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## **Better regulation by new governance hybrids?**

**Governance models and the reform  
of European chemicals policy**

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## 1 Introduction

Present regulatory decision-making at the European level is characterised by a growing diversification of regulatory approaches. This diversification is reflected in a similar broadening of modes of decision-making. Especially in environmental policy, the traditional sectoralised approach of law making on the basis of the Community method has been supplemented and sometimes substituted by new governance approaches, including “soft-law” approaches, reflexive assessments, devolution, co-regulation or integrative approaches of decision-making (Pallemaerts 1998; Héritier 2003).

These governance approaches are intended to improve the quality and efficiency of European regulation and often claim to lead to “better regulation” (European Commission, 2001), while adopting a more consensus oriented and participatory style. Expectations are great: economic aspects should be taken more seriously into account, member states and the private sector should be granted more flexibility and autonomy alike and knowledge should be adopted on a much broader basis.

However, while the limitations of traditional regulatory approaches are widely accepted and cited, it is far from evident whether or not the “new modes of governance” have a greater problem solving capacity than the old ones, which is often taken for granted. Conceptualising the differences between old and new governance approaches is quite a prominent topic at the moment. However, as we argue, this discussion needs to be refocused to a certain extent: new regulation is also quite often a combination of most of the new forms and more traditional forms of governance (hybrid regulation). Approaches of such hybrid regulatory governance increase the challenge of understanding present decision-making at EU level. And they raise the question of the performance of the interlinkages and effective combination and constellation of the different governance modes.

The ongoing reform of the European Chemicals Policy (Registration, Evaluation and Authorisation of Chemicals, REACH) is a very good test case in this regard. Chemicals control is currently a playing field for substantial and procedural innovations of European governance, spurred by the policy failure of the existing regulatory approach: Despite the fact that chemicals play an important part in nearly every aspect of our daily live and despite the fact that there are stringent testing requirements for new chemicals our knowledge about the effects of most chemicals on human health and the environment is uneven, sometimes even poor.

The reason is that the testing and registration of chemicals within a cooperative assessment process (Koch 2003) so far has been cumbersome. Whereas obligations for producers to deliver data where weak, authorities had to prove negative im-

pacts on human health and environment in a detailed risk assessment process – often described as “paralysis by analysis”. Capacity overloads, however, have led to severe delays. REACH intends far-reaching changes in the regulatory framework of chemical control. The European Commission tries to shift the burden of responsibility from public authorities to a system of shared responsibilities between public authorities and chemicals industry. Finding the right balance between regulatory control and private self-regulation is the key challenge in this regard.

In this context, the REACH process is interesting in several ways. The European Commission tries to combine different governance approaches, i.e. governance by information, obligatory self-regulation, command-and-control, cooperative devolution and proceduralisation, which alone makes the reform an interesting topic to study. However, the institutional design to arrive at a regulation inhibits also many institutional innovations, i.e. depillarization, mainstreaming or internet consultation. REACH is of high relevance for competitiveness, consumer protection, health and environmental protection concerns. The lobbying pressure by EU member states, industry associations and environmental NGOs has been and is immense. The mixture of governance mechanisms is the attempt to satisfy the magnitude of involved interests in order to increase decision-making capacity.

For policy evaluation it is interesting to assess the effects of such rather unorthodox combinations: can REACH serve (a) as a model for a creative new combination of governance modes that may open a more realistic and promising perspective for the design of governance options in other policy areas and (b) as a model for the organisation of interest mediation in highly contested policies?

Our argument is that hybrid models of governance have the potential to strengthen decision-making capacity and to improve legitimacy, effectiveness and implementation especially in a very contentious and high profile cases. However, the analysis of the reform of the European Chemicals Policy indicates that a careful design of the interlinkages between the governance modes is of crucial importance, and was not given sufficient attention in this example case. Both the decision-making process and the regulation itself offer multiple arenas for conflict-oriented and cooperative stakeholder strategies. Stakeholders antagonistic to the REACH system may use those arenas for “venue shopping” in order to undermine the functioning of the system.

This paper is organised as follows: In the next chapter we briefly reflect the discussion on old and new forms of governance in EU environmental policy and scrutinize their respective strengths and weaknesses. Chapter three briefly introduces the proposed REACH reform. We analyse to what extent different governance approaches interact within the institutional and regulatory design of REACH and how they match with the interests of involved actors. A main concern

of interest relates to the analysis of strategies of venue-shopping by different actors and their impact on the policy process. The paper ends with a preliminary overall assessment of the potentials of new hybrid regulation to improve the problem-solving capacity of European environmental governance.

## 2 Old and New Forms of Governance in EU Environmental Policies

The analysis of the different modes of European regulatory governance has received much attention among scholars throughout the last years (see: Heritier et al. 2003; Knill, 2003; Börzel, 2002; Knill and Lenschow, 2000; Scharpf 1999, 1997). Already the diversity of terminology used by different authors indicates the complexity of the issue. In a way, the attempts to conceptualise different modes of governance have even led to more confusion than clarification. Partly, this is due to the fact that modes of regulation and decision-making strongly overlap and thus are quite difficult to distinguish.

In a nutshell the governance discussion deals with changes in content and process of European decision-making, one could argue:

- *Changes in content*: i.e. the concrete choice of instruments which reflect different levels of obligation and discretion both for member states and target groups,
- *Changes in process*: i.e. how European policies, programmes and delegated processes of standard setting are developed.

Both choice of instruments and choice of process design are intrinsically inter-linked: Devolution and cooperative instruments also require an open and cooperative policy process in order to create early ownership and support by those who implement. On the other side rule based standard setting or the use of economic instruments, often leading to distributional conflicts, may require a more autonomous regulatory state imposing requirements against opposing target groups.

Before fleshing out changes in content and process, one needs to take a step back and ask how good governance turns out to be in practice. In this context, one is quickly led to the distinction by *Scharpf* regarding criteria of output- and input-legitimacy (Scharpf 1999). Since then, many scholars have embarked on the challenge to define suitable criteria to evaluate good governance against (e.g. Wolf 2002, Montpetit 2003). As regards a practical operationalisation for the further discussion of the strength and weaknesses of the different approaches of European Environmental governance, we focus on output-legitimacy criteria such as (cf. Knill and Lenschow 2003):

- The extent of capacity to take political action
- The actual degree of implementation
- The actual degree of achieving the original policy objectives.

This reflects only one evaluation dimension since no criteria for input-legitimacy are explicitly used (cf. Scharpf 1999; Abromeit 1998; Knill and Lenschow 2003). But as shown above, at least for certain instruments, output legitimacy strongly correlates with input legitimacy: a policy process not considered as legitimate by target groups, may face obstacles both in the decision-making and the implementation process. Only in an idealised majority voting model input and output legitimacy might strongly fall apart, as majority decisions may be taken against the will of very strong minorities.

## 2.1 Changes in content: Modes of governance and the choice of instruments

*Regulatory standard setting* has been the dominant governance mode of the past 30 years of the EU (Holzinger 2003). It entails the setting of detailed, obligatory substantial and procedural standards which prescribe action required from target groups. Typical examples are emission limit values, permitting and reporting requirements, quality values triggering certain actions, or the prohibition of certain activities. Their enforcement is based on a hierarchical model of top-down steering. Norm compliance is reached by means of coercion. The level of obligation thus is high, hence the level of discretion for Member States and target groups is low.

In contrast, the so called *new-instruments* show a similar high level of obligation but also a high level of discretion either for Member States or for target groups. It is a more indirect, more incentive based approach rather shaping the context where target groups take decisions than directly controlling their decisions. This group of instruments comprises framework legislation, economic instruments (such as taxes or emissions trading) and communicative instruments (such as information rights or access to justice) (cf. Knill and Lenschow 2003; see Hey et al. 2005). The predominant steering mechanism is setting incentives to initiate behavioural changes, but within a clear defined framework of action. Coercion as a steering mechanism is therefore also relevant.

Framework directives often combine legislative initiatives and define a working program that is further addressed through daughter directives, through delegation of regulatory tasks to different types of committees or Member States. Thus, framework legislation is supposed to contribute to the relief of the European legislator and to a streamlining and reduction of the volume of European legislation (Demmke 2001). Economic or informative instruments are also supposed to work



in this way: By changing incentive structures, behavioural changes and voluntarism is triggered and objectives will be reached more easily.

*Self-regulation* concerns cooperative governance arrangements with industry, including the delegation of rule and standard setting to private actors such as industry associations and the development of voluntary agreements of industry. In both cases regulatory responsibility is shifted to private actors that operate, however, in the “shadow of hierarchy”. Normally objectives are negotiated and hence reflect the interests of the target groups. Thus, the level of discretion may be high and the level of obligation low. The predominant steering mechanism is incentive-setting. However, due to the fixed objectives, coercion still is a relevant mechanism in case of failure to deliver the objectives, as is learning, because the framework for action is relatively broad.

The *Open Method of Coordination* (OMC) is an iterative process of setting guidelines and benchmarks at the European level, adopting regulatory responses at the national level whose effects will then be evaluated in the light of the agreed benchmarks (Zängle 2004). It is not of relevance for our further analysis.

## 2.2 Changes in process: Modes of governance and decision-making

So far, the dominant mode of decision-making has been the traditional Community method with its formalised decision-making rules and established consensus finding procedures. The three key institutional actors in this process are the policy-initiating European Commission and the co-deciding European Parliament and Council. The Community method has been enriched by extended phases of policy consultation with stakeholders and Member States that are mainly coordinated and moderated by the Commission, by increasingly complex sub-legal implementation processes including industry, NGOs and Member States, and by increased efforts to ensure implementation. But the Commission, Parliament and Council remain to be the decisive centre of decision.

The respective decision-making capacity is impressive. Especially in the period between 1996 and 2003 a comprehensive system of modern environmental law was completed. Generally, European environmental policy must be considered a success story of international cooperation (see for a literature review: Hey et al. 2005; Hey 1998, p. 257ff). Despite considerable variation in the quality of the individual pieces of environmental legislation a high level of protection requirements could be achieved, which was - in general - closer to the level of the pioneering countries than to the level of the laggards. Environmental policy-making could in many cases successfully avoid the “joint policy making trap”, the policy stalemate caused by a few national veto players (see: Héritier et. al. 1994; Eichener 2000).

There are several reasons for this success story. The EU has developed effective mechanisms for the diffusion of national environmental policy innovation (Héritier et al. 1996; Andersen and Liefferink 1997; Knill and Lenschow, 2005), such as spill-over effects from internal market regulation to environmental regulation that opened up opportunities for regulatory competition. With its initiation monopoly the European Commission disposes of considerable agenda setting powers and has frequently used the rich pool of national environmental policy innovations to find the best model for its own proposals. The wish to be a credible global negotiation partner as regards international environmental regimes is another driving force. The Council has developed negotiation mechanisms and tools to find agreement, despite of different national interests (Eichener 2000). National environmental ministries tried to overcome opposition at home by forming alliances at EU level. The European Parliament, especially with its personalised and sector committee based internal deliberative processes, has frequently been a hurrier for stronger environmental requirements (Kreppel, 1999, 2002; Tsebelis and Kalandrakis 1999; Tsebelis et al. 2001; Kasack 2004). The co-decision procedures proved to allow dynamic consensus finding between the three European institutions.

The Community method, with its hierarchical element of binding and enforceable regulation, has considerable potential as regards political capacity and political effectiveness, especially in the case of demanding policy problems such as redistributive policies, institutionally deeply entrenched problems which risk persistence or prisoners dilemma situations requiring binding implementation in order to avoid free-riding (Heritier 2003).

The success story, however, has its shortcomings. The most serious problem of the Community method is the implementation deficit that has persisted on the European agenda for quite a long time (Metcalfé 1992; Mendrinou 1996; Knill and Lenschow 1998). Implementation deficits can be less strongly felt in the case of internal market linked product standards than in the field of monitoring and reporting requirements, procedural law and programming (Demmke and Unfried 2001; Lübbe-Wolff 1996). Related to the poor implementation record are significant problems to achieve the original policy objectives. Despite the fact that certain emissions from stationary sources could be significantly reduced and that the overall quality of the environment has improved in many ways, current environmental outlooks of the OECD (2003) or the European Environment Agency (2004) point to a number of unsolved persistent problems and many deteriorating long-term trends such as climate change, biodiversity loss or groundwater contamination.

Furthermore, there is an obvious failure of environmental policy integration (see: EEA 2005, Lenschow 2002). The structure of environmental problems has

changed from pollution by installations towards pollution by diffuse sources. Problem-solving strategies thus require the changing of harmful sectoral market or policy trends (EEA 2005). Steps towards environmental policy integration (EPI) have been rather unsuccessful so far due to the compartmentalised structure of EU policy making (Hey 1998, 2002). Pillarized policy networks tend to externalise issues and problems that do not affect their key concerns. Reaching an agreement within a sector at EU level alone is regularly a challenging task, requiring the accommodation of often conflicting interests. Whenever possible, integration demands from other sectors are disregarded. Strategies for EPI therefore ask for mechanisms of better horizontal policy coordination. Such capacities are, however, regularly underdeveloped since modern bureaucracies are steered around sectoral and not horizontal norms and objectives (Jacob and Volkery 2004).

The new governance approaches, which are officially on the Commission agenda since the Governance White Paper (2001), aim to overcome these problems by launching a search for more non-legislative solutions and increasing the hurdles for new legislative proposals, but also by strengthening the power and responsibility of Member States and private actors in policy formulation and implementation. The approaches rely more on networks and voluntary action than on hierarchy, more on national responsibility than on EU harmonisation, more on non-governmental participation and responsibility than on state action (Héritier 2002, 2003). The basic rationale for strategies of "soft law" (Pallemarts 1998; De Sadel-eer 2002) is to provide for an overarching framework for a bundle of consecutive actions. They are intended to provide for common orientations for diverse actors. They are also building blocks for the fight over the hegemony over competing concepts of policy making, they help to legitimise measures already in the policy pipeline, keep contentious issues on the policy agenda and are part of a packaging and unpacking approach for measures, which might otherwise be dropped from the policy agenda.

These strategies are part and parcel of a more complex and holistic policy management approach of the Commission, which reaches beyond individual legal instruments adopted via the Community Method (SRU 2004; Hey et. al. 2005). At the core of those strategies is a target setting process together with those actors who have to take responsibility over implementation. By their early participation it is expected that political support for the targets, hence political and participatory capacity are strengthened (Héritier 2003, p. 108). Critics, however, argue that soft-law strategies risk having a bias of "talk without action", that rises high expectations, but fails to deliver substantial results (IEEP 2004a).

Of increasing relevance in this context are the new reflexive assessment mechanisms (Heinelt et. al. 2000), namely the introduction of impact assessments. Originally a sustainability impact assessment was intended to become a tool for

stronger coherence between Community policies and for better environmental policy integration (European Commission 2004a and b). In every case, impact assessment is intended to become an additional critical check on the appropriateness and proportionality for any proposed new environmental legislation. In practice, a combined model tends to be applied with a wide range of institutional settings from ad-hoc internal coordination to a sophisticated multi-stakeholder process reviewing extensive scientific evidence (Owens et al. 2004).

Impact assessments offer private actors the possibility to intervene very early in the decision-making process. They create a new arena for policy deliberation, where the power of the better argument might influence the shaping. Early consultation can improve the available knowledge, help to identify problems such as unintended side effects and thus strengthen the overall quality of regulation. But it can also change the character of policy-formulation within the European Commission from technocratic problem-solving of Commission officials to either political bargaining with Member States or argumentative deliberation with stakeholders. Empirical evidence has identified the risk that there is considerable pressure especially by business and related government departments to soften targets and that transaction costs to achieve specific targets are high (Héritier 2002).

We find the same pros and cons with regard to the delegation of regulatory tasks. Delegation occurs within a wide spectrum of institutional approaches that ranges from purely intergovernmental committees, over mixed structures to the widely private models of standardisation (Voelzkow et. al. 2002). Optimistic positions claim that the dominant governance mode within such bodies is argumentative deliberation and bargaining (Risse 2004; Héritier, 2003). Thus, the power of the better argument may eventually strengthen the influence of actors with less material resources, as it has been shown for international networks (Risse 2004). Critical positions, however, counter these assumptions as over-idealistic and over-generalised, pointing out that this argument holds stronger under the conditions of a strong global normative consensus (e.g. human rights) than on fundamentally more contentious issues such as the balance between precaution and competitiveness. It also may be stronger in "evident" cases than in cases where one actor has a relative informational advantage. Furthermore the relevance of deliberation relative to other forms of interactions should not be overemphasized. Informal mechanisms of socialisation into a common group identity, consensus strengthening and conflict avoiding behaviour can be frequently expected (see: Eichener 2000; Sartori 1997; Töller 2002). The social pressure for consensus may work against dissenting minority views.

The success of devolution depends on the quality, preciseness and ambition of the normative reference framework (the mandate), the composition of participat-

ing advocacy coalitions, the orientations of the informal or formal process leaders, the relative distribution of informational resources and bargaining power of actors, and informal and formal decision making and conflict solution rules. In general, networks work better for distributive or efficiency increasing issues or for complex and highly uncertain problems, where preferences are open for modification on the basis of growing evidence (Héritier 2003).

In total the success of new modes of governance depends on the type of problems and a number of context and situation specific factors. Informative, distributive, technical issues and unstructured problems seem to be more suitable for the new modes of governance than re-distributive issues or solutions for Prisoners Dilemma situations. Care has also been given to the institutional design, composition of participants and mandates. If this is not taken into account in their framing, the resulting policy may lack effectiveness or risks to be captured by powerful interests and hence to fail in terms of political legitimacy.

### 3 REACH – Experimenting with Mixed Governance Models

#### 3.1 The old approach of EU chemical control and how REACH changes it

The current system of European chemical control aims at producing information about the effects of chemicals on human health or the environment. Where risks are identified, several steps can be taken ranging from labelling obligations to the restriction or even the prohibition of use. The most important aspect of the control regime is the distinction between so called “old” and “new” substances. “Old” chemicals are those chemicals that have been marketed in the EC before 1981 when the EC Regulation for chemicals control entered into force. The “old” chemicals number about 100,000. They account for approximately 99% of all chemicals marketed. While “new chemicals” have to be notified and tested (and quite extensively for volumes above 1 tonne per year), there are only few provisions for testing of “old” chemicals. Information is required on high volume existing substances but the public authorities have to determine for which substances additional examination is required. Furthermore, the testing has to be performed or commissioned by the authorities.

The public authorities are overburdened with this task. Out of 100,000 existing substances only a few hundred have been completely assessed, also because there are insufficient incentives for manufacturers and importers to provide the authorities with necessary data. Some efforts have been taken to set up voluntary and cooperative schemes for a testing, however, the efforts have been particularly

slow (e.g. Jacob 1999). Since users of chemicals are not required to gather and to provide information as to what they are applied for, there are in particular no reliable data on exposure paths. It is estimated that, given the speed of evaluation, risk evaluations for the 4,000 most problematic existing substances will not have been completed until the year 3000 (SRU 2002). In addition, the time-consuming process of issuing substance restrictions delays the implementation of control measures. The encompassing testing requirements for “new” substances have inhibited research and development and encourage the use of “old” substances, with all the problems of lack of data.

After years of preparation, the Commission presented a new strategy for European Chemicals control in its White Paper in 2001 (CEC 2001). It took two other years to present an official proposal for a regulation (CEC 2003). The intended changes are far-reaching: So far, the burden of proof that the use of chemical substances implies a risk to human health or environment lies with the public authorities. In future, industry has to demonstrate that the chemicals substances do not pose any major risks. Failing to do so they are not allowed to market the substances. The reform intends to accelerate risk management and phase-out of substances of special concern with a new authorisation procedure. The reform furthermore imposes an obligatory system of chemical safety management over the whole production and use-chain of chemicals. The extended requirements for testing and registration of chemicals increase the costs of chemicals production.

The new strategy consists of three main phases: *Registration, Evaluation and Authorisation of Chemicals* (REACH):

*Registration:* In the registration phase, manufacturers and importers have to gather information on the properties of substances and submit registration dossiers to a central data base. This procedure applies to all substances marketed above a certain threshold (1 t/year), a number of 30,000 substances is expected. Only those substances that are registered are allowed to be marketed. Depending on the volume and on intrinsic properties, different testing requirements are imposed. If no data are submitted, marketing will be prohibited (No Data-No Market Rule). The database will be managed by the new European Chemicals Agency. To be registered, applicants have to deliver information on intrinsic properties and hazards (e.g. eco-toxicological, toxicological). Data have to be provided on the application of the substances in order to estimate the exposure. In case downstream users use the substances for other purposes than they have been tested for, additional testing is required. For volumes above 10 tonnes/year a chemical safety report is required, for volumes below chemical safety data sheets will be necessary. Registration follows a phased approach, with registration deadlines being set according to volume of the substance on the market and hazard.

*Evaluation:* Public authorities in the Member States evaluate data submitted regarding the necessity of animals testing, if proposed, or if there is reason to believe that the substance poses a risk to the environment or human health. This is required for chemicals which are produced or imported in quantities of more than 100 tonnes/year or which have certain dangerous properties (chemicals that are mutagenic, that are extremely toxic, that are highly persistent or are highly bioaccumulative, or that have molecular structures that give reason for concern). Evaluation might require the applicant to provide additional information.

*Authorisation:* An authorization procedure is to be introduced for particularly hazardous chemicals “that give rise to very high concern”. Authorisation of use will be granted by authorities only if it can be shown by the producer/importer that risks of use can be “adequately” controlled or socio-economic benefits outweigh risks. Authorization is required for carcinogenic, mutagenic or reprotoxic substances (CMR), for substances being persistent, bioaccumulative or toxic (PBT) or for substances being very persistent or very bio-accumulative (vPvB) or for substances with endocrine disruption effects.

For imported chemicals as well as products that contain a considerable amount of chemicals, the same testing requirements were demanded. The planned regulation is likely to have impacts on chemical industries in countries where risk management is based on liability, because producers can be taken accountable if there are information available on potential risks (Jacob et al. 2005).

In first instance REACH seems to be a last piece of traditional command and control type regulation, including strong re-distributive elements at the expense of chemical industry and aiming at faster and more effective control of hazardous substances. A closer look however leads to a different assessment. REACH also operates widely with the new modes of governance. It strongly relies on self-regulation, especially as regards the chemicals safety management. It relies on devolution as regards the specification of a rather generic and procedural legislative framework and as regards the strong role of stakeholders in the preparation and implementation of the system. Deliberation and hierarchy are combined in a complex system. The following section explores this combination in greater detail.

## 3.2 The governance approaches of REACH

### 3.2.1 Combining regulated self-regulation and regulatory standard setting

In total, the REACH-system consists of

- mechanisms for *public risk communication*, potentially enabling markets, consumers or the wider public to react to substances of concern

- *obligatory self-regulation* of producers as regards chemical safety and appropriate risk management along the value chain (*learning, coercion*)
- *traditional regulatory core*, relating to obligatory requirements for delivering data and the possibility for substance restrictions,– however, moderated by cooperative forms of preparing a decision (*cooperation, coercion*)
- *cooperative proceduralisation and devolution*: The Commission Proposal only establishes a framework of basic rules and procedures. This framework is in need of further standards, operational criteria, procedural guidance etc. So REACH launches a cooperative process to fill the overall framework with life (*learning, incentive*).

The instruments of direct steering by regulatory standards setting are only applied for obligatory data creation and for substances of very high concern. For such substances authorisation and restriction provide for possibilities to impose risk management measures, to restrict certain uses or to prohibit substances. It is evident that such interventions are only feasible for a minor part of substances. In the view of 30,000 substances produced in quantities of over 1t/a and of multiple uses for each substances within disperse and complex value chains any regulatory approach aspiring to manage all substances by central control would either fail due to information and capacity overload or lead to under-informed, hence inefficient and disproportionate risk management requirements. Complexity hence forces government to set priorities according to level of concern.

The assumed normal case of REACH is self-regulation on the basis of producer responsibility. Producers in cooperation with the users of the substances identify the level of "adequate control" and the appropriate quality of risk-management. Where needed, they are even in first instance responsible for classifying the substances into different categories of danger. They have to do this on the basis of harmonised procedures and obligatory aspects to be considered – similar to an environmental management system. However responsibility remains within producers and downstream users. So the core of REACH is an obligatory environmental management system related to chemicals safety, which can be classified as a form of regulated self-regulation.

Transparency rules together with increased knowledge also allow the wider public to pull the emergency break by publicly scandalising certain substances or their uses (Gleich 2002; Jacob 1999). It is evident that such a mechanism will only be applied in exceptional situations where both self-regulation and governments fail to respond to justified concerns. However, self-regulation and regulation take place in the shadow of institutionalised public attention.

Each of the different governance modes seems to improve effectiveness and efficiency. The hierarchical model is limited to situations where it is indispensable.



It hence carefully utilises scarce resources. The general rule is self-regulation within given standards. Information hence is generated and utilised decentrally offering wide discretion to manufacturers and users and at the same time allowing for learning processes.

How are these modes of governance interlinked? Traditionally self-regulation in the shadow of hierarchy (Voelzkow 1996; Prittwitz 2000) is based upon a specific incentive structure. The government intervenes only if self-regulation fails. This creates an incentive for producers to avoid government intervention and to safeguard a high level of discretion by delivering the agreed objectives.

The incentive structure of REACH is inverse: if self-regulation functions and producers signal concern, public authorities or the wider public will intervene (Führ et. al. 2005; Calliess 2003). In other words: producers have an incentive to underestimate risk in order to avoid outsider intervention into self-regulation. This seems to be a key governance problem of REACH. The regulation is partially addressing this problem by establishing a system of random check by dossier and substance evaluation for high volume substances and certain prioritised substances in order to ensure compliance, high data quality and plausible risk assessments by producers. But it can be doubted that such mechanisms create sufficient incentives for a precautionary and risk averse assessment and management practice by producers. Markets, the wider public or authorities will only discover the most obvious substances, but not the majority of "grey" cases. So far, attempts mainly by the German government to introduce a quality assurance system into the registration process within REACH in order to counterbalance this counterproductive incentive structure have failed.

### 3.2.2 Devolution and proceduralisation of complex risk decisions

Legally speaking REACH is a regulation, i.e. it does not need to be transposed into national law (Krämer 2003: 50f). However, REACH is actually a framework regulation that leaves many political questions to the discretion of the bodies created for implementation. REACH provides for a general framework of principles, rules and procedures for the many decisions of the different national and European institutions, especially as regards controlling and approving the registration dossiers, the evaluation decisions, the authorisation and restriction of substances. Most of the principles and rules are established in general terms with a need of specification before they can be practically applied.

Key issues for further specification are for instance:

- the exact information requirements for the information chain between producers and downstream users, especially as regards the level of detail of substance uses and exposure categories;

- the exact criteria under which producers may be exempt from delivering data (e.g. acknowledgment of available tests and other information sources, reading across substances, irrelevant exposure);
- The requirements for data sharing between producers of the same substance;
- An operational definition of "adequate control", which is the essential precondition for authorisation;
- Methodology and level of detail of the risk-assessment and the socio-economic analysis, which is part of the authorisation system.

The estimated cost of REACH can vary considerably according to the type of answers to such questions (see: Ahrens et al. 2005; Ostertag et. al. 2004). Costs will be high under a "worst case" hypothesis of an information maximising bureaucracy, but they can also be considerably reduced under cooperative and benign conditions. Risk Assessment and management decisions may have severe consequences for an individual producer or even, if they set the benchmark for further decisions, consequences for the industry as a whole.

REACH foresees several bodies and institutions, which are supposed to prepare such frameworks (see: Breier and Hendrix 2004), namely:

- A European Chemicals Agency, with the task of coordinating and organising the overall work (The Committees on Risk Assessment and Socio-Economic Analysis preparing decisions- on authorisation and restriction)
- A clearing committee to solve disputes on Risk Assessment and Risk Assessment
- An information exchange forum on the implementation of the regulation
- A committee of competent authorities together with the Commission making the decisions on restriction.

It is a key feature of the governance of complex risk decisions, that regulators are reluctant to prescribe exactly the level of acceptable risk (Köck 2003; Fisher 2000). This is normally done with generic terminology, such as "adequate control". Instead, they restrict themselves to define the procedures to come to a risk management decision and the roles and the composition of the preparing and deciding networks. The "administration of risk" (Köck 2003) thus is up to a wide discretion of experts judgement. This devolution of risk decisions to expert networks raises, however, concerns of legitimacy and effectiveness:

- *Legitimacy concerns:* Uncertainty and ignorance are widely discussed as key problems of decisions-making based upon expertise (Weale 2001; Godard 1997; Wynne 1992; Rasmussen 1998). If truth becomes uncertain and disputed, sound scientific evidence as basis of the rational-technological model becomes scattered (Owens et al. 2004). And risk related science necessarily is controversial. But also the deliberative model of "negotiated knowledge" by inclusive pluralistic participation of all interested parties may raise the prob-

lem how to reconcile opposing conceptual frames of participants and to aggregate different views in a decision (Owens et al. 2004). There is scepticism that such a clash of values may be properly managed only by inviting stakeholders, but excluding the wider public (Weale 2001; Abromeit 2002; Toeller 2002).

- *Effectiveness concerns:* Recent research on the functioning of Comitology shows that committees are fairly effective in resolving technical issues, in collecting evidence and in applying general norms. However, the consensus principle and the principle of mutual trust can meet their limits if less technical issues are at stake that require a political decision and thus a legitimised majority decision (Toeller 2002).

As shown above it is far from evident that all decisions that need to be taken to implement the REACH regulation are only technical in nature. Therefore it might be an unfortunate construction that the specific operationalisation and application of the generic legal standards (such as adequate control) has to be dealt with by the same bodies that prepare and hence essentially shape the risk related decisions. While this allows for a learning process on how to manage REACH best, it creates the risk that networks designed for cooperative implementation of the overall framework may be overburdened with solving highly contentious and hence political issues. Bringing the conflicts of the decision-making process into the cooperative implementation arenas hence would put the smooth functioning of the system, hence its implementation at risk.

### 3.3 Making and Preparing the Regulation

The making and preparing of the regulation is characterized by an interesting blend of cooperative and antagonistic arenas. Whereas within the cooperative arenas participants tried to reconcile conflicting objectives or even to identify synergies, the more conflict oriented arenas were used by industry-related coalitions to undermine or even to attack the regulation.

Within the making of REACH a number of institutional innovations can be observed which effectively created the multiple arenas for stakeholder venue shopping (Richardson 2001), arenas for cooperative policy development with the Commission and Council and some cooperative impact exercises. The European Parliament, some public hearings and the internet consultation, and some advocacy-oriented impact assessments were the arenas for more conflict oriented strategies.

Accordingly one can observe upward and downward cycles for the regulation, depending on which arena has the leading role in the process. Generally successful politicisation led to substantial losses compared to original plans – whereas the

cooperative exercises tended to stabilize and inherently improve the original proposal from the Commission.

### 3.3.1 Depillarization in Commission, Council and Parliament

REACH is not simply an environmental policy designed and prepared by the environmental policy community. From the very beginning, it has been an integrated policy with joint responsibility of economic and environmental ministries and respective narrow coordination mechanisms. A key innovation of the development of the REACH proposal is the systematic depillarization of the policy. In the past, chemicals policy was a segmented policy sector, partly under the control of DG Environment, especially as regards the notification of new substances and the risk assessment of some 141 priority old substances. Classification and restriction however was under the responsibility of DG Enterprise. Decision-making in Council and Parliament was segmented respectively.

#### *A joint proposal:*

##### *Negative coordination and some joint problem-solving in the Commission*

In order to form one single and consistent system of chemicals assessment and control as it is intended with REACH the -historical - segmentation of responsibility had to be overcome. The responsibility for preparing and proposing REACH became a joint responsibility of DG ENV and DG ENTR. Both prepared jointly the White Paper (CEC 2001) and the final proposal (CEC 2003). The challenge of this joint project was to merge two different agendas in order to develop a proposal with shared ownership.

DG ENTR was primarily concerned with avoiding an increase of costs due to unnecessary testing requirements. Another key concern was to relieve the testing burden for new chemicals, as this was perceived to be an innovation barrier and a competitive disadvantage vis a vis the other trade blocks (Fischer 2000). Finally, DG ENTR was keen to maintain the risk based approach of chemicals control, which would require extensive analysis of exposure, identification of critical concentrations – as well as identification of hazard.

The agenda of DG ENV and namely the Swedish Commissioner Wallström was to strengthen the use of the precautionary principle. Chemicals policy was a key concern of Sweden, which as consequence of its accession had to risk conflicts between national substance restrictions and internal market requirements. Furthermore during the 90s the precautionary principle had become a major issue in international environmental politics (O’Riordan and Jordan 1995). Bio-accumulating and persistent substances had been found in fish and marine mammals in high concentrations. These were worrying findings because such mammals are at the end of the food chain. Regulation of those “old” chemicals

should be eased. Another motivation was to clear the "burden of the past", i.e. the thousands of substances already placed on the market for decades, without proper knowledge about their properties, their potential hazards and their uses.

The 2001 White Book can be interpreted as a compromise deal between the two DGs: DG ENTR got the intended deregulation for new substances and could safeguard a risk based control system against a purely precautionary approach of regulating chemicals on basis of intrinsic properties (Nordbeck 2005). DG ENV got an effective registration mechanism for roughly 30 000 existing substances, with a strong sanctioning mechanism, according to the no-data – no market rule. Precautionary elements were cautiously introduced in the proposed regulation, as a clear signal was given that certain substance properties are cause for concern. However, the idea of demanding the substitution of very hazardous substances had to be given up, quite early.

This proposed regulation implies considerable costs to chemical industry, downstream users and importers of chemicals. Nevertheless the compromise contains some symmetry, as each DG could win one key issue while it had to compromise on an other. The compromise hence was attacked by industry and environmental NGOs, while criticism of industry was stronger.

A price for the joint preparation is the structural conservatism of the proposal. The proposal is very much path dependent, e.g. as regards the volume based testing regime or the neglect of obligatory testing requirements for issues of concern. More radical deviations, as suggested for example by the Royal Commission on Environmental Pollution (RCEP 2003) could not be put on the agenda. The RCEP proposed a radicalised priority setting system in order to better control PBT-substances based upon modelling. Such a radicalised system was not compatible with the regulatory trajectory of a volume based testing regime.

In terms of political process the advantage of this joint proposal was for long time its relative robustness. Officially DG ENTR now had to defend also those elements of the proposal, which it lost – even though it was frequently tempted to leave or to undermine the compromise. Industry hence lost for many years a key partner within the Commission for undermining the reform and had to look for other coalition partners. Eventually however, in the view of changed political constellations, DG ENTR joined the industry coalition by late summer 2005 and hence pushed for a strategy shift of the Commission against its own original proposal. In between industry coalitions only found support within the European Parliament and by heads of state (see below).

*Depillarization in the Council: the search for less cost for the same level of protection*

Pillarization is especially strong in the Council formations. Since the British presidency in 1998 several presidencies tried to hold joint Councils. In most cases joint Councils only could have a symbolic function, as the adopted joint resolutions on Transport and the Environment or Agriculture and the Environment, while at the same time legislative dossiers were negotiated in the sectoral formation. When the Commission proposal came out in October 2003, the Italian Presidency, being critical on the proposal, decided to hold the Competitiveness Council responsible for negotiating the dossier. This also found support by several prime ministers, who insisted in letters to the President of the Commission on a leaner system, which would not be a threat to competitiveness (Lind 2004).

The competitiveness Council however is not simply the Council of the ministers of Economic Affairs, who normally defend the key concerns of their respective national industries. The Competitiveness Council is a horizontal formation, with variable composition depending on the dossier. Sometimes several national ministers participate in a Council session, each being responsible for the respective dossier on the agenda.

In Germany, for example, the institutional responsibility for the dossier lies with the Environmental Ministry. Hence, the environmental ministry still was the lead ministry for coordinating the national input into the EU negotiations. A membership analysis of the Competitiveness Council negotiating REACH shows that also other countries had delegates from environmental ministries. In practice, a new negotiation mechanism between environmental and economic ministries was established at Council level. This applies especially for the Council working groups, which prepare Council sessions and try to separate technical from political issues to reduce the number of items to be decided upon at COREPER or minister level (Fouilleux et. al. 2005).

Due to the pluralist membership negotiations in the Council working groups focused on issues which promised to deliver at least the same level of protection at lower cost. It is also interesting that, while making suggestions in that direction, new partnerships between new and old Member States emerged. The most prominent example for that is the British-Hungarian proposal for a registration procedure based upon the "one-substance-one-registration" principle. This approach requires obligatory cooperation of producers for the identification of intrinsic substance properties e.g. by in vitro or in vivo testing. According to estimates this proposal might save up to 30% of registration cost. Germany launched an initiative to establish standardised exposure categories, which would ease documentation of uses along the value chain between producers and downstream users and help the identification of uses of concern within the Chemical Safety

Reports. There was considerable concern that without such categories small scale industries, which frequently are downstream users, would be overburdened by the system. Further work is also under way to improve priority setting of chemicals to be registered early.

In this context it is interesting that the several Council delegations suggest to prioritise screened PBT-and vPvB-substances, adding further precautionary elements to the Commission proposal. There are also initiatives to improve the authorization system. So despite of choosing a "business friendly" Council formation the real Council agenda has strong environmental elements.

In September 2005, in the view of foreseeable change of government in Germany, the British Presidency made a compromise proposal which sacrificed essential demands for low volume substances in order to come to a common position before a new German government could fundamentally change directions in the Council negotiations. This relatively surprising late change of strategy created a new constellation, moving the Council closer to the conservative mainstream of the European Parliament and to emerging new informal papers, produced by DG ENTR.

#### *Joint EP Committees:*

##### *Stalemate and Strategic Process Manipulation*

Traditionally decision-making in the European Parliament is sectoralised with a strong position of the lead committee and its rapporteur in framing the overall attitude of the Parliament. The process is bottom-up – the Committee is voting a report of its rapporteur, which itself then will be voted in plenary. By this mechanism a strong rapporteur can try to form a winning majority by making selective concessions to all other parties, without sacrificing his key concern (Hix et al. 2003; Mamadou et al. 2003). This is also the institutional cause for the observation that frequently the European Parliament failed as driver for environmental policy integration (Arp 1992), while it is considered to be strong as environmental policy maker.

REACH has been decided by the enhanced cooperation procedure between committees. Under the Rule 47 of this procedure, all respective committees have to agree a time table. The rapporteur of the leading committee and the draftsmen of the other participating committees are requested to agree upon a text. The lead committee should also adopt all amendments considered to be important by the other committees, as long as this does not contradict to other elements of the report. The enhanced cooperation procedure hence has a strong procedural cooperation requirement and promotes coordination between the Committees on a voluntary basis. The lead committee for REACH is the Environment Committee, whereas the Committees on Industry and on the Internal Market participate in the enhanced cooperation procedure.

As a result of this procedure, the European Parliament failed to have a first reading on REACH before the European Elections, when majorities were in favour of an environmentally ambitious legislation. It was the hope of the more industry friendly Committees that majorities would change after the 2004 elections and hence REACH would become more business friendly. Also the draft reports of the different Committees show contradictory political orientations. The rapporteur of the environmental Committee tends to endorse in principle the Commission proposal (Sacconi 2005), whereas the rapporteur of the Internal Market Committee supports the approach of the respective industry federations (Nassauer 2005). In Summer 2005 a further delay of decision-making of the Parliament was decided after new proposals from two new Member States, which were also informally supported by the services of DG ENTR and some Social Democrat and Christian Democrat MEPs. Those proposals intended to considerably reduce obligatory testing in the low volume band. Key MEP's delayed the process in the hope of a more industry friendly constellation in the Council after German elections in September 2005. Eventually in November 2005 the two antagonistic rapporteurs found a joint compromise text which fundamentally reduced registration requirements and was adopted by an overwhelming majority of MEPs. This late conversion from an antagonistic to a joint approach may be best understood as a consequence of the radical changes of support of the original Commission proposals both within the Socialist Group and the Council. The socialist rapporteur therefore had to compromise in order to save the system.

Summing up, it seems, that depillarization in the European Parliament tends to lead to a more competitive situation between the different advocacy coalitions. Each advocacy coalition finds supporters in the Parliament. In opposite to the Commission and the Council there is limited capacity to filter interest group penetration into the EP. This is basically due to the individualized bottom-up process based on rapporteurs and also on the initiatives of individual MEPs. Furthermore internal capacity to reconcile contradictory approaches on the basis of sophisticated negotiation techniques seem to be relatively limited. As a consequence aggregation of different policy approaches within the EP is relatively unpredictable. In the REACH case eventually a coalition between the two biggest parties in the Parliament could be established in late 2005, which saved the essential approach but substantially reduced testing requirements and hence costs. On the other side, authorisation requirements were toughened by a narrow majority. The Parliament's final vote came very close to the compromises found in the Council and the revised position of the Commission and hence opened up the path towards a smooth final adoption of the Regulation by all institutions.



### 3.3.2 Overall Assessment of Depillarization in REACH

Depillarization in the REACH decision-making process has reached a new quality. Earlier attempts for EPI basically kept the sectoralised system of policy preparation and decision-making unchanged. Joint Councils of the Environment and other Sectors regularly did not have decision-making power (EEA 2005). In the REACH process depillarization establishes a negotiation mechanism between the environment and the economic departments, with joint responsibility and a view of agreeing a common legally binding text.

From institutional theory it can be expected that depillarization reduces external effects of sectoral policies or at least compensates the losers of a policy. According to the typology of Scharpf and Mohr (1994) coordination may reach from mere negative coordination, which adds activities under the respective responsibilities of each participants to positive coordination, where both welfare and distributive issues are successfully addressed at the same time. In between Scharpf and Mohr understand negotiation as a way of balancing the costs and benefits of a policy (compensation model) and joint problem solving as a way to increase welfare, while neglecting the distributional aspects. Furthermore, learning as consequence of deliberation may lead to innovative approaches (see: Risse 2004).

In the REACH case the Commission has found an internal compromise, where each participant won some key issues but also had to compromise on others – which fits well into a negative coordination (additive solutions) and negotiation (mutual compensation) model. The Council working groups had a stronger profile on efficiency increasing solutions and hence went a step further towards joint problem solving. However, depillarization in Council and Commission lead to relatively path dependent solutions, not incorporating new innovative approaches. In that sense the new negotiation system was conservative, but also for a long time robust against attempts of undermining the reform as a whole.

The exception is the European Parliament. Due to its bottom-up decision-making processes based upon strategic roles of individual MEPs, it adopted a much more competitive and less cooperative approach during long periods of the decision-making process.

### 3.3.3 New forms of mediation of stakeholder concerns: the biggest ever consultation round

#### *A wide array of instruments of stakeholder involvement*

REACH is a unique case for extensive participative stakeholder involvement (Jacob and Volkery 2005; Lind 2004; Warhust 2005). The intensity, the scope and the length of consultation on REACH is singular in EU environmental policies.

One can identify different instruments of stakeholder involvement applied since 1998, some where more competitive, others more cooperative:

- *pluralistic representative discussion events*: at different occasions the Commission organised big conferences offering business, environmental and consumer organisations and member states a platform to controversially discuss approaches and ideas for the planned reform. Such events took place in an early phase in 1999, after the publication of the White Paper on Chemicals Reform in 2001, in 2003 before the Commission Proposal was adopted, and in 2005, when the European Parliament started deliberations. Those events highlighted the clash of interests between environmental and industry advocacy coalitions.
- *Internet Consultation*: In May 2003 the Commission published a draft proposal for the REACH regulation, which however prior to adoption, should be subject to scrutiny by the wider public: institutional and private actors were invited to respond an internet consultation. In total the Commission received 6400 comments. Most of them came from workers mobilised by their respective companies and trade-unions in order to complain about potential job-losses. So internet consultation was strongly used to mobilise and broaden opposition against REACH. As a result of that consultation the Commission had to make substantial concessions.
- *Impact Assessments*: Close to 40 impact assessments and pilot studies at national and EU levels have been conducted that scrutinized business impacts and the workability of REACH (Witmond et al. 2004). Frequently such impact assessments were managed by independent consultancies and invited experts from different coalitions. Some of those impact assessments were designed to mobilise against REACH or at least to fundamentally alter its design or to defend it – others were designed to test workability and hence in order to improve the implementation mechanisms of REACH.
- *Involvement in expert committees*: REACH was also intensively discussed in the meetings of the competent authorities and other expert committees already established for the implementation of previous chemicals legislation (EEB 2000). Both industry and environmental NGOs were allowed to send experts to those meetings. After the Publication of the White Paper in 2001 the Commission also has established pluralistic Technical working groups to discuss different aspects of the planned regulation.
- *The RIP – Process*: Already before the official adoption of the REACH regulation the European Chemicals Bureau was requested to coordinate work on guidance documents for the implementation of REACH. This rather uncommon step can be explained with the considerable need for further specification and establishing exact criteria and tools for chemicals control. On the

other hand, this opens up considerable discretion for the specific design of the regulation at sub-legal level. Partly multi-stakeholder expert groups and officials of member states, managed by the ECB, have started to work on those Implementation Projects since the beginning of 2005 (see <http://www.ecb.jrc.it/REACH/>).

In total the preparation and implementation is organised with a complex and multiplayer system of stakeholder input, both allowing for more antagonistic, competitive forms of public debate and for more consensus oriented technical input. The latter is especially interesting, since – as for instance with the Strategy Partnership on REACH Testing – SPORT (see Ahrens et al. 2005; Jostmann et al. 2005), serious practical implementation problems could be identified and addressed by constructive recommendations. This continuous input certainly helped the Commission to mobilise considerable knowledge, identify key concerns, cleavages among and within stakeholders and to fine-tune the design and the implementation of the REACH project.

The Commission has remained the "lonely hero" of the early preparation phase, assuming the sole responsibility on how to give weight to the different stakeholder input. The added value of such a broad consultation phase is certainly an increased outreach and a wider understanding of the complexities of the foreseen regulation. Business and authorities alike might be better prepared for implementation phase compared to legislative processes prepared and negotiated within small expert communities. The early mobilisation effect of the wide consultation hence may be helpful for the later implementation.

#### *The battle of impact assessments – and Strategies of venue shopping*

Given the fierce international competition, it was clear from the beginning that the opposition from chemicals industry, which is one of the most powerful industries in Europe, would oppose any regulation that implies major additional costs. Yet opposition was not restricted to the chemicals industry, but included non-EU countries such as the USA, Japan or Australia. However, there are certain factors that complicate lobbying against REACH. First, the reform is intended to improve the innovation activities of the industry due to the lowering of registration requirements for new substances. Secondly, chemical control is an issue of high public sensitivity. Major accidents throughout the last thirty years have contributed to a somehow negative image of the industry which is furthermore vulnerable to targeted campaigns from consumer protection and environmental NGOs. If the industry associations would refuse willingness to cooperation and only try to oppose the whole process they would run the risk of being excluded from the important processes of technical fine-tuning in expert groups and committees. Therefore, they had to act both in a cooperative and conflictive manner. The same holds true, by the way, for the environmental NGOs.

After the presentation of the White Paper estimations of probable costs became the main issue of the debate. The Commission's Impact Assessment of the White Paper stated an estimated 2.1 billion EUR for the testing of existing chemicals distributed over a time frame of twelve years for the introduction of REACH. An extensive impact assessment was commissioned by the Commission for the regulation proposal, which estimated direct costs of 1.4 to 7 billion EUR until 2012 with 3.7 billion EUR as the most likely outcome (Risk and Policy Analysis and Statistics Sweden 2002).

Associations and enterprises of chemicals industry claimed that the actual costs were dramatically higher. CEFIC estimated direct costs for testing and registration of 7-10 billion EUR (CEFIC, 2002). A survey by the British Institute for Health and Environment estimated costs of about 9 billion EUR (Institute for Health and Environment 2001). More importantly, the indirect costs were seen as a cause for serious concern. Indirect costs might evolve when the withdrawal of substances from the market causes production losses in other industries. A study on the potential impacts on the German economy became very prominent in this debate (Arthur D. Little 2002). This survey estimated overall production losses in the industry of 2.7-3.3% depending on the scenario and a loss of up to 1-1.35 Mio jobs only in Germany. A study assuming a similar economic catastrophe was presented in France (Mercer Management Consulting 2003).

What is interesting is how the Chemicals Industry engaged several Member States in the debate after it had become obvious that the European Commission would jointly defend its proposal. The lobbying activities resulted in a quite exceptional event: The prime minister of Great Britain, the president of France and the German chancellor underlined their concerns about the Proposal in a joint public letter to Commission President Prodi in September 2003 asking for revisions of the proposal. Since this was an official initiative, it called into question the initiative monopoly of the European Commission. Furthermore, the interventions finally led to transferring the institutional responsibility from the Environmental to the Competitiveness Council. Here, industry associations hoped for better possibilities of influencing the decision-making process.

This intervention from 2003, confirmed by conclusions of different European Councils, strongly contributed to a radical leaning of the official Commission proposal from October 2003 compared to earlier drafts. However, as it has been shown, the high-level intervention was not effective enough for stopping REACH or at least for modifying the approach substantially. And it led to a bunch of new studies that calculated cost for the whole system down to a sixth of the original plans of the Commission and identified a number of methodological weaknesses in the studies on behalf of the associations of chemicals industry and other industries (cf. SRU 2003). Their scientific reputation was therefore called into ques-

tion. The mainstreaming, i.e. the shifting of institutional responsibilities, hence had a clear-cut pro business effect: it diluted several important provisions. But it also protected the reform from being stopped as a whole.

Therefore, industry friendly coalitions were forced to cooperate in the implementation design of REACH. Impact Assessments of the German Länder Northrhine-Westphalia, Baden-Württemberg and Bavaria analysed severe burdens for companies on the micro-level (NRW 2003), Bavarian State Ministry for Environment, Health and Consumer Protection 2004; Ministerium für Umwelt und Verkehr Baden-Württemberg 2004). In Germany, on the federal level Ministry for the Environment commissioned an own study on costs and benefits, which revealed ambivalent effects and the need to fine-tune the proposal rather than to skip it (Ostertag et al. 2004).

At EU level the Commission accepted the continued pressure of the industry federations to start another series of studies, the most prominent being the industry financed study by KPMG (2005). Environmental and consumer organisations as well as trade-unions were invited to participate in an overall steering committee for those impact assessment as observers.

Paradoxically and despite of the fact that NGOs criticized this industry financed study for their pessimistic and biased assumptions (EEB and WWF 2005), the study concludes that negative economic effects of planned chemicals reform are moderate.

- There is little probability that there is a loss of innovation capacity due to a substantial phase out of substances.
- Big companies face little problems to cover additional registration costs.
- Small and medium sized companies may face some problems.
- There is little risk of loss of market shares or of giving up production in Europe.
- Advantages for better risk management and a consolidation of substance portfolios need to be acknowledged.

As a consequence, Chemical industry bypassed Impact Assessment arena as strategic arena for undermining REACH and directed their lobbying pressure towards the European Parliament. This proved to become a more effective approach.

So the double strategy of industry was relative successful: It cooperated in the de-politicised processes of technological problem-solving and fine-tuning together with representatives from the Commission, Member States and environmental NGOs in the institutional context of the second generation of impact assessments. Therefore it fought against a proposal which it helped to improve at the same time.

## 4 Conclusion: better regulation by new governance hybrids – a first overall assessment

In our paper, we analysed the proposed reform of Chemical Regulation regarding its innovations in first the decision making process (depillarization, impact assessment and public participation) and the actual policy instruments that are proposed to improve risk management of chemicals (in particular combinations of command and control regulation with approaches of self regulation and the devolution and proceduralisation of decision making).

REACH can be considered as a hybrid of governance modes, providing for cooperative and conflict-oriented arenas both in the decision-making and the implementation processes and combining hierarchical, cooperative and self-regulatory modes of governance.

Our findings suggest that the cooperative arenas created by REACH all helped to moderate conflicts and to make the decision-making process and the implementation process more robust. Within those cooperative arenas negotiated package deals, elements of joint problem-solving and deliberative processes could be organised and widened identification and support for the ambitious reform. The initiative for a re-regulation of chemical policy clearly came from a coalition of few Member States and the DG Environment within the Commission. This environmental coalition was able to frame the agenda, but was politically too weak to overcome opposition from other sectors. Therefore already the drafting took place not as a pure environmental policy initiative but as a joint effort of DG Enterprise and Environment. This depillarization helped to moderate conflicts during the decision making process. Furthermore, the utilisation of procedural law and the delegation of substantive problems to the implementation process contributed to opportunities for consensus oriented negotiations throughout decision-making and implementation. Even if environmental advocacy coalitions had to make substantial concessions also within the cooperative arenas, they could safeguard some of their key concerns. The cooperative arenas hence had a stabilizing effect. One may argue that without the establishment of those cooperative arenas, REACH would not have had the chance to survive the fierce attacks of the industry advocacy coalitions. So the establishment of cooperative arenas may be helpful to stabilize the process for a very conflict intensive policy, even though those cooperative arenas may lead to considerable delays of the process and substantial concessions by the environmental advocacy coalition. A similar line of arguing can be adopted for the second generation of Impact Assessments on REACH. Whereas the first generation provided a new arena for a "battle of Impact assessments", the second generation offered incentives for cooperative specifications of the overall approach.

As regards the degree of implementation only a preliminary assessment can be given: The combination of the different governance modes (regulated self-regulation, cooperative implementation mechanisms, regulated self-regulation) offers in principle the chance for an efficient use of scarce capacities and resources both of public administration and business. It is premature to assess if the foreseen tremendous workload launched by REACH is manageable or will overburden available capacities. However, as regards the interlinkages between those steering modes we could identify serious shortcomings. As self-regulation in the REACH case takes place in the shadow of state intervention, if risks are effectively identified, it is probable that producers underestimate risk in order to avoid regulatory intervention. Furthermore the cooperative networks established under the regulation risk to be overburdened to solve politically contentious questions, which should be solved at the political levels. A lesson from this might be, that the design of the interlinkages between different modes of governance (metagovernance) should receive stronger political attention in the future. The extensive use of procedural law and the postponement of substantive decisions to technical committees during the phase of decision making bears the risk of provoking stalemates within these institutions during the implementation phase. Such a trade off between the use of new forms of governance and substantive decision making in the implementation is likely to be a general problem of procedural law and self regulation.

Given the need for highly contested decisions during the implementation phase and the delegation of these decisions to institutions with a technical mandate rather than a political mandate, it is highly probable that REACH will be just another step on a long route towards achieving chemical safety and the objective to minimise harm to health and nature by chemicals.

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