

# EU Participatory Democracy from Promise to Practice: the Role of IOs and NGOs

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## 1 Introduction

The understanding of law-making within a democratic state has traditionally been closely connected to the nation state, to political organs elected by the citizens of each state.<sup>1</sup> In the current debate, this understanding is often referred to as the Westphalian paradigm, the era under which the interest of the people living in a certain geographical area is connected to the sovereign state to which the area belongs.<sup>2</sup> Under this paradigm, the response to the concern for a democratic foundation of the law produced in an international context is the appointment of the government as the main representative of the state and its people. However, globalization has impelled the need for the public to be represented in a more diverse manner.

In governance structures beyond the state, a wide range of actors since long play important roles in different spectra of law-making in a wide understanding; traditional international treaty-making, administrative rule-making and soft law production.<sup>3</sup> In the EU, participatory democracy was introduced in Article 11 in the Treaty of the European Union (TEU). Hereby participation was recognized as a value or a founding principle of the Union.<sup>4</sup> The role attributed to the actors involved in these procedures does not always distinguish between public and private: state actors, such as international organisations (IOs), and private actors, such as non-government organisations (NGOs) are able to participate in and impact the production of regulation and decision-making beyond the state.

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1 Armin von Bogdandy, *Globalization and Europe, How to Square Democracy, Globalization and International Law*, EJIL, 2004, Vol. 15 No 5, 885, p. 889.

2 Niel Walker, *Beyond boundary disputes and basic grids: Mapping the global disorder of normative orders*, I-CON, 2008, vol. 6 no 3-4, p. 373.

3 Joseph Corkin, *Constitutionalism in 3D: Mapping and Legitimizing Our Lawmaking Underworld*, 19 EUR. L. J. 2013, p. 642.

4 Joana Mendes, *Participation and the Role of Law after Lisbon: A Legal View on Article 11 TEU*, 48 CMLREV 1849, 2011, p. 1850.

In this contribution, some of the many legally created platforms available to the manifold actors seeking to impact law-making beyond the state in a European context will be sketched out. On the basis of two specific examples, the practices of using tools available within the EU participatory democracy will be analysed. Starting from a historical perspective of how a democratic foundation of international law has developed, the article seeks to relate to current doctrinal discussions on the consequences of globalisation for law-making; the erosion of the public /private divide and the fragmentation of law and law-making. More specifically, we will analyse potential consequences of enabling a wide range of actors to participate in law-making beyond the state on the legal sources to be applied within national legal orders. How can IOs and ENGOs influence the outcome of law-making procedures through EUs participatory democracy and how does it affect national legal orders?

The examples analysed here are picked from the authors ongoing work on different entities and their activities in policy-making outside the state-based legislative procedure. Within her doctoral thesis Agnes Hellner studies the governance structure for environmental matters set out in the UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (the Aarhus Convention)<sup>5</sup>. Jane Reichel is working with legal and ethical frameworks for cross-border biobanking within European research projects and is associated to a European research infrastructure, the BBMRI-ERIC.<sup>6</sup> The Aarhus governance structure and the BBMRI-ERIC represent two rather different ways for the public to interact with law-makers beyond the state in a European context. Within the Aarhus Convention governance structure, environmental NGOs (ENGOs) are considered to have a legitimate interest in environmental protection per se, the basis upon which they are granted extensive participatory rights at national, EU and international levels of government, allowing them to impact law-making in a broad sense.<sup>7</sup> The BBMRI-ERIC is an IO, with states as members, set up to promote a sector-specific area; European medical research on human biological samples and data in biobanks. Neither the Aarhus Convention nor the ERIC-regulation have as their principal aim to advance the participation of the actors in law-making as such. However, both the Aarhus Convention and the ERIC-regulation create platforms for interaction with law-makers. The position of ENGOs in relation to the Aarhus governance structure is similar to that of BBMRI-ERIC under the ERIC-regulation.

For the purpose of analyzing the role of organizations such as ENGOs and sector-specific IOs such as BBMRI-ERIC, we consider their possibilities of influencing law-making in the widest sense of the word, including therein treaty-

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5 The UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, Aarhus, 25 June 1998, entered into force the 10 October 2001.

6 The BBMRI.se, the national node to BBMRI-ERIC and financed by the Swedish Research Council, the B3Africa-project, financed under the Horizon 2020, and previously BioBankCloud, financed under FP7.

7 See Aarhus Convention, Article 3(4), which includes ENGOs in the definition of "the public".

making, administrative rule-making and judge-made law. Even though soft law as such is not included in law-making, we are very much aware that it is hardly possible to draw a strict line between the binding and the non-binding within the context of the globalized/Europeanized area of law. Participation in the production of acts within the grey-zone between binding and soft/persuasive is also considered in our over-all analysis.

Indeed, the position and role of IOs and NGOs within law-making beyond the state could be analysed at length, and that is true even if one limits the analysis to the EU law-making arena.<sup>8</sup> Here, we give only two examples of sector-specific legislative frameworks strengthening the role of IOs and NGOs when it comes to influencing international and in particular EU law. We do find that in themselves, these examples well illustrate some tendencies as regards interest representation in law-making beyond the state. When seen as a part of a general development in EU law strengthening the position of the individual and of private actors in impacting policy- and law-making, the examples are particularly illustrative of the increasingly complex yet important role of IOs and NGOs in this context.

The article is structured as follows. First, a short historical overview of interest representation in law-making, in and beyond the state, is given in section 2. In section 3, the practical examples of the participation of ENGOs in the Aarhus governance structure and BBMRI-ERIC under the ERIC-regulation are outlined. Section 4 provides a discussion regarding the general EU participatory democracy framework for participation. The paper ends with an analysis of the promises and practices of EU participatory democracy in relation to the much debated phenomena in law-making beyond the state today; the erosion of the public private divide and the fragmentation of law and law-making (section 5).

## 2 Representation of the Public – Three Stages of Development

Who may legitimately represent the sovereign people in international law-making? In 1993 MacCormick raised the question whether the connection between sovereignty and sovereign states and the ‘inexorable linkage of law with sovereignty and the state have been but the passing phenomena of a few centuries’.<sup>9</sup> As will be further elaborated below, the EU has opened its law-making procedures to other actors than its member states, within different mechanisms of participatory democracy. In this section, this development will be set into a brief historical background. At the centre of our attention lie the different stages in the development of who can participate in an organised form in law-making processes beyond the state.

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8 For a discussion relating to this topic, see R. Daniel Kelemen, *Eurolegalism, The Transformation of Law and Regulation in the European Union*, Harvard University Press, Cambridge, 2011.

9 Niel MacCormick, *Beyond the Sovereign State*, MLR, Vol. 56 January 1993 No. 1.

## 2.1 *First Stage: Before World War II*

In the first stage represented by the classic Westphalian view on the sovereign state, until the end of World War II, the nation state was seen as the natural forum for addressing issues relating to the people living within its borders. A central feature in a traditional understanding of sovereignty, even with regards to the concepts being fundamentally difficult to define in any comprehensive manner, is its focus on states having a right of being left alone, of being protected from outside interventions.<sup>10</sup> In Walkers words, “it was assumed that the questions of the just ordering of social relations were properly asked and answered only within and, to a lesser extent, between sovereign states with mutually exclusive territories, populations and government arrangements”.<sup>11</sup> Many of the basic premises of this stage are still relevant today, even though, as will be seen, there are now so many exceptions to the main rule of mutual exclusivity that it is scarcely any longer recognizable.

When the state acts on the international arena, the basic point of departure is that the state acts as one uniform entity, representing its sovereign people. The state is represented by the head of state or the government, and for an international agreement to come into place, each state involved must consent unanimously. Classical public international law thus builds on the premise that no state can be bound to follow rules it has not consented to, i.e. consensual rulemaking.<sup>12</sup> There are different theories of how international rules are to be implemented within national systems, but the main rule is that it is a question for the internal rules of the state to decide.<sup>13</sup> Each sovereign state and each sovereign people thus can have full control over their international activities.<sup>14</sup> In a democratic state, the representative of the state in international affairs, the head of state or government, therefore can be held accountable to the people, either directly or indirectly via the parliament. If a sovereign state does not wish to honour an international agreement it has entered into, this would be contrary to the principle of *pacta sunt servanda* and to state responsibility. The breach of state responsibility could in itself give rise to the possibility of the other parties

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10 Anne-Marie Slaughter, *Sovereignty and Power in a Networked World Order*, Stanford Journal of International Law, 2004, 283-327, p. 284, referring to Article 2 (7) of the UN Charter; “Nothing contained in the present Charter shall authorize the United Nations to intervene in matters which are essentially within the domestic jurisdiction of any state.”

11 Walker, *Beyond boundary disputes and basic grids: Mapping the global disorder of normative orders*, op cite, note 2, p. 373.

12 James Crawford, *Brownlie's Principles of Public International Law*, 8nd ed., Oxford University Press, 2012, p. 386.

13 Antonio Cassese, *International Law*, 2nd ed., Oxford University Press, 2005, 218.

14 Within the national constitutional order, there are usually mechanisms in place to allow the Foreign Ministry and government oversight of the contacts taken by national authorities and other entities on behalf of the state. See for example the Swedish Instrument of Government, Section 10:13.

to the agreement invoking counter-measures.<sup>15</sup> However, for international law to enter into the internal sphere of the nation state and dictate the methods to be used in the actual implementation traditionally had not at this point been considered an option.

## 2.2 *Second Stage: After World War II*

After the World War II, international law developed according to that which can be defined as a second stage. An acceptance among states, at least in the Western sphere, emerged as to the necessity of addressing issues of the non-implementation of international law. Several mechanisms for individuals to file complaints or report to different organs within international organizations were subsequently introduced, enabling the organization to investigate the complaint and make known its view on the act at hand.<sup>16</sup> An even more important step was the establishment of international courts, competent to bind states to their interpretation of international law, opening up for law-making by courts at the international level. Mechanisms with this sort of legal teeth were introduced in two European organizations emerging after 1945, the Council of Europe and the EU.<sup>17</sup> Here international courts were given the mandate to give binding verdicts on whether the Member States of the organization had implemented and interpreted the acts of the respective organization correctly. Further, individuals of the Member States were enabled to initiate the control of national measures, vis-à-vis the Council of Europe/European Court of Human Rights directly when all national remedies have been exhausted,<sup>18</sup> or vis-à-vis the EU/European Court of Justice indirectly, either via a preliminary ruling from a national court<sup>19</sup>, or via the Commission, or, at least theoretically, another Member State in an infringement proceeding.<sup>20</sup> The developments have further brought about a change towards a centralization of the interpretation of international law, away from the earlier allocation to the contracting parties at national level.<sup>21</sup> The possibility for individuals to initiate this interpretation, by taking a Member State to court, also included an important step towards legal decentralization.

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15 Joseph H.H. Weiler, *Prologue: global and pluralist constitutionalism – some doubts*, in *The Worlds of European Constitutionalism*, Gráinne de Búrca, & Joseph H.H. Weiler, (eds.), Cambridge University Press, 2012, 11.

16 See e.g. Article 41 of the International Covenant on Civil and Political Rights and Articles 18 et seq International Covenant on Economic, Social and Cultural Rights, as well as the Aarhus Convention as described above, section 2.

17 Andreas Voßkuhle, *Multilevel cooperation of the European Constitutional Courts: Der Europäische Verfassungsgerichtsverbund*, *European Constitutional Law Review*, 2010, 6, p. 175.

18 Article 34 of the European Convention on Human Rights.

19 Article 267 Treaty on the Functioning of the European Union, TEUF.

20 Article 258 and 259 TEUF.

21 Olle Mårsäter, *Folkrättsligt skydd av rätten till domstolsprövning*, (Uppsala universitet, 2005, p. 99.

### 2.3 *Third Stage: After the Fall of the Berlin Wall*

After the fall of the Berlin wall in 1989, developments in international law have again entered into a new stage, where activities at the international or global arena have multiplied, both in content and breadth. An interesting development is the growth in the number of actors involved at the global level, and the number of national organs representing the state.<sup>22</sup> It is no longer (if it ever was) the sole responsibility of the head of state or the government to act on behalf of the nation state. Today almost all public authorities have their own contacts with sister-organs in other nation states as well as international organizations active in the respective policy area. This phenomenon is especially evident within the EU, where an integrated or composite administration is taking form,<sup>23</sup> but can also be witnessed elsewhere.<sup>24</sup> In these administrative collaborations, national officials tend to play a central role, since the same individuals or groups of individuals may often represent the state in the international rulemaking procedures and in the national implementation procedure.<sup>25</sup> Further, the officials also often work closely with officials from the sister-organ when interpreting the enacted rules in individual cases.<sup>26</sup> Again, this is especially evident within the EU. Within the comitology-committees, and other groups and networks under the Commission, manifold contacts between officials from different parts of the EU and the Member States take place on a weekly basis. From the point of view of the Commission, it is evident that a close collaboration with the competent authorities within each policy area is more efficient than to collaborate with the national governments representing the Member State as a whole.<sup>27</sup>

A further trait of this development is the willingness to open up the procedures for non-state actors. As is discussed further in section 4.2, the importance of

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22 Joseph Corkin, *Constitutionalism in 3D: Mapping and Legitimizing Our Lawmaking Underworld*, 19:5 *European Law Journal*, 2013, 636-661, p. 650.

23 Eberhard Schmidt-Aßmann, *Introduction: European Composite Administration and the Role of European Administrative law*, in Oswald Jansen & Bettina Schöndorf-Haubold (ed) *The European Composite Administration*, Cambridge, Intersentia, 2011, and Hermann C.H Hofmann & Alexander Türk, *The Development of Integrated Administration in the EU and its Consequences*, *European Law Journal* vol. 13 No. 2, 2007, 253.

24 See e.g. the literature on Global Administrative Law, Sabine Cassese, *Administrative Law without the State? The Challenge of Global Regulation*, 37 *New York University Journal of International Law and Politics* 973, 2005, 663, Benedict Kingsbury, Nico Krisch, & Richard B. Stewart, *The Emergence of Global Administrative Law*, 68 *Law & Contemporary Problems* 15 (2005), 15 and Eduaordo Chitis, Bernardo Giorgio Mattarella, (eds), *Global Administrative Law and EU Administrative Law. Relationships, Legal Issues and Comparison*, Heidelberg, Springer, 2011.

25 Mauro Zamboni, *Globalization and Law-making: Time to Shift a Legal Theory's Paradigm*, *Legisprudence. International Journal for the Study of Legislation* 1/1, 2007, 125, 142.

26 Helen Wockelberg & Eva Edwardsson, *European Legal Method in Denmark and Sweden — Using Social Science Theory and Methodology to Describe the Implementation of EU Law*, *European Law Journal*, Vol. 19, Issue 3, 2013, p. 364.

27 Morten Egeberg, *Europe's Executive Branch of Government in the Melting Pot: an Overview*, in Morten Egeberg, (ed.), *Multilevel Union Administration: the Transformation of Executive Politics in Europe*, Basingstoke Palgrave Macmillan, 2006, 14.

involving the civil society, stakeholders and business in the EU legislative processes was underlined in the 2001 Commission White Paper on Governance<sup>28</sup> and introduced as part of EU democratic foundation in the Lisbon Treaty 2009, via Article 11. The EU had thereby taken an important step from the traditional form of representative democracy as its sole democratic foundation for the EU.

### **3 Examples of two Actors Beyond the State: Environmental NGOs relying on the Aarhus Convention and BBMRI-ERIC**

As set out above, neither the Aarhus Convention nor the ERIC-regulation has as its explicit aim to establish a role for their respective actors within law-making beyond the state. The Aarhus Convention aims at allowing environmental NGOs a right to information, participation (at the administrative level) and access to courts in environmental matters. The ERIC-regulation aims at setting up research infrastructure in order to facilitate and foster cross-border research within the EU and beyond. Both may however lead to the creation of platforms from where ENGOs and BBMRI-ERIC can influence law-making.

#### **3.1 Environmental NGOs and the Aarhus Convention**

The Aarhus Convention is a UN Convention and its parties have an international law based obligation to comply with it. In relation to EU law, the Aarhus Convention is a mixed agreement: both the EU and its member states are parties.<sup>29</sup> Environmental organisations – which according to the Aarhus Convention are considered to have a legitimate interest in the environment *per se*<sup>30</sup> – play a crucial role within the governance structure created by the Convention. Indeed, this is even more true if one looks at their role not only from an international law perspective, but also considers EU law as a whole, and analyses the variety of participatory rights available to NGOs at different levels of government. In the following, the mechanisms and tools available to ENGOs within this comprehensive governance structure will be described and contextualized.

##### **3.1.1 A Governance Structure Cutting National and EU Borders**

The Aarhus Convention provides compliance mechanisms that have been further elaborated through decisions taken by the meeting of the parties (the MOP) to the Convention.<sup>31</sup> In particular, the Aarhus Convention Compliance Committee (the ACCC) reviews issues of non-compliance upon referral from the Executive

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28 Commission White Paper on Governance COM(2001) 428 final, 14.

29 There are 47 parties to the Aarhus Convention, 28 of which are EU member states.

30 See the preamble to the Aarhus Convention and, in particular, Articles 2.4-5, 4, 6 and 9.

31 Article 15, Aarhus Convention. See also [www.unece.org/env/pp/mop.html](http://www.unece.org/env/pp/mop.html).



Secretary of the Economic Commission for Europe (the Secretariat)<sup>32</sup>, upon request of a party or, importantly, following a communication by any member of the public, including ENGOs.<sup>33</sup> ENGOs have made extensive use of their right to launch communications on non-compliance with the ACCC (see further below in section 3.1.2).

Since the EU is party to the Aarhus Convention, it has a duty to ensure its own institutions' compliance.<sup>34</sup> In addition to that, EU Member States – themselves parties to the Convention – have an EU law based obligation to comply with the Convention, to the extent that it is implemented into EU secondary legislation. Within the EU, institutions such as the European Commission and the Court of Justice (the CJEU) have very actively worked towards ensuring in particular member state compliance with the Convention and the EU secondary legislation implementing the Convention into EU law.<sup>35</sup> In contrast, the Union has been criticized for not itself respecting the Convention provisions on access to justice. It is still extremely difficult for an individual or an environmental (or other) organisation to be admitted as a party in a case before the EU courts.<sup>36</sup>

The Aarhus governance structure, which provides ENGOs with participatory rights before the Compliance Committee as well as before administrative and judicial bodies within the EU and the state parties to the Convention, places ENGOs in a position to possibly impact law-making at different levels, using a variety of complementary tools available in the international, EU and national con-

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32 The Secretariat handles the administration around the reporting from the parties, examines their periodical reports and prepares a “synthesis report” to each meeting of the parties, see Article 10.2 of the Convention and paragraph 5 Decision I/8 Reporting Requirements, ECE/MP.PP/2/Add.9, available at: “[www.unece.org/fileadmin/DAM/env/pp/documents/mop1/ece.mp.pp.2.add.9.e.pdf](http://www.unece.org/fileadmin/DAM/env/pp/documents/mop1/ece.mp.pp.2.add.9.e.pdf)”.

33 Decision I/7, Doc. ECE/MP.PP/2/Add. 8, available at: “[www.unece.org/fileadmin/DAM/env/pp/documents/mop1/ece.mp.pp.2.add.8.e.pdf](http://www.unece.org/fileadmin/DAM/env/pp/documents/mop1/ece.mp.pp.2.add.8.e.pdf)”, Section V.

34 In large parts, the Convention is implemented into EU law. Article section 9(1) is implemented by Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Directive 90/313/EEC, [2003] OJ L41/26. Article section 9(2) is implemented by Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending with regard to public participation and access to justice Council Directives 85/337/EEC and 96/61/EC, [2003] OJ L156/17. Article section 9(4) has been implemented in relation to actions under Article sections 9(1) and 9(2).

35 See in particular, case C-263/08, *Djurgården Lilla Värtans Miljöförening v. Stockholms kommun genom dess marknämnd* EU:C:2009:631; case C-115/09, *Bund für Umwelt und Naturschutz Deutschland, Landesverband Nordrhein-Westfalen eV v. Bezirksregierung Arnsberg*, EU:C:2011:289, case C-240/09 *Lesoochranské zoskupenie VLK v. Ministerstvo životného prostredia Slovenskej republiky*, EU:C:2011:125; case, C-72/12, *Gemeinde Altrip and Others v. Land Rheinland-Pfalz*, EU:C:2013:712 and case C-137/14, *European Commission v. Federal Republic of Germany*, EU:C:2015:683.

36 See e.g. Ludwig Krämer, *The European Court of Justice*, in Andrew Jordan and Camilla Adelle, *Environmental Policy in the EU, Actors, Institutions and Processes*, 3 ed., Earthscan Routledge, London, New York, 2013, pp. 113-131.

texts. The provisions of the Convention are interpreted at three levels of government; by the Aarhus Compliance Committee, the Court of Justice of the EU, and by national administrative authorities and courts. By intervening at all three levels, NGOs can transcend national borders and impact law-making beyond and within the state, as will be explained in the following.

### 3.1.2 Environmental NGOs in the Aarhus Governance Structure

At the UN level, ENGOs can take part in decision-making and procedures resulting in issuance of unbinding recommendations on appropriate measures to bring about full compliance with the Convention. Like parties and signatories to the Convention, ENGOs may nominate candidates for the election of the Compliance Committee.<sup>37</sup> It is the meeting of the parties to the Convention that then elects the members of the Committee: eight persons of “high moral character and have recognized competence in the fields to which the Convention relates”.<sup>38</sup> The main function of the ACCC is to consider issues of non-compliance that have been brought to its attention. Amongst other actors such as the Secretariat and the parties to the Convention, ENGOs can trigger reviews of compliance.<sup>39</sup> To date, only one reference to the ACCC has been made by the Secretariat, one request for advice or assistance from a party concerning its own implementation, and two references to the ACCC have been made by parties concerning the compliance of other parties. However, as of September 5 2016, 108 admissible references had been made to the Compliance Committee by the public. Out of these, 73 were initiated by ENGOs.<sup>40</sup> “

As soon as an ENGO submits a communication and the submission is declared admissible by the Committee, a formal discussion on the substance of the case is initiated. As a communicant an ENGO is in a position similar to that of a party in the proceedings before the Committee. The communication is forwarded to the party concerned and the communicant. Both are invited to answer questions from the Committee.<sup>41</sup> The Committee may on its own motion request and otherwise gather information as it finds appropriate, and consider any relevant information submitted to it, be it from the communicant, the party concerned or from external sources, amongst whom are experts and ENGOs.<sup>42</sup> If the ACCC establishes that the party concerned has failed to comply with the provisions of the Convention it reports and makes recommendations to the MOP

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37 Environmental organisations falling within the scope of Article 10 paragraph 5 and 7 of the Convention, *see* Article 4 of Annex to Decision I/7.

38 Paragraphs 2 and 7 of the Annex to Decision I/7.

39 Decision I/7, *op cite*, note 33, paragraph 18.

40 Information available at the Aarhus Convention Compliance Committee website as of August 12, 2016, “[www.unece.org/env/pp/cc/com.html](http://www.unece.org/env/pp/cc/com.html)”.

41 Annex to Decision I/7, paragraph 22.

42 Decision I/7, *op cite*, note 33, Section VII. *See* also Guidance Document on Aarhus Convention Compliance Mechanism, available at: “[www.unece.org/fileadmin/DAM/env/pp/compliance/CC\\_GuidanceDocument.pdf](http://www.unece.org/fileadmin/DAM/env/pp/compliance/CC_GuidanceDocument.pdf)”.

as regards appropriate measures to bring about full compliance.<sup>43</sup> Among possible response measures are issuance of ‘declarations of non-compliance’, ‘cautions’ and suspension of rights and privileges.<sup>44</sup>

### 3.1.3 Environmental NGOs in the Interplay Between the ACCC and the CJEU

While neither the ACCC nor the CJEU are bound by each others findings, it is interesting to analyse their relationship, and how the Aarhus Convention and EU procedural law relate to each other. In comparing the procedural tools afforded to ENGOs under the Convention and under EU law, one finds that the two complement each other and together strengthen the position of ENGOs in a quite remarkable way.

On the basis of to the Aarhus Convention and the EU law implementation thereof, ENGOs are increasingly allowed to appeal administrative and judicial decisions at the national level, and there raise issues of non-compliance by member states with EU law. Since, under EU law, national courts are obligated to ask the CJEU for a preliminary ruling whenever they have a question concerning the correct interpretation of EU law (Article 267 TFEU), ENGOs can indirectly reach the CJEU to address environmental concerns regulated in EU law. Whether this channel is working in a satisfactory manner is debatable, of course. The critique against the EU and the CJEU for not opening up the strict criteria for standing before the CJEU has been massive and enduring.<sup>45</sup> From that perspective it is interesting that ENGOs obtain a position similar to that of a party in a case when they communicate issues of non-compliance with the Aarhus Convention to the ACCC. The complementary character of the procedural mechanisms available to ENGOs within the EU legal order generally and under the Aarhus Convention specifically as well as the complementing functions of the tools available at the national, EU and international levels, can inter alia be seen in the *Trianel* case.<sup>46</sup> The case is also illustrative of the key position gained by ENGOs litigating and otherwise using procedural mechanisms at different levels of government.

*Trianel* was brought to the CJEU by a German Administrative Court of Appeal, following an appeal of an ENGO – a regional branch of Friends of the Earth, Germany – of a decision by a district government to grant a partial environmental permit to Trianel. In a reference for a preliminary ruling, the German court asked the CJEU if German conditions for ENGO standing were compatible with Directive 2003/35 and Article 9 paragraph 2 of the Aarhus Convention, on access to justice. Thus, in claiming its right to be admitted as a party to the proceeding, Friends of the Earth relied on the Aarhus Convention and the directive,

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43 Decision I/7, op cite, note 33, paragraph 20.

44 Ibid, paragraph 37.

45 See e.g. Ludwig Krämer, op cite, note 36.

46 Case C-115/09, *Bund für Umwelt und Naturschutz Deutschland, Landesverband Nordrhein-Westfalen eV v. Bezirksregierung Arnsberg*, EU:C:2011:289.

and indirectly on the obligation of national courts to request a preliminary ruling from the CJEU whenever there is doubt about national implementation. In substance, Friends of the Earth sought the annulment of the permit according to which *Trianel* had been allowed to construct and operate a coal-fired power-station. The ENGO was relying in particular on a provision establishing an obligation to carry out an environmental impact assessment and to ascertain that a plan or project will not adversely affect the integrity of the site. According to the German standing conditions, standing was to be granted only where the applicant relied upon an individual right. Since water and nature protection law, or the precautionary principles, did not establish such individual rights according to German law, Friends of the Earth had been denied standing in first instance. In its judgment, delivered in May 2011, the CJEU held that the domestic law, which made an action contesting a decision under the directive conditional upon the impairment of an individual right was incompatible with Article 9 paragraph 2 of the Convention as implemented in Directive 2003/35 and Directive 85/337. Environmental organisations must be given standing in their own right and should not be dependent on having to show a possible impairment of rights of individuals.

In December 2008, six months after the Friends of the Earth appeal of the environmental permit in the *Trianel* case, another German ENGO – ClientEarth – addressed similar concerns as those raised by Friends of the Earth in *Trianel* in a communication to the ACCC – hence using the international law platform in order to influence the national implementation of the Convention.<sup>47</sup> Since the questions raised by ClientEarth before the ACCC were at least in part the same as those asked by the Administrative Court of Appeal to the CJEU in *Trianel*, the ACCC suspended its proceedings until the CJEU had delivered its opinion in the latter case. Furthermore, it later decided to await the decision of the regional Higher Administrative Court after the CJEU preliminary ruling. At this point, Germany was about to amend its law on standing, and in view of these amendments, both Germany and ClientEarth submitted additional information to the ACCC. Thus, the ACCC examined the communication submitted by ClientEarth in relation to the Environmental Appeals Act as amended following the *Trianel* case.<sup>48</sup> After the amendments, ENGOs were no longer required to claim that its individual rights had been impaired in order to have standing. Nevertheless, ClientEarth withheld that the German conditions for access to justice, both with respect to standing and the scope of the review, were too restrictive.<sup>49</sup> In its findings and recommendations, issued on 20 December 2013, the ACCC stroke down on some of the requirements of the German law as amended following *Trianel*, making reference not only to the CJEU judgment in *Trianel*, but also

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47 Communication ACCC/C/2008/31 concerning compliance by Germany, ECE/MP.PP/C.1/2014/8.

48 See paragraphs 27 and 29 of the findings and recommendations with regard to communication ACCC/2008/31 concerning compliance by Germany, ECE/MP.PP/ C.1/2014/8, available at: “[www.unece.org/fileadmin/DAM/env/pp/compliance/CC-45/ece.mp.pp.c.1.2014.8\\_adv\\_edited.pdf](http://www.unece.org/fileadmin/DAM/env/pp/compliance/CC-45/ece.mp.pp.c.1.2014.8_adv_edited.pdf)”.

49 Paras. 44-52, 62, ECE/MP.PP/C.1/2014/8.

the then very recent judgment delivered by the CJEU in a different case concerning the German implementation of Article 9 of the Convention, the *Altrip* case.<sup>50</sup> As will be further discussed in section 5 below, Trianel and Communication ACCC/C/2008/31 show that ENGO participation in different procedural contexts can create synergy effects that enhance their possibilities of effectively impacting law-making.

### 3.2 *BBMRI-ERIC*

As stated above, an ERIC is an international organization established through a decision by the EU Commission, on the application of at least three Member States.<sup>51</sup> Amongst other things, it is a requirement for the establishment of an ERIC that “it is necessary for the carrying-out of European research programmes and projects, including for the efficient execution of Community research, technological development and demonstration programmes”.<sup>52</sup> The connection between an ERIC and EU research policies is thus strong. Even though the legislative competences of the EU within the field of research are largely complementary, the EU has developed into a strong actor within research policies.<sup>53</sup> Most importantly, the EU has a large research budget and can via different calls and programmes influence what research is conducted within the Union.<sup>54</sup> The ERICs are thus instrumental in this work.

#### 3.2.1 The Establishment of BBMRI-ERIC and its Common Services

The BBMRI-ERIC was established in December 2013, with its seat in Graz, Austria.<sup>55</sup> Starting put with 12 Member States, there are now 15 states that are

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50 Para. 78, 87, 89, ECE/MP.PP/C.1/2014/8, Case C-72/12, *Gemeinde Altrip and Others v. Land Rheinland-Pfalz*, EU:C:2013:712.

51 Article 9 of the ERIC Regulation.

52 Article 4 a of the ERIC Regulation.

53 Article 6.3 TFEU states ‘In the areas of research, technological development and space, the Union shall have competence to carry out activities, in particular to define and implement programmes; however, the exercise of that competence shall not result in Member States being prevented from exercising theirs’. The competences are specified in Articles 179 – 190 TFEU. The ERIC Regulation was enacted on the basis of Article 187 TFEU, mandating the EU to “set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration.” See further Matthias Ruffert & Sebastian Steinecke, *The Global Administrative Law of Science*, Berlin/Heidelberg: Springer, 2011, p. 65.

54 Jane Reichel, *Alternative Rule-Making within European Bioethics – Necessary and Therefore Legitimate?* *Tilburg Law Review* 21, 2016, 169-192, p. 178.

55 Emmanuelle Rial-Sebbag & Anne Cambon Thomsen, *Governing Biobanks Through a European Infrastructure*, Deborah Mascalzoni, (ed.) *Ethics, Law and Governance of Biobanking: National, European and International Approaches*, Springer, Dordrecht, The Netherlands, 2015.

full members, four observing states, and one international organization, IARC which is a part of WHO.<sup>56</sup> In the preamble to the BBMRI-Statutes, enacted through a Commission decision to establish the BBMRI-ERIC, it is underlined that the aim is to increase the scientific excellence and efficacy of European research and to expand and secure competitiveness of European research and industry in a global context. By establishing the BBMRI-ERIC, the Member States take open themselves to ensure support and, where appropriate, contributions to the national node connected to the infrastructure.<sup>57</sup>

According to Article 3 of its statutes, the aim of BBMRI-ERIC is to facilitate the access to resources as well as facilities and to support high quality biomolecular and medical research.<sup>58</sup> On its website, the mission of BBMRI-ERIC is said to be to ‘increase efficacy and excellence of European bio-medical research by facilitating access to the Union’s quality-defined human health/disease-relevant biological resourced through associated data in an efficient and ethically and legally compliant manner’.<sup>59</sup> It seeks to do so amongst other ways by ‘reducing the fragmentation of the bio-medical research landscape through harmonization of procedures, implementation of common standards and fostering high-level collaboration’.<sup>60</sup> In order to accomplish this, the BBMRI-ERIC will establish “common services”, services provided to the Member States and to others within the biobank community.<sup>61</sup> So far two common services are in place; a common information technology service (IT-cs), coordinating and implementing the interoperability of the existing and new biological databases of biobanks and a common service for ethical, legal and societal issues (ELSI-cs) that supports and supervises ethical and legal compliance within the activities of the ERIC.<sup>62</sup> For the purpose of this article, the ELSI-cs is the most relevant.

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56 “bbmri-eric.eu/memberstates”.

57 See preamble and Article 4 of the BBMRI-Statutes published as an annex to the Commission Implementing Decision of 22 November 2013 on setting up the Biobanks and Biomolecular Resources Research Infrastructure Consortium (BBMRI-ERIC) as a European Research Infrastructure Consortium.

58 Article 3 of the BBMRI-ERIC Statutes.

59 Available at “www.bbmri-eric.eu/web/guest/21” accessed 17 June 2016.

60 Ibid.

61 Article 3.3(e) of the BBMRI-ERIC Statutes.

62 See “bbmri-eric.eu/en/common-service”.

### 3.2.2 The Work of Common Service for Ethical, Legal and Societal Issues - ELSI-cs

The ELSI-cs was established in January 2015, after a call for tender.<sup>63</sup> It is organized in a distributed fashion, with four directors from France, Italy, the Netherlands and Sweden, as well as ELSI experts from further states involved. The main aim of the ELSI-cs is to to ‘facilitate and support cross-border exchanges of human biological resources and data attached for research uses, collaborations and sharing of knowledge, experiences and best practices.’ The main tools to reach this aim are organization of workshops and courses for the researchers in the national nodes, a help desk to answer questions, the drafting, promoting and distributing of soft law instruments, guidelines and frameworks, for an ethical and legal use of biomaterial and data. On its website,<sup>64</sup> the ELSI-cs has for example published comments of the Safe Harbor-case<sup>65</sup> and its implication for biobanking, comments to a draft revision of a recommendation from Council of Europe,<sup>66</sup> well as a Q & A on the recent General Data Protection Regulation.<sup>67</sup> The ELSI team are also preparing a policy-document for sharing and access to data, with the first report of the work published on its website.<sup>68</sup> In the longer perspective, the ELSI-cs are planning to introduce an ethics check for users of biobank-resources connected to the BBMRI-ERIC.<sup>69</sup>

### 3.2.3 BBMRI-ERIC as a Research-Coordinator

The BBMRI-ERIC has been quite successful in applying for research funds from the EU. According to its webpage, BBMRI-ERIC has been awarded €7 million additional funds through participation in the EU's 7th Framework Programme and Horizon 2020.<sup>70</sup> Several of the research projects the BBMRI-ERIC is involved in have as their aim to further ethical and legal compliance in biobanking, in Europe and beyond.<sup>71</sup> Through these engagements, the BBMRI-ERIC can

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63 See “[bbmri-eric.eu/en/common-service](http://bbmri-eric.eu/en/common-service)”.

64 Available at “[bbmri-eric.eu/elsi](http://bbmri-eric.eu/elsi)”.

65 Case C-362/14, *Maximilian Schrems v. Data Protection Commissioner*, EU:C:2015:650.

66 Council of Europe Recommendation (2006)4 on research on biological materials of human origin.

67 Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, hereafter General Data Protection Regulation 2016/679.

68 BBMRI ELSI Workshop Report Sharing and access to data and human biospecimens for the benefit of patients – Towards a BBMRI-ERIC Policy, September 08-09, 2015 Paris, France. Available at “[bbmri-eric.eu/elsi](http://bbmri-eric.eu/elsi)”.

69 Reichel, *Alternative Rule-Making within European Bioethics – Necessary and Therefore Legitimate?*, op cite, note 54, p. 183.

70 “[/bbmri-eric.eu/projects](http://bbmri-eric.eu/projects)”.

71 See for example B3Africa, “[www.b3africa.org/](http://www.b3africa.org/)” and RD-connect “[rd-connect.eu/](http://rd-connect.eu/)”.

make achievements of the projects accessible to the research community and ensure the sustainability of tools developed within the projects over time. Also other projects, some initiated and launched even before the BBMRI-ERIC was established, have been connected to the BBMRI-ERIC. This is the case with the hSERN.eu, a project which has developed a catalogue of ethical standards for human samples exchange, which is now connected available via the BBMRI-ERIC webpage.<sup>72</sup> In many research project run within traditional academic institutions, results from time-limited projects may easily be forgotten, if no long-term infrastructure can make them available. The work of the BBMRI-ERIC in preserving the results over time corresponds to one of the basic aims of the EU for establishing ERICs in general. According to the preamble of the ERIC Regulation, the main objective in introducing the ERIC is to facilitate long term European research projects by enabling them to function under a common legal framework.<sup>73</sup>

All in all, the BBMRI-ERIC and the ELSI-cs have quite a potential to influence the ethical work of biobank projects within the EU, and, with its international engagement in for example B3Africa, also beyond. This is achieved without a common regulatory framework enacted by the EU legislator, but through the infrastructures provided by the EU via the ERIC Regulation and through extensive funding from the EU directed to projects that can later be connected to the BBMRI-ERIC. By pooling the competences of bioethicists and medical law experts and by connecting former and future research projects to the infrastructure, a central platform for cross-border collaboration is built.

#### 4 Participatory Democracy in the EU

Characteristic for law-making beyond the state in our time, as discussed in section 2.3, is the presence of a multitude of actors to who engage in policy-making, regulatory or administrative procedures, representing either a state, in form of officials from public agencies at national, regional or local levels, or a private interest, in form of businesses or NGOs. The role of participation has shifted considerably in the context of globalization and is today often seen as a vehicle to legitimize the law-making beyond the state.<sup>74</sup> In this section the development of participatory democracy as a democratic foundation for the EU is discussed. Procedural mechanisms aiming at enhancing public participation

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72 “/bbmri-eric.eu/services”.

73 Paragraph 5 of the preamble to Council regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC). See further Jane Reichel, *BBMRI-ERIC – an analysis of a multi-level institutional structure in the EU and beyond* in Anna-Sara Lind & Jane Reichel (eds.), *Administrative Law beyond the State – Nordic Perspectives*, Liber Martinus Nijhoff Publishers, 2013, p. 16.

74 Joana Mendes, *Administrative Law Beyond the State: Participation at the Intersection of Legal Systems*, in Edoardo Chiti & Bernardo Giorgio Mattarella (eds), *Global Administrative Law and EU Administrative Law*, .2011, p. 111 and Benedict Kingsbury, Nico Krish & Richard B. Stewart, *The Emergence of Global Administrative Law*, 68 L. & CONTEMP. PROBS. 15, 2005, p. 16-17.



can be used by all types of entities with a policy-making agenda, among which are the two in focus in this article, ENGOs and BBMRI-ERIC. Hence, in addition to the sector-specific participatory platform created through the Aarhus governance structure in the specific context of environmental law and by the specific ERIC-regulation, there is a general framework for participation and communications, available to ENGOs and BBMRI-ERIC and enabling them to further impact law-making beyond the state.

#### **4.1 Participatory Democracy as Part of EU:s Democratic Foundation**

As set out above, Article 11 TEU introduces a participatory form of democracy as one of the foundations of the EU democratic order. It is one out of three central articles setting the stage of the EU democracy, Articles 10-12 TEU. The subject of European democracy is identified in Article 9 TEU as the Union Citizen: The Union shall in all its activities observe the principle of the equality of its citizens, who shall receive equal attention from its institutions, bodies, offices and agencies. This Article goes on to define the Union citizen, the nationals of the Member States, reaffirming the derived status and complementary nature of Union citizenship. Citizenship of the Union is in addition to, and does not replace, national citizenship.

The classic form of democracy, representative democracy through directly elected parliaments, is declared in Article 10 TEU to be the foundation of the democratic functioning of the Union. Article 10 TEU and representative democracy are the first of the three sources of democratic legitimacy listed in the EU Treaty, and can be labelled as the main source of democracy in the EU. The Union citizens are represented in a two-layered manner; direct representation via the European Parliament and indirect representation via the members of the European Council and the Council, where Union citizens are represented by their Heads of State or Government and by their governments, respectively. The organs are said to be democratically accountable either to their national Parliaments, or to their citizens. The national parliaments thus represent the citizens and hold the executive accountable for their doings within and beyond the state.<sup>75</sup>

This classic form of democracy is complemented by a participatory form of democracy as given in Article 11 TEU, further discussed in section 4.2, and by giving the national parliaments a specific platform, in Article 12 TEU. The national parliaments are here given an independent role in the political life of the EU, beyond their function in the representative democracy of Article 10 TEU.

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<sup>75</sup> See for a discussion on these issues, see Adam Cygan, *Accountability, Parliamentarism and Transparency in the EU. The Role of national Parliaments*, Edward Elgar, 2013, Deirdre Curtin, *Executive power of the European Union: Law, Practices, and the living Constitution* Oxford University Press (2009) and Leonard F.M. Besselink, *Shifts in Governance: National Parliaments and Their Governments' Involvement in European Union Decision-Making*, in Gavin Barrett (ed.), *National parliaments and the European Union: The Constitutional Challenge for the Oireachtas and other Member States Legislatures*, Clarus Press (2008).

Article 12 TEU lists six different ways by which the national parliaments “contribute actively to the good functioning of the Union,” including the task of “seeing to it that the principle of subsidiarity is respected”.<sup>76</sup> Hereby national parliaments can participate in law-making procedures outside the traditional passive role of national parliaments’ international affair.

#### **4.2 Article 11 of the TEU and its Predecessors**

Article 11 TEU begins by stating that “the institutions shall, by appropriate means, give citizens and representative associations the opportunity to make known and publicly exchange their views in all areas of Union action”.<sup>77</sup> In the following paragraphs, the Article sets forth three requirements.<sup>78</sup> The first is that the EU institutions shall maintain an open, transparent and regular dialogue with the representatives, associations and civil society. Secondly, the Commission is to carry out broad consultations with the parties concerned. Lastly, no less than one million citizens from a significant number of Member States may take the initiative of inviting the Commission, within the frameworks of its powers, to submit any proposal on matters where citizens consider that a legal act of the Union is required.

The inclusion of citizens and their organization is not new within the EU, and thus existed long before the introduction of Article 11 TEU. According to Mendes, the concept of policy-making underpinned by participation was well developed in the European Coal and Steel Community already in 1951<sup>79</sup> and was also present in the EEC Treaty from 1957.<sup>80</sup> Thus, the Economic and Social Committee, ECOSOC, functioned as an advisory board for social interests of the Union already from the start. Other organs were introduced later, such as the

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76 Paragraph b. The other five are: (a) through being informed by the institutions of the Union and having draft legislative acts of the Union forwarded to them in accordance with the Protocol on the role of national Parliaments in the European Union; (c) by taking part, within the framework of the area of freedom, security and justice, in the evaluation mechanisms for the implementation of the Union policies in that area, in accordance with Article 70 of the Treaty on the Functioning of the European Union, and through being involved in the political monitoring of Europol and the evaluation of Eurojust’s activities in accordance with Articles 88 and 85 of that Treaty; (d) by taking part in the revision procedures of the Treaties, in accordance with Article 48 of this Treaty; (e) by being notified of applications for accession to the Union, in accordance with Article 49 of this Treaty; (f) by taking part in the inter-parliamentary cooperation between national Parliaments and with the European Parliament, in accordance with the Protocol on the role of national Parliaments in the European Union.

77 TEU Art. 11.1.

78 TEU Art. 11.2-4. TEU Art. 11.1.

78 TEU Art. 11.

79 Joanna Mendes, *Participation in European Rule-Making – a Rights-based Approach*, Oxford University Press 2015, p. 80, referring among others to Article 5 of the ECSC Treaty, which states that the competences of the Community were to be carried out by the institutions with a minimum of administrative machinery and in close cooperation with the parties concerned.

80 *Ibid.*, p. 81.

Committee of Regions with the Maastricht Treaty 1993.<sup>81</sup> The social partners of the EU, representing enterprise and labor, are also involved in EU-decision-making, first introduced with the Protocol on Social Policy as part of the Maastricht Treaty, and then later included in the Treaty itself by the Amsterdam Treaty.<sup>82</sup> A further example of the EU openness to non-state actors is the development of rule-making within the Internal Market, and especially concerning the adoption of technical standards. Within the New Approach launched in the 1980s, technical standards are developed in form of voluntary rules by private entities and according to procedures laid down in a Council resolution.<sup>83</sup> These customs of participation were developed in the 2001 Commission White Paper on Governance, where the Commission underscored the general importance of involving the civil society, stakeholders and business in the EU legislative processes.<sup>84</sup> Outside the internal market, the General Data Protection Regulation have in its Article 40 introduced a mechanism for allowing ‘associations and other bodies’ to develop codes of practices, that are given an official status via an approval from national and European Data Protection Authorities.<sup>85</sup>

In the following section it will be discussed how Environmental NGOs and the BBMRI-ERIC can make use of these tools and mechanisms.

#### **4.3 *Environmental NGOs and BBMRI-ERIC as Participatory Actors within the EU***

Three specific tools for participation will be analysed here. First, the three general channels for communication according to Article 11.1-3 TEU will be discussed briefly with respect both to ENGOs and BBMRI-ERIC. The citizen’s initiative in Article 11.4 TEU will be discussed in relation to ENGOs and the procedure in Article 40 of the General Data Protection Regulation in relation to BBMRI-ERIC. The latter is a sector-specific mechanism for participation, which can be seen as an example for how organizations, private and public, can participate in law-making in its widest sense.

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81 Ibid., p. 88 and 90.

82 At present, Articles 151 – 161 TFEU. See Paul Craig, *EU Administrative Law*, Oxford University Press, 2006, p. 235.

83 Council Resolution 85/C 136/01 of 7 May 1985 on a new approach to technical harmonization and standards. See Joanna Mendes, *Participation in European Rule-Making – a Rights-based approach*, op cite, note 79, p. 120 and Corkin, *Constitutionalism in 3D: Mapping and Legitimizing Our Lawmaking Underworld*, op cite, note 22, p. 650.

84 Commission White Paper on Governance COM(2001) 428 final, p. 14. See also Communication from the Commission ‘Towards a reinforced culture of consultation and dialogue - General principles and minimum standards for consultation of interested parties by the Commission’ COM(2002) 704 final.

85 Article 40.5-11 of the General Data Protection Regulation 2016/679. This mechanism will be discussed further in section 4.3.3.

### 4.3.1 Article 11 TEU; General Channels for Communication for ENGOs and BBMRI-ERIC

Article 11.1-3 reads as follows:

- 1 The institutions shall, by appropriate means, give citizens and representative associations the opportunity to make known and publicly exchange their views in all areas of Union action.
- 2 The institutions shall maintain an open, transparent and regular dialogue with representative associations and civil society.
- 3 The European Commission shall carry out broad consultations with parties concerned in order to ensure that the Union's actions are coherent and transparent.

Exactly what is meant by the shifting phrasing in the three paragraphs seem to be a bit unclear.<sup>86</sup> The first and second paragraphs directs themselves to all institutions in more general terms, whilst the third paragraph obligates the Commission 'to carry out broad consultations'. A relevant question might be how the first and second paragraphs distinguishes itself from another type of involvement of private parties in the EU legislative procedures usually seen as less democratically legitimate, namely lobbying. The main difference between lobbying and the democratically-based participation seems to be who initiates the contact; At least this is the dividing line for the voluntary registry for lobbyists that the Commission and the European Parliament has enacted, the transparency register, where lobbyists are expected to register.<sup>87</sup> If a private organization, either business or NGO, contacts an EU institution with the objective of directly or indirectly influencing the formulation or implementation of policy or decision-making processes of the institutions, it is thus labelled lobbying. If the contact is initiated by the institution, it is a democratically-based form of participation.

Environmental NGOs have long sought to promote environmental interests in the EU. A quick search at the Commission webpage for public consultations gives at hand that environmental issues are a common topic for consultations and that they have been for quite some time.<sup>88</sup> Because environmental issues "are found at the intersection of ecosystems and human social systems"<sup>89</sup>, and environmental law deals not only with the ecosystem side of the problem it is

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86 Joanna Mendes, *Participation and the Role of Law after Lisbon*, op cite note 4, p. 1852.

87 Agreement Between the European Parliament and the European Commission on the Establishment of a Transparency Register for Organisation and Self-employed Individuals engaged in EU Policy-making and Policy Implementation, especially articles 8 - 10. According to Article 10, organizations involved in three activities are excluded from the expectations to register; activities concerning the provision of legal and other professional advice, activities of the social partners as participants in the social dialogue and activities in response to direct and individual requests from EU institutions or Members of the European Parliament.

88 Available at "[ec.europa.eu/yourvoice/consultations/links/index\\_en.htm](http://ec.europa.eu/yourvoice/consultations/links/index_en.htm)".

89 John S. Dryzek, *The Politics of the Earth: Environmental Discourses*, Oxford University Press, 1997, p. 8.

trying to solve, but also with human relations and social concerns, it can enter public debates in different shapes and contexts.<sup>90</sup> In recent years, questions of food security and agriculture have given rise to a large number of consultations, as can be seen on the Commission webpage.

Policy-making has also turned out to be an area of activity for the BBMRI-ERIC and its common service for ethical, legal and societal issues, the ELSI-cs. Since the BBMRI-ERIC was established only in 2013, and the ELISI-cs in 2015, the experiences are yet limited. Still, in this short period of time the BBMRI-ERIC has been very active in the legislative procedure for the new General Data Protection Regulation, a piece of legislation that is highly relevant for medical research and biobanking. During that specific legislative procedure BBMRI-ERIC organized several events and arranged a large number of individual meetings with parliamentarians. One of the larger events was a “Data for Health and Science Day of Action”, organized in Brussels on June 16, 2016, and after which a position paper was later published and circulated.<sup>91</sup> BBMRI-ERIC also took part in a work shop arranged by the Committee on Environment, Public Health and Food Safety, in the European Parliament.

In accordance with the definition above, some of these events and meetings may be categorized as lobbying, the initiative of contact being taken by BBMRI-ERIC, whereas others could be considered as taking part in the participatory democracy within the EU. Perhaps due to the fact that the BBMRI-ERIC is a research infrastructure set up by the EU to promote EU excellency in EU research, doors into the room of policy-makers seem to be rather open to the ERIC.<sup>92</sup> The work of BBMRI-ERIC has also been observed by Nature.<sup>93</sup>

### 4.3.2 Article 11.4 TEU: Citizens’ initiative and Environmental NGOs

Another area where ENGOs have been active is within the citizen’s initiative in Article 11.4 TEU. This is the most innovative procedure introduced in Article 11 TEU, which did not exist before the Lisbon Treaty entered into force. According to this Article and to the applicable secondary legislation,<sup>94</sup> no less than one million citizens, representing at least one-quarter of the Member States, with a minimum number of signatures from each of the states involved, can

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90 See e.g. Jonas Ebbesson, *Introduction: dimensions of justice in environmental law*, in J. Ebbesson and P. Okowa (eds.), *Environmental Law and Justice in Context*, Cambridge University Press, 2009, pp. 1-36.

91 Position Paper on GDPR, October 2015, available at “[bbmri-eric.eu/common-services](http://bbmri-eric.eu/common-services)”.

92 See further Jane Reichel, Anna-Sara Lind, Mats G. Hansson, Jan-Eric, Litton, *ERIC - A new governance tool for Biobanking*, *European Journal of Human Genetics*, 2014, p. 2.

93 Alison Abbott, *European medical research escapes stifling privacy laws*, *Nature*, 16 December 2015.

94 Regulation (EU) No 211/2011 of the European Parliament and of the Council of 16 February 2011 on the citizens’ initiative and Commission Implementing Regulation (EU) No 1179/2011 of 17 November 2011 laying down technical specifications for online collection systems pursuant to Regulation (EU) No 211/2011 of the European Parliament and of the Council on the citizens’ initiative.

invoke such an initiative.<sup>95</sup> The procedure to enact an initiative includes a one-year-period to collect the necessary signatures,<sup>96</sup> and then a three-months-period for the Member States to verify the statements of support submitted on the basis of appropriate checks, in accordance with national law and practice.<sup>97</sup> Once the initiative is validated, the Commission has three months to examine the initiative and decide how to act upon it.<sup>98</sup> The organizers will also have the opportunity to present their initiative at a public hearing organized at the European Parliament.<sup>99</sup>

Out of the three citizen initiatives that have so far been successfully processed, two have connections to environmental issues. The first initiative was named

‘Stop Vivisection’ and urged the Commission to take action to protect animals used for scientific purposes.<sup>100</sup> The second initiative concerned the right to water; ‘Water and sanitation are a human right! Water is a public good, not a commodity!’<sup>101</sup> The Commission has published its legal and political conclusions, the actions it intends to take and the reasons for taking these.<sup>102</sup> Among the initiatives that are currently open, four altogether, one targets environmental issues, namely an initiative called “Stop Plastic in the Sea!”<sup>103</sup>

### **4.3.3 Article 40 of the General Data Protection Regulation: Codes of Conducts for Processing of Personal Data and the BBMRI-ERIC**

With the new General Data Protection Regulation, a new form of sector-specific participatory law-making is introduced; the possibility for associations and other bodies to enact codes of conducts to be used when processing personal data within their organizations. Article 40.2 of the Regulation reads as follows:

Associations and other bodies representing categories of controllers or processors may prepare codes of conduct, or amend or extend such codes, for the purpose of specifying the application of this Regulation.

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95 See annex to Regulation (EU) No 211/2011 of the European Parliament and of the Council of 16 February 2011 on the citizens’ initiative.

96 Ibid., Article 5.5.

97 Ibid., Article 8.2.

98 Ibid., Article 9.1.c.

99 Ibid., Article 11.

100 Further information available at “[www.stopvivisection.eu](http://www.stopvivisection.eu)”.

101 Further information available at “[www.right2water.eu/](http://www.right2water.eu/)”.

102 Communication from the Commission on the European Citizens’ Initiative “Stop Vivisection”, C(2015) 3773 final and Communication from the Commission on the European Citizens’ Initiative “Water and sanitation are a human right! Water is a public good, not a commodity!”, COM(2014) 177 final.

103 See further “[ec.europa.eu/citizens-initiative/public/initiatives/open/details/2015/000003](http://ec.europa.eu/citizens-initiative/public/initiatives/open/details/2015/000003)”.

These codes of conducts are thus to be used within an organization, or a specific sector, in order to customize the rather complex rules of the Regulation to the specific circumstances within the field. If the code is to be enforced within a single Member State, the competent Data Protection Authority in that state may approve, register and publish the code (Article 40.5-6). If several Member States are involved, a specific procedure laid down in Article 63 of the Regulation is to be used, a ‘consistency mechanism’ allowing national and European authorities to participate (Article 40.7). According to Article 40.9, the Commission may, by way of implementing acts, decide that a code of conduct should have general validity within the Union. Finally, it may be noted that the associations and bodies drafting the code of conducts are also expected to include other stakeholders in their own process, in a participatory manner. According to recital 99 of the preamble holds that those associations and bodies which are drafting codes of conducts, ‘should consult relevant stakeholders, including data subjects where feasible, and have regard to submissions received and views expressed in response to such consultations.’

As seen above (section 3.2.1), the BBMRI-ERIC has been quite active within legislative procedure for the recently enacted General Data Protection Regulation. Now with the Regulation adopted, the BBMRI-ERIC will direct its work towards the process of enacting a code of conduct.<sup>104</sup> In its position paper on the General Data Protection Regulation, the BBMRI-ERIC notes that ‘consistent harmonised rules for research at EU level are needed to promote research collaboration Europe-wide and that opportunity to develop sector-specific rules under the aegis of the Regulation is one way of furthering harmonisation’.

## **5 Too many Chefs in the Legislative Soup or an Opportunity to Think a New?**

Returning to the question posed in the introduction, how IOs and ENGOs influence the outcome of law-making procedures through EU:s participatory democracy, it must first be stated that the first stage of international law-making described above (section 2.1) is not obsolete, at least in the sense that states still enter into agreements via representatives of the government. However, the mechanisms introduced in the second and third stages have changed the perception of international law and the perception of the sovereign state to a large extent.

In her ground-breaking work on a net-worked world order from the beginning of the millennium, Slaughter analyses concept of sovereignty in our time.<sup>105</sup> She holds that the basic feature of the classic (yet contested) understanding of the concept of state sovereignty; the right to be left alone, to have a sphere were other states cannot interfere with the internal affairs of the state, is challenged in

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104 BBMRI-ERIC, Position Paper on GDPR, p. 4.

105 Slaughter, *Sovereignty and Power in a Networked World Order*, op cite, note 10.

two fundamental aspects. First the ineffectiveness challenge, that “a state’s ability to control its own territory without external interference is no longer sufficient to allow it to govern its people effectively – to provide security, economic stability, and a measure of prosperity, clean air and water and a minimum of health standards.” Secondly, the interference challenge. “All human rights”, Slaughter says, “deliberately infringes on domestic jurisdiction of every state, denying governments the freedom to torture, murder, ‘disappear’ or systematically discriminate against their own citizens”.<sup>106</sup> She argues that the concept of sovereignty should be seen in a new light, where focus is not on being left alone, but on the right and capacity to participate in international regimes. The possibility to participate is further to be disaggregated to the different organs within the state:<sup>107</sup>

Yet, if states are acting in the international systems through their component government institutions – regulatory agencies, ministries, courts, legislatures - why shouldn’t each of these institutions exercise a measure of sovereignty specifically defined and tailored to their functions and capacities?

By disaggregating sovereignty to their component government institutions, these will be “empowered to interact with their fellow regulators to engage in the full range of activities”.<sup>108</sup>

Here, focus has been on the participation of other organs than national institutions, more specifically ENGOs and sector-specific IOs. Further, they seem to participate under more or less same conditions. If the international law-making, as is suggested here, to a certain extent is open to NGOs and IOs set up to promote a specific policy area, what happens to the legal sources at the national level? In legal doctrine on the effects of globalization, two notions have been highlighted, the erosion of the private/public divide<sup>109</sup> and the fragmentation of legal orders.<sup>110</sup> These two notions will be analysed in the context of ENGOs and the BBMRI-ERIC.

### **5.1 *Erosion of the Private/Public Divide***

As illustrated above, a wide range of participatory mechanisms are available within international and EU law, both to private actors such as ENGOs and state actors representing a sector-specific interests, such as BBMRI-ERIC. Also

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106 Ibid, p. 284.

107 Ibid, p. 325.

108 Ibid, p. 322-26.

109 See for example Claudio Michelon *The Public, the Private, and the Law*, in Cormac Mac Amhlaigh, Claudio Michelon & Neil Walker, *After Public Law*, Oxford University Press, 2013.

110 See e.g. *Fragmentation of International Law: Difficulties arising from the Diversification and Expansion of International Law*, Report of the Study Group of the International Law Commission, finalized by Martti Koskenniemi.



mechanisms themselves can be both sector-specific, as in the case of the Aarhus governance structure, or general, as Article 11 TEU.

Representing the interest of a state or of a private organisation may not be two altogether different things in this context. Even when private actors represent themselves, they do not act within a vacuum, but are part of the civil society in their respective states, or perhaps international representatives of national actors. And bodies belonging to the state may have an interest to push the policy-areas they are tasked to handle, in a manner that does not differ much from NGOs. Representing the state and the interest of the citizens and the civil society in each state can no longer, if it ever was, be the sole responsibility of the government. To the contrary, the mechanisms described above strengthen the position of specific state bodies and ENGOs and allow them to impact law-making both in and beyond the state.

A relevant question to ask is thus how ENGOs and state organs promoting their particular interests can act within the EU participatory democracy. Can one analyse their respective roles from the perspective of the EU as a whole, or is there a need to take a closer look at how they work in the different contexts? From a practical and organizational point of view, ENGOs are certainly not all the same. They have different focus, are sometimes very active internationally, sometimes national and local. They might lack resources to make use of the participatory rights they have been accorded, and fears that ENGOs would overburden courts as a result of having legal standing have proved exaggerated.<sup>111</sup> Rather than seeing ENGOs as having all the same agenda, the use made by NGOs of participatory mechanisms provided by the Aarhus governance structure and the EU generally, has a potential of influencing law-making in a variety of seemingly unforeseeable ways. The question could be raised what interests are actually represented, and in what manner.

Also the state represented by members of an IO or as public authorities can act in quite different capacities. The growing European composite administration contains ample opportunity for public actors, such as public authorities tasked with implementing a specific sector of EU law, to cooperate and exchange ideas, both formally and informally. Research shows that national officials more often turn to their colleagues at sister authorities in other Member States when ambiguities in the interpretation of the law occur, than to their own government.<sup>112</sup> As described above (section 4.3.1) the BBMRI-ERIC was quite active in the law-making processes connected to the recently enacted General Data Protection Regulation, pushing for exceptions in the Regulation which would allow medical researcher to use personal data on health without the strict limitations set out in Regulation. Other public actors take a different approach. The Article 29 Data Protection Working Party, a network for national data

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111 See e.g. SOU 2005:59 *Miljöbalken; miljö kvalitetsnormer, miljöorganisationerna i miljöprocessen och avgifter*, part 3, pp. 165-167; *Access to Justice in Environmental Matters and the Role of NGOs – Empirical Findings and Legal Appraisal*. Nicholas de Sadeleer, Gerhard Roller, Miriam Dross (eds) Europa Law Publishing, 2005 p. 75.

112 Helen Wockelberg & Eva Edwardsson, *European Legal Method in Denmark and Sweden – Using Social Science Theory and Methodology to Describe the Implementation of EU Law*, *European Law Journal*, Vol. 19, Issue 3, 2013, p. 364–38.

protection authorities established through Article 29 in the current Data Protection Directive,<sup>113</sup> identifies the protection of individual data subject as their main concern. In its opinion on the draft EU/US Privacy Shield, the agreement with the US to replace the Safe Harbor-agreement which was annulled by the Court of Justice,<sup>114</sup> the group underlined the importance of setting a high standard for data protection in cross-Atlantic affairs, stating that “European data protection authorities strongly assert the importance of the principles they defend.”<sup>115</sup> Sweden is a member both of the BBMRI-ERIC and has a representative in the Article 29 Data Protection Working Party Group, but it is far from apparent that a “Swedish” interest will be represented in the same way by the two organs, or even that the two organs would represent the same “EU” interest in the law-making processing beyond the state. Rather, it seems as the Article 29 Data Protection Working Party represents the interest of upholding data protection on behalf of the 28 EU member states, while the BBMRI-ERIC upholds the interest European excellency in biobanking on behalf of its 16 member states.<sup>116</sup>

To summarize, it seems that ENGOs, sector-specific IOs as well as national public authorities acting beyond the state may assume roles that are not so different from each other: all three categories can act in different ways and take on different functions, having in common that the actors first and foremost seem to represent the sector-specific interest they are set up to promote, be it the environment, research or any other interest.

## 5.2 *Challenges to the Internal Coherency of National Legal Sources*

As the representation of the nation state is perforated by a multitude of actors addressing cross-border issues, the state will evidently to some extent lose control over the law-making processes it is involved in or otherwise effected by. Legal sources within national law will be developed with influences from a variety of actors at several levels of government, representing different interests, depending on context and setting of the law-making procedure.

As illustrated in the example of ENGOs in the governance structure created by the Aarhus Convention and the EU, one can see that ENGOs can play a key role in impacting national implementation of the Aarhus Convention, making use of different mechanisms at different levels of government so as to as effectively as possible advance their goals. In *Trianel* and Communication

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113 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. In the General Data Protection Regulation 2016/679, the working party will be replaced by a European Data Protection Board, Article 68 in the Regulation.

114 Case 362/14, Schrems, op cite, note 64.

115 Article 29 Data Protection Working Party, Opinion 01/2016 on the EU – U.S. Privacy Shield draft adequacy decision, 16/EN WP 238, p. 4.

116 Jane Reichel & Anna-Sara Lind, *Regulating Data Protection in the EU*, in *Perspectives on Privacy*, Dörr, Dieter & Weaver, Russell L. (eds), de Gruyters publisher, 2014, p. 44.

ACCC/C/2008/31, ENGOs both challenged national law before national courts, in their turn obligated to ask the CJEU for a preliminary ruling, and initiated a review of non-compliance at the international level. Critically, ENGOs are not entitled to initiate proceedings concerning non-compliance of EU Member States with EU law before the CJEU. Therefore, the possibility for ENGOs to initiate review proceedings before the ACCC is particularly important, and it shows that opportunities lacking at one level of government may be available at another. In gaining a position similar to that of a party in the proceedings before the ACCC ENGOs have the privilege of formulating questions concerning implementation at the national and EU levels and following up on amendments made in national and EU law. While the findings of the ACCC result in unbinding recommendations to the party concerned, the *Trianel* case and the related compliance proceedings before the ACCC allows one to conclude that the ACCC further monitors how Germany amends its law following the CJEU judgment. Such mechanisms, allowing an NGO to closely follow up on judgments delivered by the CJEU, are lacking within the EU legal order. In this sense, the Aarhus governance structure creates synergy effects for ENGOs using the variety of tools available at different levels of government. Considered as a whole, the Aarhus governance structure, with its tentacles both in the international, EU, and national contexts, allow for considerable ENGO involvement in law-making.

In relation to the example of ENGOs in the Aarhus governance structure, one can note that the state is only one of the several levels on which ENGOs can seek to strengthen the environmental perspective in law-making. Both law-making and law is fragmented, and the national legislator can only to a limited extent take the role of coordinating different policy areas, or even different aspects of single policy areas. Where no legislative instance is in a position to take an overall responsibility over coordination, there is inevitably a risk of incoherency, and of losing sight of certain issues in need of attention but without a representative in the form of an actor making use of the communicative channels available. What if NGO's are very active in one area of law, but not in another? What about those who do not make use of their participatory rights, perhaps because they are lacking the time and means to organise themselves?

Also, taking a comprehensive stand in the different policy areas is challenging where (public) governance structures differ widely from one area to another.<sup>117</sup> Coming back to the example of data protection, BBMRI-ERIC and the Article 29 Data Protection Working Party, it could be expected that the BBMRI-ERIC would have a different focus and interest in the use of personal data within biobanking and medical research than the Article 29 Data Protection Working Party, if the BBMRI-ERIC had the chance to influence the outcome of a law-making procedure. However, in the current governance framework for data protection, the role and function of the data protection authorities, which the Working Party consists of, is very strong. It follows from Article 8.3 of the EU Charter of Fundamental Rights, Article 28 of the Data Protection Directive and

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117 Herwig CH Hofmann, Gerard C Rowe and Alexander H Türk, *Administrative Law and Policy of the European Union*, Oxford University Press 2011, pp. 908-911.

the *Schrems*-case discussed above, that national data protection authorities are to independently review all legal acts and measures that may interfere with the right to data protection, including EU-acts.<sup>118</sup> If the data protection authority finds that the act or measure does interfere with the right to data protection, it must take all necessary actions to have it set aside, which, in regards to EU acts, includes taking the matter to a national court which may refer the question to the Court of Justice.<sup>119</sup> With the General Data Protection Regulation, the governance structure for data protection will be even stronger and include a composite procedure for upholding a consistent interpretation of the act, in which both the Commission and the coming Data Protection Authority will play important roles.<sup>120</sup>

If the second stage described above (section 2.2) often has been criticised for leading to judicial activism by international courts, the present stage (section 2.3) may equally be said to engage in what can be described as administrative and national court activism. In many areas, conflicts of how to interpret the law may be left to the national authorities tasked with implementing EU law to resolve by themselves.<sup>121</sup> At the same time, the change in scenery opens up further arenas for IOs and NGOs to influence these procedures. An example well known to the Swedish public is a long series of cases where ENGOs have challenged administrative decisions concerning the hunting of wolves, and thereby strongly influenced the political debate on biological diversity in Sweden.<sup>122</sup> Other NGOs have been successful in pushing the interest of data protection before authorities and courts. Maximilian Schrems, the law student behind the *Schrems*-case, was backed up by the NGO Digital Rights Ireland, who joined the case before the Court of Justice. Digital Rights Ireland had previously been successful in another case, where the Court of Justice found that the Data Retention Directive was invalid due to lack of respect for the fundamental right to data protection for individuals.<sup>123</sup>

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118 Case 362/14 *Schrems*, op cite, note 65, para. 40.

119 Ibid, paragraph 64.

120 Article 63-67 General Data Protection Regulation 2016/679.

121 Luca De Lucia, *Conflict and Cooperation within European Composite Administration (Between Philia and Eris)*, Review of European Administrative Law, Vol. 5, Nr. 1, pp. 43-77.

122 See Jan Darpö, Yaffa Epstein *Thrown to the Wolves*. 2015. Nordisk miljörättslig tidskrift. pp. 7-20.

123 Case C-293/12 Digital Rights Ireland Ltd v. Minister for Communications, Marine and Natural Resources, EU:C:2014:238.

### 5.3 Concluding Remarks

To our understanding, the nation state today can to a large extent be described as perforated instead of unified in its relations to the law-making world outside its borders. A wide range of public and private actors are in a position to influence law-making beyond the state. In this article we argue that when an organisation – either non-governmental or a traditional international organisation made up by states – has achieved a platform for communication within a limited area, this can be used as a trampoline to also communicate with policy-makers at a general arena. The BBMRI-ERIC has been recognized as a European research infrastructure, and thereby a centre of excellency, to which the Member States have agreed to support over time. Hereby, the BBMRI has achieved a platform for communication with EU policy makers, as in connection to the enactment of the General Data Protection Regulation. The combined effect of the Aarhus Convention as international law, and as part of EU law, allows ENGOs to strengthen their position vis-à-vis state parties to the Convention; synergies that are well illustrated by the Trianel case and the compliance procedure related to it. Arguably, ENGOs given specific participatory rights within the Aarhus Convention can use this recognition of being a legitimate representative of the environment and of environmental interests, to render their argumentation more authoritative when entering into the general participatory democracy of the EU. Thus, both BBMRI-ERIC and ENGOs can contribute with their expertise in the legislative process and their arguments could thereby be understood to carry a certain weight. Recognition in one platform can thereby be useful also in others. To what extent the actors actually influence the outcome of law-making processes is beyond this article to investigate. It suffices here to note that there are ample opportunities, and that it may be seen as likely, or at least highly possible, that some influence has taken place.

If the nation state today is perforated instead of unified, it is only natural that the legal system will take the same form. As pointed out by Sand, “globalization and various forms of multi-level governance will have consequences for the forms and the procedures of democracy in the creation of public law and thus also of its legitimacy.”<sup>124</sup> As discussed in the introduction to this section, Slaughter has argued for a disaggregated form of sovereignty, where organs of the state can participate as sovereigns in a networked global legal order. The question is where to fit in non-state actors and sector-specific IOs in the picture. Perhaps the time of unified and coherent legal orders within each state is already passed and what we instead have to work with is legal fragments that strive at being unified and coherent across borders, sector by sector?<sup>125</sup> According to Teubner, conflicts in law cannot be expected to be resolved in a centralized

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124 Inger Johanne Sand *Globalization and the Transcendence of the Public/Private divide – What is Public Law under Conditions of Globalization?* in Cormac Mac Amhlaigh, Claudio Michelon & Neil Walker, *After Public Law*, Oxford University Press, 2013, p. 215.

125 See for an in depth analysis of the effects of transnationalization and privatization, Gunther Teubner, *Constitutional Fragments. Societal Constitutionalism and Globalization*, Oxford University Press, 2012.

manner, since the modern society has no central authority.<sup>126</sup> Perhaps we have already – in practise - moved beyond the question of how to organise the representation of different societal interests in a state by state manner, thereby having to give up on the idea to weigh together different opposing interests through the cohesive functions of a government for each state? From this perspective, the participation of a wide range of actors in law-making, engaging in issues of their interest, could be seen as a sign of vitality.

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126 *Ibid*, p. 153.