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### **‘Smoothing’ Eastern Enlargement through New Modes of Governance? Conceptualising the Role of Independent Regulatory Agencies and Non- Hierarchical Steering in Pre-accession Negotiations**

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Conceptualising the Role of Independent Regulatory Agencies and Non-Hierarchical  
Steering in Pre-accession Negotiations**

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DELIVERABLE 1

Project 15: Smoothing Eastern Enlargement: Independent Regulatory Agencies & Non-  
Hierarchical Steering (SEEIRA)

Cluster 3: Effectiveness and Capacity

**Short summary**

On 1 May 2004, the European Union (EU) faced its most challenging enlargement ever when ten new countries joined. In recent years, most enlargement research focused on theorizing the process of eastern enlargement while the application of so-called new modes of governance in the accession process has been neglected. This contribution aims at narrowing this research gap. In light of the enormous economic, political and administrative challenges posed by the EU’s eastern enlargement, we raise the question as to which extent the European Commission has applied new modes of governance to facilitate the adoption of and adaptation to EU policies in future member states already in the pre-accession phase, and what role – if at all – such new modes of governance played.

The aim of this paper is to explore theoretically-driven hypotheses from existing literature on new modes of governance and independent regulatory agencies and identify the main factors that explain variations across different policy areas and member states. To explore our research questions we proceed as follows: First, we recapitulate the work about delegation to specialized agencies and non-hierarchical steering modes as specific facets of new modes of governance. Second, we review the literature on enlargement with the aim at identifying the challenges of environmental and pharmaceutical legal harmonization in the CEECs. Third, we assess the validity of hypotheses found in the literature in the light of our preliminary empirical findings regarding the role of new modes of governance in the pre-accession process negotiations. Finally, we draw some preliminary conclusions about the role of new modes of governance for ‘smoothing’ enlargements and we identify areas of further research concerning the extent to which new modes of governance have been employed as mechanisms of conflict resolution.

**Contents**

I.	EU Enlargement and New Modes of Governance .....	3
II.	Dimensions of New Modes of Governance .....	4
III.	The EU’s <i>Acquis Communautaire</i> as a Challenge to Accession .....	10
IV.	The Case of the Pharmaceutical <i>Acquis</i> .....	14
	Designing a New Strategy: Delegation and Institutionalization .....	15
V.	The Case of the Environmental <i>Acquis</i> .....	17
	EEA: a Watchdog Without Teeth .....	18
	The IMPEL Network: A Watchdog Without Rage? .....	21
VI.	Conclusions and Prospects for Future Research .....	22
VII.	References .....	25

## I. EU Enlargement and New Modes of Governance

On 1 May 2004, the European Union (EU) faced its most challenging enlargement ever when ten new countries joined. In recent years, most enlargement research focused on theorizing the process of eastern enlargement (e.g., Friis/Murphy 1999; Schimmelfennig 2001, 2003; Schimmelfennig/Sedelmeier 2002), while the application of so-called new modes of governance in the accession process has been neglected. This contribution aims at narrowing this research gap. In light of the enormous economic, political and administrative challenges posed by the EU's eastern enlargement, we raise the question as to which extent the European Commission has applied new modes of governance to facilitate the adoption of and adaptation to EU policies in future member states already in the pre-accession phase, and what role – if at all – such new modes of governance played.

The project focuses on a novel research topic by analysing the role of independent regulatory agencies and non-hierarchical steering modes in the process of adopting and adapting the *acquis communautaire* in the Central and Eastern and Southern European member states. The aim of the project is to evaluate the extent to which new forms of governance (actors involved/steering modes) are able to render accession "smoother" by reducing the risk of implementation-conflicts in "weak" countries during the pre-accession phase and after accession. This research points to several questions: How can an institutionalised structure look like to be that efficient? Which actors are involved (e.g. national/European agencies; national/European associations; national/transnational NGOs; enterprise representatives; European Commission; national civil servants)? What roles can be played by European IRAs (e.g. transnational network coordinator; mediator; instructor)? Which steering modes (arguing; learning; persuasion; economic incentives) are used and are they efficient to facilitate conflict-resolution with regard to the adoption of the *acquis communautaire*? Is a structure that involves all relevant societal actors more legitimate than the "classical" enlargement style, which only involves governmental actors? Is there a trade-off between efficiency and legitimacy? Can new forms of governance reduce the influence of national interests during the pre-accession phase, thus reducing conflicts? By involving current EU member states as well as CEE member states the project adopts a comparative perspective between different EU member states. It will focus at the cases of environmental and pharmaceuticals harmonization where IRAs owe different tasks (i.e., information or regulation) and varying degrees of decision-making power.

The aim of this paper is to explore theoretically-driven hypotheses from existing literature on new modes of governance and independent regulatory agencies and identify the main factors that explain variations across different policy areas and member states. To explore our research questions we proceed as follows: First, we recapitulate the work about delegation to specialized agencies and non-hierarchical steering modes as specific facets of new modes of governance. Second, we review the literature on enlargement with the aim at identifying the challenges of environmental and pharmaceutical legal harmonization in the CEECs. Third, we assess the validity of hypotheses found in the literature in the light of our preliminary empirical findings regarding the role of new modes of governance in the pre-accession process negotiations. Finally, we draw some preliminary conclusions about the role of new modes of governance for ‘smoothing’ enlargements and we identify areas of further research regarding the extent to which new modes of governance have been employed as mechanisms of conflict resolution.

## **II. Dimensions of New Modes of Governance**

New modes of governance cover a wide range of different policy processes such as the open method of coordination, voluntary accords, standard setting, regulatory networks and agencies, regulation ‘through information’, benchmarking, peer review, informal agreements, as well as forms of policy experimentation in different economic sectors, where a new mix of public and private goods is aimed at (e.g., Héritier 2003). They are characterized by the principles of voluntarism (i.e., non-binding targets, soft law), subsidiarity (i.e., the delegation of decision-making competencies to member states or private actors), and inclusion (i.e. the participation of all relevant actors in the decision-making process). These “modes of political steering concern both rule-setting and rule-implementation processes including ensuring compliance with international norms”. Since new modes of governance represent an alternative to regulatory requirements (i.e., ‘hard law’), they are expected to facilitate consensual decision-making by minimizing resistance of decision makers and implementing actors as regulatory adjustment costs remain low (Héritier 2001: 9). Consequently, new modes of governance are expected to be politically more efficient and more effective (e.g., Héritier 2003; Jachtenfuchs 2001; Kohler-Koch/Eising 1999).

According to Risse (2004: 291), new modes of governance comprise two dimensions: they include “non-state actors, such as firms, private interest groups, or nongovernmental organizations (NGOs) in governance arrangements (actor dimension)”; and they put “an emphasis on non-hierarchical modes of steering (steering dimension)”. With regard to the actor dimension,

this paper reviews the potential benefits of delegating management and decision-making functions from the Commission to specialized agencies. The second dimension of new modes of governance addressed in this paper is the prevalence of non-hierarchical, non-manipulative steering modes of interaction between participants, such as ‘arguing’ and ‘persuasion’. ‘Arguing’ and ‘persuasion’ are significantly different from ‘bargaining’ as a non-hierarchical but manipulative steering mode. According to Risse (2004), both ‘bargaining’ – in terms of exchange of demands, threats, and promises – and ‘arguing’ – in terms of deliberative and truth-seeking behavior – are types of non-hierarchical steering. Yet, ‘arguing’ as well as ‘persuasion’ represent less confronting modes of interaction. This is important for rule implementation and compliance, as communicative action by ‘arguing’ and ‘persuasion’ “is crucial for social learning as an important mechanism for socializing actors into new (international) norms and rules” (Risse 2004: 300; Gehring 2004). However, in reality both mechanisms often mix up and complement each other.

Börzel and Risse (forthcoming) argue that new modes of governance are especially articulated through the existence of public-private-partnerships. They found that non-hierarchical modes of steering are essential parts of such arrangements. Public-private-partnerships – that may include administrative actors, regulators, industry, and civil society – can be described as policy networks representing a mixed model of ‘international governance’ (consisting of only governmental actors) and ‘transnational governance’ (consisting of non-state actors), in which the state acts as ‘primus inter pares’ (also Pierre/Peters 2000). Hence, regulatory networks are often characterized an ‘interpenetration’ of public and private actors Jayasuriya (2004: 12). Reinicke and Deng (2000) argue that such networks are most likely being created if established modes of policy-making show a lack of range, speed and knowledge for making appropriate and effective decisions in specific policy areas. Over time regulatory networks may become institutionalized with the establishment of formal arrangements such as advisory committees, consultation procedures and recognition by state and multilateral agencies in the implementation of policies (Dehouse 1997). The delegation of power (i.e., regulation, monitoring, cooperation, execution) to specialized agencies is an essential part of new modes of European governance since IRAs often serves as the central nodes of such regulatory networks (e.g., Hix 1998; Majone/Everson 2001; Thatcher/Stone Sweet 2002). In its White Paper on Governance, the European Commission attributes an important role to agencies for the better application of EU rules (European Commission 2001: 23).

At the EU level, the term ‘agency’ includes a great variety of activities, objectives and institutional designs (Everson et al. 1999: 31). Yatanagas (2001: 24) differentiates between four

types of European agencies: First, ‘quasi-regulatory agencies’ serving mainly the operation of the internal market or safety standards, such as the Office for Harmonisation in the Internal Market, the Community Plant Variety Office, the European Agency for the Evaluation of Medicinal Products and the European Aviation Safety Authority. Second, ‘monitoring agencies’, such as the European Environment Agency, the European Monitoring Centre for Drugs, Drug Addiction and the European Monitoring Centre on Racism and Xenophobia as well as the recently established European Food Safety Authority. Their main task is to provide comparable information and objective advice to their member states. Third, ‘agencies promoting social dialogue at the European level’, such as the European Centre for the Development of Vocational Training, the European Foundation for the Improvement of Living and Working Conditions and the European Agency for Safety and Health at Work. Most interestingly, “these agencies have a tripartite management board designed to ensure full representation of the social partners (employers and labour) as well as the Member States and the Commission, reflecting openness to civil society” (Yatanagas 2001: 24). Fourth, ‘executive agencies’, such as the European Training Foundation, the Translation Centre for Bodies in the EU, the Agency for the Reconstruction of Kosovo and the European Aviation Safety Authority. Notably, the Commission has not established formal codes governing its relations with the agencies. It exercises control through senior officials from the relevant Directorates General that participate in the Managing Boards (Yatanagas 2001: 24).

The bulk of the IRAs literature focuses on the driving forces that condition the incentives of political actors to delegate policy making competencies to them, agency design and the consequences of delegation for democratic accountability and control. Rational choice approaches conceptualise delegation to IRAs as a response to powerful functional pressures emanating from the expansion of the regulatory role of the state as a distinctive mode of social coordination (Majone, 1994; 1997a). The principal/agent framework that dominates studies of delegation to IRAs, stresses four common explanations why delegation to agencies might be beneficial for political efficiency. First, delegation is used to reduce political transaction costs emerging at the stage of negotiation between political actors (cf. Epstein/O’Halloran 2000; Héritier 2003: 203). Second, delegation to a specialized agency is expected to facilitate policy continuity given the complexity of socio-economic phenomena, the acceleration of scientific and technological developments and the growth of international interdependence. Everson et al. (1999: 21) indicate that “a reason for proposing the creation of European agencies in several areas of economic and social regulation is the perception of EU citizens and economic actors alike, that the present system – with its heavy concentration on rule-making and its

weak control of the enforcement process – is no longer able to cope with the regulatory challenges of globalised markets”. The high collective stakes attached to these challenges demand continuity of public action which is not always achieved by political actors because of short-term electoral constraints (Majone 2001; 1997b). Third, the increasing technical and scientific complexity of many regulatory issues has led to the establishment of agencies which contribute expertise in these substantive matters (Héritier 2003: 203). Mobilization of all knowledge relevant to public decision-making requires a stable relational context among peers that minimizes bureaucratic or political bias during deliberations (Moe 1990; 1995). Such a framework is hard to find within public administrations. Finally, agencies may pave the way for a closer incorporation of civil society into governmental institutions. Everson et al. (1999: 32) argue that the agencies’ separateness from government may make them a preferred mechanism for co-opting certain groups into the decision-making process. Thus, agencies function as intermediary institutions between state and civil society. Additionally, as depoliticized bodies eager to improve their own public reputation, agencies contribute credibility and reliability as well as public confidence in regulatory processes and outcomes (Pollack 1997).

The intensity of the functional pressures analysed above determines principals’ preferences on the institutional design of IRAs. The higher the functional pressures experienced by principals in a given policy area or country the more powers they will delegate to IRAs and the weaker will be the control mechanisms. Principals seeking to maximize their influence over policy outcomes, attempt to optimise the equilibrium between delegation and control in order to minimize losses from the agency’s tendency to gain political and bureaucratic autonomy. In regulatory arenas where multiple principals have veto powers over agency design, policy outcomes reflect the distribution of preferences and resources between constitutive actors. At the EU level bureaucratic politics in the framework of interactions between multiple principals is more complex comparing to national regulatory arenas. EU institutions such as the Commission can be conceptualised both as principals, when they delegate competencies to European agencies, and as agents themselves of the Council (Shapiro, 1997: 281; Yataganas, 2001: 41). Agency design and delegated powers reflect the distribution of relatively stable preferences between principals. Changes in the distribution of preferences with the addition of new actors generate different policy outcomes over time. Kelemen (2002) demonstrates how the addition of the European Parliament as a political principal on its own right, after the advent of the cooperation procedure (Art. 189b, TEU), has contributed to the emergence of more participatory and transparent agencies such as the European Food Agency, compared to the first generation of IRAs that are dominated by national government representatives. Bureaucratic politics of-

fer significant insights to the process of agency design at the initial formative period. Variations between different agencies are the outcome of changes in the distribution of preferences between constitutive actors across time. However, they fail to conceptualise synchronic variations in the role and regulatory functions of IRAs in different policy areas. In light of the enormous economic, political and administrative challenges posed by the EU's eastern enlargement why member states, the European Parliament and the Commission decide in certain policy areas to depart from established methods of pre-accession negotiations based on bilateral negotiations between the Commission and central executives of the accession countries and delegate preparatory functions to IRAs?

Empirical evidence hardly confirms the predictions of the principal/agent framework. Elected officials often experience identical functional pressures from different regulatory policy areas but agency design and the timing of delegation differ considerably across different countries and policy areas (Thatcher 2002; Thatcher and Stone Sweet 2002; Gilardi 2001; 2003a; Döhler, 2002). Challenges to the principal/agent framework draw on sociological and historical strands of new institutionalism. The first emphasise that delegation to IRAs as a choice is socially constructed (Thatcher and Stone Sweet 2002: 12; Wilks and Bartle, 2002). Elected officials often favour delegation even in the absence of significant functional pressures. Powerful knowledge-based elites, professional networks and international organizations help to diffuse delegation to IRAs as the 'best practice' in solving collective action problems (Radaelli 2000). In regulatory sectors such as telecommunications, transport, competition and broadcasting there is a strong tendency of national governments across Europe to converge toward delegation to IRAs as the dominant paradigm of regulatory governance.

Historical institutionalists emphasise that country and policy specific factors mediate functional pressures and affect both the momentum for the establishment of IRAs and their institutional design. State traditions, structures and constellation of interests in different regulatory domains, political leadership and compatibility with wider reform agendas, learning capacities of domestic actors are institutional and political properties that enable or hinder the emergence of IRAs as effective organizational responses to powerful functional pressures (Thatcher and Stone Sweet, 2002: 13). Policy specific institutional properties affect constitutive actors' preferences regarding delegation of regulatory functions to IRAs and the inclusion of non-state actors in their management structures. Beyond functional pressures that may be identical or vary across different policy areas, the ability of non-state actors in a given policy area not only to provide essential resources such as technical knowledge but also to form coalitions and engineer consensual policy making is a factor that determines constitutive actors'

preferences in favour of delegation to participatory institutions (Eberlein and Kerwer, 2002: 5; Grande 2000: 20). Pre-existing convergence of preferences between resourceful actors and the likelihood of consensual regulatory outcomes reduce the risk of ‘agency losses’ i.e. the gradual emergence of divergent preferences and agendas from the ones initially delegated by the principals in the policy area. This is not to dismiss the fundamental claims of constructivist approaches regarding the effects of delegation to regulatory networks on the gradual evolution of consensual negotiating modes of interactions between participating actors. However, given the challenges imposed by the quantitative (large number of accession countries) and qualitative (weak administrative capacities of accession countries to ensure effective legal harmonization) dimension of eastern enlargement, accommodating constellation of interests between key actors and their ability to engineer consensus by insulating from politicization pressures are key properties that affect actors’ preferences regarding the institutional design of accession negotiations. As we have argued elsewhere, and below in this paper, there are considerable variations both in member state preferences and the capacities of non-state actors to generate consensual regulatory outcomes between the two policy areas under investigation, namely environmental and pharmaceutical policies (Prange and Koutalakis, forthcoming). The persistent leaders/laggards dynamics in member state environmental performance across the EU hinders the emergence of consensual preferences between member states toward more participatory and transparent non-hierarchical modes of regulatory governance. During the formative period of the EEA, member states with weak environmental compliance performance ensured that, despite initial proposals, the agency would have no competencies over monitoring and enforcement of EU law (Kelemen 2002: 101). Moreover, the heterogeneity of decision making arenas in the framework of EU environmental policies that embrace product standards, production processes and sustainability regulations reduce the likelihood of the emergence of a clearly identifiable group of non-state actors (environmental organizations, business groups and citizen associations) capable of generating consensual regulatory outcomes. On the contrary, in the pharmaceutical area there is a tendency, from the 1990s onwards between key European multinational companies, their hosting member states and the European Commission to form a close policy community that interacts on a regular basis in the framework of major domestic and European regulatory policy reforms. Moreover, national administrations and pharmaceutical agencies with weak technical capacities have relied, long before the establishment of the EMEA, on clinical tests and approval procedures undertaken by other EU counterpart agencies (Interview, EOF, 20/11.2004). In the following part of the paper, we seek to provide preliminary empirical evidence regarding the extent to which

these policy specific properties serve as preconditions for the emergence of decentralised non-hierarchical modes of regulatory governance in the area.

### **III. The EU's *Acquis Communautaire* as a Challenge to Accession**

Rational choice approaches suggest that variations in the role of IRA in eastern enlargement stem from different functional pressures exerted to elected officials and the European Commission in the two policy areas under investigation, pharmaceutical and environmental policies. However, it is indeed very hard to sustain such a view in the light of secondary literature and relevant policy reports.

One of the biggest challenges for Central and Eastern European Countries (CEECs) regarding their EU membership is the effective implementation and compliance with EU rules. Implementing the EU *acquis communautaire* exposes their domestic institutional and regulatory structures and patterns of policy making to significant pressures for adjustment to the new regulatory regime. On the one hand, the full adoption of the *acquis* represents a unique opportunity to modernize the domestic regulatory regimes of the CEECs and expand their economic orientation to western European markets through the upgrade of their product standards to EU requirements. On the other hand, as latecomers to the EU, the CEECs face two serious problems regarding the adoption of EU legislation. First, they never had the possibility to influence European regulation according to their preferences and policy traditions. Second, they often lack adequate institutional structures and capacities to effectively implement and enforce European regulations. This double disadvantage for European latecomers has led to concerns in the new member countries about the full implementation of all EU directives, for example, for all pharmaceutical products that are on the market at the time of accession.<sup>1</sup> The environmental and pharmaceutical sectors are both highly regulated, hence new member states face high implementation costs. Thus, the incentive to call for temporary derogations has been strong in both policy areas.

Nevertheless, comprehensive legal harmonization remained the core of the EU's method of enlargement. Prospective member states are expected to take over the entire *acquis communautaire* without any permanent exceptions. The recent enlargement round significantly differed from previous enlargements regarding both the intensity of pre-accession negotiations and the instruments employed by the European Commission. The Commission's 'reinforced' pre-accession strategy was comprised by a mix of hierarchical and non-hierarchical steering

instruments. In the area of environmental harmonization, financial aid and technical assistance from PHARE, ISPA, SAPARD and LIFE programmes were made conditional upon progress on legal harmonization and were targeted in the priority areas waste, water and air pollution. Benchmarking and rigorous monitoring through annual progress reports were effective pressure instruments to accelerate the process of regulatory adaptation in the CEECs. However, pre-accession negotiations were essentially grounded on a stringent application of conditionality criteria as a means of controlling access to further stages of the negotiation process. The Commission thoroughly scrutinized domestic administrative capacities of prospective member states, screening of compatibility between pre-existing domestic regulatory approaches with EU legislation and progress in domestic regulatory adjustments. This was essentially a top-down process based on a fundamental asymmetry of interdependence in favour of the Commission regarding information and specification of legislative technical requirements for the effective implementation of various legislative acts (Baker 2000; Jehlicka 2002).

EU environmental legislation comprises over 70 directives some of which have been amended several times and supplemented with ‘daughter’ directives and 21 regulations.<sup>2</sup> These legal acts cover three main dimensions of environmental policies, namely regulations related to product standards (vehicle noise and exhaust emissions fuel quality standards, packaging waste), production processes (Integrated Pollution Prevention and Control, Water Framework Directives, nature protection directives and horizontal legislation such as Access to Environmental Information and Environmental Impact Assessment), and sustainability (most notably requirements for Environmental Policy Integration emanating from Art. 2 TEU) (Homeyer 2004). Pharmaceutical regulations comprise 18 legal acts divided into two main categories: standards for medical products for human use (10) and for veterinary products (8).<sup>3</sup>

From the outset of pre-accession negotiations, the EU has placed considerable emphasis on the free movement of goods in order to ensure that products can move freely across borders (European Commission 2002). This means that basic technical standards, product certification and metrological definitions must be governed by rules established at the EU level. The White Paper on the Preparation of the Associated Countries of Central and Eastern Europe for Integration into the Internal Market of the Union lays down the technical regulations and stan-

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<sup>1</sup> See Minutes from 3<sup>rd</sup> CADREAC Meeting, 28-29 March 1999, Častá Papiernička, Slovak Republic.

<sup>2</sup> These amendments amount to approximately 300 legal acts (<http://europa.eu.int/comm/environment/guide/guidfin.pdf>).

<sup>3</sup> Accounting to own estimates based on DG Enterprise reports there are approximately 185 amending legal acts ([http://europa.eu.int/comm/dgs/enterprise/pdf/pink\\_book\\_2003.pdf](http://europa.eu.int/comm/dgs/enterprise/pdf/pink_book_2003.pdf)).

dards which candidates have to implement in their national industries (European Commission 1995). Pharmaceutical products are one of the most complex and standardized issues in the EU. Member states have to establish regulatory structures to oversee marketing authorizations, testing, manufacturing, distribution, labeling, advertising, pricing and reimbursement. Harmonization of pharmaceutical markets was perceived to be one of the most sensitive issues of the pre-accession negotiation process due to the fundamental concerns on the part of leading multinational pharmaceutical industries regarding market authorizations and parallel trade (Tosics 2003). Thus, under the Accession Treaties new member states have to comply with EU law regarding market authorizations without specific derogations. Currently, there are two procedures for obtaining an EU authorization: the ‘centralized procedure’ managed by EMEA which is compulsory for biotechnology products and optional for other new innovative medicines; and ‘mutual recognition’, a decentralized procedure where an application approved by any member state’s pharmaceutical regulatory body is automatically accredited by all other national counter-bodies. Cyprus, Malta, Lithuania, Poland and Slovenia have negotiated transition periods for market authorizations granted under national law prior to their accession to the EU.<sup>4</sup> Parallel trade was an area with significant repercussions for legal harmonization in the EU’s pharmaceutical market. Given the considerable market fragmentation and divergence in member state pricing policies, one of the biggest fears of leading multinational pharmaceutical companies was that the CEECs’ accession to the EU, with their lower pricing levels, will spark a huge increase in parallel trade from CEECs to the rest of the internal market. As a result, the multinationals, which are increasingly dominating the markets of the CEEC region, expected that they would lose substantial sales in the leading EU markets to parallel traders exporting branded products at cheaper prices from the new member states to higher-priced old member states (Prange 2004: 76). Not surprisingly, multinational pharmaceutical companies intensively lobbied both the European Commission and member states’ governments for transition periods providing safeguard measures for a ‘substantial’ period of time (EFPIA 1997).

The core of EU environmental legislation – harmonization of production processes and sustainability – entails far reaching implications for domestic environmental policies and the corresponding institutional and administrative structures and patterns of policy making in the CEECs. Implementing the *acquis* will not only be an expensive attempt due to requirements

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<sup>4</sup> Poland has also negotiated transition periods for marketing authorizations for medical devices.

for investment in physical and administrative infrastructure.<sup>5</sup> It will also expose pre-existing domestic institutional structures and patterns of policy making to significant pressures for adjustment in order to facilitate effective implementation and compliance with EU environmental laws. On the one hand, CEECs display a number of unfavorable socio-political and administrative conditions that are likely to generate considerable problems in the process of adopting EU environmental laws in their domestic regulatory regimes. On the other hand, the legacies of the Communist experience such as excessive centralized planning, weak administrative capacities especially at the sub-national levels of government, feeble civic culture and low policy priorities on environmental protection are likely to impede effective integration of domestic environmental policy traditions into the EU regulatory regime (e.g., Baker/Jehlicka 1998; Waller 1998). Moreover, a number of recent developments associated with the abrupt transition to a market economy without well established regulatory mechanisms, such as corruption, increase reservations regarding the effectiveness of monitoring and enforcement mechanisms to facilitate compliance with EU rules.

Given the scale of required administrative adjustments and financial investments coupled with a relatively low priority of environmental protection in domestic political agendas, domestic actors' compliance incentives are contingent upon the availability of external resources, such as the structural funds. Industrial actors may, in the short term, face strong disincentives to comply with environmental process standards that reduce the competitiveness of their products in the EU markets (Scharpf 1994; Homeyer 2004). Moreover, environmental process standards are increasingly regulated by flexible procedural regulations, such as the EMAS regulation, that provide for voluntary commitments as well as monitoring and enforcement mechanisms that largely depend on civil society mobilization and awareness on the part of producers. In effect, they have limited potential to alter the initial incentives structures of private actors since they are often of non-mandatory nature (Knill/Lenschow 1999).

Despite intensive pre-accession negotiations and the application by the European Commission, for the first time, of strict conditionality criteria to ensure effective incorporation of the *aquis communautaire* in the candidate states, both the academic community and policy practitioners share the view that effective harmonization will only be possible in the long term (European Commission 2000a). Given these modest assessments, there is a general apprehension that the inclusion of ten new member states will further increase the existing implementa-

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<sup>5</sup> Reports from the Commission estimate the costs of environmental harmonization in the CEECs to range between € 100 and 200 billion.

tion deficit in the application of EU laws and lead to a lowering of EU environmental standards (Baker 2000; Carius et. al. 2000; Homeyer 2004).

How are these heterogeneous adjustment costs and compliance incentives schemes emanating from different components of the *acquis communautaire* accommodated in pre-accession negotiations between the Commission and the new member states? Given the new member states' economic, institutional and administrative disadvantages to embark upon fast harmonization, both the pharmaceutical and the environmental sector can be considered as 'least likely cases' in view of a 'smooth' enlargement. EU pharmaceutical companies have been suspicious about long transition periods in the CEECs, which would keep their higher priced goods out of the new member states which, in turn, would be allowed to export their lower priced products to the internal market. The same holds for other industrial sectors that face competitive disadvantages stemming from lower environmental production standards in the CEE region. This scenario raises the question of what role the new modes of governance based on the inclusion of non-governmental actors (e.g., specialized agencies, firms, NGOs) and non-hierarchical policy instruments (learning, arguing, persuasion) might play in shaping and altering domestic actors' initial compliance incentives schemes.

#### **IV. The Case of the Pharmaceutical *Acquis***

As noted earlier, the White Paper on the Preparation of the Associated Countries of Central and Eastern Europe for Integration into the Internal Market laid down the details concerning the adoption of Community legislation in the case of pharmaceutical and medical products (European Commission 1995: 41-48). Those regulations included the areas of quality, safety, effectiveness and marketing of pharmaceuticals. Notably, the pharmaceutical sector is one of the most standardized sectors in the internal market. Hence, the adoption of the *acquis communautaire* in this area was conceived as a tremendous task for the candidate countries. The pharmaceutical industry is a so-called 'strategic' sector for Europe characterized by a high degree of internationalization and innovation-intensity. The invention of pharmaceutical products depends on intensive investments in research and development (R&D). With regard to R&D-intensity (R&D-investment in relation to turn-over), the pharmaceutical industry sector ranks second behind aerospace. Additionally, pharmaceuticals still provide, by far, the largest positive contribution to the EU's trade balance in high-technology sectors (cf. European Commission 2000b). Multinational companies in EU member states, which invested heavily in the development and marketization of innovative products, feared a significant

economic downturn if the new member states would refuse a thorough application of EU standards.

Despite those big challenges in pharmaceutical regulation, the Commission initially did not develop a particular strategy towards the accession countries. The central negotiator on behalf of the EU was the Commission employing the White Paper as a ‘route-map’ for the implementation of EU pharmaceutical legislation. The Technical Assistance Information Exchange Office (TAIEX) was supposed to provide assistance on Community legislation, its transposition into national legislation, legal terminology, translation, training, and exchanges of experts.

This ‘old’ enlargement approach raised serious problems in the candidate countries as their regulatory structures and drug authorization processes differed significantly from the EU’s, and their institutional capacities to implement the *acquis* were weak. In several opinions on the candidate countries’ application for membership, the Commission emphasized that on pharmaceutical and chemical products legislative alignment was progressing at a slower pace than previously announced.<sup>6</sup>

#### *Designing a New Strategy: Delegation and Institutionalization*

After years of stagnation in the transposition and implementation of pharmaceutical regulations in the CEECs, the Commission – backed by member states and industry – launched a new harmonization approach placing the EMEA at the core of a more institutionalized structure, the Pan-European Regulatory Forum (PERF), in order to assist CEEC institution-building and adjustment to the *acquis communautaire* in pharmaceuticals.<sup>7</sup> This new ‘decentralized’ approach altered the enlargement mode from pure bilateral negotiations between the Commission and the delegations of the candidate countries into a regulatory arena consisting of representatives from drug regulatory agencies, industry as well as consumer and health organizations.

EMEA was established in 1993 as part of a new regulatory system that came into operation in 1995 (Lewis/Abraham 2001). EMEA’s task is to evaluate and authorize medicinal products for human and veterinary use so as to protect public health and facilitate the free circulation of

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<sup>6</sup> In its 1999 progress reports, the Commission still recorded that most of the candidate countries had achieved only a poor level of compliance with the *acquis* with regard to the free movement of goods, especially referring to the pharmaceutical sector (e.g., European Commission 1999a, 1999b, 1999c).

<sup>7</sup> Additionally, the drug regulatory authorities in the associated countries established a formal cooperation in June 1997, the so-called the Collaboration Agreement between Drug Regulatory Authorities in the European Union Associated Countries (CADREAC).

pharmaceuticals in the EU. EMEA is *de facto*, if not *de jure*, a ‘quasi’-decision-making agency as the Commission normally decides upon the recommendations of the agency. However, before reaching its decision, the Commission must consult either the committee responsible for medicinal products for human use (Committee for Proprietary Medicinal Products, CPMP) or the Committee for Veterinary Medicinal Products (CVMP). Member states also have the right to send written observations on the draft decisions of the Commission. However, in order to be effective, the adverse opinions of the two committees, or the member states, must demonstrate that an important scientific issue has escaped the notice of the applicant, the relevant scientific committee of the agency, the agency itself, and the Commission. This is considered to be rather unlikely (Everson et al. 1999: 11).

So far, PERF is a unique institutional arrangement. Following a meeting between the Commission, EMEA and the drug regulatory authorities of the CEECs in November 1997, PERF was established as a ‘structured partnership’ ‘to help the associated countries fulfil the requirements of the White Paper for Technical Regulations in respect of the pharmaceutical sector’ (EMEA 2001: 7). The first phase of PERF (PERF I) ran from September 1999 until September 2000. The programme included 31 working group meetings. PERF II, consisting of 35 meetings, a series of secondments and joint visits, was scheduled to run from June 2001 to August 2002. PERF III, which ran from January to December 2003, finally concluded the process.

PERF was based on cooperation, discourse and learning. The candidate countries were encouraged to ‘examine’, ‘identify’, ‘facilitate’ or ‘advance’ certain needs for accession. EMEA played a specific role within this framework: it served as an agenda-setter by presenting programme proposals and tender documents to the relevant committees, it acted as a mediator by contributing to the finding of compromises in difficult issue areas, and as an advisor to the Commission by monitoring and evaluating the CEECs’ implementation progress. Even more important, through its political independence, its status as a ‘quasi-independent’ agency (Dehousse 2002) and its core role within the European pharmaceutical network, it was able to keep political struggles largely out of PERF, strengthening continuity, stability and accountability in the interaction between participants. Additionally, PERF sought to assist the candidate countries’ regulatory authorities to achieve a ‘smooth’ transition to EU membership by participating in the decision-making process (i.e., the comitology committees) already during the phasing-in period.

At a very early stage, all participants underlined that “considerable achievements in terms of an improved understanding of the pharmaceutical ‘*acquis*’ had been made” (EMEA 2001: 7). This development was supported by two characteristics of the process: first, the discussions were dominated by the technical problems of the candidate countries’ regulatory drug agencies, while national interests seemed to play no role; second, PERF seems to have reduced the mutual uncertainty among actors, while enhancing efficiency through ‘transnational network building’. As a result, the programme has been implemented almost in its entirety within one year. However, remaining problems indicate that ‘regulatory learning’ within networks cannot alone bring about the adoption of the *acquis* in total, but has still to be accompanied by administrative capacity building in the accession countries. In this context, the environmental sector seems to be the best example for implementation shortcomings due to the lack of administrative capacities (cf. Homeyer et al. 2000).

Through delegation and institutionalization the Commission supported a ‘smoother’ enlargement process as compared to the ‘old’ enlargement model of purely bilateral negotiations between the Commission and national executives. The candidate countries ‘learned’ how to interpret regulations within the PERF network whose negotiation mode was based on ‘talking’ and ‘discussing’ in order to ‘explain’ EU legislation. While the Commission did not deviate from the principle that future members have to accept all EU rules (see Avery/Cameron 1998), it showed flexibility with regard to the method of conducting pre-accession negotiations with candidate countries. In the end, the Commission was able to keep the candidate countries’ demand for derogations from the *acquis communautaire* low.

## **V. The Case of the Environmental *Acquis***

Despite recent experimentation with new flexible policy instruments such as voluntary agreements, tradable permits, deposit refund systems and tax incentives, environmental harmonization does not significantly depart from the traditional Community method of regulation, namely transnational cooperation at the stage of policy formulation and decentralization in favor of the national level of implementation (application, monitoring and enforcement). Already from the beginning of the 1990s, this system has reached its limits. The accession of southern European member states (Greece 1981, Spain and Portugal 1986) with weak institutional and administrative capacities and limited or even no prior experience in pro-active environmental policies, coupled with an acceleration of legislative output that followed the launch of the internal market programme have fostered the emergence of a persistent deficit in member states’ compliance with environmental legislation (Börzel 2003; Krislov et al. 1986;

Weiler 1988; Snyder 1993; Mendrinou 1996; Tallberg 1999). The Commission's DG Environment has rather weak monitoring and enforcement capacities compared to other Directorates General, such as DG Competition (Macrory 1996). The Commission's access to information regarding member states' compliance performance depends on a rather weak system that involves three main alerting mechanisms: complaints by citizens, business, environmental NGOs, the Commission's own investigations, and petitions and questions by the European Parliament (Koutalakis 2004).

Given this dependency of the Commission on the strength of exogenous factors of monitoring and enforcement that can actually hinder harmonious and coherent application of environmental legislation across the EU, it is indeed paradoxical that during the pre-accession negotiations neither the core method of enlargement through centralized intergovernmental negotiations nor the issue of decentralization of monitoring and enforcement to specialized agencies were seriously debated. The EEA and other informal types of conflict resolution through horizontal cooperation between national compliance actors, such as the Implementation and Enforcement of Environmental Law Network (IMPEL), manifest a number of deficiencies associated with both core dimensions of new forms of governance identified in the previous sections.

#### *EEA: a Watchdog Without Teeth*

Contrary to the case of pharmaceutical regulation, environmental legal harmonization in the framework of pre-accession negotiations was a domain reserved for CEE state executives and the Commission (Lippert et al. 2001). This proved to be the Achilles' heel of CEEC's preparations for accession since the actors responsible for monitoring and enforcing environmental legislation, such as sub-national authorities, business associations and environmental NGOs, had barely experienced positive lessons leading to domestic institutional and administrative adjustments. Part of the paradox described above lies with the lack of pre-existing decentralized regulatory structures to facilitate, as in the case of pharmaceuticals, participatory policy learning in the framework of monitoring and enforcement of environmental regulations. The EEA has only recently gained momentum in monitoring the application of EU law in the member states, whereas it has no role in its enforcement.

The EEA was created in 1990 as an independent agency, but became operational only in 1994.<sup>8</sup> Its main tasks are to provide ‘objective, reliable and comparable information’ enabling the member states to take the requisite measures to protect the environment, assess the results of these measures and to ensure that the public is properly informed about the state of environment’.<sup>9</sup> In fact, the EEA is an independent agency but with limited decision-making competencies, especially regarding monitoring and enforcement of environmental law.<sup>10</sup> A high quality of information supplied by the EEA is indispensable for all stages of the policy cycle due to the complex, technical nature of environmental problems. However, the agency’s direct involvement at the stages of actual implementation, monitoring and enforcement of environmental legislation at the national level is limited. At best, the agency’s role is confined to technical assistance in relation to practical application by the Commission and the member states of certain legislative measures of a technical nature such as identifying environmental indicators, designing and monitoring reporting systems and methodologies for the application of Greenhouse Gas Monitoring mechanisms, the Habitats, the Water Framework Directive and the Waste Directives (IEEP/EIPA 2003: 48). The same holds for the evaluation of the effectiveness of legislative measures, the review of regulatory approaches adopted by EU institutions and direct support to the legislative process through developing amendments and undertaking cost-benefit appraisals of different policy options (IEEP/EIPA 2003: 46).

Yet, in a policy area where information has increasingly not only a normative but also a regulatory function, the EEA is likely to enhance its relative position in European environmental governance. The development of Environmental Policy Integration Strategies (also known as Cardiff strategies) and the 6<sup>th</sup> Environmental Action Programme’s Sustainability Policy Regime (EU SDS), which both employ methods of open coordination (i.e., establishing performance indicators, deadlines, benchmarks, formal monitoring, reporting and evaluation requirements), are likely to give a new impetus to remedy the EEA’s current weak role in policy formulation and implementation (Krämer et al. 2003).

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<sup>8</sup> Council Regulation No 1210/90 of 7 May 1990 on the establishment of the European Environmental Agency and the European Environmental Information and Observation Network.

<sup>9</sup> Legal autonomy *vis-à-vis* Community institutions and the member states was viewed as an antidote to the failure of traditional legislative instruments establishing mandatory reporting obligations to member states in policy areas such as air pollution, forest damage and quality of waters to facilitate high quality coherent data. According to a 1993 IEEP report both state of environment data and information on national policy measures were either poorly drafted or not submitted at all by member states concerned with the use of such information to initiate infringement proceedings under Art. 226 TEU.

Given the limitations regarding the EEA's standing in European environmental governance, the agency's role in pre-accession negotiations is narrower compared to the experience with the EMEA. The agency was the first EU institution to accommodate the CEECs prior to their accession to the EU.<sup>11</sup> Cooperation between the EEA and CEECs started already in 1996 through a number of PHARE programmes with the aim of improving quality of environmental information through the extension of EIONET (i.e., the network of environmental information) and ETCs (European Topic Centers), both operating under the auspices of EEA, personnel training and the strengthening of administrative resources. Currently there are five ETCs on Waste and Material Flows, Water, Air and Climate Change, Nature Protection and Biodiversity and Terrestrial Environment. They are all located outside the CEEC region, while a number of ETCs established by PHARE on Air Quality, Air Emission and Inland Water were discontinued after the termination of the implementation period of the programme in 2001. ETCs mainly comprise partners from North Western member states reflecting limited tradition and resources of weak member states in integrating scientific expertise into the policy process. However, compared to Southern member states integration of CEEC organizations into the ETCs is impeded by significantly different qualitative weaknesses of their domestic systems of environmental monitoring and reporting. While Southern member states' weaknesses are associated with the lack of credible national providers of environmental information, CEECs have long traditions of technically and scientific highly educated personnel and effective monitoring and data gathering systems (Holm-Hansen 1997). However, effective articulation of environmental data to EIONET is inhibited by the incompatibility of methods and indicators used in national monitoring systems stemming from the different composition of environmental epistemic communities and their weak sectoral integration in pre-existing regional environmental information networks (Jehlicka/Cowell 2003).

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<sup>10</sup> The EEA is a separate body with independent Management Board comprising a representative from each member state normally senior environmental policy officials, two representatives from the Commission's Directorates for Environment and Science, Research and Development and two scientific experts designated by the European Parliament.

<sup>11</sup> Negotiations on enlargement of the EEA were opened in March 2000, and the CEECs became full members in 2002.

*The IMPEL Network: A Watchdog Without Rage?*

Acknowledging the persisting problems of effective application of EU environmental law the European Council decided in 1991 to create an informal network of national enforcement authorities, the so-called Chester Network, renamed IMPEL in 1993. Similarly to PERF, the network seeks to establish horizontal contacts between national enforcement authorities in order to enhance the preparation of measures, consultation and better practical follow-up of legislation and improve consistency in implementation. The initial idea to establish a genuine European environmental inspectorate backed by the European Parliament and the then Commissioner for Environment, Ripa di Meana, was abandoned due to the reluctance of member states to surrender control in such a politically sensitive area (Schout/Claessens 1999: 258). Thus from its outset, IMPEL was a compromise between the European Commission and the member states on the institutional form of standardization of enforcement systems in order to create a 'level playing-field' and to eliminate unequal burdens imposed on industries from inconsistent national enforcement practices.

IMPEL's main objectives are to share information and experiences, discuss problems and offer practical advice, to contribute to a greater consistency of approach between fragmented legislative measures, to promote mutual understanding of the common characteristics and differences of national regulatory systems and to develop best practices and standards of permitting, inspection, monitoring and enforcement of EU environmental law by member states.

IMPEL operates as an informal network with only a small secretariat established in 1997 under the auspices of DG Environment. Its main platform of strategic decisions related to the adoption of working programmes and budgets are the plenary meetings, normally taking place twice a year. These meetings are co-chaired by the Council's 'troika' and the European Commission. In fact, its structure has been the subject of continuous experimentation. Its initial format was dominated by experts dealing with industrial installations and air pollution. It is not surprising that given the evolution of IMPEL along this thematic path, the network was dominated by more experienced enforcement specialists from northern EU member states. IMPEL was initially divided into four working groups coordinating cooperation on technical, procedural and legal aspects of permitting, compliance monitoring and inspection and managing enforcement processes. In 1997, these working groups were replaced by two standing committees specializing in legal policy and legal implementation and in practical issues of managing enforcement respectively. Currently the working group and standing committee systems have been fused into a more flexible project-based structure.

Informality has facilitated the development of mutual trust between national representatives and has served as a necessary precondition for enhancing the network's influence in the legislative process, especially regarding the development of joint views on the coherence, practicality and enforceability of EU environmental legislation, which are often used by the Commission and the Parliament as feedback information in the drafting of new legislative proposals.<sup>12</sup> Given the positive experience from IMPEL, AC IMPEL was created in 1997. AC IMPEL operated as an informal parallel network of enforcement authorities from the ten accession countries. In 2003, AC IMPEL merged with the main IMPEL network. During the five years of its activity, the network has served as a forum for transferring experience and expertise to the new member states through several PHARE projects targeted at training inspectors, the identification of specific problems of each associated country and developing administrative capacities in order to 'smoothen' the legal approximation process as well as a better understanding of the obligations emanating from the environmental *acquis*.

The effectiveness of IMPEL in 'smoothening' eastern enlargements by filling the gap between the adoption of legislation and the actual application has to be assessed in view of other available institutional alternatives. Informality of interactions between participants has facilitated the development of mutual trust and has tapered national tendencies to inhibit information regarding the actual state of domestic compliance capacities. The extent to which this perspective offers a viable institutional alternative to the creation of a truly independent decentralized enforcement agency, such as the US Environmental Protection Agency, still remains an open issue to be re-assessed in light of the first annual reports on monitoring the application of EU environmental law in the new member states.

## **VI. Conclusions and Prospects for Future Research**

This contribution illustrated the extent to which the European Commission relied upon new modes of governance (in terms of actors and steering modes) in order to assist the adoption of and adaptation to the environmental and the pharmaceutical *acquis* in future member states. We showed that with regard to pharmaceuticals, the Commission developed a new mechanism of enlargement representing a process of 'horizontal (regulatory) learning' in a 'transnational policy network' (see Peterson 2003), that is the Pan-European Regulatory Forum. PERF constitutes a public-private-partnership involving (national and European) regulators

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<sup>12</sup> IMPEL's report on Minimum Criteria for Inspections has been one of its success stories since it has served as a basis for drafting legislative proposals and for the work on the Hazardous Waste and IPPC BAT Directives.

and industry representatives. During the PERF process, candidate countries did not only ‘learn’ to understand those parts of EU pharmaceutical legislation which are uniformly implemented in all member states, but also those parts which allow for some flexibility and which are implemented in different ways in the member states. Thus, mutual understanding facilitated the internalization of legal requirements for the effective implementation of EU legislation. At the end of the enlargement negotiations, five out of ten accession countries concluded a transitional arrangement. The conviction that candidate countries have to ‘learn’ how to interpret regulations or directives was clearly a new element in the Commission’s enlargement strategy. The delegation of day-to-day business to a specialized agency was another one. EMEA was an essential part of this approach serving as a network coordinator, agenda-setter and mediator.

In the environmental area, harmonization broadly remained at the stage of the traditional Community method of transnational cooperation (or the ‘old’ mode of enlargement). Consequently, the role of the EEA regarding the pre-accession negotiations was narrower than that of the EMEA. Additionally, until 2003 there was no joint environmental network of experts from member states and candidate countries similar to PERF. IMPEL and AC IMPEL remained separate networks until their merger in 2003.<sup>13</sup> This is a rather less institutionalized approach than that of PERF. In the case of environment, ‘delegation’ and ‘institutionalization’ has never been debated, although the Commission early on recognized the exceptional challenge to the candidate countries posed by EU environmental standards (Baun 2000: 208). Indeed, the outcome of the pre-accession negotiations generates rather sceptical reflections on the actual state of environmental legal harmonization in the CEECs. Despite intensive preparatory negotiations, a total number of 56 transitional periods were granted, the longer of them extending to 2015. These derogations were granted under the condition that they would not have transboundary environmental effects and would not lead to distortions of competition. However, most of them refer to directives where IMPEL has considerable experience and expertise, namely Air Quality (6), Large Combustion Plants (8), IPPC-Bat (4), Urban Waster Waters (10), and Packaging and Packaging Waste (9).<sup>14</sup>

The differentiated pre-accession strategies followed by the Commission in the area of pharmaceutical and environmental regulations raise two central question for our future research

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<sup>13</sup> However, AC IMPEL remains a sub-network with certain distinctive activities, and a separate budget until 2005.

<sup>14</sup> See [http://europa.eu.int/comm/enlargement/negotiations/pdf/negotiations\\_report\\_to\\_ep.pdf](http://europa.eu.int/comm/enlargement/negotiations/pdf/negotiations_report_to_ep.pdf).

agenda: first, why is there so much variation across policy areas? And second, what is the role of new modes of governance for effective policy implementation after accession?

Concerning variation across policy areas, we suspect, first, that pharmaceutical policy is characterized by a more identifiable (and closed) policy community, which has managed to insulate pressures for politicization. On the contrary, environmental policy involves multiple sectors with different actors and a multiplicity of often contradicting interests. Thus, it is comparatively difficult to apply a similar approach to that used in pharmaceuticals. Second, in the case of environmental legislation, member states have been reluctant to sign a blank check assigning monitoring and enforcement responsibilities to an agency that was originally designed to provide ‘only’ information. Delegation would have reduced the member states’ political influence in the negotiation process. Third, the Commission is also reluctant to abolish its gatekeeping role regarding information on the member states’ non-compliance with EU law. The role of the EEA in monitoring and evaluating the effectiveness of existing legislative measures has, especially during the 1990s, been seriously undermined by the Commission (Everson et al. 1999: 108). Needless to say, the most influential reports on the CEECs domestic institutional capacities to effectively adopt the environmental *acquis* were assigned by the Commission to private consultants rather than to the agency.

The role of new modes of governance for effective policy implementation after accession remains an empirical question. In order to assess the ‘political efficiency’ and ‘policy effectiveness’ of new modes of governance, further policy areas and countries (old and new member states) have to be compared to gather a complete picture. In the light of even more ambitious future enlargements (e.g., Romania, Bulgaria, Croatia, Turkey) and the growing need to make EU policies more effective, it is imperative to assess whether the application of new modes of governance requires specific scope conditions, such as a minimum of political and administrative resources (‘shadow of hierarchy’) or even working systems of interest intermediation (civil society, corporatist business-government relations), in the candidate countries.

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