REPORT


Committee on the Environment, Public Health and Food Safety

Rapporteur: Andres Perello Rodriguez
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MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION


The European Parliament,

– having regard to Article 184 of the Treaty on the Functioning of the European Union,
– having regard to the Charter on Fundamental Rights of the European Union,
– having regard to Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells1,
– having regard to the World Health Organization's Guiding Principles on Human Organ Transplantation,
– having regard to the Council of Europe Convention on Human Rights and Biomedicine, and its Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin,
– having regard to the Conference on Safety and Quality in Organ Donation and Transplantation in the European Union held in Venice on 17-18 September 2003,
– having regard to Rule 48 of its Rules of Procedure,
– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Legal Affairs (A7-0103/2010),

A. whereas there are currently 56 000 patients waiting for a suitable organ donor in the EU, and it is estimated that every day 12 people die while waiting for a solid organ transplant,

B. whereas the needs of patients for transplantation in Europe are not being met owing to the limited number of organs available from both deceased and altruistic living donors,

C. whereas there are wide variations between Member States in deceased organ donation rates, ranging from 34.2 donors per million population (pmp) in Spain to 1.1 pmp in

Bulgaria, and the shortage of organs is a major factor affecting transplantation programmes,

D. whereas national policies and the regulatory framework for donations and transplantation vary substantially between Member States according to different legal, cultural, administrative and organisational factors,

E. whereas organ donation and transplantation are sensitive and complex issues, with an important ethical dimension, which require the full participation of society for their development and the involvement of all relevant stakeholders,

F. whereas organ transplantation provides the possibility of saving lives, offers a better quality of life and (in the case of kidney transplantation) has the best cost/benefit ratio when compared with other replacement therapies as well as increasing the possibilities for patients to participate in social and working life,

G. whereas the exchange of organs between Member States is already common practice, although there are wide differences in the number of organs exchanged across borders between Member States; and whereas the exchange of organs between Member States has been facilitated by international exchange organisations such as Eurotransplant and Scandiatransplant,

H. whereas at present there is neither a database covering the whole of the European Union which contains information about organs intended for donation and transplantation or on living or deceased donors, nor, moreover, a pan-European certification system which provides proof that human organs and tissues have been legally obtained,

I. whereas only Spain and few other Member States have succeeded in increasing significantly the number of deceased donations, and it has been proven that such increases are linked to the introduction of certain organisational practices that allow the systems to identify potential donors and maximise the number of deceased persons becoming actual donors,

J. whereas Directive 2004/23/EC will provide a clear legal framework for organ donation and transplantation in the European Union, with the result that in every Member State a national competent authority will be created or designated to ensure compliance with EU quality and safety standards,

K. whereas the trafficking of organs and of human beings for the purpose of removing organs constitutes a severe violation of human rights,

L. whereas there is a strong link between illegal organ trafficking and the trafficking of persons for the purpose of removing organs on the one hand and the legal system of organ donation on the other because, firstly, the non-availability of organs in the legal system acts as an incentive for illegal activities, and, secondly, illegal activities severely undermine the credibility of the legal system of organ donation,

M. whereas rates of refusal of organ donation vary widely within Europe, and such variability could be explained by the level of training and expertise of professionals in terms of
communication and family care, the different legislative approaches to consent to organ donation and their practical implementation, and other important cultural, economic or social factors that influence society’s perception of the benefits of donation and transplantation,

N. whereas living donation can be a helpful additional measure for patients who cannot get the organ they need via post-mortem transplantation, but whereas it needs to be emphasised that living donation can only be considered if any illegal activity and payment for the donation has been ruled out,

O. whereas a healthcare intervention may only be carried out after the person concerned has given free and informed consent to it; whereas that person should be given appropriate information beforehand as to the purpose and nature of the intervention as well as on its consequences and risks; and whereas the person concerned may freely withdraw consent at any time,

P. whereas Member States must ensure that organs intended for transplantation are not removed from a deceased person unless that person has been certified dead in accordance with national law,

Q. whereas living donation should be complementary to deceased donation,

R. whereas the use of organs in therapy entails a risk of transmission of infectious and other diseases,

S. whereas the fact that people are living longer is serving to reduce the quality of available organs, which in turn is leading in many cases to a reduction in the number of transplants, including in those Member States where the number of donors is increasing,

T. whereas public awareness and opinion play a very important role in increasing organ donation rates,

U. whereas work carried out by charities and other voluntary organisations in Member States increases awareness of organ donation, and whereas their efforts ultimately contribute to an increase in the numbers of people on organ donor registers,

1. Welcomes the Action Plan on Organ Donation and Transplantation (2009-2015) adopted by the Commission in December 2008, which sets out a cooperative approach between Member States in the form of a set of priority actions based on the identification and development of common objectives and the evaluation of donation and transplantation activities through agreed indicators that might help to identify benchmarks and best practices;

2. Expresses its concern over the insufficiency of available human organs for transplantation to meet patients’ needs; acknowledges that the severe shortage of organ donors remains a major obstacle preventing the full development of transplant services and the main challenge that the Member States face with regard to organ transplantation;

3. Notes the success of schemes whereby citizens are given the option of directly joining an
organ-donor register when completing certain administrative procedures, such as applying for a passport or driving licence; urges the Member States to look into adopting such schemes with a view to increasing the numbers of people on donor registers;

4. Considers that, to ensure that organs available for therapy are not wasted, it is important that there is a clearly defined legal framework regarding their use and that society trusts the donation and transplantation system;

5. Notes the importance of organisational aspects of organ procurement and stresses that the exchanging of information and best practice among Member States will help countries with low organ availability to improve their donation rates, as demonstrated, for example, by the implementation of elements of the Spanish Model in different countries both within and outside the EU which have succeeded in increasing organ donation rates;

6. Emphasises that changes to the organisation of organ donation and procurement can substantially increase and sustain organ donation rates;

7. Emphasises that the identification of potential donors has been considered one of the key steps in the process of deceased donation; stresses that the appointment of a key donation person at hospital level (transplant donor coordinator), whose main responsibility is to develop a proactive donor detection programme and optimise the entire process of organ donation, is the most important step towards improving donor detection and organ donation rates;

8. Takes note of the importance of the cross-border exchange of organs, given the need to match donors with recipients and the consequent importance of a large donor pool to cover the needs of all the patients on the waiting lists; considers that if there is no exchange of organs between Member States, then recipients that need a rare match will have very low chances of receiving an organ, while at the same time specific donors will not be considered because there is not a suitable recipient on the waiting lists;

9. Welcomes the activities of Eurotransplant and Scanditransplant, but notes that exchanges of organs outside these systems and between these systems can be significantly improved, especially for the benefit of patients in small countries;

10. Stresses that the establishment of common binding standards of quality and safety will be the only mechanism that can ensure a high level of health protection throughout the EU;

11. Stresses that donation should be voluntary and unpaid, and take place in clearly defined legal and ethical contexts;

12. Calls on Member States to ensure that a legal basis for ensuring valid consent or objection to organ donation by a deceased person or his/her relatives is clearly defined;

13. Endorses measures which aim at protecting living donors and ensuring that organ donation is made altruistically and voluntarily, without any payment other than compensation which is strictly limited to making good the expenses incurred in donating an organ, such as travel expenses, childminding costs, loss of earnings or recovery costs, prohibiting any financial incentives or disadvantages for a potential donor; urges Member
States to define the conditions under which compensation may be granted;

14. Stresses that the establishment of well-structured operational systems and the promotion of successful models at a national level are of the utmost importance; suggests that operational systems should comprise an adequate legal framework, technical and logistic infrastructure, and organisational support coupled with an effective allocation system;

15. Calls on Member States to promote the development of quality improvement programmes for organ donation in every hospital where there is potential for organ donation, as a first step, on the basis of a self-evaluation of the entire process of organ donation by specialists in intensive care and the transplant coordinator of every hospital, but seeking complementarity with external audits to the centres, if necessary and feasible;

16. Stresses that continuous education should form an essential part of all Member States' communication strategies on the issue; in particular, suggests that people should be better informed and encouraged to speak about organ donation and to communicate their wishes about donation to their relatives; notes that only 41% of European citizens seem to have discussed organ donation within their families;

17. Encourages the Member States to make it easier for living persons to make explicit statements of willingness to donate organs by offering on-line enrolment in a national and/or European donors' register with a view to speeding up procedures for verifying consent to donate organs;

18. Calls, further, on the Member States to take steps to facilitate the inclusion, on national identity cards or driving licences, of references or symbols which identify the holder as an organ donor;

19. Calls, consequently, on Member States to improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation; calls on the Commission, the Member States and civil society organisations to take part in this effort to raise public awareness of the possibility of organ donation whilst taking into account the cultural particularities of each Member State;

20. Calls on Member States to reach the full potential of deceased donation by establishing efficient systems for identifying organ donors and by promoting transplant donor coordinators in hospitals across Europe; asks Member States to evaluate and make more frequent use of organs from ‘expanded’ criteria donors (i.e. older donors or those who have certain diseases), maintaining the highest quality and safety standards by exploiting, in particular, recent biotechnological advances which limit the risk of transplanted organs being rejected;

21. Believes it is necessary to ensure that a suitable balance is struck between, on the one hand, the protection of the donor in terms of anonymity and confidentiality and, on the other hand, the ability to trace organ donations for medical purposes, in order to prevent the remuneration of organ donation and trading and trafficking in organs;

22. Emphasises that living donation should be seen as complementary to post-mortem donations; advises the Member States to allow living donation only among family
members, close relatives and between spouses and people with whom the donor has a close personal relationship, owing to the implicit danger of exploitation; insists that especially Member States that extend living donation to groups where there is no personal relationship must have strict regulations in place to prevent any kind of pressure being exerted or payment being made for the donation;

23. Stresses that living donors should be treated in accordance with the highest medical standards and without any financial burden for themselves when a medical problem occurs which is caused by the transplantation process, and any loss of earning as consequence of the transplantation or any medical problem should be avoided. The donors should be protected against discrimination in the social system;

24. Considers that all transplant system rules (allocation, access to transplant services, activity data, etc.) should be made public and be properly controlled, with a view to avoiding any unjustified discrimination in terms of access to transplant waiting lists and/or therapeutic procedures;

25. Notes that, although several Member States have introduced compulsory registration of transplant procedures and some voluntary registries also exist, no comprehensive system exists to collect data on the different types of transplantation and their outcomes;

26. Strongly supports, in consequence, the creation of national and EU-wide registers as well as the establishment of a methodology to compare the results of existing post-transplant follow-up registers of organ recipients in compliance with the existing European legal framework on the protection of personal data;

27. Supports the creation of national and EU-wide registers on the follow-up of living donors, with the purpose of better ensuring their health protection;

28. Emphasises that any commercial exploitation of organs that denies equitable access to transplantation is unethical, is inconsistent with the most basic human values, contravenes Article 21 of the Convention on Human Rights and Biomedicine and is prohibited under Article 3(2) of the EU Charter on Fundamental Rights;

29. Points out that the organ shortage is linked in two ways to organ trafficking and trafficking in persons for the purpose of the removal of organs: firstly, increased organ availability in the Member States would contribute to better monitoring of these practices, by obviating any need for EU citizens to consider seeking an organ outside the EU, and, secondly, illegal activity seriously undermines the credibility of the legal organ donation system:

30. Repeats the recommendations on the fight against the organ trade made in the Adamou report on organ donation and transplantation¹ and takes the view that these should be taken fully into account by the Commission when drafting the action plan; insists that awareness of the problem within the Commission and Europol needs to be increased;

31. Emphasises the importance of the World Health Assembly to be held in May 2010 and urges the Commission and the Council to fight strongly at WHO level for the principle of voluntary and unpaid donation;

32. Welcomes the joint Council of Europe/United Nations study on trafficking in organs, tissues and cells and trafficking in human beings for the purpose of the removal of organs;

33. Notes the report of David Matas and David Kilgour about the killing of members of Falun Gong for their organs, and asks the Commission to present a report on these allegations, along with other such cases, to the European Parliament and to the Council;

34. Urges Member States to establish mechanisms to avoid a situation where healthcare professionals, institutions or insurance companies encourage citizens of the Union to acquire an organ in third countries through practices involving trafficking in organs or in persons for the purpose of the removal of organs; urges Member States to monitor cases of this nature occurring within their territories; urges Member States to evaluate the introduction of legislative measures, including sanctions, applicable to persons promoting and / or participating in such activities;

35. Strongly rejects the behaviour of some health insurance organisations in encouraging patients to participate in transplant tourism and asks the Member States to monitor strictly and punish such behaviour;

36. Emphasises that patients who have received an organ under illegal circumstances cannot be excluded from healthcare in the European Union; points out that as in any other case a distinction should be drawn between the punishment for illegal activity and the need for treatment;

37. Stresses that the Member States should intensify their cooperation under the auspices of Interpol and Europol in order to address the problem of trafficking in organs more effectively;

38. Recognises that it is vitally important to improve the quality and safety of organ donation and transplantation; points out that this will have an impact on reducing transplant risks and will consequently reduce adverse effects; acknowledges that actions on quality and safety could have an effect on organ availability and vice versa; asks the Commission to help Member States to develop their capacity in creating and developing regulatory frameworks to enhance quality and safety;

39. Emphasises that good cooperation between health professionals and national authorities is necessary and provides added value;

40. Recognises the important role of post-transplantation care, including the appropriate use of anti-rejection therapies, in the success of transplants; acknowledges that optimum use of anti-rejection therapies can lead to improved long-term health for patients, graft survival and, hence, wider availability of organs owing to the reduced need for retransplantation, and asserts that Member States should ensure that patients have access to the best available therapies;
41. Instructs its President to forward this resolution to the Council, the Commission and the governments and parliaments of the Member States.
EXPLANATORY STATEMENT

INTRODUCTION

The Nobel Prize winner Joseph Murray was the first to report a successful kidney transplant between identical twins, performed in 1954. Since then, organ transplantation has progressively become a well established therapy of unequivocal importance. Kidney transplantation represents the best therapeutic option for patients with end stage renal disease, providing best outcomes in terms of survival, quality of life and cost-effectiveness than other renal replacement therapies. In a meta-analytic review of the medical and economical literature evaluating renal replacement therapies, published during a 20 year period, the authors concluded that renal transplantation has become more cost-effective over time. While centre haemodialysis remained between $55,000 to $80,000 per life-year (LY) saved, kidney transplantation reached values of $10,000/LY saved.1

Liver, heart and lung transplantation represent an almost unique therapeutic alternative for patients with end stage liver, heart and lung failure, although liver transplantation has been also applied for the treatment of specific pathologies not causing end stage liver failure. Pancreas transplantation, in its different modalities, has become a solution to re-establish insulin secretion in selected diabetic patients aiming to improve patient survival and quality of life. Small bowel transplantation, usually performed as a part of a multi-organ transplant, is still a relatively rare procedure, but aimed to solve life-threatening conditions.

Results with organ transplantation have also progressively improved over time, thank to the advance in surgical techniques, availability of new immunosuppressive drugs, and longer experience of the transplant surgical and medical teams. According to the OPTN/SDRD 2006 Annual report, in the USA, one, three and five-year unadjusted graft survival was 91%, 80%, and 70%, respectively, for kidney recipients of deceased non expanded criteria donors who received their grafts during the period 1999-2004. For the same follow-up periods, unadjusted graft survival for kidney recipients of expanded criteria donors was 82%, 68%, and 53%.

Improvement over time is apparent also regarding patient survival after liver transplantation. For instance, 3 year patient survival was 47.2% for patients transplanted in 1984-1987, increasing up to 76.6% for those patients receiving a liver during the period 2003-2005, according to the Spanish Liver Transplant Registry. Similar improved figures are drawn up by the European Liver Transplant Registry. While 10 year patient and graft survival were 36% and 31%, respectively for liver transplants performed during 1968 to 1988, the corresponding values were 60% and 51% for transplants performed after the year 1988.

Half-life of adult heart transplanted patients during the years 1982 to 1988 was 8.2 years, reaching 10.2 years for those patients who received their grafts during the period 1994 to 1998 and survival figures continue to improve, according to the International Registry of Heart and Lung Transplantation.

1 Dr Rafael Matesanz and Beatriz Dominguez-Gil, "Strategies to optimize deceased organ donation" Transplantation Reviews, Volume 21, Issue 4, October 2007, Pages 177-188
Many problems though ought to be solved in the field of organ transplantation: grafts are mainly lost in the long-term due to the so-called chronic rejection and death with a functioning graft, mainly occurring in the context of cardiovascular pathology. Besides, short and long-term consequences of immune-suppression decrease longevity and quality of life of organ recipients.

Despite these problems, organ transplantation faces an earliest barrier represented by the important gap existing between the number of patients waiting for a transplant and the number of patients who are indeed transplanted. This is due to the shortage of organs for transplantation in relation with organ demands. While the number of patients being included in the waiting list increases, the rate of donation and the number of organs available for transplantation does not increase or improves at a slower rate.

The result of more patients joining the waiting list with a little increase in the number of patients transplanted is a longer time in the waiting list. Time waiting for a kidney transplant is expensive and may have a negative impact on graft and patient survival. Besides, the number of patients who may die while waiting for a transplant may also increase. The shortage of organs for transplantation may be still underestimated, since the scarcity of organs may preclude physicians from including more patients into the waiting lists.

In this context, severe organ shortage represents a universal challenge in the field of organ transplantation, which should be faced under the scope of a planned and integrated approach.

THE PROCESS OF DONATION AFTER BRAIN DEATH

Deceased donation activity is primarily based on donation after brain death. It has to be outlined the fact that no more than 1% of death people and no more than 3% of people who die in the hospital hits this situation. Therefore, the number of potential brain dead donors is limited. Keeping in mind this limitation, the potential of deceased donation after brain death is difficult to reach, since organ donation and procurement is a very delicate and complex process that needs the cooperation of many actors and that can be broken at any time. Even more, the whole process should take place in a very short period of time, what enhances the weaknesses of the process itself. Several basic steps may be identified in this process:

- **Donor identification**: All potential donors should be identified at the earliest stage as possible. This early identification will facilitate donor screening and maintenance, but undoubtedly implies a proactive attitude at this first and crucial step.
- **Donor screening**: The risk of transmission of a serious disease through organ transplantation (neoplasia, infection) from the donor to the recipient should be minimized. However, it must be ensured that only organs that should be discarded are so, avoiding an unjustified loss of organs.
- **Donor maintenance**: It is essential that organs procured are kept in adequate conditions prior to retrieval. The maintenance of the potential donor’s physiological state while on intensive care and of the donor prior to and during retrieval can make a major difference to the condition of the organs. Poor donor maintenance can make organs unusable or increase the incidence of primary graft failure.
- **Consent/authorisation**: Appropriate consent or authorisation has to be obtained before organs can be removed. Countries have different legal requirements to obtain
consent: while some countries apply the presumed consent (or opting-out approach), in others specific consent (opting-in approach) has to be expressed.

- **Organ retrieval**: The surgical technique for removing organs from the body and the way those organs are subsequently handled and preserved prior to and during transportation are critical to the successful outcome of the transplant. Each year a number of organs are damaged during removal and/or transportation. Some can be repaired, but a few will have to be discarded. Coordination of retrieval activities is needed to guarantee the success of the process.

- **Organ allocation**: For some organs, particularly kidneys, hearts and paediatric organs, the successful long-term outcome of the transplant depends partly on ensuring an appropriate matching between donor and recipient. A well-organised system for allocating and transporting donated organs in the most adequate way is important. In some cases, optimum allocation will require exchange of organs between transplant organisations and countries. Co-operation between countries is increasingly important.

It is easy to understand that the process of donation and transplantation after brain death is a delicate, complex and long one. On one hand it requires from the participation of very different professionals and at every one of the steps in the process losses of the donor and/or organs may potentially occur.

Large differences in organ donation and transplant rates exist within the EU, ranging from 34-35 donors per million people in Spain to 1.1 pmp in Bulgaria in these differences cannot be easily explained and it is clear that some organisational models are performing better than others. Cooperation between the Member States should focus on identifying the most efficient systems, sharing experience and promoting best practice as well as supporting Member States whose transplant systems are not yet sufficiently developed.

The proposal of the Commission to establish a European Action Plan on Organ Donation and Transplantation for the period 2009-2015, sets out a cooperative approach between Member State based on a set of priority actions, the identification and development of common objectives, agreed quantitative and qualitative indicators and benchmarks, regular reporting and identification of best practices.
29.1.2010

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS

for the Committee on the Environment, Public Health and Food Safety


Rapporteur: Eva Lichtenberger

SUGGESTIONS

The Committee on Legal Affairs calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following suggestions in its motion for a resolution:

A. whereas the needs of patients for transplantation in Europe are not being met owing to the limited number of organs available from both deceased and altruistic living donors,

B. whereas national policies and the regulatory framework for donations and transplantation vary substantially between Member States according to different legal, cultural, administrative and organisational factors,

1. Calls on the Commission to verify, inter alia through the data contained in its own impact assessment (SEC(2008)2956), whether divergences between national laws as regards the different systems of consent to a donation from a deceased person constitute an obstacle to organ donation;

2. Asks the Member States to analyse the benefits of implementing a donation system of ‘presumed consent’ as a means of bringing about greater numbers of organ transplantations; considers that such a system fully preserves donors’ freedom of consent, as citizens can choose whether to remain within the system or opt out;

3. Stresses that closer cooperation between the Member States is vital; suggests that exchanges of best practice in the field of donation and transplantation be stepped up; asks the Member States to consider lifting restrictions on the transportation of organs across borders; considers that the existence among the Member States of a flexible system for
the transplantation, exchange, import and export of organs could save many lives by allowing more people to find suitable donors;

4. Underlines the importance of raising public awareness of organ donation and transplantation, since this can facilitate the identification of organ donors and thus increase the availability of organs; accordingly, calls on the Commission, the Member States and civil society structurally to enhance the promotion of organ donation;

5. Believes it is necessary to ensure that a suitable balance is struck between, on the one hand, the protection of the donor in terms of anonymity and confidentiality and, on the other hand, the ability to trace organ donations for medical purposes, in order to prevent the remuneration of organ donation and trading and trafficking in organs;

6. Underlines that organ trafficking, transplant commercialism and transplant tourism violate the principles of equity, justice and respect for human rights, and undermine the ethics of altruistic donation;

7. Stresses that the Member States should intensify their cooperation under the auspices of Interpol and Europol in order to address the problem of trafficking in organs more effectively;

8. Believes that combating organ trafficking should not remain the responsibility of the European Union alone. The Member States should also take measures to that end, including reducing demand, promoting organ donation more effectively, maintaining strict legislation in regard to live unrelated donors, guaranteeing transparency of national registers and waiting lists, establishing the legal responsibility of the medical profession for tracking irregularities, and sharing information;

9. Calls on the Member States to introduce standard operating procedures for tracing unethical or illegal activities and limiting the risk of such activities, particularly in connection with decisions on organ procurement and transplantation.
## RESULT OF FINAL VOTE IN COMMITTEE

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| Result of final vote | +: 22  
| | -: 0  
| | 0: 0  |
| Substitute(s) present for the final vote | Piotr Borys, Sajjad Karim, Vytautas Landsbergis, Kurt Lechner, Eva Lichtenberger, Toine Manders, Arlene McCarthy |
RESULT OF FINAL VOTE IN COMMITTEE

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<td><strong>Members present for the final vote</strong></td>
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<td><strong>Substitute(s) present for the final vote</strong></td>
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<td>Christofer Fjellner, Matthias Groote, Judith A. Merkies, Miroslav Mikolášík, Alojz Peterle, Giancarlo Scotta’, Michail Tremopoulos, Anna Záborská</td>
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<td><strong>Substitute(s) under Rule 187(2) present for the final vote</strong></td>
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<td>Josefa Andrés Barea, Dieter-Lebrecht Koch, Markus Pieper</td>
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