJD & blood transfusion is a subject of a study by the Epidemiology Dept. of the University of Utrecht.	Excluding donors who have received a transfusion of cellular blood components, fresh frozen plasma or cryoprecipitate since 1980, *has been considered is* ~~presently being considered~~. The associated donor loss is estimated at approximately 8%. Plasma donors for the preparation of anti-D immunoglobulin need to be exempted from the measure. *The Netherlands have decided not to exclude donors who have had a blood transfusion after 1980.*	Blood donors who have received a blood transfusion in the UK since 1980 are presently not permanently excluded in The Netherlands, this is considered as included in measure under 2.	*The Netherlands do not intend to introduce UK requirements on deferral of donors who have had a blood transfusion in the past.* *This has been a decision of Minister of Health after first possible case of transmission via blood in the UK.* *The recent (second) possible case will result in a re-evaluation of the decision taken earlier.*
AT	At the moment one positive cow (from CZ) was found positive for BSE. No human cases were reported so far.	This will not dramatically impact the blood supply.	This will be no problem in relation to the blood supply in Austria. (Austria defers donors who were in UK between 1980 thru 1996 or cumulative 6 months.)	Agree with the suggested wording *There is no change in Austria because we believe that the measures taken for Austrian donors are sufficient*

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PL	There are ~~13~~ 18 registered cases of BSE but no vCJD cases. So the risk of transmission of vCJD by blood is very low.	Introducing the permanent deferral of recipients of blood transfusion, could result in loss of less than 1% donors (between 0.4-1%).	The number of donors transfused in UK is extremely low in Poland, so permanent deferral has no impact of number of donations in our country. *According to very low Incidence of BSE in Poland (18 cases in cattle) we do not intend to introduce permanent deferral of any transfused donor with the exception of those transfused in UK since 1980.*	Statement was made & should not be modified.
PT	Risk of transmission of vCJD by blood not known because there is no documented case of vCJD. (probably low risk, but this is unknown)	The impact of permanent deferral of recipients of blood transfusion is about 0.59%	The impact of permanent deferral of recipients of blood transfusion since 1980 is about 0.48%	*Portuguese Blood Institute has implemented at national level, additional precautionary measures related with vCJD:* *Permanent deferral of donors who have been transfused since 1980 in addition to the other precautionary measures. This measure came into force on 4th August 2004.*
SI	There are no risk assessment studies with regard to possible transmission of vCJD. There has been no patient with diagnosis of vCJD until now & it is considered that there is no risk of transfusion transmitted vCJD at the moment.	There is no need for permanent deferral of recipients of blood transfusion from blood donation. In Slovenia, recipients of blood transfusion are temporarily deferred from blood donation for 12 months.	In the questionnaire for blood donors, there is a question on their residency in other countries. The donor, who has received a blood transfusion in the UK since 1980, would be deferred permanently.	The statement made at the 20 January meeting does not need to be modified *At present, we do not plan to introduce new precautionary measures for blood donors concerning vCJD.*

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SK	*In Slovakia, the risk of transmission of vCJD is considered to be extremely low.*	*We don't have data on numbers of donors being transfused in the past. All donors being transfused in Slovakia are defered for period of 12 month.*	*We defer donors who stay more than 6 months in UK & France during the period 1980-1996. We defer also donors being transfused in these countries.* *We do not intend to introduce new UK requirements (permanent deferral of potential donors who have had a transfusion) in Slovakia*	*We agree with statement made in Luxembourg on 20 January*
FI	Risk is virtually non-existent at the moment	The impact would be very bad indeed, the estimation today is that some 10% of donors may need to be excluded. However, no scientific study on this matter has been done.	This is not asked at present, but it may be considered as one option in the future.	The quoted statement does not need modification at present. *Consideration being given to implementing deferral of blood or blood component donors who have been transfused in UK since 1980. The policy will probably be implemented in the end of 2004 .*
SE	The risk of transmission of vCJD by blood is regarded as very low due to strict inclusion criteria for donors & due to the fact that no cases of neither vCJD nor BSE have been reported.	~~The possibility of deferring recipients of blood transfusion from blood donation is being looked into at present but no decisions have so far been taken~~. *A study in Stockholm, Sweden showed that 3% of the donors have spent 6 months or more in UK between 1980 - 1996, & that 5% of the donors have received blood transfusion (in Sweden) during the same period.*	~~Persons having received blood in the UK since 1980 are not deferred from blood donation at present.~~ *Deferral of donors who have received blood in UK since 1980 would have very little impact on the Swedish blood supply*	*A second case was to be expected & does not per se motivate any change in the Swedish policy. The risk of contracting vCJD via blood transfusion in Sweden is considered very low. Whether Swedish donors who have or may have received blood transfusion in UK after 1980 should be deferred is being discussed, presently there is no such deferral.*

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UK			Minister announced today (16 March) that the UK were introducing a measure to exclude all donors who had received a blood transfusion in the UK after 1.1 1980 on a purely precautionary principle. *Minister announced (22 July) the permanent deferral of any potential donor who is unsure if they have had a transfusion in the UK since 1980 & the permanent deferral of all platelet (apheresis) donors who have received or think they may have received blood in the UK since 1980. (Inserted by Commission)*	All the discussions have already taken & that another meeting is not necessary