Executive Power in the Making

The establishment of the European Chemical Agency (ECHA)

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Abstract

The EU is gradually expanding its executive capacity through agencies, and some of the newcomers in the agency family have a larger regulatory potential than the previous ones. This paper analyses the genesis of the European Chemical Agency (ECHA), a newly born European regulatory agency. Applying a process-tracing methodology, I analyze the process by which ECHA attained its legal framework, the processes that generated its organizational set-up, and the tensions involved in formulating its mandate. The study ascribes an independent role for institutions that goes beyond seeing functional imperatives as well as rational design as the dominant explanatory factors. The aim is to provide a clearer understanding of factors that lie behind both the breakdown and reproduction of organizational structures. The establishment of ECHA was mediated by and extracted from the pre-existing institutional framework, in particular from the Member States, and administrative continuity or change depended to a large extent on how different resources and capabilities were distributed and validated within the European institutional system.

Introduction

The EU is gradually expanding its executive capacity at the supranational level through agencies. Some of the newcomers in the agency family may be considered to have a larger regulatory potential than the previous ones as they are assigned decision-making tasks and not only tasks related to information-gathering or network management (Gehring 2008). This paper tracks the establishment of the European Chemical Agency (ECHA), a newly born European regulatory agency. ECHA represents a new platform for executive action and an exercise in regulatory centralization, as pivotal administrative functions are now exercised by one European institution rather than many at the national level. The establishment of this organization also implied a shift of coordinating capacity from the Commission to a unit outside its own jurisdiction. How can that be? How and why will an organization that is thought to challenge existing power structures within an institutional system be established?

Using a process-tracing methodology, I analyse the process by which ECHA attained its legal framework, the processes that generated and created its organizational set-up, and the experiences and tensions involved in formulating its procedures and mandate: the birth and making of the organization. The study ascribes an autonomous role for institutions and shows the inadequacy of approaching agency creation as a natural and adaptive reaction to changing conditions. The EU system did not respond automatically with the appropriate administrative innovations once the limitations of the old regime became apparent. There was no organizational solution that was functionally given. The establishment of ECHA was mediated by and extracted from the preexisting institutional framework, in particular from the Member States and administrative continuity or change depended to a large extent on how different resources and capabilities were distributed and validated within the European institutional landscape.

The study of politics and organizations presents different theories of institutional development. Theories of rational and enlightened planning compete with theories of 'environmental determinism' (Olsen 2007: 183-199). In order to make sense of 'agencification', scholars have to a large extent interpreted the development of EU level agencies along functional lines, and much of the agency literature emphasizes the need to increase administrative efficiency, reduce transaction costs in the internal market, easing the workload of the European Commission and allowing it to concentrate on its core tasks (Dehousse 1997, Geradin et al. 2005, Majone 1996, 1997b, Vos 2000, Yataganas 2001). This view has also been reflected in the White Paper on Governance (2001) where the European Commission presents itself as the principal that should seize the opportunity of delegating a share of its more technical tasks

to autonomous bodies, which will assist in operating the internal market (Dehousse 2008: 6). Hence, there is a typically explanatory pattern of these approaches to derive the creation of agencies from administrative and regulatory requirements occurring in the internal market (Borrás et al. 2007). However, this functional explanation is primarily based on the assumption that structure is determined by contextual factors: Structures exist because they match functional needs. It begins with society and portrays administrative change as reflecting functional shifts in the environments (Olsen 2007: 104). Thus, in order to explain how or why an administrative structure comes about, why a regulatory agency comes about, it is not necessary to consider the past, 'the generating processes behind a structure', or the characteristics or resources of the reformers involved (Olsen 1992: 248).

In this paper I argue that we need to go beyond an environmental account in order to explain the genesis of ECHA. ECHA was not created as a natural or automatic response to functional needs, and the agency solution was not functionally given. Different organizational solutions were brought up during the reform process, in addition to different perceptions of the problem, and I argue that in order to explore factors that lie behind both the breakdown and (re)production of organizational structures, we need to give attention to the ways institutions structure the reform process. The main point is that rather than assuming relative efficiency as an explanation, we need to 'go back and look' (Pierson 2004: 47). Hence, this paper ascribes an autonomous role for institutions; below some of the main elements of such an institutional account are spelled out.

An institutional account

Approaching the study of ECHA from an institutionalist perspective means to start from the assumption that 'institutions matter'. The birth of an organization does not start from 'a blank slate' (Pierson 2004: 151). The question is, of course, how and why institutions matter. The institutional perspective as applied in this paper emphasizes the significance of rules, procedures and norms in structuring political action (March and Olsen 1989). Institutions prescribe how political authority and power are constituted, exercised, validated and distributed (Olsen 2008b: 194). They integrate and structure a political system, organize actors, issues and resources, and structure patterns of political struggle (Egeberg 2006, Olsen 2008a, Schattschneider 1975). An institutional account emphasizes endogenous forces for change, and portrays institutions 'as having lives and deaths of their own, sometimes enduring in the face of apparent inconsistencies with their environments'(Olsen 2007: 106). As actors invest in a specific institutional

arrangement, as it becomes infused with value and meaning 'beyond the technical requirements of the task at hand'(Selznick 1957: 17), they have incentives to protect their investment. According to Pierson (2004: 160) if we know which elements of an institutional arrangement constitute important investments for which sets of actors, we are more likely to be able to identify which kinds of revisions they would consider acceptable or problematic. Hence, revisions of a political system will often be constrained and channeled by previous institutional choices, and concepts like 'historical inefficiency' and 'path dependence' suggest that the match between environments and institutional structures is not automatic and precise (Olsen 1992, Pierson 2004). New governing arrangements, like EU level agencies, do not arise reflexively or automatically in response to new conditions or functional needs. Instead, they are often extracted from and mediated by the pre-established framework of institutions (Skowronek 1982). Thus, existing institutions matter, and being first on the institutional scene often confers important and enduring advantages as each step along a particular path produces consequences that increase the relative attractiveness of that path for the next round (Pierson 2004: 18).

As the idea of path-dependence is central in order to understand why institutions 'are not plastic' and 'do not adapt swiftly' (Pierson 2004: 156), it serves as an important starting point for our analyses of the birth of ECHA. However, as we are concerned with the making of an organization that in several ways represents innovation, we need to take an additional step. As noted by Streeck and Thelen (2005: 24) '[t]here is nothing automatic about institutional stability [italics added] – despite the language of stasis and stickiness often invoked in relation to institutions'. We need to understand why some elements of a given institutional arrangement are (or are not) sticky, why some aspects are more amenable to change than others. As we recall, institutions prescribe how political authority and power are constituted and distributed (Olsen 2008b). Any given set of rules or expectations – formal or informal – that creates patterns of action will have unequal implications for resource allocation, and some institutions distribute resources to particular kinds of actors and not to others (Mahoney and Thelen 2009: 10). Power works through institutions (Orren and Skowronek 2004: 125), and a central assumption explored in this paper is that the way an organization is extracted from, and processed within, an institutional system depends on how different resources and capabilities are distributed within that system and whether these resources and capabilities can legitimately be applied among and within the different institutions involved. Those who have invested in existing arrangements may have a clear preference for continuity, but ensuring such continuity requires the ongoing mobilization of political support (Mahoney and Thelen 2009: 11); they need validation from outsiders, and lack of

validation and support 'can spur deinstitutionalization and disintegration' (Gornitzka 2007: 5).

In this paper on the birth and making of ECHA it is argued that some existing administrative structures were more amenable than others, and the institutional rules and resources faced in the course of the establishment process left important marks on the result. The very short version of the ECHA story reveals that the Commission initially attempted to preserve and expand its own regulatory capacity, and parts of the Commission demonstrated a large degree of path dependence and institutional resilience to the agency model. However, being first on the administrative scene was not enough when the financial situation and the distributive consequences of expanding existing structures were spotlighted. The lack of necessary financial resources and external support in the EU system activated internal conflicts and the breakdown of existing organizational structures. The European Parliament, which had gained increased capacity in the EU system partly through the last treaty revisions, pushed the new arrangement in a more supranational direction. The increased recognition of the European Parliament as a co-player in agency design gave this institution a key role in the process.

The structure of the paper is the following. First, I have a note on methodology and data. Second, I describe the old European control system for chemicals and the new REACH framework. Third, I trace the establishment process and discuss how we can explain the genesis of ECHA, how we can understand and make sense of what happened from the inception in Brussels until its birth in Helsinki. As I am applying the institutional framework outlined above, my analyses hinge not only on identifying the institutional system and the different rules and procedures, but in particular the internal distribution of resources, authority and power within and between the different institutions involved. How much influence is located in specific positions and roles and the resources available 'for those who occupy institutional command posts' (Olsen 2007: 15) before, during, and after the changes in question. As I try to go beyond an environmental deterministic account, I also need to consider the alternative paths through which the administrative system could have occurred. To what extent was the agency solution functionally given? Finally, I discuss what kind of institutional change ECHA represents and its potential to actually transform how powers are allocated and linked within the new European multilevel polity.

A note on methodology and data

The aim of this study is to examine how and why ECHA came about within the EU institutional apparatus by providing a clearer understanding of factors that lie behind the breakdown and/or reproduction of existing organizational structures. In order to do this I am chronologically tracing the legislative process in Brussels (from 2001 until 2006), and the preparatory process in Helsinki (from 2007 until 2008) by which ECHA obtained its mandate, organizational shape and internal procedures. The data from this process is drawn from two main sources: first, different official documents that include Commission white papers, the first Commission legal proposal on REACH, and different EP and Council positions emanating from the co-decision procedure. It also includes working programmes and reports from the preparatory work in Helsinki. All these documents are easily accessible on the EU and ECHA websites. [1] Second, I apply interview data from seven semi-structured interviews with key people involved in the establishment process from the inception in Brussels until the organizational birth in Helsinki. Thus, the interview data are drawn from key informants rather than from a wider sample of interviews in order to reach a more fine-grained explanation (Checkel 2008) on why the ECHA came about. Four former Commission officials now working in ECHA and three officials from different national regulatory agencies were interviewed in this respect[2]. Thus, I apply a combination of informant interviews and documentary evidence. The goal is to carefully map the temporal order of the various events by connecting the dynamics within the EU institutional apparatus to the final outcome and providing a more complete explanation of not only what happened, but also why it happened and consider the alternative paths through which the system could have occurred (George and Bennett 2005: 215).

The old regime for chemicals control in the EU and REACH

The latest important revision of the EU rules pertaining to chemicals was made in the late 1970s. Through this revision, a separation of old and new chemicals was introduced whereby chemicals introduced after 1981 were defined as new, and chemicals introduced before 1981 where defined as

[1]It can be noted that since EP amendments are shown in bold it is easier to track the successive changes in these documents than in the Council documents.

[2] We should be aware of a possible imbalance in the interview material as the majority of the informants are former Commission officials.

'existing'. Market access for new chemicals was granted through a notification process where national regulatory authorities were the pivotal actors, and a single notification would be recognized by all Member States. Importers and manufacturers submitted technical dossiers to the national authorities, which were in charge of checking the completeness of the file and circulating it to the Commission and the other Member States for review. However, for chemicals that were already in circulation, the imposition of information supply and testing requirements was considered too onerous and potentially disruptive to the economy. Hence, during the first decade after notification duties were introduced, EU law did not foster information supply concerning existing chemicals in a systematic way (Heyvaert 2008). To address the problem of new and old chemicals, the Council adopted the Existing Substances Regulation (793/93). Pursuant to the Existing Substances Regulation, manufacturers and importers were to report all available data directly to the Commission. The various submissions were collected by the European Chemicals Bureau (ECB) established under the auspices of the Joint Research Centre Environment Institute (JRC), which processed everything into an EU-wide database. The information then constituted the starting point for an evaluation and priority-setting exercise by national authorities under the auspices of the Commission (Heyvaert 2008: 189).

It is clear that the old regime was institutionally dominated by national authorities, in the first place national regulatory authorities. National authorities administered the notification process, performed risk assessments for new substances, acted as rapporteurs for existing ones post-1993, and through the process of Council amendment, were intimately involved in the negotiation and adoption of new restrictions. The Commission also played a prominent role, as JRC and ECB orchestrated the data-gathering and evaluation regime under the Existing Substances Regulation, and formulated and adopted the harmonized classifications for dangerous substances (Heyvaert 2008: 189).

On 1 December 2006, the European Parliament and the Council of Ministers agreed on a compromise text on REACH, the new regulatory framework for the control of chemical substances in Europe. REACH stands for the Registration, Evaluation, Authorization and Restriction of Chemicals. The regulation established the European Chemical Agency (ECHA), and it provides a regulatory framework that enables information production and decision-making relating to all chemicals circulating in the EU market. To this effect, REACH imposes a generalized registration requirement: Manufacturers or importers of chemicals produced or imported in volumes of over one tonne per year must apply for registration, with the condition that a data file

supplying health, safety, and environmental information will be submitted. [3] ECHA is responsible for managing all registration dossiers and undertakes dossier evaluation (i.e., a compliance check and evaluation of testing proposals). REACH also foresees an authorization system aiming to ensure that substances of very high concern are adequately controlled. Substances subject to authorization are included in a specific annex of the Regulation. Once they are included, the industry will have to submit applications to ECHA to obtain authorization for continued use of these substances. Finally, the Commission will head the decision stage of the authorization process. It will formulate a proposal on the basis of the opinion delivered by ECHA, which is finally adopted in comitology.

With the new procedures mapped out in REACH a new and more centralized institutional set-up to manage the regulatory framework of chemicals in the EU has been established. Most importantly, ECHA functions as the chief administrator of the scheme. Pre-market control is the dominant regulatory mechanism, and from the differences between pre- and post-market regulation, variations result in the obligatory involvement of the Agency at the first stage of the decision-making process (Krapohl 2004). Whereas previously Member State national authorities were the first point of contact with private parties complying with EU regulatory requirements, and thus the chief liaison with Community authorities, applicants for registration directly submit their applications to ECHA. In the case of applications for authorization, applicants submit to ECHA, which then orchestrates the scientific review of the application, and drafts a recommendation for the Commission. National regulatory authorities however do have an opportunity to be involved in the identification of substances for evaluation, and perform the task of substance evaluation through the Risk Assessment Committee. Additionally, the Member States are formally represented in the Member State Committee, the Management Board and in the Commission decision-making through the channel of comitology.

I will return to the shape of the multilevel polity in the last part of the paper. The following sections review the main features of the preparation and negotiation process prior to the adoption of the REACH Regulation. What happened? How and why did it happen? What is the significance of what happened? The Commission White Paper on the Strategy for a Future Chemicals Policy (2001) serves as the formal starting point of the process.

[3] Registration extends previous data-reporting requirements for the industry significantly. Most importantly, registration targets the roughly 30,000 chemicals which have been traded in substantial volumes within Europe for almost 30 years, but for which no information has been available (Pesendorfer 2006).

The Commission strategy: Building upon existing structures

In its White Paper on the Strategy for a Future Chemicals Policy (2001) the Commission outlines the outcomes of a review of the current control system and its new strategy for the registration, evaluation and authorization of chemicals in the EU. The Commission indicates that the new control system for chemical products requires the creation of a "central entity" which is foreseen as playing a key role in the administration of REACH. The appropriate format of the "entity" was then considered to be the European Chemicals Bureau (ECB), a part of the Joint Research Centre (JRC) at Ispra (Italy), which would need to be enlarged to take on the extra tasks. The expanded ECB should be a receiving body for the registration dossier, and forward the dossiers to the Member States, establish a central database on registered chemicals and perform spot-checks of the registered substances. Depending on the anticipated impact of a substance, an authorization for actual use should either be granted by Member States or by a decision at the community level. Hence, the Member States authorities would broadly retain their current responsibilities within the new system. They would be responsible for substance registration and evaluation, similar to their current responsibilities for new substances notifications, as well as checking the application of REACH within their own territories. They would also be able to suggest restrictions on the use of substances based on a structured risk assessment where they consider when EU legislative action is necessary.

Taken together, the White Paper indicates a careful and small step away from the current administrative structures, introducing a double set of procedures depending on the anticipated impact of a substance. Moreover, it suggests expanding the system within the existing Commission structures, more specifically within one particular DG: the JRC. The Council gave its opinion on the White Paper in its Conclusions June 2001 and the Parliament adopted a report on the White Paper November 2001. Both Council and Parliament endorsed the Commission's objectives outlined in the White Paper. However, in its first legal proposal on REACH the Commission suggests the establishment of an independent agency outside the Commission's formal jurisdiction. We will look at this proposal in the next section in addition to exploring some of the reasons why the Commission left the JRC "entity" behind.

The Commission's legal proposal: An agency in from the cold

The Commission proposal (COM 644 final) was transmitted to the European Parliament and the Council in accordance with the co-decision procedure November 2003. In its proposal the Commission suggests establishing an independent agency foreseen to work in partnership with ECB and national authorities in order to operate the REACH system. However, how these institutions are to work together is not clear. The proposal requires authorities to examine proposals for testing. Furthermore, it gives authorities the task of checking compliance of registration dossiers, and substance evaluation provides a mechanism for an authority to require the industry to submit more information in cases where risk is suspected. Thus, the Commission is reluctant with regard to (explicitly) granting tasks and competences to the Agency, and suggests a rather vague evaluation and authorization procedure. The Commission outlines several reasons in the proposal in order to explain why it is a good thing to establish an independent agency. According to the Commission, '[s]ubsequent enquiry has raised serious doubts as to whether an enlarged ECB would be the most effective structure to meet the much increased demands of the new system. The Commission therefore undertook a feasibility study. Having carefully examined all elements, the Commission concluded that the establishment of a separate Agency is essential for the effective implementation of the proposed REACH system'. The Commission also refers to the White Paper on European Governance (2001), 'which notes that regulatory agencies: improve the way rules are applied and enforced across the Union as well as increase the visibility for the sector concerned. The existence of a separate, independent body provides a clear focus for discussions and so raises the profile of the sector, as well as has an advantage in drawing on highly technical sectoral know-how. The Agency will be a key player in ensuring that the system has credibility with all stakeholders and the public.' Hence, the Commission's arguments are to a large extent in line with the functional approach mentioned earlier in this paper: Regulatory agencies are able to meet efficiency requirements occurring in the internal market, in addition to increasing accountability and credibility in providing a clearer distinction between politics and administration (see e.g. Majone 1996, 1997a, Vos 2000).

The White Paper on Governance was drafted and published the same year as the White Paper on the Strategy for a New Chemical Control system. It seems a bit puzzling why the Commission did not bring up the White Paper on Governance and the well known arguments on efficiency, legitimacy and credibility in the first place. How can that be? What happened within the Commission in the interim period? In the following we will look at some

unofficial reasons highlighted by key Commission officials involved in the process.

Lack of resources and internal conflicts

According to the informants one of the main reasons for proposing an "entity" within the Commission itself was that the JRC already played a role within the policy field and had a considerable stake in preserving and expanding the use of existing structures. To have the tasks allocated within the ECB under the auspices of the JRC would ensure a permanent core activity for the DG. The JRC wanted to refocus and stabilize their activities which had been in a state of flux for many years. Hence, the JRC seized the opportunity to increase its resources and organizational capabilities. The JRC had also invested heavily in the ECB in building up procedures and training people in managing the Existing Substances Regulation. The JRC wanted to keep these people, and the people involved were not interested in moving to a different place. They demonstrated very strongly that they wanted to stay in Ispra.

Moreover, according to the informants there was no willingness in the European Parliament or within the Member States to grant the Commission the appropriate resources to do the necessary tasks within the new chemical regime. As the Commission's budgetary rules are poorly constructed for financing its activities through fees from the industry, the financial situation was spotlighted. It was clear that an independent agency in contrast to the Commission could collect fees from the chemical industry and manage to be self funded. This financial concern was in particular voiced by DG Enterprise and Industry (ENTER), the founding father of another regulatory agency: the European Medicines Agency in London (EMEA). The EMEA had been established by DG ENTER in 1993, and it was able to be self funded through fees from the pharmaceutical industry. DG ENTER pinpointed this agency when the financial foundation of the JRC "entity" was hanging by a thread: 'You have an agency that actually works; it is independent, it collects fees and it is able to finance its staff. In a nutshell: it is possible!' (Interview 1 July 2008)

In addition, DG ENTER was fundamentally more positive to an agency model than the other DGs. It was tuned towards the functioning of the internal market and particularly concerned with the competitive conditions for the chemical industry. The industry's view was that it was better to have one agency in one place that makes consistent decisions rather than a complex and fragmented setup within the EU. JRC had a quite different approach. They were fundamentally afraid of losing out in the EU system, afraid of losing their position. However, JRC was perceived as a weak DG, and when the

financial question was brought up, their arguments about stability and continuity started to lose status outside their own circles. According to the informants, the other policy DGs 'did not care much for JRC's internal cuisine' (Interview 2 July 2008). Thus, for the Commission, lack of financial resources and external validation activated internal conflicts among the DGs. When JRC was losing out, DG ENTER, which was perceived as a more powerful DG than JRC internally, and had more political backing externally, had the possibility to promote the independent, self funded EMEA model. In order to avoid a situation where people physically had to move, the Commission suggested the Agency be situated in the same place as ECB in Ispra, Italy. [4]

The EP: Ensuring influence

From 2003-2006 the REACH proposal was progressing through the legislative process for its adoption by the European Parliament and the Council. The European Parliament adopted its opinion in a first reading November 2005. In the amended proposal, the Agency has a greater responsibility with regard to evaluation, the smooth running of the system and monitoring decision-making. The procedures are restructured and made clearer. The term 'authorities' is replaced by the term 'agency', and the double sets of procedures and responsibilities are deleted. The Agency alone is responsible for dossier evaluation, and the EP is also suggesting that the Agency should be responsible for the substance evaluation and the job of drawing up the list of priority substances for evaluation. To perform the substance evaluation the Agency could rely on bodies designated for that purpose by the Member States.

The EP is also amending some of the decision-making procedures in a more supranational direction. In addition to decreased national representation and increased EP representation in the Management Board, it suggests that the Member State Committee should reach agreement with a qualified majority instead of reaching a unanimous agreement as proposed by the Commission. The comitology procedure shall be in accordance with the so-called 'regulatory procedure with scrutiny'[5] instead of the 'advisory committee

[4] In 2003 it was decided that ECHA was to be located in Helsinki. This decision was made at the level of the heads of states as part of a package deal between the Finnish and Italian governments.

[5] Council Decision 2006/512/EC amending Decision 1999/468/EC laying down the Procedures for the Exercise of Implementing Powers conferred on the Commission.

procedure'[6] as suggested by the Commission. The 'regulatory procedure with scrutiny' responds to demands for greater EP involvement because it is the sole comitology procedure where agreement between the Commission and the consulted Committee of national representatives does not automatically result in adoption of the Commission proposal. Instead, even Committee-approved proposals are forwarded to the EP and the Council 'for scrutiny', and institutions may oppose the proposal by a simple (EP) or qualified majority (Council) respectively (Heyvaert 2008: 194). [7] One of the key people from DG Environment involved in the negotiations describes the process in these words:

So the EP got their way. It was difficult to insist on not giving in. The new procedure had just been adopted in order to strengthen the power of the Parliament. Then it would have been very difficult for the Council to say 'sorry we don't want you involved in any of this'. It would also have been very difficult for the Commission to argue against it (Interview 1 July 2008).

Taken together, the Parliament used its increased capacity in the EU system to press for a more supranational agency with simpler registration/evaluation procedures and more Parliament-friendly decision-making procedures. It is not surprising that the EP wanted to strengthen its own influence within the ECHA setup, but why did it push the agency in a more regulatory direction? According to the informants, on the one hand the European Parliament was lending its ear to the chemical industry which was critical both to the White paper and to the first Commission proposal (see also Persson 2007, Shörling 2004). Their starting point was not environmental concern but dissatisfaction with a system that they found too bureaucratic and complex (Pesendorfer 2006). The industry aimed for a simpler institutional setup, a one-stop shop for chemical product control. Another element for the European Parliament was that a supranational agency could decrease the influence of the Commission and Member States. The perception was that a strong agency would imply an additional player in the administrative landscape and challenge existing power structures within the policy field.

[6] The Commission is bound to take account of the advice of a committee of Member State representatives, but it has the authority to adopt its proposal even in the face of a negative committee opinion.

[7] According to one of the informants, the EP has already used their newly won comitology power within REACH. In the first comitology decision with scrutiny, they blocked the Commission's proposal and forced the Commission to withdraw the proposal (Interview 2 July 2008).

The Council: The logic of compromise

In accordance with the Parliament's opinion of December 2005, the Council reached a unanimous political agreement on a common position under the UK presidency. Not surprisingly, the Council ensures the principle of unanimity in the Member State Committee, and the composition of one representative from each Member State in the Management Board. However, the Council goes to considerable lengths to support the EP proposal. It accepts the comitology procedure with scrutiny and the simplifications of the decision-making procedures within the new control system. The Agency alone is responsible for the dossier evaluation and responsible for coordinating the substance evaluation process. The double set of procedures and responsibilities suggested by the Commission and deleted by the EP are left behind.

What happened behind the scenes in the Council? The EP amendments clearly pointed in a more supranational direction, which naturally caused some tension among the national representatives. As the scrutiny procedure was newly adopted, the Council could hardly argue against the use of this procedure. A more open question among the representatives was the substance evaluation procedure and the question of national involvement. On the one hand, some countries, including France in particular, wanted ECHA to take over the whole procedure as suggested by the Parliament. For them it was mainly a question of costs. It was cheaper to make the Agency perform the scientific evaluation rather than their own experts since the salaries are paid by industry fees. On the other hand, the countries that had played an important role under the previous legislation were most reluctant to grant the agency evaluation competence: Sweden, the Netherlands, Germany and Denmark. These countries thought that they would lose work and influence if ECHA took over the job. In the words of one of the informants: 'In the past the greatest amount of work was done by the Member States, however you view it' (Interview 2 July, 2008). For the UK the most important thing was to obtain political agreement on REACH. It was essential for the British government to get the proposal through during the UK presidency, and there was a common understanding in the Council that if the REACH negotiations went beyond the UK presidency, it would become much more difficult to find a final agreement. Thus, the national representatives were willing to compromise in order to find a political solution on REACH,[8] including the role of the ECHA.

[8] It should be noted that this paper addresses the establishment of ECHA and not the general development and negotiations of the REACH regulation. In order to get a fuller picture of REACH, the legislative journey of the draft regulation and the different political interests at stake, both in the EP and the Council, see e.g. Pesendorfer (2006), Hansen and Blainey (2006), Heyvaert (2008) and Persson (2007).

In the Common Position the national regulatory agencies are to play a more prominent and integrated role in the evaluation procedure than prescribed by the EP, mainly through the different committees coordinated by ECHA. The formal Common Position of the Council was approved in June 2006, a step that paved the way for the second reading of the proposal by the European Parliament, and final adoption by the end of 2006. In the next section we leave Brussels and look at the organizational preparations in Helsinki.

Preparations in Helsinki: Cut and paste

Primo 2007, thirty seven people seconded from the Commission were sent to Helsinki in order to build up the Agency. Essential steps in setting up the Agency were recruiting and training staff, establishing standard operating procedures and preparing the Agency's committees. The officials had a legal obligation in the REACH regulation to be done within six months, and the officials had to work fast. The mission was to get ECHA up and running as quickly as possible. During this period, the procedures for the different committees were to a large extent copied from the EMEA and the other EU level agencies in addition to the rules of procedures for the EU comitology committees. Models for internal administrative rules were taken more or less directly from the Commission, and the standard operating decision-making procedures for the Agency were primarily copied from the EMEA.

We have been Platonizing from the existing world. The procedures for the other agencies are quite easily accessible on the Internet. Our agency is quite similar to the agency in London. It is quite handy because you can contact a colleague in the EMEA and ask how you are running these kinds of things. There has been an enormous time pressure. If we did not have the existing models, it would have been impossible to do it (Interview 1 July 2008).

Thus, the establishment of ECHA implied dependence on the Commission officials to furnish it with organizational capabilities, procedures and guidelines. It also implied dependence on the Commission to furnish it with human capital. In the words of a former Commission employee:

It is possible that the Member States have a slightly more reserved attitude towards the newborn baby since it is such a Commission creature. But these matters of principles are not awfully important if the things are not done and resources are not received (Interview 2 July 2008).

The birth of ECHA: Inter- and intra-institutional dynamics

Environmental accounts begin with society and portray institutional change as a functional solution to a given problem or need (Olsen 2007: 104), and within the agency literature there is typically an explanatory pattern to derive the creation of agencies from administrative and regulatory requirements occurring in the internal market. In the White Paper on Governance (2001) and several other official position papers, the European Commission is in line with this functional approach. It presents itself as the principal that should seize the opportunity of delegating a share of its more technical tasks to autonomous bodies, which will assist in operating the internal market (Dehousse 2008: 6). However, in this paper on the birth and making of ECHA we have seen that the perception of the Commission as happily reliving it self of the technical tasks to a technical body in order to be able to concentrate on important political matters is not an accurate description of the reform process nor of the final outcome. At least the birth of ECHA appeared as a more complex, ambiguous and multifaceted process than this where the different institutions left their marks upon the result through the process. The different institutions pursued different goals and had different perceptions of what the administrative arrangement should look like. As noted by Olsen (2007: 105) multiple and conflicting goals are often pursued in the EU institutional landscape, and there is no shared understanding of administrative requirements and possibilities, and no single central reorganization authority.

Looking back, there was no solution that was functionally given. Different organizational solutions were present, and the empirics reveal that the power struggles that ensued among and within the different EU institutions seeking to gain or maintain their institutional role and position played a prominent role with regard to the final result. We recall that the Commission initially attempted to expand its own capacity within its own structures, and parts of the Commission had a considerable stake in preserving and expanding the use of existing structures. The JRC had invested heavily in the ECB and felt threatened by the establishment of an agency outside the Commission's framework. In addition, people living and working in Ispra (Italy) were emotionally attached to this place. As actors invest in a specific institutional arrangement, as it becomes infused with value and meaning 'beyond the technical requirements of the task at hand' (Selznick 1957:17), they have incentives to protect their investment. Mechanisms of self-reinforcement and path dependency make institutional structures 'sticky' (Pierson 2004). The existing institutional setup of the Commission proved to be sticky in the very first phase of the negotiation process. However, as noted in the introduction to this paper, the stickiness claim may resonate more under some conditions than

others, and ensuring continuity requires the ongoing mobilization of political support.

We recall that the Commission did not receive any external support when the power-distributional implications of expanding existing structures were spotlighted, and eventually, the power struggles and lack of unity within the Commission itself became apparent. Distributional effects and budgetary starvation tend to make conflict and change more likely (Olsen 2008a: 15) and may trigger divisions among institutional power holders (Mahoney and Thelen 2009). The Commission is not a unitary actor (Egeberg 2005), it contains different institutions with different goals and different logics of action, and these differences easily rise to the surface when resources and position are at play (Cini 1996). When JRC was losing out, DG ENTER, which was perceived as a more powerful DG than JRC internally, and had more political backing externally, seized the opportunity to promote the EMEA model. Thus, for the Commission, lack of financial resources and external validation activated internal conflicts and resulted in institutional disintegration and organizational breakdown. On the other hand, the increased recognition of the European Parliament as a co player in agency design gave this institution a key role in the process (see also Kelemen 2002). We recall that the European Parliament was on the offensive and was able to push the Commission's proposal forward in a more regulatory direction and reallocate resources in ways that increased its own influence within the new polity. Within the Council, the rationality of 'give and take', of integrating and connecting different views and concerns, reaching a compromise solution, had primacy. An essential part of this compromise solution was the integration of existing national regulatory structures within the ECHA framework, ensuring elements of institutional continuity within the new administrative setting. Hence, through the legislative process, through inter- and intra-institutional tensions, different (possible) structures came to be rejected, reflected and reconnected to the same organization. Taken together, by pointing at the interplay of several institutions as a source of both organizational breakdown and (re)production, this discussion has highlighted a source of internal dynamism which studies only focusing on environmental requirements are unlikely to capture. In Orren and Skowronek's formulation (1994: 321 quoted in Pierson 2004: 136) 'The institutions that constitute the polity… abrade against each other and, in the process, drive further change.'

Institutional adaptation

In the post-adoption phase the logic of decision-making was somewhat different than during the legislative process. The Commission was now solely

in charge, and the checks and balances of the EU system were less salient. Hence, the Commission could work fast, playing the role of a hardcore executive, without being interrupted by political obstacles. As suggested by Olsen (2008b: 195) 'there may be more or less time for analyses' and 'established concepts, schemas, and scripts allow actors to ignore or resist new evidence' (Olsen 1992: 255). In the post-negotiation phase, when the political light was dimmer and the time pressure higher, the Commission could easily work in a bounded manner, ignore alternative models and such for convenient arrangements 'in the neighbourhood' (March 1994: 28). Existing administrative structures were copied and transferred to the ECHA polity by someone who were familiar with these structures and perceived them as appropriate and satisfactory. Thus, the ECHA set-up and internal procedures were born in the shadow of local institutional structures by the pragmatic midwifery of the Commission.

In summary, the institutional forms and procedures through which the system of chemical regulation in the EU had been working would not simply give way to a new administrative arrangement as soon as its limitations became apparent. ECHA had to be negotiated and reflected through institutions, between institutions and in the shadow of institutions. Taken together, rather than assuming relative efficiency as an explanation for change or path dependency as an explanation for continuity, this study highlights the need to have a closer look at the pre-existing institutional framework, and in particular how resources are constituted, distributed and validated within that framework.

Concluding remarks: New wine in old bottles?

ECHA represents a new platform for executive action at the supranational level, and we have seen that the establishment has entailed a transformation of the previous regulatory regime for chemical control in the EU. Theoretically, I have argued that we need to move beyond a functional explanation and take endogenous dynamics of change into account in order to understand the making of this organization. I have also argued that we need to move beyond 'stickiness' and path dependency and take the power-distributional implications of an institutional system into account (Mahoney and Thelen 2009) in order to better understand both the breakdown and reproduction of organizational structures. By the same token, I want to underline that neither the self funded, regulatory agency model nor its organizational setup appeared 'from a blank slate' (Pierson 2004: 151). The European Medicines Agency (EMEA) served as an important role model, and its structures were adapted and transferred to ECHA by DG ENTER who was familiar with these

structures and could treat them as 'self-given' (Olsen 2008c: 18). We have also seen that existing national regulatory structures were carried over from the past to be reestablished within the ECHA polity by the member states, resulting in institutional layering and succession (Quack and Djelic 2005: 275). Thus, despite its novelty, the establishment of ECHA was in several ways path dependent and was 'closer to bricolage – recombining institutional fragments – than to ex nihilo creation' (ibid: 2005: 274). This finding of agencification as a result of institutional bricolage and path dependency rather than rational design is also pinpointed by Kraphol (2004) who shows that several EU level agencies have evolved from existing EU committees and adopt most of their structures, like the European Food Safety Authority (EFSA) and the European Medicinal Agency (EMEA). Other scholars have highlighted how the Council has left its marks upon agency creation in securing intergovernmental management procedures as well as integrating national regulatory authorities in the committee frameworks (see Christensen and Nielsen 2008, Dehousse 2008, Gehring and Krapohl 2007), as we have also seen in the case of ECHA.

Even if national regulatory agencies are to play a prominent role within the ECHA polity and formally represent continuity, the scene has shifted, and it is not evident that these agencies will safeguard 'a microcosm' of national control. National agencies may potentially serve several purposes (Egeberg 2003), and what Thelen (2003: 226) calls institutional conversion refers to situations where 'existing institutions are redirected to new purposes, driving changes in the role they perform and/or the functions they serve'. In the ECHA polity, national agencies are being recoupled into new configurations through the ECHA committees, and these shifting patterns of communication can affect the relationships and relative dependencies between the actors involved. The regulatory agencies of the Member States usually act at arm's length from direct political intervention in their daily business, and the officials adopt stronger sectoral allegiances than their colleagues in the ministries (Christensen and Lægreid 2006, Egeberg 2003). These sectoral allegiances may actually be amplified in a European setting as the language of expertise becomes the most valid means of communication (Gehring and Krapohl 2007, Martens 2008a). Metcalfe (2000: 36) notes in his case study of the EMEA that participation 'helps consolidate a professional identity among regulators at the European level. Representatives meet frequently with professional colleagues in a context where matters of common interest and shared problems are discussed that transcend national preoccupations' (see also Krapohl 2004). Hence, national regulatory agencies in the ECHA setting will not necessarily play the role of an intergovernmental guarantee or ensure the principle of national administrative sovereignty (Hofmann and Türk 2006). They could in the long run rather become part of, and defender of, the supranational autonomy of ECHA and contribute to transform how powers

actually are allocated and linked between the different levels within the policy field. One of the seconded Commission officials puts it this way:

We are going more in a direction of the real stuff, where the agencies have an important role, we are going away from the cozy little 'discussion agencies' on how to improve the life of workers to real decision-making agencies which are there to ensure that there is a real common market, and that the rules are the same all over Europe, with teeth and with real impact (Interview 1 July 2008).

Nevertheless, ECHA is a newly established regulatory agency, and even if it is clear that it has a larger regulatory potential than previous European agencies, it is too early to draw any firm conclusions with regard to how the organization will work, how its different parts will develop and to what extent it will be able to actually transform existing power structures in the EU. Becoming a living institution (Olsen 1997), becoming a living agency with a distinct role and identity in the EU institutional order takes time (Martens 2008b). It is hoped that future studies will tell us more about the actual implications of bringing this organization to life in the EU institutional landscape.

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