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On Functional Differentiation as the Structural Foundation of Legitimacy in European Chemicals Regulation

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Abstract

This paper analyses the potential legitimacy basis of REACH, the new regulatory system for the EC chemicals market. It is argued that three different potential sources of legitmacy exists: i) the "quasi-democratic" process within which it was established; ii) proceduralisation; and iii) through an institutional design which is aimed at fostering deliberation. This threefold legitimacy basis reflects the hybrid nature of the regulatory structure of REACH. It is, however, also argued that the underlining feature of all three forms is that they are based on or conditioned by a high level of functional differentiation. Hence, it is argued that the prevalence of functional differentiation serves as a structural condition for the construction of an adequate legitimacy basis for transnational regulatory structures. In addition, functional differentiation must be regarded as a source of legitimacy in its own right. An adequate model of transnational governing and governance in the European context must therefore systematically confront the reality and necessity of functional differentiation.

Keywords

Governance, Legitimacy, Non-majoritarian Institutions, Regulation, Risk Regulation

Rationality within REACH?[1]
On Functional Differentiation as the Structural Foundation of Legitimacy in European Chemicals Regulation

Poul Kjaer[2]

1. Introduction

Within the realm of EC market regulation the new regulatory system for the EC chemicals market, REACH (Registration, Evaluation, Authorization and Restriction of Chemicals), which was finally adopted by the European Parliament (EP) and the Council of the European Union (the Council) in December 2006 and entered into force on 1st June 2007, is the largest single reform of market regulation undertaken to date.[3]

This paper analyses the legitimacy basis of the new policy both in terms of the political process leading to the adoption of the regulation and in relation to how the regulatory system is envisaged to function when up and running. Through a reconstruction of the policy process and the regulatory structure it is shown that claims of legitimacy are based on three different sources: i) the "quasi-democratic" process within which it was established; ii) proceduralisation; and iii) – although mostly implicitly - through an institutional design which is aimed at fostering deliberation. The attempt to derive legitimacy from this threefold basis reflects the hybrid nature of the REACH governance structure. In addition, it is argued that the underlining feature of all three

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1 An earlier version of this paper was presented at the 1st Recon Workshop (WP.9) which took place in Florence on 9 March 2007 under the title Re-Reframing Transnational Governance. I would like to thank Christian Joerges and Gregory Shaffer as well other participants for extremely useful comments and suggestions. I would also like to thank Erik Eriksen and John Erik Fossum for comments on an earlier draft.

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3 According to industry sources the chemicals industry is one of the largest industrial sectors in the EC. It employs around 4 million people directly and indirectly. The EC chemicals industry has a global market share of 30%making it the world leader. In 2005 the EC exported chemicals for €110 billion and imports were €72 billion, creating a trade surplus of €38 billion. The EC chemicals industry compromises around 27. 000 companies but is dominated by a few multinational companies which produces some 70% of output. In 2004 main producers were Germany (25% of EC total), France (16 % of EC total), Italy (12% of EC total) and United Kingdom (10% of EC total). Source: European Chemical Industry Council website www.cefic.org visited on 13/2/2007.

forms is that they are based on or conditioned by a high level of functional differentiation. Hence, the prevalence of functional differentiation plays the role of a structural condition for the construction of an adequate legitimacy basis for transnational regulatory structures. It is furthermore argued that functional differentiation must be regarded as a potential source of legitimacy in its own right.

A caveat: The paper starts out with a comprehensive description of the historical background, policy objectives, institutional structures and procedures of REACH (sections 2 to 6). Hence, the informed reader might prefer to proceed immediately to the more theoretically informed discussion (sections 7 to 10).

2. The Evolution of European Chemicals Legislation

Chemicals regulation has a long history in the European context. The first directive relating to the classification, packaging and labelling of dangerous substances was adopted in 1967,[4] and has been amended seven times. The most important changes were adopted in 1979 when a harmonised notification system was introduced for all new substances being placed on the market from 1981 onwards[5] and in 1992 when risk assessments were introduced for new substances.[6] In 1976 another directive imposed specific restrictions on the marketing and use of a large number of substances.[7] In 1988 an additional directive was introduced on the classification and labelling of dangerous preparations (mixtures of two or more substances).[8] In 1993 a regulation introduced measures for the evaluation and control of existing substances, defined as substances placed on the market before 1981.[9] The regulation initiated a process aimed at testing and evaluating these substances in order to assess their potential risks. Apart from these major pieces of legislation industry sources state that more than 500 additional pieces of Community legislation are related to or have an impact on the EC chemicals industry.[10]

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4 Directive 67/548/EEC of the Council of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

5 Directive 79/831/EEC of the Council of 18 September 1979 amending Directive 67/548/EEC of the Council of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

6 Directive 92/32/EEC of the Council of 30 April 1992 amending Directive 67/548/EEC of the Council of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

7 Directive 76/769/EEC of the Council of 27 July 1976 relating to restrictions on the marketing and use of certain dangerous substances and preparations.

8 Directive 88/379/EEC of the Council of 7 June 1988 relating to the classification, packaging and labeling of dangerous preparations, revised by Directive 1999/45 EC of the European Parliament and the Council of 31 May 1999.

9 Regulation (EEC) No 793/1993 of the Council of 23 March 1993 on evaluation and control of risks of existing substances.

10 European Chemical Industry Council website www.cefic.org visited on 31 January 2007.

3. The REACH Policy Process

The policy process leading to REACH was initiated by an alliance consisting of DG Environment (formerly DG XI), certain Member States (MS) most notably Austria, Denmark, Finland, The Netherlands and Sweden and a wide range of environmentalist groups, which argued that the existing level of risk regulation in the chemicals area was insufficient and outdated. This triggered an informal meeting of the Council configuration of Environmental Ministers in April 1998 where the Commission committed itself to performing an extensive review of existing chemicals legislation,[11] in order to clarify to what extent the existing legislation contained adequate standards for risk regulation. The review identified major problems. First of all the distinction between existing substances, placed on the market before 1981, and "new" substances placed on the market after 1981. By the end of the millennium only 2700 substances fell into the category of new substances, which were subject to testing requirements. The category of "old" substances, however, contained more than 100 000 substances, only 140 of which had at the time been subject to comprehensive risk assessments carried out by MS authorities on the basis of Council Regulation 793/1993 EEC.[12] Hence, the existing system of risk assessment was characterised as being far too slow. Moreover, the existing system only focused on producers, not on downstream users. Consequently, it remained extremely difficult to acquire knowledge about the actual use of the chemical substances, and hence close to impossible to provide scientific evidence of negative impacts throughout the supply chain. The review report was adopted by the Commission in November 1998 and welcomed by the Council in December 1998.[13] In February 1999 a stakeholders meeting was held with regulators, scientists, industry, consumer and environmental representatives. In June 1999 the Council adopted a set of conclusions for a future strategy, thus acknowledging the need for a new approach to chemicals regulation, and it then called on the Commission to submit a policy document outlining a strategy. The Commission published a white paper in February 2001 outlining the REACH proposal.[14] An additional stakeholder meeting was held in April 2001. The white paper provided the basis for a draft proposal, which was debated in the Environmental Council June in 2001, leading to a resolution from the EP in November of the same year. Both institutions expressed support for a continuation of the reform process and urged the Commission to strengthen the envisaged provisions for consumer, environment, human and animal protection. Industry largely opposed the proposal.[15]

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[11] More specifically of the amended version of Directive 67/548/EEC of the Council of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, Directive 76/769/EEC of the Council of 27 July 1976 relating to restrictions on the marketing and use of certain dangerous substances and preparations, Directive 88/379/EEC of the Council of 7 June 1988 relating to the classification, packaging and labeling of dangerous preparations, revised by Directive 1999/45 EC of the European Parliament and the Council of 31 May 1999, Regulation (EEC) No 793/1993 of the Council 23 March 1993 on evaluation and control of risks of existing substances.

[12] Commission White Paper: Strategy for a future Chemicals Policy. COM (2001) 88 final, pp. 6

[13] Commission Working Document SEC (1998) 1986 Final.

[14] European Commission: White Paper. Strategy for a future Chemicals Policy. COM (2001) 88 final.

[15] The position of the EC Chemicals industry is available at http://cms.cefic.be/Templates/shwStory.asp?NID=494&HID=448 , visited 13 February 2007.

From October 2001 to February 2002 technical working groups with members from the Commission, industry, NGO's and MS authorities carried out detailed studies of the implications of the draft proposal. This was followed by an internet consultation in May-July 2003, which resulted in some 6400 submissions.[16] In May 2003 early notice was given to WTO Members.[17] This was followed up with an impact assessment which estimated the costs of REACH to be between €2.8 and €5.2 billion over a period between 11 to 15 years. The health and environmental benefits were estimated to be €50 billion over a 30 year period.[18] In the meantime the position of the MS changed. From being largely in favour of the proposal, leading MS began to increasingly oppose the initiative. In September 2003 an open letter was sent to the President of the Commission Romano Prodi from Prime Minister Tony Blair, President Jacques Chirac and Chancellor Gerhard Schröder, who, in the light of the Lisbon Strategy, stated that: "A future EC chemicals policy must be designed in such a way as to ensure environmental, health and consumer protection without endangering the international competitiveness of the European chemical industry".[19] The three Heads of State and Government, in other words, sent a strong signal that the Commission should prioritise economic concerns vis á vis environmental, health and consumer concerns, where the realization of such divergent objectives would be mutually exclusive. Shortly afterwards the issue was transferred from the Environmental Council, which so far had been the leading Council configuration, to the newly created Competitiveness Council. A similar attempt to transfer the issue from the EPs Environmental Committee to either the Committee on Industry and Trade or the Legal Affairs Committee failed. In October 2003 the draft REACH regulation was adopted by the Commission.[20] The draft regulation contained substantially weaker provisions for consumer, environment, human and animal protection than the White Paper and previous drafts. Moreover, the majority of the suggestions which the Council and Parliament had made for a strengthening of the provisions for consumer, environment, human and animal protection following the White Paper had not been incorporated. On the other hand, the general principles for a future chemicals policy as outlined in the White Paper were maintained.[21] The increasingly unfavourable environment, moreover, contributed to a shift in the power balance within the Commission, with DG Environment loosing out to the more industry friendly DG Enterprise. In January 2004 the REACH proposal was notified at the WTO

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16 For the complete list of submissions see: http://ECropa.EC/enterprise/reach/consultation/public_en.htm, visited 31/1-2007.

17 Third countries as well as the WTO regime undoubtedly had a significant influence on the outcome of the policymaking process leading to the establishment of REACH. Analyzing this aspect however falls outside the scope of this paper.

18 European Commission, DG Environment website: http://ec.ECropa.EC/environment/chemicals/background/impact_assessment_intro.htm, visited 1/2-2007.

19 The letter is available at: Http://www.smallbusinessEurope.org/en/upload/File/Issues/REACH/Letter_to_Prodi_from_Blair_Chirac_Schroder.doc

20 Commission Proposal for a Regulation concerning registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency and Amending Directive 1999/45/EC, COM(2003)644 of 29 Oct. 2003.

21 The changes did not only take place because of the resistance from the major MS and European industry but also because of fierce critique from major trading partners, notably the United States.

under the TBT agreement.[22] In July 2005 the results of a Strategic Partnership on REACH Testing (SPORT) was published.[23] SPORT was a joint initiative between the Commission, MS and industry aimed at testing the technical aspects of REACH. In November 2005 the first reading took place in the EP, producing a list of 430 provisional amendments.[24] The main changes proposed by the EP were a tougher stand on substitution requirements and a reduction in the information required in order to register a substance. This position was a result of a compromise deal between the Environment Committee and the Committee on Industry and Trade in the EP. The former sought to keep the standards as high as possible and hence negotiated a stronger position in relation to substitution. The latter, on the other hand, sought to lighten the burden on industry and hence negotiated a reduction in the information requirements. The Council adopted its common position in June 2006. [25] The Council completely or partially accepted 90% of the amendments proposed by the EP.[26] The Council, however, proposed a stronger role of MS authorities in the evaluation of substances, just as it sought to facilitate the requirements for SMEs. The Commission adopted a favourable opinion on the common position in July 2006.[27] In the second reading the EP proposed 172 amendments. In November 2006 a compromise package was agreed upon between the Council and the EP, strengthening the latter's supervisory role. The EP gained the right to appoint two members to the board of the proposed chemicals agency and the new Comitology procedure with scrutiny, which was adopted in 2006,[28] was incorporated in a number of instances. The Council agreed to a strengthening of the substitution requirements and to a review after six years of a number of outstanding issues. The Council and the Parliament finally adopted the regulation in December 2006.

4. The Policy Objectives of REACH

The version of REACH which was finally adopted has the aim of closing the "knowledge gap" in relation to chemicals placed on the market before 1981 and to drastically speed up the processes for testing and risk assessment of chemicals in general. More concretely, REACH serves multiple and partially contradictory purposes as it shall "ensure a high level of protection of human health and the environment as well as the free movement of substances … while enhancing competitiveness and

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22 World Trade Organization, notification G/TBT/N/EEC/52 of 21 January 2004. The EC response is available at European Commission, DG Enterprise website: http://ec.ECropa.EC/enterprise/reach/docs/reach/EC_wto_response_041028.pdf .

23 The report is available at: http://ec.ECropa.EC/enterprise/reach/docs/trial/sport_report_050704.pdf

24 European Parliament Legislative Resolutions P6_TA(2005)0434 and P6-TA(2005)0435 of 17 November 2005.

25 Common Positions of the Council of the European Union 7524/06 and 7525/06 of 12 June 2006.

26 Communication from the Commission to the European Parliament COM (2006) 375 final, p. 3.

27 Communication from the Commission to the European Parliament COM (2006) 375 final.

28 Decision 1999/468/EC of the Council of 28 June 1999, article 5a. Decision amended by Decision 2006/512/EC of the Council.

innovation".[29] Inspired by the 1992 Rio Declaration, REACH has "sustainable development" as an official objective. It foresees that by 2020 "chemicals are produced and used in ways that lead to the minimisation of significant adverse effect on human health and the environment".[30] Consequently, it is a declared objective of REACH "to encourage and in certain cases to ensure that substances of high concern are eventually replaced by less dangerous substances or technologies where suitable economically and technically viable alternatives are available".[31] Some 1500 substances subject to substitution requirements are already identified in the regulation.[32] The responsibility of assessing the risks and hazards of substances lies with manufacturers and importers. Hence the burden of proof is reversed when compared with the existing regulatory system, where it is the responsibility of the relevant public authorities to provide evidence of potential risks. All actors in the supply chain will moreover be obliged to ensure the safety of the substances they handle. Not only producers but also downstream users will therefore be linked up with the system. The requirements for safety assessments should be developed by the Commission, "in close cooperation with industry, Member States and other relevant stakeholders".[33] Innovation will be encouraged through a relaxation of restrictions on chemicals solely used for research and development purposes as well as through lower registration fees for new substances and through the requirement to systematically consider the possibility of substitution with less problematic substances.

5. The Institutional Form of REACH

REACH foresees the establishment of a complex institutional system, with a regulatory agency, the European Chemicals Agency, at its centre. The agency will be based in Helsinki. It is envisaged that the agency will eventually have around 400 employees,[34] making it the largest EC/EU agency. However, the agency still follows the overall structure developed for "quasi-regulatory" agencies in the European context.[35] It is "established for the purposes of manage and in some cases carrying out the technical,

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29 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, preamble, recital 1.

30 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, preamble, recital 4.

31 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, preamble, recital 12.

32 European Environmental Law Website: http://www.eel.nl/index.asp?sub_categorie=243, visited 30/1/2007.

33 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, preamble, recital 31.

34 European Commission, DG Enterprise website: http://ec.ECropa.EC/enterprise/reach/prep_agency_en.htm, visited 1 of February 2007.

35 Xénophon Yatanagas: Delegation of Regulatory Authority in the European Union. The Relevance of the American Model of Independent Agencies, Jean Monnet Working Paper, 01/2001.

scientific and administrative aspects"[36] of REACH. It consists of a Management Board, an Executive Director, a Secretariat, three committees and a so-called Forum. The Management Board will be composed of a member from each MS and a maximum of six representatives appointed by the Commission. Three of these will represent interested parties (e.g. industry, traders and consumers) and they will have no voting rights. In addition the EP will, as mentioned, be able to appoint two independent members.[37] Hence, with the present number of 27 MS the Board will have a maximum of 35 members, 32 with voting rights. The members are nominated by the MS and appointed by the Council. The criteria for selecting members of the board are relevant experience and expertise. The duration of the office is four years renewable once.[38] The Management Board shall act by a two-thirds majority of all members with the right to vote.[39]

The Management Board appoints the Executive Director on the basis of a list of candidates proposed by the Commission.[40] He/she will be responsible for the day-today management and ensuring timely co-ordination between the Agency, the Committees and the Forum as well as with other EC institutions. The appointment is for a period of 5 years renewable once.

REACH also foresees the establishment of three committees: A Committee for Risk Assessment (CfRA) and a Committee for Socio-Economic Analysis (CfSEA) as well as a Member State Committee (MSC). Each MS may nominate candidates for the CfRA and the CfSEA. The Management Board shall appoint members on the basis of the nominations. Each MS should have a minimum of one member.[41] Members are appointed for three years renewable. Each Committee shall draft a proposal for its own rules of procedure, to be approved by the Management Board.[42] The Committee members shall ensure the coordination with competent MS authorities, but shall act in an independent manner and without instructions from their respective authorities. The chairman of each committee shall be an employee of the Agency. [43] The committees shall provide MS and the Community institutions with the best possible scientific and technical advice.[44] In forming their opinions the committees shall strive towards

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[36] Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 75 (1).

[37] Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 79 (1).

[38] Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 75 (3).

[39] Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 82.

[40] Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 83 & 84.

[41] Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 85 (1,2).

[42] Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 85 (9).

[43] Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 85 (5,7,9).

[44] Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 77 (1).

reaching consensus. If consensus is not reached the opinion and grounds for the majority opinion as well as the minority position(s) shall be published.[45] The work of the committees shall be carried out through the appointment of rapporteurs for each case. The rapporteurs shall act in the interest of the Community and provide a declaration of interests in relation to the specific case they are responsible for.[46] MS shall moreover provide a list of relevant experts which can be called upon as members of ad hoc working groups under the different committees. Membership of the committees (and the Forum) shall be made public.[47] All members shall annually provide a declaration of commitment and a declaration of interests. On request, these declarations shall be accessible to the public.[48] The MSC shall "aim to reach agreement amongst Member States authorities on specific issues which require a harmonised approach"[49] and assist the Commission in its efforts to implement decisions taken on the basis of the recommendations of the CfRA and the CfSEA. Decisions of the agency or the attached committees can be contested in front of a Board of appeal.[50] Qualifications for members of the Board of Appeal shall be determined by the Commission in accordance with the procedure of regulatory committees under Comitology.[51] Any decision of the Board of Appeal (or of the Agency if no right of appeal exists) may be brought before the Court of First Instance or the Court of Justice.[52] Any decision taken by the Agency may be the subject of a complaint to the European Ombudsman.[53]

The Agency budget shall consist of a subsidy from the Community budget and of fees paid in relation to registration and the granting of authorisations. Budget and financial management is subject to the control of the Court of Auditors. The EP and Council shall be regularly informed of budgetary developments. [54] The agency shall be subject to control from the European Anti-Fraud Office (OLAF). [55] The EC regulation guiding public access to documents shall apply to the Agency.[56]

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45 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 85 (8).

46 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 87 (1).

47 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 88 (1).

48 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 88 (2).

49 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, preamble, recital 103.

50 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, articles 89 -93.

51 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 89 (4).

52 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 94.

53 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 118 (4).

54 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 96 - 97.

55 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 98.

56 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001.

The Forum shall consist of one member appointed by each MS. The period of appointment is three years renewable once. Five additional members can be appointed in order to ensure the presence of specific competences.[57] The Forum shall provide a platform "for Member States to exchange information on and to coordinate their activities related to enforcement of chemicals legislation".[58] The justification for the establishment of the Forum is that "the currently informal cooperation between Member States … would benefit from a more formal framework".[59] The role foreseen for the Forum is, however, also incorporated in a general principle which emphasises "good cooperation, coordination and exchange of information between the Member States, the Agency and the Commission regarding enforcement".[60] In addition, the role of the Forum is also supported by an emphasis on the active participation of competent MS authorities since they should, "because of their closeness to stakeholders in the Member States, play a role in the exchange of information on the risk of substances and on the obligations of natural or legal persons under chemicals legislation".[61]The Forum, however, has only an advisory role since implementing measures in relation to the regulation which are of a general nature should be adopted in accordance with the regulatory procedure with scrutiny under Comitology. [62]

6. Procedures

The procedural framework contains four elements which respectively are related to the registration, authorisation, evaluation and restriction of chemical substances falling under the scope of the regulation. Only substances which are placed on the market are affected by the regulation. Hence, substances which are only used for research and development purposes are exempted. Producers or importers who handle quantities of less than one tonne per year of a specific substance are exempted from the requirements.[63]

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57 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 86 (1).

58 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, preamble, recital 105.

59 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, preamble, recital 105.

60 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, preamble, recital 120.

61 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, preamble, recital 1119.

62 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, preamble, recitals 123 and 124 and Council Decision 1999/468/EC of 28 June 1999, article 5a. Decision amended by Council Decision 2006/512/EC. The Forum is thereby likely to gain the same function within REACH as the Advisory Forum has within the European Food safety Authority (EFSA).

63 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 7.

6.1. Registration

Any producer or importer of articles falling under the regulation shall submit a registration to the Agency, indicating the identity of the producer or importer, quantity of the substances in question, a technical dossier listing the content of the substances as well as description of the intended use. For all substances subject to registration a safety assessment is required, which shall include an assessment of hazards to human health, physicochemical hazards, environmental hazards as well as an assessment of persistency and bioaccuumulative and toxic potential, an exposure assessment and a characterisation of risks.[64] The agency shall perform a completeness check of the registration and confirm it to the extent it is considered to be complete. The agency shall inform the competent authority in the relevant MS, meaning the MS where the producer or importer is established, about the registration.[65] The registrant may continue to manufacture or import the substance in question if the Agency has not provided any indication to the contrary within three weeks of successful registration.[66] The registrant remains responsible for updating the registration [67] and is obliged to enquire whether the substance in question has already been registered by another producer or importer. [68] In case of overlap and in order to avoid duplication, potential and previous registrants shall "make every effort to reach an agreement on the sharing of information requested by the potential registrant". [69] In the case no agreement can be reached the matter may be submitted to an arbitration board. In order to facilitate the process all registrants and potential registrants shall have access to a substance information exchange forum (SIEF).[70] If testing is required in order to produce the safety assessments a SIEF participant shall inquire whether a relevant study is available from other participants. If this is the case the owner of the study shall provide proof of the costs. Both parties "shall make every effort to ensure costs of sharing the information are determined in a fair, transparent and non discriminatory way".[71] If no agreement is reached the costs shall be shared. If no study is available only one study shall be carried out and potential registrants shall share the costs. The claim for participation in a study shall be enforceable in national courts.[72] Common registration between several producers or importers is expressively allowed and encouraged.

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64 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 14.

65 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 20 (4).

66 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 21.

67 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 22.

68 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 26.

69 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 27 (2).

70 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 29.

71 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 30 (1).

72 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 30 (2, 3).

The Agency shall examine all proposals for testing and shall either i) require that the registrant(s) carry out the testing ii) decide that the test should be modified, iii) that together with the proposed tests additional tests should be made or iv) reject the proposed test. In the latter case the applicant can submit a modified proposal for testing. All tests should be carried out within a deadline specified by the Agency. If several registrants have submitted proposals for the same test they should be given the opportunity to reach agreement on who shall carry out the test. If no agreement is reached the Agency will decide who will carry out the test.[73]

6.2. Evaluation

Evaluations shall be made for three reasons: i) in order to consider whether substances which so far have not been included in the list of substances falling under the regulation should be included in the list; ii) in order to examine the possibility of delisting substances falling under the scope of the regulation because new information about the nature of the substances has become known; iii) in order to assess the impact which the placement of specific substances on the market by registrants will have.

In cooperation with the MS the Agency shall develop criteria for prioritizing which substances should be evaluated first. The prioritization shall be decided on a risk-based approach and be contained in a rolling action plan covering three years. The action plan shall be adopted by the Agency on the basis of an opinion from the MSC. The Agency shall coordinate the evaluation process and identify the MS who will carry out the evaluation of the substance.[74] MS can express interest in evaluating a specific substance. In case of disagreement among MS concerning who should evaluate a given substance the issue shall be referred to the MSC. If the committee fails to reach a unanimous agreement the Agency shall refer the issue to the Commission, which shall decide who the competent authority shall be on the basis of the regulatory comitology procedure.[75] Evaluations shall be carried out within a period of 12 months. In order to ensure a harmonised approach to evaluation, implementing measures shall be adopted where appropriate. The basis for such measures shall also be the regulatory comitology procedure.[76]After evaluation has been carried out by the competent MS authority the Agency shall inform other MS and the registrant(s). Registrants shall have the right to comment on the draft decision. Comments from registrants shall be circulated to the competent authorities of the remaining MS, who may also propose amendments to the draft decision. The Agency can modify the decision on the basis of such comments, after which the draft decision shall be resubmitted to registrant(s) and competent MS authorities for additional comments. If the MSC on the basis of the Agency's (modified) draft decision reaches a unanimous decision the Agency shall take the decision accordingly. If it fails to reach unanimous agreement, the matter shall be referred to the

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[73] Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 40 (3).

[74] Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 44.

[75] Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 45 (3).

[76] Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 47 (2).

Commission which shall take a decision. The regulatory comitology procedure shall provide the basis for adopting such a decision.[77]

6.3. Authorisation

The aim of the authorisation procedure is "to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable."[78] Hence all applicants shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution. Again a distinction is made between the general authorisation of the inclusion/exclusion of substances on the list of substances regulated by the regulation and specific authorisations concerning the use of particular substances falling under the regulation.

General Authorisations

At least every second year the Agency shall provide a recommendation concerning additional substances to be included in the list of substances requiring authorisation or which substances should be removed because, as a result of new information, they do no longer meet the criteria for inclusion in the list of substances requiring authorisation. All interested parties shall have the possibility to comment on such recommendations. The MS themselves may prepare a dossier and forward it to the Agency. If after circulation to all interested parties and the remaining MS no comments have been received the Agency may include the substance in the draft list. Prior to taking any final decision on inclusion or removal of any substances the Agency shall take into account the opinion of the MSC,[79] just as the decision shall be subject to the procedures guiding regulatory comitology procedure with scrutiny.[80] If the MSC fails to reach a unanimous agreement the matter shall be referred to the Commission which shall prepare a draft proposal subject to approval under the regulatory comitology procedure.[81]

Specific Authorisations

In relation to specific authorisations applications may be made by producers(s), importers(s) and/or downstream users. The application shall contain the identity of the applicant(s), the identity of the substance(s), a request for authorisation indicating the envisaged use of the substance(s), a chemical safety report if not already submitted

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77 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 51 (3).

78 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 55.

79 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 58 (1, 3).

80 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 58 (1, 8).

81 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 59 (9).

during registration, an analysis of alternatives including the technical and economical feasibility of such alternatives and a substitution plan where such alternatives exists.[82] The application may include a socio-economic analysis. The Agency shall acknowledge the receipt of the application and the CfRA and the CfSEA shall give their draft opinion within ten months of the date of receipt. The draft opinion of the CfRA shall include an assessment of the risk to human health and/or the environment from the use(s) of the substance(s), including the appropriateness and effectiveness of the risk management measures described in the application, as well as a risk assessment of possible alternatives. The CfSEA shall provide an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives. The applicant shall have the possibility to comment on the draft opinions. After taking these comments into consideration, the draft opinions shall be submitted to the Commission, the MS and the applicant. The Commission shall be responsible for taking a decision. In its decision the Commission shall take account of the opinion of the CfRA. Decisions shall be taken in accordance with the advisory comitology procedure.[83]

If an authorisation cannot be granted due to a negative position of the CfRA it may only be granted "if it is shown that socio-economic benefits outweigh the risk of human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies".[84] However, such a decision can only be made after taking into account the opinions of the CfRA and the CfSEA and after considering the risk posed by the use of the substance, the socio-economic benefits arising from its use, an analysis of alternatives and available information on the risks to human health or the environment of any alternative substances or technologies.[85] All authorisations shall be subject to a time-limited review.

6.4 Restrictions

The regulation provides a number of principles for laying down restrictions on specific substances in relation to how they are manufactured, placed on the marked and used. The restriction procedure is aimed at introducing new and amending existing restrictions as well as the development of particular restrictions in relation to a specific application.

If the Commission considers that a risk occurring due to placing of the market of a specific substance is not adequately controlled and needs to be addressed, it shall require the Agency to prepare a dossier on the matter. The Agency itself may prepare a dossier if it considers that risks occurring from a specific substance are not adequately controlled. MS may also propose to the Agency to prepare such a dossier. MS can also request that existing restrictions shall be re-examined. The decision to request that

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82 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 62.

83 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 64 (8).

84 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 60 (4).

85 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 60 (4).

Agency prepare a dossier concerning re-examination shall be taken by the Commission in accordance with the Comitology procedure for advisory committees.[86] All dossiers concerning restrictions shall be submitted to the CfRA and the CfSEA, which shall confirm that the dossier is in conformity with the general provisions concerning possible restrictions in the regulation. At this stage interested parties shall have the possibility to comment on the dossier. If the CfRA and the CfSEA consider the dossier to be in conformity with the general provisions they shall formulate a draft opinion on the proposed restrictions. Interested parties shall also have the opportunity to comment on the draft opinion. Taking appropriate comments into account the committees shall then adopt an opinion. The dossier and the opinions of the committees shall be referred to the Commission which shall adopt a final decision in accordance with the regulatory procedure with scrutiny under comitology.[87]

7. Hybrid Governance

The above reconstruction of the institutional structure and procedural infrastructure indicates that REACH builds on four elements, making it into a hybrid which will operate in-between hierarchy and heterarchy.[88] Firstly, at its centre there is a hierarchical nucleus: It is the outcome of a "supranational" legislative process unfolded under co-decision with full involvement of the EP. Moreover, the REACH regulation will enjoy direct effect and supremacy vis à vis national law. In addition, the requirements imposed on private actors contain a considerable element of vertical command and control; for example data and testing requirements will be harmonised in detail and hence leave little or no scope for deviations and exceptions. The internal organization of the Secretariat is, moreover, likely to be based on a traditional hierarchical model of bureaucratic organization. Hence, at first glance REACH is modelled on a classical concept of Kelsian legal hierarchy and Weberian organizational hierarchy.

But, secondly, REACH also contains a cooperative element. The regulation only establishes a framework in the form of basic principles and procedures. The fleshing out of detailed standards, criteria and guidelines will be left to the versatile interactions between the Commission, the secretariat, the committees and MS authorities. The actual evaluation of the test results provided by private actors will, moreover, be organised within a complex process where the Secretariat merely will play the role of a coordinator and facilitator whereas the actual work will be carried out by competent MS authorities, which might even sub-delegate the tasks nationally. The interaction between

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86 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 69 (5).

87 Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, article 73 (2).

88 For an instructive analysis of the hybridity of REACH see; Christian Hey, Klaus Jacob and Axel Volkery: Better regulation by new governance hybrids? Governance models and the reform of European chemicals policy. FFU-report 02-2006, Environmental Policy Research Centre, Free University Berlin.

the hierarchically organised Secretariat and its environment is therefore likely to take place through heterarchical networks, which are legally structured through the establishment of committees and their internal rules of procedures. The social embeddedness of the Secretariat is, therefore, likely to depend upon its ability to use the committees as reflexivity increasing channels, insofar as the committees will ideally enable it to receive and submit relevant information from and to its environment. Similarly, competent MS authorities will need to engage actively in the committee processes in order to "feed in" to the Europeanised regulatory processes and to stabilise their expectations vis á vis the societal impact which these processes will have. Hence, the committees can be described as networks or interaction systems, which function as "structural couplings" between organizations. [89] These couplings are introduced in order to offset the structural deficits of the organizations involved. In case of the Agency this structural deficit is expressed in its insufficient resources and lack of mandate to carry out the necessary testing and evaluation on its own. For the competent MS authorities, the structural deficit should be found in their failing ability to handle the complexity of risk assessment and risk management in the chemicals sector within an increasingly internationalised social environment, thereby introducing an incitement for sharing the work between MS authorities.

Thirdly, REACH contains an element of obligatory self-regulation as expressed in the obligation of private actors to carry out testing and ensure appropriate risk management along the value chain. These requirements are likely to encourage private actors to engage in substantial horizontal cooperation. For example, the cooperation among private actors in order to submit joint registrations and perform joint assessments is likely to lead to the establishment of a comprehensive network around the Substance Information Exchange Forum (SIEF). Such developments might in turn facilitate increased reflexivity and a higher level of embeddedness of private actors in the larger social realm, since each private actor will be forced to enter into "co-optition", in the sense that they will be forced to establish a relationship with other producers and importers which is partly based upon competition and partly on cooperation.[90] Private actors with a long-term strategy will therefore have an incentive for creating a high level of mutual trust among themselves through a stabilisation of their interactions on the basis of well-established norms.

Fourthly, REACH provides the basis for a strategy of risk communication aimed at the broader public in so far as the Agency will have the role of communicating potential risks not only to MS authorities, industry and traders but also to consumers. The communication of risks is, moreover, likely to demand a close coordination between the Agency and competent MS authorities in order to ensure that the risk communication strategy remains coherent.

The hybrid structure means that REACH does not correspond with any of the ideal type models of governance advocated throughout the last decade. REACH only establishes a "quasi-regulatory" agency, which falls short of the requirements that, according to

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[89] Eckard Kämper & Johannes F. K. Schmidt, 2000. 'Netzwerke als strukturelle Kopplung', pp. 211-235 in Johannes Weyer (Hrsg.): *Soziale Netzwerke. Koncepte und Methoden der Socialwissenschaftlichen Netzwerkforschung*. Oldenburg Verlag. München, p. 220.

[90] Gunther Teubner: Das Recht hybrider Netzwerke, pp. 550-575, *Zeitschrift für das gesamte Handelsrecht und Wirtschaftsrecht* 165, 2001, p. 563.

Majone´s theory of the regulatory state, should characterise a fully independent regulatory agency.[91] This is the case in relation to the massive decentralisation of the workload which will mainly be carried out by private actors and competent MS authorities as well as in relation to the actual decisional competences possessed by the Agency.

In contrast to Majone's vertical agency model the agency committees will play a strong role in the preparation of draft decisions just as the competence to take final decisions in most cases will remain the prerogative of the Commission on the basis of the comitology system. But even though comitology and committees more generally will play a pivotal role within REACH, the envisaged structure does not necessarily follow the line of thought developed by Joerges and Neyer under the heading of deliberative supranationalism. Joerges and Neyer argue that the "political administration" of Comitology remains the optimal institutional structure for developing legitimate market and risk regulation in the European context.[92] Although it is a weak version of a regulatory agency, the Chemicals Agency is likely to achieve a considerable influence since it will play an essential role in relation to the collection and processing of information and in the definition of policy priorities. Hence, the agency is – over time – likely to develop the features of an autonomous structure with an independent impact on the policy area in question. Hence, the question of legitimacy addressed by Joerges and Neyers will remain on the agenda, insofar as all autonomous structures are faced with a demand for legitimizing their operations vis á vis their social environment. At first glance, the latest suggestion promoted by Sabel and Zeitlin under the heading of Directly Deliberative Polyarchy (DDP) concerning a massive expansion of the Open Method Coordination (OMC) beyond the scope of its present use and into areas which currently are subject to the Community Method[93] has not been reflected in the REACH regulation. OMC-inspired instruments are, however, likely to play a certain role in the concretisation of the work of the so-called Forum, which is predicted to become a platform for the exchange of ideas and best practices. This again is likely to provide a basis for the deployment of benchmarking and evaluation tools similar to those which are typically associated with the OMC. In conclusion REACH seems to indicate a move towards a fusion of the three types of governance associated with regulatory agencies, Comitology and the OMC, insofar as the REACH system will contain elements from all three forms.

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91 Giandomenico Majone (Ed.): Regulating Europe, Routledge, London, 1996.

92 E.g. Christian Joerges: "'Deliberative Supranationalism'- Two Defences", pp. 133-151, *European Law Journal*, 8, 1, 2002; Christian Joerges and Jürgen Neyer: "Transforming strategic interaction into deliberative problem-solving: European comitology in the foodstuffs sector", pp. 609-625, *Journal of European Public Policy* 4, 1997 and; "From Intergovernmental Bargaining to Deliberative Political Processes: The Constitutionalisation of Comitology", pp. 273-299, *Journal of European Public Policy*, 3, 1997. Jürgen Neyer: Justifiying Comitology: The Promise of Deliberation, pp. 112-28 in Karlheinz Neunreither & Antje Wiener (Eds.): European Integration. Institutional Dynamics and Prospects for Democracy After Amsterdam. Oxford University Press. Oxford. 2000.

93 Charles F. Sabel & Jonathan Zeitlin: *Learning from Difference: The New Architecture of Experimentalist Governance in the European Union*, La Follette School Working Papers, No. 2006-018.

8. Hybrid Legitimacy

How is the legitimacy of REACH being constructed? Apart from administrative law provisions the REACH system claim to be based on three analytically separate but in practice partly overlapping sources of legitimacy, reflecting the hybrid nature of its construction. The first one is democracy, the second one is proceduralisation and the third one is deliberation. Hence, legitimacy is neither merely derived from a reference to a metaphysical concept of the sovereign people, which provide the foundation for most democratic theory, nor is it merely procedural or purely based on deliberation. In addition, the underlying structural foundation for all three forms is their ability to ensure the autonomy of different social spheres, or systems, while regulating their mutual impact. Hence, the underlying basis for legitimacy during the legislative process as well as in the planned operational form of REACH seems to be the dual capability of maintaining and reconciling functional differentiation through law. It can therefore be claimed that REACH reflects the structural basis of the late-modern society, insofar as functional differentiation increasingly has become the primary form of social differentiation.[94]

8.1. Functional Differentiation

The concept of functional differentiation has since Kant and Hegel been recognised as expressing the core of modernity. Hence, one of the main concerns of modern social theory has been how society could remain integrated and achieve rationality under the condition of the primacy of functional differentiation vis á vis segmentary and stratificatory differentiation. Hegel argued for a twofold solution: A containment of functional differentiated societies within the segmented form of the nation-state and a limitation of the adverse effects of functional differentiation, especially the problem of social exclusion, through a stratified corporatist system aimed at stabilizing the relationship between the social classes of the emerging industrial society.[95] This model remained empirically relevant in Western Europe until the 1960s, when the still ongoing internationalisation wave and the increased erosion of the industrial society and the social class structure which it upheld started to unfold. Hence, the ongoing transformation processes can be understood as a move towards an increased weight of

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[94] In more general terms, differentiation can be understood as a specific social form, which generates unity through difference. Segmentary differentiation, familiar from archaic societies, emphasises the sameness of different societies. Differentiation between centre and periphery (e.g. through clan structures) implies the constitution of society through the difference of one part of society towards the rest. Stratified (e.g. feudal) societies are based upon hierarchically ordered differences aimed at highlighting dissimilarity. In contrast to these earlier forms, functional differentiation is characterised by the differences between similar social systems or social spheres. Each system or sphere is thus on an equal footing with the other social systems or spheres, since each system or sphere monopolises a specific task (e.g. law, economy, science or power) which is necessary for the other system's or sphere's ability to operate and thereby for the functioning of society as a whole at the same time as they maintain their distinctness due to the specific societal function they monopolise. See Niklas Luhmann: Die Gesellschaft der Gesellschaft, Suhrkmap Verlag, Frankfurt am Main, 1997, pp. 595.

[95] G. W.F. Hegel: *Grundlinien der Philosophie des Rechts. oder Naturrecht und Staatswissenschaft im Grundrisse.* Suhrkamp Verlag. Frankfurt am Main, (1821) 1970.

functional differentiation relative to other forms of social differentiation. The EC has played and continues to play a central role in this transformation process. Together with the 1947 GATT agreement, the gradual creation of an internal market from the late 1950s onwards represented the first tentative move towards a breakdown of the containment of the economy through nation-state structures. In addition, the European institutions throughout their existence, have consistently and with much success implemented a policy program, which has been and continues to be oriented towards a systematic undermining of the steering capabilities of the nation states through so-called negative integration. The move towards positive integration through EC wide re-regulation, which has followed the majority of the moves towards negative integration, is, moreover, of a fundamentally different character than the kind of regulation traditionally pursued at the nation-state level, because of the relative weight of functional relative to stratificatory and segmentary features. One reason for this is the pre-dominance of a functionalist approach to integration which means that EC regulation is not embedded in partly stratified and partly segmented structures in the way nation state regulation traditionally has been. Hence, EC regulatory measures are not the result of corporatist exercises, just as regulatory measures tend to have a relatively one-sided focus on economics vis á vis social concerns, due to the imbalance between EC competences in the economic field relative to the area of social regulation. In addition, and although the EC is a territorially based entity itself, it is far less constrained by segmentary differentiation than the nation states. Continued enlargement and the systematic attempt to bind neighbouring countries as closely as possible to the EC tend to blur the borders. Moreover, due to its status as the largest trading block in the world most market regulation pursued in the EC is de facto global regulation insofar as EC regulatory measures tend to have massive extra-territorial effects. Most forms of EC market regulation therefore spur considerable reactions from abroad. Reactions which the EC needs to take account of. In addition, many of the economic sectors regulated are increasingly being dominated by multinational companies which are less and less embedded in a specific territorial realm.

Hence, what we are witnessing is that the social embeddedness of functional systems such as the economic system (but also of other systems such as science, media and the environmental system)[96] is increasingly being reduced. Instead, such systems increasingly operate on the basis of their own logic and their own constrained perspective of the world, without being subject to many of the limitations established by the nation-state realm. Hence, the Hegelian ambition of unifying society through an all-encompassing rational State has fallen to the wayside and been replaced by a multiplicity of increasingly autonomous systems, each of them exercising reflexion and reflexivity but only seldom achieving rationality.[97]

This development has profound implications for the role of politics in society as well as for the function of regulation through law. Whereas the main function of the political

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[96] The environmental system must be conceived of as an "imaginary" social system. See Niklas Luhmann: *Ökologische Kommunikation. Kann die moderne Gesellschaft sich auf ökologische Gefährdungen einstellen?* Westdeutscher Verlag. Opladen.1986

[97] We are here following Luhmann's definitions of reflexion as the indication of one side of a distinction, reflexivity as the continued crossing between two sides of a distinction and rationality as the simultaneous indication of both sides of a distinction. See Niklas Luhmann: *Soziale Systeme*, Suhrkamp Verlag, Frankfurt am Main, 1984, pp. 638.

system in Hegelian times was to ensure that society could be conceived of as an organism, its central function is increasingly becoming that of a coordinator and arbitrator, whose main function is to ensure a balance between different social systems rather than forging substantial unity. A balance which is aimed at minimizing asymmetries and colonizing tendencies among the functionally differentiated spheres. The political system can therefore be seen as a partial system itself, which fulfils the function of ensuring a limited coordination of coordination. This again explains the increased tendency of the political system to deploy means other than collectively binding decisions adopted through legislative processes in the exercise of its functions, since – in many instances – more micro-oriented means are more suitable for achieving coordination. Hence, the political system no longer exclusively opts for hard law as a regulatory instrument, thereby providing a challenge to the legal system and the way it has traditionally sought to stabilize normative expectations.

The development described is unfolding with different intensity within different parts of society. The area of risk regulation is probably the area where this development has advanced the most, since risks by their very nature tend to transverse stratificatory and segmentary borders. In addition, the increased focus on risks is, in the first place, closely connected with the massive increases in social complexity and contingency which provide the structural basis from which functional differentiation has emerged. It is therefore not surprising that the policy process leading to REACH as well as the planned regulatory construction has strong functionally differentiated features.

8.2. Democracy

At least in its liberal form democracy implies the ability of elected representatives to exercise decision-making power aimed at taking collectively binding decisions, while being subject to the rule of law within a (formal or material) constitutional framework. In this sense the co-decision procedure can be understood as a "quasi-democratic" procedure. "Quasi-democratic" because the law-making authority only partly lies with the EP due to the sharing of power with the Council and the Commissions monopoly on legislative initiatives. On the other hand, the legislative process leading to REACH was unfolded over an eight year within an elaborated procedural framework, allowing for an intense involvement of MS, EC institutions and private actors. In relation to private actors, it is also notable that the vast majority of the 6400 submissions, which the Commission received during its internet consultation, came from industry, trade unions and environmental NGO's, thereby indicating that non-state actors exercised a massive level of activity throughout the legislative process.

But even though REACH emerged from a relatively democratic process the outcome of the process also illustrates that the de facto influence which can be exercised through democratic procedures has its limitations. Instead of being the kind of revolution it is often described as,[98] REACH is instead the result of a long evolutionary development. A considerable part of the substantial changes introduced with REACH represents a mere update of legislation adopted from the 1960s onwards under the impression of new knowledge and increased technological capabilities of testing. Moreover, and as

[98] E.g. Candido Garcia Molynecx: IV. Chemicals, pp. 287-317, The Yearbook of European Environmental Law, vol. 6, Oxford University Press, 2006.

previously noted, the principle of prior testing before placement on the market had already been introduced in 1981, and was, in principle, extended to all products in 1993. In that sense REACH is only – albeit quite drastically - speeding up the realization of an already agreed on policy objective. In addition, the precautionary principle, which is one of the central principles of REACH, was introduced as a general policy instrument with the ratification of the Maastricht Treaty in 1993[99] and has experienced a rapid expansion of its application since the publication of the Commission communication on its use in 2000.[100] Since then, the reversed burden of proof, one of the most important elements of REACH, has, moreover, been considered a generally accepted policy tool.[101] Hence, REACH is characterised by a considerable path dependency which considerably limits the scope of possible decisions. Instead the quasi-democratic policy process leading to REACH merely formalised and expanded the use of a number of regulatory principles which had already been incrementally introduced. However, it was not only the exercise of power through democratic procedures which was faced with certain limitations. The policy-making process of REACH illustrates that political power as such is subject to structural limitations insofar as the same limitations which curtailed democracy also curtailed the exercise of brute power politics. For example, the intervention by the Heads of State and Government from the leading MS, although considerably increasing the pressure on the proponents of the proposal, did not succeed in changing the fundamental principles on which the proposal was founded. Hence, not only the role of the democratically elected EP but also the role of the MS was far more reactive than proactive throughout the process, merely capable of facilitating or impeding the process but not capable of introducing fundamental changes to the central principles on which the proposal was founded.

Moreover, the main line of conflict seems to have developed along functional lines rather than being a conflict between a supranational dimension, represented by the Commission and the EP, and, on the other hand, an intergovernmental dimension, represented by the MS acting within the Council and the European Council. The proposal was developed by DG Environment and was supported by MS environmental ministers and by the EP Environmental Committee. As noted, the ministers and the MEPs, moreover, called for stronger safety requirements than originally envisaged by the Commission. The proposal also got strong support from environmental NGO's. Hence, a surprising consensus existed among those involved in the social realm of environmental and health protection irrespectively of their institutional affiliation. In other words, as long as the policy process unfolded only within the environmental dimension of the EC reaching agreement was fairly easy. The proposal only faced substantial resistance fairly late in the policy-making process when the economic dimension of the EC, represented by industry, the Competitiveness Council, the EP Committee on Industry and Trade and DG Enterprise became aware of the potential impact on the economic sphere. As a policy proposal, which was developed within the environmental dimension of the EC, it is likely that it was "naturally biased" in the

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[99] Article 174 EC. See also Veerle Heyvaert: Guidance Without Constraint: Assessing the Impact of the Precautionary Principle on the European Community's Chemicals Policy, pp. 27-60, The Yearbook of European Environmental Law vol. 6, Oxford University Press, 2006.

[100] Commission Communication on the Precautionary Principle COM (2000)1 Final, 2 February 2000.

[101] Commission Communication on the Precautionary Principle COM (2000)1 Final, 2 February 2000, p. 21.

sense that it did not take "extra-systemic" impacts into account but merely focused on environmental concerns. It is therefore not surprising that successively it was watered down in the latter half of the policy-making process insofar as this part of the process mainly focused on minimizing the effect on other social spheres, and in this particular case especially the economic sphere. Hence, behind the objective of taking a collectively binding decision, the substantial function of the process was to ensure coordination and balancing of the environmental and the economic sphere of society and to regulate their reciprocal impact in relation to chemicals. It is exactly this objective which the regulation seeks to materialise through the principle that the highest possible environmental and health standards should be imposed as long as such requirements do not undermine core elements of the economic viability of the chemicals sector.

Since the cleavage between different functionally differentiated spheres was the main line of conflict, the question of which competences should be transferred to the Community and which should remain in the hands of the MS remained a secondary issue. Instead the main competence clashes also followed the differentiation between environmental and economic perspectives. Hence, it was not a clash which followed the logic inherent in the institutional structure of the Community as embodied in the concept of the institutional balance.[102] Rather the clash unfolded along lines which ran transversal to the EC's institutional balance. In the EP the clash was between the Committee of Environment and the Committee of Industry and Trade. As already noted, both argued that they should be the leading committee, and the position taken by the EP was nothing but a compromise between the two Committees. Within the Commission DG Environment and DG Enterprise clashed continuously on similar accounts. A central question was which Directorate General the Agency should refer to when up and running. DG Enterprise emerged as the winner of that dogfight. In the Council the clashes between the Environmental Council and the Competitiveness Council were additionally numerous. This triggered the intervention of the European Council. As the buck stopped there the Heads of State and Government were forced to indicate to the Council what the appropriate balance between environmental and economic concerns should be. Also in this case the outcome was a carefully developed equilibrium between economic and environmental perspectives.

The outcome of the legislative process was a collectively binding decision. But in contrast to, for example a Luhmannian perspective, [103] the claim that this decision was legitimate was not merely derived from the elaborated procedural framework (in this case the co-decision procedure). On the other hand, the main source of legitimacy was not derived from a reference to a metaphysical concept of the sovereign people, in the Kantian, or Hegelian sense. Instead the main source of legitimacy was derived from the functional differentiation of the policy process. The functional differentiation of the policy process allowed the environmental dimension to develop an ideal type policy proposal which enjoyed widespread support among those concerned with environmental concerns. In the latter half of the process this policy proposal was then adjusted in order to incorporate perspectives derived from the economic sphere in order to minimize the

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[102] Thereby illustrating the problems inherent in a concept of institutional balance which is not based on functional differentiation.

[103] E.g. Niklas Luhmann: Legitimation durch Verfahren, Neuwied, Luchterhand, 1978.

negative impact of the proposal on this same sphere. In this particular case the political dimension of the EU system was therefore merely acting as a kind of arbitration board between different institutional structures which acted as advocates of the economic and environmental spheres of society. Hence, any evaluation of the legitimacy of the legislative process should be developed through an assessment of the degree of concordance achieved between the perspectives of both societal spheres.

8.3. Proceduralisation

The legal infrastructure of REACH provides numerous recourses to administrative law provisions such as participation, transparency and review requirements in order to provide the regulatory framework with certain legitimacy. But behind these legal safeguards functional differentiation plays a crucial role in the way the REACH system is envisaged to operate in practice and in the way its legitimacy is being constructed. This is the case because the comprehensive procedural infrastructure of REACH is oriented towards the upholding of functional differentiation and the regulation of the mutual impact of different functional systems. Essentially, the regulation binds together five different functional systems, namely science, environment, health, and the economic and political systems within a legal frame. The function of the legal system in relation to REACH can therefore be seen as ensuring the stability and operability of a multiversal bundle of structural couplings at the same time as asymmetric relations between the systems involved are being reduced as much as possible.[104]

The legal infrastructure for risk assessment is laid down in the registration and evaluation procedures. The former procedure is largely oriented towards the private sphere, envisaging the conduct of safety assessments by registrants. The latter is mainly oriented towards the public sphere insofar as it regulates the evaluation of substances by competent MS authorities on the basis of the safety assessments provided by registrants. In spite of this distinction both procedures are subsumed under the perspective of science since the objective is to scientifically assess the substances in question. So even though the private/public distinction, which is derived from the classical State/society distinction, remains reasonably valid from an organizational perspective, the risk assessment process is framed through a logic of science which transverses the distinction. Hence, the specific language and modes or argumentation of science will be applied and act as an overlay on both sides of the private/public distinction. However, the final decision under the evaluation procedure resides with the MSC and in the case of dispute between MS with Comitology. Hence, the procedures enable a transfer of issues from the realm of science and into the "political-administration" of the MSC and Comitology.

The authorisation and the restriction procedures are aimed at ensuring appropriate risk management. As noted earlier on, general authorisations concerning the inclusion or exclusion of substances falling under the regulation foresee that the MSC will provide a unanimous opinion followed by referral of the final decision to the Commission acting under the comitology procedure with scrutiny. In the case of disagreement within the MSC Comitology also has the last say, although the decision will then be taken under

[104] For the concept of asymmetry see Poul Kjaer: Systems in Context: On the Outcome of the Habermas/Luhmann-debate, pp. 66-77, Ancilla Iuris, (www.anci.ch), 2006, pp. 75.

the regulatory procedure. In both cases the procedure, however, also enables a transfer of the dossier in question from the realm of science and into the political-administrative realm of Comitology.

In relation to specific authorisations the procedural chain foresees that the dossiers being prepared within the realm of science are transferred to an analogous structure where the CfRA and the CfSEA in separate but simultaneous processes will assess the dossiers in question on the basis of their different perspectives, namely the environmental (and health) perspective(s) and the economic perspective. If the outcomes of the analogous processes happen to converge the issue is clear and is likely to be subject to a rubberstamp decision by the Commission, which will act on the basis of the advisory comitology procedure. In the case of a difference of opinion between the CfRA and CfSEA the Commission can still act, although under very specific limitations. Hence, in case of divergent opinions the Commission and Comitology will act as a political body entrusted with taking a political decision. Also in this case the legal framework is therefore intended to ensure a transfer of dossiers from the realm of science over the intermediary realm of environment and economics to a more politicised sphere.

Concerning the restriction procedure the formal right of initiative resides in the Commission acting under the advisory procedure. Hence, the starting point is the political-administrative realm. The procedure, however, foresees that the CfRA and the CfSEA shall confirm that the proposed actions are in conformity with the general provisions before being referred back to the Commission taking a final decision on the regulatory procedure with scrutiny.

Hence, the commonality of the different procedures is that they enable a transfer of issues from one societal sphere to another and that the political administration of Comitology has the final word. The question of legitimacy is therefore reduced to an evaluation of the ability of the foreseen legal infrastructure to ensure that the perspectives emerging from different societal spheres are in concordance. Or to put it differently: That the legal infrastructure can achieve rationality in the sense that the different perspectives of science, environment, health, economics and politics converge. Taking the complexity of the issues and the multitude of perspectives into consideration constant convergence is an unlikely outcome. Hence, concordance is only likely to take place momentarily and in relation to specific dossiers. But in addition the idea of rationality through convergence will act as a regulatory idea, which is embedded in the self-understanding of regulatory structure, thereby orienting the system towards the function of systematically reducing the gap between the different perspectives. Apart from the classical input/output distinction, the process itself is therefore envisaged to be a central source of legitimacy, thereby addressing an issue which all autonomous structures are faced with, namely the demand for self-legitimation.

The focus on the process itself also, however, has consequences for the concept of rationality which the system refers to. This is the case because the strategic dimension of rationality, which often guides the distinction between input and output legitimacy due to its recourse to a concept of affected interests, is complemented by a stronger emphasis on the time dimension of rationality. This is likely to enable the system to continuously increase its reflexivity through new knowledge and to revise former positions, thereby producing a structural basis for convergence. In addition, the striving

for convergence between different social systems in itself emphases the importance of the social dimension of rationality. Hence the regulatory framework is directly oriented towards a balancing of the strategic dimension of rationality through an "uploading" of the social and the time dimensions of rationality.

An additional issue in relation to the legitimacy of the planned structure is the recourse to the political administration of Comitology and its function as an arbitrator who, apart from formally being the last step in the decision-making process, also strikes the balance in case of divergence. A central point of dispute will therefore remain of whether the comitology system is a legitimate institutional form for exercising such a political function, thereby re-casting the questions originally raised by Joerges and Neyer.

8.4. Deliberation

In the academic literature, deliberation is a disputed concept and it might not be helpful to recast the debate between proponents and opponents one more time. Irrespectively of the disputed coherency of the concept, it can, however, be argued that the REACH regulation more or less consciously refers to the concept of deliberation. This is particularly the case in relation to the way the committees are legally framed. Not only are members obliged not to take any instructions, but the regulation directly stresses the importance of reaching unanimity. In addition, as dissent will include the publication of divergent positions and in most cases also a referral of decisions upstream in the procedural chain, the committees are likely to have a strong incentive to reach agreement. This incentive is further reinforced by the obligation of the committees to provide opinions within specific time limits, thereby putting members under a moderate but constant pressure for reaching agreement. Hence, the legal structure of the committees is constructed in such a manner that consensus oriented norms are likely to become stronger features than otherwise would be the case. Whether this will suffice in order to ensure that deliberation also becomes the dominant feature is, however, an open question which will need to be the subject of detailed empirical studies.

Especially in relation to the CfRA and the CfSEA other features will, moreover, provide a structural basis which is likely to facilitate agreement. These features are derived from the strong functionally differentiated character of the committees and the strong reliance on expertise. These two elements are likely to ensure that members will possess a common knowledge base and a shared perspective on how the issues in question should be addressed. In the case of the absence of a shared frame the working process itself is likely to create such a frame in the sense that a continued repetition of procedurally framed activities is likely to produce a common "lifeworld", in the form of a shared and condensed reservoir of knowledge which the participants can draw upon in their problem-solving endeavour.[105]

[105] Rather than Habermas' concept of lifeworld we are here referring to Luhmann's reformulated version of the concept, which enables a stronger focus on the time dimension through its recourse to the concept of reiteration. In contrast to Habermas' concept Luhmann's version is moreover applicable to bureaucratic structures. See Poul Kjaer: Systems in Context: On the Outcome of the Habermas/Luhmann-debate, pp. 66-77Ancilla Iuris, (www.anci.ch), 2006, pp. 69.

Although sharing many of the features of the CfRA and the CfSE, the MSC and Comitology will operate in a more complex environment. Members of Comitology committees are likely to operate on mandates, thereby narrowing their manoeuvrability. Both the MSC and Comitology are likely to be more politicised than the CfRA and the CfSE, because of their function as balancers of different societal dimensions. At least in some cases, this function is likely to imply irreconcilable trade-offs and dilemmas where no optimal solution can be found. When confronted with such paradoxes the solution is likely to be found in the time dimension rather than in the social dimension insofar as such issues are likely to be contained through pragmatic ad-hoc solutions or de facto "non-decisions" which will be subject to review at a later date. Hence, the lower level of functional differentiation is therefore likely to somewhat reduce the deliberative potential within the MSC and the Comitology structures.

9. Contextualizing REACH

Although one should be careful about extrapolating general insights from the specific case of chemicals regulation, a general insight deriving from this case is that any model developed in order to frame the European integration process needs to take the reality and the need of functional differentiation into account. Hence, neither classical intergovernmental nor supranational theories or any variant in-between them are capable of grasping the essential line of conflict because they are based on the assumption of the primacy of segmentary differentiation. Hence, it possible to reject such theories because they remain based on methodological nationalism.[106]

The case of chemicals policy, which obviously is not fully representative since it falls under co-decision and hence represents one of the most "mature" policy areas in terms of integration, indicates, however, that segmentary differentiation, although still relevant, is not the most important form of differentiation. Rather the focus on functionally differentiated structures running transversal to the intergovernmental/supranational distinction should be increased since the main clashes of rationalities do not seem to emerge from vertical clashes between the MS and Brussels or between different social clashes but rather from the continued need to coordinate and balance highly dynamic horizontal processes which are being reproduced within different functionally delineated areas of society.

An adequate model of the EU should therefore systematically address the reality of functional differentiation. Like national parliaments the EP is characterised by three features: Segmentary differentiation on the basis of the constituencies and national affiliation of members; the distinction between left and right which traditionally was derived from a stratificatory concept of social class; and through functional differentiation between committees. In contrast to national parliaments the latter feature, however, plays a far stronger - one could argue even the decisive role - in the EP. Any

[106] Michael Zürn: *Politik in der postnationalen Konstellation. Über das Elend des methodologischen Nationalismus*, pp. 181-204 in Christine Landfried (Hrsg.): *Politik in einer entgrenzten Welt*.Verlag Wissenschaft und Politik. Köln. 2001.

attempt to conceive of the EP as representing a European *Volksgeist,* which potentially will be able to constitute unity in a Hegelian sense, is therefore bound to be even further away from reality within the EP than it was and is in the national contexts.

In relation to the overall institutional structure of the EU, Majone has, moreover, brilliantly shown that the concept of institutional balance is a pre-modern concept, which does not reflect a modern conception of a functionally differentiation of powers between a legislative, an executive and a juridical dimension.[107] Instead the concept of institutional balance refers to an idea, prevalent in the 17th and 18th centuries, of public power as resting in an organic entity. The concept of a functional differentiation of powers, however, emerged because the social realm within which public structures operated became increasingly functionally differentiated, thereby necessitating a transformation of public structures in order to make them "fit" to a new reality. The central paradox of the EU is, therefore, that it is a structure which fulfils the societal function of driving the functional differentiation of society forward at the same time as its internal institutional structures run transversal to the functionally differentiated world within which it operates. Hence, any attempt to reconfigure the EU system needs to provide solutions to this problem by pushing for a transformation of the EU into an increasingly functionally differentiated structure. Especially since such a development potentially will provide the EU with an additional source of legitimacy beyond democracy and the inclusion of those affected.

[107] Giandomenico Majone,: Delegation of Regulatory Powers in a Mixed Polity. European Law Journal, Vol. 8, No. 3, pp. 319-339, 2002.