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A Leap to Hybrid Governance for European Union Healthcare on Organ Donations

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I. INTRODUCTION

Over the last decade, the use of 'soft law' has extended the boundaries of European Union (EU) involvement in healthcare, thereby pushing the Europeanization process to involve learning and adoption rather than institution-building. Radaelli describes the process as "generating indirect pressures for adaption at national level via non-binding instruments".[1] However, the problem with soft law is that there are significant variations in its outcomes. This seems to produce better results in areas where actors share similar objectives, best practices are easily practiced and cultural sensitivities are low. Hence, this article asserts that soft law on its own merits may not be sufficient for Europeanization and that an element of hard law is required to ensure optimum outcomes. Therefore, the best solution would be to apply a hybrid model. The existence of soft law as the only mechanism for law making in the field of EU healthcare is fairly unlikely. Nevertheless, Hervey notes that "law and soft modes of health governance are becoming increasingly interwoven, thereby opening the door for hybrid EU policy instruments".[2]

Accordingly, this article will evaluate two proposals that the Organs Directive along with the Commission's Action Plan 2009-2015 can be viewed as a form of hybrid governance.[3] The Organs Directive is the first legally binding supranational risk regulation devised in the field of organ donation and transplantation. The Directive is modelled on the earlier Directive dealing with blood, tissue and cells. The Action Plan, which is soft law, will complement the Directive. The Directive and Action Plan requires additional administration procedures from the Member States with the EU Commission regularly monitoring the implementation of the work programme to ensure it is manageable for them.

Before probing the Directive, the Impact Assessment (IA) undertaken by the EU Commission on organ donations, used to determine the rationale behind the adoption of the stringent Directive with the Action Plan, will be examined. The social, economic and health impacts of the four regulatory options available to the Commission will be considered. The Directive and the Action Plan, which are finally adopted, will be discussed in detail, before the arguments are placed highlighting the fact that the Directive and Action Plan display a mode of hybrid governance. Next, the advantages and disadvantages of hybrid governance will be laid out and conclusions will be drawn to whether the hybrid model was the best form of action in EU healthcare. Lastly, in conclusion, the article will propose the emergence of an

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[1] See generally Claudi M. Radaelli, The OMC: A New Governance Architecture for the EU? Swedish Institute for Policy Studies 1 (2003).

[2] Tamara Hervey & Bart Vanhercke, Healthcare and the EU: the law and policy patchwork, 2 Cambridge University Press 84, 87 (2010).

[3] European Parliament, Council of the European Union, Commission Implementing Directive 2012/25/EU laying down information between member states of human organs intended for transplantation, 9 October 2012, 275 Official Journal of the European Union 27 (2012).

"integrated model" within the Organs Directive. This is based on the fusion of the three governance structures, namely the OMC, comitology and agencies.

II. EU GOVERNANCE IN ORGANS

The EU has competence to legislate in the area of organ transplantation. Notably, Article 168(4) (a) of the Treaty on the Functioning of the European Union ("TEFU") has empowered the Community to take "Measures setting high standards of quality and safety of organs and substances of human origin blood and blood derivatives."[4] In accordance with Article 168(7) TFEU: 'The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood'.[5]

The term '*national provisions'* highlights the differences in the national legal approaches to concerning donor consent. The term 'medical use' refers to organ donations for transplantation.[6] The sub Article stating 'The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them' highlights the special status of organ transplantation.[7]

The EU Commission justified European-wide action by pointing out that unified European action would result in European-wide diversity. The EU Commission claimed the advantages of Union action as follows: The EU facilitation of consensus-building allowing quicker implementation: economies of scale, lower transition costs in establishing the New Quality and Safety system and reduced running costs; greater fairness and contribution to solidarity; enhanced donor and recipient confidence stemming from legal clarity.[8]

However, it is noted that the requirement for a similar quality and safety regime from each EU Member State may require various adjustments to be successful at the local hospital level. On the positive side, it would ensure that it if quality and standards are standardized at the European level, then it would guarantee equal access for all European citizens. The EU Commission's first publication looked at the policy options and set objectives to promote enhanced coordination between Member States.[9] Here, the EU Commission highlighted that the Community needed to react under Article 168(4) (a) TFEU to deal with the challenges facing organ transplantation: The transfer of organs can lead to transmission of diseases

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[4] See European Commission, Communication From the Commission to the European Parliament and the Council Organ Donation and Transplantation: Policy actions at EU level, (May 30, 2007).

[5] Id. at 2.

[6] Id. at 3.

[7] Id. at 5.

[8] Id. at 10.

[9] Id. at 6.

such as Hepatitis B and C, HIV, various parasites and cancer. Although, there are a number of cross-border treatments the legal quality and safety requirements differ between Member States. Thus there was a need for the system to a standardisation of the system to ensure patients are being protected throughout Europe.[10] The EU Commission urged that measures needed to be introduced throughout the procedure to improve the quality and safety of organs, from pre-transplant evaluation procedures set for donors, to setting procedures for procurement and requirements for organ preservation and transport.[11] A system needed to be in place, which allowed donors to be traced in case of complications. National authorities were also encouraged to take active roles and establish authorized centres in Europe that would monitor safety and quality criteria. The EU Commission concluded that it would 'define the precise, balanced scope of the EU legal framework on quality and safety for human organs taking in account the dialogue it has had so far with the Member States on the issues'.[12]

Due to a shortage of donors, the Commission suggested that the EU Member States may be able to create a system by which donors could be identified, as after their death donors are lost due to lack of referral, or because the option was not presented to their relations.[13] If healthcare professionals were trained to identify potential donors, donor rates could be increased. Moreover, providing information to the healthcare professionals on transplantation may affect the donors' willingness to donate. Eighty-one per cent of Europeans agreed that the use of a donor card would facilitate organ donations after their death.[14] Given the need to establish adequate national transplant systems; good organisational and technical support is essential.[15] The document stated that a "flexible system combining a decentralized network formed by local organisations mainly focused on organ procurement, and the promotion of donation with large organisations focused on promoting organ sharing and cooperation seems to be the most effective organisational approach".[16] This

[10] Id. at 7.

[11] Id.

[12] Id. at 8.

[13] Id. at 9.

[14] C. Sabel & J. Zeitlin, Learning from Difference: The New Architecture of Experimentalist Governances is the European Union. LAFOLLETTE SCHOOL WORKING PAPER 1 (2006).

[15] Presidency Conclusions, Lisbon European Council (Mar. 23, 2000).

[16] Commission Working Document Accompanying the Proposal for a Directive on Standards of Quality and Safety of Human Organs Intended for Transplantation and Action Plan on Organ Donation and Transplantation at 8. COM (2009-2015); See Strengthened Cooperation between Member States: Impact Assessment, SEC (2008) at 2956.

would give rise to the formation of networks and experimental governance, as experimentalist tools such as open consultations would be utilized to achieve the goals of promoting organ donation.

The EU Commission emphasized the need to share best practices among the Member States to increase the number of donors and educate health care professionals. It would also encourage action at the EU level for the interchange of organs between national levels.[17] The EU Commission also proposed an Action Plan that would include qualitative, and quantative indicators, and regular reporting in order to promote greater coordination. It restated the preference for the use of the OMC type methodology utilising the Directly Deliberative Polyarchy theory (so called DDP theory) and signalled the shift away from the traditional command and control mechanisms of governance used in blood and to a lesser extent, in tissues and cells regulation.[18] Thereafter the EU Commission conducted a series of meetings with stakeholders and experts to receive feedback on the proposed Action Plan, as well as input on the drafting of the proposal for a Directive in this area. The adoption of the OMC within this area raised issues with certain stakeholders, who felt that this method would divert personnel and resources away from the actual strategies and thus was unnecessary. [19] It was also felt that there was a greater need for flexibility to

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[17] *Commission of the European Parliament and the Council:" Organ* donation and transplantation: policy actions at the EU level - Summary of the Impact Assessment. SEC (2007) 704; Commission of The European Communities for a Strategy for Europe on Nutrition. Overweight and Obesity related health issues. COM (2007) 279 final (May 30, 2007); See supra note 4.

[18] C. Sabel & J. Zeitlin, Learning from Difference: Experimentalist Governance in the European Union 2, Oxford Univ. Press (2010). The theory of (directly deliberative polyarchy (DDP) emphasises direct participation, deliberation and concrete problem solving. Sabel and Zeitlin argue that the OMC expresses the essence of DDP. It is directly deliberative because allows actors with direct field experience to bring about different reactions and open new possibilities. It is polyarchic, because it is a system, which allows local units to learn discipline and set goals for each other.

[19] Commission Staff Working Document Accompanying Document to the Communication from the Commission to the European Parliament and the Council Organ Donation and Transplantation: Policy Actions at EU Level Impact Assessment. SEC (2007) (May 30, 2007). The Open Method of Coordination (OMC) was defined by the Portuguese Presidency at Lisbon, and afterwards in terms closely modelled on the European Employment Strategy as involving a specific ensemble of elements: Fixing guidelines for the Union combined with specific timetables for achieving the goals that they set in the short, medium and long term; Establishing, where appropriate, quantative and qualitative indicators and benchmarks against the best in the world and tailored to the needs of different Member States and sectors as a

be built into any EU regulation regime. This meant that clinicians and patients needed to be granted adequate freedoms to make decisions about associated risks of the use organ transplantation, given factors such as waiting lists and organ shortage.[20]

In reaction to stakeholders' participation in organ donation and transplantation policies, DG Sanco launched an open consultation in 2006. The Commission received 73 contributions from regulators, medical and patient organisations and created a key stakeholder group from around 16 European Associations.[21] The group met in 2008 and shared information, which was then incorporated within the definitions of the policy options. The EU Commission since 2007 has held various meetings with national experts of all Member States, including Eurotransplant and Scandiatransplant, and discussed key priorities.[22]

Arguably, the EU Commission's interactions with the stakeholders and experts for feedback, along with its efforts to bring together the actors to reflect on the current issues of organ donations and develop legislation through networks, highlighted Zeitlin's network deliberative decision-making concept.[23] The theory purports a shift away from the ideals of representative democracy in which laws are only perceived to be legitimate if the electorate formulates them. Informal deliberation is not conceived from the technical elites but rather through a multitude of actors. This was particularly true as at this stage options for regulation were considered but it was not necessarily assumed at the outset that hard law would be utilized.[24]

At the time of the Impact Assessment (IA), it was recognized that 25 out of the 29 countries (EU, Turkey and Norway) surveyed had a national register, which contained the data on the origin and destination of the organs.[25] Only eight countries

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means of comparing best practices; Translating these European guidelines in to national and regional policies by setting specific targets and adopting measures, taking into account national and regional differences; Periodic monitoring, evaluation and peer review organized as mutual learning processes.

[20] Commission Staff Working Document Accompanying the Proposal for a Directive of the European Parliament and of the Council on Standards of Quality and Safety of Human Organs Intended for Transplantation and the Communication from the Commission Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation Between Member States, SEC (2008) 2956.

[21] Id.

[22] Id. at 3.

[23] See Sabel & Zeitlin, supra note 14.

[24] Id.

[25] See European Commission, supra note 4.

made reporting adverse conditions compulsory. Once a disease is found in the recipient, there is an urgent need to trace the donor to prevent the disease. However, there was no system that would allow the tracing in cross-border cases, despite more than 4000 organs being exchanged between Member States annually.[26] Organs will inevitably be related to cells and tissues. It is therefore vital that information about adverse effects and infections in a solid organ transplant can be quickly traced to a donor and immediately relayed to the tissue vigilance system, which is foreseen by the European tissue and cell directive.[27]

In the IA, DG Sanco identified four regulatory approaches in the area of organ donation and transplantation, which were devised through experimental methods.[28] The first option involved the EU Commission continuing to take actions such as its previous involvement in research programs and international cooperation.[29] The second option involved a non-regulatory approach by developing a European Action Plan on Organ Donation and Transplantation for the period 2009-2015. The third option involved the combination of an Action Plan, similarly to option 2, along with a 'flexible directive.' The fourth option involved the combination of an Action Plan with a stringent directive. This directive will be modelled on the Tissue and Cells Directive and thus contain detailed regulation about safety and quality of care needed to be enforced within the Member States.[30]

These options were assessed via a number of methods.[31] The first point of analysis of impact was a literature review. Secondly, country studies were reviewed in relation to six sample countries. Thirdly, interviews taken of stakeholders were conducted including with national and general experts in the field of organ donation. Fourthly, in order to examine the improvements four scenarios of different changes in living and deceased donation rates were developed, which were used to identify the economic and health impacts of the proposals. Fifthly, a cost consequence framework in the form of an impact matrix was used to analyse the evidence, identify the key impacts and compare them across the four options.[32]

All policy options were likely to increase donation rates. According to the IA, the best scenario would see approximately 21,000 organ transplantation operations per year saving 230,000 lives.[33] The IA suggested that options 2 and 4

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[26] Id.

[27] See European Commission, supra note 16 at 15.

[28] Id.

[29] Id. at 3.

[30] Id.

[31] Id. at 4.

[32] See European Commission, supra note 4 at 5.

[33] Id. at 4.

could lead to better economic benefits. However, the Member States needed to invest to improve the national infrastructure in this field. The evidence shows that organ transplantation allows patients to participate in social and working life. Option 3 was considered the best option to reconcile the objectives with the principles of subsidiarity and proportionality. A flexible Directive combined with an Action Plan would allow the decision-making process to be distributed, thereby including actors at the hospitals, EU Member States and European levels.

Different scenarios were used to establish the likely results that could be achieved from the different policy options. The reasoning is as follows:[34]

Proposals usually depend on national transplant systems. There is often a lack of clarity between policy outcome and actual impacts.

The multilevel governance approach in organ transplantation creates uncertainty in outcomes. The improvements to organ transplantation procedures are delivered in hospitals. As option 2 and 3 allow voluntary action, it is questionable how much of the European procedures would enter hospital systems.

The Spanish model was used as a comparator to assess potential impacts. It is the best example to illustrate that organ donation and procurement can increase and sustain organ donation rates.

The results of this comparison showed that option 3 and option 4 contained the most elements for success of the Spanish model.

The Spanish comparator was used as to produce the ideal results. The assumption was that if the Member States were to fully implement the European options then they achieve the Spanish results.

The IA realized that these were optimistic results, therefore three other scenarios were utilized: All countries achieve at least European average transplantation rate; all countries improve transplantation rate by 10%; and all countries improve transplantation rate by 30%.[35]

[34] Id.

[35] See Commission Working Document Accompanying the Proposal for a Directive on Standards of Quality and Safety of Human Organs Intended for Transplantation and Action Plan on Organ Donation and Transplantation, supra note 16 at 60.

Table 1 below will show that the policy options need to adhere to the commitment/capacity that the EU Member States are willing to submit to.

Table 1 Scenario and policy options.[36]

Element	Option 1	Option 2 Action Plan (AP)	Option 3 AP and Flexible Directive	Option 4 AP and Stringent Directive
Low commitment/capacity Member States	No change	No increase	Average increase scenarios 2 and 4	Average increase scenarios 2 and 4
High commitment/capacity of Member States	No change	High increase scenarios 1 and 3	High increase scenarios 1 and 3	High increase scenarios 1 and 3

Options 3 and 4 make compulsory changes. Thus, the results are more visible than in option 2. If the options had been compared with the Spanish model, then there would be no increase in organ donation rates under option 1. Option 2 would lead to an increase if EU Member States were willing to implement the Action Plans. However, if there is no commitment from an EU Member State then not much can be expected in relation to results. The results under options 3 and 4 are more positive as they enforce mandatory national implementation. The problem with option 4 is that with the stringent directive in place it may make organisations become reluctant to participate in organ procurement and result in reduced organ donation rates.

If the policy options are benchmarked against the Spanish model, then it can be seen that all options would promote the role of transplant donor coordinators (TDCs) in hospitals. They promote public awareness by improving the knowledge of health professionals and patient groups. Options 3 and 4 demand legal mandates, the establishment of programs and systems and training. The problems remain with the implementation as the Member States have a lower discretion within options 3 and 4.

Table 2 below outlines the options in accordance with their health, social and EU impact budgets.[37]

[36] Id. at 63.

Option	Health impacts	Social Impacts	EU Budgetary impacts
Option 1 No change	No change expected to address the current shortage in organ donations.	- No change in Quality of life and social participation /employment of donor/recipients - Varied trust and confidence in the transplant system across Member States.	- -No extra costs involved in setting up national infrastructures /registers or traceability systems. - –High long term treatment costs and loss of productivity due to increased waiting times.

[37] Id. at 71-3.

Option 2 AP	Donation rate: From 0-7,908-21,006 organs expected depending on the commitment of the Member State. -Lower predictions show no change, higher show 231,006 life years saved. -Knowledge will increase living donors. -Definite benefits to small Member States due to improved processes and removal of barriers.	-Improved care for donors/higher number of transplantation therefore better quality of care. -Does not address obstacles to social participation and employment for individuals. There would be some increase in social participation due to the increase in transplanted organs. -Public awareness and better training of transplant coordinators might increase confidence of donor families.	-Low to medium costs for voluntary measures to designate accredit establishments and more transplant coordinators. -Saving costs through standardized reporting of medical information. -Low costs for reporting requirements under the OMC. -Savings in treatment costs if Member States commit properly then up to 1.2 billion Euros. -Productivity Impact: 2.4 billion if Member State commitment is low. -Economic impact on living donor: Reduced economic risks to health care.
Option 3 Flexible Directive and AP	-Donor rate: medium to high. Between 54,320-231,006 life years saved in the upper range. -Common quality and safety standards would supplement the AP and increase organ donation.	-Legally prescribed, better access to care for living donors -Social participation and employment: Same as option2. -Better training plus quality and safety standards may increase patient safety and empower patients.	- Medium costs for running national quality systems. Very low costs to setting competent authorities. Low to medium costs for designating or authorising establishments. -Low/medium costs for adapting national traceability and adverse reporting systems. -Low costs of reporting of activities at transplantation centres. -Treatment of costs: Savings of 1.2 billion Euros at the best. -Productivity: 882 billion Euros as a

			result of modest increase in donations. -Economic Impacts on living donor: Same as option 2
Option 4 Stringent Directive and AP	-Donor rate: Medium to high Same results as option 3 for life years saved. -Living Donors: Same as option3 -Cross Border exchange: Same as option 3.	-Quality of care: Same as option3. -Social participation and employment: Same as option 2. -Trust and Confidence in transplantation: Same as option3.	-Medium/High costs for national legal quality systems - hospital level. -Low costs for establishing a national register of establishments. High costs for introduction to European standardized traceability systems. -Reporting obligations and administrative burden: Same as option3. Treatment costs: Same as option 3 Productivity: Same as option3. Economic Impact: Same as option 2.

Table 2 above illustrates that in terms of health impacts, the options will increase donation rates. The options will increase cross border exchange of organs, which will facilitate the health of urgent patients and the most vulnerable patients (i.e. children/highly sensitized). There is a degree of uncertainty with the results anticipated with option 2 because these are dependent on the discretion of the Member State's implementation. Options 3 and 4 present the highest health benefits.

In terms of social impacts, the table above also points out that the patients will have improved social lives with transplantations. European action will further allow patient trust to grow within the systems; the highest social benefits again arise from options 3 and 4. From a theoretical lens it can be observed that option 3 and 4 have the greatest social and health impacts as combing the Directive with the Action Plan allowing for the integration of the new governance and traditional law instruments. This in turn provides the maximum benefits from traditional methods

and new governance which is termed 'transformation' by Trubek and Trubek, who state that 'the introduction of new governance may be a part of the conscious design to get the best of the old and the new, by yoking the two together in an integrated process'.[38]

Looking at the situation from an economic perspective, options 2 and 4 could potentially process the greatest economic benefits. Member States need to invest in the national infrastructure of organ donation to realise these gains. Option 3 involves costs, attached to it, as it requires a national vigilance system with national registers. However, as this would be mandatory it would save costs. The same is true for option 4, yet this option carries higher implementation costs; Member States have less choice to revise their existing national systems.

In option 2 the adoption of the Action Plan will be based on the cooperation of the EU Member States through the national action plans. The Public Health Programme retains the resources with the responsibility to coordinate in this field. Option 4 entails the adoption of the stringent directive, which will be modelled under the Tissue Directive. This will require further detailed meetings and even more comitology meetings resulting in further costs to the start-up procedure. It is argued that the Commission could reduce costs incurred by the EU Member States utilise the existing work by the Council of Europe to avoid the duplicating research by experts especially in areas of data sharing, as better use should be made of the "epistemic community" of experts that are present within the area of organ research.[39]

III. ACTION PLAN (2009-2015) AND ORGANS DIRECTIVE.[40]

This section aims to provide an outline of the contents of the Action Plan and the directive.

3.1 The Action Plan

As discussed above, the Commission published a further Communication in 2008 along with the proposed directive. The Communication contained the revised Action Plan. [41] The Plan is designed to cover the work program in the field of organ transplantation in 2009-2015.[42] Ten priorities were identified to address the current

[38] D. Trubek, and L. Trubek, New Governance and Legal Regulation: Complementarity, Rivalry and Transformation Narrowing the Gap: Law and New Approaches in the EU, Columbia Journal of European Law 13 (2006-2007).

[39] P. Haas, Introduction: Epistemic, Communities and International Policy Coordination. International Organization 46 (1), (1992).

[40] Id.

[41] See Strengthened Cooperation between Member States, supra note 16.

[42] Id.

problem to enhance the quality and safety of organs, as well as the efficiency and accessibility of organ transplantations.[43] The OMC was used to set the plan to identify common objectives; set targets/indicators/benchmarking and Member States would have the independence to achieve the outlined objectives.

The following table will summarise the strategies under the 10 priorities:

Priority.	Strategies under the priority.
P1	Priorities 1-5 deal with organ availability. The ultimate aim is to increase organ procurement from deceased donors. Appointment of transplant donor co-ordinators like the Spanish system. To ensure uniformity in training these co-ordinators work will be done by following international standards.[44]
P 2	Development of agreed indicators and best practices for quality improvement programs at national level. Specialists in intensive care and the transplant co-ordinators will do this.[45]
P3	Enhancing living donation especially for kidneys.
P4	Increasing public awareness (through media) in relation to organ donation.
P5	Develop mechanisms to facilitate the identification of cross border donors.
P6-9	An organisational model needs to be developed to enhance organ procurement. The Spanish Model the model will be followed. This will involve setting up a central coordinating administrative agency, a transplant network that will operate nationally/regionally, promotion campaigns and audits on organ transplantation. Promotion of cross border exchange of organs.
P10	Promote common accreditation system for transplant/organ donation.

[43] Id.
[44] Id at 3.

[45] Id at 5-9.

The 2007 EU Commission Communication recognized that organ donation and the transplantation regulatory framework would need to be flexible, but would provide a basic quality and safety framework.[46] It would follow a similar format to the Blood and Tissues Directive taking in account the specific issues in organ donation and transplantation. As mentioned before, concerns were expressed that if the Directive were too rigid, then it would create too many administrative burdens at national levels and create obstacles.

The Organs Directive was adopted, and the EU Member States transposed it into national laws for 27 August 2012.[47] The Directive is divided into chapters containing:

- Subject matter, scope and definition;
- Quality and safety standards for organs;
- Donor and recipient protection for donor selection and evaluation;
- Obligations of competent authorities and exchange of information;
- Organ exchange with third countries and European organ exchange organisations;
- General and final provisions.

The key provisions of the Directive allow the EU Member States to establish a framework which would include procedures for identifying the donor, the consent of the donor (or family consent), set a system for traceability of organs, reporting mechanism for serious adverse events and reactions.[48]

The procedure of organ exchange between EU Member States requires a system to ensure that the traceability, quality and safety conditions are met including the safety of potential recipients.[49] This system was put in place for the protection of donors and donees alike.[50] Farrell comments that the legally binding part of the Directive does not further 'elaborate' on the allocation criteria.[51] In paragraph 20 of the Recital it is verified that the allocation of organs should be based on scientific, non-discriminatory and transparent criteria.[52] The Commission, in the implementation of the Action Plan, should take these sets of criteria into account. Similarly, the Directive ensures that organ procurement takes place appropriately. The Member States need to ensure that they can provide information on the

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[46] Id at 9-10.

[47] See European Commission, supra note 4.

[48] Id.

[49] Id.

[50] Id.

[51] AM. Farrell, Addressing Organ Shortage in The EU, Organ shortage: Ethics, Law and Pragmatism, Cambridge Univ. Press (2011).

[52] Id.

authorization of such bodies.[53] They need to ensure that suitable equipment; materials and surgical facilities are used during procurement.[54]

Chapter III of the Directive deals with the requirements with the donor and recipient protection including donor selection and evaluation. The consent regime at the national level will be respected and procurement will occur after the laws have been observed.[55] Member States need to ensure that organ donation is conducted on a non-profit basis.[56]For living donors the assessments are required by trained and competent professionals. Member States are required to ensure the highest protection of living donors to secure quality and safety of organs for transplantation.[57] It is acknowledged that there is a need for further guidelines in relation to the circumstances where living organ donation can take place, and precise listings for the type of protection that will be provided to the living donor. Donations can be refused on grounds of unacceptable health risks.[58]

IV. IS NEW GOVERNANCE THE RIGHT WAY FORWARD IN THE ORGANS CASE?

Whether the Action Plan (which is the soft law portion of the legislation) will achieve its aims seems questionable. At a national level, it has raised concerns that it will increase the administrative burdens on the on national institutions in order for them to fulfil their obligations under the Directive and Action Plan. The experts' meeting overlooked by the Commission concluded that the ten priorities are substantive and will require planning and evaluation overtime.[59]

The attraction to soft law is that it could easily become hard law. For instance, the legal effects are created by the expectations laid down in the soft law provisions. The soft law will then be incorporated in to hard law provisions as in this instance the Action Plan will complement the Organs Directive. Finally, the Commission's role to cooperate with non-state actors at national levels produces legal effects for soft law provisions.

One of the reasons new governance may seem attractive is because the CJEU has also regarded the outcomes of new governance as part of the acquis communautaire. It has been established through the CJEU's case law that the

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[53] See European Commission, supra note 32.

[54] Id. at Article 6.

[55] Id. at Article 14.

[56] Id.

[57] Id. at Article 15.

[58] Id.

[59] Commission, Experts Meeting on Organ Donation and Transplantation Action Plan: Summary Report. 11-12/March 2009.

national courts need to take recommendations into account even though they are not binding under Article 288(5) TFEU.[60] The Court has limited the EU institutions' discretion to depart from the soft law instruments, as the institutions may be in breach of general principles of law.[61] Klabbers further affirms that the moment soft law is applied within judicial/non judicial circumstances; the concept collapses either entirely or becomes hard law or no law whatsoever.[62] Member States will also be obliged to accept the soft law if they have participated in the drafting procedure of the recommendations.[63]

However, new governance mechanisms rely on the input of a variety of actors in law-making thereby enhancing the democratic legitimacy of outputs. For instance, under Article 155 TFEU (ex Article 139 EC), an agreement concluded between the social partners can be "implemented by the (signatories) in accordance with the procedures and practices specific to management and labour in the EU Member States."[64] Implementation also takes place via a Council decision in which the Council issues a Directive, which is referring to the agreement management and labour in the EU Member States and also via a Council decision in which the Council issues a Directive that refers to the agreement between the social partners. Notably, EU Member States do not need to apply the agreements reached by the social partners which are not adopted, as this represents soft law for EU Member States.[65] There is some uncertainty regarding the legal status of the agreements informally concluded by social partners. Betten comments that they "do not have another legal status other than that of an agreement between two parties falling outside the scope of Community law".[66] Furthermore it can be argued that non-state actors could assist the Commission in relation to the implementation of the soft policy coordination instruments, in particular the OMC. The stakeholders could monitor the national measures that are in place for the OMC enforcement. The effectiveness of this type of supervision will be based on the conduct of the national

[60] C-322/88 Grimaldi (1989) ECR I 4407.

[61] C-213/02 Dansk Rorindeustrie and others v. Commission (2005) ECR I-5425, 211.

[62] J. Klabbers, The undesirability of soft law. NORDIC JOURNAL OF INTERNATIONAL LAW 3 (1988) 82.

[63] C-311/94 Issel-Viliet (1996) ECR I-5023.

[64] Art. 155, Treaty on the Functioning of the European Union (2008). https://europadatenbank.iaaeu.de/user/view_legalact.php?id=15.

[65] S. Smismans, New Governance- The Solution for Active European Citizenship, or The End of Citizenship?, COLUMBIA JOURNAL OF EUROPEAN LAW (2007) 612.

[66] L. Betten, The Democratic Deficit of Participatory Democracy in Community Social Policy. EUROPEAN LAW REVIEW (1998) 28.

administration. Nevertheless, the Commission does not have sufficient material resources or legal basis to monitor the Member States in the implementation of the OMC.[67]

Lobel highlights that the governance model will supersede the classic regulatory model as the former "addresses the changes in both the goals and capabilities of legal regulation, and avoids the central deficiencies of substantive law.[68] [It] fundamentally transforms legal control into a dynamic, reflexive and flexible regime." This has led to the need for change in aspirations of law and policy. However, there is scope to improve new governance the question remains should it be applied to the organs case?

V. HYBRID FORM OF REGULATION AND THE CASE OF THE ORGANS DIRECTIVE

As mentioned above, new governance has its limitations. Democratic accountability is only guaranteed if the decision-making outputs of the new modes are subject to control by elected governmental actors who are elected through democratically legitimate policy-making procedures under a representative government. Stakeholder democracy, which is the most frequently used under new the modes of governance, does not allow control for the negative external effects of functionally delimited new modes of governance. Due to the obvious deficiencies related with soft law, EU healthcare governance could benefit from the transformation of old and new governance, where the new governance and traditional law are put together in an integrated system. Each form of governance relies on the other for its success. This method views the hybrid of old and new governance.

In the light of the discussion so far, this article contends that the Action Plan with the Organ Directive may also be seen as hybrid governance. The Directive may constitute hard law whilst the Action Plan would be seen as the soft law mechanism. The hybrid package combines both the hard law and soft law instruments. Harder instruments lend force to the softer instruments. Hybrid governance is linked to Hervey and Trubek's suggestion for a 'Transformative Directive' in the field of cross-border healthcare.[69] They suggested that both the 'old' and the 'new' could be harnessed together to develop a hybrid structure. This would ensure the benefits of experimentalism without retreating entirely beyond the legal constraints.[70] For

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[67] V. Hatzopoulos, Why the OMC is Bad for You, EUROPEAN LAW REVIEW 13(3) (2007) 309-342.

[68] O. Lobel. The Renewed Deal: The Fall of Regulation and the Rise of Governance to Contemporary Legal Thought, MINNESOTA LAW REVIEW (2004) 89.

[69] L. Trubek & T. Hervey, Freedom to Provide Health care services within the EU: An Opportunity For A Transformative Directive, COLUMBIA JOURNAL OF EUROPEAN LAW 13 (2006/2007) 623.

[70] Id. at 627.

instance, Trubek and Hervey proposed a hybrid solution in the form of a 'Transformative Directive' as they justified it as "much to offer in terms of developing and circulating solutions to the problems arising from managing healthcare provision in the context of an internal market and Europe's social model".[71] The internal market needs to be taken into account (which is predominantly treaty based) within the field of cross-border healthcare.[72] Thus a hybrid structure may seem more appropriate as it could take into account the classical methods and new methods of governance. Sabel and Zeitlin view the Directive to set the parameters and establish transparency and accountability via DDP.[73] The Directive creates obligations for accountability and hence allows participation in the context of soft law.[74] This allows for a new architecture of EU governance that operates through a hybrid mixture of soft and hard law.

Moreover, Trubek and Hervey suggest that this 'Transformative Directive' would comprise of two parts.[75] The first part would consist of hard law, which would take the form of a Directive. Its preamble would reflect the European social model. It would deal with the legal provisions on cross border healthcare and healthcare services. The second part of the 'Transformative Directive' would form new governance institutions, which would create legal rules by utilising soft law through iterative participatory processes. This would then result in a Strategy, which would allow coordination from EU Member States and the Commission. Such a Strategy would focus on the exchange of information, develop guidance, participation of stakeholders and peer review, which are essentials in new governance and are envisaged for the OMC in healthcare and long-term care.[76] In the spirit of the hybrid governance structure the Transformative Directive would regulate the standards for the Strategy (the soft law). It would promote procedural duties including accountability and transparency, and demanding the methods of the strategy to be transparent. The Directive would contain requirements for the Strategy to contain guidelines for the dealing with cross border care.[77] An example of hybrid governance is shown in The Unfair Commercial Practices Directive, which

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[71] Id. at 625.

[72] Id. at 624.

[73] See, Sabel & Zeitlin, supra note 14.

[74] Id at 14.

[75] Trubek and Hervey, supra note 69 at 636.

[76] Id at 638.

[77] Id at 639.

incorporates codes of conduct to make them binding. The Directive transforms the voluntary codes to make them binding on traders.[78]

There are examples of hybrid governance in environmental protection. Notably Directive 2008/1/EC on integrated pollution prevention and control (the IPPC directive) requires that the permit can only be obtained if environmental obligations are complied with.[79] The obligations must be based on Best Available Techniques (BAT). The Commission deals with the BAT exchange of information. The Member States and stakeholders establish the BAT reference documents (BREFs). The Commission then provides the publication of the BAT reference documents. The BAT documents are non-binding and offer details to relevant bodies on BAT based permit conditions. The BAT reference documents are highly influential. The Commission, in its proposal for an IPPC Directive, noted that there were gaps in the BAT and laid down provisions to clarify the use of BAT. In particular Article 3 of the proposal which requires Member States to "take the necessary measures to provide that the competent authorities ensure that installations are operated in such a way that: a) all the appropriate preventative measures are taken against pollution, in particular through application of the BAT," may give the Commission with legal authority it needs to limit national discretion in implementation.[80]

The Environmental Impact Assessment Directive (EIA) and the Water Framework Directive (WFD) are described as instances in which law is transformed by its relationship with new governance.[81] The EIA Directive provides tools for evaluation and adaptation allowing regular exchange between the Commission and the Member States.[82] The Commission must issue implementation reports that provide any proposed amendments to the EIA Directive to ensure it is utilized an appropriate manner.[83] The WFD has devised an informal governance forum in the

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[78] Directive 2005/29/EC. On Unfair Business to Consumer Commercial Practices in the Internal Market and Amending Council Directives 84/450/EEC, 97/7/EC, 98/27/EC, 2002/65/EC.

[79] THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 Concerning Integrated Pollution Prevention and Control.

[80] Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of Regions. Towards an Improved Policy on Industrial Relations (IPPC Proposal), 9 COM (2007) 844.

[81] Trubek and Trubek, supra note 38 at 554.

[82] J. Holder, and J. Scott, Law and New Environmental Governance in the EU, Law and New Governance in the EU and the US. Oxford: Hart Publishing, (2006).

[83] Trubek and Trubek, supra note 38 at 548.

form of the Common Implementation Strategy, which allows for the open coordination between the Member States and the Commission in the implementation of the Directive.[84]

Moreover, Velluti argues that 'a strong hybridized system of co-regulation could also reduce the putative weakness of new governance' for its lack in accountability and judicial scrutiny.[85] The problems lie in the fact that law and constitutionalism are linked to 'stateness' which are not found in new governance processes.[86] The solutions seem to lie with trying to establish the use of hybridity as effective regulatory model. Hybridity aims to develop an interconnection of the adjudication, legislation, implementation, and enforcement stages instead of seeing them as singular processes. The first stages could begin with trying to develop a model of regulation, which is sensitive to the realities in the EU system. The hybridity models would allow the EU to coexist within a multi-tiered structure but also require the need to strike a balance to ensure economic efficiency, democracy and accountability.

It is envisaged that the Organs Directive and Action Plan could be modelled with this Transformation Directive. The ten priorities of the Action Plan (soft law element) deal with benchmarking, the development of indicators and best practices. The Directive (hard law element) covers the scope of the Directive, definitions, procedures for consent, and quality and safety of the organs. The Directive sets out the framework and the legal duties for the Action Plan to operate within. These include placing the duty on the Member States to set National Quality Programs, which will include the rules on the operating procedures and traceability of the organs.[87] The institutional requirements under the Directive are firstly, the Member States being required to designate tasks to a competent authority, whose role will involve ensuring that the procurement centres and transplantation centres are audited regularly, and may suspend the centres that do not comply with the requirements of the Directive.[88] Secondly, the Directive requires the establishment of a Committee on organ transplantation, which will provide the Commission with assistance.[89] The procedural requirements of the Directive include the requirement for the National quality programs to provide procedures to verify donors, or donor's family consent

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[84] Holder and Scott, supra note 82 at 227.

[85] S. Velluti, New Governance and EU Constitutionalism: Friends or Foes?, EUSA 11th Biennial Conference 23/4/2008 LA USA.

[86] J. Shaw and A.Wiener, The Paradox of the European Polity, Harvard Law School, Jean Monnet Working Paper (2000).

[87] See European Commission, supra note 32 at Article 4.

[88] Id at Article 18.

[89] Id. at Article 26.

in accordance to the national rules.[90] There need to be procedures in place for the reporting obligations to trace donors and allow for procurement and traceability.[91]

Following Scott and Holder's conceptual framework on new governance's outcomes, the Action Plan would operate on a three-fold basis: It would provide the platform for production and exchange of data, secondly it would establish guidance and thirdly it would commit to reviewing, testing and validating the current practices.[92] The exchange and production of data are essential in the new governance procedure because without the data there are no grounds for testing the national practices.

Similarly to the Environmental Assessment Directive, the OMC type procedures will establish and devise benchmarks, indicators to mechanisms for reporting in order to test and validate national procedures.[93] This is visible through Priority Action 2, which requires the Transplant Donor Coordinators (TDCs) in hospitals to identify best practices (to increase organ availability) for deliberation among the Member States with training being provided on all aspects of organ donations. Priority 2 aims for the Member States to develop indicators to improve programs at the national level. Priority 3 furthers this ambition by devising programs to promote organ donation and creating national registers to hold data on the donors.

The role of these programs is to contribute to best practices. The establishment of guidance would be possible through Priority Action 4, which requires regular meetings with stakeholders, journalists, national experts and patient support groups to devise strategies to increase organ availability. Finally, current practices would be reviewed, tested and validated through peer-reviews. This will be possible through the use of Priorities 6-9, which focus on identifying efficient practices and improving national models. This is made possible through peers-reviews and utilising the information from the transplant network coordinators.

Moreover, it can be argued that the DDP theory would also apply to the Organs case as the experimentalist tools such as the indicators and benchmarks utilized in the Action Plan will be subject to peer-reviews. Whilst the network coordination between the TDCs, various support groups, and the committees operating both nationally and on an EU level all demonstrate direct deliberation.

Yet, the problem with the Action Plan is that it seems overly ambitious in its scope and coverage. Thus, it seems questionable whether or not it will be achieved. The same national bodies that are working on the priorities of the Action Plan will be responsible for implementation of the Directive. They face additional burdens to meet the requirements under the Directive and Action Plan. The substantive aspects of the Action Plan require detailed planning for the implementation and evaluation. There are the concerns raised by the national representatives on how the OMC will be utilized under the work programs of the Action Plan.

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[90] Id. at Article 4.

[91] Id. at Articles 4, 5, 10.

[92] Holder & Scott, supra note 82.

[93] Council Directive 85/337 O.J (L175) 40. On the Assessment of the Effects of Certain Public and Private Projects on the Environment.

The Commission has preferred the use of the OMC for the development of the expert consensus on indicators and best practices.[94] Again, the fear is that it may result in negotiations between technocratic elites and there needs be an assurance that patient interests are adequately represented. There needs to be peer-reviewing of the indicators and best practices by all sections of society to ensure dynamic accountability. Also, the hybrid Organs Directive and the Action Plan package may have the opportunity to uphold certain constitutional and substantive values. Regarding procedural values, transparency could be achieved if the operating procedures of the National programs are visible; if the minutes and audits of the Transplantation Centers are available and if the reports and registers are accessible.[95] Participation would be required from the necessary stakeholders compromising the necessary patient rights groups, and healthcare professionals. In relation to substantive principles, all the actors involved the process would be required to respect principles such as equality, and solidarity.[96]

One of the issues regarding accountability would be to determine the mechanisms for the actors involved. Accountability needs to be ensured by external bodies, which would give judgements.[97] The best option would be peer-reviews in order to review the decisions taken through dynamic accountability. Another objection, as Smisman states is the fact that participation does not imply that all stakeholders are involved, risking it a semi closed network.[98]

It is also important to consider that the EU's legal order seems to be about economic order and not about social-protection policy. Scharpf argues that the OMC is a response to constitutional imbalance between the both.[99] However, it is argued that the Directive would balance the health interests of patients and strengthen the

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[94] Treaty on the Functioning of the European Union, Art. 168(2).

[95] Directive 2010/45/EU; See European Commission, supra note 32 at Articles 4 and 9.

[96] O. Schutter and S. Deakin, Social Rights and Market Forces: Is the OMC of employment and Social Policies the Future of Social Europe. Brussels: Bruylant, (2005).

[97] C. Harlow, R. Rawlings, Promoting Accountability in Multi-level Governance. A Network Approach, European Governance Papers, Paper Bo. C-06-02, (2006)..http://connex-network.org/eurogov/pdf/egp-connex-network.org/eurogov/pdf/efp-connex-C-06.02 pdf, last visited April 5, 2017; M. Bovens, Analyzing and Assessing Public Accountability - A Conceptual Framework. European Governance Papers (2006), http://www.connex-network.org/eurogov/pdf/egp-connex-C-06-01.pdf.

[98] S. Smismans, New Modes of Governance and the Participatory Myth, (2006), European Governance Papers, http://www.connex-network.org/eurogov/pdf/egp-newgov-N-06-01.pdf.

[99] F. Scharpf, The ESM: Coping with the Challenges of Diversity, JOURNAL OF COMMON MARKET STUDIES (2002) 40 at 645-658.

OMC by bringing it within the scope of the internal market. It seems likely however, that the Directive will enhance individual rights as patients waiting for organs would be better informed due to priority 4 which promotes greater public awareness or at least care teams/hospitals would have the facilities to gain information.

VI. PROPOSAL OF THE INTEGRATED MODEL: A FUSION OF THE THREE GOVERNANCE STRUCTURES

Following the discussion on hybrid governance through the Organs Directive and Action Plan the paper proposes that the Organs Directive (Action Plan) illustrates an 'integrated model' of governance combining elements of the three forms of governance structures namely the agencies, comitology and the OMC in a coherent manner. This may be considered as a possible model for the EU's governance dimension reflecting the hybrid character of the Union. This is possible because the Organs Directive is a risk regulating structure, which reflects the general transformation of society away from danger to a risk producing structure, as the procedures relating to organs carry risks.

Such comitology structures serve as instruments that increase reflexivity as they institutionalise forms of mutual observations and information sharing between Member States. Partly due to the legal framing of comitology these structures tend, moreover to be more stable and dense compared to the OMC processes. The committees deal with complex and technical matters. Comitology also serves to ensure implementation. It provides EU Member States with a stake of the implementation of EU legislation. Comitology is based on soft power and persuasion, which in the absence of the necessary competencies and resources serve as functional equivalents to traditional demand and control mechanisms. The comitology machinery is aimed towards the Commission's efforts to ensure compliance with EU legislation thus reducing the structural deficit of the EU as regards the implementation and compliance mechanisms.

Earlier considerations made in this article highlighted that agencies tend to be networked; they are established in complex areas in which it is hard for the Commission to ensure the stability of networks. Therefore, the secretarial and networking coordination roles have been delegated to agencies that act like mini Commissions. Their intrinsic lack of discretionary competencies, limits their role to generating information and monitoring network coordination. The role of initiating and developing policies has remained largely with the Commission. Networks seem to fulfil the same function in policy areas as the agencies because the Commission also dominates them. Networks and agencies have similar roles in the areas dominated by the comitology as they operate to link hierarchical organisations, Commission, agencies and the Member State administrations, thereby ensuring that these organisations are embedded within the broader social realm.

It follows from the above discussion that governance structures can be defined as institutional formations relying on the network form and characterized by organisational and legal hierarchy, which act as structural couplings between hierarchically organized organisations, increasing the reflexive capacities of the organisations in question and thereby offsetting the structural deficits of one or more

of those organisations. In addition, and especially in those areas where agencies have emerged, Teubner's distinction between networks and hybrids gains renewed relevance.[100] Whereas the OMC processes can be understood as pure networks, which merely link organisations, especially in the more mature areas, especially those where the agencies have emerged and are increasingly characterized by governance structures which go beyond networks. Such hybrids combine hierarchical models of organisation with heterarchical structures such as Comitology and OMC instruments developing an 'integrated model' of governance which includes elements from all three forms of the governance structures (namely agencies, comitology and the OMC).

Evidently, this article seeks to demonstrate the combination of the three modes of governance (comitology, agencies and OMC) that are integrated and operate within the Directive. The OMC as an operational mode of governance is visible in Priority 2. It aims to promote quality improvement programs in order to increase organ availability and is thus required to locate best practices. In addition, priority 6 also seeks to encourage Member States to develop and constantly improve their national models, they will be in turn assisted through the provisions of peer-reviews set by the EU together these actions emulate the OMC type processes. [101] The use of comitology as a governance structure is evident through Priorities 6-9, which provide the scope for utilising the committee structures that would replicate the EU type comitology structure. The Commission will be able to gain access to the services of the expert advisory committee of the Council of Europe as it will be able draw on the previous work of the Council of Europe including setting up a coordination network which requires a committee like structure for the interaction of different actors both public and private.[102] In addition, Article 26 of the Directive also requires the establishment of committee structure as it allows for the Commission to be provided assistance from the Committee on Organ transplantation.

The need for an administrative agency is also visible in Article 10 of the Directive, which requires the formation of competent authorities that would process data. It is suggested that a full functioning EU administrative agency could be created. This agency would possess the status of a quasi-regulatory agency, which would fall short of Majone's ideal of fully independent agency. It would carry out

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[100] P. Kjaer, Between Governing and Governance: On the Emergence, *Function and Form of Europe's Post Constellation* Oxford: Hart Publishing, (2010) at 154.

[101] P. Kjaer, Systems in Context: On the Outcome of the Habermas/Luhman Debate, ANCILLA JURIS (2006) 66 at 70. OMC processes act as a specific form of structural coupling working to eliminate the lack of cognitive resources. OMC networks in effect linking Member State administrations to mutually observe each other. Therefore, OMC processes are oriented towards increasing reflexivity and potentially facilitating mutual adoption and learning, ideally transplanting experiences from one setting to the other.

[102] Work Programme of the Committee of Experts on the Organizational Aspects of Cooperation in Organ Transplantation (SP-CTO).

technical, scientific and administrative tasks. This would require a management board headed by an Executive Director who would be responsible for day-to-day management. The agency would be a valuable resource to the organ's settings as it could retrieve information for all the national centres. The agency budget shall consist of a subsidy from the Community budget and fees paid by the national contact centres to register. To ensure transparency the budget of the Agency could then be scrutinized by the EP and Council and EU on public access to documents would apply.[103] The Agency's budget could also be available along with the audits that are required by the Directive in this sense the emergence of the governance structures together means that the organ policy would mutate in a hybrid that would rely on all three forms of governance structures.

This article also asserts that such an 'integrated model' may also be visible within the EFSA or EMEA, as these conglomerates exist of elements derived from Member State administrations, the Commission, the agency secretariats, agency committees, so called forums which serve as a basis for OMC type processes, comitology committees and private actors. None of these structures function as the decisional centre. In organisational terms the agency acts as the centre while decision-making is within comitology. The continuing struggle between the EU Member States for ownership between looms behind the comitology. Therefore, such conglomerates cannot be considered to be intergovernmental or supranational as they are not an extension of the Commission or the EU Member States. Rather these structures are a third form, which tries to fit in with the old intergovernmental/supranational paradigm.

These structures are partly based on hierarchy and partly based on heterarchy. They operate within a framework of a semi hierarchy and can rely on direct effect and supremacy but not on competence-competence. Rather the CJEU relies on persuasive jurisprudence to operate. These conglomerates are characterized by the need to combine elements of control and command with the insurance of commitment by intentional norms, which sanctions obstructions of the conglomerates ability to operate. The distinction between the OMC and the comitology committee is blurred and agencies have their own personality.[104]

VII. CONCLUSION

Given the evaluation provided, this article has illuminated that the Organs Directive[105], can be viewed as an exemplar of hybrid governance used within

[103] Regulation (EC) 1049/2001 of the European Parliament and of the Council of 30 May 2001. http://www.europarl.europa.eu/RegData/PDF/r1049_en.pdf.

[104] CFI ruling stated comitology are not Community institutions just as they are not third part category in Rothrmans **v**. Commission T-188/97 ECR II 2463.

[105] Directive 2010/45/EU of the European Parliament and of the Council of 7/7/2010 on Standards of Quality and Safety of Human Organs Intended for Transplantation.

healthcare. Such is an emerging trend given the EU's Commission's paper in December 2008 containing its policies within the Action Plan on Organ Donation and Transplantation (2009-2015) (the Action Plan).[106] This Plan examined the need to improve quality and safety increase organ availability and make organ transplantations more efficient with the EU. The Plan came with the legislative proposal, which has now been adopted. The Organs Directive, which is now legally binding and will complement the Plan. Hence there will be a hybrid combination of hard and soft law operating together. The Directive (the hard law component) will deal with the organ exchange between Member States, promoting standardisation to facilitate patient mobility, as well as ensuring the health and safety of potential of organ recipients. It is hoped that the Plan (the soft law component) will deal with the gaps left by the Directive (such as details on allocation of the organs). Secondly, it is proposed within that the 'integrated model' may be utilized when applying the Organs Directive. The integrated model presents a fusion of the three governance structures the OMC, comitology and agencies. In the case of the Organs Directive it presents a 'hybrid within a hybrid' model.

[106] Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States.COM (2008) 819.