Commented [COMMENT1]:

(Amendment ##)
➔##←

19 March 1998 A4-0112/98

*

REPORT

on the proposal for a Council Recommendation on the suitability of blood and plasma donors and the screening of donated blood in the European Community (COM(97)0605 - C4-0027/98 - 97/0315(CNS))

Committee on the Environment, Public Health and Consumer Protection

Rapporteur: Mr Christian Cabrol

C O N T E N T S

Page

By letter of 15 January 1998 the Council consulted Parliament, pursuant to Article 129 of the EC Treaty, on the proposal for a Council Recommendation on the suitability of blood and plasma donors and the screening of donated blood in the European Community.

At the sitting of 16 January 1998 the President of Parliament announced that he had referred this proposal to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible.

At its meeting of 4 February 1998 the Committee on the Environment, Public Health and Consumer Protection appointed Mr Cabrol rapporteur.

It considered the Commission proposal and the draft report at its meetings of 24 February 1998 and 18 March 1998.

At the latter meeting it adopted the draft legislative resolution by 31 votes to 1.

The following took part in the vote: Kenneth Collins, chairman; Poggiolini, Dybkjær and Lannoye, vice-chairmen; Cabrol, rapporteur; Blokland, Breyer, Díez de Rivera Icaza, Eisma, Estevan Bolea (for Campoy Zueco), Flemming, Florenz, Hautala (for McKenna), Hulthén, Kokkola, Kronberger, Kuhn, Marinucci, Marset Campos (for González Álvarez), Myller (for Kirsten Jensen), Needle, Papayannakis, Pollack, van Putten, Roth-Behrendt, Schleicher, Sjöstedt (for Bertinotti), Tamino, Trakatellis, Valverde López, Virgin and White.

The report was tabled on 19 March 1998.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

A
LEGISLATIVE PROPOSAL

Proposal for a Council Recommendation on the suitability of blood and plasma donors and the screening of donated blood in the European Community (COM(97)0605 - C4-0027/98 - 97/0315(CNS))

The proposal is approved with the following amendments:

Text proposed by the Commission( )	Amendments by Parliament
(Amendment 1) Recital 9	
9. Whereas donations should be voluntary and unpaid;	9. Whereas, in accordance with Directive 89/381/EEC, donations should be voluntary and unpaid and the term 'voluntary non-remunerated donation' is defined in Council of Europe Recommendation (95)14;
(Amendment 2) Recital 12	
12. Whereas all blood and plasma used for therapeutic purposes, whether for transfusion or for further manufacture into industrially-prepared medicinal products, should be obtained from individuals whose health status is such as to ensure that transmission of disease does not take place, and that each and very blood donation should be tested in accordance with the rules which provide assurances that all necessary measures have been taken to safeguard the health of Community citizens who are the recipients of blood and blood products;	12. Whereas all blood and plasma used for therapeutic purposes, whether for transfusion or for further manufacture into industrially-prepared medicinal products, should be obtained from individuals whose health status is such as to minimize the risk of diseases transmissible by blood being transmitted, and that each and very blood donation should be tested in accordance with the rules which provide assurances that all necessary measures have been taken to safeguard the health of Community citizens who are the recipients of blood and blood products;

(1) OJ C

(Amendment 3)
Recital 19

19. Whereas measures at Community level should take into account existing guidelines, recommendations and standards in the area of blood at both national and international levels;	19. Whereas measures at Community level should take into account existing guidelines, recommendations and standards in the area of blood at both national and international levels, and in particular Recommendation (95)15 and Agreement No 26 of the Council of Europe;

(Amendment 4)
Recital 25a (new)

	25a. Whereas it has now been recognized that there may be a risk of nvCJD to blood products and it is necessary to take appropriate steps which include the use of imported blood between Member States;

(Amendment 5)
Section 3.2 a.

a. Information on their health and medical history including any relevant social and behavioural characteristics that may assist in identifying and screening out persons whose donation could present a higher risk of transmitting infections as well as those who could have contracted a recent infection that may not yet be detectable in the screening tests;	a. Information on their health and medical history including any relevant social and behavioural characteristics that may assist in identifying and screening out persons whose donation could present a risk of transmitting infections as well as those who could have contracted a recent infection that may not yet be detectable in the screening tests;

(Amendment 6)
Section 3.3 b.

b. The prospective donor's agreement that if their blood or plasma donation becomes excess to the needs of their own Member State, it may be shared with another Member State of the Community that is in need;	b. The prospective donor's agreement that if their blood or plasma donation, the components thereof and/or products prepared from the donated blood or plasma become excess to the needs of their own Member State, they may be shared with another Member State of the Community that is in need;

(Amendment 7)
Section 4

4. Member States, in order to facilitate future verification of repeat and regular donors, future tracing of donations, and future exchanges of information, establish a mutually compatible donor identification/registration system to:	4. The Member States responsible for collecting the blood and plasma, in order to facilitate future verification of repeat and regular donors, future tracing of donations, and future exchanges of information, agree to the establishment of a single donor identification and registration system common to all Member States so as to:

(Amendment 8)
Section 4.1 a.

a. Permit every donation centre in each Member State to be uniquely identified, by communicating to all other Member States and to the Commission a list of centres and their identification comprising the country code and a suitable combination of letters and numbers at their discretion;	a. Permit every donation centre in each Member State to be uniquely identified, by communicating to a central body the list of centres and their identification comprising the country code and a suitable combination of letters and numbers, in accordance with the single donor identification and registration system common to all Member States;

(Amendment 9)
Section 6.2 ba. (new)

	ba. Ensure that epidemiological data on viral markers is regularly collected, analysed and verified, use being made of uniform definitions, and that they keep themselves regularly informed of the existence of new markers.

(Amendment 10)
Section 6.2 bb. (new)

	bb. Ensure that the nature and duration of deferral criteria are based on good scientific evidence when known and that the precautionary principle prevails when that evidence is not available.

(Amendment 11)
Section 7 a.

a. Ensure that measures are in place for prospective donor identification and accurate data verification;	a. Ensure that measures are in place for prospective donor identification and accurate data verification, by means of a code that is unique and common to all Member States and is communicated to the central body;

(Amendment 12)
Section 7 b.

Does not affect the English version

(Amendment 13)
Section 9

9. TESTING OF DONATED BLOOD SAMPLES	9. TESTING OF DONATED BLOOD AND PLASMA SAMPLES
Member States, in order to ensure the safety of all blood and plasma donations:	Member States, in order to ensure the safety of all blood and plasma donations:
a. Ensure that a sample of all donations whether intended for transfusion purposes or for further manufacturing into industrially prepared medicinal products is tested for diseases transmissible by blood using licensed screening tests to eliminate units that are repeat reactive;	a. Ensure that a sample of all donations whether intended for transfusion purposes or for further manufacturing into industrially prepared medicinal products is tested for diseases transmissible by blood and/or plasma using licensed screening tests to eliminate units that are repeat reactive;
b. Ensure that all blood donations be found non-reactive for the transmissible disease markers listed in Annex 7;	b. Ensure that all blood and plasma donations be found non-reactive in licensed screening tests for the transmissible disease markers listed in Annex 7;
c. Require re-testing of the blood samples found to be reactive in an initial screening test in accordance with the general algorithm set out in Annex 8.	c. Require re-testing of the blood and plasma samples found to be reactive in an initial screening test in accordance with the general algorithm set out in Annex 8.

(Amendment 14)
Section 10 b.

b. Member States take all necessary measures to encourage the voluntary and unpaid donation of blood or plasma.	b. Member States implement the principle of voluntary and unpaid donation of blood or plasma.

(Amendment 15)
Section 10 ba. (new)

	ba. The EC shall take appropriate measures to exclude any risks related to nvCJD, donated blood and blood plasma products.

(Amendment 16)
Section 10 bb. (new)

bb. Member States take the necessary steps to collect, analyse, publish and update epidemiological data.

(Amendment 17)
Section 10 bc. (new)

bc. The EC shall bring forward binding legislation for the EU with respect to blood products, donated blood and plasma by the end of 1998 (and no later than the end of 1999).

(Amendment 18)
Annex 1, seventeenth definition

Voluntary, unpaid donation Same meaning as in Directive 89/381/EEC.	**Voluntary, unpaid donation** Council of Europe definition: 'Donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his or her own free will and receives no payment for it, either in the form of cash or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation.'.

(Amendment 19)
Annex 2, third point, sixteenth sub-point

· has a spouse who is HIV positive	· has a partner who is HIV positive

(Amendment 20)
Annex 2, fifth point

· Whether the prospective donor has travelled · outside Western Europe & North America	· Whether the prospective donor has travelled · outside the European Union If so, when? Length of stay?

(Amendment 21)
Annex 2, seventh point

· Sexual activity in Africa	· Whether the prospective donor has been sexually active in Africa: (to specify country, when and with whom)

(Amendment 22)
Annex 3, fifth definition

Does not affect the English version

(Amendment 23)
Annex 3, sixth definition

Haematocrit The packed cell volume (haematocrit) should be determined prior to donation and shall be no less than 38% for females and 40% for males. For apheresis plasma donors, the minimum shall be 38%.	**Haematocrit** Where the haemoglobin concentration has not been determined, the packed cell volume (haematocrit) should be determined prior to donation and shall be no less than 38% for females and 40% for males. For apheresis plasma donors, the minimum shall be 38%.

(Amendment 24)
Annex 3, eighth definition

Donation frequency For whole blood, the maximum number of times allowable for donations should be 6/year for men, 4/year for women and 3/year for pre-menopausal donors. For apheresis plasma, the maximum donation frequency should be twice per week.	**Donation frequency** For whole blood, the maximum number of times allowable for donations should be 4/year for men, 3/year for women and 3/year for pre-menopausal donors. For apheresis plasma, the maximum donation frequency should be twice per week.

(Amendment 25)
Annex 6, second definition

Automated plasmapheresis Maximum volume per donation **Donor weight** **Volume collected** (excluding anticoagulant) 50-67 kg625 ml 68-79 kg750 ml 80 kg or more 800 ml Minimum time interval between donations 72 hours Maximum number of donations per 7 day period 2	**Automated plasmapheresis** Maximum volume per donation: 650 ml per continuous 12 month period: 15 l **Donor weight** **Volume collected** (excluding anticoagulant) 50-67 kg625 ml 68-79 kg750 ml 80 kg or more 800 ml Minimum time interval between donations 72 hours Maximum number of donations per 7 day period 2

(Amendment 26)
Annex 6, second definition, last line

Does not affect English version

DRAFT LEGISLATIVE RESOLUTION

Legislative resolution embodying Parliament's opinion on the proposal for a Council Recommendation on the suitability of blood and plasma donors and the screening of donated blood in the European Community (COM(97)0605 - C4-0027/98 - 97/0315(CNS))

(Consultation procedure)

The European Parliament,

- having regard to the Commission proposal to the Council, COM(97)0605 - 97/0315(CNS)( ),

- having been consulted by the Council pursuant to Article 129 of the EC Treaty (C4-0027/98),

- having regard to Rule 58 of its Rules of Procedure,

- having regard to the report of the Committee on the Environment, Public Health and Consumer Protection (A4-0000/96),

1. Approves the Commission proposal, subject to Parliament's amendments;

2. Calls on the Commission to alter its proposal accordingly, pursuant to Article 189a(2) of the EC Treaty;

3. Calls on the Council to notify Parliament should it intend to depart from the text approved by Parliament;

4. Asks to be consulted again should the Council intend to make substantial modifications to the Commission proposal;

5. Instructs its President to forward this opinion to the Council and Commission.

---

(1) OJ C

B
EXPLANATORY STATEMENT

The proposal for a Council Recommendation on the suitability of blood and plasma donors and the screening of donated blood in the European Community is the logical sequel to the Commission communication on blood safety and self-sufficiency in the European Community, for which I was also rapporteur. That communication reflected the efforts made by the EU not only to promote the quality and safety of the blood collected but also to move towards attaining self-sufficiency in blood and products derived from it, which has not been achieved yet.

This Recommendation relates essentially to the first part of the previous communication, i.e. blood safety and, more particularly, to the first two conditions for ensuring such safety, namely:

- donor selection
- appropriate testing of donations

whilst disregarding the other three conditions:

* the treatment of the collected blood
* its rational use
* the monitoring of recipients of blood transfusions (haemovigilance).

A. DONOR SELECTION

As regards the selection of donors, the Recommendation defines five stages, namely:

1. Provision of information to prospective donors and the data collected on them
2. Donor registration
3. Donor suitability
4. Donor ineligibility
5. Confidentiality of data.

1. Provision of information to prospective donors

(Donation required by the Commission to be unpaid, cf. Recital 9)

The Council favours providing information to prospective donors, including explanations concerning:

(a) the characteristics of blood and plasma, and the risks of transmitting diseases to which they may give rise;
(b) the confidentiality of the information and of the tests conducted on prospective donors.

The Council thus wants prospective blood and plasma donors to be informed as well as possible about the public-spirited act they are proposing to perform, which is not, however, without consequences for them and the patients who will receive their blood. The provision of very detailed information is to be encouraged so as to improve understanding and cooperation on the part of prospective donors. It constitutes the first guarantee for ensuring blood safety.

2. Registration of donors

In order to ensure that donations can be accurately traced and donors can be tracked down after tests have been conducted on blood taken from them, the Council recommends that each Member State establishes a register of donations specifying the name or number of the donor centre and the precise donor identification in the form of a code number which guarantees the confidentiality of the information.

We think it essential that all this data should be held centrally on a single EU-wide register, under unique code numbers, so as to permit rapid consultation by any centre at which a prospective donor presents himself or which is trying to track down the donor responsible for a contaminated donation.

3. Donor suitability

The Council proposes a detailed questionnaire(Annexes 2 and 3) concerning donor suitability criteria so that donations do not adversely affect the health either of the recipients or of the donors themselves. This very thorough questionnaire satisfies the criteria specified by Parliament, which, in its resolutions on blood safety and attaining self-sufficiency by means of voluntary unpaid donations, stressed the importance of ensuring the highest level of safety in the selection of donors and the testing of donations. However, some of the questions in the questionnaire should be made more explicit as regards the dates and length of stays and sexual relationships in non-member States outside Western Europe and North America.

4. Donor ineligibility

The Council also thought it necessary to draw up ineligibility criteria for blood and plasma donors, excluding them from making donations either temporarily or permanently (Annexes 4 and 5). This new move, which involves the establishment of deferral registers is meant to provide additional safety, but might it not result in the warranted level of confidentiality being breached? Also, will the registers be held separately at each centre or kept together in a central file for simpler verification?

5. Confidentiality of data

This very important section of the proposed Council Recommendation would have benefited from more detail, notably as regards the monitoring of confidentiality, for how will it be possible to effectively preserve confidentiality given the number of donor centres in the EU and the existence of numerous registers containing data and the fact that we do not know how such data will be protected against unauthorized disclosure?

B. TESTING SAMPLES OF DONATED BLOOD

In order to ensure blood safety, the Council proposes that full and thorough testing be carried out (Annexes 7 and 8) on each sample from all donations and that these be repeated as necessary.

It would also make sense to regularly collect, analyse and verify data on viral markers for which results may have been positive in some donors and for Member States to keep themselves regularly informed of the existence of new markers.

C. VOLUME AND FREQUENCY OF DONATIONS

The Council makes an indirect reference to self-sufficiency in blood and blood products in the EU in Article 8 of its Recommendation and points out that the hitherto approved standards (in terms of volume of blood or plasma collected and of frequency of donation) have been lower than the American standards which were considered acceptable by reliable studies carried out in the USA and Sweden. Consequently, the Council is recommending that donation volumes and frequency be increased.

It would, however, be advisable to exercise caution in this area and to stay below the American standards and closer to those recommended by the Council of Europe.

CONCLUSION

Apart from those points on which comments have been made and reservations expressed in this report, and which are taken up in the proposed amendments, we feel that the Council Recommendation reflects a willingness to put into practice the proposals we formulated in our previous report, on the Commission communication on blood safety and self-sufficiency in the European Community, which Parliament adopted in its vote of ....

This set of recommendations by the Council, amended as indicated above, is sound and does not make exaggerated demands which could:

- create the impression that a zero risk exists, which would be impossible to guarantee for blood transfusions, and increase the numbers of pointless legal complaints,
- increase costs excessively without appreciable benefits,
- complicate all transfusion procedures to the extent that a transfusion would be difficult to carry out,
- increase the number of donor deferrals and thus jeopardize self-sufficiency in blood and blood products.